

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

#### VIA EMAIL ONLY

September 22, 2025

Deanna S. Mool

Deanna.mool@unchealth.unc.edu

**Exempt from Review - Replacement Equipment** 

**Record #:** 4893

Date of Request: August 13, 2025

Facility Name: Watauga Medical Center

FID #: 933533

Business Name: Watauga Medical Center, Inc.

Business #: 2040

Project Description: Replace linear accelerator

County: Watauga

Dear Ms. Mool:

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 Varian TrueBeam linear accelerator to replace the Elekta model #1672 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

Gloria C. Hale

Micheala Witchell

Micheala Mitchell Chief

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

Radiation Protection 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



August 13, 2025

Gloria C. Hale, MPH
Team Leader, CON
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services

VIA EMAIL TO: gloria.hale@dhhs.nc.gov

Re: Watauga Medical Center

Notice of Exemption for Replacement Equipment/Watauga County

Dear Ms. Hale,

Watauga Medical Center, Inc. d/b/a UNC Health Appalachian ("UNCHA") provides this notice its intent to replace its existing linear accelerator at its main campus at 336 Deerfield Road, Boone, NC and requests confirmation that the acquisition of such replacement equipment, as described in detail below, is exempt from certificate of need ("CON") review. The existing linear accelerator, which has surpassed its useful life, was put into service after receipt of a CON for Project ID# D-7908-08 on November 13, 2007.

## A. Proposed Replacement Equipment Meets the Exemption Test Under Section 184(f) of the CON Statute

UNCHA is requesting a determination that its purchase of the replacement equipment is exempt from CON review under the replacement equipment exemption provisions contained in N.C. Gen. Stat. §131E-184(f)(1)-(3) and §131E-184(g)(1)-(3).

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 set forth in G.S. 131E- 176(22) if all 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. The 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.

For the purposes of the foregoing provisions in Section §131E-184(f)(1)-(3), the monetary threshold set forth in N.C. Gen. Stat. § G.S. 131E-176(22) is as follows:

(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.

This equipment does exceed the \$3,000,000 threshold set forth in 131E-176(22), however, it does not require review based upon satisfying the requirements of 184(f)(1)-(3).

#### 1. The requirements of Section 131E-184(f)(1) are met:

In compliance with §131E-184(f)(1), the term "main campus" is defined by 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 location of the linear accelerator was, and continues to be, on the site of the main hospital building and shares the same address. The existing equipment is currently in use and located at the Seby Jones Cancer Center, which is on the main campus of Watauga Medical Center. The replacement equipment will continue to be located within Seby Jones Cancer Center on the main campus. An aerial view is provided in <a href="Exhibit A.">Exhibit A.</a>

#### 2. The requirements of Section 131E-184(f)(2) are met

Per Section (f)(2), CON# D-7908-08 was granted on November 13, 2007 when the equipment was previously replaced and is attached as <u>Exhibit B</u>. The equipment has been used beyond its expected life.

#### 3. The requirements of Section 131E-184(f)(3) are met

The Hospital is providing the required notice via this correspondence.

### B. Proposed Replacement Equipment Meets the Exemption Test Under Section 184(g) of the CON Statute

Further, the law further provides for an exemption for projects exceeding 4,000,000 when the requirements of G.S. 131E-184(g)(1)-(3) are met.

- "(g) The Department <u>shall</u> exempt from certificate of need review any capital expenditure that exceeds the four million dollar (\$4,000,000) 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."

#### 1. The requirements of Section 131E-1840(g)(1) are met:

As previously noted in Section A.1 and Exhibit A, , the location of the linear accelerator was, and continues to be, on the site of the main hospital building and shares the same address. The existing equipment is currently in use and located at the Seby Jones Cancer Center, which is on the main campus of Watauga Medical Center. The replacement equipment will continue to be located within Seby Jones Cancer Center on the main campus. Both financial and administrative control of the equipment is also housed on the main campus.

#### 2. The requirements of Section 131E-184(g)(2) are met

There will be no change in bed capacity and no addition of any facility or service as the service is currently offered in this location.

#### 3. The requirements of Section 131E-184(g)(3) are met

The Hospital is providing the required notice via this correspondence.

#### C. Cost of the Replacement Equipment meets the 131E-184(f) and (g) exceptions

The purchase price of the equipment is \$2,992,729 and software cost of \$396,955. The cost to acquire the replacement equipment – including replacement equipment installation, existing equipment removal, and remodeling of additional space – represents a total capital cost of

\$6,703,815 and is outlined in the attached Exhibit C. Exhibit C contains the costs, equipment information and the purchase contract.

#### D. Comparable Equipment

In addition to the foregoing, to qualify for replacement equipment exemption under either test, the replacement equipment must be comparable to the equipment it replaces and must be sold or otherwise disposed of when replaced. UNCHA's proposal meets this test as well. 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."

UNCHA intends to use the replacement equipment for substantially the same services for which the entity currently uses the existing equipment. The replacement equipment unit will perform all procedures currently performed on the existing equipment unit. Although it possesses some expanded capabilities due to technological improvements, the replacement equipment will perform the same general range of procedures as the existing equipment unit, see <a href="Exhibit D">Exhibit D</a>, Equipment Comparison Chart. The replacement equipment is therefore comparable medical equipment as defined in Subsection (c).

#### E. Disposition of Equipment

As part of the proposal to acquire the replacement equipment, Vannoy will de-install and take possession of the existing equipment. None of the replacement equipment units will be re-sold or re-installed in North Carolina without appropriate CON approval.

#### **Summary**

In consideration of the above, UNCHA understands that this project is exempt from CON review and requests written confirmation that the proposed replacement of the equipment, and related installation and renovation costs as described herein, are exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(f)(1)-(3), N.C. Gen. Stat. § 131E-184(g)(1)-(3), and N.C. Gen. Stat. §131E-184(a)(7).

Please do not hesitate to contact me via email <u>deanna.mool@unchealth.unc.edu</u> or via telephone at 828-268-8915, if you require any additional information.

Sincerely.

Deanna S. Mool
Chief Legal Officer

**UNC Health Appalachian** 

## Appendix A Aerial view



## STATE OF NORTH CAROLING Department of Health and Human Services Division of Health Service Regulation

#### CERTIFICATE OF NEED

for Project Identification Number D-7908-07 FID#933533

ISSUED TO: Watauga Medical Center, Inc.

