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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

February 21, 2014

Molly D. Jordan
Director of Strategic Planning
High Point Regional UNC Health Care
P.O. Box HP-5
High Point, NC 27261

Exempt from Review – Replacement Equipment

Facility:	High Point Regional UNC Health Care
Project Description:	Replace Angiography Equipment
County:	Guilford
FID #:	943251

Dear Ms. Jordan:

In response to your letter of February 18, 2014, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, a Siemens Artis Zee interventional cardiology system to replace the existing Siemens MultiStar, Serial # 3772501 angiography equipment, acquired under Certificate of Need Project I.D. # G-6221-00. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Branch with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Construction Section to determine if they have any requirements for development of 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,

Celia C. Inman

Celia C. Inman
Project Analyst

Martha J. Frisone

Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Construction Section, DHSR

HIGH POINT REGIONAL
UNC HEALTH CARE

February 18, 2014

Via Hand Delivery
Ms. Martha Frisone, Chief
Ms. Celia Inman, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: Exemption Request for Replacement Equipment

Dear Ms. Frisone and Ms. Inman:

High Point Regional Health ("HPR UNC") seeks to acquire a Single Plane Artis Zee System ("Replacement Equipment") from Siemens Medical Solutions ("Siemens"). The Replacement Equipment will replace HPR UNC's current Siemens MultiStar ("Existing Equipment") which is used in the provision of invasive vascular services to patients at High Point Regional Health. The Existing Equipment is located at 601 North Elm Street, High Point, North Carolina and the Replacement Equipment will be installed in the same location. The purpose of this letter to provide the Agency with notice and to request a determination from that HPR's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review under the replacement equipment exemption provisions contained in N.C. Gen. Stat. § 131E-184(a)(7).

The equipment being replaced has been in operation since 2001. It has recently become infeasible to operate the Existing Equipment because of mechanical and technical difficulties. The current equipment requires frequent repairs. Due to the age of the equipment, replacement parts are not readily available. This results in at least one full day of downtime each month, delaying procedures and requiring patients to be rescheduled. In addition, the current equipment provides diminished image quality, is unable to transmit images in real time, and only allows for still-frame images to be archived to our internal system. These technological challenges increase procedure time and the time associated with interpretation and reporting. Consequently, we consistently experience lengthier diagnosis times, diminished operational efficiency, and a decline in patient satisfaction.

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

> "Replacement equipment" means equipment that costs less than two million dollars ($2,000,000.00) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. § 131E-176(22a).

To qualify for this exemption, the replacement equipment must (1) cost less than $2,000,000 and (2) be "comparable" to the equipment it replaces. In addition, the existing equipment must be "sold or otherwise disposed of when replaced." HPR UNC's proposal qualifies for this exemption.

A. <u>Cost of the Replacement Equipment</u>

The total costs to acquire, install, and make operational the Replacement Equipment is $1,842,193.00, which includes construction costs of $467,000.00, equipment costs of $1,305,193 (fixed equipment and moveable equipment), and architect and engineering fees of $70,000.00. *See* Exhibit 1, Quote for Replacement Equipment; Exhibit 2, Proposed Total Capital Cost; Exhibit 3, Existing Equipment Disposal Letter. The construction costs that are needed to install and make the Replacement Equipment operational are shown in the letter from McCulloch England Associates Architects. *See* Exhibit 4, Construction Quote; *see also* Exhibit 2, Proposed Total Capital Cost. No other construction-related costs will be incurred for this project. The cost for the removal of the Existing Equipment is included in the price quotation of $1,293,193 for the Replacement Equipment itself. *See* EExhibit 3, Existing Equipment Disposal Letter.

In combination, the cost for acquiring the Replacement Equipment, installation of the Replacement Equipment, and removal of the Existing Equipment represents a total capital cost of $1,842,193. There will be no other construction costs or other capital costs associated with this replacement project. The cost is safely below the $2,000,000 threshold.

B. <u>Comparable Equipment</u>

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

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

10A N.C.A.C. 14C.0303(c).

HPR UNC intends to use the Replacement Equipment for substantially the same vascular services for which it has used the Existing Equipment. The Existing Equipment is a Siemens MultiStar that was purchased in 2001 and installed new at HPR UNC in October, 2001. A Certificate of Need was issued for the Existing Equipment on August 10, 2000 (Project I.D. # G-6221-00).

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same general range of invasive vascular services. *See* Exhibit 5, Brochure for Replacement Equipment. The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, HPR UNC does not intend to increase patient charges or per procedure operating expenses within the first 12 months after its acquisition. For further equipment comparison, please refer to Exhibit 6, the Equipment Comparison Chart.

Subsection (d) of the Regulation further provides:

> (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
>
> (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
>
> (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

10A N.C.A.C. 14C.0303(d). The Replacement Equipment will meet all three of the tests set out in Subsection (d).

The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart. *See* Exhibit 6, Equipment Comparison Chart. Both the Existing Equipment and the Replacement Equipment are used exclusively for curative and palliative treatment planning for radiation oncology, enabling HPR UNC to scan patients with immobilization devices, respiratory devices and other apparatus without compromising image quality or positioning. The Replacement Equipment is comparable to the Existing Equipment, but provides the

advantages resulting from 14 years of technological improvements. For instance, the Replacement Equipment is capable of transmitting images in real time. Further, the Replacement Equipment will not be used to provide a new health service.

Moreover, HPR UNC represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

C. **Disposition of Equipment**

As part of the proposal to acquire the Replacement Equipment from Siemens, Siemens will de-install the Existing Equipment. Upon de-installation, Siemens will remove the equipment outside of North Carolina. *See* Exhibit 3, Existing Equipment Disposal Letter.

CONCLUSION

Pursuant to these statutory provisions, and based upon the estimated costs to replace this equipment, it is our understanding that the replacement of the existing simulator equipment is exempt from the CON review process. High Point Regional respectfully requests written confirmation that the foregoing is correct.

In addition, we respectfully request that this request be considered on an **expedited basis** because HPR wishes to proceed with the replacement as soon as possible. Thank you in advance for your consideration. If you find that your need additional information, please do not hesitate to contact me at (336) 878-6095.

Sincerely,

Molly Jordan

Molly D. Jordan
Director of Strategic Planning

Exhibits

Exhibit 1	Price Quotation (Siemens Artis Zee)
Exhibit 2	Proposed Total Capital Cost Chart
Exhibit 3	Existing Equipment Disposal Letter
Exhibit 4	Construction Quote from McCulloch England Associates Architects
Exhibit 5	Brochure for Replacement Equipment
Exhibit 6	Equipment Comparison Chart

SIEMENS

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, Malvern, PA 19355
Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
Stephen Argo - (336) 210-6178

PRELIMINARY PROPOSAL

Customer Number: 0000006798

Date: 2/4/2014

HIGH POINT REGIONAL HOSPITAL
601 N ELM ST
HIGH POINT, NC 27262

Quote Nr: **1-72UJ0C Rev. 0**

Artis zee floor / Artis zee III floor

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14417017	**Interventional Cardiology** X-ray angiography system with primary clinical use in interventional cardiology, including application-specific accessories.
1	14427079	**Artis zee floor** Universal floor-mounted C-arm angiography system with a high-resolution flat detector. The motorized rotation of the floor stand into the lateral position enables complete patient access at the head end and generous patient coverage. The powerful 100 kW generator and MEGALIX Cat Plus X-ray tube with its new flat emitter technology are the prerequisites for excellent image quality. The CLEAR functionality to optimize the image impression, the CARE package to reduce radiation exposure, and DICOM standards are all included. The system has been prepared for Siemens Remote Service.
1	14417020	**Sys SW incl cardiac acquisition** Imaging system software including cardiac acquisition with frame rates of 7.5, 10, 15, and 30 f/s. Acquisition, display, and storage in 1k/12-bit matrix.
1	04453291	**DR, Single Img., 0,5 - 7,5 f/s, 1k** Digital acquisition technology with frame rates of 0.5 to 7.5 f/s, 1k /12 bit matrix and digital real-time filtration. Serial acquisitions with time-controlled and manually variable frame rate.
1	14427271	**CLEARstent** CLEARstent enables an improved display of vascular supports (stents).
1	14411216	**Cardiology** Radiographic system for medical applications with emphasis on interventional cardiology.
1	14416998	**syngo XWP for electrophysiology** High-end post processing workstation, comprising Windows XP PC with syngo-based user software and network modules.
1	14407118	**syngo InSpace EP XWP** syngo InSpace EP is used for 3D visualization of the heart including automated segmentation of one or more ventricles/vessels of the heart (especially the left atrium with display of the pulmonary veins) and supports electrophysiologists in planning, performing, and follow-up of ablations, especially of atrial fibrillation ablations.
1	14402033	**19in Color Flatscreen Display** LCD color flatscreen display with high luminance and extended field of view.
1	14401876	**Inroom Control SW-License** Software extension for InSpace 3D and InSpace EP for remote control of the syngo Workplace from the examination room via touch panel and joystick.

