



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

June 13, 2016

James Roskelly, Executive Vice President
Cone Health
1200 North Elm Street
Greensboro, NC 27401-1020

Exempt from Review – Replacement Equipment

Record #: 1961
Facility Name: The Moses H. Cone Memorial Hospital
FID #: 943494
Business Name: Cone Health
Business #: 1257
Project Description: Replace existing cardiac catheterization equipment
County: Guilford

Dear Mr. Roskelly:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 2, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Philips Allura Xper FD10 cardiac catheterization equipment to replace the Philips Integris 14551M104762 cardiac catheterization equipment. This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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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,

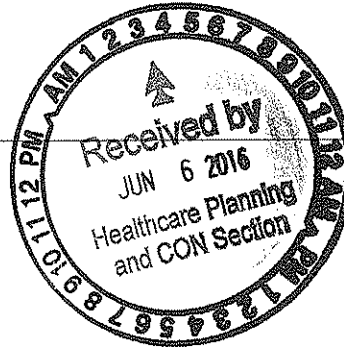


Celia C. Inman
Project Analyst
Need



Martha J. Frisone,
Assistant Chief, Certificate of

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



June 2, 2016

Ms. Martha Frisone, Assistant Chief, Certificate of Need
Ms. Celia Inman, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

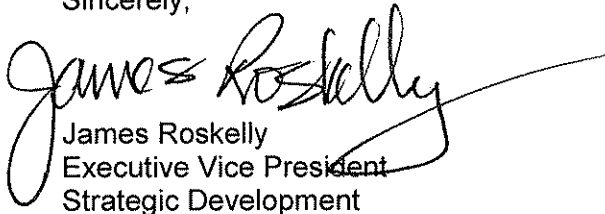
Dear Ms. Frisone and Ms. Inman:

Pursuant to Section § 131E-184 (a)(7) – Exemptions From Review – of the Certificate of Need Statute, I am writing to inform you of Cone Health's plans to replace cardiac catheterization equipment in one of its existing cardiac cath rooms at The Moses H. Cone Memorial Hospital. Exhibit 1 attached to this letter provides a comparison of the relevant information and specifications for the existing equipment and the planned replacement equipment. Of particular note, the replacement equipment will cost \$1,034,792, including the Allura Xper FD10 single-plane cardiovascular system and the Xper Flex Cardio monitoring system. The new equipment will be functionally comparable to the equipment being taken out of service. Minor renovations to the existing space result in renovation costs of approximately \$350,000. These costs were estimated by Cone Health construction management, based on knowledge and expertise with similar projects. The total proposed capital costs of \$1,384,792 for the planned equipment replacement are detailed in Exhibit 2.

The new equipment, which will be owned and operated by Cone Health, is planned to be placed in service in December 2016. The existing equipment will be removed and taken out of service by Philips Healthcare, the vendor of the new equipment, as noted on page 19 of the equipment quote. Cone Health is simply updating an important piece of equipment with newer technology that offers improved patient throughput. Indeed, the equipment to be replaced is nearly fifteen (15) years old and has exhausted its useful life. The proposed quotes from Philips for the Allura Xper FD10 cardiovascular system and the Xper Flex Cardio monitoring system, including detailed specifications, are attached as Exhibit 3.

Please let me know if I can answer any questions for you regarding this planned replacement.

Sincerely,


James Roskelly
Executive Vice President
Strategic Development

Attachments

Exhibit 1

Comparison of Existing Equipment and Planned Replacement Equipment

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Cardiovascular X-ray system	Cardiovascular X-ray system
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	N/A	N/A
Model Number	Integris	Allura Xper FD10
Serial Number	14551M104762	TBD
Provider's Method of Identifying Equipment	Serial Number	Serial Number
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	October 2001	December 2016
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.) <Use Attached Form>	\$1,381,229	\$1,384,828
Total Cost of Equipment	\$763,283	\$1,034,828
Fair Market Value of Equipment	\$0	\$1,034,828
Net Purchase Price of Equipment	\$763,283	\$1,034,828
Locations Where Operated	The Moses H. Cone Memorial Hospital	The Moses H. Cone Memorial Hospital
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	0	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	0	0
Type of Procedures Currently Performed on Existing Equipment	Adult Cardiac Cath	Adult Cardiac Cath
Type of Procedures New Equipment is Capable of Performing	Adult Cardiac Cath	Adult Cardiac Cath

Exhibit 2

Capital Costs

PROJECT CAPITAL COST

A.	<u>Site Costs</u>			
(1)	Full purchase price of land	\$	<u>0</u>	
	# Acres _____ Price per Acre \$ _____			
(2)	Closing costs	\$	<u>0</u>	
(3)	Site Inspection and Survey	\$	<u>0</u>	
(4)	Legal fees and subsoil investigation	\$	<u>0</u>	
(5)	Site Preparation Costs [Include]			
	Soil Borings			
	Clearing and Grading			
	Roads and Parking			
	Sidewalks			
	Water and Sewer			
	Excavation and Backfill			
	Termite Treatment			
	Sub-Total Site Preparation Costs	\$	<u>0</u>	
(6)	Other (Specify)	\$	<u>0</u>	
(7)	Sub-Total Site Costs			\$ <u>0</u>
B.	<u>Construction Contract</u>			
(8)	Cost of Materials [Include]			
	General Requirements			
	Concrete/Masonry			
	Woods/Doors & Windows/Finishes			
	Thermal & Moisture Protection			
	Equipment/Specialty Items			
	Mechanical/Electrical			
	Sub-Total Cost of Materials	\$	<u>0</u>	
(9)	Cost of Labor *	\$	<u>350,000</u>	
(10)	Other (Specify)	\$	<u>0</u>	
(11)	Sub-Total Construction Contract			\$ <u>350,000</u>
C.	<u>Miscellaneous Project Costs</u>			
(12)	Building Purchase	\$	<u>0</u>	
(13)	Fixed Equipment Purchase/Lease	\$	<u>1,034,792</u>	
(14)	Movable Equipment Purchase/Lease	\$	<u>0</u>	
(15)	Furniture	\$	<u>0</u>	
(16)	Landscaping	\$	<u>0</u>	
(17)	Consultant Fees			
	Architect/Engineering Fees	\$	<u>0</u>	
	Legal Fees	\$	<u>0</u>	
	Market Analysis	\$	<u>0</u>	
	Other (Specify)	\$	<u>0</u>	
	Total Consultant Fees	\$	<u>0</u>	
(18)	Financing Costs			
	(e.g. Bond, Loan, etc.)	\$	<u>0</u>	
(19)	Interest During Construction	\$	<u>0</u>	
(20)	Other (Contingency)	\$	<u>0</u>	
(21)	Sub-Total Miscellaneous			\$ <u>1,034,792</u>
D.	Total Capital Cost of Project (Sum A-C above)			\$ <u>1,384,792</u>

* Cone Health does not separate the cost of materials from the cost of labor in the construction contract

Exhibit 3

Equipment Quote

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

PHILIPS

Quotation #: 1-1810VX8	Rev: 4	Effective From: 12-May-16	To: 11-Jul-16
Presented To: MOSES H CONE HEALTH SYSTEM 1200 N ELM ST GREENSBORO, NC 27401-1004 Tel: Alternate Address:	Presented By: Brett Kimball <i>Account Manager</i> Amy Morrow <i>Regional Manager</i>	Tel: Fax: Tel: (828) 553-3118 Fax:	
Date Printed: 12-May-16			
Submit Orders To: 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 Electronics North America Corporation ("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).

f

<u>Line #</u>	<u>Product</u>	<u>Qty</u>	<u>Price</u>
	100241 Allura Xper FD10	1	\$975,865.11
Equipment Total:			\$975,865.11

