NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

May 23, 2023

Elizabeth V. Kirkman
Elizabeth.Kirkman@atriumhealth.org

Exempt from Review – Replacement Equipment

Record #:	**4190**
Date of Request:	April 20, 2023
Facility Name:	Carolinas Medical Center
FID #:	943070
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace existing high dose radiation brachytherapy equipment
County:	Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Elekta Flexitron HDR 40CH Afterloader and Imaging Ring to replace the Varian VariSource iX HDR Afterloader (ID# H600450) and GE Goldseal Lightspeed Plus CT scanner (ID #317559CN3). 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,

Julie M. Faenza
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR
Construction Section, DHSR

April 20, 2023

Ms. Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center to Replace Brachytherapy Equipment

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Carolinas Medical Center ("CMC") seeks to acquire high dose rate ("HDR") brachytherapy equipment, comprised of an Elekta Flexitron HDR 40CH Afterloader and ImagingRing ("Replacement Equipment"), to replace existing HDR brachytherapy equipment comprised of a Varian VariSource iX HDR Afterloader that was acquired in 2006 and a GE Goldseal Lightspeed Plus CT scanner ("Existing Equipment") that was acquired in 2009. Both components of the Existing Equipment are beyond the end of useful life and are at risk for service interruption. Both components of the Existing Equipment are currently housed in room 1410 on the first floor of the Levine Cancer Institute building located on the main campus of CMC at 1021 Morehead Medical Drive in Charlotte, NC (see Attachment A).

Brachytherapy, also referred to as internal radiation therapy, is a form of cancer treatment that involves placing radioactive material within a patient's body. During this treatment, an applicator, which is a device through which radioactive material is delivered, is positioned within the body. Depending on the specific type and/or location of the cancer that is being treated, the patient may receive anesthesia during this process. Ensuring correct placement of the applicator is of the utmost importance when providing brachytherapy. As such, once applicator placement has occurred, imaging is used to ensure that the applicator is in the most effective location. Once the positioning of the applicator has been verified, the afterloader is used to insert radioactive material directly into the patient's body and thus deliver internal radiation therapy.

Currently at CMC, applicator placement must be done in one of the two procedure rooms within the brachytherapy suite. The patient then must be moved to room 1410, which houses both the existing CT scanner and the existing afterloader, in order for the applicator placement to be verified and for the internal radiation to be delivered (see Attachment A). Given the size of the existing CT equipment, which is what is used to verify the position of the applicator, there is not enough space to safely allow for the delivery of anesthesia and placement of the applicator to also be done in room 1410. The two-room process that CMC currently uses is less than ideal for both patients and providers. It increases the risk of displacing the applicator during the move and extends the length of treatment, which not only impacts patient experience but also operational efficiency.

As described above, CMC seeks to replace the existing GE Goldseal Lightspeed Plus CT scanner with an Elekta ImagingRing. The ImagingRing is a much smaller, moveable CT scanner that will allow for the entire brachytherapy treatment process to occur in one room. Streamlining this process will not only increase patient safety and reduce the risk of applicator displacement but will also shorten treatment time and result in a better overall experience for brachytherapy patients.

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review under the replacement equipment exemption provisions contained in Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6 (which are codified at N.C. Gen. Stat. 131E-184(f)(1)-(3)).

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," defined as follows in the CON law:

> "Replacement equipment" means equipment that costs less than three million dollars ($3,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. 131E-176(22a). Under the provisions found at N.C. Gen. Stat. 131E-184(f)(1)-(3), the CON law provides:

> (f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the monetary threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:
>
> (1) The equipment being replaced is located on the main campus.
> (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
> (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

See Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6. The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified N.C. Gen. Stat. 131E-176(14n)) as follows:

> (14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:
>
> a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
> b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is currently housed in room 1410 on the first floor of the Levine Cancer Institute building located on the main campus of CMC, which is the site from which CMC provides clinical patient services and exercises financial and administrative control over the entire facility (see Attachment A). CMC's Facility Executive's office is located on the second floor of the main hospital building. Please find a copy of CMC's license in Attachment B.

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be "comparable" to the equipment it replaces and the equipment being replaced must be "sold or otherwise disposed of when replaced." CMC's proposal qualifies for this exemption.

A. Cost of the Replacement Equipment

The purchase price of the Replacement Equipment is $1,385,874 ($1,062,563 Afterloader and ImagingRing + $229,545 ancillary equipment + $93,766 tax). The quote for the Replacement Equipment is provided in Attachment C. The projected total capital cost of the project is $3,300,000 (including taxes and freight) and includes the removal of the Existing Equipment and installation of the Replacement Equipment, as well as minor renovation of surrounding clinical and support space. The renovations include upgrades to the electrical infrastructure in two procedure rooms, the creation of an additional workstation in the nurses' station area, additional storage space in an adjacent corridor, and the installation of an additional sink in the prep/recovery area. The total capital cost for the proposed project is provided in Attachment D.

B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located in room 1410 on the first floor of the Levine Cancer Institute building located on the main campus of CMC at 1021 Morehead Medical Drive in Charlotte, NC. The Replacement Equipment will also be located in room 1410 (see Attachment A).

C. Certificate of Need Issued for Equipment Being Replaced

The Existing Equipment was acquired in 2006 and 2009. At that time, the cost of the Existing Equipment was less than the CON reviewability threshold for "major medical equipment" under N.C.G.S 131E-176(14o) and therefore did not require a Certificate of Need. However, in 2008 CMC filed – and the Agency approved – a letter of no review regarding the acquisition of a GE Goldseal Lightspeed CT scanner to be used exclusively with existing HDR equipment. A copy of the Agency's approval of the letter of no review from 2009 is included in Attachment E.

D. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

> "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

CMC intends to use the Replacement Equipment for substantially the same HDR brachytherapy procedures for which it currently uses the Existing Equipment. The existing brachytherapy equipment, which is comprised of a VariSource iX HDR Afterloader that was acquired in 2006 and a GE Goldseal Lightspeed Plus CT scanner that was acquired in 2009, has been used to provide brachytherapy services since acquisition.

The Replacement Equipment can and will perform all procedures currently performed on the Existing Equipment, although it possesses some expanded capabilities due to technological improvements (see Attachment F for the Equipment Brochure). The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, CMC does not intend to increase patient charges or per procedure operating expenses more than 10 percent within the first 12 months after equipment acquisition. For further equipment comparison, please refer to Attachment G, the Equipment Comparison Chart.

Subsection (d) of the regulation further provides:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
(3) the acquisition of the equipment does not result in more than a 10.0 percent increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The Replacement Equipment will meet all three of tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart (Attachment G). Moreover, CMC represents the use of the Replacement Equipment will not result in an expense or charge increase greater than 10 percent within the first 12 months after acquisition as described in Subsection (d)(3).

Documentation provided in Attachment H indicates that 306 brachytherapy procedures were performed from February 2022 to January 2023 on the Existing Equipment.

E. <u>Disposition of Equipment</u>

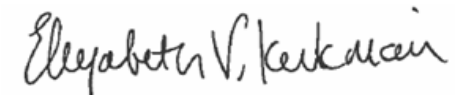
The Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate Certificate of Need approval.

CONCLUSION:

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,



Elizabeth V. Kirkman
Assistant Vice President
Atrium Health Enterprise Strategy Partners

