

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

June 21, 2021

Robert A. Hamill rhamill@hallrender.com

Exempt from Review - Replacement Equipment

Record #: 3595

Date of Request: June 14, 2021

Business Name: North Carolina Radiation Therapy Management Services, LLC

Business #: 2124

Project Description: Replace existing linear accelerator

County: Buncombe

Dear Mr. Hamill:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Elekta Versa HD to replace the Oncor Impression 5120. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Sincerely,

Ena Lightbourne Project Analyst

Gloria C. Hale

for

Lisa Pittman

Assistant Chief, Certificate of Need

cc: Radiation Protection Section, DHSR

Construction Section, DHSR

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

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

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

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Hall, Render, Killian, Heath & Lyman, LLP Perimeter Three 3015 Carrington Mill Blvd. Suite 450 Morrisville, North Carolina 27560

> Robert A. Hamill (919) 447-4970 rhamill@hallrender.com

June 14, 2021

VIA EMAIL

Ena Lightbourne
Project Analyst
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
ena.lightbourne@dhhs.nc.gov

RE: Replacement of Linear Accelerator at 179 North Buncombe School Rd, Weaverville, NC 28709

Dear Ms. Lightbourne:

We represent North Carolina Radiation Therapy Management Services, LLC ("NCRTMS"). We are writing to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("CON Section") of NCRTMS' intention to replace the linear accelerator that is currently in operation at 179 North Buncombe School Road, Weaverville, North Carolina, 28709 ("Existing Equipment"). For the reasons explained below, NCRTMS' replacement of the Existing Equipment is exempt from certificate of need ("CON") review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

1. **Description of Equipment.**

The Existing Equipment is a Siemens Oncor Impression 5120. A description of the Existing Equipment's features and capabilities is attached hereto as Exhibit A. The Existing Equipment was acquired by NCRTMS as refurbished equipment in 2014. The Existing Equipment has been in operation at Radiation Therapy Associates of Western North Carolina since that time, and is used to provide radiation therapy for the treatment of cancer. Upon replacement, the Existing Equipment will be moved out of state and disposed of.

NCRTMS intends to replace the Existing Equipment with a new Elekta VersaHD linear accelerator acquired from Elekta ("**Replacement Equipment**"). The Replacement Equipment will be used to provide the same radiation treatment to cancer patients as the Existing Equipment. The Replacement Equipment will have the same technology as the Existing

Equipment, will be functionally similar to the Existing Equipment, and will be used to provide the same cancer treatments to patients. A description of the Replacement Equipment's features and capabilities is attached hereto as Exhibit B.

The acquisition of the Replacement Equipment will not result in more than a 10% increase in patient charges or per-procedure operating expenses within the first 12 months following acquisition. NCRTMS' total cost to acquire the Replacement Equipment is approximately \$1,993,020.00. A summary of the costs to acquire and install the replacement equipment is attached hereto as Exhibit C. Documentation supporting those costs is attached hereto as Exhibit D.

2. Overview of Applicable Law.

"Replacement equipment" is exempt from CON review. N.C. Gen. Stat. § 131E-184(a)(7). "Replacement equipment" is equipment that costs less than \$2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. N.C. Gen. Stat. § 131E-176(22a). The cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making the equipment operational shall be included when calculating the total cost of replacement equipment. *Id.*

Replacement equipment is comparable to the equipment being replaced if: (i) it has the same technology as the existing equipment, although it may possess expanded capabilities due to technological advancements; (ii) it is functionally similar and used for the same diagnostic or treatment purposes and is not used to provide a new health service; and (iii) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per-procedure operating expenses within the first 12 months after replacement. 10a N.C.A.C. 14c. 0303(d).

Replacement equipment is not comparable to the equipment being replaced if, among other reasons: (i) the replacement equipment is new or reconditioned, the existing equipment was purchased second-hand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; (ii) the replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or (iii) the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment. *Id.* at (e)(1)-(3).

3. Analysis.

The Replacement Equipment constitutes "replacement equipment", as defined under Section 131E-184(a)(7), and is therefore exempt from CON review for the following reasons:

a. The total cost of the Replacement Equipment is less than \$2,000,000;

- b. The Existing Equipment will be removed from the state and disposed of;
- c. The Replacement Equipment has the same technology as the Existing Equipment;
- d. The Replacement Equipment is functionally similar to the Existing Equipment, will be used for the same treatment purposes, and will not be used to provide a new health service;
- e. The acquisition of the Replacement Equipment will not result in a 10% or greater increase in patient charges or per-procedure operating expenses within the first 12 months; and
- f. The Existing Equipment was purchased refurbished and the Replacement Equipment is new, the Replacement Equipment is being purchased more than three years after the acquisition of the Existing Equipment, and the Replacement Equipment is not capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the Existing Equipment.

On behalf of NCRTMS, we respectfully request that the CON Section provide written confirmation that NCRTMS' replacement of the Existing Equipment with the Replacement Equipment, as described herein, is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

Please do not hesitate to contact me if you have any questions or require additional information. Thank you for your review and consideration of this matter.

Sincerely,

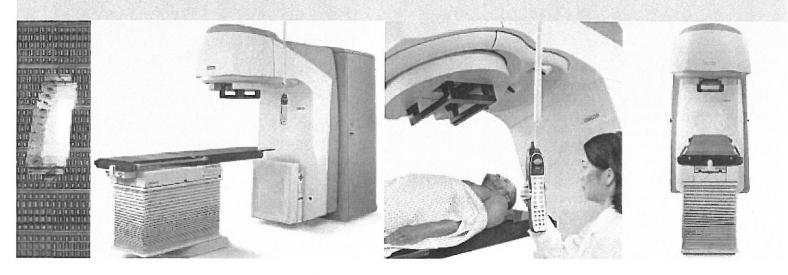
HALL, RENDER, KILLIAN, HEATH & LYMAN, LLP

Robert A. Hamill

Robert damill

Exhibit A Existing Equipment

[See Attached]



ONCOR Avant-GardeDigital Linear Accelerator



ONCOR Avant-Garde Linear Accelerator Specifications

1.0 General

These specifications describe the isocentrically-mounted ONCOR™ Avant-Garde linear accelerator for the routine clinical application of megavoltage X-ray and electron beam 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 is supplied by a klystron for the ONCOR Avant-Garde accelerator.

Note: All specifications are related to console version 8.0 or higher.

1.1 ONCOR Avant-Garde Main Features

- COHERENCE™ Therapist Workspace the only fully integrated, linac console enabling complete management of treatment through a, single syngo® based, graphical user interface.
- OPTIFOCUS™ MLC providing accurate full-field coverage with uniform penumbra incorporating fast leaf speed and low leaf leakage
- OPTIVUE™ aSi flat panel portal imager with patent-pending BEAMSYNC™ acquisition system
 — providing full automation with fast image quality and high resolution
- SUREBEAM™ Dosimetry employing patented technology to provide short beam formation and uniform dose linearity, with low X-ray contamination for electron treatments



- OPTIBEAM™ IMRT optimized IMRT delivery with verification to safely provide treatments with speed and accuracy
- OPENGATE™ Gating control based on dose and time with open connectivity to 3rd party triggering devices
- ISOPOINT™ Provides high precision radiationto-mechanical isocenter coincidence
- Patient-friendly design High patient clearance and quiet system operation
- **Eco-friendly design** Low construction costs and utilities consumption
- syngo Evolve optimize capital investment through optional Non-Obsolescence program

Unit Type	Low X-ray (MV)	High X-ray (MV)	Electron Energy Range (MeV)
	4	10	5 - 14
	6	10	6 - 21
ONCOR Avant-Garde	6	15	6 - 21
ONCOR Availt-Garde	6	18	6 - 21
	6	23	6 - 21
5.0	6	25*	6 - 21

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

Table 1.1 - Nominal Beam Energies

1.2 Nominal Beam Energies Available

ONCOR Avant-Garde accelerator provides configurations for different types of radiation (X-ray beam, electron beam) and energies as shown in *Table* 1.1.

2.0 X-Ray Beam Characteristics

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 the central axis at 10 cm depth in water, for a 10 cm x 10 cm field with 100 cm Targetto-Surface Distance (TSD). (Reference *Table 2.1*)

2.2 Depth of Maximum Ionization in Water

The depth of maximum ionization (d_{max}) for a 10 cm x 10 cm 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 cm x 10 cm field, measured at d_{max} on central axis for 100 cm TSD, is 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.

Nominal Energy (MV) [BJR17]	% Ionization at 10 cm Water	d _{max} (cm)
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

2.5 Flatness at Treatment Depth

The X-ray intensity across 80% of the major axes of symmetric square fields of 10 cm x 10 cm and greater measured at a depth of 10 cm in water and at 100 cm Target-to-Axis Distance (TAD), will 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 is 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* will not exceed 110%.

