

# North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Richard O. Brajer Secretary DHHS

Drexdal Pratt Division Director

September 15, 2015

Elizabeth V. Kirkman Assistant Vice President CHS Management Company 2709 Water Ridge Parkway, Suite 200 Charlotte, North Carolina 28217

# Exempt from Review – Replacement Equipment

Record #:

1720

Facility Name:

Carolinas Medical Center (CMC)

FID #:

943070

Business Name:

Charlotte-Mecklenburg Hospital Authority

Business #:

1772

Project Description:

Replace cardiac catheterization lab located in CMC's Cath Lab Room

#04H104

County:

Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 9, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to replace the existing Toshiba Biplane Cath Lab System, Model #DFP-8000A/W1, located in Cath Lab Room #04H104 of CMC's main campus in Charlotte, with a comparable cardiac catheterization lab. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.



# Office of the Director

http://www.ncdhhs.gov/dhsr/

Phone: 919-855-3750 / Fax: 919-733-2757

Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603 Mailing Address: 2701 Mail Service Center • Raleigh, North Carolina 27699-2701

An Equal Opportunity / Affirmative Action Employer



Elizabeth V. Kirkman September 15, 2015 Page 2

Sincerely,

Gloria C. Hale Project Analyst Martha J. Frisone,

Assistant Chief, Certificate of Need

cc:

Construction Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

Assistant Chief, Healthcare Planning



# Carolinas HealthCare System

September 9, 2015

Ms. Martha Frisone, Assistant Section Chief Healthcare Planning and Certificate of Need Section Division of Health Service Regulation N.C. Department of Health & Human Services 809 Ruggles Drive Raleigh, NC 27603



RE: The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center — Exemption Notice for Acquisition of Replacement Cardiac Catheterization Lab Equipment and Relocation of Replacement Cardiac Catheterization Lab Equipment

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC"), seeks to acquire a Toshiba Infinix Elite Cardio/Neuro Vascular Biplane Catheterization Lab System ("Replacement Equipment"). Please see Attachment A for a copy of CMC's current hospital license. The Replacement Equipment will replace CMC's current Toshiba Biplane Catheterization Lab System ("Existing Equipment"). The Existing Equipment is currently housed and in use in room 04H104 on the fourth level of CMC's main campus ("Cath Lab #8") located at 1000 Blythe Boulevard in Charlotte, NC 28203 (see Attachment B). The Replacement Equipment will be located in room 6046 (labeled Cath Lab #2) on the sixth level of CMC's main campus.

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review under the replacement equipment exemption provisions contained in Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6 (which are codified at N.C. Gen. Stat. 131E-184(f)(1)-(3)).

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," defined as follows in the CON law:

"Replacement equipment" means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. 131E-176(22a). Under the new provisions found at N.C. Gen. Stat. 131E-184(f)(1)-(3), the CON law provides:

- (f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:
  - (1) The equipment being replaced is located on the main campus.
  - (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
  - (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

See Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6. The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified N.C. Gen. Stat. 131E-176(14n)) as follows:

- (14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:
  - a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
  - b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is currently located in room 04H104 on the fourth level of CMC's main campus ("Cath Lab #8") and the Replacement Equipment will be located within in room 6046 on the sixth level (see Attachment B). The main hospital building from which Carolinas Medical Center exercises financial and administrative control over Carolinas Medical Center services is located at 1000 Blythe Boulevard, Charlotte, NC 28203 (see Attachment B). Carolinas Medical Center's President's office is located on the second floor of the main hospital building.

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be "comparable" to the equipment it replaces and the equipment being replaced must be "sold or otherwise disposed of when replaced." CMC's proposal qualifies for this exemption.

# A. Cost of the Replacement Equipment

The purchase price of the Replacement Cardiac Catheterization Equipment is \$1,494,611.30 (\$1,387,377.00 Cardiac Catheterization System + \$6,200.00 Freight + \$101,034.30 Tax). Quotes for the Cardiac Catheterization Lab Equipment by Toshiba and other supporting equipment are provided in Attachment C. The projected total

capital cost of the project is \$4,024,000 and includes the removal of the existing equipment and installation of the Replacement Equipment. The total capital cost schedule and the certified cost estimate of the renovation required to install the new equipment are provided in Attachment D.

# B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located in room 04H104 on the fourth floor of CMC's main campus ("Cath Lab #8") (see Attachment B). The Replacement Equipment will be located in room 6046 on the sixth level of CMC's main campus (see Attachment B).

# C. Certificate of Need Issued for Equipment Being Replaced

This proposal also fits within the new exemption criterion in Section 131E-184(f)(2) because the Department issued an exemption request for the Existing Equipment (see Attachment E). The Existing Equipment was purchased in 2009.

# D. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

"Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

CMC intends to use the Replacement Equipment for substantially the same Cardiac Catheterization procedures for which it currently uses the Existing Equipment. The Existing Equipment is a Toshiba Biplane Catheterization Lab System that was installed new in 2009. This Existing Equipment has been used for Cardiac Catheterization procedures since installation.

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same Cardiac Catheterization procedures. (see Attachment F for the Equipment Brochure) The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, CMC does not intend to increase patient charges or per procedure operating expenses within the first 12 months after equipment acquisition. For further equipment comparison, please refer to Attachment G, the Equipment Comparison Chart.

Subsection (d) of the regulation further provides:

- (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10.0 percent increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The Replacement Equipment will meet all three of tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart (Attachment G). Moreover, CMC represents the use of the Replacement Equipment will not result in the types of expense or charge increases described in Subsection (d)(3).

The Existing Equipment is currently in use and documentation provided in Attachment H indicates that 421 procedures were performed in the last 12 months.

# E. <u>Disposition of Equipment</u>

Please see Attachment I for a letter documenting the Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

# **CONCLUSION:**

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,
Maletar, Cellani

Elizabeth V. Kirkman Assistant Vice President

CHS Management Company

Attachments

cc: F. Del Murphy, Jr., CHS Management Company

W. Spencer Lilly, President, Carolinas Medical Center



# Carolinas HealthCare System

September 9, 2015



Ms. Martha Frisone, Assistant Section Chief Healthcare Planning and Certificate of Need Section Division of Health Service Regulation N. C. Department of Health & Human Services 809 Ruggles Dr. Raleigh, NC 27603

RE: The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center – Exemption Notice for Acquisition of Replacement Cardiac Catheterization Lab Equipment and Relocation of Replacement Cardiac Catheterization Lab Equipment

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC") seeks to replace and relocate two Cardiac Catheterization Lab Systems. Please see the two enclosed Exemption Requests. These two Cardiac Catheterization Labs will be colocated on the sixth floor of Levine Children's Hospital within CMC and will share support space. The costs of the shared support space are split evenly among the two replacements and are reflected in the capital cost of each replacement.

The first Cardiac Catheterization Lab System that will be replaced is CMC's Philips Single Plane Catheterization Lab System that is currently located in Cardiac Catheterization Lab #3. Cardiac Catheterization Lab #3 will be replaced with a Toshiba Infinix Elite Cardio/Neuro Vascular Biplane Catheterization Lab System ("Replacement Equipment") and relocated to room 6044 on the sixth level of CMC's main campus from room 06G120 on the sixth level of CMC's main campus.

The second Cardiac Catheterization Lab System that will be replaced is CMC's Toshiba Biplane Catheterization Lab System that is currently located in Cardiac Catheterization Lab #8. Cardiac Catheterization Lab #8 will be replaced with a Toshiba Infinix Elite Cardio/Neuro Vascular Biplane Catheterization Lab System ("Replacement Equipment") and relocated from to room 6046 on the sixth level of CMC's main campus from room 04H104 on the fourth level of CMC's main campus.

Thank you for your consideration of this notice.

Elyabeth V, Kukaian

Elizabeth V. Kirkman Assistant Vice President CHS Management Company

Attachments

cc: F. Del Murphy, Jr., CHS Management Company W. Spencer Lilly, President, Carolinas Medical Center Attachment A

# State of Aurth Carolina Services Aenartment of Health and Human Services Department of Health and Human Services Division of Health Service Regulation

Effective January 01, 2015, this license is issued to The Charlotte-Mecklenburg Hospital Authority

to operate a hospital known as Carolinas Medical Center/Center for Mental Health located in Charlotte, North Carolina, Mecklenburg County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

> Facility ID: 943070 License Number: H0071

Bed Capacity: 1132

General Acute 976, Rehabilitation 13, Psych 132, Substance Abuse 11,

**Dedicated Inpatient Surgical Operating Rooms: Dedicated Ambulatory Surgical Operating Rooms:** 11

**Shared Surgical Operating Rooms:** 41 **Dedicated Endoscopy Rooms:** 

Authorized by:

Secretary, N.C. Department of Health and

**Human Services** 



Director, Division of Health Service Regulation

Attachment B

COLOR KEY

Carolinas HealthCare System

August 17 2015

255-255-155

EXISTING BUILDING

255-155-000

RENOVATION



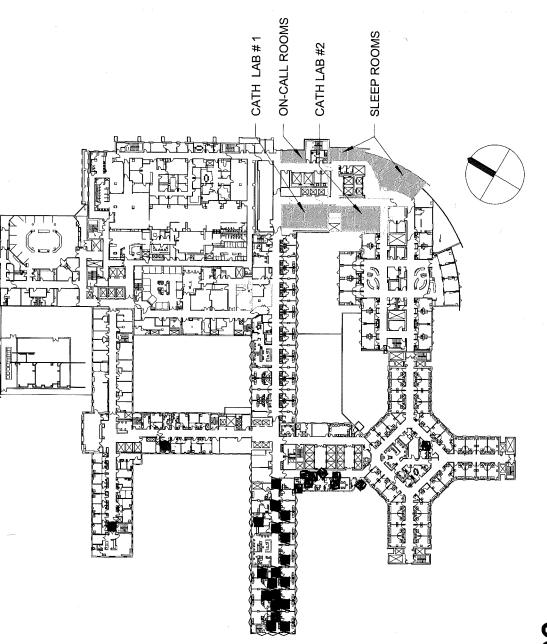
# **OVERALL PLAN - LVL 04**



**EXISTING BUILDING** 



RENOVATION



# **ENLARGED FLOOR PLAN**

Carolinas HealthCare System August 17 2015

OSR #2844601 SHVI Cath Lab Space

Attachment C



# QUOTATION/ORDER

SID NO:

30024283

ORDER SUMMARY

DATE: 8/3/2015

QUOTE NO: 72006-6

PRESENTED TO: (COMPLETE LEGAL NAME)

DELIVER TO:

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD

CHARLOTTE, NC. 28203

CAROLINAS MEDICAL CENTER

1000 BLYTHE BLVD

CHARLOTTE, NC. 28203

**EQUIPMENT SUMMARY:** 

ELT/BP/8/8.000

INFINIX ELITE CARDIO/NEURO VASCULAR **BIPLANE SYSTEM** 

SYSTEM AND TABLE CONFIGURATION

ELITE BIPLANE MAIN SYSTEM WITH CAT-850B

**TABLE** 

STEPPING UNIT FOR CAT-850B OR CAT-860B

**BASEPLATES FOR CAS-880** 

BASEPLATE FOR CAS-880 750 MM

21 INCH COLOR MONITOR

**VGA CONNECTION ADAPTER** 

LCD FLAT-PANEL COLOR MONITOR 21

This quotation shall remain valid for 60 days (not to ex All prices are F.O.B. destination.	ceed 90 days) fro	m date of submission		
Payment terms are: Cash - 0% down payment, 80% upon shipment, 20% net 30 days after shipment or upon availability for first use by purchaser, whichever comes first.				
Additional terms and conditions appear at the end of this quotation. McKesson Agreement RequiredYesN  Vital Software License Agreement RequiredXYesN				
Please return signed quotation to Toshiba America Medical Systems by email orderadmin@tams.com or fax 714-441-9320.				
ACCEPTED AGREED AND ORDERED:				
CUSTOMER REQUESTED DELIVERY DATE:		TOSHIBA REP/CONTACT	DATE	
PURCHASER'S SIGNATURE/TITLE	DATE	ZONE SALES MANAGER	DATE	



# TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

# QUOTATION/ORDER **ORDER SUMMARY**

DATE: 8/3/2015

SID NO: QUOTE

30024283 72006-6

NO:

PRESENTED TO: (COMPLETE LEGAL NAME)

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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**EQUIPMENT SUMMARY: (continued)** 

CABLE CARRIER KIT, 8'

INFINIX ARM SUPPORT (SUPINE POSITION)

MAT, ANTI-FATIGUE (FLOOR MAT)

SERVICE INSTALLATION COMPONENTS

INFINIX ANGIO WORKSTATION (AWS) WITHOUT 3-D ANGIO SOFTWARE

LCD FLAT-PANEL COLOR MONITOR 21

**IMAGE CONNECTION MODULE** 

DVI SPLITTER, EXTENDER AND TRANSMITTER

CAT7 CABLE, 100 FT

DVI EXTENDER AND RECEIVER CABLE

ADAPTER, DVI TO HDMI

**DUCT HOSE POSITION FOR CAS-820B** 

MULTIPURPOSE TABLESIDE CONTROL KEYBOARD AND MOUSE EXTENSION KIT FOR AWS, AND UP TO THREE OTHER PORTS

BLACK BOX SERVSWITCH WIZARD DVI KVM **SWITCH** 

TRIPP LITE 1-PORT USB OVER CAT5/CAT6 (Qty 2)



# QUOTATION/ORDER ORDER SUMMARY

DATE: 8/3/2015

SID NO:

30024283

0/ 2020

QUOTE NO: 72006-6

PRESENTED TO: (COMPLETE LEGAL NAME)

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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CAT7 CABLE, 100 FT (Qty 2)

INFINIX KEYBOARD AND MOUSE TABLESIDE RAIL MOUNT ASSEMBLY

USB 2.0 CABLE 10FT (Qty 2)

**USB KEYBOARD** 

MEDICAL GRADE OPTICAL MOUSE

CABLE, DVI-D M/M DUAL LINK DIGITAL VIDEO, 3 METERS (Qty 4)

INTERVENTIONAL DASHBOARD DUAL 30" MONITOR SOLUTION

58" MONITOR FOR BIPLANE

INSTALLATION KIT FOR 58" MONITOR BIPLANE

CABINET FOR LARGE LCD COLOR DISPLAY MONITOR

UNIVERSAL CONNECTION MODULE

IMAGE CONNECTION MODULE (Qty 3)

LARGE LCD MONITOR SUSPENSION FOR CAS RAILS, FOR VASCULAR SINGLE PLANE CEILING-SUSPENDED, CARDIAC SINGLE PLANE CEILING-SUSPENDED, BIPLANE AND SELECT ONLY

IMAGE CONNECTION MODULE (Qty 2)



# QUOTATION/ORDER ORDER SUMMARY

DATE: 8/3/2015

SID NO: QUOTE 30024283 72006-6

NO

PRESENTED TO: (COMPLETE LEGAL NAME)

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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UNIVERSAL CONNECTION MODULE

MOUNTING BRACKET FOR MONOCHROME
MONITOR AND CONNECTION HARDWARE (Qty 2)

19" GRAYSCALE MONITOR (Qty 2)

ROTATIONAL ANGIOGRAPHY TECHNOLOGY

SPOT FLUORO

BASE 3D ACQUISITION SOFTWARE (ALSO REQUIRES VITREA VL 3D PACKAGE)

ADDITIONAL ON-SITE APPLICATIONS TRAINING - 32 HOURS

LOW CONTRAST IMAGING FOR INFINIX AWS

3-D ROADMAP WITH NEEDLE GUIDANCE FOR INFINIX AWS

3-D MULTI MODALITY FUSION (CT & MR) ROADMAP SOFTWARE FOR INFINIX AWS

DOSE TRACKING SYSTEM KIT

IMAGE CONNECTION MODULE FOR LARGE LCD MONITORS

AWS QUANTITATIVE ANALYSIS KITS

QUANTITATIVE CORONARY ANALYSIS

QUANTITATIVE VESSEL ANALYSIS



# QUOTATION/ORDER ORDER SUMMARY

DATE: 8/3/2015

SID NO:

30024283

ATE: 6/5/2015

QUOTE NO: 72006-6

PRESENTED TO: (COMPLETE LEGAL NAME)

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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LEFT VENTRICULAR ANALYSIS (BIPLANE) KIT

TABLE MOUNTED RADIATION SHIELD

4.0 M CEILING TRACK FOR RADIATION SHIELDS, LIGHTS AND MONITORS

MAVIG CENTER MOUNTED CONTOUR CUT-OUT SHIELD 76/61 CM WITH PORTEGRA2 95/90 CM EXTENSION SPRING ARM

MAGNETIC SHIELDING KIT FOR 8" X 8" FPD

CONTROL CONSOLE WITH MUSHROOM HANDLE FOR CAT-850B/CAT-860B

WIRELESS FOOTSWITCH FOR CAT-850B AND CAT-860B BI-PLANE

TABLE SIDE RAIL SET (PAIR) FOR CAT-850B, CAT-860B OR CAT-880B

TABLE EXTENSION FOR CAT-850B, CAT-860B OR CAT-880B -- REQUIRES XBER-001A

ARMREST SET

INFINIX TABLE PAD 2" FOR CAT-850, CAT-860B, OR CAT-870

INFINIX TABLE WORK AREA PAD 2"

INFINIX EP TABLE WIDTH EXTENDER



# QUOTATION/ORDER ORDER SUMMARY

DATE: 8/3/2015

SID NO:

30024283 72006-6

.

QUOTE

NO:

PRESENTED TO: (COMPLETE LEGAL NAME)

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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MAT, ANTI-FATIGUE (FLOOR MAT)

COMPENSATION FILTER SET

POWER DISTRIBUTION UNIT FOR INFINIX-I

ADDITIONAL SYSTEM CABINET

CABINET SIDE COVER

VITREAEXTEND INTERVENTIONAL PLANNING AND ANGIO VL3D PACKAGE INCLUDES 3-D ANGIO POST PROCESSING AND A COMPREHENSIVE INTERVENTIONAL PLANNING SUITE OF CLINICAL TOOLSETS, HARDWARE, AND EDUCATION TRAINING UNITS



# QUOTATION/ORDER ORDER DETAIL

DATE: 8/3/2015

SID NO:

30024283 72006-6

QUOTE NO:

PRESENTED TO:

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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# **Special Information & Terms**

- This quotation/order will be subjected to the Agreement for Vascular equipment products between Premier Purchasing Partners, L.P. and Toshiba America Medical Systems, Inc., effective October 1, 2012. Reference contract no. PP-IM-198.
- This price is offered contingent on the purchase of two (2) Infinix vascular systems. This
  price includes the de installation, rigging, and reinstallation of Customer's existing vascular
  system.

# ELT/BP/8/8.000

# INFINIX ELITE CARDIO/NEURO VASCULAR BIPLANE SYSTEM

# PRODUCT OVERVIEW

Infinix Elite Biplane system includes a robust feature set. The following information provides an overview of the key items.

## INFINIX ELITE BIPLANE 8"X 8" SYSTEM

Meeting the challenges of today's healthcare provider, the Infinix Elite Biplane system has the ability to perform comprehensive diagnostic and interventional procedures. This system features technology designed for ease of use, increased efficiency, and improved safety and quality of care while delivering exceptional image quality with significant dose savings.

The Infinix Elite Biplane system is designed to improve the patient experience and clinical effectiveness. The C-arms are designed to allow quick access to the groin without having to pivot the gantry and to enable steep angulations for vessel profiling to aid in the visualization of coronary vessels and structures for interventional procedures.

Streamline tableside controls help keep clinicians beside the patient by allowing complete system control of imaging functions such as positioning of the C-arms, real-time changing of dose levels, managing the monitor display, and archiving patient information.



# TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

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# WorkRite Technology

The unique flexibility and design of the C-arms, combined with low-profile Flat Panel Detector (FPD) housing, offers superb ergonomic orientation enabling "line of sight" view of the monitors, while maintaining good body ergonomics for physician comfort during long complex procedures.

# **Advanced Image Processing**

The Infinix Elite digital fluoroscopic processor DFP-8000B/B2 expands on Toshiba's proprietary Advanced Imaging Processing (AIP) technology, which generates high-resolution images to enhance wire, stent, and device placement. Built-in features include Digital Angiography (DA), Digital Subtracted Angiography (DSA), enhanced fluoroscopy visualization, and Dynamic Trace imaging. The system's digital processor has multi-tasking capabilities to enhance control room workflow and reduce equipment footprint.

### **Dose Management Program**

A comprehensive set of dose management tools including grid-controlled pulsed fluoroscopy, variable dose level selection, Optibeam with virtual collimation control using LIH, electronic zoom, retrospective fluoro-store and the possibility to record and display image dose parameters.



# TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

# QUOTATION/ORDER ORDER DETAIL

DATE: 8/3/2015 SID NO:

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QUOTE

NO:

PRESENTED TO:

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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COMPONENT SUMMARY:

# SYSTEM AND TABLE CONFIGURATION

## ELITE BIPLANE MAIN SYSTEM WITH CAT-850B TABLE

# STANDARD SYSTEM COMPONENTS

•	CAS-820B/A1	C-arm, Ceiling-Mounted (Omega-Arm)
•	CAS-880A/A1	C-arm, Floor-Mounted
•	BLA-900C	Multi-filter Collimator
•	DSRX-T7444GDS	Liquid Metal Bearing X-Ray Tube (Qty2)
•	XTP-8100XG	High-Frequency X-Ray Generator 100 kW
•	TFP-800A/A1	8" x 8" Flat Panel Detector (Qty 2)
•	XGCP-882BA	Tableside Control HyperHandle
•	CAT-850B	Catheterization Table
•	XBFS-880B	Multi-Function Footswitch
•	DFP-8000B/B2	Multitasking Digital Fluoroscopy Processor
•	XIDF-MCC80B	Main Console
•	XIDF-MIC802	Intercom Kit
•	XIDF-FS801B	Control Room Footswitch
•	XIDF-W801/B1	Angio Workstation
•	XJDK-002A/V5	Dose Meter Controller
•	XJDC-009A	Dose Chamber (Qty 2)

# C-ARM, CEILING-MOUNTED (OMEGA-ARM) CAS-820B/A1

The unique ceiling-mounted Omega-arm performs fluoroscopy, radiography and digital fluorography.

## **Specifications:**

- Variable rotation speeds up to 15 degrees per second for fast C-arm angulation
- Stroke of flat panel detector movement (SID): 380 mm, motor-driven
- Isocenter height: 111 cm (43.7")

# TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

# QUOTATION/ORDER ORDER DETAIL

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SID NO:

30024283 72006-6

Q(

QUOTE NO:

PRESENTED TO:

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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# **C-Arm Movement**

- Flexible positioner that, combined with low-profile housing of the X-ray tube and FPD, optimizes imaging angles.
- Enables variable-speed axial rotations and isocentric fluoroscopy and fluorography with rotations from:

# **Omega Arm Rotation:**

- CRA 45 degrees to CAU 45 degrees (left lateral setting)
- CRA 45 degrees to CAU 45 degrees (right lateral setting)

# Omega Arm sliding:

- LAO 120 degrees to RAO 0 degrees (left lateral setting)
- RAO 120 degrees to LAO 0 degrees (right lateral setting)
- CRA 45 degrees to CAU 45 degrees (right lateral setting)

## **Auto-Positioning/Auto-Set Functions**

- Allows Specific auto-positioning settings sequentially for each study protocol.
- Enables fast initiation of C-arm positioning and system settings for the desired imaging requirements.
- Records and reproduces over 64 programs of:
  - Angulations and SID
  - Initial Field of View (FOV)
  - Table heights
  - Compensation-filter positions

### Auto-Angle

For acquired images, auto-angle stores the following for one-touch recall (can be customized to site):

- C-arm angle
- SID
- Compensation filter position
- Table height
- Magnification size
- Compensation-filter positions



# TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

# QUOTATION/ORDER ORDER DETAIL

DATE: 8/3/2015 SID NO:

30024283 72006-6

QUOTE

NO:

PRESENTED TO:

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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# Control Switch Assembly - HyperHandle

All system movements are operated from the control switch assembly, mounted at the side of the catheterization table. This enables quick positioning with high accuracy.

# **Specifications:**

- Variable rotation speeds up to 30 degrees per second for fast C-arm angulation
- Stroke of flat panel detector movement (SID): 350mm, motor-driven
- Isocenter height: 105 (41.3")

### **C-Arm Movement**

- Flexible positioner that, combined with low-profile housing of the X-ray tube and FPD, optimizes imaging angles.
- Enables variable-speed axial rotations and isocentric fluoroscopy and fluorography with rotations from:
- Arm rotation (with C-arm set to patient head end):
  - o RAO 180 degrees to LAO 120 degrees
- Arm sliding (when C-arm is set to the left side of the patient):
  - RAO 90 degrees to LAO 50 degrees

# **Auto-Positioning/Auto-Set Functions**

- Specify auto-positioning settings sequentially for each study protocol.
- Quickly initiate C-arm positioning and system settings for the desired imaging requirements.
- Record and reproduce over 64 programs of:
- Angulations and SID
- Initial Field of View (FOV)
- Table heights
- Compensation-filter positions



# QUOTATION/ORDER ORDER DETAIL

DATE: 8/3/2015 SID NO:

30024283

QUOTE

72006-6

PRESENTED TO:

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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# Auto-Angle

- For acquired images, auto-angle stores the following for one-touch recall (can be customized to site):
- C-arm angle
- SID
- Compensation filter position
- Table height
- Magnification size

# Control Switch Assembly - HyperHandle

All system movements are operated from the control switch assembly, mounted at the side of the catheterization table. This enables quick positioning with high accuracy.

# C-ARM, FLOOR-MOUNTED - CAS-880A/A1

The floor-mounted C-arm performs fluoroscopy, radiography and digital fluorography. This flexible design allows superb access to the patient and enables the steep angulation required for complex cardiac catheterization procedures.

### **Specifications:**

- Variable rotation speeds up to 50 degrees per second for fast C-arm angulation
- Stroke of flat panel detector movement (SID): 350 mm, motor-driven
- Isocenter height: 111 cm (43.7")

## Positioning Features to Enhance Workflow

The floor-mounted C-arm is designed to enhance workflow. Features include:



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### **C-Arm Movement**

- Flexible positioner that, combined with low-profile housing of the X-ray tube and FPD, optimizes imaging angles.
- Enables variable-speed axial rotations and isocentric fluoroscopy and fluorography with rotations RAO 120 degrees to LAO 120 degrees
- Sliding angle CRAN 50 degrees to CAU 90 degrees

# **Auto-Positioning/Auto-Set Functions**

- Specify auto-positioning settings sequentially for each study protocol.
- Quickly initiate C-arm positioning and system settings for the desired imaging requirements.
- Record and reproduce over 64 programs of:
  - Angulations and SID
  - Initial Field of View (FOV)
  - Table heights
  - Compensation-filter positions

### MULTI-FILTER COLLIMATOR - BLA-900C

- Five-filter collimator using industry-standard filtration materials
  - Copper 0.2 mm
  - Copper 0.3 mm 0
  - Copper 0.5 mm
  - Copper 0.9 mm
- Aluminum 2.0 mm
- Compensation filters: Fe 1.2 mm
- Remote and manual controls

# HIGH-CAPACITY X-RAY TUBE WITH LIQUID METAL BEARING - DSRX-T7444GDS (QTY 2)

- Quiet, long-lasting and efficient, this tube ensures high throughput and fail-safe imaging.
- Triple-focus design provides small-focal-spot redundancy for uninterrupted procedure in the event of fluoro filament failure
- Highly efficient, pulsed fluoroscopy with built-in, beam-hardening filters reduces dose



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Continuous, high-speed (9000 rpm) anode rotation provides immediate display of fluoroscopic and fluorographic images

### Other features include:

- Grid switched
- Maximum kV: 125 kV
- Focal spot: 0.5/0.5/0.8 mm
- Maximum ratings: 50/100 kW
- Target angle: 8 degrees
- Maximum anode heat storage: 3000 kHU
- Maximum cooling rate anode: 7799 HU/s

# HIGH-FREQUENCY X-RAY GENERATOR 100 KW - XTP-8100XG

Uses dual-inverter method for increased reliability with redundant inverter. Operates in normal/standard mode, low-dose mode and high-dose mode fluoroscopy.

### **Includes:**

- Control console
- Control cabinet
- Power cabinet with high-speed starter
- Fluoroscopy control cabinet
- System power source cabinet

# Fluorographic Ratings

- 125 kV, 800 mA (0.1 s)
- 100 kV, 1000 mA (0.1 s)
- 80 kV, 1250 mA (0.1 s)

# **Pulsed Fluoroscopy Function**

- Fluoroscopic tube voltage range: 50 kV to 120 kV
- Fluoroscopic tube current range: 200 mA peak
- Pulse width: 1.0 ms to 13 ms
- Repetition pulse rate: 30, 20, 15, 10, 7.5, 5, 3, 2, 1 exp/s (can be selected at the time of installation)

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ABC (auto brightness control) function: provides the automatic adjustment of the tube voltage or the tube voltage and tube current to maintain uniform monitor brightness

# Digital Subtraction Angiography (DSA) Functions

- Tube voltage range: 50 kV to 125 kV
- Tube current range: maximum 1000 mA (may be restricted depending on the rating of the X-ray tube assembly)
- Pulse width: 1.0 ms to 100 ms

# Digital Angiography (DA) Functions

- Tube voltage range: 50 kV to 125 kV
- Tube current range: maximum 1000 mA (may be restricted depending on the rating of the X-ray tube assembly)
- Pulse width: 1.0 ms to 25 ms

# **Parametric Imaging (PI) Functions**

- Displays an entire image sequence as a single composite DSA image that is color coded in order to characterize the contrast media dynamics and to allow easier visual evaluation
- Color Coded Circulation (CCC) can create movies by shifting color scale gradually so that it is easy to understand vessel flow

### **Acquisition Modes (Single)**

# **DA Acquisitions:**

- 30, 15, 10, 7.5, 5, 3, 2, 1 FPS at 1024x1024 x 8, 10 or 12-bits
- 60 FPS at 512x512 x 8, 10 or 12-bits

### **DSA Acquisitions:**

30, 15, 10, 6, 3, 2, 1, 0.5, 0.3 DSA at 1024x024 x 12-bits

# Acquisition Modes (Biplane)

# DA Acquisitions:

15, 10, 7.5, 5, 3, 2, 1 FPS at 1024x1024 x 8, 10 or 12-bits



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# **DSA Acquisitions:**

• 15, 10, 6, 3, 2, 1, 0.5, 0.3 DSA at 1024x1024 x 12-bits

# 8" x 8" FLAT PANEL DETECTOR - TFP-800A/A1 (QTY 2)

State –of- the- art flat panel detector technology enhances low dose imaging, offers exceptional image quality, and features Digital Subtracted Angiography (DSA) standard with superior contrast and dynamic resolution. Designed for cardiovascular imaging, the FPD has a unique 8"x8" (20 cm x 20 cm) design that enhances clinical display of fine detail during complex diagnostic and interventional procedures.

# **Specifications:**

- Multiple Fields of View
  - o 8"x8"
  - o 7" x 7"
  - o 6" x 6"
  - o 5" x 5"
- 1024x1024 detector matrix
- Frame rates up to 30 FPS
- 194 micron pixel size
- 14-bit pixel depth for extended dynamic range

# TABLESIDE CONTROL HYPERHANDLE - XGCP-882BA

Adjustable, rail-mounted, tableside control provides functional control of component movement and interface with digital console. Control features a slim profile and ergonomic design with tactile control button.



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# **CATHETERIZATION TABLE - CAT-850B**

Facilitates catheterization of cardiac, cerebral, abdominal and peripheral areas.

- 8-way panning table enables table to be used for numerous radiographic techniques, movements tracked via coordinate display.
- Ample longitudinal movement provides coverage for lower extremity procedures.
- Flat surface eases movement of patient on and off the table.

# **Specifications**

- Sliding movements (manual):
  - Longitudinal stroke: 1350 mm (53.1")
  - $\circ$  Lateral stroke:  $\pm 200 \text{ mm} (\pm 7.9")$
- Vertical movement (motor-driven):
  - o 775 mm to 1150 mm (30.5" to 45.3") (from floor level)
- Tabletop rotation range (manual pivot): 90 to -180 degrees
- Maximum patient weight:
  - o 485 lbs. (220 kg IEC) at maximum table extension
  - Can support additional loading of up to 220 lbs (100 kg) for cardiopulmonary resuscitation (CPR)
- Tabletop rotation range (manual pivot): -180 to 0 degrees
- Accessories:
  - Tabletop mat (standard)
  - o Arm Cover (option)
  - Arm support, acrylic (option)
  - Armrest, CFRP (option)



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# **MULTI-FUNCTION FOOTSWITCH - XBFS-880B**

Provides various image acquisition and other programmable functions via foot pedals and buttons, freeing the clinician's hands and allowing more focus on the patient and image display.

# MULTITASKING DIGITAL FLUOROSCOPY PROCESSOR - DFP-8000B/B2

Toshiba's digital processor provides a variety of features to enhance workflow and image processing.

# **Common Graphic User Interface**

The new digital platform comes with a graphic user interface that is common across modalities on all Toshiba devices for more intuitive operation of all systems.

### Advanced Image Processor (AIP)

Toshiba's exclusive imaging technology – AIP (advanced image processing) – is a combination of software, filters and proprietary hardware. AIP enables enhanced visualization of small devices and structures while providing real-time response to optimize the collection of critical imaging information during the most demanding procedures.

## **Advantages Over Conventional Imaging**

- Virtually "instant-on" fluoroscopy: to help capture critical information at fluoro initiation.
- Noise and anti-blooming suppression technology provides a more uniform, high-resolution presentation of the image during fluoroscopy.
- Virtually zero lag during fluoroscopic imaging further enhances visualization during movement and while manipulating wires.



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# **Proprietary Technology**

AIP proprietary computing technology brings a new dimension to the overall performance of the system, adding specific functions for either targeted or general anatomical imaging to advance treatment planning or intervention. This includes:

- Dynamic Pattern Recognition Filter (DPRF): enhances visibility with digital recognition of devices to differentiate devices from anatomy.
- Dynamic Digital Compensation Filter (DDCF): improves exam efficiency and decreases dose by reducing the need for acrylic filters.
- Super Noise Reduction Filters (SNRF): allows for better visualization of anatomy and device by reducing noise, even with acute angulations. These enhancements reduce the amount of noise and lag in digital imaging for both digital angiography (DA) and fluoroscopy.

### **Dynamic Trace**

Can be used in a panning mode while imaging the lower extremities, and for Bolus Chase examinations, for a more uniform image display and background compression. This enables visualization of greater vessel detail even when vessels overlap bone.

### Guideview Subtracted 2-D Roadmap Fluoro

Toshiba's proprietary Guideview technology is particularly useful during roadmap imaging and can reduce the amount of contrast injections and dose. Guideview provides the ability to:

- Fade background vs. vessel
- Reverse blacks and whites
- Landmark image
- Adjust brightness and contrast real-time
- Create using LIH or acquired image

The combination of these features provides the ability to better distinguish and visualize guide wires within the vessel:



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### Features include:

- Peak Pixel Roadmap provides the optimal, live, peak, fluoroscopicsubtracted roadmap image.
- Add Subtracted Fluoroscopy provides a completely subtracted display to better visualize live contrast injections or embolic materials.
- CO<sub>2</sub> DSA provides the optimal, live, CO<sub>2</sub> (low-density pixel), fluoroscopic subtracted roadmap image without the use of iodinated contrast media.

#### Fluoro Record and Fluoro Store

Enables the easy use of fluoro store and playback to further study regions of interest, potentially reducing overall radiation dose. Ideal for pediatric imaging.

- Tableside, one button control
- 90 seconds or 1020 frames of prospective recording
- 60 seconds or 900 frames of retrospective recording

#### **Digital Live Zoom**

Live zoom digitally enlarges images in real time during both fluoroscopy and digital acquisition (DA) and offers the capability to provide a dose savings alternative compared to traditional field of view (FOV) magnifications.

#### Virtual Collimation using Last Image Hold

Provides an electronic outline to position the collimator and acrylic filter without fluoroscopy, further reducing dose.

#### DA and DSA

The user-friendly, icon-driven platform provides intuitive, rapid, tableside control over image processing and data management.

### Radiographic "One Shot" Mode

Allows the capture of a single image at radiographic technique level. Image can be used as a mask for functions such as "Guideview" subtracted roadmap fluoro.

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## **Simultaneity**

True multi-tasking including:

- Image retrieval
- Image acquisition
- Post processing
- Archiving
- **Printing**

#### Prevision

Enables retrieval and display of previously acquired Infinix i-series images as reference during follow-up procedures.

## **Post-Processing Software**

- Auto-window
- Roam and zoom
- Distance measurement and stenosis ratio measurement
- Spatial filtering (edge enhancement)
- Brightness/contrast control
- Landmarking percent
- Peak trace
- CO2 trace
- Shutter control
- Annotation
- Image rotation
- Pixel shift
- Panoramic view (available with S-DSA)

# **Image Input/Single Plane:**

- 1024<sup>2</sup>/14 bits: 30 fps (maximum)
- 512<sup>2</sup>/14 bits: 60 fps (maximum)

#### **Image Input/Biplane:**

- 1024<sup>2</sup>/14 bits: 15 fps (maximum)
- 512<sup>2</sup>/14 bits: 30 fps (maximum)

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# **Image Recording Unit**

- Image Disk RAID (144 GB)
- Maximum Recording Number
- 1024<sup>2</sup> 8/10/12 bits: 118,800/95,000/79,200 loss-less compression
- 512<sup>2</sup> 8/10/12 bits: 473,000/379,000/316,000 loss-less compression
- Online recording
- DVD-R and CD-R Recording
- DICOM 3.0, 512<sup>2</sup> or 1024<sup>2</sup> 8/10/12-bits, JPEG loss-less compression

### **DICOM Conformance and Dose Reporting**

- DICOM Store/Store Commitment, Query/Retrieve
- DICOM MWM and MPPS
- DICOM Structured Dose Reporting provides a comprehensive data set of procedural dose information that is available for output to further analyze and track dose information.

#### MAIN CONSOLE - XIDF-MCC80SB

Control room console with similar functions as exam room console, which enhances workflow due to a more intuitive use of the system. From inside the control room a user can:

- Operate the ring menu
- Use pre-programmed functions
- Control collimator and filters
- Review and manipulate images

#### INTERCOM KIT - XIDF-MIC802

- Noise-reduction transformer
- Remote operator activates microphone/speaker with footswitch
- In-room microphone/speaker mounts on monitor support

#### CONTROL ROOM FOOTSWITCH - XIDF-FS801S

Footswitch that enables fluoroscopy to be initiated from inside the control room.



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### ANGIO WORKSTATION (AWS) XIDF-AWS801/B1

- Supports Analysis and Planning Software.
- Supports 3D-DA/DSA applications.
- Supports 3-D Roadmap and Multi-Modality Roadmap.
- Supports Parametric Imaging.

Note: All advance 3D and Analysis software is optional

#### Dose Meter Controller - XJDK-001A/V5

Manages dose when combined with a dose chamber (part XJDC-009A) on the front of the beam-limiting device.

## Sends the following data to the digital fluoroscopy processor:

- Exposure time
- Dose area product (DAP) in μGycm<sup>2</sup>
- Dose area product rate (DAP) in μGycm<sup>2</sup>/s
- Calculated surface dose in mGy
- Calculated surface dose in mGy/s

#### DOSE CHAMBER - XJDC-009A (QTY 2)

For cardiovascular tube. Mounted on top of the collimator to enables dose data for real-time display.

## **IMAGE MAKER EXPRESS**

Image Maker Express is an online marketing resource that helps Toshiba customers build demand for imaging service by growing their referring physician and patient relationships. Image Maker Express includes:

- Easy-to-use marketing resources and tools developed exclusively for Toshiba customers to bring together effective marketing strategies and tactics.
- A wealth of collaterals and content to create high-quality brochures, print ads and more to help market the Toshiba customer's new imaging capabilities.



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Image Maker Express Materials available include:

- Product images and logos
- Clinical images and videos
- PowerPoint presentations and promotional videos
- Brochure samples
- Customizable press releases and media tips
- Marketing strategy tutorials

#### APPLICATION TRAINING

Each system includes three phases of education.

Phase I: Two (2) attendance vouchers for a four (4) day intensive technologist-focused course held at the Toshiba Institute of Advanced Imaging in Irvine, California. Using the most advanced education approach in the industry, the two (2) attendees will participate in in-depth lectures and hands on training covering basic clinical applications, imaging techniques, protocol optimization and dose reduction technologies. The vouchers are all inclusive to include tuition, airfare, lodging and meals. This course is a prerequisite to Phase II on-site training, and should be attended by at least one technologist no earlier than two to six weeks prior to system go-live. Accredited for CE credits by the ASRT Education Foundation.

Additional vouchers to include airfare, lodging and meals are available for purchase for \$3,500 per attendee.

**Phase II:** An initial thirty-two (32) hours of on-site education will be provided at the customer facility following system go-live. This training is provided for up to four (4) imaging professionals including the two (2) that attended Phase I training, to focus on maximizing imaging techniques and protocols. Training is scheduled consecutively, Monday through Friday, 8:00am to 5:00pm, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist.

<sup>\*</sup>Offerings may vary per product



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Phase III: An additional sixteen (16) hours of on-site education will be provided for the same four (4) imaging professionals, which participated in Phase II training, approximately 8-10 weeks following installation to optimize staff proficiency and system productivity. Training is scheduled consecutively, Monday through Friday, 8:00am to 5:00pm, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist. CE credits are earned by participants that attend both Phase I and Phase II training events in their entirety.

Note: Toshiba personnel are not responsible for imaging patients, patient safety, any actual patient contact, or operation of equipment during education sessions. Toshiba will only demonstrate proper equipment operation.

The above training must be completed by no later than one (1) year from date of completion of installation. If not completed by such one-year period, Toshiba reserves the right to charge for any training provided after that.

Applications support is available by phone on the toll-free ASSIST line.

#### **CUSTOMER CARE SERVICES**

Developed with customer input, Toshiba's innovative support programs have resulted in increased customer satisfaction. The following support programs are available to customers covered under warranty:

#### InTouch Center®

This centralized service facility provides applications and service support 24 hours a day, seven days a week.

#### InnerVision<sup>TM</sup> Plus

Remote system diagnostics are available around the clock to help identify problems and provide potential solutions before care is interrupted.



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#### **Technical Assistance**

Customer support specialists are available 24/7 to help resolve technical issues in real time.

#### **Local Customer Teams**

A single call mobilizes a local team of Toshiba customer engineers. With an average of over 10 years of Toshiba experience and more than 100 hours of specialized training, they can resolve any performance issue.

#### **Parts Support**

A complete inventory of product parts maintained in 34 parts depot locations throughout the country for shipment when and where they are needed, any time of day or night.

#### INTOUCH SERVICE MAINTENANCE AGREEMENTS

Toshiba offers a variety of customizable service plans ranging from shared risk to full security maintenance agreements that provide complete system coverage.

STEPPING UNIT FOR CAT-850B OR CAT-860B

**BASEPLATES FOR CAS-880** 

**BASEPLATE FOR CAS-880 750 MM** 

21 INCH COLOR MONITOR

**VGA CONNECTION ADAPTER** 

#### LCD FLAT-PANEL COLOR MONITOR 21

- 21.3" LCD monitor
- 1600x1200 display matrix
- 420 cd/m² luminance (typical)

#### **CABLE CARRIER KIT, 8'**



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## **INFINIX ARM SUPPORT (SUPINE POSITION)**

- Patient weighted arm boards hold weight of patient's arm alongside the torso at the Infinix table edge
- Set of two

## MAT, ANTI-FATIGUE (FLOOR MAT)

#### SERVICE INSTALLATION COMPONENTS

## INFINIX ANGIO WORKSTATION (AWS) WITHOUT 3-D ANGIO **SOFTWARE**

- Supports Analysis and Planning Software.
- Supports 3D-DA/DSA applications.
- Supports 3-D Roadmap and Multi-Modality Roadmap.
- Supports Parametric Imaging.

Note: All advance 3D and Analysis software is optional. If it is desired to extend viewing and control of advanced imaging applications into the exam room the extension kit must be selected as an option and possibly other components dependent on current monitor configuration.

This AWS is compatible with DFP versions 4.50, 4.51, 5.30, 6.0 and 6.1.

#### LCD FLAT-PANEL COLOR MONITOR 21

- 21.3" LCD monitor
- 1600x1200 display matrix
- 420 cd/m<sup>2</sup> luminance (typical)



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#### **IMAGE CONNECTION MODULE**

The ICM enables extension of a single DVI video output, maximum resolution 1920x1200@60Hz, providing the ability to interface ancillary medical devices for display on the 58" monitor. The ICM typically resides in the control room, where one ICM is needed for each video output intended to be displayed on the 58" monitor.

DVI SPLITTER, EXTENDER AND TRANSMITTER

CAT7 CABLE, 100 FT

**DVI EXTENDER AND RECEIVER CABLE** 

ADAPTER, DVI TO HDMI

**DUCT HOSE POSITION FOR CAS-820B** 

MULTIPURPOSE TABLESIDE CONTROL KEYBOARD AND MOUSE EXTENSION KIT FOR AWS, AND UP TO THREE OTHER PORTS

BLACK BOX SERVSWITCH WIZARD DVI KVM SWITCH

TRIPP LITE 1-PORT USB OVER CAT5/CAT6 (Qty 2)

CAT7 CABLE, 100 FT (Qty 2)

INFINIX KEYBOARD AND MOUSE TABLESIDE RAIL MOUNT ASSEMBLY

Designed to mount on any Infinix-i tableside rail set. Easily attaches to the tableside rails and provides an adjustable platform to hold a keyboard and mouse.

The assembly has multiple pivot points to accommodate a variety of positions to provide an ergonomic friendly setup. Enables the ability to conveniently place a keyboard and mouse right at tableside to interface with exam room monitors



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Also the assembly is designed to alternately mount a touch screen of monitor at tableside. Components are included to enable this attachment.

USB 2.0 CABLE 10FT (Qty 2)

**USB KEYBOARD** 

MEDICAL GRADE OPTICAL MOUSE

CABLE, DVI-D M/M DUAL LINK DIGITAL VIDEO, 3 METERS (Qty 4)

#### INTV-DASH/BP30/2.100

#### INTERVENTIONAL DASHBOARD DUAL 30" MONITOR SOLUTION

The Interventional Dashboard brings your important computer based tools to your fingertips. Up to eight (8) different systems can be interfaced into the Interventional Dashboard, providing a single collaborative workstation with one keyboard and one mouse.

Easily modify screen inputs and video sizes for optimal customization based on clinical need or preference. One system can be controlled at a time so you can update patient charts while viewing the information you need at the same workstation.

#### Includes:

#### Two Color LCD Displays

- 4.0 mega pixel (2560 x 1600)
- 30 inch diagonal (~596 x 335 mm, H x W)
- 300 cd/m2 typical luminescence rating

#### Connection Hardware

- Interface module
- Cabling to connect Live and Reference x-ray images
- Cabling to connect four external sources



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Keyboard and Mouse

Note: The monitor / device is not for use for screening or diagnostic mammography

#### VVIEW58/BP-VL.100

#### 58" MONITOR FOR BIPLANE

The 58" monitor displays critical patient information on one display and allows easy image display size, content or pattern changes with the joystick function on the Infinix tableside control.

The 58" monitor display system:

- Combined with Infinix-i imaging capabilities and the monitor suspension system, enhances the clinical environment and provides more critical patient information in one display.
- Improves the working space by reducing the profile of the monitor assembly and connection cabling.
- Provides and displays both patient information and anatomical images in a variety of sizes and patterns.
- Can quickly change from one enlarged image to six different displays, or choose from a multitude of display combinations.
- LMM Box is an ancillary component of the Eizo Video Integration Solution that enables video connectivity of multiple devices for display on the 58" monitor.
- Package includes a video scaler to accommodate automatic recognition of variable video resolution formats includes VGA, DVI, BNC and S-Video connectors for external Video input of mobile devices (i.e. Ultrasound) used during the case.
- One (1) 19" Monochrome backup monitor is included.

#### Components

- High-resolution 58" monitor display
- Monitor guard
- Digital processor with up to 27 inputs to manage image display sizes and patterns



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- Programmable touch panel to change and arrange image sizes and display patterns based on clinical preferences
- Video scaler and DVI extender for connection of mobile devices at tableside.

Monitor suspension sold separately

## INSTALLATION KIT FOR 58" MONITOR BIPLANE

## CABINET FOR LARGE LCD COLOR DISPLAY MONITOR

Wall or floor mounted storage unit to house VVIEW electronic components.

#### UNIVERSAL CONNECTION MODULE

The UCM enables connection of a variety of mobile medical devices for video input on the 56/58'' monitor. This unique design is capable of accepting and converting video signal from; DVI, VGA, BNC, and S-Video. Only one video signal can be input at a time.

#### **IMAGE CONNECTION MODULE (Qty 3)**

The ICM enables extension of a single DVI video output, maximum resolution 1920x1200@60Hz, providing the ability to interface ancillary medical devices for display on the 56/58" monitor. The ICM typically resides in the control room, where one ICM is needed for each video output intended to be displayed on the 56/58" monitor.

A240-1092R2

LARGE LCD MONITOR SUSPENSION FOR CAS RAILS, FOR VASCULAR SINGLE PLANE CEILING-SUSPENDED, CARDIAC SINGLE PLANE CEILING-SUSPENDED, BIPLANE AND SELECT ONLY

Optimizes monitor positioning around the patient table with an articulating arm for vertical height adjustments and a column that allows virtually 360 degree rotation. The transverse provides ample side-to-side positioning with a 60-inch movement range.



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- Holds one large LCD monitor with a VESA 400 mount
- Total weight payload: 155 lbs (70.45 kg)
- Complete assembly included:
  - Bridge 0
  - Interface
  - Toshiba CAS rails
- Accommodates up to two monitor mount bracket assemblies or mounting brackets for monochrome monitors to rear-mount smaller monitors (typically 19")
- Includes attachments and grounding hardware including a 100-foot AC power cable

Other optional devices will add payload weight. Please consult with a Toshiba representative regarding adding items to this assembly.

#### VVIEW56/ICM.100

#### **IMAGE CONNECTION MODULE (Qty 2)**

The ICM enables extension of a single DVI video output, maximum resolution 1920x1200@60Hz, providing the ability to interface ancillary medical devices for display on the 56/58" monitor. The ICM typically resides in the control room, where one ICM is needed for each video output intended to be displayed on the 56/58" monitor.

## VVIEW56/UCM.100

#### UNIVERSAL CONNECTION MODULE

The UCM enables connection of a variety of mobile medical devices for video input on the 56/58" monitor. This unique design is capable of accepting and converting video signal from; DVI, VGA, BNC, and S-Video. Only one video signal can be input at a time.

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# VVIEW/BRACKET.100

## MOUNTING BRACKET FOR MONOCHROME MONITOR AND **CONNECTION HARDWARE (Qty 2)**

Mounts one 19" monochrome monitor (Toshiba Model # SMD19102TCS) at the rear of the VVIEW suspension assembly for use in fluoroscopic imaging.

Connection hardware included.

#### ML19193-B0S01

## 19" GRAYSCALE MONITOR (Qty 2)

Grayscale flat panel display monitor.

- 1 mega pixel (1280 x 1024)
- 19 inch diagonal
- High contrast ratio 900:1 and luminance 1000 cd/m<sup>2</sup>

#### XIDF-ROT801

#### ROTATIONAL ANGIOGRAPHY TECHNOLOGY

The system has integrated multiple forms of rotation technology to include high-speed C-arm rotation for 3-D acquisition and 2-D rotational capabilities. High-speed rotation provides acquisition frame rates ideal for highresolution 3-D reconstructions.

### **Specifications**

- Image size: 1024x1024; 12-bit
- Image rate (FPS): Up to 25 FPS at 1024x1024 matrix
- Acquires images throughout and up to a 200-degree C-arm arc
- X-ray exposure timing: angle trigger method
- Provides 3-D color image display for enhanced diagnosis, treatment planning and interventional procedures.

#### **Rotational DSA**

Programmable single-axis rotation (manual or auto) to optimize display area



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#### XIDF-SFL801

#### SPOT FLUORO

Spot Fluoro software takes collimation to a new level by enabling asymmetric collimation and Last Image Hold (LIH) Overlay.

With asymmetric collimation a desired region of interest (ROI) can be specified anywhere in the field of view. This off-center, free spot, collimation capability enhances workflow by allowing the collimator blades to work around the patient so repositioning is eliminated.

LIH Overlay merges the collimated live fluoro onto the full field of view LIH, on a single monitor. Reference anatomy or landmarks remain on the same monitor, enabling collimation when traditional methods restricted its use.

#### 3D-ANGIO-SW-KIT.100

# BASE 3D ACQUISITION SOFTWARE (ALSO REQUIRES VITREA VL 3D PACKAGE)

This option for Infinix systems provides the necessary software for acquisition, reconstruction and display of 3-Dimensional Angiographic image data. From the head-end approach to the patient table, the c-arm can be programmed to acquire a serial acquisition over a 200-degree arc around the target area. A special high-speed reconstruction workstation provides fast transfer and display of the 3-D images on the Vitrea VL 3-D software.

This option is integral and a prerequisite for the optional Low Contrast Imaging (CT-like data) and Roadmapping options.

#### **APPS-ONSITE-32**

#### ADDITIONAL ON-SITE APPLICATIONS TRAINING - 32 HOURS

Four (4) days, thirty-two (32) hours, of additional onsite applications support. Training is scheduled consecutively, Monday through Friday, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist.

\$7,000, inclusive of application specialist's expenses.



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Note: Toshiba personnel are not responsible for scanning patients, patient safety, any actual patient contact, or operation of equipment during education sessions. Toshiba will only demonstrate proper equipment operation.

Education expires two (2) years from the later of purchase date or warranty start date.

#### XIDF-LCI801

#### LOW CONTRAST IMAGING FOR INFINIX AWS

This feature provides for the acquisition and display of "CT-like" imaging.

- Select acquisition of 2-D image data sets of approximately 250, 400 or 600 images/projections. Approximate acquisition times:
  - o 250 images: 10 seconds
  - 400 images: 15 seconds
  - o 600 images: 20 seconds
- The higher the image number, the better the resolution of the resulting 3-D volume and MPR's (Multi-Planar Reformations).
- Image display parameters are optimized to low-contrast image densities, and are particularly useful for soft-tissue diagnosis.
- LCI images are transferred and displayed on the 3-D workstation automatically from the DFP-8000 upon completion of acquisition.

Prerequisite: 3D-ANGIO

## XIDF-3DP802/A1

#### 3-D ROADMAP WITH NEEDLE GUIDANCE FOR INFINIX AWS

Infinix-i software option to provide 3-D Angio image super-imposed over live fluoroscopy

- Superimposed 3-D image is linked to all system mechanical movements to maintain accurate alignment of 3-D image with fluoroscopy projection as c-arm or table position changes
- Device enhance processing improves visualization of fine metallic interventional devices
- Simple, convenient user interface for manual adjustment, if desired

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- Multiple display modes, solid or hollow vessel with transparency adjustment
- Needle Guidance
  - Included as standard with Toshiba's Volume Navigation 3-D Roadmap is a Needle Guidance application, which provides pathway planning and real-time guidance for percutaneous interventions

## Prerequisite:

- 3-D Angio, including XIDF-3DI801 and XIDF-AWS801 software and
- Modality image which the Needle Guidance application can fuse:
  - 3D-Angio (3D-DA, 3D-DSA) included as standard
  - LCI (Low Contrast Imaging, Requires option XIDF-LCI801
  - CT Requires option XIDF-3DP803

#### XIDF-3DP804

# 3-D MULTI MODALITY FUSION (CT & MR) ROADMAP SOFTWARE FOR INFINIX AWS

3-D Multi-Modality Fusion Roadmap is a software application that enables overlay of live 2-D fluoro images, with previously acquired 3-D image data sets, to enhance 3-D anatomical reference. The previously acquired 3-D data sets can be rendered from either a CT or MR scanner or the Toshiba Infinix systems using LCI or 3-D Angio.