Attachments

cc: Chan Roush, Vice President and Facility Executive, Carolinas Medical Center

Attachment A

Color Key

EXISTING BUILDING

PROJECT UNDER CONSTRUCTION

SCOTT DECK

MEDICAL EDUCATION BUILDING

ANNEX

RESEARCH OFFICE BUILDING

CANNON RESEARCH

ENERGY PLANT

NEW BED TOWER

CAROLINAS REHABILITATION

CAROLINAS MEDICAL CENTER

MCP DECK

MCP

MMP DECK

MMP

LEVINE CANCER INSTITUTE

LEVINE CANCER INSTITUTE

ADDITIONAL LEVINE CANCER INSTITUTE EXPANSION

LOT A PARKING DECK

SITE PLAN

BRACHYTHERAPY EQUIPMENT REPLACEMENT

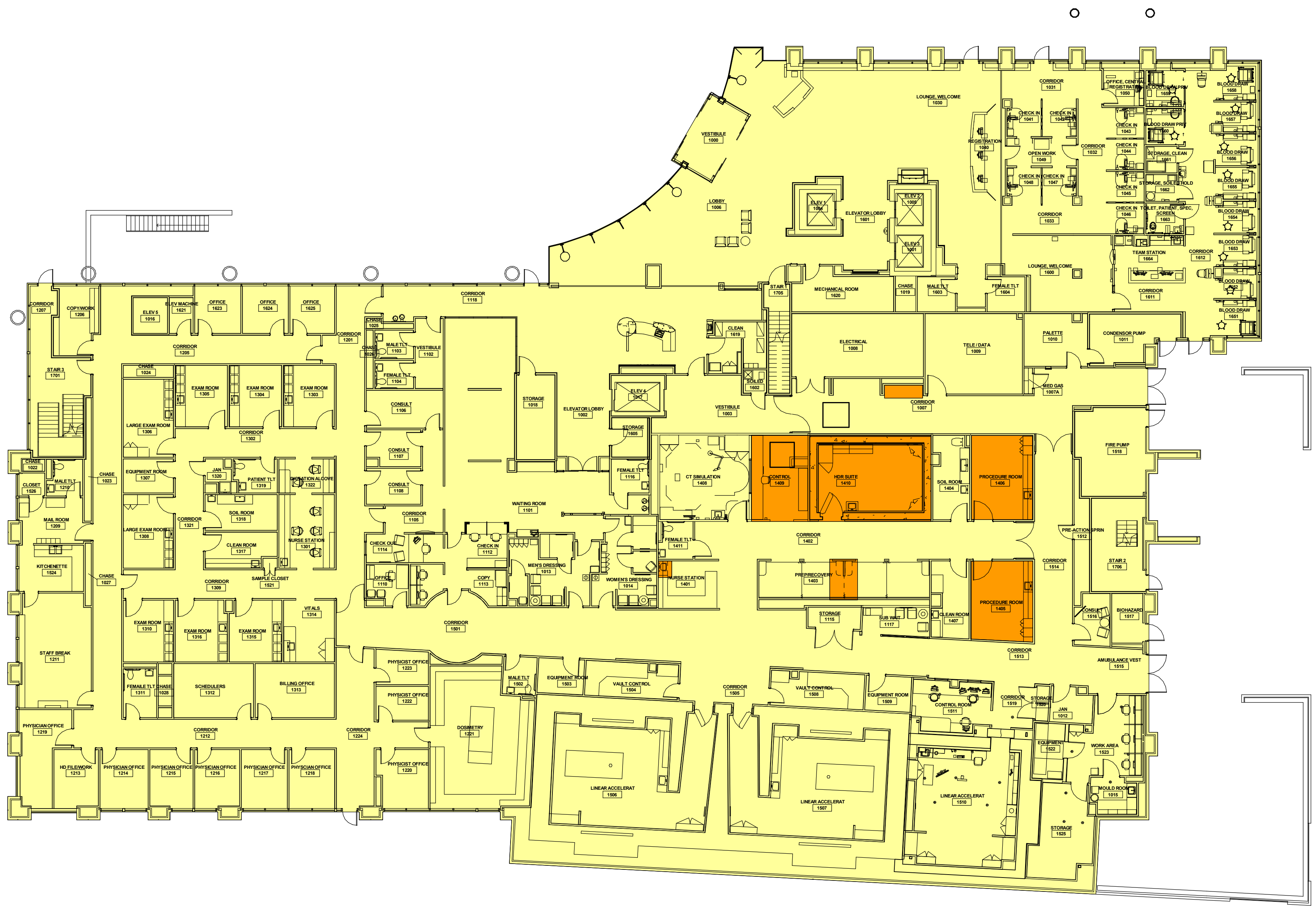
Atrium Health

03/16/23

CAROLINAS MEDICAL CENTER

Color Key

- EXISTING BUILDING
- RENOVATION



EXISTING LEVEL 01 PLAN

BRACHYTHERAPY EQUIPMENT REPLACEMENT

Atrium Health

03/16/23

CAROLINAS MEDICAL CENTER

Color Key

- EXISTING BUILDING
- RENOVATION

EXSITING LEVEL 01 ENLARGED

BRACHYTHERAPY EQUIPMENT REPLACEMENT

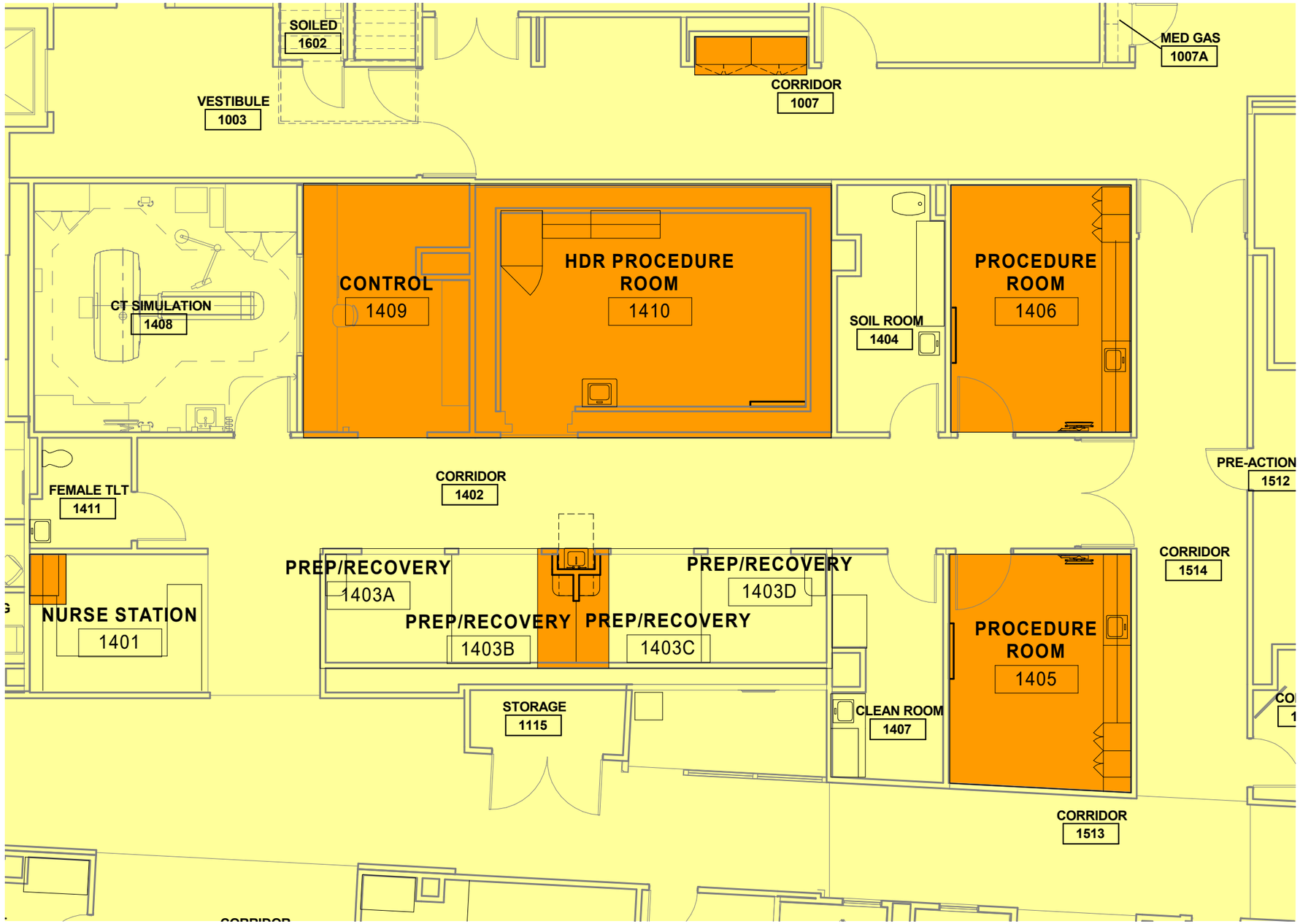
Atrium Health

03/16/23

CAROLINAS MEDICAL CENTER

Color Key

- EXISTING BUILDING
- RENOVATION



PROPOSED LEVEL 01 ENLARGED

BRACHYTHERAPY EQUIPMENT REPLACEMENT

Atrium Health

03/16/23

CAROLINAS MEDICAL CENTER

Attachment B

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 1, 2023, this license is issued to

The Charlotte-Mecklenburg Hospital Authority

to operate a hospital known as

Carolinas Medical Center/Center for Mental Health

located at Charlotte, NC, Mecklenburg County.