2.7 Field Symmetry

Symmetry is specified for symmetric fields of 10 cm x 10 cm 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 will not differ by more than 2% from the mean value of the intensities. Energies less than 6 MV are measured at a depth of 5 cm.

2.8 Field Size

The field size is defined as the distance between the 50% intensity points along each major axis for symmetrical fields (variable to 40 cm x 40 cm) at 100 cm TAD. The nominal size of the primary beam at 100 cm TAD is 50 cm in diameter.

2.9 Penumbra

The penumbra on each side of the field is defined as the distance between the 20% and 80% intensity points measured along the major axes of a 10 cm x 10 cm field at a depth of 10 cm in water at 100 cm TAD. The penumbra is 7 mm ±2 mm (MLC), as measured with a 0.084 cc thimble ionization chamber. For energies below 6 MV, penumbra is measured at a depth of 5 cm. For 25 MV the penumbra is 8 mm ±2 mm (MLC)*.

^{*} Not available in the U.S.A. and Japan

Unit Type	Low X-Ray (MV)	Dual Dose Rate for X low (MU/min)	High X-Ray (MV)	Dual Dose Rate for X high (MU/min)
	4	50 & 200	10	50 & 300
	6	50 & 200	10	50 & 300
ONCOR	6	50 & 300	15	50 & 500
Avant-Garde	6	50 & 300	18	50 & 500
	6	50 & 300	23	50 & 500
	6	50 & 300	25 ¹	50 & 500

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

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) variable dose rates are programmable from lowest to highest dose rate, in increments of 1 MU/min.

Table 2.2 - Dose Rate

3.0 Dosimetry System

SUREBEAM Dosimetry employs patented technology like SIMTEC to provide excellence in dose linearity and beam formation time, ensuring flatness and symmetry characteristics for a dose range of 1.0 MU to 9974.0 MU.

3.1 Dual 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. For fixed X-ray treatment techniques, including **OPTIBEAM IMRT** and **OPENGATE** respiratory-gated treatment deliveries, the programmed dose presets shall be resolved to 0.1 MU (fractional monitor unit). For all other treatment deliveries, including electron treatments, the dose preset resolution shall be 1 MU.

For fixed beam treatments, the primary dose monitor system terminates the treatment when reaching coincidence with the preset value. Backup termination is provided by the secondary dose monitor and time interlock systems for all treatment techniques including OPTIBEAM IMRT and OPENGATE respiratorygated deliveries.

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

3.2 Dose Monitor Performance and Linearity

For a programmed range of 1 MU to 1000 MU for Monitor 1 at the dose rate of 50 MU/min, the maximum deviation of accumulated dose measured in cGy shall be linear within ±1%.

3.3 Long Term Reproducibility

The system shall maintain the dosimetry calibration within ≤2% over a period of five working days.

3.4 Beam Formation

The beam stability is typically achieved within the first 250 msec after activated RAD ON signal. During the beam formation time, the flatness, the symmetry, and the dosimetry linearity specifications are typically met.

4.0 Electron Beam Characteristics

4.1 Energy

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

Energy is defined as the depth of the 80% ionization in water on the central axis for a 15 cm x 15 cm 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.

Nominal Energy (MeV)	Relative 30% Ionization Depth (cm)	Relative 80% Ionization Depth (cm)	X-ray Contamination (maximum)	Maximum Surface Dose (% d _{max})
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

4.2 X-ray Contamination

The X-ray contamination of the electron beam is measured in water on the central axis 10 cm beyond the depth at which the electron beam intensity is 10% of the maximum value. (See electron beam characteristics in Table 4.1)

4.3 Dose Rate

The default 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 x 15 cm fixed field applicator, is 300 MU/min.

4.4 High Dose Rate Mode

A high dose rate mode of 900 MU per minute is included for fixed-beam therapy.

4.5 Flatness

Flatness specifications are met for the fixed electron applicators and energies as shown in *Table 4.2*. The measurement is 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 does not vary by more than the tabulated value in *Table 4.2* 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 $10 \text{ cm} \times 10 \text{ cm}$ to $25 \text{ cm} \times 25 \text{ cm}$.

4.6 Symmetry

For all available energies, symmetry is specified for fixed electron applicators of 15 cm x 15 cm 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 do not differ by more than 2% from the mean value of the intensities.

4.7 Surface Dose

The surface dose is as shown in Table 4.1 for a 15 cm x 15 cm 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_{max} .

4.8 Penumbra

Width of penumbra defined 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 a circular field 5 cm in diameter, and 11.1 mm for maximum square field.

Nominal Energy	Applicator Field				
(MeV)	Average*	10 cm	15 cm	20 cm	25 cm
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	5
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 cm²) anywhere in the radiation field at the depth of 0.5 mm, to the maximum absorbed dose on the radiation beam axis does not exceed 109% (*IEC 976, 7.2.4*).

5.0 Arc Therapy

5.1 General

Bi-directional arc therapy is included for X-ray and electrons.

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 - Photon Arc Therapy, typical dose-per-degree range performance

5.2 X-ray Arc Therapy

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

5.3 Arc Dose Monitor Linearity

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

5.4 Arc Dose Monitor Reproducibility

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

Sections 5.3 and 5.4 apply for the ranges indicated in Table 5.2.

Fixed-Beam Dose Rate (MU/min)	Dose-per-Degree Range (MU/degree)
500	0.56 to 5.00
300	0.33 to 5.00
200	0.33 to 5.00

Table 5.2 - Photon Arc Therapy, specified dose-per-degree range performance

5.5 Arc Therapy with Electrons

The accelerator is provided with arc therapy in the electron mode. The MU/degree for electron arc therapy range is from 2 to 10 MU/degree.

6.0 Mechanical Parameters and Control

6.1 Gantry

The gantry rotates a nominal $\pm 180^{\circ}$. The nominal speed is 1.0 RPM.

Gantry Angle

Resolution: 0.1° Accuracy: $\pm 0.5^{\circ}$

The nominal Target-to-Isocenter Distance is 100 cm.

ISOPOINT provides industry leading radiation to mechanical isocenter coincidence.

Isocenter Tolerance: The mechanical and radiation isocenter shall be located within a sphere of 0.5 mm radius.

Mechanical isocenter: the point in space that minimizes the collimator axis error for all orientations of the gantry and collimator.

Collimator axis error: the distance between the mechanical isocenter and the collimator axis, measured normal to the collimator axis.

Radiation isocenter: the point in space that minimizes the radiation axis error for all orientations of the gantry and collimator (with symmetric openings).

Radiation axis error: the distance between the radiation isocenter and the radiation axis, measured normal to the radiation axis.

Isocenter Height: The nominal distance between floor and isocenter is 130.8 cm.

Target-to-Surface Distance: (TSD)

Optical Range Finder:

Range: 75 cm to 130 cm

Resolution: 0.5 cm

Accuracy: ± 0.2 cm at 100 TSD

Mechanical Front Pointer:

Range: 85 cm to 110 cm

Resolution: 0.5 cm

Accuracy: ± 0.5 cm at 100 TSD

6.2 Collimator

The collimator rotates 270° with OPTIFOCUS MLC about the central beam axis.

Collimator Angle

Resolution: 0.1° Accuracy: $\pm 0.5^{\circ}$

6.3 Field Size Collimators

Field sizes are defined by a set of adjustable collimator jaws designated Y (closer to the target or *inner* or inplane) and two banks of leaves designated X (farther from target or *outer* or cross-plane), capable of projecting a field size at the isocentric plane from 0 cm² to 40 cm x 40 cm.

Independently adjustable inner and/or outer collimators are included with a projected centerline overtravel at isocentric plane of 10 cm with the X-leaves (outer collimators) and 10 cm with the Y-jaws (inner collimators).

Field size displays for symmetric fields

Resolution: 1.0 mm

Accuracy: ± 2.0 mm or 1% of the field size

(whichever is greater)

6.4 X-ray-to-Light Field Coincidence

A field defining light is provided. The coincidence of the light field edges with the radiation field edges (50% intensity points) on the major axes is within 2 mm or 1% of the indicated field size, whichever is greater, at the isocentric plane for field dimension 5 cm x 5 cm to 35 cm x 35 cm.

7.0 Accessories

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

Pre-shaped lead blocks are optionally available as follows:

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

7.3 Electron Applicators

Fixed electron applicators are included in square field sizes of $10 \text{ cm} \times 10 \text{ cm}$, $15 \text{ cm} \times 15 \text{ cm}$, $20 \text{ cm} \times 20 \text{ cm}$, and $25 \text{ cm} \times 25 \text{ cm}$, as well as a 5 cm diameter circular 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 optionally available with different cone shapes. The nominal distance from the target to the end of the applicator is 95 cm.

The **Digital Electron Variable Applicator** (DEVA) is optionally available with a field size range from 3 cm x $3 \text{ cm to } 25 \text{ cm} \times 25 \text{ cm}$.

