NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • **Governor**
KODY H. KINSLEY • Secretary
MARK PAYNE • **Director, Division of Health Service Regulation**

VIA EMAIL ONLY

March 20, 2023

Randi Shultz
rshults@nshinc.com

No Review

Record #:	**4165**
Date of Request:	March 14, 2023
Facility Name:	North Carolina Specialty Hospitals
FID #:	943374
Business Name:	North Carolina Specialty Hospital, LLC
Business #:	3128
Project Description:	Acquisition of electrophysiology equipment
County:	Durham

Dear Ms. Shultz:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request,** the project as described is not governed by, and therefore, does not currently require a certificate of need. 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.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Cynthia Bradford
Project Analyst

Micheala Mitchell
Chief

K&L GATES

March 13, 2023

Gary S. Qualls
Gary.Qualls@klgates.com

T 919-466-1182

Via E-mail Delivery
Micheala Mitchell, Chief
Mike McKillip, Project Analyst
Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: North Carolina Specialty Hospital's No Review Request Regarding Electrophysiology Equipment

Dear Ms. Mitchell and Mr. McKillip:

Our client, North Carolina Specialty Hospital (the "Hospital"), makes this No Review Request to clarify that purchasing Electrophysiology ("EP") Equipment under the relevant cost thresholds does not require certificate of need ("CON") review.

I. The EP Equipment is Not Major Medical Equipment.

The type of EP Equipment that NCSH proposes to acquire is shown in Exhibit 1 (capital cost quote for EP Equipment), Exhibit 2 (EP Equipment brochure), and Exhibit 3 (optional monitor cost quote). As Exhibits 1 and 3 demonstrate, the total capital costs to acquire the EP Equipment (and associated equipment items) and make such equipment operational is below $900,000. That is well below the $2 Million threshold for major medical equipment in N.C. Gen. Stat. § 131E-176(14o). NCSH's EP Equipment will be dedicated to performing EP procedures and not cardiac catheterization procedures. Thus, NCSH's EP Equipment acquisition is not reviewable as major medical equipment.

II. The EP Equipment is Not Reviewable as Cardiac Catheterization Equipment or Services.

Likewise, NCSH's EP Equipment is not reviewable as either:

1. the acquisition of cardiac catheterization equipment under N.C. Gen. Stat. § 131E-176(16)f1.3; or

2. the development or offering of cardiac catheterization services under N.C. Gen. Stat. § 131E-176(16)f.2a.

For many years, the Agency has treated cardiac catheterization equipment and EP Equipment as separate and distinct types of equipment, despite some similarities. As one example, the 2022 Hospital Licensure Renewal Application ("LRA") shows how the Agency has treated reporting of the two types of equipment as distinct. See Exhibit 4 (LRA for NCSH).

Likewise, the Agency, until very recently, had a CON rule that very explicitly defined cardiac catheterization procedures so as to specifically exclude EP procedures. The former rule at 10A NCAC 14C .1601(4) stated as follows:

> "Cardiac catheterization procedure," for the purpose of determining utilization in a certificate of need review, means a single episode of diagnostic or therapeutic catheterization which occurs during one visit to a cardiac catheterization room, whereby a flexible tube is inserted into the patient's body and advanced into the heart chambers to perform a hemodynamic or angiographic examination or therapeutic intervention of the left or right heart chamber, or coronary arteries. **A cardiac catheterization procedure does not include a simple right heart catheterization for monitoring purposes as might be done in an electrophysiology laboratory, pulmonary angiography procedure, cardiac pacing through a right electrode catheter, temporary pacemaker insertion, or procedures performed in dedicated angiography or electrophysiology rooms.**

We are informed and believe that 10A NCAC 14C .1601(4) was repealed for unrelated reasons and that nothing about that repeal impacts the Agency's longstanding interpretation that EP Equipment and EP procedures do not constitute cardiac catheterization equipment or cardiac catheterization services pursuant to N.C. Gen. Stat. §§ 131E-176(16)f1.3 or 131E-176(16)f.2a.

III. Conclusion

Based on the foregoing information, we ask that you confirm that NCSH's acquisition of EP Equipment is not reviewable as a new institutional health service under the CON law.

If the Agency needs additional information to assist in its consideration of this request, please do not hesitate to apprise us. We thank you for your consideration of this request.

Sincerely,

Gary S. Qualls

Gary S. Qualls

Exhibit

1. Capital cost quote for EP Equipment

2. EP Equipment brochure

3. Optional monitor cost quote

4. NCSH's 2022 LRA

Exhibit 1

EXHIBIT
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1

Capital Equipment Budgetary Quotation

South TX Spine and Surgery Hospital
San Antonio, TX

Customer Number TBD

Pricing is valid through June 30, 2023.

Abbott Laboratories Inc. will require a separate, fully executed purchase agreement in order to process a customer purchase order for any items quoted in the table below.

PRODUCT DESCRIPTION	Order No.	Qty.	List Price	Customer Price
EnSite™ X EP System The EnSite™ X EP System is a catheter navigation and mapping system capable of displaying the 3-dimensional (3-D) position of conventional and Sensor-Enabled™ electrophysiology catheters, as well as displaying cardiac electrical activity as waveform traces and as dynamic 3-D isopotential maps of the cardiac chamber. The contoured surfaces of these 3-D maps are based on the anatomy of the patient's own cardiac chamber. Various software expansion modules and warranties are available. **Indications for Use** o The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. o The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures. **Clinical Benefit** o The intended clinical benefit is to provide diagnostic information to the physician to aid in the treatment of arrhythmias. **EnSite™ X Amplifier** o **The EnSite™ X EP System Amplifier** accepts signals from EnSite X SurfaceLink Module, EnSite X 20 pin and 80 pin Catheter Input Modules, the EnSite™ X Field Frame, and four (4) Patient Reference Sensors. The devices accept signals from catheters and electrodes attached to the patient and pass these signals to the EnSite™ X Amplifier. The EnSite™ X Amplifier converts these signals to a digital format and sends them to the DWS for processing and display. o **EnSite™ X EP System Field Frame.** The Field Frame generates the magnetic tracking field during an EnSite™ X EP System procedure. o **EnSite™ X EP System SurfaceLink™ Module.** Connects the EnSite™ X surface electrodes, system reference surface electrode, and ECG electrodes to the EnSite™ X Amplifier. o **EnSite™ X EP System Catheter Input Modules.** 20 pin and 80 pin modules allow for connection of standard diagnostic catheters to the EnSite™ X Amplifier. o **Four (4) EnSite™ X EP System Patient Reference Sensors,** one anterior (PRS-A) and three posterior (PRS-P) sensors with cables. o **EnSite™ X EP System ECG cable.** Connects standard ECG electrodes to the EnSite™ X Amplifier. o **Medical Grade Isolation Transformer.** When using the Amplifier Cart, the system components connected to line power through the isolation transformer. Only components on the Amplifier Cart should be connected to this isolation transformer.	ENSITE X-SYS	1	$400,000	$175,000

