NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

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

VIA EMAIL ONLY

December 19, 2023

Elizabeth V. Kirkman
Elizabeth.Kirkman@atriumhealth.org

Exempt from Review – Replacement Equipment

Record #:	**4334**
Date of Request:	December 6, 2023
Facility Name:	Carolinas Medical Center
FID #:	943070
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace a linear accelerator on the main campus
County:	Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(f)(1)-(3). Therefore, you may proceed to acquire without a certificate of need the Varian Tru Beam linear accelerator to replace the Varian Novalis Tx linear accelerator, serial # H294573. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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.

Sincerely,

Gloria C. Hale

For Julie M. Faenza
Project Analyst

Micheala Mitchell

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR
Construction Section, DHSR

December 5, 2023

Ms. Micheala Mitchell, 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: Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center to Replace Linear Accelerator Equipment

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Carolinas Medical Center ("CMC") seeks to acquire a Varian Tru Beam linear accelerator ("Replacement Equipment") to replace an existing Varian Novalis Tx linear accelerator ("Existing Equipment") that was installed in 2010 and is at the end of its useful life. The Existing Equipment is currently housed in room 1507 on the first floor of the Levine Cancer Institute building located on the main campus of CMC at 1021 Morehead Medical Drive in Charlotte, NC (see Attachment A).

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC'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 three million dollars ($3,000,000) 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. In determining whether the replacement equipment costs less than three million dollars ($3,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement 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. Beginning September 30, 2023, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.

See N.C. Gen. Stat. 131E-176(22a). Under the 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 monetary threshold[1] set forth in G.S. 131E-176(22a) 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 housed in room 1507 on the first floor of the Levine Cancer Institute building located on the main campus of CMC, which is the site from which CMC provides clinical patient services and exercises financial and administrative control over the entire facility (see Attachment A). CMC's Facility Executive's office is located on the second floor of the main hospital building. Please find a copy of CMC's license in Attachment B.

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." CMC's proposal qualifies for this exemption.

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

The purchase price of the Replacement Equipment is $3,308,068 ($2,570,328 linear accelerator + $513,465 ancillary equipment + $224,275 tax/freight). The quote for the Replacement Equipment is provided in Attachment C. The projected total capital cost of the project is $5,000,000 (including taxes and freight) and includes the removal of the existing equipment and installation of the Replacement Equipment. The total capital cost for the proposed project is provided in Attachment D.

[1]The current monetary threshold for replacement equipment is $2,971,200

B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located in room 1507 on the first floor of the Levine Cancer Institute building located on the main campus of CMC at 1021 Morehead Medical Drive in Charlotte, NC. The Replacement Equipment will also be located in room 1507 (see Attachment A).

C. Certificate of Need Issued for Equipment Being Replaced

This proposal also fits within the exemption criterion in Section 131E-184(f)(2) because the Department previously provided CON approval for the Existing Equipment. Pursuant to CON Project ID #F-8045-08, CMC was approved to relocate two of its existing linear accelerators, one of which was to be replaced. In the CON application for Project ID #F-8045-08, it was identified that an existing Novalis Radiosurgery System would be replaced with a Varian Novalis Tx linear accelerator. The Varian Novalis Tx linear accelerator, which was installed in 2010, is the Existing Equipment in this exemption request. Please find a copy of the certificate for Project ID #F-8045-08 in Attachment E.

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.

CMC intends to use the Replacement Equipment for substantially the same linear accelerator procedures for which it currently uses the Existing Equipment. The Existing Equipment is a Varian Novalis Tx linear accelerator that has been used to provide external beam radiotherapy since its installation in 2010.

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

Furthermore, CMC does not intend to increase patient charges or per procedure operating expenses more than 10 percent 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, CMC represents the use of the Replacement Equipment will not result in an expense or charge increase greater than 10 percent within the first 12 months after acquisition as described in Subsection (d)(3).

Documentation provided in Attachment H indicates that 5,000 procedures were performed from November 2022 to October 2023 on the Existing Equipment.

E. Disposition of Equipment

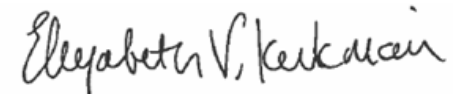
Please see Attachment I for a letter documenting the Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

CONCLUSION:

Based on the foregoing information, CMC 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
Assistant Vice President
Core Market Growth Business Development
Atrium Health

