

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

2704 Mail Service Center • Raleigh, North Carolina 27699-2704 http://www.ncdhhs.gov/dhsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief Phone: (919) 855-3873 Fax: (919) 733-8139

September 24, 2012

Mr.David French, Consultant P.O. Box 2154 Reidsville, NC 27323-2154

#### No Review

Facility: Carolina Vascular Access Holdings, LLC, Chapel Hill

Project Description: Purchase a second C-arm

County: Orange

FID#:

Dear Mr. French:

The Certificate of Need Section (CON Section) received your letter(s) of September 6, 2012 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in project include, but are not limited to: (1) increase in capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) Change in location; and (5) any increase in the number of square feet to be constructed.

In addition, you should contact the Construction Section of the DHSR Section to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.





& Page 2

Sincerely,

F. Gene DePorter, Project Analyst Certificate of Need Section

Craig R. Smith, Chief Certificate of Need Section

cc: Construction Section, DHSR



Dry.



September 6, 2012

Mr. Craig Smith
Certificate of Need Section
North Carolina Department of Health and Human Services
2704 Mail Center Service
Raleigh, NC 27699-2704

Re: Request for No Review / Carolina Vascular Access / Purchase a second portable C-Arm (x-ray unit)

Dear Mr. Smith:

I am writing on behalf of Carolina Vascular Access Holdings, LLC regarding the purchase of a second portable C-arm (x-ray unit) for use in the physician office building at 2214 Nelson Hwy, in Chapel Hill NC 27517. The purpose of this letter is to request a "letter of no review" from your office confirming that the acquisition of this additional equipment will not require a certificate of need.

As seen in the attached correspondence dated May, 22, 2012, Carolina Vascular Access Holding, LLC obtained an exemption letter from the Certificate of Need Section for the development of a physician office building and the purchase of a portable C-arm unit. The capital cost of this portable C-arm unit was \$143,730. This type of equipment is in use and remains movable within the building and has been made operational without any installation cost; no other equipment has a capital cost of greater than \$10,000.

Carolina Vascular Access Holdings, LLC now seeks a letter of no review to obtain a second portable C-arm unit because the first unit has achieved full utilization. Like the previously purchased C-arm unit, the second C-arm will be movable and can be made operational without any installation cost or other equipment. Attached is a copy of the recent quote from Philips for the purchase of the second portable C-arm unit.

The combined cost of the existing portable C-arm unit plus the additional unit is summarized below:

Previously purchased portable C-arm (quote 1-VS47VO)	\$143,729.90
Proposed second portable C-arm (quote WQ3-SMD)	<u>\$149,785.90</u>
Total combined cost	\$293,514.80

The acquisition of the second C-arm unit results in a total combined equipment purchase cost that is far below the \$500,000 threshold value of a "diagnostic center" as defined in § 131E-176 (7a) and below the \$750,000 amount for "major medical equipment" provided in § 131E-176 (14o).

Phone:

336-349-6250

Fax:

336-349-6260

Mailing Address Post Office Box 2154 Reidsville, NC 27323-2154 If you require additional information on this matter, please do not hesitate to call me at 336 349-6250.

Sincerely,

David J. French

Consultant to Carolina Vascular Access Holdings, LLC

Cc: Virginia Hamilton

Llung Aml

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



Quotation #: 1-WQ3SMD	Rev: 3	Effective From: 10-Aug-1	2 To: 24-Sep-12
Presented To:		Presented By:	
CAROLINA VASCULAR ACCESS 2214 NC 54 HWY	HOLDING LLC	Bethann Griffith-Subik <i>Account Manager</i>	Tel: (919) 677-9046 Fax: (919) 677-9047
CHAPEL HILL, NC 27517		Steve Weiss <b>Regional Manager</b>	Tel: (678) 924-6087 Fax: (678) 924-6003
Tel:			
Alternate Address:			
Date Printed: 10-Aug-12	ar ng sand kri kan da maga din sand kan king di din da nda na da na da na da na n		
Annual ving van groep de de de de se strange en tregen de de dels men de	daman ja daga samyah samahiya orona indek dijalah dijajah kilaye di kalance di kande daga dijalah di samahin d		
Submit Orders To:			
22100 BOTHELL EVERETT HWY BOTHELL WA 98021	,		
Tel: (888) 564-8643			

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).

	(a)[[6](i	Solution Summary	
Line#	Product	Qty	<u>Price</u>
	100495 BV Pulsera, rel. 2.3	1	\$149,785.90
		Equipment Total:	\$149 785 90

Solution	Summany	D/S/Fil		
Product	<u> Qty</u>	Each	<u>Monthly</u>	<u>Price</u>
100495 BV Pulsera, rel. 2.3	1	\$149,785.90		\$149,785.90

Buying Group: MEDASSETS SUPPLY CHAIN SYSTEMS INC Contract #: EP 127

Addt'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 receipt of invoice

Quotation #: 1-WQ3SMD

Rev.: 3

#### 100495 BV Pulsera, rel. 2.3

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:

Line # Part #

Description

Qty

#### 1 \*\*NNAL286

**BV Pulsera 12 Vasc Expert** 

1

The BV Pulsera is a powerful mobile fluoroscopy system for the most challenging interventional procedures. The powerful pulsed technology allows you to go the distance in longer studies, capture moving anatomy and see through your largest patient. It consists of a mobile C-arm Stand for image acquisition and a Mobile View Station, with two LCD monitors for image processing, review, archiving and display. The BV Pulsera provides outstanding image quality at lowest possible dose. The system is compact, easy to operate and is highly reliable.

The BV Pulsera 12" Vascular Expert package provides a set of advanced options to provide optimal performance in vascular surgery, including digital subtraction and higher frame rates, as well as general surgery or orthopedic surgery cases. The 12" image intensifier (31 cm) provides 70% more field of view compared to the 9" image intensifier (23 cm).

#### Mobile C-arm Stand:

- Light-weight counterbalanced multi-directional C-arm with compact image intensifier, designed for effortless positioning
- Extended rotation range for maximum projection flexibility (+90 to -45 degrees)
- Ultra-compact foot, with rear-wheel steering, including pushbar and handles for easy maneuverability and positioning of the stand
- Extended vertical movement to fit desired working height, especially for obtaining low lateral positioning
- · Dedicated parallel movement for easy positioning along operating table
- · Automatic cable deflectors
- Flat, easy to clean, user-friendly control desk with lighted display and soft-buttons for f
  flexible application-driven control
- Including:
  - · footswitch and handswitch
  - Handheld remote control
  - radiation indicator
  - system lock (requires a key to enable or disable X-ray control)
- Handheld remote control:
  - Fluoroscopy Mode selection (normal, subtraction, trace, roadmap)
  - Run loop
  - Overview
  - Retrieve previous image / run
  - Retrieve next image / run
  - Park image on reference monitor
  - Protect image / release image
  - Smart Mask
  - Unsubtract / subtract run

X-ray generation:

Quotation #: 1-WQ3SMD

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#### 100495 BV Pülsera, rel. 2-3