<u>Product</u>	<u>Qty</u>	<u>Each</u>	<u>Monthly</u>	<u>Price</u>
100241 Allura Xper FD10	1	\$975,865.11		\$975,865.11

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA **Contract #:** SCA11505G

Add'l Terms: Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for applicable T&C details. If Service Agreement is quoted its T&C of Sale are printed

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 upon receipt

Quote Summary

Qty	Product
1	NNAE861 AlluraClarity_FD10 Floor
1	NNAE854 FlexVision_XL 9 Input Package
2	FCV0587 Xper Live/Ref Slaving
1	NCVA080 Automatic Position Control (APC)
1	NCVA121 FULL AUTOCAL
1	NCVA784 Ventricular Quant.Sw pkg(Xper)
1	NCVA097 Cath Arm Support
1	NCVA783 Pivot for table base.
1	FCV0510 Long mattress cardio
1	NCVB630 FlexVision XL,Snapshot
1	NCVB294 Set of 2 additional 21in. LCDs
1	NCVB591 2ND REF for FlexVision XL
2	980306640009 Black Anti-Fatigue Floor Mat w/ Blue Logo
1	980406041009 Rad Shield w/ Arm (Contoured) 61X76
1	980406190009 PIVOTING TABLE-MOUNTED RADIATION SHIELD
1	989801220012 Cable Spooler
1	989801220273 Ceiling Track w/Column & Handle Ext
1	989801220279 LED Single Color Exam Lamp
1	989801220370 Low Load 15 kW UPS
1	989600213942 AD5 TO XPER TABLE ADAPT. PLATE
1	SP005 Contract Labor
1	SP003 Installation Labor
1	SP019 Trade in Allowance

Options

Qty	Product
1	989801220217 Q-Digital Base Station (6 User)
1	989801220275 Q-Digital Charge Docking Station 6 Port
6	989801220276 Q-Digital AIO Headset
6	989801220277 Q-RH7 Spare Battery
1	989801220284 ISM Advanced Audio Package

AlluraClarity_FD10

System Type: New
Freight Terms: FOB Destination
Warranty Terms: Part numbers beginning with two (2) asterisks (**) are covered by a System 12 Months Warranty. All other part numbers are third (3rd) party items.
Special Notations: Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date. Any rigging costs are the responsibility of the Purchaser.
Additional Terms: Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for applicable T&C details. If Service Agreement is quoted its T&C of Sale are printed

Line #	Part #	Description	Qty
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1	**NNAE861	AlluraClarity_FD10 Floor	1
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The AlluraClarity FD10 (Floor) single-plane cardiovascular system comprises a ceiling mounted G-arm stand and digital imaging X-ray system for cardiovascular diagnostic and interventional procedures.

ClarityIQ technology is the foundation of AlluraClarity systems touching every part of the imaging system.

ClarityIQ incorporates powerful state-of-the-art image processing technology, developed by Philips research, all working in real-time enabled by the latest computing technology:

- Noise and artifact reduction, also on moving structures and objects
- Image enhancement and edge sharpening;
Automatic real-time patient and accidental table motion correction on live images.
- Flexible digital imaging pipeline
- ClarityIQ systems have a flexible digital imaging pipeline from tube to display that is tailored for each and every application area such as Cardio or Neuro. This gives the flexibility to select virtually unlimited application-specific configurations.
- With ClarityIQ over 500 system parameters are fine-tuned for each application area; the result of years of Philips clinical leadership. It is now possible to filter out more X-ray radiation, use smaller focal spot sizes, shorter pulses, thereby fully utilizing the unique capabilities of the Philips MRC X-ray tube.

The AlluraClarity FD10 system uses an integrated single-host concept. The system is comprised of five functional building blocks: Geometry, X-ray Generation, Image Detection, Viewing, and User Interface. Each functional building block is explained in further detail including accessories.

GEOMETRY

The AllurClarity FD10 Stand

The floor mounted geometry segment. This component comprises the following features:

- A motorized dedicated cardiovascular floor-mounted Poly-Diagnost G-stand with a rotatable base that allows for a clear area around the patient table. The stand is capable of manual or motorized movement.
- All stand movements are motorized. The manual and motorized parking movement consists of floor-mounted rotation. The counterbalanced Dynamic Flat Detector can be positioned manually and motorized. Angulation and Rotation of the Poly Diagnost G-arm is also motorized at high speeds.
- Parking and longitudinal movement of the Poly Diagnost G stand, can be performed either manually either motorized. The longitudinal movement comprises electronic auto-stop positions, to facilitate positioning in the iso-center with ease and accuracy.
- Single operator control of stand parking or longitudinal positioning. It provides motorized base rotation at 12 degrees/s from +90 to -90 degrees, and motorized longitudinal movement at 15 cm/s over a maximum range of 260 cm.

Line #	Part #	Description	Qty
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- The projection angles for the Poly Diagnost G-arm are: Rotation 120 degrees LAO to 120 degrees RAO
- Angulation 45 degrees cranial to 45 degrees caudal
- Motorized stand movements are variable speed with a configurable maximum speed, allowing:
 - Rotation speed up to 25 degrees/s
 - Angulation speed up to 18 degrees/s
- The depth of the Poly Diagnost G arm is 105 cm.
- The stand features BodyGuard capacitive sensing collision avoidance for patient protection.
- The variable source image distance range between the x-ray tube foci and the Dynamic Flat Detector input screen is 86.5 to 123 cm.

Patient Support

Xper Table

- Patient support provided with a flat carbon fiber tabletop
- Tabletop length of 319 cm and tabletop width of 50 cm
- Floating tabletop movement of 120 cm longitudinal and 35 cm transverse
- Motorized height adjustment from 74.5 to 102.5 cm
- Maximum cantilever of 223 cm , for full patient coverage
- Maximum patient weight 250 kg plus 500 N for CPR (or 225 kg plus 1000 N) in any longitudinal position of the table top
- Xper Geometry and Imaging Modules for exam room controls.
 - The operating modules can be attached to either side of the table.

Patient Support Accessories

- Three rail accessory clamps
- Mattress pad
- Translucent catheterization armrest
- IV Pole
- Set of Cable Holders
- Set of Arm Supports (FCV0248)
- Arm Support (FCV0258)
- Patient straps
- Table-mounted radiation shield
- Antifatigue Mat with Philips logo

X-RAY GENERATION

The AlluraClarity FD10 comprises an integrated dedicated X-ray system, micro-processor controlled 100kW generator, based on high frequency converter technology. The user interface control of this X-ray Generator is incorporated into the Xper module, Xper Desktop Console, and the Xper on-screen displays.

- The Certeray generator comprises:
- X-ray generator: 100 kW

Line #	Part #	Description	Qty
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- Voltage range: 40 - 125 kV
- Program selection:
 - Pulsed X-ray up to 3.75 , 7.5 , 15 , 30, frames/s for digital dynamic exposures
 - Pulsed X-ray for pulsed fluoroscopy (3.75, 7.5, 15, 25, 30 frames/s).
 - Minimum exposure time of 1ms.
 - ECG triggered acquisition: allows acquiring one exposure for each QRS peak with selectable delay time
 - Automatic kV and mA control for optimal image quality prior to run to save dose
 - Optimal X-ray tube load incorporated in the Certeray generator
- An X-ray collimator with single semi-transparent wedged filter with manual and automatic positioning.
- SpectraBeam filtering of low energy radiation to optimize image quality and dose efficiency with the MRC-GS 0508 X-ray tube.
- Xper Beam Shaping, which means that, both shutters and wedges can be positioned on the Last Image Hold without the need for X-ray radiation.

Fluoroscopy

- Three programmable fluoroscopy modes can be selected from the Xper Imaging T.S.O. Each mode has a different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, and adaptive harmonization).
- Xper Fluoro Storage, a grab function allows storage and archiving of a single fluoro frame or the last 20 seconds of fluoroscopy. These images or runs can be archived as a regular run.

