



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

July 5, 2016

Ms. Sandy Godwin
1638 Owen Drive
Fayetteville, NC 28304

Exempt from Review – Replacement Equipment

Record #: 1980
Facility Name: Cape Fear Valley Medical Center
FID #: 030360
Business Name: Cape Fear Valley Medical Center
Business #: 335
Project Description: Replace existing linear accelerator
County: Cumberland

Dear Ms. Godwin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter dated June 28, 2016 and received in our office on July 1, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Varian TrueBeam Linear Accelerator, serial number to be determined at the time of acquisition. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

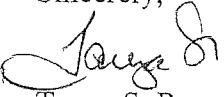
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704


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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,


Tanya S. Rupp
Project Analyst


Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

CAPE FEAR VALLEY HEALTH



FID 030360
Bus id 335
NR id 1980

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June 28, 2016

Ms. Martha Frisone, Assistant Chief
Health Planning and Certificate of Need Section
North Carolina Division of Facilities Services
809 Ruggles Dr.
Raleigh, NC 27603

Re: Replace an existing linear accelerator located at the Cape Fear Valley Cancer Treatment & CyberKnife Center

Dear Ms. Frisone:

In accordance with G.S. 131E-184(f) Cape Fear Valley Health System proposes to replace an existing linear accelerator located at the Cape Fear Valley Cancer Treatment & CyberKnife Center in Fayetteville, North Carolina. The following information and documentation is provided for your review.

- 1. A copy of the health service facility's current license.

Please see *Attachment 1* for a copy of the CFVHS 2016 License.

- 2. A copy of the certificate of need for the equipment proposed to be replaced.

The existing Siemens Mevatron linear accelerator was put into operation nearly 18 years ago as part of the CFVMC Cancer Center Expansion Project in 1996, CON Project I.D. #M-5200-95. This project included a new Medical Oncology wing, development of the Cancer Center basement, an additional linac (now being replaced) plus an additional new vault, and a 2nd simulator, along with additional Radiation Oncology expansion space. Documentation for the certificate of need for the acquisition and implementation of this equipment at that time is included in *Attachment 2*.

- 3. If no certificate of need was issued for the equipment proposed to be replaced, provide documentation that a certificate of need was not required when the equipment proposed to be replaced was initially acquired.

Not applicable, the existing equipment was acquired approximately 18 years ago as part of CON Project I.D. #M-5200-95 as discussed in #2 above.

- 4. Documentation that the equipment proposed to be replaced is currently in use. See the definition of "replacement equipment" in G.S. 131E-176(22a) and the rule at 10 NCAC 14C .0303.

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CAPE FEAR VALLEY HEALTH

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Please see *Attachment 3* for a letter from Brenda Hall, Service Line Director, Cape Fear Valley Cancer Centers, which documents that the equipment to be replaced is currently in use.

5. Documentation that the equipment proposed to be replaced will be sold or otherwise disposed of once the proposed replacement equipment is installed and operational. See the definition of "replacement equipment" in G.S. 131E-176(22a) and the rule at 10 NCAC 14C .0303.

Please see *Attachment 4* for a letter from Varian, who will be removing the equipment from CFVMC, which documents that the existing equipment will be sold or otherwise disposed of once the proposed replacement equipment is installed and operational.

6. Documentation that the proposed replacement equipment is comparable to the equipment proposed to be replaced. See the definition of "replacement equipment" in G.S. 131E-176(22a) and the rule at 10 NCAC 14C .0303.

The current Siemens Mevatron linear accelerator is 18 years old and replacement parts are no longer available. The Varian TrueBeam will provide faster, clear, better data and information than the older equipment and will be capable of meeting the treatment needs of a larger variety of cancer patients. The new equipment allow current services provided at Cape Fear Valley Cancer Treatment & CyberKnife Center to be provided faster with better equipment but will not result in the expansion of services currently provided.

Please see the Replacement Equipment Comparison Form and additional documentation included in *Attachment 5* for documentation that the proposed replacement equipment is comparable to the equipment proposed to be replaced.

7. Documentation that clinical patient services are provided at the site where the equipment proposed to be replaced is currently located.

Please see *Attachment 3* for a letter from Brenda Hall, Service Line Director, Cape Fear Valley Cancer Centers, which documents that the equipment to be replaced is currently in use at the Cape Fear Valley Cancer Treatment & CyberKnife Center at 1638 Owen Drive in Fayetteville, NC and that the replacement equipment will be located at the same location, where clinical patient services are provided. In addition, please see *Attachment 9* which includes relevant pages of the 2016 Cape Fear Valley Health System Annual Licensure Renewal Application which demonstrates that clinical patient services are provided at the Cape Fear Valley Cancer Treatment & CyberKnife Center at 1638 Owen Drive in Fayetteville.

8. Documentation that financial control of the entire licensed health service facility is exercised at the site where the equipment proposed to be replaced is currently located.



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Please see *Attachment 6* for a letter from Sandy Godwin, Executive Director, Corporate Financial & Strategic Planning for Cape Fear Valley Health System, which documents that financial control of the entire licensed health service facility is exercised at the site where the equipment proposed to be replaced is currently located.

9. Documentation that administrative control of the entire licensed health service facility is exercised at the site where the equipment proposed to be replaced is currently located.

Please see *Attachment 6* for a letter from Sandy Godwin, Executive Director, Corporate Financial & Strategic Planning for Cape Fear Valley Health System, which documents that administrative control of the entire licensed health service facility is exercised at the site where the equipment proposed to be replaced is currently located.

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Existing Equipment Location

10. The street address for the site where the equipment proposed to be replaced is currently located.

1638 Owen Drive
Fayetteville, NC 28304

11. The building name and number where the equipment proposed to be replaced is currently located.

Cape Fear Valley Medical Center
Cape Fear Valley Cancer Treatment & CyberKnife Center
1638 Owen Drive
Fayetteville, NC 28304

12. The room number where the equipment proposed to be replaced is currently located.

The existing equipment is located in the Cape Fear Valley Cancer Treatment & CyberKnife Center on the first floor, Room LA5.

13. A floor plan drawn to scale showing the location of the equipment proposed to be replaced.

Please see *Attachment 7* for a floor plan of the Cape Fear Valley Cancer Treatment & CyberKnife Center which shows the location of the equipment proposed to be replaced.



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14. A site plan drawn to scale identifying the building where the equipment proposed to be replaced is currently located.

Please see *Attachment 7* for a site plan identifying the location of the Cape Fear Valley Cancer Treatment & CyberKnife Center which shows the location of the equipment proposed to be replaced.

15. If the site where the equipment proposed to be replaced consists of multiple buildings, identify which of those buildings is the main building on the site plan.

Please see *Attachment 7* for a site plan which identifies the main hospital building on the site plan.

16. If the equipment proposed to be replaced is located in a building that is not strictly contiguous to the main building, provide documentation that the main building is located within 250 yards of the building where the equipment is currently located.

Not applicable, the equipment proposed to be replaced is located in the main hospital building.

Proposed Replacement Equipment Location

17. The street address of the site where the proposed replacement equipment will be located.

1638 Owen Drive
Fayetteville, NC 28304

18. The building name and number where the proposed replacement equipment will be located.

Cape Fear Valley Medical Center
Cape Fear Valley Cancer Treatment & CyberKnife Center
1638 Owen Drive
Fayetteville, NC 28304

19. The room number where the proposed replacement equipment will be located.

The replacement equipment will be located in the Cape Fear Valley Cancer Treatment & CyberKnife Center on the first floor, Room LA5.

20. A floor plan drawn to scale showing the location of the proposed replacement equipment.



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Please see *Attachment 7* for a floor plan of the Cape Fear Valley Cancer Treatment & CyberKnife Center which shows the location of the equipment proposed to be replaced.

21. A site plan drawn to scale identifying the building where the proposed replacement equipment will be located.

Please see *Attachment 7* for a floor plan of the Cape Fear Valley Cancer Treatment & CyberKnife Center which shows the location of the equipment proposed to be replaced.

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22. If the site where the proposed replacement equipment will be located consists of multiple buildings, identify which of those buildings is the main building on the site plan.

Please see *Attachment 7* for a site plan identifying the location of the Cape Fear Valley Cancer Treatment & CyberKnife Center which shows the location of the equipment proposed to be replaced.

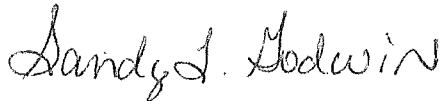
23. If the proposed replacement equipment will be located in a building that is not strictly contiguous to the main building, provide documentation that the main building is located within 250 yards of the building where the proposed replacement equipment will be located.

Not applicable, the equipment proposed to be replaced is located in the main hospital building.

The above information has been provided in accordance with the requirements identified in G.S. 131#-184(f) for replacement equipment. In addition, the capital expenditure for the project is included in *Attachment 8*.

If you have any questions concerning this request, please do not hesitate to call Brenda Hall at (910) 850-3920 or me at (910) 615-6852.

