



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

**VIA EMAIL ONLY**

April 3, 2020

Elizabeth V. Kirkman  
Elizabeth.Kirkman@atriumhealth.org

**Exempt from Review – Replacement Equipment**

**Record #:** 3250  
**Facility Name:** Carolinas Medical Center  
**FID #:** 943070  
**Business Name:** The Charlotte-Mecklenburg Hospital Authority  
**Business #:** 1770  
**Project Description:** Replace existing vascular system (including replacing a mobile intravascular ultrasound with a fixed intravascular ultrasound) and perform necessary renovations to install replacement equipment in Vascular Lab #6  
**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 March 30, 2020, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Philips Azurion 7 M20 to replace the Toshiba Infinix VF-I/SP in Vascular Lab #6. This determination is based on your representations 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, Radiation Protection, and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

**NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION  
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION**

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603  
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704  
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

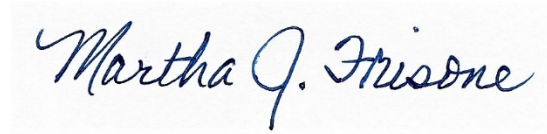
Ms. Kirkman  
April 3, 2020  
Page 2

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,



Julie M. Faenza  
Project Analyst



Martha J. Frisone  
Chief

cc: Construction Section, DHSR  
Radiation Protection Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR



# Atrium Health

March 30, 2020

Ms. Martha Frisone, 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: Exemption Request for The Charlotte-Mecklenburg Hospital Authority ("CMHA") to Replace Vascular Lab Equipment located on the campus of Carolinas Medical Center ("CMC")

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC"), seeks to acquire a Philips Azurion 7 M20 vascular 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 Infinix VF-I/SP vascular system ("Existing Equipment") that was acquired in 2011. The Existing Equipment is currently housed in vascular lab #6 in room 06D105 on the sixth floor of CMC's main hospital building located at 1000 Blythe Boulevard in Charlotte, NC 28203 (see Attachment B).

The proposed project also includes the replacement of an existing mobile intravascular ultrasound ("IVUS") unit with a fixed IVUS unit that will be located in vascular lab #6. The fixed IVUS unit will be integrated with the other vascular equipment housed in lab #6 and will therefore be better suited for the vascular procedures that are performed there.

As part of this project, CMC plans to renovate vascular lab #6 and the surrounding suite. Vascular lab #6 will undergo several infrastructure upgrades, including installing additional framing to the existing overhead support structure and relocating and enhancing the existing power supply to accommodate the Replacement Equipment. Vascular lab #6 and the surrounding suite will also undergo a number of aesthetic upgrades, including replacement of the existing flooring and ceiling and the installation of new countertops, lighting, millwork and other finishes.

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 vascular lab #6 in room 06D105 on the sixth floor of CMC’s main hospital building located at 1000 Blythe Boulevard, Charlotte, NC 28203, which is the site from which CMC provides clinical patient services and exercises financial and administrative control over the entire facility (see Attachment B). CMC’s Facility Executive’s office is located on the second floor of the main hospital building. Please see a copy of CMC’s license in Attachment A.

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 Equipment is \$1,375,504 (\$1,279,550 vascular system, injector and intravascular ultrasound + \$95,954 Tax). Quotes for the Replacement Equipment and supporting equipment are provided in Attachment C. The projected total capital cost of



the project is \$2,536,482 (including taxes and freight) and includes the removal of the existing equipment and installation of the Replacement Equipment. The total capital cost for the proposed project is provided in Attachment D.

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

The Existing Equipment is currently located in room vascular lab #6 in room 06D105 on the sixth floor of CMC's main hospital building (see Attachment B). The Replacement Equipment will also be located in vascular lab #6 (see Attachment B).

**C. Certificate of Need Issued for Equipment Being Replaced**

This proposal also fits within the exemption criterion in Section 131E-184(f)(2) because the Department previously granted an exemption for the Existing Equipment pursuant to a Settlement Agreement from April 2011 between CMHA and the Department (see Attachment E). The Existing Equipment was purchased in 2011.

**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 vascular procedures for which it currently uses the Existing Equipment. The Existing Equipment is a Toshiba Infinix VF-I/SP vascular system that was acquired in 2011. The Existing Equipment has been used for vascular 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 vascular 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).

Documentation provided in Attachment H indicates that 593 cases were performed from March 2019 to February 2020 on the Existing Equipment.

#### **E. Disposition of Equipment**

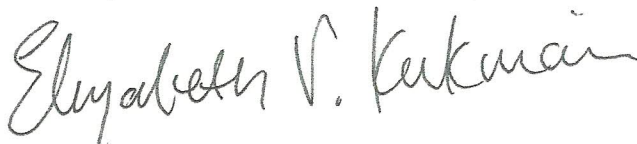
Please see Attachment I for a letter documenting the Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

#### **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,



Elizabeth V. Kirkman  
Assistant Vice President  
Atrium Health Strategic Services Group

Attachments

cc: Chan Roush, Vice President and Facility Executive, Carolinas Medical Center

# Attachment A



# State of North Carolina

Department of Health and Human Services  
Division of Health Service Regulation

*Effective January 01, 2020, 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: 1211**

**General Acute 1055, Rehabilitation 13, Psych 132, Substance Abuse 11,**

**Dedicated Inpatient Surgical Operating Rooms: 10**

**Dedicated Ambulatory Surgical Operating Rooms: 9**

**Shared Surgical Operating Rooms: 41**

**Dedicated Endoscopy Rooms: 12**

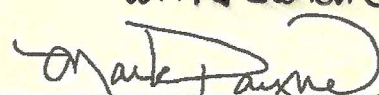
*Please note:*

*The # of ORs reflected  
here is incorrect. We  
are currently working  
with the licensee to fix it.*

Authorized by:



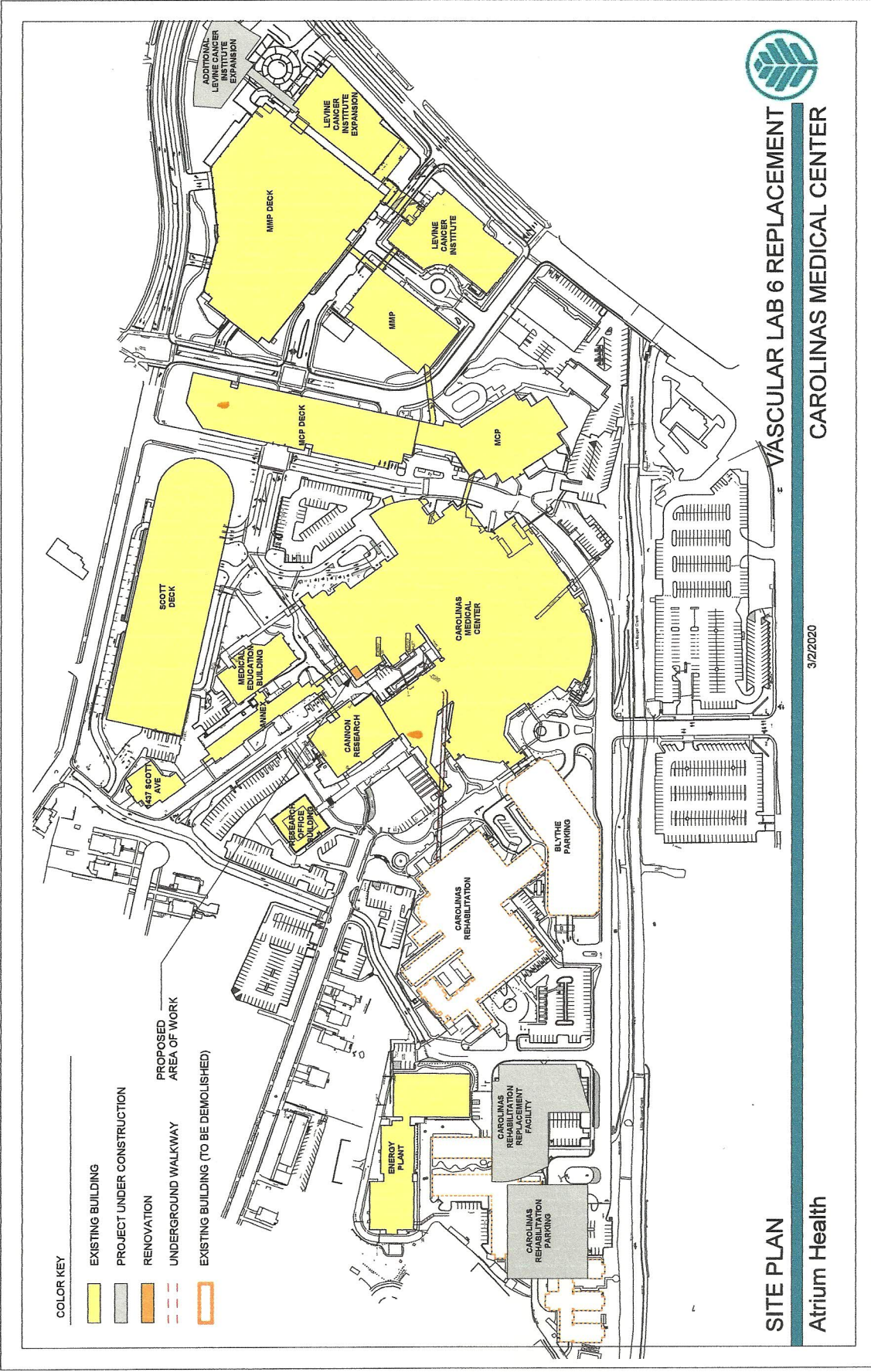
Secretary, N.C. Department of Health and  
Human Services



Director, Division of Health Service Regulation








# Attachment B



**VASCULAR LAB 6 REPLACEMENT**  
**CAROLINAS MEDICAL CENTER**

**SITE PLAN**  
**Atrium Health**

COLOR KEY

-  EXISTING BUILDING
-  PROJECT UNDER CONSTRUCTION
-  RENOVATION
-  UNDERGROUND WALKWAY
-  EXISTING BUILDING (TO BE DEMOLISHED)

PROPOSED  
AREA OF WORK



VASCULAR LAB 6 REPLACEMENT  
CAROLINAS MEDICAL CENTER

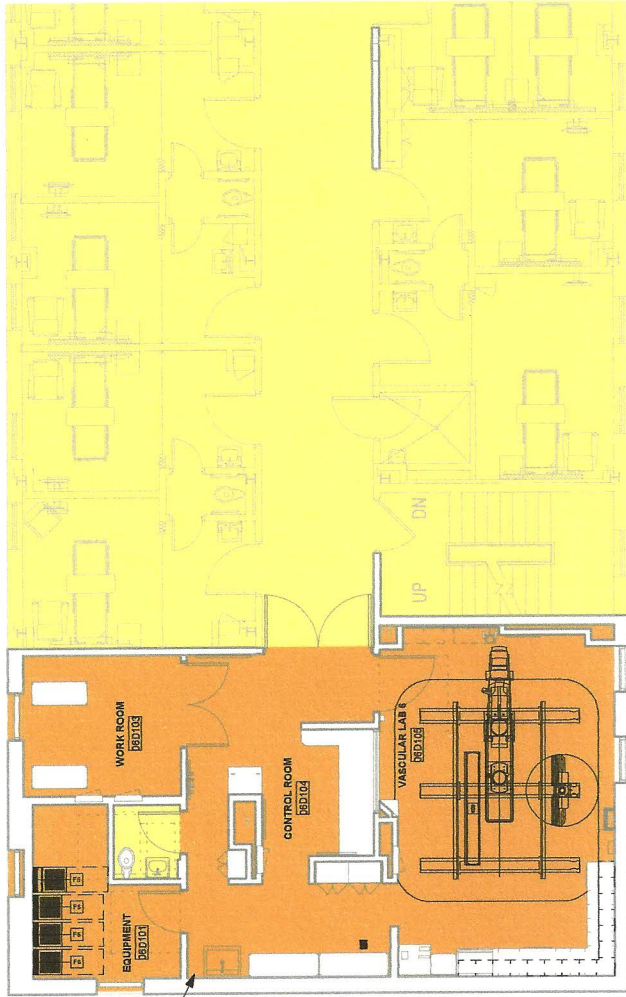
CURRENT ENLARGED LEVEL 06 FLOOR PLAN  
Atrium Health

03/02/2020



- COLOR KEY**
- EXISTING BUILDING
  - PROJECT UNDER CONSTRUCTION
  - RENOVATION
  - UNDERGROUND WALKWAY
  - EXISTING BUILDING (TO BE DEMOLISHED)

