



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

June 17, 2016

Dee Jay Zerman  
211 Friday Center Drive  
Suite G015  
Chapel Hill, NC 27517

**Exempt from Review – Replacement Equipment**

**Record #:** 1964  
**Facility Name:** UNC Hospitals  
**FID #:** 923517  
**Business Name:** University of North Carolina Hospitals  
**Business #:** 1940  
**Project Description:** Replace existing linear accelerator  
**County:** Orange

Dear Ms. Zerman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 8, 2016, the above referenced proposal 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, an Elekta Versa HD fixed linear accelerator to be located in the Radiation Therapy Department of the NC Cancer Hospital. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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

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



**Healthcare Planning and Certificate of Need Section**

[www.ncdhhs.gov](http://www.ncdhhs.gov)

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

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

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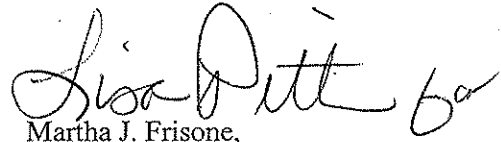


Ms. Dee Jay Zerman  
June 17, 2016  
Page 2

Sincerely,



Bernetta Thorne-Williams  
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

# UNC HOSPITALS

Hedrick Building  
211 Friday Center Drive, Suite G015  
Chapel Hill, NC 27517

June 8, 2016

Bernetta Thorne-Williams, Project Analyst  
Certificate of Need Section  
Division of Health Service Regulation, DHHS  
Mail Service Center 2704  
Raleigh, NC 27699-2704



RE: Exemption Notice / Replacement of existing linear accelerator pursuant to NCGS § 131E-184(f) / UNC Hospitals / Orange County

Dear Ms. Williams:

UNC Hospitals is planning to replace an existing linear accelerator and is requesting a determination that the replacement of this equipment is exempt from review pursuant to NCGS §131E-184(f). In conformance with NCGS §131E-184(a)(7), this request also serves as prior written notice of intent to replace the existing Siemens Primus HE 2 that was placed in service during 2003, and approaching the end of its useful life.

Since the machine is 13 years old, the frequency of downtime and needed repairs are increasing. Excessive downtime creates patient delays and exam cancellations, which dissatisfies patients, referring physicians, and staff. Downtime and system limitations also add operational costs to the service and negatively impact departmental staffing patterns. Machine does not have modern kilo voltage (kV) image guidance such as Cone Beam CT (CBCT), which is essential for accurate patient immobilization and target localization for radiation treatment. This machine also does not have Volumetric Modulated Arc Therapy (VMAT) capability, which allows dose to be tailored to the target, sparing more surrounding normal tissue. The new Elekta Versa HD machine has CBCT and VMAT capabilities. Additionally, Siemens no longer manufactures linear accelerators and will stop assuring maintenance in 2020. This end of life means no guaranteed support. Exhibit 1 contains a copy of the 2002 Certificate of Need replacement exemption for the existing linear accelerator.

This replacement also meets the requirements of NCGS §131E-184(f) as follows:

*(1) the equipment being replaced is located on the main campus.*

The existing equipment is located in the Radiation Therapy Department of the NC Cancer Hospital on the main campus of the University of North Carolina Hospitals at Chapel Hill. NCGS §131E-176(14n) defines "Main Campus" as *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 building and grounds adjacent to the main building.*"

Exhibit 2 contains a map of the UNC Hospitals main campus and the buildings. The existing linear accelerator is located in the Department of Radiation Therapy, which is in the sub-basement of the NC Cancer Hospital and where the replacement equipment will be located. The NC Cancer Hospital part of UNC Hospitals and both are part of the licensed health service facility (DHSR Acute Care License No. H0157).

The building from which UNC Hospitals provides clinical patient services and exercises financial and administrative control over the entire facility is co-located on the UNC Hospitals main campus along with the NC Cancer Hospital. These offices are physically located on the 3<sup>rd</sup> floor of the Med Wing E, connected to the original main hospital building. The locations of the financial officer and administrative officer are also indicated the map in Exhibit 2.

*(2) The Department has previously issued a certificate of need for the equipment being replaced.*

Exhibit 1 contains a copy of the Exempt from Review determination dated October 7, 2002 issued by the CON Section; the existing Primus HE 2 was that replacement.

*(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 subdivision.*

This correspondence serves as prior written notice in accordance with this requirement. Although the existing Siemens Primus HE 2 linear accelerator was state-of-the-art when acquired in 2003, due to its age it is limited in the ability to offer the technological advances of SBRT and SRS, Cone Beam, or KeV imaging capabilities. These capabilities are not available to this unit as an upgrade due to the age of the equipment. The existing system is difficult to repair and requires major efforts to keep it operational. In spite of these efforts, excessive downtime creates patient delays and exam cancellations, which dissatisfies patients, as well referring physicians, radiologists and staff. The excessive downtime and system limitations also add operational costs to the service and negatively impact departmental staffing patterns.

Following is the equipment comparison table as required in previous CON replacement requests. Although this replacement will exceed two million dollars, we are supplying the following information that the CON Section previously requested in the past as a part of its general information request for an equipment replacement exemption.

*1. A comparison of the existing and replacement equipment, using the format in the following table:*

#### *Equipment Comparison*

<b>Linear Accelerator</b>	<b>Existing Equipment</b>	<b>Replacement Equipment</b>
<b>Type of Equipment (List each component)</b>	Linear Accelerator with MeV imager, MLC and couch	Linear Accelerator with KeV, Cone Beam, high dose rate, MLC and couch, 6D Hexapod couch, SRS cones
<b>Manufacturer of Equipment</b>	Siemens	Elekta
<b>Tesla Rating for MRIs</b>	Not applicable	Not applicable
<b>Model Number</b>	Primus HE 2	Versa HD w/Hexapod
<b>Serial number</b>	3711	Not yet available
<b>Provider's Method of Identifying Equipment</b>	By model & serial #s	By model & serial #s
<b>Specify if Mobile or Fixed</b>	Fixed	Fixed
<b>Mobile Trailer Serial Number/VIN #</b>	Not applicable	Not applicable
<b>Mobile Tractor Serial Number/VIN #</b>	Not applicable	Not applicable
<b>Date of Acquisition of Each Component</b>	3/1/2003	TBD
<b>Does Provider Hold Title to Equipment or Have a Capital Lease?</b>	Own	Will own
<b>Specify if Equipment Was/Is New or Used When Acquired</b>	New	Will be new
<b>Total Capital Cost of Project (Including Construction, etc.)</b>	\$1,649,598	\$3,166,334 including linac, Arc Check, Vision RT, de-installation /removal and construction costs. See Exhibit 6 for the certified cost estimate.
<b>Total Cost of Equipment</b>	\$1,422,598	\$2,605,400 including Versa HD, Arc check and Vision RT. See Exhibit 3.
<b>Fair Market Value of Equipment</b>	Equipment is fully depreciated. Unit has no practical value.	\$2,605,400 including Versa HD, Arc check and Vision RT. See Exhibit 3.
<b>Net Purchase Price of Equipment</b>	\$1,422,598	\$2,605,400 including Versa HD, Arc check and Vision RT. See Exhibit 3.
<b>Locations Where Operated</b>	NC Cancer Hospital, Manning Drive, UNC Hospitals at Chapel Hill	NC Cancer Hospital, Manning Drive, UNC Hospitals at Chapel Hill
<b>Number of Days In Use/To be Used in N.C. Per Year</b>	365 days	365 days
<b>Percent of Change in Patient Charges (by Procedure)</b>	Not applicable	Existing procedures will have no change in patient charges. A few new patient charges will result due to new functionality of replacement equipment.
<b>Percent of Change in Per Procedure Operating Expenses (by Procedure)</b>	Not applicable	Existing procedures will have no change in patient charges. A few new types of charges will result due to functionality of replacement equipment.
<b>Type of Procedures Currently</b>	External Beam Radiation	Not applicable

<i>performed on Existing Equipment</i>	Treatment, MeV Imaging	
<i>Type of Procedures New Equipment is Capable of Performing</i>	Not applicable	External Beam Radiation Treatment, planar k V and k V Cone Beam CT Imaging, SRS & SBRT

As noted in the chart above, the total project cost is approximately \$3,166,334 including equipment and related costs necessary for the installation and operation of the replacement system. Valid quotes are attached as Exhibit 3. In addition to the equipment costs, the total project cost also includes \$469,434 for construction up fit costs, A & E costs of \$60,000, furniture costs of \$25,000 and \$11,500 for de-installation and removal costs. See Exhibit 6 for the certified cost estimate.

2. *A description of the basic technology and functions of the existing and replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or capable of being used.*

*Response:* The machine to be replaced is a Siemens Primus HE 2 which was purchased in 2003. The current equipment and the replacement equipment will perform the same general basic functions although the replacement equipment will possess expanded technological capabilities due to technological improvements. See equipment comparison chart above. UNC Hospitals does not intend to increase patient charges or current per procedure operating expenses, which is well within the 10% threshold for the first 12 months after its acquisition as contained 10A NCAC 14C .0303 Replacement Equipment. Based on this and other information included in this request, the replacement equipment is comparable medical equipment as defined in 10A NCAC 14C .0303.

3. *Brochures or letters from the vendors describing the capabilities of the existing equipment and the replacement equipment.*

*Response:* A copy of the original brochure and the original quote for the existing Siemens Primus HE 2 are included in Exhibit 1. A copy of specifications for the proposed Elekta Versa HD and associated equipment are attached as Exhibit 3.

4. *A copy of the purchase order for the existing equipment, including all components and original purchase price.*

*Response:* A copy of the original brochure and quote for the existing Siemens Primus HE 2 are included in Exhibit 1. A copy of the original purchase order for the existing Siemens Primus HE 2 is not available. The specifications for the Elekta Versa HD and the replacement treatment planning equipment are attached as Exhibit 3.

5. *A copy of the title, if any, for the existing equipment or the capital lease for the existing equipment.*

*Response:* Not applicable. The existing equipment does not have a title and is not leased.

6. *If the replacement equipment is to be leased, a copy of the proposed lease that transfers substantially all the benefits and risks inherent in the ownership of the equipment to the lessee of the equipment, in accordance with criteria in Generally Accepted Accounting Principles (GAAP).*

*Response:* Not applicable. The replacement equipment will not be leased.

7. *If the replacement equipment is to be purchased, a copy of the proposed purchase order or quotation, including the amount of the purchase price before discounts and trade-in allowance.*

*Response:* Copies of the quotes received from various vendors for the replacement equipment are contained in Exhibit 3. The existing machine as have no practical value as indicated in the quote and the equipment comparison table.

8. *A letter from the person taking possession of the existing equipment that acknowledges the existing equipment will be permanently removed from North Carolina, will no longer be exempt from requirements of the North Carolina Certificate of Need law, and will not be used in North Carolina without first obtaining a new certificate of need.*


*Response:* See Exhibit 4 for a copy of a confirmation letter from R S & A.

9. *Documentation that the existing equipment is currently in use and has not been taken out of service.*

*Response:* UNC Hospitals' equipment is currently in use as indicated and certified on the most recent Licensure Renewal Application form. The equipment will remain in use until it is replaced. See Exhibit 5 for copies of pages from the 2016 Licensure Renewal Application pertaining to linear accelerator equipment.

Please do not hesitate to contact me at 984-974-1210 if you need any additional information. Thank you for your prompt consideration of this matter.

Sincerely,

  
Dee Jay Zeman  
System Director of Regulatory Planning  
UNC HCS



North Carolina Department of Health and Human Services  
Division of Facility Services  
Certificate of Need Section  
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor  
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief  
Phone: 919-855-3873  
Fax: 919-733-8139

October 7, 2002

Dee Jay Zerman, Associate Director  
Program Planning and Development  
The University of North Carolina Hospitals  
101 Manning Drive  
Chapel Hill NC 27514

RE: Exempt from Review/UNC Hospitals/Replace existing Siemens MDX linear accelerator with new Siemens Primus HE linear accelerator/Orange County  
FID # 923517

Dear Ms. Zerman:

In response to your letter of September 26, 2002, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Siemens Primus HE linear accelerator to replace the existing Siemens MDX linear accelerator [Serial # 2011]. 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. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Michael J. McKillip, Project Analyst

Lee B. Hoffman, Chief  
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS







September 23, 2002

Mr. Michael J. McKillip  
Certificate of Need Section  
DFS, DHHS  
Mail Service Center 2704  
Raleigh, NC 27699-2704

RE: Request for Exemption / Replacement of one Linear Accelerator / UNC Hospitals

Dear Mr. McKillip:

UNC Hospitals is planning to replace one of its Linear Accelerators and is requesting a determination that the replacement of this equipment is exempt from review pursuant to 131E-184(7). We are supplying the following information that the CON Section has requested in the past as a part of its general information request for an equipment replacement.

1. A comparison of the existing and replacement equipment, using the format in the following table:

Equipment Comparisons

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	not applicable	not applicable
Model Number	Model MDX	Model Primus HE 4504200
Serial number	S/n 2011	Not available yet
Provider's Method of Identifying Equipment	By model & serial #s	By model & serial #s
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	not applicable	not applicable
Mobile Tractor Serial Number/VIN #	not applicable	not applicable

Date of Acquisition of Each Component	1990	Projected 2003
Does Provider Hold Title to Equipment or Have a Capital Lease?	UNC Hospitals owns equipment	UNC Hospitals will own the equipment
Specify if Equipment Was/Is New or Used When Acquired	New	will be new
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$909,300	\$1,649,598
Total Cost of Equipment	\$909,300	\$1,412,598
Fair Market Value of Equipment	\$10,000 (trade-in value of \$10,000)	\$1,422,598 (includes \$10,000 trade-in)
Net Purchase Price of Equipment	NA	\$1,649,598 (includes \$10,000 for trade-in and \$227,000 for renovations)
Locations Where Operated	UNC Hospitals	UNC Hospitals
Number of Days In Use/To be Used in N.C. Per Year	365 days	365 days
Percent of Change in Patient Charges (by Procedure)	NA	no change
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	no change
Type of Procedures Currently performed on Existing Equipment	Radiation teletherapy treatments	NA
Type of Procedures New Equipment is Capable of Performing	NA	Radiation teletherapy treatments

2. A description of the basic technology and functions of the existing and replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or capable of being used.

Response: The machine to be replaced is a Siemens MDX Linear Accelerator that was purchased in 1990. UNC Hospitals plans to replace this linear accelerator with a Siemens Primus unit. The current equipment and the replacement equipment will perform the same basic functions. Both are linear accelerators, which are used to perform radiation teletherapy treatments. The replacement unit will have multi-leaf collimators rather than the existing two or four collimator system. This replaces the historical blocking system with multi-leaf collimators. The replacement unit is digital and the existing unit is digital. Having a digital unit allows the unit to interface with more types of current and future accessions and software. The existing linear accelerator uses a magnetron for the power source and the replacement unit will use a klystron power source, which is more efficient and lasts longer. See Exhibit 1 for a copy of the brochure for the replacement unit.

3. Brochures or letters from the vendors describing the capabilities of the existing equipment and the replacement equipment.