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

Facility ID: 943070 ***License Number: H0071***

Bed Capacity: ***1220***

General Acute: **1064** Rehabilitation: **13** Psych: **132** Substance Use Disorder: **11**

Dedicated Inpatient Surgical Operating Rooms: ***9*** *Shared Surgical Operating Rooms:* ***43***

Dedicated Ambulatory Surgical Operating Rooms: ***11*** *Dedicated Endoscopy Rooms:* ***12***

License Categories:

.5200 Dedicated Inpatient Unit for mental disorders

.5200 Dedicated Inpatient Unit for substance use disorders

Authorized by:

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

Director, Division of Health Service Regulation

Attachment C

Agreement number: 2022-374739-BL Version: 2 Date: March 3, 2023

Purchase and License Agreement

Customer ("the **Customer**")	End-User (if not the Customer) / Site address (the "**Site**")	Supplier (the "**Supplier**")
Atrium Health fka Carolinas Healthcare System 1000 Blythe Blvd. Charlotte, North Carolina 28203 United States Fax (704) 355-2000	Atrium Health Levine Cancer Institute 1021 Morehead Drive Charlotte, NC 28204 United States	Elekta Inc. 400 Perimeter Center Terrace Suite 50 Atlanta, Georgia 30346 United States Tel 800-535-7355 Fax 770-300-9779

Elekta Inc, a Georgia company is pleased to submit the following offer to sell/license the services, hardware and/or software listed on this Cover Page and described in more detail in the attached Scope of Supply (collectively referred to as "**Deliverables**") at the prices and terms stated in this Purchase and License Agreement, which consists of this Cover Page and all exhibits attached hereto (collectively referred to as the "**Agreement**"). All definitions shall, unless otherwise provided for herein, have the meaning ascribed to them in the exhibits.

The pricing for the Scope of Supply set out in Exhibit A of the Agreement is valid until March 15, 2023 and no agreement shall exist between the Customer and Supplier (jointly referred to as the "**Parties**" and each as a "**Party**") until this Agreement is signed by both Parties. In the event the Customer takes delivery of the Deliverables without signing this Agreement taking delivery shall constitute deemed acceptance of the terms and conditions set out herein.

This Agreement shall be governed by the terms and conditions of the PREMIER HEALTHCARE ALLIANCE, L.P. GROUP PURCHASING AGREEMENT-IMAGING PRODUCTS AND SERVICES agreement, CONTRACT NUMBER: PP-IM-400, entered into between Premier Healthcare Alliance Inc. and Elekta, Inc. dated September 1, 2019.

Price and Description of Deliverables

Unless otherwise agreed in writing between the Parties, Third Party Products and consumables are not included in the scope of this Agreement. Supplier reserves the right to increase the Contract Fee yearly in accordance with the Terms and Conditions attached hereto or referenced herein.

Hardware and/or Software Price

Description	Currency	Price
Flexitron HDR 40CH including Oncentra® and Applicators		
Imaging Ring Performance Package		
Biodex-820 Table		
Total Price (*)	USD	$1,062,562.60

* Excluding Taxes and applicable Consumer Price Index or other increase.

Services

Contract Description	Service level	Term	Total Service Fee (in USD)
ImagingRing Performance Maintenance and Support Fee	Gold	60 Months	$344,000.00
Flexitron Maintenance and Support Fee	Gold	60 Months	$250,054.39
Oncentra Brachy Maintenance and Support Fee	Gold	60 Months	$112,445.61
Oncentra Prostate Maintenance and Support Fee	Gold	60 Months	$94,000.00

* Excluding Taxes and applicable Consumer Price Index or other increase.

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.

Contract Payment Schedule-Flexitron HDR 40CH including Oncentra® and Applicators ($370,500.00)

The Customer agrees to pay Supplier the Contract Price according to the following schedule:

(i) 50% of the Contract Price shall be paid within 14 days of execution of this Agreement;

(ii) 40% of the Contract Price shall be invoiced 45 days prior to shipment (delivery to carrier for shipment to Customer) of the Hardware (excluding cobalt sources, if any); and

(iii) 10% of the Contract Price shall be payable upon the date that the Acceptance Test Protocol has been successfully completed.

If the Customer does not issue a Purchase Order at the time of execution of this agreement, Elekta invoices shall reference this Purchase and License Agreement Number.

Contract Payment Schedule- Imaging Ring Performance Package ($638,732.60)

The Customer agrees to pay Supplier the Contract Price according to the following schedule:

(i) 50% of the Contract Price shall be paid within 14 days of execution of this Agreement;

(ii) 40% of the Contract Price shall be invoiced 45 days prior to shipment (delivery to carrier for shipment to Customer) of the Hardware (excluding cobalt sources, if any); and

(iii) 10% of the Contract Price shall be payable upon the date that the Acceptance Test Protocol has been successfully completed.

If the Customer does not issue a Purchase Order at the time of execution of this agreement, Elekta invoices shall reference this Purchase and License Agreement Number.

Contract Payment Schedule- Imaging Ring Performance Package ($53,330.00)

The Customer agrees to pay Supplier the Contract Price according to the following schedule:

(ii) 100% of the Contract Price shall be invoiced 45 days prior to shipment (delivery to carrier for shipment to Customer) of the Hardware (excluding cobalt sources, if any); and

If the Customer does not issue a Purchase Order at the time of execution of this agreement, Elekta invoices shall reference this Purchase and License Agreement Number.

Software

The license fee for the Software embedded in the Hardware is included in the Contract Price and there shall be no additional license fee beyond the Contract Price.

Hardware Maintenance and Support Service Fee
The Customer agrees to pay to Supplier the annual Service Fee set out in the Cover Page. The Service Fee is payable in advance on the date of expiration of the Warranty Period, and on each succeeding anniversary date of the date of expiration of the Warranty Period, while this Agreement remains in force.

Contractual Delivery Date- Flexitron HDR 40CH including Oncentra® and Applicators
The Contractual Delivery Date for the Products shall be no later than July 2023. Delivery term shall be CIP Site as defined in Incoterms 2010.

Contractual Delivery Date- Imaging Ring Performance Package
The Contractual Delivery Date for the Products shall be no later than July 2023. Delivery term shall be CIP Site as defined in Incoterms 2010.

Contractual Delivery Date- Biodex -820 Table
The Contractual Delivery Date for the Products shall be no later than July 2023. Delivery term shall be CIP Site as defined in Incoterms 2010.

Site Readiness
The Customer agrees that it shall have met all Site Requirements no later than July 2023.

Scope of Supply
The Parties hereby acknowledge and agree that the Supplier has the right to amend the Scope of Supply set out at Exhibit A prior to Delivery for reasons including but not limited to, end of life and superseded product revisions, upon written notice to Customer provided always that such change does not result in any less functionality or higher cost to the Customer.

Restrictions
The supply by the Supplier of the Deliverables is contingent upon the Supplier being able to (i) satisfy any and all applicable laws or regulations, export controls or sanctions requirements (together, the "Controls"), and (ii) obtain all necessary licenses. The Supplier shall not be liable for any non-performance or any delay in performance under this Agreement in the event that there is (i) a change in the Controls (including a change in the interpretation of the Controls by the competent authorities) or (ii) a refusal or a delay by any applicable competent authorities to issue a license or (iii) a refusal by a Third Party Supplier or financial service provider to engage in transactions with any particular country. Further, the Supplier shall not be liable for any non-Performance or any delay in performance under this Agreement where this is due to the Supplier, acting reasonably, determining that it is unsafe to send a service engineer or other personnel to the relevant country. Supplier will not be required to deliver any Products or provide Services to locations, persons, and/or entities prohibited by applicable export laws and regulations.

Miscellaneous
This Agreement 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 of this signed Agreement. 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.

Notwithstanding anything else in this Agreement, Supplier shall be entitled to list major terms of this Agreement, including the Products and Services that have been purchased and the name of the Customer in its tender, marketing and promotional materials to other customers. Further, the Supplier shall be entitled to provide Customer information to the Third Party Supplier if reasonably requested by the Third Party Supplier. The Customer hereby consents to the use of its name in connection with the foregoing.

Terms of this Agreement

THIS AGREEMENT INCLUDES THIS COVER PAGE, THE EXHIBITS ATTACHED TO THIS COVER PAGE AND THE ADDITIONAL EXHIBITS DESIGNATED IN THE TABLE SET FORTH BELOW (IF ANY), ALL OF WHICH ARE INCORPORATED INTO THIS AGREEMENT BY REFERENCE AND THE GROUP PURCHASING AGREEMENT NUMBER PP-IM-400 BETWEEN ELEKTA AND PREMIER HEALTHCARE ALLIANCE GROUP. IN THE EVENT OF ANY CONFLICT, THE CONTRACT DOCUMENTATION SHALL, UNLESS OTHERWISE SET OUT IN THIS AGREEMENT, BE GIVEN THE FOLLOWING ORDER OF PRECEDENCE:

(a) COVER PAGE.
(b) PREMIER HEALTHCARE ALLIANCE GROUP PURCHASING AGREEMENT NUMBER PP-IM-400
(c) EXHIBITS, IN THE ORDER SET FORTH BELOW.