EnSite™ X Display Workstation (DWS) The DWS consists of the workstation (computer), monitors, medical grade isolation transformer, and optional printer: o **EnSite™ X EP System Workstation.** The workstation contains the system software displaying data from the EnSite™ X Amplifier. Attached to the workstation are a keyboard and mouse for user input. o **Monitors.** Monitors are used to display patient information. One monitor is placed near the workstation and keyboard for system operation. o **Medical Grade Isolation Transformer.** All system components on the DWS cart are connected to line power through the isolation transformer. Only components of the DWS should be connected to this isolation transformer. **EnSite™ LiveView Dynamic Display** EnSite™ LiveView Dynamic Display is a feature allowing mapping data to be visualized in real time during an EnSite™ X EP System study. o The following devices are required to use EnSite™ LiveView Dynamic Display and are sold separately: Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ Software Entitlement Kit (model H702519) Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (model D-AVHD-DF16) System contains Instructions for Use (IFU). Service Coverage: Includes initial one-year manufacturer's warranty SJM Connect™ Remote Access for real time technical support through a secure broadband connection.				
Advanced Mapping Software License Advanced Mapping Software License is a set of mapping features that introduces the following new functionality: • **EnSite™ OT Near Field Detection Algorithm** – A new detection method placing the detection time at the peak frequency (sharpest point) of the signal. • **Peak Frequency maps** – A new map type based on the peak frequency (sharpness) of the map point signal. • **Emphasis maps** – A new map visualization tool where areas of interest are emphasized on the map by darkening areas on the map that do not meet user-defined criteria. **Included EnSite™ OT license features:** • Omnipolar waveforms – A calculated waveform of the optimal bipole (maximum voltage) independent of catheter orientation. Omnipolar waveforms are calculated from the bipoles of triangular three-electrode groupings, or cliques, on the Advisor™ HD Grid Mapping Catheter, Sensor Enabled™. • Activation Vectors – A mapping feature where arrows representing activation direction, calculated from EnSite™ OT waveforms, are overlaid on the map. **Included EnSite™ X EP System Wave Speed license feature:** Wave Speed maps – A new map type showing the apparent speed at which the depolarization wave travel through the cardiac tissue.	ENSITE-AM-2.0	1	$70,000	$50,000
EnSite™ Contact Force Module Contains: • EnSite™ Contact Force Module v1.0 • TactiSys™ Quartz	CFK3000	1	$55,000	$20,000

Allows contact force data to be viewed on the EnSite Velocity Cardiac Mapping System. Key benefits include an intuitive display of contact force data, easier set-up and an enhanced workflow. o Requires EnSite Velocity System Display Workstation 5 (DWS5) or higher. o Requires EnSite Precision Mapping Module part number H700386 to already be installed. Service Coverage: Includes initial one year manufacturer's warranty				
Ampere™ Generator Kit Increased efficiency and control • Designed for improved efficiency and decreased noise interference • User controlled Power or Temperature modes • New Power Control mode for: o Safire™ BLU™ Duo Ablation Catheters o Therapy™ Cool Path™ Duo Ablation Catheters o Future irrigated ablation catheters Easy to use standard options • Monitor real-time temperature and impedance data on the color LCD screen • Power, temperature, impedance and duration push-button controls • Increased lab efficiency through user presets • Easy bedside physician control with included Footswitch Solutions designed to reduce risk • Select maximum temperature for automatic modulation of power with the TempGuard mode • Manage procedural needs through user-configured variable Power Ramp-Up • Control irrigation flow rates with the Auto Flow feature • Enhanced control of RF delivery with Automatic RF shutoff parameters o For example, auto-shut off is adjustable for impedance that changes by more than 10 ohms over 5 seconds Seamless integration for the EP Lab • Ampere RF generator integrates with our EnSite™ Velocity™ System, WorkMate™ Claris™ System, Cool Point™ Irrigation Pump and all other Abbott Laboratories Inc., standard and irrigated ablation catheters. The Ampere software is also upgradable via USB connection. Includes generator and footswitch with 2.5 m cable. Specifications • RF Output Power: 1 to 100 W adjustable in steps of 1 W • Impedance Range: Measures 50 Ω to 300 Ω in steps of 1 Ω • Target Temperature: 15° C to 80° C adjustable in steps of 1° C • RF Delivery Time: 1 to 999 seconds adjustable in steps of 1 second • Control Modes: Temperature; Power • Energy Delivery Modes: Independent; Sequential; Simultaneous • Operating Parameters: Values are digitally displayed on the Ampere™ Generator front panel • Generator Dimensions: 266.7mm H x 360.68mm W x 363.22mm D (10.5" H x 14.2" W x14.3" D) • Generator Weight: 9.98 kg (22.0 lbs) • Supply Voltage: 100-240 VAC, 50/60 Hz • Safety Class: Class I; Type CF according to IEC 60601-1 Service Coverage: Includes initial one year manufacturer's warranty	H700494	1	$30,000	$12,000
Ampere™ Remote Control (includes 15m fiber cord)	H700490	1	$10,000	$5,000
Cool Point Irrigation Pump o Cool Point Irrigation Pump Includes: Pump, power cord, pole clamp, 1779 communications (connecting) cable, tubing set (1 each) and	89003	1	$15,000	$5,900