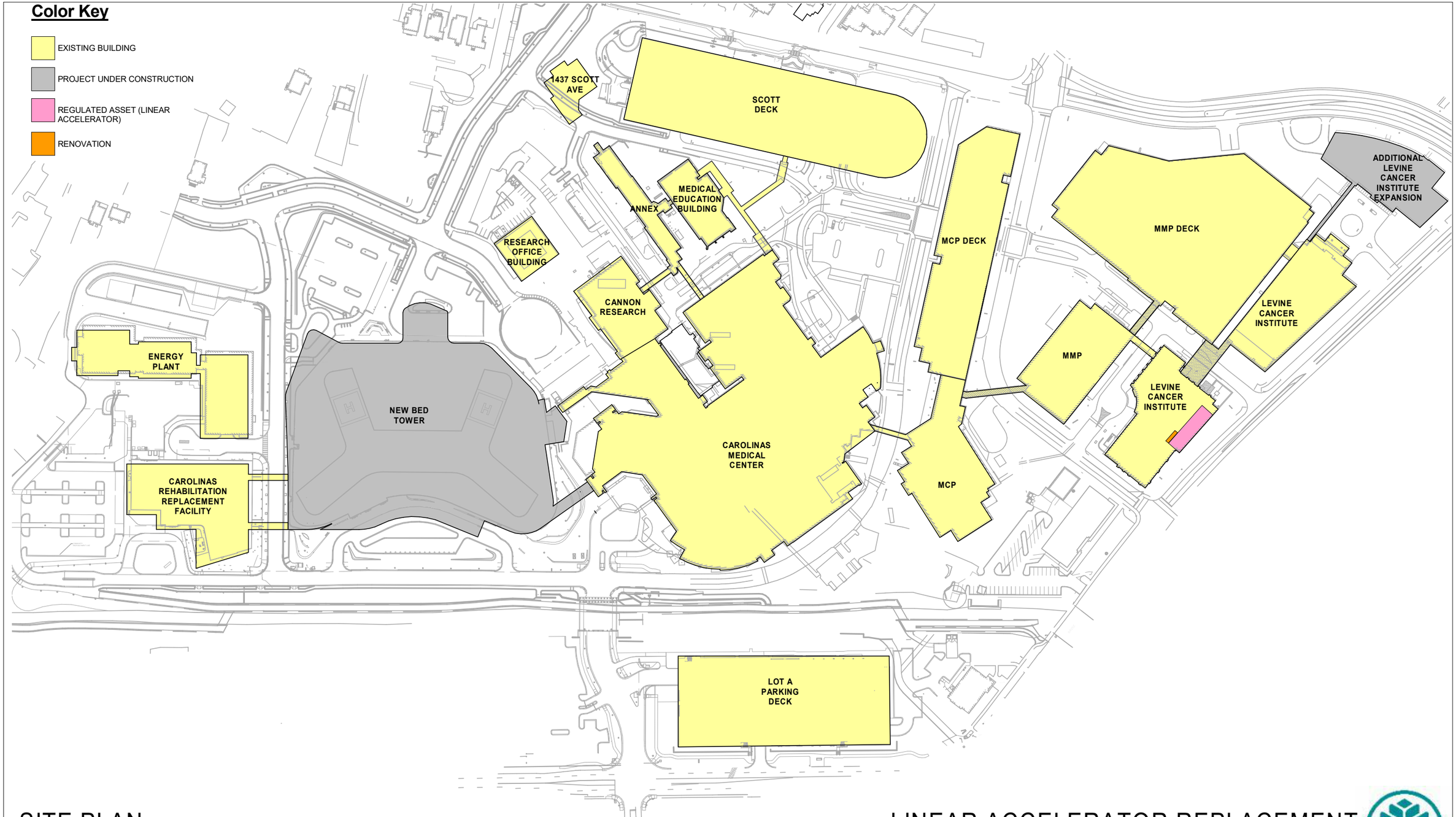
Attachments

cc: Chan Roush, Vice President and Facility Executive, Carolinas Medical Center

Attachment A

Color Key

- EXISTING BUILDING
- PROJECT UNDER CONSTRUCTION
- REGULATED ASSET (LINEAR ACCELERATOR)
- RENOVATION



SITE PLAN

LINEAR ACCELERATOR REPLACEMENT

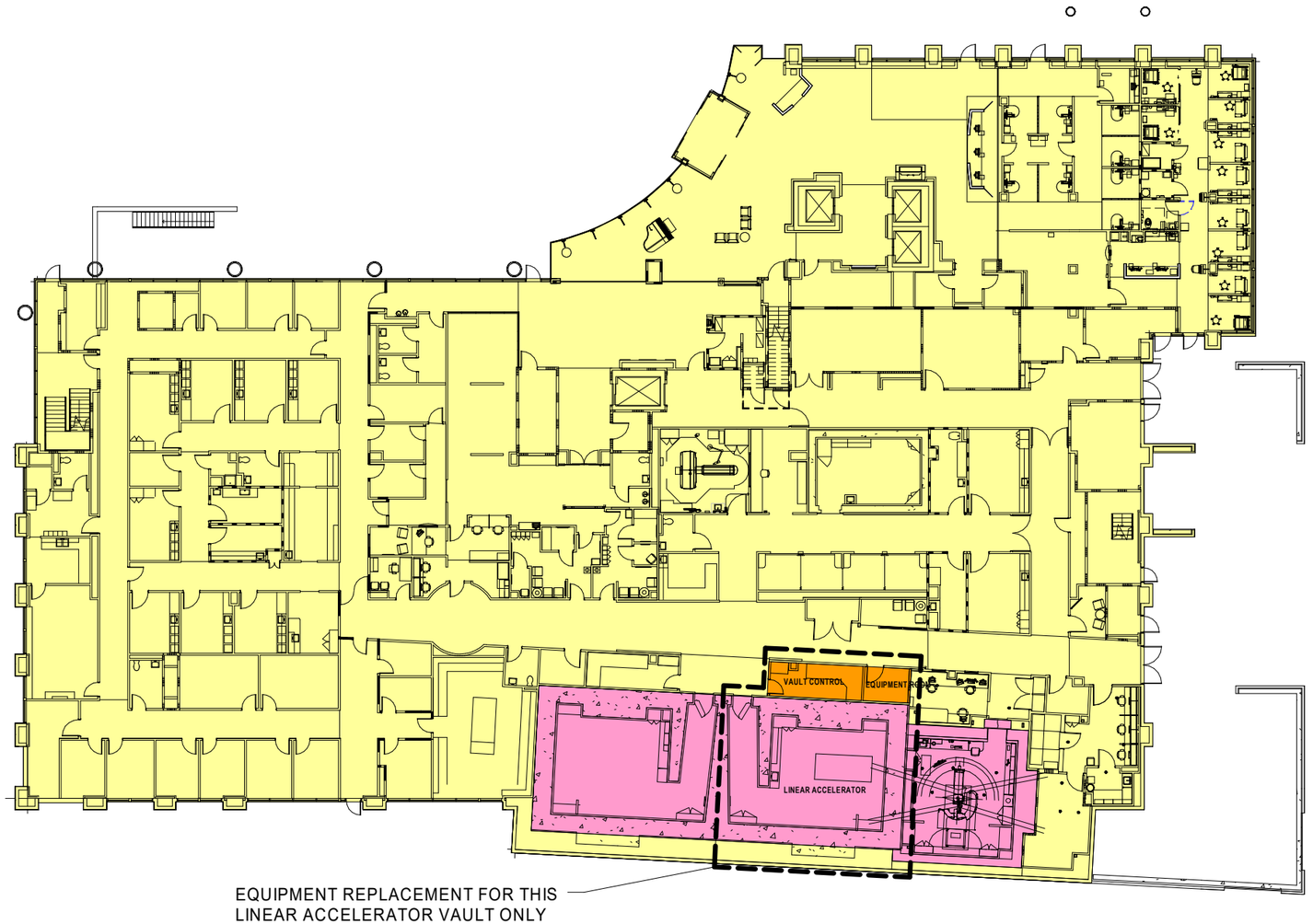
Atrium Health

10/09/23

CAROLINAS MEDICAL CENTER

Color Key

- EXISTING BUILDING
- REGULATED ASSET (LINEAR ACCELERATOR)
- RENOVATION



EQUIPMENT REPLACEMENT FOR THIS
LINEAR ACCELERATOR VAULT ONLY

EXISTING LEVEL 01 PLAN

LINEAR ACCELERATOR REPLACEMENT

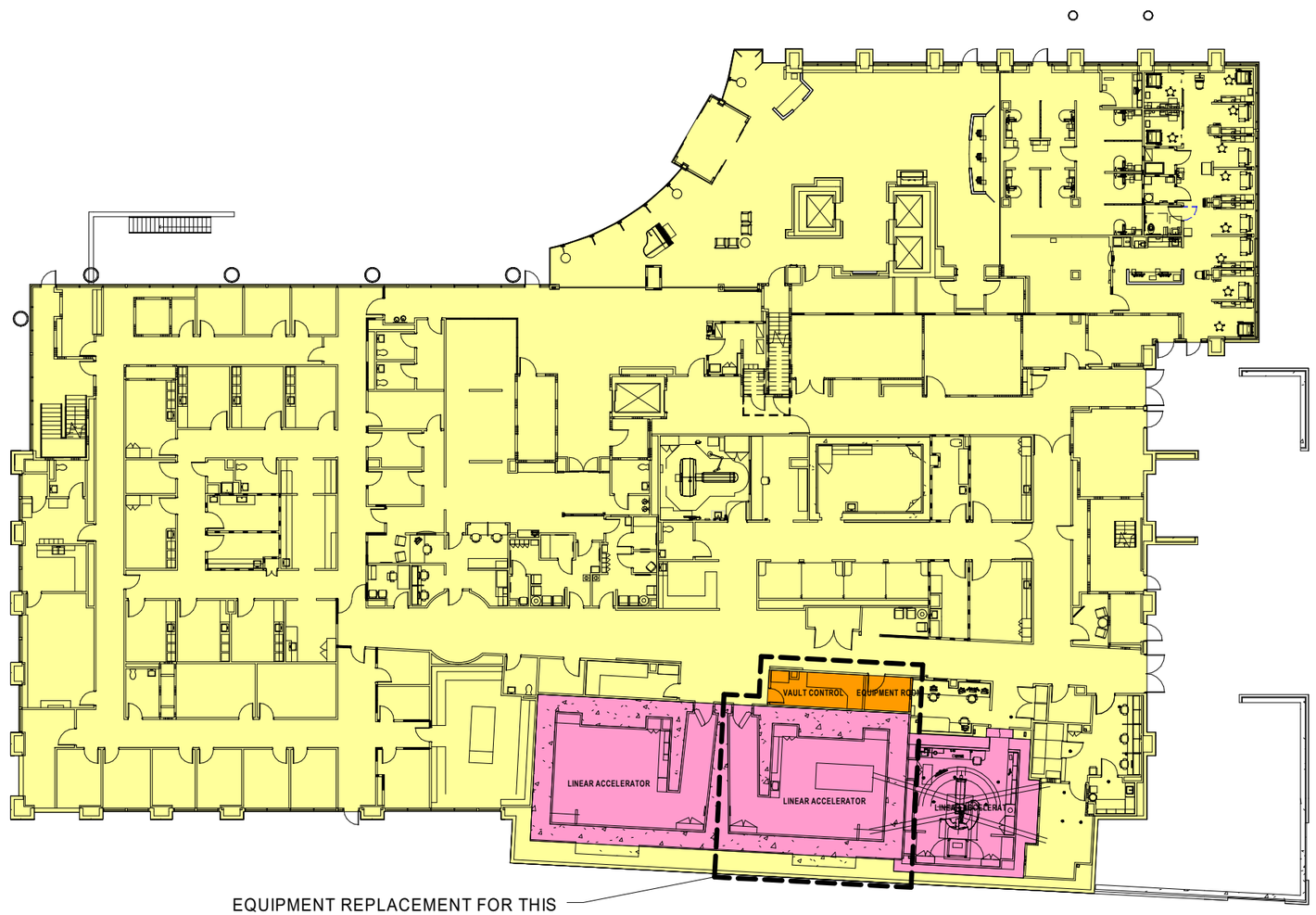
Atrium Health

10/09/23

CAROLINAS MEDICAL CENTER

Color Key

- EXISTING BUILDING
- REGULATED ASSET (LINEAR ACCELERATOR)
- RENOVATION



EQUIPMENT REPLACEMENT FOR THIS
LINEAR ACCELERATOR VAULT ONLY

PROPOSED LEVEL 01 PLAN

LINEAR ACCELERATOR REPLACEMENT

Atrium Health

10/09/23

CAROLINAS MEDICAL CENTER

Attachment B

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 1, 2023, this license is issued to

The Charlotte-Mecklenburg Hospital Authority

to operate a hospital known as

Carolinas Medical Center/Center for Mental Health

located at Charlotte, NC, Mecklenburg 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: 943070 ***License Number: H0071***

Bed Capacity: ***1220***

General Acute: **1064** Rehabilitation: **13** Psych: **132** Substance Use Disorder: **11**

Dedicated Inpatient Surgical Operating Rooms: ***9*** *Shared Surgical Operating Rooms:* ***44***

Dedicated Ambulatory Surgical Operating Rooms: ***11*** *Dedicated Endoscopy Rooms:* ***12***

License Categories:

.5200 Dedicated Inpatient Unit for mental disorders

.5200 Dedicated Inpatient Unit for substance use disorders

Authorized by:

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

Director, Division of Health Service Regulation

Attachment C

varian

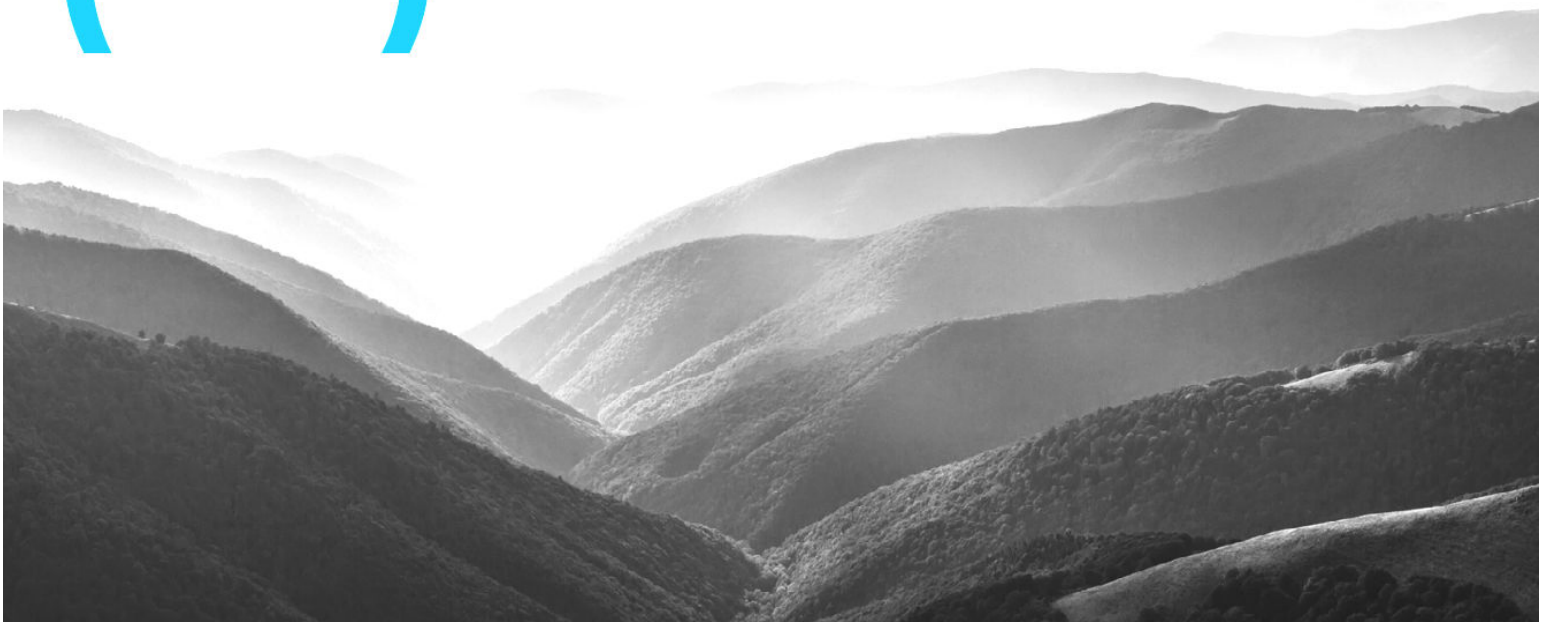
A Siemens Healthineers Company

Custom System Proposal

Quotation Number - 2023-422591

LCI TrueBeam Replacement of Novalis Tx H294573 $2,570,328

Looking further



ATRIUM HEALTH - CAROLINAS MEDICAL CENTER ("Customer")

Carnell Hampton
1021 MOREHEAD MEDICAL DR
CHARLOTTE North Carolina 28204 United States
Tel : +1 704-403-4025 or 314-440-8066 cell
Email : carnell.hampton@carolinashealthcare.org

VMS Inc, Oncology Systems

Jeffrey Boone
US District Sales Manager
Work from home
Atlanta , GA 30327 US
Tel : +1 434 977 8495x3292
Email : jeffrey.boone@varian.com

Quote Information

Quotation Number : 2023-422591	Quotation Date : August 08, 2023	Quotation Valid Until : December 15, 2023
Customer Requested Delivery Date : November 22, 2024		
Customer Procurement Contact Name : Needed		
Billing Plan	See Quote billing plan Summary on the following pages which is incorporated by reference	

Sales

Incoterms : US1: FOB: Origin	Payment Terms : 30 days net
Sales PO Required : No	

Terms and Conditions

Products and Services: Customer's access to and use of the Products, Support Services and Services (except Software-as-a-Service or Subscription Services) as indicated in this Quotation are subject to and governed by: (a) the Varian Terms and Conditions of Sale (Form RAD 1652) at: https://varian.com/RAD1652V_APR_2023.pdf and (b) any Schedules, Exhibits and/or additional terms (including third party terms) contained, attached, referenced or otherwise indicated in this Quotation. All terms and conditions provided in the website link listed in item (a) above are incorporated by reference and form part of the contract between Varian and Customer.
If there is a separate written agreement (e.g. master agreement) in effect between the parties that expressly provides for and governs the purchase and sale of the specific Products, Support Services, Services, Software-as-a-Service and/or Subscription Service set forth in this Quotation, such written agreement shall govern. Hard copies of the referenced terms and conditions and any additional terms indicated will be provided to Customer upon request.

For and on behalf of Customer

Authorized Representative : Carnell Hampton
Title :
Date : August 08, 2023

Varian Medical Systems, Inc.

Authorized Representative : Jeffrey Boone
Title : US District Sales Manager
Date : August 08, 2023

Sales Summary	
Value	Billing
0.00%	On Down Payment
80.00%	On Shipment
20.00%	On Acceptance
For orders equal or less than $100k, 100% upon shipment, net 30.	