Applies to this Agreement	List of Exhibits	Agreement Number	Date Executed
Yes	Exhibit A: Scope of Supply for Hardware and/or Software	Attached Hereto	
Yes	Exhibit A-1 and A-2: Scope of Supply for Services	Attached Hereto	
Yes	Exhibit B: General Terms and Conditions	Exhibit J of Group Purchasing Agreement PP-IM-400 between Elekta, Inc. and Premier Healthcare Alliance Group	Incorporated by Reference Upon Signature of this Agreement by both parties,
Yes	Exhibit C: Terms and Conditions for Hardwar	Exhibit J of Group Purchasing Agreement PP-IM-400 between Elekta, Inc. and Premier Healthcare Alliance Group	Incorporated by Reference Upon Signature of this Agreement by both parties,
Yes	Exhibit D: Terms and Conditions for Software	Exhibit J of Group Purchasing Agreement PP-IM-400 between Elekta, Inc. and Premier Healthcare Alliance Group	Incorporated by Reference Upon Signature of this Agreement by both parties,
Yes	Business Associate Agreement		4/26/2021
Yes	Exhibit F: Terms and Conditions for Services	Exhibit J of Group Purchasing Agreement PP-IM-400 between Elekta, Inc. and Premier Healthcare Alliance Group	Incorporated by Reference Upon Signature of this Agreement by both parties,

-Signature lines on next page-

Customer:	Carolinas Healthcare System	**Supplier:**	Elekta Inc.
Signature:	_____	Signature:	_____
Print Name:	_____	Print Name:	_____
Title:	_____	Title:	_____
Date:	_____	Date:	_____

EXHIBIT A
Scope of Supply for Hardware and/or Software

Flexitron 40-Channel Treatment Unit HDR with TCC (Treatment Control Console) and TCP (Treatment Control Panel). Requires trade-in of competitive treatment unit. Customer responsible for source removal prior to trade in. [2022-374742-BL]

Qty	Article number	Description
1	136149A02	**Flexitron HDR 40CH (100-120V)** The Flexitron system is a remotely controlled brachytherapy afterloading system. In combination with dedicated applicators, the Flexitron is suitable for intracavitary, interstitial, intraluminary, bronchial, endovascular, intra-operative, and surface brachytherapy treatment. The Flexitron HDR is a High Dose Rate brachytherapy configuration that is designed to accept Flexisource HDR (iridium-192) sources, and is available in different channel versions: 10 channels, 20 channels, and 40 channels. The treatment unit features: • Mobile treatment delivery unit with built-in source container for approved storage of up to 444 GBq (12 Ci) Ir-192. Nominal source strength for HDR Iridium-192 (370 GBq (10.0 Ci)). • Super flexible source cable made of one piece with a partial reduced diameter from Ø 0,85mm to Ø 0,5mm • Metric source stepping with a 1mm resolution to any position in the 400mm treatment window • Cyber security and patient data protection feature in compliance with regulatory standards • Enabled option for installing connectivity to OIS via DICOM Unified Worklist • Forward stepping source to ensure the most accurate treatment delivery • Channel selector that permanently monitors all connections • Additional battery powered DC motor source retraction system as back up for source return security • Additional manual source retraction system with drive motor disconnection mechanism as second back up for source return security • Integrated radiation detector for source return confirmation • Modular precision source drives which permanently monitor all source steps made Includes: • A check cable with a dummy source • One GYN SS Transfer Tube (111683 – GYN SS Transfer Tube Keyed 5) for connection to the Source Position Check Ruler and to an optional Source Verification System • Treatment Communication Console (TCC) on a desktop PC, 24” TFT display. • HDR Treatment Control Panel (TCP) including cables & installation kit • Uninterruptible Power Supply (UPS) • Flexitron HDR User Manual The Treatment Communication Console features a simple, visual user interface which facilitates easy operation of an extensive number of functions: • Importing treatment planning parameters in DICOM format from Brachytherapy planning systems via network, CD/DVD, or USB storage. • Preparation of treatments • Store and retrieve for later sessions • Monitoring and display of the ongoing treatment • Enhanced security with authorization levels • Extensive reporting • Logging of treatment and machine data

Accessories

Qty	Article number	Description
1	136192	**Transport Container for Ir192 Sources consisting of:** Internationally approved low weight tungsten transport and service container for the transportation of one Ir192 FlexiSource source to and from Flexitron units.
1	136164	**Source Exchange Tool consisting of:** The source exchange tool is required to load or unload sources from the Flexitron
1	136201	**Room Or Corridor Light Column consisting of:** Room or corridor light column to be used as additional status indicator for the Room Radiation Monitor System or treatment status indicator for the Afterloader.
1	105061	**Storage Cabinet** This Storage Cabinet is a floor mount cabinet, which can be used to store HDR and PDR Transfer tubes, accessories and applicators.
2	136197	**Transfer Tube & Accessories Holder consisting of:** Wall mounted storage for transfer tubes, adaptors, accessories & guide-wires
1	998USGEN015	**Power Conditioner**

QA & Safety Tools

Qty	Article number	Description
1	136191	**Emergency Set consisting of:** Flexitron emergency set consisting of an emergency container, forceps and cutter.
1	136196	**3 CH Source Position Check Ruler** Flexitron QC tool to verify the correct treatment position of the sources & check-cable and the length of each of the transfer tubes. The scale ranges from 0 to 400 mm. Includes a wall bracket to keep the position ruler at fixed distance to a camera and the #137183 - SPCR Adapter Set to connect GYN SS Transfer Tubes.
1	138200	**Source Position Simulator for Flexitron with dummy source cable** Source Position Simulator with a dummy source cable for measurement of the internal length of applicators and to visualize dwell positions radiographically. For use with the Flexitron HDR, PDR and Cobalt afterloaders only.
1	138227	**SPS Replacement slide with x-ray markers** Replacement slide with x-ray markers to visualize dwell positions radiographically. To be used with the Flexitron HDR, PDR or Cobalt afterloaders only.
1	136134	**Remote Controlled Camera** Camera located in the treatment room, that allows to monitor the source position in the source position check ruler, during an alignment procedure.

Iridium Sources x 4

Qty	Article number	Description
1	136147	**Flexisource Iridium-192 (Ø 0.85mm x 4.5mm), 10 Ci** The Flexitron source-capsule is connected to a super flexible drive cable for moving and positioning the source up to 1400 mm (dwell position 400). The source activity is 10 Ci +/- 10% at moment of delivery on site.
1	136148	**Flexitron Check Cable consisting of:** Check cables are to be replaced with every source replacement (at least every 6 month) Check cables are automatically included in the source supply contract.
1	997400A05	**Area E: Shipping And Handling Costs**
3	136147	**Flexisource Iridium-192 (Ã˜ 0.85mm x 4.5mm), 10 Ci** The Flexitron source-capsule is connected to a super flexible drive cable for moving and positioning the source up to 1400 mm (dwell position 400). The source activity is 10 Ci +/- 10% at moment of delivery on site.
3	136148	**Flexitron Check Cable consisting of:** Check cables are to be replaced with every source replacement (at least every 6 month) Check cables are automatically included in the source supply contract.
3	997400A05	**Area E: Shipping And Handling Costs**

Transfer Tubes and Markers

Qty	Article number	Description
2	110400	**X-ray Catheter Set GYN CT/MR for Flexitron** The X-ray catheter sets GYN are an aid using X-ray or CT imaging intended for verification and treatment planning of source positioning for Elekta GYN CT/MR applicators in combination with the Flexitron afterloader. Consisting of: Qty # Part 1 110401 CT/MR X-Ray Catheter, R1 1 110402 CT/MR X-Ray Catheter, O1 1 110403 CT/MR X-Ray Catheter, O2 1 110404 CT/MR X-Ray Catheter, IU3
1	110570	**X-ray Catheter Set GYN Stainless Steel (SS) for Flexitron** The X-ray catheter sets GYN are an aid using X-ray or CT imaging intended for verification and treatment planning of source positioning for Elekta GYN Stainless Steel applicators in combination with the Flexitron afterloader. Consisting of: Qty # Part 1 110571 CT/MR X-Ray Catheter, R1 1 110572 CT/MR X-Ray Catheter, O1 1 110573 CT/MR X-Ray Catheter, O2 1 110574 CT/MR X-Ray Catheter, IU3
4	110610	**CT marker 100 mm, Green (set of 3) for Flexitron** The CT markers are to support the Flexitron way of working for Flexible Implant Tubes. The CT markers are available in lengths that support the majority of cases using Flexible Implant Tubes. During imaging, the marker is kept in place by means of a built-in spring mechanism. The curve of the CT marker acts as a spring to prevent the CT marker from shifting in the applicator. Consisting of: Qty # Part 3 110614 CT Marker 100mm
4	110611	**CT marker 200 mm, Green (set of 3) for Flexitron** The CT markers are to support the Flexitron way of working for Flexible Implant Tubes. The CT markers are available in lengths that support the majority of cases using Flexible Implant Tubes. During imaging, the marker is kept in place by means of a built-in spring mechanism. The curve of the CT marker acts as a spring to prevent the CT marker from shifting in the applicator. Consisting of:

Qty	Article number	Description
		Qty # Part 3 110615 CT Marker 200mm
2	111650	**CT/MR GYN Transfer Tube Set (for Flexitron)** The CT/MR GYN Transfer Tube Set for Flexitron provides the option to connect CT/MR applicators to the Flexitron. Consisting of: Qty # Part 1 111651 CT/MR GYN Transfer Tube keyed # 1 1 111652 CT/MR GYN Transfer Tube keyed # 3 1 111653 CT/MR GYN Transfer Tube keyed # 5
1	137094	**Flexitron Transfer Tube Set for 6F Flexibles (1-10)**
1	137095	**Flexitron Transfer Tube Set for 6F Flexibles (11-20)**
1	137096	**Flexitron Transfer Tube Set for 6F Flexibles (21-30)**
1	137097	**Flexitron Transfer Tube Set for 6F Flexibles (31-40)**
1	111680	**GYN SS Transfer Tube Set (for Flexitron)** The GYN SS Transfer Tube Set for Flexitron provides the option to connect Stainless steel applicators with a GYN connection to the Flexitron. Consisting of: Qty # Part 1 111681 GYN SS Transfer Tube keyed # 1 1 111682 GYN SS Transfer Tub Tube keyed # 3 1 111683 GYN SS Transfer Tube keyed # 5
1	137180	**Source Position Check Ruler Adaptor Set to connect CT/MR GYN Transfer Tubes** This set is required for connecting the CT/MR GYN Transfer Tube Set (#111650) to the Source Position Check Ruler (SPCR, #136196). This set consists of the Source Position Check Ruler adapter (#137181) and a user manual.
1	137182	**SPCR Adapter Set To Connect GYN SS Transfer Tubes consisting of:** This set is required for connecting the GYN SS Transfer Tube Set (#111680) to the Source Position Check Ruler (SPCR, #136196). This set consists of the SPCR adapter (#137183) and a user manual. Note that the GYN SS adapter #137183 is also included as a standard part of the Flexitron Source Position Check Ruler (# 136196).
1	137043	**Source Position Check Ruler Adapter Set to connect 6F Catheter Transfer Tubes** This set is required for connecting a 6F Catheter Transfer Tube Set (#137094, #137095, #137096, #137097) to the Source Position Check Ruler (SPCR, #136196). This set consists of the Source Position Check Ruler adapter (#137781) and a user manual.
1	137090	**Flexitron Transfer Tube Set for 5F Flexibles (1-10)**
1	137091	**Flexitron Transfer Tube Set for 5F Flexibles (11-20)**
1	137092	**Flexitron Transfer Tube Set for 5F Flexibles (21-30)**
1	137042	**Source Position Check Ruler Adapter Set to connect 5F Catheter Transfer Tubes** This set is required for connecting a 5F Catheter Transfer Tube Set (#137090, #137091, #137092, #137093) to the Source Position Check Ruler (SPCR, #136196). This set consists of the Source Position Check Ruler adapter (#137780) and a user manual.

LumenCare Azure for Lung Brachy & Source Calibration

Qty	Article number	Description
2	110690	**LumenCare Azure, 5F x 140cm for Flexitron (5 pcs)** The LumenCare Azure is a blue flexible tube-applicator that provides an unobstructed, closed path to guide a radioactive source to the treatment area. The LumenCare Azure has centimeter marks (line + number) from 1 up to 85 cm to measure how far the catheter is inserted. A melted closed tip prevents the source cable from falling out and dirt entering. Contains a box with 5 pieces of 5F Single-use sterile catheters to be used with the Flexitron.
1	137673	**X-Ray marker # 1400BC-1, 5F for Flexitron** X-Ray marker for LumenCare Azure 5F 1400 mm for channel 1, with a length of 1400 mm for using X-Ray or CT imaging and the Flexitron afterloader. The coded markers enable each catheter to be identified and easily reconstructed for treatment planning.
1	137674	**X-Ray marker # 1400BC-2, 5F for Flexitron** X-Ray marker for LumenCare Azure 5F 1400 mm for channel 2, with a length of 1400 mm for using X-Ray or CT imaging and the Flexitron Afterloader. The coded markers enable each catheter to be identified and easily reconstructed for treatment planning.
2	137064	**Flexitron Adaptor For 5F Catheters (black)**

Applicator Clamp and Base Plate CT/MR

Qty	Article number	Description
1	189932	**CT/MR Applicator Clamp with Base Plate** The CT/MR Applicator Clamp is fully compatible with CT and MR imaging. It will not distort the images nor will it be influenced by the magnetic field. All variables such as length, rotation, sloping and angle of the inserted applicator can be fixed by turning one knob. For fixation of the applicator itself, various inserts are provided that allow fitting all available Elekta applicators within the clamp. The entire assembly requires no oil, which will allow the clamp to be easily taken apart for cleaning purposes. All clamp components can be steam sterilized. The CT/MR Applicator Clamp is attached to a base plate for immobilization in any hospital bed. Consisting of: Qty Part 1 Fixation Part 1 Base plate 4 Insert Ø 3 4 Insert Ø 6 4 Insert Ø 12
1	189982	**Set Of 4 Inserts Ø 12mm (black colored)**

Single Channel Cylinders CT/MR

Qty	Article number	Description
1	101007	**Set Of 4 Cylinders, 20mm**
2	101008	**Set Of 4 Cylinders, 25mm**
7	101009	**Set Of 4 Cylinders, 30mm**
1	101010	**Set Of 4 Cylinders, 35mm**
8	101006	**Cylinder Fixation**
8	101013	**Perineal Bar**

Qty	Article number	Description
1	101012	**Sterilizing Caps, CT/MR consisting of:** Pack of 50. To be used during sterilization of CT and MR applicators.
5	101149	**Knob PPSU**

Multi-Channel Cylinders CT/MR

Qty	Article number	Description
8	101002	VAGINALTUBE
1	110752	**Set Of Vaginal CT/MR Multi Channel Components 25mm**
1	110756	**Set Of Vaginal CT/MR Multi Channel Components 30mm**
1	101003	INTRAUTERINE TUBE 40MM/15 DEG
1	101004	INTRAUTERINE TUBE 60MM/30 DEG
1	101005	INTRAUTERINE TUBE 80MM/45 DEG
1	110787	**CT Expansion Set With Titanium Tubes** The CT Expansion set consists of a titanium intravaginal tube, three different intrauterine tubes and a sleeve which facilitates the use of these tubes in the Vaginal CT/MR Multi Channel Applicator set (part # 110750). Less invasive placement of intrauterine tubes in the uterus is enabled by this set due to their reduced outer diameter of the tubes. The set is compatible with CT imaging for volume-based treatment planning.
1	110773	**Perineal Bar Set consisting of:** The Perineal Bar Set is used with the Vaginal CT/MR Multi Channel Applicator to immobilize the applicator with respect to the patient. This set consists of a ventral and dorsal part and two levers. This Perineal Bar Set is non-metallic and therefore fully compatible with CT and MR imaging modalities. Consisting of: Qty # Part 1 110774 Perineal Bar Ventral 1 110776 Perineal Bar Dorsal 2 110779 Perineal Bar Lever
1	110774	**Perineal Bar Ventral** Compatible with the Multi channel applicator set
1	110776	**Perineal Bar Dorsal** Compatible with the Multi channel applicator set.
1	110779	**Perineal Bar Lever** Compatible with the Multi channel applicator set.
1	110771	**Set Of Fixations Screws (5 pcs) consisting of:** Spare screws for the Vaginal CT/MR Multi Channel Applicator, made out of PPSU. Consisting of: Qty # Part 5 110772 Fixation Screw
1	110778	**Applicator Clamp Set consisting of:** Set for connecting a Vaginal CT/MR Multi Channel applicator to a CT/MR Applicator Clamp 189931 and 189932. Consisting of: Qty # Part 1 110785 Applicator Clamp Adaptor 1 110779 Perineal Bar Lever

Qty	Article number	Description
1	189039	**CT Marker Set, 294mm, Yellow (package of 18)** The CT-Markers are designed to indicate source positions on CT images. The markers fit the ProGuide needle with diameters from 4F to 6F. During imaging, the marker is kept in place by means of a built-in spring mechanism. The curve of the CT marker acts as a spring to prevent the CT marker from shifting in the applicator. Consisting of: Qty # Part 18 189089 CT Marker, 294mm yellow
1	137070	**X-ray Marker Set 1, 3, 5 300mm GYN Titanium** The X-ray marker set GYN Titanium are an aid using X-ray or CT imaging intended for verification and treatment planning of source positioning for Elekta GYN Titanium applicators in combination with the microSelectron or Flexitron afterloader. Consisting of: Qty # Part 1 137590 X-ray marker #300 G-1 1 137591 X-ray marker #300 G-3 1 137592 X-ray marker #300 G-5
1	137063	**Transfer Tubes Set (Flexitron) For Gynecological (Ti) Applicators** Set of transfer tubes for gynecological titanium applicators, keyed for channel 1, 3 & 5 (black)
3	110800	**Catheter Set With Collar 6F x 293mm (10 pcs) consisting of:** Set of 10 catheters required for the Precise Dose Delivery Solution (PDDS™) in the Vaginal CT/MR Multi Channel Applicator. The catheters are flexible so they can be placed into the curved surface channels of the applicator and reach into the tip. This way the source paths are close to where it matters most, the vaginal vault. The catheters have a collar on the outside of the tubing to facilitate fixation of the catheters in the applicator, ensuring your catheter positioning during treatment.