#### Line# Part#

#### Description

#### Qty

- 15 kW Microprocessor controlled X-ray converter generator
- · Rotating anode X-ray tube for the most demanding interventional procedures
- Slim tank unit with 0.3/0.6 IEC dual focus
- Tank temperature measuring device for over-temperature detection and protection
- Integrated beam-filter to reduce the patient skin dose by 40%
- X-ray tank designed for maximum cooling capacity, allowing lengthy procedures
- Anatomical Programmed Fluoroscopy (automatic setting of fluoroscopy parameters) provides optimal image quality for each examination type

#### X-ray collimation:

- Full-lead shutters are independently, asymmetrically rotatable and movable
- Both iris and shutters can be set on Last Image Hold, avoiding the need for unnecessary radiation, or during fluoroscopy
- · Automatic Shutter Positioning feature detects anatomy and positions shutters automatically

#### Imaging system:

- · 12" (31cm) triple mode high contrast image intensifier
- Three user selectable field input sizes: 12" / 9" / 7" (31/23/17cm)
- · High resolution 1kx1k digital CCD-TV system with automatic dose-rate control

#### X-ray operation:

- · X-ray modes:
  - Low Dose Fluoroscopy
  - High Definition Fluoroscopy
  - · Pulsed fluoroscopy (max 12.5 pulses per second)
  - Half dose fluoroscopy (max 12.5 pulses per second)
  - · Quarter dose fluoroscopy (6.25 pulses per second)
  - Digital exposure
  - Pulsed exposure at a maximum rate of 15 pps, with maximum of 60 mA
  - · Radiographic mode for cassette exposures
- Anatomical Programmed Fluoroscopy (automatic setting of fluoroscopy parameters)
  provides optimal image quality for each examination type. Includes unique Orthoplus
  (boost) exam type for obtaining low noise images in large patients or dense anatomy.
  - Abdomen
  - Head/Spine
  - Ortho
  - HQ Ortho
  - Orthoplus
  - Thorax
  - Vascular (subtracted fluoroscopy)
  - Vascular HQ (subtracted fluoroscopy)
  - Vascular Cerebral (subtracted fluoroscopy)
  - Vascular CO2 (subtracted fluoroscopy)

#### Image processing:

#### 100295 3V 2015em religas

#### Line # Part #

#### Description

Qty

12-bit Digital Fluoroscopy Imaging unit, with dedicated video pipeline processor. Featuring the SmartVision imaging chain, providing the optimal image quality with lowest possible dose.

- · Image database and display:
  - Patient database including 16 images RAM memory
  - Storage of 20,000 images on hard disk at maximum 30 frames per second
  - · Mosaic overview of 16 images on one monitor
  - Run loop
  - Digital rotation, mirror left/right and up/down on last image hold
  - Video invert
- · Advanced image acquisition and processing:
  - · Body Smart anatomic adapting measuring field
  - Digital 1k x 1k throughout the entire image chain
  - Adaptive temporal recursive filtering for noise integration
  - Vignette correction
  - · Dynamic movement detection to avoid motion blur
  - Real-time 2D edge enhancement, contrast and brightness
- Complete post-processing functions:
  - Annotation
  - Post-processing edge enhancement, contrast and brightness
  - · Automatic contrast and brightness on the mobile view station
  - Zoom and roam (factor 2x real-time magnification, freely moveable to any section of the image)
  - Measurement (to precisely quantify lengths and angles in images)
- Electronic shutters (for block-out over-exposed image areas)
- · Subtracted fluoroscopy features included:
  - Trace mode (maximum opacification)
    - Roadmap mode with Smartmask
  - Trace Mode (for maximum opafication of vasculature)
  - · Roadmap Mode with SmartMask (re-use of previously acquired images)
  - · Remasking (to select the optimal mask for subtraction)
  - Landmarking (to provide a non-subtracted background image for anatomical reference)
  - Real-time pixelshift (to minimize movement artefacts)
  - View Trace (creating a trace image, post processed)
  - CO2 subtracted fluoroscopy mode
  - CO2 trace mode (trace white)
  - CO2 roadmap with smartmask (re-use of previously acquired images)

#### Mobile view station:

The ultra compact Mobile View Station perfectly fits in the surgical workflow. The unique intelligent viewing concept of the Mobile View Station provides the user with easy transportation, easy system set-up and optimal viewing capabilities.

- Flexible Monitor Positioning provides ergonomical operation, easy transport, and easy storage
  - Rotate monitors 180 degrees for optimized viewing angle
  - Fold monitors together for easy storage and transportation

#### 100495 BV Pulsera, rel 23

#### Line # Part #

#### Description

Qty

- Height adjustment: Monitors are always at optimal working height, regardless the height of the physician. Adjust the height by up to 10 inches (25cm). Height is adjusted manually and is stepless, permitting positioning at any desired height between the lowest and the highest position.
- · Veguion user interface, on screen display, alphanumeric keyboard and touchpad
- Touchscreen: Left (live) monitor gives touchscreen access to patient administration and post-processing with the touch of a finger. Image quality of the monitors is unaffected by the touchscreen
- Multiple video in/out options included:
  - Two digital video out connections (DVI-D) permits digital output of left and right monitor images without any loss of signal quality for display on compatible external monitors with DVI-D-in. Signal: 1280x1024@60Hz
  - One composite video in connection (BNC) permits display of external video signals like an endoscope or ultrasound on the right monitor of the mobile viewing station
  - One composite video out connection (BNC) permits display of live monitor image on an additional monitor or recorder
  - · Easy storage to USB flash-drive, for personal use of images
  - Note: Video and USB cables may only be connected when in compliance with the
    precautions described in IEC 60601-1-1. (e.g. extra grounding or separation, depending
    on the location and use of the connected system parts)
- Designed to integrate medical DVD Recorder, video paper/transparency printer and ViewForum Surgical Workstation
- Patient Privacy Protection Password protects system to reduce the risk of unauthorized access to patient information

#### **High Brightness LCD Monitors:**

Two Philips High Brightness 19" Color LCD monitors for superb diagnostic Image Quality. Double the light output compared to the standard LCD Monitors.

- 19" dark screen with dark frame
- · Monitor image size comparable to a 20" CRT
- TFT technology for 170 degrees viewing angle in both horizontal and vertical direction
- · Resolution: horizontal: 1280 dots, vertical: 1024 lines
- Maximum brightness: 722 cd/m2
- Minimum Contrast Ratio: >700:1
- Backlight stabilization
- Touchscreen (left)
- Height adjustment

#### Clinical Education Program for BV Pulsera Surgery Systems

Clinical Education Specialists will provide sixteen (16) hours of Surgery OnSite Education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEU credits may be available if the participant meets the guidelines provided by Philips. Depending on your system configuration, the first four (4) hours onsite may be spent configuring new equipment for specific clinical needs, as well as reviewing important safety features and quality procedures. Please read guidelines for more information. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.

#### 

#### Line# Part#

#### Description

Qty

Follow-Up OnSite Education: Clinical Education Specialists will provide sixteen (16) hours of tailored XR OnSite Education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEUs are not available in all cases.

Education entitlement expires one (1) year from equipment installation date (or purchase date if sold separately). Ref#150308-100614

#### 2 \*\*NMCA088

#### **Basic DICOM 3.0**

4

Converts the digital images of the C-arm system in DICOM compatible image formats, for transfer onto a hospital network.