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Qty	Part No.	Item Description
1	04472853	**syngo keyboard, USA** Keyboard with special syngo keys.
1	04451022	**Customer documentation, English**
1	14417202	**3D / 3D CARD Acquisition** Native rotational angiography with angle and ECG-triggering, generating the image data required for 3D reconstruction of the heart.
1	14427083	**Detector 30X40 incl.Compnts.(F)EP** High-resolution, dynamic flat detector for fully digital imaging chain, with integrated, removable grid. CAREwatch measuring chamber for detection of the dose-area product. MEGALIX 3-focus high-performance X-ray tube assembly, rotatable angio collimator including CAREfilter, integrated collision protection and StraightView.
1	14427090	**Table with Tilt** Floor-mounted swivelling patient table with telescopic foot, floating and tiltable tabletop; motor-driven stepping for digital peripheral angiography. Table control module, power-assisted.
1	14407064	**Tabletop(wide)/Mattress(thin)** Carbon fiber tabletop in wide, straight design including special foam mattress (4 cm thick). Mattress including cover.
1	14402009	**Foot Switch Monopl. (Cable)** For release of fluoroscopy, exposure and table brake as well as a configurable additional function. Cable connection.
1	14427127	**Large Display with DCS** 60" or 56" color flat screen display (including cables) for the examination room, installed on a ceiling-mounted, longitudinally mobile, swiveling, rotating, and height-adjustable display suspension system (DCS). A video controller (MDM) that can process up to 21 video input signals. Direct selection of display configurations (max. 12) via the tableside control module.
1	14427247	**LD MDM-Controller Medium 18 Inputs** The Large Display Multi Display Manager Controller Medium is one of three different video controller sizes and can be equipped with up to 18 video input channels. Up to 18 video input channels also can be shown simultaneously on the large display (LD).
1	14427300	**XWP/MMWP video cabling** This connection kit is needed to display the video signal from a unit, for example the syngo X-Workplace, on a single display or on a large display in the display suspension system (DCS) in the examination room. Note the following conditions if image content from third-party provider video signals are to be displayed on the Artis displays: - The display of external video signals depends on the operational state of the Artis system. If the Artis system has a malfunction or is shut down, the display of external video signals is not available. For this reason, do not feed the video signal into the Artis system if lacking the external video signal could result in a hazardous situation. - A third-party provider's unit may be connected only if it corresponds to the specifications of the video interface (e.g., at the MDM). - The connection may only be established by a Siemens service technician. Note: The connection must be made with fiber-optic cables to ensure that the unit's galvanic isolation is maintained. The fiber-optic cables must be ordered separately. - A third-party provider's unit must be connected by a technician from the third-party provider or by a hospital technician responsible for the equipment. - It is strongly recommended that image quality be tested by the third-party provider prior to start-up. This test ensures that the required image quality is achieved. - The system configurator is responsible for ensuring that applicable standards are maintained in the current version, e.g. 4 kV insulation Siemens will not be held liable for the inclusion of third-party provider units with respect to image quality and their suitability for clinical diagnosis.
1	14417128	**LD Input external EP kit** Contains all required connection kits for connecting the external analog and external digital video signals for the Large Display.
1	14417310	**LD input VGA ext. (ultrasound)** Analog input for an analog VGA video signal, e.g. from the ultrasound.
1	14417060	**ACE Cable Set in Equipm.Room** Image system interface to the displays in the control room if the image system is installed in the equipment room.

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PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	14407166	**C-Room DVI 1xBWD-19 (Live) -36m** One monochrome 19" flat-screen display with blue background color.
1	14409462	**ECG Interface (1)** Recording, storage and display of an ECG lead. Displayed together with the image information on a single monitor.
1	14411163	**Fluoro Loop (1)** Storage and review of dynamic fluoroscopic sequences (Fluoro Loop). The maximum storable fluoroscopic time depends on the selected pulse rate, e.g. 34 s at 30 p/s, 68 s at 15 p/s (VC21 software required). Note: With VC14 software, the values are 17 s at 30 p/s, 34 s at 15 p/s.
1	04435801	**Automap** Automatic stand positioning depending on the selected reference image and automatic reference image selection depending on the stand positioning.
1	04443516	**MULTISPACE.F** Manual stand rotation for additional work positions.
1	04435926	**DICOM HIS / RIS** Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist).
1	14417134	**LB rad. protection w/ pivot arm** For shielding the lower body against scattered radiation within the examiner's moving range. Specially designed for avoiding collisions with the tube during oblique projections, therefore especially suited for cardiology.
1	14401912	**Upper Body Rad. Protection Artis-F** To protect the upper body against scattered radiation within the operating range of the examiner, e.g. during interventional procedures.
1	14427389	**LED Exam Light** Ceiling-mounted, flexibly positionable examination light for diagnostic interventional applications.
1	14427095	**syngo Keyboard, English - US** Keyboard with special syngo keys.
1	14417219	**VOLCANO s5i Cable Set** Cable set for operating the s5i system.
1	14427170	**Safety screen for Large Display** Non-reflecting protective glass that protects the LCD panel of the 56" Large Display from mechanical damage. The protective glass can be attached to and removed from the housing.
1	14427173	**Intercom - Comfort** Communication / intercom system for communication between examination room and control room.
1	14417135	**LB rad. prot. w/ left pivot arm** For shielding the lower body against scattered radiation within the examiner's moving range. Specially designed for avoiding collisions with the tube during oblique projections, therefore especially suited for cardiology.
1	04451022	**Customer documentation, English**
1	04499104	**Pre-install Artis-F (mono)**
1	04499138	**Pre-install Artis table, std**
1	AXA_INITIAL_24	**Initial onsite training 24 hrs** Up to (24) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

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PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	AXA_FOLLOW UP_24	**Follow-up training 24 hrs** Up to (24) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	AXA_FOLLOW UP_12	**Follow-up training 12 hrs** Up to (12) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	AXA_INT_BAS _CLS	**Artis Class** AXA_INT_BAS_CLS Tuition for (1) imaging professional to attend Siemens Classroom Course at Siemens Training Center. The objective of this class is to understand the basic operations of the ARTIS systems and have an overall fundamental knowledge of standard and optional features. This class includes lunch, economy airfare, and lodging for (1) imaging professional. All arrangements must be arranged through Siemens designated travel agency. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	AXA_FOLLOW UP_12	**Follow-up training 12 hrs** Up to (12) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	AXA_WP_ADV CLS	**Advanced syngo X-Workplace Class** Tuition for (1) imaging professional to attend Siemens class at Siemens Training Center. The objective of this class is to learn advanced applications of the syngo X Workplace and review software features in an interactive setting with hands-on sessions. This class includes lunch, economy airfare, and lodging for (1) imaging professional. All arrangements must be arranged through Siemens designated travel agency. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
2	AXA_ADD_32	**Additional onsite training 32 hours** Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	EPW935515UP S	**Eaton Powerware 9355 15 kVA UPS** Includes UPS, battery, maintenance bypass panel, and one year on-site parts and labor coverage (24x7) by Eaton Powerware. This UPS is recommended when protection and uninterruptible power is required for the Artis' C-arm and table. Emergency fluoroscopy is not available with this UPS. If emergency fluoroscopy is required, the 9390 - 160 kVA UPS is recommended for the full system. One UPS per lab. Additional seismic brackets are required to make this system OSHPD approved.
1	NT60010635	**Blue anti-fatigue floor mat for hospital**
1	BLX1000073	**Bloxr XPF Starter Kit** The starter kit includes (2) aprons - medium, (2) thyroid collars - medium and (2) caps - medium. Color - pewter gray. XPF Technology: Provides 0.5 mm lead protection Durable and Flexible - Can be bent, folded and flexed without cracking or leaking radiation. Easy to clean - Machine wash or wipe down. Greener - Uses no toxic materials or heavy metals.
1	AXA_RIG_ZEE SP_STD	**Standard Rigging zee SP**
1	AXA_BUDG_A DDL_RIG	**Budgetary Add'l/Out of Scope Rigging $15,000**

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PRELIMINARY PROPOSAL

System Total: $1,293,193

OPTIONS:

Qty	Part No.	Item Description	Extended Price
1	14401883	**syngo Coronary Vessel Analysis** scientific analysis of the coronary vessels with determination of degree of stenosis, distance measurement and calibration.	+ $15,368
1	14401880	**syngo LVA Quantification** Analysis of the left ventricle with distance measurement and calibration.	+ $9,860
1	MART700PEDL	**Mark 7 Arterion, Pedestal System** The Arterion Mark 7 Pedestal contrast medium injector can be positioned anywhere at the patient positioning table on a mobile unit, for direct operation of all functions in the examination room. The injector system includes: A mobile pedestal stand with electronics unit, a contrast medium heater and a connection cable to the manual release. A support arm with injector head and a control lever for moving the injector head. A user control console with large touch screen and corresponding additional monitoring display on the injector head. Functions Pressure limitation: for 150 ml syringes 689 to 8273 kPa, corresponds to 100 to 1200 psi. . Flow rates for 150 ml syringes: 0.1 to 45 ml/s in increments of 0.1 ml/s 0.1 to 59.9 ml/min in increments of 0.1 ml/min rise/fall: 0 to 9.9 s in increments of 0.1 seconds Release delay for injection or radiation: 0 to 99.9 s in increments of 0.1 s. Adjustable volume for 150 ml syringes: 1 ml to the max. syringe capacity in increments of 1 ml. Fill rate: Variable syringe filling speed 1-20ml/s. Injection protocols: Up to 40 injection protocols possible. Parameters currently displayed on the touch screen display and on the head display: Injection speed Injection volume Remaining volume Injection duration Applied pressure Contrast medium heating: Nominal 35°C (95°F)+-5°C (9°F) Injection data memory Up to 50 injection data items stored Included in the scope of delivery Injector standard configuration 150 ml SIEMENS interface cable Operator Manual Service manual	+ $29,784
1	EPW9390160UPS	**Eaton Powerware 9390 160 kVA UPS** Includes UPS, battery, maintenance bypass panel, and one year on-site parts and labor coverage (24x7) by Eaton Powerware. Complete system backup without interruption. One UPS per lab. Not approved for sites requiring OSHPD certification. Please contact XPAS Inside Sales for configuration of an OSHPD certified configuration.	+ $56,909
1	14417457	**Connection Kit - 2nd Foot Switch** Connection kit for connecting a second tableside foot switch.	+ $952
1	14402010	**Foot Switch Monopl.(Wireless)** For release of fluoroscopy, exposure and table brake as well as a configurable additional function. Wireless connection via radio communication.	+ $4,080
1	04435868	**LV analysis** Analysis of the left ventricle with distance measurement and calibration.	+ $10,948
1	04435850	**Vessel analysis** Vessel analysis with determination of degree of stenosis, distance measurement and calibration.	+ $5,508
1	04435843	**Scientific QCA** Scientific cardiac vessel analysis with determination of degree of stenosis, distance measurement and calibration.	+ $17,136

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PRELIMINARY PROPOSAL

FINANCING: The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthcare is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthcare Sales Representative.

Siemens Healthcare

Stephen Argo
(336) 210-6178
craig.argo@siemens.com

PROPOSED CAPITAL COSTS

Project Name: **Vascular Lab Replacement**

Proponent: **High Point Regional Health**

A.	**Site Costs**			
(1)	Full purchase price of land		$	
	Acres _____ Price per Acre	$		
(2)	Closing costs		$	
(3)	Site Inspection and Survey		$	
(4)	Legal fees and subsoil investigation.		$	
(5)	Site Preparation Costs			
	Soil Borings	$		
	Clearing-Earthwork	$		
	Fine Grade For Slab	$		
	Roads-Paving	$		
	Concrete Sidewalks	$		
	Water and Sewer	$		
	Footing Excavation	$		
	Footing Backfill	$		
	Termite Treatment	$		
	Other (Specify)	$		
	Sub-Total Site Preparation Costs		$	
(6)	Other (Specify)		$	
(7)	**Sub-Total Site Costs**			$
B.	**Construction Contract**			
(8)	Cost of Materials			
	General Requirements	$		
	Concrete/Masonry	$		
	Doors & Windows/Finishes	$		
	Thermal & Moisture Protection	$		
	Equipment/Specialty Items	$		
	Mechanical/Electrical	$		
	Other (Specify)	$		
	Sub-Total Cost of Materials		$255,000.00	
(9)	Cost of Labor		$170,000.00	
(10)	Other (Specify) CONTINGENCY		$ 42,000.00	
(11)	**Sub-Total Construction Contract**			$467,000.00
C.	**Miscellaneous Project Costs**			
(12)	Building Purchase		$	
(13)	Fixed Equipment Purchase/Lease (+ Phones/Data)		$1,293,193.00	
(14)	Movable Equipment Purchase/Leas		$ 12,000.00	
(15)	Furniture		$	
(16)	Landscaping		$	
(17)	Consultant Fees			
	Architect and Engineering Fees	$70,000.00		
	Legal Fees	$		
	Market Analysis	$		
	Other (Specify) **Testing**	$		
	Sub-Total Consultant Fees		$	
(18)	Financing Costs (e.g. Bond, Loan, etc.)		$	
(19)	Interest During Construction		$	
(20)	Other (Specify) **Contingency**		$	
(21)	**Sub-Total Miscellaneous**			$1,375,193.00
D.	**Total Capital Cost of Project**			$1,842,193.00

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

Michael D. Hively AIA LEED AP NC 4550 — 2/7/14

(Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

Molly D. Jordan — Director

(Proponent - Signature of Officer) (Title of Officer)

SIEMENS Healthcare

Molly Jordan
Director of Strategic Planning
High Point Regional Health
601 North Main Street
High Point, NC 27262

Dear Molly,

I'm writing to confirm our conversation that should High Point Regional Health purchase a replacement cardiac catheterization system from Siemens Healthcare, we will remove the currently installed Siemens Multistar D system (installed in the Heart Center) and remove it from the state of North Carolina.

Please let me know if you have any further questions or concerns regarding this system.

Thank You,

Craig Argo
Account Executive
Siemens Healthcare

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway
Malvern, PA 19355
USA

Tel.: +1-888-826-9702
www.usa.siemens.com/healthcare

100 Queens Road
Suite 200
Charlotte, NC
28204
704/372-2750
fax: 704/372-6238

McCULLOCH ENGLAND ASSOCIATES ARCHITECTS

February 16, 2014
H1387/17

Ms. Molly Jordan
Director, Strategic Planning
High Point Regional Health System
601 North Elm Street
High Point, NC 27261

Re: Vascular Lab No.2 Equipment Replacement
Heart Center
High Point Regional Hospital
High Point, NC

Dear Molly,

This letter shall certify to the best of our knowledge, that the construction costs shown below are the costs which might be expected for this scope of work.

Preliminary Construction Cost Estimate

Vascular Lab No.2 Equipment Replacement

Heart Center Third Floor

Estimated Construction Cost:	$	425,000.00
Construction Contingency (10%):	$	42,000.00
Total:	$	467,000.00
Estimated Architectural/Engineering Fee:	$	70,000.00

Preliminary Estimated Construction Schedule

Vascular Lab No.2 Equipment Replacement

Heart Center Third Floor

- (1) Phase = (3) Months

February 16, 2014
H1387/17

The Preliminary Construction Cost Estimate and Schedule duration has been established based on similar Heart Cath equipment replacement projects completed over the last couple of years.

This estimate is for construction costs and Architectural/Engineering fees only. The above estimate does not include equipment, furniture, financing costs, security system costs, IT system costs, or other costs generally attributable to a project of this nature.

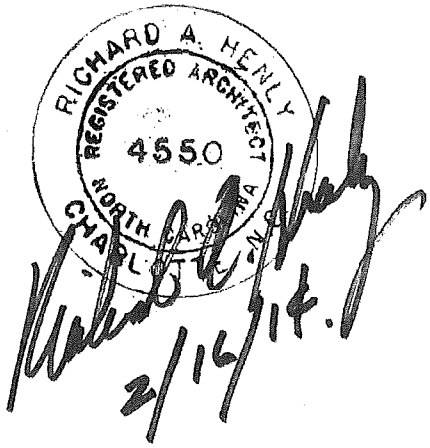
If you should require any additional information, please do not hesitate to give me a call.