operator's manual. Communication cable for the Cool Point Irrigation Pump (included with pump). Cool Point Tubing Set (sold individually). Service Coverage: Includes initial one year manufacturer's warranty				
WorkMate™ Claris™ Recording System 120 with EP-4 Cardiac Stimulator High-performance electrophysiology recording system for collecting, displaying and storing data from multiple sources within the electrophysiology (EP) lab. ▪ **Signal Clarity** - Unique ClearWave™ signal acquisition technology enables diagnosis with amplified confidence. With fast post-pacing recovery, high sample rates, and low baseline ablation noise, the electrograms displayed on the high-resolution WorkMate Claris System assist with fast and accurate diagnosis. ▪ **Enhanced Integration** - Seamless connections among multiple IT systems and platforms are designed to increase operator efficiency without sacrificing patient care. ▪ **Increased Efficiency** - Key user interface and hardware design improvements enable both current users and those new to the WorkMate Claris System to quickly become proficient with its setup and operation. TECHNICAL DESCRIPTION ***Advanced Display Workstation*** ▪ DVD-RW Drive ▪ Mouse, Custom Keyboard ▪ Basic Image Capture System (2 Black & White Inputs) ▪ Network Connection to Hospital System ▪ Inbound/Outbound Data Interface o Allows the WorkMate™ Claris™ System to connect to an external data source, archival of signals to a hospital file server ▪ Display of Signal FFT Data ▪ Ablation Data Interface (RF & Cryo) ▪ Integrated cardiac stimulator control software ***Amplifier with ClearWave™ Technology*** ▪ Up to 448 Channel Display capability ▪ 120 Intracardiac Electrode Inputs ▪ 4 Analog Input Channels ▪ 4 Analog Output Channels ▪ 4 Physiologic Input Channels ▪ 12 Surface ECG Channels ▪ Catheter Interface Module(s) ***Miscellaneous*** ▪ (4) 24" High Resolution 16:9 aspect ratio Widescreen Monitors ▪ (1) Color Printer ▪ WorkMate™ Claris™ 12 Lead ECG Cable ▪ Cables ▪ (1) Anti Fatigue Mat ***Cardiac Stimulator*** ▪ Integrated EP-4 Four Channel Cardiac Stimulator ▪ Stimulator Touch Screen Control ***Physiologic Pressure Monitoring*** ▪ (1) Pressure Transducer Cable (Up to 4 pressure Channels) ***Carts*** ▪ (1) Primary Workstation Cart - 48" ▪ (1) Bedside Slave Cart - 24" ***Warranty Information for* WorkMate™ Claris™ *only*** ▪ Service Coverage: Includes initial one year manufacturer's warranty 90 Day Warranty on Cables and Batteries	H700124	1	$300,000	$180,000
ViewMate™ Ultrasound System The ViewMate™ Ultrasound System is a fully featured imaging platform. Optimized for a 64-element phased array intra-cardiac echo (ICE) visualization, the system is compatible with the ViewFlex™ family of ICE catheters. Equipped with ZONE Sonography® Technology (ZST), the ViewMate™ Ultrasound System uses a software-driven approach to acoustic data	88900-VM	1	$110,000	$80,000

acquisition and image formation that breaks the barriers of conventional ultrasound imaging. Software: • Modes: 2D/B, M, Color Doppler (CD), Power Doppler, Pulse Wave (PW), Continuous Wave (CW), AUX CW • Auto Opt with ZST – instantly equalizes image gain and optimized sound speed compensation • Total Recall Imaging (TRI)- enabling retrospective processing • Cardiac calculations packages • Configurable cybersecurity options • DICOM networking – includes Verify, Store, Print, and Basic Modality Worklist Query service classes Hardware: • 19" color, high resolution LCD display mounted on articulating arm • OLED display for customizable mode menus • Interface Module for ICE • Rechargeable battery allows up to 1.5 hours of operation without plugging into AC power • Connect up to 3 transducers simultaneously • Multifunction USB port, Wireless ready • Minimum 120 GB Hard Drive Storage • HDMI/DVI digital video output Accessories: • Customized, durable baskets to carry supplies • 3 Lead ECG connection • Operator's manual and quick reference guide Service Coverage: Includes initial one year manufacturer's warranty				
P-8-3 Trans-esophageal (TEE) Transducer Multi-plane phased array transducer with imaging modes for M-Mode, Color Doppler, PW, TDI (tissue Doppler imaging) and CW imaging. The transducer offers three 2D frequencies, two color Doppler frequencies and one spectral Doppler frequency. The intended application is for adult imaging. Service Coverage: Includes initial one year manufacturer's warranty	H702084	1	$45,000	$32,500
L8-3 Linear Transducer Linear Array (8-3 MHz) transducer designed for peripheral vascular imaging. The transducer offers ten frequencies including three frequencies for 2D and M-Mode, two for Tissue Harmonics, one for Compound Harmonics, and two each for Color/Power and PW Doppler. Service Coverage: Includes initial one year manufacturer's warranty	H702488	1	$11,000	$9,400
Assurance Elite Service Plan **Serial Number: TBD** • Extended Product Warranty: Parts Replacement Coverage • Software Upgrades / Revisions • Universal Coverage to include 1 each of Ampere RF ablation generator, Cool Point irrigation pump, TactiSys Quartz system • Annual Preventive Maintenance • After Hour Preventive Maintenance • On-Site Service, Priority Response Level 1 (within one business days) • Shipping Level 1: First Overnight for down systems; for non-down systems, Priority Next Business-Day morning (by 10:30 AM in most U.S. areas) • 24/7/365 Telephone Technical Support: 1-855-4ST-JUDE (1-855-478-5833, option 2) • Remote System Diagnostics and Maintenance (as applicable; requires network connection and client set-up) • Loaner Systems / Components / Modules (as needed during service/repair of Covered Product)	EX908-UPG-MB	1	$70,000	$70,000

