DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

March 23, 2018

Ms. Lynn DeJaco
155 Memorial Drive
Pinehurst, NC 28374

Exempt from Review – Replacement Equipment

Record #:	**2552**
Facility Name:	FirstHealth Moore Regional Hospital
FID #:	943358
Business Name:	FirstHealth of the Carolinas, Inc.
Business #:	737
Project Description:	Replace existing electrophysiology lab
County:	Moore

Dear Ms. DeJaco:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of March 14, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Toshiba Inifinix-1 electrophysiology system to replace the existing Philips Healthcare Digital C-Arm electrophysiology system. This determination is based on your representation that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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.

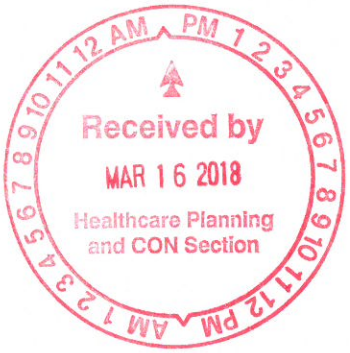
Sincerely,

Tanya S. Rupp
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Amy Craddock, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

FirstHealth
OF THE CAROLINAS



March 14, 2018

Ms. Martha Frisone
Chief, Healthcare Planning and Certificate of Need Section
Department of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Bus ID 737
NR ID 2552
F.D 943358

RE: Request for No Review Determination for Replacement of Electrophysiology System Located at FirstHealth Moore Regional Hospital / Moore County

Dear Ms. Frisone:

Pursuant to 10A NCAC 14C.0202, FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital ("FMRH") intends to replace an existing electrophysiology ("EP") system and requests a determination that such replacement is exempt from review because it falls within the definition of NCGS § 131E-184 (a)(7) and the regulations set out in 10A NCAC 14C.0303.

Statement of Facts

FHMR owns and operates two EP systems. The two EP systems performed 1,754 procedures on 1,112 patients in FY2017. Both EP systems operate 10 hours per day, Monday-Friday. The EP systems average 3.37 procedures per day per room with an average room time per case of 2.25 hours; cleaning requires an additional 30 minutes. It is FMRH's intent to replace an existing Philips Healthcare EP system with a Toshiba Medical Infinix-I system.

Exemption from Review

Pursuant to NCGS § 131E-184(a): "The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment."

NCGS § 131E-176(22a) defines "replacement equipment" as equipment that costs less than $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.

Applicable Regulations

10A NCAC 14C.0303 defines "comparable medical equipment" as equipment that "is functionally similar and which is used for the same diagnostic or treatment purposes." Replacement equipment is comparable if:

(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% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

Replacement equipment is not comparable to the equipment being replaced if the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Compliance

FMRH hereby certifies that:

1. The total estimated project cost for the replacement of the existing EP system is $1,387,852. This assumes purchase of a Toshiba Medical Infinix-I system per the attached quotation in Exhibit C.

2. The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use, which will be traded in for disposal and removed from North Carolina. A comparison of the existing and replacement equipment is provided in Exhibit B.

3. The replacement equipment is functionally similar to existing equipment and will be used for the same diagnostic and/or treatment procedures as the equipment currently in use.

4. No increase in charges will occur within the first twelve months after the replacement equipment is acquired.

5. The average cost per EP procedure increases by $86.55 (< 1.0%) as a result of the replacement. This assumes 5 years depreciation on equipment and 1,800 procedures per year on the EP systems. Savings on equipment maintenance, labor, and supplies may, in fact, offset this increase.

Determination Requested

FMRH requests that the Division of Health Service Regulation make a determination that the replacement of an EP system, as proposed herein does not constitute a new institutional health service and is thus exempt from certificate of need review.

If you require additional information concerning this request, please contact me at 910-715-1000.

Sincerely,

Lynn DeJaco
Senior Vice President and CFO

Attachments: Exhibit A - Proposed Total Capital Cost of Project
Exhibit B - Existing/Replacement Equipment Comparison
Exhibit C - Vendor Quote

EXHIBIT A

PROPOSED CAPITAL COSTS

Project name: EP System Replacement

Proponent: FirstHealth Moore Regional Hospital

Construction Contract	
(7) A&E Fee	$45,000
(8) Cost of materials/labor	$385,770
(9) Other (Please see Exhibit C)	$51,877
(10) Sub-Total Construction Contract	***$482,647***
Miscellaneous Project Costs	
(11) Building purchase	N/A
(12) Fixed equipment purchase/lease (EP System)	$704,037
(13) Mobile equipment purchase/lease (Intra-Cardiac Imaging)	$75,000
(14) Furniture	N/A
(15) Landscaping	N/A
(16) Consultant fees	N/A
(17) Financing costs (e.g. bond, loan, etc.)	N/A
(18) Other (10% Project Contingency)	$126,168
(19) Other (Specify)	N/A
(20) Sub-Total Miscellaneous	***$905,205***
(21) TOTAL CAPITAL COST OF PROJECT	**$1,387,852**

To the best of my knowledge, the above capital costs for the proposed project are complete and correct, and it is the intent of FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital to carry out the proposed project as described.