Response: A copy of a brochure from the vendor describing the replacement Siemens Primus is attached as Exhibit 1. We do not have a copy of the brochure describing the capabilities of the existing equipment.

4. A copy of the purchase order for the existing equipment, including all components and original purchase price.

Response: The original purchase requisition for the existing Siemens MDX is attached as Exhibit 2.

5. A copy of the title, if any, for the existing equipment or the capital lease for the existing equipment.

Response: Not applicable. The equipment does not have a title and will not be leased.

6. If the replacement equipment is to be leased, a copy of the proposed lease that transfers substantially all the benefits and risks inherent in the ownership of the equipment to the lessee of the equipment, in accordance with criteria in Generally Accepted Accounting Principles (GAAP).

Response: Not applicable. The replacement equipment will not be leased.

7. If the replacement equipment is to be purchased, a copy of the proposed purchase order or quotation, including the amount of the purchase price before discounts and trade-in allowance.

Response: A copy of the valid quotation received from Siemens regarding the replacement linear accelerator is attached as Exhibit 3. The installation costs for the unit are included in the contract total.

8. Confirmation that upon removal of the existing equipment for replacement with the new unit, the existing unit will no longer be conforming with the requirements of the North Carolina Certificate of Need law, and will not be used in North Carolina without first obtaining a new certificate of need if one is required.

Response: The unit is to be removed prior to the installation of the replacement unit. The existing unit will be released to Siemens, who may decide to resell to a party that is not identified at this time. The buyer will be advised that they must contact the CON Section regarding requirements for use in North Carolina, and that purchasing this unit does not grant them CON approval to provide radiation oncology services in the State of North Carolina.

9. Documentation that the existing equipment is currently in use and has not been taken out of service.

Response: UNC Hospitals currently has four linear accelerators in use as identified on our most recent Licensure Renewal Application form.

Also, enclosed as Exhibit 4 is a completed 'Proposed Total Capital Cost of Project' form which projects the total capital cost of this replacement project to be \$1,649,598. Should you require any additional information regarding the replacement of this equipment, please do not hesitate to contact me at 919-966-1129.

Sincerely,

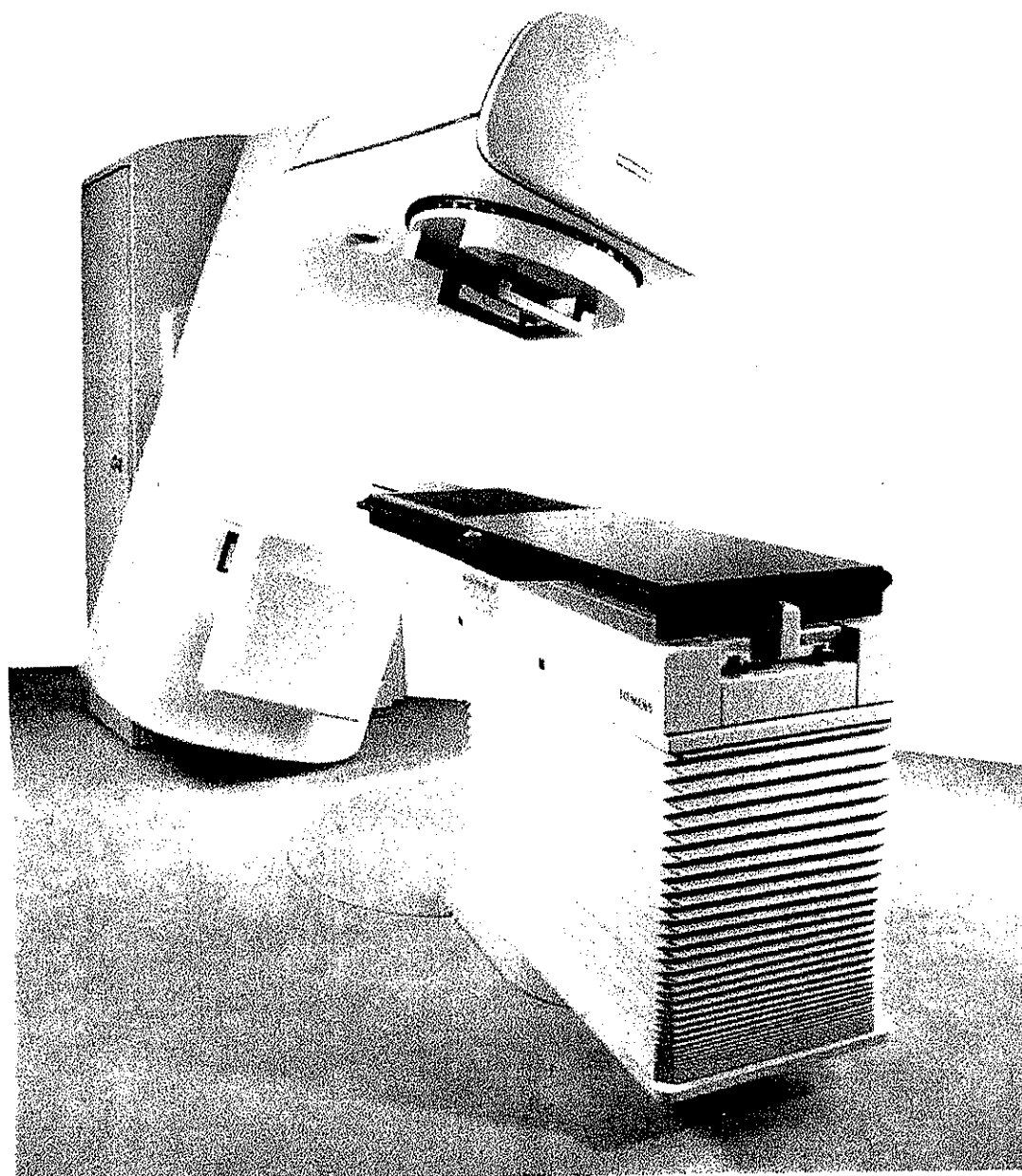


Dee Jay Zerman, Associate Director  
Planning & Program Development

**SIEMENS**

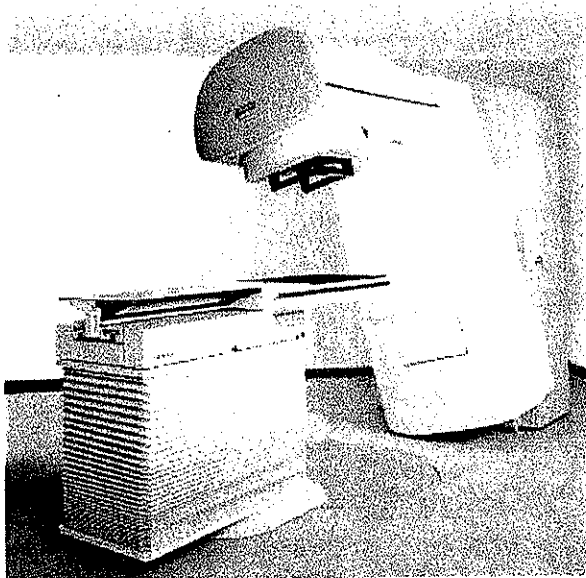
**Advanced Medical Linear Accelerator  
Specifications**

**PRIMUS Mid and Hi-Energy**



**SPECIFICATIONS**

# Advanced Medical Linear Accelerator PRIMUS Mid-energy and Hi-energy Specifications



## 1.0 General

These specifications describe isocentrically mounted, mid-energy and high-energy linear accelerators with electrons for the routine clinical application of megavoltage X-ray and/or electron beams used for radiation therapy. The energy of the electron beam is defined and controlled through the use of a 270° achromatic magnetic field bending system. RF power shall be supplied by a stationary magnetron for **PRIMUS®** Mid-energy accelerator and by a klystron for **PRIMUS®** Hi-energy Accelerator.

*Note: All specification items are related to console version 6.3 and higher*

## 1.1 PRIMUS Major Features

- Compact design
- All-digital platform
- Flexible energy configuration
- Modular design and embedded diagnostics for serviceability
- Sophisticated types of treatment heads with optional 3D-MLC
- Fully-automated with the **SIMTEC™** AFS option
- IMRT capable with the **IM-MAXX™** option
- Advanced modulator technology
- Insulated structure reduces noise
- State-of-the-art human interface for intuitive setup and delivery control

Unit Type	Low X-ray (MV)	High X-ray (MV)	Electron Energy Range (MeV)
PRIMUS Mid-Energy	3	—	—
	4	—	—
	4	—	3 - 7
	4	6	5 - 12
	6	—	—
	6	—	6 - 14
	6	10	5 - 14
PRIMUS Hi-Energy	6	15	5 - 14
	6	10	5 - 15
	6	10	6 - 21
	6	15	6 - 21
	6	18	6 - 21
	6	23	6 - 21
	6	25*	6 - 21

*\*Not available in the U.S.A., Japan*

**Table 1.1 - Nominal Beam Energies**

## Waveguide

- Standing wave accelerator structure
- $10^{-9}$  Torr vacuum
- $270^\circ$  bending magnet

## Clearance

- 43 cm, including accessory holder
- Maximum 53 cm, without accessory holder

## 1.2 Nominal Beam Energies Available

PRIMUS accelerators provide configurations for different types of radiation (X-ray beam, electron beam) and energies as shown in **Table 1.1**.

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## 2.0 X-Ray Beam Characteristics

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### 2.1 Energy

The energy of the beam is defined as the percentage ionization, relative to the central axis ionization at  $d_{max}$ , measured on a central axis at 10 cm depth in water, for a  $10\text{ cm}^2$  field with 100 cm Target-to-Surface Distance (TSD).

Nominal Energy (MV) (BJR17)	% Ionization at 10 cm Water	Dmax (cm)
3	58 ±2	0.8 ±0.2
4	63 ±2	1.0 ±0.2
6	67 ±2	1.5 ±0.2
10	74 ±2	2.5 ±0.2
15	77 ±2	3.0 ±0.2
18	78 ±2	3.2 ±0.2
23	80 ±2	3.5 ±0.2
25*	81 ±2	3.6 ±0.2

\* not available in the U.S.A., Japan

**Table 2.1 - Nominal X-ray Energies and Relative Ionization**

### 2.2 Depth of Maximum Ionization in Water

The depth of maximum ionization ( $d_{max}$ ) for a  $10\text{ cm}^2$  field with 100 cm TSD shall be as shown in **Table 2.1**.

### 2.3 Dose Rate

The fixed dose rate available for a  $10\text{ cm}^2$  field, measured at  $d_{max}$  on central axis for 100 cm TSD, shall be as shown in **Table 2.2**.

### 2.4 Low Dose Rate Mode

A low dose rate mode is available. The minimum value for the low dose rate mode is 50 MU/min.

### 2.5 Flatness at Treatment Depth

The X-ray intensity across 80% of the major axes of symmetric square fields of  $10\text{ cm}^2$  and greater measured at a depth of 10 cm in water and at 100 cm Target-to-Axes Distance (TAD), shall not vary by more than 3% (3.5% for 25 MV) from the arithmetic average of the maximum and minimum intensities in this region. For energies below 6 MV, intensity shall be measured at depth of 5 cm.

### 2.6 Off-Axis Ratio at Depth of Maximum Ionization

The off-axis ratios at the depth of maximum ionization for each X-ray energies in **Table 2.1** shall not exceed 110%.

### 2.7 Field Symmetry

Symmetry shall be specified for symmetric fields of  $10\text{ cm}^2$  and greater, measured along the major axes in water at a depth of 10 cm at 100 cm TAD. Under these conditions, the intensities integrated over opposing halves of the field shall not differ by more than 2% from the mean value of the intensities. Energies less than 6 MV shall be measured at a depth of 5 cm.

### 2.8 Field Size

The field size shall be defined as the distance between the 50% intensity points along each major axis for symmetrical fields (variable to  $40\text{ cm}^2$ ) at 100 cm TAD. The nominal size of the primary beam at 100 cm TAD is 50 cm diameter.

### 2.9 Penumbra

The penumbra on each side of the field shall be defined as the distance between the 20% and 80% intensity points measured along the major axes of a  $10\text{ cm}^2$  field at a depth of 10 cm in water at 100 cm TAD. The penumbra shall be less than 10 mm, as measured with a 0.084 cc thimble ionization chamber. For energies below 6 MV, penumbra is measured at a depth of 5 cm.

Unit Type	Low X-Ray (MV)	Dual Dose Rate (MU/min.)	High X-Ray (MV)	Dual Dose Rate (MU/min.)
PRIMUS Mid-Energy	3	50 & 100 <sup>1</sup>	—	—
	4	50 & 250	—	—
	4	50 & 200	6	50 & 200
	6	50 & 200 <sup>2</sup> or 300 <sup>3</sup>	—	—
	6	50 & 200 <sup>2</sup>	10	50 & 300
	6	50 & 200 <sup>2</sup>	15	50 & 200
PRIMUS Hi-Energy	4 <sup>4</sup>	50 & 200 or 300 <sup>5</sup>	10 <sup>4</sup>	50 & 300
	6	50 & 200 or 300 <sup>5</sup>	15	50 & 300 or 500 <sup>5</sup>
	6	50 & 200 or 300 <sup>5</sup>	18	50 & 300 or 500 <sup>5</sup>
	6	50 & 200 or 300 <sup>5</sup>	23	50 & 300 or 500 <sup>5</sup>
	6	50 & 200 or 300 <sup>5</sup>	25 <sup>1</sup>	50 & 300 or 500 <sup>5</sup>
	6	50 & 200 or 300 <sup>5</sup>	25 <sup>1</sup>	50 & 300 or 500 <sup>5</sup>

1 - Not available in the U.S.A., Japan

2 - 250 MU/min. Special Configuration Option

3 - 300 MU/min. for single X-ray PRIMUS with no upgrade capability

4 - Not available in the U.S.A.

5 - Optional item

Note: All dose rates are expressed in monitor units (MU) per minute (min.). For any given energy, 1 MU may be calibrated to deliver 1 cGy (1 rad). For Total Body Irradiation (TBI) option dose rates are programmable from lowest to highest dose rate, in increments from 1 MU/min.

**Table 2.2 - Dose Rate**

### 3.0 X-ray Dosimetry System

#### 3.1 Dosimetry System

The dual dosimetry system is arranged in a primary/secondary combination. There is an x-ray dose chamber and thin walled electron dose chamber. Dose monitor readouts shall display four digits.

For fixed beam treatments, the primary dose monitor system shall terminate the treatment when reaching coincidence with the preset value. Backup termination shall be provided by the secondary dose monitor and time interlock systems.

In case of power failure during treatment, Monitor Units (MU), arc, and time values, as well as all other treatment setup parameters shall be stored in non-volatile memory for recovery.

#### 3.2 Dose Monitor Performance

The dosimetry system performance is such that the primary system shall shut off the beam when monitor 1 reaches coincidence with monitor 1 preset plus or minus the greater of 1 MU or 1% of monitor 1 preset.

#### 3.3 Dose Monitor Linearity

Relative to monitor 1, the variation in accumulated dose over the range of 1 to 1000 MU is 1% at 50 MU/min.