3-D volumes are reconstructed using the Angio Work Station PC, then projected on the Infinix exam room monitor where it is overlaid by live 2-D fluoro images. This functionality enables real-time integration of 3-D anatomical information to better aid clinical guidance and procedure planning. Automated c-arm positioning is integrated with the 3-D anatomical reference image for enhanced clinical workflow.

Requires DFP-8000B/B2 and XIDF-AWS801/B1 or later, 3D-ANGIOKIT and 3D Roadmap software. LCI software is required when customer desires to perform tableside CT-like imaging for creating a 3D model of the LA for ablations as well as using previously acquired CT datasets.



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## **DTS-KIT.100**

#### DOSE TRACKING SYSTEM KIT

This kit also includes hardware components required for dedicated viewing in the exam room for a 56''/58'' monitor.

#### IMAGE CONNECTION MODULE FOR LARGE LCD MONITORS

The ICM enables extension of a single DVI video output, maximum resolution 1920x1200@60Hz, providing the ability to interface ancillary medical devices for display on the large monitor. The ICM typically resides in the control room, where one ICM is needed for each video output intended to be displayed on the large LCD monitor.

#### XIDF-QCA700.100

#### AWS QUANTITATIVE ANALYSIS KITS

## XIDF-QCA701

## QUANTITATIVE CORONARY ANALYSIS

Quantitative Coronary Analysis (QCA) software package for use in clinical practice and research. This software features automatic contour detection of the coronary artery of interest and analysis of its dimensions.

#### Features:

- Automatic contour detection is supported for QCA.
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of QCA can be transferred to DFP-8000B or PACS server, and can be referred in the examination room and control room.

### XIDF-QCA702

### **QUANTITATIVE VESSEL ANALYSIS**

Quantitative Vessel Analysis (QVA) software package for use in clinical practice and research. The QVA software is used for quantitative analysis of blood vessels such as the aorta, iliac arteries, renal arteries, etc. QVA supports automatic contour detection for vessels up to 50 mm in diameter.

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#### Features:

- Automatic contour detection is supported for QVA.
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of QVA can be transferred to DFP-8000B or PACS server, and can be referred in the examination room and control room.

#### XIDF-QCA704.100

#### LEFT VENTRICULAR ANALYSIS (BIPLANE) KIT

#### CAT-TRS/V2

#### TABLE MOUNTED RADIATION SHIELD

Provides additional radiation protection from direct and scatter X-ray exposure.

- Mounts on Toshiba Infinix-i tableside rails, reversible for right or left side mounting
- Three-piece radiation shield assembly:
  - o Main shield: 181 mm x 645 mm
  - o Angled side shield: 700 mm x 645 mm
  - Tabletop scatter shield: 700 mm x 700 mm (removes to facilitate patient loading)
- Wall storage holders:
  - o Upper shield: 600 mm
  - o Lower shield: 460 mm
- Includes mini-rail for mounting table-function controls, if desired.

## 4.0M-CEILING-TRACK.100

# 4.0 M CEILING TRACK FOR RADIATION SHIELDS, LIGHTS AND MONITORS

The Mavig 4.0 M Ceiling Track enables up to two devices (maximum of one light) to be mounted on a single trolley. The 360 column with trolley has one electrified pin with 330 degrees of rotation capability and a lower pin with 360 degrees of rotation. Each pin has a load capacity of 18 kgs. Each trolley comes standard with a Brake Handle Strap which makes the system more user friendly.

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#### OT90001-US

# MAVIG CENTER MOUNTED CONTOUR CUT-OUT SHIELD 76/61 CM WITH PORTEGRA2 95/90 CM EXTENSION SPRING ARM

The MAVIG Center Mounted Contour Cut-Out Shield measures 76 cm by 61 cm and includes a Portegra2 Extension Spring Arm with two arms measuring 95 cm and 90 cm. The transparent acrylic shield contains 0.50 mm Pb and is easily manipulated into position by use of a height adjustable handle.

#### XGPA-800A

#### MAGNETIC SHIELDING KIT FOR 8" X 8" FPD

The Magnetic Shielding Kit for 8 x 8" Flat Panel Detector (FPD) available for the Infinix-i series INFX-8000V, INFX-8000C and INFX-8000H systems, is to be used in conjunction with 3D electro-anatomical mapping systems such as the Biosense Webster Carto TM system. It is designed to be attached to the front of the Flat Panel Display (FPD), and reduces the effect of the magnetic field exposure to the Flat Panel Display (FPD) thus reducing the image noise caused by the magnetic field. The combined kit can reduce patient dosage.

The magnet shielding material is 0.1 mm thickness Permalloy, with dimensions 241 mm x 241 mm.

#### XBFG-850B

# CONTROL CONSOLE WITH MUSHROOM HANDLE FOR CAT-850B/CAT-860B

Mounts on the table side rails of the CAT-850B table. Functions:

- 4-way table panning
- Vertical table lift
- Table pivot
- Table lateral movement lock

Note: This console cannot be combined with CAT-870B or CAT-880B tables.

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## FOOTSWITCH/W/BP/85 0.100

# WIRELESS FOOTSWITCH FOR CAT-850B AND CAT-860B BI-PLANE

The wireless footswitch provides cable-free operation. More flexibility for the customer, and easy maintenance. This kit requires a Table Modification Kit XBFM-850A in accordance with the combined table.

#### **Key Product Features:**

- Charging time: 4.5 hours
- Standby mode time: 48 hours
- Continuous use: 20 hours
- Battery needs to be replaced after 500 hours or 1 year
- 5M max distance from transmitter
- AC Charger
- System Cable to direct connect footswitch to table
- LED indicators for charged, charging, needs charge
- LED indicators also indicates errors

Prerequisite - requires software version 6.1 or above

#### XBER-001A

# TABLE SIDE RAIL SET (PAIR) FOR CAT-850B, CAT-860B OR CAT-880B

- Designed for application with the CAT-850B, CAT-860B or CAT-880B tables only
- Tableside rail set (2), one for each side
- Designed to accommodate Infinix table controls and common accessories (e.g., I.V. pole)

#### XBET-001A

# TABLE EXTENSION FOR CAT-850B, CAT-860B OR CAT-880B --**REQUIRES XBER-001A**

Auxiliary table extension installed at the foot end of the table. Easily folds over on to the foot end of the table when not in use.

Leading Innovation

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XBAR110A

ARMREST SET

Table mounted arm rest enables support for both arms.

9409

INFINIX TABLE PAD 2" FOR CAT-850, CAT-860B, OR CAT-870

Two-inch thick Infinix table pad made with a combination of dense foam and memory foam for patient comfort in longer procedures, black stretch

vinyl cover.

9412

**INFINIX TABLE WORK AREA PAD 2"** 

2" x 27.6" x 29.5" pad for foot end of Infinix table used as a work station. Coordinates with 9409 Table pad, elevates work area to flush level with

patient pad area. Black stretch vinyl cover.

9414A

INFINIX EP TABLE WIDTH EXTENDER

Image friendly table extension provides wide surface for superior arm

support during lengthy procedures. Also provides for attachment of CARTO

heart mapping device.

**345AFS** 

MAT, ANTI-FATIGUE (FLOOR MAT)

**RIDGES-PLUS** 

**COMPENSATION FILTER SET** 

Set of seven silicone rubber compensating filters for digital subtraction arteriography of the lower extremities.

- Two rulers incorporated in midline filters
- Two Velcro straps and three foam wedges provided for patient immobilization



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#### PCDU-100VL

#### POWER DISTRIBUTION UNIT FOR INFINIX-I

Provides most of the electrical site preparation for Toshiba vascular systems. Site preparation is simpler and less expensive because all components and functions are delivered in a single roll-in cabinet. Customer provides a single 480V Three-phase power feed and the PCDU properly distributes power to the Toshiba Infinix system.

Distribution Unit includes:

- Voltage conversion
- Power Distribution

#### **CAB-100B**

#### ADDITIONAL SYSTEM CABINET

This part is required for installations to store peripheral units.

Note: Only for DFP-8000B and later versions.

#### CABS-100B

#### CABINET SIDE COVER

This side cabinet cover is required in select installations due to site limitations in the Equipment Room, such as a floor-to-ceiling support beam causing separation of cabinets. This part provides for both left and right side cover needs.

Note: Only for DFP-8000B and later versions.



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## VE-VIT-VL3DBASE/PLAN.100

VITREAEXTEND INTERVENTIONAL PLANNING AND ANGIO VL3D PACKAGE INCLUDES 3-D ANGIO POST PROCESSING AND A COMPREHENSIVE INTERVENTIONAL PLANNING SUITE OF CLINICAL TOOLSETS, HARDWARE, AND EDUCATION TRAINING UNITS

VitreaExtend Interventional Planning and Angio VL3D package provides 2-D, 3-D and 4-D advanced visualization tools within the hospital network for one diagnostic professional to view and evaluate anatomy and pathology at 5 access points. Offering outstanding image quality and clinical flexibility, the VitreaExtend Basic package includes the following:

- One year software maintenance and warranty upon delivery
- The VitreaExtend workstation (includes monitor display)
- One concurrent VitreaExtend Basic user license
- Five Access point locations
- Five hours Remote Professional Services
- Twelve VitalU Education Units
- Customer must sign Vital Images software license agreement

Rights to professional services offered with the software license will expire 6 months from the delivery date of the software to the customer or, if purchased separately, 6 months from receipt of PO. Rights to education offered with the software license will expire 12 months from the delivery date of the software to the customer.

#### **Interventional Clinical Toolsets:**

#### Vitrea XA Angio Package (VL 3D)

Vitrea's VL 3D-Angio software provides visualization and analysis tools for rotational images acquired in angiography labs. 3D angiography provides enhanced 3D views of complex anatomy.

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### **Key Features:**

- Digital subtraction angiography (DSA) protocol with preset visualization settings for 3D evaluation of vessels
- Multi-volume fusion for displays of vessels, device and bone
- Standard 3D tools for dataset work
- Single-click segmentation, with automatic centerline and lumen boundaries, on DSA and digital angiography (DA) cases
- Displays clinical angles (CRA or CAU, RAO or LAO) in WHITE which can be reproduced, and displays the angles in RED when they cannot be reproduced, and these angles update automatically as volume view is rotated
- Clinical angles can be sent back to X-ray system for positioning of the Carm with a single click (Toshiba Infinix labs only)

#### Additional Features

- A minimum version of Vitrea software may be required.
- Low contrast imaging (LCI) protocol to better visualize soft tissue densities in target anatomy or pathology (Requires Infinix LCI acquisition package)\*
- DA protocol with preset visualizations and optimal settings for vascular tool set
- Standard archival tools for saving, exporting and printing the 3D
- acquisition with movies, batches and snapshots

\*Toshiba Infinix labs only

#### Vitrea General Vessel Probe

The Vitrea Vessel Probe tool is a single-click curved planar reformatting tool used for vascular analysis. Vessel Probe supports multi-modalities, including CT, MR and XA-3D Angio datasets.

#### Additional Clinical tools based on CT Datasets:



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## **Vitrea Cardiac EP Planning**

CT Cardiac EP Planning enables analysis and assessment of the left atrium and pulmonary veins. The application provides optimized 2D and 3D views with tools for quantitative measurements and 3D model export capabilities.

## Vitrea Endovascular Stent Planning

CT Endovascular Stent Planning (EVSP) enables visualization and measurements of aortic vessels for evaluation, treatment and follow-up for aortic vascular disorders. It automates 3D segmentation of the aorta and initializes stent measurements, based on a template provided by stent manufacturers for a highly efficient workflow.

## Vitrea TAVR Analysis

CT Transcatheter Aortic Valve Replacement (TAVR) Planning assists with the assessment of the aortic valve and in pre-operational planning and postoperative evaluation of transcatheter aortic valve replacement procedures.

#### Vitrea fX Brain Analysis 4D

For use with CT DICOM image data, CT 4D perfusion is a fast and inexpensive brain-imaging modality application for totally flexible, comprehensive brain imaging used in the management of patients with various neurological disorders, ranging from acute stroke to subarachnoid hemorrhage.

- Acquire, reconstruct, and review whole brain volumes including the arteriogram, venogram, and whole-brain perfusion using this totally flexible, comprehensive toolkit.
- Vitrea fX automates imaging of cerebral blood flow, cerebral blood volume, and time-to-peak or mean transit time.
- A single-bolus dose of contrast is all that is needed for CT imaging of the cerebral vasculature.

*Note: Application is not intended for use on 3-D DICOM XA (Xray Angiography)* image data.

Note: Application is not intended for use on 3-D DICOM XA (Xray Angiography) image data.

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#### VitalU Education

VitalU education units are included with each VitreaExtend. VitalU education units included with Vitrea workstation packages can be applied in any combination toward the cost of courses offered below.

Course Title	Setting	Days	Units
Advanced Visualization			
Fundamentals	Classroom	3	2
Advanced Visualization Fundamentals - Core			
(Prerequisite: Advanced Visualization			
Fundamentals)	Classroom	1	1
Specialty Instruction for Colonography,			
Cardiovascular, Neurology or Oncology			
(Advanced)	Classroom	2	2
Advanced Enterprise Administrator	Classroom	2	3
Advanced Visualization Course	Client Facility	2	6
Enterprise Advanced Visualization	Client Facility	3	9
Four Hour Webinar Tailored to Client Site	Online	.35	1
On-Site, Five Classroom, Add-on	Client Facility	N/A	3
Include travel to classroom	N/A	N/A	2
eLearning Videos	Online	N/A	Unlimited
VitalU Webinars	Online	N/A	Unlimited

A Vital Images representative will contact the customer to set up training. Rights to education offered with the software license will expire 12 months from the delivery date of the software to the customer.

**SUBTOTAL** \$1,387,377.00

**FREIGHT** \$6,200.00

\$1,393,577.00 **TOTAL** 

**TAXES** \$101,034.30

TOTAL QUOTE PRICE \$1,494,611.30



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## **ADDENDUM**

ALL INFORMATION CONTAINED IN THIS QUOTATION IS CONFIDENTIAL AND MAY NOT BE DISCLOSED TO ANY THIRD PARTY WITHOUT TOSHIBA'S PRIOR WRITTEN CONSENT.

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#### PRODUCT WARRANTY AND SERVICES COVERAGE

#### SYSTEM WARRANTY TERMS

Toshiba America Medical Systems, Inc. (TAMS) warrants to Customer that the product(s) to be delivered hereunder will be free from defects in material, manufacturing workmanship, and title. Any product or part furnished to Customer during the warranty period (stated in the table below) to correct a warranty failure shall be warranted to the extent of the unexpired term of the warranty applicable to the repaired or replaced product or part.

The warranty period shall commence on the date the Product is delivered to Customer. However, if TAMS installs the product, the warranty period for such product shall commence on the date the installation of the product is complete. Notwithstanding the foregoing, in the event that the installation of the product is delayed for a total of thirty (30) days or more from the date of delivery for any reason or reasons for which TAMS is not responsible, the warranty period for such product may, at TAMS' option, commence on the thirtieth (30th) day from the date such product is delivered to Customer.

#### WARRANTY EXCLUSIONS

Warranty coverage does not include any defect which results, in whole or in part, from (1) negligent storage or handling of the product by Customer, its employees, agents, or contractors, (2) failure of Customer to prepare the site or provide power requirements or operating environmental conditions in compliance with any applicable instructions or recommendations of TAMS, (3) absence of any product, component, or accessory recommended by TAMS but omitted at Customer's direction, (4) any design, specification or instruction furnished by Customer, its employees, agents, or contractors, (5) any alteration of the product by persons other than TAMS, (6) combining TAMS' product with any product furnished by others, (7) combining incompatible products of TAMS, (8) improper use of the product, improper maintenance of the product by a party other than TAMS, or failure to comply with any applicable instructions or recommendations of TAMS, or (9) acts of God, acts of civil or military authority, fires, floods, strikes or other labor disturbances, war, riot, or other causes beyond the reasonable control of TAMS.

TAMS does not warrant any products not manufactured by Toshiba such as, without limitation, monitors, cameras, computer equipment, etc. Such items will be furnished subject only to the manufacturer's warranty, if any, and without any warranty whatsoever by Toshiba.

Warranty coverage also excludes consumables, including but not limited to cassettes, magazines, imaging screens, disks, cartridges, etc.

#### GLASSWARE WARRANTY

Glassware, including X-ray tubes and Image Intensifiers, are provided separate warranties. Glassware included with the purchase of a new system is governed by the glassware warranty, described below, not the system warranty.

CT X-ray tubes carry a prorated warranty based on the number of rotations shown below or 12 months, whichever comes first.

Tube Type	Prorated Warranty		
CXB-750/D/4A:AQ/RXL,AQ/LB-SERIES,	200,000 rotations*		
ASSUREPLUS-V, AQ64, AQ16, AQ8			
CXB-750/E/2A:AQ/ONE/ASSURE	150,000 rotations*		
CXB-750/F/2A:ONE-320-SERIES-V,ONE-640-	100,000 rotations*		
SERIES-V, ONE-VISION-SERIES-V			
CXB-750G/2A: PRIME-SERIES	200,000 rotations*		

<sup>\*</sup>A rotation is any 360-degree or single rotation of the gantry with X-rays on.

The following time-based warranty terms apply to all other glassware:

Tube Type	Time-Based Warranty
Liquid Bearing Tubes (DSRX-TXXXX)	12 months, non-prorated
All Other X-ray tubes	12 months, non-prorated
Image Intensifiers	18 months, non-prorated

#### GLASSWARE PRORATION CALCULATION:

Credits for glassware that fails during the warranty periods stated above will be calculated as follows:

Tubes with Prorated Rotation Warranty:

Number of Rotations Used Credit = 1 -Number of Rotations Warranted

Credit will be applied to the purchase of the replacement X-ray tube or Image Intensifier. Complete glassware coverage during warranty period may be purchased from the local services organization at an additional charge.

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#### Tubes with Non-Prorated, Time-Based Warranty:

Tubes with a non-prorated warranty will be replaced during the initial warranty period at no charge to the customer. The replacement tube carries the remainder of the original warranty. For example, a tube with a 24-month non-prorated warranty fails at month thirteen (13), the tube is replaced at no charge and carries eleven (11) months of warranty.

#### REMEDIES

If TAMS determines that any product fails to meet any warranty during the applicable warranty period, TAMS shall correct any such failure by either, at its option, repairing, adjusting, or replacing without charge to Customer any defective or nonconforming parts of the product. TAMS shall have the option to furnish either new or remanufactured replacement parts or assemblies. During the warranty period, Toshiba will furnish free of charge any upgrades, including software required to correct any defect in the warranted products or as required under applicable laws.

#### WARRANTY SERVICE

Warranty service during the applicable warranty period will be performed without charge to Customer during TAMS' normal business hours, Monday through Friday, excluding holidays. Subject to the availability of personnel, after-hours service is available upon request at an additional charge.

The remedies set forth herein are conditional upon Customer promptly notifying TAMS within the applicable warranty period of any defect or nonconformance and making the product available for correction.

#### DISCLAIMERS AND LIMITATIONS ON LIABILITY

TAMS' obligation to repair or replace defective parts will be Customer's sole and exclusive remedy for a breach of the warranty set forth above. SUCH WARRANTY WILL BE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

In no event shall TAMS be liable for special, incidental or consequential damages. Toshiba does not warrant that the operation of the warranted products will be uninterrupted.

#### WARRANTIES BY PRODUCT LINE

WIRKINGTIES DI IRODOCI ENGE									
	COMPUTERIZED	MAGNETIC RESONANCE	PACS SYSTEMS	ULTRASOUND	X-RAY	X-RAY			
	TOMOGRAPHY				VASCULAR	R/F & RAD			
SYSTEMS AND	12 Months	12 Months	12 Months	12 Months	12 Months	12 Months			
MAJOR		1.5							
COMPONENTS									
ACCESSORY	6 Months	6 Months	6 Months	6 Months	6 Months	6 Months			
OPTIONS									
REPLACEMENT &	90 Days	90 Days	90 Days	90 Days	90 Days	90 Days			
OPTIONAL PARTS									
UPGRADE	90 Days	90 Days	N/A	12 Months	6 Months	6 Months			
COMPONENTS									
MISC.	Detectors:	N/A	N/A	Transducers:	N/A	N/A			
WARRANTY ITEMS	Solid State			12 Months					
	12 Months								



Leading Innovation

#### TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

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## **TERMS AND CONDITIONS OF SALE**

- 1. GENERAL TERMS. Unless otherwise specified on the face of this document, this Quotation/Order ("Agreement") will remain valid only if accepted by Customer no later than 60 days from date of submission to Customer.
- TITLE AND RISK OF LOSS. Title and risk of loss to the Equipment purchased under this Agreement will pass to Customer: (a) if Toshiba is to provide installation, upon Toshiba's completion of installation, or (b) if Toshiba will not provide installation, upon delivery by Toshiba to a common carrier at Toshiba's facility from which the Equipment is shipped.
- 3. TERMS OF PAYMENT. Prices stated are F.O.B. Customer's facility. All taxes which are payable by Toshiba in connection with the sale, use, or possession of the Equipment (excluding income taxes), will be paid by Customer in addition to the quoted price. Terms of payment for, C.T., M.R.I, X-Ray, and the McKesson System will be cash-10% upon execution of this Agreement, 70% upon delivery, balance due upon completion of installation and/or availability for first use, whichever is earlier. Terms of payment for Ultrasound will be cash-10% upon execution of this Agreement, 90% NET upon completion of installation and/or availability for first use, whichever is earlier. All invoices paid after due date will be assessed a late payment charge of the lesser of 1 1/2% per month or the maximum rate permitted by law.
- **DELAYS.** If Customer changes the scheduled delivery date specified on the face of this document ("Scheduled Delivery Date") during the period of 120 days preceding such date, Customer will nevertheless pay the installment of the purchase price which would have been payable upon delivery, on the Scheduled Delivery Date as if delivery had been made on such date. In addition, Customer will pay all extra costs incurred by Toshiba as a result of such delay, including, without limitation, storage and transportation. Storage fees will be charged at commercially comparable rates for storage on Toshiba's site. If delivery is delayed by 12 months or more from the Scheduled Delivery Date, except through the fault of Toshiba, the price set forth in this Agreement may be increased by Toshiba to a level equal to the prevailing price in effect at the time of the revised delivery date.
- 5. ACCEPTANCE BY TOSHIBA. This Quotation/Order will not be binding on Toshiba even if signed by a Toshiba employee, until Customer's order for the Equipment is booked by Toshiba's Headquarter office.

- 6. EQUIPMENT INSTALLATION. To shiba will install all Equipment purchased under this Agreement and connect them to existing power and/or plumbing lines at no additional charge to Customer. Customer will be responsible for electrical wiring, plumbing, carpentry, plastering, painting, or all other site preparation required prior to installation and connection of the Equipment by Toshiba. Customer will provide space at the installation site for the safe storage of Toshiba's tools, test equipment and other materials used for installation at no charge to Toshiba. Customer shall, at its cost, obtain all permits and licenses required by governmental authorities in connection with the installation and operation of the Equipment. The Equipment may contain certain components, which may have been remanufactured. However, such components will meet the manufacturer's specifications for new components as of the date of completion of installation. Customer acknowledges that the System and Software are designed to operate within certain power, temperature, airborne contamination, and humidity ranges. Customer will be responsible for, without limitation: (i) preparing and maintaining the Customer facility in conformance with the Site Preparation Guide; (ii) maintaining its network infrastructure; (iii) providing Toshiba, McKesson or its subcontractors access to a network connection in or near the area of the System being serviced by the equipment service staff; and (iv) supplying computer grade AC power. The Equipment relies upon a stable grounded connection to the main power grid in order to function effectively. Customer acknowledges that AC power supply quality may be a problem in old facilities or in those facilities receiving poor quality utility service and that power conditioning may be necessary in such cases.
- 7. EQUIPMENT OPERATION. Customer agrees that all Equipment purchased under this Agreement will be operated exclusively by duly qualified technicians and/or medical doctors in a safe and reasonable manner in accordance with Toshiba's written instructions, applicable laws and regulations, and for the purposes for which such Equipment was intended.
- 8. LIMITED WARRANTY AND REMEDY. A. For the Toshiba Equipment: For the warranty period described below by product, Toshiba, as its only obligation, will replace or repair, without charge to Customer during Toshiba's normal working hours (if Customer requests warranty service outside such hours, Customer will pay overtime premium for labor), any component of the Equipment that is defective in materials or workmanship, provided such defect is reported to Toshiba within the warranty period. Toshiba's warranty

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period is as follows: (a) Systems and Major Components - one year from date of completion of installation; (b) Accessories/Options (except glassware) - six months from date of completion of installation. Components not manufactured by Toshiba will be furnished subject only to the manufacturer's warranty, if any, and without any warranty whatsoever by Toshiba. During the warranty period, Toshiba will furnish free of charge any upgrades, including software required to correct any defect in the Equipment or as required under applicable laws.

B. For the McKesson System: The McKesson System ("System") will be covered by a 12-month warranty beginning the date of completion of installation of the System (the "Warranty Period"). The warranty covers repair of any defects in materials or workmanship related to the computer equipment ("Equipment") that is included in the System purchased by Customer under this Agreement. The warranty also covers correction of any McKesson software ("Software") that does not conform with its functional specifications. In order to receive services during the Warranty Period, Customer must provide McKesson and Toshiba with remote access through a VPN. During the Warranty Period, Customer is entitled to (a) all Generally Available Software Updates except for Updates that are separately priced and marketed by Toshiba or McKesson, and (b) all Generally Available Software Upgrades, except for Upgrades that are separately priced and marketed by Toshiba or McKesson. "Software Updates" means Software modifications, enhancements, corrections, improvements, and patches to the existing functionality of Customer's licensed version of the McKesson Software (e.g., version 4.1 to 4.3 to 4.5). "Software Upgrades" means new versions and future releases of the McKesson Software (e.g. version 4.x, 5.x, 6.x). Software Updates or Upgrades that provide new features not originally purchased may be separately priced and marketed. Software Updates and Software Upgrades to the McKesson Software will be delivered remotely, on-line. The warranty does not include any non-McKesson Software, the labor and travel expenses associated with on-site installation of a Software, or any hardware addition or modification.

The warranty set forth in this Section will not apply:

- if Customer operates the Software on equipment other than Equipment purchased from Toshiba or attaches other equipment to the System not approved by Toshiba;
- if a person or entity other than McKesson or its authorized third party suppliers modifies the Software;
- as a result of Customer's improper use, abuse, neglect of the Equipment, including failure to maintain environmental conditions within the operating range specified by the Equipment

- manufacturer or accident:
- as a result of viruses or other corruption caused by external entities; or
- for damages resulting from a Force Majeure condition described in Section 13 below.
- The Following Applies to Both the Toshiba Equipment and the McKesson System: Toshiba does not warrant that the operation of the Equipment of the System will be uninterrupted. All defective parts replaced by Toshiba will become the property of Toshiba. Replacement parts may be re-manufactured. However, such parts will meet the manufacturer's specifications for new components as of the date of completion of installation. TOSHIBA'S OBLIGATION TO REPAIR OR REPLACE DEFECTIVE PARTS OR SOFTWARE WILL BE CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR A BREACH OF THE WARRANTY SET FORTH IN THIS AGREEMENT. SUCH WARRANTY WILL BE IN LIEU OF ALL OTHER WARRANTIES. EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. The warranty set forth in this Agreement will not apply to, and Toshiba will not be liable for any defects resulting from misuse, repairs performed by unauthorized third parties, accidents, acts of God, or neglect of anyone other than Toshiba.
- LIMITATION OF LIABILITY, NEITHER TOSHIBA NOR CUSTOMER WILL UNDER ANY CIRCUMSTANCES BE LIABLE FOR CONSEQUENTIAL, SPECIAL, INCIDENTAL, OR EXEMPLARY DAMAGES OR ECONOMIC LOSS ARISING OUT OF OR RELATED THE TRANSACTIONS CONTEMPLATED AGREEMENT, EVEN IF EITHER PARTY IS APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING. IN NO EVENT WILL EITHER PARTY'S LIABILITY TO THE OTHER (WHETHER BASED ON AN ACTION OR CLAIM IN CONTRACT, TORT, INCLUDING NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE) ARISING OUT OF OR RELATING TO THE TRANSACTIONS CONTEMPLATED IN THIS AGREEMENT EXCEED AGGREGATE AMOUNT ACTUALLY PAID BY CUSTOMER TO TOSHIBA UNDER THIS AGREEMENT. THE LIMITATION OF LIABILITY SET FORTH ABOVE WILL NOT APPLY TO CLAIMS FOR PERSONAL INJURY OR PROPERTY DAMAGE CAUSED BY EQUIPMENT DEFECTS, OR TO CLAIMS FOR PATENT INFRINGEMENT.
- 10. SECURITY INTEREST. Toshiba hereby reserves and Customer grants to Toshiba a security interest pursuant to the Uniform Commercial Code, in and to the Equipment (and all products and proceeds of it) until full payment of the purchase price is received.

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In the event that Customer finances its acquisition of the Equipment through a lease, conditional sale contract, secured loan agreement or other financing agreement (collectively, "Lease") with Toshiba, then the security interest in the Equipment (and all products and proceeds thereof) shall secure all obligations of Customer due and to become due under the Lease.

- 11. REMOVAL OF EQUIPMENT. Until Toshiba has received full payment of the purchase price, Customer will not remove all or any part of the Equipment from Customer's premises, nor will Customer sell, lease, transfer or otherwise part with the possession of, or permit any lien or encumbrance to be placed on all or any part of the Equipment.
- 12. REMEDIES OF TOSHIBA. If Customer fails to make any payment when due under this Agreement or under any other agreement between Customer and Toshiba, or becomes insolvent or makes an assignment for the benefit of creditors, or if a petition in Bankruptcy is filed by or against Customer, or if the financial responsibility of Customer becomes impaired or unsatisfactory in Toshiba's reasonable judgment, or if Customer otherwise breaches any of the terms and conditions of this Agreement, then Toshiba may, without prior notice or demand, defer shipments, cancel the balance of the order, suspend performance of any obligation (including without limitation, all obligations set forth under Limited Warranty And Remedy above), and/or take immediate possession of the Equipment delivered, until the full purchase price of the Equipment is paid by Customer or, at Toshiba's discretion, until security satisfactory to Toshiba is given by Customer. Any costs incurred by Toshiba as a result of suspending performance or repossession or collection will be payable by Customer. Toshiba may sell repossessed Equipment with proceeds to be applied to unpaid balance and expenses incurred in sale, repossession and collection. Customer will pay any remaining deficiency. Toshiba may exercise any other rights available to it by law.
- 13. EXCUSED PERFORMANCES. Neither party will be liable to the other for non-performance or delay in performance resulting directly or indirectly from any occurrences beyond such party's control, including without limitation, strikes or other labor troubles, acts of God, war, accidents, fires, floods, other catastrophes, inclement weather, transportation, unavailability of materials and labor, delays caused by suppliers, or laws, regulations, or acts of any governmental agency.

- 14. SOFTWARE. All rights and interest in any software that may be furnished under this Agreement, and any updates and enhancements to it, will remain the property of Toshiba. Such software is being furnished to Customer under a non-exclusive license. Customer will not, or allow others to decompile, modify, copy, reproduce, or transcribe the software nor allow third parties to use the same without Toshiba's prior written consent. Upon Toshiba's request, Customer will execute an End-User Software License Contract, in a form to be mutually agreed between the parties.
- 15. CANCELLATION. Customer may not cancel the order subject to this Agreement except with Toshiba's prior written consent. In the event of such cancellation, Toshiba will be entitled to recover any and all damages suffered by it caused by the cancellation as allowed by law, but in no event less than an amount equal to twenty percent (20%) of the purchase price for a restocking charge.
- 16. ASSIGNMENT. Neither party may assign any of its obligations under this Agreement without the prior written consent of the other party However, some of the obligations stated in this Agreement, such as the ones relating to installation of the McKesson System and warranty may be performed by Toshiba's contractors or suppliers.
- 17. EXPORT REGULATIONS. This Agreement involves products, and/or technical data that may be controlled under the U.S. Export Administration Regulations and may be subject to the approval of the U.S. Department of Commerce prior to export. Any export or re-export by Customer, directly or indirectly, in contravention of such Regulations is prohibited.
- 18. ATTORNEY'S FEES AND COSTS. In the event of any legal proceeding involving any party to this Agreement against the other relating to the subject matter of this Agreement, the prevailing party in such proceeding will be entitled to recover attorney's fees, expert fees, and court costs against the non-prevailing party.
- 19. ENTIRE AGREEMENT. This quotation as well as the attached McKesson Pass Through Terms and Conditions contains the entire agreement between the parties and supersedes all prior and contemporaneous agreements between the parties, whether oral or written, relating to its subject matter, including, without limitation, all different or additional terms and conditions which may be contained in Customer's bid documents, purchase order or any other documents furnished by Customer. The provisions of this Agreement may not be modified unless in writing and executed by both parties.



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SOFTWARE LICENSE ACREEMENT (SLA20140902)

#### **ARTICLE 1: LICENSE GRANT AND USE**

- LICENSE GRANT. UNDER THIS AGREEMENT ("AGREEMENT"), VITAL IMAGES HEREBY GRANTS YOU A NONEXCLUSIVE, NON-TRANSFERABLE LICENSE TO USE THE OBJECT CODE VERSION OF THE PRODUCTS IDENTIFIED IN THE QUOTE TO WHICH THIS AGREEMENT IS ATTACHED. YOUR USE OF THE VITAL IMAGES PRODUCTS IS LIMITED TO A SINGLE DICOM-COMPLIANT WORKSTATION, UNLESS THE QUOTE IDENTIFIES THE PRODUCTS AS SYSTEM PRODUCTS, IN WHICH CASE, YOUR USE IS LIMITED TO A SINGLE SERVER SYSTEM. SUCH USAGE IS ALSO SUBJECT TO THE NUMBER OF CONCURRENT OR BASE USERS LICENSED OR, IF YOUR LICENSE IS BASED ON STUDY VOLUME, BY AN UNLIMITED NUMBER OF USERS, AS ENUMERATED IN THE QUOTE. PRODUCTS THAT ARE NOT VITAL IMAGES PRODUCTS OR ARE MANUFACTURED BY THIRD PARTIES MAY BE USED ONLY ON A SINGLE COMPUTER OR SERVER FOR EACH QUANTITY OF THIRD PARTY PRODUCTS LICENSED, UNLESS THEY ARE IDENTIFIED IN THE QUOTE AS SYSTEM PRODUCTS. YOUR USE OF VITAL IMAGES' MEDICAL IMAGING PRODUCTS SHALL BE LIMITED TO USE BY YOUR PHYSICIANS, RADIOLOGIC TECHNICIANS, OR OTHER MEDICAL PERSONNEL UNDER A PHYSICIAN'S SUPERVISION. ALL PRODUCTS ARE TO BE USED SOLELY FOR MEDICAL VISUALIZATION AND PRESENTATION PURPOSES IN CONNECTION WITH YOUR ORDINARY AND CUSTOMARY PATIENT CARE OPERATIONS. ALL SOFTWARE IDENTIFIED OR INSTALLED AS "TEST LAB" MAY BE USED ONLY IN A NON-CLINICAL SETTING FOR THE PURPOSE OF EVALUATING WHETHER THE SOFTWARE OPERATES IN ACCORDANCE WITH ITS WARRANTY, TEST LAB SOFTWARE MAY NOT BE USED FOR PATIENT CARE OR COMMUNICATION.
- RESTRICTIONS ON USE. YOU MAY NOT (I) ENGAGE IN, CAUSE OR PERMIT THE REVERSE ENGINEERING, DISASSEMBLY, 1.2 RECOMPILATION, MODIFICATION OR ANY SIMILAR MANIPULATION OF ANY PRODUCT; (II) MAKE ANY PRODUCT AVAILABLE TO THIRD PARTIES OR USE IT TO PROCESS THIRD PARTY DATA; (III) CREATE DERIVATIVE WORKS OF ANY PRODUCT; OR (IV) SUBLICENSE, LOAN, LEASE, DISTRIBUTE, ASSIGN OR OTHERWISE TRANSFER ANY PRODUCT OR COPIES THEREOF, IN WHOLE OR IN PART, OR OTHERWISE MAKE ANY PRODUCT AVAILABLE TO THIRD PARTIES.
- COPYING. SUBJECT TO YOUR RIGHT TO USE PRODUCTS THROUGHOUT YOUR SYSTEM, AS SET FORTH IN ARTICLE 1.1, YOU MAY NOT COPY ANY PRODUCT, EXCEPT THAT YOU MAY MAKE AND MAINTAIN ONE (1) COPY OF EACH PRODUCT FOR ARCHIVAL PURPOSES. ALL COPIES MUST INCLUDE ALL VITAL IMAGES COPYRIGHT, PROPRIETARY RIGHTS AND OTHER NOTICES INCLUDED ON OR IN SUCH PRODUCT.
- OWNERSHIP. THE PRODUCTS FURNISHED TO YOU BY VITAL IMAGES ARE LICENSED, NOT SOLD, TO YOU. EXCEPT FOR THE RIGHTS EXPRESSLY GRANTED TO YOU UNDER THIS AGREEMENT, ALL RIGHT, TITLE AND INTEREST IN EACH PRODUCT AND ALL WORK PRODUCT SHALL AT ALL TIMES REMAIN THE PROPERTY OF VITAL IMAGES AND ITS LICENSORS. YOU UNDERSTAND AND AGREE THAT YOU TAKE TITLE ONLY TO THE MEDIA ON WHICH A PRODUCT IS PROVIDED, AND THAT EACH PRODUCT SHALL REMAIN THE PROPERTY OF, AND PROPRIETARY TO, VITAL IMAGES OR THE LICENSORS OF ANY THIRD PARTY SOFTWARE PRODUCTS. IF ANY COMPUTER HARDWARE IS SOLD TO YOU, YOU WILL OWN SUCH HARDWARE UPON DELIVERY.
- 1.5 REMOTE ACCESS. CERTAIN PRODUCTS FURNISHED TO YOU UNDER THIS AGREEMENT MAY ALLOW USERS TO USE THE PRODUCTS AND/OR VIEW DATA OVER THE INTERNET OR IN OTHER REMOTE MANNERS. YOU MUST ENSURE THAT ANY REMOTE ACCESS TO AND REMOTE USE OF THE PRODUCTS IS ONLY BY YOUR AUTHORIZED USERS AND IS IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THIS AGREEMENT. ADDITIONALLY, YOU ARE RESPONSIBLE FOR MAINTAINING APPROPRIATE SECURITY TO DETECT AND/OR PREVENT (1) ACCESS BY UNAUTHORIZED USERS, (II) UNAUTHORIZED USE OF ANY PRODUCT, AND (III) WRONGFUL USE OF OR ACCESS TO PROTECTED HEALTH INFORMATION AND YOUR OPERATIONAL DATA, AND YOU MUST INDEMNIFY AND HOLD VITAL IMAGES HARMLESS FROM ANY LOSSES, JUDGMENTS, DAMAGES OR EXPENSES (INCLUDING ATTORNEYS' FEES) ARISING OUT OF OR RESULTING FROM REMOTE ACCESS.



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#### **ARTICLE 2: FEES AND PAYMENT**

#### 2.1 Payment for Products and Services.

You shall pay the fees for the Products, implementation services and hardware within thirty (30) days after delivery of Products, unless stated otherwise in the Quote.

- If you licensed Vital Images Products under an unlimited user license based on Study Volume, within thirty (30) days after the end of your Annual Measurement Period, you will provide Vital Images the Annual Facility and Study Volume Report. If your Study Volume increased from the previous Annual Measurement Period, you will pay the difference between the then-current license fee list price for the Vital Images Products at the new appropriate Study Volume and the then-current license fee list price for the previously established Study Volume, plus the applicable difference in fees for Software Maintenance and Support service as described in Article 6. This fee will be due within thirty days (30) of receipt of invoice.
- (c) Mergers, acquisitions and divestitures will be treated as potential changes in your Study Volume, as will entering into other agreements with outside institutions that allow them rights to use the Vital Images Products or otherwise increase your Study Volume, requiring a certification of your new Study Volume within thirty (30) days of such event. However, a license may not be split or downgraded to a lower level.
- Payment for Software Maintenance and Support and Other Services. Payment for Software Maintenance and Support is due thirty (30) days in advance of each annual support term. Payment for other services is due thirty (30) days from receipt of the invoice for such services.
- Taxes and Costs of Collection. You are responsible for all taxes related to the products and services provided under this Agreement, except for taxes based on Vital Images' income. Vital Images may assess you a late fee equal to 1.5% per month on any amounts past due, and you will reimburse Vital Images for any costs it incurs, including reasonable attorneys' fees, to collect past due amounts.
- Accounting and Audit Rights. You agree to keep complete, true and accurate books, accounts and records for the purpose of verifying your Study Volume. Vital Images shall have the right to audit those books, accounts, and records upon reasonable advance written notice. Vital Images shall bear the cost of any such audit, unless the audit shows a Study Volume five (5) percent higher than the Study Volume certified by you, in which case you shall be responsible for all costs and expenses related to the audit. Vital Images agrees to treat your books, accounts and records as confidential at all times.

#### **ARTICLE 3: DELIVERY**

All deliveries shall be F.O.B. the warehouse or other facility of Vital Images or the manufacturer of third party products. Each Product will be delivered, as Vital Images elects: (i) by shipment via common carrier; (ii) to your agent or any other person you specify; or (iii) via provision to you of access codes allowing you to download the Products over the internet. Each Product will be accepted upon delivery.



#### TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

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#### **ARTICLE 4: CONFIDENTIAL INFORMATION**

THE PRODUCTS AND THEIR ASSOCIATED DOCUMENTATION ARE PROPRIETARY TRADE SECRET INFORMATION OF VITAL IMAGES. YOU AGREE TO MAINTAIN THE CONFIDENTIALITY OF THE PRODUCTS AND THEIR DOCUMENTATION, AND THE TERMS OF THIS AGREEMENT, AS WELL AS ANY OTHER INFORMATION OR DATA OF VITAL IMAGES WHICH IT DESIGNATES OR WHICH LICENSEE KNOWS OR HAS REASON TO BELIEVE IS PROPRIETARY TO VITAL IMAGES ("CONFIDENTIAL INFORMATION"), IN AT LEAST THE SAME MANNER AS YOU MAINTAIN THE CONFIDENTIALITY OF YOUR OWN PROPRIETARY INFORMATION, WHICH IN ANY EVENT SHALL BE AT LEAST AS RESTRICTIVE AS IS STANDARD IN THE INDUSTRY FOR SIMILAR PROPRIETARY INFORMATION. YOU MAY USE THE CONFIDENTIAL INFORMATION DURING THE TERM OF THIS AGREEMENT ONLY AS PERMITTED HEREUNDER OR AS NECESSARY IN ORDER TO USE THE PRODUCTS IN ACCORDANCE WITH THIS AGREEMENT. YOU SHALL NOT DISCLOSE OR PROVIDE ANY CONFIDENTIAL INFORMATION TO ANY THIRD PARTY AND SHALL TAKE NECESSARY MEASURES TO PREVENT ANY UNAUTHORIZED DISCLOSURE BY YOUR EMPLOYEES, AGENTS, CONTRACTORS OR CONSULTANTS **DURING THE TERM HEREOF INCLUDING APPROPRIATE INDIVIDUAL NONDISCLOSURE AGREEMENTS.** 

# **ARTICLE 5: WARRANTIES**

- LIMITED WARRANTY. VITAL IMAGES WARRANTS THAT THE MEDIA UPON WHICH THE PRODUCTS ARE PROVIDED WILL, UPON DELIVERY, BE FREE FROM DEFECTS. VITAL IMAGES WARRANTS THAT THE SERVICES WILL BE PERFORMED IN WORKMANLIKE MANNER IN ACCORDANCE WITH INDUSTRY STANDARDS. FOR SO LONG AS YOU PAY ALL AMOUNTS DUE FOR MAINTENANCE AND SUPPORT SERVICES AND INSTALL ALL UPDATES AND UPGRADES PROMPTLY AFTER THEY ARE MADE AVAILABLE TO YOU, VITAL IMAGES WILL PROVIDE SERVICE TO CAUSE THE PRODUCTS TO FUNCTION IN ALL MATERIAL RESPECTS IN ACCORDANCE WITH THEIR APPLICABLE WRITTEN SPECIFICATIONS. VITAL IMAGES SHALL HAVE NO OBLIGATION WITH RESPECT TO ANY PRODUCT, IF ITS FAILURE TO MEET THIS WARRANTY RESULTS FROM ITS (A) NOT BEING PROPERLY INSTALLED OR MAINTAINED, OTHER THAN BY VITAL IMAGES; (B) MODIFICATION, OTHER THAN BY VITAL IMAGES; (C) USE OR COMBINATION WITH PRODUCTS NOT VALIDATED IN WRITING BY VITAL IMAGES; (D) USE IN A MANNER OTHER THAN AS APPROVED OR CLEARED BY THE U.S. FOOD AND DRUG ADMINISTRATION OR THE APPLICABLE REGULATORY BODY; OR (E) YOUR FAILURE TO USE THE LATEST VERSION OF THE PRODUCTS MADE AVAILABLE TO YOU BY VITAL IMAGES. VITAL IMAGES DOES NOT WARRANT (I) THAT THE OPERATION OF ANY PRODUCT WILL BE UNINTERRUPTED OR ERROR-FREE; (II) THAT ANY ERRORS IN ANY PRODUCT WILL BE CORRECTED; (III) THAT ANY PRODUCT WILL OPERATE IN THE COMBINATIONS THAT MAY BE SELECTED FOR USE; OR (IV) THAT ANY PRODUCT WILL OPERATE IN THE COMBINATIONS THAT YOU MAY SELECT FOR USE, INCLUDING OPERATIONS THAT MAY BE AFFECTED BY FACTORS OUTSIDE THE CONTROL OF VITAL IMAGES, INCLUDING YOUR NETWORK ENVIRONMENT AND THE SPEED OF YOUR INTERNET CONNECTION. YOU ACKNOWLEDGE THAT THE PRODUCTS ARE NOT INTENDED FOR DATA STORAGE AND THAT YOU ARE RESPONSIBLE FOR STORAGE AND RETENTION OF YOUR DATA. THE PRODUCTS ARE PROVIDED AS AN AID OR ADJUNCT TO PROCESSES OR DECISIONS THAT CAN BE MADE WITHOUT USE OF THE FUNCTIONALITY WITHIN THE PRODUCTS, AND CLINICAL JUDGMENTS AND EXPERIENCE ARE NECESSARY FOR PROPER USE. VITREAVIEW DISPLAYS PATIENT STUDIES AND OTHER PATIENT DATA BUT DOES NOT INTERPRET OR PROVIDE A DIAGNOSIS. MEDICAL DIAGNOSIS IS THE RESPONSIBILITY OF THE USER. VITAL IMAGES RESERVES THE RIGHT, AT ITS SOLE DISCRETION, TO PROVIDE ADDITIONAL PRODUCTS, HARDWARE, OR SERVICES THAT MAY BE NECESSARY FOR THE PRODUCTS TO PERFORM AT THE LEVEL INTENDED AS PER THE PURCHASE AGREEMENT, WHERE A FAILURE TO PERFORM AT SUCH LEVEL IS DUE TO AN ERROR OR OMISSION BY VITAL IMAGES.
- 5.2 <u>EXCLUSIVE REMEDY. VITAL IMAGES' ENTIRE LIABILITY, AND YOUR EXCLUSIVE REMEDY, FOR ANY WARRANTY CLAIM SHALL BE FOR VITAL IMAGES, AT ITS OPTION, TO EITHER (A) REPLACE ANY DEFECTIVE MEDIA</u> WHICH PREVENTS THE AFFFECTED PRODUCT FROM SATISFYING THE LIMITED WARRANTY; OR (B) ATTEMPT TO CORRECT ANY MATERIAL AND REPRODUCIBLE ERRORS YOU REPORT IN SUCH PRODUCT.



## TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

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- WARRANTY DISCLAIMER. THE WARRANTIES SET FORTH HEREIN ARE EXCLUSIVE IN CONNECTION WITH THE PRODUCTS OR SERVICES PROVIDED BY VITAL IMAGES UNDER THIS AGREEMENT, AND ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR USE, ALL OF WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY VITAL IMAGES. REPAIR OR REPLACEMENT OF A PRODUCT DOES NOT EXTEND ITS WARRANTY PERIOD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, ANY SERVICES ARE PROVIDED ON AN "AS IS" BASIS, ALL FAULTS INCLUDED AND WITHOUT ANY WARRANTIES.
- HARDWARE WARRANTY. VITAL IMAGES WILL TRANSFER TO YOU ANY WARRANTIES IT RECEIVES FROM THE MANUFACTURER OF ANY HARDWARE ("OEM") FURNISHED TO YOU BY VITAL IMAGES, BUT VITAL IMAGES PROVIDES NO ADDITIONAL WARRANTIES BEYOND THOSE PROVIDED BY THE OEM. YOU AGREE TO RESOLVE ANY MALFUNCTION, FAULT OR DEFECT WITH RESPECT TO SUCH HARDWARE PRODUCTS DIRECTLY WITH THE OEM.
- DAMAGES LIMITATION. VITAL IMAGES AND ITS LICENSORS SHALL HAVE NO LIABILITY OF ANY KIND FOR ANY CLAIM ARISING FROM OR RELATED TO ANY USE OF THE PRODUCTS OTHER THAN AS A SUPPLEMENT TO STANDARD METHODS OF INTERPRETING RADIOLOGIC IMAGES, NOR SHALL VITAL IMAGES OR ITS LICENSORS BE LIABLE FOR ANY LOST DATA, LOST PROFITS, LOST REVENUE, OR ANY OTHER FORM OF CONSEQUENTIAL INDIRECT, INCIDENTAL, SPECIAL, OR PUNITIVE LOSS OR DAMAGE, EVEN IF VITAL IMAGES OR, IN THE CASE OF THIRD PARTY PRODUCTS, ITS LICENSORS, SHALL HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH POTENTIAL <u>LOSS OR DAMAGE, AND EVEN IF A REMEDY SET FORTH HEREIN IS FOUND TO HAVE FAILED OF ITS ESSENTIAL</u> PURPOSE. IN NO EVENT SHALL VITAL IMAGES' OR ITS LICENSORS LIABILITY OF ANY KIND UNDER ANY THEORY, INCLUDING CONTRACT AND TORT, WITH RESPECT TO THE PRODUCTS AND SERVICES COVERED BY THIS AGREEMENT AND ALL OTHER PERFORMANCE BY VITAL IMAGES UNDER THIS AGREEMENT EXCEED THE AMOUNTS PAID HEREUNDER DURING THE TWELVE MONTHS PRIOR TO THE DATE THE FACTS GIVING RISE TO SUCH LIABILITY OCCURRED.

#### **ARTICLE 6: SOFTWARE MAINTENANCE AND SUPPORT**

6.1 Description of Software Maintenance and Support. During any period in which you are current in your payment of fees for Software Maintenance and Support, you will receive Software Maintenance and Support more fully described in this Article 6, and education units more fully described in Article 7. Pursuant to Article 6.5, your Software Maintenance and Support Services will automatically renew on a recurring annual basis. As part of your Software Maintenance and Support, Vital Images may provide you with Vitrea. Innervision, a service under which Vital Images will monitor your System performance. Vitrea. Innervision shall be subject to the terms of this Agreement. The Remote Access capability of Vitrea. Innervision is also subject to the GNU General Public License 2.0 (the "GPL"), and no term of this Agreement shall apply to such component to the extent such term would conflict with the GPL.



Leading Innovation

#### TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

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- UPDATES AND UPGRADES. VITAL IMAGES SHALL MAKE AVAILABLE TO YOU IN THE FORM OF EXECUTABLE CODE, OR REVISIONS TO THE DOCUMENTATION, AS THE CASE MAY BE: (I) CORRECTIONS OR FIXES TO ERRORS IN THE PRODUCTS THAT ARE REPORTED BY YOU OR OTHER USERS (AN "UPDATE") AND (II) UPGRADES TO THE PRODUCTS WHICH ADD OR IMPROVE FUNCTIONALITY OR PERFORMANCE OF THE PRODUCTS BUT WHICH DO NOT SOLELY CORRECT OR FIX AN ERROR IN THE PRODUCTS (AN "UPGRADE"). UPGRADES AND UPDATES, TOGETHER WITH ASSOCIATED DOCUMENTATION, WILL BE PROVIDED AS AND WHEN MADE GENERALLY AVAILABLE TO PRODUCT LICENSEES. YOU SHOULD BE AWARE THAT, BECAUSE SOFTWARE MAINTENANCE AND SUPPORT MAKES AVAILABLE TO YOU THE MOST RECENT VERSION OF THE PRODUCTS, CERTAIN UPDATES OR UPGRADES MAY REQUIRE YOU TO UPGRADE THE HARDWARE ON WHICH YOU OPERATE THE PRODUCTS.
- 6.3 TELEPHONE CONSULTATION. DURING ANY OTHER PERIOD IN WHICH YOU ARE CURRENT IN YOUR PAYMENT OF FEES FOR SOFTWARE MAINTENANCE AND SUPPORT, YOU CAN RECEIVE TELEPHONE CONSULTATION CONCERNING USE AND OPERATION OF THE PRODUCTS FROM OUR TECHNICAL SUPPORT STAFF. SUCH CONSULTATION SHALL BE AVAILABLE DURING THE HOURS SET FORTH IN THE QUOTE.
- 6.4 Your Obligations. To enable Vital Images to provide Software Maintenance and Support, you shall designate a TEAM OF TRAINED INTERNAL REPRESENTATIVES, WHO WILL BE RESPONSIBLE FOR RECEIVING CALLS FROM YOUR USERS OF THE PRODUCTS AND DETERMINING WHETHER TO NOTIFY VITAL IMAGES REGARDING THE REPORTED ISSUES. YOUR DESIGNATED REPRESENTATIVES MUST PROMPTLY ADVISE VITAL IMAGES, BY TELEPHONE AT 800-208-3005, IF YOU BECOME AWARE OF ANY ERRORS IN ANY PRODUCT. IN CONNECTION WITH SUCH REPORTS, YOU SHALL PROVIDE VITAL IMAGES WITH SUFFICIENT INFORMATION SO THAT IT MAY REPRODUCE THE REPORTED ERRORS IN ITS LABORATORY SETTING, AND ANY OTHER DATA OR INFORMATION REASONABLY REQUESTED BY VITAL IMAGES AS NECESSARY FOR ITS ERROR CORRECTION ACTIVITIES. YOU SHALL ALSO PROVIDE VITAL IMAGES REASONABLE ACCESS TO YOUR FACILITY, SYSTEM AND/OR DATA COMMUNICATION RESOURCES, INCLUDING A DEDICATED SECURE WEB OR VPN CONNECTION FOR REMOTE ACCESS AND NON-PHI (PROTECTED HEALTH INFORMATION) SYSTEM PERFORMANCE MONITORING. VITAL IMAGES MAY CHARGE YOU AT ITS STANDARD RATES FOR TIME AND EXPENSES FOR ANY ADDITIONAL WORK IT PERFORMS, INCLUDING BUT NOT LIMITED TO DIAGNOSING A REPORTED PROBLEM AS RESIDING OUTSIDE OF A PRODUCT LICENSED HEREUNDER, OR RESULTING FROM YOUR NOT PERFORMING YOUR OBLIGATIONS. YOU SHALL PROMPTLY INSTALL AND THEREAFTER USE ANY UPGRADES OR UPDATES MADE AVAILABLE BY VITAL IMAGES.
- SOFTWARE MAINTENANCE AND SUPPORT. IF YOU HAVE PURCHASED SOFTWARE MAINTENANCE AND SUPPORT, YOU WILL BE BILLED SIXTY (60) DAYS IN ADVANCE OF EACH ANNUAL SOFTWARE MAINTENANCE AND SUPPORT PERIOD AT THE ANNUAL SOFTWARE MAINTENANCE AND SUPPORT AMOUNT SET FORTH IN THE QUOTE. PAYMENT FOR SOFTWARE MAINTENANCE AND SUPPORT IS DUE AT LEAST THIRTY (30) DAYS IN ADVANCE OF EACH ANNUAL SUPPORT TERM. IF YOU HAVE PURCHASED SOFTWARE MAINTENANCE AND SUPPORT FOR THIRD PARTY PRODUCTS, VITAL IMAGES RESERVES THE RIGHT TO INCREASE THE PRICE OF OR TERMINATE THE SOFTWARE MAINTENANCE AND SUPPORT FOR SUCH PRODUCTS AT THE END OF ANY ANNUAL TERM BY GIVING YOU WRITTEN NOTICE AT LEAST SIXTY (60) DAYS IN ADVANCE OF ANY ANNUAL SOFTWARE MAINTENANCE AND SUPPORT PERIOD. UPON RECEIPT OF A WRITTEN NOTICE OF A PRICE INCREASE FOR SOFTWARE MAINTENANCE AND SUPPORT ON THIRD PARTY PRODUCTS, YOU CAN ELECT TO CANCEL SUCH SOFTWARE MAINTENANCE AND SUPPORT FOR SUCH PRODUCTS BY GIVING WRITTEN NOTICE THIRTY (30) DAYS IN ADVANCE OF THE SOFTWARE MAINTENANCE AND SUPPORT PERIOD, AND YOUR PRICE FOR SOFTWARE MAINTENANCE AND SUPPORT WILL BE REDUCED ACCORDINGLY. IF YOU LICENSE ADDITIONAL PRODUCTS OR INCREASE YOUR STUDY VOLUME WHILE YOU ARE UNDER SOFTWARE MAINTENANCE AND SUPPORT, YOUR ANNUAL SOFTWARE MAINTENANCE AND SUPPORT AMOUNT WILL INCREASE AS DESCRIBED IN ARTICLE 6.7. UPON TERMINATION OF SOFTWARE MAINTENANCE AND SUPPORT FOR ANY REASON, ALL SERVICES SHALL IMMEDIATELY TERMINATE, AND, EXCEPT AS SET FORTH ABOVE WITH REGARD TO TERMINATION OF THIRD PARTY PRODUCTS, ANY AMOUNTS UNPAID FOR ANY PORTION OF THE INITIAL TERM OR ANY RENEWAL TERM SHALL BE IMMEDIATELY DUE.