Lynn DeJaco, Senior Vice-President and CFO

3/14/18
Date

EQUIPMENT COMPARISON

EXHIBIT B

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	EP System	EP System
Manufacturer of Equipment	Philips healthcare	Toshiba
Tesla Rating for MRIs	N/A	N/A
Model Number	Digital C-Arm	Infinix-I
Serial Number	00104	TBD at purchase
Provider's Method of Identifying Equipment	Research, Quality, and Price	Research, Quality, and Price
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN#	N/A	N/A
Mobile Tractor Serial Number/VIN#	N/A	N/A
Date of Acquisition of Each Component	03/2004	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	N/A	$1,387,852
Total Cost of Equipment	N/A	$704,037
Fair Market Value of Equipment	$0	$704,037
Net Purchase Price of Equipment	N/A	$704,037
Locations Where Operated	FMRH	FMRH
Number Days in Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	0.0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	< 1.0%
Type of Procedures Currently Performed on Existing Equipment	Electrophysiology	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Electrophysiology

EXHIBIT C

Project Budgeting Sheet

Project Name :	EP Lab (Rev. 1)	**Date:**	26-Feb-18
Project Number :		**Contact:** Roger Noble	**Phone:** 715-1237
Project Manager:	Michael Regenhardt	**Phone:**	715-1525

General Scope:

This budget is for "Construction Only". The Project is for the replacement of the equipment to include minor renovation of the room, along with the plumbing, mechanical and electrical.

	Cost
	(Do Not Enter Amounts Below)
A&E--A	$45,000.00
Construction--L	$385,770.00
Permits & Testing--C	$3,500.00
FF&E - IS--Q	$0.00
FF&E - Security--S	$0.00
FF&E - Materials Mgmt--N	$0.00
FF&E - Equipment--E	$0.00
Land	$0.00
Legal	$0.00
Other	$4,500.00
Contingency--R	$43,877.00
Site Development	$0.00
Total	$482,647.00

Notes: "Construction Only"

NOTE: CATEGORIES SHOULD INCLUDE A&E FEES, CONSTRUCTION, PERMITS & AGENCY, FF&E, AND CONTINGENCY

Vendors & Budget Buckets		Cost
A&E		
MEAA		$45,000.00
	Total	$45,000.00
Construction		
Budget Number		$385,770.00
		$0.00
	Total	$385,770.00
Permits & Testing		
The Village		$500.00
DHSR		$3,000.00
	Total	$3,500.00
FF&E - IS		
	Total	$0.00
FF&E - Security		
	Total	$0.00
FF&E Materials Mgmt		
		$0.00
	Total	$0.00
FF&E Equipment		
	Total	$0.00
Land		
	Total	$0.00
Legal		
	Total	$0.00
Other		
T&B Reports (Pre & Post)		$4,500.00
	Total	$4,500.00
Contingency		
10%		$43,877.00
	Total	$43,877.00
Site Development		
	Total	$0.00
	Vendors Total	**$482,647.00**

100 Queens Road
Suite 200
Charlotte NC
28204
704/372-2750
Fax: 704/372-6278

McCULLOCH ENGLAND ASSOCIATES
ARCHITECTS

February 26, 2018
P1805/11

Mr. Michael Regenhardt
Project Manager/ Planning, Design & Construction
FirstHealth of the Carolinas
35 Memorial Drive Door #3
P.O. Box 3000
Pinehurst, NC 28374

Re: A/E Letter of Proposal
EP Lab
Moore Regional Hospital

Dear Michael:

Thank you for the opportunity to provide the Letter of Proposal for the design work related to EP Lab. We have based this proposal on the following:

1. Scope is to include equipment replacement in an existing Cath Lab to become an EP Lab.
2. Coordinate all design work with the Hospital.
3. Complete the construction documents including A/E.
4. Assist the contractor during the pricing phase (meetings, calls, etc.)
5. Assist in permitting the project.
6. Follow the project through construction (submittals reviews, etc.)
7. The estimate below is based on a recent project with the non-applicable portions removed. We originally did not have information on the brand or type of equipment to be placed in the lab. Roger let us know that it would be a single c-arm floor mounted system with an exam light and 55" monitor hung from of above and no med gas work will be required. Based on this we would revise our estimate as follows. I have reviewed this with Rodgers and have assembled costs based on the same recent projects used for the original estimate.

Demo	$4,000
Fire watch allowance	$3,000
Concrete patch	$1,000
Unistrut supports allow. inadequate)	$15,000 (included incase current struct. Is
Misc. materials	$1,500

McCULLOCH ENGLAND ASSOCIATES

Clean-up labor	$2,200
Temp Labor	$7,500
Fire proofing	$4,500
Caulking	$1,500
Resilient Flooring	$10,000
Paint	$4,000
Specialties	$1,000
Remove Equipment	$1,500
GPR Scan Floor	$2,500
No Med Gas	$0
Min. HVAC	$3,500
Electrical	$150,000
Fee	$23,000
Con Cont.	$15,000
General Conditions/Stage/Log	$85,000
Applied Costs	$2,000
Insurance	$8,000
Permits	$5,000
Total	$350,700

Estimated Cost: $350,700 x 1.10 (contingency)= $385,770

Architectural and Engineering Fee

For this work, McCulloch England Associates Architects proposes the following fees:

$43,500
Reimbursable costs (printing, copying, etc.) are not included in the fees noted above. We estimate our reimbursable expenses not to exceed $1,500. This assumes 3 CA visits and 3 design visits for A/E.