Offered Products (Sales)

Scalable TrueBeam to Replace Novalis Tx H294573

Trade-In and Removal of Novalis Tx H294573

Advantage Credits

Item	Description	
1	Scalable TrueBeam to Replace Novalis Tx H294573	
1.1	**TrueBeam Base System 120 MLC** Treatment delivery system supporting X-Ray treatment delivery. Includes 120 leaf MLC with dual independent jaws, enhanced dynamic wedge, 6 MV X-ray treatment energy, 43 cm x 43 cm MV imager for radiographic, cine, and integrated imaging, Motion View CCTV camera system, treatment console with integrated audio and video systems, back pointer lasers, front pointer set and upper port film graticule to support basic quality assurance. **Features:** • Basic X-Ray treatment delivery technique package, including Static Photon, Photon Arc, and Dynamic Conformal Arc treatment delivery techniques • Intensity Modulated RadioTherapy (IMRT) treatment technique, including large field IMRT • Total Body Treatment technique package • 2D MV Radiographic and Cine Image Acquisition, 2D/2D Radiographic Image Review and match, Cine image review • Relative Portal Dosimetry Image and Integrated Image Acquisition • Matching of 2D radiographs to 3D reference images • Online addition of kV and MV imaging protocols to treatment fields, with automated generation of reference images • Online Physician Approval of Images at Treatment Console (compatible with ARIA® only) • Automated Machine Performance Check Testing, Online Machine Performance Check Review • Offline Machine Performance Check Review • Access to online marketing kit that contains a broad range of advertising, educational, promotional, and public relations materials targeted to referring physicians, patients, and the media, contact Marcom@varian.com for access **Prerequisites:** • ARIA® oncology information system for radiation oncology v11 MR4.1 or higher or compatible third-party oncology information system • Eclipse™ treatment planning system v11 MR3 or higher or compatible third-party treatment planning system • Compatible server hardware and operating system. For detailed specifications, visit: www.varian.com/hardwarespecs **Customer Responsibilities:** • Verify compatibility with third-party oncology information systems • Verify compatibility with third-party treatment planning systems • If using a scale other than IEC 60601 or IEC 61217 in the rest of the department, it may be necessary to change scales on all other machines. This may require additional purchases.	1
1.2	**TrueBeam Version 2.7**	1
1.3	**New Universal Baseframe 52" Fixed Floor**	1
1.4	**15/16 MV (BJR 11/17)** 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.5	**10/10 MV (BJR 11/17)** 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.6	**6/6 MV (BJR 11/17)** 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.7	**16 MeV, 0-1000 MU/Min** 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.8	**12 MeV, 0-1000 MU/Min** 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.9	**9 MeV, 0-1000 MU/Min**	1

Item	Description	
	25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	
1.10	**6 MeV, 0-1000 MU/Min**	1
	25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	
1.11	**PerfectPitch 6DoF Couch**	1
	The PerfectPitchTM 6-Degrees of Freedom couch system **Features:** • Image-based 6DoF patient positioning **Prerequisites:** • TrueBeam® v2.5 MR2 or higher • ARIA® oncology information system v11.1 MR1 (11.0.55) and ARIA radiation therapy management v11 MR3 (11.0.47) or higher or compatible third-party oncology information system **Customer Responsibilities:** • Verify compatibly of third-party oncology information system	
1.12	**Low-X Imaging Energy**	1
	Low-X imaging energy configuration, providing high soft tissue contrast when imaging in-line with the treatment beam.	
1.13	**RapidArc Treatment Delivery**	1
	RapidArc® Treatment Delivery is a volumetric modulated arc treatment delivery technique. **Features:** • Simultaneous modulation of MLC aperture shape, beam dose rate, and gantry angle and rotation speed during beam delivery • Supports dynamic jaw tracking and collimator rotation with supporting treatment planning system **Prerequisites:** • 120 Multi Leaf Collimator or HD120™ Multi Leaf Collimator • Eclipse™ treatment planning system v11.0 or higher • RapidArc treatment planning license • Compatible server hardware and operating system. For detailed specifications, visit: www.varian.com/hardwarespecs	
1.14	**kV Imaging System**	1
	kV Imaging system, providing 2D radiographic and fluoroscopic and 3D CBCT imaging capability. **Features:** • kV CBCT image acquisition, review, and match to 3D reference image • Radiographic image acquisition, with 2D/2D and 2D/3D image matching to reference image • Fluoroscopic image acquisition, with structure overlay on fluoroscopic images • kV CBCT image acquisition with a long field of view, provided by merging multiple indexed CBCT images	
1.15	**Additional MotionView CCTV Camera System**	1
	Additional set of two Motion View CCTV cameras and displays. Camera placement is at customer discretion. **Features:** • Two pan, tilt, zoom CCTV cameras • Two desktopLCD displays with built in camera controls • Adjustable viewing angle for patient privacy • Push button pan, tilt, zoom, and home position control **Prerequisites:** • Motion View camera system, provided with linac system.	
1.16	**Main Circuit Breaker Panel**	1

Item	Description	
	Main circuit breaker panel, interfacing to a single power input feed from the facility Mains. Circuit breakers provide independent over-current protection for equipment at the console and in the treatment room. UL and IEC/CE certified.	
1.17	**NLS: English**	1
1.18	**Advantage Contract Credits**	31
	Advantage Credits can be utilized for Varian's Professional Services, such as on-site applications training, education, consulting (in applicable regions), and third-party services including clinical schools that are purchased through Varian. For further details, please reference the attached Terms and Conditions. **Notes:** • Offer is valid for 24 months after purchase	
1.19	**10X High Intensity Mode**	1
	40 cm x 40 cm maximum field size, dose rate range 400-2400 MU/min in 400 MU/min steps.	
1.20	**6X High Intensity Mode**	1
	40 cm x 40 cm maximum field size, dose rate range 400-1400 MU/Min in 200 MU/min steps.	
1.21	**Triggered Imaging**	1
	Automated intrafraction 2D kV radiographic imaging, with images triggered by respiration phase or amplitude, gantry angle, time period, or MU. Automated image-based beam hold on fiducial markers, based on user-defined marker motion thresholds. **Features:** • Respiration Triggered Imaging • MU Triggered Imaging • Gantry Triggered Imaging • Time Triggered Imaging • Autobeam Hold **Prerequisites:** • Respiratory Motion Management System	
1.22	**Advanced Resp Motion Management System**	1
	Stereoscopic optical system for managing patient respiration motion during treatment delivery and imaging. **Features:** • Stereoscopic optical imager, including marker block for tracking patient respiration motion • Respiratory gated treatment delivery • Respiratory gated MV image acquisition and online review, respiration synchronized cine image acquisition and online review • Respiratory gated kV image acquisition and online review, respiration synchronized fluoroscopic image acquisition and online review	
1.23	**Filtrine Water Chiller**	1
	A closed loop water cooling system, providing clean water at a constant flow, pressure, and temperature for cooling a high energy medical linear accelerator. Ideal for sites where a dependable source of clean water for cooling is not available.	
1.24	**Additional In-Room Monitor System**	1

Item	Description	
	Additional in-room monitors that can be placed at customer discretion.	
1.25	**Power Cond., 3phase 50KVA**	1
	Transtector 50KVA, 3-phase power conditioning unit, providing transient protection, line power regulation, and Input and Output circuit breakers for over-current protection. UL and IEC/CE certified. **Notes:** • Supports voltage configurations from 208 to 600 VAC and in 50 or 60 Hz for US and ROW applications.	
1.26	**Motion Management Interface**	1
	Motion management interface is an integrated interface for validated external devices that provide patient positioning, patient and target motion monitoring, and/or respiratory gating. The Motion management interface supports connection of up to four external devices, two of which may be used for respiratory motion management or high speed beam hold. **Features:** • 4-DoF or 6-DoF patient positioning capability for compatible validated devices and couch configurations • Integrated external device beam hold and image-based patient repositioning workflow • Patient-specific external device activation and patient plan verification	
1.27	**VCD Option, couch mounted**	1

	Couch-mounted display system provides visual feedback to the patient for respiration stabilization or breath hold position during respiratory gated image acquisition or treatment delivery.
	
	Features:
	
	• 2 rechargeable batteries and charging system
	• Video interface for optional use of customer-provided video goggles
	• Wireless display system with adjustable count mount
	
	Prerequisites:
	
	• TrueBeam® v2.7 or higher
	• One of the following:
	  • Advanced Respiratory Motion Management System
	  • Basic Respiratory Motion Management System
	  • Respiratory Motion Management System
	  • Optical Imager	

1.28	**Gated CBCT**	1
	Provides the ability to acquire CBCT images synchronized with patient respiration (free-breathing or breath hold). **Features:** • Gated CBCT Imaging License: CBCT image acquisition, image review, and image match to respiratory gated reference image. • Short Arc CBCT Imaging License: CBCT image acquisition using a 120-150 degree arc, image review, and image match to respiratory gated reference image. Short arc CBCT is an option for single breath hold CBCT data acquisition. **Prerequisites:**	

Item	Description	

	• One of the following: ,
	  • Advanced Respiratory Motion Management System
	  • Basic Respiratory Motion Management System
	  • Respiratory Motion Management System
	  • Optical Imager
	• kV Imaging System	

1.29	**4D CBCT Imaging Package**
	
	4D Cone-Beam Computed Tomography (CBCT) Package. Provides the ability to acquire an 4D CBCT images for patient positioning and review target motion analysis at the time of treatment delivery or review target motion analysis post treatment delivery.
	
	Features:
	
	• 4D kV CBCT Image Match Review License: 4D CBCT image acquisition, image review, and image match to structure or Maximum Intensity Projection (MIP) at the time of treatment delivery
	• 4D CBCT Image Acquisition License: 4D kV CBCT image acquisition in Advanced Reconstructor Mode for post-treatment image reconstruction, viewing, and offline analysis
	
	Prerequisites:
	
	• TrueBeam® v2.7
	• One of the following:
	  • Advanced Respiratory Motion Management System
	  • Basic Respiratory Motion Management System
	  • Respiratory Motion Management System
	  • Optical Imager
	• kV Imaging System
	• ARIA® oncology information system v11.1 MR1 (11.0.55) or higher or compatible third-party oncology information system
	• ARIA oncology information system for radiation oncology or Eclipse™ treatment planning system
	• v11 MR3 (11.0.47) or higher
	• ARIA oncology information system v15.1 or higher is required for review of 4D kV CBCT images in ARIA Offline Review
	• Compatible server hardware and operating system. For detailed specifications, visit: www.varian.com/hardwarespecs
	
	Customer Responsibilities:
	
	• Verify compatibly third-party oncology information system
	• Initiate Smart Connect application to allow remote monitoring
		1

1.30	**Iterative CBCT** Iterative CBCT provides improved detectability of stationary or gating-immobilized soft tissue anatomy. **Features:** • Iterative CBCT license • Reconstruction computer with GPU hardware	1
1.31	**SunNuclear Micro+ Fixed Laser System (Green)** SunNuclear Micro+ Laser Kit for patient alignment with Horizontal Remote-Controller Sagittal Line Laser **Features:** • One (1) MICRO+ Green Remote-Controlled Ceiling Crosshair Laser • Two (2) MICRO+ Green Remote-Controlled Lateral Crosshair Lasers • One (1) MICRO+ Green Remote-Controlled Sagittal Line Laser	1

Item	Description	
	Prerequisites: • TrueBeam v2.5 MR2 or higher or C-Series v9.5	

1.32	**CIVCO UCT Long Extension PKG**
	
	The CIVCO® Universal Couchtop™ (UCT) Long Extension (LE) package for use on the TrueBeam™ platform
	Features:
	• Modular design with no support beams
	• Compatible with the standard TrueBeam 4 degrees of freedom (4DoF) couch and the PerfectPitch™ 6 degrees of freedom (6DoF) couch
	• The package includes:
	  • CIVCO Universal Couchtop™ (UCT)
	  • UCT LE Interface Plate
	  • Rectangular Extension
	  • End Plate Attachment
	  • Reference Device and Lok-Bar for TrueBeam
	  • Prodigy™ 2 Lok-Bar
	  • Wall Storage Mount
	Prerequisites:
	• LaserGuard™ II collision detection system
	• One of the following:
	  • Edge™ System v2.7 or higher with the Calypso® System
	  • Edge System v2.7 or higher with the Varian Head Frame
	  • TrueBeam System v2.7 or higher
	  • VitalBeam™ System v2.7 or higher
	Customer Responsibilities:
	• Verify third-party accessories compatibly
	Notes:
	• UCT LE is not validated for use with HyperArc™ High-Definition Radiotherapy
	• Safe Working Load when installed with:
	  • TrueBeam 4DoF couch: 485 lbs. (220 kg)
	  • PerfectPitch 6DoF couch: 410 lbs. (186 kg)
		1