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- RENEWAL. AS OF THE END OF EACH APPLICABLE SOFTWARE MAINTENANCE AND SUPPORT PERIOD, SOFTWARE MAINTENANCE AND SUPPORT SHALL BE AUTOMATICALLY RENEWED ON THE SAME TERMS AND CONDITIONS AS STATED HEREIN FOR SUCCESSIVE TWELVE (12) MONTH PERIODS UNLESS EITHER PARTY GIVES THE OTHER PARTY WRITTEN NOTICE AT LEAST NINETY (90) DAYS PRIOR TO THE ANNUAL RENEWAL DATE OF ITS ELECTION NOT TO RENEW. SOFTWARE MAINTENANCE AND SUPPORT SHALL BE PROVIDED DURING EACH RENEWAL PERIOD AT THE THEN-CURRENT PRICES CHARGED BY VITAL IMAGES. FEES FOR EACH RENEWAL TERM SHALL BE AUTOMATICALLY BILLED BY VITAL IMAGES AT LEAST SIXTY (60) DAYS BEFORE THE COMMENCEMENT OF THE NEXT RENEWAL PERIOD. PAYMENT FOR SOFTWARE MAINTENANCE AND SUPPORT IS DUE AT LEAST THIRTY (30) DAYS IN ADVANCE OF EACH ANNUAL SUPPORT TERM. VITAL IMAGES SHALL HAVE NO OBLIGATION TO PROVIDE ANY SERVICE OR UPDATES DURING ANY PERIOD IN WHICH YOU HAVE NOT PAID.
- 6.7 LICENSES OF ADDITIONAL PRODUCTS AND INCREASES IN STUDY VOLUME OR NUMBER OF CONCURRENT OR BASE USERS. IF YOU LICENSE ADDITIONAL PRODUCTS, INCREASE YOUR STUDY VOLUME OR ADD TO THE NUMBER OF CONCURRENT OR BASE USERS LICENSED HEREUNDER DURING A SOFTWARE MAINTENANCE AND SUPPORT PERIOD, THE INITIAL SOFTWARE MAINTENANCE AND SUPPORT PERIOD FOR THE ADDITIONAL PRODUCTS SHALL BE PRORATED SO THAT ITS ANNUAL COMMENCEMENT AND TERMINATION ARE CONCURRENT WITH THE SOFTWARE MAINTENANCE AND SUPPORT PERIOD FOR YOUR OTHER PRODUCTS. YOU MAY ALSO RECEIVE INCREMENTAL EDUCATION UNITS AS SET FORTH IN THE QUOTE. THESE INCREMENTAL EDUCATION UNITS WILL EXPIRE CONCURRENTLY WITH YOUR OTHER EDUCATION UNITS. Thereafter, in addition to paying the additional license fee as described in Article 2, your Software Maintenance and SUPPORT RENEWAL FEE WILL INCREASE BY THE ANNUAL SOFTWARE MAINTENANCE AND SUPPORT AMOUNT PER PRODUCT, STUDY OR CONCURRENT OR BASE USER SET FORTH IN THE QUOTE.
- 6.8 ANTIVIRUS. YOU ARE RESPONSIBLE FOR THE ACQUISITION AND IMPLEMENTATION OF ANTIVIRUS SOFTWARE AND MICROSOFT SERVICE PACKS ON ALL WORKSTATIONS AND SERVERS USING THE PRODUCTS. VITAL IMAGES RECOMMENDS ANTIVIRUS ACTIVE SCANNING **EXCLUSIONS FOR ALL PATIENT DATA.**
- DISCLAIMER. VITAL IMAGES SHALL HAVE NO OBLIGATION TO PROVIDE SERVICES FOR A VERSION OF A PRODUCT FOR MORE THAN TWELVE (12) MONTHS AFTER IT HAS BEEN DISCONTINUED OR UPDATED BY AN UPGRADE OR UPDATE. PROVISION OF SOFTWARE MAINTENANCE AND SUPPORT DOES NOT INCLUDE THE OBLIGATION TO PROVIDE TO YOU ANY PRODUCTS, MODULES OR SYSTEMS DEVELOPED BY VITAL IMAGES OR ITS LICENSORS THAT ARE MARKETED BY VITAL IMAGES AS DISTINCT PRODUCTS, MODULES OR SYSTEMS FROM THE PRODUCTS WITHIN THE PACKAGES YOU LICENSED.

### **ARTICLE 7: PROFESSIONAL SERVICES AND EDUCATION**

7.1 INSTALLATION. INSTALLATION OF THE PRODUCTS CONSISTS OF PROJECT MANAGEMENT, COORDINATING AN INSTALLATION PLAN WITH YOU, AND LOADING EACH PRODUCT ON COMPUTER(S) OR SERVER(S) AT YOUR DESIGNATED SITE AND ACTIVATING THE LICENSE FOR SUCH PRODUCT. YOU WILL INSTALL ALL UPGRADES AND UPDATES, UNLESS YOU WISH FOR VITAL IMAGES TO INSTALL SUCH UPDATES AND Upgrades, for an additional charge. You agree to provide VITAL IMAGES WITH CERTAIN INFORMATION ABOUT THE ENVIRONMENT IN WHICH THE PRODUCTS ARE TO BE INSTALLED, INCLUDING INFORMATION ABOUT THE NETWORK AND CONFIGURATION YOU PLAN FOR THE PRODUCTS, AS WELL AS NAMES AND CONTACT INFORMATION FOR INFORMATION TECHNOLOGY AND CLINICAL PERSONNEL RESPONSIBLE FOR THE INSTALLATION. INSTALLATION SERVICES TO BE PROVIDED AND FEES FOR INSTALLATION SERVICES SHALL BE INCLUDED IN THE QUOTE. VITAL IMAGES MAY CHARGE YOU ADDITIONAL TIME AND EXPENSES IF THE TIME IT INCURS TO PERFORM THE INSTALLATION IS EXTENDED, IF IT RECEIVES INCORRECT OR INCOMPLETE INFORMATION FROM YOU, OR IF INSTALLATION IS DELAYED BECAUSE OF THE UNAVAILABILITY OF YOUR ENVIRONMENT OR RESPONSIBLE PARTIES. FEES FOR INITIAL AND ANY ADDITIONAL INSTALLATION SERVICES ARE BASED ON VITAL IMAGES' THEN-CURRENT STANDARD RATES. ALL RIGHTS TO INSTALLATION AND OTHER PROFESSIONAL SERVICES WILL EXPIRE SIX (6) MONTHS FROM THE DATE OF DELIVERY OR FROM THE DATE OF INVOICING IF PURCHASED SEPARATELY. YOU SHALL BE RESPONSIBLE FOR INSTALLING HARDWARE PRODUCTS IN A LOCATION OF YOUR CHOICE. NO HARDWARE INSTALLATION SERVICES ARE TO BE PROVIDED BY VITAL IMAGES UNDER THIS AGREEMENT, UNLESS OTHERWISE STATED IN A SEPARATE WRITTEN AGREEMENT.

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- 7.2 EDUCATION. YOU MAY RECEIVE INITIAL AND/OR ONGOING USER AND ADMINISTRATOR EDUCATION AS PART OF YOUR PURCHASE OF EDUCATION MAY INCLUDE COLLABORATIVE DEVELOPMENT OF AN EDUCATION PLAN, AND ANY COMBINATION OF CLASSROOM, DISTANCE AND ONLINE LEARNING (ELEARNING) THAT IS WORKFLOW-BASED CLINICAL FUNCTIONALITY FOR USERS (PHYSICIANS AND TECHNOLOGISTS) AND IT-BASED FOR ADMINISTRATORS. USER EDUCATION CONSISTS OF BASIC PRODUCT FUNCTIONALITY OVERVIEW AND SPECIFIC CLINICAL PACKAGE WORKFLOWS WHILE MANIPULATING IMAGES IN MULTIPLE DIMENSIONS. ADMINISTRATOR EDUCATION CONSISTS OF HARDWARE CONFIGURATION, SYSTEM SETUP, DEPLOYMENT AND ADMINISTRATION OF LICENSES FOR THE PRODUCTS, BASIC TROUBLESHOOTING, AND DICOM CONNECTIVITY. ALL RIGHTS TO RECEIVE EDUCATION EXPIRE ON AN ANNUAL BASIS, COMMENCING WITH THE DATE OF DELIVERY OR DATE OF INVOICING IF PURCHASED SEPARATELY AND WILL EXPIRE AND NOT CARRY OVER FROM YEAR TO YEAR. YOUR ANNUAL EDUCATION UNITS MAY BE USED TO RECEIVE EDUCATION DURING THAT YEAR, ACCORDING TO VITAL IMAGES' THEN CURRENT EDUCATION OFFERINGS AND THE NUMBER OF UNITS TO BE USED TO RECEIVE ANY PARTICULAR OFFERING. EDUCATION UNITS USED FOR ON-SITE LEARNING AT YOUR LOCATION MUST BE SCHEDULED FOR CONSECUTIVE DAYS WITH A TWO-DAY MINIMUM. EDUCATION UNITS USED FOR CLASSES AT A VITAL IMAGES LOCATION INCLUDE TUITION ONLY FOR THE EVENT. CANCELLATION OF ON-SITE EDUCATION SESSIONS OR REGISTRATIONS FOR OPEN ENROLLMENT CLASSES FEWER THAN TWO WEEKS IN ADVANCE OF THE EVENT CAUSES FORFEITURE OF THE ASSOCIATED EDUCATION UNITS.
- 7.3 OTHER SERVICES. ANY SERVICES NOT SET FORTH HEREIN, INCLUDING BUT NOT LIMITED TO ADDITIONAL INSTALLATION, EDUCATION, CONSULTATION, CUSTOM SOFTWARE DEVELOPMENT OR ANY OTHER SERVICES, WILL BE SET FORTH IN A SEPARATE AGREEMENT. RELATED TO ANY ADDITIONAL SERVICES, YOU AGREE TO PROVIDE VITAL IMAGES WITH ALL REQUESTED INFORMATION AND ADMINISTRATIVE AND TECHNICAL SUPPORT AS SUCH ARE REASONABLY REQUESTED BY VITAL IMAGES.

#### **ARTICLE 8: TERM AND TERMINATION**

8.1 THIS AGREEMENT SHALL COMMENCE ON THE DATE HEREOF AND CONTINUE UNLESS AND UNTIL TERMINATED IN ACCORDANCE WITH ARTICLE 8.2.

#### 8.2 TERMINATION.

- Either party may terminate this Agreement at any time if the other party breaches any of its obligations under this Agreement and fails to cure such breach within thirty (30) days after receipt of written notice of such breach.
- Either party may terminate Software Maintenance and Support at the end of the full contracted duration without cause by providing Vital Images with written notice at least ninety (90) days prior to the expiration of any period for which you have contracted. Except as set forth in this Section 8.2(a) or 8.2(b), Software Maintenance and Support may not be terminated before the expiration of the duration of the Software Maintenance and Support contract.
- Vital Images may terminate this Agreement and all Licenses and services hereunder (i) if you fail to pay the appropriate fees based on increases in your Study Volume or if you fail to provide Vital Images the Annual Facility and Study Volume Report per Section 2; (ii) if you misrepresent your Study Volume in order to reduce your obligation to Vital Images; (iii) as contemplated by Section 9.2; or (iv) upon your (a) becoming insolvent; (b) commencing, or having commenced against you (without dismissal within sixty (60) days), any bankruptcy, insolvency, liquidation, or similar proceeding under any U.S. or foreign law; (c) making an assignment for the benefit of your creditors; (d) admitting in writing your inability to satisfy your debts in the ordinary course of business or that your business or financial condition indicates that you are unable to continue as a going concern; or (e) taking an action resulting in or directed to ceasing, on a permanent basis, your business or relevant operations. You agree to allow remote access to Vital Images to discontinue your use of the Products.



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EFFECT OF TERMINATION. UPON TERMINATION OF THIS AGREEMENT FOR ANY REASON, ALL SOFTWARE LICENSES AND SERVICES SHALL IMMEDIATELY TERMINATE, AND YOU SHALL RETURN TO VITAL IMAGES ALL CONFIDENTIAL INFORMATION. ARTICLES 1, 4, 5, 9, AND 10 SHALL SURVIVE ANY TERMINATION OF THIS AGREEMENT. TERMINATION OF THIS AGREEMENT SHALL NOT RELIEVE YOU FROM PAYING ANY AMOUNTS TO BE PAID UNDER CONTRACTS EXECUTED PRIOR TO THE DATE OF TERMINATION, INCLUDING AMOUNTS OWED UNDER SOFTWARE MAINTENANCE AND SUPPORT CONTRACTS FOR PERIODS AFTER THE DATE OF TERMINATION, UNLESS YOU HAVE TERMINATED THE AGREEMENT PURSUANT TO SECTION 8.2(A). UPON ANY TERMINATION OF A SOFTWARE LICENSE, YOU SHALL (A) IMMEDIATELY CEASE ALL USE OF ANY PRODUCT COVERED BY SUCH SOFTWARE LICENSE; AND (B) CERTIFY IN WRITING TO VITAL IMAGES WITHIN THIRTY (30) DAYS AFTER SUCH TERMINATION THAT YOU HAVE DESTROYED, PERMANENTLY ERASED OR RETURNED TO VITAL IMAGES SUCH PRODUCT AND ALL COPIES THEREOF.

#### **ARTICLE 9: ADVERSE REACTIONS; RECALLS**

- ADVERSE EVENT REPORTING. YOU SHALL INFORM VITAL IMAGES, BY TELEPHONE OR FACSIMILE, WITHIN FORTY-EIGHT (48) HOURS AFTER YOU CONCLUDE THAT USE OF OR ERRORS IN ANY PRODUCT MAY THREATEN HUMAN SAFETY OR LIFE, DESCRIBING IN REASONABLE DETAIL THE FACTS GIVING RISE TO SUCH PERCEIVED THREAT. UNLESS OTHERWISE REQUIRED BY APPLICABLE LOCAL LAWS, YOU SHALL ADVISE VITAL IMAGES OF ANY SUCH THREAT PRIOR TO MAKING ANY REPORT OR FILING WITH THE U.S. FOOD AND DRUG ADMINISTRATION ("FDA") OR ANY COMPARABLE REGULATORY BODY IN OTHER COUNTRIES.
- 9.2 PRODUCT RECALL; CORRECTIVE ACTION. IF VITAL IMAGES BELIEVES THAT A CORRECTIVE ACTION WITH RESPECT TO ANY PRODUCT IS DESIRABLE OR REQUIRED BY LAW, OR IF THE FDA OR ANY OTHER ANY GOVERNMENTAL AGENCY HAVING JURISDICTION SHALL REQUEST OR ORDER ANY CORRECTIVE ACTION WITH RESPECT TO SUCH PRODUCT, INCLUDING ANY RECALL, CUSTOMER NOTICE, RESTRICTION, CHANGE, CORRECTIVE ACTION, MARKET ACTION OR PRODUCT CORRECTION, VITAL IMAGES SHALL PROMPTLY NOTIFY YOU. YOU SHALL COMPLY WITH ALL REASONABLE DIRECTIONS REGARDING SUCH CORRECTIVE ACTION, INCLUDING THE RETURN OF THE AFFECTED PRODUCT(S) TO VITAL IMAGES AT VITAL IMAGES' EXPENSE OR PROMPTLY ADOPT AND INSTALL ANY CORRECTION MADE AVAILABLE TO YOU BY VITAL IMAGES. IF ANY PRODUCT IS REQUIRED TO BE RETURNED TO VITAL IMAGES PURSUANT TO THIS SECTION 9.2 AND NO REPLACEMENT IS PROVIDED THEREFORE, VITAL IMAGES SHALL REFUND TO YOU ANY UNEARNED LICENSE FEES PAID (THE AMOUNT OF THE LICENSE FEE YOU PAID FOR THE PRODUCT, LESS A REASONABLE VALUE FOR USE DETERMINED BY PRORATING THE LICENSE FEE PAID ON A THIRTY-SIX (36) MONTH STRAIGHT LINE AMORTIZATION METHOD, COMMENCING WITH DELIVERY).

#### **ARTICLE 10: MISCELLANEOUS**

- 10.1 ASSIGNMENT. YOU MAY NOT ASSIGN OR OTHERWISE TRANSFER YOUR RIGHTS OR OBLIGATIONS UNDER THIS AGREEMENT EXCEPT WITH THE PRIOR WRITTEN CONSENT OF VITAL IMAGES, WHICH CONSENT SHALL NOT BE UNREASONABLY WITHHELD. THIS AGREEMENT SHALL BE BINDING ON THE PARTIES HERETO AND THEIR RESPECTIVE SUCCESSORS AND PERMITTED ASSIGNS. ANY PROHIBITED ASSIGNMENT SHALL BE NULL AND VOID.
- NOTICES. NOTICES UNDER THIS AGREEMENT SHALL BE GIVEN BY REGISTERED OR CERTIFIED MAIL, POSTAGE PREPAID, RETURN RECEIPT REQUESTED, BY PRIVATE COURIER SERVICE, OR BY FACSIMILE ADDRESSED TO THE RESPECTIVE ADDRESSES OF THE PARTIES AS FIRST ABOVE WRITTEN OR AT SUCH OTHER ADDRESSES AS THE RESPECTIVE PARTIES MAY DESIGNATE BY LIKE NOTICE FROM TIME TO TIME. NOTICES SO GIVEN SHALL BE EFFECTIVE UPON THE EARLIER OF (A) RECEIPT OF THE NOTICE, OR (B) THE FIFTH (5TH) DAY FOLLOWING DOMESTIC MAILING OR THE TENTH (10<sup>TH</sup>) DAY FOLLOWING INTERNATIONAL MAILING.



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- EXPORTS AND U.S. GOVERNMENT RIGHTS. THE PRODUCTS FURNISHED TO YOU MAY BE SUBJECT TO EXPORT AND OTHER RESTRICTIONS UNDER THE LAWS AND REGULATIONS OF THE UNITED STATES OF AMERICA. YOU HEREBY AGREE THAT YOU SHALL NOT TRANSFER, EXPORT OR RE-EXPORT, DIRECTLY OR INDIRECTLY, ANY PRODUCT OR TECHNICAL DATA RECEIVED FROM VITAL IMAGES TO ANY DESTINATION OR ENTITY SUBJECT TO EXPORT OR OTHER RESTRICTIONS UNDER THE LAWS AND REGULATIONS OF THE UNITED STATES OF AMERICA UNLESS PRIOR WRITTEN AUTHORIZATION IS OBTAINED FROM VITAL IMAGES AND THE APPROPRIATE UNITED STATES AGENCY. THE PRODUCTS ARE PROVIDED WITH RESTRICTED RIGHTS. USE, DUPLICATION OR DISCLOSURE BY THE U.S. GOVERNMENT IS SUBJECT TO RESTRICTIONS AS SET FORTH IN (A) THIS AGREEMENT PURSUANT TO DFARS 227.7202-3(A); (B) SUBPARAGRAPH (C)(1)(I) OF THE RIGHTS IN TECHNICAL DATA AND COMPUTER SOFTWARE CLAUSE AT DFARS 252.227-7013; OR (C) THE COMMERCIAL COMPUTER SOFTWARE RESTRICTED RIGHTS CLAUSE AT FAR 52.227-110 SUBDIVISION (C)(1) AND (2), AS APPLICABLE. CONTRACTOR/MANUFACTURER IS VITAL IMAGES, INC., 5850 OPUS PARKWAY, SUITE 300, MINNETONKA, MN 55343 U.S.A.
- ENTIRE AGREEMENT. THIS AGREEMENT CONSTITUTES THE ENTIRE AGREEMENT OF THE PARTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF AND SUPERSEDES ALL PRIOR AGREEMENTS, UNDERSTANDINGS, NEGOTIATIONS AND PROPOSALS, WHETHER ORAL OR WRITTEN, RELATED TO THE SAME SUBJECT MATTER. TERMS AND CONDITIONS IN A CUSTOMER PURCHASE ORDER THAT CONTRADICT OR ADD TO THE TERMS AND CONDITIONS HEREIN SHALL NOT APPLY BETWEEN THE PARTIES, UNLESS EXPRESSLY AGREED TO IN WRITING BY VITAL IMAGES. THIS AGREEMENT MAY BE EXECUTED BY FACSIMILE AND IN TWO OR MORE COUNTERPARTS AND EACH SUCH COUNTERPART SHALL BE DEEMED AN ORIGINAL HEREOF. THIS AGREEMENT MAY NOT BE MODIFIED, AMENDED, RESCINDED, CANCELED OR WAIVED, IN WHOLE OR IN PART, EXCEPT BY WRITTEN AMENDMENT SIGNED BY BOTH PARTIES HERETO. IF ANY PROVISION OF THIS AGREEMENT IS FOUND UNENFORCEABLE UNDER ANY OF THE LAWS OR REGULATIONS APPLICABLE THERETO, SUCH PROVISION TERMS SHALL BE DEEMED STRICKEN FROM THIS AGREEMENT, BUT SUCH INVALIDITY OR UNENFORCEABILITY SHALL NOT INVALIDATE ANY OF THE OTHER PROVISIONS OF THIS AGREEMENT. NO FAILURE BY EITHER PARTY TO TAKE ANY ACTION OR ASSERT ANY RIGHT HEREUNDER SHALL BE DEEMED TO BE A WAIVER OF SUCH RIGHT IN THE EVENT OF THE CONTINUATION OR REPETITION OF THE CIRCUMSTANCES GIVING RISE TO SUCH RIGHT
- Relationship. This Agreement does not make either party the employee, agent or legal representative of the other for any purpose whatsoever; each party shall be acting as an independent contractor. Neither party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other party.
- 10.6 GOVERNING LAW. THIS AGREEMENT SHALL BE GOVERNED BY AND INTERPRETED UNDER THE LAWS OF THE STATE OF MINNESOTA, U.S.A., EXCLUDING (A) ITS CHOICE OF LAW RULES, AND (B) THE UNITED NATIONS CONVENTION ON THE INTERNATIONAL SALE OF GOODS. ALL ACTIONS RELATING TO THE MATTERS COVERED BY THIS AGREEMENT SHALL BE VENUED IN THE FEDERAL OR STATE COURTS IN HENNEPIN COUNTY, MINNESOTA, AND EACH PARTY AGREES TO THE JURISDICTION OF SUCH COURTS.
- 10.7 FORCE MAJEURE. IF THE PERFORMANCE OF ANY OBLIGATION HEREUNDER, EXCEPT THE MAKING OF PAYMENTS HEREUNDER, IS PREVENTED, RESTRICTED OR INTERFERED WITH BY REASON OF FIRE, FLOOD, EARTHQUAKE, EXPLOSION OR OTHER CASUALTY OR ACCIDENT, STRIKES OR LABOR DISPUTES, INABILITY TO PROCURE OR OBTAIN DELIVERY OF PARTS, SUPPLIES OR POWER, WAR OR OTHER VIOLENCE, ANY LAW, ORDER, PROCLAMATION, REGULATION, ORDINANCE, DEMAND OR REQUIREMENT OF ANY GOVERNMENTAL AGENCY, OR ANY OTHER ACT OR CONDITION WHATSOEVER BEYOND THE REASONABLE CONTROL OF THE AFFECTED PARTY, THE PARTY SO AFFECTED, UPON GIVING PROMPT NOTICE TO THE OTHER PARTY, SHALL BE EXCUSED FROM SUCH PERFORMANCE TO THE EXTENT OF SUCH PREVENTION, RESTRICTION OR INTERFERENCE.



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#### **ARTICLE 11: DEFINITIONS**

- 11.1 "Annual Facility and Study Volume Report" means a report to be completed and executed by an authorized OFFICIAL OF LICENSEE.
- "ANNUAL MEASUREMENT PERIOD" MEANS AN ANNUAL TWELVE-MONTH PERIOD BEGINNING UPON DELIVERY ON WHICH LICENSEE'S STUDY VOLUME WILL BE MEASURED.
- 11.3 "CONCURRENT USER" OR "BASE USER" MEANS A USER THAT HAS LOGGED ON TO VITAL IMAGES PRODUCTS.
- "LICENSEE" MEANS THE LEGAL ENTITY ENTERING INTO THE QUOTE AND THIS SOFTWARE LICENSE AGREEMENT, WHICH HAS LEGAL AUTHORITY AND RESPONSIBILITY FOR ALL FACILITIES WITHIN THE SYSTEM, AS IDENTIFIED ON THE QUOTE OR OTHERWISE PROVIDED IN WRITING TO VITAL IMAGES.
- "PRODUCT" MEANS A COMPUTER SOFTWARE PRODUCT, IN OBJECT CODE FORM ONLY, AND ANY RELATED USER DOCUMENTATION AS MADE AVAILABLE TO YOU BY VITAL IMAGES, AS IDENTIFIED IN THE QUOTE.
- "STUDY" MEANS A COLLECTION OF ONE OR MORE MEDICAL IMAGES GENERATED FOR A SINGLE PATIENT FROM A SINGLE MODALITY AS A SINGLE DIGITAL IMAGING AND COMMUNICATIONS IN MEDICINE UNIQUE IDENTIFIER (DICOM UID) AND, FOR VITREAVIEW, AN IMAGE WITH A STUDY INSTANCE UNIQUE IDENTIFIER (SIUID).
- 11.7 "STUDY VOLUME" MEANS THE TOTAL NUMBER OF STUDIES GENERATED BY YOUR SYSTEM DURING YOUR ANNUAL MEASUREMENT PERIOD. YOUR PURCHASED LEVEL OF STUDY VOLUME SHALL BE SET FORTH ON THE QUOTE.
- 11.8 "System" and related terms:
  - "Enterprise Enablement Software" means the Vital Image Management System ("VIMS") and VitreaCore software for (a) a Server System.
  - "Server System" means a System utilizing one instance of the Enterprise Enablement Software.
  - "System(s)" means the entirety of Concurrent Users or Base Users, Product, System Product, and hardware within the structure of a single workstation or single Server System.
  - "System Product" means an application that is available to all authorized Concurrent or Base Users of the System.

11.9"THIRD PARTY PRODUCTS" MEANS ONCOLOGY FUSION AND OTHER PRODUCTS MANUFACTURED BY THIRD PARTIES, SUCH AS CEDARS-SINAI, MEDIS, MERGE, MEVIS, MIRADA, OLEA AND TOMTEC.

11.10 "VITAL IMAGES PRODUCTS" MEANS THOSE PRODUCTS CONTAINED WITHIN VARIOUS CONFIGURATIONS MANUFACTURED AND OFFERED BY VITAL IMAGES THAT YOU MAY LICENSE UNDER THIS AGREEMENT. VITAL IMAGES PRODUCTS DO NOT INCLUDE SOFTWARE OR



## TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

# QUOTATION/ORDER ORDER DETAIL

DATE:

SID NO:

30024283

8/3/2015

**QUOTE** NO:

72006-6

PRESENTED TO:

CAROLINAS MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC. 28203

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HARDWARE MANUFACTURED BY THIRD PARTIES, BUT WHICH ACQUISITION WILL BE GOVERNED BY THE TERMS AND CONDITIONS OF THIS AGREEMENT.

#### The following additional terms and conditions apply to you if you acquire Microsoft SQL Server and/or Remote Desktop Services ("RDS") from Vital Images:

- Terms and Conditions. Use of the Vital Images Products requires use of Microsoft SQL Server and/or RDS, which is embedded within the Products. Your use of Microsoft SQL Server and/or RDS is subject to your consent to the Microsoft Software License Terms ("Microsoft License Terms") for Microsoft SQL Server and/or RDS, which are located at: http://www.microsoft.com/about/legal/useterms. If you do not consent to the Microsoft License Terms, you should discontinue use of the Microsoft SQL Server and/or RDS.
- B. Warranties and Disclaimer of Warranties. Any warranties for Microsoft SQL Server and/or RDS are set forth in the Microsoft License Terms. TO THE EXTENT PERMITTED BY APPLICABLE LAW, MICROSOFT DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
- LIMITATION OF LIABILITY. TO THE EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL MICROSOFT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, AS A RESULT OF USE OR INSTALLATION OF MICROSOFT SQL SERVER.
- Reports. You hereby grant Vital Images permission to inform Microsoft of your entity's name and address, including the country in which you are located.

#### The following additional terms and conditions apply to you if you acquire VitreaACCESS™-Remote from Vital Images:

- Freeware. Notwithstanding the terms and conditions of this Agreement, all or any portion of VitreaACCESS™-Remote ("VAR") which constitutes non-proprietary HP software or software provided under public license by third parties ("Freeware"), is licensed to you subject to the terms and conditions of the software license agreement accompanying such Freeware whether in the form of a discrete agreement, shrink wrap license or electronic license terms accepted at time of download. Use of the Freeware by you shall be governed entirely by the terms and conditions of such license.
- B. CONSENT TO USE OF DATA. You agree that HP and its affiliates may collect and use technical information you provide in relation to support services related to VAR. HP agrees not to use this information in a form that personally identifies you except to the extent necessary to provide such services.
- DISCLAIMER OF WARRANTIES. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, HP AND ITS SUPPLIERS PROVIDE VAR "AS IS" AND WITH ALL FAULTS, AND HEREBY DISCLAIM ALL OTHER WARRANTIES AND CONDITIONS, EITHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF TITLE AND NON-INFRINGEMENT, ANY IMPLIED WARRANTIES, DUTIES OR CONDITIONS OF MERCHANTABILITY, OF FITNESS FOR A PARTICULAR PURPOSE, AND OF LACK OF VIRUSES ALL WITH REGARD TO VAR. Some states/ jurisdictions do not allow exclusion of implied warranties or limitations on the duration of implied warranties, so the above disclaimer may not apply to you in its entirety.



## TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

# QUOTATION/ORDER ORDER DETAIL

DATE:

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- LIMITATION OF LIABILITY. Notwithstanding any damages that you might incur, the entire liability of HP and any of its suppliers under any provision of this Agreement and your exclusive remedy for all of the foregoing shall be limited to the greater of the amount actually paid by you separately for VAR or U.S. \$5.00. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL HP OR ITS SUPPLIERS BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES WHATSOEVER (INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS OR CONFIDENTIAL OR OTHER INFORMATION, FOR BUSINESS INTERRUPTION, FOR PERSONAL INJURY, FOR LOSS OF PRIVACY ARISING OUT OF OR IN ANY WAY RELATED TO THE USE OF OR INABILITY TO USE VAR, OR OTHERWISE IN CONNECTION WITH ANY PROVISION OF THIS AGREEMENT, EVEN IF HP OR ANY SUPPLIER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND EVEN IF THE REMEDY FAILS OF ITS ESSENTIAL PURPOSE. Some states/jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.
- Use. You may use VAR on a single computer "Your Computer") which is supported by VAR. If VAR is provided to you via the internet and was originally licensed for use on more than one computer, you may install and use VAR only on those computers. You may not separate component parts of VAR for use on more than one computer. You do not have the right to distribute VAR. You may load VAR in Your Computer's temporary memory (RAM) for purposes of using VAR.



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Carolinas Medical Center 1000 Blythe Blvd Charlotte NC 28203-5812 Care Area: Anesthesia Attn: Chris Hollar 1000 Blythe Blvd Charlotte Customer Number:

1-25JJ8D

NC 28203-5812

Quotation Expiration Date: 10-11-2015

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (iii) if no Governing Agreement is identified, the following documents:

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation.

No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties.

By signing below, each party certifies that it has not made any handwritten modifications.

Governing Agreement:

CSS-GEHC MVA July 15 2011

Terms of Delivery:

**FOB DESTINATION** 

Billing Terms:

100% billing at Ship Completion

Payment Terms:

Net Due in 60 Days

Total Quote Net Selling Price:

\$126,592.56

IMPORTANT CUSTOMER ACTION:			
options you are indicating a cash p signature, then you may NOT elect to GE HFS Loan	ayment method for this	he financing options below. By signing below without checking arrangement. If "GE HFS Loan" or "GE HFS Lease" is NOT se Healthcare Financial Services (GE HFS) at a later date to fund this	lected at the time of
GE HFS Lease			
Third-Party Lease (Please in	dentify finance company)		
	· ·	nd an indication in the form of payment section below) will by its duly authorized representative as of the date set fort	
CUSTOMER		GE HEALTHCARE John Dresser	07-14-2015
Authorized Customer Signature	Date	Signature	Date
Print Name	Print Title	PeriOperative Care Sales Specialist	
Purchase Order Number (if applic	able)	Email: Barclay.Dresser@med.ge.com Office: 800-345-2700 ext 4265 Mobile: 704-840-4505 Fax: 704-973-9719	



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**Total Quote Selling Price** Trade-In and Other Credits **\$126,592.56** \$0.00

**Total Quote Net Selling Price** 

\$126,592.56

## To Accept this Quotation

Please sign and return this Quotation together with your Purchase Order To:

Barclay Dresser

Office: 800-345-2700 ext 4265

Mobile: 704-840-4505

Email: Barclay.Dresser@med.ge.com

Fax: 704-973-9719

#### **Payment Instructions**

Please **Remit** Payment for invoices associated with this quotation to:

Datex-Ohmeda, Inc. PO Box 641936

Pittsburgh, PA 15264-1936

#### To Accept This Quotation

- Please sign the quote and any included attachments (where requested).
- If requested, please indicate, your form of payment.
- If you include the purchase order, please make sure it references the following information
  - The correct Quote number and version number above
  - The correct Remit To information as indicated in "Payment Instructions" above
  - The correct SHIP TO site name and address
  - The correct BILL TO site name and address
  - The correct Total Quote Net Selling Price as indicated above



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Line #	QTY	Item#	DESCRIPTION	Ext Sell Price
	2		Avance CS2	
1	2	1009-9050-000	Avance CS2	\$94,357.64
			Avance CS2	
	2	M1231557	Frame 2 Vaporizer Trolley	
			Frame 2 Vaporizer Trolley	
	2	M1231736	Manuals and Software English for USA	
			Manuals and Software English for USA	
	2	M1231592	DISS Pipeline Fittings, ANSI Colors O2 Right, O2 Drive	
			DISS Pipeline Fittings, ANSI Colors O2 Right, O2 Drive	
	2	M1231574	N2O Pipeline DISS Fitting	
			N2O Pipeline DISS Fitting	
	2	- M1231676	AC Inlet 100-120V NEMA Power Cord and 4 Isolated Outlets	
	: -	-	AC Inlet 100-120V NEMA Power Cord and 4 Isolated Outlets	
	2	M1231768	Single Slot Module Rack for Airway Module	
			Single Slot Module Rack for Airway Module	
	2	1009-8220-000	Non-circle (switched) SCGO	
			Non-circle (switched) SCGO. If ordered, machine does a positive test for leaks, menu selection for Jackson Reese	
	2	1009-8159-000	Bag support arm	
			Bag support arm	
	2	1009-8174-000	Low Flow Active AGSS. Includes needle valve for flow regulation and three liter bag.	
4		· .	Low Flow Active AGSS (High Vacuum, variable flow with bag indicator) AGSS closed system with needle valve for flow regulation and 3L bag for visual indication of operation. Requires the following vacuum disposal system: High Vacuum 30 SLPM extract flow @ 12 in Hg (305 mm Hg) extract flow is limited to 30 L/min or less; Includes: Swivel DISS EVAC connection on needle valve assembly. One reusable scavenging bag.	



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Line # QTY	Item #	DESCRIPTION	Ext Sell Price
2	2074679-001	Suction Regulator 3 Mode DISS Pipeline Fitting	
		Suction Regulator 3 Mode DISS Pipeline Fitting	
2	M1231583	Cylinder Supply O2 Pin Indexed Inboard	
		Cylinder Supply O2 Pin Indexed Inboard	
2	M1231585	Cylinder Supply AIR Pin Indexed Inboard	
		Cylinder Supply AIR Pin Indexed Inboard	
2	M1231591	Cylinder Supply N20 Pin Indexed Outboard	
		Cylinder Supply N20 Pin Indexed Outboard	~1
2	M1231688	Pressure Control Modes Suite	
		PCV, PCV-VG, SIMV PCV-VG Ventilation Modes	
2	M1231689	Spontaneous Breathing Modes Suite	
S (1) (2) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4		SIMV PCV, SIMV VCV, PSVPro-Ventilation Modes	
2	M1231690	CPAP-PSV Ventilation Mode	
	•	CPAP-PSV Ventilation Mode	
2	M1231691	VCV Cardiac Bypass Mode	
		VCV Cardiac Bypass Mode	
2	M1238517	ecoFLOW Software Option	
		ecoFLOW Software Option	
2	1009-3260-000	Drawer storage insert, large	
		Drawer storage insert, large	
2	1009-3276-000	Drawer storage insert, small	
		Drawer storage insert, small	
2	M1228544	Lower right side rail mounting kit	
		Lower right side rail mounting kit	
2	M1231573	Suction Bottle Mounting Arm	
غ -		Suction Bottle Mounting Arm	



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Line #	QTY	Item #	DESCRIPTION	Ext Sell Price
	2	1009-8469-000	Folding side shelf	
			Folding side shelf, Factory Install, Aespire-Avance	
2	2	M1199109	CARESCAPE Respiratory Module, E-sCAiO	\$14,800.00
			CARESCAPE Respiratory Module, E-sCAiO	
3 ,	2	M1182629	D-fend Pro Water Trap Dark Steel Blue (for E-sCAiO) (1 case / 10 units)	\$312.28
			D-fend Pro Water Trap Dark Steel Blue (for E-sCAiO) (1 case / 10 units)	
4	2	8004463	Exhaust line with Colder fitting, 18cm/7in	\$28.16
			Exhaust line with Coulter fitting, 18cm/7in, disposable, pkg of 1 pcs	
5	2	M1161568	B650, F5 mounting bracket	\$633.00
			B650, F5 mounting bracket	8 1 - 4
6	2	2063807-001	Flat panel vertical mount kit	- - \$466.50
			Flat panel vertical mount kit	
7	2	1001-3626-000	Dovetail utility basket mount (side mount)	\$132.00
			Dovetail utility basket mount (side mount)	
8	4	1006-4192-000	Dovetail hook	\$24,48
			Dovetail hook for the rail system	
9	2	1407-7021-000	EZ Change Module	\$805.60
			EZ Change Module	
10	2	M1229644	ABS Start-up Kit, 72 in. LimbO, Bag Support Arm	\$36.00
	,		ABS START UP KIT, 72 IN LIMBO, BAG SPRT ARM OPT V S GXXXXX98	
11	2	8004459	ABS Bag Arm Connector, reusable	\$31.92
			ABS bag arm connector, reusable, 1 pc	
12	2	8004515	Patient tube, hytrel	\$42.90



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Line # QTY	Item #	DESCRIPTION	Ext Sell Price
		Patient tube, hytrel, adult, reusable, 0,9m/36in, pkg of 1 pcs	
13 2	M1173311	Multi Absorber Medisorb EF, Disposable, white to violet 6 canisters /case	\$168.72
		Multi Absorber Medisorb EF, Disposable, white to violet 6 canisters /case	
14 4	1503-3858-000	Offset Flow Sensor - disposable	\$313.12
		Offset Flow Sensor - disposable	
15 2	1407-7001-000	Flow Sensor Holder	\$466.64
	 	Flow Sensor Holder	
16 2	1006-8082-000	Suction Mounting Post	\$784.32
		Suction Mounting Post	
17 2	M1229718	Long cable management arm	\$743.28
		Long cable management arm	
18 2	M1229719	Short cable management arm	\$389.12
		Short cable management arm	
19 2	0210-5022-300	Cylinder Gasket, 19 OD HPO2 6.35 ID 1.5 T	\$12.34
		Cylinder Gasket, 19 OD HPO2 6.35 ID 1.5 T	
20 2	1001-3269-000	CASTrGARDs 12.7 cm/5 in grey, set of four	\$351.12
٠		CASTrGARDs 12.7 cm/5 in grey, set of four	
21 2	1503-3857-000	Plug O2 Port Kit	\$34.16
		Plug O2 Port Kit (allows the oxygen cell to be removed when using M-gas for oxygen monitoring)	
22 2	1001-8896-000	Auxiliary dovetail lamp kit, goose neck	\$1,174.96
	· .	Auxiliary dovetail lamp kit, goose neck, 110V USA (USA, Japan, and Canada)	
23 2	1406-3220-000	Breathing Circuit Hook	\$13.02
		Breathing Circuit Hook	



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Line # QTY Item# **DESCRIPTION** Ext Sell Price 2 24 0231-1518-810 DISS H-I-T, NCG, O2 hose assembly, 4.6 m/15 ft \$342.00 DISS H-I-T, NCG, O2 hose assembly, 4.6 m/15 ft 25 2 0231-1518-811 DISS H-I-T, NCG, N2O hose assembly, 4.6 m/15 ft \$342.00 DISS H-I-T, NCG, N2O hose assembly, 4.6 m/15 ft 26 2 0231-1518-812 DISS H-I-T, NCG, Vac hose assembly, 4.6 m/15 ft \$363.28 DISS H-I-T, NCG, Vac hose assembly, 4.6 m/15 ft 2 27 0231-1518-813 DISS H-I-T, NCG, Air hose assembly, 4.6 m/15 ft \$387.60 DISS H-I-T, NCG, Air hose assembly, 4.6 m/15 ft 28 2 M1109160 User Training (onsite) - training of clinical & non-clinical staff on \$2,736.00 equipment User Training (onsite) - training of clinical & non-clinical staff on equipment Per day (one day minimum) Instructor-led course which includes fundamental equipment training, including hands on, workbook and simulations. This course is designed to enable the user the knowledge to become proficient in using the system. The training is delivered using lecture, workbook and simulations. 29 2082320-001 **GO-LIVE CLINICAL SUPPORT** \$5,472.00 **GO-LIVE CLINICAL SUPPORT** 30 2 2020786-343 Avance CS2 Online Clinical Training \$828.40 This course is designed to give participants the information and product knowledge needed to proficiently operate the Avance CS2 anesthesia system. The course features interactions, extensive graphics and "Check Your Knowledge" sections to assist the user in learning the system functionality. It consists of eight topic modules: Overview, Vaporization, Advanced Breathing System, Operation, Ventilation Modes, Spirometry, Procedures and Checkout. **Quote Summary: Total List Price:** \$167,129.58 **Total Quote Discount (24.25%)** (\$40,537.02)



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Line # QTY	Item #	DESCRIPTION	Ext Sell Price
		Total Extended Selling Price Total Quote Net Selling Price:	\$126,592.56 \$126,592.56
		(Quoted prices do not reflect state and local taxes if applicable)	

Delivery date set at time of order.

If this Quotation contains a trade-in, such trade-in shall be governed by the terms and conditions set forth on the Trade-In Addendum to GE Healthcare Quotation attached to or provided with this Quotation.

Service Option invoicing will be separate from the equipment.

If this Quotation has demo/refurbished equipment on it, the quote is valid for 7 days only and is subject to availability.

All GE Healthcare pricing is confidential and proprietary. Any reporting requires GE's consent.



## **General Terms and Conditions**

# **GE** Healthcare

These GE Healthcare General Terms and Conditions supplement and incorporate by reference the GE Healthcare Quotation that identifies the Product and/or Service offering purchased or licensed by Customer and the following documents, as applicable, if attached to or referenced in the Quotation: the GE Healthcare (i) Warranty(ies); (ii) Additional Terms and Conditions or Statement of Service Deliverables and Product Schedule; and (iii) Product or Service Terms and Conditions, (collectively, referred to as the "Agreement").

References herein to "Products" and "Services" mean the Products (including equipment and software) and Services identified on the applicable GE Healthcare Quotation. References herein to "Healthcare IT Products" are (i) those software products identified in the Quotation as a "Centricity" product, any third party software licensed for use in connection with the Centricity software, all hardware used to operate the Centricity or the third party software, and services provided with respect to the implementation, installation or support and maintenance of the Centricity or the third party software, and/or (ii) any software, product or service that is included in a Quotation which Quotation is designated as an "Healthcare IT Quotation".

#### 1. General Terms.

- 1.1. Confidentiality. Each party will treat the terms of this Agreement and the other party's written, proprietary business information as confidential if marked as confidential or proprietary. Customer will treat GE Healthcare's (and GE Healthcare's third party vendors') software and technical information as confidential information whether or not marked as confidential and shall not use or disclose to any third parties any such confidential information except as specifically permitted in this Agreement or as required by law (with reasonable prior notice to GE Healthcare) or as is required by the U.S. Federal government in its capacity as a customer. The receiving party shall have no obligation with respect to any information which (i) is or becomes within the public domain through no act of the receiving party in breach of this Agreement, (ii) was in the possession of the receiving party prior to its disclosure or transfer and the receiving party can so prove, (iii) is independently developed by the receiving party and the receiving party can so prove, or (iv) is received from another source without any restriction on use or disclosure. GE Healthcare understands that Customer may be subject to State Open Records laws. Customer shall not be prohibited from complying with such Open Records laws if required to do so; however, Customer shall (a) promptly notify GE Healthcare in writing of any such Open Records laws requests, (b) give GE Healthcare sufficient time to challenge the request or redact any necessary information to the extent permitted by law, and (c) only provide such information as is necessary to comply with such Open Records laws.
- 1.2. Governing Law. The law of the State where the Product is installed or the Service is provided will govern this Agreement.
- 1.3. <u>Force Majeure</u>. Neither party is liable for delays or failures in performance (other than payment obligations) under this Agreement due to a cause beyond its reasonable control. In the event of such delay, the time for performance shall be extended as reasonably necessary to enable performance.
- 1.4. Assignment; Use of Subcontractors. Neither party may assign any of its rights or obligations under this Agreement without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however, that either party may transfer and assign this Agreement without the other party's consent to any person or entity (except to a GE Healthcare competitor) that is an affiliate of such party or that acquires substantially all of the stock or assets of such party's applicable business if any such assignee agrees, in writing, to be bound by the terms of this Agreement, including the payment of any existing or outstanding fees and invoices. Subject to such limitation, this Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and permitted assigns. This Agreement shall not be terminable in the event of any Customer stock or asset sale, merger, acquisition or change in control, unless otherwise expressly agreed to in writing by GE Healthcare. GE Healthcare may hire subcontractors to perform work under this Agreement (including, but not limited to, work that involves access to Protected Health Information as such term is defined in 45 C.F.R. § 160.103 ("PHI")), provided that GE Healthcare will at all times remain responsible for the performance of its obligations and duties under this Agreement.
- 1.5. <u>Amendment; Waiver; Survival</u>. This Agreement may be amended only in writing signed by both parties. Any failure to enforce any provision of this Agreement is not a waiver of that provision or of either party's right to later enforce each and every provision. The terms of this Agreement that by their nature are intended to survive its expiration (such as the confidentiality provisions included herein) will continue in full force and effect after its expiration.
- 1.6. <u>Termination</u>. If either party materially breaches this Agreement and the other party seeks to terminate this Agreement for such breach, such other party shall notify the breaching party in writing, setting out the breach, and the breaching party will have sixty (60) days following receipt of such notice to remedy the breach. If the breaching party fails to remedy the breach during that period, the other party may terminate this Agreement by written notice to the breaching party. If GE Healthcare determines in good faith at any time that there are material credit issues, with this Agreement, then GE Healthcare may terminate this Agreement (including warranty services hereunder) immediately upon written notice to Customer. For the avoidance of doubt, this Agreement is not terminable for convenience and may only be terminated in accordance with this Agreement.
- 1.7. Entire Agreement and Waiver of Reliance. This Agreement constitutes the complete and final agreement of the parties relating to the Products and/or Services identified in the Quotation. The parties agree that they have not relied, and are not relying, on any oral or written promises, terms, conditions, representations or warranties, express or implied, outside those expressly stated or incorporated by reference in this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing and signed by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless

GE Healthcare General Terms and Conditions (Rev 08.14)

agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products and/or Services, shall constitute an agreement by either party to any such terms. The parties agree that any provision in this Agreement in 'all caps' type satisfies any requirements at law or in equity that provisions be conspicuously marked.

#### 2. Compliance.

- 2.1. <u>Generally</u>. Each party will comply with the requirements of Federal and State laws and regulations that are applicable to such party. This Agreement is subject to GE Healthcare's on-going determination that Customer and this Agreement comply with all applicable laws and regulations, including those relating to workplace safety, FDA matters, Federal Healthcare Program Anti-kickback compliance, export/import control and money laundering prevention. CUSTOMER ACKNOWLEDGES THAT THE PRODUCTS ARE OR MAY BE SUBJECT TO REGULATION BY THE FDA AND OTHER FEDERAL OR STATE AGENCIES. CUSTOMER SHALL NOT USE OR PERMIT THE PRODUCTS TO BE USED IN ANY MANNER THAT DOES NOT COMPLY WITH APPLICABLE FDA OR OTHER REGULATIONS OR FOR ANY NON-MEDICAL, ENTERTAINMENT, OR AMUSEMENT PURPOSES. Customer shall not use or permit the Product to be used or operated by any person who does not have sufficient knowledge to competently perform the required task and who is not fully trained on the operation of the Product. Customer is solely responsible for ensuring that Customer and its employees, licensed and unlicensed healthcare staff, representatives, agents and/or contractors who operate, maintain and/or have access to the Products and/or Services, excluding GE Healthcare employees, representatives, agents and/or contractors ("Customer Personnel") are properly trained and fully competent on the operation of the Product. Further, Customer represents that it is purchasing the Products for its own use consistent with the terms of this Agreement and that it does not intend to re-sell the Products to any other party or to export the Products outside the country to which GE Healthcare delivers the Products.
- 2.2. Cost Reporting. Customer represents and warrants that it shall comply with (a) the applicable requirements of the Discount Statutory Exception, 42 U.S.C. 1320a-7b(b)(3)(A), and the Discount Safe Harbor, 42 C.F.R. § 1001.952(h), with respect to any discounts Customer may receive under this Agreement and (b) the Warranties Safe Harbor, 42 C.F.R. § 1001.952(g), with respect to any price reductions of an item (including a free item) which were obtained as part of a warranty under this Agreement. Customer agrees that, if Customer is required to report its costs on a cost report, then (i) the discount must be based on purchases of the same good bought within a fiscal year; (ii) Customer must claim the benefit in the fiscal year in which the discount is earned or in the following year; (iii) Customer must fully and accurately report the discount in the applicable cost report; and (iv) Customer must provide, upon request, certain information required to be provided to Customer by GE Healthcare as a seller or offeror, as appropriate. If Customer is an individual or entity in whose name a claim or request for payment is submitted for the discounted items, the discount must be made at the time of the sale of the good; and Customer must provide, upon request, certain information required to be provided to Customer by GE Healthcare as a seller or offeror, as appropriate. GE Healthcare agrees to comply with the applicable requirements for sellers or offerors under the Discount Safe Harbor, as appropriate.
- 2.3. <u>Network Security and Site Access Control</u>. Customer shall be solely responsible for establishing and maintaining network security, virus protection, backup and disaster recovery plans for any data, images, software or equipment. GE Healthcare shall not be responsible for any recovery of lost data or images. Customer shall comply with all applicable laws and regulations related to site access control.
- 2.4. <u>Environmental Health and Safety</u>. GE Healthcare shall have no obligation to provide Products and/or perform Services until Customer (i) provides and maintains a suitable, safe and hazard-free location and environment for the GE Healthcare Products and personnel performing Services in material compliance with all applicable Federal, State, and local requirements, as well as any written requirements provided by GE Healthcare; (ii) performs GE Healthcare recommended routine maintenance and operator adjustments on the Product; and (iii) ensures that any service not provided by GE Healthcare is performed, and GE Healthcare Products are used, in accordance with applicable user documentation.

Customer shall provide written information to GE Healthcare personnel who will be present on Customer's site about Customer's safety procedures and practices as well as a list of any hazardous materials, such as asbestos, lead or mercury, on or near Customer's site that GE Healthcare personnel may come in contact with and any associated Safety Data Sheets. Customer shall be responsible for taking all necessary actions to properly abate, remove and/or remediate any hazardous conditions or materials, including removing blood, body fluids and other potentially infectious materials. GE Healthcare shall have no responsibility to abate, or liability for, any existing hazardous conditions at Customer site. Customer shall be responsible for proper management, storage and disposal of all service and/or installation-related waste, unless GE Healthcare is legally required to take back the materials (e.g., batteries, WEEE, packaging).

- 2.5. <u>Parts Not Supplied By GE Healthcare</u>. GE Healthcare recommends the use of parts that it has (i) validated through configuration and (ii) received from authorized suppliers. GE Healthcare is not responsible for the quality of parts supplied by third parties to Customer. GE Healthcare cannot assure Product functionality or performance when non-GE Healthcare parts are used on the Product.
- 2.6. <u>Training</u>. Any Product training identified in the Quotation shall be in accordance with GE Healthcare's then-current training offerings and terms. Customer agrees that completion of GE Healthcare's training offerings does not guarantee that Customer and Customer Personnel are fully and completely trained on the use, maintenance, and operation of the Product or that completion of GE Healthcare's training will satisfy any licensure and/or accreditation standards. Customer further agrees that it is Customer's sole and non-delegable duty to ensure that Customer and Customer Personnel are properly trained on and fully qualified in the use and operation of the Product. Unless otherwise stated in the training catalog description, training must be completed by Customer within twelve (12) months after (i) the date of Product delivery for training purchased with Products; (ii) the start date for Services for training purchased with Services; or (iii) the date Customer purchases training if such training is not purchased with Products and/or Services. If training is not completed within the applicable time period due to no fault of GE Healthcare, GE Healthcare's obligation to provide the training will expire without refund.
- 2.7. <u>Medical Diagnosis and Treatment</u>. All clinical and medical treatment and/or diagnostic decisions are the sole responsibility of Customer and Customer Personnel. Customer agrees that GE Healthcare is in no way responsible for the clinical and medical treatment and/or diagnostic decisions made by Customer and Customer Personnel.