336 Deerfield Road Boone, NC 28607

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

SCOPE:

Replace existing linear accelerator with a new linear accelerator and replace

existing simulator with a new simulator/Watauga County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION:

Watauga Medical Center, Inc.

336 Deerfield Road Boone, NC 28607

**MAXIMUM CAPITAL EXPENDITURE:** 

\$3,574,166

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE: October 15, 2008

This certificate is effective as of the 13th day of November, 2007.

Chief, Certificate of Need Section Division of Health Service Regulation

#### **CONDITIONS**

- 1. Watauga Medical Center shall materially comply with all representations made in its certificate of need application.
- 2. Watauga 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.
- 3. Watauga Medical Center shall not perform any general diagnostic computed tomography (CT) procedures on the Simulix Evolution CT Scanner Simulation System.
- 4. Watauga 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 of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on October 17, 2007.

#### TIMETABLE

Order Equipment	January 1, 2008
Operation of Equipment	October 1, 2008

#### CAPITAL COST SUMMARY - Watauga Medical Center, Inc. - Linear Accelerator Replacement

Site Costs				
(1) Full purchase price of land	\$	-		
Acres 0, Price Per Acre 0				
(2) Closing costs	\$	-		
(3) Site Inspection and Survey	\$	-		
<ul><li>(4) Legal fees and subsoil investigation</li></ul>	\$	-		
(5) Site Preparation Costs [Include] Soil Borings				
Clearing and Grading Roads and Parking Sidewalks				
Water and Sewer Excavation and Backfill Termite Tre				
Sub-Total Site Preparation Costs	\$	-		
(6) Other (Specify) - Permits	_\$	29,660		00.000
(7) Sub-Total Site Costs Construction Contract			\$	29,660
Construction Contract				
(8) Cost of Materials [Include]				
General Requirements Concrete/Masonry Woods/Doors & Windows/Finishes				
Thermal & Moisture Protection				
Equipment/Specialty Items				
Mechanical/Electrical				
Sub-Total Cost of Materials	\$	1,318,642		
(9) Cost of Labor	\$	1,510,556		
(10) Other (DHSR Review Fee)	\$	-		
(11) Sub-Total Construction Contract Miscellaneous Project			\$	2,829,198
Miscellaneous Project Costs				
(12) Building Purchase	\$	-		
(13) Fixed Equipment Purchase/Lease	\$	2,992,729		
(14) Movable Equipment Purchase/Lease	\$	396,955		
(15) Furniture	\$	65,000		
(16) Landscaping	\$	98,523		
(17) Consultant Fees				
Architect and Engineering Fees Legal Fees				
Market Analysis CON Preparation				
Project Management				
Sub-Total Consultant Fees	\$	284,250		
(18) Financing Costs (e.g. Bond, Loan, etc.)	\$ \$ \$	-		
(19) Interest During Construction	<del>\$</del>	7 500		
(20) Other (Specify) Signage (21) Sub-Total Miscellaneous	Φ	7,500	\$	3,844,957
(21) Sub-Total Miscella lecus			Ψ	0,044,001
(22) Total Project Capital Cost (Sum A-C above)			\$	6,703,815

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and it is my intent to carry out the proposed project as described.

RICK CASSANY

CFO 8/13/2025



## Capital Expenditure Request Worksheet (Over \$5,000 with a useful life not less than 1 year.)

Description of Equipment: Varian Tru Beam Linear Accelerator		Amount in Capital Bu	Amount in Capital Budget:				
Varian	Tru Beam Li	near	Accelerator		Date Needed: ASA	P	
Deliver i	tem to <i>(upon ap</i>	proval)	£		Dept. Acct. Unit #:5(	000-602-340706	
Dept/F	loor/Room:				Comments: Part of cons	struction project le 5000-602-340706-170005	<del></del>
To the	Attention of:				5000-25-01	3488	•
Pr	riority Rating		Reason for Reque	est	Estimated Co	<b>st</b> (Attach at least 2, prei	ferably 3 bids)
■ Urger □ Neces	nt ssary	f. 1 .	☐ New Service ☐ Replacement		\$2,992,729.00	Purchase F	Price
	omically Desira ement Disposi		☐ Improved Service ☐ Code Compliance ☐ Increased Volume			Shipping	•
☐ Trade ☐ Retain	-In ned		☐ Other		_	Training Other	
Dispo	sal		Current unit is end of life- also quoted E	Elekta	10010	Less Trade	-In
			_	Net Cost			
				d Revenues, Expenses and	Expense Savings		
<u> </u>	or Signature _				Date		
<del></del>	ls (route order	)		· -	II electrical equipment is		☐ Yes ☐ No
Initials	Date	D.	· (D : D :	<b> </b> -	Vill a service contract be		☐ Yes ☐ No
MR	4/21/2025		tor of Requesting Dept.  Materials Mgmt.		yes, is this included in the endor?	ie proposai from the	☐ Yes ☐ No
MR	4/21/2025		FPlant Operations**	11	no, give details of servic	e needs.	☐ Yes ☐ No
		Info/(	Computer Service**	li	n-house education?	☐ Yes ☐ No	
		Biom	edical*‡	Į:	service school/training	required?	☐ Yes ☐ No
	VP of Requesting Dept.		V	/ill engineering/biomed s	upport?	☐ Yes ☐ No	
W	4 29 25	Chief	Financial Officer 🕂	V	Vill support be provided b	y an outside source?	☐ Yes ☐ No
Chief Operations Officer				-Board A	marel on	111	
MR	4/21/2025		Materials Mgmt.			waves on	4/27/25
			uter equipment or software ment for direct patient con		construction involved.		
If Appalachian Regional Healthcare Foundation funds are being used:							
f Appala	chian Regional	Health	ncare Foundation funds a	re b	eing used:		