McCulloch England Associates Architects appreciates the opportunity to work with you, Moore Regional Hospital and FirstHealth of the Carolinas. If you should have any questions regarding this proposal, please do not hesitate to contact me.
You may authorize these services by signing one copy of this proposal letter and returning it to our office for our records.

Sincerely,

McCulloch England Associates Architects

Michael K. Satterfield, AIA LEED AP

Date

TOSHIBA MEDICAL

Made For life

QUOTATION/ORDER SUMMARY

DATE: 9/25/2017
SID #: 30044166
QUOTE #: 111058-2

PRESENTED TO:

FIRSTHEALTH MOORE REGIONAL HOSPITAL
35 MEMORIAL DR
PINEHURST, NC. 28374

DELIVER TO:

FIRSTHEALTH MOORE REGIONAL HOSPITAL
35 MEMORIAL DR
PINEHURST, NC. 28374

VL/CARD/2.000
INFINIX-I FOR INTERVENTIONAL CARDIOVASCULAR

SPECIAL INFORMATION & TERMS

- This price is offered contingent on the receipt of a purchase order and signed quotation by September 29, 2017.
- This system includes a twenty-four (24) month warranty excluding Vital Images products and products not manufactured by Toshiba as identified in the Product Warranty and Service Coverage, Warranty Exclusions section of this quote.

This quotation shall remain valid until 09/29/2017.
All prices are F.O.B. destination.
Payment terms are: Cash - 0% down payment, 80% upon shipment, 20% net 45 days upon completion of installation and/or availability for first use, whichever is earlier.

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 August 1, 2017. Reference contract no. PP-IM-288

Please return signed quotation to Toshiba America Medical Systems by email OrderAdmin@tams.com or fax 714-441-9320.

ACCEPTED AGREED AND ORDERED:

PURCHASER'S SIGNATURE/TITLE _____ DATE _____

TOSHIBA REP / CONTACT _____ DATE _____

TOSHIBA MEDICAL

Made For life

EQUIPMENT SUMMARY:

VL/CARD/2.000 **INFINIX-I FOR INTERVENTIONAL CARDIOVASCULAR**

PART NUMBER	QTY	DESCRIPTION
VE-ELT/FM8-880/8.100	1	SYSTEM KIT: INFINIX-I CORE+ (FLOOR MOUNT) 8"X8" FPD SYSTEM WITH CAT-880B HYBRID TABLE
	1	MAIN UNIT: INFINIX-I CORE+ (FLOOR MOUNT) 8"X8" FPD SYSTEM WITH CAT-880B HYBRID TABLE
	1	OVER HEAD HANDGRIPS / ARMREST FOR CAT-880B
	1	SINGLE ARM BOARD
	1	MUSHROOM HANDLE
	1	HEAD-END DRAPE HOLDER FOR CAT-880B
	1	2" TABLE PAD FOR CAT-880B
	1	SUPPORT ARM LOCK KIT
	1	CABINET SIDE COVER
	1	CABINET CORNER COVER
	1	21" COLOR MONITOR KIT
	1	LCD FLAT-PANEL COLOR MONITOR 21
	1	SUPINE POSITION SCOOP ARM SUPPORT
	1	ANTI-FATIGUE FLOOR MAT
	1	MAVIG TABLE MOUNTED RADIATION SHIELD
	1	COPPER PHANTOM FOR WAKE UP PROGRAM
	1	WAKEUP CHECK PROCEDURE BOOKLET
MONITOR/STAND-19-KIT.100	2	MONITOR KIT: 19" COLOR MONITOR WITH BASE PLATE - CONTROL OR EXAM ROOM
LARGELCD/B2.100	1	LARGE 58" LCD MONITOR - MEDICAL GRADE
	1	INSTALLATION CABLES FOR LARGE LCD MONITOR
	1	CABINET FOR LARGE LCD COLOR DISPLAY MONITOR
	1	UNIVERSAL CONNECTION MODULE FOR LARGE LCD MONITOR
	5	IMAGE CONNECTION MODULE FOR LARGE LCD MONITORS
A240-1092R2	1	LARGE LCD MONITOR SUSPENSION FOR CAS RAILS FOR BIPLANE, CEILING AND DUAL PLANE SYSTEMS
XBHG-002A	1	OVER HEAD HANDGRIPS / ARMREST FOR CAT-880B
XBER-001A	1	TABLE SIDE CONTROL EXTENSION RAIL SET (PAIR)