Sincerely,



Sandy T. Godwin
Executive Director, Corporate Financial & Strategic Planning
Cape Fear Valley Health System

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

*Effective May 26, 2016, this license is issued to
Cumberland County Hospital System, Inc.*

*to operate a hospital known as
Cape Fear Valley Medical Center
located in Fayetteville, North Carolina, Cumberland County.*

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

Facility ID: 943057

License Number: H0213

Bed Capacity: 611

General Acute 501, Rehabilitation 78, Psych 28, Substance Abuse 4,

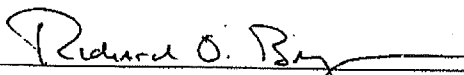
Dedicated Inpatient Surgical Operating Rooms: 5

Dedicated Ambulatory Surgical Operating Rooms: 0

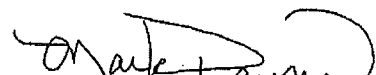
Shared Surgical Operating Rooms: 13

Dedicated Endoscopy Rooms: 4

Authorized by:



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



Director, Division of Health Service Regulation



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
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Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

June 1, 2016

Mr. Michael Nagowski, CEO
Cape Fear Valley Medical Center
P O Box 2000
Fayetteville, NC 28302

**Re: General Acute Bed Addition (11)
CON/Project I.D: M-10294-14**

Effective: 05/25/2016

Dear Mr. Nagowski:

A new license is enclosed which reflects the following:

From	To
General Acute Beds: 490	General Acute Beds: 501

This license is issued pursuant to Chapter 131E-75 et seq., Hospital Licensure Act. The new license should be posted in a public area.

Notice of Right to Appeal. You have the right to appeal this decision pursuant to the provisions of Article 3 of Chapter 150B of the North Carolina General Statutes. In order to preserve this right, you must file a petition for contested case hearing in the Office of Administrative Hearings. Your petition must be received by the Office of Administrative Hearings no later than thirty days after the date on which this letter was mailed to you. For complete instructions on the filing of a petition, you may write or call the Office of Administrative Hearings at the following address and telephone number:

Office of Administrative Hearings
6714 Mail Service Center
Post Office Drawer 27447
Raleigh, NC 27699-6700 - Telephone (919) 431-3000



<http://www.ncdhhs.gov/dhsr/>

Phone: 919-855-4620 / Fax: 919-715-3073

Location: 1205 Umstead Drive v Dorothea Dix Hospital Campus v Raleigh, N.C. 27603

Mailing Address: 2712 Mail Service Center • Raleigh, North Carolina 27699-2712

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Mr. Michael Nagowski, CEO
June 1, 2016
Page Two

If you file a petition for contested case hearing, you must also serve a copy of the petition on the Department of Health and Human Services. You may serve the Department by mailing a copy of your petition to Emery E. Milliken, General Counsel, at the following address: Department of Health Service Regulation, Office of Legal Affairs, Adams Building, Room 111, 2005 Mail Service Center, Raleigh, NC 27699-2005.

We will notify the appropriate agencies by copy of this letter. Please contact our office if there are any questions about this process.

Sincerely,

Linda M. Johnson

Linda M.. Johnson, Administrative Assistant II
Acute and Home Care
Licensure and Certification Section

Enclosure

cc: Construction Section Chief
Medical Facility Planning
Certificate of Need Section Chief
DMA



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June 28, 2016

Ms. Martha Frisone, Assistant Chief
Health Planning and Certificate of Need Section
North Carolina Division of Facilities Services
809 Ruggles Dr.
Raleigh, NC 27603

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Re: Replace an existing linear accelerator located at the Cape Fear Valley Cancer Treatment & CyberKnife Center
Attachment 2 – Documentation of Certificate of Need

Dear Ms. Frisone:

I am the Executive Director, Corporate Financial & Strategic Planning at Cape Fear Valley Health System. CFVHS is replacing an older, Siemens Mevatron linear accelerator with a new Varian TrueBeam linear accelerator. The proposed replacement equipment will be located at the Cape Fear Valley Cancer Treatment & CyberKnife Center at 1638 Owen Drive in Fayetteville, NC. This location is part of the main hospital at Cape Fear Valley Medical Center.

The existing Siemens Mevatron linear accelerator was put into operation nearly 18 years ago as part of the CFVMC Cancer Center Expansion Project in 1996, CON Project I.D. #M-5200-95. This project included a new Medical Oncology wing, development of the Cancer Center basement, an additional linac (now being replaced) plus an additional new vault, and a 2nd simulator, along with additional Radiation Oncology expansion space. We have been unable to locate the original CON for this project. Please consider this letter as documentation that a certificate of need was received when the equipment was initially acquired.

We look forward to receiving notification from the Certificate of Need Section that the replacement equipment is consistent with the statutory language and is indeed exempt from CON review.

Please do not hesitate to contact me with any questions.

Sincerely,

Sandy T Godwin
Executive Director, Corporate Financial & Strategic Planning
Cape Fear Valley Health System



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June 17, 2016

Ms. Martha Frisone, Assistant Chief
Health Planning and Certificate of Need Section
North Carolina Division of Facilities Services
809 Ruggles Dr.
Raleigh, NC 27603

Re: Replace an existing linear accelerator located at the Cape Fear Valley Cancer Treatment & CyberKnife Center

Dear Ms. Frisone:

I am the Service Line Director for all of the Cape Fear Valley Cancer Centers. In this role I am responsible for the day to day operations of our existing cancer centers including the Cape Fear Valley Cancer Treatment & CyberKnife Center and Cape Fear Valley Health Pavilion North Cancer Center (HPNCC) in Fayetteville and the CFV Cancer Center @ Harnett located in Dunn, NC, providing hematology and medical oncology services. Additionally, I will be responsible for the Cancer Center @ Central Harnett when it becomes operational at the end of 2018.

This letter is to provide documentation that the linear accelerator that CFVHS is proposing to replace, Serial # 2834 installed in 1998, is currently in daily use at the Cape Fear Valley Cancer Treatment & CyberKnife Center at 1638 Owen Drive in Fayetteville, NC. The proposed replacement equipment will be located in the same location as the current equipment.

The proposed replacement equipment, Varian's TrueBeam Linear Accelerator, will enable our Cancer Program to deliver complex radiation treatments to patients faster, with more precision, and with more imaging and treatment delivery options that are available with today's state-of-the-art technology. Attached to this letter is the brochure for the TrueBeam Linear Accelerator.

We look forward to receiving notification from the Certificate of Need Section that the replacement equipment is consistent with the statutory language and is indeed exempt from CON review.

Please call me directly with any questions you may have. Thank you for your time in reviewing this linear accelerator replacement request.

Sincerely,

Brenda Hall, MBA, RTT
Service Line Director
Cape Fear Valley Cancer Centers
910-615-6905

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Varian Medical Systems, Inc.

Corporate Headquarters

3100 Hansen Way
Palo Alto, CA 94304-1038

Telephone: 1.650.493.4000
Toll Free: 800.544.4636

www.varian.com

May 4, 2016

Ms. Martha Frisone
Assistant Chief
Health Planning and Certificate of Need Section
North Carolina Division of Facilities Services
809 Ruggles Dr.
Raleigh, NC 27603

Dear Martha Frisone:

In response to your request for information on the status of Siemens Mevatron with serial number 2834, this letter confirms that Varian Medical Systems, with assistance from Legacy Transportation Systems, will remove above referenced equipment from the facilities of Cape Fear Valley Medical Center for shipment to storage at a Legacy-managed storage facility of its choosing, where it will subsequently be scrapped.

The purpose of this letter is to confirm removal and final disposition of above referenced equipment only.

Sincerely,

A handwritten signature in dark ink, appearing to read "Matthew Carvalho", with a long, sweeping underline.

Matthew Carvalho
Sales Operations Manager
matt.carvalho@varian.com
[+1 650 424 6267](tel:+16504246267)

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Siemens	Varian
Tesla Rating for MRIs	NA	NA
Model Number	Mevatron	TrueBeam
Serial Number	2834	TBD
Provider's Method of Identifying Equipment	Serial #	Serial #
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	February, 1998	Anticipated acquisition Jan. 2017
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Will hold title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	NA (Construction Cost was part of larger CON project and not broken out for just linac space)	\$408,017
Total Cost of Equipment	\$395,925 in 1998 + \$150,000 upgrade in 2003	\$2,750,000
Fair Market Value of Equipment	NA	2,750,000
Net Purchase Price of Equipment	NA	2,750,000
Locations Where Operated	Cape Fear Valley Medical Center	Will be operated at Cape Fear Valley Medical Center
Number Days In Use/To be Used in N.C. Per Year	Available for us 365 days per year	Will be available use for 365 days per year
Percent of Change in Patient Charges (by Procedure)	NA	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0
Type of Procedures Currently Performed on Existing Equipment	NA	NA
Type of Procedures New Equipment is Capable of Performing	NA	Faster treatment delivery, higher precision, imaging capabilities, SBRT capabilities, gating capabilities, etc.