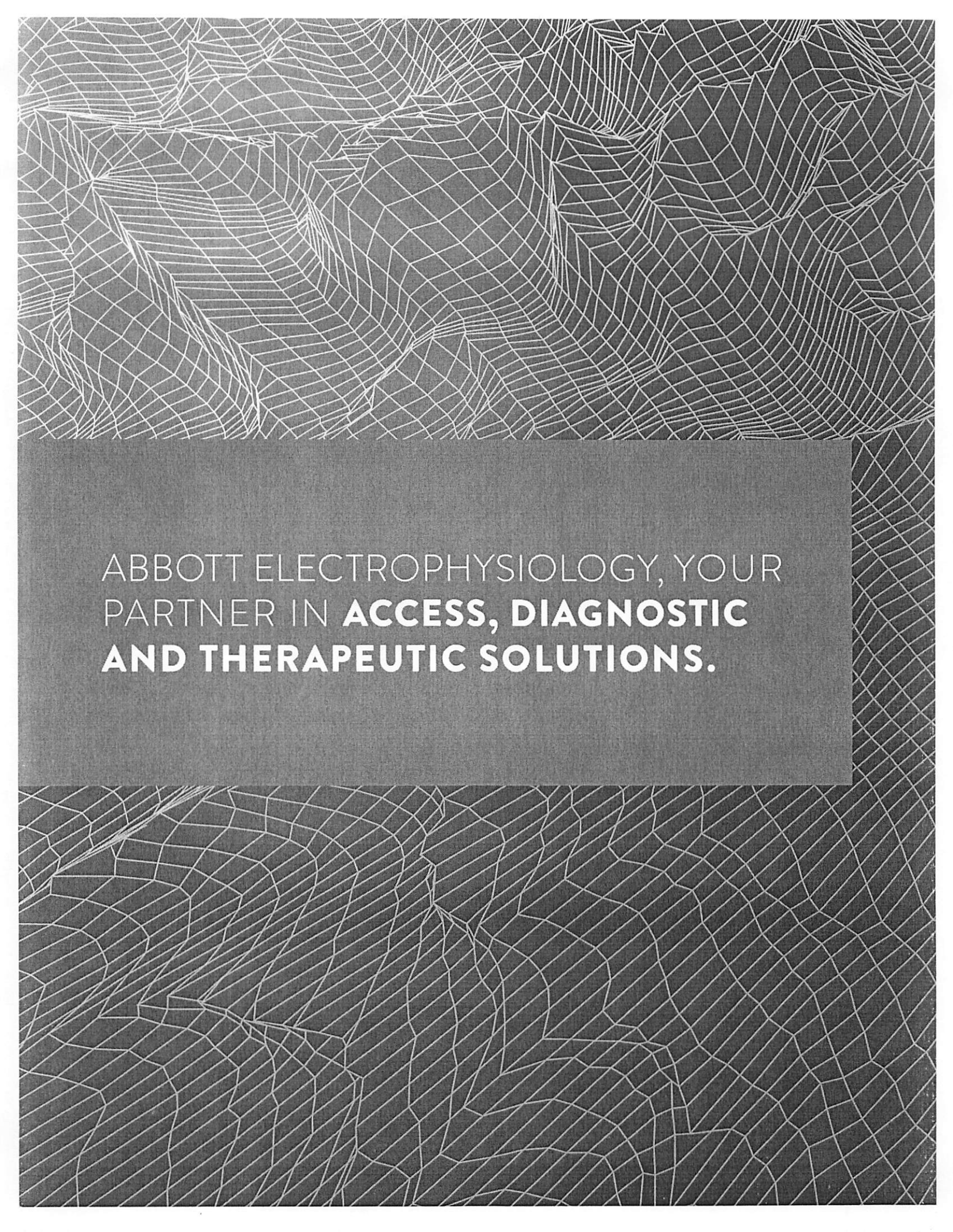
• **Technical User Training** Course Credits (as applicable) • **Advanced Training** Package (as applicable) • 20% Parts and Services Discount • Most Up-to-Date Commercially Available Hardware Upgrades / Revision • Commercially available Software Expansion Modules • Technology Performance Package: replacement coverage for select normal wear-and-tear items (final coverage determination by ALI • Remote Support accessories (hardware & software package) Exclusions / Purchased Separately Coverage for Connections between EnSite Cardiac Mapping Systems and non-Abbott RF Generators (ex. Cables and hardware modules)				
Fiber Optic Cable - Duplex LC/LC	H700180	3	$1,500 ($500/each)	$1,500 ($500/each)
			Total	**$641,300**

Exhibit 2

Abbott

ENCOMPASSING EP.
EMPOWERING CARE.