PROPOSED AREA OF WORK



VASCULAR LAB 6 REPLACEMENT  
 CAROLINAS MEDICAL CENTER

03/02/2020

PROPOSED ENLARGED LEVEL 06 FLOOR PLAN  
 Atrium Health



# Attachment C

PHILIPS HEALTHCARE  
A division of Philips North America LLC  
22100 Bothell Everett Highway  
P.O. Box 3003  
Bothell, Washington 98041-3003

# PHILIPS

<b>Quotation #:</b> 1-1WI09S4	<b>Rev:</b> 6	<b>Effective From:</b> 15-Jan-20	<b>To:</b> 31-Mar-20
<b>Presented To:</b> CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY DBA ATRIUM HEALTH 1000 BLYTHE BLVD CHARLOTTE, NC 28203-5871  Tel:  <b>Alternate Address:</b>	<b>Presented By:</b> Kimberly Bates <i>Account Manager</i>  John Hill <i>Regional Manager</i>	<b>Tel:</b> (704) 467-9256 <b>Fax:</b>  <b>Tel:</b> (800) 722-7900 x6806 <b>Fax:</b>	
<b>Date Printed:</b> 15-Jan-20			
<b>Submit Orders To:</b> 22100 BOTHELL EVERETT HWY BOTHELL WA 98021  Tel: (888) 564-8643 Fax: (425) 458-0390			

This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips North America LLC ("Philips") and is intended for use only by the customer whose name appears on this quotation. It may not be disclosed to third parties without the prior written consent of Philips.

**IMPORTANT NOTICE:** Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

## Quote Solution Summary

<u>Line #</u>	<u>Product</u>	<u>Qty</u>	<u>Price</u>
	100237 Azurion 7 M20	1	\$1,128,857.80
Equipment Total:			\$1,128,857.80

## Solution Summary Detail

<u>Product</u>	<u>Qty</u>	<u>Each</u>	<u>Monthly</u>	<u>Price</u>
100237 Azurion 7 M20	1	\$1,128,857.80		\$1,128,857.80

**Buying Group:** CAROLINAS HEALTHCARE SYSTEM SCA

**Contract #:** CAA0013200

**Add'l Terms:**

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

**Payment Terms: 0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice**

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## Quote Summary

100237 Azurion 7 M20

Qty	Product
1	NNAE771 Azurion 7 F20
8	FCV0588 Isolated Wall Connection Box
1	NCVD069 ClarityIQ.
2	FCV0824 video WCB on rear side 1st MCS
2	FCV0812 live/ref slaving for ER
1	FCV0809 addl 27" LCD Exam Room
1	NCVD061 optional ref monoplane
1	NCVA694 Subtracted Bolus Chase
1	NCVA101 peripheral X-ray filter
1	NCVA851 Swivel for table base.
1	NCVC199 Wireless footswitch: mono-plane version
1	NCVD064 extension to FlexVision Pro
1	NCVD072 SmartMask Monoplane
1	NCVD081 Touch Screen Module Pro
1	NCVD078 FD Dual Fluoro monoplane
1	NCVD128 storage extension
1	NCVD032 FlexVision XL HD + 2 LCD's
1	NCVD178 IW Hardware
1	NCVD052 addl integr. for 2F 3rd p boom
1	FCV0510 Long mattress cardio
1	NCVC664 SmartPerfusion
2	FCV0589 Legacy Video Convertor
1	980406041009 Rad Shield w/ Arm (Contoured) 61X76
1	989801220012 Cable Spooler
1	989801220037 M LED 3MC Light
1	989801220273 Ceiling Track w/Column & Handle Ext
1	989801220375 Black Anti-fatigue Floor Mat w/logo.
1	989801220388 Lower Body Protection
1	989801220514 · Compact Low Load Fluoro UPS – Standard
1	NNAE957 Clinical Education Program for SmartPerfusion
1	NNAE159 30Fr/sec Extension
1	SP003 Installation Labor
1	Third Party Item Additional ceiling mounted monitor



## Quote Summary

100237 Azurion 7 M20

Qty	Product
1	Third Party Item MedRad Injector Interface cable
1	SP019 Trade in Allowance

### Options

Qty	Product
1	989801220158 Mark 7 Arterion, Table Mount

# Quotation

**Sales Support**  
tel (800) 633-7231  
fax (412) 406-0952  
[radiologysolutions.bayer.com](http://radiologysolutions.bayer.com)

**Bayer HealthCare LLC**  
1 Bayer Drive  
Indianola, PA 15051



Quote No. Q-00034353

**This quotation has been prepared for: Carolinas Healthcare System**

**Issued on** 1/22/2020

**Valid until** 3/31/2020

**Trade-in required** Yes

## Your Bayer Sales Team:

**Anthony Capuzzi** 724-940-7453, , [anthony.capuzzi@bayer.com](mailto:anthony.capuzzi@bayer.com)

## Quotation Overview

**PREMIER RADIOLOGY T7 & T8 Pricing Applied**

Bayer's diagnostic imaging products, software, and equipment service help healthcare teams in radiology address their critical

**Please note:** If pricing and terms of this [order/quote] 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.

### Imaging Products and Services

Product Name

YOUR PRICE

Arterion - Medrad® Mark 7 Arterion® Injection System

**TOTAL** (Local taxes, shipping and/or handling to be invoiced when applicable)

**TOTAL**

**SHIPPING & HANDLING**

\$163.46

**GRAND TOTAL** (Local taxes, shipping and/or handling to be invoiced when applicable)

**\$30,528.86**

If your organization is tax exempt, please notify Sales Support at 1-800-633-7231.

# Quotation

**Sales Support**  
tel (800) 633-7231  
fax (412) 406-0952  
[radiologysolutions.bayer.com](http://radiologysolutions.bayer.com)

**Bayer HealthCare LLC**  
1 Bayer Drive  
Indianola, PA 15051



Quote No. Q-00034353

**This quotation has been prepared for: Carolinas Healthcare System**

**Issued on 1/22/2020**

**Valid until 3/31/2020**

**Trade-in required Yes**

## Your Bayer Sales Team:

**Anthony Capuzzi 724-940-7453, , [anthony.capuzzi@bayer.com](mailto:anthony.capuzzi@bayer.com)**

*If you are using this quote as a purchase order, please complete the Acceptance and Billing information below:*

## Acceptance and Billing

Your signature below indicates your acceptance of this Agreement, including the terms and conditions included as part of this document. Please complete the information below, along with your Purchase Order referencing Quote # Q-00034353, and email this form to Sales Support at [risalesupport@bayer.com](mailto:risalesupport@bayer.com) AND your SC, Anthony Capuzzi, at [anthony.capuzzi@bayer.com](mailto:anthony.capuzzi@bayer.com).