8.0 Leakage Radiation Specifications

8.1 X-ray Leakage Radiation to the Patient Plane

The leakage radiation intensity, averaged over 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, does not exceed 0.1% of the unattenuated useful beam.

8.2 X-ray Leakage Radiation Outside the Patient Plane

The leakage radiation intensity, averaged over an area, 1 m from the path of the accelerated electrons, except in the patient plane specified in Section 8.1, does not exceed 0.1% of the maximum intensity of the unattenuated useful beam. Leakage radiation is measured with a 30 cc ionization chamber with a 1 cm thick buildup cap.

8.3 Adjustable Collimator Transmission

The X-ray transmission through one set of adjustable collimator jaws does not exceed 0.5% of the unattenuated beam. The transmission value is the average value measured according to *IEC 601-2-1* measurement methods.

9.0 Utility Requirements

Note: For further details, refer also to the Product Planning Guide for the ONCOR accelerator.

9.1 Incoming Power Requirements

400 VAC (international), 480 VAC (USA) 03-phase delta, 50 Hz or 60 Hz

9.2 Facility Water Cooling Specifications and Recommendations

The ONCOR Avant-Garde system is designed to connect to a constant 28 l/min (7.5 gal/min) facility cooling water loop to be provided by the customer.

Note: Please pay close attention to the differential pressure requirements when purchasing a commercially available chiller system to ensure that it meets the requirements for ONCOR Avant-Garde. It is highly recommended to acquire the Siemens suggested water chiller.

- a) Facility water maximum inlet pressure 552 kPa (80 PSI). Pressure drop minimum 241 kPa (35 PSI).
- b) Facility water maximum inlet temperature 25° C (77° F), minimum inlet temperature 16° C (60° F), optimum inlet temperature 18°C (65°F).
- c) The heat dissipation from the linear accelerator to water is shown in *Table 9.1*.

Quality of water:

- Total dissolved solids (CaCO₃) <250 PPM, total suspended solids <30 PPM (annual average)
- Dissolved gasses: Hydrogen Sulfide (H₂S) <0.05 PPM
- Total hardness (CaCO₃) <85 PPM
- A 50-micron in-line filter with 95% efficiency is required. Water shall be free of iron bacteria and manganese bacteria.

Unit Type	Standby	Treatment mode
ONCOR	7.0 kW	30 kW
Avant-Garde	(24,000 BTU/hr.)	(102,000 BTU/hr.)

Table 9.1 - ONCOR Avant-Garde Heat Dissipated to Water

9.3 Air Conditioning

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

Unit Type	Standby	Treatment Mode
ONCOR	2.7 kW	6.5 kW
Avant-Garde	(9,212 BTU/hr.)	(22,178 BTU/hr.)
Control	0.3 kW	0.3 kW
Console	(1,024 BTU/hr.)	(1,024 BTU/hr.)

Table 9.2 - ONCOR Avant-Garde Heat Dissipated to Air

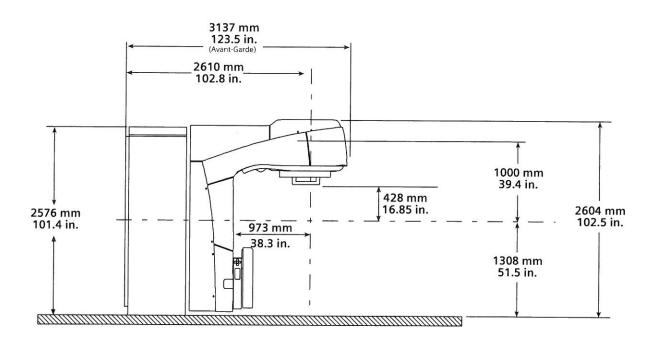


Figure 10.1 - Dimensions of the ONCOR Avant-Garde System

9.4 Treatment Room Ventilation

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

10.0 Physical Characteristics

10.1 Dimensions and Weights

Table 10.1 provides the weight of the ONCOR Avant-Garde. Figure 10.1 depicts the dimensions of the ONCOR Avant-Garde system.

Unit Type	Weight (kg)	Weight (lbs.)
ONCOR Avant-Garde	7730	17,000

Table 10.1 -Weight of the ONCOR Linear Accelerator

Minimal service clearance is outlined in Figure 10.2.

11.0 IEC and EN Requirements

The ONCOR Avant-Garde 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:

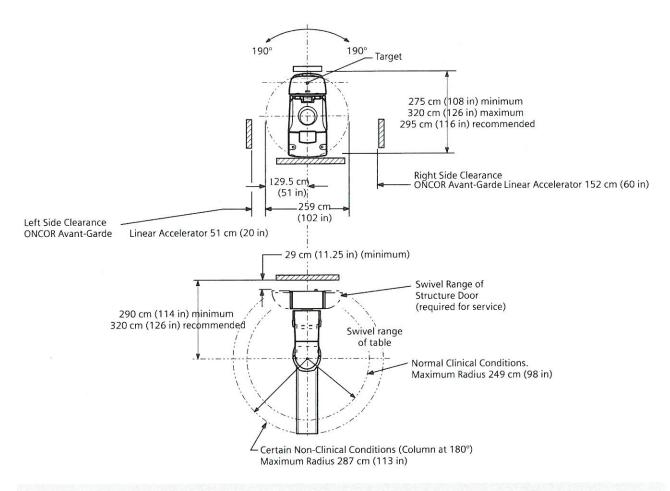


Figure 10.2 - Service Clearance Dimensions of the ONCOR Avant-Garde System

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

12.0 OPTIFOCUS Multileaf Collimator

The OPTIFOCUS MLC is fully integrated within ONCOR Avant-Garde and **COHERENCE Therapist workspace** as well as the control console, and single in-room hand pendant.

OPTIFOCUS optimizes clinical productivity by eliminating patient specific blocks, therefore, decreasing patient treatment time. The double-focused MLC is the main component for efficient and verifiable **OPTIBEAM IMRT** deliveries.

Field Size

The OPTIFOCUS MLC consists of 39 pairs of leaves with 1 cm leaf width and two outer pairs of leaves with 0.5 cm leaf width. It provides conformal shaping capabilities for irregular target volumes in size of up to 40 cm x 40 cm (refer to *Figure 13.1*).

Leaf Positioning Accuracy

The leaf positioning accuracy — whether in block mode or conformal mode — shall be such that at all gantry positions, the positioning accuracy is within ±1.0 mm or 1%, whichever is greater, measured at a SAD of 100 cm under radiation for a symmetrical field in direction of leaf travel.

MLC Leakage Data

Per IEC, the 6 MV X-ray transmission through one set of adjustable collimator jaws or leaves or between one set of adjustable collimator leaves, expressed as a percentage of the unattenuated beam, shall not exceed the values listed in the *Table 13.1*.

Note: X-ray transmission through one set of adjustable collimator jaws or leaves or between one set of adjustable collimator leaves shall be measured 10 cm from the central axis in the isocentric plane at a depth of d_{\max} in water at 100 cm TSD. It is referenced to the unattenuated beam measured on the central axis at a depth of d_{\max} in water at 100 cm TSD for a 10 cm x 10 cm field.

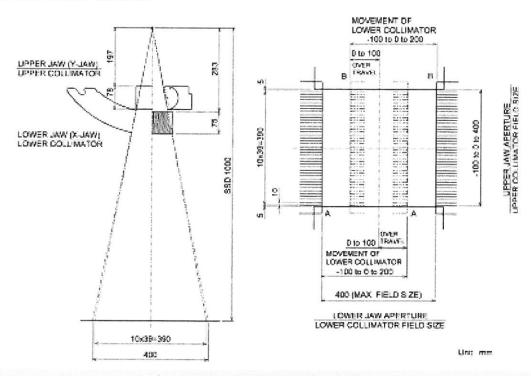


Figure 13.1 - OPTIFOCUS MLC Field Size

Mean X-ray (6 MV) Transmission along the In-plane profile for Percentage of Unattenuated Beam	0.7%
Maximum X-ray Transmission Through Jaws or Leaves, Percentage of Unattenuated Beam	1.0%
Maximum X-ray Transmission Between Leaves, Percentage of Unattenuated Beam	1.5%

Table 13.1 - MLC leakage data

Per IEC, the average 6 MV X-ray transmission through the inner (Y) jaws shall not exceed 0.5% of the unattenuated beam.

Note: The output of the unattenuated beam is measured on the central axis at a depth of d_{max} in water at 100 cm TSD for a 10 cm x 10 cm field.

Per IEC, the maximum 6 MV X-ray transmission through the inner (Y) jaws shall not exceed 2% of the unattenuated beam.

Note: The output of the unattenuated beam is measured on the central axis at a depth of d_{max} in water at 100 cm TSD for a 10 cm x 10 cm field.