Advanced Skin Package (Leipzig / Valencia FT / Freiburg Flap)

Qty	Article number	Description
1	592976	**Freiburg Flap**
1	189367	**Cutter Flexible Implants**
1	110820	**Valencia Ft Skin Applicator Set** This Flexitron HDR applicator is a tungsten shielded applicator designed for surface lesions utilizing a contact treatment technique. This applicator is equipped with a unique fixed flattening filter that will provide you with a flat homogeneous isodose pattern. It can be used for superficial and intra-oral lesions. The applicators are available in two sizes: 20 and 30mm diameter. Consisting of: Qty # Part 1 110821 Valencia Ft Skin Applicator, d=20mm 1 110822 Valencia Ft Skin Applicator, d=30mm 2 085115 Cap with marker ring, d=20mm 2 085116 Cap with marker ring, d=30mm 2 085118 Cap, d=20mm 2 085119 Cap, d=30mm 1 084158 Sterilizing Caps, 3.2mm (pack of 50)
1	189786	**Adaptor 1000+ Well Chamber**
1	189282	**Radio Opaque Button White, 6F consisting of:** Box of 72
1	189850	**X-Ray Catheter Set, 30cm (19-30)** X-ray marker set numbered from 19-30, with a length of 300mm for use in combination with the microSelectron

Qty	Article number	Description
		and Flexitron afterloader. The coded markers enable each catheter to be identified and easily reconstructed for treatment planning. Consisting of: Qty # Part 1 189852 X-Ray Catheter no.19, 30cm 1 189853 X-Ray Catheter no.20, 30cm 1 189854 X-Ray Catheter no.21, 30cm 1 189855 X-Ray Catheter no.22, 30cm 1 189856 X-Ray Catheter no.23, 30cm 1 189857 X-Ray Catheter no.24, 30cm 1 189858 X-Ray Catheter no.25, 30cm 1 189859 X-Ray Catheter no.26, 30cm 1 189860 X-Ray Catheter no.27, 30cm 1 189861 X-Ray Catheter no.28, 30cm 1 189862 X-Ray Catheter no.29, 30cm 1 189863 X-Ray Catheter no.30, 30cm
1	085041	**Leipzig Applicator, d = 10mm**
1	085042	**Leipzig Applicator, d = 20mm**
1	085043	**Leipzig Applicator, d = 30mm**
1	085114	**Cap, d = 10mm With Marker Ring**
1	085115	**Cap, d = 20mm With Marker Ring**
1	085116	**Cap, d = 30mm With Marker Ring**
1	085117	**Cap, d = 10mm**
1	085118	**Cap, d = 20mm**
1	085119	**Cap, d = 30mm**
1	189300	FLEX IMPLANT TUBE 6F30CM SL36X
1	089420	**X-Ray Catheter Set, 30cm (1-18)** X-ray marker set numbered from 1-18, with a length of 300mm for use in combination with the microSelectron and Flexitron afterloader. The coded markers enable each catheter to be identified and easily reconstructed for treatment planning. This set is a combination set of the sets #089082 & #089083. Consisting of: Qty # Part 1 089421 X-Ray Catheter no.1, 30cm 1 089422 X-Ray Catheter no. 2, 30cm 1 089423 X-Ray Catheter no. 3, 30cm 1 089424 X-Ray Catheter no. 4, 30cm 1 089425 X-Ray Catheter no. 5, 30cm 1 089426 X-Ray Catheter no. 6, 30cm 1 089427 X-Ray Catheter no. 7, 30cm 1 089428 X-Ray Catheter no. 8, 30cm 1 089429 X-Ray Catheter no. 9, 30cm 1 089430 X-Ray Catheter no. 10, 30cm 1 089431 X-Ray Catheter no. 11, 30cm 1 089432 X-Ray Catheter no. 12, 30cm 1 089433 X-Ray Catheter no. 13, 30cm 1 089434 X-Ray Catheter no. 14, 30cm 1 089435 X-Ray Catheter no. 15, 30cm 1 089436 X-Ray Catheter no. 16, 30cm 1 089437 X-Ray Catheter no. 17, 30cm 1 089438 X-Ray Catheter no. 18, 30cm 1 089439 Measuring wire, 30cm

Qty	Article number	Description

Geneva Universal Tandem & Ovoid Applicator Set CT/MR

Qty	Article number	Description
1	189677	**Smit Sleeve, l=40mm, d= 6mm (box of 10)** The Smit sleeve can be placed in the uterus and sutured to the cervix, to enable the intrauterine tube to be reinserted without dilatation. Advantage: The next insertion of the intra-uterine tube can be done without anesthesia, no need to insert the applicator in an Operation Room.
1	189679	**Smit Sleeve, l=60mm, d=6mm (box of 10)** The Smit sleeve can be placed in the uterus and sutured to the cervix, to enable the intrauterine tube to be reinserted without dilatation. Advantage: The next insertion of the intra-uterine tube can be done without anesthesia, no need to insert the applicator in an Operation Room.
1	189681	**Smit Sleeve, l= 70mm, d= 6mm (box of 10)** The Smit sleeve can be placed in the uterus and sutured to the cervix, to enable the intrauterine tube to be reinserted without dilatation. Advantage: The next insertion of the intra-uterine tube can be done without anesthesia, no need to insert the applicator in an Operation Room.
1	189682	**Smit Sleeve, l=80mm, d=6mm (box of 10)** **T** he Smit sleeve can be placed in the uterus and sutured to the cervix, to enable the intrauterine tube to be reinserted without dilatation. Advantage: The next insertion of the intra-uterine tube can be done without anesthesia, no need to insert the applicator in an Operation Room.
2	101015	**CT/MR Sterilization Box** The Sterilization box does not include the additional accessories tray.
1	170780	APPLICATOR LIBRARY FILES
1	189714	INSERTION TOOL
1	101012	**Sterilizing Caps, CT/MR consisting of:** Pack of 50. To be used during sterilization of CT and MR applicators.
1	189040	**Cleaning Brush Ø 2.5 x 250, Set of 3**
1	189043	**Cleaning Brush Ø 6.5 x 100, Set of 3**
1	189693	**CT marker Set, 294mm, Yellow (package of 12)** The CT-Markers are designed to indicate source positions on CT images. The markers fit the ProGuide needle with diameters from 4F to 6F. During imaging, the marker is kept in place by means of a built-in spring mechanism. The curve of the CT marker acts as a spring to prevent the CT marker from shifting in the applicator. Consisting of: Qty # Part 12 189089 CT Marker, 294mm yellow
2	110231	PROGUIDE 6F S 294MM (5X)
3	110268	**Set Of 5 Obturators 6F, L=294mm**
2	110230	**ProGuide Needle 6F Round 294mm consisting of:** Set of 5 Single packed, Delivered Sterile
1	200758	**Combined Applicator Pretreatment + Clinical support training** 2 day onsite clinical assistance and applicator training by an Elekta Application Specialist (up to two people from clinical site maximum attendance, otherwise additional cost will apply). This training is applicable for physicians, physicists, dosimetrists, therapists and nursing. Applicator assembly, optional parts, sterilization and clinical use will be a part of the training. This on-site visit requires pre-scheduling with Elekta Training Department (3-4 weeks