The DICOM image formats are:

- · Secondary Capture (SC) with/without text and X-ray
- · Angiography (XA- multi frame)

The Basic DICOM 3.0 supports:

- DICOM print
- DICOM store

The Store functionality enables 1k x 1k image transfer to DICOM compliant workstations (for offline processing of images, dynamic reviewing of runs, storing images/runs on CD-R), to PACS systems and to a PC environment (PC should be equipped with DICOM viewer).

The Basic DICOM package is fully embedded in the BV family system architecture, ensuring top image quality by loss-less digital image to DICOM translation and a highly intuitive, seamless integrated user-interface.

Compatible with:

- BV Endura release 2.x
- BV Pulsera release 2.x

#### 3 \*\*NMCA298 Advanced DICOM/IHE

1

Advanced DICOM/IHE functionality, for workflow optimalization.

The Advanced DICOM/IHE supports:

- · Modality Worklist Management (MWL) for communications with the RIS/HIS system
- Modality Performed Procedure Step (MPPS)
- Storage Commit (SC)

The Advanced DICOM/IHE package is fully embedded in the BV family system architecture, ensuring top image quality by digital image conversion to DICOM and a highly intuitive, seamless integrated user-interface.

Full compliance to the IHE Scheduled Workflow integration profile as an Acquisition Modality Actor

Compatible with:

- · BV Pulsera software release 2.4.x
- BV Endura release 2.3

### 4 \*\*NNAL250 Laser aiming device i.i. - 12"

Laser Aiming Device for use at the Image Intensifier side. Including battery power supply with auto-switch off circuitry.

The Laser Aiming Device is mainly used as a positioning device.

Class 2 laser product (see product information).

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## 100495 BV Pulsera, rel. 2.3

## **NET PRICE**

## \$149,785.90

Buying Group:	MEDASSET'S SUPPLY CHAIN SYSTEMS INC	Contract #: EP 127
Addt'l Terms:		
and any specific	solution will reference a specific Buying Group/Contr terms and conditions which will apply to that single on the Conditions of Sale will apply to the quoted solution	act Number representing an agreement containing discounts, fees quoted solution. If no Buying Group/Contract Number is shown, n.
	system listed on purchase order/orders represents a ris to be individually billed and paid.	a separate and distinct financial transaction. We understand and agree that
Price above	does not include any applicable sales taxe	S.
The prelimina	ary delivery request date for this equipmen	t is:
If you do not	issue formal purchase orders indicate by i	nitialing here
Tax Status:		
Taxable	Tax Exempt	
If Exempt, ple the certificate		Number:, and attach a copy of
Delivery/Insta	allation Address:	Invoice Address:
Contact Pho		Contact Phone #:
Purchaser ap	oproval as quoted:	Date:
Title:		
This quotatio	n is signed and accepted by an authorized , terms and conditions stated herein.	I representative in acknowledgement of the system

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## Philips Standard Terms and Conditions of Sale

The products and services listed in the quotation are offered by Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips") only under the terms and conditions described below.

- 1. Price: Taxes. The purchase price stated in the quotation does not include applicable sales, excise, use, or other taxes in effect or later levied. Unless Customer provides Philips with an appropriate exemption certificate reasonably in advance of the date the product is available for delivery, Philips shall invoice Customer for those taxes, and Customer shall pay those taxes in accordance with the terms of
- 2. Cancellation, Philips' cancellation policies are set forth in the applicable schedule attached to these Terms and Conditions of Sale.

3. Payment Terms.

3.1 Unless otherwise specified in the quotation, Philips will invoice Customer, and Customer will immediately pay such invoice on receipt for each product in accordance with the payment terms set forth in the applicable schedule attached to these Terms and Conditions of Sale:

3.2 Orders are subject to Philips' on-going credit review and approval.

3.3 Customer shall pay interest on any amount not paid when due at the maximum rate permitted by applicable law. If Customer fails to pay any amount when due, in addition to any other rights or remedies available to Phillips at law or in equity, Phillips may discontinue the performance of services, discontinue the delivery of the product, or deduct the unpaid amount from any amounts otherwise owed to Customer by Philips under any agreement with Customer. In any action initiated to enforce the terms of the quotation following a Customer default or product cancellation under an order arising from the quotation, Philips shall be entitled to recover as part of its damages all costs and expenses, including reasonable attorneys' fees, in connection with such action.

3.4 Credit Card. Philips, at its discretion, will accept a credit card for payment on orders with a net value of \$50,000 or less.

4. Trade - In. If Customer will be trading-in any equipment ("Trade-In"), then:

4.1 Customer represents and warrants that Customer has good and marketable title to such Trade-In;
4.2 Title to the Trade-In shall pass from Customer to Philips upon Philips making the new equipment available for first patient use. Removal of the Trade-In from Customer's site shall occur no later than the date Philips makes the new product available for first patient use, unless otherwise agreed in writing between Philips and the Customer, and

4.3 Notwithstanding anything to the contrary in any Business Associate Addendum ("BAA"), Customer represents and warrants that Customer has removed or de-identified all Protected Health Information ("PHI") from the Trade-In equipment as of the date the equipment is removed. To the extent Customer has not done so, Customer agrees to reimburse Philips for any out-of-pocket costs Philips incurs to remove or de-identify PHI from the Trade-In.

4.4 If (a) the condition of the Trade-In is not substantially the same when Philips removes the Trade-In (ordinary wear and tear excepted) as it was when Philips quoted the Trade-In value; or (b) Customer delays the removal of the Trade-In, then Philips may reduce the price quoted for such Trade-In or cancel the Trade-In and Customer will pay the adjustment amount within thirty (30) days of receipt

4.5 If Philips does not receive possession of the Trade-In, Philips will charge Customer, and Customer will pay within thirty (30) days of receipt of invoice, the amount of the Trade-In allowance.

- 4.6 Evidence that Customer intends to trade in an asset as part of the purchase or lease of any product(s) shall be in the form of, but not limited to: (a) receiving a trade in quote and/or authorization from Philips on the value of the asset to be traded in; (b) providing Philips with serial numbers of assets to be traded in; and/or, (c) providing Philips with a de-installation date to remove an existing asset in order to install Philips quoted equipment.
- 5. Leases. If Customer desires to convert the purchase of any product to a lease, Customer will arrange for the lease agreement and all other related documentation to be reviewed and approved by Philips not later than ninety (90) days prior to the date of the availability for delivery of major components of the product. The Customer is responsible for converting the transaction to a lease, and is required to secure the leasing company's approval of all of these Terms and Conditions of Sale. No product will be delivered to the Customer until Philips has received copies of the fully executed lease documents and has approved the same.
- 6. Security Interest. Customer hereby grants to Philips a purchase money security interest in the products until all payments have been made. Customer shall sign any financing statements or other documents necessary to perfect Philips' security interests in the products. Where permitted by applicable law, Customer's signature on the quotation or on a purchase order issued as a result of the quotation gives Philips the right to sign on Customer's behalf and file any financing statement or other documents to perfect Philips' security interest in the product.

7. Shipment and Risk of Loss.

 7.1 The applicable schedule attached to these Terms and Conditions of Sale shall apply for delivery.
 7.2 Title to any product (excluding software), and the risk of loss or damage to any product shall pass to the Customer F.O.B. destination. Customer shall obtain and pay for insurance covering such risks at destination.