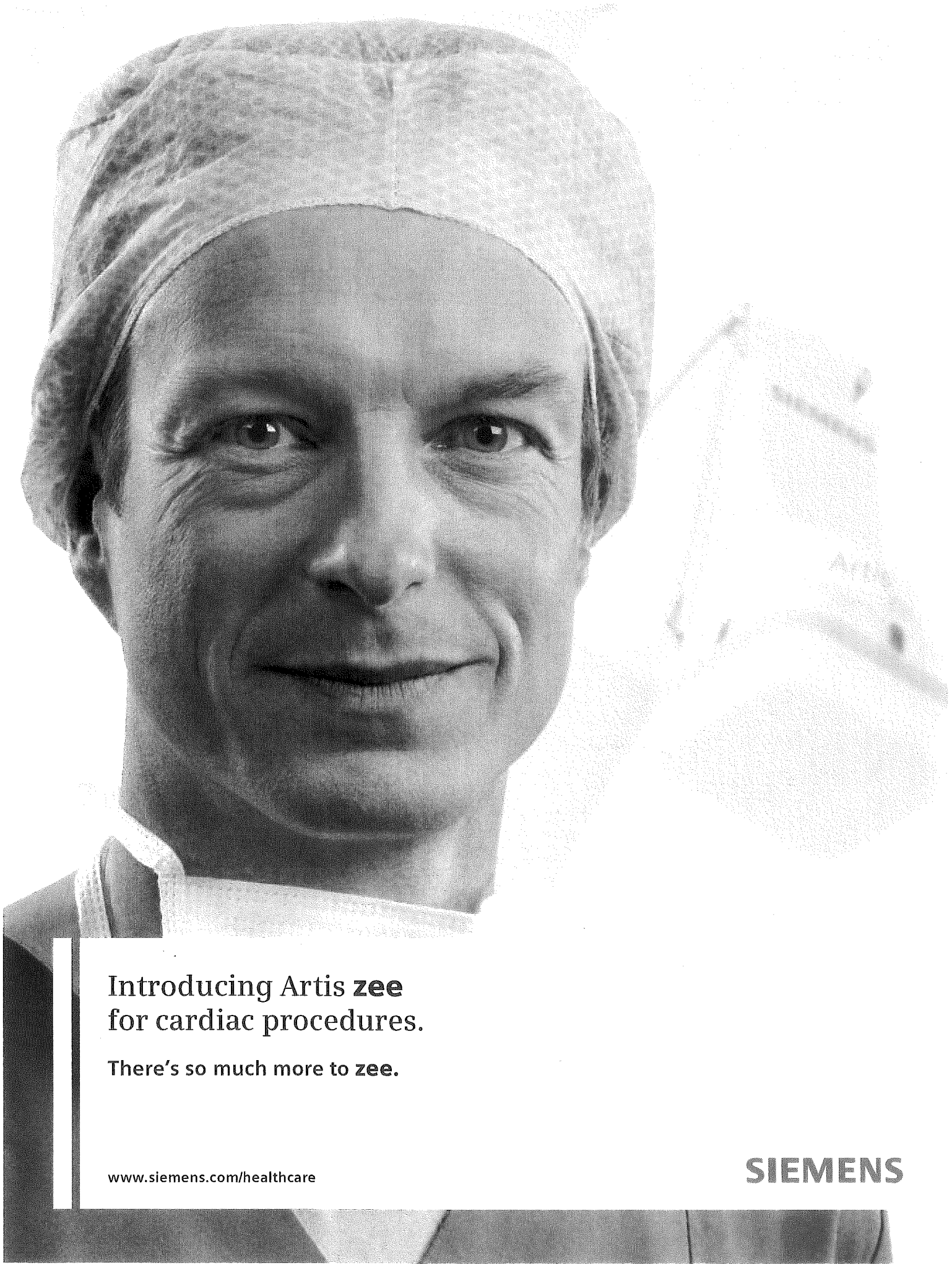
Sincerely,

McCULLOCH ENGLAND ASSOCIATES ARCHITECTS

Richard A. Henly, AIA LEED AP
Vice President

CC: Jim Morton
Arnold Clark
Daryl Herbert



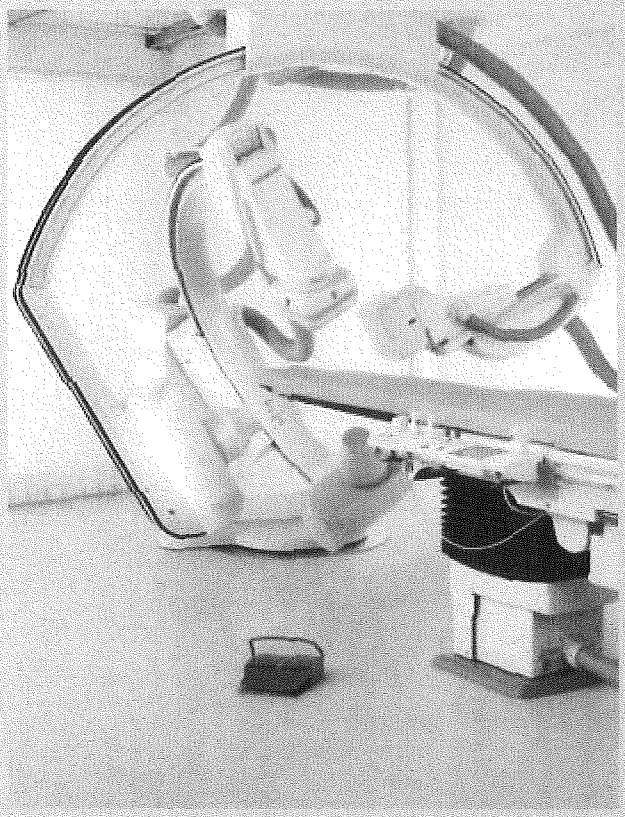

Introducing Artis zee
for cardiac procedures.
There's so much more to zee.
www.siemens.com/healthcare
SIEMENS

zee more, do more.

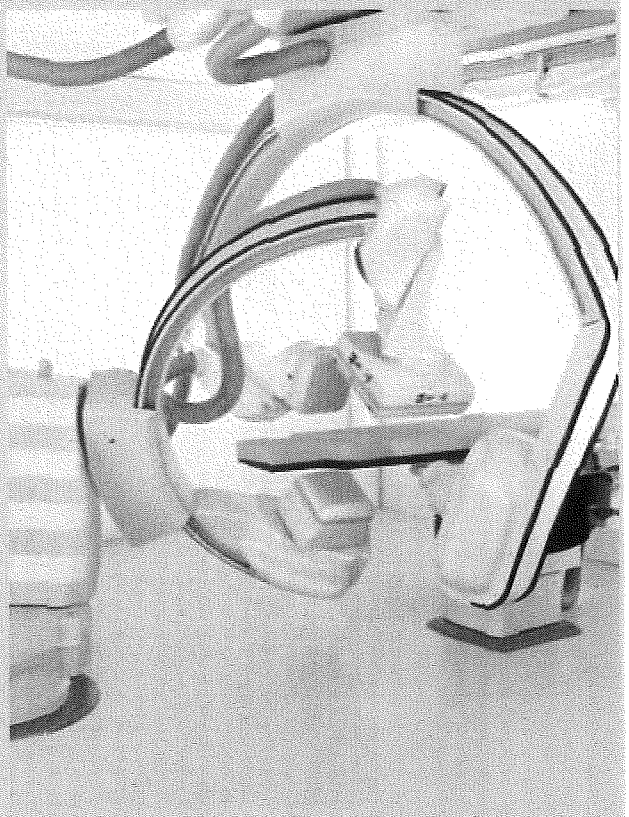
The field of interventional cardiology has never been more demanding. To enhance patient outcomes and remain on the cutting edge, you need an imaging system that enables you to care with greater speed, efficiency, and precision.

The answer is Artis zee®, a major advance in interventional imaging that supports you in three critical ways. Its innovative new Artis zee imaging chain offers outstanding image quality, so you can make better clinical decisions. Its workflow enhancements help your clinical team function more efficiently. And it's an investment you can make with confidence, backed by the industry's most comprehensive customer care program, Life. Life continuously develops your skills, productivity, and technology.

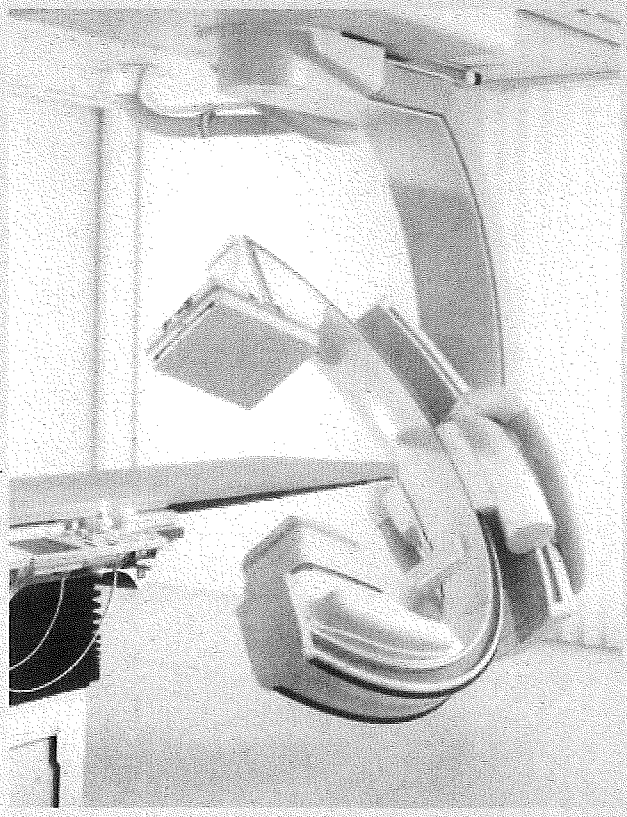
In an increasingly competitive healthcare marketplace, Artis zee gives you the versatility and advanced capabilities you need to deliver enhanced, faster and more effective care.



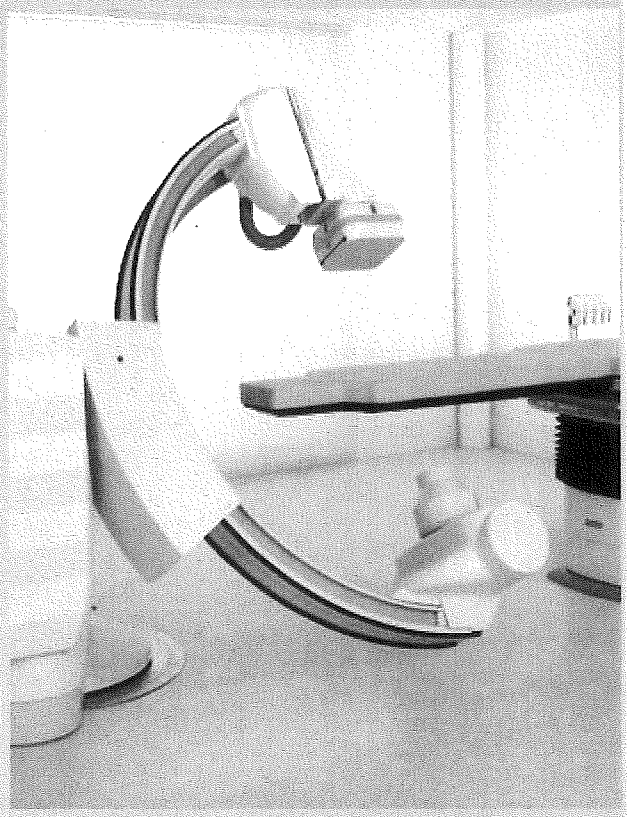
The Artis **zee** biplane system with two small detectors (20 x 20) enables biplane acquisition with up to 60f/s.