14.0 OPTIVUE 1000 aSi Flat Panel Portal Imager

The **OPTIVUE™ 1000** amorphous Silicon (aSi) portal imager is fully integrated within ONCOR Avant-Garde and COHERENCE Therapist workspace as well as the control console, and single in-room hand pendant.

OPTIVUE utilizes patent-pending BEAMSYNC acquisition technology for excellence in image quality and resolution. OPTIVUE's fully automated deployment and retraction - supervised by a collision detection system - optimizes clinical productivity and portal imaging workflow by eliminating the need to enter the treatment room to position film or manually deploy the detector.

Active imaging area: 40 cm x 40 cm

Resolution: 1024 pixel x 1024 pixel

Pixel depth: 16 bit

Pixel pitch: 0.4 mm (400 microns)

f50 ≥ 0.41 lp/mm

Positional repeatability: ± 1.0 mm Positional accuracy: ± 2.0 mm

Motor-controlled vertical and longitudinal movements

(relative to isocenter):

Vertical travel range: 115.0 cm to 160.0 cm

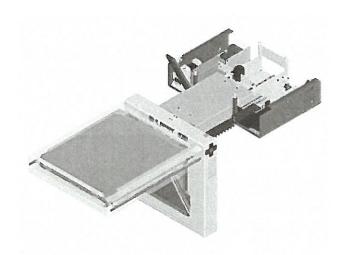


Figure 14.1 - OPTIVUE aSi flat panel portal imager with positioning unit

OPTIVUE supports different types of image acquisition; free running mode, single or continuous scan mode using BEAMSYNC (Rad On as trigger).

15.0 ZXT Patient Treatment Table

The ZXT® Treatment Table is included with the ONCOR Avant-Garde. The ZXT treatment table is isocentrically-mounted, enabling vertical, longitudinal, and transversal motions. Rotation about the beam axis and pedestal movement is also available. Please refer to the ZXT data sheet for additional information.

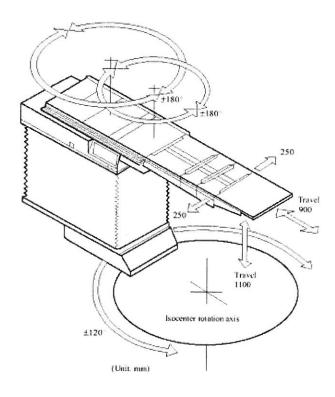


Figure 15.1 - ZXT Patient Treatment Table

Carbon Fiber Table Top

As an option for the ZXT table, a Carbon Fiber Table Top provides superior patient setup and reproducible patient positioning and immobilization for even the most complex treatments.

16.0 COHERENCE Therapist Workspace

COHERENCE Therapist Oncology workspace combines a comprehensive treatment delivery system and unique portal imaging application — for accurate and efficient patient positioning — with a flexible Oncology Information System.

An effective **Oncology Workflow Solution™** for radiation therapy treatment delivery and recording, COHERENCE Therapist provides the following clinical advantages:

- Auto assisted patient positioning
- OPTIVUE aSi flat panel portal imager support with automated deployment, positioning and retraction
- · Automatic portal image acquisition
- DICOM RT support Multi-Segment fields and Fractional Monitor Units
- OPTIFOCUS MLC support
- Integration of portal imaging and treatment delivery into one workflow
- Single user interface for most clinical activities

COHERENCE Therapist workspace provides easy, safe and accurate delivery of industry-leading techniques such as:

- Virtual MicroMultileaf Collimator (HD-270)
- SIMTEC AFS
- SIMTEC IM-MAXX

16.1 Virtual MicroMultileaf Collimator

The **Virtual MicroMultileaf Collimator** (HD-270) provides a user-selectable leaf resolution up to a 2 mm leaf width, providing further reduction of dose to healthy tissue and critical structures.

16.3 OPTIBEAM IMRT with SIMTEC IM-MAXX Option

The **SIMTEC IM-MAXX**® option optimizes sequencing of IMRT segments that enables ONCOR Avant-Garde to deliver IMRT safely and efficiently.

16.4 Treatment Verification and Delivery

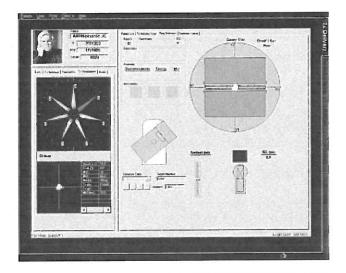


Figure 16.1 - COHERENCE Therapist Treatment Delivery

- Dynamic display of geometric parameters
- Graphical representation for ease of visualization
- Color coded for verification and tolerance checking
- Large fonts for easier readout in the treatment room
- Advanced treatment techniques, such as IMRT, in one integrated workspace
- Auto sequencing of fields for fast efficient treatment delivery

16.5 Patient Positioning and Portal Imaging

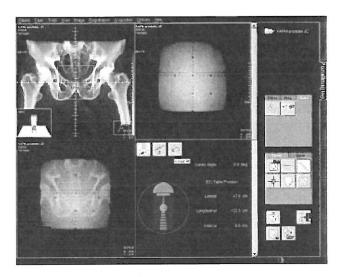


Figure 16. 2 - COHERENCE Therapist Patient Positioning

- · Automated image acquisition
- Automatic synchronization with Reference Image
- Interactive alignment of Portal Image with Reference Image
- User definable reference points or structures for alignment
- · Automated calculation of positioning offset
- · Verification of patient positioning
- Recording of actual treatment delivery

16.6 Patient Data Management LANTIS

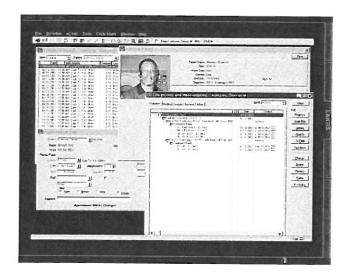


Figure 16.3 - COHERENCE Therapist LANTIS

- Comprehensive Patient Data Management
- · Flexible Patient Scheduling
- Medical Oncology integration
- Multi-vendor support; Linacs, Treatment Planning systems, Simulators
- · Intuitive Clinical Assessments
- · Extensive reporting tools
- Secure data access

17.0 OPENGATE

OPENGATE allows external device control of the radiation delivery functions of the ONCOR Avant-Garde accelerator during *e.g.*, respiratory gated therapy treatments.

Siemens OPENGATE allows the clinical user to choose the type of external control device to utilize with ONCOR Avant-Garde. Input signals from such a device can be the result of patient parameters such as chest movement, respiratory cycle, or a switching mechanism.

OPENGATE provides a dedicated mode and user interface for a safe and seamless delivery process according to IEC safety requirements including MU monitor 1, MU monitor 2, and timer back-up.

18.0 LANTIS Oncology Management System

The ONCOR Avant-Garde accelerator can be supplied with a comprehensive information management that extends to medical oncology as well as radiation oncology.

LANTIS has more clinical and administrative modules than any other system, providing clinical accuracy and workflow efficiency benefits for all users in oncology.

Additional specifications for all of LANTIS components are available within separate documents.

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Siemens **Medical Solutions** that help

Siemens Medical Solutions USA, Inc. Oncology Care Systems 4040 Nelson Avenue Concord, California 94520 USA Tel.: +1 (925) 246-8200

Order No. **A91004-M2630-G7-1-4A00** Product of USA 8M GP 10.03

<u>Exhibit B</u> Replacement Equipment

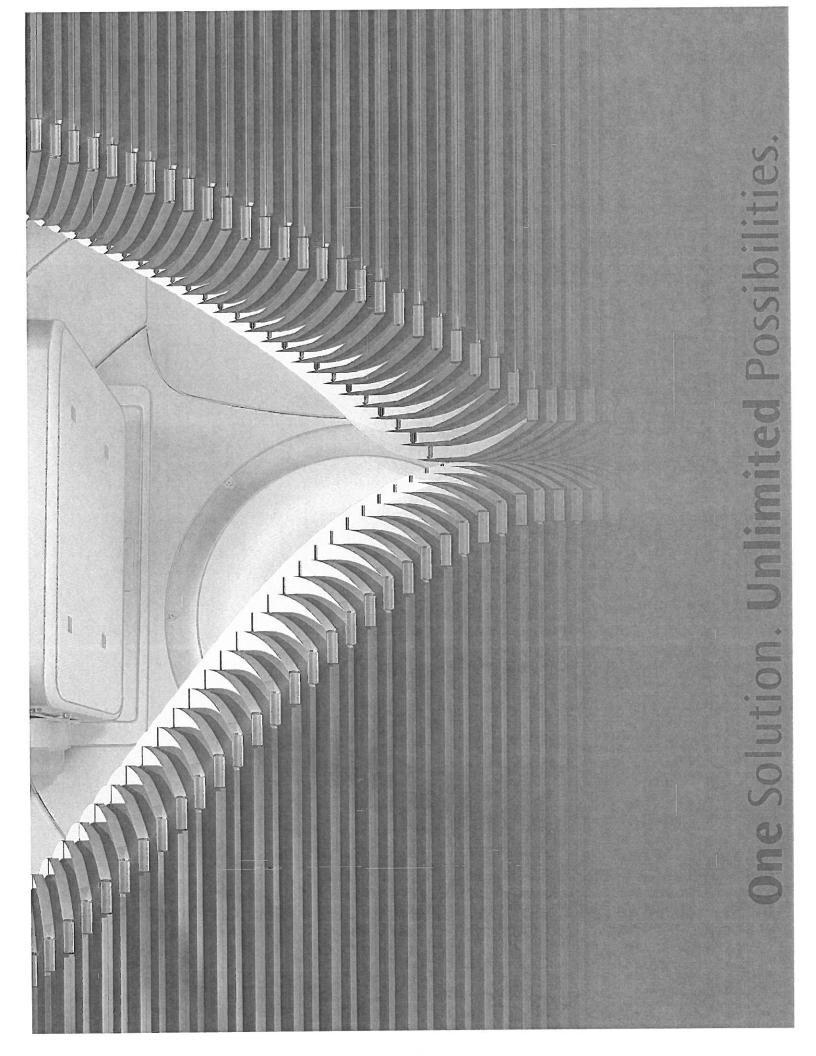
[See Attached]