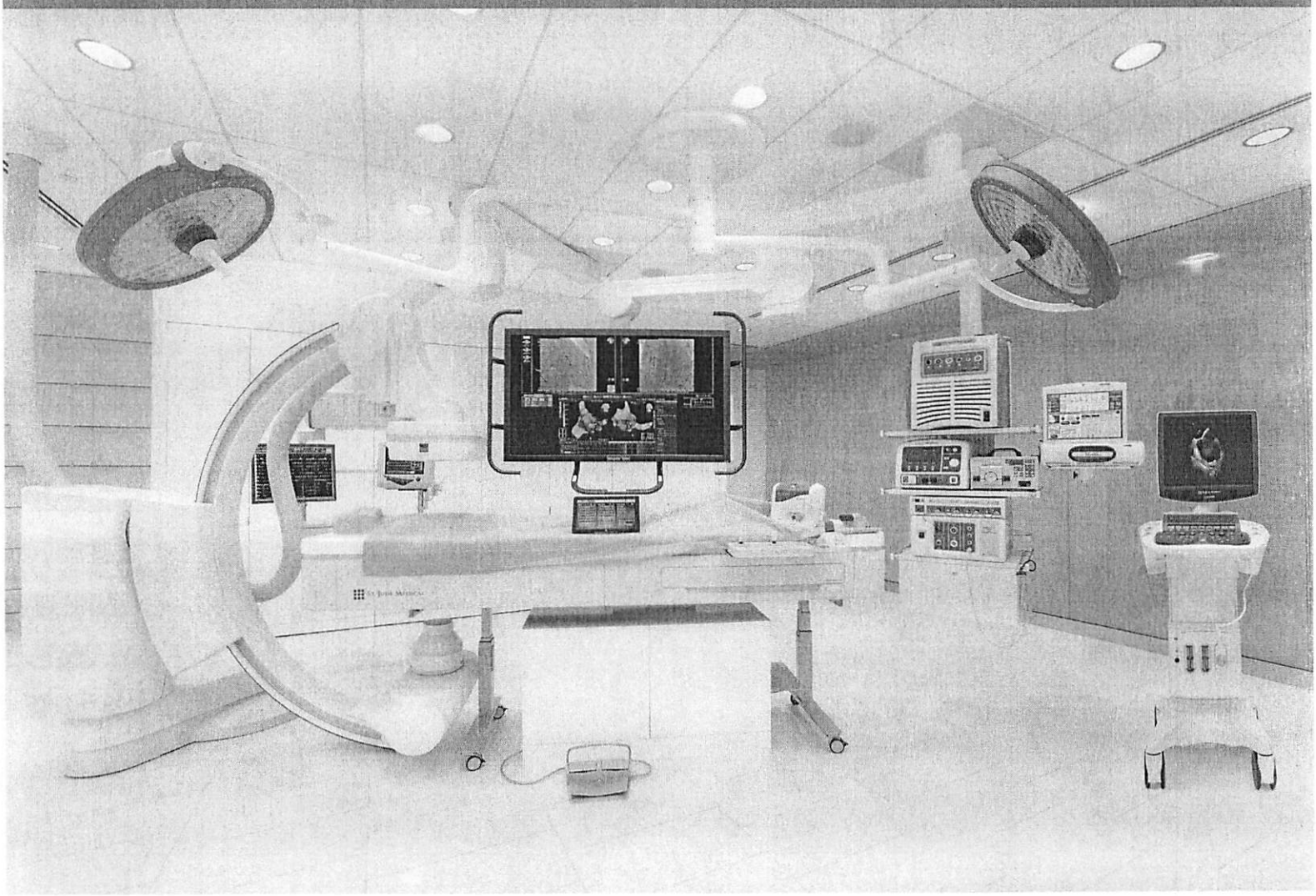
ABBOTT ELECTROPHYSIOLOGY SOLUTIONS


ABBOTT ELECTROPHYSIOLOGY, YOUR
PARTNER IN **ACCESS, DIAGNOSTIC
AND THERAPEUTIC SOLUTIONS.**

WHEN CARE IS DELIVERED EFFECTIVELY AND WITH FLEXIBILITY, IT MAKES A DIFFERENCE IN PATIENTS' LIVES.

The Abbott electrophysiology (EP) solution is one of the industry's most comprehensive suite of products, featuring elevated technologies that are designed for effective performance to help provide **access, diagnose and manage arrhythmias.**

With breakthrough technology, performance-enhancing integration, and open-platform designs, the Abbott EP solution expands your options for each stage in the EP procedural pathway to help you as you care for your patients.



ABBOTT ELECTROPHYSIOLO

ACCESS

MANEUVERABILITY AND STABILITY

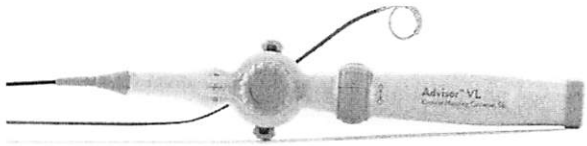
Navigate diverse vasculature and reach hard-to-access sites within the heart with solutions that include a selection of sizes and technologies to accommodate complicated anatomies.

AGILIS™ NXT INTRODUCER

DIAGNOSTIC SOLUTIONS

THE POWER OF CHOICE

With the Advisor™ family of diagnostic mapping catheters you have tools to access challenging anatomy in simple to complex cases using a trusted handle and shaft platform.



ADVISOR™ VL MAPPING CATHETER, SENSOR ENABLED™

ADVISOR™ HD GRID MAPPING CATHETER, SENSOR ENABLED™

SEE THINGS DIFFERENTLY

Produce high-density 3D cardiac maps with this fast[1], accurate[2] and easy-to-use[3] catheter, featuring a first-of-its-kind electrode configuration for high-density mapping.

ADVISOR™ FL CIRCULAR MAPPING CATHETER, SENSOR ENABLED™

GY SOLUTIONS

EP SYSTEMS

DISCOVER THE SYNERGY

Perform even challenging EP and interventional procedures by integrating diagnostics, visualization and mapping with the EnSite Precision Cardiac Mapping System and ViewMate™ Ultrasound Console.

Combine other advanced individual technologies that work together synergistically to support your procedural success.

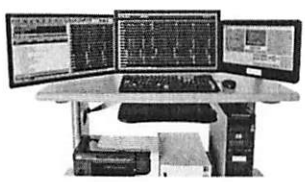
ENSITE PRECISION™ CARDIAC MAPPING SYSTEM

AUTOMATED.[4] FLEXIBLE.[4]* PRECISE.[5]

Map the most complex cases with a considerable reduction in radiation exposure.[5,6]

VIEWMATE™ ULTRASOUND CONSOLE

WORKMATE CLARIS™ RECORDING SYSTEM

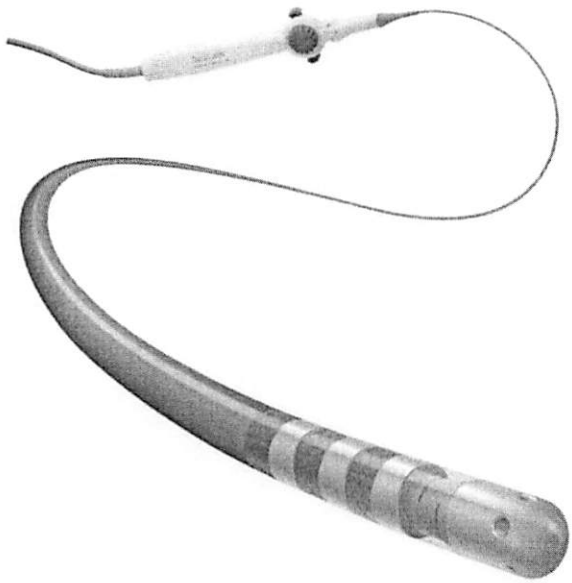


VANTAGEVIEW™ SYSTEM

THERAPEUTIC

ACCURACY MATTERS

Address atrial arrhythmias for both contact force (CF) and non-CF cases with Abbott therapeutic catheters.



TACTICATH™ CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED™

FLEXIBLE TIP AND OPTIMAL HANDLING

Combine the same contact-force sensing technology from TactiCath™ Quartz Contact Force Ablation Catheter Cardiac Mapping System for the best in accurate[7], effortless handling** and integrated[8,9] performance.

