

DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE DIRECTOR

April 10, 2018

Bill Schiff, Strategic Services & Network Development Private Diagnostic Clinic, PLLC 4825 Creekstone Dr, Suite 250 Durham NC 27705

No Review

Record #:

2562

Facility Name:

Private Diagnostic Clinic/Apex Private Diagnostic Clinic, PLLC

Business Name: Business #:

1478

Project Description:

Acquisition of a flat film radiology system at a medical office building

located at 1545 Orchards Villa Avenue in Apex

County:

Wake

Dear Mr. Schiff:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of March 22, 2018 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request,** the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

Please contact this office if you have any questions.

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV TELEPHONE 919-855-3873 LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603 MAILING ADDRESS: 2704 MAIL SERVICE CENTER •RALEIGH, NC 27699-2704 Mr. Schiff April 10, 2018 Page 2

Sincerely,

Michael J. McKillip

Project Analyst

Martha J. Frisone, Chief

Healthcare Planning and Certificate of Need Section

Bus # 1478 PDL



March 22, 2018

Ms. Martha Frisone Chief, Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603



RE: Request for No Review Determination for Acquisition of Imaging Equipment at Private Diagnostic Clinic/Apex, Wake County

Dear Ms. Frisone:

Private Diagnostic Clinic, PLLC (PDC), intends to acquire and operate certain medical diagnostic equipment at a medical office building (MOB) that currently exists at 1545 Orchards Villa Avenue in Apex. PDC requests a determination that acquisition and operation of this equipment at this location does not constitute the development of a "diagnostic center" pursuant to NCGS 131E-176(7a) and will not otherwise be subject to certificate of need (CON) review.

PDC plans to acquire a new flat film radiology system. For purposes of this request, PDC has analyzed the cost of this medical diagnostic equipment which individually costs more than \$10,000. The flat film radiology system costs \$278,447, including sales tax.

PDC is planning to upfit a portion of the MOB in order to accommodate this medical diagnostic equipment. The upfit space will be designed as a business occupancy solely for outpatient use. The spaces will house the x-ray room and Tech work room for Duke Orthopaedics. As noted on the attached letter from PDC's architect, the space within the MOB totals 325 square feet of the clinic space, with an upfit cost of \$65,000. The line drawing accompanying the architect's letter portrays the shaded medical diagnostic equipment space within the medical clinic spaces.

The total cost for making the equipment operational is \$343,447 (\$65,000 + \$278,447). NCGS 131E-176(7)(a) states "Diagnostic center" means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers,

and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

Based on the information provided in this letter, PDC requests a determination from the Division of Health Service Regulation that the acquisition of this medical diagnostic equipment will not constitute the development of a "diagnostic center" pursuant to NCGS 131E-176(7)(a) and will not otherwise be subject to CON review.

I appreciate your attention to this matter. Please contact me at 919.668.1823 regarding any questions concerning this request.

Sincerely,

Bill Shiff

Vice President, Strategic Services & Network Development

Attachments: Architect Letter and Line Drawing

Vendor Equipment Quotation



February 7, 2018

Ms. Martha Frisone, Assistant Chief Healthcare Planning & Certificate of Need Section Division of Health Service Regulation N.C. Department of Health and Human Services 809 Ruggles Drive Raleigh, North Carolina 27626-0530

RE: Private Diagnostic Clinic, PLLC

Duke Orthopaedics of Apex 1545 Orchard Villas Ave.

Apex, NC 27502

Dear Ms. Frisone:

It is my understanding that Private Diagnostic Clinic, PLLC, will be submitting to the Certificate of Need Section information pertaining to upfit of a Medical Office Building (MOB) currently existing in Wake County, North Carolina.

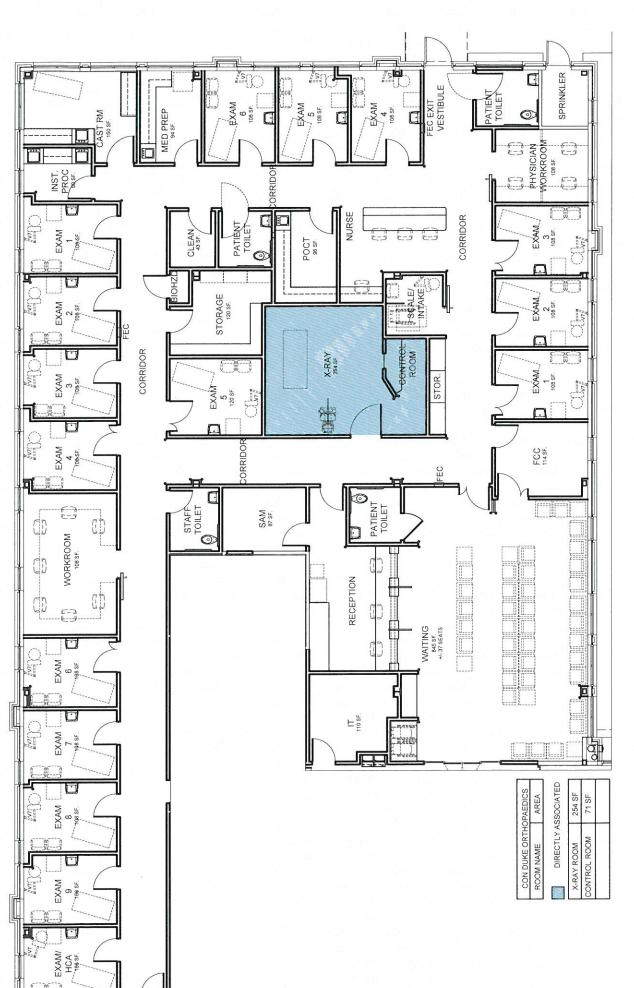
The MOB upfit spaces will be designed as a Business Occupancy solely for outpatient use. This space will house an x-ray room and ancillary orthopaedic spaces

The Orthopaedic clinic involves 325 SF of space for the clinic's diagnostic areas. The anticipated project cost, including A/E fees, construction, and reimbursable expenses is approximately \$65,000 Site work and equipment is <u>not</u> included in this estimate.

If I can be of any further assistance on this matter, please feel free to contact me directly.

Sincerely,

Pierre Mercier, AIA, EDAC Project Architect









Carestream

Medical Imaging Solutions

CHANNEL PARTNER

Quantum Overhead Mounted Radiographic System with Carestream DRX -1 CORE DR System and New Fuji D-EVO GL Long Length Imaging Detector with FSX Console and Fixed Floor Stand

Prepared Exclusively For:

Kenan Erginer

1545 Orchard Villas Avenue Apex, NC 27502 Phone: (919)

Proposal Number: DOApex_20180316.03
File Name: Duke.Ortho.Apex.Overhead.LLI.Fuji.2018.Final

Prepared By: Kelly Bryan kelly@trianglexray.com
919-605-2324 mobile

Triangle X-ray - Raleigh 4900 Thornton Road, Suite 117 Raleigh, NC 27616 Triangle X-ray - Richmond 1518 Willow Lawn Dr. Richmond, VA 23230

919.876.6156 www.trianglexray.com



This proposal is valid through June 30, 2018

CONFIDENTIALITY NOTICE:

The information contained in this document is confidential and is intended for the exclusive use of the individual(s) and entity(ies) named as recipients in the document. If you are not an intended recipient of this document, please notify me immediately and shred this material. Any disclosure, distribution, or copy of this document is strictly prohibited. Thank you.

Introduction and Overview

Who is Triangle X-Ray?

Triangle X-Ray specializes in the latest x-ray technology & equipment systems available to offer the proper digital imaging solution to meet your needs. We are channel partners for some of the largest recognized companies in the industry in order for you to stay competitive in an ever changing world. At Triangle X-Ray, we provide sales, project management, installation, application training, and most importantly, local service & support.

Whether your needs are for low or high volume Radiographic procedures, we provide CR or DR Solutions to meet those demands along with the latest in PACS & DICOM Archives. Accessories include Laser Printing Systems, Film Digitizers, & Film at an aggressive cost savings.

THIS IS OUR QUOTATION ON THE GOODS NAMED, SUBJECT TO AND INCLUDES THE TERMS AND CONDITIONS ON THE SIGNATURE PAGE AND ON THE REVERSE SIDE HEREOF.

