

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 5, 2025

Greg Billings gbillings@catawbavalleymc.org

Exempt from Review – Replacement Equipment

Record #: 4882

Date of Request: August 6, 2025

Facility Name: Catawba Valley Medical Center

FID #: 933080

Business Name: County of Catawba

Business #: 2949

Project Description: Replace linear accelerator

County: Catawba

Dear Mr. Billings:

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). Therefore, you may proceed to acquire without a certificate of need the TrueBeam H194828 linear accelerator to replace the TrueBeam PCSN H191150 linear accelerator. 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

Team Leader

Micheala Water 10

Gloria C. Hale

Micheala Mitchell Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

Radiation Protection Section, DHSR

Construction Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873



July 31, 2025

<u>Via Electronic Mail Only</u>
Ms. Micheala Mitchell, Chief, Healthcare Planning and Certificate of Need Section Ena Lightbourne, Project Analyst
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Equipment Replacement at Catawba Valley Medical Center/Catawba County

Dear Ms. Mitchell:

Pursuant to NCGS 131E-184(f) and 184(g), Catawba Valley Medical Center (CVMC) is writing to inform you of our intent to replace one of the two fixed Linear Accelerators located in our main campus hospital facility in Hickory. CVMC requests confirmation that this equipment replacement complies with the regulations set out in NCGS 131E184(a)(7), NCGS 131E-184(g), NCGS 131E-176(22a), and NCAC 14C .0303, as exempt from certificate of need review.

The hospital originally acquired and began using the existing Varian TrueBeam H191150 Linear Accelerator in 2011. CVMC intends to replace the existing Linear Accelerator with a new Varian TrueBeam Linear Accelerator. The Varian system has been operating daily, used for hospital patients. The existing Linear Accelerator is 14 years old and has exhausted its useful life (see Attachment 1). CVMC is simply updating this important patient treatment system with newer technology that offers state-of-the-art quality of care for patients.

Via this letter, CVMC affirms that it will trade-in the Varian TrueBeam H191150 Linear Accelerator for removal from operation at CVMC. Because it has exceeded its useful life, Varian Medical intends to scrap the existing Linear Accelerator. CVMC has confirmed that the replaced existing Linear Accelerator will be removed from North Carolina and will not be used again in North Carolina.

Applicable Regulations

Pursuant to NCGS 131E-184(a)(7):

"The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment."

NCGS 131E-176(22a) states: "(22a) Replacement equipment. -

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."

According to correspondence from DHSR Chief of Healthcare Planning and Certificate of Need, dated October 30,2024, the FY 2025 capital cost threshold for Replacement Equipment is \$3,089,400.

Per NCAC 14C .0303:

"(a) This Rule defines the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a). (b) "Currently in use" means that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service during the 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section. (c) Replacement equipment is not "comparable" if: (1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or (2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption."

GS 131-184(g) defines an additional exemption:

- (g) The Department shall exempt from certificate of need review any capital expenditure that exceeds the monetary threshold set forth in G.S. 131E-176(16)b. if all of the following conditions are met:
 - (1) The sole purpose of the capital expenditure is to renovate, replace on the same site, or expand the entirety or a portion of an existing health service facility that is located on the main campus.
 - (2) The capital expenditure does not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.

(3) The licensed health service facility proposing to incur the capital expenditure shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

Compliance

CVMC hereby certifies that:

- The total project cost for the replacement Varian TrueBeam with HyperSight & RapidArc
 Dynamic Linear Accelerator, including the equipment, construction, rigging and
 installation, and all other costs, is \$4,711,916.00, as shown on the attached capital cost
 form
 - (Attachment 2). Please see the Varian TrueBeam with HyperSight & RapidArc Dynamic Linear Accelerator equipment quote of \$4,513,108.00 (Attachment 3). CVMC will locate the replacement Linear Accelerator in an existing vault within the main building of the hospital. This site is the "main campus" as defined in NCGS 131E-176(14n) for Catawba Valley Medical Center (License # H0223). CVMC contractor confirms that the projected construction cost required to accommodate the replacement Linear Accelerator is estimated at \$198,808.00, including labor and materials plus architect and engineering fees (Attachment 4). The cost to remove the existing Varian TrueBeam H191150 from CVMC will be borne by Varian Medical, and Varian Medical is including delivery, rigging, and installation costs in the quotation for the new Linear Accelerator.
- 2. The replacement Linear Accelerator will be installed at CVMC for the sole purpose of replacing comparable equipment currently in use. The replaced equipment will be relocated out of CVMC and North Carolina. The existing Varian TrueBeam H191150 Linear Accelerator has been used at least 10 times to provide a health service in the last 12 months. A comparison of the existing and proposed replacement equipment is provided in the attached table (Attachment 5).
- 3. The replacement Linear Accelerator is functionally similar to the existing equipment and will be used for the same therapeutic procedures as the equipment currently in use. The replacement equipment is a full-featured Varian TrueBeam with HyperSight & RapidArc Dynamic Linear Accelerator, with features that do not change the basic technology or result in the provision of a new health service or type of procedure.
- 4. CVMC will have no increase in charges that is related to this transaction within the initial twelve months after the replacement Linear Accelerator is acquired.
- 5. The average cost per procedure at CVMC will not increase by more than 10 percent

- during the initial 12 months of service as a result of the Varian TrueBeam with HyperSight & RapidArc Dynamic Linear Accelerator replacement.
- 6. The proposed expenditure exceeds the Replacement Equipment Threshold
- 7. The proposed expenditure will replace the linear accelerator on the main campus of Catawba Valley Medical Center. Attachment 6 shows the location of the existing and proposed replacement linear accelerator in the main hospital building on the first floor. This building is on the main campus as defined in GS 131E-176(14n), where clinical services are provided and in which financial and administrative control occurs. The replacement will use the vault that currently houses the equipment that will be replaced.
- 8. The capital expenditure does not result in a change in bed capacity or any other new institutional health service.

CVMC requests that the Division of Health Service Regulation confirm that replacement of the existing Varian TrueBeam H191150 as proposed herein does not constitute a new institutional health service and is Exempt from certificate of need review pursuant to NCGS 131E-184(g). Please contact me at 828.326.2765 regarding any questions concerning this request.

Sincerely,

Mag Billingo

Greg Billings, MSN, RN-BC, NEA-BC

Vice President & Corporate Compliance Officer

Attachments:

- 1. Varian Medical TrueBeam PCSN H191150 End-of-Life Notice
- 2. Project Capital Cost Form
- 3. The Varian TrueBeam with HyperSight & RapidArc Dynamic Linear Accelerator Equipment Quote
- 4. Revels Contractor Construction Estimates
- 5. Equipment Comparison Table
- 6. Directory showing location of the linear accelerator on the main campus

ATTACHMENT 1



Varian
A Signers Healthineers Company

Varian Medical Systems 3100 Hansen Way

Palo Alto, CA 94304

650.493.4000 800.544.4636

varian.com

May 28, 2025

Dear Catawba Valley Medical Center,

Since 2010, the TrueBeam radiotherapy system has served the radiotherapy community well, earning a reputation for quality, efficiency, and reliability. The TrueBeam radiotherapy system was designed with the expectation that these treatment delivery devices will be utilized under high dose, high dose modulation, frequent imaging, and high patient throughput.