X-ray Tube

The AlluraClarity FD10 includes a Maximus ROTALIX Ceramic tube assembly MRC-GS 05 08 and cooling unit CU 3101 for cardio-vascular systems. Comprising:

- 0.5/0.8 mm nominal focal spot values maximal 45 and 85 kW

IMAGE DETECTION

The AlluraClarity FD10 comprises the following image detection chain:

- A 25 cm (10 in.) diagonal triple-mode Dynamic Flat Detector. It comprises a 6"/8"/10" triple mode Dynamic Flat Detector
- The outer detector box diameter is 37 cm diagonal square
- The digital output of the Flat detector is a 1024 x 1024 matrix at 14 bit depth and the detector pixel pitch is 184 micron by 184 micron
- The DQE (0) is 75% providing high conversion of X-ray into a digital image, while maintaining a high MTF.

VIEWING

The AlluraClarity FD10 comprises the following components in order to display the clinical images in the control and examination rooms:

Displays

Examination Room

Line #	Part #	Description	Qty
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Two 19-inch monochrome LCD monitors

- 19-inch monochrome TFT-LCD display
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These monitors are not delivered when FlexVision XL, EP Cockpit or EP Cockpit XL is selected.

The monitor ceiling suspension in the exam room can be configured to accommodate 3, 4, 6, or 8 LCD monitors and includes motorized height adjustment. The height adjust feature is dependent on the room ceiling height. When FlexVision XL, EP Cockpit or EP Cockpit XL is selected the monitor ceiling suspension is configured for one of those options.

- The first reference channel is for the display of reference images or runs, controlled by infra-red remote-control Xper Viewpad.
- The On-Screen Display provides status information on stand rotation, angulation, display of system messages, X-ray tube load status, selected fluoroscopy mode, selected detector Field of View, and both the rate and accumulation of the dose area product and skin dose.

Control Room

One 19-inch color LCD monitor

- 19-inch color TFT-LCD display

Control Room

One 19-inch monochrome LCD monitor

- 19-inch monochrome TFT-LCD display
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These control room monitors are not delivered when EP Cockpit or EP Cockpit XL is selected.

Acquisition

The acquisition segment coordinates the parameters for automatic exposure control. The program is selected via the Xper module or Xper Desktop Console.

This AlluraClarity offers a storage capacity of:

- 100,000 images at matrix size of 1024 x 1024, 10-bit
- Maximum number of examinations is 999, with no limit to the maximum number of images per examination

USER INTERFACE

Xper is comprised of three elements: 1) Xper Settings, which customizes the system to each user preferred settings; 2) Xper User Interface 3) Xper Integration, which makes advanced integration

Line #	Part #	Description	Qty
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functionality available such as DICOM Query / Retrieve, background archiving, and Xper Fluoro Storage.

The Xper User Interface comprises a range of User Interface modules in the Examination Room, including On-Screen Display.

On-Screen Display

- X-ray indicator and X-ray tube temperature condition
- Gantry position in rotation and angulation and Source Image Distance
- Detector field size display
- Selected Frame speed
- Fluoroscopy mode
- Integrated fluoroscopy time
- Stopwatch
- Skin Dose: dose rate with X-ray, cumulated dose with no X-ray
- Dose Area Product: dose rate with X-ray, cumulated dose with no X-ray
- Graphical bars for indication of Body Zone specific dose rate and accumulated skin dose levels, related to the 2 Gy level

Remote Intercom

A separate intercom, which is connected independently from the system that allows separate placement of the intercom at the preferred working position in the control room and examination room.

Xper ViewPads

The Xper ViewPad contains the preprogrammed function settings. The system is provided with two Xper ViewPads. The following functions are provided:

- Run and image selection
- File and run cycle
- File overview
- Store to Reference image file
- Copy image to photo file
- Digital (fixed) zoom and panning
- Recall reference images, which means switching control of Xper ViewPad function from live to reference monitor
- Laser pointer, intended to point at regions of interest on the imaging monitors
- LED indication of laser pointer on/off and battery low

Tablesides Modules

One Xper Module is provided for use at either the tableside or in the control room. This module uses a touch screen, which can be operated when draped with sterile covers. The Xper Module contains the following functionality:

- Acquisition settings
- Selection of Xper Setting allows the user to set frame rates and x-ray generation settings applicable for the type of the preferred intervention

Line #	Part #	Description	Qty
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- Automatic positioning recall to allow the stand position to match the reference image.
- Image Processing

The Xper Geometry T.S.O. module can be positioned on all sides of the patient table, while keeping the button operation intuitive. The Xper Geometry T.S.O. provides the following functionality:

- Tabletop float and table height position
- Source Image Distance selection
- longitudinal movement of the Gantry along the ceiling
- Gantry rotation in an axis perpendicular to the ceiling
- Store and recall of two scratch gantry positions including SID
- Emergency stop button

The Xper Imaging T.S.O. module can also be positioned at three sides of the patient table, while keeping the button operation intuitive. The Xper Imaging T.S.O. provides the following functionality:

- Fluoroscopy Flavor selection defined per Xper Setting
- Shutters and Wedge positioning
- Xper Fluoro Storage and Grab
- Selection of the Detector field size
- Shutters positioning
- Reset of the fluoroscopy buzzer

Pan Handle

The Pan Handle is an extension of the control facility for floating movements of the table top.

Control Room

The control room comprises an Xper Review Module, a keyboard, a mouse. The Xper Review Module offers the basic functions for review. The Xper Review Module contains the following functionality:

- Power on/off
- Tagarno wheel to control the review of a patient file
- File and run cycle
- Contrast, Brightness, and Edge enhancement settings
- File, Run, Image stepping and run and file overview
- Delete run
- Image invert and digital zoom
- Reset fluoroscopy timer and enable/disable X-ray

System information is displayed on the bottom of the data monitor:

- Stopwatch and Time
- System guidance information

Line #	Part #	Description	Qty
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- Dose Area Product (DAP), Skin Dose, and accumulative dose
- Frame speed settings, fluoroscopy mode, and accumulated fluoroscopy time
- Exposure and fluoroscopy settings as Voltage (kV), Current (mA) and pulse time (ms)
- Geometry information as rotation, angulation, and SID

The workflow is divided in scheduling, preparation, acquisition, review, and archive.

Scheduling

The patients can be added, listed and selected per date, physician, and intervention type. Previous DICOM patient studies can be uploaded with the DICOM Query Retrieve function.

Patient management protocols are flexible and allow for multiple studies to be selected under one patient identification number. This means that new studies can be appended to an earlier patient file. Furthermore, each study can contain multiple examinations to allow for split administrative purposes. Each examination contains multiple files, i.e. acquisition file, reference file, and QA results file.

Preparation

The preparation page provides the information of the room and patient preparation of each individual physician. The preparation page is customizable per Xper Setting and allows each physician to provide his or her own room protocols.

Acquisition

The acquisition page contains information on the current selected patient.

Review

- The review page allows for reviewing of patient's:
- Previous examination cases
- Review of other DICOM XA or DICOM SC studies.

Coronary Quantification Software Package

Functions:

diameter measurement along the selected segment

- cross sectional area
- %-stenosis
- pressure gradient values
- stenotic flow reserve
- calibration routines

In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.

Analysis of the targeted vessel segment has been simplified by the single click function: positioning of the mouse on or close to the stenotic area and apply one click is enough to get the relevant segment detected, including the reference diameters and stenosis diameter.

Line #	Part #	Description	Qty
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RIS/CIS DICOM Interface

This package allows communication of the Allura Xper system with a local information system (CIS or RIS). The interface uses the DICOM Worklist Management (DICOM WLM) and Modality Performed Procedure Step (DICOM MPPS) standards.