<u>Carestream / Quantum Overhead Radiographic System –</u>
<u>DRX-1 CORE Detector Image Processing with New Fuji LLI</u>
<u>DR System</u>



Q-RAD SYSTEM/QG-50-R10-T600

50 kW/125 kVp Digital Deluxe Radiographic Generator A

- · Digital Imaging Ready, ULTRA High Frequency Power, 120 kHz PLUS
- 50 kW output; (according to IEC 60601)
- mA Range: 25 to 630
- kVp Range: 40 to 125 kVp, in 1 kVp increments
- mAs Range: 0.1 800

- Timer Range: 0.001 6.3 seconds
- "APR" Anatomical Programmed Radiography (100 APR Views / 5000 Techniques) for Std. and Custom Views
- · Large Graphic Color LCD Display for APR and Technique Information, includes Date/Time Feature
- Self-Diagnostics, Anode Heat Monitor, Error Messaging, Auto Shut-off Timer, History Reporting Log, Ethernet communication
- Nominal Input Power 380 480 VAC (+/- 10%) Three Phase

X-Ray Tube (TOSHIBA): 3" Radiographic X- Ray Tube A

0.6 / 1.2 mm Focal spots sizes with 300,000 Heat Unit capacity

150 kVp, High/Standard speed rotor, 120 anode target angles, 90 degree arms

DRX Core 3543 Wireless CSI Detector for Ascend

DRX Core Wireless 3543 (14x17) CsI Detector ONLY. Wireless, cassette-size, 35×43 cm Cesium Detector for fast workflow and instant access to images. Fits into standard Bucky trays and the wireless capability makes it also

ideal for tabletop use.

Wireless standard: 802.11n Pixel Pitch: 139x139 External Dimensions: 35X43 Cassette (ISO 4090) 38.35X45.95X1.47cm Weight: 3.4kg/7.5lbs

DRX Detector Battery (3)

Detector Battery Charger

Wireless Access Point - US

QG-28VPS Auxiliary Power Supply

QG-28VPS Auxiliary Power Supply

QG-DIG Digital Interface: Digital interface logic control (QMI HSS)

This item provides a High Speed Starter (HSS) capability to the Generator

AEC ELECTRONICS FOR CSH GENERATORS

AEC Electronics Board for Carestream Generator

R80-AEC Ionization Chamber (2)

R80-AEC Ionization Chamber

With Three (3) Fields for use with Table and/or Wall Stand; includes Hardware

RS-590 "CMT" Ceiling Mounted Tube Support

RS-590 "CMT" Ceiling Mounted Tube Support

Telescopic column with 65" (165.1 cm) of vertical travel, with focus-floor distance of 10" (25.4 cm), in a 9' ceiling. (Telescopic column can achieve up to 70.86" (180 cm) of vertical travel, if installed in a 9'-10.89" (302 cm) ceiling room)

- Longitudinal travel range of 136.2" (346cm), with standard rail length of 14'(4.25 meters)
- Transverse travel range of 84.64" (215 cm) with standard rail length of 10' (304.8 cm)
- Tube rotation about Vertical axis:
 -154°/ +182°, with detents at 0° and
 +/- 90°
- Tube rotation about Horizontal axis: +/- 120°, with detents at 0° and +/- 90° Standard Operator
 Handgrip incorporates a 10" high quality display screen providing with multi-function switches Cable
 concealment and management system

NOTE: Includes Unistrut Mounting Hardware Includes 80 foot HV Cable

QRAD Longitudinal Rail 14 FT for RS 590 (2)

RS-59T4 RS-590 Platform for 3 QG-TV10-IPC TECHVISION RS-590

Qt-750 Quiet-Lift Elev/Float-Top Table

"QUIET-LIFT" Elevating/Float-Top Radiographic Table: (EXTRA WIDE DESIGN, FOR LARGE PATIENT COMFORT)

- Static 650 lb. (295.5 kg) Dynamic 600 lb(272.2 kg) Patient Weight Capacity.
- Elevating Range of 21.6" 32.5" (55 --82.5 cm) w/collision avoidance electronics and safety lock-out control switch.
- Tabletop length: 85" (216 cm) with 30.3" (770 cm) of longitudinal travel.
- Tabletop width: 35.5" (90 cm) with 6.0" (152.5 cm) of transverse travel.
- "Flat-Top" Table design for easy patient transfer and cleaning, with low
 absorption material. FAIL-SAFE electromagnetic braking
- system ensures safe, easy use.
- · Recessed Foot Switches and MultiFunction Hand Control, for ALL table movements (Floating and Elevating).
- Includes adjustable patient handgrips, mounted along concealed accessory rails on the sides of table.
- Includes Bumpers for Table QT-BMP4

Power input: 115 VAC/60 Hz/single phase/10 Amp (Specify for Intl use: 220 VAC / single phase / 50Hz/ 5 amp).

R20-1010M 103 lines/inch (40 lines / cm); 10:1 ratio, 34"- 44" Focus

Rotating Digital Receptor Tray - Table

Allows for landscape/portrait rotation of portable DRX detector for Tables 65 Ft. (20m) Extended Table Cables

(2) R80-AEC-C65 AEC Interface Cable: (65ft) for use with AEC electronics and Ionization Chamber

OW-420 "VERTI-Q" Vertical Wall Stand 14" X 17"

- Features the exclusive "EZ-Glide" Hand control for easy and precise movement, grip rotates +105
- Custom enclosed frame for attractive appearance includes patient chin rest
- Low absorption front cover material with cassette and AEC Indicators
- Vertical Travel: 60.0 (+/- 1.0)" (1524.0
 - mm) with a 15.0 (+/- 0.5)" (381.0 mm) minimum Focal Spot-to-Floor Distance FAIL-SAFE electromagnetic braking

system plus integral counterbalancing, ensure safe and easy use

Accepts cassette sizes of up to 14" x 17" (35 x 43 cm)

NOTE: If Power Supply is Required - PS-8 (AY20-084) Must Be Ordered Separately

*Specifications are subject to change.

R20-1010L 103 lines/inch (40 lines / cm); 10:1 ratio, 40"- 72" Focus

Rotating Digital Receptor Tray - Left Side Loading Wall Stands

Allows for landscape/portrait rotation of portable DRX detector for left side loading Wall Stands

QW-HG30 Patient "Overhead" Handgrip: Mounts to "VERTI-Q" Wall Stand

Grip can be rotated, with lock positions at 0°, 90° and 180° (grip may be removed, for certain positions) QW-HG20 Patient "Side Mounted" Handgrips: (one set), Mounts to "VERTI-Q" WallStand 65 Ft.(20m) Extended Wall Stand Cables

"Ralco" Manual Collimator

- · White LED light source
- Multilayer Collimator Technology
- · Alignment laser light for patient and cassette tray positioning, plus rectangular light field
- · High resistance resin mounting flange (allowing rotation of the collimator)
- Retractable tape Measure
- Two Accessory Rails

40"- 72" SID cassette size scales (metric also available 100cm and 180cm)

CARESTREAM Remote Management Services

State-of-the-art technology that allows Carestream Health to proactively monitor, diagnose and fix malfunctioning equipment even before it stops working. Provided to all warranty and contract customers, and available for current PACS, IMS, RIS, CR and DR product lines. **QUANTUM BRANDING KIT FOR Q-RAD**

Q-CONNECT-CS INTEGRATION

23 inch Widescreen Touchscreen

R-CPU-DRX Q-RAD Digital Console

R-CPU-DRX DRX-Series DR Console

- Includes QG-DIG-DRX: DRX integration for Quantum x-ray generator for pre-configured technique for each view.
- PC minimum hardware (Cat # 1010834) HP5800; 500GB HDD, 1.8 GHz Duo Core PC, 4 GB RAM, Keyboard, Mouse
- Barcode scanner for patient registration and wireless detector enable/disable
- EVP-Plus Image Processing (Cat # 1010719)
- High-order, multi-frequency image processing; high-contrast and low- contrast visualization of bone and soft tissue
- Consistent fixed-look body part processing and Improved Image processing of un-known body
- Choice of adaptive image processing "Looks"
- · Simple orthogonal reprocessing controls
- Procedure Code Mapping software to automatically map RIS codes to

specific views for each examination

- Grid detection and suppression
 - software automatically detects and suppresses gridline artifacts
- Automated and manually adjusted Black Masking eliminates flare for better viewing
- Low Exposure Optimization reduces Quantum Noise in areas of low exposure to preserve detail
- CD/DVD image burning in DICOM format with DICOM Viewer (Cat # 1010768)
- · Annotations including Text, Distance Measurements, Angles, Cobb Angle, Comments, Electronic Markers,
- · Image manipulations for Flip. Rotate, Pan, Zoom, Invert Grayscale, Brightness, Latitude, and **Detail Contrast**
- DICOM-Store and DICOM-Print (multiple connections allowed) and DICOM Storage Commit
- DICOM Modality Worklist (Cat # 1010750)
- Automated Patient registration; configurable query filter and polling interval
- IHE Scheduled Workflow and Patient Information Reconciliation (Cat# 1010826).
- IHE Consistent Presentation of Images for consistent presentation of images at PACs destinations
- MPPS color-scheme status for scheduled, started, completed, arrived.
- Security Audit Log supports privacy regulation requirements
- Cisco Security Agent monitors for evidence of malicious software; provides threat protection and mitigation
- Repeat/Reject Analysis and exposure data monitors staff performance, productivity, and patient
- Configurable anonymous Emergency/ Trauma Defaults
- Pre-configured SNOMED codes for multi-accession procedure mapping, hanging protocols, and patient