We understand how important the TrueBeam radiotherapy system has been to your clinic and your patients. Due to technological obsolescence, component obsolescence, and advances in technology, it has become necessary to discontinue standard support of TrueBeam systems PCSN H191985 or earlier. Consequently, Varian will no longer offer support or maintenance of the noted TRUEBEAM and version(s) 2.7.4001/ PCSN H191150 after December 31, 2027.

We will continue to seek to provide support for systems under agreements until then, depending on parts availability. Varian service will address mandatory safety concerns and provide Limited Support only. TrueBeam service contracts for your machine will not be renewed beyond December 31, 2027.

Your TrueBeam PCSN H191150 is affected by this notification. Service and replacement parts will be provided based on availability.

Standard support for your TrueBeam will continue to be available through **December 31, 2027**, subject to replacement part availability. Before December 31, 2027, your local district manager will contact you to discuss a transition to a Limited Support program.

Limited Support will have no guarantees and is conditional on parts availability. Renewal potential will be determined annually, based on availability of parts and commercial feasibility of continued support. The Limited Support program will have the following conditions:

- Commercially reasonable efforts will be used to maintain existing systems, given the global limited supply on replacement parts.
- No uptime guarantees will be offered.
- Varian will make commercially reasonable efforts to continue onsite, remote, Help Desk, and training support.
- No software upgrades including bug fixes, other than mandatory safety actions.
- No guarantees of interoperability among oncology information systems, treatment planning software, and third-party systems.
- No compatibility with future Varian releases

The window between the End of Support announcement and the effective End of Support date is designed to give your institution the opportunity to create a thoughtful replacement plan for existing systems. Over the coming months, your local Varian representative will continue to work with you and your team to help create a fleet replacement plan to ensure minimum disruption to your clinic.



By signing the attached Return Response Form, your institution acknowledges that you understand that your TrueBeam System with PCSN H191150 will reach End of Support on **December 31, 2027**.

Thank you for using Varian products. We look forward to continuing to work with you to create a world without fear of cancer.

Sincerely,

Vidhya Krishnamurthi (Oct 2, 2024 14:34 PDT)

Vidhya Krishnamurthi Director, C-Arm Linac Portfolio Treatment Delivery Systems Varian Medical Systems Steve Leonard (Sep 26, 2024 15:31 EDT)

Steve Leonard Senior Vice President Global Customer Service Varian Medical Systems



RETURN RESPONSE RESPONSE IS REQUIRED

Subject:

Product End of Support

Affected Product:

TRUEBEAM

Affected Versions:

2.7.4001

UDI:

N/A

Reference ID:

EOS-00052

Serial Number:

H191150,

Functional Location: H-HICKORY

.....

-NC-US-001

Thank you for reviewing the above referenced END OF SUPPORT letter.

| Please check ALL appropriate boxes and return this Response form at your earliest convenience. |
|--|
| Your response is required to comply with legal and regulatory requirements. |

I have received, read and understand the instructions provided in the notification referenced above.

All affected site personnel have been advised of the content of the notification.

A copy of the notification has been retained and posted with our current product labeling.

This device(s) is no longer deployed at our site. Affected Product: TRUEBEAM

Have any adverse events been associated with the referenced product at your site? □ YES □ YES If yes, please contact Varian Clinical HelpDesk *IMMEDIATELY* +1.888.827.4265.

Kindly complete the following information. If you have any questions regarding this form, please do not hesitate to contact Varian Clinical HelpDesk +1.888.827.4265, or support@varian.com.

| Name | Lan Hurst, XAS DABF, RSO |
|------------------|---|
| Title | Medical Physiciat and Directur |
| Telephone Number | (828) 326 - 3856 |
| E-mail Address | LHUBST @ CVMC .US |
| Firm Name | Catawba Volley Medical Conter 810 Fairgrove Church Rd. |
| Street Address | 810 Fairgrove Church Rd. |
| City | Hickory 9 |
| State/Province | Hickory, 9 |
| Country | USA |

PLEASE RETURN COMPLETED RESPONSE FORM AS SOON AS POSSIBLE. Thank you for your cooperation.

EMAIL TO: returnresponse@varian.com

ATTACHMENT 2

Projected Capital Cost Form

| Building Purchase Price | N/A |
|-------------------------------------|--------------------------|
| Purchase Price of Land | N/A |
| Closing Costs | N/A |
| Site Preparation | N/A |
| Construction/Renovation Contract(s) | \$198,808.00 |
| Landscaping | N/A |
| Architect / Engineering Fees | Included in Construction |
| Medical Equipment | \$4,513,108.00 |
| Non-Medical Equipment | N/A |
| Furniture | N/A |
| Consultant Fees (specify) | N/A |
| Financing Costs | N/A |
| Interest during Construction | N/A |
| Other (specify) | |
| Total Capital Cost | \$4,711,916.00 |

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.

| Mrs Billing | |
|----------------------------|------------------------|
| | Date Signed: 7/28/2025 |
| Signature of Officer/Agent | - |
| | |
| <u>VP Compliance</u> | |
| Title of Officer/Agent | |

Date of Last Revision: 5.17.19

ATTACHMENT 3



Custom System Proposal

Quotation Number - 2025-502268-2

TrueBeam with HyperSight & RapidArc Dynamic to Replace TrueBeam H191150 and EDGE v2.7 to v4.1 @ \$4,513,108. Pricing contingent upon closure no later than 6-6-2025.



*** Confidential - Proposal is intended for Recipient and Recipient's Site Representatives Only ***



Catawba Valley Medical Center ("Customer")

810 FAIRGROVE CHURCH RD
HICKORY North Carolina 28602-9617 United States

Tel: +1 828 326 3856

Email: lenhurst@charter.net

For and on behalf of Varian Medical Systems

Brian Bass District Sales Manager 3290

Atlanta, GA 30327 United States of America

Tel: 9194135344

Email: brian.bass@varian.com

*** Confidential - Proposal is intended for Recipient and Recipient's Site Representatives Only ***

| Quote Information | | | |
|---|--|--|---------------------------------------|
| Quotation Number : 2025-502268-2 | | Quotation Date : May 30, 2025 | Quotation Valid Until : June 06, 2025 |
| Customer Requested Delivery Date : February 19, 2027 | | | |
| Customer Procurement Contact Name : Needed | | | |
| Billing Plan See Quote billing plan Summary on the following page | | pages which is incorporated by reference | |
| Sales | | | |
| Incoterms : DPU Site Insured | | Payment Terms : 30 | days net |
| Sales PO Required : Yes | | | |

Quotation Total

Quotation Total: US \$4,513,108.00

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_US_EN_OCT_2024 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, 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 __Dennis Johnson__

Dennis Johnson (Jun 5, 2025 13:04 EDT)

Authorized Representative : Len Hurst

Title:

Date: May 30, 2025

For and on behalf of Varian Medical Systems

Authorized Representative : Brian Bass

Title: District Sales Manager

Date : May 30, 2025

Billing Summary



| 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. | |

Quotation Summary



Offered Products (Sales)

| Trade-In for TrueBeam H191150 | Included |
|--|----------|
| Eclipse RapidArc Dynamic | Included |
| Knowledge Hour Program | Included |
| Advantage Credits | Included |
| Travel and Lodging for Training | Included |
| RapidArc Dynamic Advanced Clinical Implementation | Included |
| HyperSight Advanced Imaging Implementation Support | Included |
| CATAWBA VALLEY MEDICAL CENTER | |
| TrueBeam | Included |
| Catawba Valley Medical Center | |
| EDGE Upgrade H194828 (H194828) | Included |
| Eclipse RapidArc/MCO GPU Workstation | Included |



| Site: | CATAWBA VALLEY MEDICAL CENTER |
|-------|-------------------------------|
| 1.0 | TrueBeam |
| | |

1.1 TrueBeam Base System 120 MLC

1

Treatment delivery system 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, upper port film graticule to support basic quality assurance, and drum phantom for Machine Performance Check (MPC).