FLEXABILITY™ IRRIGATED ABLATION CATHETER, SENSOR ENABLED™

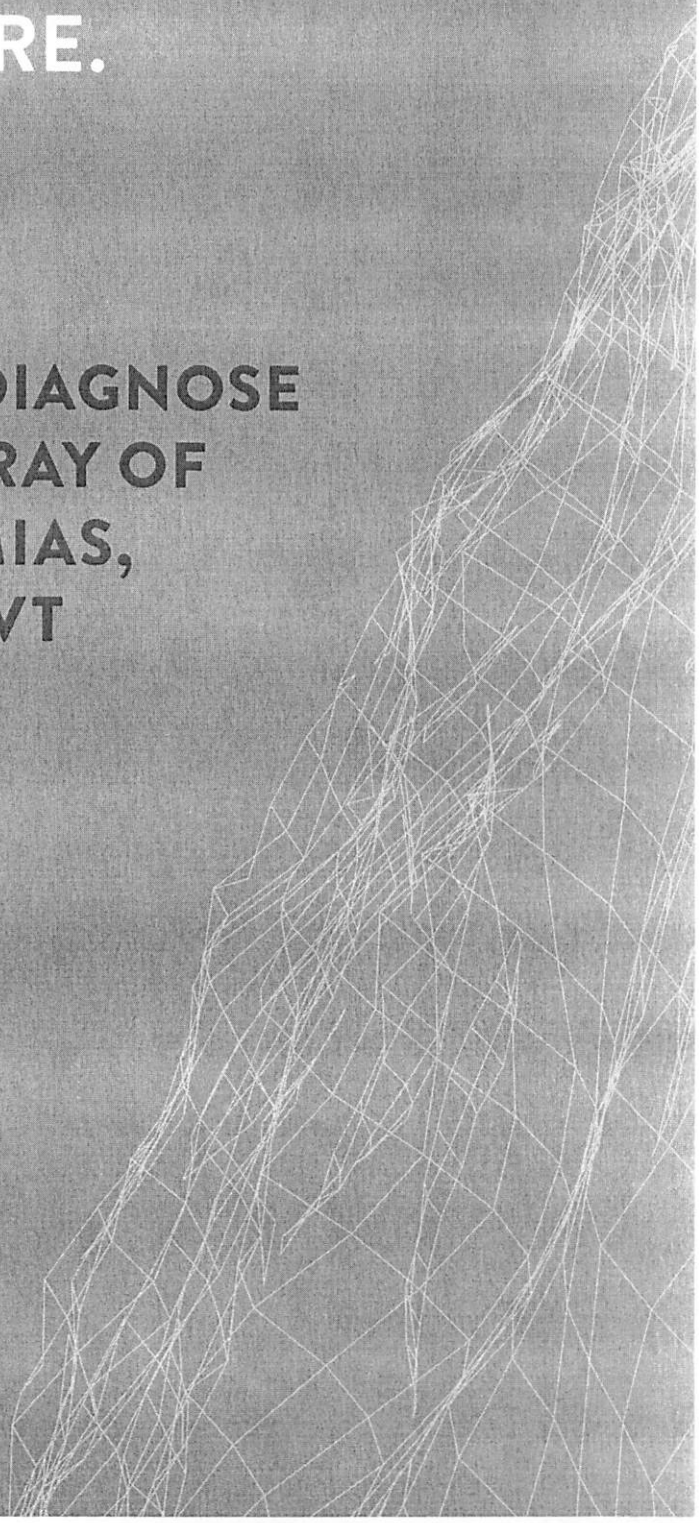
UNIQUE FLEXIBLE TIP

Feel the difference of an ablation catheter with a unique flexible tip for directed flow, and optimal handling. The FlexAbility™ ablation catheter, SE, integrates fully with the EnSite Precision™ cardiac mapping system and features a next-generation shaft design for reliability, accuracy and consistent performance.

ENCOMPASSING EP.

EMPOWERING CARE.

THE VERSATILITY TO DIAGNOSE AND MANAGE AN ARRAY OF CARDIAC ARRHYTHMIAS, INCLUDING AF AND VT



*The open-platform feature of the EnSite Precision™ cardiac mapping system allows for use of almost any catheter for mapping, thus offering superior flexibility as compared to the CARTO1 system by BioSense Webster, which limits use to BioSense Webster catheters only.

**Effortless handling is based on how physicians scored catheter handling characteristics during an initial market release.

References

1. Abbott. Report on file. 90299533.
2. Abbott. Report on file. 90262900.
3. Abbott. Report on file. 90355919.
4. Ptaszek LM, Moon B, Rozen G, Mahapatra S, Mansour M. (2018). Novel automated point collection software facilitates rapid, high density electroanatomic mapping with multiple catheter types. J Cardiovasc Electrophysiol, 29(1), 186-195. https://doi.org/10.1111/jce.13368.
5. Abbott. Data on file. Report 90237452.
6. Abbott. Data on File. Report 90114565.
7. Abbott. Data on File. Report 90430651.
8. Abbott. Data on File. Report 90214738.
9. Abbott. Data on File. Report 90253949.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuals.sjm.com or eifu.abbottvascular.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

United States – Required Safety Information

Indications: The TactiCath™ Quartz Contact Force Ablation Catheter and TactiCath™ Ablation Catheter, Sensor Enabled™ are indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used in conjunction with a compatible RF generator and three-dimensional mapping system. **Contraindications:** Do not use for any of the following conditions: certain recent heart surgery; prosthetic valves; active systemic infection; use in coronary vasculature; myxoma or intracardiac thrombus, or an interatrial baffle or patch; retrograde trans-aortic approach in patients with aortic valve replacement. **Warnings:** It is important to carefully titrate RF power; too high RF power during ablation may lead to perforation caused by steam pop. Contact force in excess of 70 g may not improve the characteristics of lesion formation and may increase the risk for perforation during manipulation of the catheter. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Implantable pacemakers and implantable cardioverter/defibrillator may be adversely affected by RF current. Always verify the tubing and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air can cause potential injury or fatality. The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data. **Precautions:** The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established; careful consideration must be given for the use of the device in prepubescent children. When using the catheter with conventional EP lab system or with a 3-D navigational system, careful catheter manipulation must be performed, in order to avoid cardiac damage, perforation, or tamponade. Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter. Care should be taken when ablating near structures such as the sino-atrial and AV nodes. **Potential Adverse Events:** Potential adverse events include, but are not limited to, cardiovascular related complications, including groin hematoma, pericardial effusion and infection. More serious complications are rare, which can include damage to the heart or blood vessels; blood clots (which may lead to stroke); tamponade; severe pulmonary vein stenosis; heart attack; esophageal fistula, or death.