Orientation

Exam Tutor displays positioning icons

as visual coach for each unexposed view in an exam

- Preview image displayed for each acquisition; configurable for "auto- accept" and ready for next exposure.
- · DICOM Image transmission configurable as DX or CR modality

• Image re-assignment for patient/study/ view reconciliation/correction

Configurable high/low watermarks for image retention, with continuing retention of patient demographics **DR Accessories**

FDR D-EVO GL Long-Length DR Detector

FDR D-EVO GL + Fixed Stand

FDR D-EVO GL is the world's first single exposure, long-length DR detector. It offers the supreme image quality that FDR D-EVO is known for as well as the ability to capture a single 17" x 49" exposure. FDR D-EVO GL's innovative imaging technology allows the acquisition and display of a full-format image in just 9-20 seconds and a 17" x 17" image in just 6 seconds. A full 3" wider than the traditional field of view for long length imaging, it accommodates patients more inclusively. By capturing a long-length image with a single exposure, patient hold times are reduced along with motion-induced artifacts and retakes, which help improve patient satisfaction and reduce dose.

FDR D-EVO GL Detector

- 17" x 49" active imaging area
- 52.7" x 22.3" x 2" external dimensions, 43 lbs.
- 150μ pixel pitch (2832 x 8228 active imaging area pixel matrix)
- 26 second cycle time for 17" x 49", 10 seconds for 17" x 17"
- Patented ISS capture technology to improve dose efficiency
- Noise reduction circuitry improves DQE and visibility in dense
- SmartSwitch technology (automatic x-ray detection)

Floor-mounted detector stand

- Accommodates FDR D-EVO GL 17" x 49" detector
- Secures to the floor and wall for stability and a slim profile
- Fully manual and counter-balanced, for fast positioning requirements
- Rotating Bucky supports portrait and landscape orientations
- Space requirements: 76" tall x 27.9" wide x 12.5" deep



(DQE) areas

without electrical

The FDX Console:

Simplifies and speeds workflow with an extra-large image display area, an easy-to-read, customizable interface and an intuitive arrangement of operation buttons to make exams faster for both the technologist and the patient.

- Hardware includes desktop CPU (Windows 7 Professional, 32-bit, Core i5 processor with 3.2GHz, 4G RAM, 500GB HDD), keyboard, mouse, 19" color touchscreen monitor and barcode scanner.
- Integrated MC functionality
- DICOM CR Store for connectivity to PACS
- FDX Console Human markers and menus

- Dynamic Visualization™ advanced image processing presents images with optimal clarity. Includes FNC (Flexible Noise Control) to suppress noise without loss of diagnostic information or sharpness and MFP (Multi-Frequency Processing) providing overall density uniformity for all anatomical regions.
- Technologist editing tools such as automatic and manual Shutters (black borders) and movable annotation markers
- Auto trimming simplifies off-center imaging of small anatomy by recognizing the collimated area and applying it to the full screen for optimized display at PACS.
- QC adjustments including exam reprocessing, sensitivity, latitude, density and contrast
- Free Text Annotation with commenting text annotation marker capability
- Image Magnification for enhanced full screen, magnification and zoom image display tools
- Basic security features include user restriction and are customizable by technologist log in/out.
- Statistical Analysis reporting of the patient image database, including reason for image rejection coding, for reject or other performance analyses.

Software - Included

Stitching software and DICOM Modality Worklist are **INCLUDED.** FDR D-EVO GL requires a minimum of FDX Console V9.0 running on Dell 790 or HP.

FDX Console Stitching

FDX Console stitching software joins (stitches) up to three acquisition areas exposed for scoliosis or long-leg exams to return a single, complete image. FDX Console stitching software supports CR and FDR D-EVO stitching, as well as FDR D-EVO GL long-length exposures. (Single License)

FDX Console DICOM Modality Worklist

FDX Console DICOM Modality Worklist streamlines the patient scheduling and the delivery of those images to PACS.

SE Cables

FDR D-EVO GL SE-Cable 20M

OPTIONS Anti Scatter Grids:

FDR D-EVO GL Physical Grid 10-1 103 LPI – \$4,000.00 FDR D-EVO GL Physical Grid 8-1 103 LPI – \$4,000.00

FDR D-EVO GL Physical Grid 6-1 103 LPI - **\$4,000.00**

FDX CONSOLE VIRTUAL GRID SW - \$3,785.00

DETECTOR ACCIDENT PROTECTION PLAN (Drop Rider) for DRX PANEL

Provides warranty year replacement availability of DRX panel resulting from accidental drop breakage or other major event within Carestreams' warranty policy

Panels replaced under the detector Accident Protection Plan will be replaced at a fixed cost of \$5,000.00 / drop occurrence or liquid damage.

DRX-1 Drop Rider/Accident Protection for the Warranty (12 Months) Period: Duke Pricing \$2,500.00 (Included in Price)

TOTAL INSTALLED PRICE FOR OVERHEAD RAD ROOM:

DUKE PRICING: \$148,497.00

Drop Rider Included in Purchase Price for Warranty Year*

TOTAL INSTALLED PRICE FOR FUJI D-EVO GL LONG LENGTH SYSTEM: \$134,950.00

EQUIPTMENT LISTED ABOVE:

TOTAL: \$283,447.00

Customer Appreciation Loyalty Discount (-\$5,000.00)
TOTAL INSTALLED PRICE: \$278,447.00

SERVICE AFTER ONE YEAR WARRANTY:

Annual Service Agreement on Above Overhead Radiographic System with DRX-1 DR System Including Drop Rider Protection:

\$24,775.00*

					\$24,773.U	JU
				1 	Initial if Orderi	ng
Ann	ual Service	e Agree	ment on Fuj	i D-EVO LLI	System: \$20,225.0	<mark>)0</mark> *
					Initial if Orderi	ng

WARRANTY: Triangle X-ray will provide a twelve months warranty on all parts and labor. Service contract pricing for additional years to be charged at Duke's discounted service pricing structure.

FREIGHT CHARGES: Approx. \$1500.00

DRX System extended warranty and ACCIDENT PROTECTION PROGRAM (APP)

Carestream makes available DRX System post warranty parts / telephone support agreements and detector Accident Protection Plan (APP). DRX System warranty and post warranty contracts covers all parts including the detector and include Carestream Center of Excellence phone support. The detector warranty and post warranty coverage is for normal wear and tear that occurs to the detector under normal use conditions. For added protection against damage caused by a major event, Carestream makes available a DRX Detector Accident Protection Plan. This product is only available to customers whose systems are under warranty or those systems that are covered with a post warranty combined parts / telephone support / APP agreement. The warranty year APP and post warranty APP and parts agreements are available for purchase at time of initial purchase order (Point of Sale or POS) of the DRX system or at any time during the warranty period. Pricing for warranty year APP and post warranty support agreements purchased at POS or purchased after POS is noted in the chart above. For APP or Post Warranty products purchased after POS, coverage will go into effect after a 15 days waiting period and continue for the balance of the warranty or post warranty agreement period. Terms and Conditions of the APP and post warranty agreements are stated below and are subject to change without notice.