1.33	**VCD w/Couch Mount - Civco**	1
2	Trade-In and Removal of Novalis Tx H294573	
2.1	**Remove/Dispose of Novalis Tx H294573** Removal of Novalis Tx H294573	1
2.2	**Trade-In Discount for Novalis Tx H294573** Trade-In Discount forNovalis Tx H294573	1
3	Advantage Credits	
3.1	**Advantage Contract Credits** Advantage Credits can be utilized for Varian's Professional Services, such as on-site applications training, education, consulting (in applicable regions), and third-party services including clinical schools that are purchased through Varian. For further details, please reference the attached Terms and Conditions. **Notes:** • Offer is valid for 24 months after purchase	
3.2	**Additional Advantage credits** (Qty : 200, Credit per Qty : 1.0) Undefined Advantage credits	200.0

Item	Description

Summary of Advantage Contract Credits Quoted Above

Section 3

Year 1 Total	200.0
Total Credits	200.0

Sales Price Table

Advantage Credits
Supplemental Terms and Conditions

(Form RAD 10442)

These Advantage Credits Supplemental Terms and Conditions ("**Supplemental Terms**") modify and supplement the Varian Terms and Conditions of Sale (Form RAD 1652, current version issued with the Quotation) (the "**Terms and Conditions of Sale**"). The terms of the applicable Varian Quotation ("**Quotation**"), its attachments, including the Terms and Conditions of Sale, are incorporated herein by this reference, and together with these Supplemental Terms and any applicable Third Party Terms (as defined in the Quotation) (collectively referred to as the "**Agreement**") will apply and govern the use by Customer of Advantage Credits.

1. General

The Varian Advantage Credit Program (the "**Program**") offers customers the ability to purchase Advantage Credits in advance that can be applied toward designated Varian Professional Services including certain consulting (e.g. specified and limited implementation and optimization services), on-site training, educational courses and a limited number of services provided by designated third party service providers, including clinical schools and physics commissioning services. Advantage Credits provide flexibility for the Customer to apply them interchangeably for those designated services available under the Program without having to modify the underlying Quotation and related purchase order. However, Varian must be notified in advance and in writing of any requested changes to selected services.

2. Expiration Schedule

Advantage Credits expire according to the following schedule:

Type of Order	Expiration Date
Advantage Credits only (no Varian products)	24 months from date of order
Advantage Credits with one or more Varian products	24 months from first date of product/service acceptance
Multiyear agreement	End of the term of agreement

3. Scopes of Work

Varian or its third party service providers may, at their discretion, set forth in a written Scope of Work (SOW) a description of the services to be provided by Varian or the third party service provider. If the services that will be purchased with Advantage Credits are defined within the Quotation, Varian will offer the specific services listed for the amount of Advantage Credits indicated. If Advantage Credits in the Quotation are "**Undefined**", Varian will indicate the number of Advantage Credits required for a particular service at the time the Customer wants to use them.

4. Third Party Service Providers

4.1 Certain services are provided by and through third party service providers that are not affiliated with Varian, namely clinical schools and physics services (e.g. commissioning). Varian disclaims any warranty or performance obligations related to any third party service provider and will act solely as a pay agent, to collect fees for services from Customer and to pay fees for such services to the third party service provider. Customer has the final decision to purchase services through Varian third party service providers or to select another service provider outside of the Quotation and Varian does not make any recommendations to use third party service providers.

4.2 **Changes to Third Party Service Providers by Customer.** Customer shall have a one-time right to request in writing that a third party service provider be replaced with an alternate provider that is participating in the Program. If Varian, at its sole discretion, approves the request, Customer shall be subject to any related termination fees and additional costs incurred by Varian or the third party service provider and other terms and conditions indicated in the

SOW and/or Quotation. Customer, the third party service provider, and if applicable, its subcontractors, shall have full responsibility for services as defined in the Quotation or SOW, as applicable, and Varian shall have no responsibility, obligation and/or liability whatsoever for those services. The third party service provider shall not be construed to be a subcontractor, employee, or agent of Varian. Varian will forward any requests for warranty work that it receives from Customer to the third party service provider. Except as otherwise provided in this section of the Quotation, the Terms and Conditions of Sale shall apply to this section just as it applies to all other parts of the Quotation.

4.3 **Changes to Third Party Service Providers by Varian.** Varian reserves the right, at its sole discretion, to change, from time to time, its list of third party providers that participate in the Program.

5. Performance of Services

All services shall be performed by Varian or the third-party service provider under permits, licenses, authority, supervision, and control of Customer and its staff, including licensed physicists, physicians, and other qualified healthcare professionals. Customer and its staff shall have the requisite permits (including applicable certificates of need), licenses, and authority to oversee and have such services performed on Customer’s behalf.

6. Service Offerings

Varian reserves the right, at its sole discretion, to change the designated services which are offered under the Program at any time without prior notice. Varian will work with Customer to offer a mutually acceptable alternative or apply affected credits toward other offerings within the Program.

Quotation Total

	Quotation Total	US $2,570,328.00

Attachment D

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CMC (LCI Morehead) LINAC Vault 1507 Replacement

Provider/Company: Atrium Health

(1)	Purchase price of land	0
(2)	Closing costs	0
(3)	Site Preparation	0
(4)	Construction/Renovation Contract	968,810
(5)	Landscaping	0
(6)	Architect/Engineering Fees	106,900
(7)	Medical Equipment	3,308,068
(8)	Non Medical Equipment	0
(9)	Furniture	0
(10)	Consultant Fees (CON Fees, Legal Fees)	N/A
(11)	Financing Costs	N/A
(12)	Interest During Construction	N/A
(13)	Other (IS, Security, Internal Allocation)	616,222
(14)	**Total Capital Cost**	5,000,000

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

10/16/23

(Signature of Licensed Architect or Engineer) *DATE*

Sales taxes have been included in these equipment costs. However, because Atrium Health is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that Atrium Health initially incurs for this medical equipment purchase will be refunded to Atrium Health, and thus will reduce the capital costs that Atrium Health actually incurs for the equipment by $223,574.95.

Attachment E

STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED

for
Project Identification Number #F-8045-08
FID #945053

ISSUED TO: **The Charlotte Mecklenburg Hospital Authority**
d/b/a Carolinas Medical Center
1000 Blythe Boulevard
Charlotte, NC 28203

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: **Relocate the existing radiation therapy department, including two linear accelerators, one of which will be replaced and the other enhanced, to a new outpatient building on the hospital campus/ Mecklenburg County**

CONDITIONS: **See Reverse Side**

PHYSICAL LOCATION: **Carolinas Medical Center**
1000 Blythe Blvd.
Charlotte, NC 28203

MAXIMUM CAPITAL EXPENDITURE: **$ 22,150,000**

TIMETABLE: **See Reverse Side**

FIRST PROGRESS REPORT DUE: **February 15, 2009**

This certificate is effective as of the 28th day of July, 2008.

Lee B. Hoffman by CRSAC
Chief, Certificate of Need Section
Division of Health Service Regulation

CONDITIONS:

1. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with all representations made in the certificate of need application.

2. Upon completion of the project, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall be licensed for no more than two linear accelerators.

3. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not construct physical space for more than two linear accelerator vaults.

4. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center 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 or that would otherwise require a certificate of need.

5. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall dispose of the existing Novalis Radiosurgery linear accelerator.

6. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance and compliance with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on July 23, 2008.

TIMETABLE:

Contract Award (Notice to Proceed)	November 1, 2008
Completion of Final Drawings and Specifications	March 18, 2009
25% Completion of Construction	December 1, 2009
50% Completion of Construction	February 1, 2010
Ordering of Equipment	February 1, 2010
Completion of Construction	April 1, 2010
Occupancy/Offering of Service(s)	July 1, 2010

Attachment F

TrueBeam System

Product Specifications

varian
A Siemens Healthineers Company

Table of Contents

The TrueBeam® system specifications in this document are identified as belonging to two categories: performance specifications and descriptive specifications. Performance specifications will be demonstrated at the time of product installation, in accordance with the purchased product configuration and Varian Medical Systems' customer acceptance testing procedures. Descriptive specifications are representative of system performance but are not demonstrated at installation.

Beam Performance Specifications

Table 1: X-ray Energy Configurations

X-ray Energy Configurations	Nominal Energy Description (MV) per BJR11/BJR17						
Performance Specifications	**4/4[1]**	**6/6[2]**	**8/8[2]**	**10/10[2]**	**15/16[3]**	**18/23[3]**	**20/25[3]**
D_{max} (cm)[4]	1.20 ± 0.20	1.60 ± 0.15	2.00 ± 0.15	2.40 ± 0.15	2.90 ± 0.15	3.30 ± 0.15	3.50 ± 0.15
% depth dose at 10 cm depth[4]	63.0 ± 1.0	67.2 ± 1.0	71.0 ± 1.0	74.1 ± 1.0	77.4 ± 1.0	80.2 ± 1.0	82.0 ± 1.0
Flatness							
(10 x 10 cm^2 to 20 x 20 cm^2)[5,6]	±3.0%	±3.0%	±3.0%	±3.0%	±3.0%	±3.0%	±3.0%
(20 x 20 cm^2 to 30 x 30 cm^2)[5,6]	±2.5%	±2.5%	±2.5%	±2.5%	±2.5%	±2.5%	±2.5%
(30 x 30 cm^2 to 40 x 40 cm^2)[5,6]	±2.5%	±2.5%	±2.5%	±2.5%	±2.5%	±2.5%	±3.0%
Symmetry[5,7]	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Minimum dose rate (MU/minute)[8]	5	5	5	5	20	20	20
Maximum dose rate (MU/minute)[8]	250	600	600	600	600	600	600
Arc dose rate range (MU/degree)[8,9]	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60
Maximum field size at isoplane	40 cm x 40 cm	40 cm x 40 cm	40 cm x 40 cm	40 cm x 40 cm	40 cm x 40 cm	40 cm x 40 cm	40 cm x 40 cm

1 The 4 MV energy configuration supports the following dose rates (MU/min): 5, 10, 15, 20, 30, 40, 50, 100, 150, 200, and 250.

2 The 6 to 10 MV energy configurations support the following dose rates (MU/min): 5, 10, 15, 20, 40, 60, 80, 100, 200, 300, 400, 500, and 600.

3 The 15 to 20 MV (per BJR 11) energy configurations support the following dose rates (MU/min): 20, 40, 60, 80, 100, 200, 300, 400, 500, and 600.

4 Depth of ionization applies to a 10 x 10 cm^2 field size measured at 100 cm source-to-surface distance (SSD).

5 Flatness and symmetry are measured at 100 cm SSD, at a depth of 10 cm, within the 80% full width at half maximum (FWHM) region along the inplane and crossplane central axes, using 10 x 10 cm^2, 20 x 20 cm^2, 30 x 30 cm^2, and 40 x 40 cm^2 field sizes.

6 Flatness is defined as the maximum variation from the X-ray dose delivered within the central 80% FWHM region, normalized to the dose output at beam centerline.

7 Symmetry is defined as the maximum difference between the X-ray dose delivered to any two points that are equidistant and symmetrical about the central axis and within the central 80% FWHM region.

8 Dose output (MU) is defined as 1 cGy delivered to a tissue-equivalent material at D_{max} and 100 cm SSD, with a 10 x 10 cm^2 field size. Measurement of dose output under conditions different than those defined herein may result in a higher or lower dose output than specified. Dose rate is specified at D_{max}, as described in note 4.