Qty	Article number	Description
		lead time). Includes travel, accommodation and expenses for trainer.
2	152001	**Ovoid Tube 1** This non-metallic MR safe ovoid tube ensures easy insertion, the tube is designed to attach a interstitial ovoid with possibility to insert parallel needles in the ovoid, includes a integrated fixation mechanism to fixate the ovoid tube on the intrauterine tube.
2	152002	**Ovoid Tube 2** This non-metallic MR safe ovoid tube ensures easy insertion, the tube is designed to attach a interstitial ovoid with possiblity to insert parallel needles in the ovoid, includes a integrated fixation machanism to fixate the ovoid tube on the intrauterine tube.
1	152003	**Ovoid Tube 1 - Interstitial Ovoid 13 mm** This non-metallic MR safe ovoid the tube includes the smallest interstitial 13mm ovoid with possibility to insert parallel needles in the ovoid, includes a integrated fixation mechanism to fixate the ovoid tube on the intrauterine tube.
1	152004	**Ovoid Tube 2 - Interstitial Ovoid 13 mm** This non-metallic MR safe ovoid the tube includes the smallest interstitial 13mm ovoid with possibility to insert parallel needles in the ovoid, includes a integrated fixation mechanism to fixate the ovoid tube on the intrauterine tube.
1	152005	**Intrauterine Tube 0 mm** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator to treat vaginal cuff.
1	152006	**Interstitial Tube 15°** This non-metallic MR safe unique component enables to insert a parallel needle through the tube for treatment of the after hysterectomy cases. To use in combination with Guiding tube for interstitial tube and a proguide needle 294mm.
2	152007	**Intrauterine Tube 30 mm 15°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 15°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152008	**Intrauterine Tube 40 mm 15°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 15°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152009	**Intrauterine Tube 50 mm** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 15°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152010	**Intrauterine Tube 60 mm 15°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 15°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152011	**Intrauterine Tube 70 mm 15°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 15°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152012	**Intrauterine Tube 80 mm 15°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 15°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152013	**Intrauterine Tube 30 mm 30°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 30°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152014	**Intrauterine Tube 40 mm 30°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 30°,

Qty	Article number	Description
		includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152015	**Intrauterine Tube 50 mm 30°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 30°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152016	**Intrauterine Tube 60 mm 30°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 30°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152017	**Intrauterine Tube 70 mm 30°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 30°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152018	**Intrauterine Tube 80 mm 30°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 30°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152019	**Intrauterine Tube 30 mm 45°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 45°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152020	**Intrauterine Tube 40 mm 45°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 45°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152021	**Intrauterine Tube 50 mm 45°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 45°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152022	**Intrauterine Tube 60 mm 45°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 45°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152023	**Intrauterine Tube 70 mm 45°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 45°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
2	152024	**Intrauterine Tube 80 mm 45°** Non-metallic MR safe intrauterine tube with small diameter shaft (4mm) suitable for Geneva applicator 45°, includes integrated fixation mechanism to click easily the ovoid tubes on the intrauterine tube.
1	152025	**Interstitial Ovoid Pair 15 mm** Interstitial ovoids pair with 15° angle needle to insert parallel needles
2	152026	**Interstitial Ovoid Pair 20 mm** Interstitial ovoids pair with 15° angle needle to insert parallel needles
2	152027	**Interstitial Ovoid Pair 25 mm** Interstitial ovoids pair with 15° angle needle to insert parallel needles
1	152028	**Interstitial Ovoid Pair 30 mm** Interstitial ovoids pair with 15° angle needle to insert parallel needles
1	152029	**Interstitial Ovoid Pair 35 mm** Interstitial ovoids pair with 15° angle needle to insert parallel needles
1	152030	**Interstitial Ovoid Pair 40 mm** Interstitial ovoids pair with 15° angle needle to insert parallel needles

Qty	Article number	Description
1	152037	**Rectal Retractor 20 mm** Non-metallic rectal retractor to click on the Geneva applicator below the ovoids.
2	152038	**Rectal Retractor 30 mm** Non-metallic rectal retractor to click on the Geneva applicator below the ovoids.
2	152040	**Spreading Clip** The spreading clip for Geneva applicator tubes to set the spreading distance or fixate the tubes onto the cervical stopper.
2	129003	**Bracelet for guiding tubes** After insertion of the needles the bracelet can be attached on the applicator tubes to short the guiding tubes with proguides needles in for an easy overview and keep all the needles close to the applicator.
2	129004	**Number tag for guiding tubes** To identify the needle numbers, number tags can be used by attaching them on the guiding tubes.
2	129001	**Guiding tubes for interstitial lunar ovoids 5x1** The guiding tube allows to easily insert and guide the needles when the applicator is inserted in the patient, and to be able to insert and lock the needles outside the patient.
2	129002	**Guiding tubes for vaginal caps 5x1** The guiding tube allows to easily insert and guide the needles when the applicator is inserted in the patient, and to be able to insert and lock the needles outside the patient.
2	152032	MR safe clip to fixate the Ovoids Tubes on the Intrauterine Tube of the Geneva applicator.
1	090695ENG	PROGUIDE NEEDLE

Venezia Advanced GYN Applicator Set CT/MR

Qty	Article number	Description
1	189714	INSERTION TOOL
2	126003	**Interstitial Lunar Ovoid Tube 26mm 60° Right**
2	126004	**Interstitial Lunar Ovoid Tube 26mm 60° Left**
1	126005	**Interstitial Lunar Ovoid Tube 30mm 60° Right**
1	126006	**Interstitial Lunar Ovoid Tube 30mm 60° Left**
1	126009	**Vaginal Cap 26mm Right**
1	126010	**Vaginal Cap 26mm Left**
1	126011	**Vaginal Cap 30mm Right**
1	126012	**Vaginal Cap 30mm Left**
2	101015	**CT/MR Sterilization Box** The Sterilization box does not include the additional accessories tray.
1	101012	**Sterilizing Caps, CT/MR consisting of:** Pack of 50. To be used during sterilization of CT and MR applicators.
2	126013	**Intrauterine tube 0mm**
1	126001	**Interstitial Lunar Ovoid Tube 22mm 60° Right**

Qty	Article number	Description
1	126002	**Interstitial Lunar Ovoid Tube 22mm 60° Left**
1	126007	**Vaginal Cap 22mm Right**
1	126008	**Vaginal Cap 22mm Left**
3	137290	**Needle Locking Tool** For use with part #137280.
2	126014	**Intrauterine tube 30mm 30°**
2	126015	**Intrauterine tube 40mm 30°**
2	126016	**Intrauterine tube 50mm 30°**
2	126017	**Intrauterine tube 60mm 30°**
2	126018	**Intrauterine tube 70mm 30°**
2	126019	**Intrauterine tube 30mm 15°**
2	126020	**Intrauterine tube 40mm 15°**
2	126021	**Intrauterine tube 50mm 15°**
2	126022	**Intrauterine tube 60mm 15°**
2	126023	**Intrauterine tube 70mm 15°**
1	170780	APPLICATOR LIBRARY FILES
2	189714	INSERTION TOOL
4	137287	**Lock Insert Set For 6F Plastic Needles** Contains 20pcs. Delivered non sterile.
1	189040	**Cleaning Brush Ø 2.5 x 250, Set of 3**
1	189040	**Cleaning Brush Ø 2.5 x 250, Set of 3**
2	189043	**Cleaning Brush Ø 6.5 x 100, Set of 3**
1	110290	**MR Line Marker Set** Makes gynecological CT/MR applicators visible on MR-imaging. The Line-marker, consisting of a plastic tube to be filled with fluid, will be placed inside the source-channel of the concerning intrauterine-, ovoid- and ring-tubes of the applicators. Consisting of: Qty # Part 4 110342 MR Line Marker
1	189693	**CT marker Set, 294mm, Yellow (package of 12)** The CT-Markers are designed to indicate source positions on CT images. The markers fit the ProGuide needle with diameters from 4F to 6F. During imaging, the marker is kept in place by means of a built-in spring mechanism. The curve of the CT marker acts as a spring to prevent the CT marker from shifting in the applicator. Consisting of: Qty # Part 12 189089 CT Marker, 294mm yellow
2	110268	**Set Of 5 Obturators 6F, L=294mm**
2	110230	**ProGuide Needle 6F Round 294mm consisting of:**