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

### Payment terms

30 days due net

### Terms of Delivery

PITTSBURGH

### Customer contact

### Address

1000 Blythe Blvd  
Charlotte, NC 28203

### Billing Information

1000 Blythe Blvd  
Charlotte, NC 28203

### Customer Number

3827302

### Phone

### Additional Customer Comments

### PO#

Write PO number

### PO Amount

Write PO amount

### Customer Approver

Write customer name

### Customer Approver Title

Write customer title

### Billing Email Address (if applicable)

Write email address

### Customer Approver Signature

X

### Date

Please print and sign

MM/DD/YYYY

BAYER, the Bayer Cross, Certegra, P3T, Medrad, Stellant, XDS, Veris, Spectris Solaris, Spectris, DirectCARE, PartnerCARE, VirtualCare, SelectCARE, Mark 7 Arterion, and Mark V ProVis are registered trademarks of the Bayer group of companies. Radimetrics, MRXperion, Avanta, Twist & Go, and VFlow are trademarks of the Bayer group of companies.

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All Pricing is in U.S. Currency.





## **Bayer Product Terms and Conditions**

Please click on the relevant product name below to review terms and conditions

### DEVICES

[Bayer Product Terms and Conditions](#)



**Exhibit A  
Equipment Price List  
Volcano Products**

<b>Qty.</b>	<b>Part Number</b>	<b>Product</b>	<b>Price</b>
1	797403	<b>IntraSight 5</b>	\$120,000.00
		<i>IntraSight interventional applications platform. Includes IntraSight CPU, on (1) CPU Base, Operator's Manual, Power Transformer, Cable Pre-Install Kit, Power Supply, Connection Box, Mouse, Keyboard, 19" Monitor Kit, DICOM Network Connection and Windows10 OS.</i>	
1		<b>Imaging (IVUS) License</b>	Included
		<i>Includes: Digital, Rotational and ChromaFlo, IVUS</i>	
1		<b>Touch Screen Module</b>	Included
1		<b>iFR<sup>®</sup> Hyperemia Free Lesion Assessment Modality</b>	Included
1		<b>FFR<sup>®</sup> Modality</b>	Included
1		<b>Philips Remote Services</b>	Included
1		<b>One (1) Year Warranty</b>	Included
		<i>iFR Hyperemia-Free Lesion Assessment Modality. CORE Interface, Operator's Manual. Customer agrees that use of the iFR Application Software License with interface to CORE is subject to the terms of the End User License Agreement</i>	
1		<b>Installation Cost</b>	Included
1		<b>One (1)-Year Warranty</b>	Included
		<b>TOTAL AMOUJNT DUE:</b>	<b>\$120,000.00</b>

**Exhibit B  
Customer Facility(ies)**

**Delivery Location(s):** Disposable Products and Equipment are to be delivered to the following location(s):

CMC – Main Campus – Master  
1000 Blythe Blvd.  
Charlotte, North Carolina 28203

FOR PHILIPS USE ONLY	
Philips MP1:	94015857
SPNC:	1053
VOLC:	720061

**Exhibit C  
Equipment Specifications  
IntraSight**

<b>Platform Overview</b>	<b>IntraSight interventional applications platform</b> (Includes iFR, FFR, and IVUS modalities, PIM, FM-PM, TSM, Monitor, Keyboard, and Mouse)	
<b>Power Requirements</b>	System Input	100, 120v, 220, 240VAC, 50/60Hz, 1000VA
	Workstation	100 – 240V, 50/60Hz, 825VA
	Monitor	100V – 240V 50/60Hz, 39W
<b>Dimensions</b>	Workstation	H= 17", W= 10", D= 16.5"
	TSM (Touch Screen Module) with articulating tableside mount	H= 7", W= 11.9" D= 9" (Articulating arm extends to a max depth of 16.5" and/or 20" above the top of the bedrail)
	Monitor	H= 15"-19" (adjustable stand), W= 15.8", D= 9.7"
	Connection Box	H= 9.95", W=2.95", D= 7.75"
<b>Processing and Data Storage</b>	Processor	1 CPU with 2.3GHz (maximum turbo frequency of 3.2GHz). 12 core total. 2400 MHz BUS.
	Memory	32GB SD RAM
	Hard Drive Capacity	1TB SSD SATA
	Digital Archiving Capacity	Local, DVD, DICOM Network (incl. Worklist management, DICOM Store)



**Exhibit D  
Additional Terms and Conditions  
Volcano Equipment**

**1. Limited Warranty.** Volcano warrants that the System(s) will meet the Specifications and the provisions of the Operator’s Manual supplied by Volcano (the “Operator’s Manual”) commencing on the date on which the System(s) is/are installed for one (1) year (the “Warranty Period”). This Limited Warranty is subject to the following conditions: (i) the System(s) must be correctly installed; (ii) the System(s) must be operated and stored in accordance with the Specifications and the Operator’s Manual; and (iii) the System(s) must be operated by trained personnel according to approved clinical guidelines.

Volcano’s sole obligation under this Limited Warranty shall be to provide parts and labor required to cause the System(s) to operate in accordance with the specifications during the Warranty Period. Volcano, in its sole discretion, reserves the right to use new or like new parts in servicing or repair of the System(s).

**2. Service Agreement Options.** By written agreement of the parties, Customer agrees to purchase maintenance and service coverage for each placed System at any time during the Term of this Agreement by contacting [igtbservicecontracts@philips.com](mailto:igtbservicecontracts@philips.com). For informational purposes, the current Service Agreement pricing is provided below.

**3. Philips Remote Service (“PRS”).** If requested by Volcano, Customer will provide Volcano with outbound internet access over SSL; at all times during the warranty period provide full and free access to the equipment and the Customer network for Volcano’s use in remote servicing of the product, remote assistance to personnel that operate the products, updating the products software, transmitting automated status notifications from the product and regular uploading of products data files (such as but not limited to error logs and utilization data for improvement of Volcano products and services and aggregation into services). Customer’s failure to provide such access will constitute Customer’s waiver of the maintenance service and will void support or warranty coverage of product malfunctions until PRS access is provided.