#### Capital Expenditure Request Worksheet - Page 2

Radiation Oncology

D BKH D CIVIH B WIVIC I	TAKH2 LIAK	IMA Department Nam	16			
***************************************	Estimated Ar	nual Revenues, Expense	s and Expense S	avings		
Additional Expe	enses		Increment	al Revenue	S	
Item	Amount	Charge It	:em	Volume		Amount
Salaries						
Supplies						
Insurance .						
Service Contract						
Other						
Total		Total				
Justification for Request: Cu	rrent unit is e	nd of life, parts are di	fficult to find,	and unit	consis	stently is down
Bid Summary				1		
	Vendor		Date	^-	<u> </u>	Amount
	Varian		4/22/20			992,729.00
	Elekta	· · · · · · · · · · · · · · · · · · ·	11/5/20	24	<b>\$</b> 2,	200,000.00
						· · · · · · · · · · · · · · · · · · ·
Reason for Vendor Selection	(To be complet	ed by Dir. of Materials Ma	anagement)			
□Low Bidder						
□Only Source						
□Contract Used						
■0therUNC approved d	levice, also in	nproved technology for	or the future c	of treatme	nts pr	rovided,
*Materials Management Use	Only					
Vendor	V# 14615	Varian Medi	ral Scielans	- t.,		-
P0 #	8875	Varian Medi 47-CAP	CA CASACHIO			
Utilization Date	5/4/2					
Activity Code (from Finance)						
Asset GL (from Finance)	5000-2	5-013488				
*Finance Department Use On	lγ					
Accounting Unit Code						
Туре						
Useful Life (AHA Guide)						, .
Date of Service						
Asset #						



#### **Custom System Proposal**

Quotation Number - 2024-463384-2

TrueBeam Package with SRS and SBRT Capabilities- \$2,992,729 PO or Signed quote by 4-30-2025 will ensure Delivery by 9-30-2025.



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



Seby B. Jones Regional Cancer Center at Watauga

Regional ("Customer")

Richard Cassady 336 DEERFIELD RD

**BOONE North Carolina 28607-5008 United States** 

Tel: 828-514-3573

Email: Richard.cassady@unchealth.unc.edu

For and on behalf of Varian Medical Systems

Jeffrey Boone

District Sales Manager

3290

Atlanta, GA 30327 United States of America

Tel: 7047379395

Email: jeffrey.boone@varian.com

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

Quotation Number : 2024-463384-2 Quotation Date : April 22, 2025 Quotation Valid Until : May 30, 2025

Customer Requested Delivery Date : September 30, 2025

Customer Procurement Contact Name : Needed

Billing Plan See Quote billing plan Summary on the following pages which is incorporated by reference

Sales

Sales
Incoterms: DPU Site Insured
Payment Terms: 30 days net
Sales PO Required: Ves

Ouotation Total

Quotation Total: US \$2,992,729.00

#### 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: <a href="https://varian.com/RAD1652V\_US\_EN\_OCT\_2024">https://varian.com/RAD1652V\_US\_EN\_OCT\_2024</a> 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 or behalf of Customer

Authorized Representative : Richard Cassady

Title: CFO

Date: April 22, 2025

PO# 887547-CAP

For and on behalf of Varian Medical Systems

Authorized Representative : Jeffrey Boone

Title: District Sales Manager

Date: April 22, 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)	Offer Price
WATAUGA MEDICAL CENTER TrueBeam	US \$3,010,330.00
Adhoc	US \$-17,601.00



#### Item Description

Site: WATAUGA MEDICAL CENTER	
1.0 TrueBeam	
Offer Price: US\$ 3,010,330.00	

#### 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, Molion 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:

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

# 1.2 New Universal Baseframe 52" Fixed Floor 1 1.3 15/16 MV (BJR 11/17) 1 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min. 1 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 1.5 6/6 MV (BJR 11/17) 1



Item	Description	
1.6	12 MeV, 0-1000 MU/Min	1
	25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	
1.7	9 MeV, 0-1000 MU/Min	1
	25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	
1.8	6 MeV, 0-1000 MU/Min	1
	25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	
1.9	IGRT Couch Top	1
	Image Guided RadioTherapy (IGRT) carbon fiber treatment couch top, free of metal or other radiation-opaque materials.	
	Features:	
	<ul> <li>Indexed Immobilization® for compatible accessories</li> <li>Couch top interface for mounting patient immobilization and quality assurance devices at the head of the couch</li> <li>Lock bar for indexed positioning of equipment or immobilization devices on the couch top</li> <li>Handrail for couch positioning, with hooks for temporary pendant placement during patient set up</li> </ul>	
1.10	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	
1.11	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.	
1.12	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	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 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	
1.14	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.	



1

#### Description ltem 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 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 VCD Option, couch mounted 1.15 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 VCD w/Couch Mount - IGRT 1.16 1.17 **Gated CBCT** 1 Gated Cone-Beam Computed Tomography (CBCT) provides the ability to acquire CBCT images synchronized with patient respiration (free-breathing or breath hold). 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 Haskris Water Chiller: TrueBeam Platform 1 1.18 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. Prerequisites: Edge™, TrueBeam™, or VitalBeam™ system v2.5 or higher

Haskris Switch Panel: TB and Hal

1.19



Item	Description	
	An emergency water switchover system for the TrueBeam™ and Halcyon® platforms.  Prerequisites:  Halcyon or Ethos™ radiotherapy system v1.0 or higher, Edge™, TrueBeam, or VitalBeam™ system v2.5 or higher	
1.20	Additional MotionView CCTV Camera System	1
	Additional set of two Motion View CCTV cameras and displays. Camera placement is at customer discretion.	
	Features:	
	<ul> <li>Two pan, tilt, zoom CCTV cameras</li> <li>Two desktopLCD displays with built in camera controls</li> <li>Adjustable viewing angle for patient privacy</li> <li>Push button pan, tilt, zoom, and home position control</li> <li>Prerequisites:</li> </ul>	
	Motion View camera system, provided with linac 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:	
	<ul> <li>Supports voltage configurations from 208 to 600 VAC and in 50 or 60 Hz for US and ROW applications.</li> </ul>	
1.24	Supp. Phantom Kit	1
	Supplemental imaging phantom kit for measuring resolution and contrast of kV and MV imaging systems.	
	Features:	
	<ul> <li>Leeds TOR 18FG phantom for measuring spatial resolution and contrast of kV imaging system</li> <li>MV contrast phantom for measuring contrast performance of MV imaging system</li> <li>Geometric phantom, mounted on IGRT couch top-compatible lock bar. Can be used for quality assurance of image guidance workflow.</li> </ul>	
	Prerequisites:	
	MV imaging system	
1.25	NLS: English	1
1.26	STD TRNG: TB Platform On-Site	1



#### Item Description

The on-site review of the TrueBeam/Edge/VitalBeam components includes imaging and use cases for support of patient treatment for therapists. This support is to ensure that personnel who attended the classroom training are able to operate the TrueBeam Platform machine in a safe and effective manner in the clinical environment.

#### Features:

- · Includes support for TrueBeam/Edge/VitalBeam
- · Offer is valid for 18 months after installation of product

#### Prerequisites:

TrueBeam Platform classroom trainings

#### Notes:

· Training is non-refundable and non-transferable

#### 1.27 STD TRNG: Two Day Follow Up

1

Two Day Follow Up Training. This follow up training is conducted after the initial training has been completed to ensure safe and efficient use of the product.