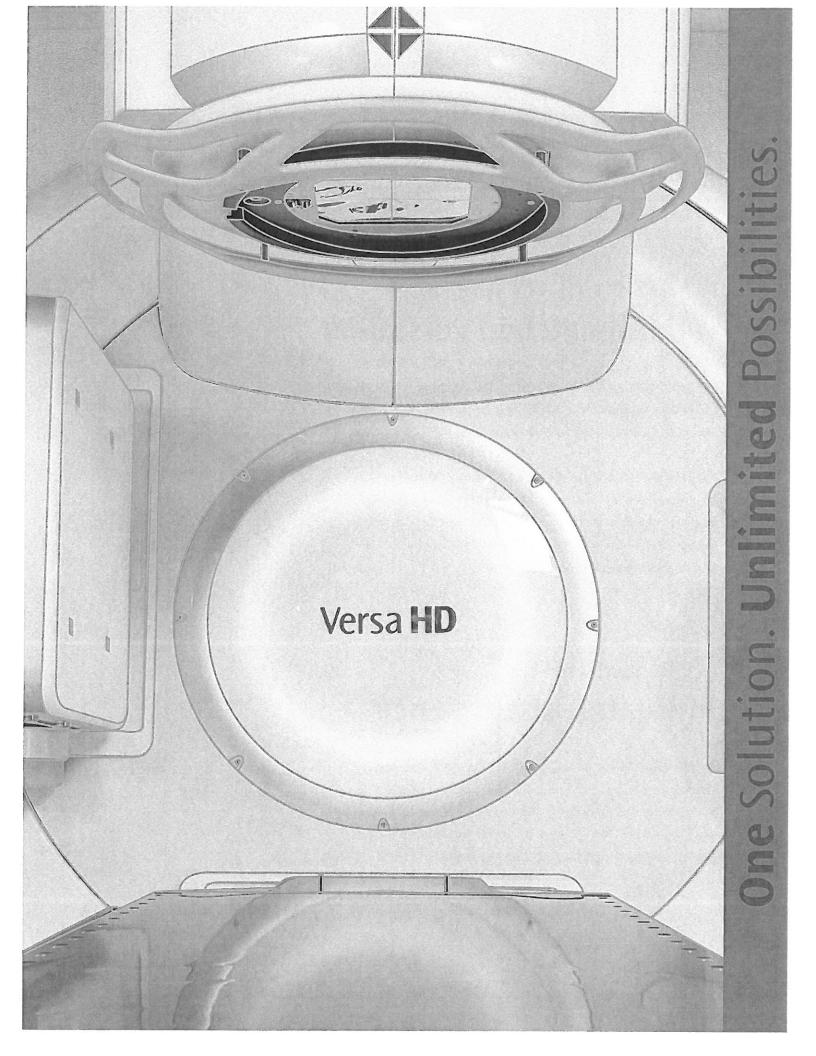
Versa **HD**



Versa HD

The convergence of conventional radiotherapy with advanced stereotactic precision.





Versa HD"

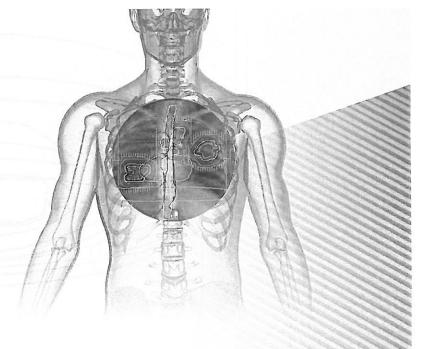
A single delivery system with **unmatched versatility**

Recognizing the emergence of increasingly advanced therapies combined with unprecedented demands to maximize health care resources, Elekta is pleased to introduce Versa HD™.

Providing the flexibility to safely and efficiently deliver the full spectrum of conventional radiotherapy techniques, Versa HD advances modern cancer care with the added versatility to deliver sophisticated linear accelerator-based stereotactic treatments — all within a single delivery system.

New standards in treatment efficiency

Elekta's new and innovative High Dose Rate mode leverages the latest advances in flattening filter-free beam technology and provides maximum dose rates three times higher than previous generation Elekta linear accelerators. With the option to deliver conventional and high dose rates, Versa HD enables highly sophisticated therapies without compromising treatment times.

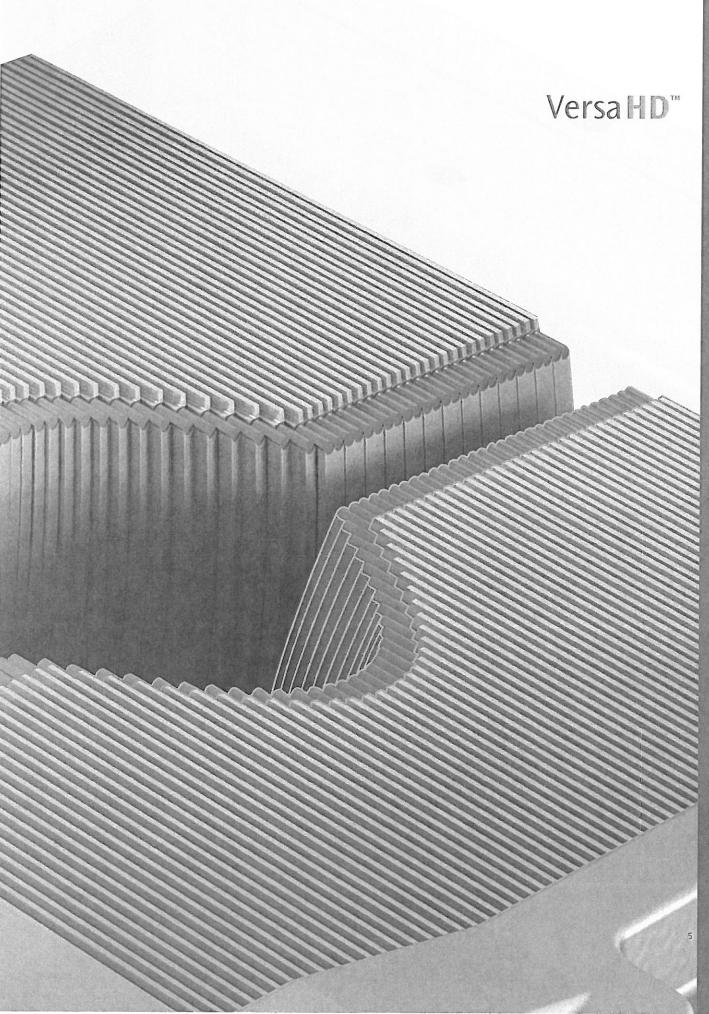


Superior target conformance

Versa HD features Agility™, Elekta's revolutionary multi-leaf collimator. Agility utilizes 160 fine-resolution leaves, a 40 cm x 40 cm treatment field and leaf speeds more than two times faster than other MLC systems. The patented Rubicon™ leaf-positioning technology of Agility verifies leaf movement in real time, providing extreme precision, high reliability and enhanced conformance for a broad range of cases.