9 Dose rates specified herein are in effect maximum dose rate settings. TrueBeam automatically varies actual dose rate to synchronize with axis motion for optimal treatment delivery efficiency.

Table 2: High-Intensity Mode (HIM) X-ray Energy Configurations

HIM X-ray Energy Configurations	Energy Configuration Description[1]							
Performance Specifications	**6X HIM**				**10X HIM[2]**			
D_{max} (cm)[3]	1.50 ± 0.15				2.34 ± 0.15			
% depth dose at 10 cm depth[3]	64.3 ± 1.0				71.8 ± 1.0			
Field intensity at 10 cm depth[1,4]	Measurement point from central axis				Measurement point from central axis			
	±2 cm	±4 cm	±6 cm	±18 cm	±2 cm	±4 cm	±6 cm	±18 cm
% dose (10 cm x 10 cm)[5,6]	97.5 ± 2.0	90.5 ± 2.0	-	-	95.5 ± 2.0	85.5 ± 2.0	-	-
% dose (40 cm x 40 cm)[5,6]	-	-	90.0 ± 2.0	59.5 ± 2.0	-	-	80.0 ± 2.0	45.0 ± 2.0
Symmetry[7]	2.0%				2.0%			
Minimum dose rate (MU/min)[8-10]	400				400			
Maximum dose rate (MU/min)[8-10]	1400				2400			
Arc dose rate range (MU/deg)[8,11]	0.1 to 60				0.1 to 60			
Maximum field size at isoplane	40 cm x 40 cm				40 cm x 40 cm			

1 Field intensity is relative to the central axis dose normalized to 100%.

2 The 10X high intensity energy configuration supports the following dose rates (MU/min): 400, 800, 1200, 1600, 2000, and 2400.

3 Depth of ionization applies to a 10 x 10 cm^2 field size measured at 100 cm SSD.

4 The % dose for a 30 cm x 30 cm field size is:
- For 6X at 4 cm (94.5 ± 2.0)%; at 14 cm (66.0 ± 2.0)%
- For 10X at 4 cm (88.5 ± 2.0)%; at 14 cm (53.0 ± 2.0)%

5 Relative dose and symmetry are specified at 100 cm SSD, using a 10 cm x 10 cm and 40 cm x 40 cm field sizes.

6 Nominal field intensity distributions for high intensity X-ray energies are measured as shown in figures 1 and 2, on the right.

7 Symmetry is defined as the maximum difference between the X-ray dose delivered to any two points that are equidistant and symmetrical about the central axis and within the central 80% FWHM region, measured at a depth of 10 cm.

8 Dose output (MU) is defined as 1 cGy delivered to tissue-equivalent material at D_{max} and 100 cm SSD, with a 10 cm x 10 cm field size. Measurement of dose output under conditions different than those defined herein may result in a higher or lower dose output than specified.

9 Maximum and minimum nominal dose rates are specified at D_{max} and central axis. Dose rate will fall off lateral to the central axis in accordance with the lateral fall off of the field intensity.

10 The 6X high intensity energy configuration supports the following dose rates (MU/min): 400, 600, 800, 1000, 1200, and 1400.

11 Dose rates specified herein are in effect maximum dose rate settings. TrueBeam automatically varies actual dose rate to synchronize with axis motion for optimal treatment delivery efficiency.

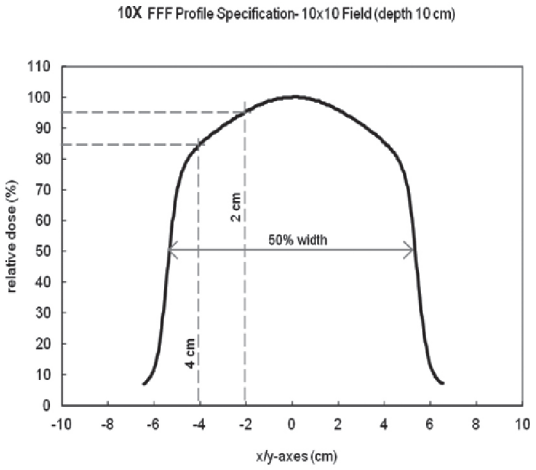


Figure 1: 10X high intensity energy configuration field intensity profile for a 10 cm x 10 cm field size, measured at a depth of 10 cm.

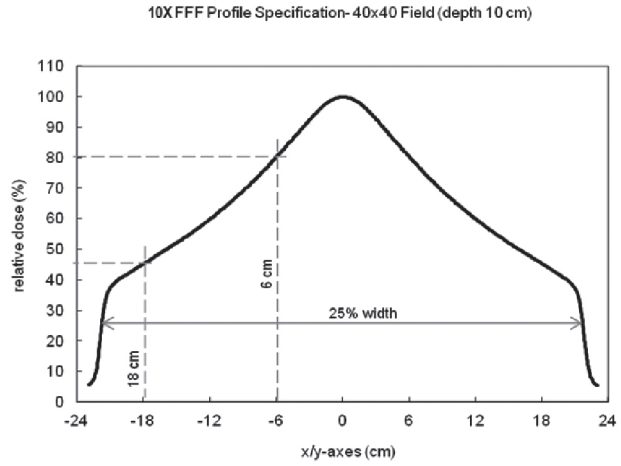


Figure 2: 10X high intensity energy configuration field intensity profile for a 40 cm x 40 cm field size, measured at a depth of 10 cm.

Table 3: Low 2.5X Imaging Energy Configuration

Low 2.5X imaging energy configuration is utilized for MV image acquisition only and not available for treatment delivery.

Low 2.5X Imaging Energy Configuration				
Descriptive Specifications				
D_{max} (cm)[1]	0.8 ± 0.2			
% depth dose at 10 cm depth[1,2]	52.0 ± 2.0			
Field intensity at 5 cm depth	Measurement point from central axis		Field intensity[3]	
% dose (40 cm x 40 cm)	±6 cm	±18 cm	96.5% ± 2.0%	74.0% ± 2.0%
Symmetry[2,4]	3.0%			
Maximum dose rate (MU/min)[5,6]	60			
Maximum field size at isoplane	40 cm x 40 cm			

1 Depth of ionization applies to a 10 x 10 cm^2 field size measured at 100 cm SSD.

2 Relative dose and symmetry are specified at 100 cm SSD, using 10 cm x 10 cm and 40 cm x 40 cm field sizes.

3 Field intensity is relative to the central axis dose normalized to 100%.

4 Symmetry is defined as the maximum difference between the X-ray dose delivered to any two points that are equidistant and symmetrical about the central axis and within the central 80% FWHM region, measured at a depth of 5 cm.

5 Dose output (MU) is defined as 1 cGy delivered to tissue-equivalent material at Dmax and 100 cm SSD, with a 10 cm x 10 cm field size. Measurement of dose output under conditions different than those defined herein may result in a higher or lower dose output than specified.

6 Maximum and minimum dose rates are specified at D_{max} and central axis. Dose rate will fall off lateral to the central axis in accordance with the lateral fall off of the field intensity.

Table 4: Electron Energy Configurations

Energy Configurations (MeV)	6	6 HD-TSE[1]	9	9 HD-TSE[1]	12	15	16	18	20	22
Performance Specifications										
Depth of ionization[2]										
90% (cm, ±0.1)	1.71	-	2.68	-	3.77	4.67	4.87	5.29	5.58	5.66
80% (cm, ±0.07)	1.90	-	2.95	-	4.15	5.20	5.45	6.09	6.57	6.83
50% (cm, ±0.1)	2.32	-	3.52	-	4.91	6.19	6.52	7.41	8.10	8.59
30% (cm)	≤2.70	-	≤3.90	-	≤5.40	≤6.80	≤7.30	≤8.15	≤9.30	≤10.00
Radial and transverse flatness[3,4] measured at 85%/2	±5.0%	-	±4.5%	-	±4.5%	±4.5%	±4.5%	±4.5%	±4.5%	±4.5%
Symmetry[5] measured at 85%/2 (plane normal to CAX)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Maximum dose rate (MU/min)[1]	1000	2500	1000	2500	1000	1000	1000	1000	1000	1000
Arc dose rate range (MU/degree)[7,8]	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60	0.1 to 60
Descriptive Specifications										
Diagonal flatness[3,4] measured at 85%/2	±5.0%[3]	-	±5.0%	-	±5.0%	±5.0%	±5.0%	±5.0%	±5.0%	±5.0%
X-ray contamination[6]	≤2%	≤2%	≤2%	≤2%	≤2%	≤5%	≤5%	≤5%	≤5%	≤5%

1 Dose output (MU) is defined as 1 cGy delivered to a tissue-equivalent material at D_{max} and 100 cm SSD using a 15 x 15 cm^2 electron applicator for all energies with the exception of the high dose total skin electron (HDTSE) energies. Dose rate is specified at D_{max}, measured using 100 cm SSD, using a 15 x 15 cm^2 electron applicator for all electron energies with the exception of the HDTSE energies. HDTSE energy specifications apply to a 36 x 36 cm^2 field size.

2 Depth of ionization applies to the 15 x 15 cm^2 applicator field size, using a water phantom at 100 cm SSD, a 5 cm gap between the bottom of the open field aperture and the water surface.

3 Flatness is defined as the maximum variation from the mean electron ionization delivered within the central 80% FWHM region, measured for 10 x 10 cm^2 through 25 x 25 cm^2 fields. See note 5.

4 Diagonal flatness for 6 MeV energy configuration is ±6.0% for a 10 x 10 cm^2 field, ±5.0% for 15 x 15 cm^2 through 25 x 25 cm^2 fields.

5 Symmetry is defined as the maximum difference between the ionization delivered to any two points that are equidistant and symmetrical about the central axis and within the central 80% FWHM region, measured at a depth of 85%/2 for 10 x 10 cm^2 through 25 x 25 cm^2 fields.

6 X-ray contamination is specified in water at a 100 cm SSD, a depth of 10 cm beyond the depth of the 10% isodose line, using a 15 x 15 cm^2 electron applicator.

7 Dose output (MU) is defined as 1 cGy delivered to a tissue-equivalent material at D_{max} and 100 cm SSD, with a 10 x 10 cm^2 field size. Measurement of dose output under conditions different than those defined herein may result in a higher or lower dose output than specified. Dose rate is specified at D_{max}, as described in note 4.

8 Dose rates specified herein are in effect maximum dose rate settings. TrueBeam automatically varies actual dose rate to synchronize with axis motion for optimal treatment delivery efficiency.

Table 5: General X-ray and Electron Energy Configuration[1]

The following performance specifications apply to all energy configurations, except low X-ray imaging.

Performance Specifications	Specification[2]
Dose output per monitor unit versus dose rate[3]	±1% or ±1 MU
Dose output per monitor unit versus total dose[3-5]	1% or 0.5 MU at a fixed gantry angle
Dose output per monitor unit repeatability[3]	±1% or ±1 MU
Dose rate linearity[3]	±1% or ±1 MU/min
Dose output per monitor unit versus gantry angle	±1.5% or ±1.5 MU
Descriptive Specifications	**Specification**
X-ray beam symmetry deviation versus gantry and collimator angles	±1.5%

1 For additional TrueBeam, TrueBeam® STx , and Edge® IEC accompanying documents, please refer to the following documents: Type Tests (P1007278); Site Tests and Procedures (P1007279); Functional Performance Characteristics- IEC 60976, Medical Electron Accelerators (P1007370).

2 Whichever is greater.

3 Measured with gantry at 0 per IEC 61217.

4 Total dose linearity for X-ray energy configurations is specified based on a minimum total dose of 5 MU.

5 Total dose linearity for high intensity X-ray energy configurations is specified based on a minimum total dose of 50 MU.

Mechanical Performance Specifications

Supported Scale Conventions: IEC 60601 and IEC 61217

Table 6: Isocenter Specifications

All scale references below are per IEC 61217.