8. Installation. Site Preparation. Remote Services.
8.1 Installation. Customer shall provide Philips of conditions at or near the site, including any hazardous materials, that the products before installation. Customer shall advise Philips of conditions at or near the site, including any hazardous materials, that could adversely affect the installation or pose a health or safety risk to Philips' personnel, and shall ensure that those conditions are corrected and hazardous materials removed, and that the site is fully prepared and available to Philips before installation work begins. Customer shall ensure, at no charge to Philips, that there are no obstacles preventing Philips from moving the product from the entrance of the Customer's premises to the installation site. Customer shall be responsible, at its expense, for rigging, the removal of partitions or other obstacles, and restoration work. The products will be installed during normal working hours. Philips will unpack the product, construct applicable pads (if required for certain products), connect the product to a safety switch or breaker to be installed by the Customer, and calibrate and test the product. If local labor conditions, including but not limited to a requirement to utilize union labor, require the use of non-Philips employees to participate in the installation of the product, then such participation of non-Philips employees shall be at Customer's expense. In such case, Philips will provide engineering supervision during the installation.

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- 8.2 Site Preparation. Except where Philips has agreed in writing to provide construction services for a fee pursuant to a construction agreement and scope of work signed by Customer, Customer shall be responsible, at its expense, for the preparation of the installation site where the product will be installed including any required structural alterations. Customer shall provide any and all plumbing, carpentry work, conduit, wiring including communications and/or computer wiring, network equipment, power supply, surge suppression and power conditioning (except to the extent they are expressly included in the quotation), fire protection and environmental controls, ground fault and isolation system, and other fixtures and utilities required to properly attach, install, and use the product. Site preparation shall be in compliance with all safety, electrical, and building codes relevant to the product and its installation and use. The sufficiency of any installation site plans shall be the responsibility of Customer. Customer, at its expense, shall obtain all permits and licenses required by federal, state, or local authorities in connection with the installation and operation of the product, including any certificate of need and zoning variances. PHILIPS MAKES NO WARRANTY AND ASSUMES NO LIABILITY FOR THE FITNESS OR ADEQUACY OF THE SITE IN WHICH THE PRODUCT IS TO BE INSTALLED OR USED, CUSTOMER INDEMNIFIES PHILIPS AGAINST ANY CLAIMS, INCLUDING SUBPOGATION CLAIMS, ARISING EROM CLISTOMER'S SITE PREPARATION RESPONSIBILITIES.
- zoning variances. PrilLIP'S MARES NO WARRANTY AND ASSUMES NO LIABILITY FOR THE FITNESS OR ADEQUACT OF THE SITE IN WHICH THE PRODUCT IS TO BE INSTALLED OR USED. CUSTOMER INDEMNIFIES PHILIPS AGAINST ANY CLAIMS, INCLUDING SUBROGATION CLAIMS, ARISING FROM CUSTOMER'S SITE PREPARATION RESPONSIBILITIES.

  8.3 Remote Services Network ("RSN"). Customer will (a) provide Philips with a secure location at Customer's premises to store one Philips RSN router (or a Customer-owned router acceptable to Philips at Customer's option) for connection to the equipment and to Customer's network, and (b) at all times during the warranty period provide Philips with full and free access to the router and a dedicated broadband Internet access node, including but not limited to public and private interface access, suitable to establish a successful connection to the products through the Philips RSN and Customer's network for Philips' 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 Philips products and services and aggregation into services). Customer's failure to provide such access at the scheduled time will constitute Customer's waiver of the scheduled planned maintenance service and will void support or warranty coverage of product malfunctions until such time as planned maintenance service is completed or RSN access is provided. Customer agrees to pay Philips at the prevailing demand service rates for all time spent by Philips service personnel waiting for access to the products.

9. Product Warranty.

- 9.1 (a) If a separate product warranty prints as part of this quotation, that product warranty applies to your purchase and is incorporated herein; otherwise Section 9.2-9.7 shall apply unless the product is identified under 9.1 (b). (b) For Patient Monitoring and Cardiac Resuscitation and InnerCool products, the product warranty document can be found at: www.healthcare.philips.com/main/terms\_conditions/, or can be provided upon request.
- 9.2 Hardware/Systems. Philips warrants to Customer that the Philips equipment (including its operating software) will perform in substantial compliance with its performance specifications in the documentation accompanying the products, for a period of 12 months beginning upon availability for first patient use.
- 9.3 Stand-alone Licensed Software. For a period of ninety (90) days from the date Philips makes Stand-alone Licensed Software available for first patient use, such Stand-alone Licensed Software shall substantially conform to the technical user manual that ships with the Stand-alone Licensed Software. "Stand-alone Licensed Software" means sales of Licensed Software without a contemporaneous purchase of a server for the Licensed Software. If Philips is not the installer of the Stand-alone Licensed Software, the foregoing warranty period shall commence upon shipment.
- 9.4 If the start of the installation is delayed for any reason beyond the control of Philips for more than thirty (30) days following the date that Philips notifies Customer that the major components of the product are available for delivery, the warranty period begins on the thirty-first (31st) day following that date.
- 9.5 Philips' sole obligations and Customer's exclusive remedy under any product warranty are limited, at Philips' option, to the repair or the replacement of the product or a portion thereof within thirty (30) days after receipt of written notice of such material breach from Customer ("Product Warranty Cure Period") or, upon expiration of the Product Warranty Cure Period, to a refund of a portion of the purchase price paid by the Customer, upon Customer's request. Any refund will be paid to the Customer when the product is returned to Philips. Warranty service outside of normal working hours (i.e, 8.00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips' observed holidays), will be subject to payment by Customer at Philips' standard service rates.

  9.6 This warranty is subject to the following conditions: the product (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
- 9.6 This warranty is subject to the following conditions: the product (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 dully qualified personnel in a safe and reasonable manner in accordance with Philips' written instructions and for the purpose for which the products were intended; and (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the product; and Customer is to notify Philips immediately if the product at any time fails to meet its printed performance specifications. Philips' obligations under any product warranty do not apply to any product defects resulting from improper or inadequate maintenance or calibration by the Customer or its agents; Customer or third party supplied interfaces, supplies, or software including without limitation loading of operating system patches to the Licensed Software and/or upgrades to anti-virus software (except DAT file changes) running in connection with the Licensed Software without prior validation approval by Philips; use or operation of the product other than in accordance with Philips' applicable product specifications and written instructions; abuse, negligence, accident, loss, or damage in transit; improper site preparation; unauthorized maintenance or modifications to the product, or viruses or similar software interference resulting from connection of the product to a network. Philips does not provide a warranty for any third party products furnished to Customer by Philips under the quotation; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described herein and in the applicable product-specific warranty document are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a product warranty.
- 9.7 THE WARRANTIES SET FORTH HEREIN AND IN PHILIPS' WARRANTY DOCUMENT WITH RESPECT TO A PRODUCT (INCLUDING THE SOFTWARE PROVIDED WITH THE PRODUCT) ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE PRODUCT, THE SOFTWARE, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, WHETHER WRITTEN, ORAL, STATUTORY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Philips may use refurbished parts in the manufacture of the products, which are subject to the same quality control procedures and warranties as for new products.
- 10. Phillips Proprietary Service Materials. Any Phillips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Phillips and its authorized agents to install and to test the products or to assist Phillips and its authorized agents to maintain and to service the products under warranty or a separate support agreement with Customer. Customer agrees to restrict access to such software and documentation to Phillips' employees and those of Phillips' authorized agents only and to permit Phillips to remove its Proprietary Service Materials upon request.