trueBEAM

VARIAN
medical systems

THE TRUEBEAM SYSTEM

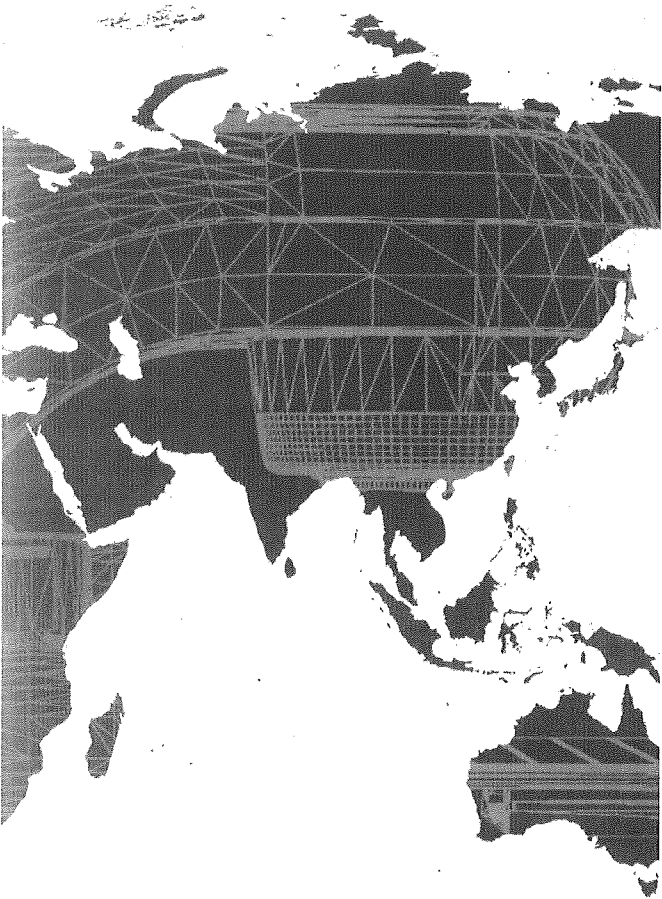




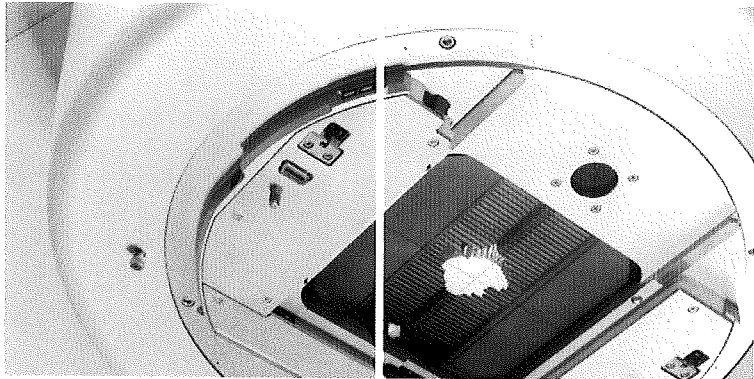
THE TRUEBEAM SYSTEM.
BUILT BY VARIAN,
INSPIRED BY OUR
CUSTOMERS.

The TrueBeam™ system brings some of the most innovative thinking in cancer care into your clinic. This advanced technology offers a range of capabilities that turn leading research into integrated care. With these advances, you have more options for patients and more opportunities for your clinic.

Such versatility is why the TrueBeam system has been adopted by top clinics around the world. With this rapid growth, TrueBeam and Varian Medical Systems can help position your clinic at the forefront of the global fight against cancer. We know where we're headed. Join us on the journey.

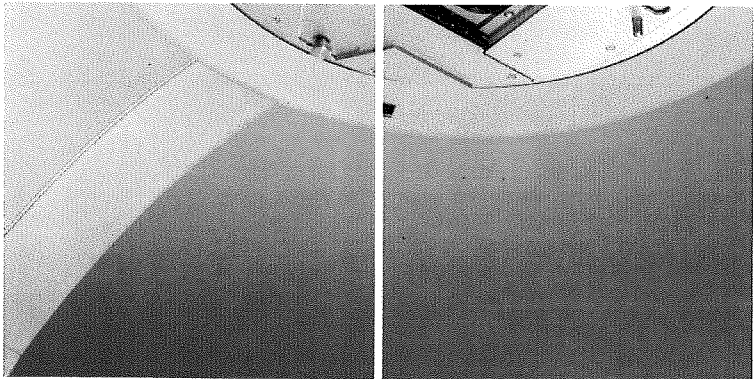
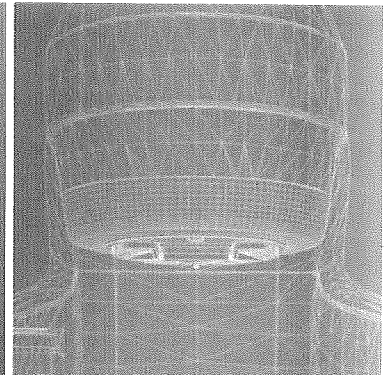


PROVEN AS A TECHNOLOGY.
POSSIBILITIES AS A RESULT.



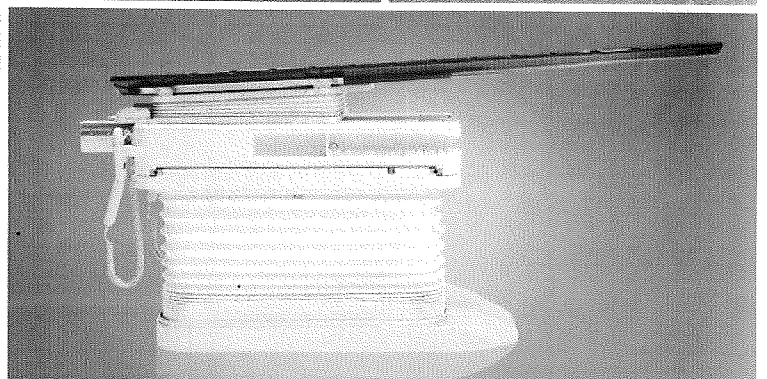
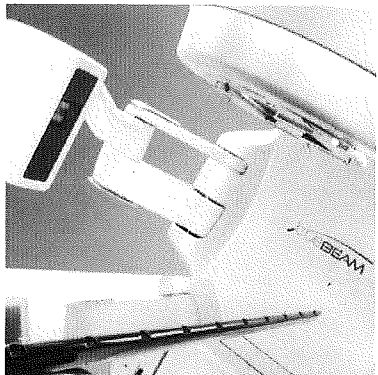
< **MULTI-LEAF
COLLIMATOR**

High definition
120 MLC option for
radiosurgery applications



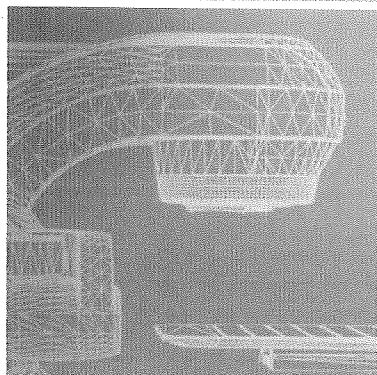
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SYSTEM**

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reduced dose



^ **PERFECTPITCH™
6 DEGREES OF
FREEDOM COUCH**

Patient positioning
in 6-degrees for
enhanced precision



Expand your offerings with the system built to help you grow.

The TrueBeam system is designed to address a diverse range of clinical cases such as those in the lung, liver, head and neck, and more. TrueBeam integrates respiratory gating, real-time tracking, imaging and treatment delivery to create a streamlined system. With this integration, you can take advantage of the latest treatment techniques, including SBRT, SRS, RapidArc[®] and Gated RapidArc[®].

Interface with multiple technologies for imaging and disease-specific solutions on the TrueBeam system's flexible open architecture. Integrate with the ARIA[®] oncology information system and the Eclipse[™] treatment planning system to simplify planning and manage treatment workflows. Save time and condense tasks with automated, customizable sequences. With this full spectrum of innovative tools, the TrueBeam system puts current advances in your hands.

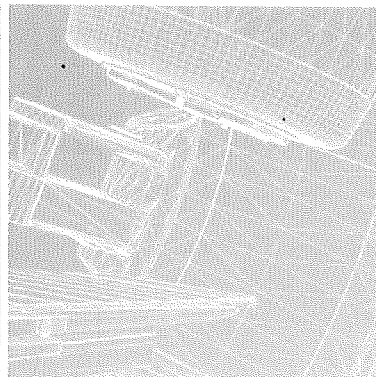
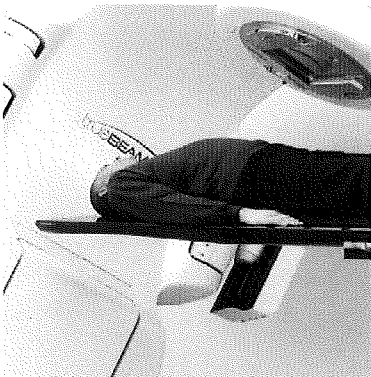
**REMOTE >
OPERATION**