#### 3.4 Dose Monitor Reproducibility

Any value in a series of repeated irradiations within the range of preset values 50 MU to 1000 MU shall not exceed the calculated average of the series by more than 1 MU or 2% of monitor 1 preset, whichever is greater.

### 4.0 Electron Beam Characteristics

#### 4.1 Energy

Nominal electron beam energies shall be available within the energy limits specified for a particular unit type (see electron range in **Table 1.1**).

Energy shall be defined as the depth of the 80% ionization in water on the central axis for a 15 cm<sup>2</sup> fixed electron applicator (95 cm) with 100 cm TSD.

Depth values are given as the distances from the water surface to the center of a 0.084 cc thimble ionization chamber.

#### 4.2 X-ray Contamination

The X-ray contamination of the electron beam shall be measured in water on the central axis 10 cm beyond the depth at which the electron beam intensity is 10% of the maximum value. Under these conditions, the X-ray intensity for a 15 cm<sup>2</sup> fixed



Nominal Energy (MeV)	Maximum Relative 30% Ionization Depth (cm)	Relative 80% Ionization Depth (cm)	X-ray Contamination (maximum)	Maximum Surface Dose (% d <sub>max</sub> )
3	1.8	1.3 ± 0.2	0.5%	73
4	2.2	1.5 ± 0.2	0.5%	74
5	2.5	1.7 ± 0.2	1.0%	77
6	2.8	2.0 ± 0.2	1.3%	79
7	3.2	2.3 ± 0.2	1.5%	81
8	3.7	2.7 ± 0.2	1.7%	83
9	4.1	3.0 ± 0.2	2.0%	85
10	4.6	3.4 ± 0.2	2.0%	87
12	5.3	4.0 ± 0.2	2.0%	90
14	6.0	4.5 ± 0.2	3.0%	92
15	6.8	5.0 ± 0.2	3.0%	93
16	7.3	5.3 ± 0.2	3.2%	93
18	8.2	6.0 ± 0.2	3.5%	93
20	9.3	6.5 ± 0.2	4.0%	93
21	9.4	6.7 ± 0.2	4.0%	93

**Table 4.1 - Electron Beam Characteristics**

electron applicator for 100 cm TSD shall not exceed 2% of maximum intensity for energies below and including 12 MeV. For energies above 12 MeV, the value shall not exceed 5% of maximum intensity.

#### 4.3 Dose Rate

The normal dose rate for fixed-beam therapy, measured on the central axis at the point of maximum ionization, with 100 cm TSD, with a 15 cm<sup>2</sup> fixed field applicator, shall be 300 MU/min.

#### 4.4 High Dose Rate Mode

A high dose rate mode of 900 MU per minute shall be available for fixed-beam therapy.

#### 4.5 Flatness

Flatness specifications shall be met for the fixed electron applicators and energies as shown in **Table 4.2**. The measurement shall be made on the central axis at the depth of maximum ionization for 100 cm TSD.

Under the above conditions, the electron beam intensity along the major axes shall not vary by more than the tabulated value in percent from the arithmetic average of the maximum and minimum intensities in the region of evaluation.

The region of evaluation is defined by two points on the major axis, 15 mm inside the points of 50% beam intensity for profiles, taken in maximum dose buildup depth, for field sizes of 10 cm<sup>2</sup> to 25 cm<sup>2</sup>.

#### 4.6 Symmetry

For all available energies, symmetry is specified for fixed electron applicators of 10 cm<sup>2</sup> and greater measured along the major axes at the depth of maximum intensity. Under these conditions, the intensities integrated over opposing halves of the field shall not differ by more than 2% from the mean value of the intensities.

#### 4.7 Surface Dose

The surface dose shall be as shown in **Table 4.1** for a 15 cm<sup>2</sup> fixed electron applicator with 100 cm TSD. Water equivalent plastic blocks are used in the buildup region to measure the dose. The values are expressed as a percentage of d<sub>max</sub>.

#### 4.8 Penumbra

Width of penumbra as the maximum distance along the major axes between the 80% and 20% points of the absorbed dose at standard measurement depth (IEC 976, 7.3) is between 10 mm for small (circle) field 5 cm<sup>2</sup> and 11.1 mm for maximum square field.

Nominal Energy (MeV)	Applicator Field				
	Main*	10 cm	15 cm	20 cm	25 cm
3	±8.3	5	8	10	10
4	±6.3	5	6	7	7
5	±5.8	5	6	6	6
6	±4.8	4	5	5	5
7	±4.8	4	5	5	5
8	±4.8	4	5	5	5
9	±4.0	3	4	4	4
10	±3.8	3	4	4	4
12	±3.5	3	3	4	4
14	±3.3	3	3	3	4
15	±3.3	3	3	3	4
16	±3.3	3	3	3	4
18	±3.3	3	3	3	4
20	±3.5	3	3	4	4
21	±4.0	3	3	4	6

\* average over field sizes

**Table 4.2 - Flatness Variation for Electron Beams Using Fixed, Square Field Electron Applicators (in %)**

#### 4.9 Maximum Ratio of Absorbed Dose

The maximum value of the ratio of the absorbed dose (averaged over not more than 1 cm<sup>2</sup>) anywhere in the radiation field at the depth of 0.5 mm to the maximum absorbed dose on the radiation beam axis shall not exceed 109% (IEC 976, 7.2.4)

#### 5.3 Arc Therapy with Electrons

The accelerator can be provided with arc therapy in the electron mode. The dose-per-degree for electron arc therapy shall range from 2 to 10 MU/degree.

#### 5.4 Arc Dose Monitor Performance

The dosimetry system shall have a performance such that the primary system shall be within 1 MU or 2% of monitor 1 preset, whichever is greater.

### 5.0 Arc Therapy

#### 5.1 General

Bi-directional arc therapy shall be available for X-ray and electrons.

#### 5.5 Arc Dose Monitor Linearity

For different preset MU-to-arc ratios (arcs greater than 60°), the variation from preset to delivered MU shall not exceed 1 MU or 2% or monitor 1 preset, whichever is greater.

#### 5.2 X-ray Arc Therapy

The PRIMUS accelerator is capable of bi-directional X-ray arc therapy. The dose-per-degree (MU/degree) for X-ray arc therapy is based on fixed-beam dose rate as shown in **Table 5.1**.

#### 5.6 Arc Dose Monitor Reproducibility

Any value in a series of repeated MU-to-arc irradiations (arcs greater than 60°), shall not differ from the calculated average of the series by more than 2 MU or 3%, whichever is greater.

Fixed-Beam Dose Rate (MU/min)	Dose-per-Degree Range (MU/degree)
500	0.56 to 16.67
300	0.33 to 10.00
200	0.22 to 6.67

**Table 5.1 - Arc Therapy, Dose-per-Degree Range**

Sections 5.5 and 5.6 apply for the following ranges in **Table 5.2**

Fixed-Beam Dose Rate (MU/min.)	Dose-per-Degree Range (MU/degree)
500	0.55 to 6.67
300	0.33 to 5.00
200	0.33 to 5.00

Table 5.2

## 6.0 Mechanical Parameters and Control

### 6.1 Gantry

The gantry rotates a nominal  $\pm 180^\circ$  at two speeds. The nominal low and high speeds shall be 0.2 and 1.0 RPM, respectively.

Gantry display (local and remote):

Display Resolution:  $0.1^\circ$   
Display Accuracy:  $\pm 0.5^\circ$

The nominal Target-to-Axis Distance shall be  $100 \pm 0.5$  cm.

Isocenter height (nominal):  $130.8 \pm 2$  cm (51.5 in.)

Target to Surface Distance (TSD):

Optical Range Finder:

Range: 75 cm to 130 cm  
Resolution: 0.5 cm  
Accuracy:  $\pm 0.2$  cm at 100 TSD

Mechanical Front Pointer:

Range: 85 cm to 110 cm  
Resolution: 0.5 cm  
Accuracy:  $\pm 0.5$  cm at 100 TSD

Backpointer indication:

Optical Range: 80 cm to 150 cm

### 6.2 Collimator

The collimator shall rotate a nominal  $\pm 180^\circ$  with HPD and  $270^\circ$  with MLC about the beam axis.

Collimator display (local and remote):

Display Resolution:  $0.1^\circ$   
Display Accuracy:  $\pm 0.5^\circ$

### 6.3 Field Size Collimators

Field sizes shall be defined by two orthogonal sets of adjustable collimator jaws designated Y (closer to the target or 'inner') and X (farther from target or 'outer') capable of projecting a field size at the isocentric plane from  $0 \text{ cm}^2$  to  $40 \text{ cm}^2$ .

Optional independently adjustable inner and/or outer collimators are available with a projected centerline overtravel at isocentric plane of 2 cm with the outer collimators and 10 cm with the inner collimators.

Field Size displays for symmetric fields (local and remote):

Digital Resolution: 1.0 mm  
Digital Accuracy:  $\pm 2.0$  mm or 1% of the indicated field size (whichever is greater)

### 6.4 X-ray-to-Light Field Coincidence

A field defining light shall be provided. The coincidence of the light field edges with the radiation field edges (50% intensity points) on the major axes shall be within 2 mm or 1% of the indicated field size, whichever is greater, at the isocentric plane for field dimension 5 cm to maximum.

### 6.5 Retractable Beamshield

To reduce treatment room shielding requirements, the unit can be equipped with a motorized retractable beamshield instead of the counterweight.

The beamshield intercepts a geometric projection of a  $40 \text{ cm}^2$  field at isocentric plane when the collimator is in the  $0^\circ$ ,  $90^\circ$ ,  $180^\circ$  or  $270^\circ$  position. For other collimator angles, firmware prevents the geometric field from exceeding the beamshield. The average transmission of the beamshield does not exceed 0.1% of the primary beam.

*NOTE: For room shielding calculations, account must be taken for X-rays scattered by the beamshield and patient.*

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## 7.0 Accessories

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### 7.1 Wedge Filters

In-plane and Cross-plane 15°, 30°, 45°, and 60° wedge filters are available.

#### Field Size

Wedge direction: 25 cm for 15°, 30° and 45° wedges;  
20 cm for 60° wedge

Non-wedge direction: 30 cm for all wedges

All wedge filters are coded and interlocked for the correct field size.

### 7.2 Beam Blocks

Standard lead blocks:

Dimensions: 2.5 cm x 2.5 cm x 7.5 cm high  
3.5 cm x 5.0 cm x 7.5 cm high  
5.0 cm x 5.0 cm x 7.5 cm high

Maximum recommended beam block weight: 15 kg (33 lbs.).

### 7.3 Electron Applicators

Fixed electron applicators are available in square field sizes of 10 cm, 15 cm, 20 cm, and 25 cm, as well as a 5 cm diameter applicator. The nominal distance from the target to the end of the applicator is 95 cm.

Seven small field round cones, ranging in diameter from 2 cm to 8 cm, are available. A variable electron applicator is also available (DEVA) with a field size range from 3 cm<sup>2</sup> to 25 cm<sup>2</sup>.

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## 8.0 Leakage Radiation Specifications

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### 8.1 X-ray Leakage Radiation to the Patient Plane

The leakage radiation intensity, averaged over any 100 cm<sup>2</sup> area, in a circular area of 2 m radius centered on and perpendicular to the central axis of the beam at isocenter and outside the projection of the primary collimator, shall not exceed 0.1% of the unattenuated useful beam (as measured in Section 2.3). A 4/10 MV configuration shall have a value of 0.2% at 10 MV.

### 8.2 X-ray Leakage Radiation Outside the Patient Plane

The leakage radiation intensity, averaged over any 100 cm<sup>2</sup> area, 1 m from the path of the accelerated electrons, except in the patient plane specified in Section 8.1, shall not exceed 0.1% of the maximum intensity of the unattenuated useful beam (as measured in Section 2.3). Leakage radiation is measured with a 30 cm<sup>3</sup> ionization chamber with a 1 cm thick buildup cap. A 4/10 MV configuration shall have a value of 0.2% at 10 MV.

### 8.3 Adjustable Collimator Transmission

The X-ray transmission through one set of adjustable collimator jaws shall not exceed 0.5% of the unattenuated beam as measured in Section 2.3. The transmission value shall be the average value measured according to IEC 601-2-1 (2nd Revision Draft) measurement methods.

### 8.4 Treatment Room Shielding for Neutrons

The required treatment room shielding against neutrons is dependent on both geometry and materials. As a guideline for the planning of treatment room shielding, **Table 8.1** contains some values of the number of neutrons produced per X-ray cGy (as measured in section 2.3) for various energies.

Nominal X-ray Energy (MV)	Neutron/X-ray (number / cGy)
Below 10	Negligible
10	$5.0 \times 10^8$
15	$8.0 \times 10^9$
18	$2.5 \times 10^{10}$
23	$4.0 \times 10^6$

**Table 8.1 - Neutrons Produced per X-ray cGy**

## 9.0 Utility Requirements

Note: For further details, refer also to Product Planning Guide for the PRIMUS Mid-energy and PRIMUS Hi-energy accelerators.

### 9.1 Electrical 480 V (USA), 380 V (International)

A preferred, dedicated  $\pm 10\%$ , 50 Hz or 60 Hz,  $\pm 1$  Hz, 3-phase WYE, neutral and ground power system. Refer to Product Planning Guide #5496208 for further detail.

### 9.2 Facility Water Cooling Specifications and Recommendations

The PRIMUS Hi-energy system is designed to be connected to a constant 28 l/min. (11.5 l/min. for PRIMUS Mid-energy) facility cooling water loop to be provided by the customer. The interface between the PRIMUS system and the cooling system are two pipe connections located at the rear of the machine base.

Note: A customer can purchase a commercially available chiller system that meets the requirements for the PRIMUS system, especially considering the differential pressure requirements.

- Facility water maximum inlet pressure 552 kPa (80 PSI) 5.6 kg/cm<sup>2</sup> (80 PSI), (minimum inlet pressure 2.1 kg/cm<sup>2</sup> (30 PSI)). Nominal differential pressure is 1.4 kg/cm<sup>2</sup> (20 PSI)]. Pressure drop minimum 241 kPa (35 PSI)
- Facility water maximum inlet temperature 25° C (77° F), minimum inlet temperature 16° C (60° F), optimum inlet temperature 18° C (65° F).
- The heat dissipation from the machine to water is shown in **Table 9.1**.

Unit Type	Standby	Treatment mode
PRIMUS Mid-Energy	0.5 kW (1706 BTU/hr.)	8.5 kW (29,343 BTU/hr.)
PRIMUS Hi-Energy	6.6 kW (22,519 BTU/hr.)	30 kW (102,400 BTU/hr. *)

\* Commercially available chiller system may be adapted, meeting the requirements for PRIMUS

**Table 9.1 - PRIMUS Heat Dissipated to Water**

Quality of water:

- Dissolved solids in facility water not to exceed 100 PPM. Total dissolved solids (CaCO<sub>3</sub>) <250 PPM, total suspended solids <30 PPM (annual average)
- Dissolved gasses: Hydrogen Sulfide (H<sub>2</sub>S) <0.05 PPM
- Total hardness (CaCO<sub>3</sub>) <85 PPM
- A 50-micron in-line filter with 95% efficiency is recommended. Water should be free of iron bacteria and manganese bacteria

### 9.3 Air Conditioning

- Overall air conditioning shall provide for a room temperature between 20° C (68° F) and 26° C (78° F), and 65% maximum relative humidity.
- The heat dissipated from the machine to air is shown in **Table 9.2**.