#### 2.8. Use of Data.

- (a) <u>Protected Health Information</u>. To the extent GE Healthcare creates, receives, maintains, transmits or otherwise has access to any PHI in the course of performing under this Agreement, GE Healthcare shall only use and disclose such PHI as permitted by the administrative simplification section of the Health Insurance Portability and Accountability Act of 1996, Pub. Law 104-191 (August 21, 1996), its implementing regulations, and the Health Information Technology for Economic and Clinical Health ("HITECH") Act and its implementing regulations (collectively, "HIPAA"), and the applicable Business Associate Agreement between the Parties.
- (b) Other Information. Customer agrees that GE Healthcare may also create, receive, maintain, transmit and otherwise have access to machine, technical, system, usage and related information that is not PHI, including, but not limited to, information about Customer's Product, Service, system and software, that is gathered periodically to facilitate the provision of Product support, consulting, training and other services to Customer (if any), and to verify compliance with the terms of this Agreement. GE Healthcare or its agents may use such information to provide, develop or improve GE Healthcare's products or services.
- 2.9. <u>Compliance with Customer Policies</u>. GE Healthcare will use commercially reasonable efforts to respect Customer policies to the extent that such policies apply to GE Healthcare under this Agreement, and do not materially contradict GE Healthcare policies, provided that Customer furnishes to GE Healthcare a complete copy of said policies prior to GE Healthcare's commencement of performance under this Agreement. Under no circumstances, however, will GE Healthcare's failure, or the failure of GE Healthcare's employees or contractors, to respect Customer policies constitute a material breach by GE Healthcare under this Agreement, unless such failure is willful and materially and adversely affects GE Healthcare's ability to perform its obligations under this Agreement.
- 2.10. <u>Insurance</u>. GE Healthcare shall maintain insurance coverage in accordance with its standard certificate of insurance, a copy of which is available upon Customer's request.
- 2.11. <u>Excluded Provider</u>. GE Healthcare represents that, to its knowledge, neither it nor its employees performing services under this Agreement have been excluded from participation in any Federal Healthcare Program. In the event an employee performing services under this Agreement is excluded, GE Healthcare will replace such employee within a commercially reasonable time. In the event GE Healthcare is excluded, Customer may terminate this Agreement upon written notice to GE Healthcare.

#### 3. Disputes; Liability; and Indemnity.

- 3.1. <u>Waiver of Jury Trial</u>. UNLESS OTHERWISE EXPRESSLY PROHIBITED BY APPLICABLE LAW, EACH PARTY EXPRESSLY WAIVES ALL RIGHTS TO A JURY TRIAL IN CONNECTION WITH ANY DISPUTE ARISING UNDER THIS AGREEMENT.
- 3.2. <u>Limitation of Liability</u>. GE HEALTHCARE'S ENTIRE LIABILITY AND CUSTOMER'S EXCLUSIVE REMEDY FOR ANY DIRECT DAMAGES INCURRED BY CUSTOMER FROM ANY CAUSE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN AN ACTION IN CONTRACT, TORT, PRODUCT LIABILITY, STATUTE, EQUITY OR OTHERWISE, ARISING UNDER THIS AGREEMENT OR RELATED HERETO, SHALL NOT EXCEED: (A) FOR PRODUCTS OR SERVICES, OTHER THAN SERVICES UNDER AN ANNUAL SERVICE CONTRACT, THE PRICE FOR THE PRODUCT OR SERVICE THAT IS THE BASIS FOR THE CLAIM; OR (B) FOR ANNUAL SERVICE CONTRACTS, THE ANNUAL CONTRACT PRICE FOR THE SERVICE THAT IS THE BASIS FOR THE FOREGOING LIMITATION OF LIABILITY SHALL NOT APPLY TO GE HEALTHCARE'S DUTIES TO INDEMNIFY CUSTOMER IN ACCORDANCE WITH THIS AGREEMENT. THE LIMITATION OF LIABILITY SHALL APPLY EVEN IF THE LIMITED REMEDIES FAIL OF THEIR ESSENTIAL PURPOSE.
- 3.3. <u>Exclusion of Damages</u>. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY UNDER THIS AGREEMENT (OR OTHERWISE IN CONNECTION WITH THE PRODUCTS AND SERVICES) FOR ANY INDIRECT, SPECIAL, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR FOR LOSS OF PROFITS, REVENUE, TIME, OPPORTUNITY OR DATA, WHETHER IN AN ACTION IN CONTRACT, TORT, PRODUCT LIABILITY, STATUTE, EQUITY OR OTHERWISE. THE EXCLUSION OF DAMAGES SHALL APPLY EVEN IF THE LIMITED REMEDIES FAIL OF THEIR ESSENTIAL PURPOSE.
- 3.4. IP Indemnification. GE HEALTHCARE WILL DEFEND, INDEMNIFY AND HOLD HARMLESS CUSTOMER FROM ANY THIRD PARTY CLAIMS FOR INFRINGEMENT OF UNITED STATES INTELLECTUAL PROPERTY RIGHTS ARISING FROM CUSTOMER'S USE OF GE HEALTHCARE MANUFACTURED EQUIPMENT AND/OR GE HEALTHCARE PROPRIETARY SOFTWARE LISTED IN THE QUOTATION (COLLECTIVELY, "INFRINGING PRODUCT") IN ACCORDANCE WITH THEIR SPECIFICATIONS AND WITHIN THE LICENSE SCOPE GRANTED IN THIS AGREEMENT. IF ANY SUCH CLAIM MATERIALLY INTERFERES WITH CUSTOMER'S USE OF SUCH EQUIPMENT AND/OR SOFTWARE, GE HEALTHCARE SHALL, AT ITS OPTION: (I) SUBSTITUTE FUNCTIONALLY EQUIVALENT NON-INFRINGING PRODUCTS; (II) MODIFY THE INFRINGING PRODUCT SO THAT IT NO LONGER INFRINGES BUT REMAINS FUNCTIONALLY EQUIVALENT; (III) OBTAIN FOR CUSTOMER AT GE HEALTHCARE'S EXPENSE THE RIGHT TO CONTINUE TO USE THE INFRINGING PRODUCT; OR (IV) IF THE FOREGOING ARE NOT COMMERCIALLY REASONABLE, REFUND TO CUSTOMER THE PURCHASE PRICE, AS DEPRECIATED (BASED ON FIVE (5) YEAR STRAIGHT-LINE DEPRECIATION), FOR THE INFRINGING PRODUCT. ANY SUCH CLAIMS ARISING FROM CUSTOMER'S USE OF SUCH INFRINGING PRODUCT AFTER GE HEALTHCARE HAS NOTIFIED CUSTOMER TO DISCONTINUE USE OF SUCH INFRINGING PRODUCT AND OFFERED ONE OF THE REMEDIES SET FORTH IN CLAUSES (I) THROUGH (IV) ABOVE ARE THE SOLE RESPONSIBILITY OF Customer. This section represents customer's sole and exclusive remedy (and ge healthcare's sole and exclusive liability) REGARDING ANY INFRINGEMENT CLAIM ASSOCIATED WITH SUCH INFRINGING PRODUCT. THE ABOVE INDEMNIFICATION OBLIGATION IS CONDITIONAL UPON CUSTOMER PROVIDING GE HEALTHCARE PROMPT WRITTEN NOTICE OF THE INFRINGEMENT CLAIM AFTER RECEIVING NOTICE OF SUCH CLAIM, ALLOWING GE HEALTHCARE TO CONTROL THE DEFENSE OF SUCH CLAIM, AND REASONABLY COOPERATING WITH GE HEALTHCARE IN SUCH DEFENSE. GE HEALTHCARE'S RIGHT TO CONTROL THE DEFENSE AND DISPOSITION OF THE INFRINGEMENT CLAIM SHALL INCLUDE THE RIGHT TO SELECT COUNSEL TO REPRESENT CUSTOMER AT GE HEALTHCARE'S EXPENSE; PROVIDED, HOWEVER, THAT CUSTOMER MAY RETAIN ADDITIONAL COUNSEL AT CUSTOMER'S EXPENSE. ANY EXPENSES, INCLUDING LEGAL FEES AND COSTS, INCURRED BY CUSTOMER PRIOR TO TENDERING CONTROL OF THE DEFENSE TO GE HEALTHCARE SHALL NOT BE REIMBURSABLE BY GE HEALTHCARE. NOTWITHSTANDING ANY OTHER PROVISION IN THIS AGREEMENT, GE HEALTHCARE SHALL NOT HAVE ANY OBLIGATION TO CUSTOMER HEREUNDER FOR INFRINGEMENT CLAIMS BASED ON OR RESULTING FROM: (A) USE OF SUCH INFRINGING PRODUCT IN COMBINATION WITH ANY COMPUTER SOFTWARE, TOOLS, HARDWARE, EQUIPMENT, MATERIALS, OR SERVICES, NOT FURNISHED OR AUTHORIZED IN WRITING FOR USE BY GE HEALTHCARE: (B) USE OF SUCH INFRINGING PRODUCT IN A MANNER OR ENVIRONMENT OR FOR ANY PURPOSE FOR WHICH GE HEALTHCARE DID NOT DESIGN OR LICENSE IT, OR IN VIOLATION OF GE HEALTHCARE'S USE INSTRUCTIONS; OR (C) ANY MODIFICATION OF SUCH INFRINGING PRODUCT BY CUSTOMER OR ANY THIRD PARTY. GE HEALTHCARE SHALL NOT BE RESPONSIBLE FOR ANY COMPROMISE OR SETTLEMENT OR

CLAIM MADE BY CUSTOMER WITHOUT GE HEALTHCARE'S WRITTEN CONSENT. THIS INDEMNIFICATION OBLIGATION IS EXPRESSLY LIMITED TO THE GE HEALTHCARE MANUFACTURED EQUIPMENT AND/OR GE HEALTHCARE PROPRIETARY SOFTWARE LISTED IN THE QUOTATION.

3.5. General Indemnification. GE HEALTHCARE AGREES TO RELEASE, INDEMNIFY AND HOLD CUSTOMER HARMLESS FOR ANY THIRD PARTY DAMAGES CUSTOMER BECOMES LEGALLY OBLIGATED TO PAY RELATED TO BODILY INJURY OR DAMAGE TO REAL PROPERTY OR TANGIBLE PERSONAL PROPERTY TO THE EXTENT THAT SUCH DAMAGES ARE DETERMINED TO BE PROXIMATELY CAUSED BY A MANUFACTURING DEFECT, DESIGN DEFECT, NEGLIGENT FAILURE TO WARN, NEGLIGENT INSTALLATION, OR NEGLIGENT SERVICE WITH RESPECT TO PRODUCTS DESIGNED AND MANUFACTURED BY GE HEALTHCARE AND SUPPLIED TO CUSTOMER UNDER THIS AGREEMENT. GE HEALTHCARE SHALL HAVE NO OBLIGATION TO RELEASE, INDEMNIFY AND HOLD CUSTOMER HARMLESS FOR ANY DAMAGES CAUSED BY (I) CUSTOMER'S FAULT OR ANY LEGAL EXPENSES INCURRED BY CUSTOMER IN DEFENDING ITSELF AGAINST SUITS SEEKING DAMAGES CAUSED BY CUSTOMER'S FAULT AND/OR (II) ANY MODIFICATION, CHANGES AND/OR ALTERATIONS TO THE GE HEALTHCARE PRODUCT BY CUSTOMER OR A THIRD PARTY NOT AUTHORIZED OR APPROVED IN WRITING BY GE HEALTHCARE.

CUSTOMER AGREES TO RELEASE, INDEMNIFY AND HOLD GE HEALTHCARE HARMLESS FROM ANY THIRD PARTY DAMAGES THAT GE HEALTHCARE BECOMES LEGALLY OBLIGATED TO PAY RELATED TO BODILY INJURY OR DAMAGE TO REAL PROPERTY OR TANGIBLE PERSONAL PROPERTY TO THE EXTENT THAT SUCH DAMAGES ARE DETERMINED TO BE PROXIMATELY CAUSED BY CUSTOMER'S AND/OR CUSTOMER PERSONNEL (I) MEDICAL DIAGNOSIS OR TREATMENT DECISIONS; (II) MISUSE OR NEGLIGENT USE OF THE PRODUCT; AND/OR (III) USE OF THE PRODUCT IN A MANNER OR ENVIRONMENT, OR FOR ANY PURPOSE, FOR WHICH GE HEALTHCARE DID NOT DESIGN IT, OR IN VIOLATION OF GE HEALTHCARE'S RECOMMENDATIONS OR INSTRUCTIONS ON USE.

THE INDEMNIFICATION OBLIGATIONS SET FORTH IN THIS <u>SECTION 3.5</u> ARE CONDITIONAL UPON THE INDEMNIFIED PARTY PROVIDING THE INDEMNIFYING PARTY PROMPT WRITTEN NOTICE OF THE THIRD-PARTY CLAIM AFTER RECEIPT OF NOTICE OF SUCH CLAIM, ALLOWING THE INDEMNIFYING PARTY TO CONTROL THE DEFENSE AND DISPOSITION OF SUCH CLAIM, AND REASONABLY COOPERATING WITH THE INDEMNIFYING PARTY IN THE DEFENSE. THE INDEMNIFYING PARTY SHALL NOT BE RESPONSIBLE FOR ANY COMPROMISE MADE BY THE INDEMNIFIED PARTY OR ITS AGENTS WITHOUT THE INDEMNIFYING PARTY'S CONSENT.

#### 4. Payment and Finance.

- 4.1. Generally. The payment and billing terms for the Product(s) and/or Service(s) are stated in the Quotation.
- 4.2. Late Payment. Failure to make timely payment is a material breach of this Agreement, for which (in addition to other available remedies) GE Healthcare may suspend performance under the GE Healthcare agreement at issue or suspend the provision of support and maintenance or licenses for the Product(s) licensed or sold under that agreement until all past due amounts are brought current. If GE Healthcare so suspends, GE Healthcare will not be responsible for the completion of planned maintenance due to be performed during the suspension period and any product downtime will not be included in the calculation of any uptime commitment. Interest shall accrue on past-due amounts at a rate equal to the lesser of one-and-one-half percent (1.5%) per month or the maximum rate permitted by applicable law. Customer will reimburse GE Healthcare for reasonable costs (including attorneys' fees) relating to collection of past due amounts. Any credits and/or unapplied cash that may be due to Customer under an agreement may be applied first to any outstanding balance. If Customer has a good faith dispute regarding payment for a particular Product (or subsystem thereof) or Service, Customer shall notify GE Healthcare in writing of such dispute within twenty (20) days of the invoice date and shall work with GE Healthcare in good faith to promptly resolve such dispute. GE Healthcare may revoke credit extended to Customer and designate Customer and all agreements with Customer to be on credit hold because of Customer's failure to pay for any Products or Services when due, and in such event all subsequent shipments and Services shall be paid in full on receipt.
- 4.3. <u>Taxes</u>. Prices do not include sales, use, gross receipts, excise, valued-added, services, or any similar transaction or consumption taxes ("Taxes"). Customer shall be responsible for the payment of any such Taxes to GE Healthcare unless it otherwise timely provides GE Healthcare with a valid exemption certificate or direct pay permit. In the event GE Healthcare is assessed Taxes, interest or penalty by any taxing authority, Customer shall reimburse GE Healthcare for any such Taxes, including any interest or penalty assessed thereon. Each party is responsible for any personal property or real estate taxes on property that the party owns or leases, for franchise and privilege taxes on its business, and for taxes based on its net income or gross receipts.
- Loaner Systems. If GE Healthcare provides a loaner system ("Loaner") to Customer pursuant to the terms of this Agreement, such Loaner shall be subject to the following provisions: (i) the Logner shall be for Customer's temporary use, and Customer agrees to keep the Logner at the location identified in the Quotation, and shall not move the Loaner to another location without GE Healthcare's prior written consent; (ii) Customer agrees to return the Loaner to GE Healthcare on or before the date on which GE Healthcare returns Customer's Product to Customer, and if Customer does not return the Loaner within such time period, GE Healthcare may repossess the Loaner with ten (10) days prior written notice or invoice Customer for the full list price of the Loaner; (iii) the Loaner, and all programs, information, data, business information, or other information pertaining to such Loaner shall remain GE Healthcare property; (iv) title remains with GE Healthcare, but risk of loss passes to Customer upon delivery of the Loaner; (v) Customer agrees to maintain the Loaner in proper operating condition and in accordance with GE Healthcare's operating instructions and return it to GE Healthcare in this condition, normal wear and tear excepted; (vi) Customer will not repair, or permit others to repair, the Loaner without the prior written consent of GE Healthcare; (vii) Customer agrees to furnish GE Healthcare reasonable access to the Loaner with prior notification; (viii) as Customer does not own the Loaner and is not paying GE Healthcare for its use, it is Customer's responsibility to ensure that any charge or claim submitted by Customer to a government healthcare program or patient is submitted accordingly; (ix) prior to returning the Loaner to GE Healthcare, Customer shall ensure the complete deletion of any and all information, including PHI, that may have been stored in the Loaner, or any of its accessories; (x) such deletion shall be completed in accordance with any user instructions provided by GE Healthcare and/or industry standards; (xi) in the event Customer is unable for technical reasons to complete the deletion, Customer shall provide immediate notice of this to GE Healthcare, and GE Healthcare staff shall use commercially reasonable efforts to facilitate the deletion of information; (xii) Customer agrees to indemnify GE Healthcare for any loss whatsoever resulting from any information that is not removed from the Loaner and GE Healthcare shall have no obligations whatsoever in connection with any information that is not properly removed from such Loaner by Customer. It is within GE Healthcare's sole discretion to provide Customer with a Loaner while warranty or Service repairs are ongoing. This provision is not applicable to GE Healthcare IT Products.



## **Product Terms and Conditions**

# **GE** Healthcare

These GE Healthcare Product Terms and Conditions supplement and incorporate by reference (i) the GE Healthcare Quotation that identifies the Product offering purchased or licensed by Customer; (ii) the following documents, as applicable, if attached to or referenced in the Quotation: the GE Healthcare (a) Warranty(ies) and (b) Additional Terms and Conditions; and (iii) the GE Healthcare General Terms and Conditions, (collectively, referred to as the "Agreement").

#### 1. Commercial Logistics.

#### 1.1. Order Cancellation and Modifications.

- 1.1.1. Cancellation and Payments. If Customer cancels an order at any time without GE Healthcare's prior written consent, GE Healthcare has the right to charge Customer a cancellation fee of up to one-and-one-half percent (1.5%), with a maximum amount of up to \$5,000, of the price of the Products ordered. If the cancellation occurs less than thirty (30) days prior to the scheduled delivery date of any portion of the order, GE Healthcare has the right to charge Customer a cancellation fee of up to ten percent (10%), with a maximum amount of up to \$50,000, of the price of the Products ordered. GE Healthcare will retain as a credit any payments received up to the amount of the cancellation charge. If Customer cancels an order for Products for which GE Healthcare has provided site evaluation services, Customer will also pay GE Healthcare reasonable charges for such services performed prior to cancellation. If applicable for the order, Customer will pay all progress payments (other than the final payment) prior to final Product calibration, and GE Healthcare may, at its option, delay final calibration until required progress payments are received. If Customer fails to schedule a delivery date with GE Healthcare within six (6) months after order entry, GE Healthcare may cancel Customer's order upon written notice to Customer. For the avoidance of doubt, GE Healthcare IT Product Quotations and orders are non-cancellable.
- 1.1.2. Order Modifications. No modifications may be made to an order without GE Healthcare's prior written consent. The Product configuration listed in the Quotation is based upon information furnished to GE Healthcare by Customer, and Customer is responsible to provide and pay for modifications, if any, to the configuration due to inaccuracies or incompleteness of the information furnished to GE Healthcare by Customer, changes in Customer's needs or requirements, or for other reasons attributable to Customer.
- 1.1.3. Exchanges and Substitutions. Prior to acceptance as defined in Section 1.5 below, GE Healthcare may, in its sole and reasonable discretion, exchange or substitute installation-related items having similar features, functionality and pricing as the originally delivered installation item that result in no price change to the Customer. This section shall not apply to Healthcare IT Products.
- 1.1.4. <u>Used Product Orders</u>. Products identified as pre-owned, refurbished, remanufactured or demonstration Products have been previously used ("Used Products"); they are not new. When delivered and/or released to Customer, such Used Products may have received reconditioning, as necessary, to meet GE Healthcare performance specifications. Since Used Products may be offered simultaneously to several customers, their sale to Customer is subject to their availability. If the Used Products are no longer available, (i) GE Healthcare will attempt to identify other Used Products in its inventory that meet Customer's needs, and (ii) if substitute Used Products are not acceptable to Customer, GE Healthcare will cancel the order and refund any deposit Customer has paid for such Used Products.
- 1.2. Site Preparation. If applicable, Customer will be responsible, at its sole expense, for evaluating and preparing the site where the Products will be installed in accordance with GE Healthcare's site preparation requirements and applicable laws. Customer must provide GE Healthcare with prompt written notice if Customer is unable to prepare the site before the mutually agreed installation date. Upon receipt of such notice, GE Healthcare will reschedule the installation to a mutually agreed date. Customer shall be liable for any costs or expenses GE Healthcare or its representatives incur resulting from Customer's failure to provide GE Healthcare with timely notice of Customer's failure to properly prepare the site. GE Healthcare may, in its discretion, delay delivery or installation if GE Healthcare determines that the site has not been properly prepared or there are any other impediments to installation; provided that GE Healthcare gives Customer written notice of such delay stating the reasons therefor. If GE Healthcare provides site evaluation services, such services are intended only to assist Customer in fulfilling Customer's responsibility to ensure that the site complies with GE Healthcare's applicable site preparation requirements.

### 1.3. Transportation, Title and Risk of Loss; Delivery; Returns.

- 1.3.1. <u>Transportation, Title and Risk of Loss.</u> Unless otherwise indicated in the Quotation, shipping terms are FOB Destination. Title and risk of loss to equipment passes to Customer upon delivery to Customer's designated delivery location. Software is licensed to Customer; no title to or other ownership interest in such software passes to Customer.
- 1.3.2. <u>Delivery.</u> When feasible, GE Healthcare reserves the right to make delivery in installments. All such installments shall be separately invoiced and paid for when due, without regard to subsequent deliveries. At the time of such delivery, Customer will pay GE Healthcare for any amounts due upon delivery. As a matter of convenience, GE Healthcare may invoice multiple installment deliveries on a consolidated basis; however, this does not release Customer from the obligation to pay for each installment delivery provided by GE Healthcare. Delivery dates are approximate. For GE Healthcare software or documentation, delivery means the first to occur of: (i) communication to Customer through electronic means that allows Customer to take possession of the first copy or product master or (ii) delivery to Customer's designated delivery location.
- 1.3.3. <u>Product Returns</u>. Customer shall not have any right to return Products for a refund after delivery except for products shipped in error that are different from the Products listed in the Quotation.

- 1.3.4. <u>Replaced Component Returns</u>. Except for Healthcare IT Products, for upgrades and revisions Customer agrees to return any replaced component to GE Healthcare at no charge to GE Healthcare.
- 1.4. <u>Installation, Certification and Professional Services</u>. GE Healthcare will provide Product assembly, installation and calibration, as required, at no additional charge, except (i) for items excluded herein and/or (ii) as otherwise indicated in the Quotation. If installation services are identified in the Quotation, GE Healthcare will perform such services from 8am to 5pm local time, Monday-Friday, excluding GE Healthcare holidays, in accordance with applicable GE Healthcare installation guides and/or project plans. After hours installation is available for an additional fee. Customer will review the applicable GE Healthcare installation guides and/or project plans, and perform Customer's obligations as set forth in those materials. Upon completion of assembly, installation and calibration of the Products, as applicable, GE Healthcare will perform prescribed tests using its own performance specifications, instruments and procedures to verify that the Products meet GE Healthcare's applicable performance specifications.

#### 1.4.1. Customer-Supplied Items.

- Customer will install necessary system cable and assemble any necessary equipment or hardware not provided by GE Healthcare, unless agreed otherwise in writing by the parties.
- For Products that will be operated on or in connection with Customer supplied hardware or software, Customer is responsible for ensuring that such hardware and software conform to GE Healthcare's minimum hardware and software requirements as made available to Customer.
- Unless GE Healthcare has agreed in writing to maintain responsibility for an applicable service, Customer will be responsible for enabling the connectivity and interoperability between Customer-supplied hardware or software or other systems or devices and the Product, including, without limitation, procuring and installing any modifications, interfaces or upgrades consistent with GE Healthcare's written specifications.
- Unless otherwise agreed in writing by GE Healthcare, Customer is solely responsible for the (i) performance of and payment for any applicable rigging and/or facility costs and (ii) installation of accessory items.
- If applicable for the Product, electrical wiring and outlets, computer network infrastructure, conduit, cabinetry modification, wall mounts, ventilation and any other site preparation are not included in the purchase price and are the responsibility of Customer, unless otherwise agreed in writing by GE Healthcare.
- 1.4.2. <u>Network</u>. Unless Customer has elected to purchase network preparation and certification Services from GE Healthcare as set forth in the Quotation, Customer is solely responsible for ensuring that Customer's network is adequate for the proper operation and performance of the Products and otherwise meets GE Healthcare's written network configuration requirements.
- 1.4.3. <u>License</u>, <u>Permits</u>, <u>and Approvals</u>. Customer shall obtain and maintain all licenses, permits and other approvals necessary for installation, use and disposal/recycling of the Products, including, but not limited to, any government licenses required to use radioactive sources for Products that require the use of such sources. GE Healthcare will ship such sources to Customer only after Customer provides GE Healthcare with satisfactory evidence that Customer has obtained all required licenses for such sources. In addition, Customer will provide all radioactive sources for calibration and performance checks of Products that require the use of such sources. GE Healthcare will file any required Federal and State reports relating to its installation activities. GE Healthcare will not install, test, certify or provide its own software license or warranty for Products that are not listed in its on-line catalog or price pages at the time of sale (such Products are normally identified by NL or NW series numbers), unless otherwise agreed in writing by GE Healthcare.
- 1.4.4. <u>Non-GE Healthcare Labor</u>. If local labor conditions make it impractical to, or GE Healthcare is directed not to, use GE Healthcare's employees or pre-qualified contractors for the installation, all work will be performed by Customer's laborers or outside labor at Customer's expense; provided that GE Healthcare will, at Customer's request, furnish guidance for installation. GE Healthcare is not responsible for the quality or adequacy of any work performed by any party other than GE Healthcare or its pre-qualified contractors.
- 1.4.5. Non-GE Healthcare Installation. For Products that GE Healthcare is obligated to install under the terms of this Agreement, if GE Healthcare delivers the Product but fails to perform its installation obligations, then in such event Customer shall nevertheless be obligated to pay GE Healthcare an amount equal to (a) the Product purchase price set forth in the Quotation, if the Product purchase price and the installation Services price are shown as separate line items in the Quotation, or (b) if the Product purchase price and installation Services price are not shown as separate line items in the Quotation, then the Product purchase price less the fair market value of the applicable installation Services, taking into account the type of Product and level of installation required ("Installation Service FMV"). An independent third party shall determine the Installation Service FMV. Notwithstanding any other provision of this Agreement to the contrary, either the discharge of Customer's obligation to pay for installation Services shown as a separate line item(s) in the Quotation or the deduction of the Installation Service FMV, as applicable, shall be Customer's sole and exclusive remedy (and GE Healthcare's sole and exclusive liability) in the event GE Healthcare fails to perform its installation obligations under this Agreement.
- 1.4.6. Information Technology Professional Services ("ITPS"). ITPS must be performed within twelve (12) months of the later of the date (i) Customer orders ITPS or (ii) of Product delivery, ("ITPS Performance Date"). If ITPS is not performed within twelve (12) months of the ITPS Performance Date for reasons other than GE Healthcare's failure to perform, GE Healthcare's ITPS performance obligation will expire without refund. ITPS includes clinical applications training, project management, HL7/HIS systems integration, database conversion, network design and integration and separately cataloged software installations. This section shall not apply to Healthcare IT Products.
- 1.5. <u>Acceptance</u>. Unless expressly provided otherwise in this Agreement, Customer shall be deemed to have accepted a Product delivered by GE Healthcare under this Agreement on the earlier of: (i) if GE Healthcare installs the Product, five (5) days after GE Healthcare notifies Customer that it has completed assembly and the Product is operating substantially in accordance with GE Healthcare's published performance specifications; (ii) if GE Healthcare does not install the Product, five (5) days after delivery of the Product to Customer; or (iii) the date Customer first uses the Product for patient use.

- 1.6. <u>Warranties</u>. Product warranties (if applicable) are set forth in the GE Healthcare warranty forms delivered with the Quotation. GE Healthcare may use refurbished parts in new Products. Any part for which GE Healthcare has supplied a replacement (excluding biomed parts, which shall be properly disposed of by Customer) shall become GE Healthcare property.
- 1.7. Third Party Products and Services. If GE Healthcare has agreed to provide any third party products and/or services (other than GE Healthcare accessories and supplies) to Customer as part of the Quotation, including but not limited to any Commitment Account/Non-Inventory items, (i) GE Healthcare is acquiring such products and/or services on Customer's behalf and not as a supplier of such products and/or services, (ii) GE Healthcare provides no warranties or indemnification of any kind, express or implied, with respect to such products and/or services (warranties or indemnification, if any, on such products and/or services will be provided by the manufacturer or service provider), (iii) Customer is solely responsible for ensuring that the acquisition and use of such products and/or services is in compliance with applicable laws and regulations, including applicable FDA regulations, and (iv) Customer is solely responsible for any and all claims resulting from or related to the acquisition or use of such products and/or services. This section shall not apply to Healthcare IT Products.

#### 2. Software License.

- 2.1. License Grant. GE Healthcare grants to Customer a non-exclusive, non-transferable license to use for Customer's internal business purposes the GE Healthcare software, third-party software and Documentation solely for use on the Products and at the location (or, for mobile systems, in the specific vehicle) as identified in the Quotation, subject to the license scope and Documentation and other restrictions set forth in this Agreement. "Documentation" means the GE Healthcare user manuals, on-line help functions, technical specifications and user instructions regarding the operation, installation and use of the software as made available by GE Healthcare to Customer under this Agreement. Customer may only use third-party software provided by GE Healthcare together with the GE Healthcare software and will comply with all third-party software license terms included in any click or shrink wrap license or of which GE Healthcare otherwise makes Customer aware. To the extent permitted by applicable law, licensors of third-party software shall be third-party beneficiaries of this Agreement with respect to third-party software sublicensed under this Agreement. Customer may permit its employees, agents, independent contractors and healthcare providers with privileges at Customer's facilities to use the software and Documentation; provided, however, that Customer shall be responsible for any acts of such third parties that are inconsistent with this Agreement. Notwithstanding the foregoing, independent contractors that supply products comparable to the software shall be provided access to the software only with GE Healthcare's prior written consent and subject to any conditions GE Healthcare deems appropriate to protect its confidential and proprietary information. Customer acknowledges that GE Healthcare may request Customer and Customer Personnel to register online as a licensee for receipt of certain service software and related Documentation.
- 2.2. Additional License Terms. Without GE Healthcare's prior written consent, Customer may not: (i) copy, sublicense, distribute, rent, lease, loan, resell, modify or translate the software or create derivative works based thereon, except that to the extent applicable, the software may be configured as specifically permitted in the Documentation; (ii) directly or indirectly decompile, disassemble, reverse engineer or otherwise attempt to learn the source code, structure, algorithms or ideas underlying the software; (iii) provide service bureau, time share or subscription services based on the software; (iiv) remove, obscure or modify any markings, labels or any notice of the proprietary rights, including copyright, patent and trademark notices of GE Healthcare or its licensors; (v) electronically transfer the software outside Customer's intranet or network dedicated for the software, unless otherwise authorized in writing by GE Healthcare; or (vi) publicly release the results of any testing or benchmarking of the software without the prior written consent of GE Healthcare. Customer may transfer authorized copies of the software, and Documentation to a party that purchases or otherwise acquires the equipment and accepts any applicable license terms, except for software and Documentation that are (a) not a part of the base system standard operating software or Documentation for the equipment and (b) generally provided by GE Healthcare to its customers for a separate fee or charge. Advanced service software is subject to a separate fee and eligibility criteria and licensed under a separate agreement with GE Healthcare.
- 2.3. <u>Backups</u>. Customer may make a reasonable number of copies of the software in machine-readable form solely for backup, training, testing or archival purposes, so long as applicable license fees are paid. Customer shall reproduce on any such copy the copyright notice and any other proprietary legends that were on the original copy. GE Healthcare and its licensors, as applicable, retain all ownership and intellectual property rights to the software and Documentation. If Customer acquires any rights to the software or Documentation, Customer hereby assigns all of those rights to GE Healthcare or its licensors, as applicable. No license rights are granted (whether by implied license or otherwise), to Customer, except as specifically provided in this section.
- 2.4. <u>Remedies</u>. Customer agrees that a violation of GE Healthcare's license, confidentiality or intellectual property rights will cause irreparable harm to GE Healthcare for which the award of money damages alone are inadequate. In the event of any breach of this provision, GE Healthcare shall be entitled to seek injunctive relief in addition to immediately terminating the license granted herein and requiring that Customer cease use of the software and return all copies of stand-alone software in any media in addition to seeking any other legal or equitable remedies available to GE Healthcare. This paragraph shall survive the termination of this Agreement.

#### 3. Payment and Finance.

- 3.1. <u>Security Interest</u>. Customer grants GE Healthcare a purchase money security interest in all items of hardware or equipment listed in the Quotation until full payment is received, and Customer shall perform all acts and execute all documents as may be necessary to perfect GE Healthcare's security interest.
- 3.2. <u>Leases</u>. If Customer is acquiring use of Products through an equipment lease ("Lease") with an equipment lessor ("Lessor"), certain provisions of this Agreement (including, but not limited to, terms related to payment, title transfer, warranties, and software licenses) may be modified as agreed to in writing between GE Healthcare, the applicable Lessor, and/or Customer, as the case may be. Acceptance of the Products as between GE Healthcare and Lessor will be defined by this Agreement; acceptance of the Products as between Lessor and Customer will be defined by the lease agreement. Notwithstanding the foregoing, if the Lessor does not comply with the terms of this Agreement, Customer shall continue to be responsible for the payment obligations hereunder.
- 3.3. <u>Failure to Pay.</u> If, after Product delivery, Customer does not make any payments for the Products within forty-five (45) days after such payments are due, GE Healthcare may, upon ten (10) days prior written notice to Customer, either (a) enter upon Customer's site and remove the Products or (b) temporarily disable the Products so that they are not operational.

GE Healthcare Product Terms and Conditions (Rev 08.14)



# Additional Terms and Conditions: Monitoring Solutions

## **GE Healthcare**

These GE Healthcare Additional Terms and Conditions: Monitoring Solutions supplement and incorporate by reference the GE Healthcare (i) Quotation that identifies the Product offering purchased or licensed by Customer; (ii) Warranty(ies); (iii) Product Terms and Conditions; and (iv) General Terms and Conditions, (collectively, referred to as the "Agreement").

- 1. Software Updates. As part of the purchase of a "Covered Product" (as this term is defined below) set forth in the Quotation, Customer is entitled to receive software "Updates" (as this term is defined below) at no additional charge if and when such Updates become commercially available and subject to the following terms and conditions: (i) Customer's entitlement to no additional charge software Updates is limited to the applicable parts warranty period for the Covered Product that will utilize the software Update; (ii) Customer's entitlement to no additional charge software Updates expires upon commercial release of a software "Upgrade" (as this term is defined below) for the Covered Product purchased by Customer; (iii) Customer is not eligible to receive software Upgrades at no charge; and (iv) Customer is required to pay for any associated services (including but not limited to installation and trouble shooting) rendered by GE Healthcare associated with software Updates except for those software Updates being released pursuant to regulatory requirements.
- 2. **Definitions.** An "Update" is a change in the software that provides error corrections and/or enhances the functionality of a current software release. An Update does not involve major changes or provide significant, new functional capabilities or applications, or changes to the software architecture or file structure. Updates may be identified by a number to the right of the first or second decimal point, such as x.1 or x.y.1.

An "Upgrade" is a change in the software that provides new functional capabilities or applications, enhancements and/or major changes to the software architecture or file structure along with the latest error corrections. Upgrades may be identified by a release number that is to the left of the first decimal point, such as 1.x.

"Covered Product" means the following GE Healthcare products: Central Stations, CARESCAPE patient monitors, Dash patient monitors, Solar patient monitors, Patient Data Module, and Telemetry servers.



# Warranty Statement (United States)

## **GE Healthcare**

This GE Healthcare Warranty Statement (United States) supplements and incorporates by reference (i) the GE Healthcare Quotation that identifies the Product offering purchased or licensed by Customer; (ii) the following documents, as applicable, if attached to or referenced in the Quotation: the (a) Warranties and (b) Additional Terms and Conditions; (iii) the GE Healthcare Product Terms and Conditions; and (iv) the GE Healthcare General Terms and Conditions, (collectively, referred to as the "Agreement").

- 1. Warranted Products. These warranties cover the purchase and use of the following GE Healthcare products:
- Magnetic Resonance
- Computed Tomography
- Mammography
- Positron Emission Tomography (including scanners, cyclotrons & chemistry labs)
- Nuclear
- X-ray

- Surgical Navigation Systems
- Cardiology
- Ultrasound
- Bone Mineral Densitometry
- Physiological Monitoring
- Small Animal Imaging
- C-Arms
- Advantage Workstation and Server
- Anesthesia Delivery
- · Respiratory Care
- Gold Seal
- Phototherapy and other infant care accessories
- Microenvironments, including Giraffe®, Panda®, Care Plus® and Ohio® Infant
- Warmer Systems
- Corometrics® Fetal Monitors

#### 2. GE Healthcare Warranties.

- 2.1 Scope. GE Healthcare warrants that its services will be performed by trained individuals in a professional, workman-like manner. GE Healthcare will promptly re-perform any non-conforming services for no charge as long as Customer provides reasonably prompt written notice to GE Healthcare. The foregoing service remedy, together with any remedy provided herein, are Customer's sole and exclusive remedies (and GE Healthcare's sole and exclusive liability) for warranty claims. These exclusive remedies shall not have failed of their essential purpose (as that term is used in the Uniform Commercial Code) as long as GE Healthcare remains willing to repair or replace defective warranted products or re-perform any non-conforming services for no charge, as applicable, within a commercially reasonable time after being notified of Customer's warranty claim. NO OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, QUIET ENJOYMENT, SYSTEM INTEGRATION AND DATA ACCURACY, WILL APPLY.
- 2.2 <u>Term Usage</u>. "Warranted Product" is a collective term which includes both the above-listed GE Healthcare manufactured equipment and licensed software, with the exception of Healthcare IT Products, purchased by and/or licensed to (as applicable) Customer under the relevant GE Healthcare Ouotation.
- 2.3 <u>Equipment Warranty</u>. Except as indicated otherwise below, GE Healthcare warrants the equipment will be free from defects in title and that for one (1) year from the Warranty Commencement Date (as defined below) (i) the equipment will be free from defects in material and workmanship under normal use and service and (ii) except for equipment manufactured in compliance with Customer's designs or specifications, the equipment will perform substantially in accordance with GE Healthcare's written technical specifications for the equipment (as such specifications exist on the date the equipment is shipped) (the "Specifications"). This warranty covers both parts and labor and is available only to end-users that purchase the equipment from GE Healthcare or its authorized distributors. Customers purchasing through an authorized distributor must contact GE Healthcare promptly following such purchase to enable this warranty.
- 2.4 <u>Software Warranty.</u> Except as indicated otherwise below, GE Healthcare warrants for ninety (90) days from the Warranty Commencement Date that (i) the licensed software will perform substantially in accordance with the applicable Documentation (as defined herein), (ii) it has not inserted any Disabling Code (as defined herein) into the licensed software and (iii) it will use reasonable commercial efforts consistent with industry standards to scan for and remove any software viruses before installation of the applicable Warranted Product. Where an item of equipment has software code embedded in it, the code will only be considered licensed software under this warranty statement if the applicable GE Healthcare Quotation provides a separate part number for that software. Except as indicated otherwise below, GE Healthcare warrants that it has the right to license or sublicense the licensed software to Customer for the purposes and subject to the terms and conditions set forth in the Agreement. As used in this warranty statement, (i) "Disabling Code" means computer code that is designed to delete, interfere with, or disable the normal operation of the Warranted Product; provided, however, that code included in the licensed software that prevents use outside of the license scope purchased for the software will not be deemed to be Disabling Code and (ii) "Documentation" means the GE Healthcare user manuals, on-line help functions, technical specifications and user instructions regarding the operation, installation and use of the software as made available by GE Healthcare to Customer.
- 2.5 <u>Used Products.</u> GE Healthcare's (i) Gold Seal Products (certain pre-owned GE Healthcare equipment), (ii) Ultrasound demonstration systems, and (iii) certified pre-owned Bone Mineral Densitometry Products are all provided with GE Healthcare's standard warranties carrying the same duration as the new equipment warranty, but in no event exceeding one (1) year (unless otherwise provided in writing

- by GE Healthcare). Except as expressly provided in this paragraph or in the applicable GE Healthcare Quotation, all other pre-owned, refurbished, remanufactured or demonstration equipment is not warranted by GE Healthcare.
- 2.6 <u>Healthcare IT and GE Brand Specialty Components</u>. GE Healthcare IT Products and GE Brand Specialty Components (Detectors, Probes, X-Ray Tubes and Image Intensifier Tubes) are covered by a separate warranty statement provided in an applicable GE Healthcare Quotation.
- 2.7 Third-Party Software and Equipment. This warranty statement does not cover Third-Party Software and Equipment (as defined herein) delivered with the Warranted Products (commonly identified by NL or NW series numbers in GE Healthcare's Quotation). "Third-Party Software and Equipment" means any non-GE Healthcare software or equipment (i) delivered to Customer in the third-party manufacturer/supplier's packaging and with its labeling or (ii) for which GE Healthcare expressly indicates (either in the GE Healthcare Quotation or in the product documentation) that the software or equipment is provided with the third-party manufacturer/supplier's warranty in lieu of a GE Healthcare warranty. Such products are covered by the third-party manufacturer/supplier's warranties, to the extent available. Anesthesia monitor mounting solutions Third-Party Software and Equipment purchased directly from GE Healthcare will not be treated as Third-Party Software or Equipment.
- 3. Warranty Commencement. Unless expressly provided otherwise in this warranty statement or the applicable GE Healthcare Quotation, the warranty period begins (the "Warranty Commencement Date") on the earlier of: (i) if GE Healthcare installs the Warranted Product, five (5) days after GE Healthcare notifies Customer that it has completed assembly and the Warranted Product is operating substantially in accordance with GE Healthcare's Specifications; (ii) if GE Healthcare does not install the Warranted Product, five (5) days after delivery of the Warranted Product to Customer; (iii) the date Customer first uses the Warranted Product for patient use; or (iv) if GE Healthcare is contractually required to install the Warranted Product, the thirtieth (30<sup>th</sup>) day following shipment to the end-user Customer if installation is delayed for reasons beyond GE Healthcare's reasonable control. The warranty period for any Warranted Product or component furnished to correct a warranty failure will be the unexpired term of the warranty applicable to the repaired or replaced Warranted Product.
- 4. Remedies. If Customer promptly notifies GE Healthcare of Customer's warranty claim during the warranty period and makes the Warranted Product available for service, GE Healthcare will, at its option (i) with respect to equipment, either repair, adjust or replace (with new or exchange replacement parts) the non-conforming Warranted Product or components of the Warranted Product and (ii) with respect to GE Healthcare's licensed software, either correct the non-conformity or replace the applicable licensed software. GE Healthcare may, at its sole discretion and subject to (i) availability; (ii) any applicable regulatory approvals; and (iii) Section 5 of the GE Healthcare General Terms and Conditions, provide Customer with a comparable loaner system during periods of extended service to the Warranted Product. Warranty service will be performed without charge from 8:00am to 5:00pm (local site time), Monday-Friday, excluding GE Healthcare holidays, and outside those hours at GE Healthcare's then prevailing service rates and subject to the availability of personnel. For certain Warranted Products, GE Healthcare will perform warranty service only at an authorized service center or, in some instances, via a secure, remote connection to a GE Healthcare online center. With respect to GE Healthcare's warranty for the services it provides to Customer, Customer's exclusive remedy is set forth in Section 2.1 above.

Warranty claims for the Warranted Products should be directed through GE CARES at 1-800-437-1171. Warranty claims for accessories and supplies items should be directed through 1-800-558-5102.

5. Limitations. GE Healthcare shall not have any obligation to Customer hereunder if the warranty claim results from or arises out of: (a) the use of the Warranted Product in combination with any software, tools, hardware, equipment, supplies, accessories or any other materials or services not furnished by GE Healthcare or recommended in writing by GE Healthcare; (b) the use of the Warranted Product in a manner or environment, or for any purpose, for which GE Healthcare did not design or license it, or in violation of GE Healthcare's recommendations or instructions on use; or (c) any alteration, modification or enhancement of the Warranted Product by Customer or any third party not authorized or approved in writing by GE Healthcare. In addition, this warranty does not cover the Warranted Product to the extent it is used in any country other than the country to which GE Healthcare ships the Warranted Product (unless GE Healthcare expressly agrees otherwise in writing). GE Healthcare does not guarantee that licensed software will operate without error or interruption.

In addition, these warranties do not cover: (i) any defect or deficiency (including failure to conform to Specifications and/or Documentation, as applicable) that results, in whole or in part, from any improper storage or handling, failure to maintain the Warranted Products in the manner described in any applicable instructions or specifications, inadequate back-up or virus protection or any cause external to the Warranted Products or beyond GE Healthcare's reasonable control, including, but not limited to, power failure and failure to keep Customer's site clean and free of dust, sand and other particles or debris; (ii) the payment or reimbursement of any facility costs arising from repair or replacement of the Warranted Products or parts; (iii) any adjustment, such as alignment, calibration, or other normal preventative maintenance required of Customer; (iv) expendable supply items; (v) stockpiling of replacement parts; (vi) any failure of the Warranted Products to use or correctly process dates (other than systemic miscalculations not due to date value format); and (vii) products not listed in GE Healthcare's Accessories and/or Supplies catalogs at the time of sale, and all service manuals are provided AS IS. For network and antenna installations not provided by GE Healthcare or its authorized agent(s), network and antenna system troubleshooting will be billable at GE Healthcare's standard service rates.

For MR systems, these warranties do not cover (i) any defect or deficiency that results, in whole or in part, from failure of any water chiller system supplied by Customer and (iii) for MR systems with LHe/LN or shield cooler configured superconducting magnets (except for MR Systems with LCC magnets), any cryogen supply, cryogenic service or service to the magnet, cryostat, coldhead, shield cooler compressor or superconductive or resistive shim coils unless the need for such supply or service is caused by a defect in material or workmanship covered by these warranties (GE Healthcare's MR Magnet Maintenance and Cryogen Service Agreement is available to provide supplemental coverage during the warranty period).

For Proteus XR/a, Definium and Precision 500D x-ray systems, these warranties do not cover collimator bulbs.

#### 6. Exceptions to GE Healthcare Standard Warranties Described Above.

Partial System Equipment Upgrades for CT, MR, X-Ray, PET (Scanners, Cyclotrons and Chemistry Labs) and Nuclear systems: Six (6) months (warranty applies only to the upgraded components)

**Cyclotron and Radiopharmacy:** Unless expressly provided otherwise in the applicable GE Healthcare Quotation, the Warranty Commencement Date for Cyclotron and/or Radiopharmacy Products begins on the earlier of (i) three (3) months after the date on which GE Healthcare has completed the mechanical installation, or (ii) the date on which final testing of the Product has been successfully completed. GE Healthcare's sole liability and Customer's exclusive remedy for a breach of warranty is limited to repair, replacement or refund at GE Healthcare's sole option. Any such repairs or replacement will not extend the warranty period.

X-Ray High Voltage Rectifiers and TV Camera Pick-Up Tubes: Six (6) months

X-Ray Portable (Wireless & Tethered) Digital Detectors: Warranty does not cover damage caused by any use that does not conform to OEM guidelines, fire, power failures or surges, or abuse which is defined as use that causes fluid invasion, holes, deep scratches, or the detector case to crack

FlashPad Wireless Detector: In addition to the standard warranty, GE Healthcare will also provide coverage for detector damage due to accidental dropping or mishandling (e.g., spills). In the event such accidental damage occurs, GE Healthcare shall provide Customer with one (1) replacement detector during the warranty period at no additional charge. If subsequent accidental damage occurs during the warranty period, each additional replacement shall be provided to Customer at a charge of \$30,000 per replacement detector. Warranty coverage for the detector and its components also excludes failures due to detrimental exposure, abuse, theft, loss and/or fire. If the warranty is voided by these conditions, repair or replacement of the detector and/or the components is the Customer's responsibility.

GE OEC New or Exchange Service/Maintenance Parts: Ninety (90) days

GE OEC Refurbished C-Arms: Twelve (12) months after installation

HealthNet Lan, Advantage Review — Remote Products: Ninety (90) days

Vivid T8: Three (3) years parts and labor, includes TEE probes purchased with the Vivid T8

Vivid i, Vivid e, Vivid q, Voluson i, Voluson e and LOGIQBook XP: Standard warranty includes (i) repair services at GE Healthcare service facilities, (ii) three (3) business day turnaround repair time for systems shipped via overnight delivery (where available), measured from the date of shipment (GE Healthcare is not responsible for delays in overnight shipment), (iii) seventy-two (72) hour loaner systems or probe replacement service via Fed Ex (shipping charges included), and (iv) technical support via telephone from 7:00 am to 7:00 pm Central Time, Monday-Friday, excluding GE Healthcare holidays. For an additional charge, GE Healthcare may provide (a) field support/service, (b) preventative maintenance, and/or (c) coverage for system damage due to accidental dropping or mishandling with a maximum of two (2) replacement systems during the term of the warranty.

Vscan, LOGIQ e BT12 and later versions, and Venue 40 and 50 version BT12 and later versions: Supplemental warranty terms and conditions specific to Vscan systems, LOGIQ e BT12 and later version systems, and Venue 40 and 50 version BT12 and later version systems shall be as set forth in the Additional Terms and Conditions and Warranties for Ultrasound & Vscan Products attached to the Quotation.

**Ultrasound Partial System Equipment Upgrades:** Ninety (90) days (Warranty applies only to the upgraded components. Customer will not be credited the value of this warranty against pre-existing warranties or service agreements).

**Bone Mineral Densitometry Partial System Equipment Upgrades:** Thirty (30) days (Warranty applies only to the upgraded computer, printer and monitor components. Customer will not be credited the value of this warranty against pre-existing warranties or service agreements).

CARESCAPE Monitors B450, B650 and B850, and Dash: Three (3) years parts and one (1) year labor coverage, excluding displays

**B40 Monitors:** Two (2) years of parts only coverage, excluding displays, and one (1) year labor with (i) repair services performed at GE Healthcare service facilities; or (ii) onsite repair if deemed necessary by GE Healthcare, during such labor warranty period.

MAC 800, 1200, 1600 and 2000: Three (3) years of parts and labor

CARESCAPE V100 Vital Signs Monitors: Two (2) years parts and labor

Exergen: Four (4) years parts and labor

**Batteries:** Ninety (90) days, except (i) for LOGIQBook and Vscan batteries, which are warranted for twelve (12) months and (ii) for Nickel cadmium or lead acid batteries for X-ray and mammography systems (which will carry a sixty (60)-month warranty prorated as shown below). For Nickel cadmium or lead acid batteries for X-ray and mammography systems, warranty service will be performed without charge from 8:00 a.m. to 5:00 p.m. (local site time), Monday-Friday, excluding GE Healthcare holidays, and outside those hours at GE Healthcare's then prevailing service rates and subject to the availability of personnel only during the first twelve (12) months of the sixty (60)-month warranty period. For X-ray and mammography systems, if nickel cadmium or lead acid batteries need replacement during their applicable warranty period, Customer will pay the price of the replacement battery in effect on its delivery date less a Pro Rata Credit Allowance (as defined herein). The Pro Rata Credit Allowance for batteries that fail less than twelve (12) months after the warranty begins is one hundred percent (100%). The Pro Rata Credit Allowance for batteries that fail more than twelve (12) months after the warranty begins is:

1 - (# of Mos. After Warranty Commencement /60) x 100%

For the purpose of Pro Rata Credit Allowance, a fraction of a month less than fifteen (15) days will be disregarded, and a fraction of a month equal to or greater than fifteen (15) days will be regarded as a full month.

Giraffe® Shuttle Batteries: Ninety (90) days

Care Plus® Incubator: Three (3) years parts, one (1) year labor

Ohio® Infant Warmer Systems, Panda® iRes Warmers, Giraffe® Warmer and Giraffe® OmniBed: Seven (7) year parts warranty on heater cal

BiliBlanket® Plus High Output Phototherapy System: Two (2) years on Light Box and eighteen (18) months on Fiberoptic Pad

Microenvironment and Phototherapy expendable components, this includes but is not limited to patient probes, probe covers and light bulbs: Thirty (30) days

Corometrics® Fetal Monitoring Systems: Warranty includes: (i) Warranty Commencement at the earlier of (a) if GE Healthcare or Customer installs the Warranted Product, five (5) days after completion of installation of the Warranted Product or (b) forty (40) days after shipment of the Warranted Product; (ii) two (2) years parts, one (1) year labor; and (iii) repair services at GE Healthcare service facilities during labor warranty period or onsite repair if deemed necessary by GE Healthcare.

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Corometrics® Nautilus Transducers: Two (2) years of parts and labor
Oximeters: Three (3) years from installation, or thirty-nine (39) months from GE Healthcare invoice, whichever occurs sooner

Tec 7 Vaporizers: Three (3) years of parts and labor Tec 6 Plus Vaporizers: Two (2) years of parts and labor

Accessories and Supplies: GE Healthcare's catalog and/or website includes a "Service/Warranty Code" which identifies the installation, warranty, applications and post-warranty service, if any, provided for each accessory and supply product. Following are the warranty periods

for accessories and supplies:

Service/Warranty Code T	100 Years
Service/Warranty Code V	25 Years
Service/Warranty Codes X	15 Years
Service/Warranty Code ZZ	5 Years
Service/Warranty Codes F	3 Years
Service/Warranty Codes D, J, N, O, R or Z	2 Years
Service/Warranty Codes A, B, C, E, G, L, P, Q, S or Y	1 Year
Service/Warranty Code H	6 Months
Service/Warranty Code K	3 Months
Service/Warranty Code M	1 Month
Service/Warranty Code W	Out of Box Failure Only



# Warranty Codes For Accessories And Supplies

## **GE Healthcare**

These GE Healthcare Warranty Codes For Accessories and Supplies supplements and incorporates by reference (i) the GE Healthcare Quotation that identifies the Product offering purchased or licensed by Customer; (ii) the following documents, as applicable, if attached to or referenced in the Quotation: the (a) Warranties and (b) Additional Terms and Conditions; (iii) the GE Healthcare Product Terms and Conditions; and (iv) the GE Healthcare General Terms and Conditions, (collectively, referred to as the "Agreement").

Service / Warranty Codes. If Customer promptly notifies GE Healthcare of its warranty claim and makes the Product available for service, GE Healthcare will provide the warranty service indicated in the applicable Service/Warranty Code description. The terms and conditions of GE Healthcare's Warranty Statement(s) apply to all warranty claims. Basic Service Premise for Products – GE Healthcare Field Engineers will take the first call for service and either provide direct support or arrange for support from the manufacturer or its dealers as indicated by the individual Service/Warranty Code. If the Service/Warranty Code calls for Product return for repair or in-warranty exchange, Customer must return the Product as GE Healthcare directs. GE Healthcare provides warranty service from 8:00 AM to 5:00 PM local time Monday-Friday EXCLUDING GE HEALTHCARE HOLIDAYS. If a Service/Warranty Code provides for warranty service to be performed on Customer's site, such service is available outside the above hours at GE Healthcare's prevailing service rates and subject to the availability of personnel.