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
- · Image only sessions
- Unplanned Treatment Mode up to 5 fractions
- · Fraction number displayed on in-room monitor
- · Match environment layout for 2D/2D and 2D/3D layouts default to the 2-panel
- · Custom DRR templates that are created in Eclipse will be available on the TrueBeam Platform
- Online access to a marketing kit that contains a broad range of advertising, educational, promotional, and public relations materials targeted to referring physicians, patients, and the media
- Electronic Dynamic Wedges (EDW)
- Large field IMRT

Prerequisites:

- ARIA oncology information system for radiation oncology v15.1 through v17.0, or ARIA OIS v18.0 or higher, or compatible third-party oncology information system
- Eclipse treatment planning system v15.1 or higher, or compatible third-party treatment planning system
- If third-party OIS:
 - Authentication Server for third-party OIS (Hardware and Software) or
 - · Authentication Server for third-party OIS (Software only)

Customer Responsibilities:

- · Verify compatibility with third-party oncology information systems if applicable
- · Verify compatibility with third-party treatment planning systems if applicable
- 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.

Notes:

T..... Da a 1/4 4

· Multiple patient name in Japan market is applicable for Kanji, Kana and Romaji characters to identify the patient

| 1.2 | IrueBeam V4.1 | 1 |
|-----|---|---|
| 1.3 | 18/23 MV (BJR 11/17) | 1 |
| | 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min. | |
| 1.4 | 10/10 MV (BJR 11/17) | 1 |
| | 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min. | |
| 1.5 | 6/6 MV (BJR 11/17) | 1 |
| | 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min. | |
| 1.6 | 20 MeV, 0-1000 MU/Min | 1 |



| Item | Description | |
|------|---|---|
| | 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min. | |
| 1.7 | 16 MeV, 0-1000 MU/Min | 1 |
| | 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min. | |
| 1.8 | 12 MeV, 0-1000 MU/Min | 1 |
| | 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min. | |
| 1.9 | 9 MeV, 0-1000 MU/Min | 1 |
| | 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 | 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. | |
| 1.13 | 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. | |
| 1.14 | Low-X Imaging Energy | 1 |
| | Low-X imaging energy configuration, providing high soft tissue contrast when imaging in-line with the treatment beam. | |
| 1.15 | Delta Couch | 1 |
| | Delta Couch supports automated management of treatment plan-based shifts from initial set up mark to treatment isocenter. Features: Delta couch shift set-up Prerequisites: | |
| | TrueBeam® v2.7 or higher ARIA® oncology information system for radiation oncology v11.0 MR4.1 or higher, or compatible third-party oncology information system Customer Responsibilities: Verify compatibility with third-party oncology information systems if applicable | |
| 1.16 | 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

1.17 kV Imaging System

1

 $\underset{-}{\text{kV}}$ 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 online.

Prerequisites:

- ARIA oncology information system for radiation oncology v15.1 through v17.0, or ARIA OIS v18.0 or higher, or compatible third-party oncology information system
- · TrueBeam Platform v3.0 or higher

Customer Responsibilities:

· Verify compatibility with third-party oncology information systems if applicable

1.18 Advanced Resp Motion Management System

1

Advanced Respiratory Motion Management System is a 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

Prerequisites:

- TrueBeam®, VitalBeam, or Edge v2.7 and higher
- · kV Imaging System

1.19 Gated CBCT

Gated Cone-Beam Computed Tomography (CBCT) provides the ability to acquire CBCT images synchronized with patient respiration (free-breathing or breath hold).

Features:

- Gated CBCT Imaging License
- 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 can be used for single breath hold CBCT data acquisition.

Prerequisites:

- TrueBeam®, VitalBeam, or Edge v2.7 or higher
- · One of the following:
 - Advanced Respiratory Motion Management System
 - · Basic Respiratory Motion Management System
- · kV Imaging System

1.20 Accelerated 4D CBCT Reconstruction

1

License and hardware package for 4D CBCT accelerated reconstruction

Features:

- 4D kV CBCT License
- · 4D CBCT Reconstruction on GPU License Package
- · 4D kV CBCT Image Match Review License

Prerequisites:

- TrueBeam Platform v3.0 or higher
- kV Imaging System
- Basic Respiratory Motion Management or Advanced Respiratory Motion Management System

1.21 Additional In-Room Monitor System

1



| | Additional in-room monitors that can be placed at customer discretion. | |
|------|--|---|
| 1.22 | Main Circuit Breaker Panel | 1 |
| | 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. | |
| 1.23 | 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. | |
| 1.24 | Supp. Phantom Kit | 1 |
| | Supplemental imaging phantom kit for measuring resolution and contrast of kV and MV imaging systems. | |
| | Features: | |
| | Leeds TOR 18FG phantom for measuring spatial resolution and contrast of kV imaging system MV contrast phantom for measuring contrast performance of MV imaging system Geometric phantom, mounted on IGRT couch top-compatible lock bar. Can be used for quality assurance of image guidance workflow. Prerequisites: | |
| | MV imaging system | |
| 1.25 | 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 | |
| 1.26 | NLS: English | 1 |
| 1.27 | Vertical LAP Apollo Green Room Laser Kit | 1 |
| | LAP Apollo Green Room Laser Kit for patient alignment with Vertical Remote-Controlled Sagittal Line Laser. Features: 1 Apollo Green Remote-controlled Ceiling Crosshair Laser 2 Apollo Green Remote-controlled Lateral Crosshair Lasers 1 Apollo Green Vertical Remote-Controlled Sagittal Line Laser | |
| 1.28 | Quick Ref Guide - English | 1 |
| 1.29 | HyperSight Imaging Solution HyperSight™ for TrueBeam® Platform | 1 |

Item

Description



| Item | Description |
|------|-------------|
| _ | Contractor |

- Gantry speed up to 1.5 RPM for Imaging and motions between treatment fields.
- CBCT Metal Artifact Reduction
- · HU Accuracy and Uniformity
- · Extended Field of View reconstruction
- Quart phantom for HU calibration
- 27" Console Monitors

Prerequisites:

- TrueBeam or Edge™ v4.1 or higher
- · ARIA® oncology information system (OIS) v15.1 v18.0 or higher, or compatible third-party
- Eclipse™ treatment planning system v15.1 or higher, or compatible third-party
- If third-party OIS:
 - Authentication Server for third-party OIS (Hardware and Software) or
 - Authentication Server for third-party OIS (Software only)

1.30 Advantage Contract Credits

39

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

1.31 Enhanced 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:

Arbitrarily shaped fiducial detection for Auto Beam Hold (ABH)

Prerequisites:

- TrueBeam® or Edge™ v4.0 or higher
- Advanced Respiration Motion Management System or Basic Respiration Motion Management System

1.32 RapidArc Dynamic Treatment Delivery

1

RapidArc Dynamic Treatment Delivery incorporates static-angle ports and dynamic rotation of the collimator during the treatment arc(s).