IMPORTANT NOTES:

1. DRX Systems (including detector) include the initial year parts warranty coverage in the purchase price

- 2. For best pricing, the DRX Accident Protection Plan (APP) for the first / warranty year must be purchased on the same Purchase Order as the DRX System, DRX Mobile Retrofit Kit, Q-RAD Integrated DRX System, or DRX Revolution System.
- 3. For best pricing, purchase of post warranty combined detector APP and Parts/Telephone Support products must be committed at POS of the DRX System.
 - a. The Warranty Year APP should be purchased on the same PO as the DRX System.
 - b. All post warranty DRX service products committed at POS must be ordered on a separate Purchase Order to Carestream. This purchase order should accompany the DRX "System" Purchase order. Quantum will forward the purchase order for post warranty service products to Carestream.
 - c. For those post warranty service products listed above committed by purchase order at Point of Sale (PoS) you will be invoiced by Carestream approximately 1 month prior to warranty or extended warranty expiration date.
- 4. Post warranty APP and Parts/Telephone support products may be purchased annually before the warranty or most current post warranty agreement expires.
- 5. If purchasing a post warranty combined parts/telephone/APP contract for more than one detector on the same purchase order (Example: Dual panel system order), your Purchase Order must clearly show each APP ordered.
- Any post warranty service product purchased after POS but before expiration of either the product warranty or the current product service contract will be eligible for renewal at the "After POS / during Warranty" pricing above.
- 7. Dealer must contact their Quantum Medical Imaging Dealer Channel Manager for a quote to sell any post warranty service agreement if the DRX product (detector or full system) is more than 61 days out of warranty or past post warranty agreement expiration date. These systems will be subject to a system inspection by Carestream.
- 8. If your customer chooses to purchase a warranty year APP after POS, the purchase price for APP will be as noted above with the effective date of the APP the initial installation date of the DRX.
- 9. Please contact your Quantum Dealer Channel Manager for pricing if your customer skips a year (did not purchase the detector APP for warranty year) and decides to purchase a post warranty combined detector APP/Parts/Telephone support contract or combined detector APP/Parts/Telephone support agreement. These systems will be subject to a system inspection by Carestream.

Terms and Conditions for DRX Detector Accident Protection Program and Post Warranty Parts Programs

- Warranty period begins on date of installation or 30 days after shipment of original order, whichever occurs first.
- · Warranty and parts agreement is for replacement parts only. Charges for labor or consumable parts will be billed accordingly
- · Warranties are non-transferable
- Warranty period detector Accident Protection Program purchased after Point of Sale (POS) will be billed at the rate noted in
 the table on page 5. The coverage will go into effect after a 15 day waiting period after receipt of the Purchase order for the
 APP and will remain in effect for the balance of the product's warranty period.
- This Detector Accident Protection Program is for U.S. installations only.
- Post warranty detector Accident Protection Programs and Parts/Telephone service agreements may be purchased at Point of Sale (POS). If so, line items must be included on the System Purchase Order or on a separate purchase order received at the same time as the System purchase order.
- Post Warranty Detector Accident Protection Programs and Parts/Telephone service agreements purchased after installation must be purchased prior to the expiration of the product warranty or prior to expiration of a post warranty service agreement.
- Whether purchased at POS or after installation, post warranty products will be invoiced by Carestream approximately 1 month prior to warranty expiration.
- Under the Detector Accident Protection Program you will be billed \$5,000 for each detector replaced due to shock or drop damage, \$10,000 for each detector replaced due to liquid damage.
- In all cases, replacement detectors will come from Carestream Parts Services. Replacement detectors may be new or refurbished. All replacement detectors are tested to verify they meet manufacturer's new detector specifications.
- For post warranty service agreements that are purchased after the warranty or a post warranty service agreement has expired, the System may be subject to inspection by Carestream at customers' expense.
- Installation report must be submitted to Quantum Medical Imaging, within 30 days of installation for warranty to be valid
- Shipping costs are not included in extended warranty and are the responsibility of purchaser

INCLUDED ITEMS:

- ✓ Plan Review from ProPhysics to register system with the Radiation Division of North Carolina (post-installation survey responsibility of customer)
- ✓ Complete room drawings to include all mechanical, electrical, and plumbing requirements

- ✓ Software provided and installed, with applications, on additional customer provided viewing stations
- √ Removal and disposal of existing equipment

EXCLUDED ITEMS:

- ✓ Networking hardware, network connections for stations and servers, and high-speed internet services
- ✓ Room construction
- ✓ Freight charges on all equipment listed above.

TERMS OF PAYMENT:

25% Due on order

50% Due upon availability for shipment

25% Plus freight and applicable sales taxes due immediately upon first clinical use

ESTIMATED DELIVERY: 30 Days

(from receipt of order and 25% deposit)

FOB: Factory

TRIANGLE X-RAY CO. TERMS OF SALE

In the event there are any objections; notify us immediately. Only the following conditions apply and shall be binding on the Seller regardless of any conditions contained in either party's quotes, purchase order or invoices. This Agreement is made and entered between Triangle X-Ray referred to as "Vendor" or "Seller" and Duke University & Duke Medicine, Durham, North Carolina 27708, a nonprofit corporation, herein after referred to as "Duke" or "Buyer".

In consideration of the covenants, agreements and stipulations expressed here, for the provision of maintenance and service of Carestream DRX system, it is mutually agreed as follows:

- 1. **CONTRACT**. No order or quotation is binding on Seller and no contract is formed until Seller's written acceptance of the order on Seller's own form. Any special terms or conditions noted on the face of Seller's quotation on which this order is based is incorporated herein by reference and made a part hereof as though specifically set forth.
 - a. The Vendor agrees to provide DUKE with a scope of maintenance services quotation as requested. No work or services will be performed until DUKE has reviewed and approved all scope of maintenance services quotations.
 - b. All corrective, preventative, or scheduled maintenance documentation/field service reports must be emailed to ce-drh@dhe.duke.edu

C.

d.

- 2. **DELIVERY**. FOB Destination prepay and add. Freight should be invoiced to the same PO.
- 3. **WARRANTY**. Seller warrants to the Buyer that equipment is free from defects in material and workmanship as specified by manufacturer under normal operation conditions. This warranty shall apply only to the original purchaser and original location of delivery. Triangle X-Ray's liability under this warranty shall be limited to repairing or replacing a defective product. Triangle X-Ray may elect between repair or replacement.
 - (a) Seller warrants equipment will be acceptable for maintenance.
 - (b) Seller reserves the right to supply any parts or labor necessary to make equipment acceptable for a maintenance agreement.
 - (c) Seller also reserves the right to replace or have hardware returned for full credit including any deposit paid by Buyer. This warranty agreement does not include repair due to damage of the Equipment caused by misuse, abuse, fire or water damage or any kind of damage not involved with the normal use of this equipment. Also not included is repair of damage, alterations or an improper repair by a party unauthorized by Contractor. Triangle X-Ray is the sole determiner of what is/is not misuse and/or abuse.

Warranty also includes the following:

- > Standard 12 Month Labor & Parts Warranty. Any changes to standard Warranty will be stated above Signature Line & Proposal. This includes, but not limited to: new, used, and/or refurbished equipment.
- > Extended Warranty available upon request
- Monday-Friday, 8am-5pm telephone technical support & on-site support is standard; excluding nights, weekends, and holidays. Any changes to standard Warranty will be stated above Signature Line & Proposal.
- Phone Response Priority. Service Call is analyzed through a combination of help desk and remote support.
- > On-Site Response Priority. If trouble shooting remotely does not repair the issue, then the call is elevated to an on-site support/repair.
- Repair includes Labor, Travel, & Parts

Shift Coverage Upgrade: (Are available upon request)

- Manufacturer's warranty period begins at clinical acceptance, which is defined as first successful clinical use. This may occur at installation or after installation. Regardless of when first successful use occurs, clinical acceptance is defined as a separate action from successful installation.
- Clinical Acceptance will not be unreasonably withheld.
- > Only Clinical Engineering may sign the clinical acceptance form. Execution by any other signatory is not valid. Until Clinical Engineering signs the document, the warranty period cannot begin.
- Contractor shall not connect or hook up to any utility (plumbing, electrical, HVAC, etc.), in any way or form on Duke property without express written approval of Duke's Engineering & Operations Department (E&O) for Duke University Health System installations and/or Duke's Facilities Management Department (FMD) for Duke Campus installations. Approval shall be obtained, in advance, for each request before the start of any work. Failure to follow may result in Agreement breach.
- 4. **TERMINATION**, **REDUCTION IN QUANTITY**, **RESCHEDULING DELIVERY**. Any cancellation of the order by Buyer shall result in a minimum cancellation fee of 25% of the amount of the order cancelled, which amount shall be paid to the Seller.
- 5. **BUYER SPECIFIED SOURCES**. Where Buyer supplies parts and/or materials to be used in connection with the work to be performed and material to be furnished by the Seller, subcontract work of any kind is performed by Seller by a source specified or selected by Buyer, Buyer assumes, and Seller is correspondingly relieved from all responsibility where the merchandise supplied by Seller is other than as warranted and where the reason therefore is due to work performed by the source so specified or selected by Buyer or parts supplied by Buyer. Buyer further agrees that in such instances Buyer will defend, at no cost to Seller, every suit which shall be brought against Seller by reason of the defects in such parts supplied by Buyer or operations so subcontracted at Buyer's request.
- 6. **TAXES**. This agreement is entered into pursuant to North Carolina Direct Pay Permit Number 00209 issued to Duke University. Under this Direct Pay Permit, the North Carolina Department of Revenue has granted Duke University permission to purchase tangible personal property without prepayment of the North Carolina sales or use tax, Accordingly, the Vendor shall not add any State of North Carolina or local sales tax.