#### Features:

- Training plan details will be provided by the training management team as part of your product implementation process
- Duration and Location: 2 days onsite

#### Prerequisites:

Initial product training completed

#### Notes:

- · Offer is valid for up to 18 months after installation of product
- · Non-transferable to other products and services and non-refundable

#### 1.28 INCL ED: TB201 TB Platform Physicists

1

TrueBeam Physics and Administration: TrueBeam Physics and Administration course is designed for personnel (primarily Medical Physicists) responsible for the acceptance, commissioning, and QA program development of the TrueBeam in the clinical environment. It is recommended that the student attend the TrueBeam Physics and Administration course shortly before the installation of the TrueBeam. The course provides instruction of the basic delivery components, basic imaging components, and a general overview of the motion management system components. Machine commissioning, calibration, and QA of the machine are included. The course subject matter is presented from a clinical use perspective. Primary emphasis is on the overall commissioning, calibration, and QA of the TrueBeam and its components. Extensive hands-on laboratory exercises are included.

#### Features:

- · Includes support for TrueBeam/Edge/VitalBeam
- Includes Tuition and Materials for ONE person
- · Length: 4.5 days
- · Offer is valid for 18 months after installation of product

#### **Customer Responsibilities:**

- Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals)
   Notes:
- · Training is non-refundable and non-transferable

#### 1.29 INCL ED: TB101 TB Platform Operations

1

TrueBeam Operations is a course designed for personnel (primarily Radiation Therapists) responsible for the routine operation and clinical use of the TrueBeam. It is recommended that students attend the TrueBeam Operations course shortly before clinical use and the commencement of patient treatments. The course provides instruction of the basic delivery components, basic imaging components, and a general overview of the motion management system components. The course subject matter is presented from a clinical use perspective. Primary emphasis is on the overall understanding of the TrueBeam function and operation to include imaging and respiratory gating. Extensive hands-on laboratory exercises are included. The attendees of this class will be provided tools to allow them to instruct other clinical staff upon their return.



#### Features: Includes support for TrueBeam/Edge/VitalBeam Includes Tuition and Materials for ONE person Length: 4 days Offer is valid for 18 months after installation of product **Customer Responsibilities:** Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals) · Training is non-refundable and non-transferable 1.30 INCL ED: CL222 Respiratory Gating 1 The Respiratory Gating course provides training for physicists and therapists, to obtain knowledge of principles and practices of respiratory gating in radiation oncology for clinical implementation. Features: Includes support for TrueBeam Platform Includes Tuition and Materials for ONE person Length: 2 days Offer is valid for 18 months after installation of product **Customer Responsibilities:** Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals) · Training is non-refundable and non-transferable 1.31 Vertical LAP Apollo Green Room Laser Kit 1 LAP Apollo Green Room Laser Kit for patient alignment with Vertical Remote-Controlled Sagittal Line Laser. 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 1.32 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 1.33 TrueBeam v4.1 Accelerated 4D CBCT Reconstruction 1.34 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

Item

Description



Item	Description	
1.35	Authentication Svr, 3rd Party OIS HW/SW	1
	Computer server hardware to support a single installation of the Varian System Database and shared framework Varian Service Portal (VSP) software.  Features:  1 Rack Server to support up to 10 TrueBeam Platform machines and 25 users.  Windows Operating System and client access licenses  Microsoft SQL server software and licenses  VSP software at v15 or higher  Prerequisites:  TrueBeam platform v3.0, 4.0, or 4.1  Customer Responsibilities:  Space, cooling, power, and any external network devices/ports to connect the system to the customer's network.  Perform any required maintenance including contacting server provider.  Notes:  "None"	
1.36	STD TRNG: Remote Training	1
	Standard remote training  Features:  Customized training plan details will be provided by the training management team after the initial discussion of customer needs Training Type and Location: One remote training session up to 2 (two) hours with a clinical applications specialist  Customer Responsibilities: Remote access to the customer software may be required Review all product documentation available on MyVarian.com in advance Customer Release Notes Instruction for Use  Must have access to a phone and computer with internet connection  Notes: Remote session should be scheduled within 30 (thirty) 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	
1.37	Quick Ref Guide - English	1
1.38	Varian Vol Mod Arc Treatment Delivery  A volumetric modulated arc treatment delivery technique, providing the capability to simultaneously modulate aperture shape, dose rate, gantry angle, and speed during beam delivery. When used with Respiratory Motion Management System, provides the capability for Gated VVMAT.	1
	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 Leaf MLC	
1.39	HyperSight Imaging Solution  HyperSight™ for TrueBeam® Platform Features:  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	1



#### Item Description

· 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)

Site	WATAUGA MEDICAL CENTER	
2.0	Adhoc	
	Offer Price : US -\$17,601.00	
2.1	Trade-In Discount	1
	Trade-In of Existing Elekta Linac	
2.2	Remove/Dispose Existing Equipment	· <b>1</b>
	Removal of Existing Elekta Linac	
2.3	Travel and Lodging	5
	Travel and Lodging for Training for 5 team members	



 Sales Price Table
 TradeIn-Cancellations
 US \$-40,000.00

 Sales Total
 US \$2,992,729.00

Quotation Total US \$2,992,729.00





Acknowledge by email to kmiller@apprhs.org and sgowdy@apprhs.org with availability, Ship date, and Reference Nbr upon receipt of this PO. If freight contractually applies ship freight collect via UPS acct# 87X911. All shipments over 150 lbs. call TRIOSE 866-241-2268 ext. 204 for routing. Our PO# must be on all shipment labels and/or Bills of Lading. Attention members of ARHS (WMC, CMH) will not pay the Medical Device Excise Tax.