Rev.: 3

11. Patent Infringement Claims.

11.1 Philips shall indemnify, defend, and hold harmless Customer against any new claim that a Philips Product provided in the quotation infringes, misappropriates, or violates any third party intellectual property right, whether patent, copyright, trademark, or trade secret, provided that Customer:

(a) provides Philips prompt written notice of the claim;
(b) grants Philips full and complete information and assistance necessary for Philips to defend, settle, or avoid the claim; and

(c) gives Phillips sole control of the defense or settlement of the claim.

11.2 The provisions of this section shall not apply if the product is sold or transferred.

- 11.3 If (a) a Philips Product is found or believed by Philips to infringe such a claim; or, (b) Customer has been enjoined from using the Philips Product pursuant to an injunction issued by a court of competent jurisdiction, Philips may, at its option, (i) procure the right for Customer to use the product, (ii) replace or modify the product to avoid infringement, or (iii) refund to Customer a portion of the product purchase price upon the return of the original product. Phillips shall have no obligation for any claim of infringement arising from: Phillips' compliance with Customer's designs, specifications, or instructions; Philips' use of technical information or technology supplied by Customer, modifications to the product by Customer or its agents; use of the product other than in accordance with the product specifications or applicable written product instructions; use of the product with any other product, if infringement would have been ayoided by the use of a current unaltered release of the products; or use of the Philips Product after Philips has advised Customer, in writing, to stop use of the Philips Product in view of the claimed infringement. Philips will not be liable for any claim where the damages sought are based directly or indirectly upon the quantity or value of products manufactured by means of the products purchased under this quotation, or based upon the amount of use of the product regardless of whether such claim alleges the product or its use infringes or contributes to the infringement of such claim. The terms in this section state Philips' entire obligation and liability for claims of infringement, and Customer's sole remedy in the event of a daim of infringement.
- 12. <u>Limitation of Liability.</u> THE TOTAL LIABILITY, IF ANY, OF PHILIPS AND ITS AFFILIATES FOR ALL DAMAGES AND BASED ON ALL CLAIMS, WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING FROM A PRODUCT, LICENSED SOFTWARE, AND/OR SERVICE IS LIMITED TO THE PRICE PAID HEREUNDER FOR THE PRODUCT, LICENSED SOFTWARE, OR SERVICE. THIS LIMITATION SHALL NOT APPLY TO:

(a) THIRD PARTY CLAIMS FOR BODILY INJURY OR DEATH CAUSED BY PHILIPS' NEGLIGENCE OR PROVEN PRODUCT

DÉFECT; (b) CLAIMS OF TANGIBLE PROPERTY DAMAGE REPRESENTING THE ACTUAL COST TO REPAIR OR REPLACE PHYSICAL PROPERTY DAMAGE;

(c) OUT OF POCKET COSTS INCURRED BY CUSTOMER TO PROVIDE PATIENT NOTIFICATIONS, REQUIRED BY LAW, TO THE EXENT SUCH NOTICES ARE CAUSED BY PHILIPS UNAUTHORIZED DISCLOSURE OF PHI; and,

(d) FINES/PENALTIES LEVIED AGAINST CUSTOMER BY GOVERNMENT AGENCIES CITING PHILIPS UNATHORIZED DISCLOSURE OF PHI AS THE BASIS OF THE FINE/PENALTY SUCH FINES OR PENALTIES SHALL CONSTITUTE DIRECT DAMAGES.

- 13. DISCLAIMER. 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, BUSINESS INTERRUPTION, LOSS OF DATA, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT.
- 14. Confidentiality. Each party shall maintain as confidential any information furnished or disclosed to one party by the other party whether disclosed in writing or disclosed orally, relating to the business of the disclosing party, its customers and/or its patients, and the quotation and its terms, including the pricing terms under which Customer has agreed to purchase the products. Each party shall use the same degree of care to protect the confidentiality of the disclosed information as that party uses to protect the confidentiality of its own information, but in no event less than a reasonable amount of care. Each party shall disclose such confidential information only to its employees having a need to know such information to perform the transactions contemplated by the quotation. The obligation to maintain the confidentiality of such information shall that (a) is or becomes generally available to the public without violation of this Agreement or any other obligation of confidentiality or (b) is lawfully obtained by the receiving Party from a third party without any breach of confidentiality or violation of law.

- 15. Compliance with Laws & Privacy.
   15.1 Each party shall comply with all laws, rules, and regulations applicable to the party in connection with the performance of its obligations in connection with the transactions contemplated by the quotation, including, but not limited to, those relating to affirmative action, fair employment practices, FDA, Medicare fraud and abuse, and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Health care providers are reminded that if the purchase includes a discount or loan, they must fully and accurately report such discount or loan on cost reports or other applicable claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, as required by federal law (see 42 CFR 1001.952[h])
- 15.2 In the course of providing project implementation related services and/or warranty services to Customer, hereunder, it may be necessary for Philips to have access to, view and/or download computer files from the products that might contain Personal Data. "Personal Data" means information relating to an individual, from which that individual can be directly or indirectly identified. Personal Data can include both personal health information (i.e. images, heart monitor data, and medical record number) and non-health information (i.e. date of birth, gender). Philips will process Personal Data only to the extent necessary to perform and/or fulfill its project implementation related service, warranty service and/or warranty obligations hereunder.

15.3 It is Customer's responsibility to notify Philips if any portion of the order is funded under the American Reinvestment and Recovery Act ("ARRA"). To ensure compliance with the ARRA regulation, Customer shall include a clause stating that the order is funded under ARRA on its purchase order or other document issued by Customer.

16. Excluded Provider. Philips represents and warrants that Philips, its employees and subcontractors, are not debarred, excluded, suspended or otherwise ineligible to participate in a federal health care program, nor have they been convicted of any health care related crime for the products and services provided under this Agreement (an "Excluded Provider"). Phillips shall promptly notify Customer when it becomes aware that Philips or any of its employees or subcontractors, providing services hereunder, have become an Excluded Provider whereupon Customer may terminate this order by express written notice for product and services not yet shipped or rendered.



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

2704 Mail Service Center • Raleigh, North Carolina 27699-2704 https://www.ncdhbs.gov/dbsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief Phone: (919) 855-3873 Fax: (919) 733-8139

May 22, 2012

Mr. David French, Consultant P.O. Box 2154 Reidsville, NC 27323-2154

Rb: Exempt from Review/Carolina Vascular Access Holdings, LLC./ Development of a Physicians Office Building and the purchase of a portable C-arm unit.

Dear Mr. French:

In response to your letter of April 18, 2012 (received on April 23, 2012), the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S. §, 131E-181(a)(9) and being under the capital threshold for N.C.G.S. 131E-176(14p). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need. However, you may need to contact the Construction Section of the Division of Health Service Regulation to determine if they have any special requirements for the proposed project.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely.