Duke will not render any payment for any Medical Device Excise Tax. Duke does not recognize the general application or understanding of a "sales or use tax" as being applicable to the Medical Device Excise Tax. There is no legal obligation between the IRS and Duke related to any reporting or payment of the Medical Device Excise

Tax. Duke reserves the right to short-pay invoices or with hold off-setting amounts for any erroneously rendered payment for the Medical Device Excise Tax.

- 7. **APPLICABLE LAW**. The parties agree that any action concerning, relating to, or involving this contract must be venued in Wake County, North Carolina and the parties hereby consent to the jurisdiction of the courts of such county. Failure at any time of Seller to enforce any provision of this contract, or to exercise any option hereunder, or to require performance by Buyer of any provision hereof, shall in no way be construed as a waiver nor in any way affect the right of Seller to thereafter enforce each and every provision. A waiver by Seller or any term or condition hereof shall not be deemed a waiver of any other term or condition hereof nor a future waiver thereof.
- 9. **IDEMNIFICATION PROVISION**. Each Party (an "Indemnitor") hereby agrees to indemnify and hold harmless the other Party, its directors, officers, employees, and its Affiliates and their directors, offices, and employees (each, an "Indemnified Party") against and from all liabilities, damages, costs, and expenses ("claims"), arising from negligent, reckless, or intentionally harmful acts of the Indemnitor or its employees or Affiliates, which cause damage or harm, or threaten to cause damage or harm, to an Indemnified Party. In the even that any Claim is made which may, or does, result in the right of indemnity hereunder, the Indemnified Party shall promptly give notice to the Indemnitor and shall permit the Indemnitor the opportunity to defend the Claim with counsel reasonably satisfactory to the Indemnified Party. The provisions of this section shall survive any termination or expiration of this Agreement.
- 10. **EXCLUDED ITEMS.** The Customer is responsible for all Electrical, Plumbing and Structural work including (Labor and Materials) required to prepare site for Equipment Installation and/or cabling additional network infrastructure including but not limited to T1 connections, routers, bridges and Ethernet hub and drops in order to properly install, operate and maintain the equipment.
- 11. **ADDITIONAL**. If Equipment is to be connected to an existing network, we will need access to the Information System Server, IP address, AE titles, and any other applicable data information. Triangle X-ray Company is not responsible for the existing networks, establishing networks or interfacing to existing networks. If Triangle X-ray Company is asked to help with interfacing to an existing network, the customer will be charged our normal hourly rate for time and materials required.

DEFINITIONS/TERMS & CONDITIONS OF EXTENDED WARRANTY &/OR SERVICE AGREEMENT

1. DEFINITIONS/TERMS & CONDITIONS.

1.1 As used in this Agreement:

"Equipment" means the equipment listed on the attached Quote.

"Extended Warranty Services" means services that are purchased and paid for at the time Customer purchases the Equipment. The term of the Extended Warranty Services will commence upon acceptance of the Equipment pursuant to the Triangle X-ray Company Direct Terms of Sale and is identified in the attached Quote.

"Service Agreement" means an agreement for services that is purchased subsequent to the original purchase of Equipment or already existing; such as the radiographic systems stated above. The term of the Service Agreement is identified on the attached Quote.

"Service Plan" means the Triangle X-ray Company Service Plan selected by Customer and listed on the

applicable Quote.

"On-Site Coverage Hours" means time period(s) selected by the Customer and listed in the applicable Quote. In this case, our On-Site Coverage Hours are:

 Monday-Friday, 8am-5pm telephone technical support & on-site support; excluding nights, weekends, and holidays.
 Any order requiring installation:

Installation will be done during weekend or night hours to minimize the clinical impact. As is industry standard, this time will be billed at daytime 8-5pm hours.

"Major Release" – For the purpose of this Agreement, "Major Release" means a release of a piece of software which is not merely a revision or a bug fix release but which contains significant changes such as;

- 1) Architectural modifications or enhancements
- 2) Addition of a reasonably complex function(s)
- 3) Changes to existing functionality in multiple software modules
- 4) Inclusion of a number of lesser features or defect repairs
- 1.2 These terms and conditions (this "Agreement") if fully executed, apply to Service Agreements and Extended Warranty Services.

2. SERVICES.

- 2.1 During the On-Site Coverage Hours selected by Customer, Triangle X-ray Company will perform the following services ("Services") as applicable:
 - a. Provide repair service, labor, parts, & travel at no charge (excluding glassware on the radiographic systems).
 - b. Replace malfunctioning parts, excluding supplies or consumables
 - c. Perform the recommended number of Periodic Maintenance (PM) calls to clean, test, and maintain the Equipment in an operating condition consistent with Triangle X-ray Company specifications
 - d. Provide telephone support
 - e. Triangle X-ray Company will support software on existing system. Support for any older software version will be made available at Triangle X-ray Company's sole discretion and may be chargeable.
 - f. Triangle X-ray Company will perform all service & support in a professional and workmanlike manner and that we will re-perform them if they are not performed correctly the first time.

Service Agreement also includes the following:

- > 12 Month service coverage on all equipment listed above that is placed under this agreement.
- Monday-Friday, 8am-5pm telephone technical support & on-site support; excluding nights, weekends, and holidays.
- Phone Response Priority. Service Call is analyzed through a combination of help desk and remote support.
- > On-Site Response Priority. If trouble shooting remotely does not repair the issue, then the call is elevated to an on-site support/repair.

Except as otherwise provided in this Agreement, Customer will be charged for any Services work performed outside the On-Site Coverage Hours.

2.2 In addition to the Standard Services listed above, Triangle X-ray Company may provide additional (optional) services based upon the Service Plan selected or required by Customer. Such additional service options must be detailed and accepted on the service proposal above and may include:

Call Continuation Option: If Customer has elected a Service Plan which includes this service option, then: When a Services call is started during On-Site Coverage Hours and the work extends beyond the On-Site Coverage time period, Customer will not be charged for the work hours outside the On-Site Coverage Hours. This is a 20% service contract premium.

Response Time Goal Option: If Customer has elected a Service Plan which includes this service option, then: When, due to circumstances within Triangle X-ray Company's control, Triangle X-ray Company fails to meet the response time goal applicable for the selected Service Plan and Customer's location, Services work performed outside the On-Site Coverage Hours, for the applicable service call, will be free of charge to Customer. For purposes of this service, "Response Time" means the number of On-Site Coverage Hours elapsed between Triangle X-Ray Company's receipt of a service call and Triangle X-ray Company's arrival at Customer's location for the purpose of servicing the Equipment. We provide industry standard 4 hour on-site response time guarantee. If on-site response is delayed past the 4 hours for any reason, any after hour service required as a result of this delayed response, will be credited as normal contract service response time and will be included in that service call at no additional charge. Scenario: Triangle receives call at noon, service engineer does not arrive until 5:00pm, one hour of labor will be included with no additional after hour charges.

Uptime Guarantee Option: If Customer has elected a Service Plan which includes this service option, then: When Equipment for which an Uptime Guarantee is provided fails to perform in accordance with the guarantee, Triangle X-ray Company will extend the term of the applicable Extended Warranty or Service Agreement, as specified in the applicable Uptime Guarantee. This option standard carries a 20% Service Contract Premium. This option carries a 99% uptime guarantee based on normal working hours for the facility. If actual 100% downtime occurs on equipment covered exceeds the 1% downtime limit, additional support time will be accrued at the rate of 5x actual 100% downtime realized beyond the guaranteed amounts. Scenario: Once 1% downtime maximum hours are reached, for each hour the equipment is down 100% to the point that all services performed on the equipment are no longer possible, for the time the equipment is 100% down, additional service coverage will accrue at a rate of 5 hours per hour of downtime).