Ship To  AWMC - WMC MAIN STOREROOM  WATAUGA MEDICAL CENTER 336 Deerfield Road  Main Storeroom  Boone NC 28607	Mail Invoice To Appalachian Reg Healthcare System Accounts Payable 155 Furman Drive, Suite 202 Boone, NC 28607
Purchasing Contact Miller, Kathy kathy.miller@unchealth.unc.edu	

#### Purchase Order

PO Number	PO Code
887547	CAP
Status	Purchase Date
Original	2025-05-06
SHOW PO NUMBER ON ALL SHIPPIN BILLS OF LADING, COPIES OF PACKI SHIPMENTS, FAILURE TO COMPLY W SHIPMENTS AND NONPAY OF INVOICE	NG LIST MUST ACCOMPANY ALL JLL RESULT IN REJECTION OF

Vendor	Shipping Method
14615 - VARIAN MEDICAL	BEST WAY
SYSTEMS INC	
3100 HANSEN WAY	
PALO ALTO	
CA	
94304	
Contact	Ship Terms
CUSTOMER SERVICE	FREE ON BOARD DESTINATION
1-800-544-4636	
1-512-382-1633	
Account Number	Freight Terms
	3RD PARTY BILL

Ĭ	Comments	The state of the s	ng mananangga.		
1	_				

Process Level	Terms	: Discount Days	Discount Percent	First Net Days
5000 - WATAUGA MEDICAL	N15			15
CENTER				

Lines							
Line	Item	Vendor Item	Deliver Date	Quantity	UOM	Unit Cost	Extended Amount
1	QUOTATION # 2024-463384- 2 - TrueBeam Package with SRS and SBRT Capabilities	QUOTATION # 2024-463384-2	September 30, 2025	1	EΑ	2,992,729.00	2,992,729.000

	Add On Charge Summary
Add On Charge Total	0.00
	Tax Summary
Purchase Order Vendor Invoiced Tax Total	0.00
Purchase Order Tax Total	0.00

Goods Total	~,00~,, ~0.00
Order Total	•

#### Trailer Comments

Supplier's commencement of delivery of goods or performance of services constitutes supplier's assent to and express acceptance of this P.O. subject to the terms and conditions located at <a href="https://www.unchealthcare.org/poterms">https://www.unchealthcare.org/poterms</a>

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## Harnessing the latest innovations for the fight against cancer

Advances in radiation therapy are accelerating, creating new options for treatment and new sources of optimism in the fight against cancer. However, translating innovations into better outcomes for patients and clinics requires more than piecemeal adoption of new solutions. It requires an integration of capabilities on multiple levels.

The high-precision TrueBeam® radiotherapy system is uniquely capable of integrating hardware, software, treatment regimens, safety features, third-party solutions, new innovations, and support. The result is designed so that care teams can harness transformative technology and collaborate more effectively—so clinics can expand treatment options, grow their business, and accelerate new healthcare initiatives.







Hardware



Software



Treatment Regimens



Partner Solutions



Comprehensive Support



New Innovations



Safety Features



## Integrated capabilities for integrated care

#### It all comes together here.

TrueBeam has proven its capabilities in treating a broad range of cancer cases with exceptional speed and accuracy in top clinics around the world. However, its value extends far beyond its features and functions.

By bringing together diverse capabilities and resources, the TrueBeam system enables clinicians to focus on patients and treatments rather than systems and technologies. And that is designed to make it possible for clinics to deliver more comprehensive and effective care.





## Innovation, collaboration, outcomes... they're all connected

By serving as the focal point of multi-layered integration, the TrueBeam system facilitates the kind of innovation and collaboration that results in new treatment options for patients, new opportunities for clinics, and new advances in the fight against cancer. The net result is better outcomes for all stakeholders: patients, clinicians, researchers, and administrators.



# Hardware, software, and safety features that work well individually—and better together.

## Agile Architecture Controlled by Maestro

- Open, extensible architecture
- Maestro control system orchestrates components
- Synchronizes dosage, motion, and imaging for fast, efficient treatment

#### Fast, Accurate Imaging System

- Improved imaging of soft tissue targets through reduced motion artifacts
- Faster cone-beam CT (CBCT) acquisitions for breath-hold treatments than prior versions
- Improved visibility for certain targets with large motion

### Flexible, High-Performance Beam Generation

- O-8 electron energies and 7 photon energies
- High intensity modes
- Ability to tailor treatment with higher precision than prior versions

#### Gated RapidArc® Radiotherapy Technology to Account for Tumor Movement

- Expands RapidArc radiotherapy treatments to moving tumors
- Faster treatments of tumors that move with respiration
- Monitors patient treatment with triagered imaging

#### IDENTIFY™ system<sup>1</sup>

- Has three high precision stereo vision cameras with sub-millimeter accuracy<sup>2</sup> and with a refresh rate of 5-10 frames/second<sup>3</sup>
- Supports a non-invasive, markerless technique to track the surface of a patient in real time during treatment
- Accommodates a variety of treatments and techniques including stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and deep inspiration breath hold (DIBH)



## HyperArc® High-Definition Radiotherapy

- High-quality, easy delivery of non-coplanar stereotactic radiosurgery (SRS) treatments
- Automated and simplified operations
- Safe, efficient, and accurate
- Designed for patient safety, treatment efficiency, and accuracy

## PerfectPitch™ 6 Degrees of Freedom (6DoF) Couch

- More flexibility in patient setups
- Adds pitch and roll axes
- Potential to treat more patients with higher accuracy

#### ARIA® Oncology Information System

- Compare acute responses to treatment and long-term clinical outcomes
- Develop disease-specific clinical protocols
- Make confident decisions with rule-based decision support

#### Eclipse™ Treatment Planning System and RapidPlan® Knowledge-Based Planning

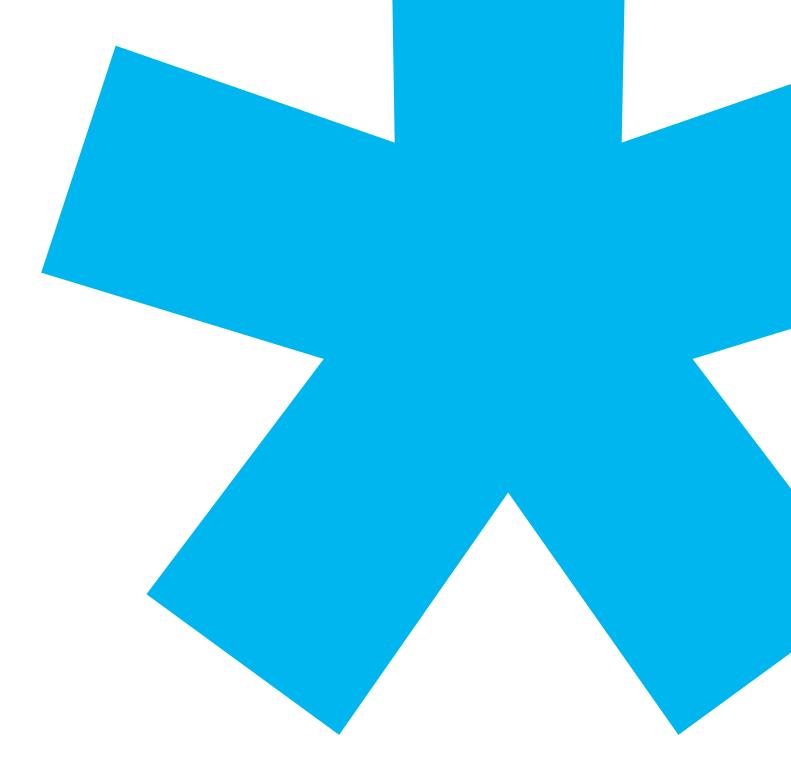
- Designed to increase physician productivity
- Customize plans leveraging advanced clinical expertise
- Develop plans for virtually every type of radiotherapy