Advanced capabilities with a simple interface



**VARIAN CALYPSO[®] >
SYSTEM FOR
PROSTATE**

Real-time tracking to enhance tumor targeting during radiation treatment

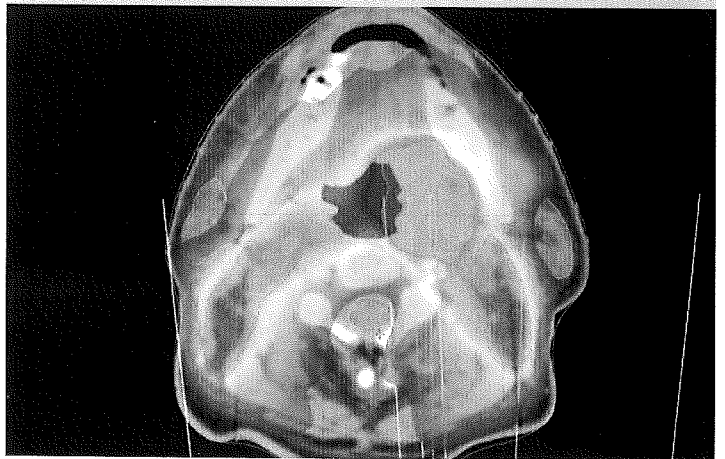
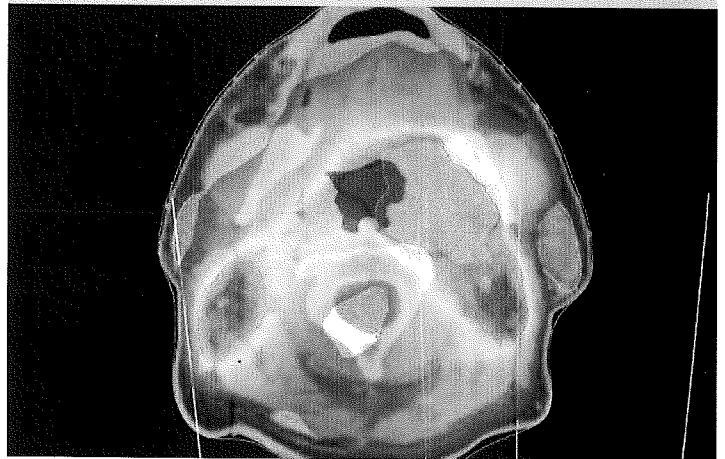
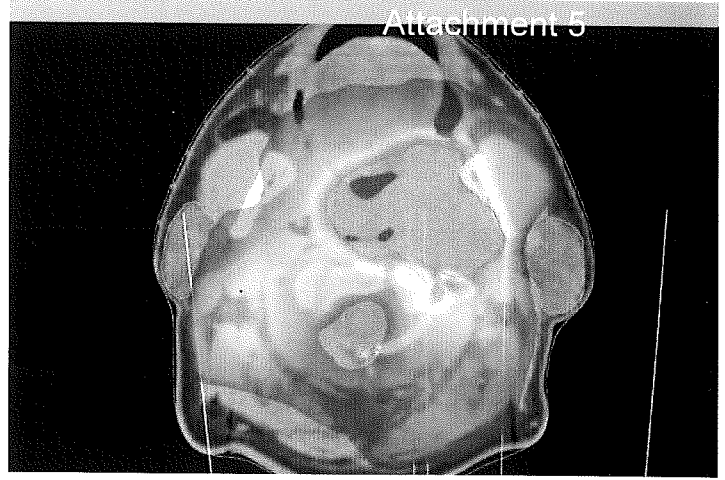


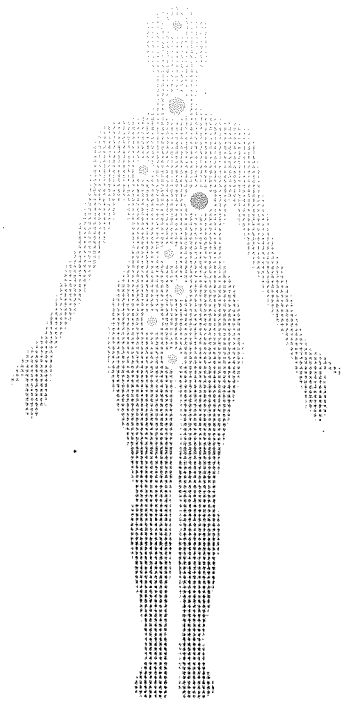
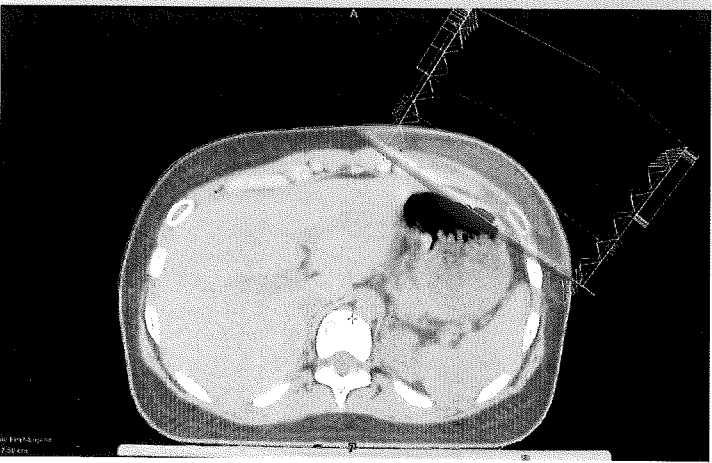
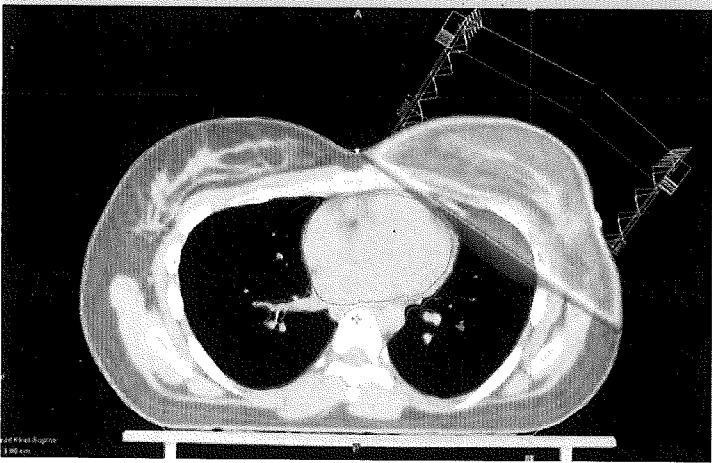
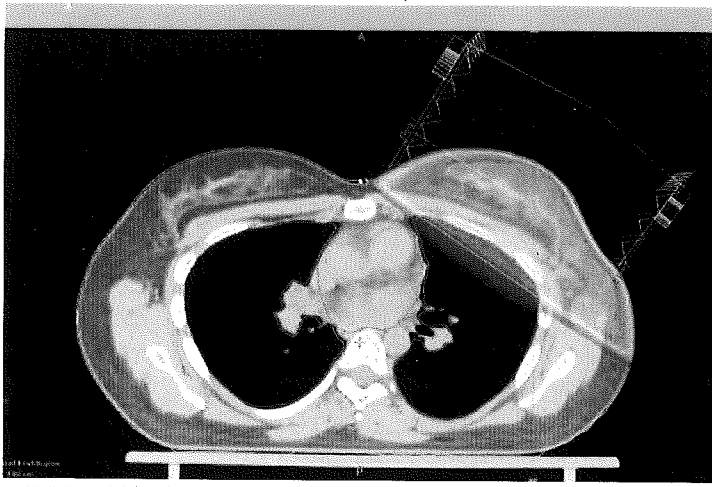
MORE OPTIONS FOR A WIDE VARIETY OF CANCER CASES.

Address a diverse range of cancer cases with the TrueBeam system. Areas located in close proximity to critical structures or significant changes in anatomy during the course of treatment can make difficult targets for clinicians. See how the TrueBeam system addresses the technical challenges of these four common cancer types.

HEAD AND NECK

- Multiple arcs, partial arcs or a combination can be planned and seamlessly delivered using RapidArc radiotherapy technology
- A range of diagnostic imaging studies can be introduced in treatment planning to assist in accurate contouring of the target
- The real-time control system synchronizes and choreographs all elements of delivery 10 times per second
- Imaging hardware and software allow capture of high-quality cone-beam CT images with lower concomitant dose
- Integration of SmartAdapt™ deformable registration algorithms provide a convenient means for clinicians to account for anatomical changes during the course of treatment





BREAST

- IMRT tools such as field-in-field help create treatment plans designed to minimize radiation exposure of the heart and healthy lung tissue
- Treat patients in the prone position using the Pivotal™ treatment solution for prone breast care to help minimize dose to critical structures such as the heart and lung
- Use Varian Calypso® technology and the Surface Beacon® Transponder for real-time deep inspiration breath hold to help ensure accuracy
- Integration of technologies such as real-time beam gating on a respiratory trigger can allow the reduction of treatment margins when compared to a full ITV-based treatment

VERSATILE TECHNOLOGIES FOR VERSATILE TREATMENTS.