Unit Type	Standby	Treatment Mode
PRIMUS Mid-Energy	2.0 kW (6,824 BTU/hr.)	4.1 kW (13,989 BTU/hr.)
PRIMUS High-Energy	2.7 kW (9,212 BTU/hr.)	6.5 kW (22,178 BTU/hr.)
Control Console	0.3 kW (1,024 BTU/hr.)	0.3 kW (1,024 BTU/hr.)

**Table 9.2 - PRIMUS Heat Dissipated to Air**

### 9.4 Treatment Room Ventilation

The treatment room must be adequately ventilated at all times. An exhaust blower must be utilized during operation of the linear accelerator. The exhaust system should have a minimum of two exchanges of room volume per hour, depending on room size and airflow pattern.

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## 10.0 Physical Characteristics

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### 10.1 Dimensions and Weights

**Table 10.1** provides the dimensions and weights of the PRIMUS system. **Figure 10.2** depicts the dimensions of the PRIMUS system.

A minimum distance of 2.9 meters (114.0 in.) from isocenter to the rear wall for service is required. A minimum distance of 1.5 meters (5 ft.) from one side is required for service access.

#### Base frame dimensions

For the table base frame following maximum space is required:

H x L x W      330 mm x 3391 mm x 1600 mm  
(13.0 in. x 133.5 in. x 63.0 in.)

Unit Type	Height	Length	Width	Weight*
PRIMUS	2604 mm 102.5 in.	3086 mm 121.5 in.	1433 mm 56.4 in.	7730 kg 17,000 lb.

\* Component weights include counterweight = 2,155kg / 4,741 lb.  
Beamshield replaces counterweight = 2,449kg/5,388 lb.

**Table 10.1 -  
Dimensions and Weights of the PRIMUS Models**

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## 11.0 Radiation Shielding Protection Requirements

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Requirements for room and radiation description are described in PRIMUS product planning guide. Refer to Linear Accelerator Product Planning Guide 54 98 261.

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## 12.0 IEC and EN Requirements

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The PRIMUS accelerator meets the functional performance specifications and tolerances, and safety specifications if not otherwise specified, according to the latest edition (including the amendments) of the following Technical reports of the IEC, EN and CE.

IEC 976 Medical electron accelerators - Functional performance characteristics 1989

IEC 977 Medical electron accelerators in the range 1 MeV to 50 MeV - Guidelines for functional performance characteristics - 1989

IEC 60601-2-1 Safety of Medical Equipment. Part 2: Particular requirements for the safety of medical electron accelerators in the range 1 MeV to 50 MeV, 1998

IEC 1217 Radiotherapy equipment. Coordinates, movements and scales - 1996

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## Integrated Systems for the Total Oncology Care Solution

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The following chapters describe the configurable and optional components for a total oncology care solution. Additional specifications for all these components are available within separate documents. These chapters only describe technical possibilities.

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## 13.0 Oncology Management System

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The PRIMUS accelerator can be supplied with a verification system capable of record and/or verification functions as well as patient data management. The **LANTIS®** Oncology Management System meets the clinical information requirements in a radiotherapy environment. Please refer to the LANTIS data sheet for additional information.

### 13.1 PRIMEVIEW Graphical Human Interface

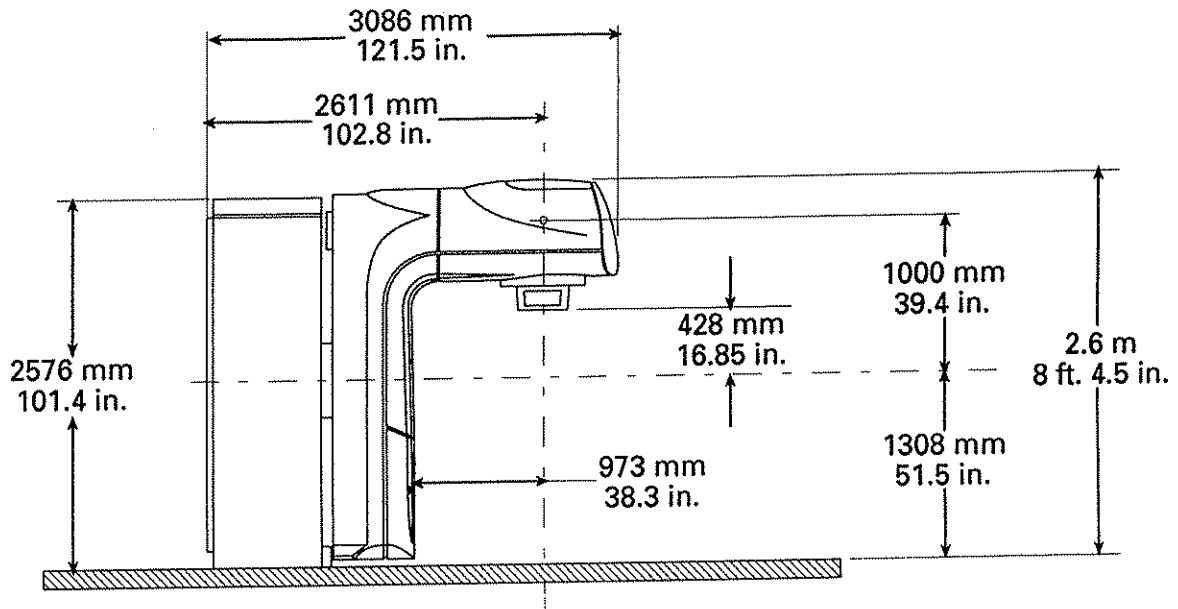
**PRIMEVIEW™** the modern, state-of-the-art human interface between the LANTIS Oncology Management System and the PRIMUS accelerator provides the clinical world with the tools necessary for advanced therapy techniques and better clinical workflow. Please refer to the PRIMEVIEW data sheet for additional information. PRIMEVIEW can also be configured as a stand-alone verification system for conventional, conformal, and advanced therapy.

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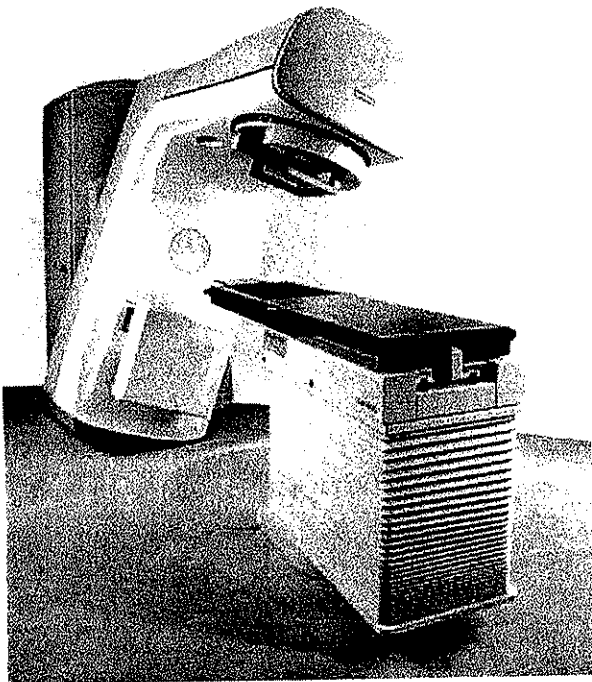
## 14.0 ZXT Treatment Table

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The **ZXT®** Treatment Table is available with the PRIMUS system. The ZXT treatment table is isocentrically-mounted providing vertical, longitudinal, and transverse motions. Rotation about the beam axis and pedestal rotation shall also be available. Please refer to the ZXT data sheet for additional information.



**Figure 10.2 - Dimensions of PRIMUS System (mm)**



#### 14.1 Carbon Fiber Table Top

An option for the ZXT Table provides flexible patient setup and reproducible patient positioning and immobilization

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#### 15.0 VIRTUAL WEDGE Option

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The **VIRTUAL WEDGE™** option provides dynamic emulation for conventional hard wedges contributing to better clinical workflow and efficiency. Please refer to the VIRTUAL WEDGE data sheet for additional information.

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#### 16.0 3-D Multi-Leaf-Collimator (3-D MLC)

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The 3-D MLC is fully integrated with the accelerator and its software, console, keyboard, and single in-room hand pendant. It optimizes clinical productivity by decreasing patient treatment time. Please refer to the 3D-MLC Data Sheet for additional information.

## 16.1 HD-270 MLC

With the **HD-270™** MLC further reduction of the dose to healthy tissue and critical structures by a process that creates a virtual MLC, with to a 2 mm resolution for each leaf. Please refer to the HD-270 MLC Data Sheet for additional information.

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## 17.0 SIMTEC Automated Field Sequencing (AFS)

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Productivity is the essential gain of this tool, especially when a PRIMUS system is equipped with VIRTUAL WEDGE, 3-D MLC and ZXT treatment table control and verification option. Please refer to the **SIMTEC** data sheet for additional information.

### 17.1 IMRT with the IM-MAXX Option

The **IM-MAXX™** option provides a rapid field sequencing and segmentation process which enables the PRIMUS system to deliver IMRT safely and efficiently. Please refer to the IM-MAXX Data Sheet for additional information.

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## 18.0 IMFAST

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The **IMFAST™ Enhancement** Option optimizes beam fluence distributions and minimizes treatment time for Intensity Modulated Radiation Therapy (IMRT) to be delivered by a Siemens medical linear accelerator equipped with 3D-MLC. IMFAST may be embedded within an RTP system or may be used as stand-alone system. Please refer to the IMFAST Data Sheet for additional information.

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## 19.0 BEAMVIEW Portal Imaging

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The **BEAMVIEW®** Electronic Portal Imaging Device (EPID) continuously monitors patient treatment ports using exit dose radiation. It is used to improve the quality of patient treatments by assuring accurate placement of the radiation beam, blocks, MLC and field alignment. Please refer to the BEAMVIEW Data Sheet for additional information.

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## 20.0 Gated Option

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A PRIMUS system configured with the Gated Option allows an external gating signal to control the treatment cycle of the accelerator. The gating technology is embedded in the PRIMUS control architecture to ensure safe and accurate gated therapy.



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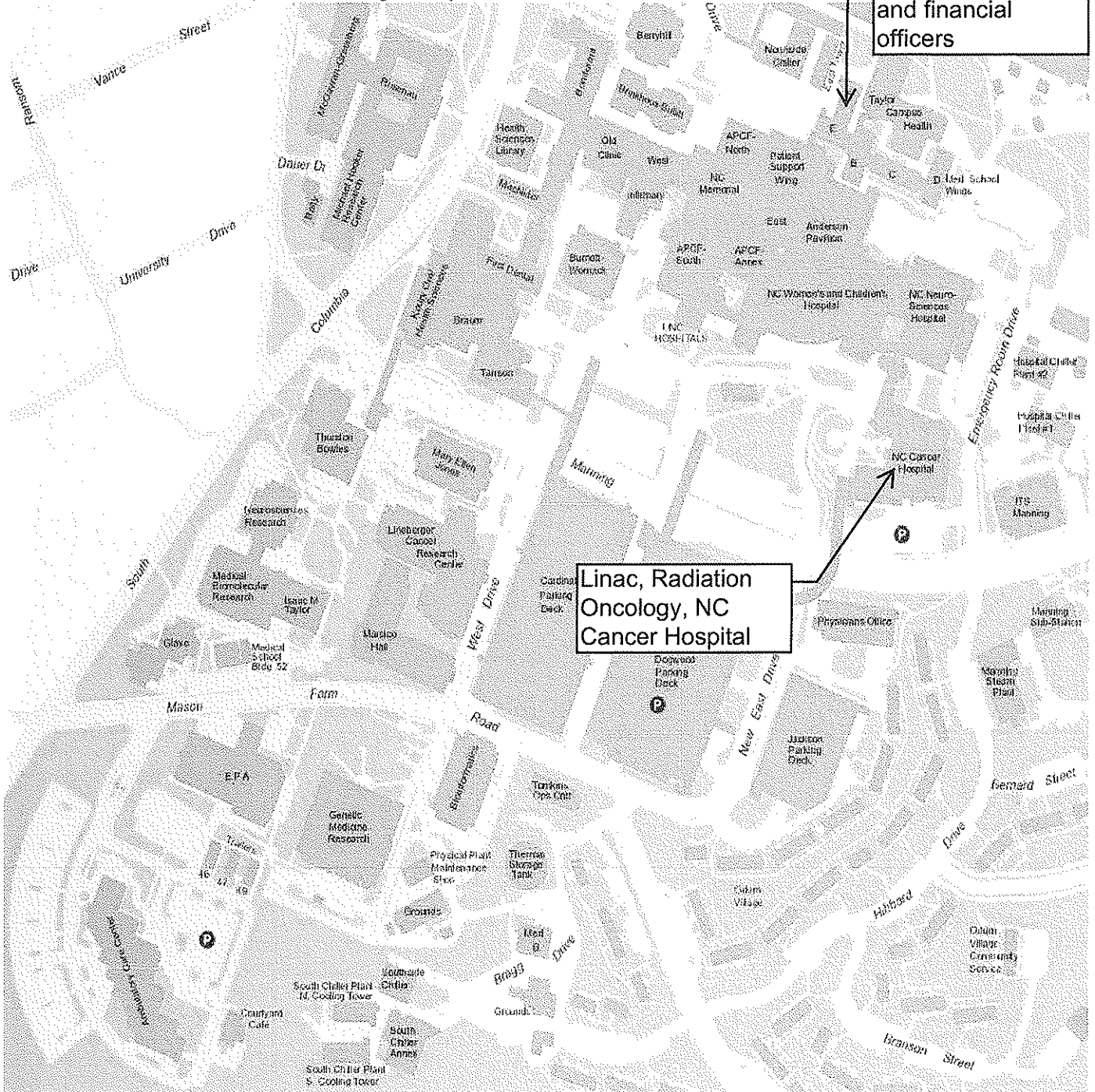
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Valid Until: July 31, 2016

*Prepared For:*

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

Elekta VersaHD (Replace Primus)	<b>Total Products List Price:</b>	\$8,843,421.41
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*The price under this Quotation reflects a discount of \$6,393,421.41 USD. If customer is an entity that reports its costs on a cost report required by the Department of Health and Human Services or a state healthcare program, the customer must fully and accurately report any discount that has been provided by Elekta under the final agreement between the parties in the applicable cost report and provide information upon request by the Secretary of Health and Human Services or a state agency. A reportable discount may be set out above or exist in the form of undertakings made by Supplier elsewhere in this Agreement.*