## Applied Intelligence Systems for Deeper Insights

- Mine your data for actionable intelligence
- Consolidate scans and treatment plans for new insights
- Transition to data-based decision-making

#### Safety Capabilities to Enhance Confidence

- Simple, automated operation
- Multiple layers of safety built in
- Constant accuracy checks



## An innovative ecosystem of oncology solutions.

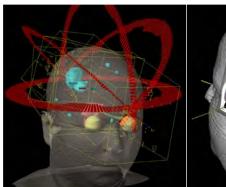
\*\*We are elevating cancer care through ingenuity.

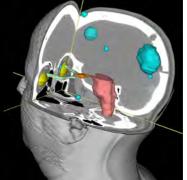


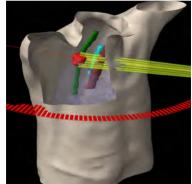
# More choices for a wider range of cancer cases

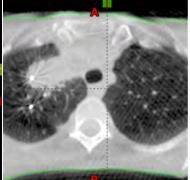
The depth and breadth of technology integration in the TrueBeam platform is designed to enable clinicians to treat a wider array of cancer cases using a diverse range of radiation therapies.

Clinical cases in head and neck cancers, lung, breast, prostate, liver, and more are addressed by TrueBeam using SRS, stereotactic body radiation therapy (SBRT), HyperArc, volumetric modulated radiation therapy (VMAT), intensity-modulated radiation therapy (IMRT), image-guided radiotherapy (IGRT) and RapidArc radiotherapy.







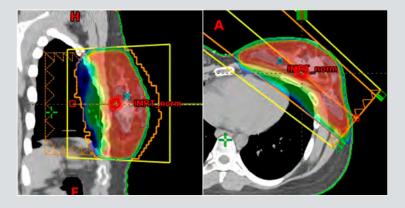


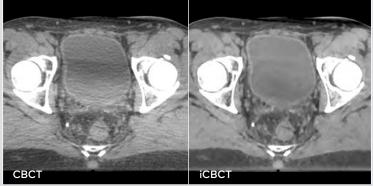
### **Multiple Brain Metastases**

- HyperArc high-definition radiotherapy enables single-click delivery of fully automated non-coplanar cranial SRS treatments. New algorithms in treatment planning allow collision-free single isocenter delivery with steep dose gradients
- Leveraging the Eclipse treatment planning infrastructure, HyperArc allows planning of single and multiple metastases as well as primary brain tumors
- The HD120<sup>™</sup> multileaf collimator sculpts the dose with high conformity while sparing surrounding tissue and/or organs at risk
- The PerfectPitch 6 DoF couch allows precise patient positioning based on 3D image guidance

### Lung

- Online 4D CBCT allows you to visualize target motion in 3D, verifying target motion is as expected from the treatment plan. Automated acquisition of multiple 3D CBCT data sets, all synchronized with respiration, allows 3D patient setup using a specific respiration phase, an averaged motion image, or a maximum intensity projection image
- With gated CBCT, image acquisition occurs during the planned beam-on time only, reducing image artifacts due to motion, and allowing visualization of the target under planned treatment delivery conditions
- Short arc CBCT allows fast 3D CBCT image acquisition within a single breath hold
- The Visual Coaching Device provides patients with active feedback on their respiration, allowing respiration stabilization for free breathing gated treatment delivery, and consistent breath-hold motion extent for breath-hold treatment



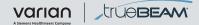


### **Breast**

- Delta couch shift supports initial patient setup using a single stable tattoo mark, with a pre-programmed automated shift to the treatment isocenter
- Eclipse IMRT tools, such as field-in-field planning, help create treatment plans designed to minimize radiation exposure of heart and lung tissue
- Real-time respiratory gating supports deep inspiration breath-hold treatments for left lung, allowing reduction of treatment margins due to target motion and minimizing exposure of heart tissue

### **Prostate**

- Intrafraction motion during treatment delivery can be detected using fully automated radiographic imaging, with image acquisition triggered on monitor unit, time, or gantry angle increments
- Auto beam hold tracks implanted fiducial positions during triggered image acquisition, automatically asserting a beam hold when a fiducial is detected to be out of position
- On-demand imaging allows you to initiate kV, MV, and CBCT images at any time during the treatment
- Iterative CBCT reconstruction is designed to provide unparalleled image quality, enhancing bony anatomy and soft tissue visualization



# Open to innovation from multiple sources

No one knows where the next innovation in cancer treatment will come from. One thing is certain: great ideas come from everywhere, and great ideas should be shared. The more open you are to integration, the sooner your patients and your clinic will benefit.

Varian is committed to cultivating an environment that connects you in multiple dimensions. To the integrated features and functions of the TrueBeam system. To the added value of our full suite of oncology solutions. To the complementary innovations of our vibrant partner ecosystem. To the latest research and breakthrough concepts in development. And to the entire oncology community—from diagnosis to survivorship.

### TrueBeam Developer Mode: Endless Collaborative Research Opportunities

The Developer Mode option allows for broad experimentation in a non-clinical environment. This expanded access is designed to give clinicians and physicists an efficient and effective means to innovate with new treatment and imaging techniques in a research mode. Advanced manipulation of mechanical and dose axes puts the dynamic beam, imaging, and gating features of the TrueBeam system at the fingertips of researchers.

### Collaborative Ecosystem: Expanding the Reach

TrueBeam further extends clinical options by integrating with solutions, technologies, and innovations from our strong and growing ecosystem of third-party companies, including Epic electronic medical records systems, the Cerner Patient Observer™ system, Brainlab ExacTrac Dynamic®, VisionRT AlignRT®, and C-Rad Catalyst HD devices and more.