If a hospital has an Allura Xper system and an information system it can receive patient and examination request information from the information system and report examination results in order to:

- Eliminate the need for retyping patient information on the Allura Xper
- Prevent errors in typing patient names and registration numbers (ensuring consistency with IS information to prevent problems in archive clusters auto-search for a name in case of later retrieval)
- Inform the IS about the acquired images and radiation dose

Upon request from the Allura Xper system the complete worklist with all relevant patient and examination data is returned from the IS to the Allura Xper system. For each patient the following information will be shown on the Allura Xper after it has been retrieved from the IS:

Patient Identification:

- Patient name
- Patient ID
- Birth date
- Sex

Examination/Request Information:

- Accession number
- Scheduled procedure step start time
- Scheduled performing physician's name

It is possible at all times to enter patient demographics information manually within the Allura Xper system in case of an emergency or in case the local Information System connection is down.

On request of the clinical user the Allura Xper will report the following information about the selected patient to the IS:

Patient Identification:

- Patient name
- Patient ID
- Birth date
- Sex

Examination/Request Information:

- Accession number
- Performed procedure step status start/end date and time
- Performing physician's name
- Referenced image sequence

Radiation dose:

- Total time of fluoroscopy

Line #	Part #	Description	Qty
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- Accumulated fluoroscopy dose
- Accumulated exposure dose
- Total dose
- Total number of exposures
- Total number of frames

Further detailed information can be found in the Allura Xper DICOM Conformance Statement.

The interface requires an EasyLink (hardware and software) if the IS is not compliant with DICOM Work List Management and Modality Performed Procedure Step.

Radiation Dose Structured Report

Collection of dose relevant parameters and settings and export to a DICOM database (e.g. PACS, RIS), according IEC60601-2-43, 2nd Edition.

The reported data can be used for, for example:

- Quality improvement: evaluating trends in X-ray dose performance per facility, system and operator.
- RDSR enables analysis of average dose levels & variance for routinely performed exams and procedures.
- Typical system usage can be extracted from the data.

Secondary Capture Dose Report

- The Secondary Capture Dose Report function allows the user to save & transfer, manually or automatically, a patient Dose Report to PACS in DICOM secondary capture format.
- The dose report will be stored in the related patient image folder.

Archive

Continuous Autopush (NCVA090)

Continuous Autopush is an archive accelerator which ensures that background archiving continues with minimal disruptions.

Clinical studies can be archived to a CD or a PACS. The archive process can be completely automated and customized with Xper Settings. Parameters like multiple destinations and archive formats can be selected to the individual needs.

The Xper DICOM Image Interface enables the export of clinical images to PACS. The export formats are based on DICOM 3.0 protocols. The system exports clinical studies in Cardiac DICOM XA Multi-Frame or DICOM Secondary Capture formats.

- The export format is configurable in 512x512 or 1024x1024.
- The examination can be sent to multiple destinations for archiving and reviewing purposes.
- The Xper DICOM Image Interface provides DICOM Storage and DICOM Storage Commitment Services.
- The DICOM Query/Retrieve function allows older DICOM XA MF and DICOM SC studies to be uploaded in the system. Furthermore, additional information can be appended to a study, while keeping the patient identification the same.

Line #	Part #	Description	Qty
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Clinical Education Program for Allura Systems

Essentials OffSite Education:

Philips will provide up to two (2) Cardiovascular Technologists, Registered Technologists Registered Nurses, or other system operator as selected by customer, with in-depth didactic, tutorial, and hands-on training covering basic functionality and work-flow of the cardiovascular imaging system. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation.

In the event that an EP Navigator workstation has also been ordered, the offsite training course will be tailored to focus on the electrophysiology functionality of the FD system and the EPN workstation.

In the event that your main FD system will be dedicated to Cardiac applications your offsite training course will be tailored to focus on the Cardiac functionality.

This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. This class is a prerequisite to your equipment handover OnSite Education. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. **Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801292102 (CV Full Travel Pkg OffSite) is purchased with all OffSite courses.**

Handover OnSite Education:

Philips Education Specialists will provide twenty-eight (28) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 28 hours, and must include the two OffSite education attendees. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. **It is highly recommended for systems that are fully loaded or for customers with a large number of staff members to also purchase 989801292099 (CV Add OnSite Clin Educ 24h).**

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref# 106107-110915

2	**NNAE854	FlexVision_XL 9 Input Package	1
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The FlexVision XL9 input package provides eight isolated wall connection boxes.
Isolated Wall Connection Box

This Isolated Wall connection Box facilitates connection of the video source via standard DVI cable/connector and lossless transfer of the video signal over the approximate 30 m cable distance. It can be mounted in the exam room or in the control room, depending on the location of the video source.

The quantity of the VWCB's has to be calculated as follows:

For each video signal to FlexVision XL on Vascular System: 9 VWCB

Note:

No VWCB is required in case a video signal is connected directly to a dedicated LCD from the following sources:

Line #	Part #	Description	Qty
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1) Xper Live/ref Slaving

2) Interventional HW (XtraVision), ViewForum, Xcelera (only if workstations are powered by Allura Xper)

3)Xper IM

3	**FCV0587	Xper Live/Ref Slaving	2
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This option contains a kit to split the Live or Ref video source from the Allura Xper. The total amount of Xper Live/Ref Slaving that can be selected is maximal. 4. Additional monitors are not included in this option and must be ordered separately. This kit contains a video splitter and a cable set for one slave monitor. The Slave monitor is not powered by Allura.

4	**NCVA080	Automatic Position Control (APC)	1
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The Automatic Position Controller (APC) for Integris Allura Flat Detector systems provides two modes of operation:

- Preset Position Sequence; the sequence of projections is determined per Xper Settings. Each set contains a maximum of 10 positions. Positions can be recalled in sequence or directly. The projection sequence comprises rotation, angulation, and SID settings, related to the selected reference image.
- Reference driven positioning. The projections on the reference monitors can be recalled with the push of a button. The reference driven positioning recollects the rotation, angulation, and SID.

5	**NCVA121	FULL AUTOCAL	1
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The AutoCal option is a software package to be used in conjunction with quantitative analysis software packages. It provides an auto calibration procedure for an object to be analyzed that is placed in the iso-center. When the object to be analyzed (e.g. Left Ventricle Vessel Segment) is placed in the iso-center AutoCal avoids the need to:

- acquire an additional image series containing a sphere or grid for calibration purposes
- calibrate manually on a calibration object (e.g. catheter) displayed in the image or image series to be analyzed

6	**NCVA784	Ventricular Quant.Sw pkg(Xper)	1
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Left Ventricular Quantification Software Package. Software package for the analysis of single plane Left ventricular angiograms. Calculates the Ejection fraction and local wall motion parameters in different formats.

