DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

February 15, 2018

Elizabeth Kirkman
CHS Strategic Services Group
2709 Water Ridge Parkway, Suite 200
Charlotte, North Carolina 28217

Exempt from Review – Replacement Equipment

Record #:	**2515**
Facility Name:	Carolinas HealthCare System Cleveland
FID #:	953106
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace an existing linear accelerator
County:	~~Mecklenburg~~ Cleveland (HW)

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of February 6, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to replace the existing linear accelerator, Elekta Precise MRT 6001, located in room #1038 of the Grover Building, with an Elekta Infinity. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

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Sincerely,

Gloria C. Hale
Team Leader

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

February 6, 2018

Carolinas HealthCare System

Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System Cleveland – Exemption Notice for Acquisition of Replacement Linear Accelerator ("Linac")

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System Cleveland ("CHS Cleveland"), seeks to acquire an Elekta Infinity Linear Accelerator ("Replacement Equipment"). Please see Attachment A for a copy of CHS Cleveland's current hospital license. The Replacement Equipment will replace CHS Cleveland's current Elekta Precise ("Existing Equipment"). The Existing Equipment is currently housed on the first floor in the Grover Building, Room #1038 adjacent to/connected to CHS Cleveland's main hospital building located at 201 East Grover Street in Shelby, NC 28150 (see Attachment B).

The purpose of this letter is to provide the Agency with notice and to request a determination that CHS Cleveland's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review under the replacement equipment exemption provisions contained in Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6 (which are codified at N.C. Gen. Stat. 131E-184(f)(1)-(3)).

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

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

See N.C. Gen. Stat. 131E-176(22a). Under the new provisions found at N.C. Gen. Stat. 131E-184(f)(1)-(3), the CON law provides:

> (f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

(1) The equipment being replaced is located on the main campus.
(2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
(3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

See Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6. The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified N.C. Gen. Stat. 131E-176(14n)) as follows:

(14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:

a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is currently located in room 1038 on the first floor of the Grover Building on CHS Cleveland's main campus (see Attachment B). The main hospital building from which Carolinas HealthCare System exercises financial and administrative control over Carolinas HealthCare System Cleveland is located at 201 East Grover Street, Shelby, NC 28150 (see Attachment B). Carolinas HealthCare System Cleveland President's office is located on the second floor of the main hospital building.

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be "comparable" to the equipment it replaces and the equipment being replaced must be "sold or otherwise disposed of when replaced." CHS Cleveland's proposal qualifies for this exemption.

A. Cost of the Replacement Equipment

The purchase price of the Replacement Linac Equipment is $1,814,481 ($1,691,824 Linac with freight + $122,657 Tax). The quote for the Linac Replacement Equipment from Elekta is provided in Attachment C. The projected total capital cost of the project is $2,760,000 (including taxes and freight) and includes the removal of the existing equipment and installation of the Replacement Equipment. The total capital cost schedule and the certified cost estimate of the renovation required to install the new equipment are provided in Attachment D.

B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located in room 1038 on the first floor of CHS Cleveland's Grover Building (see Attachment B). The Replacement Equipment will be located in the same location as the Existing Equipment (see Attachment B).

C. Certificate of Need Issued for Equipment Being Replaced

This proposal also fits within the new exemption criterion in Section 131E-184(f)(2) because the Department issued a Certificate of Need for the Existing Equipment (see Attachment E). The Existing Equipment was acquired in 2003.

D. Comparable Equipment

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

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

CHS Cleveland intends to use the Replacement Equipment for substantially the same radiation oncology procedures for which it currently uses the Existing Equipment. The Existing Equipment is an Elekta Primus that was installed new in 2003. This Existing Equipment has been used for radiation oncology procedures since installation.

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same radiation oncology procedures (see Attachment F for the Equipment Brochure). The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, CHS Cleveland does not intend to increase patient charges or per procedure operating expenses within the first 12 months after equipment acquisition. For further equipment comparison, please refer to Attachment G, the Equipment Comparison Chart.

Subsection (d) of the regulation further provides:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and

(3) the acquisition of the equipment does not result in more than a 10.0 percent increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The Replacement Equipment will meet all three of tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart (Attachment G). Moreover, CHS Cleveland represents the use of the Replacement Equipment will not result in the types of expense or charge increases described in Subsection (d)(3).

Documentation provided in Attachment H indicates that 5,140 procedures were performed from January 1, 2017 to December 31, 2017 on the fixed existing equipment.

E. Disposition of Equipment

Please see Attachment I for a letter documenting the Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

CONCLUSION:

Based on the foregoing information, CHS Cleveland hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,

Elizabeth V. Kirkman

Elizabeth V. Kirkman
Assistant Vice President
CHS Strategic Services Group

Attachments

cc: Brian Gwyn, President, Carolinas HealthCare System Cleveland

Attachment A

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2017, this license is issued to

The Charlotte Mecklenburg Hospital Authority

to operate a hospital known as

Carolinas HealthCare System Cleveland

located in Shelby, North Carolina, Cleveland County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 953106

License Number: H0024

Bed Capacity: *241*

General Acute 241

Dedicated Inpatient Surgical Operating Rooms: 1
Dedicated Ambulatory Surgical Operating Rooms: 0
Shared Surgical Operating Rooms: 6
Dedicated Endoscopy Rooms: 4

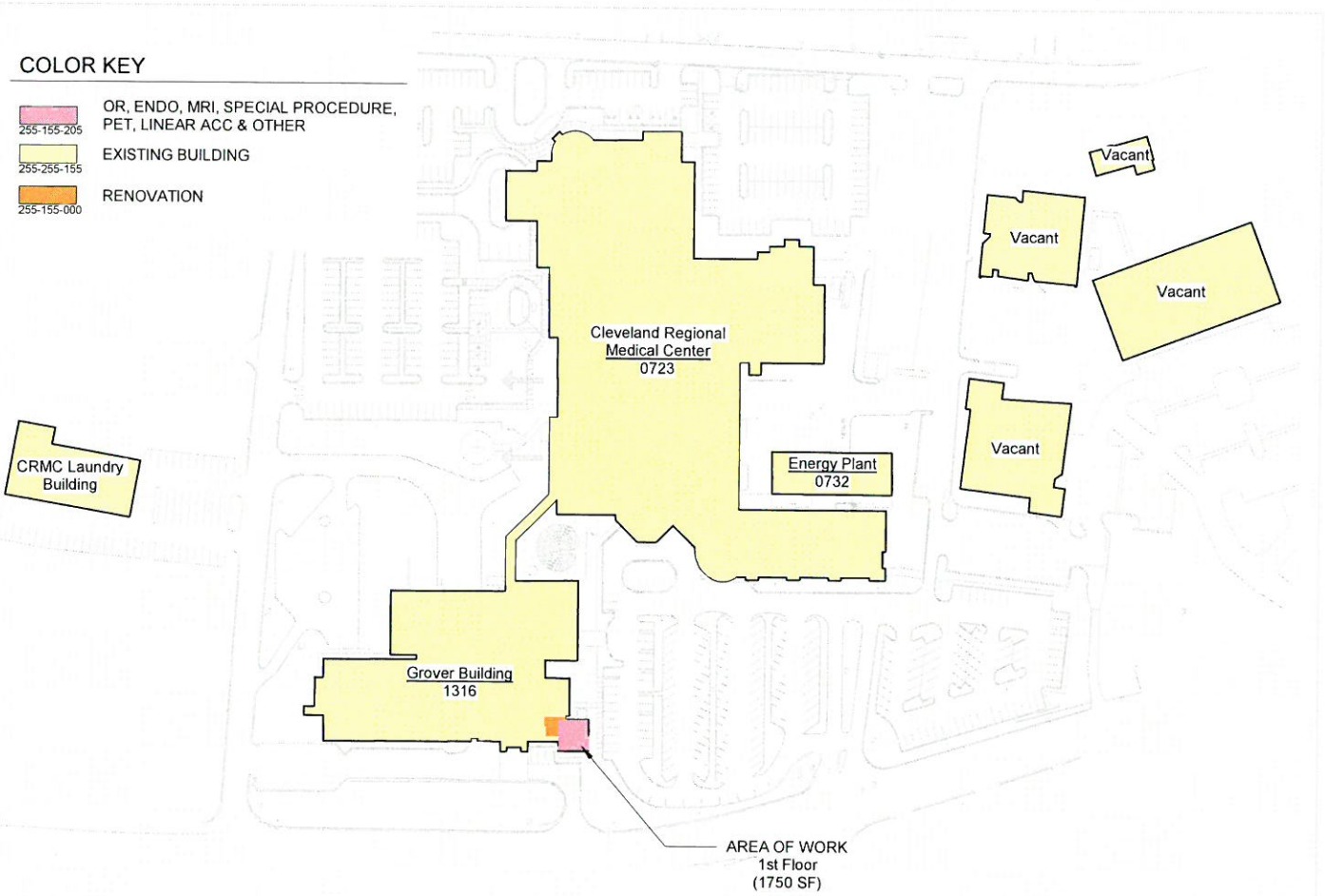
Authorized by:

Richard O. Bay

Secretary, N.C. Department of Health and Human Services

Director, Division of Health Service Regulation

Attachment B



Site Plan

Linear Accelerator Replacement

Carolinas HealthCare System

02/06/18

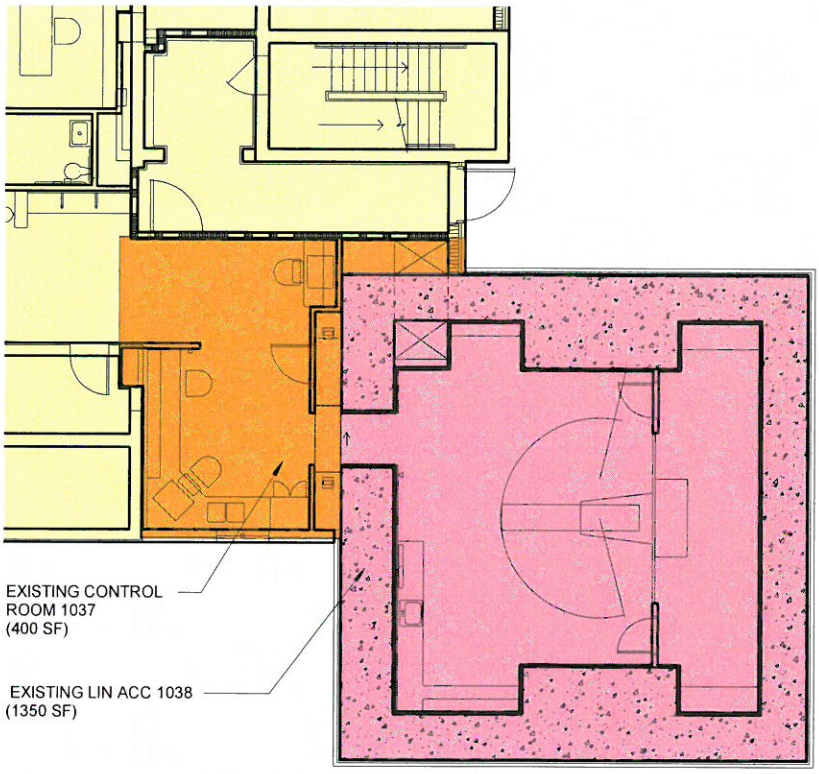
CHS Cleveland

COLOR KEY

255-155-205 OR, ENDO, MRI, SPECIAL PROCEDURE, PET, LINEAR ACC & OTHER

255-255-155 EXISTING BUILDING

255-155-000 RENOVATION



1st Floor - Existing Plan

Linear Accelerator Replacement

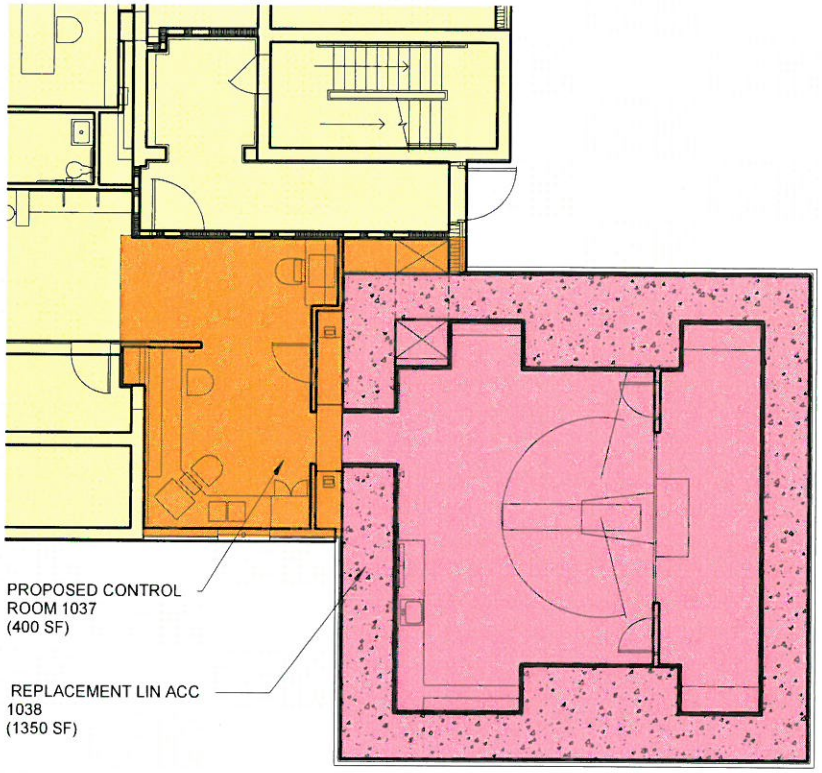
Carolinas HealthCare System *02/06/18* CHS Cleveland

COLOR KEY

255-155-205 OR, ENDO, MRI, SPECIAL PROCEDURE, PET, LINEAR ACC & OTHER

255-255-155 EXISTING BUILDING

255-155-000 RENOVATION



1st Floor - Proposed Plan

Linear Accelerator Replacement

Carolinas HealthCare System *02/06/18* CHS Cleveland

Attachment C

Quotation:2017-191944-CB
November 30, 2017

Elekta

Oncology | Brachytherapy | Neuroscience | Software | Services

Elekta is pioneering significant innovations and clinical solutions for treating cancer and brain disorders.
We provide intelligent and resource-efficient technologies that improve, prolong and save patient lives.

Quotation Number: 2017-191944-CB

Quotation Date: October 13, 2017

Valid Until: March 31, 2018

Prepared For:

Carolinas Heathcare System Cleveland

201 E Grover ST
Shelby, North Carolina 28150-3917
US
(t) (980) 487-3099
(f) (980) 487-3615

Prepared By:

Chris Broyles
North Carolina Sales Client Manager

400 Perimeter Center Terrance, Suite 50
Atlanta, GA 30346
(t) 704.322.3493
(c) +1 7046998788
chris.broyles@elekta.com

Currency: USD

Elekta is pleased to submit the following Quotation for the products, software licenses, and/or services described herein at the prices and terms stated.

Carolinas Healthcare Cleveland - Elekta Infinity Bundle	**Total Offer Price:**	$1,691,824.08

For U.S. customers, this purchase is subject to the discount provisions of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and the discount safe harbor regulations at 42 C.F.R. § 1001.952(h). In accordance with such provisions, Customer shall fully and accurately report all prices paid net of discounts where appropriate, and as appropriate, in the costs claimed or charges made under any Federal or State healthcare program, and provide information upon request to Medicare, Medicaid and other applicable federal and state health care programs on all discounts and price reductions received from Supplier.

Subject to Elekta, Inc. Terms and Conditions or those previously negotiated.

State, local, VAT and other taxes, and import/export licenses are not included in this Quotation

Scope of Supply

Qty	Description
1	

Qty	Description
1	**Elekta Infinity™** Dual modality digital accelerator provides: • a choice of up to three different x-ray energies and up to 9 electron energies • Agility™, Elekta's integrated multi-leaf collimator, that provides full field high resolution beam shaping (5mm at isocentre), a 40 x 40cm treatment field and effective leaf tip speed of up to 6.5cm/sec, capable of covering multiple targets with interdigitation and island shapes • A broad spectrum of delivery techniques from 3D Conformal Radiotherapy to IMRT, VMAT- VMAT enables simultaneous and dynamic movement of the MLC while rotating the gantry in combination with varying the dose rate, gantry speed and or collimator angle to deliver a highly conformal dose. • XVI, offering 2D and 3D kV image guidance for advanced soft tissue visualization supporting image guided treatment workflows . XVI Software options VolumeView™, MotionView™ and PlanarView™ are included. • iViewGT™, offering 2D MV imaging capability supporting image guided treatment workflows • remote system diagnostic ready and will function with the optional Elekta IntelliMax™ service monitoring and support system. IntelliMax is enabled through software and is available during the original system warranty period or through purchase of an Elekta Advanced Service Agreement • Precise Treatment Table™ which comprises a vertical lift mechanism, couch base and the control system • low isocentric height of 124cm.
1	**Stereotactic MV Isocenter Setup** Service to evaluate the MV (Gantry), and combined MV (Gantry) and table isocenter using software tool based on the Winston Lutz test. The following values will be achieved at 6 MV; • MV isocenter (Gantry): ≤ 0.7 mm radius • Combined MV isocenter (Gantry) and table isocenter: ≤ 1.mm radius.
1	**Goalpost Assembly** Elekta Synergy® Platform, Elekta Synergy®, Elekta Infinity™, Elekta Axesse™ and Versa HD™ compatible standard goalposts.
1	**Agility ™ Kit** Agility - fully integrated 160 leaf Beam Shaping Device with fine resolution leaves (0.5 cm wide) across the full 40x40 cm field size. The MLC comes with a Treatment Control System Rack Cabinet and Integrity R3.X software which includes integral leaf calibration workflows. Agility is designed to support high resolution stereotactic radiation therapy and volumetric arc therapy (VMAT), providing high conformance beam shaping for these advanced delivery techniques. It also supports conventional and electron based radiation techniques.

1 **Agility ™ - Linac Parts**

1 **Agility head covers and touchguard - Non Axesse**
Required for all Elekta delivery systems with the Agility beam shaping device.

1 **Integrity™ R3.2 control system software** Integrity is the latest generation of Elekta's fully digital treatment control system software for systems with Agility™. Integrity is built on the latest LynX OS platform and is the monitoring and control foundation of Elekta treatment delivery systems. Integrity additionally supports Continuously Variable Dose Rate, dynamic and VMAT deliveries.

1 **MOSAIQ Sequencer PC**
This option provides a MOSAIQ Sequencer PC that can be mounted in the Agility Treatment Control system cabinet.

1 **6 MV Low Energy Photon**

1 **10 MV Mid Energy Photon**

1 **15 MV High Energy Photon**

1 **6 MeV Electron Energy**

1 **9 MeV Electron Energy**

1 **12 MeV Electron Energy**

1 **15 MeV Electron Energy**

1 **18 MeV Electron Energy**

1 **U.S.A. Electron Flatness**
Electron flatness according to U.S.A. standards, optimized at 100 cm.

1 **Standard Set of Aperture Plate Electron Beam Applicators**
Field sizes:

- 6 x 6 cm, SSD 95 cm
- 10 x 10 cm, SSD 95 cm
- 14 x 14 cm, SSD 95 cm
- 20 x 20 cm, SSD 95 cm

Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator latch mounting system enables easy and rapid attachment.

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1 **PreciseBEAM™ VMAT**
Provides Volumetric Intensity Modulated Arc Therapy which offers simultaneous dynamic control of the MLC, diaphragms, gantry and collimator. It allows continuous variable MU/degree along the arc.

1 **Combined Interdigitation & CVDR license**
License providing interdigitation and Continuously Variable Dose Rate (CVDR) functionality.

1 **VMAT Treatment Planning System Manual**

1 **VMAT CAT (Volumetric Arc Therapy Customer Acceptance Test)**

1 **Response™ Gating Control System for Digital Accelerators**
Response provides a seamless interface that supports automated gated treatment delivery for a range of delivery techniques on the Elekta Digital Accelerator. The gating signal can be provided by a validated external motion management system, such as the Active Breathing Coordinator™.

1 **SYNERGISTIQ ™ Software License**
Enables the XVI functionality to support SYNERGISTIQ. SYNERGISTIQ integrates MOSAIQ® and XVI into a consolidated and synchronized user interface.

1 **Software Media Pack, SYNERGISTIQ™ Clients**

1 **SYNERGISTIQ ™ Monitor kit**
Specification for Extender/Receiver and cable for a remote monitor. Required for sites that use SYNERGISTIQ with a remote monitor in the treatment room.