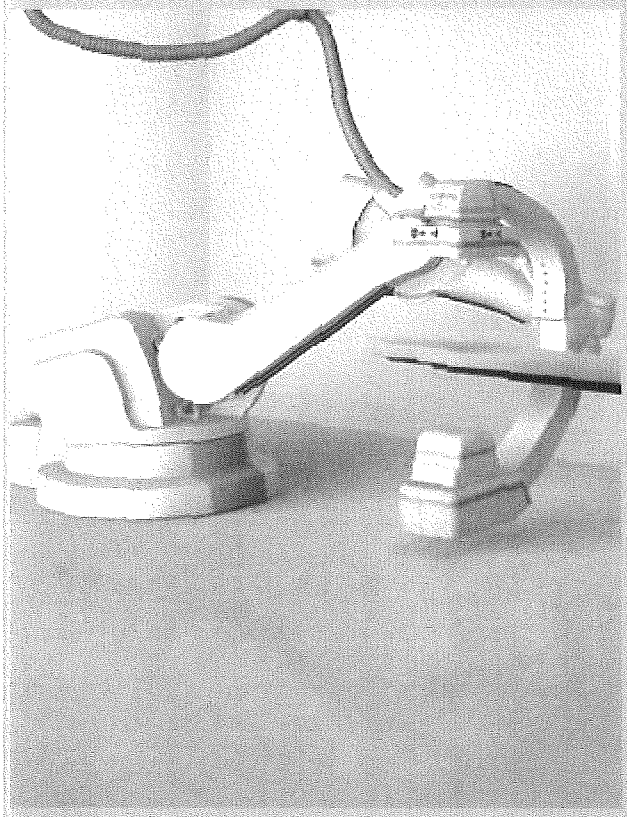
The Artis **zee** biplane system with mixed detectors (20 x 20 and 30 x 40) provides increased coverage ideally suited for imaging structural heart diseases.



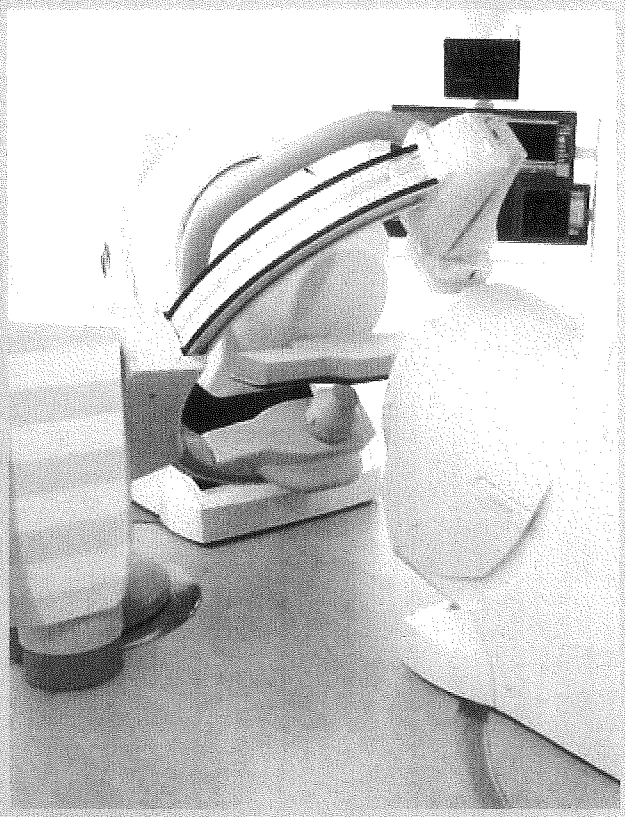
The Artis **zee** ceiling-mounted system features a 20 x 20 or 30 x 40 flat detector and enables flexible positioning around the patient.



The Artis **zee** floor-mounted system features a 20 x 20 or 30 x 40 flat detector and enables easy patient acces s.

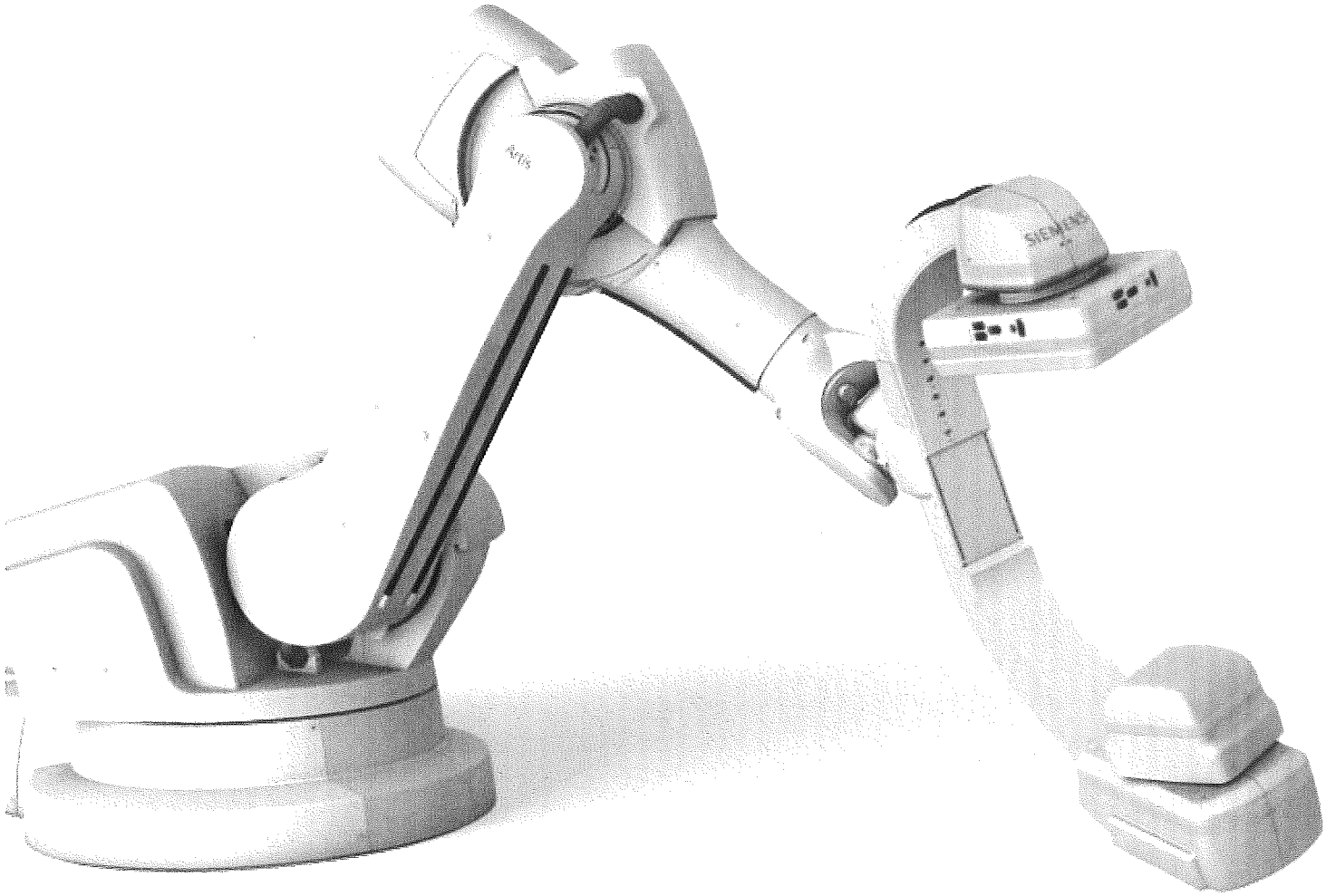


Artis **zeego** is the revolutionary multi-axis system that literally bends to your will. Its unrivaled flexibility makes it ideal for virtually all cardiovascular procedures in cath labs and hybrid rooms.



The Artis **zee** floor-mounted with magnetic navigation offers excellent precision in guidewire and catheter steering (also available as biplane solution).

The Artis **zee** family includes a full range of configurations to meet virtually any interventional imaging need.



Artis zeego, part of the new Artis zee family is a revolutionary, multi-axis imaging system for cardiovascular procedures. It offers a variable working height and enables large volume 3D imaging. Artis zeego® can be positioned with greater flexibility and precision than a conventional system, making it an ideal solution for hybrid rooms.

Open this flap to see the rest of the Artis zee family

Take a good look.

Enhanced precision with 3D imaging.

CT-like imaging with *syngo*® DynaCT Cardiac. Using rotational angiography and special reconstruction algorithms, *syngo* DynaCT Cardiac creates CT-like 3D and 4D images of the beating heart right in the cath lab to support procedure planning. *syngo* DynaCT Cardiac also reduces costs by minimizing the need for pre-procedural CT or MR imaging.