Functions:

- Various LV-volumes
- Ejection Fraction
- Cardiac Output
- Centerline Wall Motion
- Slager Wall Motion
- Regional Wall Motion
- Calibration routines

Line #	Part #	Description	Qty
		In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.	
		Comprising:	
		<ul style="list-style-type: none"> software license 	
		Compatible with:	
		. Allura Xper FD 10 Rel 3 and FD10/10 Rel 2 onwards	
		. Allura Xper FD20 Rel 2, FD20/10 Rel 2 onwards	
7	**NCVA097	Cath Arm Support	1
		For brachial catheterisation and digital imaging technique The support is made of X-ray transparent material with exception of the fixingclamp and pivots.	
8	**NCVA783	Pivot for table base.	1
		For angiographic- and interventional procedures of the upper peripherals. Provides improved table access for patient transfer. Allows pivoting of the table base around its vertical axes. Pivot range from -90 degrees to + 180 degrees (or -180 to +90 degrees) with locked positions on 0, -13/+13 (facilitating arm-angiography) and -90/+90 and 180 degrees.	
		Comprising:	
		<ul style="list-style-type: none"> pivot device with graduated scale to be mounted on the universal floor plate of the table. 	
		Compatible with Xper Table	
9	**FCV0510	Long mattress cardio	1
		Patient mattress, thickness 70 mm, length 3165 mm, width 500 mm	
10	**NCVB630	FlexVision XL,Snapshot	1
		FlexVision XL is an integrated viewing solution designed to give you full control over your viewing environment. The FlexVision XL provides the ability to: <ul style="list-style-type: none"> Display information from up to 8 sources simultaneously (incl. third party systems) on the Philips 58-inch color LCD with LED backlight in the Exam Room. Resize and/or enlarge information at any stage during the case. Select and customize viewing lay-outs of the Philips 58-inch color LCD via the Xper table-side module Overview connected equipment (incl. third party systems) from a single location. The FlexVision XL consists of: <ul style="list-style-type: none"> DVI video composition unit. <ul style="list-style-type: none"> The DVI video composition unit allows the user to direct and switch the video output of all connected medical equipment to specific sub windows of the Philips 58-inch color LCD with LED backlight in the Exam Room. The DVI video composition unit is operated from the Xper tableside module. The DVI video composition unit supports a wide variety of display formats (up to 1920x1200) Up to 9 external inputs are connected to the DVI video composition unit via Wall Connection Box(es). Medical grade, high resolution color LCD in the Exam Room 	

Line #	Part #	Description	Qty
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- o This display supports the image quality requirements for monochrome X-ray images as well as color images and replaces all displays normally delivered with an Allura Xper FD or AlluraClarity system for the Exam Room.
- o Main characteristics are:
 - 58-inch, 8 Megapixel color LCD
 - Native resolution: 3840x2160
 - Brightness: Max: 700 Cd/m2 (typical) stabilized: 400 Cd/m2
 - Contrast ratio: 4000:1 (typical)
 - Wide viewing angle (approx. 176 degrees)
 - Constant brightness stabilization control
 - Lookup tables for gray-scale, color and DICOM transfer function
 - Full protective screen Ingress Protection: IP-21
 - Large color LCD control (Xper Module)
- o Resize and/or enlarge information at any stage during the case via the Xper table-side module in the Exam or Control Room
- o Select viewing lay-outs via the Xper table-side module in the Exam Room
- o Create new layouts by matching inputs to desired locations on preset templates.

- Monitor Ceiling Suspension
 - o Monitor ceiling suspension for use in the Exam Room carries the 58-inch color LCD, providing highly flexible viewing capabilities. The monitor ceiling suspension is height-adjustable and moveable along ceiling rails. It can be positioned on either side of the table.

- Snapshot
 - o The snapshot function allows the user to store/save a screen-capture of any image on the 58-inch display as a DICOM Secondary Capture image to a connected PACS. The snapshot-all function allows the user to store/save a screen-capture for each displayed image in the Exam Room / Control Room as separate DICOM Secondary Capture images .

11	**NCVB294	Set of 2 additional 21in. LCDs	1
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Two 21inch additional displays are located on top of the monitor ceiling suspension frame which carry the 56 inch large screen color LCD display.

These 2 additional LCD's can be used to display additional video sources or used as display back up for Hemo and Xray Live images. These LCD's have a fixed content.

Main characteristics of back-up displays are:

- 21.3 inch, 2 Megapixel color LCD display
- Max. resolution: 1600x1200
- Brightness: 450 Cd/m2
- Contrast ratio : 550:1

Line #	Part #	Description	Qty
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- Wide viewing angle (approx. 170 degrees)
- Constant brightness stabilization control
- Independently selectable brightness settings for monochrome and color images
- Independently selectable lookup table for gray-scale, color and DICOM transfer function

FCV0587, "XPer Live/Ref Slaving" required when displaying X-Ray Live as back-up.

12	**NCVB591	2ND REF for FlexVision XL	1
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2nd REF for FlexVision XL is optional on FlexVision XL. Second Ref images will be displayed on the large screen monitor.

13	**980306640009	Black Anti-Fatigue Floor Mat w/ Blue Logo	2
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Blue Anti-Fatigue Floor Mat w/ Logo

14	**980406041009	Rad Shield w/ Arm (Contoured) 61X76	1
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Contoured Rad Shield with Arm rest. 61X76

15	**980406190009	PIVOTING TABLE-MOUNTED RADIATION SHIELD	1
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Table-mounted radiation shield for additional protection of physician and staff against scatter radiation. The shield consists of two protective parts: a lower shield and an upper shield. The shield is specially designed for use with the AD5 patient table.

The table mounted radiation shield provides the following features:

- Mounting to either the right or left table accessory rails;
- Pivoting into the required working position;
- Pivoting into the parking underneath the tabletop facilitating patient preparation;
- The upper shield can be positioned upright providing optimal protection or can be folded down for free access to the patient.

The table mounted radiation shield includes:

- Lower shield measuring 70 cm high 80 cm wide 0.5 mm Pbequivalence;
- Upper shield measuring 40 cm high 50 cm wide 0.5 mm Pbequivalence;
- Mounting clamp;

Docking device for wall mounting.

16	**989801220012	Cable Spooler	1
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17	**989801220273	Ceiling Track w/Column & Handle Ext	1
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Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.

18	**989801220279	LED Single Color Exam Lamp	1
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Line #	Part #	Description	Qty
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LED Single Color M LED130F
Examination Lamp

Portegra2 Extension/Spring Arm Combination with M LED 130F,
Single Color, incl. Power Supply

Light in new dimension LED lamps support your daily operations through innovative technology and design. In addition to advantages provided by MAVIG with all light equipment, LED technology offers the following enhanced features:

- Faceted multi-lens system
- In-depth illumination
- Superior color rendition
- Extension arm 750mm
- Spring arm 900mm
- LED-Examination-light
- Operating voltage is 24V DC. The lamp is supplied with a transformer, should it be used with 230V.

Technical data LED 130F:

- Light intensity at 1 meter distance: 60.000 Lux
- Color rendering index: Ra = 95
- Focusable: yes
- Focusable size of the light field: 14-25 cm
- Color temperature: 4500 Kelvin
- Electronic light intensity control at the lamp head: standard dimming range: 50 - 100 %
- Temperature increase in head area: 0.5° C
- Mains: 230 V / 60 Hz
- Power consumption: 28 W
- Number of LEDs: 19
- Life-span of the LEDs: > 40.000 h
- Diameter of the lamp head: 33 cm
- Working distance: 70 - 140 cm
- Height Adjustment: 117 cm

19	**989801220370	Low Load 15 kW UPS	1
	MGE Galaxy 5000 80 kVA Low Load – 15kW UPS G5TUPSU80KPLL Adjacent MGE Galaxy 5000 Battery Cabinet with one full string of batteries and standard Galaxy 5000 Adjacent battery Temp sensor. High Voltage 6 Alarm Relays Card MGE GALAXY 5000 Remote Alarm Status Panel MGE SNMP/Web Communication Card Top Feed Auxiliary Cabinet		

In the event of a power loss the UPS provides emergency power to allow system function but limits the X-Ray function to the use of fluoroscopy for up to 15 minutes.