1 **kiloVoltage Cone-beam CT Hardware for Elekta Infinity™**

1 **40kW kV generator - 480V**
The integrated 40kW kV generator provides multiple settings control via the XVI software. Acquisition parameters are configured within the preset protocol function in the XVI software, and is user configurable. The generator and X-ray tube have been optimized for the 3D VolumeView™ imaging, as well as the 2D radiographic type exposures of PlanarView™ and MotionView™.

1 **Control System hardware for XVI R5.0.3**
The XVI control system is a high specification PC which supports all aspects of the IGRT process including 2D, 3D and 4D kV image acquisition, reconstruction, and analysis using a suite of registration functionality.

1 **Base XVI License**
The XVI 5.x base license includes the following features as standard:

- PlanarView™: 2D kV radiograph mode
- MotionView™: 2D kV fluoroscopic mode
- VolumeView™: 3D kV volumetric imaging mode
- Segmental MotionView™ and VolumeView™: Pause/Restart 2D fluoro or 3D volumetric acquisitions manually.

1 **Symmetry™ License**
Symmetry is primarily indicated for respiratory motion management. It offers a unique 4D IGRT online solution that is correlated to internal organ movement. It facilitates for the planned dose to be delivered to the volume where the target spends most of its time in. This allows for margin reduction and baseline shift compensation, supporting treatment deliveries during free-breathing with no surrogates. The use of Symmetry does not require planning on a 4D reference CT.

1 **Critical Structure Avoidance**
Critical Structure Avoidance allows the registration of two separate areas of anatomy, utilizing both the clipbox and the Shaped Registration Region of Interest. XVI software will calculate the relationship of both areas of anatomy to the proposed correction vectors and alert the user if the target has moved closer to the critical structures due to anatomical changes. The user can then choose to select a compromise between the two areas, or send the patient for re-planning.

1 **3D Shaped Registration Region of Interest**
The 3D Shaped Registration Region of Interest can be generated from any structure imported from the treatment planning system, or created manually using tools in the software. This allows generation of a 3D registration volume that conforms to anatomical structures.

1 **3D Automated Seed Match License**
Offers an optimized 3D registration algorithm to register implanted markers, without compromising on 3D volumetric information.

1 **Distributed Review**
Distributed Review allows the sending of XVI CBCT data to MOSAIQ® for review at any MOSAIQ® workstation, as well as the primary XVI workstation.
Pre-requisites:

- Distributed Imaging/Treatment
- DICOM CT Export (+/- Auto DICOM CT Export).

1 **Distributed Imaging**
Distributed Imaging allows the transfer a patient between XVI systems without having to prepare the registration settings on the secondary XVI system, through MOSAIQ®.

1 **Elekta XVI Basic Calibration Kit - Bearing Phantom Assembly**
Specially designed geometric calibration phantom for kV to MV isocentre alignment. Suitable for the XVI system with the iBEAM® evo couch top.

1 **Couch top Adaptor kit for QA Phantom**
Single ball phantom table top adapter kit. This attachment supports the single ball bearing phantom which is used to calibrate the XVI imaging software to the mechanical isocenter. Fits the iBEAM®, iBEAM® evo, HexaPOD™ evo and Connexion™ couch tops.

1 **XVI Daily QA Phantom Kit**
Daily QA Phantom for kV and MV projection imaging and kV VolumeView™. Checks the laser and light field coincide and additionally provides a spreadsheet for recording and analyzing trend results.

1 **XVI Water Calibration Kit**

Water phantom calibration kit for XVI calibration. It provides a reduction in CBCT image ring artefacts in addition to image quality improvements.

1 **VolumeView™ Contrast phantom**
QA phantom to enable measurement of high resolution and contrast resolution and other image quality parameters of the VolumeView images acquired on the XVI workstation.

1 **2D Image Quality Phantom**
Image quality phantom use for 2D kV image quality to determine the low contrast and spatial resolution of XVI 2D images (PlanarView™ images). This test tool is used for the 2D image quality of the Customer Acceptance Test for XVI and can be used to monitor image quality over a period of time.

1 **Automated DICOM CT export license**
This tool uses DICOM Auto-Push for 3D images. DICOM Auto-Push automatically exports the CBCT image when you accept or save a 3D VolumeView reconstruction.

1 **Manual DICOM RT Image Export**
This tool uses DICOM to export 2D PlanarView images manually from XVI.

1 **Auto DICOM RT Image Export**
This tool uses DICOM Auto-Push for 2D images. DICOM Auto-Push automatically exports the image when you acquire a 2D PlanarView image.

1 **DICOM CT export license**
This tool uses DICOM to export the 3D images manually from XVI to MOSAIQ®, or any 3rd party DICOM-based tool.

1 **DICOM 4D export**
4D DICOM export allows the user to export to a third party system the CBCT data as generated by Symmetry™ of:

- Average phases
- All phases
- Single phase.

1 **Archive and retrieve to network**
Performs automatic archiving of patient images to a pre-defined network location, outside of MOSAIQ®. Archiving can be scheduled, and the network location can be specified at will. The same tool performs retrieval of files from the same location.

1 **Extra Collimators**
Provision of additional XVI collimators for imaging. Includes:

- VolumeView cassettes: L10, M2, L2.

1 **Elekta Infinity™ iViewGT™**
This kit contains all of the components for iViewGT including;

- A MK 6 imaging control system cabinet with the iViewGT software R3.4.1. pre-installed.
- A rigid and fully retractable slim line MV imaging detector arm with a large, square active detector area and wide lateral and longitudinal movement adjustments. The arm has automatic and manual arm movements and is fully interlocked.

1 **iViewGT™ R3.4.1 Installation Kit**

1 **iViewGT™ R3.4.1 Software License**

1 **iViewGT ™ R3.4.1 Software License Collation**
Third Party License toolkit necessary for supporting iViewGT.

1 **Remote Retraction of the iViewGT™ detector - 30M**
This kit allows Remote Retraction of the iViewGT detector from the Function Key Pad.

1 **DICOM 3.0 software interface for image transfer**
The international standard interface protocol for network transfer of medical images.

1 **iViewGT™ IMRT Verification Software License**
This software expands existing iViewGT functions to verify multiple segment beams for IMRT. The iViewGT image acquisition is triggered automatically and the image taken depends on whether the user selects single, multiple or movie image.

1 **Template Matching Software License**
The template matching option enables the user to compare the portal image with a nominated reference image for any set-up error. The set-up error is measured by matching visible anatomy and the field edge on the referenced image with the portal image. The user can move the templates to provide an image displacement.

1 **Patient Auto Select Software License**
This enables the prescription selected on the Linac to automatically select or create that patient record on iViewGT™ or iViewC™ using the iCom-Vx protocol. In addition, images will automatically be acquired and stored in the iViewGT / iViewC database without further operator intervention.

1 **Software License Image Approval**
This allows the user, assigned with the 'review' permission, to approve or disapprove any image within iViewGT™ or iViewC™.

1 **Las Vegas Calibration Phantom**
The Las Vegas phantom is a device that is used to check image quality of a portal imaging device at different megavoltage energies both at acceptance and as part of the corrective maintenance procedure.

1 **iBEAM® evo Couchtop**
The iBEAM evo Couchtop has no metallic components apart from the rails. The Couchtop comes complete with the following extensions;

- iBEAM evo Extension 415
- indexing bar
- iBEAM evo Extension removable rails EP (aluminum).

The table top comes with a fixed rail at the foot end of the couch and a removable, light weight rail for the superior couch end.

1 **Precise Treatment Table™ or Pedestal Pit Kit**

--

This kit provides the necessary fixings, floor boards and template to install a Precise Treatment Table into a custom built pit or a modified Pedestal pit.

1 **Independent X/Y movement of table top**
To save time, in reaching the desired position, this kit allows the X/Y brakes to be released independently.

1 **Beam Block Tray - Star Pattern**
Lexan beam block tray with holes in a star pattern. Trays are designed with threaded, removable plugs for the coding of each block. Specially designed for use with the Elekta shadow tray assembly.

1 **Hook and Latch Magnification Graticule**
Solid Frame Port Film magnification graticule that attaches directly to the linac, taking the place of the coded shadow tray, thus providing more clearance between the patient and the accessory.Used in treatment verification for situations where simultaneous fitment of blocking tray is not required.

1 **Electron Beam Field Shaping System**
For use with Electron applicators from Elekta and allows the user to easily provide Electron Beam field shaping. The system comprises:

- A Universal leveling template with an adjustable arm for securing styro-foam inserts- Set of five (5) rubber molds compatible with Elekta Electron applicators
  - 6cm x 6cm
  - 10cm x 10cm
  - 14cm x 14cm
  - 20cm x 20cm
  - 25cm x 25cm

Provided as part of the system is one (1) Hot Wire Cutter.

4 **19-inch Control Room LCD Monitor**

1 **Table ASU License**
In addition to normal linac ASU, the user is able to separately request the auto setup of the table isocenter from inside and outside the room.

1 **Delivery Parameters Log File Convertor**
Enables a user to upload log files and have them converted into csv format.

1 **Software License Linac Record**
The Daily Record Function allows the Treatment System radiation beam information to be recorded on a continuous basis. Every time the beam is turned on it records the incidence: patient treatments or port films. This can be used as a back up for record and verify systems or for billing purposes.

1 **Software license Linac Record to file**
The Software license Linac record to file offers the user the option to configure the Linac (in Service Mode) to send the data to network file rather than to a printer.

1 **Extended Service License**
This license allows the user extra service tools/functionality.

1 **Extender Cards**
Extender cards for fault diagnosis on the Electrical Interface Module (EIM).

1 **Linear Accelerator Manual Set**

1 **Customer Interface Terminal Board**

1 **Turbo Starter Kit for Linear Accelerators**
Ancillary equipment required for the installation and maintenance of any Precise Digital Accelerator. Comprising:

- Rotary vacuum pump
- Turbo molecular pump attachment for rapid pump down times and higher roughing vacuum.

1 **General Function Key Pad**
The Function Key Pad provides the following features:

- MV Start, Interrupt and Terminate
- LEDs to indicate radiation on / off status
- Linac Assisted Setup (ASU) - facilitating automatic gantry and diaphragm rotations
- Table ASU - facilitating automatic table translations and isocentric setup
- Imaging ASU - facilitating automatic remote retraction of the iViewGT™ detector.

1 **XVI cable reeling**

1 **Remote Automatic Table Movement License**
This license enables the user to make the translation correction movements remotely and automatically at the Precise Treatment Table™. This movement can either take place following a registration as part of an on-line VolumeView imaging workflow or the table can be moved remotely and automatically to coordinates entered into MOSAIQ®.