## A GE Healthcare directly, or through a sub-contractor, provides the following:

Installation; parts; on-site warranty service to repair, adjust or replace (at GE Healthcare's option and using new or exchange replacement parts) non-conforming products or parts; applications training in some cases (with additional charge); and post-warranty service, at prevailing hourly billed service ("HBS") rates and, in some cases, under GE Healthcare service contracts.

#### B GE Healthcare directly provides the following through GE Healthcare's Global Parts Operation (GPO):

New or exchange replacement parts at no charge to correct non-conforming products or parts during the warranty period; new or exchange replacement parts at GE Healthcare's normal prices for post-warranty repairs. *Note:* Installation, applications training and onsite service is the Customer's responsibility. However, GE Healthcare's Field Engineers may be available at prevailing HBS rates. Contact GE CARES for availability.

#### C GE Healthcare arranges for the third-party Product Manufacturer or its dealers to provide the following:

Installation (in some cases with an additional charge); parts; on-site warranty service to repair, adjust, or replace (at the manufacturer's or dealer's option and using new or exchange replacement parts) non-conforming products or parts; applications training in some cases (some with additional charge); and post-warranty service at prevailing service rates.

#### D GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Basic functional troubleshooting (no technical labor) with supplier phone support and repair or replacement (at the manufacturer's or dealer's option) of defective products or parts. *Note:* The battery for Service/Warranty Code **D** has a 1-year warranty. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

#### E GE Healthcare directly, or through a sub-contractor, provides:

Installation (in some cases with an additional charge); basic functional troubleshooting (no technical labor) with supplier phone support; and coordination of <u>unit</u> exchange or loaner program for in-factory service.

#### GE Healthcare arranges for the third-party Product Manufacturer or its dealers to provide in-factory service:

At no charge during the warranty period and at manufacturers or dealer's prevailing service rates outside of the warranty period. Products must be returned to the manufacturer or dealer, at GE Healthcare's expense during warranty and Customer's expense after warranty, for repair.

#### F GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Basic functional troubleshooting (no technical labor) with supplier phone support and replacement of non-conforming products or parts, which Customer returns to the manufacturer or dealer during the warranty period. **Note:** For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

#### G, J, O and Q GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Start up and commissioning; basic functional troubleshooting (no technical labor) with supplier phone support 24/7; and warranty service to repair, adjust, or replace (at the manufacturer's or dealer's option) non-conforming products or parts (excluding installation, time and material). **Note:** The UPS battery for Service/Warranty Code **G** has a 9-year pro-rated warranty to cover non-conforming material. Start up and commissioning for Service/Warranty Code **O** applies only to 10 KVA and above. The UPS battery for Service/Warranty Codes **O** and **Q** has a 1-year warranty to replace the product. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate. Warranty service for Service/Warranty Codes **G** and **O** is provided On-site. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

#### H, K, L and M GE Healthcare directly provides the following:

Exchange of non-conforming products, which Customer returns to GE Healthcare during the warranty period. **Note:** Installation, parts, applications training, and on-site service is the Customer's responsibility.

#### N, R and S GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Installation; Preventative Maintenance; and parts and labor. **Note:** Post-warranty service, at manufacturer's prevailing HBS rates, and in some cases, under GE Healthcare service contracts. The battery for Service/Warranty Code R has a 1-year warranty. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

#### P GE Healthcare directly provides the following:

Replacement of non-conforming components. **Note:** Installation, parts, applications training, and on-site service is the Customer's responsibility.

#### T, V and X GE Healthcare directly provides the following:

Replacement of Product only; GE Healthcare will not replace patient records; and product is warranted only for image legibility. **Note:** Installation, parts, applications training, and on-site service is the Customer's responsibility.

#### W GE Healthcare directly provides the following:

Replacement of Product only for Out of Box failure. **Note:** Installation, parts, applications training, and on-site service is the Customer's responsibility.

#### Y and Z GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

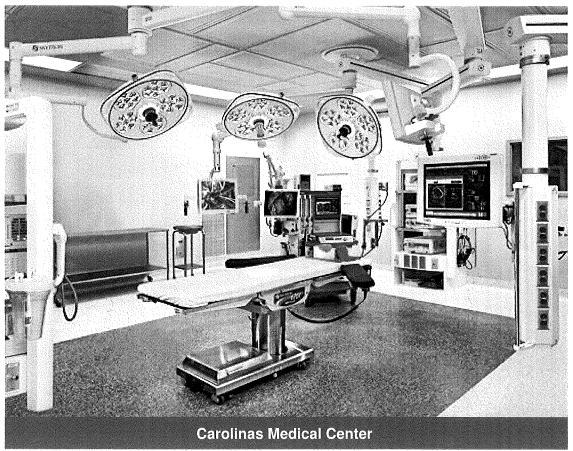
Basic functional troubleshooting (no technical labor) with supplier phone support and replacement of non-conforming components. **Note:** All electrical components (excluding the UPS) for Service/Warranty Code **Z** have a 1-year warranty. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

#### ZZ GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Basic functional troubleshooting (no technical labor) with supplier phone support and replacement of non-conforming components. **Note:** The battery for Service/Warranty Code **ZZ** has a 2-year warranty for stationary applications and a 6-month warranty for mobile application. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.



# **Skytron Response To Request For Quotation From**



Skytron AR 24 Recessed CATH Lab light

PRESENTED BY: Brian McCulloch



July 20, 2015





July 20, 2015

Carolinas Medical Center 1000 Blythe Blvd Charlotte NC 28203-5871

Chris Hollar CMC

Chris,

Below is ther requested quote for the CMC Blythe Pediatric Cath Lab project. We provided a Tier II pricing level instead of Tier I, which is where this order fell. In addition, we provided a partnership discount to bring the total equipment discount to over 22%

You will notice the Collier's quote for installation follows this Skytron quote. We feel this is an conservative estimate for installation and should be able to come in under in reality.

Best Regards,

Brian McCulloch Collier's





#### Summary - presented July 20, 2015

Quote:59010 - 1 Date:07/09/2015 Expires:12/31/2015

Collier's PO Box 16328

Sales Rep:Brian McCulloch

Charlotte NC 28297-6178

Email: bmcculloch@colliersmedical.net

Phone:800-638-3569

Facility: Carolinas Medical Center 1000 Blythe Blvd Charlotte NC 28203-5871

Attn:Chris Hollar, CMC

GPO:Premier Healthcare Alliance Inc Tier 2

We are pleased to quote the following Skytron Products for your review.

w.,	4 -44	List Price	Contract Price
Lights	t .	\$47,040.00	\$38,337.60
Equipment Total		\$47,040.00	\$38,337.60
Partnership Discount	-		\$-2,000.00
Handling		\$272.53	\$272.53
Total Investment		\$47,312.53	\$36,610.13
		Customer Savings	\$10,702.40

#### **Terms and Conditions**

Terms

PP-OR-960 -

Booms - 25% with PO, 65% Net 30 Delivery, 10% balance; paid within the lesser of (a) Net 30 days after installation, or (b)

Net 60 days after delivery.

Lights - Net 30 days following date of invoice

PP-OR-967 -

Tables - Net 30 days following date of invoice

PP-OR-1139 -

SkyVision - 50% with PO, 25% upon delivery, 25% within 45 days of acceptance (Acceptance within 30 Days of install)

Shipping and Taxes are not included in this quote unless itemized above.

Warranty

3 years parts and labor on contracted equipment

1 year on SkyVision

1 year parts and labor on non-contracted equipment

90 days on replacement parts, supplies, spare bulbs (for surgical lights), pads (for surgical tables) and accessory items

15 years on sterilizer pressure vessel (steam chamber and jacket)

**FOB** 

Destination, prepaid and added

All shipments subject to handling charge

Delivery

120 Days ARO and/or receipt of SIGNED submittal and deposit if applicable.

Deposit

. 25% deposit required for Lights/Booms upon order acceptance. See "Terms"

50% deposit required for SkyVision, VACS upon order acceptance 25% deposit required for non-contracted products upon order acceptance

50% deposit required for Custom products upon order acceptance

**Contract Code** 

PP-OR-960; PP-OR-967, PP-OR-1139

Issue PO To

Skytron, LLC | PO Box 888615, Grand Rapids, MI 49588-8615 | 616-656-2900 \* Please include the entire quote number on

your P.O.

**Submit PO To** 

Email to orders@skytron.us or fax to 616-656-2906

Remit To

Skytron, LLC | 16208 Collections Center Drive, Chicago, IL 60693 | 616-656-2900

Acknowledgement	Signature:	Date:
	Name:	Title:





# Lights

Quote: 59010 - 1
 Date: 07/09/2015
Expires: 12/31/2015

Facility: Carolinas Medical Center

1000 Blythe Blvd Charlotte NC 28203-5871

Qty	Ext Qty	Item Number	Description	List Price	List Price Ext	Contract Price	Contract Price Ext
2	2	AR-24-KA4	Argos II system, consisting of 4 AR24 light heads, B5-011-100 quad wall control. B5-012-39 probe, B5-012-40 charger and wall control back box	\$23,520.00	\$47,040.00	\$19,168.80	\$38,337.60
			Lights Total		\$47,040.00 List Price	. с	\$38,337.60 ontract Price



http://www.skytron.us/products/pages/lights.html



#### **Supplemental Terms and Conditions**

#### **Drawing Change Fee.**

\$200.00 drawing change fee will be invoiced after 2nd drawing revision.

#### **Change Order Fee**

Change order fees, equal to five percent (5%) of order total, apply if order changes occur within 60 days prior to shipment.

#### Cancellation Fee.

Eight percent (8%) cancellation fee will be invoiced or deposit will be forfeited on cancelled items of an equipment order.

#### Minimum Order Fee.

Orders with a product total less than \$25.00 are subject to a \$20 non-refundable minimum order fee added to the invoice.

#### Re-Stocking Fee.

- a. Equipment 20% re-stocking fee will apply to all returns for credit. Refurbishment charges, if any, will be calculated upon inspection of the goods when received. All returns to be authorized by Skytron in advance.
- b. Parts \$50.00 re-stocking fee for inspection/testing, plus up to five percent (5%) of item cost for repair/refurbishing charge (not to exceed \$2,500 per item). Non-warranty part returns with a List Price less than \$100.00 per item will not be accepted.
- c. Re-Stocking policy does not supersede Skytron's North American Warranty policy, Demo policy, or Table Pad Return policy.

#### Cable Installation.

Pricing is inclusive of the installation of up to 15 communication cables provided by the minimally invasive surgery equipment supplier at the time of the installation of Skytron product. Additional cables can be installed for a price of \$100.00 each. Please verify number of cables for accurate pricing. Skytron SkyVision systems are exempt.

#### Final Adjustments.

Final adjustments included in all installation pricing.

#### Miscellaneous.

- a. Unless otherwise noted, Skytron reserves the right to make product improvements, discontinue products, and change prices without notice.
- Orders are subject to credit approval.
- c. Unless otherwise noted or previously negotiated, quoted amounts Do Not Include freight costs and applicable taxes. Freight and tax rates in effect at time of shipment will be applied.
- d. Buyer expressly agrees that no terms and conditions shall supersede those in this quote without express, written consent of Skytron.



#### **Service Terms and Conditions**

#### Working Hours.

All service and installation pricing is based on normal working hours, 8 AM to 5 PM, Monday thru Friday, excluding holidays.

#### Disconnection and Removal of Existing Equipment.

If required, for a fee, Skytron can disconnect and remove existing equipment.

#### Union Labor

Facilities requiring the use of union labor must be identified as such for quoting purposes.

#### Seismic Requirements.

Please notify Skytron's Service Manager for installations having specific seismic requirements. Skytron is not responsible for any x-raying of the floor, structural ceiling through bolting, and associated fasteners.

#### Trade-in Equipment.

Please notify Skytron's Service Manager for installation where trade-in equipment will be present.

#### Combination Products.

For integrated products combining lighting and equipment pendants, include installation pricing for both individual units.

#### Scheduling.

Contact Skytron's Service Manager a minimum of 15 working days prior to desired installation date. Large and intensive projects requiring multiple phases require a minimum 60-day notice before installation commences. Please contact Skytron's National Service Manager or Sales Representative.

#### Service Contracts.

A signed service contract is required. A preliminary evaluation of product may be required for product that has been in use for some time.

#### Electrical Connections, Final Tie-Ins and Finishes.

All final tie-ins of electrical connections, plumbing and media must be made by a qualified and licensed individual. Skytron does not provide final tie-in services due to local licensing regulations. Finish work (e.g., caulking and trim) is the responsibility of others. Installation of standard product moldings or trim is included in the pricing provided.



#### Quotation

Ouote To: CAROLINAS HEALTHCARE **SYSTEM** 1000 Blythe Blvd **CHARLOTTE NC 28203-5812**  Bayer HealthCare LLC 1 Bayer Drive Indianola, PA 15051

Quotation number: 0020016779 Customer number: 0000174391 Date: 07/15/2015

Page:

Valid from:

07/15/2015 to

09/30/2015

Trey Karn Professional Sales Consultant 864-415-2397 trey.karn@bayer.com

We deliver according to the following terms and conditions:

Currency: USD

Terms of payment: 30 d. w/o discount of inv. net

Terms of delivery:

Free carrierFOB SHIPPING POINT

ltem	Part No	Qty	Unit Price	UoM	Amount
1	84397504	· · ·			
1	ART700 PEDL	1 PCE	35,000.00	1 PCE	35,000.00
	MARK 7 ARTERION, I	PEDESTAL, SYSTEM ,MC			
	Discount (Value)		9,800.00-		9,800.00-
	Net value		25,200.00		25,200.00
	**IDN MEMBER DISC	OUNT**			
2	60720582				
	ART 700 PJ150	1 PCE	488.00	1 PCE	488.00
	ASSY, PRESS JACK, 1	50ML,MK 7 ARTERION,MC			
	Discount (%)		13.66-		136.64-
	Net value		351.36		351.36

If pricing and terms of this order are based upon your current Group Purchasing Organization (GPO) affiliation, any change to your current affiliation may require a new quote or updated terms and pricing.



#### Quotation

ltem	Part No	Qty	Unit Price	UoM	Amount
3	84138363				
	ART 700 VFL VARIABLEFLOW,MARK	1 PCE 7 ARTERION	5,000.00	1 PCE	5,000.00
	Discount (Value)		2,150.00-		2,150.00-
	Net value		2,850.00		2,850.00
4	59942968				
	INS ART 700-P INSTALL MARK 7 ARTEI	1 PCE RION PEDESTAL	1,275.00	1 PCE	1,275.00
	Net value		1,275.00		1,275.00
5	83917911				
	VIRTUALCARE				
	100% Discount				
-			Sub	Total	29,676.36
			Т	otal	29,676.36

NOTE: If using signed quote as a purchase order please complete the following information:

Print Name:	
Signature:	
Title:	
PO #:	
Phone #:	-

If pricing and terms of this order are based upon your current Group Purchasing Organization (GPO) affiliation, any change to your current affiliation may require a new quote or updated terms and pricing.



#### BAYER PRODUCT TERMS AND CONDITIONS

If Customer is a member of a group purchasing organization ("GPO") who has a contract with Bayer, the terms of that GPO Agreement will supercede the terms herein.

The following terms and conditions will not apply to the license of Bayer's Radimetrics or Certegra products. Such products are subject to a separate license agreement.

- 1. Modifications. The prices and terms on this Quote are not subject to verbal changes or other agreements unless approved in writing by Bayer.
- 2. Acceptance. Bayer's products and services are sold only under the terms and conditions stated on this quotation. Acceptance of any Purchase Order is expressly and exclusively made conditional on your assent to these terms and conditions. Any different or additional terms and conditions that may appear in your Purchase Order or any other document sent by you, shall have no effect. Bayer expressly objects to and rejects all inconsistent or additional terms, conditions and limitations contained on any of your forms or other writings. If you do not communicate your objection to these terms and conditions in writing and within a reasonable time, or if you accept the goods covered by this Quote, you will be deemed to have accepted these terms and conditions and they will control in all instances. If the Products include embedded software or if you are purchasing software, BY HAVING THE SOFTWARE INSTALLED AND USING THE SOFTWARE PURCHASED HEREUNDER, YOU AGREE TO BE BOUND BY THE TERMS OF THIS AGREEMENT. IF YOU DO NOT AGREE TO THE TERMS OF THIS QUOTE, DO NOT INSTALL OR USE THE SOFTWARE AND NOTIFY BAYER IMMEDIATELY.
- 3. Pricing. Prices are based on costs and conditions existing on the date of this Quote and may be changed by Bayer before final acceptance. The pricing for products provided pursuant to this Quote may reflect or be subject to discounts, rebates, or other price reduction programs. Please be advised that you are obligated to: a) fully and accurately disclose the amount of any such discounts, rebates, or other price reductions in your cost reports or claims for reimbursement to Medicare, Medicaid, or health care programs requiring such disclosure and b) provide such documentation to representatives of the Secretary of the Department of Health and Human Services and state agencies upon request. Unless noted otherwise, the value of any product listed as \$0.00 on this Quote may constitute a discount that you should evaluate when filing such reports. You may request additional information from Bayer in order to meet your reporting or disclosure obligations, by writing to the address set forth in this Quote. All payments are due net thirty (30) days on the total invoiced amount. For all new customers Bayer requires a thirty percent (30%) pre-payment for all capital equipment orders, unless otherwise agreed to by Bayer. Bayer must approve any payment terms other than net thirty (30) days.
- 4. Shipping. All shipping dates are tentative. Bayer will make every reasonable effort to meet shipping dates referenced in this Quote. However, Bayer will not be liable for its failure to meet any such date.
- 5. Installation. The cost of installation is not included in the product price and is your responsibility unless otherwise stated. For details on equipment installation, you should consult with your Bayer Sales Representative or refer to your Products Manual, which is included with your equipment.

If this Quote includes installation of an overhead counterpoise system (OCS) it is your responsibility to ensure a suitable mounting location for the system. The counterpoise ceiling plate is required to be installed prior to Bayer installation of the counterpoise system and installed in accordance with the specifications listed in the installation manual. The OCS ceiling plate should always be installed by a qualified Structural Engineer and/or Architect. In addition, if applicable building codes require the use of a conduit, you are responsible for ensuring that a conduit is available prior to Bayer's installation.

If this Quote includes a Certo wireless network it is your responsibility to ensure the approval of the Information Technology Department to allow the operation of the wireless network at your site.

If this Quote includes a Spectris Solaris with an Integrated Continuous Battery Charging System (iCBC), installation will require a standard power outlet in the scan room, or authorization to install a filter through the penetration panel.

6. License. If the Products include embedded software, or if you are purchasing software, Bayer grants to you a non-exclusive license to use such software provided by Bayer, solely in connection with, or to operate, the Products. Use of the software for any other purpose is strictly prohibited. This license is effective on the date you begin using the Products and software and will continue in effect unless you return the Products or software or if the license is terminated because

Please reference the quote number on your PO and fax to 412-406-0952



you breach any provision of these Terms. Upon termination you shall immediately cease use of all software and shall return the Products and software to Bayer. The software copyright is owned by Bayer and is protected by United States copyright laws and international treaty provisions. Bayer does not transfer title to the software to you, but retains the rights to make and license the use of all copies. You shall not copy, translate, disassemble, or decompile nor create or attempt to create, by reverse engineering or otherwise, the source code from the object code of the software. You are not permitted to modify or make derivative works of the software and ownership of any unauthorized modification or derivative work shall vest in Bayer.

7. Warranty. Bayer warrants that all new Bayer products are free from defects in workmanship or material under proper, normal use and service for a period of one year (12 months) from shipment, unless a longer period is provided on the warranty with the products, or as otherwise provided herein.

Bayer warrants that all refurbished Bayer products shall perform in accordance with the documentation provided, under proper, normal use and service for a period of the shorter of a) 90 days from installation or b) six months from shipment, unless a longer period is provided on the warranty with the products, or as otherwise provided herein.

If this Quote includes a Monitor, peripheral accessories on the Monitor such as pulse oximeter sensors, extension cables, power cables, fiber optic cables, ECG leads, capnography accessories (excluding patient connections), blood pressure cuffs, batteries, and extension tubing are warranted for a period of 90 days from the date of installation, but not to exceed six months from the date of shipment.

If this Quote includes disposable products or angiographic catheters, Bayer's warranty shall be limited to repair or replacement of any defective disposable product or angiographic catheter upon receipt of the defective product and a Bayer Return Goods Authorization. You acknowledge that the disposables and the equipment are a system and your actions regarding your equipment may invalidate your warranty on the disposables.

During the warranty period, there shall be no charge for any action deemed necessary by Bayer, including parts, travel, or labor to fulfill the terms of the warranty, during local business hours of 8:30 a.m. to 5:00 p.m., Monday through Friday, except holidays.

Your actions may invalidate this warranty. If Bayer determines that an equipment or disposable problem is due to any of the following, you agree to pay Bayer for all labor, travel, material handling and shipping at Bayer's, or Bayer's agents, standard rates:

- a) Malfunction or damage due to spillage of any type of fluid in or on the unit.
- b) Malfunction due to operator error, including failing to follow specified provisions of the Operations Manual.
- c) Malfunction or damage due to unauthorized modification or repair. Unauthorized actions may jeopardize functionality, reliability, or operator and patient safety. Therefore any unauthorized modification or repair shall render this warranty void and relieve Bayer from any further obligation. Bayer must review and authorize all modifications and repairs. This service may be obtained by contacting the Bayer Service Department.
- d) Malfunction or damage due to the use of non-Bayer or non-approved accessories. The use of accessories in connection with the equipment may jeopardize functionality, reliability or operator and patient safety. Therefore any use of non-Bayer or non-approved accessories (such as non-Bayer disposables or in the case of any PET/CT product, the use of vials or vial shields that are not approved by Bayer) shall render this warranty void and relieve Bayer from any further obligation.
- e) Damage by fire, floods, or other disaster commonly known as "Acts of God".
- f) If the Products include any Counterpoise system, any system malfunction, damage or failures due to improper installation or not meeting Bayer's specific requirements for level and plumb and/or loading as specified in the Bayer manuals.
- g) If the Products include any Counterpoise system, any ceiling or wall support structure used to mount or support an Injector Head Counterpoise System is excluded from Bayer's warranty. Bayer does not in any way warrant such structure.
- 8. Warranty Exclusions. EXCEPT AS PROVIDED IN THE ABOVE WARRANTY SECTION, BAYER EXPRESSLY DISCLAIMS ALL WARRANTIES OR CONDITIONS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY,

Please reference the quote number on your PO and fax to 412-406-0952



NONINFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE (WHETHER OR NOT BAYER IS AWARE OF YOUR INTENDED USE OF THE PRODUCT), AND ALL SUCH WARRANTIES ARE EXPRESSLY EXCLUDED. IN NO EVENT SHALL BAYER BE LIABLE FOR ANY LOST PROFITS OR INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR OPERATION OF BAYER'S PRODUCT OR SERVICE. Some states do not allow the exclusions on limitation of incidental or consequential damages, so the above limitations may not apply. This Limited Warranty gives you specific legal rights and you may also have other rights.

- 9. Software Warranty. If the Products include embedded software or if you are purchasing software, Bayer warrants that the software will substantially conform to the functional specifications contained in the Operations Manual for one year following delivery. This warranty shall not apply if you use the software in a manner that is not authorized or not in accordance with the user instructions or if you modify the Products or the software or if a party other than Bayer provides service to the Products or software. Bayer does not warrant that the software will operate uninterrupted or that it will be free from minor defects or errors that do not materially affect its performance. Your sole and exclusive remedy for any damages or loss in any way connected with the software whether due to Bayer's negligence or breach of any other duty shall be, at Bayer's option: i) to bring the performance of the software into substantial compliance with the functional specifications or ii) return of an appropriate portion of any payment by you with respect to the portion of the software that is not functioning.
- 10. Indemnification. Bayer agrees to indemnify, defend and hold you harmless from any liability, loss, expense, cost, claim or judgment (including attorneys fees), arising out of any claim for property damage, or personal injury or death where the product is alleged to have caused or contributed to the damage, injury or death, provided that this indemnification does not extend to injuries, damages or death to the extent caused by the negligence, reckless disregard or intentional acts of you or any third party.
- 11. Force Majeure. Bayer will not be responsible for delays or non-performance directly or indirectly caused by any acts of God, fire, explosion, flood, war, accident, action by governmental authority, inability to procure supplies and raw materials, delays in transportation, work stoppage, court order, and other causes beyond Bayer's reasonable control.
- 12. Compliance With Laws/Export. In addition to any rights and remedies specifically identified here in this Quote, Bayer shall have all rights and remedies conferred by law. Bayer shall not be required to perform its obligations under this Quote if you have defaulted (e.g. failed to pay) under this Quote or any other contract involving Bayer. This Agreement shall be construed in accordance with the laws of the Commonwealth of Pennsylvania, United States of America. You warrant that you are and will remain in compliance with all export and reexport requirements, laws and regulations of the United States of America and any other applicable export and reexport laws and regulations.
- 13. HIPAA. Bayer represents that it is not a Business Associate as defined in the Health Insurance Portability and Accountability Act ("HIPAA"). The functions Bayer is required to perform hereunder do not require the use or disclosure of Protected Health Information ("PHI"). To the extent any disclosure of PHI does occur, it is incidental and covered under the incidental disclosure rule found in 45 CFR 164.502(a)(1). In addition, to the extent any such incidental disclosure does occur, Bayer agrees to keep all such information confidential.

# **Integration Budgets**

#### Each Lab to include:

- SPI-3 Integration System (18 Input x 16 Output)
  - o 19" Touch Panel Interface Control Room
  - 19" Touch Panel Interface Procedure Room
  - o HD PTZ Room Camera
  - Video Connectivity Module (Polycom)
  - 2 55" Wall Displays (Procedure Room & Control Room)
  - $\circ$  3 26" Viewing Monitors (patient left, right, & anes boom) \$6,000 per
  - Digital Capture Device \$18,000
  - All Cabling and Installation
  - o \*Tom may have a Polycom that would reduce this quote

#### 2 LAB TOTAL - \$384,000

#### • Stryker EIZO (Large 8mp Display)

- o 60" 8MP EIZO Display
- Corresponding LMM (Large Monitor Manager)
- Table Side, Control Room & IPAD Layout Control
- Downscaler to allow Display Image to be routed in 1080P for added visualization
- All Cabling and Installation

-2 LAB TOTAL - \$346,982,76 -

# **Booms & Lights Budgets**

#### Lab 1 (EP Capable Room):

- o EP Boom \$29,025
- Large EIZO Monitor Boom \$34,020
- Anes Boom w/Monitor Bracket \$23,540
- o Perfusion Boom \$12,400
- F 528 Surgical Light with HD Camera/Radiation Shield/Monitor Suspension (Patient Right)
   \$48,700
- o F 528 Surgical Light/Monitor (Patient Left) \$22,910

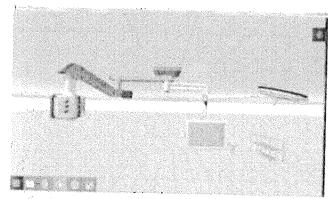
TOTAL - \$170,595

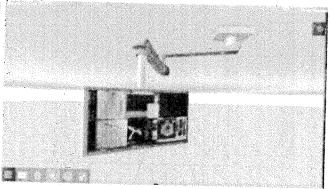
#### Lab 2:

- Large EIZO Monitor Boom \$34,020
- o Anes Boom w/Monitor Bracket \$23,540
- o Perfusion Boom \$12,400
- o F-528 Surgical Light with HD Camera/Radiation Shield/Monitor Suspension (Patient Right) -
- \$48,700
- o F 528 Surgical Light/Monitor (Patient Left) \$22,910

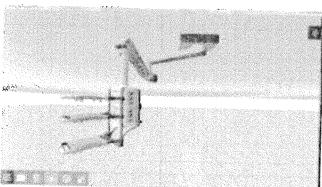
#### TOTAL - \$141,570

#### Images of Lights/Booms Suspensions:

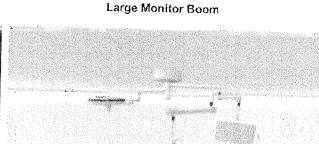




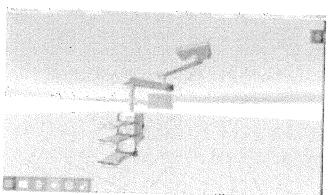
Perfusion Boom/ F528/ Monitor Suspension



EP Boom



F528 wCam /Rad Shield/ Monitor Suspension



Anes Boom with Monitor Arm

**Print Date** 7/28/15

**PRICING SUPPLEMENT - PURCHASE** 

37777-01

Omnicelle

5111045

**Pricing Supplement ID** Master Agreement ID

CMC Peds Cath Lab

**Quote:** 5111045

Carolinas Medical Center **Ship To ID** 10166

1000 Blythe Boulevard Charlotte NC 28203

**Summary By Product** 

07/24/15 **Expiration Date** Start Date

01/30/16

Carolina Health Sys

**Price List** 

Carolinas Medical Center 1000 Blythe Boulevard **Bill To ID** 10166

Charlotte NC 28203

# Support Services Term / Level 12 Months/Gold

				Product		Monthly	Monthly Services
Product	Description	Qty.	Contract List Price	Unit Price	<b>Extended</b> Price	<b>Unit</b> Services	<b>Extended Services</b>
MDA-FRM-004	OMNIRX HALF-CELL G4	-	\$10,200.00	\$10,200.00	\$10,200.00	\$59.16	\$59.16
MDA-SCN-003	2D SAFETYSTOCK G4 (OMNIRX, TT, HALF RX)	-	\$1,257.00	\$1,257.00	\$1,257.00	makaka manusi manusi manuka kanaka ja makakaka kanaka kanaka kanaka kanaka kanaka kanaka kanaka kanaka kanaka	
MSA-OPT-006	FLEXLOCK WITH TEMPCHECK (50FT) INSTL G4	-	\$2,040.00	\$2,040.00	\$2,040.00	\$15.76	\$15.76
OLL12	12-BIN LOCKING DRAWER	-	\$2,400.00	\$2,400.00	\$2,400.00		
OLMD24	24-BIN LIGHTED MATRIX DRAWER	-	\$1,170.00	\$1,170.00	\$1,170.00		
OMD48	96-Bin Matrix Drawer	_	\$945.00	\$945.00	\$945.00		
OS3DRXU	THREE DRAWER PHARMACY MODULE	-	\$3,010.00	\$3,010.00	\$3,010.00	· · · · · · · · · · · · · · · · · · ·	
OSPPO	Profile Driven Option	-	\$1,860.00	\$1,860.00	\$1,860.00	\$12.61	\$12.61
SRD-IDR-021	TOUCH & GO FOR G4 LID CONSOLE	-	\$957.00	\$957.00	\$957.00		
			Total Product	THE CONTRACT OF THE CONTRACT O	\$23,839.00	VERTICAL AND THE CONTRACT OF T	
			<b>Total Support Services</b>	rt Services	\$1,050.36	man erform synamic property of the error of the milder on a Victorial Wildelphan Lands	
			Total Shippi	Total Shipping & Handling	\$739.46		
			<b>Grand Total</b>		\$25,628.82		A THE REAL PROPERTY AND A PROPERTY AND A STREET AND A STREET ASSESSMENT AND A STREET ASSESSMENT ASS

Page 1 of 3

**Pricing Supplement ID** 

CMC Peds Cath Lab **Quote:** 5111045

**Carolinas Medical Center** 

1000 Blythe Boulevard Charlotte NC 28203

10166

Ship To ID

37777-01

Supplement

Start Date

07/24/15

**Expiration Date** 

**Price List** 

Carolina Health Sys

10166 Bill To ID Carolinas Medical Center 1000 Blythe Boulevard

Charlotte NC 28203

# Support Services Term / Level 12 Months/Gold

- This Pricing Supplement is subject to and incorporates by reference all of the terms and conditions as set forth within the Master Agreement identified
- Any terms and conditions on any Purchase Order issued in conjunction with this Pricing Supplement shall be for reference purposes only and shall not become a part of the terms and conditions of this Pricing Supplement. 'n
- Customer acknowledges and agrees that it is Customer's obligation to pay the amounts as set forth on this Pricing Supplement and that such payment obligations are governed by the terms and conditions of the above referenced Master Agreement including all applicable scheduled, attachments and m
- The undersigned hereby acknowledges that he/she has the authority to sign this Pricing Supplement and bind the Customer to the terms and conditions of this Pricing Supplement. 4.

CUSTOMER:	Signature:	Print Name:	ïtle:	Date:	
OMNICELL, INC.	Signature: Signature:	Print Name:	Title:	Date:	

\*\* Please fax all document pages to (650) 251-6240

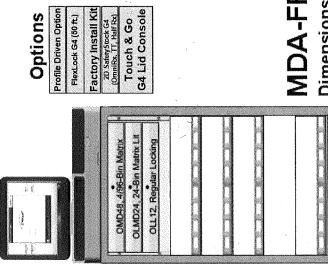
Mountain View, CA 94043 Phone: (650) 251-6000 Fax: (650) 251-6240 Omnicell, Inc. 590 E. Middlefield Road Attn: Sales Operations

/ CMC Peds Cath Lab

ID 5111045

**Print Date** 7/28/15

# Par Location: PAR 1



# MDA-FRM-004 Pharmacy

Dimensions: 27.90W  $\times$  57.70H  $\times$  26.60D



/ Revision No:

Attachment D

#### PROPOSED TOTAL CAPITAL COST OF PROJECT

Pro	oject n	ame:	CMC Main SHV	'I Cath Lab Space #	‡ 2		
Pro	ovider/	Company:	Carolinas Health				<del></del>
	<b>~</b> •						
<b>A</b> .		Costs	01 1				
	(1)	Full purchase price of					N/A
	(0)	Acres	Price ner Acre	_\$			
	(2)	Closing costs	_				N/A
	(3)	Site Inspection and S					N/A
	(4)	Legal fees and subso					N/A
	(5)	Site Preparation Cos Soil Borings	ts				
		Clearing-Earthwo	ork				
		Fine Grade for SI	ah				
		Roads-Paving					
		Concrete Sidewal	ks				
		Water and Sewer					
		Footing Excavation	o <b>n</b>				
		Footing Backfill					
		Termite Treatmer	nt				
		Other (Specify)					
		Sub-Total Site Pr	enaration Costs				N/A
	(6)	Other (Snecify)					N/A
	(7)	Sub-Total Site Cost	s				N/A
3.	Cons	truction Contract					
	(8)	Cost of Materials					
		General Requiren	nents			included	
		Concrete/Masona	rv			included	
		Woods/Doors & '	Windows/Finishes			included	
		Thermal & Moist	ure Protection			included	
		Equipment/Specia	altv Items			included	
		Mechanical/Elect	rical			included	
		Other (Snecify)				included	
		Sub-total Cost of Ma	terials				included
	(9)	Cost of Labor					included
	(10)	Other (Snecify)					included
	(11)	Sub-Total Construc	tion Contract				\$1,013,000
Ţ.,	Misce	ellaneous Proiect Cos	ts				
	(12)	<b>Building Purchase</b>					N/A
	(13)	Fixed Equipment Pur	chase/Lease			<del></del>	\$1.608.000
	(14)	Movable Equipment	Purchase/Lease				\$528.000
	(15)	Furniture					\$12.400
	(16)	IS/Security					\$185,600
	(17)	Consultant Fees				<del> </del>	WIOJ.WW
		Architect and Eng	ineering Fees			\$108,500	
		Legal Fees				N/A	
	•	Market Analysis				N/A	
		Other (TB DHSR)	) ·			\$19.500	
		Other (Admin)				\$234,000	
		Sub-Total Consultant	Fees				\$362,000
	(18)	Financing Costs (e.g.					N/A
		Interest During Const					N/A
		Other (Project Contin					\$315.000
		Sub-Total Miscellan					\$3.011.000
	(22)	Total Capital Cost of	f Ducioat (Com A C	7 ala)			04.004.000

#### PROPOSED TOTAL CAPITAL COST OF PROJECT

**Project Name:** 

CMC Main SHVI Cath Lab Space # 2

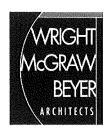
Provider/Company:

Carolinas Healthcare System

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

TVUUVMQUW\_NC 3963

(Signature of Licensed Architect or Engineer)



August 26, 2015

Mr. Craig R. Smith, Chief Certificate of Need Section Division of Health Services Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

Re:

CMC SHVI Cath Lab Space 2

Dear Mr. Smith:

Having worked with Carolinas HealthCare Systems to develop the design for the reference project, Wright McGraw Beyer Architects, p.a. is pleased to provide the cost certification letter. The probable cost is based on the drawings included with the CON submittal. The estimated construction cost reflects our experience with similar healthcare projects. Wright McGraw Beyer Architects, p.a. certifies to the best of their knowledge the construction cost of \$1,013,000.00.

Please call me if you have any questions or comments.

Sincerely,

Wright McGraw Beyer Architects, p.a.

Todd R. McGraw, AIA, NCARB, LEED AP

Managing Principal

TITUUMMQUW

North Carolina License #3963

TRM/hh



2201 Water Ridge Pkwy. Suite 550 Charlotte, NC 28217 P. 704.535.6374 F. 704.535.9827

www.wmba.net

Attachment E

STATE OF NORTH CAROLINA COUNTY OF MECKLENBURG		IN THE OFFICE OF ADMINISTRATIVE HEARINGS 11 DHR 0360
THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a	)	
CAROLINAS HEALTHCARE SYSTEM,	)	
Petitioner,	)	
V.	)	
N.C. DEPARTMENT OF HEALTH AND	)	
HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,	) ) )	
Respondent.	)	l .
STATE OF NORTH CAROLINA	minima no	IN THE OFFICE OF ADMINISTRATIVE HEARINGS
COUNTY OF MECKLENBURG		11 DHR 0698
THE CHARLOTTE-MECKLENBURG	)	
HOSPITAL AUTHORITY d/b/a CAROLINAS HEALTHCARE SYSTEM,	)	
Petitioner,		
<b>v.</b>	)	
N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF	)	
HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,	)	
Respondent.	)	

#### SETTLEMENT AGREEMENT

This Settlement Agreement (the "Agreement") is entered into by The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System ("CMHA") and the North Carolina Department of Health and Human Services, Division of Health Service Regulation,

Certificate of Need Section (the "Agency" or the "CON Section") (collectively referred to hereinafter as "the Parties" and individually as "a Party").

#### RECITALS

#### September 5, 2008 Replacement Equipment Notice

WHEREAS, on or September 5, 2008 CMHA submitted a letter containing an Exemption Notice to replace a nine year old Phillips Vascular Imaging System with a Toshiba Bi-Plane X-Ray System (hereinafter referred to as the "September 2008 Replacement Equipment") at Carolinas Medical Center ("CMC") without a Certificate of Need ("CON") pursuant to the exemption provisions in N.C. Gen. Stat. § 131E-184(a)(8) of the CON law.

WHEREAS, on April 1, 2010 and October 19, 2010, pursuant to requests for additional information from the Agency, CMHA submitted additional information regarding the September 2008 Replacement Equipment.

WHEREAS, by letter dated December 14, 2010, the Agency notified CMHA that it had denied its Exemption Notice, asserting that the replacement equipment proposed is not comparable to the existing medical equipment currently in use, and therefore, does not allegedly meet the definition of replacement equipment exempt from review in accordance with N.C. Gen. Stat. § 131E-184(a)(7). In addition, the Agency denied CMHA's Exemption Notice on the basis that the 2010 State Medical Facility Plan only identified seven (7) cardiac catheterization labs rather than eight (8) labs at CMC.

WHEREAS, on January 13, 2011, Petitioner filed a Petition for a Contested Case Hearing initiating the above-captioned contested case, identified as 11 DHR 0360, challenging the Agency's decision to deny Petitioner's Exemption Notice for the September 2008 Replacement Equipment ("September 2008 Contested Case").

#### November 2008 Replacement Equipment Notice

WHEREAS, on or November 20, 2008 CMHA submitted a letter containing an Exemption Notice to replace a nine year old Trexx Cardiac Imaging System with a Toshiba Infinix VF-I Vascular X-Ray System (hereinafter referred to as the "November 2008 Replacement Equipment") at CMC without a CON, pursuant to the exemption provisions in N.C. Gen. Stat. § 131E-184(a)(8) of the CON law.

WHEREAS, on April 1, 2010 and October 19, 2010, pursuant to requests for additional information from the Agency, CMHA submitted additional information regarding the November 2008 Replacement Equipment.

WHEREAS, by letter dated December 23, 2010, the Agency notified CMHA that it had denied its Exemption Notice, asserting that the replacement equipment proposed is not comparable to the existing medical equipment currently in use, and therefore, does not allegedly meet the definition of replacement equipment exempt from review in accordance with N.C. Gen. Stat. § 131E-184(a)(7).

WHEREAS, on January 24, 2011, Petitioner filed a Petition for a Contested Case Hearing initiating the above-captioned contested case, identified as 11 DHR 0698, challenging the Agency's decision to deny Petitioner's Exemption Notice for the November 2008 Replacement Equipment ("November 2008 Contested Case").

WHEREAS, Petitioner's September 2008 and November 2008 Exemption Notices are collectively referred to as the Exemption Notices and the projects referenced therein are collectively referred to as the Replacement Equipment Projects.

WHEREAS, there are no known intervenors that have an interest in either of the abovecaptioned Contested Cases (collectively "the Contested Cases"). WHEREAS, pursuant to N.C. Gen. Stat. § 150B-22, it is the policy of the State to settle disputes between State agencies and other persons whenever possible.

WHEREAS, pursuant to this policy, the Parties have discussed settlement of these contested cases.

WHEREAS, in the context of settlement negotiations, Petitioner has submitted additional information to the Agency since the filing of the Contested Case petitions, allowing the Agency to determine that Petitioner's Proposed Projects are exempt from Agency review, such that the Agency may approve Petitioner's Replacement Equipment Projects.

WHEREAS, the execution of this Settlement Agreement does not constitute an admission of error by any Party and does not constitute a concession by any Party regarding any issue in the Contested Cases.

WHEREAS, for and in consideration of the mutual promises and agreements contained herein, which the Parties agree constitute good and satisfactory consideration to resolve all issues among the Parties involving the Contested Cases; and to resolve other issues, disputes, and potential disputes described herein.

NOW THEREFORE, pursuant to N.C. Gen. Stat. §§ 150B-22 and 31(b), and subject to the approval of the Director of the Division of Health Service Regulation (the "Director"), the Parties agree to resolve these Contested Cases in the manner set forth below.

#### <u>AGREEMENT</u>

1. <u>Petitioner's Voluntary Dismissal with Prejudice</u>. Within five (5) business days after the Director approves this Settlement Agreement, CMHA shall file notices of voluntary dismissal ("the Voluntary Dismissal"), with prejudice, in the Office of Administrative Hearings in the Contested Cases, 11 DHR 0360 and 11 DHR 0698.

- 2. Replacement Equipment. The Agency authorizes CMHA to replace, without a CON, a nine year old Phillips Vascular Imaging System with a Toshiba Infinix VF-I Vascular X-Ray System located at CMC and a nine year old Trexx Cardiac Imaging System with a Toshiba Bi-Plane X-Ray System located at CMC, as the equipment is described in CMHA's September 5, 2008 and November 20, 2008 Exemption Notices. The Agency further authorizes CMHA to locate the Toshiba Infinix VF-I Vascular X-Ray System at the location of the nine year old Trexx Cardiac Imaging System and to locate the Toshiba Bi-Plane X-Ray System at the location of the nine year old Trexx Cardiac Imaging System without a CON.
- 3. <u>Release.</u> Each Party hereby releases all other Parties, their officials, employees, and representatives, from any and all liability or claims that have arisen or might arise out of: (a) the Agency's review of the Exemption Notices; or (b) the Contested Cases.
- 4. Expenses. The Parties agree that each shall bear its own expenses, including attorneys, fees, and that no claim for such costs or expenses shall be made by one Party against the other.
- 5. <u>Effect of Approval.</u> If approved by the Director, this Agreement shall resolve all issues involved in, or arising out of, the Contested Cases.
- 6. Effect of Disapproval. If this Agreement is not approved by the Director, it shall be null and void and the Parties shall be entitled to proceed with the Contested Cases. In that event, the Director's review of this Agreement as provided herein shall not prejudice his authority to render the final Agency decision following the hearing in this matter in accordance with Article 3 of Chapter 150B of the North Carolina General Statutes. In addition, if this Agreement is not approved by the Director, the Parties agree that it shall be inadmissible at the hearing in the Contested Cases for any purpose.

- 7. Waiver of Right to Appeal Agreement. The Parties irrevocably waive any right to initiate an appeal from this Agreement, assuming that any such right exists; provided that nothing in this Agreement shall be construed to waive any claim for enforcement or breach of this Agreement. The Parties reserve the right to intervene in any appeal of this Agreement that might be filed by any third parties.
- 8. Merger. The Parties further agree and acknowledge that this written Agreement sets forth all of the terms and conditions among all of them concerning the subject matter of this Agreement, superseding all prior oral and written statements and representations and that there are no terms and conditions among the Parties, except as specifically set forth in this Agreement.
- 9. <u>Modification or Waiver.</u> No modification or waiver of any provision of this Agreement shall be effective unless it is in writing. Any modification or waiver must be signed by authorized representatives of the Parties and must be adopted and approved by the Director.
- 10. <u>No Strict Interpretation Against Drafter.</u> Each of the Parties has participated in the drafting of this Agreement and has had the opportunity to consult with counsel concerning its terms. This Agreement shall not be interpreted strictly against any one Party on the ground that it drafted the Agreement.
- 11. <u>Recitals and Headings.</u> All parts and provisions of this Agreement, including the recitals and paragraph headings, are intended to be material parts of the Agreement.
- 12. <u>Authority to Settle.</u> The undersigned represent and warrant that they are authorized to enter into this Agreement on behalf of the Parties to this Agreement.
  - 13. <u>Ex Parte Presentation</u>. Petitioner authorizes counsel for the Agency to present this

Agreement to the Director, ex parte.

- 14. <u>Effective Date.</u> This Agreement shall be effective as of the day and year on which it is adopted and approved by the Director of the Division of Health Service Regulation.
- 15. <u>Binding Effect.</u> This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective legal representatives, successors, and assigns.

IN WITNESS WHEREOF, the Parties have executed two originals of this Settlement Agreement, with one original copy being retained by each Party.

# THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a CAROLINAS HEALTHCARE SYSTEM

F. Del Murphy, Jr. Vice President, CHS Management Company	Date	
K&L GATES LLP		
By: Colleen In Crowley	4-19-11	
Gary S. Qualls Colleen M. Crowley Susan K. Hackney 430 Davis Drive, Suite 400 Morrisville, NC 27560 Telephone: (919) 466-1182	Date	

ATTORNEYS FOR PETITIONER

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION

By: Caigle Smith	Date:	4.20-11
Craig R. Smith, Chief		લક
ROY COOPER Attorney General		
By: Stephen a Bu	Date:	4-19-11
Stephanie Brennan		The state of the s
Assistant Attorney General		
N.C. Department of Justice		
P.O. Box 629		
Raleigh, NC 27602-0629		

COUNSEL FOR THE NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION

#### APPROVAL AND ADOPTION

The foregoing Settlement A	Agreement is here	by APPROVED	AND ADOPTED	this the
21'' day of $4(c)$	2011.	•		******
	****		•	
MANOW 5				
Drexdall Pratt, Director				
Division of Health Service Deculat	ion			•



# Carolinas HealthCare System

James E.S. Hynes Chairman

Michael C. Tarwater, FACHE Chief Executive Officer

> Joseph G. Piemont President & COO

> > January 13, 2011

Mr. Craig R. Smith, Chief Certificate of Need Section Division of Health Service Regulation 701 Barbour Drive Raleigh, North Carolina 27603-0530

RE: Replacement of Cardiac Catheterization Room #6 on the Carolinas Medical Center Campus

Dear Mr. Smith:

In addition to the information provided in prior correspondence on November 20, 2008, April 1, 2010 and October 19, 2010 I am providing clarifying information that will demonstrate that the project to replace cardiac catheterization room #6 at Carolinas Medical Center (CMC) did in fact meet the definition of replacement equipment exempt from review in accordance with N.C.G.S. 131E-184(a)(7).

The cardiac catheterization department at CMC consists of seven cardiac catheterization rooms and one vascular lab. Cardiac catheterization room #6 operates as a pediatric cardiac catheterization lab. I have included a table as Attachment 1 that shows the configuration of the cardiac catheterization department before the equipment replacements and relocations that took place in 2008 and 2009.

The equipment replacement project for the pediatric cardiac catheterization lab (Room #6) included a change in location of the equipment. The pediatric catheterization lab (Room #6) and the vascular lab (Room #8) swapped locations. The reason for the change in location was due to the architectural requirements of the new pediatric cardiac catheterization equipment that could not be met in Room #6.

The responses to Replacement Equipment Question #2 and the equipment capability responses included in the Equipment Comparison provided in Attachment 1 and

Mr. Craig R. Smith January 13, 2011 Page 2

Attachment 2, respectively of our original letter on November 20, 2008 were incorrect. Our responses incorrectly compared the original equipment to the replacement equipment that was to be located in each room at the completion of the projects when the rooms switched functions. Please see Attachment 2 of this letter for replacement pages that include a corrected answer to Question 2 and a corrected Equipment Comparison matrix with the changes highlighted in yellow.

We would like to resolve this matter in a timely fashion and we would appreciate a response from you as soon as possible. If you have any questions or require further information regarding this project, please contact me at 704-355-0314. Sincerely,

Greg S. Bass, Director

CHS Management Company

Attachments

# **Attachment 1**

Cardiac Catheterization Department Equipment Inventory

# Carolinas Medical Center Cardiac Catheterization Lab Equipment Inventory

	Before Replacement Projects in 2008 and 2009							
Room #	Room Type	Manufacturer	Model	Serial #	Install Date			
	Cardiac Cath	Philips	Allura FD10	54	10/1/2004			
	Cardiac Cath	Philips	Integris V5000	S4F632829A	11/13/1999			
3	Cardiac Cath	Philips	Allura FD10	53	7/1/2004			
4	Cardiac Cath	Philips	Allura Xper FD10	202	10/1/2005			
5	Cardiac Cath	Philips	Allura FD9	40	9/11/2003			
6	Pediatric Cardiac Cath	Trexx	X4233	AP-MZ69-030 LAT-MZ89-003				
7	Cardiac Cath	Philips	Allura FD9 BiPlane	MCV-2817				
8	Vascular Lab	Philips	Integris V5000	4875440	8/1/2002			

Room #	Room Type	Manufacturer	Model	Serial #	Install Date
1	Cardiac Cath	Philips	Allura FD10	54	10/1/2004
2	Cardiac Cath	Toshiba	2335129-4	0000055010BU8	6/20/2008
3	Cardiac Cath	Philips	Allura FD10	53	7/1/2004
4	Cardiac Cath	Philips	Allura Xper FD10	202	10/1/2005
5	Cardiac Cath	Philips	Allura FD9	40	9/11/2003
6	Vascular Lab	Toshiba	Infinix VF-i	99A0913088	6/18/2009
7	Cardiac Cath	Philips	Allura 9 BiPlane	MCV-2817	12/2/2002
8	Pediatric Cardiac Cath		Infinix CF-I/BP	W1B08Y2046	1/12/2009

# **Attachment 2**

Revised Replacement Equipment Questions and Equipment Comparison

# Attachment 1 Replacement Equipment Questions/Answers

1. A comparison of the existing and replacement equipment, using the format in the attached format.

Attachment 2 provides a side-by-side comparison of existing and the proposed replacement equipment.

2. A description of the basic technology and functions of the existing and replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or capable of being used.

Existing equipment is used for physiological and angiographic studies using image intensifier fluoroscopy and digital imaging for the following types of procedures: cardiac angiography, angiographic examination of congenital heart defects, venograms, angioplasty, and implantation of stainless steel stents and other implantable devices.

Replacement equipment will be used for physiological and angiographic studies using image intensifier fluoroscopy and digital imaging for the following types of procedures: cardiac angiography, angiographic examination of congenital heart disease, venograms, angioplasty, implantation of stainless steel stents and other implantable devices.

3. Brochures or letters from the vendors describing the capabilities of the existing and replacement equipment.

A brochure for the existing cardiac catheterization equipment could not be found. The brochure for the replacement equipment is provided as Attachment 3.

4. A copy of the purchase order for the existing equipment, including all components and original purchase price.

Due to the age of the equipment an original PO could not be found.

5. A copy of the title, if any, for the existing equipment or the capital lease for the existing equipment.

Carolinas Medical Center owns the equipment. No title was issued.

Carolinas Medical Center – Cardiac Cath Lab Room #6 Replacement Questions/Answers Page 2

6. If the replacement equipment is to be leased, a copy of the proposed capital lease that transfers substantially all the benefits and risks inherent in the ownership of the equipment to the lessee of the equipment, in accordance with criteria in Generally Accepted Accounting Principles (GAAP).

Not applicable. The replacement equipment will be purchased.

7. If the replacement equipment is to be purchased, a copy of the proposed purchase order or quotation, including the amount of the purchase price before discounts and trade-in allowance.

A price quotation provided by Toshiba America Medical Systems is provided as Attachment 4.

8. A letter from the person taking possession of the existing equipment that acknowledges the existing equipment will be permanently removed from North Carolina, will no longer be exempt from requirements for the North Carolina Certificate of Need law, and will not be used in North Carolina without first obtaining a new certificate of need.

A letter from Transtate Equipment Company related to the disposal of the existing equipment is provided as Attachment 5.

9. Documentation that the existing equipment is currently in use and has not been taken out of service.

The existing Lab #6 equipment is currently in operation. Attachment #6 includes a report documenting the 319 procedures performed with this equipment year-to-date through November 17.

10. Proposed Total Capital Cost of Project form.

Refer to Attachment #7 for a description of the total project costs and a certified construction estimate.

Carolinas Medical Center — Cardiac Cath Lab Room #6 Replacement Attachment 2 - EQUIPMENT COMPARISON

	Evicting Equipment	T-0
Type of Equipment (List each component)	Transfer Smooth	replacement Equipment
Manifacturer of Equipment	Calulac Calli Lab	Vascular Lab
Symmetric of Equipment	Trexx Medical Systems	Toshiba
Testa Rating for MRIs	N/A	N/A
Model Number	X4233	Infinix CF-I/RP
Serial Number	AP-MZ69-030 LAT-MZ89-003	WIBORY2046
Provider's Method of Identifying Equipment	Site # 45	Site
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	NA	N/A
Date of Acquisition of Each Component	11/13/1999	000001/1
Does Provider Hold Title to Equipment or Have a Capital Lease?	Purchased	Purchase
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use>		\$1.706.000
Total Cost of Equipment		\$884.260
Fair Market Value of Equipment		\$884.260
Net Purchase Price of Equipment		\$884.260
Locations Where Operated	Carolinas Med. Ctr. Cath Lab	Carolinas Med. Ctr. Cath Lab
Number Days in Use/To Be Used in N.C. per Year	M-F 5 days/week	M-F 5 days/week
Percent of Change in Patient Charges (by procedure)	0	%8
Percent of Change in Per Procedure Operating Expenses (by procedure)	0	0
Type of Procedures Currently Performed on Existing Equipment	— Physiologic and angiographic studies using image intensifier for Cardiac Catheterizations, Aortography, and Percutaneous therapeutic procedures.	
Type of Procedures New Equipment is Capable of Performing		Physiologic and angiographic studies using image intensifier for Cardiac Catheterizations, Aortography, and Percutaneous therapeutic procedures.