Performance Specifications	Specification
Gantry and collimator isocenter accuracy	≤0.5 mm radius
Gantry, collimator, and couch isocenter accuracy	≤0.75 mm radius
Descriptive Specifications	**Specification**
Target to gantry axis distance	100 ± 0.2 cm
Isocenter height (relative to the floor)	129.5 cm + 0.5 cm/-0 cm

Table 7: Gantry Specifications

All scale references below are per IEC 61217.

Performance Specifications	Specification
Rotational accuracy	≤0.3 degrees
Rotation range	±185 degrees from the vertical
Descriptive Specifications	**Specification**
Rotation speed	Variable from 0 to 1 RPM

Table 8: Collimator Specifications

All scale references below are per IEC 61217.

Performance Specifications	Specification
Rotational accuracy	≤0.5 degrees
Rotational reproducibility	≤0.3 degrees
Rotation range	±175 degrees
Coincidence of light field and radiation field (50% isodensity line)[1]	1.5 mm
Cross hair intersection alignment to collimator	±0.5 mm
Descriptive Specifications	**Specification**
Rotational speed, no accessories	Variable from 0 to 2.5 RPM
Rotational speed, with accessories	Variable from 0 to 1 RPM
Optical range finder	70 to 156 cm range, 0.5 cm resolution, accurate to ±0.1 cm at 100 cm
Mechanical front pointer	75 to 110 cm range, 0.2 cm resolution, accurate to ±0.1 cm, at 100 cm
Independent Upper and Lower Jaws	
Performance Specifications	**Specification**
Upper jaw positional accuracy	±2 mm for static fields
Lower jaw positional accuracy	±1 mm for static fields
Descriptive Specifications	**Specification**
Travel range – lower jaws	-2 cm to +20 cm
Travel range – upper jaws	-10 cm to +20 cm
Jaw speed	Variable from 0 cm/sec to a maximum speed of 2.5 cm/sec

1 Measured at 100 cm SSD with minimum buildup for any field size.

Table 9: 120 Multileaf Collimator (MLC) Specifications

All scale references below are per IEC 61217.

Performance Specifications	Specification
MLC leaf end position accuracy at all leaf positions relative to the collimator axis[1]	±1 mm
MLC leaf end position reproducibility at all leaf positions relative to the collimator axis[1]	±0.5 mm
Descriptive Specifications	**Specification**
Number of leaves	120
Central high resolution leaf width (central 20 cm, leaf width projected at isocenter)	5 mm
Outboard leaf width (outer 20 cm, leaf width projected at isocenter)	10 mm
Maximum static field size[2]	40 cm x 40 cm
Maximum static aperture field size[2]	30 cm x 40 cm
Maximum intensity-modulated radiation therapy (IMRT) field size[2]	34 cm x 40 cm
Maximum leaf retract position	20.1 cm from centerline
Maximum leaf extend position	-20.0 cm over beam centerline
Maximum displacement between adjacent leaf ends at a single carriage position	15 cm
Average leaf transmission[3]	<2.5%
Maximum interleaf leakage[3]	<3.0%
Maximum combined collimator leakage (jaws and MLC closed), all energies[4]	<0.02%
Mean leakage-area product per Gy delivered[5]	<0.15 mGy-m^2
Maximum carriage speed	Variable from 0 to 1.2 cm/sec
Maximum leaf speed	Variable from 0 to 2.5 cm/sec
Relative leaf accuracy (leaf end to leaf end)	0.25 mm
Minimum static leaf gap (leaf end to leaf end)	0.0 mm
Minimum dynamic leaf gap (leaf end to leaf end)	0.5 mm
Leaf end penumbra at D_{max}[6,7]	<4.5 mm
Leaf interdigitation	Yes
Independent leaf and carriage motion	Yes

1 Projected at the isoplane, with backup jaw coverage.

2 Maximum physical field size, projected at the isoplane.

3 Leakage specified as percentage of total dose per field or dose segment, measured with jaws fully retracted, using 4 MV through 10 MV energy configurations and 6X and 10X high intensity energy configurations. Significant reduction in interleaf transmission is provided with static jaw shielding outside the treatment aperture or dynamic jaw tracking of aperture.

4 Maximum combined collimator leakage includes MLC and jaws and is measured for all energies. Mean leakage is 0.01%.

5 Mean leakage-area product represents integral leakage dose over the combined aperture area defined by the MLC and jaws. Leakage area product is calculated based on using 1 Gy dose output, a 5 cm radial MLC aperture and a jaw aperture of 10.4 cm x 11.6 cm.

6 Penumbra defined as 20 to 80% leaf end, measured using 10 cm x 10 cm field size, 6 MV at D_{max}, 100 cm source-to-axis distance (SAD).

7 For additional TrueBeam, TrueBeam STx , and Edge IEC accompanying documents, please refer to the following documents: Type Tests (P1007278); Site Tests and Procedures (P1007279); Functional Performance Characteristics- IEC 60976, Medical Electron Accelerators (P1007370).

Table 10: HD120 Multileaf Collimator (MLC) Specifications

All scale references below are per IEC 61217.

Performance Specifications	Specification
MLC leaf end position accuracy at all leaf positions relative to the collimator axis[1]	±1 mm
MLC leaf end position reproducibility at all leaf positions relative to the collimator axis[1]	±0.5 mm
Descriptive Specifications	**Specification**
Leaf side accuracy relative to the collimator axis, projected at isoplane (gantry at 0)[2]	≤0.2 mm
Number of leaves	120
Central high resolution leaf width (central 8 cm, leaf width projected at isocenter)	2.5 mm
Outboard leaf width (outer 14 cm, leaf width projected at isocenter)	5 mm
Maximum static field size[3]	40 cm x 22 cm
Maximum static field size with MLC retracted	40 cm x 40 cm
Maximum static aperture field size[3]	30 cm x 22 cm
Maximum IMRT field size[3]	34 cm x 22 cm
Maximum leaf retract position	20.1 cm from centerline
Maximum leaf extend position	-20.0 cm over beam centerline
Maximum displacement between adjacent leaf ends at a single carriage position	15 cm
Average leaf transmission[4]	<2.0%
Maximum interleaf leakage[4]	<2.5%
Maximum combined collimator leakage (jaws and MLC closed), all energies[5]	<0.02%
Mean leakage-area product per Gy delivered[6]	<0.15 mGy-m^2
Maximum carriage speed	Variable from 0 to 1.2 cm/sec
Maximum leaf speed	Variable from 0 to 2.5 cm/sec
Relative leaf accuracy (leaf end to leaf end)	0.25 mm
Minimum static leaf gap (leaf end to leaf end)	0.0 mm
Minimum dynamic leaf gap (leaf end to leaf end)	0.5 mm
Leaf end penumbra at D_{max} [7,8]	≤3.5 mm
Leaf interdigitation	Yes
Independent leaf and carriage motion	Yes

1 Projected at the isoplane, with backup jaw coverage.

2 Represents alignment of MLC to collimator Y-axis, based on center leaf edge position under static conditions, gantry at 0 degrees.

3 Maximum physical field size, projected at the isoplane.

4 Leakage specified as percentage of total dose per field or dose segment, measured with jaws fully retracted, using 4 MV through 10 MV energy configurations and 6X and 10X high intensity energy configurations. Significant reduction in interleaf transmission is provided with static jaw shielding outside the treatment aperture or dynamic jaw tracking of aperture.

5 Maximum combined collimator leakage includes MLC and jaws and is measured for all energies. Mean leakage is 0.01%.

6 Mean leakage-area product represents integral leakage dose over the combined aperture area defined by the MLC and jaws. Leakage area product is calculated based on using 1 Gy dose output, a 5 cm radial MLC aperture and a jaw aperture of 10.4 cm x 11.6 cm.

7 Penumbra defined as 20 to 80% leaf end, measured using 10 cm x 10 cm field size, 6 MV at D_{max}, 100 cm SAD.

8 For additional TrueBeam, TrueBeam STx , and Edge IEC accompanying documents, please refer to the following documents: Type Tests (P1007278); Site Tests and Procedures (P1007279); Functional Performance Characteristics- IEC 60976, Medical Electron Accelerators (P1007370).

Table 11: Treatment Couch Specifications (4DOF)

All scale references below are per IEC 61217.

Performance Specifications	Specification
Rotational accuracy for fine patient positioning, 0 to ±6 degrees	≤0.3 degrees
Rotational accuracy for large rotations, greater than ±6 degrees	≤0.4 degrees
Spatial translational accuracy for fine patient positioning (±5 cm about mechanical isocenter)[1-6]	≤0.5 mm
Integrated image-guided radiation therapy (IGRT) couch top weight limit[6]	228 kg (502 lbs)
Qfix® kVue™ or Calypso® kVue couch top weight limit[4,6]	200 kg (440 lbs)
Qfix kVue One weight limit	225 kg (496 lbs)
CIVCO® Universal Couchtop™ Long Extension/Kevlar Extension weight limit	220 kg (485 lbs)
Descriptive Specifications	**Specification**
Travel range (nominal)	
Lateral	49 cm (+/- 24.5 cm couch top center from centerline)[7]
Vertical (±1 cm)	106 cm (-65.5 cm to +40.5 cm, couch top relative to isoplane)[7]
Longitudinal	145 cm (-51.5 cm to +93.5 cm, couch tip relative to isocenter)[8]
Rotational (yaw) about isocenter	±95 degrees

1 Performance for the specified couch top, with a patient weight of 30 to 135 kg, within a vertical travel range extending from couch top positioned at isocenter to -20 cm below isocenter.

2 For patients with a weight below 30 kg or over 135 kg (kVue couch and IGRT couch tops), the spatial translational accuracy performance specification for small patient shifts (±5 cm) is 0.7 mm and for large patient shifts (±20 cm) is 1.9 mm.

3 Addition of immobilization devices onto the couch tops specified above defines a new couch system configuration. Quality assurance testing of each new couch system configuration should be performed under patient weight conditions as performance may be affected by mechanical tolerances and patient weight distribution changes introduced by the immobilization device.

4 Substitution of kVue couch inserts other than the inserts specified above defines a new couch system configuration. Quality assurance testing of each new couch system configuration should be performed under patient weight conditions as performance may be affected by the size, weight, and longitudinal extension of the couch insert.

5 Addition of immobilization devices to the front edge of the couch tops specified above defines a new couch system configuration that has a weight distribution shifted forward on the couch top and not in accordance with the specifications above. Quality assurance testing of each new extended couch top system configuration should be performed under representative forward patient weight distribution conditions as performance may be affected by mechanical tolerances and weight distribution shifts introduced by the immobilization device.

6 Measured using weight distributed according to IEC 60601-2-46:2011: Particular requirements for the basic safety and essential performance of operating tables.

7 Specifications for kVue couch tops same as above.

8 Longitudinal travel range specification for kVue couch tops: 145 cm (-35.3 cm to +109.7 cm).

Table 12: PerfectPitch 6 Degrees of Freedom (6DoF) Couch Specifications

All scale references below are per IEC 61217.

Performance Specifications	Specification
Rotational (yaw) accuracy for fine patient positioning, 0 to ±6 degrees	≤0.3 degrees
Rotational (yaw) accuracy for large rotations, greater than ±6 degrees	≤0.4 degrees
Accuracy for fine patient positioning (±5 cm about mechanical isocenter with 6DoF)[1-7]	≤0.5 mm
Integrated IGRT couch top weight limit	200 kg (440 lbs)
Qfix® kVue™ or Calypso® kVue couch top weight limit[5,7]	155 kg (341 lbs)
Qfix kVue One weight limit	188 kg (414 lbs)
CIVCO® Universal Couchtop™ Long Extension/Kevlar Extension weight limit	186 kg (410 lbs)
Descriptive Specifications	**Specification**
Travel range (nominal)	
Lateral	49 cm (± 24.5 cm couch top center from centerline)[8]
Vertical (±1 cm)	96.5 cm (-57 cm to +40.5 cm, couch top relative to isoplane)[9]
Longitudinal	145 cm (-51.5 cm to +93.5 cm, couch tip relative to isocenter)[10]
Pitch and roll about isocenter	±3 degrees
Rotational about isocenter	±95 degrees

1 Performance for the specified couch top, with a patient weight of 30 to 135 kg, within a vertical travel range extending from couch top positioned at isocenter to -20 cm below isocenter.