Features:

- 1 (one) Dynamic Collimator license
- 1 (one) RapidArc Dynamic Treatment Delivery license

Prerequisites:

- TrueBeam or Edge SN 2001 and higher
- TrueBeam or Edge v4.1 or higher
- 120 Multi Leaf Collimator or HD120 Multi Leaf Collimator
- · RapidArc Treatment Delivery
- · RapidArc Dynamic Planning, with Eclipse v18.1 or higher
- ARIA v18.0 or ARIA Core v18.1 or higher

Customer Responsibilities:

Verify compatibility with third-party oncology information systems if applicable

1.33 Existing Baseframe 52" Fixed Floor

1

Use of existing baseframe may require modification.

1.34 SuperFAST Installation - Existing Basefr

1

Accelerated 12-day installation of TrueBeam®, TrueBeam STx, VitalBeam™, or Edge® on existing base frame with prior system rigging and network availability.

Features:



· Completion of installation of all features required for commissioning readiness

Prerequisites:

- · Recently ordered new system that has not yet been installed
- Eclipse[™] Treatment Planning System
- · 24/7 access to the facility
- All items on pre-installation checklist complete
- Customer agreement to scope of work

Notes:

- Varian will complete installation to a minimum of beam, collimator, and MV imaging system readiness for commissioning activities.
- Varian will return within 30 days from completion of customer commissioning to complete installation and acceptance of all remaining items that were not required for system commissioning, including kV imaging, Rapid Arc, respiratory motion management system.
- · This service does not include additional construction or commissioning support.

1.35 Qfix kVue One Couch Top

1

The Qfix® kVue™ One couch top for the TrueBeam™ platform

Features:

- · Modular design with no support beams
- · Compatible with Calypso® system
- Compatible with the standard TrueBeam 4 degrees of freedom (4DoF) couch and the PerfectPitch™ 6 degrees
 of freedom (6DoF) couch
- Includes:
 - · Qfix kVue One couch top base frame and back panel
 - · kVue Low-e standard indexing insert
 - · kVue tip extension insert
 - Service overlay
 - · QA locating bar
 - Calypso compatible indexing bar

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
 - Edge System v2.7 or higher with the Optical Surface Monitoring System (OSMS)
 - TrueBeam System v2.7 or higher
 - VitalBeam™ System v2.7 or higher

Customer Responsibilities:

Verify third-party accessories compatibly

Notes:

2.1

- kVue One is not validated for use with HyperArc™ High-Definition Radiotherapy
- · Safe Working Load when installed on:
 - TrueBeam 4DoF couch: 496 lbs. (225 kg)
 - PerfectPitch 6DoF couch: 414 lbs. (188 kg)

2.0 Trade-In for TrueBeam H191150

Trade-In Discount

1

Trade-In for TrueBeam H191150

2.2 Remove/Dispose Existing Equipment

1

Remove TrueBeam H191150

Site: Catawba Valley Medical Center 3.0 EDGE Upgrade H194828 (H19482

3.1 v2.7 to TrueBeam Platform v4.1

1

This provides an upgrade from TrueBeam® Platform v2.7 to v4.1

Features:

· Image only sessions



- Unplanned Treatment Mode up to 5 fractions
- Fraction number displayed on in-room monitor
- · Match environment layout for 2D/2D and 2D/3D layouts default to the 2-panel
- Custom DRR templates that are created in Eclipse will be available on the TrueBeam Platform
- · CBCT Mode Editor
- · IEC 60601-2-1 Fourth Edition compliant
- Microsoft[®] Windows[®] 10

Prerequisites:

- TrueBeam Platform v2.7
- ARIA® oncology information system (OIS) v15.1 v18.0 or higher, or compatible third-party
- Eclipse™ treatment planning system v15.1 or higher, or compatible third-party
- If third-party OIS:
 - Authentication Server for third-party OIS (Hardware and Software) or
 - Authentication Server for third-party OIS (Software only)

Customer Responsibilities:

- · Verify compatibility with third-party OIS and treatment planning systems if applicable.
- TrueBeam supports IEC 60601 or IEC 61217 scales only.

4.0 Eclipse RapidArc Dynamic

4.1 RapidArc Dynamic Planning Core

1

Eclipse RapidArc Dynamic Planning facilitates dynamic arc treatments by integrating static-angle ports and dynamically rotating the collimator during the treatment arc(s). Treatments are produced through volumetric dose optimization to generate intensity modulated dose distributions.

Features:

RapidArc Dynamic Planning for one (1) user

Prerequisites:

- Eclipse v18.1 or higher
- RapidArc Planning
- Eclipse FAS or calculation workstation with minimum 16GB GPU memory
- TrueBeam v4.1 or higher
- · RapidArc Dynamic Treatment Delivery

4.2 Install on Existing/Customer Server

1

4.3 NC RapidArc Dynamic Planning (TBOX)

1

Eclipse RapidArc Dynamic Planning facilitates dynamic arc treatments by integrating static-angle ports and dynamically rotating the collimator during the treatment arc(s). Treatments are produced through volumetric dose optimization to generate intensity modulated dose distributions.

Features:

RapidArc Dynamic Planning for one (1) user

Prerequisites:

- Non-Clinical Eclipse v18.1 or higher
- · Eclipse T-Box Software Package
- · Non-Clinical RapidArc Planning
- · Eclipse FAS or calculation workstation with minimum 16GB GPU memory

4.4 STD TRNG: RapidArc Dynamic Onsite

1

Standard onsite RapidArc® Dynamic training at Go-Live. Intended audience includes system configurators, quality assurance authorities, quality assurance performers, planners, and radiation prescribers.

Features:

- Customized training plan details will be provided by the training management team after the initial discussion of customer needs
- Training Type: Onsite at customer location

Prerequisites:

- Completion of the Varian RD100 RapidArc Dynamic Planning Video Series on VarianThink
- · Review of the RapidArc Dynamic Planning Workbook on MyVarian
- Completion of the pre-onsite remote session
- · RapidArc Dynamic licenses installed and accepted



Customer Responsibilities:

- Review all product documentation available on MyVarian.com in advance
 - Eclipse[™] treatment planning system Customer Release Notes
 - Eclipse Photon and Electron Instruction for Use

Notes:

- · Offer is valid for up to 18 months after purchase
- · Non-transferable to other users, products, and services and non-refundable

4.5 STD TRNG: RapidArc Dynamic Remote

2

Standard onsite RapidArc® Dynamic training. Intended audience includes system configurators, quality assurance authorities, quality assurance performers, planners, and radiation prescribers.

Features:

- Customized training plan details will be provided by the training management team after the initial discussion of customer needs
- Training Type: One (1) pre-onsite or post-onsite remote training session up to two (2) hours with a clinical
 applications specialist

Prerequisites:

- Must have access to a phone and computer with internet connection
- · Completion of the Varian RD100 RapidArc Dynamic Planning Video Series on VarianThink
- Review of the RapidArc Dynamic Planning Workbook on MyVarian

Customer Responsibilities:

- · Remote access to the customer software may be required
- · Review all product documentation available on MyVarian.com in advance
 - Eclipse[™] treatment planning system Customer Release Notes
 - Eclipse Photon and Electron Instruction for Use

Notes:

- Remote session should be scheduled within thirty (30) days of completing any applicable video learning
 modules
- Offer is valid for up to 18 months after purchase
- · Non-transferable to other users, products, and services and non-refundable

4.6 INCL ED: RD101 RapidArc Dynamic WS

1

The RapidArc® Dynamic treatment planning and delivery workshop enables participants to implement RapidArc Dynamic treatment planning and treatment delivery and make it part of the clinical routine. The training is designed to enable users to be competent and confident in using RapidArc Dynamic planning tools within the Eclipse™ treatment planning system and treatment delivery on the TrueBeam® system. Users will be provided the knowledge to help them gain mastery of RapidArc Dynamic planning concepts and complexities as well as experience RapidArc Dynamic treatment delivery on the TrueBeam. Users will learn and practice treatment planning strategies to develop clinically acceptable treatment plans for a quick adoption of this treatment planning technique. Intended audience includes system configurators, quality assurance authorities, quality assurance performers, planners, and radiation prescribers.