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## Scope of Supply

Qty	Description	List Price	License Term
1	<b>DICOM Information Manager for MOSAIQ Data Director</b> Core module MOSAIQ Data Director. Provides standards based, full fidelity storage for all DICOM objects and DICOM RT. Provides non-DICOM storage support for many file formats and highly configurable data storage, migration and organization rules for both.	35,000.00	Perpetual
5	<b>DICOM Device Connectivity for MOSAIQ Data Director</b> Access to data from DICOM sources (5 Per Core DICOM License)DICOM Data Connectivity including access to imaging devices, treatment planning systems, DICOM-based data generation devices.  DICOM Data Connectivity including access to imaging devices, treatment planning systems, DICOM-based data generation devices.	0.05	Perpetual
1	<b>MOSAIQ IGRT Connectivity for Elekta</b> Connectivity kit including the RTD and Elekta delivery platform, interface to Elekta MLC/IMRT, interface to iViewGT electronic portal imaging device and connectivity to the XVI including volumetric imaging.	104,500.00	Perpetual
1	<b>Connectivity to Elekta VMAT</b> Support for Elekta VMAT treatment techniques.	15,000.00	Perpetual
1	<b>SYNERGISTIQ (Elekta Bundle)</b> Consolidates and synchronizes MOSAIQ and Elekta IGRT Device.	149,000.00	Perpetual
1	<b>KVM Extender Kit for In-Room SEQUENCER Monitor</b> Contract pass-through 3rd party product. Includes: 1 x ACS4001A-R2 Black Box ServSwitch Single DVI-D CATx KVM Extender, USB 1 x A3L980-150-BLUS Belkin CAT6 150' patch cable, RJ45 1 x 26911 Cables to Go DVI-D M/M Display Cable - 6.6 ft	1,472.32	NA
1	<b>HP LCD Monitor for MOSAIQ Workstations</b> Contract pass-through 3rd party product. Includes: 1 x C9V76A8#ABA HP EliteDisplay E221 21.5-inch LED Backlit Monitor	505.58	NA
1	<b>HP Keyboard and Mouse for MOSAIQ Workstation</b> Contract pass-through 3rd party product. Includes: 1 x KF885AA#ABA HP USB MOUSE AND KEYBOARD KIT	45.90	NA
1	<b>SYNERGISTIQ PC Hardware for MOSAIQ</b>	2,363.00	NA
<b>Total Price</b>			<b>\$307,886.85</b>
<b>Software Discount</b>			<b>\$107,886.84</b>
<b>Total Offer Price for</b>			<b>\$200,000.00</b>

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Qty	Description
1	<p><b>Elekta Versa HD™</b> Versa HD™ provides:</p> <ul style="list-style-type: none"> <li>• Digital accelerator with exclusive cover set design;</li> <li>• Agility™, Elekta's integrated multi-leaf collimator that provides full field high resolution beam shaping (5mm at isocentre), a 40 x 40cm treatment field and effective leaf tip speed of up to 6.5cm/sec, capable of covering multiple targets with interdigitation and island shapes;</li> <li>• 6MV and 10MV flattened energies delivered as standard;</li> <li>• A broad spectrum of delivery techniques from 3D Conformal Radiotherapy to IMRT, VMAT and SRT techniques;</li> <li>• XVI, offering 2D and 3D kV image guidance for advanced soft tissue visualization supporting image guided treatment workflows, XVI Software options VolumeView™, MotionView™ and PlanarView™ are included;</li> <li>• iViewGT™, offering 2D MV imaging capability supporting image guided treatment workflows.</li> </ul>
1	<p><b>Goalpost Assembly</b> Elekta Synergy® Platform, Elekta Synergy®, Elekta Infinity™, Elekta Axesse™ and Versa HD™ compatible standard goalposts.</p>
1	<p><b>Versa HD standard cover set.</b></p>
1	<p><b>Integrity™ R3.2 control system software</b> Integrity is the latest generation of Elekta's fully digital treatment control system software for systems with Agility™. Integrity is built on the latest LynX OS platform and is the monitoring and control foundation of Elekta treatment delivery systems. Integrity additionally supports Continuously Variable Dose Rate, dynamic and VMAT deliveries.</p>
1	<p><b>Hardware Upgrade Kit - Integrity™ R3.1</b></p>
1	<p><b>High Dose Rate Mode Hardware Upgrade Kit</b></p>
1	<p><b>Integrity™ 3.1 Software Upgrade Kit</b></p>
1	<p><b>15 MV High Energy Photon</b></p>
1	<p><b>6MV High Dose Rate Software Licence</b> High Dose Rate Mode provides flattening filter free beam delivery of 6MV beams at dose rates up to 1,400 MU/min, as well as reduction in scatter, lowering whole body radiation doses.</p>
1	<p><b>10MV High Dose Rate Software Licence</b> High Dose Rate Mode provides flattening filter free beam delivery of 10MV beams at dose rates up to 2,200 MU/min, as well as reduction in scatter, lowering whole body radiation doses.</p>
1	<p><b>6 MeV Electron Energy</b></p>
1	<p><b>9 MeV Electron Energy</b></p>
1	<p><b>12 MeV Electron Energy</b></p>

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- 1 **15 MeV Electron Energy**
- 1 **U.S.A. Electron Flatness**  
Electron flatness according to U.S.A. standards, optimized at 100 cm.
- 1 **Standard Set of Aperture Plate Electron Beam Applicators**  
Field sizes:
- 6 x 6 cm, SSD 95 cm
  - 10 x 10 cm, SSD 95 cm
  - 14 x 14 cm, SSD 95 cm
  - 20 x 20 cm, SSD 95 cm
- Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator latch mounting system enables easy and rapid attachment.
- 1 **Factory Data Match**  
The option of matching one or more new Elekta machines to each other and/or to an Elekta machine already installed on a customer site. The match is carried out during production of the new machines and the match is made to the factory data recorded in production for the existing Elekta machine.
- 1 **VMAT CAT (Volumetric Arc Therapy Customer Acceptance Test)**
- 1 **Response™ Gating Control System for Digital Accelerators**  
Response provides a seamless interface that supports automated gated treatment delivery for a range of delivery techniques on the Elekta Digital Accelerator. The gating signal can be provided by a validated external motion management system, such as the Active Breathing Coordinator™.
- 1 **SYNERGISTIQ™ Software License**  
Enables the XVI functionality to support SYNERGISTIQ. SYNERGISTIQ integrates MOSAIQ® and Elekta Synergy® into a consolidated and synchronized user interface.
- 1 **Software Media Pack, SYNERGISTIQ™ Clients**
- 1 **kiloVoltage Cone-beam CT Hardware for Versa HD™**
- 1 **40kW kV generator - 480V**  
The integrated 40kW kV generator provides multiple settings control via the XVI software. Acquisition parameters are configured within the preset protocol function in the XVI software, and is user configurable. The generator and X-ray tube have been optimized for the 3D VolumeView™ imaging, as well as the 2D radiographic type exposures of PlanarView™ and MotionView™.
- 1 **Control System hardware for XVI R5.0.3**  
The XVI control system is a high specification PC which supports all aspects of the IGRT process including 2D, 3D and 4D kV image acquisition, reconstruction, and analysis using a suite of registration functionality.
- 1 **Base XVI Licence**  
The XVI 5.x base license includes the following features as standard:
- PlanarView™: 2D kV radiograph mode
  - MotionView™: 2D kV fluoroscopic mode

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- VolumeView™: 3D kV volumetric imaging mode
  - Segmental MotionView™ and VolumeView™: Pause/Restart 2D fluoro or 3D volumetric acquisitions manually.
- 1 **Intrafraction Imaging License**  
Provides the ability to acquire kV images during the delivery of an MV treatment field. Intra-fraction imaging allows you to:
    - Acquire images (2D fluoro) for a specified time, and then move directly into a 3D volumetric acquisition.
    - Acquire a 3D volumetric image during conformal, IMRT or VMAT MV deliveries to measure intrafraction movement.
    - Perform Intra-fraction 3D or 4D volumetric imaging and registration per arc during dual (or multiple) arc procedures, allowing table corrections in between arcs.
  - 1 **Symmetry™ License**  
Symmetry is primarily indicated for respiratory motion management. It offers a unique 4D IGRT online solution that is correlated to internal organ movement. It facilitates for the planned dose to be delivered to the volume where the target spends most of its time in. This allows for margin reduction and baseline shift compensation, supporting treatment deliveries during free-breathing with no surrogates. The use of Symmetry does not require planning on a 4D reference CT.
  - 1 **Critical Structure Avoidance**  
Critical Structure Avoidance allows the registration of two separate areas of anatomy, utilizing both the clipbox and the Shaped Registration Region of Interest. XVI software will calculate the relationship of both areas of anatomy to the proposed correction vectors and alert the user if the target has moved closer to the critical structures due to anatomical changes. The user can then choose to select a compromise between the two areas, or send the patient for re-planning.
  - 1 **3D Automated Seed Match License**  
Offers an optimized 3D registration algorithm to register implanted markers, without compromising on 3D volumetric information.
  - 1 **Distributed Review**  
Distributed Review allows the sending of XVI CBCT data to MOSAIQ® for review at any MOSAIQ® workstation, as well as the primary XVI workstation.  
Pre-requisites:
    - Distributed Imaging/Treatment
    - DICOM CT Export (+/- Auto DICOM CT Export).
  - 1 **Distributed Imaging**  
Distributed Imaging allows the transfer a patient between XVI systems without having to prepare the registration settings on the secondary XVI system, through MOSAIQ®.
  - 1 **Elekta XVI Basic Calibration Kit - Bearing Phantom Assembly**  
Specially designed geometric calibration phantom for kV to MV isocentre alignment. Suitable for the XVI system with the iBEAM® evo couch top.
  - 1 **Couchtop Adaptor kit for QA Phantom**  
Single ball phantom table top adapter kit. This attachment supports the single ball bearing phantom which is used to calibrate the XVI imaging software to the mechanical isocenter. Fits the iBEAM®, iBEAM® evo, HexaPOD™ evo and Connexion™ couchtops.
  - 1 **Kit, XVI Daily QA Phantom**  
Daily QA Phantom for kV and MV projection imaging and kV VolumeView™ checks Laser and lightfield coincide additionally Spreadsheet for recording and analyzing trend results.
  - 1 **XVI Water Calibration Kit**

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

- 1 **VolumeView™ Contrast phantom**  
QA phantom to enable measurement of high resolution and contrast resolution and other image quality parameters of the VolumeView images acquired on the XVI workstation.
- 1 **2D Image Quality Phantom**  
Image quality phantom use for 2D kV image quality to determine the low contrast and spatial resolution of XVI 2D images (PlanarView™ images). This test tool is used for the 2D image quality of the Customer Acceptance Test for XVI and can be used to monitor image quality over a period of time.
- 1 **Versa HD™ iViewGT™**  
This kit contains all of the components for iViewGT including;
  - A MK 6 imaging control system cabinet with the iViewGT software R3.4.1. pre-installed.
  - A rigid and fully retractable slim line MV imaging detector arm with a large, square active detector area and wide lateral and longitudinal movement adjustments. The arm has automatic and manual arm movements and is fully interlocked.
- 1 **iViewGT™ Amorphous Silicon detector panel**
- 1 **iViewGT™ R3.4.1 Installation Kit**
- 1 **iViewGT™ R3.4.1 Software Licence**
- 1 **iViewGT™ R3.4.1 Software Licence Collation**  
Third Party License toolkit necessary for supporting iViewGT.
- 1 **Remote Retraction of the iViewGT™ detector - 30M**  
This kit allows Remote Retraction of the iViewGT detector from the Function Key Pad.
- 1 **DICOM 3.0 software interface for image transfer**  
The international standard interface protocol for network transfer of medical images.
- 1 **iViewGT™ IMRT Verification Software License**  
This software expands existing iViewGT functions to verify multiple segment beams for IMRT. The iViewGT image acquisition is triggered automatically and the image taken depends on whether the user selects single, multiple or movie image.
- 1 **Template Matching Software License**  
The template matching option enables the user to compare the portal image with a nominated reference image for any set-up error. The set-up error is measured by matching visible anatomy and the field edge on the referenced image with the portal image. The user can move the templates to provide an image displacement.
- 1 **Patient Auto Select Software License**  
This enables the prescription selected on the Linac to automatically select or create that patient record on iViewGT™ or iViewC™ using the iCom-Vx protocol. In addition, images will automatically be acquired and stored in the iViewGT / iViewC database without further operator intervention.
- 1 **Software License Image Approval**  
This allows the user, assigned with the 'review' permission, to approve or disapprove any image within iViewGT™ or iViewC™.
- 1 **HexaPOD™ evo RT System Integration Licence**

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This licence package will provide the following integration features:

- Interface to MOSAIQ for automated patient ID and treatment site loading for departments using MOSAIQ 2.5 or higher.
- Control of Precise Table with iGUIDE for Systems with Integrity 3.2.

**1 HexaPOD™ evo RT CouchTop with iGUIDE® 2.0**

This HexaPOD evo RT System with iGUIDE 2.0 is a robotic patient positioning system with 6DOF to correct patient positioning misalignments. This package includes all the necessary hardware and software for a complete HexaPOD evo RT System installation. Consists of;

- HexaPOD evo Module
- iBEAM evo Extension 415
- iBEAM evo Extension 650
- BEAM evo Indexing Bars
- Hand Held Control
- Enable Switch Board
- iGUIDE 2.1 Workstation
- 2 monitors, 2 keyboards and 2 mice (Workstation / Terminal)
- iGUIDE Tracking System & Mounting Bar Reference Frame Set.

**1 iBEAM® evo Extension 650**

The iBEAM evo Extension 650 is designed to support the patients upper body and extends off the end of the iBEAM evo Couchtop by 650 mm, thus allowing for treatment of the prostate of very tall patients.

**1 Fraxion™ Stereotactic System**

The Fraxion™ Stereotactic System contains all the necessary components to generate individual patient set-ups with mouthpieces, double edge layered thermoplastic mask or combination of both. Additionally it comes with the Stereotactic Frame and Isocenter Alignment Tool.

**1 Linac Table top Adapter iBEAM evo (2DoF)**

The Linac Table top Adapter is the primary mechanical interface between the Elekta Fraxion™ Frame or the Leksell G Frame Holder and the respective table top of the linear accelerator. The Elekta Fraxion Frame or the Leksell G Frame Holder fixes directly to the Linac Table top Adapter, which supports the frame in a rigid, vertical orientation. Fine adjustments of the position of the frame, and thus of the patient's head, can be made by using the TILT and ROTATE controls. When in place, the Fraxion Frame or the Leksell G Frame Holder is secured to the Linac Table top Adapter by two 6mm socket head cap screws, which are retained in the Adapter. The screws are held in place by c-clips and are accessed from the posterior aspect of the Linac Table top Adapter.

**1 BodyFIX® 14 System Stereotactic Frameless for indexed table tops**

This is a system for indexed table tops. It's ideal for immobilization and accurate repositioning of the patient from planning to treatment delivery. It is the solution for use with IGRT for dose escalated hypofractionated treatment delivery. It is designed for the treatment of the total body. The stereotactic target positioner and localizer is not included.

**2 BodyFIX® 14 BlueBAG™ plus HIP 700x1825/50L**

**2 BodyFIX® 14 BlueBAG™ plus HIP 700x2025/60L**

**2 BodyFIX® 14 BlueBAG™ plus HIP 850x2025/80L**

**1 Active Breathing Coordinator™**

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Active Breathing Coordinator provides non-invasive, internal immobilization of anatomies affected by respiratory motion. Active Breathing Coordinator supports automated assisted breath-hold gating of the MV beam in conjunction with the Response gating interface, as well as manual gating capability without Response.