<u>IntraSight Full Care &amp; Tech Maximizer</u>	<u>IntraSight 5</u>
Full Care IntraSight with Remote Service – List Price Per Unit/Per Year	\$14,900
Point of Sale Discount for 1 year/ Per Unit	\$10,000
Point of Sale Discount for 2 years/ Per Unit	\$18,500
Point of Sale Discount for 3 years/ Per Unit	\$25,500
Tech Maximizer for 5 Years	\$60,000.00

# Attachment D

**PROPOSED TOTAL CAPITAL COST OF PROJECT**

**Project name:** CMC Main Vascular Lab 6 Renovation  
**Provider/Company:** Atrium Health

(1) Purchase price of land	0
(2) Closing costs	0
(3) Site Preparation	0
(4) Construction/Renovation Contract	709,432
(5) Landscaping	0
(6) Architect/Engineering Fees	190,189
(7) Medical Equipment	1,375,504
(8) Non Medical Equipment	
(9) Furniture	7,870
(10) Consultant Fees (CON Fees, Legal Fees)	
(11) Financing Costs	
(12) Interest During Construction	
(13) Other (IS, Security, Internal Allocation)	253,486
(14) <b>Total Capital Cost</b>	<b>2,536,482</b>

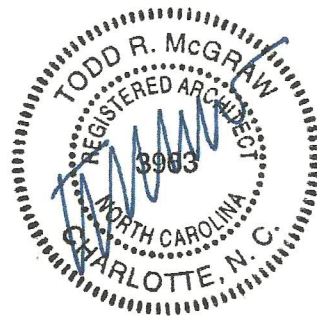
*I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.*

*[Handwritten Signature]*

*3/3/2020*

(Signature of Licensed Architect or Engineer)

DATE



Sales taxes have been included in these equipment costs. However, because Atrium Health is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that Atrium Health initially incurs for this medical equipment purchase will be refunded to Atrium Health, and thus will reduce the capital costs that Atrium Health actually incurs for the equipment by \$ 95,954.



# 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. )

STATE OF NORTH CAROLINA  
COUNTY OF MECKLENBURG

IN THE OFFICE OF  
ADMINISTRATIVE HEARINGS  
11 DHR 0698

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. )

**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 above-captioned 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.

#### **AGREEMENT**

1. Petitioner's Voluntary Dismissal with Prejudice. 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. Release. 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. Effect of Approval. 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. Modification or Waiver. 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. No Strict Interpretation Against Drafter. 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. Recitals and Headings. All parts and provisions of this Agreement, including the recitals and paragraph headings, are intended to be material parts of the Agreement.

12. Authority to Settle. The undersigned represent and warrant that they are authorized to enter into this Agreement on behalf of the Parties to this Agreement.

13. Ex Parte Presentation. Petitioner authorizes counsel for the Agency to present this

Agreement to the Director, *ex parte*.

14. Effective Date. 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. Binding Effect. 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.  
F. Del Murphy, Jr.  
Vice President, CHS Management Company

\_\_\_\_\_  
Date

**K&L GATES LLP**

By: Colleen M. Crowley  
Gary S. Qualls  
Colleen M. Crowley  
Susan K. Hackney  
430 Davis Drive, Suite 400  
Morrisville, NC 27560  
Telephone: (919) 466-1182

4-19-11  
Date

ATTORNEYS FOR PETITIONER

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

By: Craig R. Smith  
Craig R. Smith, Chief

Date: 4.20.11  
CRS

**ROY COOPER  
Attorney General**

By: Stephanie A Brennan  
Stephanie Brennan  
Assistant Attorney General  
N.C. Department of Justice  
P.O. Box 629  
Raleigh, NC 27602-0629

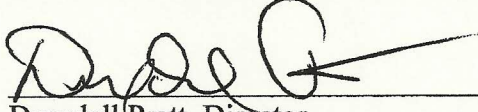
Date: 4-19-11

*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 Agreement is hereby APPROVED AND ADOPTED this the  
21<sup>st</sup> day of April, 2011.



---

Drexhall Pratt, Director  
Division of Health Service Regulation

# Attachment F





**PHILIPS**

Image guided therapy

*Azurion 7*

With **Azurion**,  
performance and superior  
care become one



Treating patients. It's what you do. You strive every day to provide the best patient care, quickly and reliably, no matter which procedure you are performing. So try to imagine an increased number of procedures, for more patients, carried out consistently and efficiently with fewer preparation errors. Workflow can be optimized and performed on an intuitive platform designed to make your day a lot easier.