Features:

- Topics covered include:
 - Introduction to RapidArc Dynamic Treatment Planning
 - Overview of Arc Tools and Optimization
 - Treatment Planning practice on the Eclipse treatment planning system highlighting clinical disease sites with increasing complexity
 - RapidArc Dynamic Treatment Delivery concepts with hands-on practice on the TrueBeam 4.1 Treatment Delivery System
- Training Type and Location: Classroom at the nearest Varian Education Center that offers this course

Prerequisites:

- Completion of the Varian course RD100 RA Dynamic on the VarianThink platform
- Review of the RapidArc Dynamic Planning Workbook on MyVarian

Customer Responsibilities:

- Review all product documentation available on MyVarian.com in advance
 - Eclipse Treatment Planning Customer Release Notes
 - Eclipse Photon and Electron Instruction for Use

Customer Responsibilities:

• All travel expenses (airfare, hotel, rental car, meals, and travel incidentals)

Notes:

- · Includes tuition and materials for one person
- · Offer is valid for up to 18 months after installation of product
- Non-transferable to other users, products, and services and non-refundable



4.7 INCL VT: RD100 RA Dynamic VarianThink

1

The RapidArc® Dynamic Video Series on VarianThink includes an overview of the complete RapidArc Dynamic workflow and covers configuring operating limits in RT Administration, RapidArc Dynamic treatment planning in Eclipse™ treatment planning, and treatment delivery on the TrueBeam® system. The video series enables participants to master RapidArc Dynamic treatment planning concepts and treatment delivery aspects to make it part of the clinical routine. The training is designed to enable users to be competent and confident in using RapidArc Dynamic planning tools within the Eclipse™ treatment planning system and treatment delivery on the TrueBeam system. Intended audience includes system configurators, quality assurance authorities, quality assurance performers, planners, and radiation prescribers.

Features:

- Eclipse topics covered include:
 - RapidArc Dynamic Overview
 - Configuring Operating Limits for RapidArc Dynamic
 - Arc Tools
 - Create a RapidArc Dynamic Plan
 - RapidArc Dynamic Optimization
 - · Automatic Skin Flash Tool
 - RapidArc Dynamic Plan Evaluation
 - · Modifying RapidArc Dynamic Plans
 - RapidArc Dynamic Conflict Resolution
 - TrueBeam topics covered include:
 - · Dynamic RapidArc Static Collimator
 - Dynamic RapidArc with Collimator Rotation
 - Training Type: e-learning modules via the VarianThink™ online platform

Prerequisites:

- Basic knowledge of computers and the Windows operating system
 - Basic knowledge of Eclipse™ treatment planning system v15.5 or higher
 - Basic knowledge of ARIA® oncology information system v15.1 or higher

Customer Responsibilities:

· Must have a computer or device with internet access to view online content

Notes:

- Offer is valid for up to 18 months after installation of product
- Access to course content is valid for up to 365 days from initial access of the course on the VarianThink online platform
- Non-transferable to other users, products, and services and non-refundable

Site: Catawba Valley Medical Center 5.0 Eclipse RapidArc/MCO GPU Workstation

5.1 RapidArc Planning Additional

1

An additional RapidArc® planning for one (1) user

Features:

· RapidArc Planning for one (1) user

Prerequisites:

· Eclipse RapidArc Planning

5.2 Eclipse Advanced Planner Desktop

1

Feature(s):

- Contouring and Image Registration Tools
- 2D and 3D Photon Dose Calculation
- 4D Planning and Image Support
- 2D and 3D Brachytherapy Dose Calculation
- · Conformal Arc Planning
- IMRT Planning



Item **Description** · Eclipse Scripting API DICOM RT Prerequisites: Eclipse Calculation Workstation 5.3 **Eclipse GPU Workstation** An Eclipse Calculation Workstation that includes a GPU (Graphics Processing Unit) card Prerequisites: · Eclipse v15.5 or higher 5.4 27" LCD Monitor (16.9) 5.5 Install on Existing/Customer Server 6.0 **Knowledge Hour Program** 6.1 **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 6.2 Knowledge Program - Knowledge Hour 16.0 (Qty: 2, Credit per Qty: 8.0) A customized knowledge program designed to enhance clinical knowledge for ongoing product adoption of Varian hardware and software. The Knowledge Hour webinar provides product specific learning and is designed to provide continuing education. Intended audience includes Radiation Oncologists, Physicists, Nurses, Dosimetrists, Radiation Therapists, and ancillary staff. Features: Applications Trainer will conduct a product specific remote workshop related to a Varian machine or software product including but not limited to: ARIA® oncology information system Eclipse™ treatment planning system TrueBeam® system HyperArc™ RapidPlan Multi Criteria Optimization (MCO) Velocity™ Customized training plan details will be provided by the training management team after the initial discussion of customer needs Training Type: 1 (one) hour remote session Prerequisites: Must create MyVarian and Certificate Manager accounts **Customer Responsibilities:** • Must have access to a telephone and computer with an internet connection Offer is valid for up to 24 months after purchase or per the Terms and Conditions This is a remote continuing education training offering that has potential CE credits available upon completion 6.3 Knowledge Program - Knowledge Hour 16.0

(Qty: 2, Credit per Qty: 8.0)



A customized knowledge program designed to enhance clinical knowledge for ongoing product adoption of Varian hardware and software. The Knowledge Hour webinar provides product specific learning and is designed to provide continuing education. Intended audience includes Radiation Oncologists, Physicists, Nurses, Dosimetrists, Radiation Therapists, and ancillary staff.

Features:

- Applications Trainer will conduct a product specific remote workshop related to a Varian machine or software
 product including but not limited to:
 - ARIA® oncology information system
 - Eclipse™ treatment planning system
 - TrueBeam® system
 - HyperArc™
 - RapidPlan
 - Multi Criteria Optimization (MCO)
 - Velocity™
- Customized training plan details will be provided by the training management team after the initial discussion of customer needs
- Training Type: 1 (one) hour remote session

Prerequisites:

Must create MyVarian and Certificate Manager accounts

Customer Responsibilities:

Must have access to a telephone and computer with an internet connection

Notes:

- Offer is valid for up to 24 months after purchase or per the Terms and Conditions
- · This is a remote continuing education training offering that has potential CE credits available upon completion

6.4 Knowledge Program - Knowledge Hour

16.0

(Qty: 2, Credit per Qty: 8.0)

A customized knowledge program designed to enhance clinical knowledge for ongoing product adoption of Varian hardware and software. The Knowledge Hour webinar provides product specific learning and is designed to provide continuing education. Intended audience includes Radiation Oncologists, Physicists, Nurses, Dosimetrists, Radiation Therapists, and ancillary staff.