- The ergonomic design provides flexibility and ease of use.
- The laptop can be used on the trolley or off taken out and used in the treatment control room.
- The basket gives ample room for the mouthpiece, nose clips and other items.
- The display, keyboard and mouse on the trolley can be moved and used patient side.
- The trolley includes storage positions for items like the mouth-piece fixation and patient control switch, for ease of storage and transport.

**1 Mouth Piece and Filter Kit (standard; qty 20 )**

Kit of 20 Mouthpiece & Filter assemblies to replace those discarded after use. For use with the Active Breathing Coordinator™.

**1 Active Breathing Coordinator™ Trolley Keyboard**

The Active Breathing Coordinator trolley keyboard should be purchased locally to suit the needs of the user using the specifications detailed in PRT 0127.

**1 Active Breathing Coordinator™ Laptop Specification**

The Active Breathing Coordinator laptop should be purchased locally using the specifications detailed in PRT 0128.

**1 3L Spirometer Calibration Syringe for Active Breathing Coordinator™**

3 liter manual Spirometer Calibration Syringe for quality assurance of the Active Breathing Coordinator.

**1 Active Breathing Coordinator™ R3.0 Media Kit**

**1 Cat 5 Network cable 30 meters**

Required to connect the Active Breathing Coordinator™ system in the treatment room to the laptop in the control room.

**1 Stereotactic Circular Collimator Holder (also used for Apex Cone Baseplate)**

A single holder used to attach the individual stereotactic circular collimator to the host machine integrated radiation head and align it to the central axis of the beam.

**1 Coded shadow tray assembly - Short**

Provides a means for attaching X-ray shadow blocks onto the head of the Linear Accelerator or Simulator. Comprising:

- Shadow tray assembly with hook and latch mounting, and multi-way plug connector
- Two removable parallel transparent Perspex™ trays, one of which may be coded.

**1 Beam Block Tray - Star Pattern**

Lexan beam block tray with holes in a star pattern. Trays are designed with threaded, removable plugs for the coding of each block. Specially designed for use with the Elekta shadow tray assembly.

**1 Hook and Latch Magnification Graticule**

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

**1 Electron Beam Field Shaping System**

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

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

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- 10cm x 10cm
- 14cm x 14cm
- 20cm x 20cm
- 25cm x 25cm

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

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

##### 1 **IMKM**

The In-room Monitor and Keyboard function provides the operator with access to all clinical and service functions available at the control console from inside the treatment room.

Comprising:

- Cable switching connectors for attaching the in-room monitor to the treatment control system.

##### 1 **In-room Monitor, Keyboard and Mouse Local Procurement Specification**

##### 1 **Delivery Parameters Log File Convertor**

Enables a user to upload log files and have them converted into csv format.

##### 1 **IntelliMax™ Intelligent Agent**

This License provides only the IntelliMax Intelligent Agent license. Any provision of services relating to the use of data collected by the Agent (via the IntelliMax Enterprise) should be negotiated as part of the Service Contract between the Customer and the BU/distributor. IntelliMax Intelligent Agent requires a dedicated PC. Provision of this PC must be negotiated between the Customer and the Elekta BU/Distributor. A specification of the PC can be obtained from your Elekta representative. IntelliMax Intelligent Agent also requires a direct internet connection to the Agent PC opening secure port 443 (https).

##### 1 **Extender Cards**

Extender cards for fault diagnosis on the Electrical interface Module (EIM).

##### 1 **Customer Interface Terminal Board**

##### 1 **Turbo Starter Kit for Linear Accelerators**

Ancillary equipment required for the installation and maintenance of any Precise Digital Accelerator. Comprising:

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

##### 1 **Room Lasers, Green, Remote**

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

##### 1 **Applications Training for Standard Therapy on the Desktop**

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

##### 1 **Applications training for iViewGT™**

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

**1 XVI Applications Training**

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

**1 HexaPOD™ evo RT System Training**

The 2-day HexaPOD evo RT CouchTop and iGUIDE® course (travel inclusive) provides training for 4 radiation therapists in the clinical use of the HexaPOD evo RT CouchTop and iGUIDE software. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in radiation therapy.

**1 Linac Labor Warranty**

**1 Standard Rigging & Handling**

Basic rigging of Linac to first floor or ground floor location. Elekta will provide the necessary crew to offload, uncrate, rigging and machinery moving required to set system as per plan, and remove debris. Basic rigging excludes use of a crane or rigging down an elevator shaft.

Standard Rigging includes:

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

Supply a crew, including a rigging supervisor.

- Include the cost of all associated resource and expenses, including related travel time.
- Complete all rigging activities in a single day.

Standard Rigging excludes:

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

**1 Open Air Graticule**

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The Open Air Graticule is intended to be used for Radiation Therapy to project a scale of defined increments on port film images which can aid in treatment setup and verification. The Open Air Graticule does not require the use of a shadow tray holder and can be attached directly to the head of the Precise Treatment System or SL Linac. It consists of two wires delineating the X & Y axis of the treatment field. This model of graticule is ideal for MLC customers and especially those using Elekta's iView & iViewGTTM. Because the open air graticule has a minimal transmission factor, with Physic's approval, the customer does not have to re-enter the treatment room after the port film to deliver the treatment. Please see product User manual for specific treatment information.

#### 1 **Elekta Site Marketing Program**

Elekta's Strategic Marketing and Referral Techniques (SMART) program provides a comprehensive array of general and technology-specific marketing tools and resource materials to help you cultivate your investment. If purchased separately via a third party, this package could be valued at \$12,000.00 USD.

Following is a content overview of the program:

- Elekta Site Marketing Templates & Materials Package - CD-ROMs contain PowerPoint presentations, suggested copy, brochures, videos and templates to help your center market to patient populations and referring physicians, as well as product images that can be used to produce brochures, patient education pieces, advertising, etc. Templates and design source files may be customized by your center to align with your specific outreach or branding.
- Secure Website - Following a brief registration process, you will have 24-hour marketing support via secure online access to the most current SMART images, video materials, tools and templates, guidebooks and tutorial material. Download design files or templates to facilitate customization and meeting time-sensitive deadlines, or video files for use in consultation, on targeted website landing pages, or as calls-to-action. Quickly reference guidebooks, suggested marketing timelines and strategies, when and where you need them.
- Educational Outreach - Periodic WebEx presentations offer virtual learning opportunities that support practice growth objectives within evolving market strategies. Email publications keep you informed on best practices within traditional and virtual marketing channels. Additional opportunities include live events to coincide with regional / national meetings, such as Elekta's Oncology Users Meeting, to provide updates on getting the most out of your SMART tools, as well as evolving market trends.

#### 1 **Aperture Plate Electron Beam Applicator 25 x 25 cm**

Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator.

The X-ray diaphragms are then set automatically to the optimum position.

A unique hook and latch mounting system enables easy and rapid attachment.

#### 1 **Applications training for Active Breathing Coordinator™**

A 2 day on site Applications training for ABC is given for a maximum of 4 operators. This course ensures that the operators are confident and able to use the ABC and all purchased licensed options safely and efficiently. The course does not provide training in the principles or techniques used in radiation therapy.

#### 1 **Elekta Versa HD™ - Optional XVI Cassettes**

Provision of additional XVI collimators, in Elekta Versa HD colours, for Imaging. Includes:

- VolumeView cassettes: L10, M2, L2
- XVI Cassette holder.

#### 1 **Linac Installation**

#### 1 **Drayage**

#### 1 **Closed Circuit TV System - Color**

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

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**1 Intercom system for patient and radiographer communication**

The ASK-4@ 501-TLI-CF is a single zone audio monitoring system with 2-way talk/listen capabilities. It consists of a remote speaker/microphone and audio base station with built-in microphone and speaker.

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

Includes:

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

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

Includes:

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

**1 Physics 1: Medical Accelerator Introduction**

**Objective**

After completing this course, attendees will:

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

**Course Content**

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

The application has been made to CAMPEP for 31.2 Medical Physics Continuing Education Credits (MPCEC.)

**Duration**

5-day training at Elekta's Region North America LINC

**Target Group**

- Medical Physicists
- Medical Physics Students

**Pre-requisites**

None

**1 Volumetric Modulated Arc Therapy (VMAT) QA**

**Objectives**

After completing this course, attendees will:

- Explain the clinical rationale for the VMAT treatment technique.
- Evaluate the key factors influencing the quality of VMAT plans.

Elekta, Inc., 400 Perimeter Center Terrace, Suite 50, Atlanta, GA 30346

Phone: 770 300 9725 | Fax: 770 670 2323 | [www.elekta.com](http://www.elekta.com)

*All terms, conditions, pricing, product, and service information must remain confidential and should not be disclosed to any other party especially consultant firms such as MDB, ECRI, etc.*



Quotation Number: 2016-120199-CB

Quotation Date: March 15, 2016

Valid Until: July 31, 2016

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

#### Content

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

#### Duration

1 day

#### Target Audience

- Certified Medical Physicists
- Medical physics students

#### Prerequisites

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

### 1 Medical Accelerator Quality Assurance

After completing this course, attendees will:

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

#### Course Content

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

#### Duration

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

#### Target Group

Certified Medical Physicists  
Medical Physics Students

#### Pre-requisites

None

- 2 Elekta will provide reasonable and necessary travel to support completion of the Off-Site Education & Training course(s) purchased under this Agreement. This Travel Support includes reasonable and necessary airfare and accommodations booked at least three (3)



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weeks in advance through Elekta's approved travel agent, proof of course registration at the time of booking is required. Extended airfare and accommodations beyond the duration required to travel and attend the course(s) is not permitted. This Travel Support also includes reasonable and necessary local transportation costs and up to \$100 (USD) per person per day to cover reasonable and necessary meals, which will be paid by Elekta directly to Customer (not to Customer employees) upon receipt of invoice, proof of course completion and supporting receipts. This Travel Support is available for up to two (2) years after date of Acceptance, no exceptions permitted. Price - \$1,700.00 USD.

- 1 Elekta will provide reasonable and necessary travel to support completion of the Off-Site Education & Training course(s) purchased under this Agreement. This Travel Support includes reasonable and necessary airfare and accommodations booked at least three (3) weeks in advance through Elekta's approved travel agent, proof of course registration at the time of booking is required. Extended airfare and accommodations beyond the duration required to travel and attend the course(s) is not permitted. This Travel Support also includes reasonable and necessary local transportation costs and up to \$100 (USD) per person per day to cover reasonable and necessary meals, which will be paid by Elekta directly to Customer (not to Customer employees) upon receipt of invoice, proof of course completion and supporting receipts. This Travel Support is available for up to two (2) years after date of Acceptance, no exceptions permitted. Price - \$2,000.00 USD.
- 1 **Power Distribution Unit for Elekta® Linear Accelerator - 480 Volt Input**  
The PDCU incorporates a transformer, output circuit breakers, filtering for high frequency noise, distortion, and transient pulse suppression, in one cabinet. This reduces site preparation costs and complexity for the customer.

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Vision RT Ltd  
Dove House,  
Arcadia Avenue,  
London  
N3 2JU  
Tel: +44 20 8346 4300  
Fax: +44 20 8346 4634  
Email: sales@visionrt.com

**Prepared For** Shiva Das PhD, Chief of Physics  
University of North Carolina - UNC  
Site: UNC Hospital

**Customer** University of North Carolina - UNC  
University of North Carolina Hospitals  
Department of Radiation Oncology  
Room 1043  
101 Manning Drive EG001  
Chapel Hill  
North Carolina 27514-4226  
USA

**Date Issued** 21 Oct 2015  
**Quotation No.** TN102115B3  
**Date Revised** 25 Oct 2015

**Prepared By** Tim Nicholson  
**Email** tnicholson@visionrt.com  
**Mobile** +1 904 6166117  
**Offer Expires** 29 Jul 2016

Summary of Offer	Qty
AlignRT system for patient setup, surveillance (including advanced treatments) for the Elekta Linac. Includes three camera units and interface to "Response" which allows automated beam hold on the Elekta Linac.	1

Code#	Description	Qty	Price (USD)
ALRT-PS-STD	<b>AlignRT: Real Time Patient Positioning, Tracking and Surveillance</b> <i>Including</i> AlignRT camera unit AlignRT workstation; Remote console in control room AlignRT v.5.x Patient Tracking Software DICOM RT Import Module AlignRT calibration plate PSU for AlignRT HD Camera	1 2 1 1 1 1 1	<b>Included</b> Included Included Included Included Included Included

ALRT-AS-STD	<b>Advanced Surveillance</b> <i>Including</i>	1	<b>Included</b>
	AlignRT camera unit	1	Included
	AlignRT software upgrade: 3 camera support	1	Included
ALRT-ELEKTA-RESPONSE	<b>Interface to Elekta's Gating (Beam Hold) "Response" Interface</b> <i>Including</i>	1	<b>Included</b>
	Vision RT's interface to Elekta's Gating (Beam Hold) "Response" Interface to the Elekta Linac. Customer must purchase the "Response" interface from Elekta. See note below. (see note 1)	1	Included
Installation and training for all items quoted(see note 2)			

List Price	\$349,000
Discount	\$260,000
<b>OFFER PRICE</b>	<b>\$89,000</b>

**\*The above price excludes taxes and shipping costs.**

**\*\*This price quotation is a special offering for trading in the currently installed 3 camera AlignRT system to the new HD camera system. All replaced equipment will be returned to Vision RT and will become the property of Vision RT. The very special pricing will only be valid if the customer accepts delivery on or before 29th July 2016.**

**The traded-in system does not include any warranty or customer training. Additional training may be purchased at Vision RT's standard rates.**

**Notes:**

- 1 (a) There are certain Elekta system pre-requisites for this interface to operate correctly. In order to establish these requirements and any related pricing, please consult your local Elekta sales representative. (b) The interface to "Response" does not yet form part of the clinical release of Vision RT's AlignRT or GateRT software. It will be installed and configured at no additional charge as soon as it is included in a clinical release of the software. (c) GateRT should only be used for respiratory gating for patients that are suitable candidates for respiratory gating in accordance with Elekta's accompanying documents (instructions and guidance). Note that patients with short respiratory cycles may not be suitable candidates for respiratory gating.
- 2 Standard or Vision RT modified Product mounting brackets are provided by Vision RT as part of the normal installation of the Product. Any additional mounting or fixing mechanism or construction cost required to use the Product in treatment room(s) shall be the responsibility of customer.

This Quotation is subject to Vision RT's standard terms and conditions of sale (the "Terms and Conditions") as attached. Defined Terms in this Quotation shall have the same meaning as given to them in the Terms and Conditions.

No warranty included.

Full product support during any service plan will only be available if the customer provides internet access to Vision RT to allow Axeda support.