Indications: The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. **Contraindications:** The catheter is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch via transseptal approach. This device should not be used with patients with active systemic infections. The catheter is contraindicated in patients who cannot be anticoagulated or infused with heparinized saline. **Warnings:** Cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Careful consideration must therefore be given for the use of this catheter in pregnant women. Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures. Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid device component damage, thromboembolism, cerebrovascular accident, cardiac damage, perforation, pericardial effusion, or tamponade. Risks associated with electrical stimulation may include, but are not limited to, the induction of arrhythmias, such as atrial fibrillation (AF), ventricular tachycardia (VT) requiring cardioversion, and ventricular fibrillation (VF). Catheter materials are not compatible with magnetic resonance imaging (MRI). **Precautions:** Maintain an activated clotting time (ACT) of greater than 300 seconds at all times during use of the catheter. This includes when the catheter is used in the right side of the heart. To prevent entanglement with concomitantly used catheters, use care when using the catheter in the proximity of the other catheters. Maintain constant irrigation to prevent coagulation on the distal paddle. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. If irrigation is interrupted, remove the catheter from the patient and inspect the catheter. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion. Always straighten the catheter before insertion or withdrawal. Do not use if the catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if any of the irrigation ports are blocked. Catheter advancement must be performed under fluoroscopic guidance to minimize the risk of cardiac damage, perforation, or tamponade.

Indications: The EnSite Precision™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite Precision™ System interfaces to either the MediGuide™ Technology System or the EnSite Precision™ Module to combine and display magnetic processed patient positioning and navigation mapping information. When used with the EnSite™ Array™ Catheter, the EnSite Precision™ Cardiac Mapping System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. OR, when used with an EnSite Precision™ Surface Electrode Kit, the EnSite Precision™ Cardiac Mapping System is intended to display the position of conventional electrophysiology (EP) catheters in the heart. **Warnings:** Refer to the ablation catheter labeling for a listing of adverse events related to the use of this device in conjunction with radio frequency ablation, as a part of the diagnosis and treatment of cardiac arrhythmias. For patient safety, any connections that directly connect the patient to the EnSite Precision Cardiac Mapping System must be routed through the appropriate module: EnSite Precision Link, Sensor Enabled™ NavLink, EnSite Precision Field Frame, ArrayLink, CathLink, SJM ECG Cable, RecordConnect, or GenConnect. When using the EnSite Precision Module full protection against the effects of cardiac defibrillator discharge and other leakage currents is dependent upon the use of appropriate cables. Refer to the ablation catheter labeling for a listing of adverse events related to the use of this device in conjunction with radio frequency ablation, as a part of the diagnosis and treatment of cardiac arrhythmias. **Precautions:** Do not operate the EnSite Precision Field Frame within 10 meters (m) of another operating Field Frame. Do not place the EnSite Precision Field Frame cable inside the measurement volume or wrap it around the Field Frame, as it may create a magnetic interference. Do not coil the EnSite Precision Field Frame cable. The cable carries enough electric current that a magnetic field will be created when the cable is placed in a circular formation. This magnetic field may disturb the Field Frame's magnetic field. Do not place the EnSite Precision Link, Sensor Enabled™ within 1 m of the EnSite Precision Field Frame - Do not place tool cables within 30 millimeters (mm) of the EnSite Precision Field Frame cable. If placed this close—particularly if the cables are parallel to each other—the tool cable may become subject to electromagnetic interference. Metallic equipment used in close proximity to the magnetic field during the procedure, such as a sterile drape holder, may affect Sensor Enabled (SE) points and SE field scaling accuracy. Do not use the EnSite Precision Cardiac Mapping System in the presence of other magnetic fields. Do not drop the EnSite Precision Field Frame or subject it to impact. Physical damage to the Field Frame may alter the Field Frame's factory calibration.

Indications: The Agilis™ NxT Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart. **Contraindications:** The Agilis™ NxT Steerable Introducer is contraindicated for known or suspected atrial myxoma, Myocardial Infarctions within the last two weeks, Unstable angina, Recent Cerebral Vascular Accident (CVA), Patients who do not tolerate anticoagulation therapy, Patients with an active infection and Presence of atrial thrombus. **Warnings:** Do not alter this device in any way. Only those physicians who are trained in transseptal procedures and SJM catheter delivery systems should use this device. Do Not reuse this device. Thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from reuse of this device. Maintain continuous hemodynamic monitoring throughout procedure. Always observe acceptable hemodynamics prior to advancing the dilator or any other component. **Precautions:** US federal law restricts this device to sale by or on the order of a physician. Carefully read instructions before use of device to help reduce potential risks and complications associated with transseptal procedures, such as air emboli and/or perforation of the aorta and left atrium (LA). (Perforation of the aorta and LA not included for 82 cm device). Inspect all components before use. Do not use if package or items in kit appear to be damaged or defective. The French size specified represents the inner diameter of the introducer sheath. **Potential adverse events:** Cardiac perforation, Embolus, Cerebrovascular accident, Death, Atrial fibrillation, Dissection and Heart block.

Indications: The FlexAbility™ Ablation Catheter, Sensor Enabled is intended for use with the compatible irrigation pump and a compatible RF cardiac ablation generator. The catheter is intended for creating endocardial lesions during cardiac ablation procedures (mapping, stimulation, and ablation) for the treatment of typical atrial flutter. **Contraindications:** In patients with active systemic infection. In patients with intracardiac mural thrombus or those who have had a ventriculotomyor atriotomy within the preceding four weeks. **Warnings:** Catheter ablation procedures present the potential for significant x-ray exposure. The long-term risk of protracted fluoroscopy has not been established. Careful consideration must be given for the use of the device in prepubescent children and pregnant women. The longterms risks of RF ablation lesions have not been established. The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data. Always verify the tubing and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air can cause potential injury or fatality. **Precautions:** If the irrigation pump alarm sounds, terminate RF delivery. If impedance rises suddenly that does not exceed the preset limit, power delivery should be manually discontinued. Always maintain constant irrigation to prevent coagulation within and around electrodes. Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Care should be taken when ablation near electrically vulnerable,thin-walled or other arterial structures. If irrigation is interrupted, immediately inspect and reflushthe catheter outside of the patient. Reestablish irrigation flow prior to placing catheter in the body. Do not attempt ablation without using an irrigation pump. **Potential adverse events:** Potential adverse events include, but are not limited to, cardiovascular and anesthesia-related complications, including inadvertent AV block.