TOSHIBA MEDICAL

Made For life

PART NUMBER	QTY	DESCRIPTION
XBET-001A	1	FOOT-END TABLE EXTENSION (REQUIRES XBER-001A)
9407	1	KNEE SUPPORT PAD
PX17-36730-1	1	I/V STAND
4.0M-CEILING-TRACK4.0.100	1	MAVIG 4.0 M CEILING TRACK FOR RADIATION SHIELDS, LIGHTS AND MONITORS
OT90001-US	1	MAVIG PORTEGRA2 (95/90 CM) EXTENSION SPRING ARM WITH CENTER MOUNTED CONTOUR CUT-OUT SHIELD (61X76 CM)
LE90043	1	MAVIG PORTEGRA2 (90/95 CM) EXTENSION SPRING ARM WITH M130 LED LAMP - EXTENDED ARM
XIDF-QCA850/B.100	1	BASIC KIT FOR CLINICAL ANALYSIS APPLICATION
XIDF-QCA851	1	QUANTITATIVE CORONARY VESSEL ANALYSIS - 9MM OR LESS
XIDF-QCA852	1	QUANTITATIVE VESSEL ANALYSIS - 9MM OR ABOVE
XIDF-QCA853	1	LEFT VENTRICULAR ANALYSIS (SINGLE PLANE)
XIDF-AWS801/B3.100	1	SYSTEM KIT: INFINIX-I ANGIO WORKSTATION (AWS) WITHOUT 3-D ANGIO SOFTWARE
	1	IMAGE CONNECTION MODULE FOR LARGE LCD MONITORS
	1	MULTIPURPOSE TABLESIDE CONTROL KEYBOARD AND MOUSE EXTENSION KIT FOR AWS, AND UP TO THREE OTHER PORTS
XIDF-DTS802	1	DOSE TRACKING SYSTEM
DFP-UPS-9PX6K-APT0713.100	1	SYSTEM KIT: UPS FOR INFINIX-I DIGITAL PROCESSOR
6700012	1	PDU-VASCULAR

TOTAL QUOTE PRICE
Applicable Sales Tax Additional

$704,037.00

FINANCE OPTIONS:
Finance options are available through Toshiba America Medical Credit (TAMC), a program of Toshiba America Medical Systems, Inc.

TAMC OFFERINGS:

- Fair Market Value, $1.00 Buy Out (Lease to Own), and Loan structures
- Finance terms ranging from 12 months to 84 months
- Financing for 3rd party assets (including, but not limited to leasehold improvements & I.T.)

TAMC BENEFITS:

- No progress payments. Payments begin after delivery and installation
- Upgrades to the current technology platform can be financed.
- Flexible finance structures, such as deferred payments, tiered repayments, and bridge financing, to meet cash flow needs

TAMC finance options are subject to credit underwriting, approval, and a fully executed contract.

For more information, please contact Trish Malone, Dir. Financial Programs at:
TMalone@tams.com or +1 714 669 1226

INFINIX-I FOR INTERVENTIONAL CARDIOLOGY

Optimized for Interventional Cardiologists, Infinix-i has the tools, the technology and the system to help clinicians reduce risk and save time in a complex and demanding clinical environment. Combining industry-leading image quality and dose management capabilities with exclusive ergonomic features and an array of advanced imaging applications, Infinix-i can enhance performance for every patient and every procedure.

Designed in collaboration with cardiologists, Infinix-i improves the way we work without changing the way we work. With exclusive technology like WorkRite, it allows the performance of lengthy procedures more comfortably and effectively.

The Infinix-i is strategically designed to help you grow with your practice. Image the most complex coronary or peripheral artery diseases while enabling structural heart interventions. The unique mechanical design is perfectly suited to enable flexible position for faster, safer exams while creating an integrated cath lab environment.

WorkRite Technology:
The unique flexibility and design of the C-arm, combined with low-profile FPD housing, offers better ergonomic orientation enabling "line of sight" over the system and patient to view the display monitors. The Infinix-i product line has an extensive lateral C-arm movement, at the head end of the table, affords an exceptional advantage when accessing the upper extremities, such as in a radial or brachial procedure. The flexible mechanical design provides extensive longitudinal travel to allow full body coverage from the patients head to the toes without panning the table.

Customizable features and award-winning training help you to accelerate and increase utilization of Infinix-i system innovations to enhance efficiency and help you improve patient care.

COMPONENT SUMMARY:

PART NUMBER	QTY	DESCRIPTION
VE-ELT/FM8-880/8.100	1	SYSTEM KIT: INFINIX-I CORE+ (FLOOR MOUNT) 8"X8" FPD SYSTEM WITH CAT-880B HYBRID TABLE
	1	MAIN UNIT: INFINIX-I CORE+ (FLOOR MOUNT) 8"X8" FPD SYSTEM WITH CAT-880B HYBRID TABLE

STANDARD SYSTEM COMPONENTS

• CAS-880A/A1	Multi-Axis C-arm, Floor mounted
• BLA-900C	Multi-filter Collimator
• XTP-8100XG	High-Frequency X-Ray Generator 100 kW
• DSRX-T7444GDS	Liquid Metal Bearing X-Ray Tube
• TFP-800A/A1	8″ x 8″ Flat Panel Detector
• XGCP-880BA	Tableside Control HyperHandle
• CAT-880B	Standard Catheterization Table
• XBFS-880S	Multi-Function Footswitch
• DFP-8000B/B2	Multitasking Digital Fluoroscopy Processor
• XIDF-MIC802	Intercom Kit
• XIDF-MCC80S	Main Console
• XIDF-FS801S	Control Room Footswitch
• XJDK-001A/V5	Dose Meter Controller
• XJDC-009A	Dose Chamber

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

The Infinix-i Core+ 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:

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

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

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)
  - 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

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.