2 For patients with a weight below 30kg or over 135kg (IGRT couch top) the spatial accuracy performance specification for small shifts (+/-5cm) is ≤0.7mm and for large vertical and longitudinal shifts (+/-20cm) is ≤2.5mm.

a. For patients with a weight below 30kg or over 135kg (IGRT couch top) the spatial accuracy performance specification for large lateral shifts (+/- 20cm) is ≤2.8mm.

3 For the kVue couch top the spatial accuracy performance specification for small shifts (+/-5cm) is ≤0.7mm and for large shifts (+/-20cm) is ≤2.5mm.

4 Addition of immobilization devices onto the couch tops specified above defines a new couch system configuration. Quality assurance testing of each new couch system configuration should be performed under patient weight conditions as performance may be affected by mechanical tolerances and patient weight distribution changes introduced by the immobilization device.

5 Substitution of kVue couch inserts other than the inserts specified above defines a new couch system configuration. Quality assurance testing of each new couch system configuration should be performed under patient weight conditions as performance may be affected by the size, weight, and longitudinal extension of the couch insert.

6 Addition of immobilization devices to the front edge of the couch tops specified above defines a new couch system configuration that has a weight distribution shifted forward on the couch top and not in accordance with the specifications above. Quality assurance testing of each new extended couch top system configuration should be performed under representative forward patient weight distribution conditions as performance may be affected by mechanical tolerances and weight distribution shifts introduced by the immobilization device.

7 Measured using weight distributed according to IEC 60601-2-46:2011: Particular requirements for the basic safety and essential performance of operating tables.

8 Specifications for kVue couch tops same as above.

9 Vertical travel range specification for kVue couch tops: 93 cm (-52.5 cm to +40.5 cm).

10 Longitudinal travel range specification for kVue couch tops: 145 cm (-35.3 cm to +109.7 cm).

Table 13: MV Imager Specifications

All scale references below are per IEC 61217.

Performance Specifications	Specification
Imager alignment to MV radiation isocenter (at 150 cm source-to-imager distance (SID))	≤0.5 mm
Imager travel range (applications may further limit travel ranges)	
Vertical (along the beam axis)	-80.0 to +0.0 cm
Lateral	-16.0 to +15.5 cm
Longitudinal (at 150 cm SID)	-13.5 to +30.5 cm
Treatment Energy Imaging Performance Specifications	**Specification**
Minimal settable exposure	0.1 MU (Low X imaging, 6 MV)
Dose rates for portal image acquisition (150 cm SID, full resolution)	50 to 2400 MU/minute[1]
Dose rates for portal dosimetry (100 cm SID, full resolution)	50 to 2400 MU/minute[2]
Contrast resolution (full resolution, 6 MV, 1.5 MU/frame, 2 frames, hole diameter 15 mm)	0.15%
Maximum image acquisition rate, limited by image protocol selected	20 fps
Small object detection (lead, tungsten, or tantalum wire)	0.5 mm
MV Imaging Descriptive Specifications	**Specification**
MV imager deployment (x, y, z = 0, 0, 50 for image receptor target)	
Retracted to mid position	4 seconds
Mid to deployed position	8 seconds
Retracted to deployed position	9 seconds
Receptor model	aS1200
Active imaging area	43.0 x 43.0 cm^2
Pixel matrix	1280 x 1280 640 x 640
A/D conversion	16 bit
Imager lifetime	>4 years under normal use[4]
MTF (f50) measured with slit (typical)	0.35 cycles/mm (6 MV typical) 0.55 cycles/mm (Low X, typical)
Portal dosimetry linearity (6 MV, full resolution, 5 to 100 MU range)	0.5%
Lag, 1st frame (@7.5 fps)	1.5%
MV beam energy range (per BJR11)	2 to 20 MV
Portal imaging using high intensity energies	Yes
Typical radiographic image exposure	1.5 MU[3]
Maximum exposure (dosimetry mode)	Any permissible irradiation

1 Saturation at 12 MU/frame; equivalent to 7200 MU/minute; @ 150 cm SID.

2 Saturation at 5.3 MU/frame; equivalent to 3200 MU/minute; @ 100 cm SID.

3 1.0 MU when using low X imaging.

4 Assuming a delivered dose to the imager of ~500 cGy per day at detector level or ~2500 cGy (MU) per day at isocenter level.

Table 14: kV Imager Specifications

All scale references below are per IEC 61217.

kV Imager Performance Specifications	Specification
kV imager alignment to MV radiation isocenter (imager at 150 cm SID)	≤0.5 mm
kV imager travel range (applications may further limit travel ranges)	
Vertical (along the beam axis)	81.5 to 0.8 cm
Lateral	16.5 to +17.5 cm
Longitudinal (150 cm SID)	16.0 to +29.0 cm
kV Imager Descriptive Specifications	**Specification**
Receptor model	RTI4030iL
Active imaging area	39.9 x 30.0 cm^2
Pixel matrix	1424 x 1072 (binned 2x2)
A/D conversion	
Single gain	16 bit
Dynamic gain	N/A
Operating modes	
Single gain (fluoroscopy mode)	1424 x 1072, 11 fps
Single gain (full resolution image mode)	1424 x 1072
Dynamic gain mode	N/A
Maximum exposure	1983 uRad (low gain mode)
MTF @ 1 lp/mm	>50%
Spatial resolution measured using TOR 18FG (2 x 2 binned mode)	N/A (similar to PaxScan, data not yet available)
DQE(0) (using RQA5 kV beam quality)	>60%
Non-uniformity	N/A
Grid	15:1 with 71% transmission
Dynamic range	
Fluoroscopy mode	8,700:1
Single full resolution image mode	8,700:1
Dynamic gain mode	13,300:1
Lag, 1st frame	<2% (7 fps, 2x2 binning)

X-ray Generator Descriptive Specifications	Specification
Generator type	200 kHz, 50 kW
kV range	40 to 140 kV
kV accuracy	
Entire kV range	±5%
70 to 85 kV	±2%
mA range	10 to 630 mA
mA accuracy	±5%
mAs range	0.1 to 1000 mAs
mAs accuracy	±10%
Exposure time	1 to 6300 ms
Exposure time accuracy	
5 to 6300 ms	2%
1 ms, 4 ms	10%
Auto tube calibration	Yes
Anatomical programs	Yes
kV Imaging Mechanical Specifications	**Specification**
Deployment of kV imaging arms [x, y, z = 0, 0, 50 for image receptor target]	
Retracted to mid position	10 seconds
Mid to deployed position	13 seconds
Retracted to deployed position	17 seconds
kV Dosimetric Descriptive Specifications	**Specification**
Radiographic exposures	
@75 kVp; @100 cm	75 µGy/mAs
@100 kVp; @100 cm	131 µGy/mAs
@125 kVp; @100 cm	196 µGy/mAs
kV Imaging Storage Descriptive Specifications	**Specification**
Maximum length of fluoroscopy sequence that can be saved to the information system (excludes sequences with excessive noise)	5 minutes

kV Imager Source/X-ray Tube Descriptive Specifications	Specification
X-ray tube model	Varex GS 1542
Target angle	14 degrees
Target diameter	133 mm
Heat capacity	
Anode	1,500,000 HU (1110 kJ)
Housing	2,000,000 HU (1480 kJ)
Anode cooling	
Maximum anode heat dissipation	3950 HU/s (2800 W)
Usable anode heat dissipation	2960 HU/s (2100 W)
Source spot	
Small (nominal 0.4 mm)	0.4 to 0.6 mm x 0.6 to 0.85 mm
Large (nominal 1.0 mm)	1.0 to 1.4 mm x 1.4 to 2.0 mm
Focal spot superimposition	
X-axis; Y-axis	±0.5 mm
X-ray Collimation Descriptive Specifications	**Specification**
Field size at isocenter (X-ray tube at 100 cm)	
Minimum	2.0 cm x 2.0 cm
Maximum	50 cm x 50 cm
Asymmetric blade motions at isocenter (X-ray source at 100 cm), minimal size recommended	
X1	+3.5 to -25 cm
X2	-3.5 to +25 cm
Y1	+3.5 to -25 cm
Y2	-3.5 to +25 cm
Blade motions at isocenter (with no gantry motion between measurements)	
Accuracy	±1% of the source-imager distance
Reproducibility	±1 mm
Automated bow-tie deployment	
No bow-tie to full fan bow-tie	<10 seconds (8 seconds typical)
No bow-tie to half fan bow-tie	<20 seconds (13 seconds typical)
Half fan bow-tie to full fan bow-tie	<10 seconds (8 seconds typical)
Full fan bow-tie to half fan bow-tie	<10 seconds (8 seconds typical)
Automated Ti filter deployment	
None to Pos1	<10 seconds (8 seconds typical)
None to Pos2	<20 seconds (13 seconds typical)
Pos1 to Pos2	<10 seconds (8 seconds typical)
Pos2 to Pos1	<10 seconds (8 seconds typical)
Field opening follows the imager	Yes, configurable On/Off

Table 15: kV CBCT Specifications

All scale references below are per IEC 61217 – Deployed CBCT modes.

Deployed CBCT Modes	Head	Pelvis	Spotlight	Thorax	Short Thorax	Image Gently	Pelvis Large	4D Thorax
Descriptive Specifications								
Voltage (kVp)	100	125	125	125	125	80	140	125
Tube current (mA)	15	60	60	15	30	20	75	40
Pulse duration (ms)	20	20	25	20	20	10	25	20
Frame rate (fps)	15	15	15	15	15	15	15	7
Scan arc (degrees)	200	360	200	360	140	200	360	360
Gantry rotation speed (degrees/second)	6	6	6	6	6	6	6	3
Scan duration (seconds)	33	60	33	60	<24	33	60	120
Number of projections	500	900	500	900	350	500	900	840
Exposure (mAs)	150	1080	750	270	210	100	1688	672
$CTDI_{vol}$, norm (mGy/100 mAs)[1]	2.1	1.5	1.6	1.5	1.6	0.94	2.2	1.5
$CTDI_{vol}$ (mGy)[1]	3.2	16	12	4	3.4	0.94	37	10
Fan type	Full fan	Half fan	Full fan	Half fan	Full fan	Full fan	Half fan	Half fan
Default pixel matrix	512 x 512	512 x 512	512 x 512	512 x 512	512 x 512	512 x 512	512 x 512	512 x 512
Slice thickness (mm)	2	2	2	2	2	2	2	2
Reconstruction methods	• FDK • Iterative CBCT	• FDK • Iterative CBCT	• FDK	• FDK	• FDK	• FDK • Iterative CBCT	• FDK • Iterative CBCT	• FDK

CBCT Image Acquisition and Reconstruction	
Descriptive Specifications	**Specification**
CBCT acquisition and reconstruction methods.[2]	3D CBCT [Both Standard (FDK) and Iterative CBCT reconstruction methods] 4D CBCT Gated CBCT[7] Extended length CBCT
HU accuracy[3-5] (Measured using the sensitometry insert of the Catphan 504/604. Applies to full-fan and half-fan modes.)	±50 HU
HU uniformity[4-6] (Measured using the uniformity region of the Catphan 504/604. Applies to full-fan and half-fan modes.)	±40 HU (±30 HU typical)
Spatial resolution – full-fan (Measured using the high resolution insert of the Catphan 504/604. Reconstructed with 0.5 mm pixel size and slice thickness of 2 mm.)	≥6 lp/cm (7 lp/cm typical)
Spatial resolution – half-fan (Measured using the high resolution insert of the Catphan 504/604. Reconstructed with 0.9 mm pixel size and slice thickness of 2 mm.)	≥4 lp/cm (5 lp/cm typical)
Spatial resolution – limiting (Measured using the high resolution insert of the Catphan 504/604. Reconstructed with 0.2 mm pixel size and slice thickness of 2 mm.)	≥12 lp/cm (14 to 15 lp/cm typical)

1 Measurement uncertainty ±30%.

2 Noise in reconstructions using Iterative CBCT (when using the "Standard" reconstruction filter and "Medium" noise suppression) is 60%, or less, of the noise in Standard (FDK) reconstructions. This applies to Head and Pelvis CBCT modes.