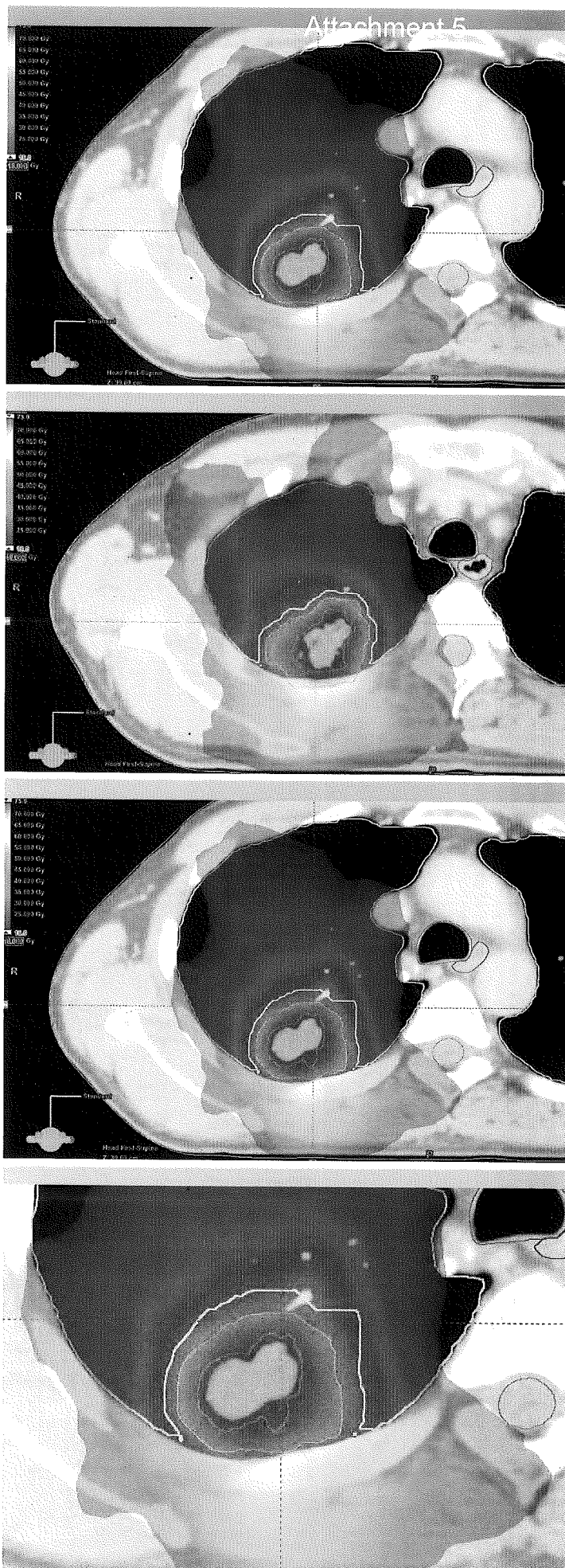
A breadth of technology provides versatility for treatments throughout the body.

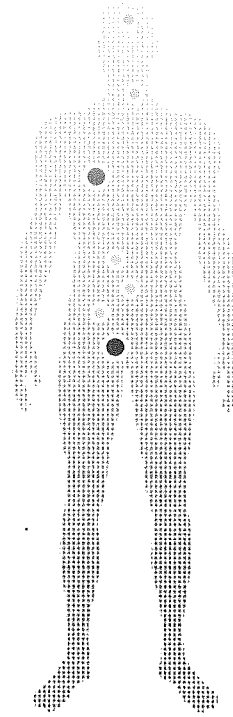
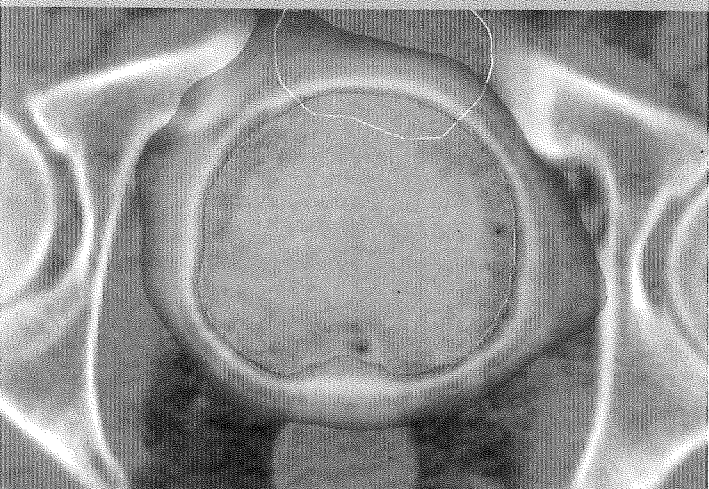
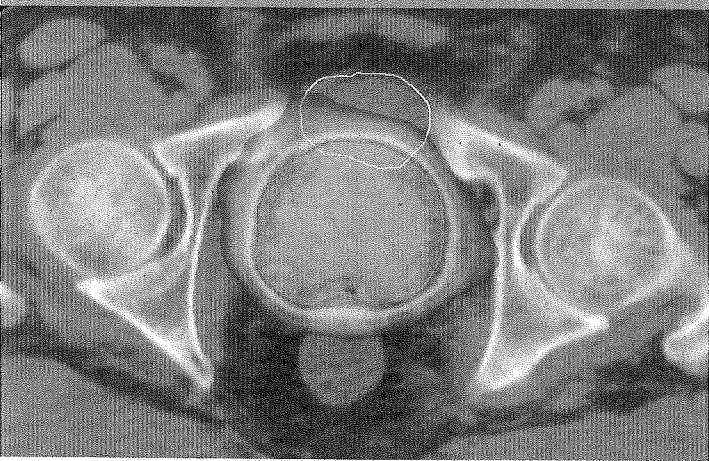
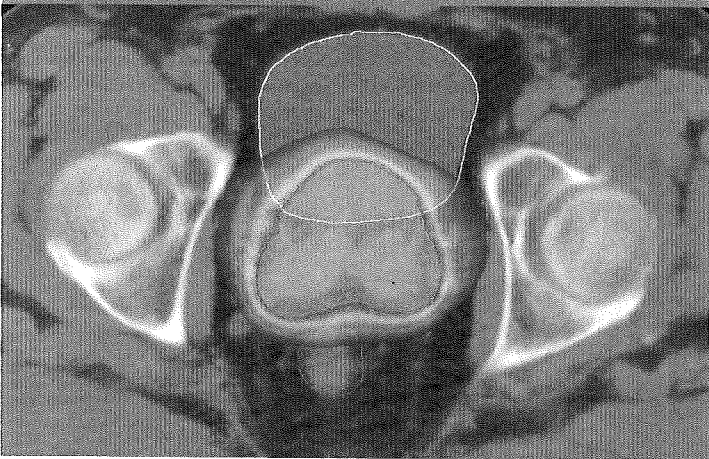
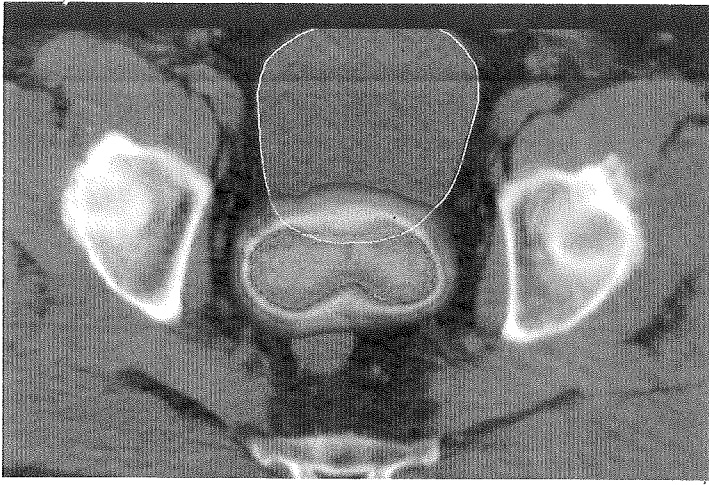
LUNG

- To reduce discrepancies between planned dose and delivered dose, Varian's Acuros[®] XB algorithm provides Monte Carlo equivalent dose calculations
- Contour propagation, intermediate dose calculation and a fine calculation grid all contribute to create an efficient and desired treatment plan
- Respiratory gating allows the reduction of irradiated volumes when compared with large ITV-based approaches¹
- Fluoroscopic, KV, MV and CBCT, along with the capability to mix and match from the menu of imaging possibilities, allow clinicians to tailor treatment delivery
- Triggered imaging based on respiratory gating to visualize targets in real time during treatment
- 2400 MU/minute, the highest dose rate in the industry, allows rapid delivery of large fractions²

¹ Data on file

² September, 2013

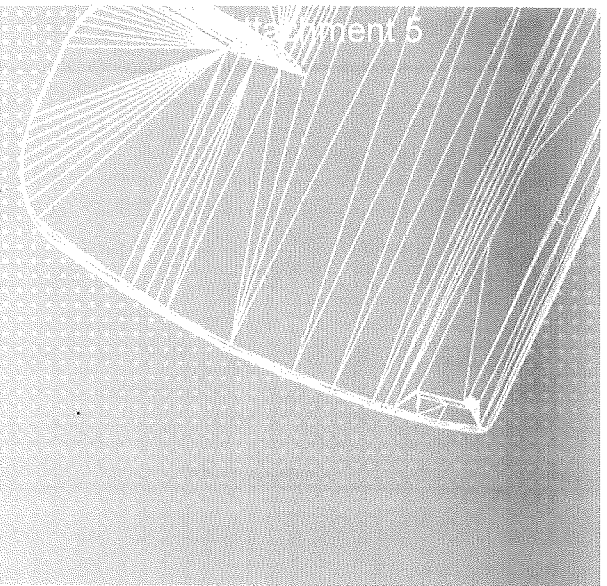




PROSTATE

- Using Smart Segmentation® knowledge-based contouring, physicians can take advantage of built-in expert cases or create their own cases to standardize treatment across the institution.
- Deliver treatment with speed and accuracy using RapidArc® radiotherapy technology and Eclipse™ treatment planning system
- Deliver fast hypofractionated prostate SBRT treatments using High Intensity Mode at 1400 MU/minute or 2400 MU/minute
- Track and correct, in real time, prostate drift and sporadic motion with Varian Calypso® system for prostate

FIND MORE PATHS
TO TREATMENT
AND MORE PATHS
TO GROWTH.