Azurion enables you to provide superior care



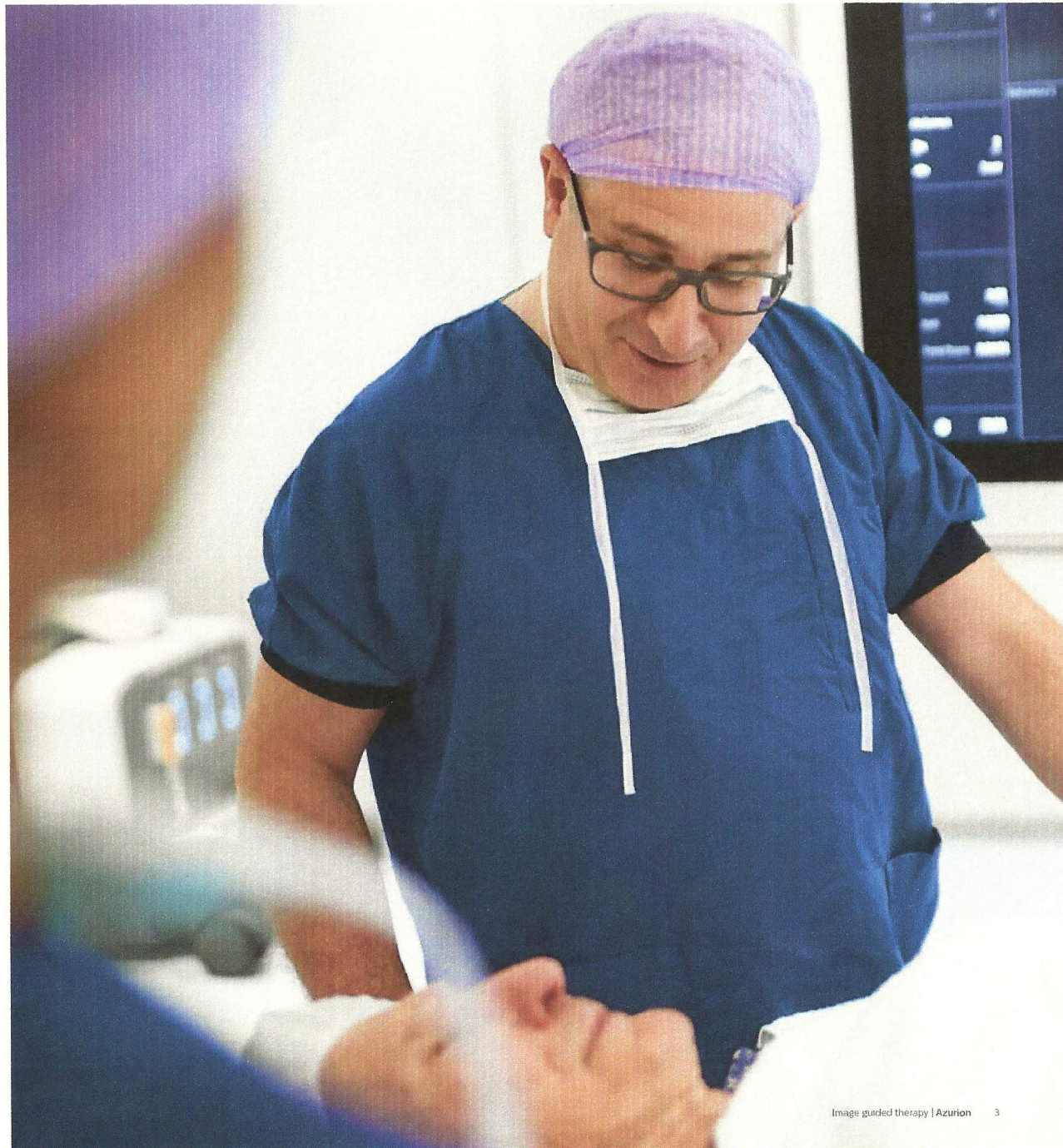
Azurion helps you optimize your lab performance



An easy-to-use platform supports you in quickly and easily performing diverse procedures

This is exemplified by our Azurion 7. This next-generation image guided therapy platform allows you to easily and confidently perform a wide range of routine and complex procedures with a unique user experience, helping you optimize your lab performance and provide superior care. Azurion is powered by ConnectOS, a real-time multi-workspot technology designed specifically for the Azurion interventional suite

Intensive user testing has guided the entire development process to make the system easy to use. With this latest Philips innovation in image guided therapy, we reinforce our commitment to you and your patients. Our goal is to help you effectively meet today's challenges so that you are ready for the future.







Azurion enables you  
**to provide  
superior care**

In a simulation study with over 60 users globally,

**100%** believe that the possibility to display Checklists & Protocols on the system will help minimize preparation errors<sup>1</sup>

As patient volumes rise and procedures become more complex, how do you maintain high standards of quality and safety in your healthcare facility?

**Simplified set-up and operation**

The Azurion 7 uses a range of ProcedureCards to help optimize and standardize system set-up for all your cases, from routine to advanced procedures. The system will automatically select the appropriate ProcedureCard(s) based on the RIS/HIS/CIS code of the scheduled procedure.

ProcedureCards can increase the consistency of exams by offering presets (e.g. most-frequently used, default protocols and user-specified settings) on the procedure, physician or department level. In addition, hospital checklists and/or protocols can be uploaded into the ProcedureCards to help safeguard the consistency of interventional procedures and reduce preparation errors.

**Full control at table side through FlexVision Pro**

With FlexVision Pro you have full control, at table side, of all applications in the interventional lab. Not only does this improve workflow within the exam room, it helps reduce the need for team members to leave the sterile area and walk to the control room during procedures. This can save time and help avoid delays.

**Insightful image guided therapy**

We have pioneered a steady stream of innovations in Live Image Guidance that help clinicians determine the most advantageous course of treatment with confidence, including StentBoost Live, Dynamic coronary roadmap, aneurysm flow, EchoNavigator, HeartNavigator, EP Navigator, OncoSuite, XperCT and many more. All these advanced interventional tools are seamlessly integrated into the Azurion 7 to support your clinical workflow.

“The FlexVision Pro is fantastic! I can **control everything** from table side without sterility breaks.”

Marco van Strijen, MD



# High standards of safety and **low radiation exposure**

As you look for new radiation dose management strategies to continue to enhance patient and staff safety, while maintaining and enhancing your level of care, we can support you in meeting your goals.

#### **Managing dose efficiently**

Several Azurion 7 features have a positive impact on dose. Our Dose management solutions help you take control over patient care, staff safety, and regulatory compliance with a comprehensive suite of radiation dose management tools, training, and integrated product technologies. The MRC200+ X-ray tube incorporates SpectraBeam filtration, which helps maintain image quality at a low dose. The Zero Dose Positioning function lets you pan the table, change table height or field-of-view on your Last Image Hold (LIH) image. This means you can already see the effect of moving the table or changing the field-of-view on your region of interest to prepare your next run without using fluoroscopy.

#### **High quality images at a low x-ray dose**

ClarityIQ technology that provides high quality imaging for a comprehensive range of clinical procedures, achieving excellent visibility at low X-ray dose levels for patients of all sizes.

Over 500 system parameters have been fine-tuned to use the full potential of ClarityIQ technology for each application area, enabling superb visualization in many different application areas.

#### **Managing dose across your organization**

Philips DoseAware provides instant, time-stamped feedback in the exam room so you can immediately adjust working habits to manage radiation exposure with your staff.

A critical component in providing exceptional patient care is strong radiation control and management. We can help you create a comprehensive dose management program with DoseWise Portal at its core. This turnkey dose management solution gives you control over patient dose and staff occupational dose. It increases transparency across the entire enterprise and enables you to make data-driven decisions concerning quality initiatives and radiation management.





With Azurion we help you to  
**optimize your lab performance**

To address rising cost pressures, what can you do to improve efficiency and productivity in your lab?

**Save time through Instant Parallel Working**

The Azurion 7 interventional suite has been specifically designed to save time by enabling interventional team members to do two tasks at the same time in the exam room and control room - without interrupting each other. As an example, while fluoroscopy/exposure is taking place, a technologist in the control room can instantly review previous images from the same patient, prepare the next exam or finish reporting on another patient. This leads to higher throughput and faster exam turnover without compromising quality of care.