**CONDITIONS OF PAYMENT**

The terms of payment are as follows:

**30% due within 14 days of Order Confirmation**

**60% due within 30 days of shipment**

**10% due within 30 days of Completion Certification**



3275 Suntree Blvd.  
 Melbourne, FL 32940  
 Phone: +1 321-259-6862  
 Fax: +1 321-757-0066

# Quotation

Questions? Contact: Mark Loftus x2260 MarkLoftus@sunnuclear.com

**BILL TO** UNC- University of North Carolina  
 Hospitals  
 Shiva Das  
 101 Manning Dr.  
 Chapel Hill, NC 27517

**SHIP TO** UNC- University of North Carolina  
 Hospitals  
 Shiva Das  
 101 Manning Drive  
 Chapel Hill, NC 27514

Date	09/29/15
Quote #	00430103
Date Exp.	12/31/15
Terms	Net 30
Ship Via	UPS Ground
	Service
FOB	Shipping Point

For Purchase Order processing, please email orders to [Orders@sunnuclear.com](mailto:Orders@sunnuclear.com)

Item	Part #	Description	Qty	Unit Price	Extended Price
1	1220000-0Z	ArcCHECK™ 4D Isotropic Arc Delivery QA Cylindrical detector array designed for rotational delivery QA and conventional IMRT QA, with 21cm in diameter and 21cm long. 1386 detectors, active area of 0.64mm², update frequency of 50ms. Includes SNC Patient analysis software (Machine QA features are included, 25 meter power-data cable, USB cable, power supply (110/220 V), case, 1 year of hardware maintenance and 1 year of software maintenance. See product datasheet for minimum PC requirements.	1	\$ 59,950.00	\$ 59,950.00
2	1220000-1Z	ArcCHECK® CavityPlug™ Two piece PMMA (15 cm Diameter, 21 cm Length) cylindrical insert for ArcCHECK® cavity. Outer plug accommodates range of inner plug options. Includes solid inner plug and single inner custom drilled plug of customer choice - please specify ion chamber type. Additional inner plugs available.	1	\$ 3,450.00	\$ 3,450.00
3	TRNG-T1	Customer Training One day on site product training. Includes one full day of in depth product training by a qualified Sun Nuclear representative. Refer to Product Training Datasheet (attached) for the number of training units that need to be allocated for each product (one training unit = 1 day). Additional consecutive days can be purchased at a discounted price. Allow 4 weeks minimum for scheduling.  <b>Day of Training for ArcCHECK</b>	1	\$ 3,000.00	\$ 3,000.00
<b>Total Investment:</b>					<b>\$ 66,400.00</b>



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# Quotation

Questions? Contact: Mark Loftus x2260 [MarkLoftus@sunnuclear.com](mailto:MarkLoftus@sunnuclear.com)

This quotation is a confidential document containing privileged information that is not to be disclosed to parties outside of quotee and Sun Nuclear Corporation. (Disclosure to GPOs is considered a violation of confidentiality) Disclosure of this information to third parties voids terms and pricing outlined in the quotation.

## Sun Nuclear Corporation Terms & Conditions

1. All purchases approved for Net terms are due 30 days from the shipping date or services.
2. Shipping terms are FOB Shipping Point.
3. Payment with credit cards is restricted to SNC products and services of less than \$2,500. A 3% convenience charge will be added to any payment processed for special order products (resale items) and any SNC product of service with a sales price greater than \$2,500
4. Prices do not include applicable taxes. SNC will collect and remit the appropriate taxes for some U.S. states. If applicable taxes are not on Customer Purchase Order, Customer is responsible for remittance of appropriate taxes.
5. Undisputed past due accounts are subject to a late service fee charge of 18% per annum (1.5% per month), or the maximum allowed by law.
6. Any payment made in respect of credit transactions shall first be applied to the accumulated service charge, if any, and thereafter to the principal amount of the outstanding debt.
7. SNC will assess handling charges in the amount of \$100.00 for any dishonoured check received from the Customer.
8. All products shipped are subject to recourse by SNC until paid in full. Upon request from SNC, Customer agrees to immediately relinquish and return all unpaid equipment in its original condition to SNC, subject to a 20% restock fee or costs required to return equipment to its original condition, whichever is higher.
9. The parties agree that the Customer's sole and exclusive remedy for defective products shall be limited to the stated warranty provided by SNC for its manufactured products, or the warranty assigned by SNC to the extent provided by the manufacturer (resale items) of the particular component or system. The Customer agrees that no other remedy (including, but not limited to, incidental or consequential damages for lost profits, lost sales, injury to person or property, transportation charges or other incidental or consequential loss) shall be available.
10. Customers who cancel or postpone scheduled training/education/installation services are subject to cancellation fees (minimum of \$500 not to exceed \$3,000) for resource allocations and non-recoverable scheduling costs (i.e., hotels, airfare, reservations, etc.).
11. Travel allowance for customers attending courses at the Sun Nuclear Training Center is limited to \$800 for one day training (\$1,000 for two day training) for itineraries requiring airfare and \$500 for itineraries requiring ground transportation.
12. Customer is liable for invoicing of unused training days 90 days after product shipment.
13. Customer agrees to advise SNC of any defective product(s) and/or any disputed invoice(s) in writing within 10 days of receipt. Failure to properly notify SNC of any dispute and /or defective goods constitutes a waiver of any and all such disputes, provided, however, that this provision shall in no way affect or limit Customer's rights under SNC warranty, or where such is limited by law.
14. Subject to SNC approval, Customer may return unused product within 30 days from the shipping date subject to a 20% restocking fee and Customer must pay for the return shipping charges. Generally, returns after 30 days will not be considered. All approved returns must have an RMA (Return Materials Authorization) number issued by SNC. Special order products (Resale items) cannot be returned without the express written consent of the manufacturer. Customer must pay for the return shipping charges. Unauthorized returns (i.e., those without an RMA # provided) will be rejected and returned at Customer's expense.
15. SNC Support Contracts and Maintenance Agreements are non-refundable or transferable. Multi-year SNC Support Contracts may not be cancelled for current coverage period amounts that have been billed to the customer by SNC. Remaining Multi-year SNC Support Contract coverage periods that have not been billed to the customer by SNC may be cancelled if the customer no longer offers Radiation Oncology Services or should SNC no longer be able to provide services associated with the Agreement. SNC at its discretion may prorate the charges should one of these circumstances arise.
16. Customer hereby agrees to indemnify SNC for all collection fees, legal fees and all other fees and expenses which SNC incurs should Customer's account be in arrears.
17. SNC software is only licensed to the original purchaser and the license is not transferable.
18. SNC requires that when (i) the standard warranty has ended and lapsed by more than 365 days, (ii) a previously purchased contact has expired and lapsed by more than 365 days or (iii) there has been a transfer of product ownership, the equipment must be inspected and a reinstatement fee paid before placing such equipment under a new support services contract. The inspection and reinstatement fee is non-refundable and does not apply to the purchase of the support services contract. Equipment which has had a transfer of ownership and has not been inspected by SNC is eligible for standard repair pricing.
19. SNC reserves the right to modify these terms, require advance payment, and cancel any order.
20. SNC sales representatives do not have the authority to bind SNC or make any representation in respect of credit or any other matter which deviates from standard policy. All special arrangements or requirements must be confirmed in writing with an authorized person from SNC.

Rev.2/2014



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# Quotation

Questions? Contact: Mark Loftus x2260 MarkLoftus@sunnuclear.com

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<b>Customer's Acceptance</b> (ONLY to be completed in lieu of a hard copy purchase order)	
By:	_____
Printed Name:	_____
Title:	_____
Date:	_____
PO#:	_____
<b>After completion, please scan and email to <a href="mailto:Orders@sunnuclear.com">Orders@sunnuclear.com</a> or fax to +1 321-757-0066.</b>	



# Equipment: Machine Removal Agreement

## Client Contact

Shiva K. Das, Ph.D., DABR | [shivadas@email.unc.edu](mailto:shivadas@email.unc.edu)  
UNC Health Care  
101 Manning Drive  
Chapel Hill, NC 27514

## RS&A Contact

David Stith | [dstith@rsainc.net](mailto:dstith@rsainc.net)  
465 Forum Parkway  
Rural Hall, NC 27045  
P: (800) 320-4332

## Statement of Work

**Objective:** Inspect, remove, and dispose of UNC Health Care's radiation therapy equipment.  
**Equipment:** Siemens Primus (S/N 3711)  
**Location:** UNC Cancer Hospital | 101 Manning Drive | Chapel Hill, NC 27514  
**Approach:** As part of this project, RS&A will:  

- Assign a dedicated project coordinator to oversee all activities.
- Assign a qualified engineer team to perform all activities.
- Coordinate all activities with facility staff.
- Provide all equipment needed to complete the work.
- Perform a pre-job site walk down and machine inspections prior to beginning removal/install activities.

**Start Date:** To be added  
**Reference #:** OP-005484

## Pricing

Below is a pricing breakdown by activity:

Line Item	Amount
1 Complete pre-inspection of facility.	\$ Included
2 De-install and remove existing machine.	\$ 14,500
3 Travel and expenses	\$ Included
- <b>Adjustments:</b> Existing Client Credit	\$ (3,000)

**Sub-Total \$ 11,500**

*Note: Does not include applicable taxes.*



**Equipment:  
Machine Removal Agreement**

**Acceptance of Agreement**

**By signing below, the Client hereby agrees to the pricing, terms, and conditions of this agreement:**

<b>Client:</b>	University of North Carolina at Chapel Hill 101 Manning Dr. Chapel Hill, NC 27514	
<b>Authorized Signature:</b>		<b>Date:</b>
<b>Printed Name:</b>		
<b>Contract PO #:</b>		
<b>Tax Number (if exempt):</b>		
<b>Provider:</b>	RS&A, Inc. ("RS&A") 465 Forum Parkway Rural Hall, NC 27045	
<b>Authorized by:</b>		<b>Date:</b>
	Kenneth C. Wolff RS&A President and CEO	

**Attachments:**

- Terms and Conditions



## **Equipment: Machine Removal Agreement**

Client and RS&A (collectively, the "Parties") enter into this Equipment Services ("Contract" or "Agreement") and agree as follows. Additional qualifications or adjustments are to be included by addendum only.

1. **PLAN** – RS&A will work with the Client to best define their objectives, desired outcomes and key considerations throughout the project. RS&A will utilize its discovery questionnaire to determine the following information:

1.1 Determine the facility's future plans and needs as they relate to desired upgrades of existing equipment or additional equipment procurement. This includes, but is not limited to, machine and financial specifications (e.g., budget).

1.2 Evaluate existing machine(s) at Facility. For Facilities that have existing machines, RS&A will complete a machine evaluation to determine current operating condition, useful remaining life, and estimated market value (bank, third party acquisition, and trade-in).

1.3 Inspect Facility to assess any physical considerations, constraints, or limitations. This inspection includes, but is not limited to, room dimensions, shielding requirements, electrical requirements, base frame needs, and other construction related needs.

1.4 RS&A will provide a site planning summary to the Client (the "Site Evaluation") in which RS&A outlines its findings and recommendations. This will include, but is not limited to, any construction or facility infrastructure related items necessary to install the desired Equipment.

1.5 Client shall review the Site Evaluation. If Client elects not to proceed with RS&A's recommendations, then it shall provide RS&A with written notice within thirty (30) days of the date on the Site Evaluation that it elects to terminate this Agreement. If Client fails to give written notice to terminate, then it shall be presumed that Client elects to proceed with RS&A's recommendations.

2. **PROCURE** – If applicable, RS&A will monitor the equipment market and provide Client with notices of machine options that meet the necessary specifications provided in the Site Evaluation. Upon identification of a machine that meets the desired specifications (the "Equipment"), RS&A agrees to the following:

2.1 RS&A will conduct an on-site inspection of the Equipment in alignment with its Quality Assurance program (the "Inspection Report"). The Inspection Report will include, without limitation, (i) the Equipment's operational and visual functionality and (ii) RS&A's recommendation regarding whether to accept or reject the Equipment. RS&A will provide a copy of its Inspection Report to the Client.

2.2 If Client desires to accept the Equipment, it must notify RS&A in writing within forty-eight (48) hours of RS&A's delivery of the Inspection Report to Client. If Client does not respond within 48 hours, then it is presumed that Client rejects the Equipment.

2.3 Upon acceptance of the Equipment by Client, RS&A will contract with the seller of the Equipment ("Seller") to purchase the Equipment on behalf of the Client. RS&A will provide the necessary funds to hold the Equipment, which may include a required down-payment or escrow amount. RS&A will coordinate the purchase and acquisition of the Equipment, including without limitation, machine acquisition and removal, title transfer, software licensing and registration fees, and relocation or temporary storage. This Agreement with then be amended to include the machine specifications of the Equipment purchased (see Attachment B).

3. **INSTALL** – Once the Equipment is identified and under contract with the Seller, the Parties shall move forward with the plans for installing the Equipment as outlined in this Section.

3.1 **Project Coordinator.** RS&A will appoint a project coordinator (the "Project Coordinator") to work with the Client and manage the installation of the Equipment. The Project Coordinator will be the main contact for Client and is charged with overseeing the project which may include: (i) Coordinating project activities, (ii) Developing an Installation Schedule, (iii) Attending project meetings and preparing meeting summaries (progress to date, next steps, issues log), (iv) Establishing a project contact list, (v) Supporting the Client with change management exercises (e.g., communications plan), (vi) Executing installation procedures to perform and verify the work, and (vii) Issuing project milestone acceptance letters.





## **Equipment: Machine Removal Agreement**

3.2 **Installation Schedule.** The Parties will meet and prepare an installation schedule (the "Installation Schedule"). Both Parties shall use commercially reasonable efforts to comply with the Installation Schedule.

3.3 **Site Preparation.** RS&A will work with the Client to prepare the Site ("Site Preparation") to install the Equipment. The Site Preparation may include, but is not limited to, the following:

3.3.1 **Removal of Existing Equipment.** If a machine is currently installed at the Facility and is being replaced (the "Existing Equipment"), RS&A will remove and disposition the Existing Equipment as it deems appropriate. RS&A will manage any disposal requirements for radiative material associated with the removal of the Existing Equipment. Accessories such as photon wedges, accessory trays, electron cones, couch top panels and treatment accessories will be removed with the Existing Equipment. Unless otherwise noted, RS&A will take possession (in full) of any removed equipment and accessories as part of this agreement.

3.3.2 **Disconnection of Utilities.** Client is responsible for disconnecting the electrical, air, and plumbing systems from the Existing Equipment prior to removal of the Existing Equipment and installation of the Equipment.

3.3.3 **Construction Activities.** Client is responsible for any activities required to configure the Facility to install the Equipment at the Facility. Such items may include without limitation (i) electrical, plumbing or other utility requirements, (ii) vault preparation and requirements, (iii) additional shielding, (iv) floor or wall repairs, (v) any code compliance requirements, (vi) chiller installations, (vii) IT requirements and configurations or (viii) any other infrastructure/construction requirements to install the selected Equipment. See Attachment C for a breakdown of roles/responsibilities (Note: This may be altered to meet the needs of this Agreement and should be included by addendum).

3.3.4 **Permits.** Client is responsible for (i) obtaining any required permits to possess and install the Equipment and (ii) complying with all state, federal and local regulations in connection with Equipment.

3.3.5 **Radiation Controls.** The radiation control regulations in several regions prohibit RS&A from delivering equipment until the Client can provide evidence of meeting certain requirements. This may include verifying that the Client has licensed or registered their equipment and/or registered their facility. Client shall obtain their license or file their registration in a timely manner to avoid delivery and installation delays, which may occur if these requirements have not been met.