Features:

- Applications Trainer will conduct a product specific remote workshop related to a Varian machine or software
 product including but not limited to:
 - ARIA® oncology information system
 - Eclipse™ treatment planning system
 - TrueBeam® system
 - HyperArc™
 - RapidPlan
 - · Multi Criteria Optimization (MCO)
 - Velocity™
- Customized training plan details will be provided by the training management team after the initial discussion of customer needs
- Training Type: 1 (one) hour remote session

Prerequisites:

Must create MyVarian and Certificate Manager accounts

Customer Responsibilities:

• Must have access to a telephone and computer with an internet connection

Notes:

- · Offer is valid for up to 24 months after purchase or per the Terms and Conditions
- · This is a remote continuing education training offering that has potential CE credits available upon completion

7.0 Advantage Credits

7.1 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



Item **Description** 7.2 40.0 Product Apps Sp ARIA RadONC (per hour) (Qty: 40, Credit per Qty: 1.0) Additional ARIA Radiation Oncology onsite training is available for previously trained Varian products. Sold and delivered by hours. 8.0 Travel and Lodging for Training 8.1 Travel and Lodging 1 Travel and Lodging that is purchased through Varian can only be used for attendance of education courses at a Varian Education Center and Varian clinical schools. Travel and Lodging cannot be used to attend tradeshows, or any event not related to Varian education and training courses. Allowance is applied only to the Travel and Lodging expenses, including airfare, hotel accommodations at a Varian preferred hotel, and a rental car. The customer is responsible for any expenses outside of the allowance. Travel and Lodging charges, including any booking fees, will be direct billed and are not reimbursable if travel is booked outside of the travel agents used by Varian Medical Systems only. Once the customer's course registration is confirmed, the customer will contact Varian's designated travel agency to make the necessary travel arrangements and must provide their Varian sales order number. The Travel and Lodging allowance expires 24 months from the acceptance date of the equipment. Any remaining balance is non-refundable and cannot be traded for other products or services. 9.0 RapidArc Dynamic Advanced Clinical Implementation 9.1 **CTS Custom SOW** 1 CTSI will design a custom scope of work and pricing for a service 10.0 HyperSight Advanced Imaging Implementation Support 10.1 **CTS Custom SOW**

CTSI will design a custom scope of work and pricing for a service



Summary of Advantage Contract Credits Quoted Above

| Section 6.0 | |
|---------------|------|
| Year 2 Total | 16.0 |
| Year 3 Total | 16.0 |
| Year 4 Total | 16.0 |
| Total Credits | 48.0 |
| Section 7.0 | |
| Year 4 Total | 40.0 |
| Total Credits | 40.0 |



Sales Price Table

| Sales The Table | |
|-----------------------|-------------------|
| TradeIn-Cancellation: | s US \$-75,000.00 |
| Sales Tota | US \$4,513,108.00 |
| Quotation Tota | US \$4,513,108.00 |



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 Confidential 2025-502268-2 May 30, 2025 Page 19 of 23

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.

RapidArc Dynamic Advanced Clinical Implementation

A team of Varian Physics and Dosimetrist Consultants will work with your clinical and operations teams to build preparedness around a RapidArc Dynamic Program. This engagement is intended build on the fundamentals taught during entitlement training and expand into processes and procedures, quality assurance, and tips for effective planning.

Scope of Work:

- 1. Site Readiness Assessment:
 - A Varian AOS Physicist will work remotely with the Clinical Team to assess the clinic's technical readiness to treat patients with RAD
 - o Recommendations regarding patient immobilization, Quality Assurance (QA), and clinical workflow.
 - System configuration
 - Machine limits specific to RAD
 - Review ELM configuration
 - Creation of RAD specific templates
- 2. Review Machine and Patient QA specific to RAD:
 - Varian AOS will work with the on-site Physics team, providing recommendations for RAD-specific machine QA equipment and procedures.
 - Recommendations will be provided regarding patient specific treatment QA, either utilizing existing QA equipment or providing recommendations for robust systems.
- 3. Basics of RAD planning
 - o Anatomy-specific RAD planning
 - Using templates
 - o Adjustment of optimization parameters
 - Review and use of anatomy-specific "cookbooks"
 - Post planning checks
 - This package is for a single existing Eclipse® site and database

Prerequisites:

ARIA® OIS for RO v18.1 or higher

Customer Responsibilities:

- · Secured internet access
- Performance of patient CT scans
- Clinical and Treatment go-live timelines available
- Core users representing radiation oncology patient process

Notes:

- This service does not include TPS Commissioning.
- This service does not include general configuration of Treatment Planning System, Treatment Delivery Systems, or connectivity between systems.

HyperSight Advanced Imaging Implementation Support

This program is intended to help the clinical team to ensure optimal performance of the HyperSight Imaging System for their intended scope of clinical use.

Scope of Work:

Site readiness assessment:

- A Varian AOS physicist will work remotely with the clinical team to assess the clinic's technical readiness to implement the HyperSight Imaging System
- Remote review of imaging workflows currently in place

• On site Engagement:

- A Varian AOS Clinical Physicist will review existing on-board imaging workflows and CBCT protocols
- The Varian AOS Clinical Physicist will work with the on-site physics team to acquire a new IsoCal/SysCal (and MPC test) to ensure optimal system alignment
- The Varian AOS Clinical Physicist will work with the on-site physics team to implement CBCT protocols specific to different anatomies and imaging requirements
- The Varian AOS Clinical Physicist will work with the on-site physics team to set appropriate defaults to utilize the implemented CBCT protocols
- The Varian AOS Clinical Physicist will acquire benchmark images using an ACR 464 CT phantom, a Sun Nuclear Advanced Electron Density phantom, and the HyperSight-equipped machine's standard QA phantom (Quart)
- The Varian AOS Clinical Physicist will evaluate the suitability of CBCT and extended-CBCT images for contouring and dose calculation
- The Varian AOS Clinical Physicist will work with the on-site physics team to review effective QA procedures for the HyperSight system

Follow Up:

- The Varian AOS Clinical Physicist will provide a written report summarizing the work and findings, including any recommendations for program or process improvements
- The Varian AOS Clinical Physicist will be available to the on-site physics team to make any CBCT protocol or workflow adjustments based on clinical experience for up to 3 months after the on-site visit

Deliverables:

- Remote initial consultation
- One (1) day of on-site implementation support by a Varian AOS Clinical Physicist
- QA program recommendations
- Image quality evaluations and baselines
- On-going remote consultation

Prerequisites:

TrueBeam, Edge, Ethos or Halcyon with the HyperSight Imaging System installed and accepted

Customer Responsibilities:

- Familiarity with CBCT matching
- Recent IsoCal/SysCal calibration
- MPC implementation



Quotation Total

Quotation Total US \$4,513,108.00

Document 1 of 3



Monday, June 30, 2025

Todd Cook (Len Hurst)
Catawba Valley Cancer Center

Catawba Valley Health System Hickory, NC

Varian TrueBEAM Linear Accelerator Renovation:

Todd/Len,

Revels Contracting Services, Inc. appreciates the opportunity to bid this project. This price is based on site specific vendor Drawing #25-011475, dated 04/22/2025 and a site visit. This price is strictly budgetary, pending final drawings and/or agreement on the Scope of Work.

This price does not include any medical equipment, nor the transportation, and/or the installation of such equipment.

Material and Labor:

All for the Sum of = **\$198,808.00**

One Hundred Ninety Eight Thousand Eight Hundred Eight Dollars

The length of the project portion of this project will be approximately 4 weeks with the provision that RCS, Inc. will have full access to the project work area for the full length of the proposed project timeline without any interference from other sources such as de-installing or installing medical equipment, or facility performed work.