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Exhibit 3

EXHIBIT
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PRODUCT DESCRIPTION	Order No.	Qty.	List Price	Customer Price
VantageView™ System: **12 inputs** The VantageView System is an integrated HD monitor viewing system which allows the physician to view all pertinent case information in a single monitor with the same image clarity and resolution as individual system screens. The system consists of a Quad HD 58" monitor showing up to eight separate displays on one screen displaying pixel image of 3940x2160. The system accepts up to 16 inputs of any analog or digital system in the lab. Other parts include: - (1) One on-demand touch panel with proprietary software allows user to set and change pre-sets for viewing displays (8 users with 8 presets each- up to 64 different configurations), - (1) Isolated Equipment Rack: Video controls and computer are housed in an isolated cabinet. It can be stored in a corner of the lab, control room or outside the lab. - (4) Patch Point Connection Boxes: used to connect all inputs to the Equipment Rack and monitor. Each Connection Box can receive up to four inputs connected by fiber optic cables; a single fiber cable exits the Connection Box and connects to the Equipment Rack. - (1) Wheeled Cart, IFU: Instructions for Use, - Service Coverage: Includes initial one year manufacturer's warranty **VantageView System Installation** On-site installation to an approved and properly installed boom. Additional hardware maybe required for retrofitting. A project manager will be assigned to ensure configuration and installation requirements are communicated. Please note the following: All pricing is budgetary. Installations may require an assessment and additional work. Pricing does not account for any structural or ceiling support modifications. Should additional work or costs be incurred, scopes and proposals will be presented at that time and a Change of Work order mutually agreed upon prior to commencing.	VS100003	1	$275,000	$200,000
Installation Services (For Boom Installation and/or Structural Room Modification) Please note the following: All pricing is budgetary. New Boom installations and structural modifications may require an assessment and additional work for adequate and approved support of the new Boom and VantageView System. Some structural needs may not be known until after work has started. Should additional work or costs be incurred, scopes and proposals will be presented at that time and a Change of Work order mutually agreed upon prior to commencing.	VVINSTALL	1	$10,000	$10,000
VantageView Touchscreen	A21843	1	$3,000	$2,600

Exhibit 4

EXHIBIT
tabbies
4

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

TO: **North Carolina Specialty Hospital -- Durham**

FROM: Azzie Y. Conley, RN, Section Chief

SUBJECT: **2022 Hospital License Renewal Application**

PLEASE READ CAREFULLY

Enclosed is your 2022 License Renewal Application. Please complete this license renewal application and return the original no later than January 14, 2022 to the address below.

Mailing Address
Acute and Home Care
Licensure and Certification Section
1205 Umstead Drive
2712 Mail Service Center
Raleigh, NC 27699-2712

Overnight Address (UPS and FedEx Only)
Acute and Home Care
Licensure and Certification Section
1205 Umstead Drive
Raleigh, NC 27603

Data on file with the Division indicates that your facility/entity is a **Hospital** totaling **18** beds. Your annual licensure fee, as authorized by G.S. 131E-77, is **$565.00**. This amount is comprised of a base fee of **$250.00** plus an additional per bed fee of **$17.50**.

Payment should be in the form of check, money order or certified check and must be payable to "NC - DHSR." Payment should include the facility's license number and be submitted with your license renewal application. A separate check is required for each licensed entity.

Your completed license renewal application **and** the **annual licensure fee** must be received by January 14, 2022 to ensure your license remains valid. Failure to possess a valid license may compromise your facility's ability to operate and/or adversely impact its funding sources.

8. **Specialized Cardiac Services** *continued* (for questions, call Healthcare Planning at 919-855-3865)

b. Cardiac Catheterization and Electrophysiology

Cardiac Catheterization, as defined in NCGS 131E-176(2g)	Diagnostic Cardiac Catheterization**	Interventional Cardiac Catheterization***
1. Number of Units of Fixed Equipment	0	
2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger	0	0
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	0	0
4. Number of Procedures* Performed in Mobile Units	0	0
Dedicated Electrophysiology (EP) Equipment		
5. Number of Units of Fixed Equipment	0	
6. Number of Procedures on Dedicated EP Equipment	0	

*A **procedure** is defined as one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. Count each visit only once, regardless of the number of diagnostic, interventional, and/or EP catheterizations performed during that visit. For example, if a patient has both a diagnostic and an interventional procedure in one visit, count it as one interventional procedure.

** "a cardiac catheterization procedure performed for the purpose of detecting and identifying defects or diseases in the coronary arteries or veins of the heart, or abnormalities in the heart structure, but not the pulmonary artery." 10A NCAC 14C .1601(9)

*** "a cardiac catheterization procedure performed for the purpose of treating or resolving anatomical or physiological conditions which have been determined to exist in the heart or coronary arteries or veins of the heart, but not the pulmonary artery." 10A NCAC 14C .1601(16)

Number of fixed or mobile units of grandfathered cardiac catheterization equipment owned by hospital (i.e., equipment obtained before a CON was required): N/A

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all non-grandfathered fixed or mobile units of cardiac catheterization equipment owned by hospital:

Name of Mobile Vendor, if not owned by hospital: N/A

Number of 8-hour days per week the mobile unit is onsite: N/A 8-hour days per week.
(Examples: Monday through Friday for 8 hours per day is 5 8-hour days per week. Monday, Wednesday, & Friday for 4 hours per day is 1.5 8-hour days per week)

From: Mitchell, Micheala L
To: Stancil, Tiffany C
Cc: Mckillip, Mike
Subject: FW: [External] No Review Request for NC Specialty Hospital"s Acquisition of EP Equipment
Date: Monday, March 13, 2023 11:09:07 AM
Attachments: 20230313_Dear Ms. Mitchell and Mr. McKillip_ Our client, North C.pdf

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Tiffany,

Would you mind logging this and assigning to Terris?

Thanks,

Micheala Mitchell, JD
NC Department of Health and Human Services
Division of Health Service Regulation
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Monday, March 13, 2023 11:02 AM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Mckillip, Mike <mike.mckillip@dhhs.nc.gov>
Subject: [External] No Review Request for NC Specialty Hospital's Acquisition of EP Equipment

Micheala and Mike:

Attached for filing is a No Review Request for NC Specialty Hospital's Acquisition of EP Equipment. Please confirm receipt for my records.

Thanks

Gary

Gary S. Qualls
Partner
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
Phone: 919-466-1182
Fax: 919-516-2072
gary.qualls@klgates.com
www.klgates.com