1 **Agility™ Service Tool**
Tool to support maintenance of the Agility beam shaping device.

1 **Room Lasers, Green, Remote**
Set of 4 green room lasers with remote control adjustment. Comprising 3 crosshair and 1 line sagittal laser. Featuring fine lines (< 1mm), high precision adjustment at the isocenter and stable mounting bracket. Inclusive of switchable (110v to 240v) power supply and universal main adaptor.

1 **Applications Training for Standard Therapy on the Desktop**
The 2-day Standard Precise Desktop Course (travel time inclusive) provides training for 4 Radiation Therapists in the clinical use of the Precise Desktop Digital Linear Accelerator. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in Radiation Therapy.

1 **Applications training for iViewGT™**

The 3-day iViewGT training course (travel time inclusive), provides training for 4 radiation therapists in the clinical use of the iViewGT imaging system. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in radiation therapy.

1 **XVI Applications Training**
The 4-day XVI training course (travel time inclusive) provides training for Radiation Therapists in the clinical use of the X-ray Volume Imaging portion of the Elekta Digital Accelerators. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in Radiation Therapy, CT, or Diagnostic Imaging. This course is given at the customer site for a maximum of 4 users.

1 **Weekend Rigging & Handling**
Basic rigging of Linac to first floor or ground floor location outside of Elekta's normal working hours. Elekta will provide the necessary crew to offload, uncrate, rigging and machinery moving required to set system as per plan, and remove debris. Basic rigging excludes use of a crane or rigging down an elevator shaft.
Standard Rigging includes:

- Make one pre-installation site visit and delivery project management.
- Drill holes for equipment fasteners
- Supply a 12,000 lb capacity forklift during the off loading procedure.
- Stage and uncrate the linac machine, move all components into the facility, and set as directed.
- Remove and dispose of all packaging that will not be reused.
- Transport the base, gantry and beam arm into the facility/bunker on transport trolleys supplied by Elekta.
- Set the base frame in place (Elekta will level).
- Set the gantry drum onto the base frame.
- Set beam arm into the gantry.
- Install counterweight holder and stack the counterweights.
- Supply a manual gantry lifting system to perform aforementioned setting activities and all necessary tools.
- Supply a crew, including a rigging supervisor.
- Include the cost of all associated resource and expenses, including related travel time.
- Complete all rigging activities in a single day.

Standard Rigging excludes:

- Crane service.
- Elevator, or shaft deliveries.
- No clear access to the building (exterior).
- Interior obstruction en route to treatment room.
- Any shoring needed to protect the structure from the weight of the system.
- Any shoring and/or plating needed to build temporary dock or landing area for the unit.
- Extra long delivery routes, distances in excess of 150' from offload site to the treatment room.
- Overtime, weekend, premium time, unless Weekend Rigging selected.
- Additional travel expenses should the project exceed the time allotted in this scope for reasons beyond Elekta or our contractor's control.
- Additional man-hours, manpower, travel expenses, or equipment required due to delays caused by incorrect site preparation, waiting time, or delays not caused by Elekta or our contractor will be itemized and billed to the customer at then current rates.

1 **Open Air Graticule**
The Open Air Graticule is intended to be used for Radiation Therapy to project a scale of defined increments on port film images which can aid in treatment setup and verification. The Open Air Graticule does not require the use of a shadow tray holder and can be attached directly to the head of the Precise Treatment System or SL Linac. It consists of two wires delineating the X & Y axis of the treatment field. This model of graticule is ideal for MLC customers and especially those using Elekta's iView & iViewGTTM. Because

the open air graticule has a minimal transmission factor, with Physic's approval, the customer does not have to re-enter the treatment room after the port film to deliver the treatment. Please see product User manual for specific treatment information.

1 **Aperture Plate Electron Beam Applicator 25 x 25 cm**
Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator.
The X-ray diaphragms are then set automatically to the optimum position.
A unique hook and latch mounting system enables easy and rapid attachment.

1 **Intercom system for patient and radiographer communication**
The ASK-4® 501-TLI-CF is a single zone audio monitoring system with 2-way talk/listen capabilities. It consists of a remote speaker/microphone and audio base station with built-in microphone and speaker.

1 **Agility™ Beam Arm Cover (new white)**

1 **Order two sets of pre defined terminated cable kits**
Pre installation treatment room and Inter bay terminated cable kits.

1 **Elekta Infinity Drum and Ring Cover Set**

1

1 **iViewGT™ Amorphous Silicon detector panel for production systems.**

1 **Closed Circuit TV System - Color**
The standard CCTV system consists of two Samsung SNP-5321 (1.3 Megapixel HD) dome-shaped color cameras and two pan/tilt/zoom control mounts allowing the operator full control of both cameras. An 18.5 inch flat screen monitor is also provided and supports a resolution of up to 1360 x 768.

1 **Additional Closed Circuit TV System Camera**
This optional camera can be added to the standard CCTV system to create a three camera CCTV system. The additional camera consists of one Samsung SNP-5321 (1.3 Megapixel HD) dome-shaped color camera and one pan/tilt/zoom control mount allowing the operator full control of the additional camera.

1 **iViewGT Linac Specific Activation License – Sun Nuclear**
Allows for connectivity between the iViewGT database and the specified 3rd party dosimetry system. One license per linac.

1 **Medical Gases SF6 for Installation and Service**
Includes:

- 44-liter cylinder for SF6 gas
- 115 lbs of SF6 gas
- Regulator
- Delivery.

1 **Medical Gases Nitrogen for Installation and Service**

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Includes:

- 16-liter cylinder for Nitrogen (N2) gas
- Nitrogen (N2) gas
- Regulator
- Delivery.

2 **Physics 1: Medical Accelerator Introduction**
Objective
After completing this course, attendees will:

- Identify different components of an Elekta linear accelerator.
- Operate the linear accelerator's controls.
- Summarize the system communication and the different protocols used.
- Operate the accelerator in service and clinical modes.
- Perform calibration of dosimetry system.
- Understand fundamentals of MLC control system, optical tracking, and calibration.
- Outline the operation of imaging systems for IGRT and perform basic quality assurance.

Course Content

- Theory of Operation
- Control Sytem and System Communication
- Beam Measurement and Dosimetry
- Agility Beam Limiting Device
- Imaging Systems and Introduction to IGRT

The application has been made to CAMPEP for 31.2 Medical Physics Continuing Education Credits (MPCEC.)
Duration
5-day training at Elekta's Region North America LINC
Target Group

- Medical Physicists
- Medical Physics Students

Pre-requisites
None

2 **Medical Accelerator Quality Assurance**
After completing this course, attendees will:

- List all AAPM TASK GROUP 142 REPORT report tests and their recommended frequency.
- Perform Dosimetry, mechanical, safety, respiratory gating, universal wedge, MLC, and imaging tests and evaluate results of these tests.
- Evaluate all AAPM TG 142 report tests and determine applicability of each test to their clinical setting.
- Analyze potential causes of test failures in order to assist in determining necessary corrective actions in conjunction with Elekta and/or Field System Engineer.
- List Elekta linear accelerator characteristics and how they apply to TASK GROUP 142 REPORT accelerator QA.

Course Content

- During this course, participants will learn about the philosophy and purpose of the recommendations given in the AAPM TASK GROUP 142 REPORT report: Quality assurance of medical accelerators.

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- The recommended tests listed in the AAPM TASK GROUP 142 REPORT report will be presented and evaluated during this course in order for medical physicist to understand the clinical rational of each test, evaluate the necessity of each test for their specific clinical setting, and how to execute the tests in their clinical setting.
- The application has been made to CAMPEP for Medical Physics Continuing Education Credits (MPCEC).

Duration
3-day training at Elekta's Region North America LINC

Target Group
Certified Medical Physicists
Medical Physics Students

Pre-requisites
Physics 1 : Medical Accelerator Introduction

2 **Volumetric Modulated Arc Therapy (VMAT) QA**
Objectives
After completing this course, attendees will:

- Explain the clinical rational for the VMAT treatment technique.
- Evaluate the key factors influencing the quality of VMAT plans.
- List advantages and limitations of VMAT treatment technique.
- Explain the method by which VMAT is delivered by an Elekta linear accelerator.
- List the constraints required by the delivery system to ensure optimal treatment planning.
- Evaluate which aspects of VMAT must be tested prior to clinical use.
- Perform Picket Fence with Gantry Rotation, synchronization of dose rate and gantry speed, and synchronization of dose rate and MLC speed tests to evaluate proper performance of the Elekta medical accelerator.
- Develop and execute commissioning benchmark tests to determine baseline system performance for routine quality control testing post future repairs, upgrades, or cal checks.
- Discuss implementation strategies for patient specific measurement to determine gamma pass rate of the delivered plan.

Content
During this one-day course, attendees will learn the rationale for VMAT as a treatment technique and the different methods for creating VMAT treatment plans. The course will also cover VMAT delivery, commissioning, and quality assurance for the Elekta medical accelerator as well as advantages and limitations for VMAT as a treatment technique. The application has been made to CAMPEP for 7.75 Medical Physics Continuing Education Credits (MPCEC).
Duration
1 day
Target Audience

- Certified Medical Physicists
- Medical physics students

Prerequisites

- Physics 1: Medical Accelerator Introduction
- Quality Assurance of Elekta Medical Accelerators.

1 **Power Distribution Unit for Elekta® Linear Accelerator - 480 Volt Input**
The PDCU incorporates a transformer, output circuit breakers, filtering for high frequency noise, distortion, and transient pulse suppression, in one cabinet. This reduces site preparation costs and complexity for the customer.