# Comprehensive service, collaborative support

Varian provides responsive service that helps keep your TrueBeam system online, your clinicians productive, and your patient satisfaction scores high. You get the right parts and the most up-to-date software, installed and maintained the right way by Varian-trained professionals — virtually anywhere in the world. We combine a full range of capabilities, including:

### **Knowledge and Experience**

Varian service professionals receive up-to-date classroom instruction, on-the-job training, and advanced workflow tools, and give you exclusive access to Varian product engineers and system designers.

#### SmartConnect® Plus

Remote equipment monitoring automatically alerts Varian to potential issues, proactively diagnoses the issue, and can expedite repairs before problems escalate.

### **Proprietary Processes**

We maintain detailed, tested protocols for maintaining your equipment in the most efficient way — while keeping patients and staff safe.

### **Planned Maintenance Program**

Regularly scheduled parts maintenance and replacement can help you potentially avoid catastrophic failures.



### **OEM Parts**

The exclusive use of Varian parts helps ensure proper design, pre-testing, and integration with all system components.

### **Software Upgrades**

We provide software and security updates that protect hospital and patient data.

### **Professional Services Tailored to Your Requirements**

Varian's Professional Services organization delivers a wide range of programs tailored to your needs, helping you achieve higher clinical availability, more efficient workflows, safer use of technology, faster treatment times, and a more relaxed patient experience.



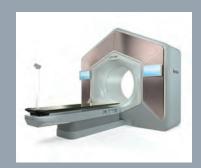
### More options for your patients



### more opportunities for your clinic



TrueBeam®/VitalBeam® Systems



Halcyon®

#### **Ethos**®



Edge® System

Dedicated Full-Body



ProBeam®



BRAVOS®

Afterloader System

Planning and Delivery



Eclipse™



**ARIA®** 



Velocity™





Noona®









## Imagine a world without the fear of cancer

Varian Medical Systems has been a pioneer in the field of oncology for more than 70 years. During this time, we have introduced innovative treatment techniques, equipment, and software that have been used to treat tens of thousands of cancer patients worldwide. Today we offer products and services to advance the entire treatment process. Our work creates a community of those affected by cancer, so we can unite around our common goal to fight this disease.





### Expanding the boundaries of hope

- 1. Not available in every market. Please check availability with your sales representative.
- 2. Based on Varian IDENTIFY Specification Sheet RAD10699B. Varian Medical Systems, Inc. 2021.
- 3. Based on Varian IDENTIFY Specification Sheet RAD10699B. Based on 10 cm x 10 cm region of interest (ROI). Varian Medical Systems, Inc. 2021.
- 4. Product features described in this document relate to TrueBeam version 3.0.

### **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.

#### Important Safety Information

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.

### Varian A Siemens Healthineers Company

USA, Corporate Headquarters ar Manufacturer

Headquarters Europe, Eastern Europe, Middle & Near East, Africa



# TrueBeam 4.1\* HyperSight imaging solution

With larger images, better contrast, and greater speed, our re-engineered CBCT imaging takes you beyond what's possible with conventional linac-based systems, all designed to enhance existing workflows and enable new ones.

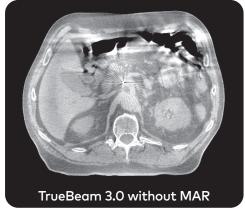


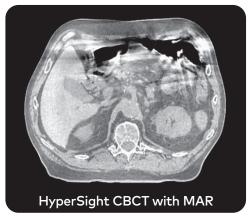
### IMAGE QUALITY

### **Going Beyond IGRT**

- HyperSight improves image quality in terms of spatial and contrast resolution. This is designed to improve the ability to more precisely target tumor volumes and increase sparing of healthy tissue.
- HyperSight comes with a metal artifact reduction algorithm improving image quality for patients with hip prostheses and metal or dental implants.
- The image reconstruction algorithm and the increased Field of View (FOV) delivers improved visualization of the entire patient volume and surrounding organs at risk (OARs)—aimed at generating more precise treatment plans.

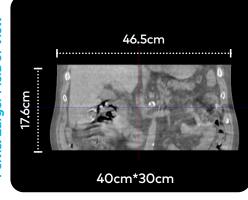
Metal Artifact Reduction (MAR)

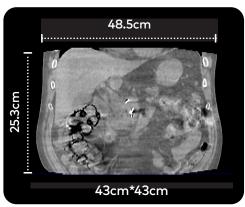




Images courtesy of UH Seidman Cancer Center, Cleveland.



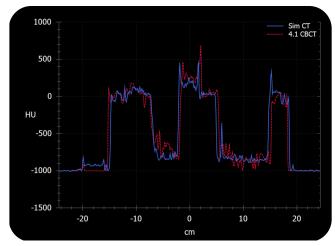




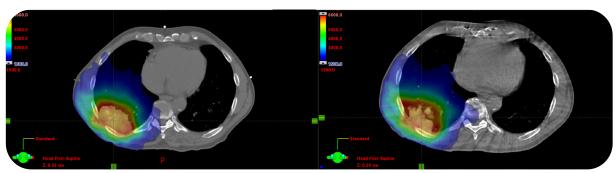
Images courtesy of UH Seidman Cancer Center, Cleveland.

### Images you can plan on

- HyperSight offers Hounsfield Unit (HU)
   accuracy approaching that of conventional
   CT simulators, allowing calculation of dose
   distribution directly on the CBCT image.
   This allows for an easier and more efficient
   offline adaptive workflow.
- TrueBeam's unique guided workflow, together with HyperSight CBCT images, help enable offline adaptive therapy.



Dose calculation and HU comparison CT (red) vs. HyperSight CBCT (blue).



Images courtesy of UH Seidman Cancer Center, Cleveland.

### SPEED.



### A single breath is all you need

- HyperSight acquires images for all anatomical sites in only 14 to 40 seconds. It enables a 50% faster gantry rotation (vs. TrueBeam 3.0) for imaging and sequencing between fields for improved efficiency during IMRT.
- This significant reduction in CBCT acquisition time reduces motion-related artifacts due to patient movement and improve treatment precision.
- Shorter image acquisition time may minimize patient discomfort and anxiety due to less breath-hold during CBCT acquisitions and less time on the couch.

<sup>\*</sup>HyperSight is a purchasable option on TrueBeam 4.1.

### More options for your patients, more opportunities for your clinics

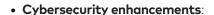
For over a decade, TrueBeam has continued to provide new and improved features with enhanced integration to better meet the needs of clinicians and patients. Today, the latest advancement to the platform, TrueBeam 4.1, offers more flexibility in daily workflows while seeking to bring users peace of mind with enhanced safety features.