The full potential of **High Dose Rate delivery**

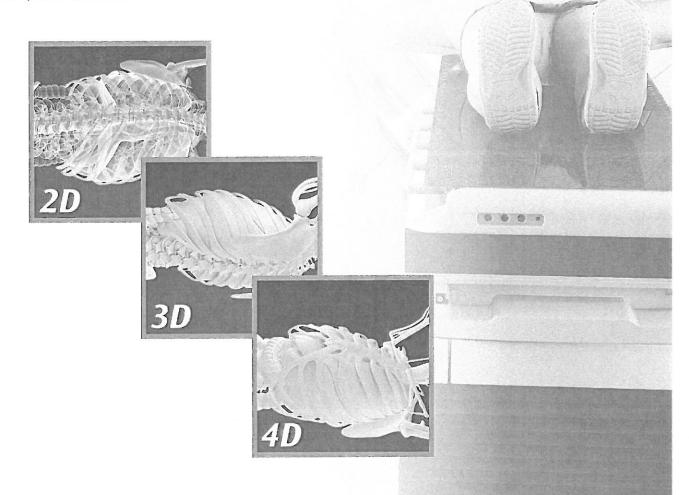
With Versa HD, the unique combination of ground-breaking MLC leaf speeds with High Dose Rate mode means clinicians can, for the first time, explore the full capabilities of high dose rate delivery and take advanced therapies such as VMAT, SRS and SRT to new levels.



VersaHD™

Soft tissue imaging during delivery

With the ability to image during treatment delivery, Versa HD provides an opportunity to reduce treatment time-slots to improve clinical efficiency. Combining imaging and treatment delivery also reduces the likelihood of patient movement and changes in internal organ position during the treatment session. This means that patient care is further enhanced while giving clinicians the flexibility to provide a patient-specific workflow.



Anatomically correlated 4D imaging

Unique to Elekta, Versa HD delivers state-of-the-art 4D soft tissue visualization to manage respiratory motion and accurately target mobile lung tumors — a difficult task before the introduction of this advanced technology. 4D image guidance technology allows clear visualization of moving targets to enable margin reduction to set new standards in lung treatment.

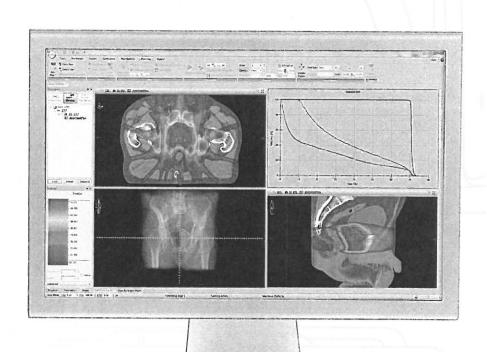
Integrated care management for radiation and medical oncology

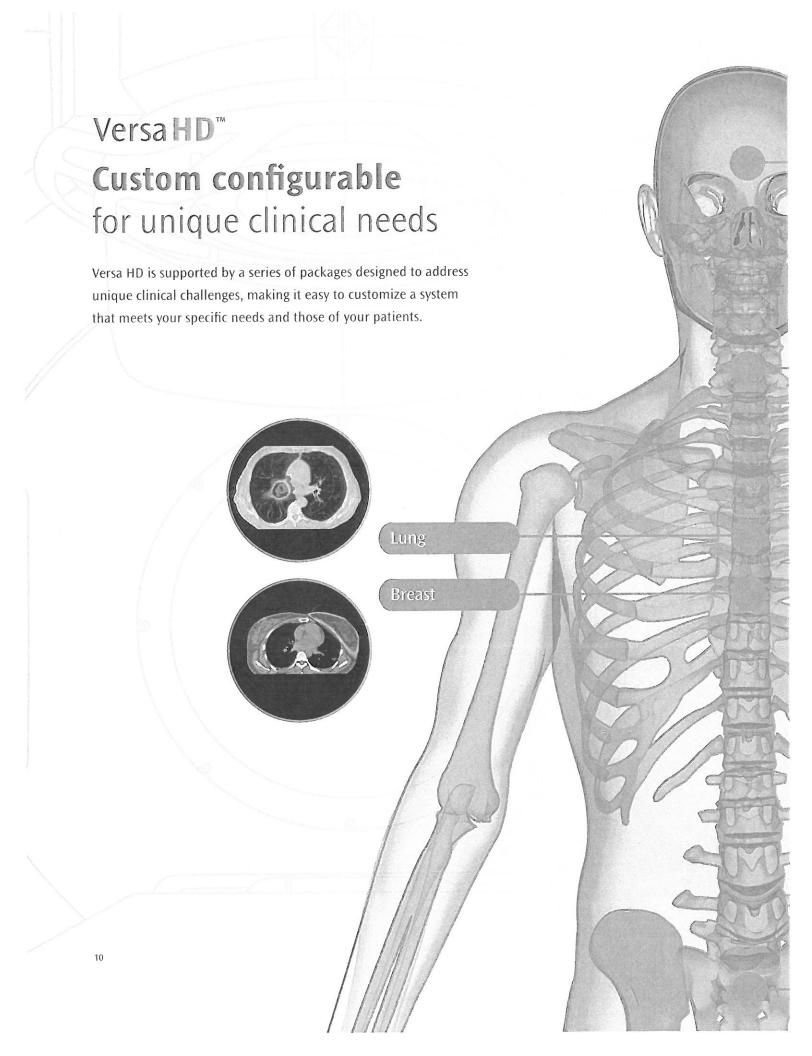
Versa HD is supported by Elekta's integrated software solutions to deliver immediate access to clinical and patient information. Rapid access to this data enables multi-disciplinary teams to make more informed treatment decisions. MOSAIQ enables clinicians to effortlessly coordinate the patient's entire continuum of oncology care. Through a powerful combination of clinical and patient data available at the user's fingertips, personalized treatments can be created across multiple modalities specific to each patient's disease. Advanced workflow customization and automation supports faster, more effective patient throughput, leading to greater efficiency and a paperless practice.

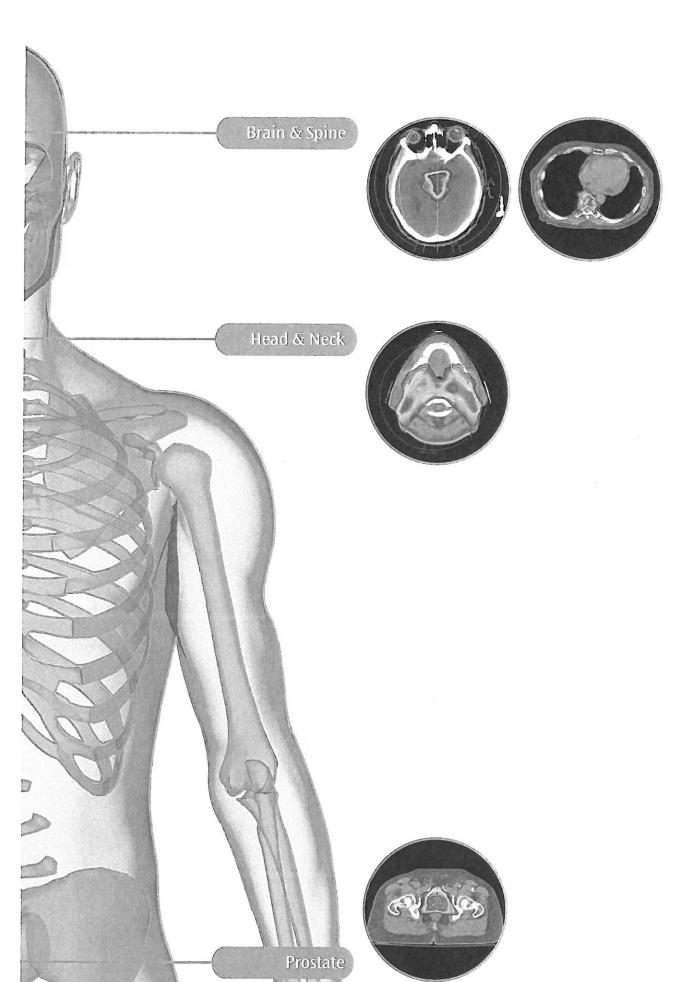


Precision plans for all major treatment techniques

With sophisticated tools to make planning easier, reproducible and clinically reliable, Monaco® redefines treatment precision and conformance, enabling the delivery of the most advanced 3D CRT, IMRT, VMAT and SBRT therapies. Powered by the Monte Carlo algorithm, the most accurate dose calculation currently available, Monaco leads the way in dose conformity, delivery efficiency and sparing of organs-at-risk. Combining these capabilities with modern architecture technology, Monaco sets a new standard in accuracy and speed, reducing planning and treatment times and improving plan quality.