3.3.6 **Facility Plan.** Certain regions require that RS&A must verify the Client has had their facility plan review approved by the regional radiation control agency before the delivery of equipment can be authorized.

3.4 **Delivery and Install of Equipment.** Once the Site Preparation is complete (including permitting), RS&A will finalize the acquisition, removal and delivery of the Equipment to the Facility. RS&A will install the Equipment to operate within manufacturer specifications. Upon completion of the mechanical and electrical installation process, RS&A will be present with the Facility's designated staff (e.g., Physics) to administer manufacturer acceptance testing procedures. The completion of the installation process is defined as when acceptance testing is done and signed off by the Client (acceptance letter).

4. **OPERATE** - RS&A will support the Facility's transition to the new Equipment as appropriate. This includes, but is not limited to, the following:

4.1 **Train Personnel.** Prior to operations, RS&A will train Facility personnel on the new equipment. This will be scheduled and coordinated with the Client in advance of completing Equipment installation. As part of one-year service agreement, RS&A will provide technical support to the Client to ensure a seamless transition to the new Equipment.

4.2 **Treat Patients (i.e., Equipment Operations).** Client shall properly operate all Equipment and related controls in accordance with the applicable operating manuals and recommended procedures and ensure that qualified personnel are provided for such operations, including any product calibration. Client shall operate the Equipment continuously in environmental and electrical conditions that meet or exceed the manufacturer's specifications for the Equipment. Client shall be responsible to perform the daily care of the Equipment. In any instances where the Equipment is not operated within the defined product specifications and operating procedures supplied by the



## **Equipment: Machine Removal Agreement**

equipment manufacturer, any repairs necessitated thereby shall be conclusively presumed the result of Client's negligence, and will be invoiced on a time and material basis.

### **5. PRICING AND PAYMENT TERMS**

5.1 The price for the services rendered under this Agreement shall be equal to the "Pricing" as outlined on summary page (the "Fee").

5.2 All payments are net due upon completion of the Client acceptance testing document. Past due balances are subject to a service charge of the maximum amount permitted by law. If collection action is required to collect any amount due under this Agreement, then Client agrees to be responsible for the payment of all past dues, late fees, accrued interest and reasonable attorneys' fees by RS&A to collect such sums. Payments shall be made by certified check payable to RS&A, Inc. or by wire transfer.

5.3 **Exclusions.** Pricing does not include (i) any construction related costs in the vault (e.g., additional shielding or floor repair), (ii) compliance issues, utility services, chiller installs, IT requirements, etc., (iii) local, state, and federal taxes or (iv) any construction, demolition, or repair work that might be required.

5.4 **Licensure.** Client may be subject to re-licensing fees associated with the transfer of ownership on used equipment. The Original Equipment Manufacturers (OEM) regulates license transfer policies and only the OEM can supply license transfers. RS&A shall not be responsible for any license fees subsequently charged by the Original Manufacturer, unless specifically agreed upon.

#### **5.5 Refund Policy.**

5.5.1 Client may elect to terminate this Agreement by providing written notice to RS&A. Once RS&A has entered into a binding contract with the Seller, all funds paid under this Agreement shall be non-refundable.

### **6. REPRESENTATIONS AND WARRANTIES**

#### **6.1 RS&A Representations and Warranties.** RS&A represents and warrants as follows:

6.1.1 The services will conform to the Equipment manufacturer's specifications and applicable laws and regulations.

6.1.2 RS&A has full power and authority to enter into and to perform its obligations hereunder.

6.1.3 The execution, delivery and performance of this Contract by RS&A have been duly authorized by all necessary action. This Contract and all other documents delivered to Client will be, duly executed and delivered on behalf of RS&A by duly authorized agents of RS&A, and the legal, valid and binding obligations of RS&A enforceable in accordance with their respective terms.

#### **6.2 Client Representations and Warranties.** Client represents and warrants as follows:

6.2.1 By entering into this Contract, Client shall not be in violation of any contract with another party, including without limitation, any exclusive right by the manufacturer to service the Equipment.

6.2.2 Client has full power and authority to enter into and to perform its obligations hereunder.

6.2.3 The execution, delivery and performance of this Contract by Client have been duly authorized by all necessary action. This Contract and all other documents delivered to RS&A will be, duly executed and delivered on behalf of Client, and the legal, valid and binding obligations of Client enforceable in accordance with their respective terms.

### **7. MISCELLANEOUS**

#### **7.1 Disclaimer of Warranties.**

7.1.1 THE WARRANTY FOR MATERIALS AND EQUIPMENT IS A MANUFACTURER'S WARRANTY ONLY, AND RS&A PROVIDES NO OTHER WARRANTIES WHATSOEVER, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY, ANY IMPLIED



## **Equipment: Machine Removal Agreement**

WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AND ANY IMPLIED WARRANTIES OTHERWISE ARISING FROM COURSE OF DEALING OR TRADE.

### **7.2 Limitation of Liability.**

7.2.1 Notwithstanding anything in this Agreement to the contrary, RS&A shall have no responsibility or liability for delays however caused. In no event shall RS&A be liable for any indirect, special, incidental, consequential or punitive damages, losses or expenses including, but not limited to, loss of use, loss of profits, or loss of goodwill. Any liability of RS&A is expressly limited to payments actually received by RS&A under this Contract.

7.2.2 Client hereby agrees to hold harmless RS&A and its respective officers, employees, agents, representatives, and their respective successors and assigns from and against any and all loss, liability, damages, claims, causes of action, costs, and expenses, including but not limited to attorney's fees and other types of liability, whether accrued, absolute, contingent or otherwise, arising out of or related to use of any of the Equipment at any time. Client alone is responsible for costs required to comply with all requirements imposed by law or regulation relating in any way to personal safety prior to use or operation of Equipment.

7.3 **Computer Software.** Computer software (including, without limitation, source code, object code, application software, server and Client software, operating system software, and software implemented as firmware) provided with the Equipment remains the property of the original equipment manufacturer (the "OEM") or the OEM's licensors. All software licensing and registration fees, including machine licensing and portal imaging licensing must be addressed with the OEM. RS&A agrees to work with the Client to obtain all necessary software for the Equipment.

7.4 **Third Party Beneficiary.** Nothing in this Agreement is intended or should be construed to give any third person, including a patient of Client, any legal or equitable rights under this Agreement.

7.5 **Entire Agreement.** This Agreement, including any schedules, price lists and exhibits that may be attached hereto, constitutes the entire understanding and agreement between the parties and supersedes any and all prior and contemporaneous oral or written representations, communications, understandings and agreements between the parties with respect to the subject matter contained herein and in the schedules, price lists and exhibits attached hereto. A modification of the terms and conditions hereof by any separate terms and conditions offered by Client must be signed by RS&A in order to become binding on RS&A and enforceable by Client. The parties acknowledge and agree that neither party is entering into this Agreement on the basis of any representation, understanding, agreement or promise not expressly set forth in this Agreement.

7.6 **Confidential Information.** Each Party agrees not to use any Confidential Information of the other party for any purpose except for performing their respective obligations pursuant to this Agreement. Each Party agrees to limit disclosure of any Confidential Information of the other party to those agents, business consultants, representatives or employees of the receiving party who are required to have the information in order to evaluate or engage in discussions concerning the contemplated business relationship. Neither Party shall reverse engineer, disassemble or decompile any software or other tangible objects which are provided as the other party's Confidential Information. "Confidential Information" means any information relating to, available to, or disclosed pursuant to this Agreement, including, but not limited to, information relating to either party's products, services and/or service plans, trade secrets, inventions, data, designs, reports, analyses, costs, prices and names, patients, patient information, customer lists, finances, marketing plans, business plans, strategic plans or business opportunities.

7.7 **Attorney's Fees.** If any legal action is brought for the enforcement of this Agreement or because of an alleged dispute, breach, default, or misrepresentation in connection with any of the provisions of this Agreement, the prevailing party or parties shall be entitled to recover their reasonable attorney's fees and other costs incurred in that action or proceeding, in addition to any other relief to which they may be entitled.

7.8 **Counterparts and Facsimile Signatures.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same Agreement. For purposes of this Agreement, signatures sent via facsimile shall be deemed originals and shall have the same force and effect as if they were originals.

7.9 **Force Majeure.** Neither party shall be liable in damages or have the right to terminate this Agreement for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its



## **Equipment: Machine Removal Agreement**

control including, but not limited to Acts of God, government restrictions (including the denial or cancellation of any export or other necessary license), wars, adverse weather conditions, insurrections and/or any other cause beyond the reasonable control of the party whose performance is affected.

7.10 **Governing Law.** This Contract shall be governed by and construed in accordance with the laws of the state of North Carolina. Client hereby irrevocably consents to the venue and jurisdiction of the courts in Forsyth County, North Carolina.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]



**Equipment:  
Letter of Intent**

May 3, 2016

To whom it may concern,

This letter is to notify of the disposition of the Siemens Primus linear accelerator (S/N: 3711), located at:

University of North Carolina at Chapel Hill  
101 Manning Drive  
Chapel Hill, NC 27514

This accelerator will be removed and taken possession by:  
RS&A Inc.  
465 Forum Parkway  
Rural Hall, NC 27045

In accordance with this removal, RS&A assures that this unit will not be reinstalled to a CON location in North Carolina.

A handwritten signature in black ink, appearing to read 'David Stith'. The signature is fluid and cursive, with the first name 'David' being more prominent than the last name 'Stith'.

David Stith  
Director, Equipment Services  
RS&A Inc.

~~DEC 16 2015~~

DEC 16 2015

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 # H0157

Medicare # 340061

FID #: 923517

PC HS

Date 12/17/15

License Fee:

\$15,597.50

2016  
HOSPITAL LICENSE  
RENEWAL APPLICATION

Legal Identity of Applicant: University of North Carolina Hospitals at Chapel Hill  
(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: University of North Carolina Hospitals  
Other: UNC Hospitals;  
Other: \_\_\_\_\_

Facility Mailing Address: 101 Manning Dr  
Chapel Hill, NC 27514

Facility Site Address: 101 Manning Dr  
Chapel Hill, NC 27514  
County: Orange  
Telephone: ~~(919)966-4131~~ (984) 974-5111  
Fax: (919)966-3709 (984) 974-7772

Administrator/Director: Gary L Park  
Title: President  
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: GARY L. PARK Title: PRESIDENT  
(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: DEE JAY ZERMAN Telephone: 984-974-1210

E-Mail: DJ.ZERMAN@UNCHEALTH.UNC.EDU

**PAID**

CK NO. 617105

DATE 12-16-15

\$15,597.50

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
<b>Simple Treatment Delivery</b>		
77401	Radiation treatment delivery	
77402	Radiation treatment delivery (<=5 MeV)	17
77403	Radiation treatment delivery (6-10 MeV)	9
77404	Radiation treatment delivery (11-19 MeV)	5
77406	Radiation treatment delivery (>=20 MeV)	
<b>Intermediate Treatment Delivery</b>		
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)	
<b>Complex Treatment Delivery</b>		
77412	Radiation treatment delivery (<=5 MeV)	9902
77413	Radiation treatment delivery (6-10 MeV)	9166
77414	Radiation treatment delivery (11-19 MeV)	2391
77416	Radiation treatment delivery (>= 20 MeV)	
<b>Other Treatment Delivery Not Included Above</b>		
77418	Intensity modulated radiation treatment (IMRT) delivery	7865
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator	63
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	540
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	155
	Neutron and proton radiation therapy	
	Limb salvage irradiation	542
	Hemibody irradiation	
	Total body irradiation	150
<b>Imaging Procedures Not Included Above</b>		
77417	Additional field check radiographs	15696
<b>Total Procedures – Linear Accelerators</b>		<b>38301</b>
<b>Gamma Knife® Procedures</b>		
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®)	
<b>Total Procedures – Gamma Knife®</b>		

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 1053 (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) 6\*  
 2. Of the TOTAL number above, number of Linear Accelerators configured for stereotactic radiosurgery 2  
 3. Of the TOTAL number above, Number of CyberKnife® Systems: 1 *ELEKTA VERSA*  
 Other specialized linear accelerators 2 Identify Manufacturer of Equipment *TOMOTHERAPY*

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 13 IE-176(24b))) 2

*\*NOTE: 6 LINACS DO NOT INCLUDE 1 MOBILTRON USED FOR IDRT IN THE OR.*

**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	<u>10</u>



**PROPOSED TOTAL CAPITAL COST OF PROJECT**

**A. Site Costs**

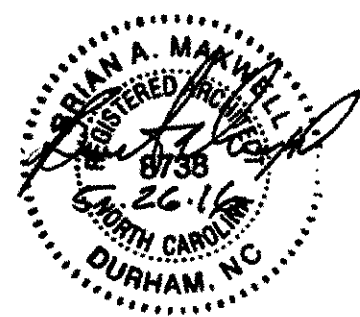
(1) Full purchase price of land	\$	0	
Acres _____ Price per Acre \$ _____			
(2) Closing costs	\$	0	
(3) Site Inspection and Survey	\$	0	
(4) Legal fees and subsoil investigation	\$	0	
(5) Site Preparation Costs			
Soil Borings	\$	0	
Clearing - Earthwork	\$	0	
Fine Grade for Slab	\$	0	
Roads - Paving	\$	0	
Concrete Sidewalks	\$	0	
Water and Sewer	\$	0	
Footing Excavation	\$	0	
Footing Backfill	\$	0	
Termite Treatment	\$	0	
Other (Specify)	\$	0	
Sub-Total Site Preparation Costs	\$	0	
(6) Other (Specify)	\$	0	
(7) Sub-Total Site Costs			\$ 0

**B. Construction Contract**

(8) Cost of Materials			
General Requirements	\$	39,111	
Concrete/Masonry	\$	15,000	
Woods/Doors & Windows/Finishes	\$	19,521	
Thermal & Moisture Protection	\$	0	
Equipment/Specialty Items	\$	6,000	
Mechanical/Electrical	\$	84,018	
Other ( )	\$	61,678	
Sub-Total Cost of Materials	\$	225,328	
(9) Cost of Labor	\$	150,219	
(10) Other: Construction Contingency	\$	93,887	
(11) Sub-Total Construction Contract			\$ 469,434

**C. Miscellaneous Project Costs**

(12) Building Purchase	\$	0	
(13) Fixed Equipment Purchase	\$	2,605,400	
(14) Movable Equipment Purchase	\$	0	
(15) Furniture	\$	20,000	
(16) Landscaping	\$	0	
(17) Consultant Fees			
Architect and Engineering Fees	\$	60,000	
Legal Fees	\$	0	
Market Analysis	\$	0	
Sub-Total Consultant Fees	\$	60,000	
(18) Financing Costs (e.g. Bond, Loan, etc.)	\$	0	
(19) Interest During Construction	\$	0	
(20) Other: De-install and Removal	\$	11,500	
(21) Sub-Total Miscellaneous			\$ 2,696,900
(22) Total Capital Cost of Project (Sum A-C above)			\$ 3,166,334



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

Brian A. Maxwell  
 Signature of Licensed Architect or Engineer