# Carolinas HealthCare System

James E.S. Hynes Chairman

Michael C. Tarwater, FACHE Chief Executive Officer

> Joseph G. Piemont President & COO

> > October 19, 2010

Ms. Carol L. Hutchison, Project Analyst Certificate of Need Section Division of Health Service Regulation 701 Barbour Drive Raleigh, North Carolina 27603-0530

RE: Information Requested for Replacement Equipment for Cardiac Catheterization Lab #6 at Carolinas Medical Center

Dear Ms. Hutchison:

I have attached the additional information items you requested in your correspondence of May 26, 2010 for the above referenced project. The specific items requested include:

- 1. The proposed location of the replacement Toshiba VF-I Vascular X-ray system within CMC. (The attached drawing for Level 6 at CMC has the location of cardiac catheterization lab #6 labeled)
- 2. A signed letter from Transtate Equipment Co.

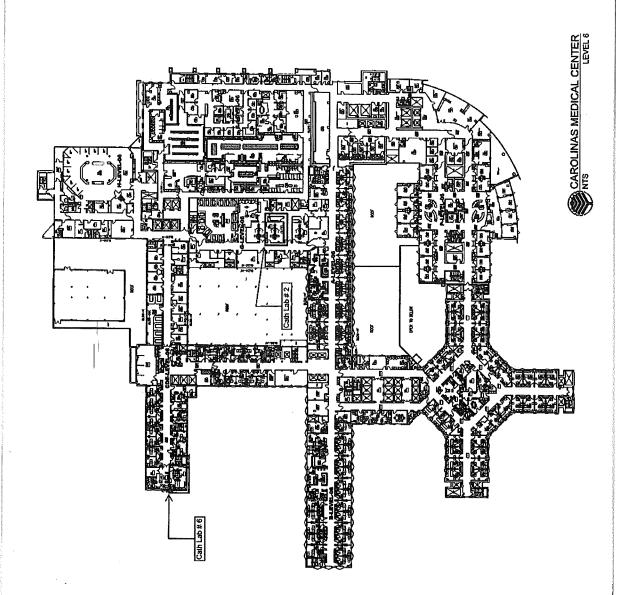
If you have any questions or require further information regarding this project, please contact me at 704-355-0314.

Sincerely,

Greg S. Bass, Director

**CHS Management Company** 

Attachments



# Transtate equipment company, inc.

1821 Glenwood Ave., Raleigh, N.C. 27608 e-mail: Transtate@nc.rr.com tel: 800-710-9996

November 18, 2008

Kevin Collier RCIS Clinical Supervisor, Cardiac Cath Lah Carollnas Med CT. Charlotte, NC 28232-2861

Dear Mr. Collier,

Thank you for entrusting us with the task of de-installing and disposing of the TREX cardiac cath/angio system at Carolinas Medical Center. As we discussed, Transtate will be us-installing the system in January 2009. As agreed, Transtate will charge the hospital \$7,500 for this service.

In response to any inquiry you may receive from the state of N. Carolina, please inform any inquiring state agency that Transtate will de-install this system, break it into parts and transport them outside the state of North Carolina.

Transtate is registered with NC Dept of Facility Services, Radiation Protection Services as a x-ray sales and service company. All questions can be referred directly to me at the address and phone # listed below. A copy of this notice should be retained by the hospital and may also be supplied to the state for their records. Please let me know it I can be of any additional assistance.

Best wishes,

Dan Wheeler

President, Transtate Equipment Company

1821 Glenwood Ave Raleigh, NC 27608 (919) 835-3609 off

(919) 345-4744 cell



# Carolinas HealthCare System

James E.S. Hynes Chairman

Michael C. Tarwater, FACHE Chief Executive Officer

> Joseph G. Piemont President & COO

> > April 1, 2010

Ms. Carol L. Hutchison, Project Analyst Certificate of Need Section Division of Health Service Regulation 701 Barbour Drive Raleigh, North Carolina 27603-0530

RE: Information Requested for Replacement Equipment for Cardiac Catheterization Lab #6 at Carolinas Medical Center

Dear Ms. Hutchison:

I have attached the additional information items you requested for the above referenced project. The specific items requested include:

- 1. Current number of existing cardiac catheterization units located and operating at CMC including equipment identification and installation dates.
- 2. Floor plan showing the location of existing and proposed equipment.
- 3. Corrections and explanations on the signed capital cost table.

If you have any questions or require further information regarding this project, please contact me at 704-355-0314.

Sincerely,

Greg S. Bass, Director

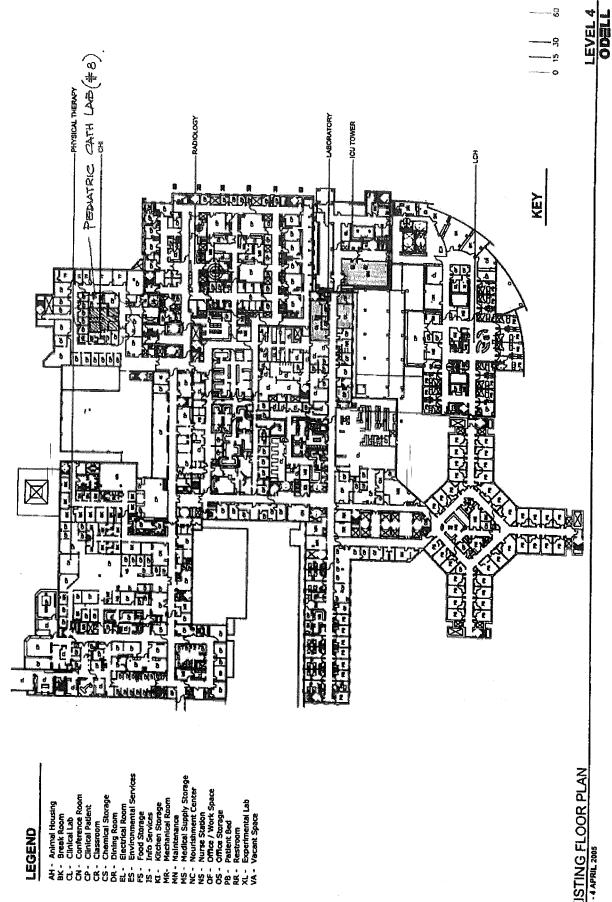
CHS Management Company

Attachments

# Carolinas Medical Center Cardiac Catheterization Lab Equipment Inventory

	Before Replacement Projects												
Cath Lab Room	Manufacturer	Model	Serial#	Install Date									
	Philips	Allura FD10	54										
2	Philips	Integris V5000	S4F632829A	11/13/1999									
3	Philips	Allura FD10	53										
4	Philips	Allura Xper FD10	202	10/1/2005									
5	Philips	Allura FD9	40	9/11/2003									
6	Trexx	X4233	AP-MZ69-030 LAT-MZ89-003	11/13/1999									
	Philips	Allura FD9 BiPlane	MCV-2817	12/2/2002									
8	Philips	Integris CV 3M	501H014762/000001	11/13/1999									

LEVEL 6



EXISTING FLOOR PLAN

Category		_	1	Capital C	
Bonds, insurance, surveys, testing, (build	long stall at		apital Cos	t Line Ite	m Comments
insurance, performance bonds);	iers risk, storage	s			
Utility costs during construction, includi			50	0 B (11)	-
and relocations:	ng ututty extensions	s			There are no utility extensions or
The state of the s				-	relocations as part of this project
Parking and paving costs;		\$			This project will utilize existing
Parking and paving costs;				-	parking areas
Architect and engineering fees including expenses;	reimburseable	s			
			50,00	0 C (17)	
Construction management fees or costs;		5	25,000	0 B (11)	
Interior and activities				<u> </u>	This project will utilize existing
Interior and exterior signage;		5		-	signage
Permits and fees for impact studies: envi	ronment, asbestos,				-36
building, zoning, etc., sprinkler water tap	fees; highway	\$			ĺ
access rees;		1	1,500	B (11)	}
Cable TV connections: wiring and/or har dishes and equipment:	dware; external	T .	3,000	1	
dishes and equipment:		\$	250	B (11)	1
Computer wiring: hardware and/or softv	vare (information			15(11)	
systems wiring, power elc.);		\$	35,000	R/111	
Telephone wiring/system including equip	ment:	\$	5,000		
All consultants: construction, phasing, int	erior design.	*	3,000	B (11)	
programmatic, etc.;	- 1	\$	E 000	77 (24)	
Exterior lighting, walks, rails, ramps, and	protective barriers		5,000	B (11)	
(tences/etc.);		\$		i	This project will utilize existing
Spare parts such as initial change of air filt	ore:	~	2 500		exterior components
All types of movable equipment: furniture	linane costa	\$	2,500	B (11)	
desks, chairs, medical equipment, art work	Ato.	\$			
All types of fixed equipment, including mo	ving and m		165,000	C (14)	
installation costs;	ving and re-	\$		ľ	One Toshiba InfinixVF-I single Pla
Startup costs such as cleaning, advertising,			884,260	C (13)	including options
moving, grand opening, etc.;	marketing,	\$	!		
Bearing often		·	2,000	B (11)	1
Security equipment, wiring, hardware, soft		\$			This project will utilize existing
Moving costs and other costs associated with	ware, etc.;	Ψ.	-	<u></u>	security equipment
existing space or building (most associated Wil	in leaving an				
existing space or building (post occupancy	repairs, clean-up,	\$			·
removal of telephone systems, lease require moving out, etc.);	ments when	<b>J</b>			This project does not involve movie
Interior Life Cafety			-		costs or leaving existing space
Interim Life Safety measures and/or OSHA	requirements	\$			- B crossing space
during construction (labor + materials);		J	3,000	B (11)	1
				· · · · · · · · · · · · · · · · · · ·	There are no known life safety code
Comments	l,	<b>.</b>	i		JCAHO Plant, Licensure and OSHA
Correction of existing life safety code, JCAH	O Plant,	\$	1		deficiencies to correct as part of this
Licensure and OSHA deficiencies;			- 1		project
					This project will utilize existing
17. 6 · 1	9	3	ľ		vehicles maintanesses to
Vehicles, maintenance, storage buildings;	1		_ [	i	vehicles, maintenance and storage buildings
			<del></del>		
	l s		1		This project will be funded using
Cost of financing:	1	•			accumulated reserves and will
Legal fees associated with the project: leases	Avreemente				require no financing
disputes, deeds, consultation etc.;	s specification,		ľ	ļ	There are no legal fees as part of this
					project.
			- 1	· · · · · · · · · · · · · · · · · · ·	This project will be funded using
Interest during construction on construction l	5		1	j.	accumulated reserves and will
	Oans		» J	[,	require no financing

_					
у.	Building equipment and systems necessary to implement emergency management plan, such as, generators, snow removal equipment, extra fuel storage, etc.;  Outstanding life code deficiencies or major repairs needed to	\$			This project will utilize existing building equipment and systems necessary to implement emergency management plans
Z.	maintain existing building safety, longetivity, and compliand with codes, regulations, and/or JCAHO requirements where applicable;				There are no known life code deficiencies or major repairs required as part of this project
	Handicap accessibility requirements to assure compliance	\$	·····		part of this project
aa.	with ADA;	] 3	1,000	B (11)	
bb.	Painting, wallpaper, all interior finishes;	\$	7,500		
	Carpet, floor tile, ceramic tile, operating room special			<del>                                     </del>	
cc.	flooring, etc.;	s	6,000	B (11)	
dd.	Demolition costs, including permits, hauling, special disposa costs;	ş	454,490		
ee.	Partnership fees, incorporation fees, privilege licenses etc.;	\$			The project does not involve a partnership, corporation or privileg license
ff.	Costs for elevator and botler certifications;	\$	-		The project will utilize existing elevators and boilers
	Costs associated with compliance with final review comments				The state of the s
	by all reviewing regulatory agencies, including actual				
	construction costs, design change costs if any, and	\$			
<u>gg.</u>	modification of contracts (cost, profit, overhead);	1	2,000	B (11)	
ıh.	A reasonable contingency cost to complete the work;	\$	50,000	B (11)	
	Costs associated with completion of final system		***************************************	\/_	
	certifications, including but not limited to medical gas	5			
i.	certification to comply with NFPA99 test criteria;	İ	2,500	B (11)	
	Costs for certification and testing of patient special electrical				
	systems to comply with NFPA99 and the National Electrical	ا م			
	Code (impedance, equipotential, and current leakage tests for	\$			
•	fixed patient equipment);		1,500	B (11)	
1.	Costs for fire alarm certification and sprinkler system	· <b>S</b>		`	
k.	certification prior to occupancy;	<b>D</b>	2,000	B (11)	
	Costs associated with field labeling of any equipment that is				
	not listed and labeled by a NC recognized safety testing lab	\$	1		There is no field lableing required as
•	(E.G., UL, ETL., MET., etc.);				part of the project.
	Costs to provide certification by the X-Ray shielding designer				F
	that the radiation shielding has been designed and installed	œ	-		
	per approved plans, specifications, and regulations (radiology	\$	ĺ		1
m,	installations only):		.	8 (11)	Done In-House
n.	Costs of all additive change orders known at this time;	\$		· · · · · · · · · · · · · · · · · · ·	None at this time

	Ψ.	
()/()	\$_	1,706,000
I certify that, to the best of my knowledge, the costs of the proposed above are complete and correct	proje	ct named
The said to be a second		
(Eric Cebula, AIA)	-	

Lassure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as Calling The State (Suzabhe Freeman, President Carolinas Medical Center)



# Carolinas HealthCare System

James E.S. Hynes Chairman

Michael C. Tarwater, FACHE Chief Executive Officer

> Joseph G. Piemont President & COO

> > November 20, 2008

Ms. Lee B. Hoffman, Chief Certificate of Need Section Division of Health Service Regulation 701 Barbour Drive Raleigh, North Carolina 27603-0530

RE: Replacement of Cardiac Catheterization Lab #6 on the Carolinas Medical Center Campus

Dear Ms. Hoffman:

Carolinas Medical Center is planning to replace a nine-year-old Trexx Cardiac Imaging System with a Toshiba Infinix VF-i Vascular X-Ray System. The projected total capital expenditure for the removal of the existing equipment, renovation of the room and installation of the replacement cardiac catheterization equipment is \$1,706,000.

Based upon the project as described above, pursuant to N. C. G. S.§ 131 E-184 (a)(7), this letter serves as notification of our intent to proceed with this project. We would appreciate your written concurrence that this project is exempt from CON review. If you have any questions or require further information regarding this project, please contact me at 704-355-0314.

Sincerely,

Greg S. Bass, Director

**CHS Management Company** 

Attachments

Attachment F

# Basic Technology/Functions of Existing and New Equipment

Existing Equipment	Replacement Equipment
Biplane Cath Lab System	Biplane Cath Lab/EP System
Basic Angiography	3D Angiography

# TOSHIBA

Leading Innovation >>>

Product Data
No. MPDXR0299EAB

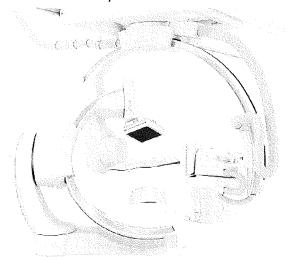
INTERVENTIONAL ANGIOGRAPHY SYSTEM

\* Infinix CF-i/BP Infinix VF-i/BP

# INFX-8000V-

- Type S -

Multi-axis biplane for cardiovascular -



### SYSTEM OUTLINE

Cardio and Vascular intervention demands speed, precision, and optimum performance. The INFX-8000V is designed to take advantage of the latest technological innovations to reduce dose and to save time. A revolutionary graphic user interface and a multi-tasking computer enable the system to fully meet the requirement for optimum image quality, safety, ease of use, advanced efficiency and improved workflow. The unique multi-axis floormounted system enables unprecedented patient access and is supplied with the latest generation Flat Panel Detector to present high quality fluoroscopic and fluorographic images.

\* For the USA and Canada the system is registered as Infinix<sup>™</sup> CF-i or Infinix VF-i, for national regulations. INFX-8000V series includes a floor mounted multi-axis positioner.

# **FEATURES**

#### • Flat Panel Detector

- Wide range of detector sizes to meet your clinical needs
- · 20 cm × 20 cm (8" × 8")
- $\cdot$  30 cm  $\times$  30 cm (12"  $\times$  12")
- $\cdot$  30 cm  $\times$  40 cm (12"  $\times$  16")
- High contrast
- No distortion
- High-resolution dynamic image
- Compact housing

#### Prevision

Previously acquired INFX-8000 images can be retrieved and displayed using only the patient ID reference for use as reference images for follow-up procedures.

#### Sequential Navigation Comprises

- Synchro Position

Position according to examination flow can be set by "one touch".

- Synchro Map

"One touch" positioning of the C-arm can be obtained by using a reference image.

"One touch" reference image selection according to the C-arm position is available.

- Synchro Program

Programming of each exam can be established according to the needs of each user and automated advance from one step in a program to the next is triggered using "one touch".

#### Simultaneity Full

The digital system is multi-tasking permitting a wide range of tasks to be managed simultaneously without interference of one with another.

#### Dose Management Program

A comprehensive set of dose management tools including grid controlled pulsed fluoroscopy, variable dose level selection, Optibeam with virtual collimation control using LIH, electronic zoom, retrospective fluoro-store and the possibility to record and display image dose parameters.

#### Graphic User Interface

Revolutionary graphic user interface using the most advanced intuitive and interactive software capabilities.

#### Multi-Tasking Capability

Simultaneous functionality for image retrieval, image acquisition, post processing, archiving and printing of images.

#### DICOM Performance

DICOM PRINT, STORAGE, STORAGE COMMITMENT, Q&R, MWM, MPPS, and RDSR are standard.

#### High Fluoroscopic Image Quality

SNRF (Super Noise Reduction Filter) and ADCF (Advanced Digital Compensation Filter) provide real time enhancement of fluoroscopic images to obtain optimum image quality under the most difficult circumstances.

#### Guaranteed System Reliability

Fail-safe operation using RAID technology to safeguard acquired data and to maintain ongoing operation.

#### Wide Range of Applications

- -3D acquisition
- CT-like imaging
- Rotational DA/DSA
- Stepping DSA
- 2D/3D roadmap



# INFX-8000V -Type S- Multi-Axis Biplane System

				For	USA			
		Infinix C	F-i/BP		Infinix \	/F-i/BP		]
		INFX-	INFX-	INFX-	INFX-	INFX-	INFX-	1
Unit	Model Name	8000V/A7	8000V/A8	8000V/A9	8000V/AA	8000V/AB	8000V/AC	Note
		FPD8/FPD8	FPD8/FPD8	FPD12/FPD12	FPD12/	FPD1216/	FPD1216/	
			Tilting Table	Standard Table	FPD12	FPD12	FPD12	
		1			Tilling lable	Standard Table	Tilting Table	
Standard Configuration								
<core system=""></core>								
C-arm Support	CAS-880A/A1	9			9	9	•	
Omega-arm Support	CAS-820B/A1	•		•	0	•	•	
Tableside Console	XGCP-882BA		9	•	•	•	•	
X-ray Generator	XTP-8100XG	● × 2	●× 2	●× 2	●× 2	●x 2	●x 2	
	CAT-850B	•		•	_	•	_	
Catheterization Table	CAT-880B				•	<del>-</del>	•	
Tilting Table I/F Kit	XGTT-880A		•	_	•		•	
Footswitch	XBFS-880B		•	•	•	•	•	
FOOUSWILCTI	XBHG-001A		_	•		-	•	
Handgrip	<b>)</b>	1	_	_	_	_		
	XBHG-002A		•			<u> </u>	_	
Free Slide Grip	XBFG-001A	•	•	•	•	•	•	
System Manual	XAAM-8KV02E/W6		•	•	•	•	•	
System Service Kit	XAAS-005B/U1	•		•	•	_ ; ●	•	
Duct Hose Position Option	XGCO-820A			•			•	Factory option
for CAS-820B	1.0.00					<u> </u>		Table y spins.
<x-ray &="" detector="" image="" tube=""></x-ray>	T						T	I
:	DSRX-T7444GDS	● × 2	• x 2				<i>a</i> =	Focal spot 0.5/0.5/0.8
LM Bearing X-ray Tube Assembly	DSRX-T7445GFS	_	_	• x 2	● × 2			Focal spot 0.4/0.6/0.9
	DSRX-T7345GFS			. –	_	● × 2	● x 2	Focal spot 0.3/0.6/1.0
Starter	ST-7008	● x 2	● x 2	● × 2	● × 2	● × 2	● x 2	
LBT Cable Kit	TLA-7008	● × 2	● × 2	● × 2	● × 2	● × 2	● x 2	
High-Voltage Cable for CAS-880A	HCM-150LCS/8V	•	•	•	•	•	•	
High-Voltage Cable for CAS-820B	HCM-150LCS/30	•	•	•	•	•	. •	
Heat Exchanger	HEX-125	● × 2	• × 2	● × 2	• × 2	• × 2	●×2	
Heat Exchanger Hose	HEH-10040	• × 2	• × 2	● × 2	● × 2	• × 2	• × 2	
Trock and the agent those	XGTM-048C	0	•	- ~ _				
X-ray Tube Assembly Mount Kit	XGTM-028N		_	•	•	<u> </u>	_	
for CAS-880A	XGTM-028A					•	•	
V T) 4 11 14 118	XGTM-042C	•	•	_		-	-	
X-ray Tube Assembly Mount Kit for CAS-820B								
	XGTM-032N	_		•	•	•	•	
System Parts	XAAP-8KV06C	•	•	. •	•	•	•	
	TFP-800A/A1	• x 2	● × 2	_		<u> </u>		20 cm × 20 cm (8" × 8")
Flat Panel Detector	TFP-1200A/C1	_		● x 2	● x 2		_	30 cm × 30 cm (12" × 12")
	TFP-1200A		_	_	_	•	•	, , , ,
	TFP-1216A/A1	_		_		•	•	30 cm × 40 cm (12" × 16")
Flat Bould Ball and Addition	XGFM-088B/E1	•	•				_	
Flat Panel Detector Mount Kit for CAS-880A/A1	XGFM-128B/E1	-	_	•	•	_	_	Removable grid.
10, 0, 10 000, 7/11	XGFM-168A/E1	_	I –	_		•	•	1
Flat Panel Detector Mount Kit	XGFM-082B/E1	•	•	_	_	-	_	December 211
for CAS-820B/A1	XGFM-122B/E1	_	_	•	•	•	•	Removable grid.
	BLA-900C	• × 2	● × 2	_	_	<del>  -</del>	_	
X-ray Beam Limiting Device	BLA-900A	-		• x 2	• x 2	• x 2	• × 2	
<digital system=""></digital>		1		1 - "-	,			
Digital Radiography	DFP-8000B/B2		•		•		•	SNRF kit is included.
Biplane System Kit	XIDF-BPS801/DV	•		•	•		•	For DVI connection
Main Console C	XIDF-MCC80B							LOU DALCOURCHOLL
		•	•	•	•	•	•	
Power ON Switch Box	XIDF-PON801	•	9	8	•	•	•	
Footswitch for Fluoroscopy	XIDF-FS801B	0	•	•	•	0	•	
Microphone Kit	XIDF-MIC802		•	•	•		•	
<signal output=""></signal>			T			т	·	
DVI Unit	XIDF-DVI801		•	0	0	•		For DVI connection
<dosimeter></dosimeter>								
	XJDC-009A	• x 2	• × 2				_	
Hon Chambar for Docimeter								
Ion Chamber for Dosimeter	XJDC-016A	_		● x 2	● × 2	● x 2	● × 2	

Mortitor Integration System   XMEZ-LMMCR1   0   0   0   0   0   0   0   0   0						For				
Unit Model Name  BOOWNAD SOURCES 9000WAD 9000WAD 9000WAD PROPERTY										
FPOSPTOS PROSPTOS PROSPTOS PROSPTOS PROSPTOS PROTECTIVE PROTEST PROTES		Unit	Model Name							Note
PPUBPP-ND   PPUBPP-ND   PUBPP-ND   PPUBPP-ND   PPUBPP-ND   Stream to the control facility   Strea		Unit	Wodel Name	8000V/A7	8000V/A8	8000V/A9				Note
Selectable Units				FPD8/FPD8	FPD8/FPD8	FPD12/FPD12				
Selectable Units Selectable Units Selectable Units are not included in the shortest configuration. These heres must be ordered financially. Selectable Months: Selectable Of B. Elbor of them must be ordered with the system. Copreter Months: Selectable Units Months: Place Selectable Months: Supervision for 4 LCD MSF-0AA  Months: Place Selectable Months: Supervision for 5 LCD MSF-0AA  Months: Supervision for 5 LCD MSF-0AAA  Months: Supervision for 5 LCD MSF-0AAA  Months: Supervision for				Standard Table	Tilting Table	Standard Table				
Salectable units are not included in the abundant configuration. These Rems must be ordered if inquired. Colystem Monitors Coloration Monitors Coloration Monitors Coloration Monitors The Monitor integration System integrates the Angle Workstation, 3D workstation, Henro monitors, etc. (up to 5 channots) into a single 27" monitor and miskes it possible from operations in all vinctows using one keyboard and crite mouse.  Monitor integration System  XMEZ-LMMCRI  Monitor integration System  XMEZ-LMMCRI	L		l	<u></u>	I	l	Titting lable	Otalidaid Iabic	Tilding lable	L
System Munitors - States A Definer of them must be ordered with the system.  Color LOS Monitor   C.DL2013A-1A   0   0   0   0   0   0   0   0   0										
According Monitors   CDL20184-1A						it required.				**************************************
Country   Coun	<8	<del></del>	ther of them must be	ordered with t	he system.					
Monitor Invagration Systems	A				· · · · · · · · · · · · · · · · · · ·					
* The Markital' Integration System integrates the Anglo Morrisation, 2D workstation, Herno moritors, etc. (up to 8 channels) into a single 27* morotor and makes it possible from preparations in all windows using one keyboard and one mouse.    Markital' Integration System   XMEZ-LMMCR1   0	Ľ	Color LCD Monitor	CDL2013A-1A	0	0	0	0	0	0	
Monitor Integration System		* The Monitor Integration System in	tegrates the Angio W	orkstation, 3D	workstation,	Hemo monitor	s, etc. (up to 8	channels) into	a single 27" ı	monitor and makes it possible to per-
Monitor inlegration System  Monitor inlegration System  Monitor inlegration System  Monitor inlegration System  Monitor inlegrated Monitor Accessory Kit  Integrated Monitor  Control Room Monitor  Integrated Monitor Accessory Kit  Integrated Monitor Accessory Kit  Integrated Monitor  In	Ì	-,-			T					This kit, XIDF-INA801, and XIDF-
Integrated Monitor Accessory Rix   XIDF-INABD1   0   0   0   0   0   0   0   0   0	В	Monitor Integration System	XMEZ-LMMCR1	0	•	•	0	0	0	DVI801 are required when video inputs are wanted to integrate. For the USA, this kit is procured local
Integrated Monitor Accessory Kit   XIDF-INABO1   Ø Ø Ø Ø Ø Ø Ø Ø Ø are variand to integrate. For the USA, this kit is proc.										This kit, XMEZ-LMMCR1, and XIDF-
Monochrome LCD Monitor   SMD-19102-TD   ox 4   ox						0	0	0	•	are wanted to integrate. For the USA, this kit is procured local-
### Comparison of the EUD Monitor of A or D must be ordered with the system.  ### Comparison of A or D must be ordered with the system.  ### Comparison of A or D must be ordered with the system.  ### Comparison of A Compar	<0	Control Room Monitor> *Choose or		dered with the	system.		·			
For 4 LCD Monitors   Monochrome LCD Monitor   SMD-19102-TC   or equivalent   Ox 4	М	onochrome LCD Monitor		<b>⊙</b> × 4	<b>⊙</b> × 4	<b>⊙</b> × 4	<b>0</b> × 4	<b>0</b> × 4	<b>0</b> × 4	SMD-19102-TD is a locally procured unit.
Monochrome LCD Monitor  SMD-19102-TC or equivalent  Moritor Suspension for 4 LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitors  SMD-19102-TC or equivalent  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  SMD-19102-TC or equivalent  MSF-06A  MSF-06A  MSF-06A  MONOCHROME MSF-06A  MS	< r	n-Room Monitor> *One of A or D m	nust be ordered with	the system.						
A Monitor Suspension for 4 LCD Monitor Suspension for 4 LCD Monitor Suspension for 5 LCD Monitor Suspension for 6 LCD Monitor Suspension Service Monochrome LCD Monitor Suspension for 6 LCD Monitor Suspension for 6 LCD Monitor Suspension for 6 LCD Monitor Suspension Service Monochrome LCD Monitor Service Monochrome LC		For 4 LCD Monitors								
A Monitor Suspension for 4 LCD MSF-04A		Monochrome LCD Monitor		⊙ × 4	<b>⊙</b> × 4	<b>⊙</b> × 4	⊙ × 4	⊙ × 4	⊙ × 4	SMD-19102-TC is a locally procured unit.
Extended Lateral Rails for Monitor Suspension  -For 6 LCD Monitors  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monitor Suspension for 6 LCD Monitors  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent  SMD-19102-TC or equivalent  SMD-19102-TC or equivalent  SMD-19102-TC or equivalent  SMD-19102-TC is local put  Monitor Suspension for 6 LCD Monitors  Extended Lateral Rails for Monitor  Suspension  Extended Lateral Rails for Monitor  Suspension  SMD-19102-TC or equivalent  SMD-19102-TC is local put  Monitor Suspension for 8 LCD  Monitors  Suspension  MSF-08A  O O O O O Factory option.  Factory option.  For S8' LCD Monitor-  Large-Screen Monitor  Monochrome LCD Monitor  Suspension for 58' LCD  Monitor	A		,	0	0	0	<b>o</b> `	0	0	Select one monitor suspension from IDI1000F series and MSF series. For USA, IDI1000F series monitor
Four additional monitors can counted   Four additional			XGMR-MSF021	0	•	0	0 1	0	0	, ,
Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monitor Suspension for 6 LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent  Monitor Suspension for 8 LCD Monitor-  C Monitor Suspension for 8 LCD Monitor-  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  Extended Lateral Rails for Monitor  Suspension For SB* LCD Monitor-  Large-Screen Monitor  Monochrome LCD Monitor  SMD-19102-TC, or SD-10-10-10-10-10-10-10-10-10-10-10-10-10-	$\vdash$									
Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monitor Suspension for 6 LCD Monitor  Monitor Suspension for 6 LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor-  Large-Screen Monitor  Monochrome LCD Monitor  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor-  Large-Screen Monitor  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monochrome LCD Monitor  Monochrome LCD Monitor  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monitor Suspension for 58" LCD  Monitor  Monitor Suspension for 58" LCD		For 6 LCD Monitors	ı	ı				ı	1	I=
Monitor Suspension for 6 LCD MSF-06A		Monochrome LCD Monitor		<b>⊙</b> × 4	⊙ × 4	<b>⊙</b> × 4	<b>⊙</b> × 4	<b>⊙</b> × 4	<b>⊙</b> × 4	mounted. SMD-19102-TC, CDL2013A-1A or equivalent
Extended Lateral Rails for Monitor Suspension  -For 8 LCD Monitor-  Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monitor Suspension for 8 LCD Monitor  Extended Lateral Rails for Monitor  Monitor Suspension for 8 LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC or equivalent (SMD-19102-TC is local pu  Monitor Suspension for 8 LCD Monitor  Extended Lateral Rails for Monitor Suspension  -For 58* LCD Monitor-  Large-Screen Monitor  Monitor Suspension for 58* LCD Monitor-  Monitor Suspension  MEZ-LMM021/A1	В		MSF-06A	0	•	0	0	0	. •	Select one monitor suspension from IDI1000F series and MSF series. For USA, IDI1000F series monitor suspensions are procured locally.
For 8 LCD Monitor-  Monochrome LCD Monitor  SMD-19102-TC or equivalent  O × 4			XGMR-MSF021	0	0	0	0	0	0	outportois to are produced to out y
Monochrome LCD Monitor  SMD-19102-TC or equivalent  Monitor Suspension for 8 LCD Monitor  Extended Lateral Rails for Monitor  SMD-19102-TC, or equivalent  MSF-08A  M	1		L	L	L	J	İ	l .	<u> </u>	
Monitor Suspension for 8 LCD Monitors  Extended Lateral Rails for Monitor Suspension For 58" LCD Monitor  Large-Screen Monitor Monochrome LCD Monitor (Backup)  MSF-56A	С			<b>⊙</b> × 4	⊙ × 4	<b>⊙</b> × 4	<b>⊙</b> × 4	<b>⊙</b> × 4	<b>⊙</b> × 4	SMD-19102-TC, CDL2013A-1A or
Extended Lateral Rails for Monitor Suspension For 58" LCD Monitor Large-Screen Monitor Monochrome LCD Monitor (Backup)  MSF-56A  MSF-			MSF-08A	•	0	0	0	0	0	(Sins 10102 10 io local parchase.)
-For 58" LCD Monitor Large-Screen Monitor  Monochrome LCD Monitor  (Backup)  Monitor Suspension for 58" LCD Monitor  Monitor Suspension for 58" LCD Monitor  Extended Lateral Ralls for Monitor Suspension  Extended Lateral Ralls for Monitor Large Monitor Accessory Kit 2  XIDF-LMA802/BS  O  O  O  O  O  O  O  O  O  O  O  O  For DVI Connection This kit is required to convesional to digital signal of His kit is required to		Extended Lateral Rails for Monitor	XGMR-MSF021	•	0	0	0	0	0	Factory option.
Large-Screen Monitor XMEZ-LMM021/A1	$\vdash$		1	l	1				1	
Monochrome LCD Monitor SMD-19102-TC, or equivalent			VMEZ LAMMOOTZAT					6		Locally propured 1:="
Monitor Suspension for 58" LCD Monitor  MosF-56A  MosF-5		Monochrome LCD Monitor	SMD-19102-TC,						<del></del>	SMD-19102-TC is a locally procured
Monitor  Description:  Monitor									This kit includes connecting cables	
Suspension Large Monitor Accessory Kit 2 XIDF-LMA802/BS		Monitor	MSF-56A	0	0	0	0	0	0	between DFP-8000B/B2 and XMEZ- LMM021/A1.
This kit is required to conve signal to digital signal of HE	D	Suspension	XGMR-MSF021		1					
signal to gigital signal of HE		Large Monitor Accessory Kit 2	XIDF-LMA802/BS	0	0	0	0	0	0	-
AD Converter Kit  XMEZ-PDC001  O  O  O  peripheral equipments have analog outputs and all DVI-the video composer include		AD Converter Kit	XMEZ-PDC001	•	•	•	•	0	•	This kit is required to convert analog signal to digital signal of HDMI only if peripheral equipments have only analog outputs and all DVI-I inputs of the video composer included in XMEZ-LMM021/A1 are occupied.

For USA



				For	USA			
		Infinix C	F-i/BP		Infinix V	/F-i/BP		
Unit	Model Name	INFX- 8000V/A7	INFX- 8000V/A8	INFX- 8000V/A9	INFX- 8000V/AA	INFX- 8000V/AB	INFX- 8000V/AC	Note
		FPD8/FPD8 Standard Table		FPD12/FPD12 Standard Table	FPD12/ FPD12 Tilting Table	FPD1216/ FPD12 Standard Table	FPD1216/ FPD12 Tilting Table	
Options								
<for c-arm="" support=""></for>								
Satellite Console	XGCP-882AA	0	0	0	0	0	0	
Base Plate (1400 mm)	XGBP-880A	0	0	0	0	0	0	
Base Plate (750 mm)	XGBP-880B	0	0	0	0	0	0	
<u> </u>	XGPA-800A	O × 2	0 × 2	_	_	_	_	For 20 cm × 20 cm FPD
Magnetic Shielding Kit	XGPA-1200A			O × 2	0 × 2	0	0	For 30 cm × 30 cm FPD
	XGPA-1216A	_	_	_		0	0	For 30 cm x 40 cm FPD
<pre><for catheterization="" table=""> *1 : For CAT-850B *2 : For CAT-880B</for></pre>	•	*1	*2	*1	*2	*1	*2	
Base Plate	XBBP250B	0	0	0	0	0	0	
Additional Footswitch	XBFS-880B	0	0	0	0	0	0	Preferred option. Same functionality as the standard footswitch.
Wireless Footswitch	XBFS-880WB	0	0	0	0	0	0	Only for USA. This kit requires a table modification kit (XBFM-850A or XBFM-880A) in accordance with the combined table.
	XBFM-850A	0		0	_	0	<u> </u>	accordance with the combined table.
Table Modification Kit	XBFM-880A	0	0	_	0		0	
Arm Cover	XBAC-001A	0	0	0	0	0	0	
Alli Cover	XBAR-001A		0	_ ·	0	_	0	One is included in CAT-850B.
Armrest	XBAR110A	0	0	0	0	0	0	One is included in CAT-650B.
Arm Support	XBAS-001A		0	_	0	_	0	For system with CAT-850B, this kit is
				_				already in the standard configuration.
Handgrip	XBHG-001A XBHG-002A	0 -	0	.0	_ O	O   -	0	Above-Head Armrest
Free Slide Grip for CAT (Mushroom SW)	XBFG-001A	0	0	0	0	0	0	
Tabletop Control Console	XBFG-850B	0	_	0	_	0	_	
Extension Ralls	XBER-001A	0	0	0	0	0	0	
Extension Tabletop	XBET-001A	0	0	0	0	0	0	When this option is used, XBER-001A is also required.
Head-End Table Control Switch Kit	XBHR-001A	0	_	0	-	0		This option includes XBFG-001A.
Tabletop Rotation Lock Kit for CAT- 850B	XBRL-001A	0	_	0	-	0	_	
Tabletop Mat	XBTM-001A	0	_	0	_	0	_	Tempur mat. For system with CAT- 880B, a tempur mat is already in the standard configuration.
Accessories Table Rail	XBAM-001A	_	0	_	0	_	0	
Drape Holder	XBDB-001A	_	0	_	0		0	
<for system="" video=""></for>								-
Additional LCD Monitor	SMD-19102-TC	0	0	0	0	0	0	Locally procured unit.
	SMD-19102-TD	0	0	0	0	0	0	
Color LCD Monitor	CDL2013A-1A	0		0	0	0	0	For XIDF-ESD801
<for cabinet=""></for>	CAR 100D					T ~		T
System Cabinet Cabinet Side Cover	CAB-100B CABS-100B	0	0	0	0	0	0	
Cabinet Side Cover  Cabinet Corner Cover	CABC-100B		0	<b>-</b>	0			
<pre><for digital="" system=""></for></pre>	JUABU-100B	0	0	0		0	0	
Additional Reference Monitor Kit	XIDF-REF802/DV	0	0	0	0	0	0	This kit is required when DVI is used for the signal output. Additional monitor SMD-19102 $\times$ 2 is required.
Biplane System Kit 3 (High Speed Fluoroscopy Kit)	XIDF-BPS803/B1	0	0	_	_	_	_	
Review Console	XIDF-RVC801	0	0	0	0	0	0	
Rotational DSA	1	1	·					
Rotational DSA Kit	XIDF-ROT801	0	0	0	0	0	0	XIDF-AWS801/B1 and XIDF-3DI801 are required.
Stepping DSA								
Stepping DSA Kit	XIDF-STP801	0	0	0	0	0	0	XBSD-850B is also required for the system with CAT-850B.
Stepping Unit for Catheterization Table (Factory Option)	XBSD-850B	0	-	0		0		This unit must be ordered to perform Stepping DSA with CAT-850B.
3D-Angio 3D-Angio Application Software	XIDF-3DI801	0	0	0	0	0	0	XIDF-AWS801/B1 and XIDF-ROT801
		.1		1	L		L	are also required.

				For	USA			
		Infinix C			Infinix V			
Unit	Model Name	INFX- 8000V/A7	INFX- 8000V/A8	INFX- 8000V/A9	INFX- 8000V/AA	INFX- 8000V/AB	INFX- 8000V/AC	Note
		FPD8/FPD8 Standard Table		FPD12/FPD12 Standard Table	FPD12/ FPD12 Tilting Table	FPD1216/ FPD12 Standard Table	FPD1216/ FPD12 Tilting Table	
LCI	,	-		γ				
Low Contrast Imaging Kit	XIDF-LCI801	o	0	0	0	0	0	XIDF-3DI801, XIDF-AWS801/B1 and XIDF-ROT801 are required to operate LCI.
Spot Fluoroscopy								
Spot Fluoroscopy Kit	XIDF-SFL801	0	0	0	0	0	0	
UPS		1						
UPS Connection Kit	XIDF-UPS801	0	0	0	0	o	0	The compatible UPS is Pulsar MX4000RT.
Combinable Unit								
<3D-Recon PC>			,	,				
Angio Workstation (3D-Recon PC)	XIDF-AWS801/B1	0	0	0	0	0	0	This kit does not include the monitors for the Angio Workstation. Please order one or two Angio Workstation Monitor Kits (XIDF-AMK801).
Option for Angio workstation (X  * All following options require XIDF-AW  Output>		)						
Angio Workstation Monitor Kit	XIDF-AMK801	0	0	0	0	0	0	Monitor for Angio Workstation
Angio Workstation Additional Monitor Kit	XIDF-AMK802	0	0	0	0	0	0	Signal distributor
Cose Tracking System>								
Dose Tracking System Kit	XIDF-DTS802	0	0	0	0	0	0	
<analysis software=""></analysis>	MBI B10002		-					
Basic Kit for Clinical Analysis Application	XIDF-QCA700	0	0	0	0	0	0	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
QCA Kit	XIDF-QCA701	0	- 0	0	0	0	0	XIDF-QCA700 is required.
QVA Kit	XIDF-QCA702	0	0	0	0	0	0	XIDF-QCA700 is required.
LVA Kit	XIDF-QCA703	0	0	0	0	0	0	XIDF-QCA700 is required.
LVA-BP Kit	XIDF-QCA704	0	0	0	0	0	0	XIDF-QCA700 and XIDF-QCA703 are required.
RVA Kit	XIDF-QCA705	0	0	0	0	0	0	XIDF-QCA700 is required.
3DQCA Kit	XIDF-QCA706	0	0	0	0	0	0	XIDF-QCA700 and XIDF-QCA701 are required.
Stent Enhancer Kit	XIDF-QCA707	0	0	0	0	0	0	XIDF-QCA700 is required.
<roadmap></roadmap>				٧				
3D Roadmap		Ţ						
3D Roadmap Kit	XIDF-3DP802/A1	0	0	0	0	0	0	XIDF-3DI801 and XIDF-ROT801 are required.
Multi-Modality Roadmap								
Multi-Modality Roadmap Kit (CT, MR)	XIDF-3DP804	0	0	0	0	0	0	This kit requires XIDF-3DI801, XIDF-ROT801, and XIDF-3DP802/A1.
<tavr support=""></tavr>								
TAVR Support Kit	XIDF-TAV801/A1 XIDF-TAV803/A1	0	0	0	0	0	0	For XIDF-TAV801/A1, it includes 3mensic by PMI. For XIDF-TAV803/A1, A-Valve by PMI is also included with 3mensio by PMI. Please select XIDF-TAV801/A1 or XIDF- TAV803/A1, XIDF-AWS801/B1 must be V6.0 or later.
Mitral Analysis for TAVR Support Kit	XIDF-TAV804/A1	0	0	0	0	0	0	XIDF-TAV801/A1 or XIDF-TAV803/A1 is required.
Left Atrium Appendage Analysis for TAVR Support Kit	XIDF-TAV805/A1	0	0	0	0	0	0	XIDF-TAV801/A1 or XIDF-TAV803/A1 is required.
Regurgitation Analysis for TAVR Support Kit	XIDF-TAV806/A1	0	0	0	0	0	0	XIDF-TAV803/A1 is required.



# INFX-8000V -Type S- Multi-Axis Biplane System

Standard Configuration <core system=""> C-arm Support Omega-arm Support CAS- Tableside Console XGCI X-ray Generator Catheterization Table CAT- Tilting Table I/F Kit Footswitch System Manual System Service Kit  <abc &="" <x-ray="" detector="" image="" kit="" service="" system="" tube="" w6="" xaan="" xaas="">  STASS  CAS-  CAS-  CAT-  CA</abc></core>	5-880A/A1 5-820B/A1 5-882BA -8100XG -850B -880B T-880A S-880B M-8KV02E/ S-005B IX-T7444GDS IX-T7445GFS	• • • • • • • • • • • • • • • • • • •	INFX-8000V/G8 FPD8/FPD8 Tilting Table	INFX-8000V/G9 FPD12/FPD12 Standard Table		INFX-8000V/GB FPD1216/ FPD12 Standard Table	INFX-8000V/GC FPD1216/FPD12 Tilting Table	Note
Standard Configuration  Core System> C-arm Support CAS- Tableside Console X-ray Generator CAT- Tilting Table VF Kit Footswitch System Manual System Service Kit XAAS XAAS XAAS XAAS XAAS XAAS XAAS XAA	5-880A/A1 5-820B/A1 5-820B/A1 5-882BA 8-8100XG -850B -880B T-880A S-880B M-8KV02E/ S-005B XX-T7444GDS XX-T7445GFS	Standard Table	Tilting Table	Standard Table	Tilting Table	FPD12 Standard Table	FPD12 Tilting Table	
<core system="">           C-arm Support         CAS-           Omega-arm Support         CAS-           Tableside Console         XGCf           X-ray Generator         XTP-           Catheterization Table         CAT-           Tilting Table I/F Kit         XGTI           Footswitch         XBFS           System Manual         XAAN           W6         System Service Kit         XAAS           <x-ray &="" detector="" image="" tube="">         DSRX</x-ray></core>	8-820B/A1 5P-882BA 8-8100XG 8-850B 8-880B T-880A S-880B M-8KV02E/ S-005B XX-T7444GDS XX-T7444GFS	• • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • •	• × 2	• • • • • • • • • • • • • • • • • • •	
<core system="">           C-arm Support         CAS-           Omega-arm Support         CAS-           Tableside Console         XGCf           X-ray Generator         XTP-           Catheterization Table         CAT-           Tilting Table I/F Kit         XGTI           Footswitch         XBFS           System Manual         XAAN           W6         System Service Kit         XAAS           <x-ray &="" detector="" image="" tube="">         DSRX</x-ray></core>	8-820B/A1 5P-882BA 8-8100XG 8-850B 8-880B T-880A S-880B M-8KV02E/ S-005B XX-T7444GDS XX-T7444GFS	• • • • • • • • • • • • • • • • • • •	• × 2 — • • • • • • • • • • • • • • • • • •	• × 2 • •	• × 2 — • • • • • • • • • • • • • • • • • •	• × 2 •	• × 2 —	
C-arm Support         CAS-           Omega-arm Support         CAS-           Tableside Console         XGCI           X-ray Generator         XTP-           Catheterization Table         CAT-           Tilting Table I/F Kit         XGTI           Footswitch         XBFS           System Manual         XAAN           W6         System Service Kit         XAAS <x-ray &="" detector="" image="" tube="">         DSR2</x-ray>	8-820B/A1 5P-882BA 8-8100XG 8-850B 8-880B T-880A S-880B M-8KV02E/ S-005B XX-T7444GDS XX-T7444GFS	• • • • • • • • • • • • • • • • • • •	• × 2 — • • • • • • • • • • • • • • • • • •	• × 2 • •	• × 2 — • • • • • • • • • • • • • • • • • •	• × 2 •	• × 2 —	
Omega-arm Support CAS- Tableside Console XGCf X-ray Generator XTP- Catheterization Table CAT- Tilting Table I/F Kit XGTI Footswitch XBFS System Manual XAAN W6 System Service Kit XAAS <x-ray &="" detector="" image="" tube=""> DSRX</x-ray>	8-820B/A1 5P-882BA 8-8100XG 8-850B 8-880B T-880A S-880B M-8KV02E/ S-005B XX-T7444GDS XX-T7444GFS	• • • • • • • • • • • • • • • • • • •	• × 2 — • • • • • • • • • • • • • • • • • •	• × 2 • •	• × 2 — • • • • • • • • • • • • • • • • • •	• × 2 •	• × 2 —	
Tableside Console         XGCf           X-ray Generator         XTP-           Catheterization Table         CAT-           Tilting Table I/F Kit         XGTI           Footswitch         XBFS           System Manual         XAAN W6           System Service Kit         XAAS <x-ray &="" detector="" image="" tube="">         DSR3</x-ray>	2P-882BA -8100XG -850B -880B T-880A S-880B M-8KV02E/ S-005B	• × 2 • • • • • • • • • • • • • • • •	• × 2 — • • • • • • • • • • • • • • • • • •	• × 2 • •	• × 2 — • • •	• × 2 • — —	• × 2 —	
X-ray Generator XTP- Catheterization Table CAT- CAT- Tilting Table I/F Kit XGTI Footswitch XBFS System Manual XAAN W6 System Service Kit XAAS    System Service Kit IMAGE   XAAN W6   System Service Kit IMAGE  System Service Kit IMAGE  System Service IMAGE	-8100XG -850B -880B T-880A S-880B M-8kV02E/ S-005B XX-T7444GDS XX-T7445GFS	• x 2 • • • • • • • • • • • • • • • • •	• × 2 - • • •	• × 2 • — — — •	- •	• × 2 • — —	• x 2	
Catheterization Table  CAT- CAT- CAT- Titting Table I/F Kit Footswitch  System Manual  System Manual  System Service Kit  XAAS	-850B -880B T-880A S-880B M-8KV02E/ S-005B XX-T7444GDS XX-T7445GFS	•	-	- -	- •	<u> </u>	•	
Catheterization Table  CAT- Tilting Table I/F Kit  Footswitch  System Manual  System Manual  System Service Kit  XAAS  X	-880B T-880A S-880B M-8KV02E/ S-005B XX-T7444GDS XX-T74445GFS	•	•	-	•	_	•	
Tilting Table I/F Kit XGTT Footswitch XBFS System Manual XAAN W6 System Service Kit XAAS <a href="X-ray Tube &amp; Image Detector">XAAN</a> DSRX	T-880A S-880B M-8KV02E/ S-005B X-T7444GDS X-T7445GFS	•	•			_	•	
Footswitch XBFS System Manual XAAN W6 System Service Kit XAAS <x-ray &="" detector="" image="" tube=""> DSR3</x-ray>	S-880B M-8KV02E/ S-005B X-T7444GDS X-T7445GFS	•	•		•	•	<del> </del>	
System Manual XAAN W6 System Service Kit XAAS <a href="X-ray Tube &amp; Image Detector">XAAS</a> DSR3	M-8KV02E/ S-005B 8X-T7444GDS 8X-T7445GFS	•	•	•				
System Service Kit XAAS <x-ray &="" detector="" image="" tube="">  DSR3</x-ray>	X-T7444GDS X-T7445GFS				•	•	•	
<x-ray &="" detector="" image="" tube=""></x-ray>	X-T7444GDS X-T7445GFS				•	•	•	
DSR	X-T7445GFS		· · · · · ·			-		1
1	X-T7445GFS	• × 2	• × 2	_	_	_	T -	Focal spot: 0.5/0.5/0.8
			-	• x 2	• × 2		_	Focal spot: 0.4/0.6/0.9
DSR)	X-T7345GFS				-	• × 2		Focal spot: 0.3/0.6/1.0
Starter ST-7		• × 2	● × 2	• × 2	• × 2	• × 2	• × 2	1 000 000 0.0 0.0 1.0
	-7008	• × 2	• x 2	• × 2	• × 2	• x 2	• × 2	
	И-150LCS/8V	0	9	9	9	•	•	
	M-150LCS/30	•		•	•	•	•	
Heat Exchanger HEX-		• × 2	• × 2	• × 2	• × 2	• x 2	• × 2	
	H-10040	• x 2	• x 2	• x 2	• x 2	• x 2	• x 2	
<u> </u>	M-048C	9	9			_		
X-ray Tube Assembly Mount Kit	M-028N	_		•	•			
HOL CAS-SUDAVA I	M-028A		_	_	_	•		
	M-042C	9			_			
read resolved resolved read read read read read read read re	M-032N	_	_	•			•	
7.011	P-8KV06C		•	•	•	•	•	
	-800A/A1	• x 2	• × 2	_	_	_	_	20 cm × 20 cm (8" × 8")
TEP-	-1200A/C1	_		● × 2	• × 2		_	,
THat Panel Detector ——	-1200/VOT	_			-		•	30 cm × 30 cm (12" × 12")
	-1216A/A1	_	_		_	•	•	30 cm × 40 cm (12" × 16")
	M-088B/E1	•	•	<b>-</b>		_	_	SO SITE A TO SITE (12 A TO )
Flat Panel Detector Mount Kit	M-128B/B1	_		•		_	_	Removable grid.
HOL CAS-GOUA	M-168A/E1	_	<del></del>			•	•	ji lemovasio gila.
	M-082B/E1	•		_			_	
	M-122B/E1	_	_		•	•	•	Removable grid.
BI A-	-900C	● x 2	● x 2	_	_	_	_	
IX-ray Ream Limiting Device	-900A	_	_	● × 2	● x 2	• x 2	• x 2	
<digital system=""></digital>	····	<u> </u>	L	1				
	2-8000B/B2	•		•	•	•	•	SNRF kit is included.
	-BPS801/DV	•	•	•	•	•	•	For DVI connection
	-MCC80B	•	•	•	•	•	•	
	F-PON801	•	•	•	•	•	•	
	F-FS801B		•	•	•	•		
	F-MIC802	•	•	•	0			
<signal output=""></signal>			***************************************					
	F-DVI801		•		0	•	9	For DVI connection
<dosimeter></dosimeter>								
Ion Chamber for Dosimeter	C-009A	● × 2	• × 2	_	_			
XJD0	C-016A	_		● x 2	• × 2	● x 2	● x 2	
Dose Area Product Meter XJDh	K-002A/V5			•	•	9	•	

Selectable Units
\* Selectable units are not included in the standard configuration. These items must be ordered if required.