MULTI-FILTER COLLIMATOR - BLA-900C

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

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)
- 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

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 1024x1024 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

DSA Acquisitions:

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

HIGH-CAPACITY X-RAY TUBE WITH LIQUID METAL BEARING - DSRX-T7444GDS

- Includes a standard 36 month non-prorated tube warranty for all new systems
- 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
- 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

8" x 8" Flat Panel Detector - TFP-800A/A1

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 diagnostic and complex interventional procedures.

Specifications:

- Multiple Fields of View
  - 8"x8 "
  - 7" x 7"
  - 6" x 6"
  - 5" x 5"
- 1024x1024 detector matrix
- Frame rates up to 30 FPS
- 194 micron pixel size
- DQE of 77±5 %
- 16-bit pixel depth for extended dynamic range

Tableside Control HyperHandle - XGCP-880BA

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 buttons, enhancing the user experience.

Catheterization Table - CAT-880B

Facilitates catheterization of cardiac, cerebral, abdominal and peripheral areas. As a Hybrid Catheterization Table, can also support some open surgical procedures. Microprocessor-controlled longitudinal movement enables table to be used for numerous radiographic techniques, movements tracked via coordinate display. The flat service eases movement of the patient on and off the table.

Specifications

- Sliding movements (manual):
  - Longitudinal stroke: 1,350 mm (53.1")
  - Lateral stroke: ±200 mm (±7.9")

- Vertical movement (motor-driven):
  - 754 mm to 1054 mm (29.7" to 41.5") (from floor level)

- Tilt:
  - 16 degrees (head up) and 16 degrees (head down). Motor drive for longitudinal shift when tilted.

- Lateral Tilt:
  - 16 degrees Left and 16 degrees Right. (Manual lateral panning is possible, even when tilted laterally).

- Tabletop rotation range (manual pivot):
  - +90 to 0 degrees
  - 0 to -90 degrees

- Maximum patient weight:
  - 551 lbs. (250 kg IEC) at maximum table extension
  - Can support additional loading of up to 220 lbs (100 kg) for cardiopulmonary resuscitation (CPR)

- Tabletop Material – Carbon fiber reinforced plastic (CFRP)

- Accessories:
  - Tabletop mat (standard)
  - Arm Cover (option)
  - Arm support, acrylic (option)
  - Armrest, CFRP (option)

MULTI-FUNCTION FOOTSWITCH - XBFS-880S

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: to provide a more uniform, high-resolution presentation of the image during fluoroscopy.
- Virtually zero lag during fluoroscopic imaging: to further enhance visualization during movement and while manipulating wires.

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

- Use in a panning mode while imaging the lower extremities, and for Bolus Chase examinations, for a more uniform image display and background compression. This provides 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
- The combination of these two features provides the ability to better distinguish and visualize guide wires within the vessel
  - Landmark image
  - Adjust brightness and contrast real-time
  - Create using LIH or acquired image

Features include:

- Peak Pixel Roadmap – provides the optimal, live, peak, fluoroscopic-subtracted roadmap image.
- Add Subtracted Fluoroscopy – provides a completely subtracted display to better visualize live contrast injections or embolic materials.
- CO_2 DSA – provides the optimal, live, CO_2 (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.

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 Recording Unit

- High-capacity, high-speed disk (RAID Level 3):
- Maximum recording number:
- 1024x1024 8/10/12-bits: 118,800/95,000/79,200 loss-less compression
- Online recording
- DVD-R and CD-R Recording
- DICOM 3.0, 512x512 or 1024x1024 8/10/12-bits, JPEG loss-less compression
- Up to 4,800 frames at 512x512 x 8 bits

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.

INTERCOM KIT - XIDF-MIC802

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

MAIN CONSOLE - XIDF-MCC80S

- 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

FOOTSWITCH FOR CONTROL ROOM - XIDF-FS801S

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

DOSE METER CONTROLLER FOR DUAL PLANE - 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 $\mu Gycm^2$
- Dose area product rate (DAP) in $\mu Gycm^2/s$

- Calculated surface dose in mGy
- Calculated surface dose in mGy/s

DOSE CHAMBER - XJDC-009A

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.

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

**Offerings may vary per product*

APPLICATION TRAINING

Each system includes a three phase education program and the industry exclusive Performance Pro guarantee.

Performance Pro is a unique approach to education utilizing blended learning with the promise of technical proficiency and optimal productivity. If for any reason the customer is not satisfied with any portion of the training, Toshiba will conduct that portion of the training again, at no charge.