20	**989600213942	AD5 TO XPER TABLE ADAPT. PLATE	1
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Line #	Part #	Description	Qty
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21	SP005	Contract Labor Labor and services to remove and dispose of existing Philips H5000 equipment.	1
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22	SP003	Installation Labor Weekend delivery and first weekend installation labor.	1
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23	SP019	Trade in Allowance Customer represents and warrants that (i) Customer has, and shall have when title passes, good and marketable title to the equipment being traded in and (ii) has the authority to effect such trade in. Product: MCV2786 INTEGRIS H5000C Serial Number: 101216 Manufacturer: PHILIPS HEALTHCARE	1
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Trade-In authorization number: 40308
Trade-In Value: \$0.00
De-install Date: 7/15/2016

Customer will be trading-in equipment that is described on the attached System Disclosure Form (the "Trade-In"), which Trade-In the parties agree (i) will be removed on the De-install Date and (ii) is currently in the condition as represented on the System Disclosure Form. In addition, the parties agree as follows:

1. Customer represents and warrants that Customer has good and marketable title to the Trade-In as of the date of this Quotation and will have good and marketable title when Philips removes the Trade-In from Customer's site (the "Removal Date");
2. Title to the Trade-In shall pass from Customer to Philips on the Removal Date, unless otherwise agreed by Philips and the Customer;
3. Notwithstanding anything to the contrary in any Business Associate Addendum, Customer represents and warrants that as of the Removal Date all Protected Health Information will have been de-identified or removed from the Trade-In;
4. Philips may test and inspect the Trade-In prior to de-installation. If the condition of the Trade-In is not substantially the same on the Removal Date (ordinary wear and tear excepted) as it is identified on the System Disclosure Form, then Philips may reduce the price quoted for the Trade-In;
5. If the removal date is delayed until after the De-Install Date, unless Philips causes the delay, then Philips may reduce the price quoted for the Trade-In by six percent (6%) per month.
6. Philips is responsible for normal de-installation costs of the Trade-In.
7. The trade-in value will not include costs associated for any facility modifications and/or rigging required for de-installation and must be accounted for separately.
8. Customer is responsible for all plumbing necessary to properly drain coolant from chiller system and cap the lines.
9. Prior to the Removal Date, Customer shall remove from the room all equipment that is not being de-installed.

*****PROMOTIONS*****

Promotion Name	Description
Mono Closer 2016-Q2	Philips is pleased to offer this special promotional discount of \$50,000 with the purchase of a monoplane Allura system. To be eligible for this promotion, orders must be received by June 30, 2016.

*****PROMOTIONS*****

Promotion Name	Description
SmartPath Loyalty Promotion 2016-Q2	This special Customer Loyalty promotion provides an additional discount of \$50,000 to existing Interventional X-ray customers with selected Integris systems installed. In addition to the dollar discount this promotion provides, the Customer Loyalty Program can reduce room down time and room construction costs by installing the Allura Xper System within the existing room footprint. All orders for this promotion must be received on or before June 30, 2016.
AlluraClarity New System Promotion (Monoplane) 2016-Q2	Philips is pleased to offer this special \$50,000 discount for customers purchasing AlluraClarity systems. To take advantage of this promotion, customer orders must be placed prior to June 30, 2016.

NET PRICE

\$975,865.11

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA Contract #: SCA11505G

Add'l Terms: Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for applicable T&C details. If Service Agreement is quoted its T&C of Sale are printed

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.

Price above does not include any applicable sales taxes.

The preliminary delivery request date for this equipment is: _____.

If you do not issue formal purchase orders indicate by initialing here _____.

Tax Status:

Taxable _____ Tax Exempt _____

If Exempt, please indicate the Exemption Certification Number: _____, and attach a copy of the certificate.

Delivery/Installation Address:

Invoice Address:

Contact Phone #:

Contact Phone #:

Purchaser approval as quoted:

Date:

Title:

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.

OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
1	**989801220217	Q-Digital Base Station (6 User) The Q-Digital Base Station 6 user includes the following items: One BASE STATION Q-RB/N Operating frequency: 1.910-1.930 GHz Power requirements: 100-240v AC voltage sensing (mains cable supplied) Dimensions H x W x D: 205mm x 255mm x 42mm Weight: 800g Headset capacity: Up to 6 headsets per base station.	1	\$2,094.08	\$2,094.08	_____
2	**989801220275	Q-Digital Charge Docking Station 6 Port CHARGER Q-RCH Capacity: 6 port Power requirements: 12v c/w external power supply Dimensions H x W x D: 110mm x 330mm x 100mm Weight: 1kg Mounting: Wall/desk Charge modes: Fast charge	1	\$522.24	\$522.24	_____
3	**989801220276	Q-Digital AIO Headset HEADSET Q-RH7/N Frequency: 1.910-1.930 GHz Weight: 50g Battery: Removable Lithium Ion Charge time: 2.5 hours Battery capacity between charges: 8 hours push-to-talk, 6 hours talk-lock Operating modes: Vox, talk-lock and push-to-talk standard Voice prompts (range + charging): Registration status, battery low and out-of-range voice prompts standard Volume control: 5-stage, slide button up/down Microphone: Noise canceling	6	\$327.68	\$1,966.08	_____
4	**989801220277	Q-RH7 Spare Battery	6	\$46.08	\$276.48	_____
5	**989801220284	ISM Advanced Audio Package The Premium Audio Package is comprised of the following items: Control System - Touchscreen Control Package offers touchscreen control with 7" Touch panel Advanced Audio Communication System with Hands Free Telephony - Advanced audio uses an echo cancelling audio communication system with the EasySuite touchscreen to call or receive a telephone call. The hands-free system utilizes O.R. loudspeakers and 1 boom mounted microphones with no handset required. MP3 Audio and Charging Interface - Universal MP3 music interconnection system allows any 3.5mm jack-enabled personal audio device to play music through the Advanced Audio System. Provides integrated charging capability via USB.	1	\$25,095.20	\$25,095.20	_____

OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
		Speaker Upgrade for AAC (adds 2 additional speakers for Exam Room) Upgrade adds two recessed ceiling mounted speakers to the Standard Audio System, or Advanced Audio System, for a total of four speakers per Operating Room.				
		PTT Control Room Communication System with Control Room Loudspeakers - Push to talk intercom microphone system for control room plus two recessed ceiling mounted speakers for Control Room.				
		Ambient Room Lighting Control Enables touch panel control of room lights using customer provided lighting controller. Functions include on/off and ability to select multiple lighting presets.				

CARDIOVASCULAR (CV) SYSTEMS

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. The terms and conditions of the quotation are incorporated into this warranty document. The capitalized terms herein have the same meaning as set forth in the quotation.

TWELVE-MONTH SYSTEM WARRANTY

Philips warrants to Customer that the Philips Vascular and Cardiac Systems (the "System") as delivered to Customer will perform in substantial compliance with its performance specifications for a period of twelve (12) months upon first patient use. Any glassware or flat detectors provided with the System is subject to special warranty terms set forth below.

PLANNED MAINTENANCE

During the warranty period, Philips personnel will schedule planned maintenance visits, in advance, at a mutually agreeable time on weekdays, between 8:00 A.M. and 5:00 P.M. local time, excluding Philips observed holidays.

SYSTEM UPGRADES

Any commercially available upgrade to the System which is hereafter installed by Philips during the original term of the System warranty shall be subject to the warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire on the later of: a) upon termination of the initial twelve (12) month warranty period for the System on which the upgrade is installed or b) after ninety (90) days for parts only from the date of installation.

MRC X-RAY TUBES

Philips warrants to Customer, for the warranty periods further specified in this section, that the Philips X-Ray tube will be substantially free from defects in material and manufacturing workmanship, which impair performance under normal use as specified in Philips product descriptions and specifications.

The warranty period for MRC tubes provided with Customer's purchase of a new or refurbished X-ray system shall be the shorter of thirty-six (36) months after installation or thirty-eight (38) months after date of shipment from Philips. The warranty period for purchases of replacement tubes shall be the shorter of twelve (12) months after installation or fourteen (14) months after date of shipment from Philips.

MRC TUBE WARRANTY EXCLUSION

The above warranty shall not apply to X-ray tubes outside the United States and Canada. Philips' obligations under the product warranty do not apply to any product defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the product; or, to viruses or similar software interference resulting from the connection of the product to a network.