### **Improved Flexibility**

- Introducing Enhanced Triggered Imaging\*
   The auto-beam hold (ABH) functionality is extended to irregularly shaped fiducials such as Visicoil, Gold Anchor, Surgical Clips, making patient monitoring, and a precise treatment more accessible.
- CBCT Mode Editor helps to improve the operational efficiency by allowing the input of data quickly and intuitively.



- **IEC 4th edition** compliant, improving the safety of medical devices:
  - Jaw tracking default for modulated fields
  - Console displays show planned and actual gantry rotation, and MLC leaf position during treatment
  - Console displays up to 4 external devices connected via Management Motion Interface (MMI)



- TrueBeam 4.1 release has implemented many best practices for information assurance and policy requirements for security programs as defined by the Defense Information Systems Agency (DISA).
- The Operating System, platform components, and applications are hardened using STIG (Security Technical Implementation Guide) guidelines to improve the overall security posture of the system.





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.

#### Important Safety Information

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.

### Medical Advice Disclaimer

Varian as a medical device manufacturer cannot and does not recommend specific treatment approaches. Individual treatment results may vary. phantom.

Not available for sale in all markets.

Certain features are optional. Please speak with your sales person for more information.

varian

USA, Corporate
Headquarters and
Manufacturer

Varian Medical Systems, Inc 3100 Hansen Way Palo Alto, CA 94304 Tel: 650.424.5700 800.544.4636 varian.com

Eastern Europe, Middle & Near East, India, Africa Siemens Healthineers International AG Steinhausen, Switzerland Asia Pacific Headquarters Varian Medical Systems Pacific, Inc. Kowloon, Hong Kong Tel: 852.2724.2836

Australasian Headquarter: Varian Medical Systems Australasia Pty Ltd. Sydney, Australia Tal: 61 2 9485 0100

Enhanced Triggered Imaging on TrueBeam and Edge

Latin American Headquarter Varian Medical Systems Brasil Ltda. São Paulo, Brazil Tel: 55 11 3457 2655

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# Appendix D Equipment Comparison Table

And

**Procedure Listing** 

### **EQUIPMENT COMPARISON**

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Туре	Linear	Linear
(e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Accelerator	Accelerator
Manufacturer	Elekta	Varian
Model number	1672	TrueBeam
Other method of identifying the equipment (e.g., Room#, Serial Number, VIN#)	Vault 2 / Asset 438	Vault 1
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	9/1/2008	PO issued 5/6/2025
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>		\$ 6,703,815
Total cost of the equipment	\$ 2,737,827	\$ 2,992,729
Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach>	Watauga Medical Center Seby B. Jones Regional Cancer Center 336 Deerfield Rd., Boone, NC 28607 Vault #2	Watauga Medical Center Seby B. Jones Regional Cancer Center 336 Deerfield Rd., Boone, NC 28607 Vault #1
Document that the existing equipment is currently in use	Yes	N/A
Will the replacement equipment result in any increase in the average charge per procedure?		No
If so, provide the increase as a percent of the current average charge per procedure		N/A
Will the replacement equipment result in any increase in the average operating expense per procedure?		Yes
If so, provide the increase as a percent of the current average operating expense per procedure		14%
Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	See Attached	

Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>		See Attached
--	--	--------------

Date of last revision: 5/17/19

Type of procedures that both the existing and replacement equipment will perform:

### **Common CPT Codes Used with a Linear Accelerator**

### **Treatment Planning & Physics**

- 77301 Intensity modulated radiation therapy (IMRT) plan, dose-volume histograms
- 77307 Teletherapy isodose plan, complex, with basic dosimetry
- 77332 Treatment devices, design and construction, simple
- 77334 Treatment devices, design and construction, complex
- 77336 Continuing medical physics consultation per week
- 77338 MLC IMRT design and construction, per plan

### **Treatment Delivery**

- 77373 Stereotactic body radiation therapy (SBRT) delivery
- 77385 IMRT delivery, simple
- 77386 IMRT delivery, complex
- 77412 Radiation treatment delivery > 1 MeV, complex

### **Guidance / Imaging During Treatment**

- 77387 Guidance for localization of target volume for radiation treatment delivery
- 77417 Therapeutic radiology port films

### **Special Procedures**

• 77470 – Special treatment procedure (used for complex cases or unusual setups)

From: <u>Hale, Gloria</u>
To: <u>Stancil, Tiffany C</u>

Subject: FW: [External] Watauga Medical Center-Request for Exemption Letter-Replacement of Linear Accelerator

**Date:** Thursday, August 14, 2025 8:29:25 AM

**Attachments:** arhs-uncha-linear acceleration CON exemption request letter 2025-08-13.pdf

Appendix A-aerial view.pdf

Exhibit B-Linear Accelerator Replacement CON dated November 2007 (003).pdf

Exhibit C- costs purchase agreement and flier for CER Varian Tru Beam Linear Accelerator.pdf

Exhibit D -equipment comparison and common procedures.pdf

It looks like this came directly to me. Sending to you to log.

### Gloria C. Hale, MPH

Team Leader, CON
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services

(I am in the office Mondays and Thursdays. I am working remotely on the other days, therefore email is typically the best way to reach me.)

Main: 919-855-3873 gloria.hale@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building 2704 Mail Service Center Raleigh, NC 27699-2704

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From: Mool, Deanna < Deanna. Mool@unchealth.unc.edu>

**Sent:** Wednesday, August 13, 2025 5:40 PM **To:** Hale, Gloria <gloria.hale@dhhs.nc.gov>

Subject: [External] Watauga Medical Center-Request for Exemption Letter-Replacement of Linear

Accelerator

You don't often get email from deanna.mool@unchealth.unc.edu. Learn why this is important

**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.

Ms. Hale,

Please find enclosed the request for exemption for replacement of the linear accelerator at Watauga Medical Center. I can provide any additional information needed to process our exemption request. I can be reached by email at: <a href="mailto:deanna.mool@unchealth.unc.edu">deanna.mool@unchealth.unc.edu</a>. My direct line is 828-268-8915.

Thank you.

Best Regards,

Deanna S. Mool
Chief Legal Officer
Appalachian Regional Healthcare System, Inc. d/b/a UNC Health Appalachian
336 Deerfield Road
Boone, NC 28607
828-268-8915
deanna.mool@unchealth.unc.edu

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