This price is good for: 120 Days Expiration Date of: Oct-30-2025

If you have any questions or if we can be of any further assistance, please do not hesitate to contact us at your earliest convenience. Again, we appreciate this opportunity and look forward to working with you in the very near future.

| Sincerely, | Accepted by: |
|--------------------------------------|--------------|
| | Title: |
| Jodie Landsteiner Account Manager | Date: |
| Revels Contracting Services, Inc. | P.O. #: |



Revels Contracting Services, Inc. 5620 Gallagher Drive Gastonia, NC 28052 704-864-2000

June 30, 2025

Divisional Breakdown of Cost

Catawba Valley Health Systems

Hickory, NC

Site Preparation for the Installation of Varian TrueBEAM, Room # Linear Accelerator

| General Requirements | \$25,086.00 |
|--|---|
| Payment & Performance Bond | \$0.00 |
| Architectural and Engineering | \$24,088.00 |
| Existing Conditions | \$8,319.00 |
| Concrete | \$11,366.00 |
| Masonry | \$0.00 |
| Metals | \$10,091.00 |
| Wood, Plastics & Composites | \$26,070.00 |
| Thermal & Moisture Protection | \$752.00 |
| Openings | \$0.00 |
| Finishes (Interior Finishes) | \$37,983.00 |
| Specialties | \$2,287.00 |
| Equipment | \$0.00 |
| Furnishings | \$0.00 |
| Special Work | \$797.00 |
| Conveying Equipment | \$0.00 |
| Fire Suppression | \$4,803.00 |
| Plumbing | \$5,763.00 |
| Heating, Ventilating, & Air Conditioning | \$4,803.00 |
| Electrical | \$36,600.00 |
| Communications | \$0.00 |
| Electronic Safety & Security | \$0.00 |
| Earthwork | \$0.00 |
| Exterior Improvements | \$0.00 |
| Utilities | \$0.00 |
| | Payment & Performance Bond Architectural and Engineering Existing Conditions Concrete Masonry Metals Wood, Plastics & Composites Thermal & Moisture Protection Openings Finishes (Interior Finishes) Specialties Equipment Furnishings Special Work Conveying Equipment Fire Suppression Plumbing Heating, Ventilating, & Air Conditioning Electrical Communications Electronic Safety & Security Earthwork Exterior Improvements |

Total Project Cost =

\$198,808.00



Hevels Contracting Services, Inc. 5620 Gallagher Drive Gastonia, NC 28052 704-864-2000

June 30, 2025

Scope of Work Catawba Valley Health Systems Hickory, NC

Varian TrueBEAM Linear Accelerator Renovation:

The Summary of Work for this project includes:

Division 1 - General Requirements

- 1. Provide Sealed A&E Drawings.
- 2. Provide a Site Superintendent and Project Management.
- 3. Provide Closeout Documentation prior to patient use.
- 4. Provide daily and final clean-up of the project area. Terminal cleaning by customer.
- 5. Provide Local Permitting & Inspections.

Division 2 - Existing Conditions

- 1. This project has selective demolition including all shelving in procedure room, base and uppers at sink, all millwork in control room, flooring, sink and faucet/ hardware and acoustical ceiling tiles only.
- 2. Provide adequate dust protection and air filtration using Scrubbers with HEPA filters.

Division 3 - Concrete

- 1. Provide GPR concrete as necessary for concrete cutting and coring.
- 2. Provide core drilling of concrete as necessary for new conduits for new equipment interconnect runs.
- 3. Sawcut concrete to extend water lines to gantry.
- 4. Concrete thickness is assumed adequate to support new equipment and to remain.

Division 4 - Masonry

1. No work in this contract.

Division 5 - Metals

1. Provide and install ceiling supports for Varian supplied ceiling mount monitor post in procedure room.

Division 6 - Wood, Plastics & Composites

- 1. Provide and install new solid surface countertop on new base cabinets and upper cabinets in the control room.
- 2. Provide and install 8' of base cabinets, overhead cabinets, and solid surface countertop in procedure room at sink area.
- 3. Provide and install approximately 22 LF of 20" deep wall shelving in procedure room.

Division 7 - Thermal & Moisture Protection

1. Fire stop all penetrations related to RCS Scope of Work.

Division 8 - Openings

1. No work in this contract.

Division 9 - Finishes

- 1. Provide and install new acoustical ceiling tiles in existing grid in procedure room only.
- 2. Provide leveling per vendor specifications.
- 3. Provide and install LVP flooring with 6" rubber base in procedure room.
- 4. Remove wall paper throughout the procedure room and skim coat to paint.
- 5. Provide and install paint to walls, door and door frame in procedure room.

Division 10 - Specialties

- 1. Provide and install (5) corner guards (bottom flush to floor) in procedure room.
- 2. Provide and install approximately 16 LF of wainscot height acrovyn wall protection in procedure room.

Division 11 - Equipment

1. No work in this contract.

Division 12 - Furnishings

1. No work in this contract.

Division 13 - Special Construction

- 1. Existing concrete walls and existing lead doors are assumed adequate and to remain.
- 2. No work in this contract.

Division 14 - Conveying Equipment

1. No work in this contract.

Division 21 - Fire Suppression

1. Provide and install fire/heat detectors during project work when ceilings are removed.

Division 22 - Plumbing

- 1. Replace existing sink with a stainless steel sink and faucet in same location in the procedure room.
- 2. Existing to remain.

Division 23 - Heating, Ventilating & Air Conditioning

1. Provide a pre-construction test to verify system meets vendor cooling requirements.

Division 26 - Electrical

- 1. Rework and reuse existing warning lights and emergency stops and tie-in to new equipment.
- 2. This project has selective electrical demolition including any electrical not to be reused.
- 3. Rework, reuse, and add conduits, electrical duct, and electrical boxes as necessary for new equipment.
- 4. Provide and install a loadside feeder.
- 5. Reuse existing lineside feeder (assumed adequate).
- 6. Provide labeling for RCS installed devices.
- 7. Provide and install the Varian provided main disconnect panel in same location.
- 8. Existing breaker at distribution panel is assumed adequate and to remain.
- 9. Existing lights to remain.
- 10. Provide power termination during equipment installation.
- 11. Provide ground impedance test.

Division 27 - Communications

- 1. Building Management Systems (BMS/DDC Controls), conduit, wiring, connections, and programming to existing energy management systems are not included.
- 2. Written acceptance of final testing and connection to BMS is the responsibility of the owner.
- 3. No work in this contract.