MRC TUBE WARRANTY REMEDIES

If a tube is found to fail during the warranty period, and if, in the best judgment of Philips, the failure is not due to neglect, accident, improper installation, use contrary to instructions, or the exclusions stated above, Philips' tube warranty liability hereunder is limited to, at Philips option, the repair or replacement of the tube. Any replacement tube would have a warranty period equal to the balance of the warranty period left on the tube replaced.

IMAGE INTENSIFIER TUBES

Philips warrants the image intensifier tubes provided with the System, if any, will be free from defects in material and manufacturing workmanship for twenty-four (24) months. Claims must be made within twenty-four (24) months after installation or twenty-seven (27) months after date of shipment from Philips, whichever occurs first. If an image intensifier tube fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the tube, Philips will provide a prorated credit towards the purchase of a replacement tube from Philips as follows:

USAGE	CREDIT
0 to within 12 months	100%
12 to within 13 months	50%
13 to within 14 months	46%
14 to within 15 months	42%
15 to within 16 months	37%
16 to within 17 months	33%
17 to within 18 months	29%
18 to within 19 months	25%
19 to within 20 months	21%
20 to within 21 months	17%
21 to within 22 months	12%
22 to within 23 months	8%
23 to within 24 months	4%

Tubes received by Philips under this warranty that are found to meet all test specifications will be returned to the Customer and the warranty will continue as of the original date of installation. Examination of the returned tube may necessitate its destruction, but Philips' liability shall, in any case be limited to repair or replacement as aforesaid, only if in its sole opinion the tube has been properly used, installed and applied and has not been subjected to neglect, accident, or improper installation, or use. Transportation charges and risk of loss, both ways, of returned or replaced tubes shall be at the expense of the Customer.

DYNAMIC FLAT DETECTORS

Philips warrants the flat detectors provided with the System, if any, will be free from defects in material and manufacturing workmanship for twelve (12) months. Claims must be made within twelve (12) months after installation or fifteen (15) months after date of shipment from Philips, whichever occurs first. If a detector fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the detector, Philips will provide Customer a replacement detector at no additional charge.

SYSTEM SOFTWARE AND SOFTWARE UPDATES

The software provided with the System will be the latest version of the standard software available for that System as of the 90th day prior to the date the System is delivered to Customer. Updates to standard software for the System that do not require additional hardware or equipment modifications will be performed as a part of normal warranty service during the term of the warranty.

All software is and shall remain the sole property of Philips or its software suppliers. Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product. No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

Any Philips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the System, to assist Philips and its authorized agents to maintain and to service the System under a separate support agreement with Customer, or to permit Customer to maintain and service the System. Customer agrees to restrict the access to such software and documentation to Philips' employees and those of its authorized agents, and to authorized employees of Customer only.

WARRANTY LIMITATIONS

Philips' obligations under the System warranty are limited, at Philips' option, to the repair or the replacement of the System or a portion thereof, or to a credit or refund of a portion of the purchase price paid by Customer. Any refund or credit will be paid to Customer when the System is returned to Philips. Certain of the parts used in the manufacture or installation of, or in the replacement parts for, this System may contain refurbished components. If such components are used, they will be subject to the same quality control and inspection procedures as all other components in the System. Any System warranty is made on condition that Philips receives written notice of a System defect during the warranty period, and within thirty (30) days following the discovery of the defect by Customer. Philips' obligations under the System warranty do not apply to any System defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the System; or to viruses or similar software interference resulting from the connection of the product to a network. Philips does not provide a warranty for any such third party products furnished to Customer by Philips; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described above are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a System warranty. Repairs or replacement parts do not extend the term of this warranty.

THE WARRANTIES SET FORTH IN THIS WARRANTY DOCUMENT WITH RESPECT TO THE SYSTEM (INCLUDING THE SOFTWARE PROVIDED WITH THE SYSTEM), GLASSWARE, AND DETECTORS ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE SYSTEM, SOFTWARE, GLASSWARE, DETECTORS, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ACCESS TO SYSTEM

Philips shall have full, free and safe access to the System and Customer's operation, performance and maintenance records for the System, on each scheduled or requested warranty service visit. Philips shall also have access to and use of any machine, service, attachment, features or other equipment required to perform the necessary service contemplated herein at no charge to Philips. Customer waives warranty service if it does not provide such access to the System and Customer's records. Should Philips be denied access to the System and Customer's records at the agreed upon time, a charge equal to the appropriate hourly rate will be accepted by Customer for "waiting time."

WARRANTY SERVICE

In the event it is not possible to accomplish warranty service within normal working hours (8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips observed holidays), or in the event Customer specifically requests that warranty service be performed outside of Philips normal working hours, Customer agrees to pay for such services at Philips standard service rates in effect. Maintenance Agreements are available for extended coverage.

TRANSFER OF SYSTEM

In the event Customer transfers or relocates the System, all obligations under this warranty will terminate unless Customer receives the prior written consent of Philips for the transfer or relocation. Upon any transfer or relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications. Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed. Any System which is transported intact to pre-approved locations and is maintained as originally installed in mobile configurations will remain covered by this warranty.

CONDITIONS

This warranty is subject to the following conditions: the System (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips), (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips written instructions and for the purpose for which the products were intended, (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the System, and (d) Customer is to notify Philips immediately in the event the System at any time fails to meet its printed performance specifications.

LIMITATIONS OF LIABILITY AND DISCLAIMERS

The liability, if any, of Philips AND ITS AFFILIATES for damages whether arising from breach of the terms in the quotation, breach of warranty, negligence, indemnity, strict liability or other tort, or otherwise with respect to the products and services is limited to an amount not to exceed the price of the product or service giving rise to the liability.

IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF THE TERMS IN THIS QUOTATION, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT. PHILIPS SHALL HAVE NO LIABILITY FOR ANY GRATUITOUS ADVICE PROVIDED TO THE CUSTOMER.

FORCE MAJEURE

Philips and Customer shall each be excused from performing its obligations arising from any delay or default caused by events beyond its reasonable control including, but not limited to: acts of God, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.

Philips system specifications are subject to change without notice Document Number 4535 983 03234 999

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

PHILIPS

Quotation #: 1-1ECCN9H	Rev: 2	Effective From: 25-May-16	To: 27-Jun-16
Presented To: CONE HEALTH 1200 N ELM ST GREENSBORO, NC 27401-1004 Tel: Alternate Address:	Presented By: Chris Mason <i>Account Manager</i> John Baumann <i>Regional Manager</i>	Tel: (615) 517-6955 Fax: Tel: Fax:	
Date Printed: 25-May-16			
Submit Orders To: 22100 BOTHELL EVERETT HWY BOTHELL WA 98041 Tel: Fax: (425) 458-0390			

This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips Electronics North America Corporation ("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>
	100751 Xper Flex Cardio	1	\$58,926.50
Equipment Total:			\$58,926.50

Quotation Summary

<u>Product</u>	<u>Qty</u>	<u>Each</u>	<u>Monthly</u>	<u>Price</u>
100751 Xper Flex Cardio	1	\$58,926.50		\$58,926.50

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA **Contract #:** SCA11505G

Add'l Terms: Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for applicable T&C details. If Service Agreement is quoted its T&C of Sale are printed

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: 10% With Signed Acceptance of the Quotation, 70% Upon Delivery of Major Components, 20% Due When the Product is Available for First Patient Use, Whichever Occurs First, Net due upon Receipt

Quote Summary

Qty	Product
1	P_860335_SF1 Side Stream ETCO2
1	P_860335_SF5 FFR Measurement Volcano
1	P_860338_UG9 PM5 to Xper Flex Cardio Upgrade
1	P_860337_DS1 4:3 LCD HQ Display (19 inch)
1	P_860337_AC8 UPS - Medical Grade
1	P_860337_DM6 Xper Flex Cardio Table Mount
1	P_860337_CK1 Installation Cable Kit Control Room
10	989801200724 Contracts - Onsite PS Hours
40	989801200726 Contracts - Remote PS hours
1	FNA0857 Total number of Facilities

100751 Xper Flex Cardio

System Type: New
Freight Terms: FOB Destination
Warranty Terms: Part numbers beginning with two (2) asterisks (**) are covered by a System 12 Months Warranty. All other part numbers are third (3rd) party items.
Special Notations: Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date. Any rigging costs are the responsibility of the Purchaser.
Additional Terms: Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for applicable T&C details. If Service Agreement is quoted its T&C of Sale are printed

Line #	Part #	Description	Qty	Each	Price
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1	**P_860335_SF1	Side Stream ETCO2	1	\$7,014.90	\$7,014.90
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Incorporates Side Stream End Tidal CO2 monitoring capabilities to Xper Flex Cardio devices via external Philips Sidestream cable (M2741A)

- Monitoring accomplished via nasal canula.