Phase I: Two (2) attendance vouchers for a four (4) day technologist-focused course held at the Toshiba Institute of Advanced Imaging in Irvine, California. This course provides the fundamentals of operating Toshiba's Infinix-i VL system, including a variety of VL exams performed with the latest dose reduction techniques. This course includes in-depth lectures and hands-on training. At the completion of the course, the attendee will be proficient in the following applications and operations: basic to advanced VL imaging console operation, system menus, system default protocols, post-processing image data, and basic troubleshooting. This course is all inclusive of the following: tuition, airfare (booked by Toshiba), lodging, and meals. Accredited for CE credits by the ASRT Education Foundation.

Phase II: An initial thirty-two (32) hours, of on-site education will be provided at the customer facility during 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, protocols and system operation. Training is scheduled consecutively, Monday through Friday, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist. CE credits are earned by participants that attend the Phase II training event in its entirety.

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 6-8 weeks following installation to optimize staff proficiency and system productivity.

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 training is offered to the Customer at no charge, providing that it is completed no later than one (1) year after the warranty start date.

Additional classroom and onsite training is available for purchase.

Applications support is available by phone on the toll-free ASSIST line, 1-800-521-1968.

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

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.

**The Infinix-i Core + is the INFX-8000V (SP)*

1 **OVER HEAD HANDGRIPS / ARMREST FOR CAT-880B**
This armrest allows the patient's arms to rest comfortably when they are positioned above the patient's head.

For use with CAT-880B Table

1 **SINGLE ARM BOARD**
Carbon fiber arm rest for the right or left side. One is included standard with CAT-850B table.

1 **MUSHROOM HANDLE**
Table mounted for convenient, quick positioning of floating tabletop with magnetic brake release.

1 **HEAD-END DRAPE HOLDER FOR CAT-880B**
Mounted on the edge of catheterization table to keep the drape away from the patient's face.

1 **2" TABLE PAD FOR CAT-880B**
Two-inch thick table pad to increase patient comfort during long procedures.
- Made with a combination of dense foam and memory foam.
- Has a black, stretch cover.

Fits CAT-880B tabletop.

1 **SUPPORT ARM LOCK KIT**

1 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.

1 CABINET CORNER COVER

This part is required for installations in which the electronics cabling for Infinix-i must be routed to floor-level cable race rather than the usual ceiling-level cable race. This part provides for both left and right end covers, whichever is needed per cable routing at individual site installation.

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

1 21" COLOR MONITOR KIT

1 LCD FLAT-PANEL COLOR MONITOR 21

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

1 SUPINE POSITION SCOOP ARM SUPPORT

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

1 ANTI-FATIGUE FLOOR MAT

1 MAVIG 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:
  - Main shield: 181 mm x 645 mm
  - Angled side shield: 700 mm x 645 mm
  - Tabletop scatter shield: 700 mm x 700 mm (removes to facilitate patient loading)
- Wall storage holders:
  - Upper shield: 600 mm
  - Lower shield: 460 mm
- Includes mini-rail for mounting table-function controls, if desired.

1 **COPPER PHANTOM FOR WAKE UP PROGRAM**
Wake Up Check test phantom for daily QA.

Includes 2mm copper and instructions to be used for the Wakeup Check protocol, which checks the imaging conditions for DA, DSA and One Shot acquisition.

1 **WAKEUP CHECK PROCEDURE BOOKLET**

MONITOR/STAND -19-KIT.100 2 **MONITOR KIT: 19" COLOR MONITOR WITH BASE PLATE - CONTROL OR EXAM ROOM**

LARGELCD/B2.100 1 **LARGE 58" LCD MONITOR - MEDICAL GRADE**
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.

Components

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

1 **INSTALLATION CABLES FOR LARGE LCD MONITOR**

1 **CABINET FOR LARGE LCD COLOR DISPLAY MONITOR**
Wall or floor mounted storage unit to house large LCD monitor electronic components.

1 **UNIVERSAL CONNECTION MODULE FOR LARGE LCD MONITOR**
The UCM enables connection of a variety of mobile medical devices for video input on the large LCD monitor. This unique design is capable of accepting and converting video signal from; DVI, VGA, BNC, and S-Video. Only one video signal can provide input at a time.

5 **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.

A240-1092R2 1 **LARGE LCD MONITOR SUSPENSION FOR CAS RAILS FOR BIPLANE, CEILING AND DUAL PLANE SYSTEMS**
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.

- Holds one large LCD monitor with a VESA 400 mount
- Total weight payload: 155 lbs (70.45 kg)
- Complete assembly included:
  - Bridge
  - 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.

XBHG-002A 1 **OVER HEAD HANDGRIPS / ARMREST FOR CAT-880B**
This armrest allows the patient's arms to rest comfortably when they are positioned above the patient's head.