Division 28 - Electronic Safety & Security

1. No work in this contract.

Division 31 - Earthwork

1. No work in this contract.

Division 32 - Exterior Improvements

1. No work in this contract.

Division 33 - Utilities

1. No work in this contract.

Exclusions

The following items are specifically excluded from this RCS Proposal:

- 1. Asbestos testing and/or removal. (RCS will require a letter from the Owner prior to the start of project as to the existence of asbestos)
- 2. Any extended installation due to State, Government, or Local Code changes or upgrades.
- 3. Payment and Performance Bonds.
- 4. Any work involving Unistrut other than specified, millwork other than specified, doors, windows, walls other than specified, flooring other than specified, acoustical ceiling other than specified, medical gas, plumbing other than specified, HVAC other than specified, sprinklers, nor electrical other than specified.
- 5. Any work involving structural support to facility, including floor or concrete integrity, floor loading, and/or the movement of medical equipment thereof.
- 6. Any upgrades to existing power conditions.
- 7. Any work involving isolated power.
- 8. Any work involving emergency power.
- 9. Any work involving moving any major utilities such as water, steam, chilled water, medical gas, HVAC and duct, electrical, etc. (can be completed upon a cost plus basis if required)
- 10. Any work involving major utilities under the concrete slab such as electrical, plumbing, etc.
- 11. Any work involving telephones, data, intercom, music, code blue, nurse call, alarms, security systems, etc.
- 12. Building Management Systems (BMS/DDC Controls), conduit, wiring, connections, and programming to existing energy management systems are not included.
- 13. Written acceptance of final testing and connection to BMS is the responsibility of the owner.
- 14. Emergency power, generators, automatic transfer switch, switch gear, or UPS systems.
- 15. Any electrical testing and/or certification other than specified by RCS, Inc.
- 16. Any work involving equal potential bonding of any existing electrical panels serving the same patient care vicinity.
- 17. Physicist analysis and/or report of existing lead shielding; nor any work related to the results of such report.
- 18. Any work involving lead shielding to walls, floor, or ceiling.
- 19. State plan review and/or room licensing fees.
- 20. Any medical imaging equipment and/or the transportation, rigging, installation, or de-installation of such equipment.
- 21. Any other work or services other than specified in this Scope of Work.

Qualifications

The Proposal and Scope of Work are qualified by and subject to the following:

- 1. This Scope of Work is proprietary and is not to be shared or distributed without written permission from Revels Contracting Services, Inc.
- 2. This Proposal and Scope of Work is confidential information and is the sole property of Revels Contracting Services, Inc., exclusively.
- 3. This Proposal and Scope of Work is for Catawba Valley Health Systems.
- 4. Medical use equipment will be by Varian.
- 5. Architects and Engineers will be selected by RCS, Inc.
- 6. All work is to be performed during normal business hours.
- 7. This Proposal assumes that the existing floor is of adequate structural design to support the proposed new equipment.
- 8. A clear and unrestricted access route to and from the project work site will be provided.
- 9. Any changes to the Scope of Work will be by written change order, only.
- 10. Any delay time beyond the control of RCS, Inc. will be considered a change order and will be billed on a cost plus basis.
- 11. The length of the project portion of this project will be approximately 4 weeks with the provision that RCS, Inc. will have full access to the project work area for the full length of the proposed project timeline without any interference from other sources such as de-installing or installing medical equipment, or facility performed work.
- 12. This price is good for: 120 Days Expiration Date of: Oct-30-2025

Terms of Contract

1. Upon signed acceptance, this Proposal and Scope of Work will become inclusive as a contract. The total sum for the project will be invoiced in progress payments. The amount of the drawings (if drawings are included) and 20% of general conditions (or 20% of project, depending on size) will be invoiced prior to work beginning. 10% retainage will be withheld and will be invoiced at the end of the project upon acceptance of the work by the owner. Any options taken will be invoiced in full upon completion of that option. All invoices will be due upon receipt.

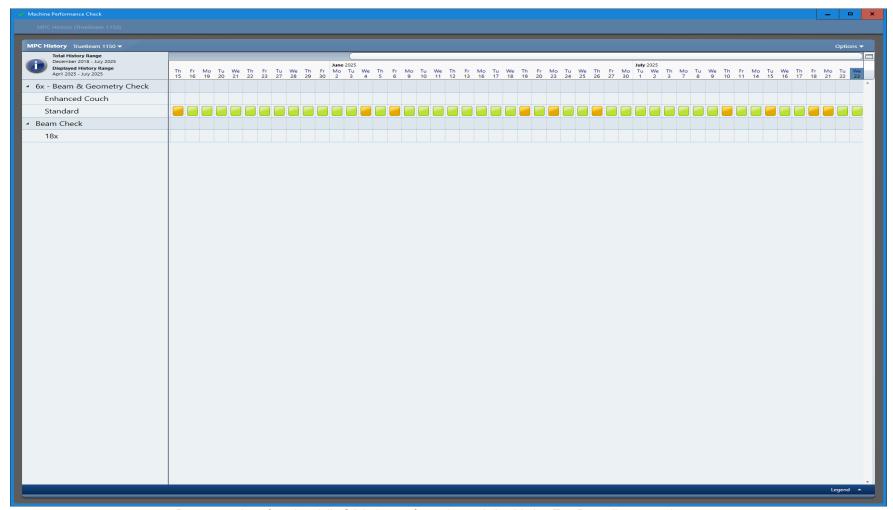
Work can be scheduled for this project upon signed acceptance of this Proposal and/or the issuance of a purchase order number.

This Proposal and Scope of Work is confidential information and is the sole property of Revels Contracting Services, Inc., exclusively.

ATTACHMENT 5

EQUIPMENT COMPARISON

| | EXISTING EQUIPMENT | REPLACEMENT EQUIPMENT |
|--|--------------------------|--------------------------|
| Туре | | |
| (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment) | Linear Accelerator | Linear Accelerator |
| Manufacturer | Varian Medical | Varian Medical |
| Model number | TrueBeam PCSN H191150 | TrueBeam |
| Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #) | | |
| Is the equipment mobile or fixed? | Fixed | Fixed |
| Date of acquisition | October 2011 | January 2026 |
| 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 <attach a="" capital="" cost="" form="" projected="" signed=""></attach> | | \$4,711,916 |
| Total cost of the equipment | | \$4,513,108 |
| Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach> | Radiation Oncology | Radiation Oncology |
| Document that the existing equipment is currently in use | Attached | |
| Will the replacement equipment result in any increase in the average charge per procedure? | No | No |
| If so, provide the increase as a percent of the current average charge per procedure | | |
| Will the replacement equipment result in any increase in the average operating expense per procedure? | No | No |
| If so, provide the increase as a percent of the current average operating expense per procedure | | |
| Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach> | Attached | |
| Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach> | | Identical |



Documentation of routine daily QA being performed on existing Varian TrueBeam linear accelerator.

<u>Procedures Performed on Varian TrueBeam Linear Accelerator</u>

Conventional external beam Radiation Therapy with photons and electrons, Intensity-Modulated Radiation Therapy (IMRT), Stereotactic Body Radiation Therapy (SBRT), Image-Guided Radiation Therapy (IGRT), Surface Guided Radiation Therapy (SGRT) with Respiratory Gating.

From: Kelly Ivey

Lightbourne, Ena; Stancil, Tiffany C To:

Greg Billings, Nancy Lane Cc:

Subject: [External] Catawba Valley MC - Exemption Request

Date: Tuesday, August 5, 2025 9:41:27 AM

Attachments: Outlook-40gyke4s

Catawba Valley MC Exemption Request 08.05.25.pdf

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Ena.

Attached is a request for CON Review Exemption for replacement equipment at Catawba Valley Medical Center. Please respond to this email as confirmation of receipt.

Let me know if you need additional information; otherwise, we look forward to your quick response.

Thanks,

Kelly Ivey kivey@pda-inc.net 919.754.0303 www.pdaconsultants.com





CONFIDENTIALITY NOTICE: This message is confidential and intended solely for the use of the person (s) to whom it is addressed. If you are not the person named, or responsible for delivering it to that person, be aware that disclosure, copying, distribution or use of this information is strictly PROHIBITED. If you have received this communication in error, or are uncertain as to its proper handling, please immediately notify the sender, delete this e-mail and destroy any copies in any form immediately.