4 **Education & Training Travel Support (4-6 day course)**

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Elekta will provide reasonable and necessary travel to support completion of the Off-Site Education & Training course(s) purchased under this Agreement. This Travel Support includes reasonable and necessary airfare and accommodations booked at least three (3) weeks in advance through Elekta's approved travel agent, proof of course registration at the time of booking is required. Extended airfare and accommodations beyond the duration required to travel and attend the course(s) is not permitted. This Travel Support also includes reasonable and necessary local transportation costs and up to $100 (USD) per person per day to cover reasonable and necessary meals, which will be paid by Elekta directly to Customer (not to Customer employees) upon receipt of invoice, proof of course completion and supporting receipts. This Travel Support is available for up to two (2) years after date of Acceptance, no exceptions permitted. Price - $2,000.00 USD (ea)

1 Elekta will make reasonable endeavors during installation to achieve:

- MV isocenter radius, at 6MV flat, for gantry radiation isocenter of 0.6mm radius; and
- MV isocenter radius, at 6MV flat, for the combined gantry + collimator + treatment table rotation radiation isocenter of 0.75mm radius

Qty	Description
1	

Qty	Description	License Term
1	**MOSAIQ IGRT Connectivity for Elekta** Connectivity kit including the RTD and Elekta delivery platform, interface to Elekta MLC/IMRT, interface to iViewGT electronic portal imaging device and connectivity to the XVI including volumetric imaging.	Perpetual
1	**Connectivity to Elekta VMAT** Support for Elekta VMAT treatment techniques.	Perpetual
1	**SYNERGISTIQ** SYNERGISTIQ integrates MOSAIQ and Elekta IGRT devices into a consolidated and synchronized user interface that brings together, in a coordinated manner, the various systems that are required for Image Guided Radiotherapy.	Perpetual

Qty	Description	License Term
1	**MOSAIQ Setup Intelligence** Image-Guided Treatment Management (IGTM) system that includes support for automated patient set up, image registration and analysis tools to assist the user in evaluating the quality of patient setup based on quantitative comparisons between the reference image and the port film, as well as trend analysis.	Perpetual

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Patient positioning system that includes image registration and analysis tools to assist the user in evaluating the quality of patient setup based on quantitative comparisons between the reference image and the port film, as well as trend analysis.

1	**Upgrade Only - Convert Licenses to 3D Offline Image Assessment**	Perpetual
1	**MOSAIQ On-Site Training - 2 day** On-site training visit by Elekta trainer focusing on agreed-upon goals, format, and agenda.Training duration is 2 business days and is conducted during regular working hours.	NA

Quotation Number: 2017-191944-CB Quotation Date: October 13, 2017 Valid Until: March 31, 2018

SERVICE AGREEMENT

Prepared For:

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This Quotation ("Quote") is an initial non-binding estimate only which is provided for information purposes only and does not constitute an offer capable of acceptance.

Any agreement entered into pursuant to this Quote shall be subject to the Supplier's standard terms and conditions.

The quote is subject to variation caused by product registration, price fluctuation, sanctions, credit checks, compliance, customs and other local regulations, product and resource availability, payment terms and methods, terms of delivery, regulatory clearance, code of conduct, regional geo-political stability amongst others.

The supplier reserves the right not to accept an Order based on any Quote and shall have the right not to disclose the reason for any such refusal.

The supplier is please to submit the following quote for the services, hardware and/or software listed set out below and as more particularly in the attached Scope of Supply (collectively referred to as the "Deliverables").

Products and Product description	Service level	Total list price (in USD)	Discount	Total Service Fee (in USD)
Elekta Infinity™	Gold	$1,388,870.00	28.11 %	$998,500.00

Unless otherwise agreed in writing between the Parties, Third Party Products and consumables are not included in the scope of this Agreement.

The Elekta Care Contract Fee, set forth above does not include the annual maintenance and support service fees for any software previously purchased or licensed by Customer under separate Purchase and License Agreements with Supplier or an Affiliate of Supplier.

Elekta

Quotation Number: 2017-191944-CB

Quotation Date: October 13, 2017 Valid Until March 31, 2018

Scope of Supply

Exhibit A-1

Elekta Care™ Gold for Elekta Oncology - TBD

Annual Hardware Maintenance & Support Fee:	USD	$277,774.00
Discount:		28.11 %
Annual Hardware Maintenance & Support Fee offer price:	USD	$199,700.00
Term in months:		60
Contract Start Date:		Upon expiry of the Warranty period
Total Hardware Maintenance & Support Fee:	USD	$998,500.00
Price is based on invoice schedule:		Annually

Payment Schedule	Periodic Payment		Annual Amount	
Annual Payment (IN ADVANCE)	USD	$199,700.00	USD	$199,700.00
Bi-Annual = 2%	USD	$101,847.00	USD	$203,694.00
Quarterly = 4%	USD	$51,922.00	USD	$207,688.00
Monthly = 6%	USD	$17,640.17	USD	$211,682.00

Service Hours and Response Time

Remote Services accepted:	Yes
Estimated Spare Part Response Time:	Within 24 hours (excluding weekends and holidays)
Estimated Onsite Response Time:	Within 12 working hours (excluding weekends and holidays)
Uptime Guarantee:	97%

Note: the Uptime Guarantee module shall only be applicable if Elekta Remote systems, including IntelliMax, are installed and available for use on the Site and Unique Components Coverage is chosen as a module.

Covered products:

Qty	Part Number	Description	Serial #
1	SO089-Y	Agility™ - Gold	
5	SO014-Y	Electron Energies - Gold	
3	SO003-Y	Photon Energies - Gold	
1	SO098-Y	Response™ - Gold	
1	SO023-Y	Elekta Infinity™ - Gold	
1	SO067-Y	VMAT - Gold	

1	SO069-Y	XVI Imaging - Gold	
1	SO025-Y	iViewGT™ - Gold	

Selected optional services:

Qty	Part Number	Description
1	OO_USPC_THY	Unique Spare Parts Thyratron replacement coverage
1	OO_USPC_MLCC_AG	Unique Spare Parts Coverage Agility Camera
1	OO_USPC_ELG	Unique Spare Parts Electron Gun replacement coverage
1	OO_USPC_IVGTPNL	Unique Spare Parts iViewGT Panel replacement coverage
1	OO_USPC_XVIPNL	Unique Spare Parts XVI Panel replacement coverage
1	OO_USPC_XRAYTB	Unique Spare Parts Xray Tube replacement coverage
1	OO_USPC_IONCMB	Unique Spare Parts Ion Chamber replacement coverage
1	OO_USPC_MAGSTD	Unique Spare Parts Magnetron replacement coverage

Elekta Care™ Gold for Elekta Oncology

Labor and parts coverage		
	Management Service Reviews	•
	Hardware and Software Safety Releases	•
	Genuine Elekta Parts Availability	•
	Spare Parts	•
	Unique Components Coverage	Optional
	Corrective Maintenance (Emergency Support)	•
	Planned Maintenance	•
Software support		
	Software Updates	•
	Software Upgrades	•
System availability		
	Uptime Guarantee	•
	Technical support (Email/Phone)	•
	Application support (telephone)	•
	Technical Information Supply	•
Technology Refresh		
	Technology Refresh	Optional
Remote services		
	Remote Services Technical Online Support	•
	Remote Services Application Online Support	•
	Remote Services Alerts & Notifications	•
	Remote Services Remote Access	Optional
	Remote Services Data Access	Optional
Business services		
	Online Customer Portal (SupportPlus™)	•

Agreed Available Time: In consideration for the Service Fee above the Services shall be provided during the Agreed Available Time, as defined below:

Agreed Available Time consists of Normal Office Hours plus any Agreed Overtime Hours, if any are listed below.
Additional Hours are any hours worked outside of the Agreed Available Time and will be charged at applicable time and material rates.

Note: all times, dates and holidays are those observed by the local Elekta office of the country in which the Site is located.

Normal office hours:

[08:00 - 17:00] Monday to Friday excluding holidays

Agreed available time:

Elekta Infinity™

[08:00 - 21:00] Monday to Friday excluding holidays

End of Life and Guaranteed Support: The supply of Services is subject to the End of Life and End of Guaranteed Support policy as appended in Exhibit C. Any reference to End of Life and End of Guaranteed Support in this Agreement shall be as defined in Exhibit C.

Removed Parts: Any part removed from the Products and replaced by a replacement part by or on behalf of Elekta under this Agreement shall become the property of Elekta upon removal. Elekta shall be free to dispose of or use any removed parts at its discretion.

Exhibit A-2

The following section describes all the Elekta Care™ service modules available. Each section shall only apply where it is specifically referred as an included module in Exhibit A-1.

1. LABOR AND PARTS COVERAGE

1.1 Management Service Reviews
The local Elekta service manager will conduct a periodic management meeting. This will take place either in person or remotely as agreed between the Parties, with the intention of reviewing the performance of both Elekta and the Products, and to mutually plan any activities or changes needed for the period ahead.

1.2 Hardware/Software Safety Releases
The supply, and, where the Customer is unable to do so itself, installation of all software and hardware releases declared by Elekta, via the publication of a mandatory Field Change Order, as necessary to maintain the safe operation of the Products.

1.3 Genuine Elekta Parts Availability
Availability of Unique Elekta product spare parts, Field Replaceable Units or modification kits by Elekta's Lifecycle Stock Control Management System to ensure availability throughout the expected system lifetime.

1.4 Spare Parts
Should any Product or part be defective in material or workmanship and/or does not perform according to the Product's Specifications, Elekta shall supply and deliver at its cost any replacement spare parts necessary to restore compliance with the Specifications. Consumable parts and Unique Components or those parts required to be replaced as part of the planned maintenance are not covered by this module.

Elekta may use refurbished parts and components to replace any defective parts or component.

Customer's rights under this module shall not apply if the Product or part is a Third Party Product or is defective as described above due to (a) accident or negligence or intentional act or omission of customer or customer's representative (b) if the Product or parts have been used or stored in a manner not authorized by Elekta, (c) lack of routine care or maintenance as indicated by Elekta, (d) modification of the Product not performed by a certified Elekta engineer, (e) the Product or part being declared End of Guaranteed Support or End of Life.

1.5 Unique Components Coverage
Unique Components are spare parts not covered under the general Spare Parts Module. The same terms as applicable to the Spare Parts module above are applicable to this module. This module shall only apply if the Service Agreement is for a minimum duration of 3 years or has been in existence and renewed in the 3 years preceding the replacement of the Unique Component.

The Unique Components are:

- All Imaging panels
- All X-Ray Tubes
- All Ion Chambers
- All MLC Cameras
- All Magnetrons
- All Thyratrons
- All Image Intensifiers
- All Electron Guns

1.6 Corrective Maintenance (Emergency Support)
On-site technical support by Elekta-certified engineers to resolve urgent technical issues.

The service includes a report detailing any actions undertaken and any additional work the engineer recommends needs to be addressed.

Emergency Support is carried out during the Agreed Available Time. Any activity undertaken by Elekta engineers outside of the Agreed Available Time will be charged at applicable overtime rates.

The response time to guarantee an on-site visit is as specified in exhibit A-1 of this Agreement.

Any spare parts needed for the repair are not included in this option. Inclusion of travel time and costs are only included if specifically agreed between the Parties in writing.