After Hours Preventative Maintenance Option: If Customer has elected a Service Plan, which includes this service option, then: Triangle X-ray Company will provide preventive maintenance (PM) service outside the On-Site Coverage Hours at no additional charge to the Customer. This option carries a 50% service contract premium.

- 2.3 Triangle X-ray Company reserves the right to use or supply reconditioned, remanufactured, refurbished or used equipment, parts and components in the repair or replacement of the Equipment as long as there is no diminishment in functionality.
- 2.4 If for any reason the above equipment becomes obsolete (Carestream Health no longer provides parts for repairing the equipment), the unit will be dropped from the above service contract immediately. There must be a six month advanced notice so that Duke can prepare. If the foregoing occurs, any prepaid amounts will be refunded. Triangle X-Ray Company will continue to service and maintain the unit as desired by the customer billed time and materials. This will be at our standard hourly rate for service, travel and parts repairs, less the same discount for the service contract.

3. SERVICES NOT INCLUDED.

This Agreement does not cover the following types of service work and/or any services work provided under the following circumstances:

- a. Equipment problems resulting from Customer's failure to follow the Equipment operating instructions (such as Customer overriding, bypassing, or defeating interlock switches on equipment or devices);
- b. Equipment problems resulting from unauthorized modifications to the Equipment and/or unauthorized service on the Equipment;
- c. misuse or abuse of the Equipment;
- d. Damage to Triangle X-ray Company equipment due to its use with other equipment including but not limited to use with incompatible or defective equipment;
- e. Equipment relocation or service required as a result of relocation;
- f. Equipment problems resulting from power abnormalities such as lightning strikes or inadequate electrical wiring;
- g. Equipment problems due to electrical work external to the Equipment;
- h. Equipment problems due to failure of Customer to conform to Equipment site specifications;
- i. Rebuilding or reconditioning of Equipment;
- j. Equipment problems resulting from the use of attachments, accessories, or other items not marketed with or as part of the Equipment;
- k. Equipment problems resulting from the use of software not authorized and/or approved in writing by Triangle X-ray Company;
- Remote communications link will not be established without a fully executed BAA and DSA and only
 with permission from Clinical Engineering at Duke. Repair of damage caused by: accident, vandalism,
 transportation, fire, water, acts of God burglary, or other similar causes;
- m. Coverage of X-Ray tubes and workstation monitors is an option on all levels of Service Agreements and will be covered if selected by Customer on the attached Quote.
- n. Supply items;
- o. Display Calibration

When Services work is provided in any of the above circumstances, or if those types of services are provided, Customer will be billed for the work (labor and parts) at Triangle X-ray Company's prevailing Time and Materials rates.

4. LIMITATION OF LIABILITY.

TRIANGLE X-RAY COMPANY WILL NOT BE RESPONSIBLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES IN CONNECTION WITH THIS AGREEMENT, INCLUDING BUT NOT LIMITED TO DAMAGES RESULTING FROM THE SALE, USE, OR IMPROPER FUNCTIONING OF THE EQUIPMENT OR SOFTWARE, OR PERFORMANCE UNDER THIS AGREEMENT, REGARDLESS OF THE CAUSE. SUCH DAMAGES FOR WHICH TRIANGLE XRAY COMPANY WILL NOT BE RESPONSIBLE, INCLUDE, BUT ARE NOT LIMITED TO, LOSS OF REVENUE OR PROFIT, DOWNTIME COSTS, LOSS OF USE OF THE EQUIPMENT, COST OF ANY SUBSTITUTE EQUIPMENT, FACILITIES OR SERVICES. The foregoing does not apply in cases of third party injury or death.5. CANCELLATION/TERMINATION.

- 5.1 Extended Warranties are not cancelable but are transferable upon written notice to Triangle X-ray Company.
- 5.2 Except as otherwise provided in this paragraph 5.2, this Services Agreement is non-cancelable by Customer during the 12month coverage and will be able to be canceled with ninety days notice prior to each anniversary date. Notwithstanding the foregoing, Customer may terminate this Agreement upon thirty (30) days prior written notice to Triangle X-ray Company if Triangle X-ray Company is in material breach or default of the Agreement, provided that Triangle X-ray Company may avoid such cancellation by curing the condition of breach or default within such 30 day notice period. If breach of contract is not cured, Customer will be provided with a refund of any Customer pre-payments for periods of Service Coverage terminated by Customer.

Exception to the foregoing will occur if Triangle X-ray breaches the Compliance, Identity Security or Confidentiality portions of the Agreement, in which case, termination may be immediate without opportunity for cure.

- 5.3 Customer's failure to pay any amount due under this Agreement within 10 days Triangle X-ray Company may, at its option, (i) withhold performance under this Agreement until a reasonable time after all defaults have been cured, (ii) declare that all sums due or about to become due under this Agreement, are immediately due and payable, (iii) commence collection activities for all sums due or to become due hereunder, including, but not limited to costs and expenses of collection, reasonable attorney's fees, (iv) terminate this Agreement without notice to Customer and issue a new invoice to Customer for an amount equal to the greater of (i) the portion of the Extended Warranty or Service Agreement fee attributable to the time period beginning on the date payment was due and ending on the date this Agreement is terminated (the "Default Billing Period") or (ii) time and materials charges attributable to any Services performed by Triangle X-ray Company during the Default Billing Period, and (v) pursue any other remedies permitted by law. If Triangle X-ray Company determines that its ability to provide the Service Coverage is hindered due to unavailability of parts or trained personnel, then Triangle X-ray Company may terminate this Agreement upon notice to the Customer and provide Customer with a refund of any Customer pre-payments for periods of Service Coverage terminated by Triangle X-ray Company.
- 5.4 Customer will pay for any Services performed after the effective termination date at Triangle X-ray Company's prevailing Time and Materials Service rate.

6. BILLING & TERMS OF PAYMENT.

- 6.1 An annual billing for each year of a Service Agreement will be made in advance to the Customer. Payment will be due thirty days after the receipt of the invoice by Duke Accounts Payable. Customer is liable for the agreed to annual charge beginning on the Agreement effective date. Any Extended Warranty/Service Agreement that have an approved payment schedule will be invoiced in full for the remaining balance due for the unused portion of the contract.
- 6.2 In the event Customer requests service beyond the scope of the Service Plan selected by the Customer, it is Customer's responsibility to provide a valid purchase order at time of call placement if one is required for payment of Triangle X-ray Company invoices. If Customer's failure to provide a purchase order results in delayed payment to Triangle X-ray Company, Customer will be responsible for late payment charges in accordance with Triangle X-ray Company's applicable payment policy.
- 7. PROPERTY OF TRIANGLE X-RAY COMPANY. Maintenance material, tools, documentation, software keys, diagnostics, and test equipment provided by Triangle X-ray Company shall remain the exclusive property of Triangle X-ray Company. Such items loaned by Triangle X-ray Company to Customers must be returned within 30 days.
- **8. ASSIGNMENT.** Neither party may assign this Agreement without the prior written consent, of which consent will not be unreasonably withheld, and any attempted assignment without prior written consent will be void. All terms, conditions and provisions contained herein are applicable to any and all of the Vendor's employees, agents and subcontractors who perform, directly or indirectly, any work or fulfill, directly or indirectly, any obligation pursuant to this Agreement.
- **9. TAXES.** There are no taxes upon the purchase of this service agreement. If Customer is exempt from any taxes, Customer will certify such exemption in a form as required by Triangle X-ray Company prior to execution of this Agreement. Where Customer is permitted and agrees to pay such taxes directly to the taxing

authority, Customer will certify such fact in a form as required by Triangle X-ray Company prior to execution of this Agreement.

This agreement is entered into pursuant to North Carolina Direct Pay Permit Number 00209 issued to Duke University. Under this Direct Pay Permit, the North Carolina Department of Revenue has granted Duke University permission to purchase tangible personal property without prepayment of the North Carolina sales or use tax. Accordingly, the Vendor shall not add any State of North Carolina or local sales tax.

Duke will not render any payment for any Medical Device Excise Tax. Duke does not recognize the general application or understanding of a "sales or use tax" as being applicable to the Medical Device Excise Tax. There is no legal obligation between the IRS and Duke related to any reporting or payment of the Medical Device Excise Tax. Duke reserves the right to short-pay invoices or with hold off-setting amounts for any erroneously rendered payment for the Medical Device Excise Tax.