Include:

- One box (10 each) disposable Adult CO2/O2 Nasal Canulas (M2750A)
- One box (10 each) disposable Pediatric CO2/O2 Nasal Canulas (M2751A)

2	**P_860335_SF5	FFR Measurement Volcano	1	\$10,974.60	\$10,974.60
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The FFR Measurement for Volcano option enables a Volcano SmartMap(tm) device to be connected to Xper Flex Cardio physiomonitoring system for integrated Fractional Flow Measurements.

Features

- Compatibility with Volcano SmartMapTM device allowing use of Volcano guide wires for monitoring pressure waveforms
- Ability to record a sample of the pressure waveform
- Real time, dynamic FFR measurement and capture
- Retrospective review of FFR pressure waveform

Requires

- Model 6500 SmartMap Pressure Instrument (not included)
- *Customer is responsible for purchasing the SmartMap Model 6500 device and compatible guide wires directly from Volcano Corporation

3	**P_860338_UG9	PM5 to Xper Flex Cardio Upgrade	1	\$31,784.80	\$31,784.80
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This is for customers upgrading their current Xper Physiomonitoring 5 system to the Xper Flex Cardio Control Room configuration. Existing PM5 Host and Front End components become the property of and must be returned to Philips Andover location.

Xper Flex Cardio Control Room configuration is a physiomonitoring/hemodynamic system that is optimized for the cath lab environment. The system allows for monitoring the patient's vital signs as well as allows for hemodynamic measurements required during interventional procedures. This Control Room configuration consists of a signal acquisition unit that is installed within the procedure room and a computer workstation in the x-ray control room. This configuration is typically used within the cath lab, hybrid OR and multi-purpose labs where cardiac monitoring is required. User logins allow for networking to a central database server for archival of case procedure information. The system outputs the monitored signals to a Medical Grade boom display within the procedure room, while dual LCDs displays connected to the control room workstation can be used for all of the hemodynamic and information management functionality.

Software Features:

- Physiomonitoring, manual or automated entry of patient information in case details, sampling of waveforms, charting, hemodynamics

Line #	Part #	Description	Qty	Each	Price
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-Non-clinical functionality available via Xper Information Management modules loaded on the control room workstation

Xper Information Management modules included:

- Hemodynamic control software
- Charting for case procedure documentation
- Hemodynamic calculations
- Vitals capture
- Arterial Trees
- Custom Forms
- Transcription
- Inventory
- Scheduler
- Data Analysis
- Registries

Optional Features:

- FFR Measurement for Volcano and/or St. Jude
- End Tidal CO2 (Side Stream and/or Main Stream)
- 16 Lead ECG
- ECG Analysis using Philips DXL Algorithm

Optional Features:

- Xper IM Patient Status Viewer

Minimum Hardware included:

- Flex Cardio device (Model FC2010)
- Workstation
- Dual 22" LCD Displays
- Keyboard
- Mouse

Monitoring functionality included:

- NIBP
- Respiration
- Temperature
- 12-lead ECG
- SpO2
- Cardiac output (Thermodilution)
- Invasive pressures (4 channels)

Requires:

- Xper IM Data Center SW R1.5. Note: Existing networks to which a Flex Cardio is to be added will be upgraded to R1.5 at time of room installation
- Table Mount
- 19" LCD Medical Grade Boom Monitor

NOTE:

- Pressure transducers, or adapter cables, are not included.
- Contact: Fogg System Company
- USA: 1-800-525-0292
- <http://www.foggssystem.com/>

4	**P_860337_DS1	4:3 LCD HQ Display (19 inch)	1	\$877.70	\$877.70
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100751 Xper Flex Cardio

Line #	Part #	Description	Qty	Each	Price
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19" Medical Grade LCD Color Display (1280 x 1024 resolution) for mounting on suspension boom in procedure room, or for use with client workstations

- Includes VGA Cable (To be pulled / installed by customer). Cable not included with Boom monitor if purchased with a hemodynamic system, as the cable is included with that product.

5	**P_860337_AC8	UPS - Medical Grade	1	\$160.80	\$160.80
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Medical grade UPS for use with Xper Information Management Flex Cardio servers

6	**P_860337_DM	Xper Flex Cardio Table Mount	1	\$368.50	\$368.50
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This Xper Flex Cardio Table Mount is a customized mounting system and is required to mount FC2010 to x-ray table. The mount includes cable management to minimize clutter of cables connected to the FC2010 device.

*This wall mount is optimized for the Philips Allura X-ray table, but could be used for x-ray tables from other manufacturers.

7	**P_860337_CK1	Installation Cable Kit Control Room	1	\$911.20	\$911.20
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Provides all installation cables required for normal installation, Flex Cardio Control Room.

8	**989801200724	Contracts - Onsite PS Hours	10	\$174.20	\$1,742.00
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Philips Healthcare applies disciplined project management methodology to delivery of each engagement. Our methodology closely parallels the Project Management Institute's (PMI) worldwide -recognized framework of Initiating, Planning, Executing, Controlling and Closing. The Philips team, led by an experienced project manager, will work with you throughout the duration of the project to deliver the products and services described in this quotation. Team members typically include the following:

- Implementation Specialists - responsible for technical work such as installation and configuration of the system hardware and software
- Application Consultants – responsible working within the clinical environment providing expertise in workflow, application configuration and training
- Integration Engineer – responsible for development and testing of HIS and clinical interfaces

The work effort to implement your solution is based upon the specific configuration that has been defined in the quotation. The Statement of Work (SOW) or Project Scope Document (PSD) describes how the solution will be implemented within your environment.

For Government accounts, signed meeting minutes of the work effort involved can also be used as a substitute for the signed SOW.

9	**989801200726	Contracts - Remote PS hours	40	\$127.30	\$5,092.00
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Philips Healthcare applies disciplined project management methodology to delivery of each engagement. Our methodology closely parallels the Project Management Institute's (PMI) worldwide -recognized framework of Initiating, Planning, Executing, Controlling and Closing. The Philips team, led by an experienced project manager, will work with you throughout the duration of the project to deliver the products and services described in this quotation. Team members typically include the following:

Line #	Part #	Description	Qty	Each	Price
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10	**FNA0857	Total number of Facilities	1		
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LIST PRICE	\$87,950.00
DISCOUNT	\$29,023.50
	\$0.00
NET PRICE	\$58,926.50

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA Contract #: SCA11505G

Add'l Terms: Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for applicable T&C details. If Service Agreement is quoted its T&C of Sale are printed

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Price above does not include any applicable sales taxes.

The preliminary delivery request date for this equipment is: _____.

If you do not issue formal purchase orders indicate by initialing here _____.

Tax Status:

Taxable _____ Tax Exempt _____

If Exempt, please indicate the Exemption Certification Number: _____, and attach a copy of the certificate.

Delivery/Installation Address:

Invoice Address:

Contact Phone #:

Contact Phone #:

Purchaser approval as quoted:

Date:

Title:

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.