Versa HD"

Safety by design

Versa HD was designed with patient safety in mind:

- Decrease collision risks with touch-activated patient protection and the market's largest isocenter clearance
- Reduce non-therapeutic doses with the lowest radiation transmission of any commercially available MLC
- Visualize broad regions-of-interest with the industry's largest IGRT cone-beam CT field-of-view
- Audit and safely orchestrate multiple linac functions with Elekta's seventh generation digital control system

rsa HD

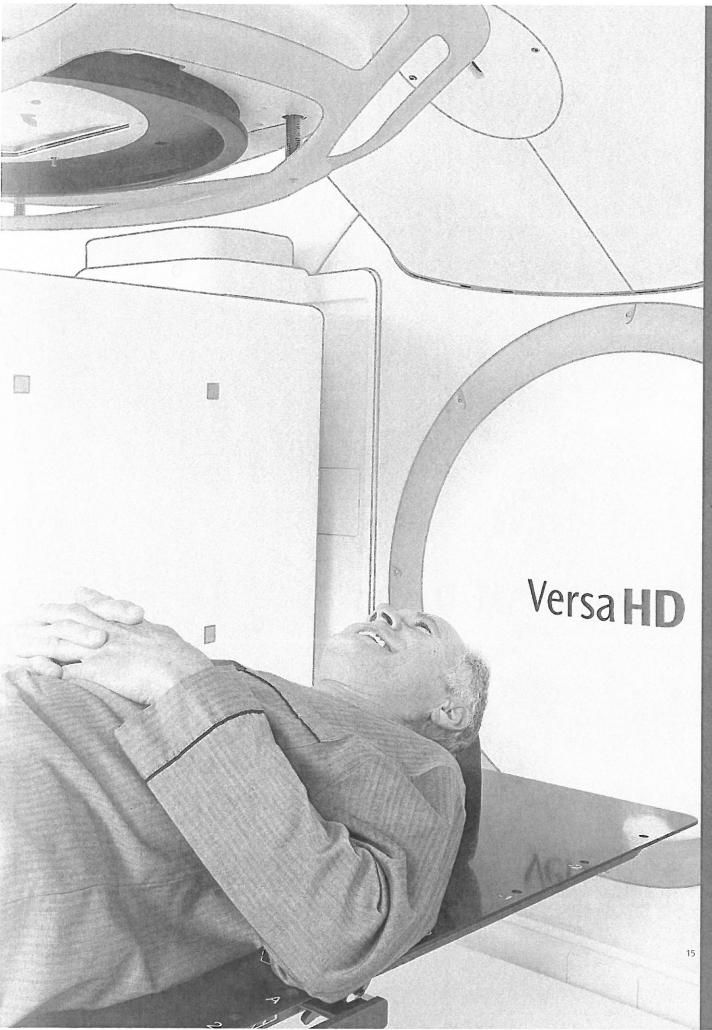
VersaHD™

Elevated patient experience

Versa HD is designed with new ergonomic features and softer streamlined shapes, creating a confident and relaxed treatment environment. Combining low mechanical noise with ambient lighting effects, Versa HD was designed with patient comfort in mind.

Real-time **remote system monitoring**

Elekta Remote Services proactively monitors key system functions in real time and provides notification of potential problems before they occur. With more than 25 years of digital linear accelerator expertise, Elekta provides Versa HD users with fewer delays and reduced downtime.



www.VersaHD.com

www.VersaHD.com



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) ELEKTA

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Exhibit C
Cost Summary

		Cost
Land	N/A	N/A
Equipment	Elekta VersaHD	\$1,350,000
Sales Tax	8%	\$108,000
Supplemental Shielding	N/A	N/A
Construction	Contractor	\$400,000
A/E Fees	Summit Designs	\$39,148
Professional Fees		\$30,000
Contingency	15% Construction/Design	\$65,872
Total Project Cost		\$1,993,020

Exhibit D

Documentation Supporting Costs

[See Attached]



Quotation Date: March 05, 2021

Date: March 11, 2021

Quotation

Prepared for:

21st Century Onc NC Weaverville ACCOUNTS PAYABLE 179 N BUNCOMBE SCHOOL RD WEAVERVILLE, North Carolina 28787-9615 United States Prepared by:

Robby Adams Healthcare Sales Director - Linac 400 Perimeter Center Terrace, Suite 50 Atlanta GA 30346

(t) +1 770 670 2503 (c) 404-513-3260 robby.adams@elekta.com

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

The estimated pricing set out in this Quote shall expire June 01, 2021

Hardware and/or Software Price

Description	Currency	Price
Total List price (*)	USD	\$7,103,506.57
Total Discount (*)	USD	\$5,753,506.53
Total Price (*)	USD	\$1,350,000.00

^{*} Excluding Taxes

For U.S. customers, this purchase is subject to the discount provisions of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and the discount safe harbor regulations at 42 C.F.R. § 1001.952(h). In accordance with such provisions, Customer shall fully and accurately report all prices paid net of discounts where appropriate, and as appropriate, in the costs claimed or charges made under any Federal or State healthcare program, and provide information upon request to Medicare, Medicaid and other applicable federal and state health care programs on all discounts and price reductions received from Supplier.

Price Payment Schedule

Unless otherwise agreed, all fees shall be due and payable in full upon final signature of an agreement. State, local, VAT and other taxes, and import/export licenses are not included in this Quotation.

Software

Unless otherwise agreed, the license fee for the Software embedded in the Hardware is included in the Price set forth above.

Delivery Date

Delivery date for the Deliverables is estimated to be within 120 days from date of agreement subject to payment of fees due. Delivery term shall be CIP Site as defined in Incoterms 2010.

Pricing confidentiality

This Quote and the pricing terms set out herein are negotiated between the Customer and Supplier and may be unique to the Customer. Therefore, and except as otherwise provided by law, Customer hereby agrees to keep the pricing arrangement confidential for a period of no less than three (3) years from the date signed quote. Customer will not use this Confidential Information in furtherance of its business, or the business of anyone else, whether or not in competition with the Supplier.



Quotation Date: March 05, 2021

Date: March 11, 2021

Purchase Order: _____



Quotation Date: March 05, 2021

Date: March 11, 2021

EXHIBIT A Scope of Supply for Hardware and/or Software

Elekta Versa HD™ Versa HD™ provides:

Digital accelerator with exclusive cover set design;

- 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;
6MV and 10MV flattened energies delivered as standard;
A broad spectrum of delivery techniques from 3D Conformal Radiotherapy to IMRT, VMAT and SRT techniques;
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;
iViewGT™, offering 2D MV imaging capability supporting image guided treatment workflows.
IntelliMax™ Intelligent Agent license is included. 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 interrect connection to the Agent PC opening secure port 443 (https). direct internet connection to the Agent PC opening secure port 443 (https).

Stereotactic MV Isocenter Setup
Service to evaluate the MV (Gantry), and combined MV (Gantry) and table isocenter using software tool based on the Winston Lutz test. The following values will be achieved at 6 MV;

- MV isocenter (Gantry): ≤ 0.7 mm radius
- Combined MV isocenter (Gantry) and table isocenter: ≤ 1.mm radius.

Goalpost Assembly

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Elekta Synergy® Platform, Elekta Synergy®, Elekta Infinity™, Elekta Axesse™ and Versa HD™ compatible standard goalposts.

- Versa HD standard cover set.
- High Dose Rate Mode Hardware Upgrade Kit

6MV High Dose Rate Software License

High Dose Rate Mode provides flattening filter free beam delivery of 6MV beams at dose rates up 1,400 MU/min, as well as reduction in scatter, lowering whole body radiation doses.

10MV High Dose Rate Software License

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.

- 6 MeV Electron Energy
- 9 MeV Electron Energy
- 12 MeV Electron Energy
- 15 MeV Electron Energy

U.S.A. Electron Flatness

Electron flatness according to U.S.A. standards, optimized at 100 cm.

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.



Quotation Date: March 05, 2021

Date: March 11, 2021

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Standard Set of Aperture Plate Electron Beam Applicators 1 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.

VMAT CAT (Volumetric Arc Therapy Customer Acceptance Test)

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™.

SYNERGISTIQ ™ Software License

Enables the XVI functionality to support SYNERGISTIQ. SYNERGISTIQ integrates MOSAIQ® and XVI into a consolidated and synchronized user interface

Software Media Pack, SYNERGISTIQ™ Clients

SYNERGISTIQ ™ Monitor kit

Specification for Extender/Receiver and cable for a remote monitor. Required for sites that use SYNERGISTIQ with a remote monitor in the treatment room.

kiloVoltage Cone-beam CT Hardware for Versa HD™

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™.

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.

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.

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.

3D Automated Seed Match License

Offers an optimized 3D registration algorithm to register implanted markers, without compromising on 3D volumetric information.

Hounsfield Units

Hounsfield Unit (HU) Scaling uses calibration measurements to calculate the HU mean accuracy to ±40 HU for the small field of view for specified imaging conditions. HU Scaling changes the pixel values for the 3D VolumeView images. HU calibration provides greater soft tissue detail, ensuring a more accurate picture of where dose is being delivered, aiding in critical structure avoidance.



Quotation Date: March 05, 2021

Date: March 11, 2021

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).

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Distributed Imaging allows the transfer a patient between XVI systems without having to prepare the registration settings on the secondary XVI system, through MOSAIQ®.