- 10. CONVERSION FROM TIME AND MATERIALS SERVICE. In the event the Equipment is not currently being serviced by Triangle X-ray Company under the original Equipment warranty, an Extended Warranty or a Service Agreement, Triangle X-ray Company reserves the right to inspect the Equipment prior to the start date of a Service Agreement. In the event such an inspection identifies Equipment repairs, which Triangle X-ray Company deems necessary prior to the commencement of the Service Agreement, Triangle X-ray Company will notify Customer of the nature and estimated costs for such repairs and the start date of the Service Agreement will be delayed until such repairs have been made. The costs for repairs identified during the inspection will be billed to the Customer using Triangle X-ray Company's prevailing Time and Materials service rates.
- **11. CUSTOMER ORDERS.** The terms and provisions of this Agreement shall prevail over any conflicting or additional terms or provision appearing in any purchase order, quote, or other instrument issued by either party at any time.
- 12. GOVERNING LAW AND JURISDICTION. This Agreement shall be governed by and construed in accordance with the laws of the State of North Carolina without regard to its conflict of laws principles.
 13. ELECTRICAL EQUIPMENT COMPLIANCE. Equipment or materials supplied under this Agreement shall comply with the applicable sections of the North Carolina State Building Code including, but not limited to, the suitability requirements of the National Electric Code. Suitability shall be evidenced by listing and labeling.

In the state of North Carolina, all medical equipment must be listed, labeled and tagged by a National Approved Testing Agency (CSA, Entela, ETL, MET Labs, TUV-America, TUV-Rheinland and UL). There is no exception. In addition to being labeled by a National Approved Testing Agency, food equipment must also be labeled by NSF (National Sanitation Foundation).

If the Vendors equipment is not suitably electrically labeled, the Vendor (upon University's request and permission) will at their expense pay for an independent electrical testing to meet or exceed North Carolina Electrical Codes.

- **14. SOCIAL SECURITY ACT.** Customer agrees that it is aware of and will comply with Section 1128 B of the Social Security Act (42 USC 1320a-7b) when seeking reimbursement from any government entity for products or services supplied under this agreement. Specifically, Customer acknowledges that the Act may require proper disclosure of any discounts, rebates, credits, reimbursements, and other programs provided under this Agreement.
- **15. MEDICARE / MEDICAID.** In accordance with the Medicare and Medicaid Amendments of 1980, Public Law 96-499, Triangle X-ray Company will make available, upon written request by the Secretary of Health and Human Services or the U.S. Comptroller General or their duly authorized representatives, the contract and books, documents, and records necessary to verify the costs associated with the services furnished under this agreement. Access to books and records shall be made available for four (4) years after the furnishings of such services.

REPRESENTATION

Vendor hereby warrants to DUKE that:

- A. Existence. It is a corporation duly organized, validly existing, and in good standing under the laws of the State of North Carolina and is duly qualified to do business in the State of North Carolina and has full power and authority to enter into and fulfill all the terms and conditions of this Agreement.
- B. Corporate Authority. The Officer(s) of Vendor have full power and authority to execute the Agreement on behalf of Vendor and, in executing this Agreement on behalf of Vendor, bind Vendor to all the terms and conditions.
- C. Solvency. It is financially solvent, able to pay its debts as they mature, and possessed of sufficient working capital to perform all its duties and obligations and to satisfy all the terms and conditions of this Agreement.
- D. Experience. It is experienced in and competent to provide all the services required by this Agreement and to fully satisfy all the terms and conditions of this Agreement.
- E. Personnel. It has the experience, capability and resources, including but not limited to sufficient personnel and supervisors, to efficiently and expeditiously perform the Services required and fully satisfy all the terms and conditions in this Agreement in a professional and competent manner.
- F. Third Party Litigation. There is no suit or action, or legal, administrative, arbitration, or other proceeding or governmental investigation affecting Vendor pending, or to the best knowledge and belief of Vendor, threatened against Vendor which materially or adversely affects the business of Vendor relating to this Agreement. Vendor further warrants and represents that there is no outstanding judgment, decree, or order against Vendor, which affects Vendor's ability to provide services under this Agreement in any way.
- G. Binding Obligation. This Agreement is a valid and binding obligation of Vendor in accordance with its terms.
- H. Truthfulness of Representation of Warranties. No representation or warranty by Vendor in this Agreement or any document contains or will contain any untrue statement or material omissions, or will omit to state any material fact necessary to make the statements and warrants that all representations and warranties made by Vendor in this Agreement and any document provided shall be true and correct as of the date of the execution with the same force and effect as if they had been made on the date.

STANDARD OF PERFORMANCE

- A. Vendor agrees to perform the services under this Agreement with the standard of care, skill and diligence normally provided by a professional organization in the performance of such services.
- B. While on DUKE premises, Vendor, its employees and subcontractors will adhere to the DUKE policies and regulations including but not limited to parking, traffic and security regulations and with all other ordinances, laws, and regulations that may be required by Federal, State, and Local Governments or Insurance and Health Agencies while performing work and supplying parts or materials under this Agreement.
- C. Vendor shall give prompt written notice to DUKE in the event of any significant change in the Vendor's personnel, labor relations, financial condition, trade style, including but not limited to notice of anticipated or actual work stoppages.

- D. All Vendor's activities will be at its own risk and Vendor is hereby given notice of its responsibility to make arrangements to guard against physical, financial, and other risks as appropriate.
- E. Vendor agrees to furnish its own transportation to and from DUKE at no additional cost. Vendor will supply all equipment, tools, materials, parts, supplies, and labor required to perform the assigned work unless otherwise arranged with DUKE.
- F. Vendor shall permit inspection of its operations on DUKE premises at any time by DUKE to determine that standards of quality, safety and cleanliness are being met.
- G. Vendor shall advise DUKE Procurement Services in writing and in advance of all plans or activities that may reasonably pose a danger or nuisance to members of DUKE Community or general public or to the physical facilities of DUKE. Procurement Services shall approve all schedules and methods proposed for such work before the start of work.
- H. Vendor shall notify DUKE promptly of any expected delay in the performance of services. Vendor will be liable for all delays unless the delay is caused by matter(s) beyond Vendor's reasonable control.
- I. Vendor warrants that it complies with the Copeland "Anti-Kick Back" Act (18 U.S.C. 874) as supplemented in Department of Labor Regulations (29CFR, Part 3).
- J. Vendor warrants that it's not delinquent on the repayment of any Federal debt as required under FAR 52.209-5 and FAR 52.209-60.
- K. Vendor is responsible to remove from premises and to dispose of properly all portions of all materials, components, systems that contain or consist of hazardous substances, which Vendor has used, removed, or caused to be removed as part of this Agreement.
- L. If the activities covered under this Agreement result in the generation, accumulation, or storage of hazardous or regulated chemical(s) or solid waste, the Vendor must provide a written Hazardous/Regulated Waste Management Plan. This written Plan must be submitted prior to work beginning under the Agreement. The Plan must include the following:

A defined list of generated waste.

The process (es) that will result in the generation of waste.

The process of accumulating the waste.

The source and type of container to be used for the accumulation of the waste.

Description of Container Labeling.

Security during on-site storage.

Description of the process/vendor for ultimate disposal of waste.

PROPERTY DAMAGE OR THEFT

DUKE shall have no responsibility for the loss, theft, mysterious disappearance of, or damage to, equipment,

tools, materials, supplies, and other personal property of Vendor or its employees, which may be brought onto DUKE premises or stored at DUKE except for damage caused by direct and sole negligence of DUKE.

The Vendor shall be responsible for the loss, theft, mysterious disappearance of, or damage to, equipment, tools, materials, supplies and other property of University, which is used by the Vendor.

WARRANTY OF TITLE

Vendor represents that it has absolute title to and full right to dispose of the parts or materials used in the performance of providing maintenance and services described on the face of this order without violating or infringing upon the rights of third parties, and that there are no liens, claims, or encumbrances of any kind against such parts or materials, and that it will warrant and defend the same against the lawful claims and demands of all persons.

TITLE OF TOOLING

Design, tools, jigs, dies, fixtures, templates, patterns, drawings, and other information and things (herein collectively called tools) paid for or furnished by DUKE shall be DUKE property and Vendor shall not encumber or dispose of them in any way. Vendor shall maintain such tools in first class condition. Such tools shall be used exclusively for production under DUKE Agreement.

INSURANCE & LIABLILITY

Vendors providing services, parts or materials will procure and maintain the following insurance:

Worker's Compensation: Statutory limits

Employers Liability: \$1,000,000 each accident

Commercial General Liability including Products/Completed Operations Liability: \$5,000,000 each occurrence / \$10,000,000 aggregate including bodily injury and property damage; personal/advertising injury; contractual; premises/operations; independent Vendors; products and completed operations.