1.7 Planned Maintenance
Elekta shall perform site visits for the purposes of planned maintenance ("PM"). The number and duration of the visits required shall vary according to the products covered and will be in accordance with the Elekta planned maintenance schedules published at the time.

Unless specifically agreed otherwise, all planned maintenance will be carried out during Normal Office Hours.

Elekta will make available the recommended schedule including the duration of visits, time between visits and general scope of work at the beginning of each agreement year. Mutually convenient dates will then be agreed upon between Elekta and the Customer. Should additional work be required over the agreed planned activity, this will be charged at Elekta's current rates.

The cost of supply of spare parts or consumables other than those identified by Elekta as being part of the standard planned maintenance and found to be required during the planned visits are not included in this module.

Elekta shall issue a report detailing the actions undertaken during the planned maintenance visits and any additional recommended work.

2. SOFTWARE SUPPORT

There are various possible Software Support modules depending on your selected service agreement level: Software Updates, Software Upgrades and New Licensable Software, as defined below. To each module, the "General Conditions" below shall apply.

2.1 Software Updates

Updates are minor improvements, patches, or service pack releases to a version of software, but do not upgrade the software to the next major version (if one exists).

2.2 Software Upgrades

Upgrades are major software releases of feature enhancements and performance improvements to existing licensed software functionality. This option does not cover the transition onto alternative or next generation platforms.

2.3 General Conditions

Updates/Upgrades do not include the supply of any new licensed software modules should they exist in the Update or Upgrade being provided.

Updates/Upgrades/New Licensable Software may only be installed as part of this module if the customer is on the most current software release at the time this Agreement is entered into.

Updates/Upgrades/New Licensable Software installation will be scheduled at times convenient to both the Customer and Elekta, but within Normal Office Hours. The responsibility for installation may be that of Elekta or Customer, depending which Software is being installed.

The supply and/or installation of any necessary hardware or software to run any Updates/Upgrades/New Licensable Software is not included, unless required by local laws or regulations, or if the Update/Upgrade/New Licensable Software falls within the description of the Hardware/Software Safety Releases module, in which case the provisions of the Hardware/Software Safety Release module apply.

The Customer shall ensure adequate personnel are present on Site at the time of (remote) installation to assist with the installation of the Updates/Upgrades/New Licensable Software. Elekta may install the Updates/Upgrades/New Licensable Software remotely, in which case the Customer shall give Elekta sufficient access to the relevant systems and Products.

On-site training is not included, unless specifically agreed otherwise, for Updates and Upgrades. The duration of any training and whether this is performed remotely or on site will depend upon the specific features and will be agreed between the Parties. On-site application training for the new features (New Licensable Software) is included and shall take place at the time of installation.

3. SYSTEM AVAILABILITY

3.1 Uptime Guarantee

Elekta hereby guarantees that the Hardware will achieve an annual Uptime listed in the Scope of Supply for the duration of this Agreement.

Uptime statistics will be evaluated for each successive twelve (12) month period from the Effective Date ("Contract Year").

Uptime percentage will be calculated using the following formula:

$$\text{UPTIME} = \frac{\text{Agreed Available Time - Downtime}}{\text{Agreed Available Time}}$$

For the purposes of the Uptime calculation, Agreed Available Time shall be as noted in the Scope of Supply and shall exclude time set aside by the customer or in mutual agreement between the customer and Elekta for planned activities such as planned maintenance, system modifications, improvements and/or updates or customer-initiated treatment shutdowns.

Downtime with the exclusions set out below, means the aggregate hours within the Agreed Available Time during a Contract Year, when the Product(s) are inoperable solely due to system failure in the Product(s) which, as a result thereof, cannot be used for patient treatment. For the avoidance of a doubt, if a specific system component is inoperable but a patient can still be treated, the Product(s) will be classified as degraded and not constitute Downtime.

Downtime begins when a Customer calls Elekta Care Support during the Agreed Available Time notifying that, due to an unplanned event, the Customer is no longer able to treat patients and the Product(s) is available for immediate servicing. Downtime continues until repair has been completed and the Elekta engineer returns access to the Product(s) back to the customer for them to initiate QA procedures and thereafter allow clinical use to recommence. Start and end of Downtime shall be as documented within the Elekta service management system.

Any repair time or inoperability that occurs outside the Agreed Available Time is excluded from the Downtime calculation.

All system failures, damage or malfunction of the Product(s) caused by the Customer or a third party either through act or failure to act (e.g. through misuse, operator error) or by breach of the Customer's undertakings under the Agreement (including failure to act according to manuals and handbooks) or by external causes beyond Elekta's control (e.g. power failure or failure of environmental systems) are excluded from the downtime calculation.

Where applicable, enabled Remote Services and Unique Component Coverage, as defined in this Agreement, are pre-requisites for any uptime guarantee commitment.

If the Hardware fails to achieve the specific Uptime criteria on average over a Contract Year, then Customer shall benefit from a discount, applicable to the agreed service for the applicable Product for the Contract Year following that in which the Uptime has not been met. This discount shall be the sole and exclusive remedy for any failure to meet the Uptime Guarantee.

Percentage Uptime		Elekta Care					
From	To	Platinum LGK	Gold LGK	Platinum Linac	Gold Linac	Platinum Brachy	Gold Brachy
99	100	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
98	99	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
97	98	5.0%	0.0%	2.0%	0.0%	2.0%	0.0%
96	97	10.0%	0.0%	3.0%	3.0%	3.0%	3.0%
95	96	20.0%	0.0%	4.0%	4.0%	4.0%	4.0%
94	95	50.0%	20.0%	5.0%	5.0%	5.0%	5.0%
93	94	50.0%	30.0%	6.0%	6.0%	6.0%	6.0%
92	93	50.0%	40.0%	7.0%	7.0%	7.0%	7.0%
91	92	50.0%	50.0%	8.0%	8.0%	8.0%	8.0%
90	91	50.0%	50.0%	9.0%	9.0%	9.0%	9.0%
< 90	90	50.0%	50.0%	10.0%	10.0%	10.0%	10.0%

3.2 Technical Support - Email/Phone
Access to the Elekta Care Support line or an Elekta Care representative, providing technical assistance and advice to ensure optimal system uptime.

Access to Elekta Care Support is provided during Normal Office Hours only.

3.3 Application Support - Telephone
Direct access to the Elekta Care Support line, providing clinical and applications expertise to ensure optimal use of the system.

Access to Elekta Care Support is provided during Normal Office Hours only.

3.4 Technical Information Supply
Includes provision of technical information and bulletins designed to keep the Customer up-to-date with regards to the covered products.

Typical information includes, but is not limited to:
- Current and pending software updates & upgrades,
- Upcoming events and training opportunities,
- Important service announcements.

4. REMOTE SERVICES
In order to benefit from Remote Services and to ensure uptime guarantees, equipment must be connected to an IntelliMax Agent where available or WebEx where Elekta IntelliMax™ is not available.

IntelliMax Agent software is installed on a standalone workstation or virtual machine. The IntelliMax Agent communicates with applicable products and acts as a gateway to the IntelliMax Enterprise (outbound via the internet). For more information see Elekta IntelliMax Security Information, available from your Elekta representative.

Should remote access to the desktop of the device be reasonably necessary, IntelliMax Connect allows for either attended (mandatory for treatment machines) or unattended access (configurable during installation for software systems). Access via Elekta IntelliMax, and details of any files transferred are recorded in an audit log which is available on upon request for a period of 12 months after the transfer.

Customer acknowledges and agrees that notwithstanding the provisions contained in Customers Elekta Purchase and License Agreement, Elekta shall have the ability to remotely monitor Elekta supplied systems on the Customers network via Elekta IntelliMax™ to gain information and aid in diagnosis and correction of system issues. Remote Access/screen sharing, if permitted, is configurable separately and can be set to only allow visibility of the customer's screens when initiated by the customer.

4.1 Remote Services Technical Online Support
Secure remote access and phone communication for quick problem resolution, pre-checks prior to on-site visits and over the shoulder support.

This option is a prerequisite for any Uptime Guarantee unless otherwise agreed.

Technical Online Support is only available during Normal Office Hours.

4.2 Remote Services Application Online Support
Secure controlled remote access and phone communication for guided application advice to safeguard clinical availability and enable refresher training.

Applications Online Support is only available during Normal Office Hours.

4.3 Remote Services Alerts and Notifications
The ability to receive e-mail of system failures or recommended pre-emptive actions before problems occur.

Alerts and Notifications are available at any time when the Elekta system is running and connected to Elekta IntelliMax™.

5. BUSINESS SERVICES

5.1 Online Customer Portal (Support Plus)
Access to the Elekta Customer Portal providing a range of useful system and product information.

Information on the portal changes all the time, but typically includes:

- Proactive & preventive information and articles
- Frequently Asked Questions
- Knowledge bases
- Documentation
- Useful training information

Attachment D

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: Carolinas Healthcare System – Cleveland Linear Accelerator Replacement

Provider/Company:

(1)	Purchase price of land	0
(2)	Closing costs	0
(3)	Site Preparation	0
(4)	Construction/Renovation Contract	$482,717
(5)	Landscaping	0
(6)	Architect/Engineering Fees	$64,500
(7)	Medical Equipment	$1,814,481
(8)	Non Medical Equipment	0
(9)	Furniture	$3,000
(10)	Consultant Fees (CON Fees, Legal Fees, Design Fees)	0
(11)	Financing Costs	0
(12)	Interest During Construction	0
(13)	Other (IS, Security, Internal Allocation)	$395,302
(14)	**Total Capital Cost**	$2,760,000

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

2/5/18

(Signature of Licensed Architect or Engineer) *DATE*

PAUL DAMIAN HUNEYCUTT REGISTERED ARCHITECT 11241 NORTH CAROLINA CHARLOTTE, N.C.

Sales taxes have been included in these equipment costs. However, because CHS is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that CHS initially incurs for this medical equipment purchase will be refunded to CHS, and thus will reduce the capital costs that CHS actually incurs for the equipment by $122,657.

February 5, 2018

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

Re: Carolinas Healthcare System – Cleveland Linear Accelerator Replacement
Shelby, NC

Chief Frisone,

Having worked with Carolinas HealthCare System to develop the design for the referenced project, Wright McGraw Beyer Architects, p.a. is pleased to provide the cost certification letter. The probable cost is based on the drawings included with the CON submittal. The estimated construction cost reflects our experience with similar healthcare project. Wright McGraw Beyer Architects, p.a. certifies to the best of our knowledge the construction cost **of $482,717.00**

Please call me if you have any questions or comments.