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

MRT 9931 ADAPTOR KIT. PHANTOM

XVI Daily QA Phantom Kit
Daily QA Phantom for kV and MV projection imaging and kV VolumeView™. Checks the laser and light field coincide and additionally provides a spreadsheet for recording and analyzing trend results.

XVI Water Calibration Kit

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

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.

2D TEST OBJECT, MRT 10321

DICOM 4D export

4D DICOM export allows the user to export to a third party system the CBCT data as generated by Symmetry™ of:

- Average phases
- All phases
- Single phase.

Archive and retrieve to network

Performs automatic archiving of patient images to a pre-defined network location, outside of MOSAIQ®. Archiving can be scheduled, and the network location can be specified at will. The same tool performs retrieval of files from the same location.

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.

iViewGT™ R3.4.1 Installation Kit

iViewGT™ R3.4.1 Software License

iViewGT ™ R3.4.1 Software License Collation

Third Party License toolkit necessary for supporting iViewGT.

Remote Retraction of the iViewGT™ detector - 30M

This kit allows Remote Retraction of the iViewGT detector from the Function Key Pad.



Quotation Date: March 05, 2021

Date: March 11, 2021

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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.

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 setup 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.

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.

Software License Image Approval

This allows the user, assigned with the 'review' permission, to approve or disapprove any image within iViewGT™ or iViewC™.

Las Vegas Calibration Phantom

The Las Vegas phantom is a device that is used to check image quality of a portal imaging device at different megavoltage energies both at acceptance and as part of the corrective maintenance procedure.

HexaPOD™ evo RT System Integration License

This license 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.

iBEAM® evo Extension 650 1

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 patient's.

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.

Beam Block Tray - Star PatternLexan 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.

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.

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

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

5 19-inch Control Room LCD Monitor



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Description Extender Cards Extender cards for fault diagnosis on the Electrical Interface Module (EIM). Customer Interface Terminal Board 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.

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.

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.

Applications training for iViewGT™

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.

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.

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.

Linac Labor Warranty



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Weekend Rigging & Handling

Basic rigging of Linac to first floor or ground floor location outside of Elekta's normal working hours. 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
- 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.
- iViewGT™ Amorphous Silicon detector panel for production systems.
- Drayage

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- Linac Installation 1
- 1 Open Air Graticule

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.

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Education & Training Travel Support (4-6 day course)
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 (ea)

Control System hardware for XVI R5.0.4

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.

XVI 5.0.4 Software Licenses



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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.

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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.

Intercom system for patient and radiographer communication 1

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.

Medical Gases SF6 for Installation and Service

Includes:

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- Cylinder
- Regulator
- Delivery

Medical Gases Nitrogen for Installation and Service

Includes:

- Cylinder
- Regulator
- Delivery

2 **Elekta Linear Accelerator Physics**

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 Sytem 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.)

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

Target Group

- Medical Physicists
- Medical Physics Students

Pre-requisites

None



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2 **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
- 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

Physics 1: Medical Accelerator Introduction

2 Volumetric Modulated Arc Therapy (VMAT) QA Objectives

After completing this course, attendees will:

- Explain the clinical rational for the VMAT treatment technique.
- Evaluate the key factors influencing the quality of VMAT plans. 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 A Frame for Installation/Service

Includes:

- A Frame
- Trolley
- Hoist (pulley)

Delivery Note: Not required if iBeam is in place.



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CHY 480VAC INPUT TRANSFORMER ONLY SYSTEM Software Media Kit, Integrity 4.0.5 MRT 29661 SHFR400 KV GENERATOR MAINS FILTER ASSEMBLY Control system CCP Pre-install cable kits 1 Elekta Linac Onsite Applications Training/Support 1 Onsite applications training follow up and/or applications support for the Elekta Linac. An Elekta Applications Specialist will review Elekta Linac workflows with staff, give workflow recommendations, and help address any problem areas. Maximum of 6 users: Radiation Therapists, Medical Physicists, Radiation Oncologist Duration: 2 days Location: Customer site

Elekta Stereotactic Radiosurgery and Stereotactic Body Radiotherapy Physics Course 2

During this 4-day course, participants will learn the physics behind the operation of an Elekta Medical Accelerator with Agility MLC, APEX

MLC, and Stereotactic Cones.

Students will build on the principles of operation of the accelerator as addressed in Elekta Medical Accelerator Physics 1 and the quality assurance aspects taught in Elekta Machine QA. Students will learn about the principles of each of the systems in regards to their Commissioning, Quality Assurance and Application for SRS and SBRT. Objectives

After completing this course, attendees will:

- Be able to accept, commission and QA the SRS/SBRT solution
 - Perform small field dosimetry

 - Perform commissioning measurements
 Describe the relationship of various isocenters in the accelerator
 - Perform Winston Lutz tests
 - Explain patient immobilization options
 - Describe IGRT options for patient positioning verification Explain appropriate routine QA tests

 - Perform End to End testing
 - Understand requirements of AAPM TG54, TG 101 and ASTRO Target Safety reports

Target Audience

- Certified Medical Physicists
- Medical Physics students

Prerequisites

Physics 1: Medical Accelerator Introduction

Pricing Includes

Tuition for one student

Pricing Does Not Include

- Airfare
- Travel-related expenses

Your eligibility for this course expires:

- Purchased with new equipment twenty-four (24) months after Acceptance or first clinical use, whichever occurs first.
- Purchased directly 24 months after Purchase Order is accepted.

MONACO MASTER BEAM MODELS 1

1 Linac removal & destruction by 3rd party.



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Description

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Elekta Linear Accelerator Physics Training
This course will cover the Theory of Operation, Control System and System Communication, Beam Measurement and Dosimetry, Agility Beam Limiting Device, Imaging Systems and Introduction to IGRT on the Medical Accelerator.

Medical Accelerator Quality Assurance Training 1

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.

Volumetric Arc Therapy Quality Assurance Training

During this 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.

iViewGT Linac Specific Activation License - DOSIsoft

This license is required to enable connectivity with iViewGT and is licensed per iViewGT workstation.

In Room Optical Kit

XVI Advanced Imaging Symmetry Training (Online)
This course is delivered 100% online as a virtual instructor led training. Users will learn how to create XVI Symmetry presets, prepare reference images for Symmetry, acquire Symmetry scans, and register Symmetry scans. This will be an interactive hands-on course that utilizes an Elekta XVI training database for practice exercises. Users will also have access to additional clinical educational content from Elekta Clinical Partners.

Target Audience

Radiation Therapists, Medical Physicists, Radiation Oncologist

Duration:

Online virtual instructor led training sessions will be delivered as 2, 1 hour sessions.

Location:

Online

HexaPOD™ evo RT System with iGUIDE® 2.2

The system consists of

- HexaPOD evo RT Couchtop with homogeneous carbon fiber couchtop
- Handheld controller
- iBEAM evo Extension 750 long
- iBEAM evo Extension 415
- iBEAM Indexing bars
- iGUIDE Reference Frame
- EnableSwitch board
- iGUIDE workstation iGUIDE 2.2 software
- iGUIDE tracking system
- iGUIDE terminal
- iGUIDE calibration Kit MIMI

HexaPOD evo - Universal Camera Mount - Kit

The Universal Camera Mount is part of the HexaPOD evo RT System and will be shipped form the service warehouses. The independent shipment from the warehouses enables a pre-installation of the UCM if required.

CONNECTIVITY, MONITORING AND REMOTE ACCESS DURING WARRANTY

For Linac:

In order to provide the warranty for the Products, the Customer agrees to provide dedicated high-speed broadband internet connections suitable to establish a remote connection to the necessary components including but not limited to Linac and associated components and facilitate the realization of the required remote infrastructure, as agreed by the Parties.



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If the Customer fails to provide the access described in this section and so the solution is not connected to Elekta IntelliMax[®] or equivalent Elekta approved solution (including any temporary disconnection), the Customer waives its rights to receive services and any uptime guarantees.

IntelliMax Agent software is installed on a standalone workstation or virtual machine. The IntelliMax Agent communicates with applicable products and acts as a gateway to the IntelliMax Enterprise (outbound via the internet). More than one IntelliMax Agent may be required for full connectivity. For more information see Elekta IntelliMax® Security Information, available from your Elekta representative.

Should remote access to the desktop of the device be reasonably necessary, IntelliMax Connect allows for either attended (mandatory for treatment machines) or unattended access (configurable during installation for software systems). Access via Elekta IntelliMax[®], and details of any files transferred are recorded in an audit log which is available on upon request for a period of 12 months after the transfer.

The Customer acknowledges and agrees that notwithstanding the provisions contained in Customer's Elekta Purchase and License Agreement, Elekta shall have the ability to remotely monitor Elekta supplied systems on the Customers network via Elekta IntelliMax[®] to gain information and aid in diagnosis and correction of system issues. Remote Access/screen sharing, is configurable separately and can be set to only allow visibility of the customer's screens when initiated by the customer.