**Imagine an easier work day**

You can combine different user centric workspots (FlexVision Pro, FlexSpot and touch screen modules) to view control and run applications where and when needed. So you have the tools in hand to manage procedure quality and patient care. Together these flexible workspots allow you to customize your workflow to boost efficiency.

In a simulation study with over 60 users globally,

**91%** believe that the system will help reduce procedure time<sup>1</sup>

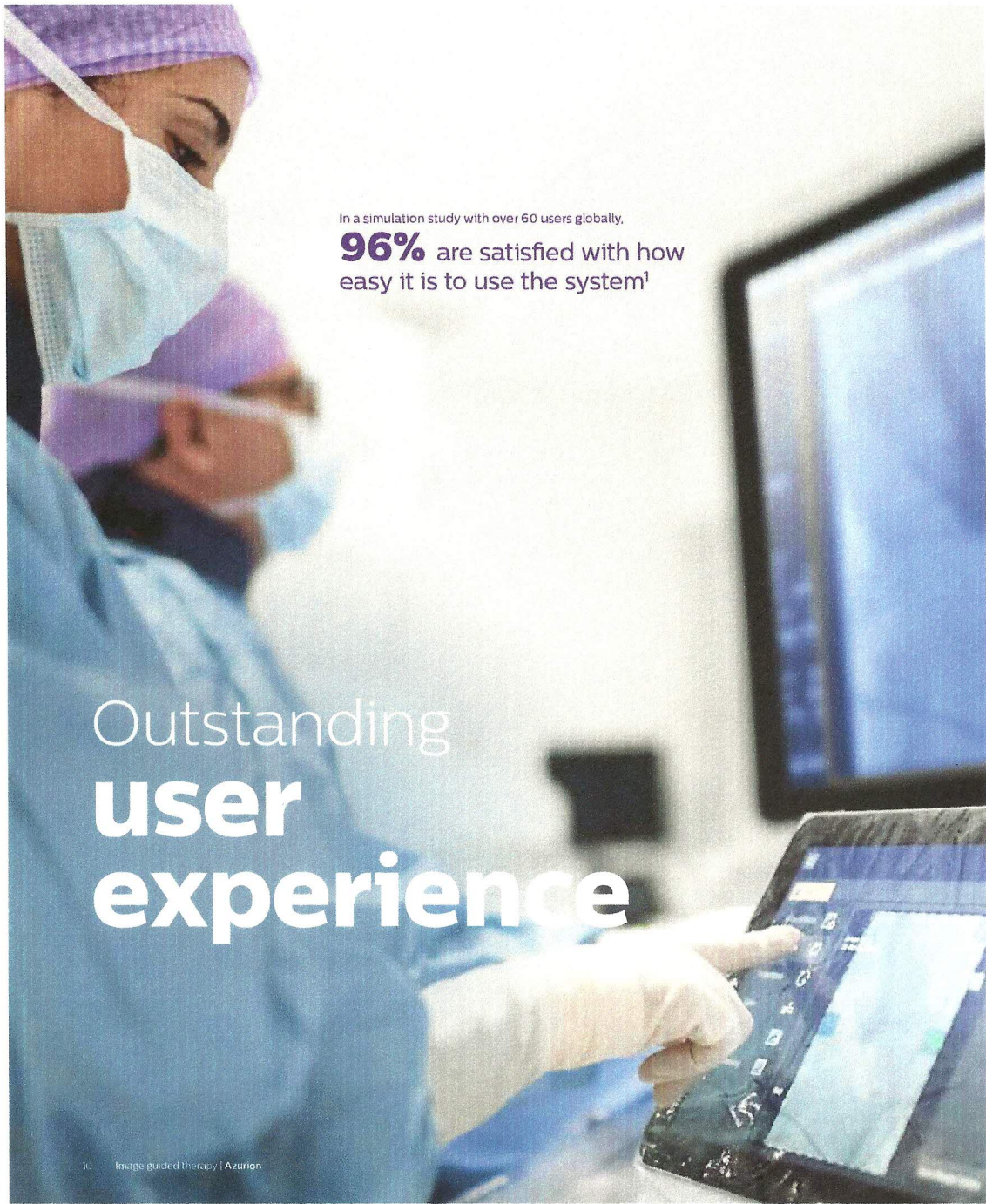


Touch screen module Pro

FlexSpot

FlexVision Pro





In a simulation study with over 60 users globally,

**96%** are satisfied with how easy it is to use the system<sup>1</sup>

# Outstanding user experience

Studies have documented the adverse impact that poor usability, design and ergonomics can have on medical procedures and patient safety.<sup>2</sup> How can you make it easy for your staff to use imaging solutions?

#### **We do this by:**

Giving you cutting edge guidance, ease of use and responsiveness in our standardized Azurion user interface. It is designed to anticipate what you need, when you need it, to make procedures flow intuitively and easily. An extensive user-centric design process was carried out for the Azurion system. Clinical users tested the user interface at different stages during the iterative development process to ensure that the system would be easy to use, learn and remember. The new workflow approach was further evaluated by 61 physicians and technologists in Europe and the USA in a simulated environment

#### **Designed around you and your procedure**

All Azurion systems and interventional tools use the same standardized user interface to support training. Use has been further simplified through a sophisticated help function. You can access digital user guides with one click for on-the-spot assistance.

#### **The next step in ease of use**

All controls feature the latest advances in ease of use. On screen, you can see easily information against the distinctive black background where active applications are highlighted. Backlit icons and distinctly shaped buttons on the Control Module promote intuitive operation. The touch screen module Pro<sup>2</sup> offers tablet-like control at table side – select, zoom and pan with your fingertips and display X-ray images on its screen. All controls are designed for easy cleaning to meet stringent sterility requirements.

#### **Less clutter and faster workflow**

FlexSpot gives you access to all applications from Philips and other vendors in one compact, customizable workplace that can significantly reduce clutter and accelerate workflow. You can drag and drop applications and set the display to re-arrange and re-size as applications are opened and closed.



# The next-generation **image guided therapy platform**

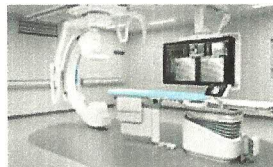
Azurion is the next-generation Image Guided Therapy platform that provides a foundation for today and the innovations of tomorrow. It is backed by innovative services and support that offer a lifetime of benefits, reinforcing our commitment to you and your patients.