For use with CAT-880B Table

XBER-001A	1	**TABLE SIDE CONTROL EXTENSION RAIL SET (PAIR)** • 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	1	**FOOT-END TABLE EXTENSION (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.
9407	1	**KNEE SUPPORT PAD** White coated pad for below the waist elevation of the upper leg via support behind the knee.
PX17-36730-1	1	**I/V STAND**
4.0M-CEILING-TRACK4.0.100	1	**MAVIG 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.
OT90001-US	1	**MAVIG PORTEGRA2 (95/90 CM) EXTENSION SPRING ARM WITH CENTER MOUNTED CONTOUR CUT-OUT SHIELD (61X76 CM)** 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.
LE90043	1	**MAVIG PORTEGRA2 (90/95 CM) EXTENSION SPRING ARM WITH M130 LED LAMP - EXTENDED ARM** The MAVIG M130F LED Lamp provides 60,000 LUX of focusable light ranging from 14 to 25 cm field size. Includes a 95/91 cm suspension arm.
XIDF-QCA850/B.100	1	**BASIC KIT FOR CLINICAL ANALYSIS APPLICATION**
XIDF-QCA851	1	**QUANTITATIVE CORONARY VESSEL ANALYSIS - 9MM OR LESS Application** XIDF-QCA850 is required. XIDF-QCA851 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 PACS server and can be referred to in the examination room and control room.

XIDF-QCA852 1 **QUANTITATIVE VESSEL ANALYSIS - 9MM OR ABOVE**

Application

XIDF-QCA850 is required. XIDF-QCA852 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 PACS server and can be referred to in the examination room and control room.
- Table side operation is available.

XIDF-QCA853 1 **LEFT VENTRICULAR ANALYSIS (SINGLE PLANE)**

Application

XIDF-QCA850 is required. XIDF-QCA853 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 PACS server and can be referred to in the examination room and control room.
- Table side operation is available.

XIDF-AWS801/B3.100 1 **SYSTEM KIT: INFINIX-I ANGIO WORKSTATION (AWS) WITHOUT 3-D ANGIO SOFTWARE**

1 **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.

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

XIDF-DTS802 1 **DOSE TRACKING SYSTEM**

DTS provides a virtual patient dose map with real time tracking of estimated peak and accumulated skin dose during an interventional procedure.

- Color-coded and easy to read 3D spatial visualization of radiation exposure to the patient and clear indication of radiation distribution.
- Real time feedback enables the clinician to make procedural adjustments and thus limit exposure in any area for prolonged periods.
- Estimation of peak skin dose available on cardiovascular/neurovascular procedures.

Please note: Dose Tracking System requires AWS 6.0 (XIDF-AWS801/B1). Additional monitors for exam room viewing may be required depending on current configuration and are not included.

DFP-UPS-9PX6K-APT0713.100 1 **SYSTEM KIT: UPS FOR INFINIX-I DIGITAL PROCESSOR**

This UPS provides protection for the imaging RAID and the electronics in the Digital Processor from being damaged during any unexpected power interruption from the main power line. Further than that, when the battery in the UPS is fully charged, this UPS is capable of handling any black out or brown out for up to 10 minutes without needing to reset the full vascular system.

During the black out, the main power supply to the X-ray generator will be out, hence not possible to perform X-ray exposure or C-arm motion. However, the Digital Processor and all the system monitors in the lab will be up and running due to the protection of this UPS. Once power is restored from the main power line, all X-ray acquisition functions and the lab mechanical motion can be performed, almost instantaneously, avoiding the need for power recycling of the vascular system.

6700012 1 **PDU-VASCULAR**

The Toshiba PDU-VASCULAR power distribution unit (PDU) is the next generation PDU designed for Toshiba's vascular x-ray system. This PDU accepts 277/480VAC, 3Ø mains input power and provides 277/480VAC non-isolated power to the XTP generator output power AND 120/208VAC, 1Ø isolated power to various power outputs.

The PDU-VASCULAR unit is enclosed in a standard, floor mount PDU enclosure similar in shape and size to its predecessor PCDU-100VL.

Includes:

- Mains input breaker with undervoltage protection
- Remote EPO capability
- Isolation transformer (120/208V outputs only).
- TEALwave filters
- Valuetrap suppressors
- PQube power monitoring

PRODUCT WARRANTY AND SERVICE COVERAGE

SYSTEM WARRANTY TERMS

Toshiba warrants that the Equipment will be free from defects in material and workmanship, for the duration and subject to the terms and conditions stated below. Any part furnished to Customer during the warranty period (stated in the table below) to correct a warranty failure will be warranted to the extent of the unexpired term of the warranty applicable to the Equipment.

The warranty period will 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 Toshiba is not responsible, the warranty period for such product may, at Toshiba' 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 Toshiba, (3) absence of any product, component, or accessory recommended by Toshiba 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 Toshiba, (6) combining Toshiba's product with any product furnished by others that is not approved by Toshiba, (7) combining incompatible products of Toshiba, without Toshiba's prior approval, (8) improper use of the product, improper maintenance of the product by a party other than Toshiba, or failure to comply with any applicable instructions or recommendations of Toshiba, or (9) acts of God, fires, floods, strikes or other labor disturbances, or other causes beyond the reasonable control of Toshiba.

Toshiba does not warrant any products not manufactured by Toshiba such as, without limitation, monitors, cameras, computer equipment, injectors, and lasers. 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 batteries, storage media, positioning pads, table pads, cassettes, magazines, printer consumables, and power units.

GLASSWARE WARRANTY

X-ray Vascular tubes are covered under a separate warranty. X-ray Vascular tubes included with the purchase of a new system is governed by the glassware warranty, described below, not the system warranty.