3 Valid only if HU calibration has been performed.

4 Values apply only when using the IGRT couch top.

5 Does not apply to 4D Thorax and 4D Spotlight modes.

6 Valid only if HU and blade calibrations have been performed

7 It is possible to use both standard and Iterative CBCT reconstruction methods with gated CBCT acquisition.

Descriptive Specifications	Specification
Low contrast detectability (Measured using the high resolution insert of the Catphan 504/604. Dose Index of 16 mGy $CTDI_{vol}$ – Pelvis mode – with 0.9 mm pixel size and 2 mm slice thickness.)	1.0%; 15 mm, 9 mm diameter objects visible
Reconstruction field of view (diameter)	Head scans: 0 to 25.0 cm Body scans: 0 to 46.0 cm
Reconstruction length (3D CBCT)[8]	Head scans: 18.0 cm Body scans: 17.0 cm
Reconstruction length (Extended length)[8]	Two scans Full-fan: 35 cm Two scans Half-fan: 33 cm Three scans Full-fan: 51 cm Three scans Half-fan: 48 cm
Extended length acquisition - combining multiple scans to form a CBCT dataset with a larger reconstruction length.	Combine 2 to "n" scans, where "n" is limited by the longitudinal motion of the couch.
Available reconstruction matrices	128 x 128, 256 x 256, 384 x 384, 512 x 512
Slice thickness (mm)	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 10.0
Acquisition and reconstruction times for 512 x 512 reconstruction matrix (from instant when start button is pressed until the reconstructed result is displayed in the imaging application.)[10]	200 degree 3D CBCT scan: 53 s (+10/-5 s) 360 degree 3D CBCT scan: 80 s (+40/-10 s) Short Thorax mode: 45 s (+10/-5 s)[9] 360 degree 4D CBCT scan: 215 s (+40/-10 s) Gated CBCT: patient dependent
CBCT workload (thermal considerations only)	>50 pelvis scans/hour
Gantry rotation velocity	1.0 to 6.0 degrees/second in steps of 0.5 degrees/second
Radiation Dose Structured Report (RDSR) support	DICOM object containing $CTDI_{vol}$ and DLP (dose length product) for each CBCT scan can be optionally generated and saved to a user-specified location.

8 Subtract 6 mm from these values - per scan - when using Iterative CBCT reconstruction methods.

9 kV beam on time is ~23-1/3 s.

10 The Iterative CBCT reconstruction adds 15 s, 7 s, and 23 s to these values when using the Head, Pelvis Fast, and Pelvis Iterative CBCT reconstruction methods. Note: These values apply to medium sized patients; larger patients require longer reconstruction times.

Table 16: Imaging During Treatment

Triggered Imaging	
Description	The acquisition of kV images at regular intervals during treatment delivery.
Available triggers	Time; MU; gantry angle; respiratory gating signal
Triggers that continue to initiate kV image acquisition, even when treatment beam is paused.	Time; respiratory gating signal
Minimum interval between images	3 s; or, equivalent in MU or gantry angle
Maximum number of triggered images—in one sequence—that can be saved to the information system.	100[1]
Auto Beam Hold	
Description	The automated detection of implanted fiducials in triggered images, along with logic to pause the treatment beam if the fiducials are detected outside of a tolerance region
Modes of operation	Disabled; passive; active
Passive mode	Fiducials are detected; the detected locations are shown on the display; but the treatment beam is never held.
Active mode	Fiducials are detected; the detected locations are displayed on the display; and, the treatment beam can be held - depending upon fiducial locations.
Ignore detection failure	Optional configuration to ignore the result from one image when fiducials are not detected.[2]
Minimum number of fiducials	1
Typical number of fiducials	3 to 4
Tolerance region	Spherical region or defined by a structure contoured at the time of treatment planning
Size of spherical tolerance region	2 - 40 mm diameter
Fiducial shapes supported	Spherical or cylindrically shaped fiducials[3]
Custom detection option: Allowed width of fiducials	1 to 5 mm[4]
Custom detection option: Allowed length of fiducials	2 to 5 mm[5]

1 When the number of triggered images exceeds 100, uniform sampling of the image sequence is performed to reduce the number of images.

2 Fiducials detected outside of the tolerance region always stop the beam.

3 Must have approximately the same shape, or appearance, when viewed at all gantry angles.

4 Algorithms can detect fiducials +/- 50% of the selected size - although with reduced confidence.

5 Algorithms can detect fiducials +/- 50% (spherical shapes) +20%/-50%(cylindrical shapes) of the selected size - although with reduced confidence.

Table 17: Respiratory Motion Management Specifications (Optional)

All scale references below are per IEC 61217.

Advanced Patient Motion Monitoring System	Specification
Acquisition rate	30 fps
Reflector type	Passive – 4 spheres
Couch rotation range where reflectors are detected reliably[1]	±60 degrees
Tracking volume when placed at 2.0 to 2.5 m from isocenter	0.50 m^3
Beam-on latency (ms)	200 (75 – 110 typical)
Beam-off latency (ms)	160 (40 – 75 typical)
Latency in triggering a kV image	80 ms
Latency in triggering an MV image	120 ms
Maximum supported breathing rate (breath per minute)	25
Minimum motion needed to initiate optical system for respiratory gating	4 mm
Basic Patient Motion Monitoring System	**Specification**
Acquisition rate	25 fps
Reflector type	Passive – 4 spheres
Couch rotation range where reflectors are detected reliably[1]	± 50 degrees
Tracking volume when placed at 2.0 to 2.5 m from isocenter	0.35 m^3
Beam-on latency (ms)	210 (85 – 120 typical)
Beam-off latency (ms)	170 (50 – 85 typical)
Latency in triggering a kV image	80 ms
Latency in triggering an MV image	120 ms
Maximum supported breathing rate (breath per minute)	25
Minimum motion needed to initiate optical system for respiratory gating	4 mm

1 Assumes the reflectors remain within the tracking volume.

Table 18: Visual Coaching Device[1] (VCD) Specifications (Optional)

All scale references below are per IEC 61217.

Descriptive Specifications	Specification
Visual prompt options	Slide, curve, dog
Data connection to the monitoring system	Wireless
Power source	Rechargeable lithium ion battery[2]
Battery lifetime per charge	~ 3.5 hours[3]
Low battery warning	Yes
External battery pack charger	Yes[4]
Charging time	~ 4 hours
Support for external displays	Yes[5]

1 Purchasable option.

2 Two rechargeable battery packs are provided with each VCD. An external power supply can be connected to the VCD as backup in case a fully charged battery pack is not available.

3 Without powering any external display device via USB power connector.

4 Provided with the VCD.

5 Digital video output, which can be used to connect an external monitor, projector or goggles.

Table 19: Integrated Conical Collimator Verification and Interlock System Specifications (ICVI)

All scale references below are per IEC 61217.

Descriptive Specifications	Specification
Conical collimators (mm)[1]	4, 5, 7.5, 10, 12.5, 15, 17.5
Maximum jaw size	5 cm x 5 cm
Electronic verification of collimator and jaws	Yes
Average leakage[2,4]	< 0.1%
Maximum leakage[2, 4]	< 0.2%
Penumbra at D_{max}[3, 4]	< 2.0 mm
Energy compatibility	6X and 10X high intensity modes, 6 MV, 10 MV
Performance Specifications	**Specification**
Conical collimator and mount alignment to collimator	≤0.4 mm

1 Projected at the isoplane

2 Leakage specified for 6X and 10X high intensity energy configurations per IEC 60601-2-1, leakage through beam limiting devices

3 Penumbra defined as 20-80% leaf end, measured using 10 cm x 10 cm field size, 6X high intensity energy configuration at D_{max}, 100 cm SAD

4 For additional TrueBeam, TrueBeam STx , and Edge IEC accompanying documents, please refer to the following documents: Type Tests (P1007278); Site Tests and Procedures (P1007279); Functional Performance Characteristics- IEC 60976, Medical Electron Accelerators (P1007370).

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Specifications subject to change without notice. Not all features and options listed in this document are available in all markets.

Intended Use Summary

Varian Medical Systems' linear accelerators are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Safety

Radiation treatments may cause side effects that can vary depending on the part of the body being treated. The most frequent ones are typically temporary and may include, but are not limited to, irritation to the respiratory, digestive, urinary or reproductive systems, fatigue, nausea, skin irritation, and hair loss. In some patients, they can be severe. Treatment sessions may vary in complexity and time. Radiation treatment is not appropriate for all cancers.

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RAD10989 11/2021

Attachment G

EQUIPMENT COMPARISON – CMC (LCI Morehead) LINAC Replacement

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, etc.)	Linear Accelerator	Linear Accelerator
Manufacturer	Varian	Varian
Model name/number	Novalis Tx	Tru Beam
Other method of identifying the equipment (e.g., Serial Number, VIN #)	H294573	Not Available Until Installed
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2010	2023 / 2024
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project	N/A	$5,000,000
Total cost of the equipment	Not available due to system transition	$2,756,677
Location of the equipment	LCI Morehead, Room #1507	LCI Morehead, Room #1507
Document that the existing equipment is currently in use	Existing equipment performed 5,000 procedures from Nov 2022 to Oct 2023	N/A
Will the replacement equipment result in any increase in the **average charge per procedure**?	N/A	No
If so, provide the increase as a percent of the current average charge per procedure	N/A	N/A
Will the replacement equipment result in any increase in the **average operating expense per procedure**?	N/A	No
If so, provide the increase as a percent of the current average operating expense per procedure	N/A	N/A
Type of procedures performed on the existing equipment	External beam radiotherapy	N/A
Type of procedures the replacement equipment will perform	N/A	External beam radiotherapy

Attachment H

LCI Morehead LINAC, Room 1507 Volume by Month	
Month	**Volume**
Nov-22	410
Dec-22	378
Jan-23	278
Feb-23	418
Mar-23	380
Apr-23	385
May-23	456
Jun-23	492
Jul-23	445
Aug-23	582
Sep-23	475
Oct-23	301
Total	**5,000**

Attachment I

varian
A Siemens Healthineers Company

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304
650.493.4000
800.544.4636
varian.com

Courtney S. Dobbelaer
Manager, Capital Acquisitions
Supply Chain Management

November 9, 2023

RE: Linear Accelerator

Hello Courtney,

This letter is to confirm that Varian intends to remove the Trilogy linear accelerator, SN H294573, from the Atrium facility at Levine Cancer Institute in Morehead, NC under quote 2019-213516-10. Varian will not install this unit in the state of North Carolina without an appropriate Certificate of Need (CON) issued by the appropriate state governing body. Please let me know if you have any questions or require further assistance.

Yours sincerely,

Varian Medical Systems

James Yester

James Yester
Project Manager
James.yester@varian.com
(336) 403-8584

From: Huber, Brighid K
To: Hunt, Tiffany C; Waller, Martha K; Faenza, Julie M
Subject: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center
Date: Tuesday, December 5, 2023 10:06:36 PM
Attachments: 2023 CMHA dba CMC LINAC Replacement Exemption Request.pdf

Good evening,

Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Carolinas Medical Center to replace an existing linear accelerator.

Thank you, and please let me know if you have any questions.

Best,

Brighid

Brighid Knoll Huber, MHA, ATC
Enterprise Strategy Partners
Mobile: 724-986-6214

Atrium Health
Carolinas HealthCare System is Atrium Health

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