INNOVATIVE. INTELLIGENT. INTUITIVE.

Medicine does not advance on its own. We pursued innovative technology and the insights of our customers to arrive at this impressively intelligent solution. With the TrueBeam system, your clinic now has the tools to initiate a wide spectrum of advanced treatment options for specific disease sites.

ARCHITECTURE & MAESTRO

Dynamic performance for speed and efficiency

Behind the scenes of the TrueBeam system's advanced performance lies Maestro™ — an innovative control system. Maestro conducts the TrueBeam system by directing, synchronizing and monitoring all of the system's fully integrated, functional components or "nodes." Maestro's sophisticated orchestration of dose, motion and imaging reflects each of the system's moving parts, making treatment fast and efficient. Open up new possibilities for image-guided and motion-managed treatment techniques with this innovative architecture. The TrueBeam system's design also supports SmartConnect® technology, an on-demand remote support feature that allows your Varian service or helpdesk representative to provide immediate, real-time desktop sharing.

BEAM GENERATION

Exceptional performance and technology without compromise

At the heart of the TrueBeam system is a beam generation technology that's patented and unique. This beam generation system can be configured with zero to eight electron energies and up to seven photon energies, including two High-Intensity Modes for stereotactic radiosurgery and hypofractionated stereotactic body radiotherapy treatments. You can now better tailor radiation treatment programs with the advanced versatility found in the TrueBeam system.

IMAGING

A treatment range so generous, it includes space to breathe

The TrueBeam system opens the door to leading edge treatment with advanced positioning and real-time tracking solutions—including a full range of innovative and powerful imaging tools. Generate quality images without compromise through lower dose imaging. Create customized imaging protocols to enable faster, easier imaging with intelligent automation. Gated RapidArc® technology allows you to monitor patient breathing and compensate for tumor motion while quickly delivering dosage. The powerful imaging technologies in the TrueBeam system are an ideal complement to its integrated gating and motion-management system. With such a supportive system, you can image and treat with confidence.

DEVELOPER MODE

Turn possibilities into action

The Developer Mode option allows a broad range of 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 your fingertips.*

* Developer Mode is not for use on humans. Treatment decisions should not be made based on data derived from Developer Mode.

SAFETY AND SPEED

Simple automated operation

Visual cues built into the TrueBeam system provide an intuitive operating environment and can help to enhance safety and reduce operation times. For instance, buttons on the controls light up in the correct order to guide the operator through each step. Built-in layers of safety have been added throughout the system, including a Collision Avoidance function to help avoid problems. As an added safeguard, the system automatically performs accuracy checks every ten milliseconds, throughout the entire treatment. And at the control console, you can visually monitor your patient using Safewatch, the CCT camera system. With these design improvements, the therapist can focus even more on the patient.

EDGE TECHNOLOGY

Access to full-body real-time tracking

The Edge™ radiosurgery system is a clinical turnkey system developed to aid clinicians in performing non-invasive ablative treatments throughout the body wherever radiation treatment is indicated. With its precision and speed, this system can potentially treat a wide range of conditions across a variety of specialties including urology, pulmonology and neurosurgery.

The Varian Edge™ intracranial SRS package is designed to provide real-time tracking and motion management solutions for radiosurgical lesions. The Varian Optical Surface Monitoring System tracks the motion of an intracranial target in real-time and without additional ionizing radiation dose. Even slight motion can potentially be assessed in real-time with the help of 3D surface mapping of the patient's external surface.

The Edge Extracranial SABR Package provides accurate and precise target tracking to keep the radiation focused on the tumor, minimizing exposure to healthy tissue. Utilizing the Calypso™ system internal transponders, even a slight movement of the target can be detected, so you can keep the tumor in the path of the radiation beam. With Calypso, you can confidently treat with tighter margins, escalate dose or accelerate treatments with SABR, which can help reduce some potential side effects for patients.

6 DEGREES OF FREEDOM COUCH

Experience more freedom in patient setups

The new PerfectPitch™ 6 degrees of freedom couch is designed to advance patient positioning during radiotherapy and radiosurgery procedures by providing two additional rotational motion axes: pitch and roll. This patient positioning option may enable enhanced accurate target positioning and precise beam delivery and can reduce treatment margins in select clinical cases.

BROADEN YOUR FUTURE IN CANCER CARE.

You can have improved workflow and clinical processes, plus the technology to enable precise treatments that take only minutes. Take a step forward to prepare for the future in cancer care.

With TrueBeam, your clinic is ready tomorrow and beyond.



IMAGINE A WORLD WITHOUT THE FEAR OF CANCER.

Varian Medical Systems has been a pioneer in the field of oncology for over 60 years. During this time, we 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 for those affected by cancer, so we can unite around our common goal to fight this disease.



SELECTED SPECIFICATIONS

OUTPUT ENERGIES

X-ray (MV)	4, 6, 8, 10, 15, 18, 20
High intensity mode	6X, 10X
Maximum output dose rates	4 MV at 250 MU/min; all others at 600 MU/min 6X HI at 1400 MU/min; 10X HI at 2400 MU/min
Electron (MeV)	6, 9, 12, 15, 16, 18, 20, 22
HDTSE	6 HDTSE, 9 HDTSE
Maximum output dose rates	1000 MU/min HDTSE Energies at 2500 MU/min

MECHANICAL PERFORMANCE

Gantry and collimator isocenter accuracy	≤ 0.5 mm radius
Gantry, collimator and couch isocenter accuracy	≤ 0.75 mm radius
Gantry rotational accuracy	≤ 0.3 degrees

IMAGING OPTIONS

kV range	40 - 140 kV
mAs range	0.1 - 1000 mAs
Modes	kV planar, kV CBCT, fluoroscopic imaging
Pixel matrix	2048 x 1536 1024 x 768

CBCT

Field of view	0 - 25 cm (head scans); 0 - 46 cm (body scans)
Slice thickness	1 mm - 5 mm in 0.5 mm increments; 10 mm

MULTILEAF COLLIMATOR

Millennium™ 120 Leaf MLC

Center	5 mm width x 40 pairs
Peripheral	10 mm width x 20 pairs
Maximum static field size	40 cm x 40 cm

High Definition 120 Leaf MLC

Center	2.5 mm width x 32 pairs
Peripheral	5 mm width x 28 pairs
Maximum static field size	40 cm x 22 cm

USA, Corporate Headquarters and Manufacturer

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 Palo Alto, CA 800.544.4636
 Fax: 650.493.5637
varian.com/truebeam

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Varian Medical Systems
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 Helsinki, Finland
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Varian Medical Systems
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 Buc, France
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 Darmstadt, Germany
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Varian Medical Systems
 India Pvt Ltd.
 Chennai Branch, India
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Varian Medical Systems
 India Pvt Ltd.
 Delhi Branch, India
 Tel: 91.11.4316.2102

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Varian Medical Systems
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 Milano, Italy
 Tel: 39.02.921.351

The Netherlands

Varian Medical Systems
 Nederland B.V.
 Houten, The Netherlands
 Tel: 31.30.634.0506

Russia

Varian Medical Systems
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 Tel: 7.495.604.44.23/24

Scandinavia

Varian Medical Systems
 Scandinavia A/S
 Herlev, Denmark
 Tel: 45.44.500.100

Spain

Varian Medical Systems
 Ibérica, S.L.
 Madrid, Spain
 Tel: 34.91.33.44.800

United Kingdom /Ireland

Authorized Representative
 in the EU
 Varian Medical Systems
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 Crawley, UK
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 Tel: 81.3.4486.5010

Australia

Varian Medical Systems
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 Sydney, Australia
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Latin American Headquarters

Brasil

Varian Medical Systems
 Brasil Ltda.
 São Paulo, Brasil
 Tel: 55.11.3457.2655

Devices or features presented in this brochure may not be available for sale in all markets.

Intended Use Summary

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

Safety

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

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Michael Nagowski, Chief Executive Officer
Bradley Broussard, MD, Chief of Staff

May 2, 2016

- BEHAVIORAL HEALTH CARE
- BLADEN COUNTY HOSPITAL
- CAPE FEAR VALLEY MEDICAL CENTER
- CAPE FEAR VALLEY REHABILITATION CENTER
- HEALTH PAVILION HOKE
- HEALTH PAVILION NORTH
- HIGHSMITH RAINEY SPECIALTY HOSPITAL

Ms. Martha Frisone, Assistant Chief
Health Planning and Certificate of Need Section
North Carolina Division of Facilities Services
809 Ruggles Dr.
Raleigh, NC 27603

Re: Replace an existing linear accelerator located at the Cape Fear Valley
Cancer Treatment & CyberKnife Center

- BLOOD DONOR CENTER
- CANCER CENTER
- CARELINK
- CAPE FEAR VALLEY HOMECARE & HOSPICE, LLC
- CUMBERLAND COUNTY EMS
- FAMILY BIRTH CENTER
- HEART & VASCULAR CENTER
- HEALTHPLEX
- LIFELINK CRITICAL CARE TRANSPORT
- PRIMARY CARE PRACTICES
- SLEEP CENTER

Dear Ms. Frisone:

I am the Executive Director, Corporate Financial & Strategic Planning at Cape Fear Valley Health System. CFVHS is replacing an older, Siemens Mevatron linear accelerator with a new Varian TrueBeam linear accelerator. The proposed replacement equipment will be located at the Cape Fear Valley Cancer Treatment & CyberKnife Center at 1638 Owen Drive in Fayetteville, NC. This location is part of the main hospital at Cape Fear Valley Medical Center.