F. Gene DePorter, Project Analyst

Craig Spain, Ciner Certificate of Need Section

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**FGD** 



17. General Terms. The following additional terms shall be applicable to the purchase of a product

17.1 Force Majeure. Each party shall be excused from performing its obligations (except for payment obligation) 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 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

17.2 Bankruptcy. If Customer becomes insolvent, is unable to pay its debts when due, files for bankruptcy, is the subject of involuntary bankruptcy, has a receiver appointed, or has its assets assigned, Phillips may cancel any unfulfilled obligations, or suspend performance;

however, Customer's financial obligations to Philips shall remain in effect.

17.3 **Assignment.** Customer may not assign any rights or obligations in connection with the transactions contemplated by the quotation without the prior written consent of Philips, which consent shall not be unreasonably withheld, and any attempted assignment without such consent shall be of no force or effect.

17.4 Export. Customer shall assume sole responsibility for obtaining any required export authorizations in connection with Customer's

- export of the products from the country of delivery.

  17.5 **Governing Law.** All transactions contemplated by the quotation shall be governed by the laws of the state where the equipment will be installed, without regard to that state's choice of law principles, and expressly excluding application of the Uniform Computer Information Transactions Act ("UCITA"), in any form. EACH PARTY, KNOWINGLY AND AFTER CONSULTATION WITH COUNSEL, FOR ITSELF, IT'S SUCCESSSORS' AND ASSIGNS, WAIVES ALL RIGHT TO TRIAL BY JURY OF ANY CLAIM ARISING WITH RESPECT TO THIS AGREEMENT OR ANY MATTER RELATED IN ANY WAY THERETO.
- 17.6 Entire Agreement. These Terms and Conditions of Sale, the terms and conditions set forth in the quotation and the applicable Philips' product-specific warranty document constitute the entire understanding and agreement by and between the parties with respect to the transactions contemplated by the quotation, and supersede any previous understandings or agreements between the parties, whether written or oral, regarding the transactions contemplated by the quotation. The pricing in the quotation is based upon the terms and conditions in the quotation. No additional terms, conditions, consents, waivers, alterations, or modifications shall be binding unless in writing and signed by the parties. Customer's additional or different terms and conditions, whether stated in a purchase order or other
- document issued by Customer, are specifically rejected and shall not apply to the transactions contemplated by the quotation.

  17.7 Headings. The headings in the quotation are intended for convenience only and shall not be used to interpret the quotation.

  17.8 Severability. If any provision of the quotation is deemed to be illegal, unenforceable, or invalid, in whole or in part, the validity and enforceability of the remaining provisions shall not be affected or impaired, and shall continue in full force and effect.
- 17.9 **Notices.** Notices or other communications shall be in writing, and shall be deemed served if delivered personally, or if sent by facsimile transmission, by overnight mail or courier, or by certified mail, return receipt requested and addressed to the party at the address set forth in the quotation.
- 17.10 Performance. The failure of Customer or of Philips at any time to require the performance of any obligation will not affect the right to require such performance at any time thereafter. Course of dealing, course of performance, course of conduct, prior dealings, usage of trade, community standards, industry standards, and customary standards and customary practice or interpretation in matters involving the sale, delivery, installation, use, or service of similar or dissimilar products or services shall not serve as references in interpreting the terms and conditions of the quotation.

17.11 Obligations. Customer's obligations are independent of any other obligations the Customer may have under any other agreement, contract, or account with Philips. Customer will not exercise any right of offset in connection with the terms and conditions in

the quotation or in connection with any other agreement, contract, or account with Philips.

17.12 Additional Terms. The Product specific schedules listed below are incorporated herein as they apply to the equipment listed on the quotation and their additional terms shall apply solely to Customer's purchase of the products specified therein.

If any terms set forth in a schedule conflict with terms set forth in these Terms and Conditions of Sale, the terms set forth in the schedule shall govern:

(a) Schedule 1: Interventional X-Ray (iXR), Diagnostic X-Ray (DXR), Computed Tomography (CT), Magnetic Resonance (MR), Positron Emission Tomography (PET), Nuclear Medicine (NM), Radiation Oncology (PROS), Women's Healthcare (WHC), and Ultrasound Products (including Image Guided Intervention and Therapy (IGIT) products).

#### LICENSED SOFTWARE

1. License Grant.

1.1 Subject to any usage limitations for the Licensed Software set forth on the product description of the quotation, Philips grants to Customer a nonexclusive and non-transferable right and license to use the computer software package ("Licensed Software") in accordance with the terms of the quotation. The License shall continue for as long as Customer continues to own the product, except that Philips may terminate the License if Customer is in breach or default. Customer shall return the Licensed Software and any authorized copies thereof to Philips immediately upon expiration or termination of this License.

1.2 The License does not include any right to use the Licensed Software for purposes other than the operation of the product. Customer may make one copy of the Licensed Software in machine-readable form solely for backup purposes. Philips reserves the right to charge for backup copies created by Philips. Except as otherwise provided under section 1.6, Customer may not copy, reproduce, sell, assign, transfer, or sublicense the Licensed Software for any purpose without the prior written consent of Philips. Customer shall reproduce Philips' copyright notice or other identifying legends on such copies or reproductions. Customer will not (and will not allow any third party to) decompile, disassemble, or otherwise reverse engineer or attempt to reconstruct or discover the product or Licensed Software by any means whatsoever

1.3 The License shall not affect the exclusive ownership by Philips of the Licensed Software or of any trademarks, copyrights, patents, trade secrets, or other intellectual property rights of Philips (or any of Philips' suppliers) relating to the Licensed Software.

1.4 Customer agrees that only authorized officers, employees, and agents of Customer will use the Licensed Software or have access to the Licensed Software (or to any part thereof), and that none of Customer's officers, employees, or agents will disclose the Licensed Software, or any portion thereof, or permit the Licensed Software, or any portion thereof, to be used by any person or entity other than those entities identified on the quotation. Customer acknowledges that certain of Philips' rights may be derived from license agreements with third parties, and Customer agrees to preserve the confidentiality of information provided by Philips under such third party license agreements.

1.5 The Licensed Software shall be used only on the product(s) referenced in the quotation.

1.6 Customer may transfer the Licensed Software in connection with sale of the product to a healthcare provider who accepts all of the terms and conditions of this License; provided that Customer is not in breach or default of this License, the Terms and Conditions of Sale, or any payment obligation to Philips.

- 2. Modifications.
  2.1 If Customer modifies the Licensed Software in any manner, all warranties associated with the Licensed Software and the products shall become null and void. If Customer or any of its officers, employees, or agents should devise any revisions, enhancements, additions, modifications, or improvements in the Licensed Software, Customer shall disclose them to Phillips, and Phillips shall have a non-exclusive royalty-free license to use and to sub-license them.
  2.2 The Licensed Software is licensed to Customer on the basis that (i) Customer shall maintain the configuration of the products as they were originally designed and manufactured and (ii) the product includes only those subsystems and components certified by Philips. The Licensed Software may not perform as intended on systems modified by other than Philips or its authorized agents, or on systems which include subsystems or components not certified by Philips. Philips does not assume any responsibility or liability with respect to unauthorized modification or substitution of subsystems or components. unauthorized modification or substitution of subsystems or components.