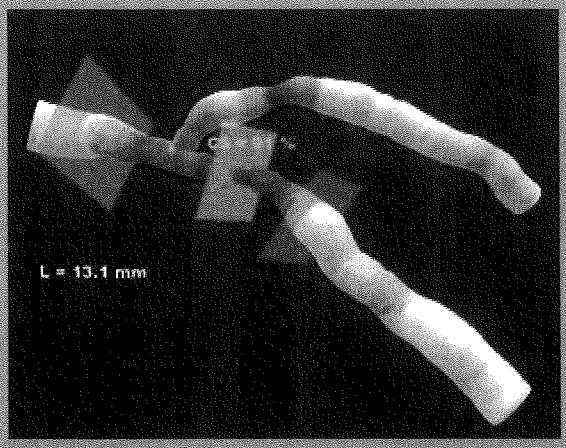
Intra-procedural 3D visualizations with *syngo* DynaCT Cardiac.

Quick and convenient segmentation of cardiac structures with *syngo* InSpace EP.

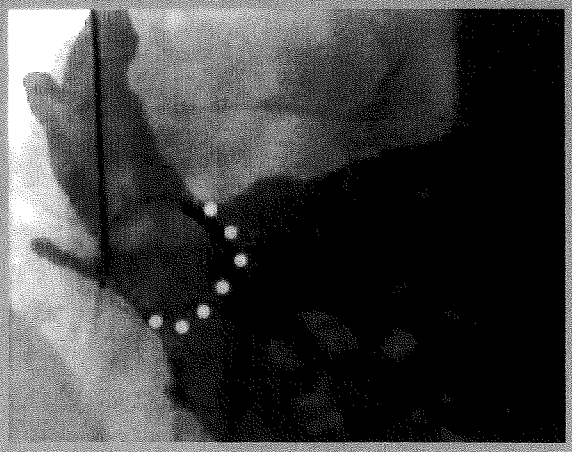
Automatic surface extraction with *syngo* InSpaceEP. *syngo* InSpace EP optimizes your EP workflow and supports the planning of ablation procedures. By integrating pre-procedural cardiac CT/MR images or intra-procedural *syngo* DynaCT Cardiac images, the result is a quick and convenient segmentation of the cardiac chambers. The 3D segmentation image is displayed in the examination room and can be rotated or explored via an endoscopic view.

The Artis zee imaging chain offers a range of key advances that enhance both 2D and 3D imaging and enable faster, and more precise procedures.

Accurate lesion measurement with *syngo* IC3D. Using two projections, *syngo* IC3D generates a 3D model of a vessel that can be rotated freely in space with no foreshortening effects, enabling you to precisely assess a lesion's diameter profile and the degree of stenosis. It also enables accurate measurement of lesion length to simplify stent selection.



Confident quantification of lesion in 3D with *syngo* IC3D.

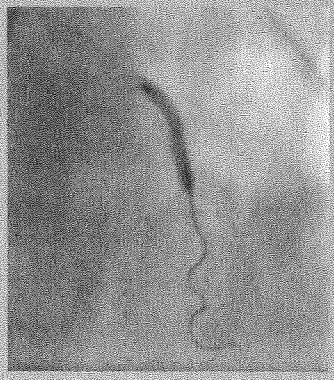


2D/3D overlay for improved orientation of devices with *syngo* iPilot.

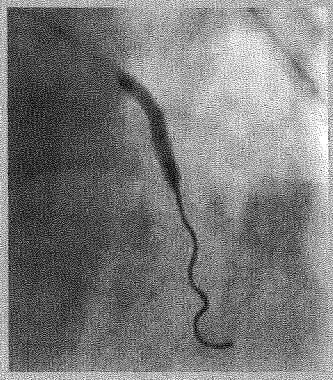
Effective guidance with *syngo* iPilot. *syngo* iPilot enables the overlay of 3D segmentation results and live fluoroscopy. The fusion of 2D and 3D information improves catheter guidance during ablations of atrial fibrillations and other complex interventions.

Improved visualization in low dose imaging.

Advanced temporal filtration uses an intelligent motion detection algorithm that is capable of separating moving from non-moving objects in the fluoroscopic image. The non-moving objects can be integrated from image to image thus reducing the noise level significantly. The result is a sharp image with a significantly reduced noise level.



Fluoroscopy image with conventional temporal filtration.



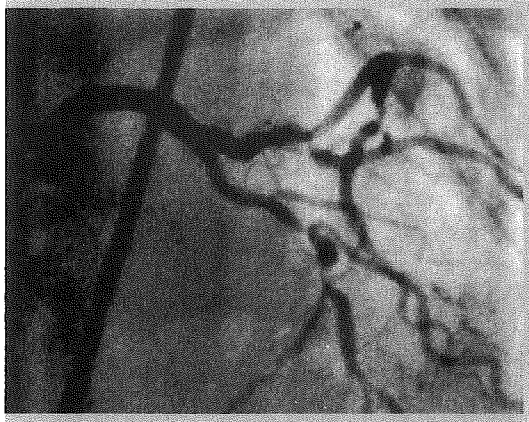
Fluoroscopy image with advanced temporal filtration.

Enhanced Clarity. Artis **zee's** new imaging chain enables a new real-time processing algorithm that improves cardiac image quality significantly, even under difficult circumstances such as steep angulations and/or obese patients. It is based on a real-time image content analysis and application of automatically optimized filter parameters. The result is images with reduced noise, clearly defined vessel edges, and better contrast.

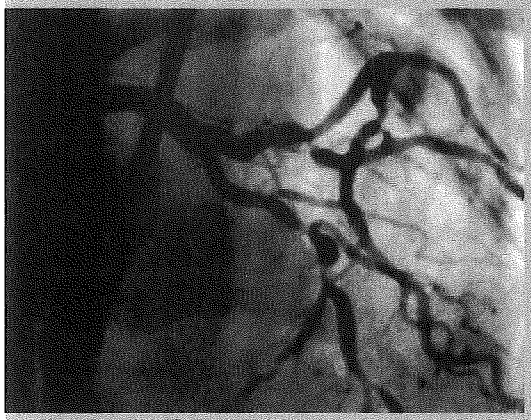
Enhanced imaging with reduced radiation exposure

We CARE about dose reduction. Our CARE *(Combined Applications to Reduce Radiation Exposure)* package reduces the radiation dose for patients and the clinical team, while still providing high image quality and diagnostic confidence:

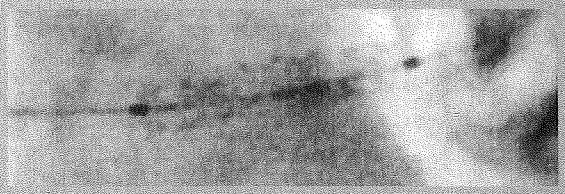
- CAREVISION provides pulsed fluoroscopy during lengthy examinations to reduce radiation dose.
- CAREPROFILE enables the radiation-free positioning of all collimators and filters for further dose reduction.
- CAREPOSITION enables you to reposition the patient under visual control without radiation.
- CAREFILTER is a specially designed copper prefiltration system that automatically adjusts the filter to the patient's anatomy.



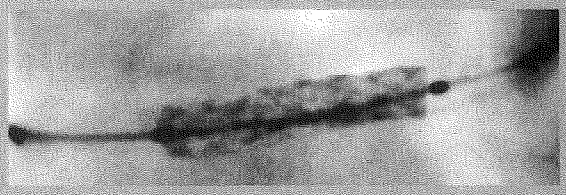
Left coronary artery without image processing.



Same image as above with advanced noise reduction and edge enhancement.

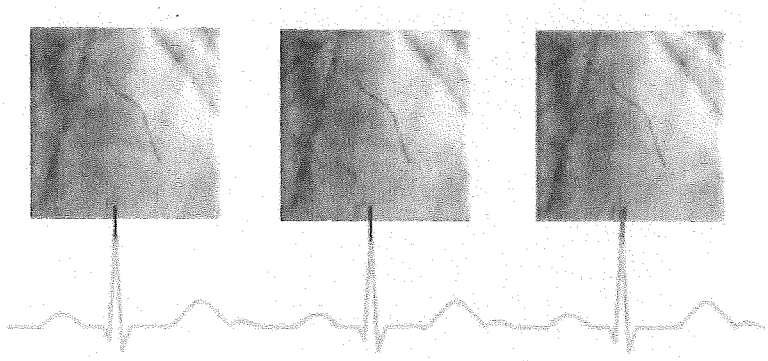


Control of device deployment without IC Stent.



Same image as above with IC Stent.

IC Stent. A deployed stent is sometimes hard to see which makes it difficult for the physician to judge proper outcome of the procedure. IC Stent is a processing package that enhances the visibility of the deployed stent. All it requires is the simple push of a button at tableside. Everything else is fully automatic. The result is available in less than 30 seconds. IC Stent is simple and easy to use and helps to improve the long-term success of the interventional procedure.