All administrative and financial control for CFVMC are exercised at the site where the equipment proposed to be replaced is currently located. This is documented through this letter and reflected on the Cumberland County Hospital System, Inc. 2016 Annual Licensure Renewal Application on page 1 and page 3.

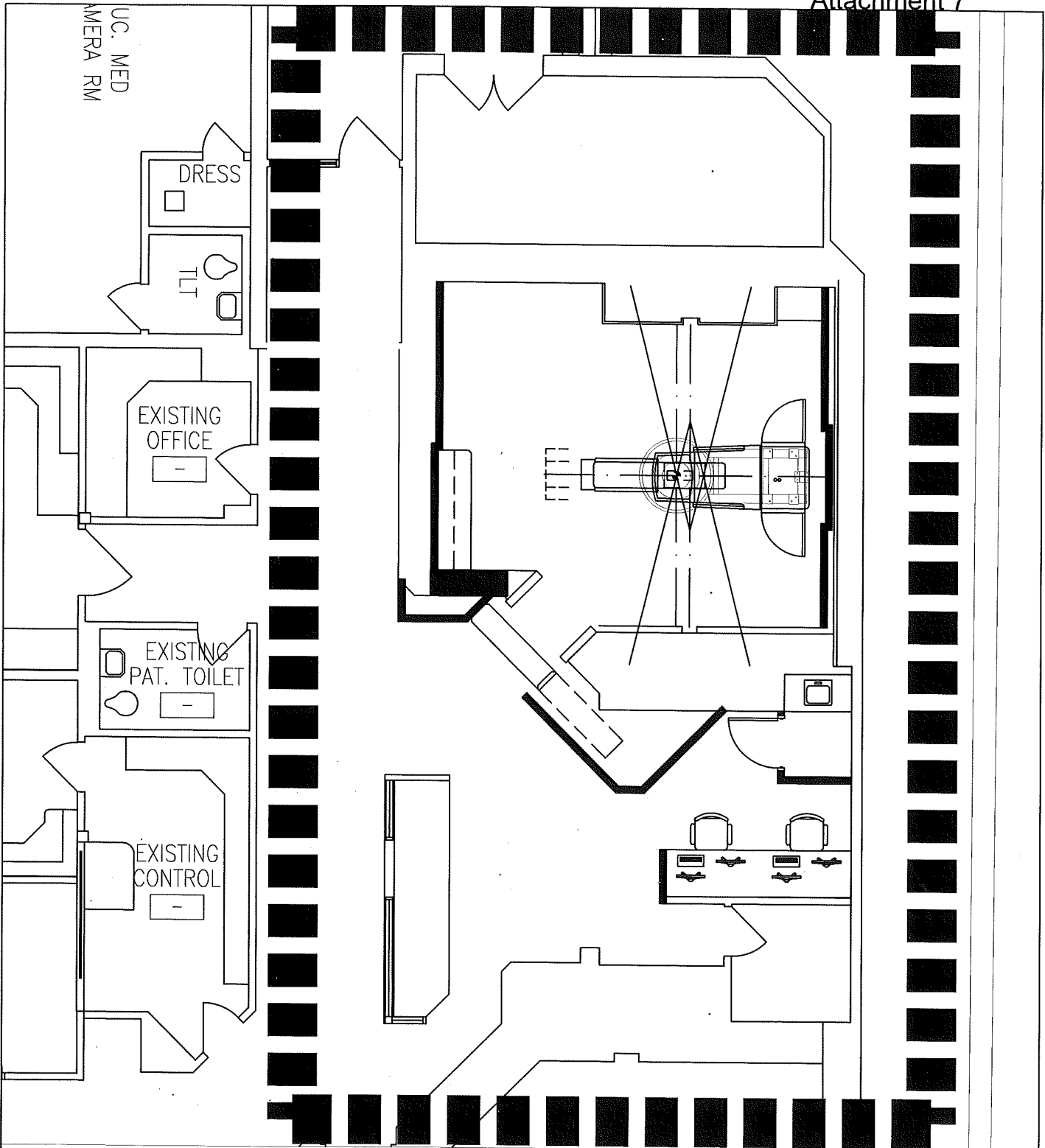
We look forward to receiving notification from the Certificate of Need Section that the replacement equipment is consistent with the statutory language and is indeed exempt from CON review.

Please do not hesitate to contact me with any questions.

Sincerely,

Sandy T Godwin
Executive Director, Corporate Financial & Strategic Planning
Cape Fear Valley Health System

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1
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EXISTING FIRST FLOOR WITH RENOVATIONS PLAN

1/8" = 1'-0"

LTC
ASSOCIATES

912 LADY ST. SUITE 300
COLUMBIA, SC 29201
803 . 254 . 9082 VOX
803 . 252 . 7200 FAX

owner:
Cape Fear Valley Health System,
Cape Fear Valley
1638 Owen Drive
Fayetteville, North Carolina

project name
FIRST FLOOR
CANCER CENTER
LINEAR ACCELERATOR
REPLACEMENT
project number
16023

title: PARTIAL FLOOR PLAN - LA5

Issued for: REVIEW

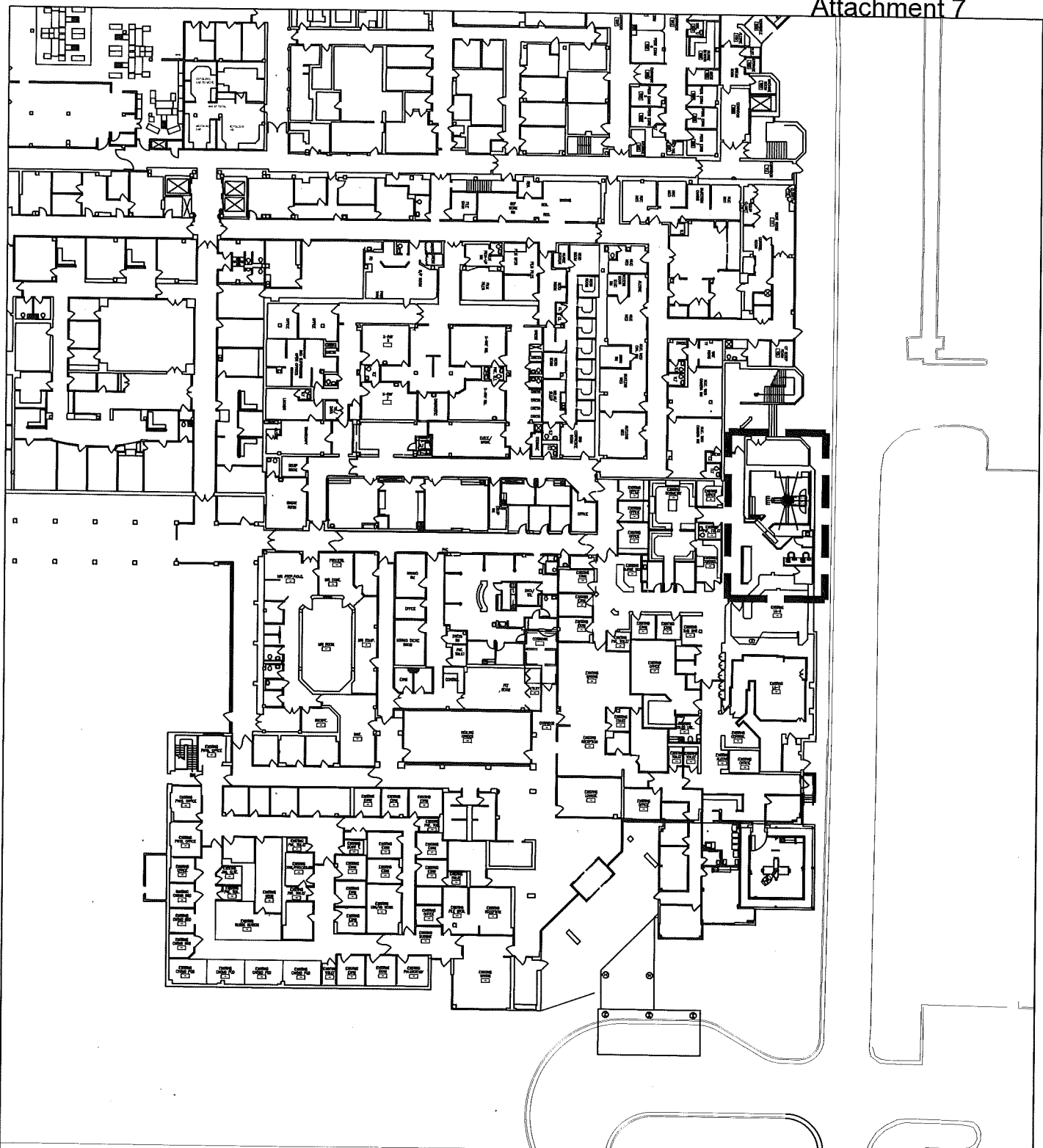
date: 06/21/2016

from:

drawn by: LEK

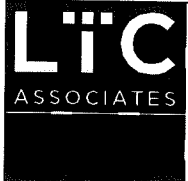
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1
-

SITE PLAN FOR CANCER CENTER - LA5 REPLACEMENT
N.T.S.