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Schedule 1
Interventional X-Ray (iXR), Diagnostic X-Ray (DXR), Computed Tomography (CT), Magnetic Resonance (MR),
Positron Emission Tomography (PET), Nuclear Medicine (NM), Radiation Oncology (PROS), Women's Healthcare (WHC), and Ultrasound (US) products (including Image Guided Intervention and Therapy (IGIT) Products)

1. Payment Terms.

Unless otherwise specified in the quotation, Philips will invoice Customer, and Customer will pay such invoice on receipt, as follows: 1.1 For Interventional X-Ray (iXR), Diagnostic X-Ray (DXR), Computed Tomography (CT), Magnetic Resonance (MR), Positron Emission Tomography (PET), Nuclear Medicine (NM), Radiation Oncology (PROS), and Women's Healthcare (WHC):

(a) 10% of the purchase price shall be due with Customer's acceptance of the quotation.

- (b) 70% of the purchase price shall be due on delivery of the major components of the product. Product installation will not begin until Customer has paid this portion of the purchase price.
- (c) 20% of the purchase price shall be diale when the product is available for first patient use. Available for first patient use means the product has been installed and substantially meets Philips' published specifications.

1.2 For Ultrasound(US) products (including IGIT Products):

(a) 100% of the purchase price shall be due thirty (30) days from Philips' invoice date.

- 1.3 If the start of the installation is delayed for any reason beyond the control of Philips for more than thirty (30) days following the date that Philips notifies customer that the major components of the product are available for delivery, the unpaid portion of the purchase price shall be due on the thirty-first (31st) day following such date.
- 2. <u>Cancellation</u>. The quotation is subject to change or withdrawal prior to written acceptance by Customer. All purchase orders issued by Customer are subject to acceptance by Philips. If Customer cancels an order prior to product shipment, Customer shall pay a cancellation charge of fifteen percent (15%) of the net order price. Orders are non-cancellable for products shipped

3. <u>Delivery.</u>
3.1 Philips will use reasonable efforts to ship the product to the Customer by: (a) by the mutually agreed upon shipment date; or (b) by the date stated in the quotation; or (c) as otherwise agreed in writing. Philips will ship the product according to Philips' standard commercial practices. Philips will deliver the equipment during normal working hours, 8:00 - 5:00 PM, in the time zone where the Customer is located. Philips may make partial shipments. Philips will pay shipping costs associated with product shipment.

3.2 Prior to the shipment of any product, Philips may change the construction or the design of the product without notice to the

Customer so long as the function, footprint, and performance of the product are not substantially altered. 3.3 If Customer requests a delay in the date major components of the product are available for delivery, then Philips will place the product in storage and the unpaid portion of the purchase price shall be due. Customer will reimburse Philips for all storage fees incurred

upon receipt of invoice.

 4. Additional Customer Installation Obligations for Magnetic Resonance.
 4.1 Customer shall provide any and all Site preparation and shall be in compliance with all RF or magnetic shielding and acoustical suppression and building codes relevant to the product and its installation and use.

4.2 Customer's contractor or Customer's architect is required to provide detailed information on the proposed Helium Exhaust Pipe for their MRI system prior to installation to ensure safety specifications are being met. Required Details include:

(a) Architectural drawing or sketch with complete dimensions including lengths, bending radii, bending angles, and pipe diameters for entire Helium Exhaust Pipe run from RF enclosure to discharge location.

Completed Helium Exhaust Pipe Verification Checklist (Provided by Local Philips Project Manager)

(c) Picture showing the area where the Helium Exhaust Pipe will discharge.

4.3 Magnets will not be released for delivery unless and until Helium Exhaust Pipe details are provided for verification and have been confirmed to meet all life safety specifications

5. Additional Terms Related to Sales of IGIT Products.

- 5.1 As part of installation, Philips will connect the IGIT product to such DICOM compatible scanners as Customer may designate (in writing), including CT and MR scanners and, if ultrasound navigation is included in the product, an iU22 ultrasound system. 5.2 If Customer requires that Philips connect the IGIT product to more than two (2) scanners or other devices, then Philips shall invoice Customer and Customer shall pay for installation services at Philips' then-current daily service rate. Additionally, Customer shall (a) make the scanner(s) the Customer has designated available to Philips' installation representative, (b) create and provide a data set of the installation phantom on or before the installation date, and (c) have its IT representative available to assist in connecting the IGIT product to Customer's DICOM devices during the agreed installation time. If such installation and connection is delayed due to Customer failing in its obligations described in this section, then Philips may invoice Customer and Customer shall pay either for (a) any time that Philips spends waiting at the site for such obligation to be fulfilled, at Philips' then-current service rate, or (b) reasonable travel expenses if Philips has to reschedule such installation
- 5.3 Training on the IGIT Product is not included with the purchase of the IGIT product unless it is separately identified on the quotation.

 6. Additional Terms Related to Sales of the Intellispace Breast Solution, including the MammoDiagnost VU.
 6.1 Installation. Philips will install the Intellispace Breast Solution and perform installation tests on the application running with the hardware provided as part of the solution, including the MammoDiagnost VU. Philips also configures and provides interfaces to the equipment and information systems set forth in a statement of work signed by Philips and the Customer. Interfaces set forth in Subsection 6.2 below are Customer's responsibility and are not part of Parts installation deliverables.

6.2 Customer's Interface Obligations for Third Party RIS and MIS Applications. Customer is responsible to develop and implement

interfaces from the Licensed Software running on the client workstation to any third party Radiology Information System ("RIS") or Mammography Information System ("MIS") or to contract with the RIS and/or MIS vendor to have them perform these interface obligations on Customer's behalf. Interfacing the solution from the solutions server is not permitted. Philips shall provide Customer an API toolkit for the Licensed Software to aide Customer to perform such interface tasks. The successful and reasonably timely completion of these projects takes good faith efforts on the part of both Philips and Customer, especially when Customer has third party interfaces to develop and implement. A project implementation plan is based on completion dates mutually agreed by the parties that should be

reflective of the obligations of both parties. These dates are entered into the project implementation plan for this solution (the "Project Implementation Plan"). In the event Customer has not fulfilled its interface obligations by the dates set forth in the Project Implementation Plan, Customer will sign Philips' acceptance (MDIR) document for the Philips deliverables sold and pay the final payment described in Subsection 1.1(c), provided that Philips has installed the Philips deliverables and provided the interfaces Philips is responsible for pursuant to Subsection 6.1, and that the Philips deliverables substantially meet Philips' published specifications.

6.3 Prior Validation of Operating System Updates and/or Upgrades, Patches introduced by operating system oem's or upgrades to antivirus software can impact the performance and functionality of the applications that run on them and affect patient safety. Philips shall perform validation testing of certain Microsoft operating systems and MacAfee anti-virus software during the warranty period. Philips shall have no obligation to validate any other third party operating system or anti-virus software. Customer shall not install or use (a) operating system patches, updates or upgrades; (b) anti-virus updates (except to the DAT files, i.e., virus definitions); or, (c) upgrades to anti-virus search engines, collectively (a)-(b) prior to validation testing and approval by Philips ("Unauthorized Updates"). Philips shall have no liability, including, without limitation, for warranty claims, arising from use of the Licensed Software with Unauthorized Updates. In the event Philips discovers that Customer is using an Unauthorized Update with the Licensed Software Philips shall have the right to require Customer to roll back to the most recently validated versions of operating systems and anti-virus, prior to performing any support.