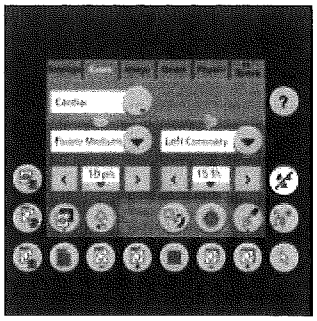


ECG triggered fluoroscopy sequence showing guidewire positioning.

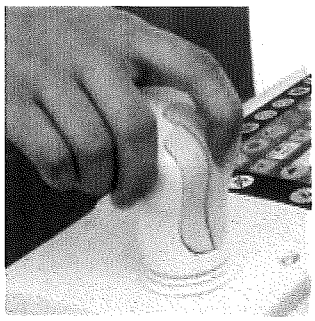
ECG-triggered pulsed fluoroscopy virtually freezes the motion of the heart by using the patient's ECG to trigger the image acquisition at the same point in the heart cycle. By reducing the pulse rate to one pulse per heart cycle, ECG-triggered fluoroscopy reduces the overall x-ray dose. Ideal for ablations and other long-lasting fluoroscopy procedures.

Don't work harder than you have to.

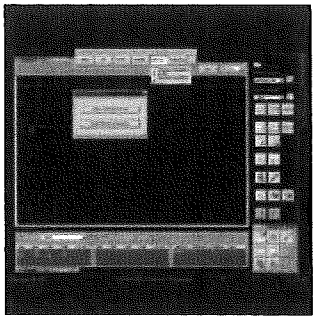
As demand for interventional procedures increases, so does the need for your clinical team to function more efficiently. Artis **zee** meets the challenge with new, ergonomically designed controls that streamline workflow through every phase of care delivery.



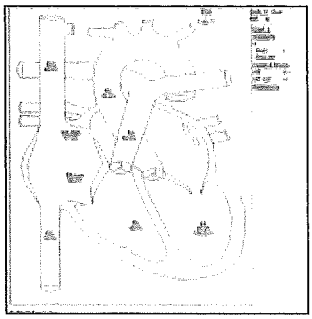
The new Artis **zee** slimline tableside control panel features easy-to-read *syngo* icons that are faster to use. The system data display enables a new menu-driven workflow for faster acquisition of 3D images.



The new mouse-like control is easier to operate and can be positioned on the right or left-hand side to maximize operator comfort.

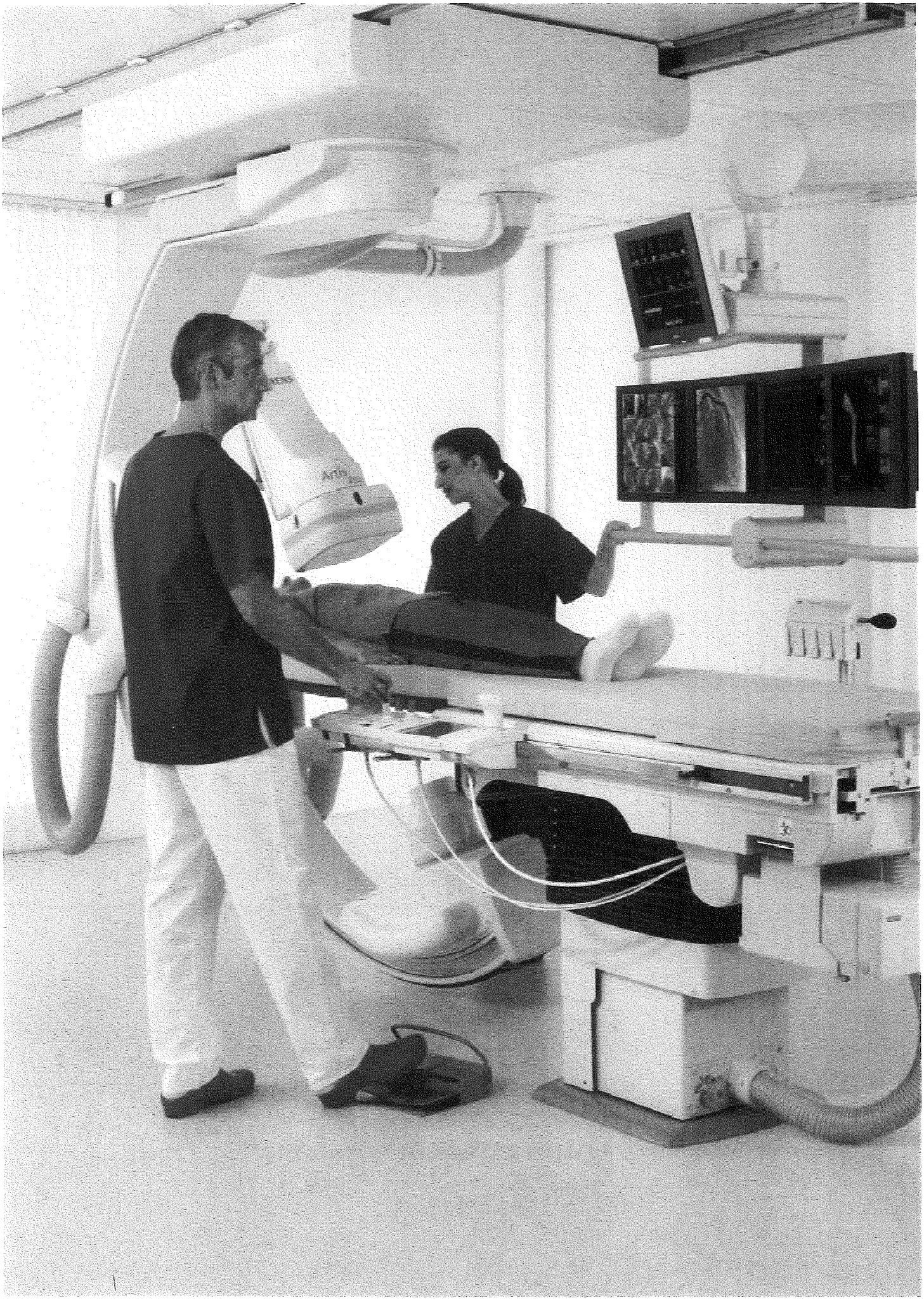


Artis **zee** features the AXIOM Sensis XP recording system, the first completely integrated recording system to combine both electrophysiology, hemodynamics, and reporting in one unit that can be operated by unique workflow support programs.



AXIOM Sensis XP offers convenient database management, automated report generation, and seamless integration with the hospital information system.

The new mouse efficiently guides the user through the workflow of 3D acquisition.



Smooth operator.

Healthcare providers have recognized the benefits of performing both minimally invasive surgical procedures and traditional cardiac angiographic procedures in the same room. Artis zee systems are designed to conform to the requirements of surgery, anesthesiology, and cardiology, and provide efficient space and equipment management in sterile conditions while enabling excellent image results.

Position flexibility — Artis **zee** systems can be easily moved to a parked position, when imaging is not required during a hybrid procedure. This enables excellent access to the patient during surgery from all sides. The system table allows both lateral and longitudinal tilt, matching the demands of an OR environment.

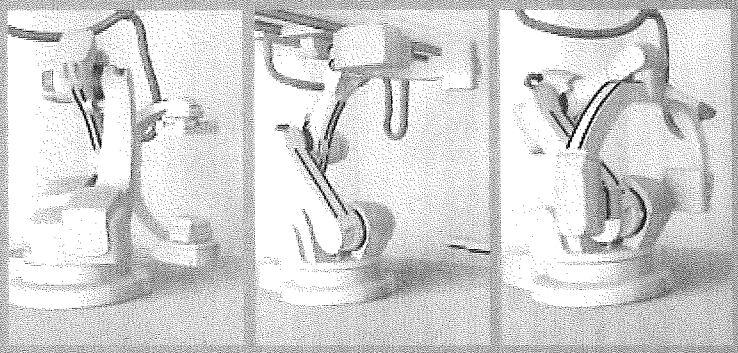
Image excellence — Artis **zee** features a new imaging chain with state-of-the-art components and processing capabilities. High-end cardiac imaging facilitates outstanding pre-procedural diagnostic information as well as post-therapeutic quality control. And all with significantly reduced radiation exposure for patient and personnel. In addition, 3D imaging of the beating heart during the procedure enhances the diagnostic information and supports the therapeutic planning process.

Accessories — Artis **zee** tables feature support rails that accommodate arm supports, anesthesia drape holders, infusion bottle holders, trays, and other surgical equipment. A trolley can be used to operate the system from a convenient position in the OR and an additional monitor suspension can be mounted.