<	<system monitor=""> *Select A or B. Either of them must be ordered with the system.</system>										
_	<system monitor=""></system>										
- 1	Color LCD Monitor	CDL2013A-1A	0	0	•	0	0	0			

Г					For regions of	her than USA			
	Unit	Model Name	INFX- 8000V/G7	INFX- 8000V/G8	INFX- 8000V/G9	INFX- 8000V/GA	INFX- 8000V/GB	INFX- 8000V/GC	Note
	Omt	Wodel Name	FPD8/FPD8 Standard Table	FPD8/FPD8 Tilting Table	FPD12/FPD12 Standard Table	FPD12/FPD12 Tilting Table	FPD1216/ FPD12 Standard Table	FPD1216/ FPD12 Tilting Table	
	<monitor integration="" system=""> * The Monitor Integration System form operations in all windows</monitor>	integrates the Angi	o Workstation, and one mouse	3D workstati	ion, Hemo mon	itors, etc. (up t		<u> </u>	27" monitor and makes it possible to per-
В	Monitor Integration System	XMEZ-LMMCR1	•	0	•	0	0	0	This kit, XIDF-INA801, and XIDF-DVI801 are required when video inputs are wanted to integrate.  For Europe, this kit is a locally procured unit.
	Integrated Monitor Accessory Kit		0	0	0	0	0	0	This kit, XMEZ-LMMCR1, and XIDF- DVI801are required when video inputs are wanted to integrate.
<(	Control Room Monitor> *Choose		ordered with the	ne system.			r	·	
М	onochrome LCD Monitor	ML19193, SMD-19102-TD or equivalent	⊙ × 4	⊙ × 4	⊙ × 4	⊙ × 4	⊙ × 4	⊙ × 4	SMD-19102-TD is a locally procured unit for Europe. ML19193 (Except for Europe)
<u>&lt; </u>	n-Room Monitor> *One of A or D	must be ordered w	ith the system.						
	For 4 LCD Monitors	r	<u></u>	T	T-"			1	11-2-24-2-1
	Monochrome LCD Monitor	ML19193, SMD-19102-TC or equivalent	⊙ × 4	⊙ × 4	⊙ × 4	⊙ × 4	⊙ × 4	⊙ × 4	SMD-19102-TC is a locally procured unit for Europe. ML19193 (Except for Europe)
Α	Monitor Suspension for 4 LCD Monitors	MSF-04A	0	0	0	0	0	0	Select one monitor suspension from IDI1000F series and MSF series.
	Extended Lateral Rails for Monitor Suspension	XGMR-MSF021	0	· •	0	•	0	0	Factory option. This kit is required only if the lateral movement of MSF series are expected to be extended by 770 mm to enhance clearance at both sides around the table.
	For 6 LCD Monitors								
	Monochrome LCD Monitor	ML19193, SMD-19102-TC or equivalent	<b>⊙</b> × 4	⊙ × 4	<b>⊙</b> × 4	⊙ × 4	<b>⊙</b> × 4	⊙ × 4	Two additional monitors can be mounted. ML19193, SMD-19102-TC, CDL2013A-1A or equivalent (SMD-19102-TC is local purchase for Europe.) ML19193 (Except for Europe)
В	Monitor Suspension for 6 LCD Monitors	MSF-06A	0	0	0	0	0	0	Select one monitor suspension from IDI1000F series and MSF series.
	Extended Lateral Rails for Monitor Suspension	XGMR-MSF021	0	•	0	0	•	•	Factory option. This kit is required only if the lateral movement of MSF series are expected to be extended by 770 mm to enhance clearance at both sides around the table.
	For 8 LCD Monitor		,		,			•	
3	Monochrome LCD Monitor	ML19193, SMD-19102-TC or equivalent	⊙ × 4	⊙ × 4	• • • • • • • • • • • • • • • • • • •	<b>⊙</b> × 4	<b>⊙</b> × 4	• • × 4	Four additional monitors can be mounted. ML19193, SMD-19102-TC, CDL2013A-1A or equivalent (SMD-19102-TC is local purchase.)
С	Monitor Suspension for 8 LCD Monitors	MSF-08A	0	0	0	0	0	•	
	Extended Lateral Rails for Monitor Suspension	XGMR-MSF021	0	•	•	0	•	•	Factory option. This kit is required only if the lateral movement of MSF series are expected to be extended by 770 mm to enhance clearance at both sides around the table.
	For 58" LCD Monitor				•		'		
	Large-Screen Monitor	XMEZ-LMM021/ A1	0	0	•	0	0	0	For Eurpe, locally procured unit.
	Monochrome LCD Monitor (Backup)	ML19193, SMD-19102-TC, or equivalent	⊙ × 2	⊙ × 2	<b>⊙</b> × 2	<b>⊙</b> x 2	<b>⊙</b> × 2	⊙ × 2	SMD-19102-TC is a locally procured unit.
	Monitor Suspension for 58" LCD Monitor	MSF-56A	•	•	•	0	0	0	This kit includes connecting cables between DFP-8000B/B2 and XMEZ-LMM021/A1.
D	Extended Lateral Rails for Monitor Suspension	XGMR-MSF021	0	0	0	0	0	<b>•</b>	Factory option. This kit is required only if the lateral movement of MSF series are expected to be extended by 770 mm to enhance clearance at both sides around the table.
	Large Monitor Accessory Kit 2	XIDF-LMA802/BS	0	0	0	0	0	0	For DVI Connection
	AD Converter Kit	XMEZ-PDC001	•	0	•	0	•	•	This kit is required to convert analog signal to digital signal of HDMI only if peripheral equipments have only analog outputs and all DVI-I inputs of the video composer included in XMEZ-LMM021/A1 are occupied.  For Europe, this kit is a locally procured unit



		For regions other than USA						
Unit	Model Name	INFX- 8000V/G7	INFX- 8000V/G8	INFX- 8000V/G9	INFX- 8000V/GA	INFX- 8000V/GB	INFX- 8000V/GC	NI-I-
Onit	woder name	FPD8/FPD8		FPD12/FPD12 Standard Table		FPD1216/ FPD12	FPD1216/ FPD12	Note
		Standard Table	Tilling lable	Standard labre	Thung lable	Standard Table	Tilting Table	
Options						-		
<for c-arm="" support=""></for>		,		r	ſ			
Satellite Console	XGCP-882AA	0	0	0	0	0	0	
Base Plate (1400 mm)	XGBP-880A	0	0	0	0	0	0	
Base Plate (750 mm)	XGBP-880B	0	0	0	0	0	0	
Duct Hose Position for CAS-820B	XGCO-820A	0	0	0	0	0	0	Factory option
	XGPA-800A	O × 2	0 × 2		_	_		For 20 cm × 20 cm FPD
Magnetic Shielding Kit	XGPA-1200A	_	-	0 × 2	O × 2	0	0	For 30 cm × 30 cm FPD
	XGPA-1216A		-		_	0	0	For 30 cm × 40 cm FPD
<pre><for catheterization="" table=""> *1 : For CAT-850B *2 : For CAT-880</for></pre>	ND.	**	*0	**	*0	**	+0	
Base Plate		*1	*2	*1	*2	*1	*2	
Base Plate	XBBP250B	0	0	0	0	0	0	
Additional Footswitch	XBFS-880B	0	0	0	0	0	0	Preferred option. Same functionality as the standard footswitch.
Wireless Footswitch	XBFS-880WB	0	0	0	0	0	0	Only for USA, Europe and Turkey. This kit requires a table modification kit (XBFM-850A or XBFM-880A) in accord- ance with the combined table.
Table Modification Kit	XBFM-850A	0	_	0	-	0		
	XBFM-880A	_	0		0	-	0	
Arm Cover	XBAC-001A	0	0	0	0	0	0	
Armrest	XBAR-001A		0	_	0	_	0	One is included in CAT-850B.
Allilest	XBAR110A	0	0	0	0	0	0	
Arm Support	XBAS-001A	_	0	-	0	_	0	For system with CAT-850B, this kit is already in the standard configuration.
  Handgrip	XBHG-001A	0	_	0	-	0		Above-Head Armrest
r la lugrip	XBHG-002A	_	0	_	0	_	0	Above-Head Armrest
Free Slide Grip for CAT (Mushroom SW)	XBFG-001A	0	0	0	0	0	0	
Tabletop Control Console	XBFG-850B	0	_	0	_	0	_	
Extension Rails	XBER-001A	0	0	0	0	0	0	
Extension Tabletop	XBET-001A	0	0	0	0	0	0	When this option is used, XBER-001A is also required.
Head-End Table Control Switch Kit	XBHR-001A	0		0	_	0	_	This option includes XBFG-001A.
Tabletop Mat	XBTM-001A	0	_	0	_	0		Tempur mat, For system with CAT-880E a tempur mat is already in the standard configuration.
Accessories Table Rail	XBAM-001A	_	0 -	· —	0		0	
Drape Holder	XBDB-001A	_	0	<u> </u>	0	· —	0	
<for system="" video=""></for>								
	ML19193	0	0	0	0	0	0	ML19193 (Except for Europe)
Additional LCD Monitor	SMD-19102-TC	0	0	0	0	0	0	Locally procured unit.
	SMD-19102-TD	0	0	0	0	0	0	Locally procured unit.
Color LCD Monitor	CDL2013A-1A	0	0	0	0	0	0	For XIDF-ESD801
External Signal Display Kit	XIDF-ESD801	0	0	0	0	0	0	
<for cabinet=""></for>	T= . = .	T	T			1	1	<b>V</b>
System Cabinet	CAB-100B	0	0	0	0	0	0	
Cabinet Side Cover	CABS-100B	0	0	0	0	0	0	
Cabinet Corner Cover	CABC-100B	0	0	0	0	0	0	
<for digital="" system=""></for>	Т		·		,	r	1	
Additional Reference Monitor Kit	XIDF-REF802/DV	. 0	0	0	0	0	0	This kit is required when DVI is used for the signal output. Additional monitor SMD-19102-TC × 2 or ML19193 × 2 are required.
Biplane System Kit 3 (High Speed Fluoroscopy Kit)	XIDF-BPS803/B1	0	0	_	_	_	_	
Review Console	XIDF-RVC801	0	0	0	0	0	0	
Rotational DSA			_					
Rotational DSA Kit	XIDF-ROT801	0	0	0	0	0	0	XIDF-AWS801/B1 (For CE-marked regions XIDF-AWS801/S2 and XIDF-AWS801/G2) and XIDF-3DI801 are required.
Stepping DSA		1	<u> </u>	L	L	l	L	Taria vicir opioot are required.
Stepping DSA Kit	XIDF-STP801	0	0	0	0	0	0	XBSD-850B is also required for the system with CAT-850B.
Stepping Unit for Catheterization Table (Factory Option)	XBSD-850B	0	_	0	_	0	_	This unit must be ordered to perform Stepping DSA with CAT-850B.

Unit	Model Name	INFX- 8000V/G7	INFX- 8000V/G8	INFX- 8000V/G9	INFX- 8000V/GA	INFX- 8000V/GB	INFX- 8000V/GC	Note
Onit	Woder Warrie	FPD8/FPD8 Standard Table		FPD12/FPD12 Standard Table	Tilting Table	FPD1216/ FPD12 Standard Table	FPD1216/ FPD12 Tilting Table	
3D-Anglo								
3D-Angio Application Software	XIDF-3DI801	0	0	0	0	0	0	XIDF-AWS801/B1 (For CE-marked regions XIDF-AWS801/S2 and XIDF-AWS801/G2) and XIDF-ROT801 are also required.
LCI								
Low Contrast Imaging Kit	XIDF-LCI801	0	0	0	0	0	0	XIDF-3DI801, XIDF-AWS801/S2, XIDF- AWS801/G2 and XIDF-ROT801 are required to operate LCI.
Spot Fluoroscopy								
Spot Fluoroscopy Kit	XIDF-SFL801	0	0	0	0	0	0	
UPS								
UPS Connection Kit	XIDF-UPS801	0	0	0	0	0	0	The compatible UPS is Pulsar MX4000RT.
Multiple Language Option								
Multi Language (French) Kit	XIDF-MLFR01	0	0	0	0	0	0	Factory option
Multi Language (Spanish) Kit	XIDF-MLES01	0	0	0	0	0	0	Factory option
Multi Language (German) Kit	XIDF-MLDE01	0	0	0	0	0	0	Factory option
Multi Language (Italian) Kit	XIDF-MLIT01	0	0	0	0	0	0	Factory option
Multi Language (Portuguese) Kit	XIDF-MLPT01	0	0	0	0	0	0	Factory option
Multi Language (Russian) Kit	XIDF-MLRU01	0	0	0	0	0	0	Factory option

#### Combinable Unit

<Output>

Angio Workstation Monitor Kit

<3D-Recon PC> *Except for coun	ntries where CE markin	g is required			***************************************	**********************	***************************************	
Angio Workstation (3D-Recon PC)	XIDF-AWS801/B1	0	0	0	0	0	0	This kit does not include the monitors for the Angio Workstation. Please order one or two Angio Workstation Monitor Kits (XIDF-AMK801).
<3D-Recon PC> *Only for countri	es where CE marking	is required						
Angio Workstation Software (3D-Recon PC)	XIDF-AWS801/S2	0	0	0	0	0	0	Both of XIDF-AWS801/S2 and XIDF-AWS801/G2 are needed. This kit does not include the monitors for the Angio Workstation. Please order one or two Angio Workstation Monitor Kits (XIDF-AMK801).
Angio Workstation Hardware (3D-Recon PC)	XIDF-AWS801/G2	0	0	0	0	0	0	

Monitor for Angio Workstation

# Option for Angio workstation (XIDF-AWS801/B1 or XIDF-AWS801/S2 and XIDF-AWS801/G2) \* All following options require XIDF-AWS801/B1 or XIDF-AWS801/S2 and XIDF-AWS801/G2 in accordance with whether CE-mark is required or not.

XIDF-AMK801

Angio Workstation Additional XIDF-AMK802 Signal distributor Monitor Kit <Dose Tracking System> For regions where CE-mark is not required. XIDF-DTS802 Dose Tracking System Kit For regions where CE-mark is required, both options are needed. XIDF-DTS802/S1 XIDF-DTS802/H1 <Analysis Software> Basic kit for Clinical Analysis XIDF-QCA700 

Application QCA Kit XIDF-QCA701 o XIDF-QCA700 is required. QVA Kit XIDF-QCA702 XIDF-QCA700 is required. LVA Kit XIDF-QCA703 XIDF-QCA700 is required. XIDF-QCA700 and XIDF-QCA703 are LVA-BP Kit XIDF-QCA704 required. RVA Kit XIDF-QCA705 ō XIDF-QCA700 is required. XIDF-QCA700 and XIDF-QCA701 are 3DQCA Kit XIDF-QCA706 required. Stent Enhancer Kit XIDF-QCA707 XIDF-QCA700 is required. <Roadmap> --3D Roadmap--

XIDF-3DI801 and XIDF-ROT801 are XIDF-3DP802/A1 3D Roadmap Kit required. --Multi-Modality Roadmap--This kit requires XIDF-3DI801, XIDF-ROT801 and XIDF-3DP802/A1. Multi-Modality Roadmap Kit XIDF-3DP804 (CT, MR)



				For regions ot					
Unit	Model Name	INFX- 8000V/G7	INFX- 8000V/G8	INFX- 8000V/G9	INFX- 8000V/GA	INFX- 8000V/GB	INFX- 8000V/GC	- Note	
Oliji		FPD8/FPD8 Standard Table		FPD12/FPD12 Standard Table	Tilting Table	FPD1216/ FPD12 Standard Table	FPD1216/ FPD12 Tilting Table		
<tavr support=""></tavr>									
TAVR Support Kit	XIDF-TAV801/A1	0	0	0	0	0	0	For XIDF-TAV801/A1, it includes 3mensio by PMI. For XIDF-TAV803/A1, A-Valve by PMI is also included with 3mensio by PMI.	
.,	XIDF-TAV803/A1							Please select XIDF-TAV801/A1 or XIDF- TAV803/A1. XIDF-AWS801/B1 must be V6.0 or later.	
Mitral Analysis for TAVR Support Kit	XIDF-TAV804/A1	0	0	0	0	0	0	XIDF-TAV801/A1 or XIDF-TAV803/A1 is required.	
Left Atrium Appendage Analysis for TAVR Support Kit	XIDF-TAV805/A1	0	0	0	0	0	0	XIDF-TAV801/A1 or XIDF-TAV803/A1 is required.	
Regurgitation Analysis for TAVR Support Kit	XIDF-TAV806/A1	0	0	0	0	0	0	XIDF-TAV803/A1 is required.	

#### **COMPATIBLE ITEMS**

#### Injectors

MARK V PLUS

MARK V PROVIS

MARK VII

**AVANTA** 

**AVIDIA** 

ANGIOMAT 6000

ANGIOMAT ILLUMENA

CVi

Rempress

#### Video Products

The combined equipment should meet the requirements below.

For connection, contact your Toshiba representative. Input (any of the following)

- 1600 × 1200 (UXGA), V: 60 Hz/ H: 75 kHz, color R, G, B: 0.7 V<sub>D-D</sub> H, V: TTL level (HD D-SUB connection for R, G, B, H, V, or DVI-D connection)
- 1280 × 1024 (SXGA), V: 75 or 60 Hz/ H: 80 kHz, monochrome

VIDEO: 0.7 V<sub>p-p</sub> H, V: TTL level (BNC connection for VIDEO, H, V, or DVI-D connection)

Down scan converter DSC-X001A (option) output

- 525 lines (NTSC), V: 59.94 Hz/ H: 15.734 kHz, interlaced 1 V<sub>p-p</sub> (BNC connection for composite video, MINI DIN connection for separation video)
- 625 lines (PAL), V: 50 Hz/ H: 15.625 kHz, interlaced 1 V<sub>p-p</sub> (BNC connection for composite video, MINI DIN connection for separation video)

#### **Network Devices**

The combined equipment should meet the requirements below. For connection of the following units, contact your Toshiba representative

1 opi oddinativoi	
Data format	DICOM 3.0
Communication protocol	TCP/IP protocol
Hardware interface	Ethernet

#### **Patient Monitoring Equipment**

The combined equipment should meet the requirements below. For connection of the following units, contact your Toshiba representative.

- Analog signal output
- Output signal:

±5 V

· Electrically insulated from the human body

# **IVUS Imaging System**

s5i

### **UPS**

Pulsar MX4000RT

#### PERFORMANCE AND SPECIFICATIONS

#### Floor-Mounted C-arm Support (CAS-880A/A1)

• Isocenter height:

1,110 mm (43.7")

C-arm interior radius:

890 mm (35.0")

- Distance between the X-ray tube focus and FPD input surface:
  - -TFP-800A/A1, TFP-1200A/C1:

900 mm to 1,250 mm (35.4" to 49.2")

- TFP-1216A/A1:

900 mm to 1,200 mm (35.4" to 47.2")

C-arm rotation

- Rotation angle:

RAO 120° to LAO 120°

- Rotation speed

· Normal:

10°/s (maximum, at biplane set-

30°/s (maximum, at single plane

setting)

Rotational DSA

(option):

40°/s (maximum)

· 3D-Angio (option):

50°/s (maximum)

C-arm sliding

- Sliding angle:

CRA 50° to CAU 90°

- Sliding speed

· Normal:

10°/s (maximum, at biplane set-

20°/s (maximum, at single plane

setting)

Rotational DSA

(option):

30°/s (maximum)

• FPD near/away movement

- Movement distance: 350 mm (13.8")

(TFP-800A/A1, TFP-1200A/C1)

300 mm (11.8") (TFP-1216A/A1)

- Movement speed:

100 mm/s (maximum)

- Operation: Operation using the control console and the FPD near/away movement control switches on the side of the FPD

C-arm floor base rotation

- Range:

+135°/-135° 10°/s (maximum)

- Movement speed:

C-arm column rotation

+90°/-90°

- Movement speed:

10°/s (maximum)

FPD rotation

- Range:

- Range:

+70°/-70°

(TFP-800A/A1, TFP-1200A/C1)

+135°/-135° (TFP-1216A/A1)

- Movement speed:

30°/s (maximum)

(depends on the arm angle)

Collimator rotation

- Range:

+70°/-70° (TFP-800A/A1)

+135°/-135°

(TFP-1200A/C1, TFP1216A/A1)

- Movement speed:

30°/s (maximum)

(depends on the arm angle)



• Lateral movement (only when the C-arm is set at the patient head end)

- Range:

1,800 mm (70.9") or ±900 mm

(35.4")

- Movement speed:

150 mm/s

 Longitudinal movement (only when the C-arm is set at the patient left or right side)

- Range:

2,000 mm (78.7") or +1,100 mm

(43.3") [foot end]/-900 mm

(35.4") [head end]

- Movement speed:

150 mm/s

Safety mechanism

- Interference prevention software:

Used to monitor the possibility of interference with the patient or the catheterization table used in combination.

- Touch sensors:

Used to detect contact with the patient, hospital staffs or units used in combination. When a touch sensor detects contact, the C-arm support unit stops automatically.

- Emergency stop switches:

Used by the operator to turn OFF the power of the mechanical drive sections of the C-arm support and catheterization table unit in an emergency. Emergency stop switches are located on the C-arm support unit control switch.

- Image rotation correction:

The FPD and the beam limiting device are rotated to correct for image rotation due to the C-arm insertion angle. The images on the monitor are always displayed with the head end of the catheterization table shown at the top of the monitor.

# Automatic functions

- Auto-positioning:

Up to 64 settings for the fluorographic angle, SID, table height, floor base rotation, column rotation, compensation filter, tilting position (when CAT-880B is used), FOV, and Live Zoom can be registered. In addition, auto-positioning settings can be specified sequentially for each study protocol (sequential auto-positioning).

– Auto-park:

The C-arm can be retracted automatically.

- Auto-angle:

The C-arm angle, SID, compensation filter position, table height, FOV, Live Zoom, and tilting position (CAT-880B) with which selected MAP images (still images) were acquired can be reproduced with one-touch operation.

X-ray grid

- TFP-800A/A1

· Interspace material: Carbon fiber

· Grid ratio:

13:1

· Grid density:

70 lp/cm

· Focusing distance:

100 cm

· Removal grid type

- TFP-1200A/C1, TFP-1216A/A1

· Interspace material: Aluminum

· Grid ratio:

13:1

· Grid density:

68 lp/cm

· Focusing distance: 100 cm

· Removal grid type

• Ion chamber for dosimeter combination:

The cumulative dose during a study and the dose rate during X-ray exposure can be displayed on the image display monitor. For the dose value, DICOM MPPS or DICOM RDSR output from the digital unit is possible.

### Ceiling-Suspended Ω-arm Support (CAS-820B/A1)

• Isocenter height:

1,110 mm (43.7")

• Ω-arm inner radius:

1,340 mm (52.8")

• Distance between the X-ray tube focus and

FPD input surface:

950 mm to 1,330 mm

(37.4" to 52.4")

• Ω-arm rotation

- Rotation angle

· Left Lateral (LL)

settina:

CRA 45° to CAU 45°

Right Lateral (RL) setting:

CRA 45° to CAU 45°

- Rotation speed

· Normal:

10°/s (maximum, at biplane set-

15°/s (maximum, at single plane

setting)

• Ω-arm sliding

- Sliding angle

· Left Lateral (LL)

setting

LAO 120° to LAO 0°

RAO 120° to RAO 0°

· Right Lateral (RL) setting

Sliding speed · Normal:

10°/s (maximum, at biplane set-

ting)

15°/s (maximum, at single plane

setting)

• FPD near/away movement

- Movement distance:

380 mm (15.0")

- Movement speed:

100 mm/s (4"/s) (maximum)

- Operation:

Operation using the control switches on the tableside con-

sole

X-ray tube/FPD, simultaneous vertical movement

- Range:

±70 mm

- Speed: 10 mm/s

• FPD/Collimator rotation for TFP-1200A and TFP-1200A/C1

- Range:

+45°/-45°

(not effective when the SID range is more than 1200 mm)

- Movement speed:

15°/s (maximum)

 Longitudinal movement Biplane set position to

park position:

2,200 mm

- Biplane set position to

patient foot side:

1,200 mm

– Movement speed: Lateral movement

Movement distance:

490 mm (390 mm center to

patient left side.

100 mm center to patient right

200 mm/s (maximum, variable)

side at LL position)

- Movement speed:

100 mm/s (maximum, variable)

Safety mechanisms

- Interference prevention

software:

Used to monitor the possibility of interference between the arms in the biplane setting. When the C-arm and Ω-arm come into the zone where they may interfere with each other, the speeds of both arms

decrease automatically.

- Touch sensors:

Used to detect contact with the patient or units used in combination. When a touch sensor detects contact, the Ω-arm support unit stops automatically.

- Emergency stop switches:

Used by the operator to turn OFF the power of the mechanical drive sections of the arm support and catheterization table unit in an emergency.

Emergency stop switches are located on the control switch.

Automatic functions

– Auto-positioning:

Up to 64 settings for the fluorographic angle, SID, table height, compensation filter position, column rotation, tilting position (when CAT-880B is used), FOV and Live Zoom can be registered. In addition, auto-positioning settings can be specified sequentially for each study protocol (sequential auto-positioning).

- Auto-angle:

The C-arm angle, SID, compensation filter position, table height, FOV, Live Zoom, and tilting position (CAT-880B) with which selected MAP images (still images) were acquired can be reproduced with one-touch operation.

- Auto-setting/parking: The  $\Omega$ -arm can automatically be set to the standard position or

the retraction position.

- Auto Map:

The  $\Omega$ -arm angle with which the selected MAP image (still image) was acquired can be reproduced by one-touch operation.

X-ray grid

- TFP-800A/A1

· Interspace material: Carbon fiber

· Grid ratio:

13:1

· Grid density:

70 lp/cm

· Focusing distance: 100 cm

-TFP-1200A and TFP-1200A/C1

· Interspace material: Aluminum

· Grid ratio:

13:1

· Grid density:

68 lp/cm

· Focusing distance: 100 cm

• Ion chamber for dosimeter combination:

The cumulative dose during a study and the dose rate during X-ray exposure can be displayed on the image display monitor. For the dose value, DICOM MPPS or DICOM RDSR output from the digital unit is possible.

\* Biplane setting:

 $\Omega$ -arm is in the following position.

Longitudinal distance

from isocenter:

±100 mm

Lateral distance

from isocenter:

±100 mm

# X-ray Tube Assembly

	DSRX-	DSRX-	DSRX-
	T7444GDS*	T7445GFS*	T7345GFS*
Focal spot (mm)	0.5/0.5/0.8	0.4/0.6/0.9	0.3/0.6/1.0
Short-time maxi- mum rating (kW)	50/100	30/50/100	17/48/100
Target angle (°)	8	9	11
Anode heat storage capacity (kHU)	3000	3000	3000
Maximum cooling rate of the anode	5.5 kW (7700 HU/s)	5.5 kW (7700 HU/s)	5.5 kW (7700 HU/s)

<sup>\*</sup> X-ray tube assembly with liquid metal bearing

#### X-ray Beam Limiting Device (BLA-900C)

X-ray exposure field

– Square blades:

(Maximum) Approx. 340 mm × 340 mm (on the plane 900 mm

from the focus)

(Minimum) Approx. 10 mm × 10 mm (on the plane 1330 mm

from the focus)

• Leakage dose:

Less than 0.75 mGy/h

(including X-ray tube assembly)

Conditions:

Distance of 1000 mm from the

focus; 125 kV, 18 mA

Dose adjustment filter

- Aluminum 2.0 mm

- Copper 0.2 mm (Approx. 6 mm aluminum equivalent)

- Copper 0.3 mm (Approx. 8 mm aluminum equivalent)

- Copper 0.5 mm (Approx. 13 mm aluminum equivalent)

- Copper 0.9 mm (Approx. 22 mm aluminum equivalent) Condition: 70 kV/HVL, 2.5 mm Al or

75 kV/HVL, 2.7 mm Al



• Dose adjustment filter operation:

Automatic selection becomes possible if dose adjustment filter operation is registered in the fluorographic program.

Compensation filters

- Filter material:

Fe 1.2 mm

- Number of filters and

shapes:

Two left/right filters (heart-

shaped and straight filters can

be switched)

One center filter (straight)

- Rotation range:

Approx. ±135° for each (filter rotation, opening, and closing can be performed independently)

- Rotation speed: Approx. 60° seconds

- Auto-operation:

Program setting of compensa-

tion filter positions linked with auto-positioning is possible.

• Dose area product meter:

Ion chamber for dosimeter (XJDC-009A) can be mounted on the front of the beam limiting device (in the X-ray tube cover).

· Beam limiting device

rotation:

±70°

### X-ray Beam Limiting Device (BLA-900A)

X-ray exposure field

- Square blades:

(Maximum) Approx. 400 mm ×

 $400~\mathrm{mm}$  (on the plane  $900~\mathrm{mm}$ 

from the focus)

(Minimum) Approx. 10 mm × 10 mm (on the plane 1330 mm

from the focus)

• Leakage dose:

Less than 0.75 mGy/h

(including X-ray tube assembly)

Conditions:

Distance of 1000 mm from the

focus; 125 kV, 18 mA

- Dose adjustment filter
- Aluminum 1.8 mm
- Copper 0.2 mm (Approx. 6 mm aluminum equivalent)
- Copper 0.3 mm (Approx. 8 mm aluminum equivalent)
- Copper 0.5 mm (Approx. 13 mm aluminum equivalent)

Condition:

70 kV/HVL, 2.5 mm Al or

75 kV/HVL, 2.7 mm Al

• Dose adjustment filter operation

Automatic selection becomes possible if dose adjustment filter operation is registered in the fluorographic program.

Compensation filters

- Filter material:

Fe 1.2 mm

- Number of filters and

shapes:

Two left/right filters (heart-shaped

and straight filters can be switched)
One center filter (straight)

- Rotation range:

Approx. ±60° for each (filter rotation, opening, and closing can be

performed independently)

- Rotation speed:

Approx. 6 seconds/120°

- Auto-operation:

Program setting of compensa-

tion filter positions linked with auto-positioning is possible.

• Dose area product meter:

Ion chamber for dosimeter (XJDC-016A) can be mounted on the front of the beam limiting device (in the X-ray tube cover).

Beam limiting device

rotation:

±135°

X-ray Flat Panel Detector (TFP-1216A/A1)

• Input size

397.3 mm x 298.0 mm (16" x 12")

298.0 mm x 298.0 mm (12" x 12") 198.7 mm x 198.7 mm (8" x 8") 149.0 mm x 149.0 mm (6" x 6")

\* Two additional zoom levels are available using the FOV switch on the main, tableside, and satellite consoles:

106.4 mm × 106.4 mm (4.3" × 4.3")\*

82.8 mm × 82.8 mm (3.3" × 3.3")\*

• Active area:

391.5 mm x 292.2 mm

Pixel size:

194 x 194 µm

Matrix size:

2048 x 1536 (Full field)

Bit depth:

14 bits

Operation mode:

2048 x 1536, maximum 6.0 fps

(Non-binned)

1024 x 768, maximum 30 fps

(2 x 2 binning)

1024 x 1024, maximum 30 fps

(Non-binned)

Resolution:

2.6 lp/mm

• DQE:

65% or more (0 lp/mm)

Note: When the following input sizes are selected with the C-arm positioned oblique to the patient, the SID setting specified below is recommended. If the SID setting is less than the specified value, the corners of the images may be cut off.

Input size

- $\cdot \dot{\text{For}}$  397.3 mm x 298.0 mm (16" x 12"), the SID should be 109 cm or more.
- $\cdot$  For 298.0 mm x 298.0 mm (12" x 12"), the SID should be 96 cm or more.

X-ray Flat Panel Detector (TFP-1200A/C1)

• Input size

298.0 mm × 298.0 mm (12" × 12") 254.0 mm × 254.0 mm (10" × 10") 198.7 mm × 198.7 mm (8" × 8") 149.0 mm × 149.0 mm (6" × 6")

\* Two additional zoom levels are available using the FOV switch on the main, tableside, and satellite consoles:

106.4 mm × 106.4 mm (4.3" × 4.3")\* 82.8 mm × 82.8 mm (3.3" × 3.3")\*

Active area:

194 × 194 μm

Pixel size:Matrix size:

194 × 194 μm 1536 × 1536 (Full field)

294.1 mm × 294.1 mm

• Bit depth:

14 bits

Operation mode:

1536 × 1536, maximum 12 fps

(Non-binned)

1024 × 1024, maximum 30 fps

(Non-binned)

768 × 768, maximum 30 fps

 $(2 \times 2 \text{ binning})$ 

512 × 512, maximum 60 fps

(Non-binned)

Note: 5122, 60 fps is available for less

than 8" input size.

Resolution:

2.6 lp/mm

• DQE:

77±5 % (lp/mm)

Note: When the following input sizes are selected with the C-arm positioned oblique to the patient, the SID setting specified below is recommended. If the SID setting is less than the specified value, the corners of the images may be cut off.

Input size

 $\cdot$  For 298.0 mm  $\times$  298.0 mm (12"  $\times$  12"), the SID should be 110 cm or more.

# X-ray Flat Panel Detector (TFP-1200A)

Input size

298.0 mm × 298.0 mm (12" × 12") 254.0 mm × 254.0 mm (10" × 10")

198.7 mm × 198.7 mm (8" × 8") 149.0 mm × 149.0 mm (6" × 6")

\* Two additional zoom levels are available using the FOV switch on the main, tableside, and satellite consoles:

106.4 mm × 106.4 mm (4.3" × 4.3")\*

82.8 mm × 82.8 mm (3.3" × 3.3")\*

Active area:

294.1 mm × 294.1 mm

Pixel size:

194 × 194 μm

Matrix size:

1536 × 1536 (Full field)

• Bit depth:

14 bits

• Operation mode:

1536 × 1536, maximum 12 fps

(Non-binned)

1024 × 1024, maximum 30 fps

(Non-binned)

 $768 \times 768$ , maximum 30 fps

 $(2 \times 2 \text{ binning})$ 

 $512 \times 512$ , maximum 60 fps

(Non-binned)

Note: 5122, 60 fps is available for less

than 8" input size.

Resolution:

2.6 lp/mm

• DQE:

65% or more (0 lp/mm)

Note: When the following input sizes are selected with the C-arm positioned oblique to the patient, the SID setting specified below is recommended. If the SID setting is less than the specified value, the corners of the images may be cut off.

#### nput size

For 298.0 mm  $\times$  298.0 mm (12"  $\times$  12"), the SID should be 110 cm or more.

#### X-ray Flat Panel Detector (TFP-800A/A1)

Input size

198.7 mm × 198.7 mm (8" × 8") 173.8 mm × 173.8 mm (7" × 7") 149.0 mm × 149.0 mm (6" × 6") 124.2 mm × 124.2 mm (5" × 5")

\* Two additional zoom levels are available using the FOV switch on the main, tableside, and satellite consoles:

103.5 mm × 103.5 mm (4.2" × 4.2")\*

88.7 mm × 88.7 mm (3,6" × 3,6")\*

Active area:

194 mm × 194 mm

Pixel size:

194 μm × 194 μm

Matrix size:

 $1024 \times 1024$ 

Bit depth:

14 bits

Operation mode:

1024 × 1024, maximum 30 fps

512 × 512<sup>(\*\*)</sup>, maximum 60 fps \*\* Binning from 4 pixels to 1 pixel

• Resolution:

2.6 lp/mm

• DQE:

65% or more (0 lp/mm)

Note: When the following input sizes are selected with the C-arm positioned oblique to the patient, the SID setting specified below is recommended. If the SID setting is less than the specified value, the corners of the images may be cut off.

#### Input size

· For 198.7 mm  $\times$  198.7 mm (8"  $\times$  8"), the SID should be 101 cm or more.



#### **Catheterization Table**

	CAT-850B	CAT-880B			
Longitudinal movement	1,350 mm (53.1")				
Lateral movement	±200 mm (±7.9")	±200 mm (±7.9")			
Tabletop vertical movement					
- Stroke	775 mm to 1,150 mm	754 mm to 1,054 mm			
	(30.5" to 45.3")	(29.7 to 41.5")			
- Speed		20 mm/s			
Tabletop dimensions					
- Length	2,950 mm (116.1")	2,950 mm (116.1")			
- Width	450 mm (17.7'	") (chest section)			
Tabletop rotations	+90° to -180°	+90° to -90°			
Sliding movement for lower-extremity peripheral DSA					
<ul> <li>Stepping mode</li> </ul>	Maximum 7 s	steps/8 stages			
<ul> <li>Stepping speed</li> </ul>	1.7 s or less/step (	step width: 220 mm)			
Loading strength					
Maximum permissible table load	240 kg	270 kg			
<ul> <li>Maximum permissible table load including standard accessories</li> </ul>	220 kg	250 kg			
Additional loading during cardiopulmonary resuscitation (CPR)	100 kg				
Inherent filtration					
- Tabletop	Max. 1.5 mm aluminum equivalent (	tube voltage: 100kV: HVL, 3.6 mm Al)			
- Arm cover		otion			
- Aim cover		(tube voltage: 100 kV: HVL, 3.6 mm Al)			
<del>-</del>	Option	Included in CAT-880B			
- Tabletop mat	Approx. 0.5 mm aluminum equivalent (tube voltage: 100 kV: HVL, 3.6 mm Al)	Approx. 0.5 mm aluminum equivalent (tube voltage: 100 kV: HVL, 3.6 mm Al)			
	Included in CAT-850B	Option			
- Arm support	Approx. 0.7 mm aluminum equivalent	Approx. 0.7 mm aluminum equivalent			
	(tube voltage: 100 kV: HVL, 3.6 mm Al)	(tube voltage: 100 kV: HVL, 3.6 mm Al)			
- Arm rest	Option Approx. 0.4 mm aluminum equivalent (tube voltage: 100 kV: HVL, 3.6 mm Al)				
Tilting	лургол. од пин аанили одичаст	(labo vollago, 100 kv. 11v L, 0.0 mill Al)			
<del>-</del>		+16° to -16°			
- Range	-	(Same for head-up/head-down and right-up/left-up)			
- Speed	<del>-</del>	Approx. 1.5°/s (head-up/head-down) Approx. 3°/s (right-up/left-up)			

#### X-ray High-Voltage Generator (XTP-8100XG)

Rating

- High-voltage

generation:

Inverter method

- Fluorographic ratings: 125 kV, 800 mA (0.1 s)

100 kV, 1000 mA (0.1 s)

- Fluoroscopic rating

· Continuous

fluoroscopy:

125 kV, 4 mA

· Pulsed fluoroscopy: 120 kV, 200 mA peak

(Long-time maximum output: 2.2 kW (3.0 kW under 70% HU))

- Maximum nominal

electric power:

100 kW

• Fluorographic functions

DSA functions

· Tube voltage range: 50 kV to 125 kV

· Tube current range: Maximum 1000 mA (may be

restricted depending on the rat-

ing of the X-ray tube assembly)

· Pulse width:

1.0 ms to 100 ms

The X-ray conditions during DSA are fixed.

- DA functions

· Tube voltage range: 50 kV to 125 kV

· Tube current range: Maximum 1000 mA (may be

restricted depending on the rating of the X-ray tube assembly)

· Pulse width: 1.0 ms to 25 ms

Note: Limited to 30 ms according to the system setting.

- ABC function

· Auto mode: In order to keep the monitor

brightness uniform, the tube voltage, tube current, and pulse width can be set to vary automatically according to changes in the object thickness. The tube voltage and tube current are automatically calculated from

the fluoroscopic X-ray conditions.

· Lock mode: After fluorography starts, the fluorographic conditions are

fixed to the set lock conditions after the set lock delay time has

elapsed.

- One-shot fluorographic function

· Tube voltage range: 50 kV to 125 kV

· Tube current range: Maximum 1000 mA (may be

restricted depending on the rating of the X-ray tube assembly)

· Pulse width:

1.0 ms to 100 ms

Note: Limited to 30 ms according to the system setting.

· X-ray condition:

Automatically calculated from the fluoroscopic X-ray conditions.

· Fluorographic condition setting

Though the fluorographic conditions for each type of fluorography are set automatically, the fluorographic conditions can also be set manually in the following ranges.

- Tube voltage

setting range:

50 kV to 125 kV (2-kV steps)

- Tube current

setting range:

20 mA to 1000 mA (16 steps)

- Exposure time setting range

DSA fluorography: DA fluorography:

1.0 ms to 100 ms 1.0 ms to 25 ms

- One-shot

fluorography:

1.0 ms to 100 ms

Note: Limited to 30 ms according to

the system setting.

- mAs usable range

· One-shot

fluorography:

0.5 mAs < \* < 100 mAs

· DSA fluorography:

100 mAs or less

Focal spot selection

The focal spot is set automatically according to the tube current. However, it can also be set manually or in a fluorographic program. If a program is selected, the corresponding focus size is set automatically.

Continuous fluoroscopy function

- Fluoroscopic tube

voltage range:

50 kV to 125 kV

- Fluoroscopic tube

current range:

0.5 mA to 4 mA

- Fluoroscopic time

setting range (Timer):

Maximum 5 minutes

- Cumulative

fluoroscopy time:

Up to 999 minutes

- ABC function:

In order to keep the monitor brightness uniform, the tube voltage or tube voltage and tube current are automatically adjusted according to changes in the object thickness. For the ABC brightness level, adjustment in

seven steps is possible.

- DOSE LIMIT function: Controls the patient input dose

so that it does not exceed the

specified value.

• Pulsed fluoroscopy function

- Fluoroscopic tube

voltage range:

50 kV to 120 kV

- Fluoroscopic tube

current range:

10 mA to 200 mA

- Pulsed width:

1.0 ms to 13.3 ms (may be restricted depending on the rating of the X-ray tube assembly and the repetition pulse rate)

- Fluoroscopic time

setting range:

Maximum 5 minutes

- Repetition pulse rate: 1, 2, 3, 5, 7.5, 10, 15, 20, 30 exp/s

(can be selected at the time of

installation)

- Cumulative fluoroscopy

time:

Up to 999 minutes

- ABC function:

In order to keep the monitor brightness uniform, the tube voltage or tube voltage and tube current are automatically adjusted according to changes in the object thickness. For the ABC brightness level, adjustment in seven steps is possible.

- DOSE LIMIT function: Controls the patient input dose so that it does not exceed the

specified value.

- Fluoroscopy mode:

By registering the desired combinations of dose, pulse rate, and additional filter type in advance, it is possible to switch the fluoroscopic dose in \*2 steps (normal/high), 3 steps (low/normal/high), or 4 steps (low/mid/ normal/high) at the control console in the examination room.

\* 2 steps are only for USA.

- Fluoroscopic dose selection:

Three modes (low/normal/high) are available for FPD input dose

setting.

# Digital Radiography (DFP-8000B/B2)

• Image input section

- Input image

· Single plane:

1024<sup>2</sup>, 14 bits: 512<sup>2</sup>, 14 bits: 30 fps (maximum) 60 fps (maximum)

· Biplane:

1024<sup>2</sup>, 14 bits: 512<sup>2</sup>, 14 bits

15 pps (maximum) 30 pps (maximum)

(pairs per second)

• Image recording unit

- Image disk:

**RAID (144 GB)** 

- Maximum recording number

· 1024<sup>2</sup> 8/10/12 bits: 118800 / 95000 / 79200

· 512<sup>2</sup> 8/10/12 bits: 473000 / 379000 / 316000



Map image recording:

Up to 999 map images can be recorded for each study. Map images can be recorded as photo images. After the study is terminated, the map images are automatically deleted.

Photo image recording: Up to 999 photo images can be

saved on the image disk.

• Output for the image display monitor

- Fluoroscopic images

· Display system:

Two systems for the examination/control rooms for fluoroscopic/fluorographic images

Image display:

 $1280 \times 1024$ , 75 or 60 Hz, monochrome (BNC connection for VIDEO, H/V or DVI-D con-

nection)

- System monitor

· Display system:

One system for the control room 1600 × 1200, 60 Hz, color

- Image display:

(HD D-SUB connection for R, G, B, H/V or DVI-D connection)

Fluoroscopy

- Input image:

1024<sup>2</sup> matrix, 10 bits

- Pulse rate

· Single plane:

Continuous 1, 2, 3, 5, 7.5, 10, 15, 20, 30 exp/s (can be selected at the time of installation)

· Biplane:

1, 2, 3, 5, 7.5, 10, 15, 20\*, 30\* exp/s (can be selected at the

time of installation)

\*: option (XIDF-BPS803/B1)

- Fluoroscopy mode selection:

- \* Two modes (normal/high), three modes (low/normal/ high), or four modes (low/mid/normal/high) are available. The mode can be selected at the tableside console.
- \* Two modes are only for USA.
- Fluoroscopic image processing:

Noise reduction spatial filter, signal enhancement spatial filter, recursive filter, gray-scale processing, dynamic range compression, display gamma processing

- Fluoroscopic image operation: Image magnification, image rotation, subtraction, peak hold, image addition
- Graphic display:

The current position and movement status of the beam limiting device and compensation filters are displayed graphically on the fluoroscopic LIH image without fluoroscopy.

Fluoroscopy roadmapping processing

- Subtraction:

Blood vessels and the guide wire can be visualized using fluorographic or fluoroscopic images as mask images. Mask images are generated from fluoroscopic images by performing peak/bottom-trace processing, LIH, and summed averaging. It is also possible to use DSA fluorographic images as mask images. Deviation between a fluoroscopy and a mask image is adjusted automatically.

- Landmark image

display:

Background images (mask images, bones, and blood vessels containing contrast medium) and the guide wire are displayed by roadmapping. Fluorographic images are used as mask images.

Linkage zoom:

The fluoroscopy image and roadmap image are zoomed simulta-

neously.

- Auto pixel shift:

Auto pixel shift for the roadmap mask image is available at the

tableside.

• Fluoroscopy/Fluoro-roadmap image acquisition:

Still image acquisition: An LIH image can be recorded on the image disk.

Dynamic image acquisition:

- F-REC:

The set maximum time (90 s) or 1020 frames (maximum) can be

recorded on the image disk.

- F-STORE:

Fluoroscopic/fluoro-roadmap images for up to the last 10 seconds can be recorded on the image disk after fluoroscopy/ fluoro-roadmap is completed. This can be extended to a maximum of 30 seconds, 900 frames.

#### DA

- Single-plane acquisition mode

· 1024<sup>2</sup>, 8/10/12 bits: 1, 2, 3, 5, 7.5, 10, 15, 30 fps

(can be selected at the time of

installation)

· 512<sup>2</sup>, 8/10/12 bits:

1, 2, 3, 5, 7.5, 10, 15, 30, 60 fps\* (can be selected at the time of

installation)

\* 5122 mode is available with TFP-800A/A1 or TFP-1200A/C1.

\* 5122, 60 fps is only available for less than 8" input size for TFP-1200A/C1.

#### Biplane acquisition mode

· 1024<sup>2</sup>, 8/10/12 bits: 1, 2, 3, 5, 7.5, 10, 15 pps

(can be selected at the time of

installation)

· 512<sup>2</sup>, 8/10/12 bits:

1, 2, 3, 5, 7.5, 10, 15, 30 pps\*

(can be selected at the time of

installation)

\* 5122 mode is available with TFP-800A/A1, or TFP-1200A/C1.

\* 5122, 30 pps is only available for less than 8" input size for TFP-1200A/C1.

Fluorographic time:

600 seconds (maximum) or

2047 frames (maximum)

- X-ray conditions:

ABC operation is performed during fluorography by estimating the fluorographic conditions from the immediately preceding fluoroscopic conditions (no test exposure).

- Image processing

during fluorography:

Dynamic range compression,

spatial filter, gray-scale processing

#### DSA

- Single plane acquisition mode

· 1024<sup>2</sup> 12 bits:

1/3, 1/2, 1, 2, 3, 6, 10, 15, 30 fps (can be selected at the time of

installation)

- Biplane acquisition mode

· 10242 12 bits:

1/3, 1/2, 1, 2, 3, 6, 10, 15 pps

(can be selected at the time of

installation)

- Stage setting:

Mask 1 stage + Contrast 5 stag-

es (maximum)

- Stage common

parameters:

Acquisition matrix, number of bits

- Stage individual

parameters:

Acquisition rate, number of

acquisition frames, delay

between stages

- Fluorographic time:

600 seconds (maximum) or

1023 frames (maximum)

(Sum of the mask stage and the

contrast stage)

- Image processing

during fluorography:

Subtraction, spatial filter, gray-

scale processing

One-shot fluorography

One-shot fluorography can be performed from the control or examination room.

- Acquisition mode:

1024<sup>2</sup>, 12 bits (A single frame is recorded on the image disk.)

- Fluorographic conditions:

The fluorographic conditions are estimated from the immediately preceding fluoroscopic conditions (no test exposure).

Rotational DA (Manual Rotation)

Contrast images can be acquired while rotating the arm.

Study protocols/fluorographic programs

Once the study protocols and fluorographic protocols are set, the required operations can be minimized by selecting the appropriate protocols and programs during a study. Fluorographic program groups belonging to study protocols that have been selected in advance can be selected during a study.

- Number of registered study protocols:

100 (maximum)

- Study protocols:

Up to 50 fluorographic protocols, parameters in fluoroscopy mode, and UI customization data, and up to 64 C-arm auto-positioning data can be preset.

- Fluorographic programs:

The fluorographic technique, image acquisition parameters, X-ray fluorographic conditions, View ID, etc. can be preset.

- Fluorographic program selection:

Manual selection and automatic selection synchronized with auto-positioning are possible.

Image processing

The following image processing operations can be performed in the control or examination room for fluorographic images. Image processing parameters can be changed during operation, corresponding to each region and technique.

- Spatial filter processing
- Gray-scale processing
- Scattered radiation correction processing
- Negative/positive reversal
- Display gamma function
- Image magnification (desired magnification ratio: 1.0 to 5.0 times), panning
- Summed average (mask/live addition for up to 64 frames (maximum))
- Subtraction
- Landmarking
- Scanned image inversion (Fluoroscopic/Fluorographic images can be inverted in the up/down and left/right directions)
- Auto-windowing
- Image reversal (Simple left/right or up/down inversion)
- Image rotation

An automatic image rotation function is provided so that images are always displayed on the monitor with the head end of the tabletop shown at the top of the monitor regardless of the angle setting or C-arm insertion direction.



Shutter display

The electric shutter can be manually or automatically displayed on the image. For automatic display, the shutter is displayed on the beam shielding area of the last frame. This can be displayed during dynamic image playback in examination or review mode on the examination room monitors.

Auto-pixel shift

The amount of shift between mask images and live images caused by motion artifacts is detected and is automatically corrected or is corrected in the specified ROI.

- Manual pixel shift

This can be performed using the keyboard and mouse.

- Panoramic View
- Stereo Display (using rotational DSA or 3D-DSA images)
- Annotation (characters, arrows, segments, rectangle,
- Peak/Bottom trace function
- SNRF processing

Digital image processing filter reduces noise in dynamic images without generating afterimages. It can be used for radiographic images as well as for fluoroscopic images.

Image selection

- Thumbnail view:

A  $7 \times 1$  or  $5 \times 1$  thumbnail view screen is displayed and the desired image can be selected.

- Catalog display:

A  $4 \times 4$  or  $2 \times 2$  catalog screen is created and the desired image

can be selected.

- Retrieving dynamic images from map images: From the map image (still image) display status, the original dynamic images can be played back by one-touch operation.

– Auto Map:

Fluorographic images (reference images (still images or dynamic images)) that were acquired at an angle close to the current C-arm angle can be selected and played back by one-touch operation.

Image playback

- Automatic playback:

Acquired images are automatically played back after fluorogra-

phy is performed.

Playback start:

After the images are selected,

playback starts.

- Changing the

playback speed:

Playback (forward/backward) can be performed at different

speeds.

- Image feeding:

Image feeding in the forward/ backward directions is possible.

- Reciprocating

playback:

Reciprocating image playback is

- Full playback:

Full dynamic image playback is

possible for each study.

Playback section:

Playback is possible for a speci-

fied section.

Biplane image display: Biplane image display can be

done on the fluoroscopy/refer-

ence monitors.

Analysis functions

- Distance measurement

- Simplified stenosis ratio measurement (comparison calculation between two segments)

- Calibration

· Automatic calibration: Automatic calculation is per-

formed based on the C-arm support and table location infor-

mation.

· Manual calibration:

Calculation is performed by using a calibration object or by entering the PID and the desired tabletop height.

Parallel processing

- The following processing operations can be performed independently in the examination and control room, (using the system monitor, mouse, and keyboard) during an examination.

· Image selection, image playback, and image processing for a desired patient

· Reference image recording

· Photo image recording

· Image analysis

· Imager output

· Media recording

· DICOM transfer/reception Imager output, media recording, and DICOM transfer/ reception can be performed in the background.

Physiological waveform data

- Display channel:

The two channels for the electrocardiogram and the bloodpressure waveform are displayed

independently.

- Acquisition:

Acquired at the same time as the fluoroscopic and fluorographic images (stored with the

corresponding images) DICOM transfer is possible.

- Transfer, recording:

Transferring the data as DICOM-

related information is possible.

• Image storage - CD-R recording

· Images:

Dynamic images, still images · Related information: Patient information, study infor-

mation, physiological waveform

· Recording method: Compliance with DICOM 3.0. (5122 or 10242, 8/10/12 bits,

JPEG loss-less compression)

· Recording image

frame:

4800 images maximum (assuming 512<sup>2</sup>, 8 bits)

· Recording operation: Manual or automatic back-

ground recording can be performed after examination.

DVD±R recording

Images: Dynamic images, still images
Related information: Patient information, study infor-

mation, physiological waveform

· Recording method: Compliance with DICOM 3.0.

(512<sup>2</sup> or 1024<sup>2</sup>, 8/10/12 bits,

JPEG loss-less compression)

· Recording operation: Manual or automatic back-

ground recording can be performed after examination.

• Patient registration/appointments

- Number of

appointments:

200 or more

- Appointment items:

Patient ID, patient name, sex,

date of birth, study protocols, examining physician, other

- Appointment method

- · Keyboard entry
- · DICOM MWM
- For a previously examined patient, a new appointment can be made after retrieving the existing patient information and study information.

(Up to 10,000 study histories can be stored.)

- Previous image reference
- Images acquired during previous studies (DICOM XA images) to be referred to during the study can be set when a new appointment is made.
- · Images acquired during previous studies can be imported from the following.

CD-R/DVD±R

Network server

- \* Some restrictions may apply to this function depending on the specifications of the dynamic image PACS to which the system is connected or the characteristics of the images to be stored.
- Dose management:

Dose chamber:

XJDC-009A (for TFP-800A/A1) XJDC-016A (for TFP1200A,

TFP1200A/C1, TFP-1216A/A1)

- Dose meter: XJDK-002A/V5

Dose management can be performed by mounting a ion chamber for dosimeter on the front of the beam limiting device (inside the X-ray tube cover).

- The cumulative dose is displayed.
- An alarm can be displayed when the cumulative dose exceeds the threshold dose.
- The dose ratios at the time of fluoroscopy and fluorography are displayed (on the fluoroscopic monitor and system monitor).
- The dose for each fluorographic image is recorded as related information.
- The total dose, fluoroscopic dose, and fluorographic dose for each study are output as study results (DICOM MPPS or DICOM RDSR). If there is no network for Radiation Exposure Monitoring, the same information can be stored as a study image.

- Imager output
  - DICOM print (imager connection)
- Network functions

The following network functions are supported. (Connection checks are required at the time of actual connection.)

For the compatibility, refer to the DICOM conformance statement.

- DICOM Storage (Storage SCU): Image transfer
- DICOM Storage Commitment (image transfer and storage check)
- DICOM Query/Retrieve, SCU XA images can be handled.
- Some restrictions may apply to this function depending on the specifications of the dynamic image PACS to which the system is connected or the characteristics of the images to be stored.
- DICOM Modality Worklist Management
   Patient/study information acquisition
- DICOM Modality Performed Procedure Step Study result response
- DICOM Radiation Dose Structured Report
- System Security Functions for personal information (HIPAA etc.)
- User certification

Identifies and certifies the user by user ID and password.

- User management/Authority management
   Limits available functions depending on each user's qualifications.
- Audit trail (audit log)

Records the life cycle (generation, display, update, output, and deletion) of the personal information, system operation (startup, termination, change of setting, etc.), and events related to security (login error, network down, etc.)

- Emergency user

Enables a person whose ID and password have not been registered to use the system in an emergency. Available functions are limited to a minimum.

- Screen locking

examination.

Automatically locks the display screen when operation is not performed for a certain period.

Note, however, that the screen is not locked during

X-ray tube protection

If the heat level of the X-ray tube anode exceeds 30% of the rated heat storage capacity, a dialog is displayed instructing the user to wait or shut down the system to protect the X-ray tube.

Emergency stop switch

When Emergency stop switch is pushed during exposure of X-rays, exposure of X-rays will stop at once. Even when Emergency stop switch is not released, if fluoroscopy or radiation is carried out again, X-rays will be exposed.



#### **User Interface**

- Control room
  - · Operating procedures: GUI operation using the main console, mouse, and keyboard
- Examination room
  - Operating procedures: Tableside console and GUI operation on the fluoroscopic/reference monitor
  - Operable functions: Settings for C-arm support/table operation, field size, image selection, playback, image processing, fluoroscopy mode selection, fluoroscopic timer resetting, fluorographic programs, etc. can be performed from the examination room.