6.4 Customer's Network Connectivity Obligations. Customer must have network connectivity between the IntelliSpace Breast solution and the h

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#### SURGICAL MORNE CLARM 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 Surgical Mobile C-Arm System (the "System") as delivered to Customer will perform in substantial compliance with its performance specifications for a period of twelve (12) months from its availability for first patient use. The glassware is subject to special warranty terms set forth herein.

During the warranty period, Philips' service personnel shall provide one (1) inspection call up to twelve (12) hours in duration approximately thirty (30) days prior to warranty expiration. This inspection shall be scheduled in advance at a mutually agreeable time on weekdays, between 8:00 A.M. and 5:00 P.M., excluding Philips observed holidays.

#### SYSTEMHEGRADES

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

## DIAGNOSTIC X-RAY TUBES MONOBLOCK X-RAY SOURCE (BV PULSERA)

Philips Monoblock X-ray source installed as part of the BV PULSERA will perform for a period of twelve (12) months or will be replaced by Philips at no charge to the customer. Claims must be made within twelve (12) months after installation and fourteen (14) months after date of shipment from Philips.

DIAGNOSTIC X-RAY TUBES (BYLIBRA AND BYENDURA)
Philips FO17 X-ray tube installed as part of the BY LIBRA and BY ENDURA will perform for a period of twelve (12) months or will be replaced by Philips at no charge to the customer. Claims must be made within twelve (12) months after installation and fourteen (14) months after date of shipment from Philips.

Philips warrants its X-ray image intensifier tubes to be free from defects in material and workmanship for twenty-four (24) months. Claims must be made within twenty-four (24) months after installation and twenty-seven (27) months after date of shipment from Philips.

Credit for any failure acknowledged as Philips liability will be prorated on the following schedule:

USAGE			(	REDIT
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.

#### 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 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.

#### WARRASTY I BETATERAS

WARRANTY LIBITATIONS
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 cortain 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 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 darnage 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. Repairs or replacement parts do not extend the term of this warranty. Repairs or replacement parts do not extend the term of this warranty. parts do not extend the term of this warranty.

THE WARRANTIES SET FORTH IN PHILIPS WARRANTY DOCUMENT WITH RESPECT TO THIS SYSTEM (INCLUDING THE SOFTWARE PROVIDED WITH THE SYSTEM) ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE SYSTEM, THE SOFTWARE, 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 vist. 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 walves 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 "walting 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 Fiday, 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.

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#### 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.

CURRENTIANS

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 manufacturing facilities.

Philips system specifications are subject to change without notice Document Number 4535 983 03243 999

## Non Disclosure Agreement for Philips Confidential Pricing Information

The parties specified below agree to the following terms:

#### A. Philips

. A establish		
Name	Philips Healthcare, a division of Philips Electronics North America Corporation	
Address	22100 Bothell-Everett Highway, Bothell, WA 98021 United States of America	

#### B. Company

- 1	NI	CAROLINA VASCULAR ACCESS HOLDING LLC
	Name	CAROLINA VASCOLAR ACCESS HOLLING LLC
	Address	2214 NC 54 HWY CHAPEL HILL, NC 27517

#### C. Confidential Information

I	Authorized Purpose	To evaluate Philips' confidential information relating to pricing for imaging equipment ("Pricing") in connection with
		the potential purchase of such imaging equipment.
l	Period	Begins on the date Pricing is first disclosed and continues for 5 years from date Pricing is last disclosed.

#### D. Philips Contact

Name	Bethann Griffith-Subik
Title	
Telephone	(919) 677-9046
Fax	(919) 677-9047
e-mail	
Signature	

Company Contact

Name	
Title	
Telephone	
Fax	
e-mail	
Signature	

- The following terms and conditions (the "Agreement") apply to Pricing disclosed by Philips and its Affiliates ("Philips") to Company and its
  Affiliates ("Company"), in connection with the Authorized Purpose.
  - (a) Subject to Philips' prior written consent, Company may disclose, or request that Philips disclose, Pricing to Company's Affiliates that need to know the Pricing for carrying out the Authorized Purpose, provided they are advised of and agree to be bound by this Agreement. Company is responsible for any breach of this Agreement by its Affiliates.
  - (b) An Affiliate is any corporation, company, or other entity, that: (i) is under the Control of a party hereto; or (ii) has Control of a party hereto; or (iii) is under common Control with a party hereto. For this purpose "Control" means that more than fifty percent (50%) of the controlled entity's shares or ownership interest representing the right to make decisions for such are owned or controlled, directly or
- 2. Philips may disclose Pricing to Company with respect to the Authorized Purpose in writing, orally, or otherwise. All information is assumed to be Pricing, and confidential, if the confidential or proprietary nature is reasonable under the circumstances.
- 3. All Pricing disclosed by Philips shall remain Philips' the property. Company does not, by implication, estoppel, or otherwise, acquire any intellectual property right, title, or ownership, nor a license to any such intellectual property right, with respect to any Pricing disclosed by Philips hereunder.

ALL PRICING IS PROVIDED ON AN "AS IS" BASIS, WITHOUT ANY WARRANTY WHATSOEVER. PHILIPS SHALL HAVE NO LIABILITY WHATSOEVER RESULTING FROM THE USE OF THE INFORMATION PROVIDED.

- 4. Company shall:
  - (a) not use the Pricing for any purpose other than the Authorized Purpose;
  - (b) not disclose the Pricing to any third party;
  - (c) protect the Pricing against disclosure in the same manner and with the same degree of care with which Company protects its own confidential information but not less than a reasonable degree of care; and
  - (d) limit circulation of the Pricing to Company's employees as have a need to know in connection with the Authorized Purpose.

    These obligations shall survive the termination of this Agreement. Philips may terminate this Agreement at any time by means of a written notice to Company shall return to Philips, or certify destruction of, all Pricing, immediately upon termination or expiration of this
- 5. Information disclosed by Philips to Company pursuant to this Agreement shall not be confidential to the extent that the information:
  - (a) is or becomes part of the public domain without violation of this Agreement or any other obligation of confidentiality,
  - (b) is known by Company prior to disclosure by Philips;
  - (c) is lawfully obtained by Company from a third party without any breach of confidentiality or violation of law, or
  - (d) is developed by Company completely independently of any such disclosure by Philips.
- 6. If Company is required, pursuant to administrative or judicial action or subpoena, to disclose the Pricing, Company shall use its best efforts to maintain the confidentiality of the Pricing, e.g. by asserting in such action any applicable privileges. Immediately after gaining knowledge or receiving notice of such action or subpoena, Company shall notify Philips and give Philips the opportunity to seek any other legal remedies so as to maintain such Pricing in confidence, including a reasonable protective order.
- 7. Company may not transfer or assign any or all of its rights and/or obligations or delegate the performance of any or all of its obligations under this Agreement, directly or indirectly, through acquisition, merger or otherwise, without the prior written consent of Philips. Any transfer, assignment or delegation in contravention of the foregoing shall be void.
- 8. Company shall not disclose, export or release the Pricing in contravention of any applicable laws or regulations.
- This Agreement shall be governed and construed in accordance with the laws of the State of New York, without giving effect to its conflict of laws provisions.
- 10. This Agreement contains the entire understanding of the parties and supersedes any previous understandings or agreements with respect to the subject matter hereof. This Agreement may be amended only in writing signed by authorized representatives of each party.

Pricing NDA ver1 - 8/9/07

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