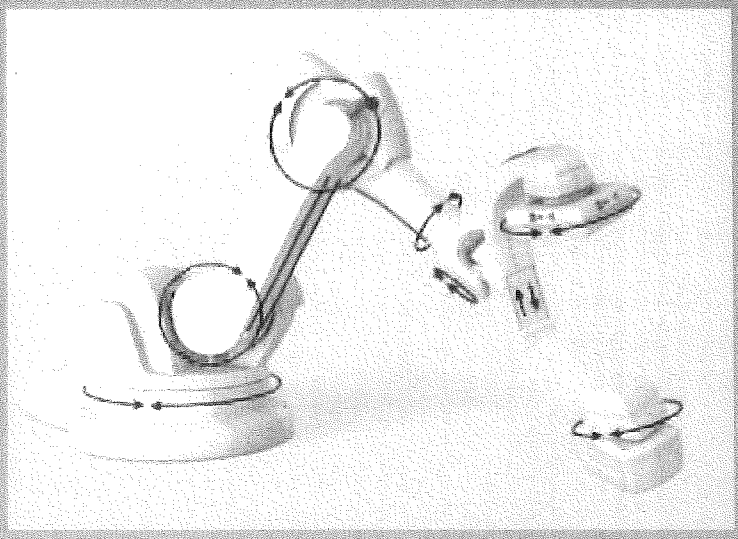
Patient management — Advanced 3D imaging applications enhance decision-making during procedures and can eliminate the need to transfer patients to CT.

Meet **zeego**, the world's most flexible surgical assistant.

Artis **zeego**, the revolutionary, multi-axis system is also ideal for cardiac procedures in the operating room. It offers more angulations than conventional systems, and its flexible working height makes procedures much more comfortable for the clinical team. Artis **zeego** also features special park positions that allow easier access to the patient.



Artis **zeego**'s exceptional flexibility and outstanding ergonomics enable you to perform hybrid procedures with more efficiency, precision, and comfort. Artis **zeego** can be stowed in a variety of compact positions to make the most of the limited space available in OR environments.



Due to its multiple axes, Artis **zeego** offers unmatched flexibility for complete head-to-toe coverage and the advantage of a variable working height reducing fatigue.

Looks good on the bottom

line.

A new interventional imaging system represents a substantial investment for any healthcare enterprise. Artis **zee** was specifically designed to provide value for your investment today and in the years ahead.

Fast, efficient, and precise care.

Artis **zee's** advanced 3D imaging capabilities enhance the decision-making of clinicians and facilitate faster and more effective procedures. Its ergonomic controls streamline workflow and improve patient throughput. Its OR capabilities help you make maximum use of your cath lab. And its ability to generate *syngo* DynaCT Cardiac images reduces the need for costly and time-consuming pre-procedural CT scans.

Your investment in the a new Artis **zee** marks the beginning of an important relationship that will last over many years. Siemens is proud to offer you tailored selection of programs and services that will help ensure imaging excellence, enhance your workflow and give you investment confidence.

Life is a learning opportunity

From installation planning to turnover you will benefit from our experienced and highly competent project management team. Our world-class onsite applications training will help to ensure that you realize the full imaging and workflow potential of your new Artis **zee**. Dedicated e-learning helps to maintain knowledge levels, and offers access to useful tricks and tips 24/7. Plus A wide range of international clinical workshops and fellowships in radiology and cardiology are also available should you wish to further expand your clinical knowledge, or widen your diagnostic and treatment portfolio.

Staying ahead of the curve

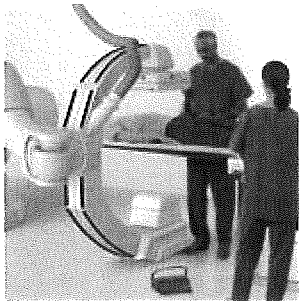
As an Artis **zee** customer you can also benefit from the most modern proactive service technologies including Guardian Program™, which significantly reduces unplanned downtime by detecting problems before they occur.

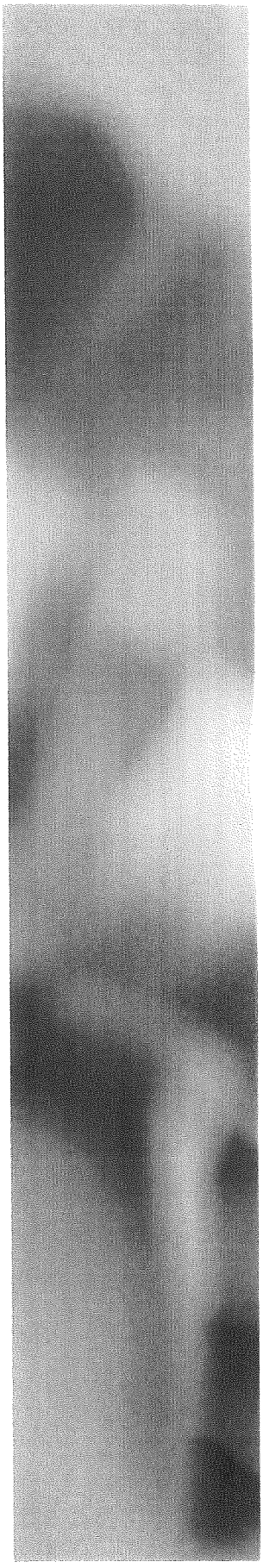
Looking forward

Your new Artis **zee** has been designed with the future in mind, and Siemens is committed to sharing that future with customers who invest in Artis **zee** today. *syngo* Evolve for Artis **zee** is your investment in the future, today. Opting for *syngo* Evolve for Artis **zee** will enable you to participate in future innovations via a managed upgrade program, helping you to stay at the cutting edge of imaging excellence and enhanced workflow.

zee the possibilities.

Siemens has been expanding the boundaries of cardiology for nearly a century. Over the decades, we have developed a host of innovations that have made diagnostic imaging faster and more effective, and that have enabled millions around the world to live longer, healthier lives. Artis zee is the latest illustration of that legacy of forward thinking. And as medical science continues to explore the possibilities of interventional imaging, Artis zee will be ready to help you translate that progress into higher levels of care.





Not all features are necessarily standard

Please find fitting accessories:
www.siemens.com/medical-accessories

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Telephone: +49 9131 84-0
www.siemens.com/medical

www.siemens.com/healthcare

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MultiStar	Siemens Artis Zee
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	NA	NA
Model Number	3772501	NA
Serial Number	303140	NA
Provider's Method of Identifying Equipment	Hospital Asset Tag	Hospital Asset Tag
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	7/27/2001	NA
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	Holds title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	$1,518,656.30	$1,842,193.00
Total Cost of Equipment	$1,196,876	$1,293,193.00
Fair Market Value of Equipment	NA	$1,293,193.00
Net Purchase Price of Equipment	NA	$1,293,193.00
Locations Where Operated	601 N. Elm St High Point NC	601 N. Elm St High Point NC
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%
Type of Procedures Currently Performed on Existing Equipment	Invasive Vascular	
Type of Procedures New Equipment is Capable of Performing		Invasive Vascular

STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Facility Services

CERTIFICATE OF NEED
for
Project Identification NumberG-6221-00
FID #943251

ISSUED TO: **High Point Regional Health System**
601 North Elm Street
High Point, NC 27262

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: **High Point Regional Health System shall acquire one unit of cardiac catheterization equipment to be used exclusively for a third special produces room and shall locate the equipment in the outpatient pavilion/Guilford County**

CONDITIONS: **See Reverse Side**

PHYSICAL LOCATION: **High Point Regional Health System**
601 North Elm Street
High Point, NC 27262

MAXIMUM CAPITAL EXPENDITURE: **$1,816,367**

TIMETABLE: **See Reverse Side**

FIRST PROGRESS REPORT DUE: December 1, 2000

This certificate is effective as of the 10th day of August, 2000.

Lee B. Hoffman

Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

1. High Point Regional Health System shall materially comply with all representations made in its certificate of need application.

2. High Point Regional Health System shall not perform any cardiac catheterization procedures, as defined in T10 NCAC 03R .1613(5), with the equipment in the Special Procedures lab.

3. High Point Regional Health System shall not report the additional equipment in the Special Procedures lab as cardiac catheterization equipment or report the procedures performed on this equipment as cardiac catheterization procedures on the Hospital License Renewal Application form or any other document or inventory.

4. Prior to issuance of the certificate of need, High Point Regional Health System shall provide the Certificate of Need Section with documentation that each Special Procedures team will consist of at least one physician licensed to practice medicine in North Carolina with training and current experience specifically in cardiovascular disease and radiation sciences.

5. Prior to issuance of the certificate of need, High Point Regional Health System shall provide the Certificate of Need Section with documentation that the staff of the proposed second special procedures or angiography lab will be certified in cardiopulmonary resuscitation and advanced cardiac life support.

6. High Point Regional Health System shall acknowledge acceptance and compliance with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance and compliance with all conditions stated herein to the Certificate of Need Section was received by the Certificate of Need Section on August 5, 2000.

TIMETABLE

Financing

Obtaining funds necessary to undertake project _____ February 29, 2000

Design

Completion of preliminary drawings _____ October 1, 2000
Completion of final drawings and specifications _____ February 1, 2001
Approval of final drawings and specifications by
Construction Section, DFS _____ April 1, 2001

Construction

Approval of Site by Construction Section, DFS _____ April 1, 2001
Contract Award _____ May 1, 2001
25% completion of construction _____ June 1, 2001
50% completion of construction _____ July 1, 2001
75% completion of construction _____ August 1, 2001
Completion of construction _____ September 1, 2001
Occupancy/offering of service(s) _____ October 1, 2001

Acquisition of Medical Equipment

Ordering equipment _____ February 1, 2001
Arrival of equipment _____ August 1, 2001
Operation of equipment _____ October 1, 2001

Other Milestones

Licensure of facility _____ September 15, 2001