Tube Type	Time-Based Warranty
Liquid Bearing Tubes (DSRX-TXXXX)	36 months, non-prorated

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 on the system. For example, a tube with a 12-month non-prorated warranty fails at month eleven (11), the tube is replaced at no charge and carries a one (1) month of warranty.

REMEDIES

If Toshiba determines that any product fails to meet the above-mentioned warranty during the applicable warranty period, Toshiba will 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. Toshiba will have the option to furnish either new or remanufactured replacement parts or assemblies. However, remanufactured parts will meet the manufacturer's specifications for new components as of the date of completion of installation. All defective parts replaced by Toshiba will become the property of Toshiba.

SOFTWARE UPDATES

Toshiba will furnish to Customer, free of charge for the life of the Equipment, all Toshiba software or hardware upgrades to the Equipment purchased by Customer, which are intended to correct a safety risk. Software updates offering enhancements to previously purchased software features will be provided during the term of the warranty, if they do not require hardware modifications or additions. Software upgrades providing new features or capabilities not originally purchased, will be made available for purchase by Customer upon request when compatible with the originally purchased hardware. Toshiba retains the sole right to determine whether a software release is considered an update or an upgrade for which Customer will be charged. The above items will be performed only during the Covered Hours stated in the warranty. Service required outside these hours will be billed at Toshiba's differential rates in effect at the time such items are provided to Customer.

WARRANTY SERVICE

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

Customer must promptly notify Toshiba within the applicable warranty period of any defect that is covered by the warranty, and make the Equipment promptly available for repair and maintenance.

DISCLAIMERS AND LIMITATIONS ON LIABILITY

Toshiba' obligations stated above 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.

Toshiba does not warrant that the operation of the Equipment will be uninterrupted.

WARRANTIES BY PRODUCT LINE

ITEM TYPE	X-RAY VASCULAR
EQUIPMENT	12 Months
ACCESSORY OPTIONS	6 Months
REPLACEMENT & OPTIONAL PARTS*	90 Days
UPGRADE COMPONENTS	6 Months

* The above 90-day period applies only to parts that are not furnished pursuant to a warranty repair for the Equipment. Any part furnished to Customer during the warranty period to correct a warranty failure will be warranted to the extent of the unexpired term of the warranty applicable to the System.

TERMS AND CONDITIONS OF SALE

1. 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.

2. 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 will be as stated in the first page of this Quotation. 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.

3. DELAYS. If Customer changes the scheduled delivery date specified on the first page of this Quotation/Order ("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.

4. EQUIPMENT INSTALLATION. Toshiba 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. 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, 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.

5. 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.

6. LIMITED WARRANTY AND REMEDY. A. 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 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 parts, including software required to correct any defect in the Equipment or as required under applicable laws.

B. 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.

7. LATEST HARDWARE AND SOFTWARE AT TIME OF DELIVERY. Toshiba agrees that the Equipment ordered by Customer will, at the time of delivery to Customer, contain, at no additional charge to Customer, the latest hardware and software manufactured by Toshiba for such Equipment that are commercially available in the United States and which are provided as part of Toshiba's standard configuration for such Equipment at the time of delivery. This commitment applies only to components and not an upgrade to the entire system. Furthermore, it is limited to hardware and software that (a) have been ordered by Customer, and not any optional or other items that were not ordered by Customer, and (b) are cleared by the FDA as of the date of delivery of the Equipment.

8. LIMITATION OF LIABILITY. A. 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 TO THE TRANSACTIONS CONTEMPLATED IN THIS AGREEMENT, EVEN IF EITHER PARTY IS APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING.

B. IN NO EVENT WILL TOSHIBA'S LIABILITY TO THE CUSTOMER (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 THE 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.

9. 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. 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.

10. 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.

11. REMEDIES OF TOSHIBA. If Customer fails to make any payment when due under this Agreement, 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 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.

12. EXCUSED PERFORMANCES. Except for Customer's payment obligations hereunder, 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, delays caused by suppliers, or laws, regulations, or acts of any governmental agency.

13. 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. In the event a third party's software is furnished to Customer, Customer may be required to execute a software license agreement as requested by such third party as a condition to delivery and/or purchase of the third party's product. Toshiba will furnish Customer with a copy of such license agreement for its review and execution. In the event Customer sells the Equipment to a third party, the purchaser thereof will have the same rights and obligations with respect to any Toshiba software as Customer. Customer will need to make its own determination whether it needs to obtain any consent from a third party for non-Toshiba software.

14. CANCELLATION. Customer may not cancel the order subject to this Agreement except with Toshiba's prior written consent. In the event of cancellation without Toshiba's written consent, Toshiba will be entitled to recover liquidated damages in an amount equal to twenty percent (20%) of the purchase price of the Equipment

15. 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 items not manufactured by Toshiba and the warranty thereof may be performed by Toshiba's contractors or suppliers.

16. 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.

17. 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 reasonable attorney's fees, expert fees, and court costs against the non-prevailing party.

18. ENTIRE AGREEMENT. This quotation 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.