#### **Enjoy a lifetime of benefits**

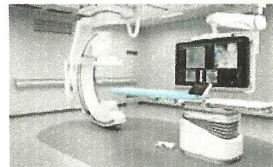
The entire Azurion family is designed around a single, standardized hardware and software platform. New solutions and innovations are added as they evolve. And as your requirements change you can easily integrate additional functionality and third-party applications.

#### **Azurion 7**

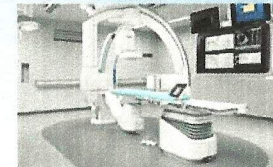
You can choose a system with either a 12" or a 20" Flat Detector to meet your application requirements. With its new 12" Flat Detector, the 7 Series provides high-resolution imaging over a large field-of-view with flexible projection capabilities, making it ideal for cardiac interventions. The entire coronary tree can be visualized in a single view with minimal table panning. Enhance visibility for diverse cardiac and vascular procedures with the excellent image quality and broad coverage of the next generation 20" Flat Detector. For a hybrid suite solution, the Azurion 7 the next generation 20" Flat Detector can be combined with the FlexMove option.



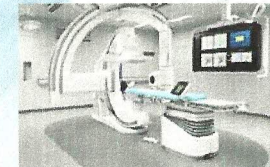
Azurion 7 C12



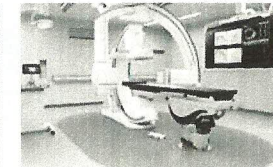
Azurion 7 C20



Azurion 7 B12/12



Azurion 7 B20/15



Azurion 7 B20/12 with OR table

#### **Azurion 7 biplane**

The Azurion 7 biplane is available in different configurations to support neuro, congenital heart, structural heart, electrophysiology and other complex cardiac and vascular interventions. The biplane system with two 12" Flat Detectors provides high-resolution imaging and positioning flexibility to reveal critical anatomical information during congenital heart and electrophysiology procedures. Enhance insight and certainty during neuro interventions with the perfect fit design that pairs a 20" frontal with a 15" lateral detector. The biplane system with a 20" and 12" Flat Detector provides exceptional clarity of detail and navigational precision to support a wide range of challenging cardiac and vascular interventions.





## High productivity combined **with low cost of ownership**

Flexible financing and advanced service and support help you maintain peak performance and deliver cost-efficient care.

### **Increase your return on investment**

To help you fully leverage your financial, technological and staffing resources and realize a high return on your investment, we offer professional support through our experienced network of over 7,000 field service engineers, as well as a flexible service offering that includes innovative financing solutions tailored for the healthcare community. Our broad range of healthcare consulting and education programs can help you further enhance the efficiency and efficacy of your care delivery process.

### **Make the most of every day**

Staying on top of today's complex healthcare environment is challenging enough without a constant concern of keeping your systems up and running smoothly. We are dedicated to tackling whatever issues you may have, and if needed will be working day and night until the job is done. Philips Remote Services aim to help you maintain peak performance of your equipment, deliver uninterrupted patient care and address your most complex technical problems before they impact patient care. Our RightFit service portfolio provides software and hardware updates to ensure that your system is up to date. Together, this approach can extend the utilization and lifetime of your suite.

### **Unlock your potential**

Philips Healthcare Education can help unlock the full potential of your staff, technology and organization to meet new challenges through innovative, meaningful and evidence-based healthcare education. Our comprehensive clinical, technical and business-related courses, programs and learning paths are designed to help you meet the challenges of controlling costs, streamlining workflow and improving patient care.





This material is not for use in the United States

Some features are optionally available.  
Not all features are available on all systems.  
Please check with your Philips representative for local availability.

1. Results obtained during user tests performed in the period of November 2015–February 2016. The tests were designed and supervised by Use-Lab GmbH, an independent and objective usability testing engineering consultancy and user interface design company. The tests involved 31 US-based clinicians (16 physicians and 15 technicians) and 30 European-based clinicians (15 physicians and 15 technologists), who performed procedures using Azurion in a simulated interventional lab environment.
2. Gurses A, Ozok AA, Pronovost PJ. Time to accelerate integration of human factors and ergonomics in patient safety. *BMJ Qual Saf.* 2012;21:347–51.

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**How to reach us**  
Please visit [www.philips.com/azurion](http://www.philips.com/azurion)  
[healthcare@philips.com](mailto:healthcare@philips.com)



# Attachment G



**EQUIPMENT COMPARISON - Carolinas Medical Center Vascular Lab #6 Replacement**

	<b>EXISTING EQUIPMENT</b>	<b>REPLACEMENT EQUIPMENT</b>
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Vascular system	Vascular system
Manufacturer	Toshiba	Philips
Model number	N/A	N/A
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Infinix VF-I/SP	Azurion 7 M20
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2011	2020
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	\$2,536,482
Total cost of the equipment	\$884,260	\$1,375,504
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	CMC 6 <sup>th</sup> Floor, Room 06D105	CMC 6 <sup>th</sup> Floor, Room 06D105
Document that the existing equipment is currently in use	The existing equipment performed 593 cases from March 2019 to February 2020	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	No
Will the replacement equipment result in any increase in the <b>average operating expense per procedure</b> ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	Vascular procedures	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Vascular procedures

Date of last revision: 5/17/19

# Attachment H

### CMC Peripheral Vascular Lab #6 Volumes

Month	Volume
Mar-19	42
Apr-19	46
May-19	53
Jun-19	34
Jul-19	51
Aug-19	49
Sep-19	36
Oct-19	50
Nov-19	47
Dec-19	54
Jan-20	66
Feb-20	65
<b>Total</b>	<b>593</b>



# Attachment I

IMEXSAL, CORP.  
7821 LAUREL AVE.  
CINCINNATI, OH 45243  
STEVEN A. LYNCH, PRESIDENT  
MARY GAUCHE - SALES  
TEL: 513-272-6703 FAX: 513-272-6744  
E-MAIL ADDRESS:[mgauche@imexsal.com](mailto:mgauche@imexsal.com)

January 10, 2020

Philips Healthcare  
595 Miner Rd.  
Cleveland, OH 44143

RE NATID No. 109517 / Atrium Carolinas Medical Center / Charlotte, NC

Imexsal, Corp. agrees not to reinstall the 2007 Toshiba Infinix VFI Cath Lab, S/N 99A0913088 in the State of North Carolina without the appropriate CON approval.

Please let me know if you have any further questions.

Thank you,  
*Mary Gauche*  
Sales