912 LADY ST, SUITE 300
COLUMBIA, SC 29901
803 . 254 . 9082 VOX
803 . 252 . 7200 FAX

owner:
Cape Fear Valley Health System
Cape Fear Valley
1638 Owen Drive
Fayetteville, North Carolina

project name
FIRST FLOOR
CANCER CENTER
LINEAR ACCELERATOR
REPLACEMENT
project number
16023

title: SITE PLAN - LA5
REPLACEMENT PROJECT
issued for: REVIEW
from: _____
drawn by: LEK

date: 06/21/2016

SITE PLAN

Attachment 7

Cape Fear Valley Cancer
Treatment & CyberKnife Center
at 1638 Owen Drive



A. Site Costs				
(1) Full purchase price of land				
# Acres _____				
Price per Acre \$ _____				
(2) Closing costs				
(3) Site Inspection and Survey				
(4) Legal fees and subsoil investigation				
(5) Site Preparation Costs [Include]				
Soil Borings				
Clearing and Grading				
Roads and Parking				
Sidewalks				
Water and Sewer				
Excavation and Backfill				
Termite Treatment				
Sub-Total Site Preparation Costs		\$	-	
(6) Other (Specify)				
(7) Sub-Total Site Costs			\$	-
B. Construction Contract				
(8) Cost of Materials [Include]	\$110,322.00			
General Requirements				
Concrete/Masonry				
Woods/Doors & Windows/Finishes				
Thermal & Moisture Protection				
Equipment/Specialty Items				
Mechanical/Electrical				
Sub-Total Cost of Materials	\$ 110,322.00			
(9) Cost of Labor		\$205,014.00		
(10) Other (Infection Control Measures)		\$13,710.00		
(11) Sub-Total Construction Contract			\$ 329,046.00	
C. Miscellaneous Project Costs				
(12) Building Purchase				
(13) Fixed Equipment Purchase/Lease		\$2,750,000		
(14) Movable Equipment Purchase/Lease				
(15) Furniture				
(16) Landscaping				
(17) Consultant Fees				
Architect/Engineering Fees	\$41,450.00			
Legal Fees				
Market Analysis				
Other (Construction Contingency)	\$32,905.00			
Total Consultant Fees		\$ 74,355.00		
(18) Financing Costs (e.g. Bond, Loan, etc.)				
(19) Interest During Construction				
(20) Other (Building Permit Fees)		\$4,616.00		
(21) Sub-Total Miscellaneous			\$ 2,828,971.00	
D. Total Capital Cost of Project				
(Sum A-C above)				\$ 3,158,017.00

REC'D JAN 13 2016

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
1205 Umstead Drive, 2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only

License # H0213

Medicare # 340028

FID #: 943057

PC LS

Date 1/15/16

License Fee:

\$11,250.00

2016
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: Cumberland County Hospital System, Inc.
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: Cape Fear Valley Medical Center
Other: Southeastern Regional Rehabilitation Center;
Other: _____

Facility Mailing Address: P O Box 2000
Fayetteville, NC 28302-2000

Facility Site Address: 1638 Owen Dr
Fayetteville, NC 28304
County: Cumberland
Telephone: (910) ~~609-4000~~ 615-6700
Fax: (910) ~~609-6160~~ 615-6160

Administrator/Director: Michael Nagowski
Title: CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Michael Nagowski Title: CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:
Name: Sandy Godwin Telephone: 910-615-6852
E-Mail: stgodwin@capefearvalley.com

PAID
CK NO. 891488
DATE 1-13-16
\$11,250

2016 Renewal Application for Hospital:
Cape Fear Valley Medical Center

License No: **H0213**
 Facility ID: **943057**

All responses should pertain to **October 1, 2014 through September 30, 2015.**

11. Linear Accelerator Treatment Data (including Cyberknife® & Similar Equipment)

CPT Code	Description	# of Procedures
Simple Treatment Delivery		
77401	Radiation treatment delivery	
77402	Radiation treatment delivery (<=5 MeV)	151
77403	Radiation treatment delivery (6-10 MeV)	20
77404	Radiation treatment delivery (11-19 MeV)	14
77406	Radiation treatment delivery (>=20 MeV)	
Intermediate Treatment Delivery		
77407	Radiation treatment delivery (<=5 MeV)	
77408	Radiation treatment delivery (6-10 MeV)	
77409	Radiation treatment delivery (11-19 MeV)	
77411	Radiation treatment delivery (>=20 MeV)	
Complex Treatment Delivery		
77412	Radiation treatment delivery (<=5 MeV)	9,974
77413	Radiation treatment delivery (6-10 MeV)	1,273
77414	Radiation treatment delivery (11-19 MeV)	1,888
77416	Radiation treatment delivery (>= 20 MeV)	
Other Treatment Delivery Not Included Above		
77418	Intensity modulated radiation treatment (IMRT) delivery	4,389
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator	26
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	77
G0339	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery in one session or first fraction	
G0340	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery, fractionated treatment, 2nd-5th fraction	
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)	
	Pediatric Patient under anesthesia	
	Neutron and proton radiation therapy	
	Limb salvage irradiation	
	Hemibody irradiation	
	Total body irradiation	
Imaging Procedures Not Included Above		
77417	Additional field check radiographs	1,940
Total Procedures – Linear Accelerators		19,752
Gamma Knife® Procedures		
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of one session; multisource Cobalt 60 based (Gamma Knife®)	
Total Procedures – Gamma Knife®		

2016 Renewal Application for Hospital:
Cape Fear Valley Medical Center

License No: **H0213**
 Facility ID: **943057**

All responses should pertain to October 1, 2014 through September 30, 2015.

11. Linear Accelerator Treatment Data *continued*

a. Number of patients who received a course of radiation oncology treatments on linear accelerators (not the Gamma Knife®). Patients shall be counted once if they receive one course of treatment and more if they receive additional courses of treatment. For example, one patient who receives one course of treatment counts as one, and one patient who receives three courses of treatment counts as three.
 # Patients 1,025 (This number should match the number of patients reported in the Linear Accelerator Patient Origin Table on page 35.)

b. Linear Accelerators
 1. TOTAL number of Linear Accelerator(s) 5
 2. Of the TOTAL number above, number of Linear Accelerators configured for stereotactic radiosurgery 1
 3. Of the TOTAL number above, Number of CyberKnife® Systems: 1
 Other specialized linear accelerators _____ Identify Manufacturer of Equipment Accuray

c. Number of Gamma Knife® units 0

d. Number of treatment simulators ("machine that produces high quality diagnostic radiographs and precisely reproduces the geometric relationships of megavoltage radiation therapy equipment to the patient."(GS 131E-176(24b))) _____

12. Telemedicine

- a. Does your facility utilize telemedicine to have images read at another facility? No
- b. Does your facility read telemedicine images? Yes

13. Additional Services:

a) Check if Service(s) is provided: (for dialysis stations, show number of stations)

	Check		Check
1. Cardiac Rehab Program (Outpatient)	✓	5. Rehabilitation Outpatient Unit	✓
2. Chemotherapy	✓	6. Podiatric Services	✓
3. Clinical Psychology Services	✓	7. Genetic Counseling Service	✓
4. Dental Services	✓	8. Number of Acute Dialysis Stations	11

2016 Renewal Application for Hospital:
Cape Fear Valley Medical Center

License No: **H0213**
 Facility ID: **943057**

All responses should pertain to **October 1, 2014 through September 30, 2015.**

Patient Origin – Linear Accelerator Treatment

Facility County: Cumberland

In an effort to document patterns of utilization of linear accelerators in North Carolina, hospitals are asked to provide the county of residence for patients served on linear accelerators in your facility. Report the number of patients who receive radiation oncology treatment on equipment (linear accelerators, CyberKnife®, but not Gamma Knife®) listed in Section 11 of this application. Patients shall be counted once if they receive one course of treatment and more if they receive additional courses of treatment. For example, one patient who receives one course of treatment counts as one, and one patient who receives three courses of treatment counts as three. **The number of patients reported here should match the number of patients reported in Section 11.a. on page 21 of this application.**

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	113
7. Beaufort		43. Harnett	55	79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen	40	45. Henderson		81. Rutherford	
10. Brunswick	1	46. Hertford		82. Sampson	33
11. Buncombe		47. Hoke	37	83. Scotland	1
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston	2	87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee	5	89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus	19	60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland	712	62. Montgomery		98. Wilson	
27. Currituck		63. Moore	5	99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin	3	67. Onslow		102. South Carolina	2
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	1
34. Forsyth		70. Pasquotank		105. Other States	1
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		Total No. of Patients	1,025

2016 Renewal Application for Hospital:
Cape Fear Valley Medical Center

License No: H0213
Facility ID: 943057

All responses should pertain to October 1, 2014 through September 30, 2015.

This application must be completed and submitted with ONE COPY to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation prior to the issuance of a 2016 hospital license.

AUTHENTICATING SIGNATURE: The undersigned submits application for the year 2016 in accordance with Article 5, Chapter 131E of the General Statutes of North Carolina, and subject to the rules and codes adopted thereunder by the North Carolina Medical Care Commission (10A NCAC 13B), and certifies the accuracy of this information.

Signature: Michael Nagowski Date: 1/11/16

PRINT NAME
OF APPROVING OFFICIAL Michael Nagowski

Please be advised, the license fee must accompany the completed application and be submitted to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, prior to the issuance of a hospital license.