Sincerely,

Wright McGraw Beyer Architects, p.a.

Damian Huneycutt, AIA
Principal, Studio Director
North Carolina License #11241

2105 Water Ridge Parkway Suite 450
Charlotte, NC 28217
704.535.6374
www.wmba.net

Attachment E

STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Facility Services

CERTIFICATE OF NEED
for
Project Identification Number C-6374-01
FID# 953106

ISSUED TO: **Cleveland Regional Medical Center**
201 Grover Street
Shelby, NC 28150-3315

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

SCOPE: **Cleveland Regional Medical Center/Acquisition of radiation therapy treatment equipment which includes a replacement linear accelerator and a replacement simulator unit; construction of a linear accelerator vault and an oncology waiting room; and renovation of existing hospital space for radiation therapy clinical and administrative offices and the radiation therapy simulator/Cleveland County**

CONDITIONS: **See Reverse Side**

PHYSICAL LOCATION: **Cleveland Regional Medical**
201 Grover Street, Shelby, NC 28150-3315

MAXIMUM CAPITAL EXPENDITURE: **$5,059,667.00**

TIMETABLE: **See Reverse Side**

FIRST PROGRESS REPORT DUE: **July 30, 2002**

This certificate is effective as of the 24th day of July, 2001.

Lee B. Hoffman

Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS:

1. Cleveland Memorial Hospital, Inc. shall materially comply with all representations made in its certificate of need application.

2. Cleveland Memorial Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.

3. Cleveland Memorial Hospital, Inc. shall not perform any general diagnostic computed tomography (CT) procedures on the CT Scanner Simulation System.

4. Prior to the issuance of the certificate of need, Cleveland Regional Medical Center shall provide to the Certificate of Need Section, the fair market value of each piece of radiation therapy equipment, simulator, and other related equipment it proposes to acquire.

5. Prior to the issuance of the certificate of need, Cleveland Memorial Hospital, Inc. shall acknowledge in writing to the CON Section acceptance and compliance with all conditions stated herein.

A letter acknowledging acceptance and compliance with all conditions stated in the conditional approval letter was received by the CON Section on July 10, 2001.

TIMETABLE:

Completion of final drawings and specifications	August 10, 2001
Approval of final drawings and specifications by Construction Section, DFS	October 10, 2001
Ordering Equipment	June 10, 2002
Contract Award	June 11, 2002
25% completion of construction	July 30, 2002
50% completion of construction	September 11, 2002
75% completion of construction	October 30, 2002
Completion of construction	December 11, 2002
Arrival of Equipment	November 1, 2002
Operation of Equipment	December 1, 2002
Offering Service	December 18, 2002

Attachment F

Elekta

Elekta Infinity™

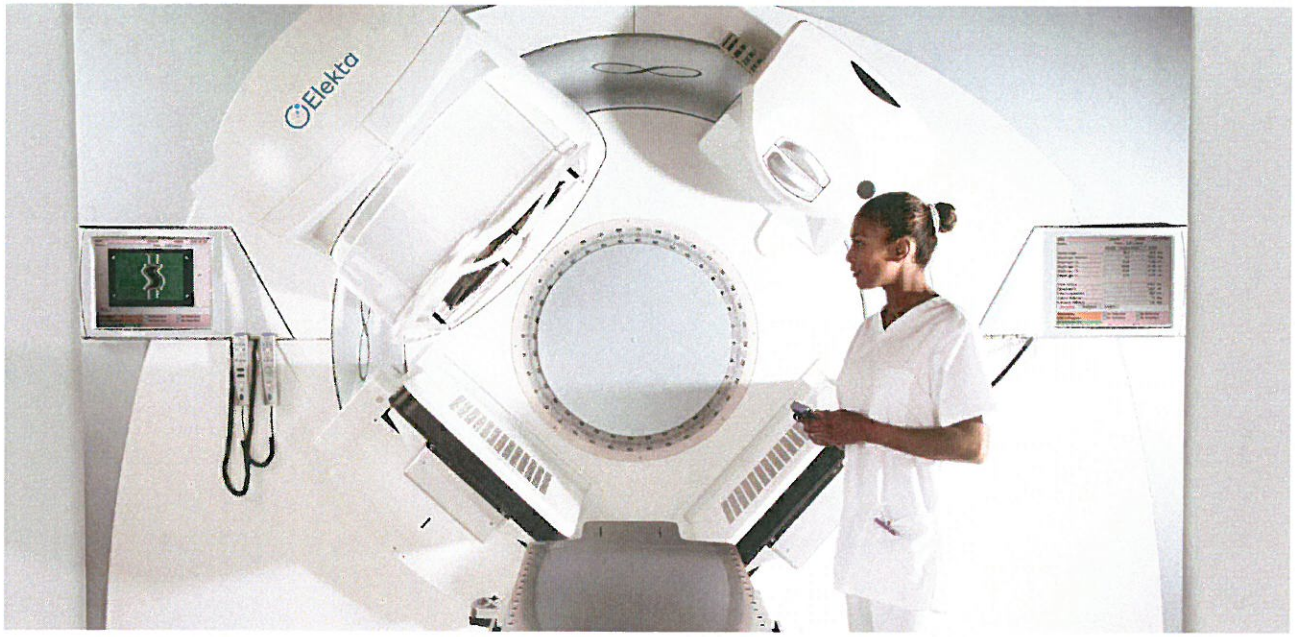
Digital accelerator for advanced treatments

Redefining treatment precision, speed and control

Confidence

to increase conformance and speed without compromising target coverage

Set yourself apart with comprehensive radiation therapy treatment capabilities from Elekta, the innovator in oncology solutions. Built on market-proven, seventh generation digital technology, Elekta Infinity™ redefines treatment precision, speed and control. It is a fully integrated treatment system that allows you to personalize your imaging and treatment workflows. For your patients, Elekta Infinity delivers precision dose conformance, fast treatment speed and ultra-low dose safeguards. For your treatment team, this highly responsive, intuitive treatment system frees you to focus on patients and benefit from efficient workflow. Using Elekta Infinity, the freedom to deliver superior treatment results is now in your hands.



Why Elekta Infinity?

- Volumetric intensity modulated arc therapy (VMAT) delivery with single or multiple arcs for efficient dose distributions
- Improve conformance and speed without compromising target coverage
- Advanced 2D, 3D and 4D imaging solutions
- Large field volumetric imaging with sophisticated guidance tools
- Scalability for easy migration to next-generation treatment planning systems
- Seventh generation integrated digital control system with proven performance and safety
- Real-time assurance that the intended dose is delivered as precisely as it was planned

"Treatment was delivered perfectly with Elekta Infinity. I can tell you the therapists were absolutely thrilled and immediately had numerous recommendations of patients they thought would benefit from VMAT, and that was based primarily on the time efficiency of delivery."

David R. Asche, MS Director of Physics and Engineering,
RAS Radiation Oncology Centers Sacramento, CA USA

Outstanding flexibility

Elekta Infinity™ with VMAT gives you the flexibility to dynamically control multiple treatment parameters while the beam is on and rotating. For the first time, you can tailor treatment plans to optimize dose to the tumor and spare surrounding healthy tissue. Elekta Infinity can optimize the accuracy and speed of delivery by simultaneously manipulating the gantry position, gantry speed, MLC leaves, dose rate and collimator angle.

See Before Treating

Elekta VolumeView™ imaging is integrated into Elekta Infinity, enabling you to routinely confirm target and organ at risk positions immediately before treatment. Elekta X-ray volumetric imaging (XVI) enables you to routinely confirm size, shape and position of the target volume compared to plan, as well as the position of critical adjacent structures.

Choose Your Approach

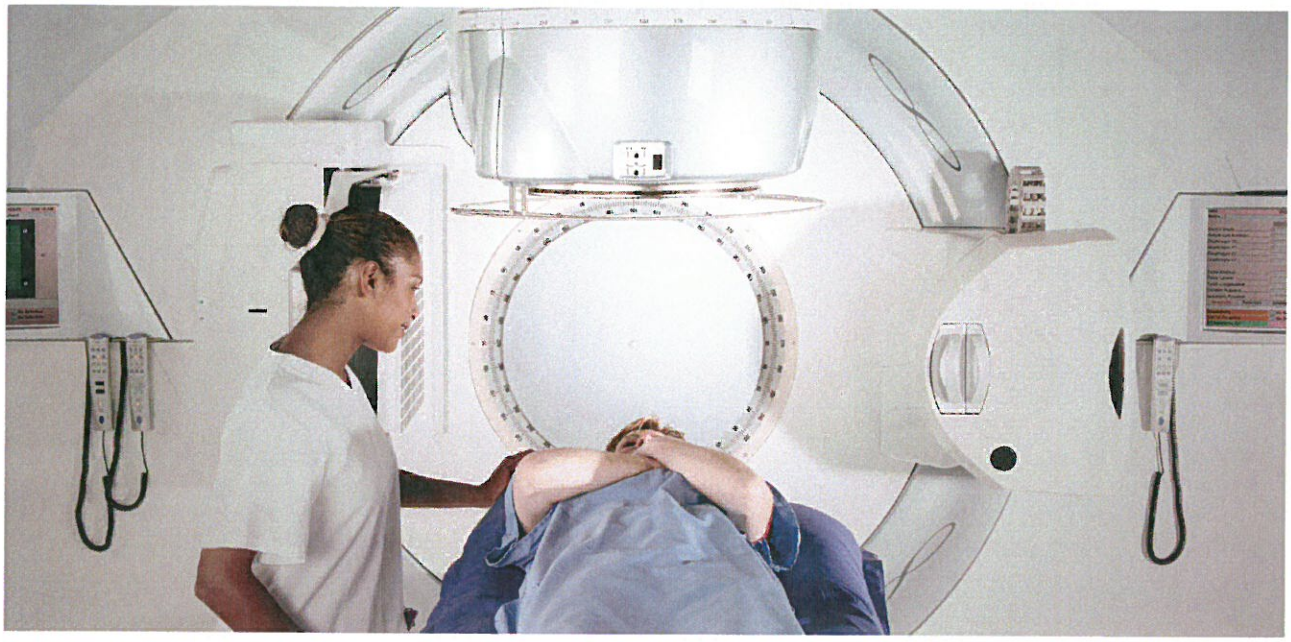
Elekta Infinity offers you a choice – use a single arc or choose multiple arcs to optimize the VMAT plan. For many cases a single-arc VMAT plan may be sufficient to achieve the desired dose distribution. For complex anatomical sites a multiple-arc VMAT plan can deliver superior target coverage while sparing healthy tissue and adjacent critical structures. The clinical advantages of either multiple- or single-arc VMAT deliveries are enhanced by the use of non-coplanar treatment techniques.