Automobile liability: \$5,000,000 with bodily injury & property damage for owned & non-owned vehicles.

Duke University Health System must be named as Additional Insured with respect to General Liability coverage insofar as it pertains to the work done/service provided/product delivered to the university. Your policy must be Primary as to any other valid and collectible insurance, but only as to acts of the named insured.

The foregoing coverages and limits are to be considered as minimum requirements and in no way limits the liability of the Vendor. A certificate of insurance with the coverage as cited above and listing Duke University Health System as the certificate holder, must be submitted to Duke Procurement Services before work begins by the Vendor for DUKE annually.

Coverages represented on the certificates of insurance must show policy numbers, effective dates and limits. All policies shall evidence insurance written by a carrier licensed in the State of North Carolina and rated at least "A" in A.M. Best's Key Rating Guide. Renewal certificates of insurance shall be provided annually until the work is completed and for three years following the completion of work.

PROTECTION OF WORK, PROPERTY AND PERSONS

During the progress of the work under this Agreement, the vendor shall take extreme precautions against the possibility of fire on DUKE property and maintain adequate protection of the work on adjacent and/or public property, and shall be responsible for any damage or injury due to Vendor's (and employees, agent, and/or assignees) act or neglect. Vendor assumes entire responsibility and liability for any and all damage or injury of any kind or nature whatever (including death or personal injury resulting) to all persons, whether employees of the Vendor or otherwise, and to all property, caused by, resulting from or arising out of the Vendor's negligence.

OCCUPATIONAL SAFETY AND HEALTH ACT

Vendor will comply with the Occupational Safety and Health Act of 1970, including all federal and state standards and regulations in accordance with the act. Vendor is responsible for compliance with this act by its agents, employees, suppliers, assignees, and subcontractors. Vendor is also responsible for supplying all materials and services under this Agreement in compliance with this act. Vendor agrees to indemnify DUKE and save it harmless from all loss and damage (including attorney's fees) arising from the failure of Vendor to comply with this act.

CONFIDENTIALITY

Vendor may be engaged in the performance of Services for DUKE set forth herein and in connection therewith will be furnished or given access to knowledge, information, data, and confidential or privileged documents ("Documentation") which are confidential and proprietary to DUKE. Vendor further understands and agrees that DUKE licenses the use of computer software and/or documentation and other such data ("Computer Products") from various computer vendors, whose Computer Products are the valuable and confidential property of such vendors. With regard to such products, DUKE has undertaken certain confidentiality and non-disclosure obligations, and Vendor understands and agrees that they may have access to such Computer Products. Vendor agrees that during, or at any time after the termination of the performance of Services pursuant to this Agreement, Vendor shall use such Computer Products or Documentation only for the purposes of performing Services under this Agreement and shall not use for itself or for any other person or business; or divulge or convey to any person or business any such Computer Products or Documentation.

This documentation expressly excludes information, which has been previously published or is otherwise in the public domain (other than by or through Vendor in breach of this Agreement). Vendor further agrees not to reproduce, or use for any purpose other than the work specified hereunder such information delineated in paragraph above without the prior written approval of DUKE. Use of said information above shall be restricted to Vendor's personnel who have an express need to know in order that the obligations of the Agreement be fully met. Vendor further agrees to take all necessary steps, as DUKE may direct to assure the obligations of this Section are fulfilled and that any subcontract hereunder contains the provisions set forth in this Section.

Vendor acknowledges that the unauthorized use or disclosure of Computer Products or Documentation may give rise to irreparable injury to DUKE or its computer vendors and that accordingly any one of them may seek and obtain injunctive relief against Vendor or any individual furnished by Vendor hereunder to prevent the breach or threatened breach of any promise made in this Agreement in addition to any other legal remedies which may be available to them. The obligations of Vendor stated in this paragraph shall remain in full force and in effect after termination of this Agreement.

IDENTITY SECURITY

Contractor shall take reasonable measures to protect against unauthorized access to, or use of, personal information of patients, students, employees, or customers of Duke, including individual social security numbers, as required by law, and shall give notice to Duke without unreasonable delay and in no event later than fifteen (15) calendar days after discovery of the breach. Contractor shall have in place, and provide copies to Duke upon request, information security policies and procedures to protect against unauthorized access to or use of personal information.

DUKE COMPLIANCE PLAN

Contractor acknowledges that it has been informed that Duke Medicine has implemented a compliance program for a number of purposes including, but not limited to, ensuring that the provision of, billing for, and care at Duke Medicine is in compliance with applicable Federal and State laws ("Compliance Plan") and all Duke Medicine operations are conducted in accordance with applicable laws and regulations. Contractor acknowledges that it has received a copy of the Duke Medicine Code of Conduct. Contractor further states that 1) It has not been convicted of a criminal offense related to healthcare, 2) It is not currently under sanction, exclusion, or restriction, indictment or administrative settlement (civil or criminal) by a federal or state enforcement, regulatory, administrative, or licensing agency or otherwise ineligible for federal or state program participation, and 3) It is not currently listed on the General Service Administration List of Parties Excluded from the Federal Procurement and Non-Procurement Programs. Contractor will notify Duke Medicine in the event of any investigation, civil or criminal, of any of the above.

Contractor will notify Duke Medicine promptly of any allegation of unethical behavior, wrongdoing, or violation of Duke Medicine policies or procedures or federal or state laws or regulations.

Duke Medicine, upon Contractor's request, shall make available such other information relating to its Compliance Program as is appropriate to assist Contractor in adhering to the policies set forth in the Code of Conduct developed as part of the Compliance Plan. Contractor is invited to attend educational sessions of Duke Medicine related to its Compliance Program. The failure of Contractor to conduct its activities in accordance with the Code of Conduct and Compliance Program shall constitute a material breach of this Agreement and Duke Medicine shall have the absolute right to terminate this Agreement immediately. Contractor agrees to verify that its employees and subcontractors meet all the requirements outlined above prior to their performing services under this Agreement.

COURT RECORDS CHECK

As part of Vendor's hiring process, Vendor shall, with respect to staff who will perform services on-site at DUKE, conduct background checks (county to county criminal record checks, local checks, and out-of-town checks) in accordance with all applicable legal requirements.

Background checks shall be conducted on current name, social security identification, date of birth, address, maiden name, and any alias names of which Vendor as actual notice. These court records checks are for the purpose of identifying convictions for criminal offenses, including felonies or misdemeanors.

Vendor will only assign staff to DUKE who have passed the required background checks.

DUKE reserves the right to refuse and/or terminate the services of any Vendor's staff member who has an

unacceptable background and records check.

VENDOR REPRESENTATIVE CREDENTIALS

Each vendor representative will be credentialed through the Duke approved web based system, prior to their first visit to Duke on behalf of his/her company. For details, see vendor policy @www.procurement.duke.edu. Failure to follow may result in contract breach.

FDA RECALL

In the event that the products covered hereunder become the subject of an FDA communication such as an untitled letter, warning letter or similar FDA notice from which an enforcement action could reasonably be anticipated; or any form of regulatory product withdrawal from commerce, whether voluntary or involuntary, such as Class I, II or III Recall; by which, from any of the foregoing, Duke may reasonably conclude that the product no longer meets its intended purpose, regulatory requirements, or standard of care; Duke shall have the right to terminate this Agreement without penalty upon 30 days written notice to Contractor of Duke's intentions to terminate.

ENTIRE AGREEMENT. This Agreement, including any Appendices and Exhibits attached hereto, is the entire agreement of the parties and supersedes all prior agreements and understandings, whether written or oral, with respect to the subject matter of this Agreement. This Agreement can be modified only by a written amendment executed by authorized representatives of Customer and Triangle X-ray Company.

CUSTOMER'S AUTHORIZED SIGNATURE	DATE		
TITLE	PO#		
	tutes a final agreement and customer agrees to the tions" stated above.		
Ron Shaw			

TRIANGLE X-RAY COMPANY AUTHORIZED SIGNATURE

DATE

IF ACCEPTED PLEASE RETURN A SIGNED COPY OF THIS QUOTATION WITH A COPY OF YOUR SIGNED QUOTATION AND PURCHASE ORDER TO: TRIANGLE X-RAY BY MAIL OR FAX TO 919-872-3986

IF THIS EQUIPMENT IS FOR RESALE, PLEASE INCLUDE END CUSTOMER INFORMATION