### **DIMENSIONS**

Dimensions L × W × H mm (in)
572 × 506 × 2205 (22.5 × 19.9 × 86.8)
572 × 506 × 2205 (22.5 × 19.9 × 86.8)
572 × 506 × 2205 (22.5 × 19.9 × 86.8)
414 × 450 × 417 (16.3 × 17.7 × 16.4)
772 × 506 × 2205 (30.4 × 19.9 × 86.8)
1,950 × 645 × 2,388 (76.8 × 25.4 × 94.0)
809 × 2,446 × 1,958 (31.9 × 96.3 × 77.1)
2,950 × 750 × 780 (116.1 × 29.5 × 30.7)
2,950 × 750 × 754 (116.1 × 29.5 × 29.7)

#### Selectable Units

# < For Monitor and Monitor Suspension > Image Display Monitor

(ML19193 / CDL2013A-1A / MX270W / MDSC-8258 RL\*1, 2, 4)

	Image display monitor (LCD)	System monitor (LCD)	Monitor for external signal display kit (LCD)	Monitor integrated system (LCD)	Large-screen monitor (LCD)
Model name	ML19193 or equivalent	CDL2013A-1A or equivalent	CDL2013A-1A or equivalent	MX270W* <sup>3</sup> or equivalent	MDSC-8258 RL*1,2,4 or equivalent
LCD size	376.3 mm × 301.1 mm Diagonal length: 19.0 inches	434 mm × 326 mm Diagonal length: 21.3 inches	434 mm × 326 mm Diagonal length: 21.3 inches	596.7 mm × 335.6 mm Diagonal length: 27.0 inches	1270 mm × 721 mm Diagonal length: 58.0 inches
Color /monochrome	Monochrome	Color	Color	Color	Color
Resolution	1280 × 1024 matrix	1600 × 1200 matrix	1600 × 1200 matrix	2560 × 1440 matrix	3840 × 2160 matrix
Maximum brightness (0.7 Vp-p input) typ.	1500 cd/m²	440 cd/m <sup>2</sup>	440 cd/m <sup>2</sup>	300 cd/m <sup>2</sup>	700 cd/m <sup>2</sup>
Scanning frequency Vertical Horizontal	75 Hz 80 kHz	60 Hz 75 kHz	60 Hz 75 kHz	29.5 to 61 Hz 31 to 89 kHz	60 Hz 130.08 kHz
Automatic brightness adjustment function	Provided	None	None	Provided	Provided
Tilt mechanism	Provided	Provided	Provided	Provided	None

<sup>\*1:</sup> Locally procured unit only available for the USA and Europe.

<sup>\*</sup> Selectable units are not included in the standard configuration. These items must be ordered if required.

<sup>\*2:</sup> A touch panel console for the display layout is included

<sup>\*3:</sup> MX270W is included in XMEZ-LMMCR1

<sup>\*4:</sup> MDSC-8258 RL is included in XMEZ-LMM021/A1

### Monitor Suspension (for LCD) (MSF-08A)

- Types
- MSF-08A for 8 LCD monitors
- Monitors that can be mounted

ML19193, SMD-19102-TC, CDL2013A-1A, or equivalent

- Max. width:

460 mm

– Max. height:

380 mm

Specifications

- Operation method:

Manual operation

- Maximum weight of

monitor:

10 kg

Longitudinal

movement:

Max. 3928 mm (may be restricted depending on the layout)

- Lateral movement:

Approx. 2172 mm (may be

restricted depending on the lay-

out)

- Support column

rotation:

360°

- Support column

vertical movement:

Approx. 350 mm

# Monitor Suspension (for 58" LCD) (MSF-56A)

- Types
- MSF-56A for 58" LCD and 2 LCD monitors
- Monitors that can be mounted LX560W and ML19193 or SMD-19102-TC or equivalent
- Max. width

(for 58" LCD/LCD):

1319 mm / 460 mm

- Max. height:

(for 58" LCD/LCD):

776 mm / 370 mm

Specifications

– Operation method:

Manual operation

- Maximum weight of monitor

(for 58" LCD/LCD):

50 kg / 15 kg

- Longitudinal movement:

Max. 3928 mm (may be restricted depending on the layout)

- Lateral movement:

Max. 2472 mm (may be restricted depending on the layout)

- Support column

rotation:

±180°

- Support column

vertical movement:

Approx. 350 mm

# Monitor Suspension (for LCD) (MSF-04A/MSF-06A)

- Types
- MSF-04A for 4 LCD monitors
- MSF-06A for 6 LCD monitors
- Monitors that can be mounted

SMD-19102-TC, CDL2013A-1A, or equivalent

- Max. width:

460 mm

- Max. height:

370 mm

Specifications

Operation method: N

Manual operation

- Maximum weight of

monitor:

10 kg

- Longitudinal movement: Max. 3928 mm (may be restrict-

ed depending on the layout)

- Lateral movement:

Approx. 2472 mm (may be

restricted depending on the lay-

out)

- Support column

rotation:

±180°

Support columvertical

movement range:

Approx. 350 mm

# Large Monitor Accessory Kit 2 (XIDF-LMA802/BS)

This kit includes a signal converter, a stand for mounting the touch panel console, and other components. The kit is required when the 58" monitor is used in combination with DVI Connection.

# Integrated Monitor Accessory Kit (XIDF-INA801)

This kit contains a mounting kit for XIDF-PON801 and connecting cable. This kit, XMEZ-LMMCR1, and XIDF-DVI801 are required when integration of video inputs is desired.

# **OPTIONS**

# < For C-arm Support > Satellite Console (XGCP-882AA)

Additional control console. (with stand).

#### Base Plate (XGBP-880A / XGBP-880B)

Unit for mounting the base plate to the floor.

XGBP-880A:

1400 mm

XGBP-880B:

750 mm

# **Duct Hose Position Option for CAS-820B** (XGCO-820A)

This is an option for changing the duct hose position for CAS-820B. This option provides more room between the CAS-820B and the monitor suspension. (Factory option)

# Extended Lateral Rails for Monitor Suspension (XGMR-MSF021A)

This option allows lateral movement of the MSF series to be extended by 485 mm to increase clearance on both sides around the table. (Factory option)

#### Magnetic Shielding Kit (XGPA-800A)

- Compatible detector: TFP-800A/A1

– Material:

Permalloy

– Size:

241 mm × 241 mm

- Thickness:

0.1 mm

- X-ray transmission:

80±10 %

(70 kVp: Dose adjustment filter Cu 0.3 mm, Acrylic 20 cm)



### Magnetic Shielding Kit (XGPA-1200A)

- Compatible detector: TFP-1200A and TFP-1200A/C1

- Material:

Permallov

- Size:

328 mm × 382 mm

- Thickness:

0.1 mm

- X-ray transmission:

80±10 %

(70 kVp: Dose adjustment filter

Cu 0.3 mm, Acrylic 20 cm)

# Magnetic Shielding Kit (XGPA-1216A)

- Compatible detector: TFP-1216A/A1

- Material:

Permallov

- Size:

360 mm × 450 mm

- Thickness:

0.1 mm

- X-ray transmission:

80±10 %

(70 kVp: Dose adjustment filter

Cu 0.3 mm, Acrylic 20 cm)

# < For Catheterization Table > Base Plate (XBBP250B)

Unit for mounting the base plate to the floor.

# Additional Footswitch (XBFS-880B)

Pedal footswitch with function switches

(Preferred option. Same functionality as the standard footswitch.)

# Wireless Footswitch (XBFS-880WB)

The wireless Footswitch provides cable-free operation. More flexibility for the customer, and easy maintenance. This kit requires a Table Modification Kit (XBFM-850A or XBFM-880A) in accordance with the combined table.

For CAT-850B, XBFM-850A For CAT-880B, XBFM-880A

Features

- Charging time:

4.5 hours

- Standby mode time: 48 hours

- Continuous use:

20 hrs.

- Battery needs to be replaced after 500 hrs or 1 year.

- 5M max distance from transmitter

- AC Charger

- System Cable to direct connect footswitch to table

- LED indicators for Charged, Charging, needs charged

- LED indicators also indicate errors (Only for USA, Europe and Turkey.)

#### Arm Cover (XBAC-001A)

Carbon plate for expanding the width of the tabletop (for CAT-850B, CAT-880B).

#### Armrest (XBAR-001A)

Arm rest for the right or left side, made of carbon. One is included in CAT-850B.

#### Armrest (XBAR110A)

For both arms.

## **Arm Support (XBAS-001A)**

This kit is required to support patient arms. This option is only for systems with CAT-880B because this kit is included in CAT-850B as standard configuration.

#### Handgrip (XBHG-001A / XBHG-002A)

This is the above-head armrest for LV.

This armrest allows the patient's arms to rest comfortably when they are positioned above the patient's head.

XBHG-001A: for CAT-850B XBHG-002A: for CAT-880B

#### Free-Slide Grip (XBFG-001A)

Tabletop free switch.

#### Tabletop Control Console (XBFG-850B)

Console for operating the catheterization table. (mounted to the catheterization table) (for CAT-850B)

### **Extension Rail (XBER-001A)**

Kit for extending the side rail of the catheterization table toward the head or foot-end (for CAT-850B, CAT-880B).

# **Extension Tabletop (XBET-001A)**

Auxiliary table for temporary placement of the catheter. (installed at the foot-end of the tabletop) (for CAT-850B. CAT-880B).

#### Head-End Table Control Switch Kit (XBHR-001A)

Kit for mounting the tabletop operating switches at the head end of the tabletop (for CAT-850B).

#### Tabletop Mat (XBTM-001A)

5-cm-thick low-resilience tabletop mat for catheterization table (for CAT-850B).

#### Accessories Table Rail (XBAM-001A)

Rail mounted on the head-end of the catheterization table. An intravenous drip hanger can be mounted to this rail (for CAT-880B).

#### **Drape Holder (XBDB-001A)**

This drape holder is mounted on the catheterization table and keeps the drape away from the patient's face (for CAT-880B).

### < For Video System > External Signal Display Kit (XIDF-ESD801)

Kit for entering, selecting, and displaying signals from a vital signs monitor, IVUS, VTR, etc.

### < For Cabinet > System Cabinet (CAB-100B)

System cabinet for storing peripheral units.

#### **Cabinet Side Cover (CABS-100B)**

Kit required for systems with a special layout, such as systems installed across a beam (Refer to the site planning manual.)

#### Cabinet Corner Cover (CABC-100B)

Kit required for systems in which the cabinet is installed in the corner of the room (Refer to the site planning manual.)

# < For Digital System > Additional Reference Monitor Kit (for Biplane) (XIDF-REF802/DV)

For DVI Connection

Kit required when two additional monitors for biplane reference image display are used.

#### Biplane System Kit 3 (XIDF-BPS803/B1)

High-speed fluoroscopy kit.

# **Review Console (XIDF-RVC801)**

Dial operation unit for image review.

# Rotational DSA (XIDF-ROT801)

- Applicable C-arm

support:

Floor-mounted C-arm support

CAS-880A

Acquisition mode:

1024<sup>2</sup> 12 bits

- Acquisition speed:

Maximum 25 fps

Since X-ray exposure is performed using the angle trigger method, the acquisition speed changes depending on the acquisition mode and the rotation speed of the C-arm support.

- Rotation mode:

Mask - Return - Contrast acquisition (MRC method)

Mask - Contrast acquisition (MC method)

Mask - Return - Contrast - Contrast acquisition (MRCC method)

Mask - Contrast - Contrast acquisition (MCC method)

- Fluorographic program:

The rotation angle, direction, and the rotation speed of the C-arm support can be preset in the fluorographic program.

- · Stage common parameters: Acquisition matrix, number of bits, rotation speed, acquisition rate, number of acquired frames
- · Stage individual parameters: Delay between stages
- · Maximum rotation speed:

Rotation direction	When the C-arm is	When the C-arm is		
	set to the head-end	set to the side of the		
	position	patient		
LAO/RAO	40°/s	30°/s		
CAU/CRA	20°/s	20°/s		

- X-ray exposure timing: Set the C-arm support to the same angles during mask/contrast image acquisition and during X-ray exposure (image acquisition). (Angle trigger method)
- Rotational DA (Automatic Rotation)
  - This function is included in XIDF-ROT801.
  - Contrast images can be acquired while rotating the arm by automatic rotation sequence.
  - This operation is similar to that of rotational DSA sequence.

- X-ray control is ABC.
- Maximum rotation speed: 50°/s
- Maximum slide speed (CRA/CAU): 20°/s

# Stepping DSA **Stepping Unit for Catheterization Table** (XBSD-850B) Stepping DSA Kit (XIDF-STP801)

Peripheral DSA

Lower-extremity stepping DSA can be performed by moving the tabletop from the control or examination room.

- Applicable C-arm

support:

Floor-mounted C-arm support

CAS-880A

– Number of steps:

7 steps/8 stages (maximum)

- Stepping speed:

1.7 s or less/step

- Acquisition mode:

(step width: 220 mm)

1024<sup>2</sup>, 12 bits, 1, 2, 3, 6, 10, 15 fps

(can be selected at the time of

installation)

### Low Contrast Imaging Kit (XIDF-LCI801)

3D-DA for Low contrast imaging can be performed from the control or examination room (only when the C-arm is set to the head-end position).

- Data acquisition range:

RAO 100° to LAO 100°

- Rotation speed:

Max. 25°/s

- Acquisition technique:

LCI (LCI-Fast, LCI-Middle, LCI-High)

- 3D reconstruction image type:

Low contrast image

(MPR etc.) Fine Voxel image

- LCI acquisition mode

· LCI-Fast acquisition:

 $1024 \times 1024$ , 12 bits

Approx. 250 frames C-arm rotation speed is

25°/s.

· LCI-Mid acquisition:

 $1024 \times 1024$ , 12 bits Approx. 400 frames C-arm rotation speed is

15°/s.

· LCI-High acquisition:

 $1024 \times 1024$ , 12 bits Approx. 600 frames

C-arm rotation speed is

- High resolution reconstruction mode:

The following acquired data before the reconstruction is selectable.

- · Data of the center area (512 × 512) extracted from  $1024 \times 1024$  acquired data acquisition.
- Data reduced from 1024 × 1024 acquired data to  $512 \times 512$
- Metal artifact reduction

Metal artifacts can be reduced.



# **Spot Fluoroscopy Kit (XIDF-SFL801)**

This kit enables Spot Fluoroscopy. Spot Fluoroscopy allows fluoroscopy to be performed within an ROI while continuing to display a still image outside the ROI.

The position and the size of ROI can be changed with table side console XGCP-880BA.

# **UPS Connection Kit (XIDF-UPS801)**

This kit is required in order to connect a compatible UPS to the DFP-8000B/B2.

# Multi Language (French) Kit (XIDF-MLFR01)

This Multi Language kit is required to display GUI and messages in French. (Factory option)

# Multi Language (Spanish) Kit (XIDF-MLES01)

This Multi Language kit is required to display GUI and messages in Spanish. (Factory option)

# Multi Language (German) Kit (XIDF-MLDE01)

This Multi Language kit is required to display GUI and messages in German. (Factory option)

# Multi Language (Italian) Kit (XIDF-MLIT01)

This Multi Language kit is required to display GUI and messages in Italian. (Factory option)

# Multi Language (Portuguese) Kit (XIDF-MLPT01)

This Multi Language kit is required to display GUI and messages in Portuguese. (Factory option)

# Multi Language (Russian) Kit (XIDF-MLRU01)

This Multi Language kit is required to display GUI and messages in Russian. (Factory option)

# **COMBINABLE UNIT**

### < 3D Recon PC >

3D-Angio

# 3D-Angio Application Software (XIDF-3DI801) Angio Workstation (XIDF-AWS801/B1, XIDF-AWS801/S2 and XIDF-AWS801/G2)

- 3D-DA/DSA can be performed from the control or examination room. (Only when the C-arm is set to the headend position)
- Data acquisition

range:

RAO 100° to LAO 100°

- C-arm rotation speed: 50°/s

- Fluorography

techniques:

3D DSA and 3D DA

- Reconstruction image type:
  - · Blood vessel display in 3D from rotational DSA images
  - Blood vessel display in 3D from rotational DSA images/Visualization of interventional device images from mask images/Interventional device display in 3D (Depending on the functions of the workstation used in combination, blood vessel and interventional device images can be fused after acquisition (device fusion).)
  - · Display in 3D from rotational DA images

- 3D DSA acquisition mode:

1024<sup>2</sup> 12 bits:

2°/frame: C-arm rotation speed

50°/s or less

1°/frame: C-arm rotation speed

30°/s or less\*

\*(When the C-arm rotation speed of 30°/s is selected, acquisition is performed at intervals of 1.2°/frame.)

- 3D DA acquisition mode:

1024<sup>2</sup> 12 bits:

2°/frame: C-arm rotation speed

50°/s or less

1°/frame: C-arm rotation speed

30°/s or less\*

\* (When the C-arm rotation speed of 30°/s is selected, acquisition is performed at intervals of 1.2°/frame.)

- Time for image transfer and Angio Workstation:
   When this Angio Workstation is used in combination, the reconstruction time for 3D-DA acquisition is less than 5s in the fastest mode.
- Parametric Imaging

Parametric Imaging displays an entire image sequence as a single composite DSA image that is color-coded in order to characterize the contrast media dynamics and to allow easier visual evaluation.

Color Coded Circulation (CCC) can create movies by shifting color scale gradually so that it is easy to understand vessel flow.

The parameters used are as follows.

- Time To Peak (TTP)
- Time To Peak Alpha(TTPα)\*1
- Peak Height (PH)
- Area Under Curve (AUC)
- Time To Arrival (TTA)
- Time To Arrival Alpha (TTAα)\*1
- Mean Transit Time (MTT)
- Mean Transit Time Alpha (MTTα)\*1

# **OPTION FOR ANGIO WORKSTATION**

# < Output >

# Angio Workstation Monitor Kit (XIDF-AMK801)

This option includes a monitor for the Angio Workstation. A monitor is not included with XIDF-AWS801/B1 or XIDF-AWS801/S2 and XIDF-AWS801/G2, so this option may be required. Multimonitor display is also available for the Angio Workstation, and up to 2 sets of this option can be used in combination. For multimonitor display, the Angio Workstation Additional Monitor Kit (XIDF-AMK802) is also required.

# Angio Workstation Additional Monitor Kit (XIDF-AMK802)

This option includes a signal distributor to support multimonitor display for the Angio Workstation. For multimonitor display, 2 sets of Angio Workstation Monitor Kit (XIDF-AMK801) are also required.

<sup>\*1:</sup>For TTPα, TTAα, and MTTα, weighting is performed for each pixel using the PH value in addition to imaging using TTP, TTA, and MTT as a parameter.

# < Dose Tracking System > Dose Tracking System Kit (XIDF-DTS802, XIDF-DTS802/S1 and XIDF-DTS802/H1)

 A map is displayed to indicate the distribution of skin dose for the patient estimated from the X-ray conditions and geometric position information of each unit obtained during the study.

# < Analysis Software > Basic Kit for Clinical Analysis Application (XIDF-QCA700)

Application

This is platform software for running the clinical analysis applications such as QCA, QVA, LVA, LVA-BP, RVA, QCA3D, and Stent Enhancer.

- Features
- DICOM Viewer for 2D XA images.

# QCA Kit (XIDF-QCA701)

Application

XIDF-QCA700 is required. XIDF-QCA701 is a QCA (quantitative coronary analysis) software package for use in clinical practice and research. This software features automatic contour detection of the coronary artery of interest and analysis of its dimensions.

- Features
  - Automatic contour detection is supported for QCA.
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of QCA can be transferred to the DFP-8000B or PACS server and can be referred to in the examination room and control room.

# **QVA Kit (XIDF-QCA702)**

Application

XIDF-QCA700 is required. XIDF-QCA702 is a QVA (quantitative vessel analysis) software package for use in clinical practice and research.

The QVA software is used for quantitative analysis of blood vessels such as the aorta, iliac arteries, renal arteries, etc.

QVA supports automatic contour detection for vessels up to 50 mm in diameter.

- Features
  - Automatic contour detection is supported for QVA.
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of QVA can be transferred to the DFP-8000B or PACS server and can be referred to in the examination room and control room.

## LVA Kit (XIDF-QCA703)

Application

XIDF-QCA700 is required. XIDF-QCA703 is an LVA (left ventricular analysis) software package for use in clinical practice and research. This software supports automatic contour detection of the left ventricle, volume calculation, and wall motion analysis. LVA can be applied to images acquired during left ventricular diagnosis.

- Features
  - Automatic contour detection is supported for LVA.
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of LVA can be transferred to the DFP-8000B or PACS server and can be referred to in the examination room and control room.

# LVA-BP kit (XIDF-QCA704)

Application

XIDF-QCA700 and XIDF-QCA703 are required. XIDF-QCA704 is an LVA-BP (left ventricular analysis, biplane analysis) software package for use in clinical practice and research. LVA-BP can be applied to images acquired during left ventricular diagnosis with biplane imaging. This software supports automatic contour detection of the left ventricle, volume calculation, and wall motion analysis.

- Features
- Automatic contour detection is performed for LVA using frontal and lateral images.
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of LVA-BP can be transferred to the DFP-8000B or PACS server and can be referred to in the examination room and control room.

# **RVA Kit (XIDF-QCA705)**

Application

XIDF-QCA700 is required. XIDF-QCA705 is an RVA (right ventricular analysis) software package for use in clinical practice and research. This software supports user-specified contour detection of the right ventricle, volume calculation, and wall motion analysis. RVA can be applied to images acquired during right ventricular diagnosis.

- Features
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of RVA can be transferred to the DFP-8000B or PACS server and can be referred to in the examination room and control room.



# 3DQCA Kit (XIDF-QCA706)

### Application

XIDF-QCA700 and XIDF-QCA701 are required. XIDF-QCA706 is a 3D-QCA (three-dimensional quantitative coronary analysis) software package for use in clinical practice and research. This software features reconstructions of stenotic coronary arteries and allows quantitative cross-sectional information to be displayed.

- Features
- Automatic contour detection is supported for 3D-QCA.
- Permits single-segment analysis and bifurcation analysis.
- Report files of 3D-QCA can be transferred to the DFP-8000B or PACS server and can be referred to in the examination room and control room.

# Stent Enhancer Kit (XIDF-QCA707)

### Application

XIDF-QCA700 is required. XIDF-QCA707 is a stent enhancement software package for use in clinical practice and research. This software supports depiction of the stent by suppressing anatomical structures and background noise in a single XA image acquired while the delivery balloon is still in place after deployment of the stent.

### Features

- Both automatic and user-specified marker detections are supported.
- Enhanced images can be transferred to the DFP-8000B or PACS server as capture files and can be referred to in the examination room and control room.

# < Roadmap > 3D Roadmap Kit (XIDF-3DP802/A1)

This kit requires XIDF-3DI801, XIDF-AWS801/B1 or XIDF-AWS801/S2 and XIDF-AWS801/G2.

A 3D image (only an image of vessels (3D-DSA) or an image of bones and vessels (3D-DSA, 3D-DA)), a fluoroscopic image, and a device-enhanced image generated from the fluoroscopic image can be superimposed and displayed (only when the C-arm is set at the patient head end and the tilt angle of the tabletop is 0°). For easier alignment of 3D images, DICOM images can be also overlapped.

When the C-arm is not at the patient head end, the positioning data must be adjusted manually for superimposition.

3D image display changes according to the system conditions such as the C-arm angle, SID, field size, tabletop height, and tabletop panning.

A needle guidance function enables positioning of the C-arm to the optimum viewing position and display of a puncture guide line for assistance. (3D auto-angle is available for both frontal and lateral arms.)

A portion of the left atrium can be automatically extracted from 3D data. (Left atrium segmentation)

# Multi-Modality Roadmap Kit (CT, MR) (XIDF-3DP804)

This kit requires XIDF-3DI801, XIDF-3DP802/A1, XIDF-AWS801/B1 or XIDF-AWS801/S2 and XIDF-AWS801/G2.

A 3D image from CT and MR, a fluoroscopic image, and a device-enhanced image generated from the fluoroscopic image can be superimposed automatically and displayed (when the C-arm is set at the patient head end and the tilt angle of the tabletop is 0°). For easier alignment of 3D (CT or MR data) images, DICOM images can be also overlapped. When the C-arm is not at the patient head end, the positioning data must be adjusted manually for superimposition. As long as DICOM CS permits, 3D volume data (CT and MR) acquired by systems from companies other than Toshiba systems is also available.

Superimposition can be performed manually. 3D image display changes according to system conditions, such as the C-arm angle, SID, field size, tabletop height, and tabletop horizontal movement.

The LCD monitor for displaying multi-modality roadmap images in the control room is included in this kit. The monitor for image display in the examination room is not included.

A needle guidance function enables positioning of the C-arm to the optimum viewing position and display of a puncture guide-line for assistance. (3D auto-angle is available for both frontal and lateral arms.)

A portion of the left atrium can be automatically extracted from 3D data. (Left atrium segmentation)

# < TAVR Support > TAVR Support Kit (XIDF-TAV801/A1, XIDF-TAV803/A1)

- XIDF-TAV801/A1
  - This kit allows the feasibility of a transapical, transfemoral, or subclavian valve replacement procedure to be assessed. This can combine 2D scan slices into comprehensive 3D models of the patient, and can display X-ray Angio data. Auto angle of the C-arm is available.
- XIDF-TAV803/A1
  - In addition to providing the features of XIDF-TAV801/A1, this kit also makes it easier to determine the optimal projection angle for transcatheter aortic valve replacement (TAVR) based on 3D images generated using two 2D images of the aortic root.

# Mitral Analysis for TAVR Support Kit (XIDF-TAV804/A1)

XIDF-TAV801/A1 or XIDF-TAV803/A1 is required. XIDF-TAV804/A1 allows the feasibility of a mitral valve replacement procedure to be assessed.

# Left Atrium Appendage Analysis for TAVR Support Kit (XIDF-TAV805/A1)

XIDF-TAV801/A1 or XIDF-TAV803/A1 is required. XIDF-TAV805/A1 allows the feasibility of a left atrium appendage closure procedure to be assessed.

# Regurgitation Analysis for TAVR Support Kit (XIDF-TAV806/A1)

XIDF-TAV803/A1 is required. XIDF-TAV806/A1 allows the quantification of aortic regurgitation after a TAVR procedure using single 2D images.

# INSTALLATION CONDITIONS

# **Examination Room**

Minimum installation

space:

Standard/W5.2 m  $\times$  L7.2 m

(W204.7 inches × L283.5 inches)

Ceiling height

2,900 mm to 3,000 mm

# **Power Requirements**

• Three-phase power supply

- Method:

Three-phase current

- Nominal line voltage:

380 V, 400 V, 415 V, 440 V,

480 V

- Line frequency:

50-60 Hz

 Allowable voltage fluctuation range

(for no load):

Within 10% of the nominal voltage

- Allowable power

impedance:

380 V 0.08 Ω or less

400 V 0.09 Ω or less 415 V 0.09 Ω or less 440 V 0.10 Ω or less 480 V 0.12 Ω or less

- Rating of the circuit

breaker:

380 V, 400 V, 415 V, 440 V,

480 V 100 A

- Recommended

capacity of the power

transformer:

100 kVA or more

- Momentary power

interruption:

Within 1/2 cycle

• Single-phase power supply

- Method:

Single-phase current

- Nominal line voltage:

200 V, 220 V, 230 V, 240 V

- Line frequency:

50-60 Hz

 Allowable voltage fluctuation range

(for no load):

Within 10% of the nominal voltage

- Rating of the circuit

breaker:

200 V 40 A

- Recommended

capacity of the power

transformer:

6 kVA or more

- Momentary power

interruption:

Within 1/2 cycle

# **Operating Requirements**

Ambient temperature	18°C to 33°C
Relative humidity	35% to 70% (No condensation)
Atmospheric pressure	800 hPa to 1,060 hPa
Ambient atmosphere	Use the system in a fluorography room that is free from flammable gases.

\* When the dose area product meter is used in combination, the following requirements should also be satisfied. Absolute humidity: 20 g/m³ or less (e.g. Relative humidity of 65% or less at 30°C, relative humidity of 55% or less at 33°C)

# **During Transportation and Storage**

Ambient temperature	5°C to 45°C
Relative humidity	30% to 80% (No condensation)
Atmospheric pressure	500 hPa to 1,060 hPa

\* Water should be emptied, when the water-cooled X-ray tube and water-cooled unit are to be transported.

# Grounding

Grounding must be provided in compliance with all applicable legal requirements for medically used electrical equipment.

# **COMPLIANCE**

Federal Food, Drug and Cosmetic Act (FFDC ACT) 510 Code of Federal Regulations Title 21 (21 CFR) 1010/1020

Council Directive 93/42/EEC

Concerning Medical Devices (Medical Device Directive)

- IEC 60601-1 (2005)
- IEC 60601-1-2 (2007)
- IEC 60601-1-3 (2008)
- IEC 60601-1-6 (2010)
- IEC 60601-1-9 (2007)
- IEC 60601-2-28 (2010)
- IEC 60601-2-43 (2010)
- IEC 62304 (2006)
- IEC 62366 (2007)
- IEC 60627 (2001)
- IEC 60580 (2000)



# MASS

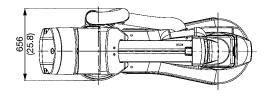
Name of Component	Model Name	Mass [kg] (lb)
C-arm Support	CAS-880A/A1	1000 (2200)
Omega-arm Support	CAS-820B/A1	1135 (2497)
Tableside Console	XGCP-882BA	4.2 (9.2)
X-ray Generator	XTP-8100XG	220 (484.0)
Oath day Tald	CAT-850B	457 (1005.4)
Catheterization Table	CAT-880B	625 (1375.0)
Tilting Table I/F Kit	XGTT-880A	16.4 (36.1)
Footswitch	XBFS-880B	4.7 (10.3)
System Manual	XAAM-8KV02E/W6	manual manual
System Service Kit	XAAS-005B	4.6 (10.1)
LM Bearing X-ray Tube Assembly	DSRX-T7345GFS	45 (99.0)
	DSRX-T7445GDS	46 (101.2)
	DSRX-T7444GDS	45 (99.0)
Starter	ST-7008	19 (41.8)
LBT Cable Kit	TLA-7008	9.6 (21.1)
High-Voltage Cable	HCM-150LCS/8V	40 (88.0)
	HCM-150LCS/30	40 (88.0)
Heat Exchanger	HEX-125	30 (66.0)
Heat Exchanger Hose	HEH-10040	25 (55.0)
X-ray Tupe Assembly Mount Kit	XGTM-048C	28 (61.6)
	XGTM-028A	17 (37.4)
	XGTM-028N	17 (37.4)
	XGTM-042C	62 (136.4)
	XGTM-032N	61 (134.5)
System Parts	XAAP-8KV06C	122.3 (269.1)
Flat Panel Detector	TFP-800A/A1	70 (154.0)
	TFP-1200A/C1	67 (147.4)
	TFP-1200A	67 (147.7)
	TFP-1216A/A1	79.5 (174.9)
Flat Panel Detector Mount Kit	XGFM-082B/E1	53.5 (117.7)
	XGFM-088B/E1	77.5 (170.5)
	XGFM-122B/E1	75 (165.3)
	XGFM-122B/E1	76 (167.2)
	XGFM-128B/E1	78 (171.6)
	XGFM-168A/E1	90.5 (199.1)

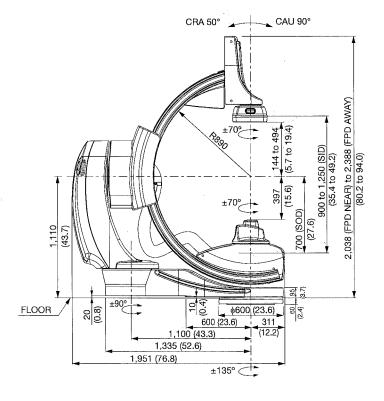
Name of Component	Model Name	Mass [kg] (lb)
V D Lie W D. i .	BLA-900C	7.0 (15.4)
X-ray Beam Limiting Device	BLA-900A	13.9 (30.6)
Digital Radiography	DFP-8000B/B2	420 (924)
Biplane System Kit	XIDF-BPS801/DV	56 (123.2)
Biplane System Kit 3 (High Speed fluoroscopy Kit)	XIDF-BPS803/B1	2.1 (4.6)
Main Console C	XIDF-MCC80B	2.0 (4.4)
Power ON Switch Box	XIDF-PON801	1.0 (2.2)
Footswitch	XIDF-FS801B	0.5 (1.1)
Microphone Kit	XIDF-MIC802	22 (48.5)
	XJDC-009A	0.2 (0.4)
Ion Chamber for Dosimeter	XJDC-016A	0.4 (0.9)
Dose Area Product Meter	XJDK-002A/V5	8.2 (18.0)
DVI Unit	XIDF-DVI801	25 (55)
LCD Color Monitor	CDL2013A-1A or equivalent	11.2 (24.7)
Monitor Integration System	XMEZ-LMMCR1	17 (37.4)
Integrated Monitor Accessory Kit	XIDF-INA801	2.8 (6.2)
LCD Monitor	ML19193	9.2 (20.3)
Monitor Suspension for 8 Monitors	MSF-08A	210 (463.0)
Monitor Suspension for 58" LCD Monitors	MSF-56A	227 (499.4)
Monitor Suspension for 4 Monitors	MSF-04A	195 (430.0)
Monitor Suspension for 6 Monitors	MSF-06A	213 (469.7)
Extended Lateral Rails for Monitor Suspension	XGMR-MSF021A	93.6 (205.9)
Large-Screen Monitor	XMEZ-LMM021/A1	63 (138.6)
AD Converter Kit	XMEZ-PDC001	1.1 (2.4)
Large Monitor Accessory Kit 2	XIDF-LMA802/BS	46.6 (102.5))
Satellite Console	XGCP-882AA	15.2 (33.4)
Base Plate (1400 mm)	XGBP-880A	377 (829.4)
Base Plate (750 mm)	XGBP-880B	103 (226.6)
Duct Hose Position for CAS-820B	XGCO-820A	15.0 (33.0)
Magnetic Shielding Kit	XGPA-800A	0.1 (0.2)
	XGPA-1200A	0.1 (0.2)
	XGPA-1216A	0.1 (0.2)
Base Plate for CAT-850B, CAT-880B	XBBP250B	230 (506.0)
Wireless Footswitch	XBFS-880WB	6.1 (13.4)
	XBFM-850A	1.4
Table Modification Kit	XBFM-880A	(3.0) 1.3 (2.9)

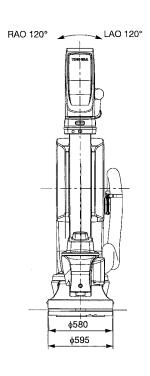
Name of Component	Model Name	Mass [kg] (lb)
Arm Cover	XBAC-001A	1.9 (4.2)
Armrest	XBAR110A	3 (6.6)
Arm Support	XBAS-001A	0.8 (1.8)
Handarin (Abaya Hand Armyadt)	XBHG-001A	5.2 (11.4)
Handgrip (Above-Head Armrest)	XBHG-002A	5.0 (11.0)
Free-Slide Grip	XBFG-001A	5 (11.0)
Tabletop Control Console	XBFG-850B	3 (6.6)
Extension Rails	XBER-001A	8 (17.6)
Extension Tabletop	XBET-001A	2 (4.4)
Head-End Table Control Switch Kit	XBHR-001A	5 (11.0)
Tabletop Mat	XBTM-001A	5 (11.0)
Accessories Table Rail	XBAM-001A	1.6 (3.5)
Drape Holder	XBDB-001A	0.7 (1.5)
External Signal Display Kit (IVUS, 3D Workstation, PACS)	XIDF-ESD801	24.6 (54.1)
System Cabinet	CAB-100B	100 (220.5)
Cabinet Corner Cover	CABC-100B	25 (55.0)
Cabinet Side Cover	CABS-100B	29 (63.8)
Additional Reference Monitor Kit	XIDF-REF802/DV	2.6 (5.7)
Review Console	XIDF-RVC801	1.0 (2.2)
Rotational DSA Kit	XIDF-ROT801	0.1 (0.2)
Stepping DSA Kit	XIDF-STP801	0.6 (1.3)
Stepping Unit for Catheterization Table	XBSD-850B	11 (24.2)
3D-Angio Application Software	XIDF-3DI801	0.1 (0.2)
Low Contrast Imaging Kit	XIDF-LCI801	0.1 (0.2)
Spot Fluoroscopy Kit	XIDF-SFL801	0.1 (0.2)

Name of Component	Model Name	Mass [kg] (lb)
UPS Connection Kit	XIDF-UPS801	13.0 (28.6)
Multi Language (French) Kit	XIDF-MLFR01	0.1 (0.2)
Multi Language (Spanish) Kit	XIDF-MLES01	0.1 (0.2)
Multi Language (German) Kit	XIDF-MLDE01	0.1 (0.2)
Multi Language (Italian) Kit	XIDF-MLIT01	0.1 (0.2)
Multi Language (Portuguese) Kit	XIDF-MLPT01	0.1 (0.2)
Multi Language (Russian) Kit	XIDF-MLRU01	0.1 (0.2)
Angio Workstation (3D Recon PC)	XIDF-AWS801/B1	21.5 (47.3)
Angio Workstation Monitor Kit	XIDF-AMK801	5.0 (11.0)
Angio Workstation Additional Monitor Kit	XIDF-AMK802	2.0 (4.4)
Dose Tracking System Kit	XIDF-DTS802	2.5 (5.5)
Basic Kit for Clinical Analysis Application	XIDF-QCA700	0.5 (1.1)
QCA Kit	XIDF-QCA701	0.1 (0.2)
QVA Kit	XIDF-QCA702	0.1 (0.2)
LVA Kit	XIDF-QCA703	0.1 (0.2)
LVA-BP Kit	XIDF-QCA704	0.1 (0.2)
RVA Kit	XIDF-QCA705	0.1 (0.2)
3DQCA Kit	XIDF-QCA706	0.1 (0.2)
Stent Enhancer Kit	XIDF-QCA707	0.1 (0.2)
3D Roadmap Kit	XIDF-3DP802/A1	0.5 (1.1)
Multi-Modality Roadmap Kit (CT, MR)	XIDF-3DP804	0.1 (0.2)
TAVR Support Kit	XIDF-TAV801/A1 XIDF-TAV803/A1	0.5 (1.1)
Mitral Analysis for TAVR Support Kit	XIDF-TAV804/A1	0.1 (0.2)
Left Atrium Appendage Analysis for TAVR Support Kit	XIDF-TAV805/A1	0.1 (0.2)
Regurgitation Analysis for TAVR Support Kit	XIDF-TAV806/A1	0.1 (0.2)

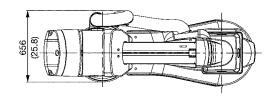


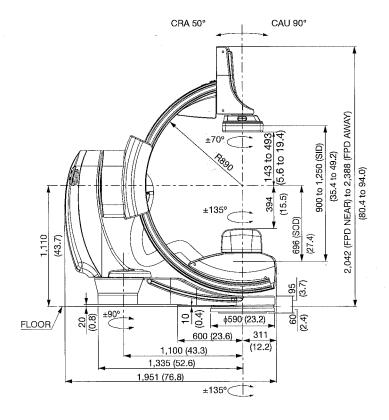


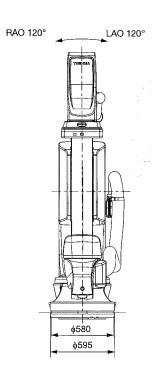




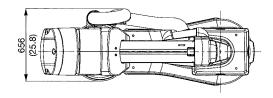
C-arm Support (CAS-880A/A1 with TFP-800A/A1)

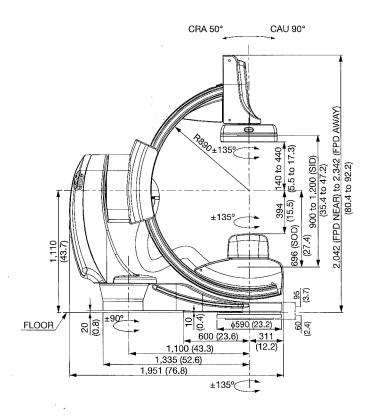


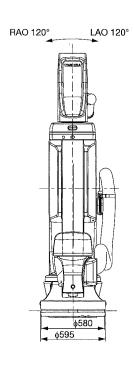




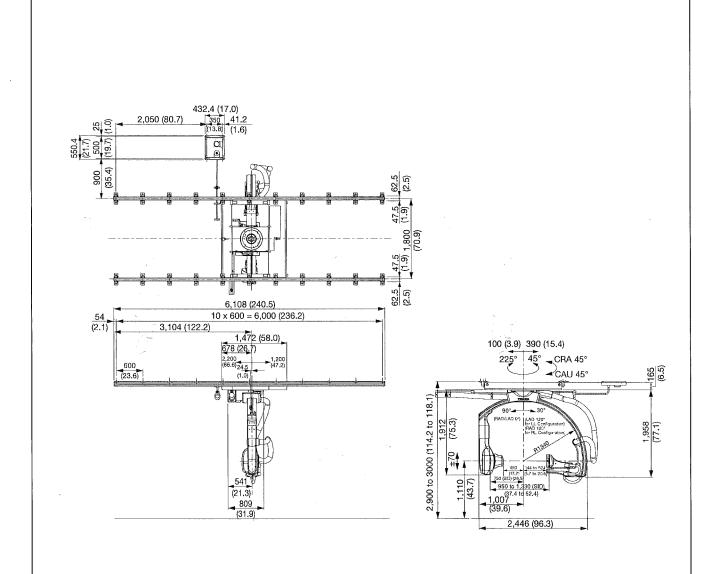
C-arm Support (CAS-880A/A1 with TFP-1200A/C1)





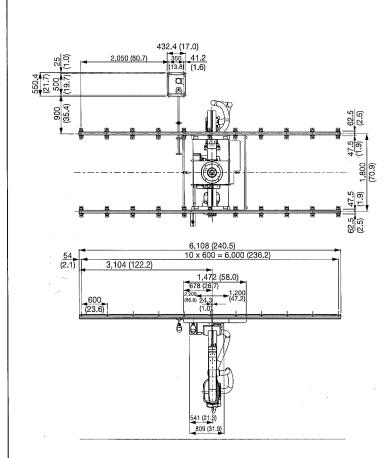


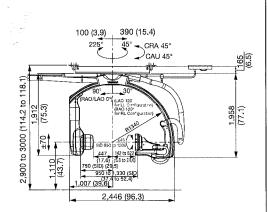
C-arm Support (CAS-880A/A1 with TFP-1216A/A1)



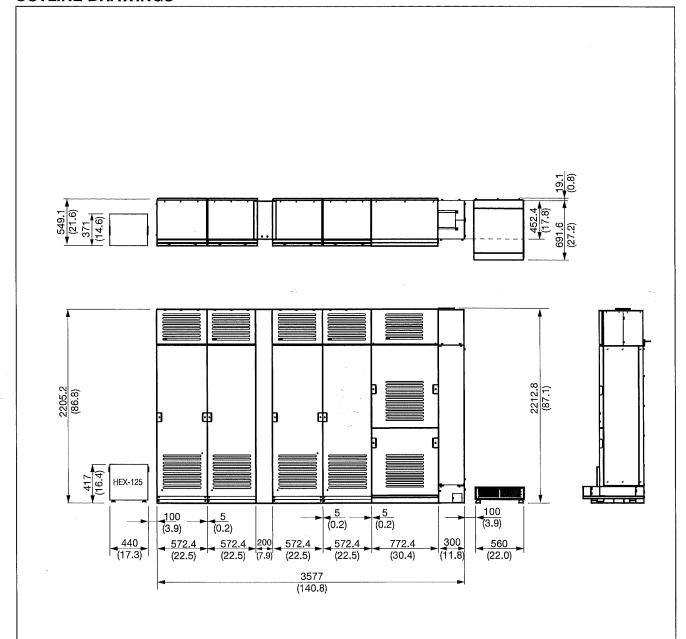
Omega-arm Support (CAS-820B/A1 with TFP-800A/A1)





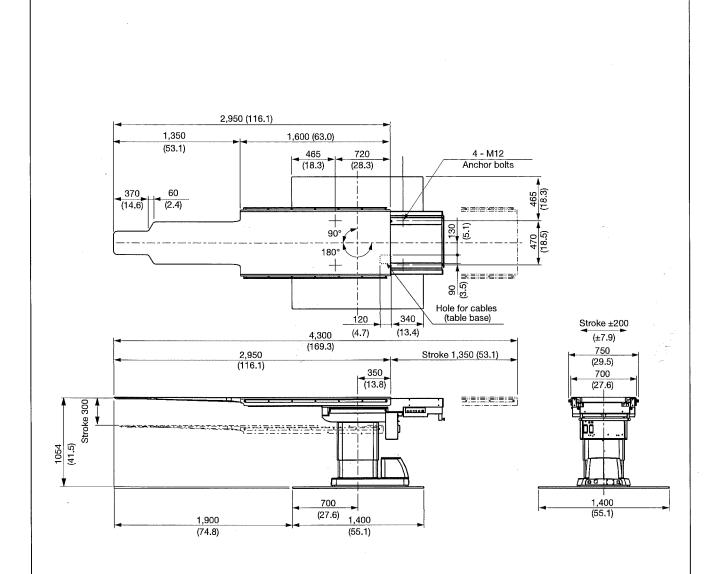


Omega-arm Support (CAS-820B/A1 with TFP-1200A)

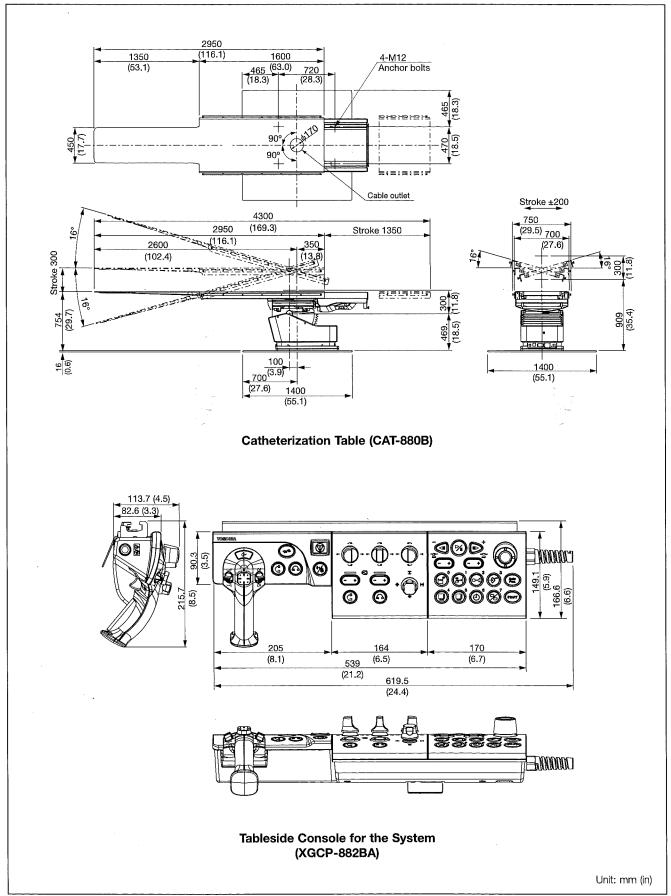


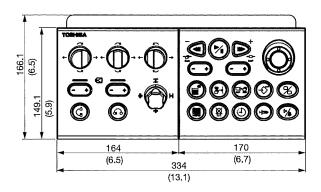
X-ray Generator, C-arm Cabinets, and Digital Radiography Main Unit (XTP-8100XG, CAS-880A/A1, CAS-820B/A1, DFP-8000B/B2)

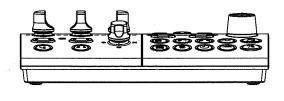


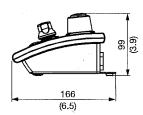


Catheterization Table (CAT-850B)

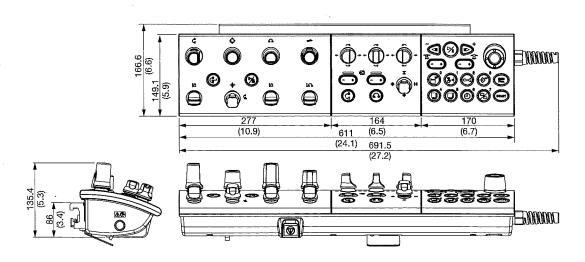




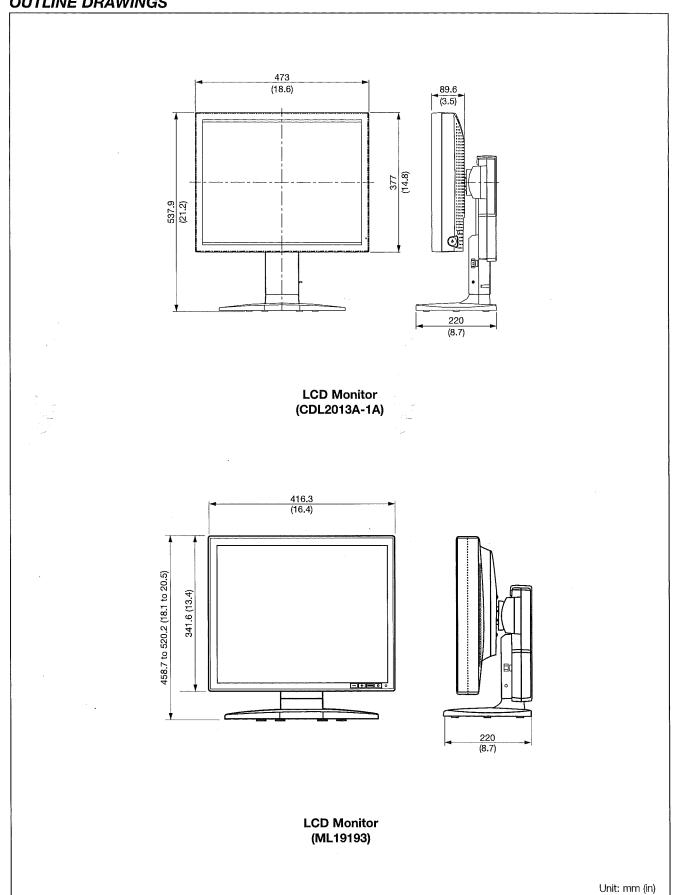


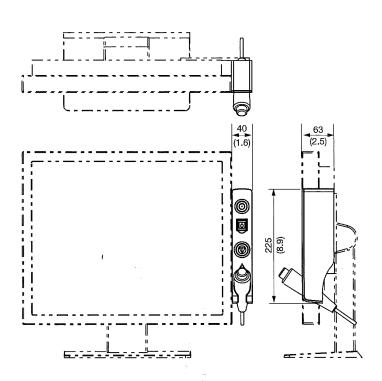


Main Console C for the System (XIDF-MCC80B)

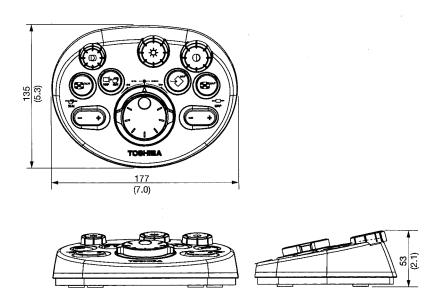


Satellite Console (Option) (XGCP-882AA)

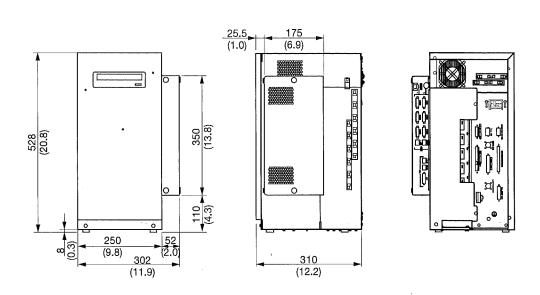




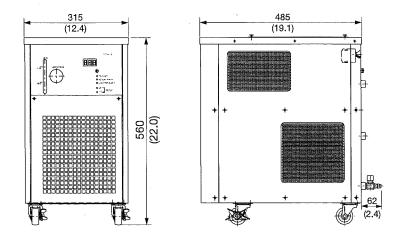
Power ON Switch Box (XIDF-PON801)



Review Console (XIDF-RVC801) (Option)

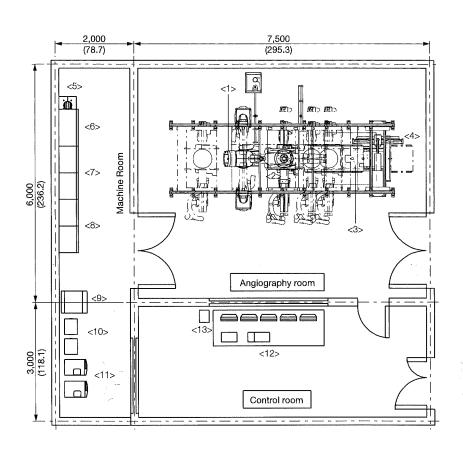


Digital Radiography (DFP-8000B/B2)



**FPD Coolant Circulator** 

# TYPICAL LAYOUT



- <1> Floor-mounted C-arm Support (CAS-880A)
- <2> Ceiling-suspended Ω-arm Support (CAS-820B)
- <3> Catheterization Table (CAT-850B)
- <4> Ceiling-Suspended Monitor
- <5> Cabinet Side Cover
- <6> System Cabinet (DFP-8000B/B2 Main Unit)
- <7> Power Cabinet (XTP-8100XG)
- <8> CAS Control Cabinet
- <9> RAID Unit (DFP-8000B/B2)
- <10> X-ray Tube Heat Exchanger (HEX-125)
- <11> FPD Coolant Circulator
- <12> System Console
- <13> System Cabinet for Control Room

Unit: mm (in)

### **TOSHIBA MEDICAL SYSTEMS CORPORATION**

1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan

# http://www.toshibamedicalsystems.com

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To shiba Medical Systems Corporation meets internationally recognized standards for Quality Management System ISO 9001, ISO 13485.

To shiba Medical Systems Corporation Nasu Operations meets the Environmental Management System standard ISO 14001.

Infinix is a trademark of Toshiba Medical Systems Corporation.

Attachment G

# **EQUIPMENT COMPARISON (For Cath Lab #8)**

Interventional Procedures		
Left and Right Heart Caths,	N/A	Type of Procedures New Equipment is Capable of Performing
	Interventional Procedures	
N/A	Left and Right Heart Caths,	Type of Procedures Currently Performed on Existing Equipment
None	None	Percent of Change in Per Procedure Operating Expenses (by procedure)
None	None	Percent of Change in Patient Charges (by procedure)
253	253	Number Days in Use/To Be Used in N.C. per Year
CMC – 1000 Blythe Blvd.	CMC – 1000 Blythe Blvd.	Locations Where Operated
\$2,136,000	\$884,260	Net Purchase Price of Equipment
N/A	\$612,126	Fair Market Value of Equipment
\$2,136,000	\$884,260	Total Cost of Equipment (Cardiac Catheterization Equipment Only)
\$4,024,000	\$1,706,000	Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use>
New	New	Specify if Equipment Was/Is New or Used When Acquired
Title	Title	Does Provider Hold Title to Equipment or Have a Capital Lease?
Fall 2016	January 2009	Date of Acquisition of Each Component
N/A	N/A	Mobile Tractor Serial Number/VIN #
N/A	N/A	Mobile Trailer Serial Number/VIN #
Fixed	Fixed	Specify if Mobile or Fixed
CHS Asset # / Serial #	CHS Asset # / Serial #	Provider's Method of Identifying Equipment
Not Available Until Installed	W1B08Y2046	Serial Number
ELT/EP/8/8.000	DFP-8000A/W1	Model Number
N/A	N/A	Tesla Rating for MRIs
Toshiba	Toshiba	Manufacturer of Equipment
Vascular Biplane Cath Lab	ı	
Infinix Elite Cardio/Neuro	Biplane Cath Lab System	Type of Equipment (List each component)
Replacement Equipment	Existing Equipment	
		EQUALITATION CONTRACTOR OF (E.O. CHOM MIND (FO)

Attachment H

# Case Volume September 2014 - August 2015: Cardiovascular Lab #8

Sep-14	30
Oct-14	40
Nov-14	33
Dec-14	36
Jan-15	29
Feb-15	27
Mar-15	31
Apr-15	46
May-15	29
Jun-15	44
Jul-15	41
Aug-15	35
Total	421

Attachment I



Toshiba America Medical Systems, Inc. 1965 Evergreen Blvd., Suite 300, Duluth, GA 30096 Tel: (770) 331 - 0675 jkeating@tams.com www.medical.toshiba.com

AUGUST 12, 2015

Chris Hollar
Manager, Equipment Planning
Carolinas Healthcare System
4828 Airport Center Pkwy., Charlotte, NC 28208

Dear Chris,

In reference to the equipment trade-in on quotations # 72006-6 # 71923-4, Toshiba agrees not to sell such equipment to any other customer unless such customer agrees to obtain CON approval, if required."

Warm regards,

John K. Keating

ZONE VICE PRESIDENT, MID SOUTH