Less Overall Radiation

Elekta Infinity with VMAT requires significantly fewer MUs than conventional techniques, reducing total MU delivery by up to 50%. VolumeView™ imaging also delivers high precision localization at ultra-low doses, allowing you to confidently image every day without fear of unnecessary risk to patients.

"Elekta Infinity will give us a competitive advantage over other centers in our area, additionally, the ability to treat with the highest degree of accuracy will benefit our patients tremendously."

Kyle Antes, MS Director and Chief Physicist,
Presbyterian Cancer Center, Dallas, TX, USA



More quality time

The less time a patient spends on the treatment table, the better. Shorter treatment times not only improve patient comfort, but also reduce the inaccuracies resulting from patient movement during treatment delivery – speed is an essential element of accurate treatment.

Totally Targeted Minutes

Elekta Infinity™ dramatically reduces treatment delivery time – to less than two minutes in some cases and with integrated imaging and highly conformal VMAT delivery, you can perform most treatment sessions in five minutes or less.

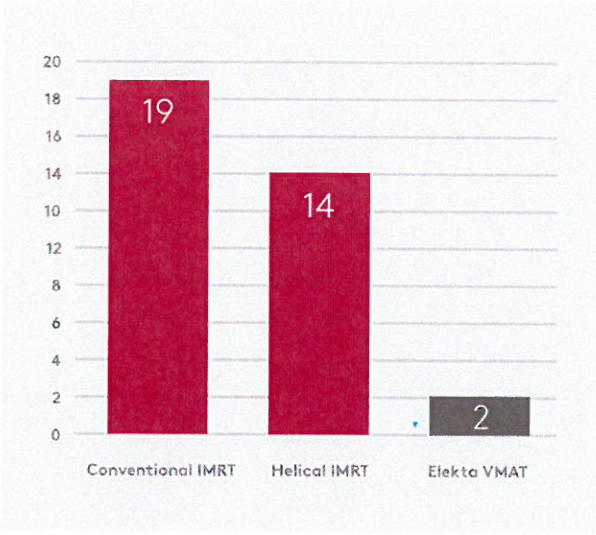
Fast and Accurate

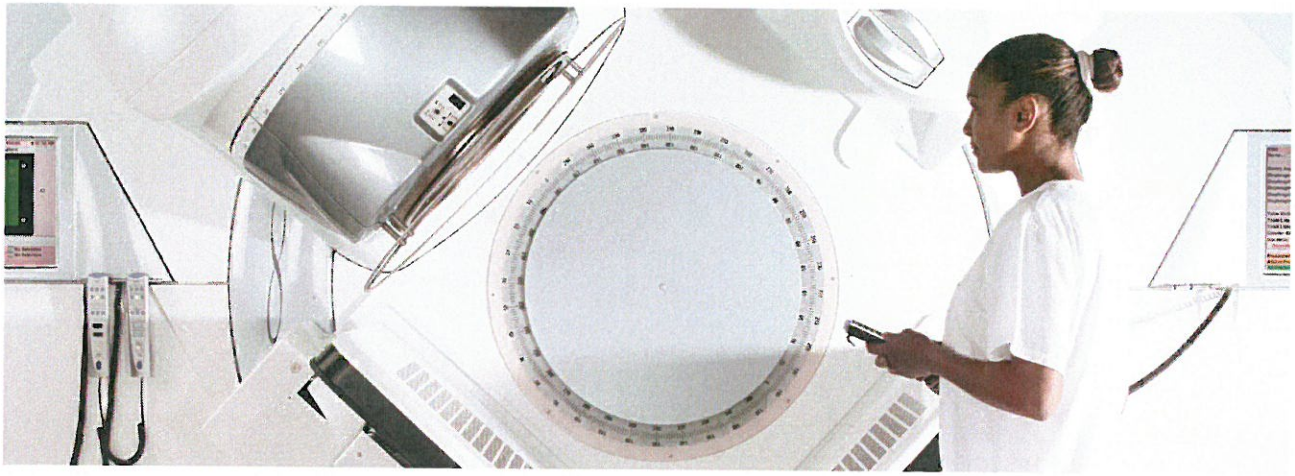
Volumetric imaging delivers high-quality images at ultra-low doses, so you can quickly and confidently image every day before treatment. In three minutes or less, you can verify patient position, pinpoint the target and visualize adjacent critical structures. With quick, efficient treatment delivery, patients are less likely to move, which improves accuracy while limiting the whole-body dose of radiation they receive over time.

More Flexible Time

Reducing the time each patient spends in the treatment room increases the opportunity to treat more patients per day. Elekta Infinity gives you the opportunity to bring flexibility to your clinical schedule.

Typical complex treatment time (minutes)





Every step enhanced

With ultra-low dose and rapid beam shaping, Elekta Infinity™ delivers radiation only where you place it. Elekta Infinity protects patients with real-time, point-to-point monitoring. You can be confident of safeguarding surrounding tissue and reducing the risks associated with radiation. Elekta has always focused on optimizing every step of the care process so that you can focus on what matters most - patient care.

Above All Else – Safety

The integrated beam shaping of Infinity is designed for the needs of modern treatment techniques such as VMAT. It limits interleaf and overall patient plane leakage for lower dose volumes to critical structures. In addition, advanced digital monitoring technology in the Elekta Infinity control system constantly tracks all delivery parameters during treatment. Combined with completely machine-independent verification through MOSAIQ® image-integrated oncology information system (OIS), you can be confident that treatments are delivered exactly as planned.

On Time – Not Overtime

The speed and precision of Elekta Infinity help you complete scheduled treatments on time. All imaging, planning, treatment and OIS capabilities are integrated with Elekta Infinity, enabling your team to quickly and easily move from one step to the next. A built-in workflow manager streamlines treatment sessions, enabling everyone on your team to focus on the patient and treatment – instead of the technology. Now you can go home on time and minimize overtime requirements.

Integrated from Start to Finish

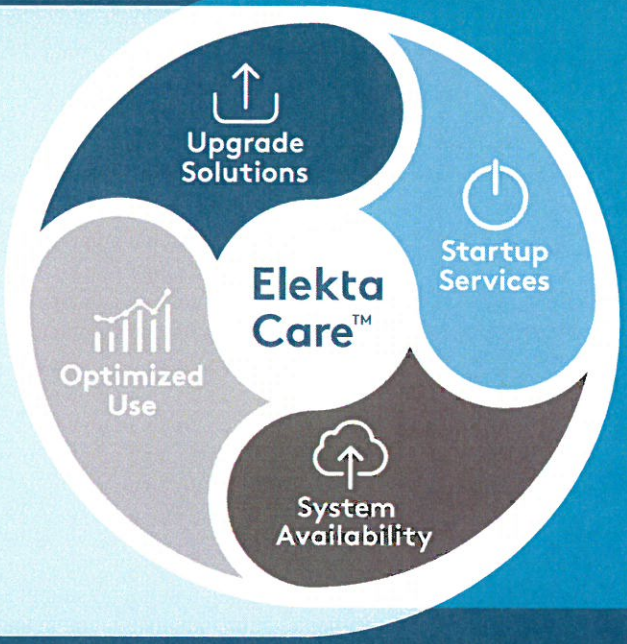
The powerful OIS fully integrates workflow for the entire clinical and administrative staff. This includes comprehensive EMR systems that facilitate communication, increase productivity and elevate efficiency to an entirely new level – from start to finish.

"We have found that for complex cases the use of multiple arcs allows us to achieve a more uniform dose in the target and enables improved sparing of critical structures."

David Shepard PhD, Director of Medical Physics,
Swedish Cancer Institute Seattle, Washington

Elekta Care™

Elekta Care is designed to help you maximize the use of your Elekta technology, so you can focus on your patients and your practice.



Professional Services

Service & Support

Elekta Care™ supports you from startup through your product's lifecycle with comprehensive options from education, training and upgrades to solutions allowing you the highest uptime and improved operational efficiency.

To learn more, visit
elekta.com/elektacare

We are healthcare technology innovators, specializing in radiotherapy treatments for cancer and brain disorders.

We help clinicians to improve patients' lives through our forward-thinking treatment solutions and oncology informatics, creating focus where it matters to achieve better outcomes.

Elekta

Elekta Offices

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Art. No. LPCINF170901 v1.0

Attachment G

2018 CHS Cleveland Linac Replacement
EQUIPMENT COMPARISON

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Elekta Precise	Elekta Infinity
Tesla Rating for MRIs	N/A	N/A
Model Number	MRT 6001	
Serial Number	105925	Build not begun
Provider's Method of Identifying Equipment	Serial Number	Serial Number
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	August 2003	2018
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	$5,168,152	$2,760,000
Total Cost of Equipment	$1,441,960	$1,814,481
Fair Market Value of Equipment	$10,000	$1,814,481
Net Purchase Price of Equipment	$1,441,960	$1,814,481
Locations Where Operated	Carolinas HealthCare System Cleveland	Carolinas HealthCare System Cleveland
Number Days in Use/To Be Used in N.C. per Year	253	253
Percent of Change in Patient Charges (by procedure)	No change	No change
Percent of Change in Per Procedure Operating Expenses (by procedure)	No change	No change
Type of Procedures Currently Performed on Existing Equipment	External Beam radiotherapy	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	External Beam radiotherapy

Attachment H

2017 CHS Cleveland	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
Linac Procedures	394	463	389	319	523	493	462	407	426	520	362	382	5,140

Attachment I

Equipment:
Letter of Intent

November 30, 2017

To whom it may concern,

Thank you for your consideration and trust in RS&A as a service partner through the years. This letter is to notify of the disposition of the Elekta Precise linear accelerator (S/N: 105925), located at:

Levine Cancer Institute – Cleveland
201 E Grover St
Shelby, NC 28150

This accelerator will be removed and taken possession by:

RS&A Inc.
465 Forum Parkway
Rural Hall, NC 27045

In accordance with this removal, RS&A assures that this unit will not be reinstalled to a CON location in North Carolina. Let us know if you have any questions and looking forward to seeing you again soon.

David Stith
Director, Equipment Services
RS&A Inc.