Qty	Article number	Description
		Set of 5 Single packed, Delivered Sterile
2	110231	PROGUIDE 6F S 294MM (5X)
1	189601	**ProGuide Sharp Needle Set, 6F x 240mm consisting of:** This type of flexible implant needle is specifically manufactured for the Elekta remote afterloader. The disposable plastic needle has a sharp integrated closed tip to enable easy penetration of the skin surface. The needle tip is hollow to allow for a more distal source position. ProGuide Sharp Needle Set includes 3 pouches of 6 needles (total 18 Needles), 6 ProGuide obturators, User Guide and Sterilization Advice.
1	200758	**Combined Applicator Pretreatment + Clinical support training** 2 day onsite clinical assistance and applicator training by an Elekta Application Specialist (up to two people from clinical site maximum attendance, otherwise additional cost will apply). This training is applicable for physicians, physicists, dosimetrists, therapists and nursing. Applicator assembly, optional parts, sterilization and clinical use will be a part of the training. This on-site visit requires pre-scheduling with Elekta Training Department (3-4 weeks lead time). Includes travel, accommodation and expenses for trainer.
2	129003	**Bracelet for guiding tubes** After insertion of the needles the bracelet can be attached on the applicator tubes to short the guiding tubes with proguides needles in for an easy overview and keep all the needles close to the applicator.
2	129004	**Number tag for guiding tubes** To identify the needle numbers, number tags can be used by attaching them on the guiding tubes.
2	126200	**Fixation element** Can be used as additional fixation of the tubes , and/or to fixate the applicator on the applicator clamp.
2	126201	**Fixation Clip** Required to fix the fixation element on the tubes, and/or to fixate the perineal template dorsal 0° and 12° on the tubes.
1	126202	**Perineal Template Dorsal 0°** To treat the parametrium extension up to IVB stages , the needles can be inserted through the perineal template, under 0° and can be locked with the lock inserts using the locking tool. *Proguide sharp needles 6F 200mm or 240mm and tungsten obturators 200mm or 240mm are required.
1	126203	**Perineal Template Dorsal 12°** To treat the parametrium extension up to IVB stages the needles can be inserted through the perineal template, under 12° and can be locked with the lock inserts using the locking tool. *Proguide sharp needles 6F 200mm or 240mm and tungsten obturators 200mm or 240mm are required.
1	126204	**Perineal Template Ventral 0°** To treat the ventral side of the uterus , parametrium and/or the bladder extensions , stages up to IVB, the needles can be inserted through the perineal template, and can be locked with the lock inserts using the locking tool. *Proguide sharp needles 6F 200mm or 240mm and tungsten obturators 200mm or 240mm are required.
1	126205	**Perineal Bar** Perineal bar to fixate the applicator to the pelvic area of the patient.
1	126206	**Perineal Lever** Required part to fixate the perineal template on the perineal part dorsal and/or on the fixation element.
2	129001	**Guiding tubes for interstitial lunar ovoids 5x1** The guiding tube allows to easily insert and guide the needles when the applicator is inserted in the patient, and to be able to insert and lock the needles outside the patient.
2	129002	**Guiding tubes for vaginal caps 5x1** The guiding tube allows to easily insert and guide the needles when the applicator is inserted in the patient, and to be able to insert and lock the needles outside the patient.

Qty	Article number	Description
1	77700573MAN	LOCK INSERT ENGLISH
1	090695ENG	PROGUIDE NEEDLE

Shielded Cylinder Applicator Set

Qty	Article number	Description
1	084320	**Shielded Cylindrical Applicator Set** The Shielded Cylindrical Applicator Set is designed for intracavitary treatments when partial shielding is required. • Tungsten alloy segments for 90°, 180° and 270° shielding. • Position of the shielding is shown by markers. • Cylinders in four different diameters. • Stainless steel shields or plastic fillers are available as an option. Consisting of: Qty # Part 1 084321 Central Tube 1 084329 Tungsten Shielding, 180° 2 084328 Tungsten Shielding, 90° 1 084322 Cylinder, d = 25mm 1 084323 Cylinder, d = 30mm 1 084324 Cylinder, d = 35mm 1 084325 Cylinder, d = 40mm 1 084327 Fixing Nut 1 084158 Sterilizing Caps, 3.2mm 1 094239 Sterilization Advice Chart 1 090609 User Guide Shielded Cylindrical Applicator Set
2	084348	**Plastic Filler, 90° Geometry**
1	084349	**Plastic Filler, 180° Geometry**

Ring Applicator Set Stainless Steel

Qty	Article number	Description
3	084050	**Ring Applicator Set** The stainless steel Ring Applicator Set is attractive for its simplicity, fixed geometry and fast planning. A rectal retractor can be used to push the rectal/vaginal wall to a fixed distance from the source. This set contains ring tube at 30°, 45° and 60°. Consisting of: Qty # Part 1 085095 Ring Applicator Set, 30° 1 085096 Ring Applicator Set, 45° 1 085097 Ring Applicator Set, 60° 1 084072 Perineal bar 1 084056 Ring Tube, d = 34mm, 30° 1 084055 Ring Tube, d = 34mm, 45° 1 084054 Ring Tube, d = 34mm, 60° 1 084051 Ring Cap, d = 34mm 1 084158 Sterilizing Caps, 3.2mm

Flexitron Installation / Operator Training / First Treatment Support

Qty	Article number	Description
1	199107	**Installation Flexitron** Installation of the Flexitron. Estimated installation time is 4 days. Structural alterations are not included. Travel, accommodation and subsistence expenses will be itemized and charged separately unless travel and accommodation are included in this quotation.
1	200709	**Flexitron Operator Training** This 1 day on-site training addresses the user aspects of the Flexitron (HDR, PDR or Cobalt) and is intended to familiarize the hospital staff with operating the system and handling the safety issues. The course consists of demonstrations, discussions and hands-on cases for practical use. Maximum number of participants is 4. Travel, accommodation and subsistence expences will be itemized and charged separately unless travel and accommodation are included in this quotation.
1	200758	**Combined Applicator Pretreatment + Clinical support training** 2 day onsite clinical assistance and applicator training by an Elekta Application Specialist (up to two people from clinical site maximum attendance, otherwise additional cost will apply). This training is applicable for physicians, physicists, dosimetrists, therapists and nursing. Applicator assembly, optional parts, sterilization and clinical use will be a part of the training. This on-site visit requires pre-scheduling with Elekta Training Department (3-4 weeks lead time). Includes travel, accommodation and expenses for trainer.
1	998USTCINSTALL	**Travel and Accommodation for Installation 4 days**
1	998USTC1DAY	**Travel and Accommodation 1 day**

Oncentra Brachytherapy Applications Training (Remote - 4-Day Course) x 3 Attendees

Qty	Article number	Description
1	200778	**Remote Oncentra Brachy Application training** User/Application training for Oncentra Brachytherapy treatment planning software. This remote training part number is for one participant, and observers are not included. The course is intended for physicists, physicians, and dosimetrists. The total duration is 32 hours and should be completed within a maximum of 15 consecutive working days. A specific course schedule is agreed upon together with the customer.
1	200778	**Remote Oncentra Brachy Application training** User/Application training for Oncentra Brachytherapy treatment planning software. This remote training part number is for one participant, and observers are not included. The course is intended for physicists, physicians, and dosimetrists. The total duration is 32 hours and should be completed within a maximum of 15 consecutive working days. A specific course schedule is agreed upon together with the customer.
1	200778	**Remote Oncentra Brachy Application training** User/Application training for Oncentra Brachytherapy treatment planning software. This remote training part number is for one participant, and observers are not included. The course is intended for physicists, physicians, and dosimetrists. The total duration is 32 hours and should be completed within a maximum of 15 consecutive working days. A specific course schedule is agreed upon together with the customer.

Prostate Stepper Templates 5F & 6F

Qty	Article number	Description
3	189066	**Prostate Stepper Template, 5F** The Prostate Stepper Template is designed for guidance and fixation of ProGuide plastic needles and can be used with stainless steel needles as well. The square lightweight template has a universal grid array and an advanced needle fixation with a disposable plate that locks up to 30 needles in a movement. Compatible with wide range of stepper devices and ultrasound grid resolutions. Template holders and Grid faceplates need to be ordered separately. Consisting of: Qty # Part 1 189160 Front Plate Stepper, 5F 1 189157 Base Plate Stepper, 5F

Qty	Article number	Description
		1 189166 Fixation Plate Support assy 1 189164 Set of 10 disposable Fixation Plates, 5F (5x2) 1 189167 Eccentric Axle 2 189170 Assembly Bolt Template 1 189205 Assembly Screwdriver 1 189173 Fixation Screwdriver 1 1 189041 Cleaning Brush Ø3 x 100, Set of 3 1 189043 Cleaning Brush Ø6.5 x 100, Set of 3
1	189164	**Set Of 10 Disposable Fixation Plates, 5F (5x2)**
3	189072	**Stepper Holder Set, OncoSelect consisting of:** The OncoSelect Stepper Holder is designed for fixation of a Prostate Stepper Template on an OncoSelect stepper. It is normally used in combination with the Grid Face Plate Set that corresponds to the ultrasound system that is applied. Consisting of: Qty # Part 1 189076 OncoSelect Stepper Holder Assembly 6 189168 Fixation Bolt Template 1 598027 Allen Key Screwdriver 3mm 1 Sterile. Advice Chart Stepper Holder/Grid Faceplate
3	189074	**Grid Face Plate Set, B&K consisting of:** The B&K Grid Face Plate Set is used in combination with a Stepper Holder and a Prostate Stepper Template and indicates template grid coordinates according to B&K rectal ultrasound systems. The Grid Face Plate is screwed to the front of the Stepper Holder. An additional L-frame grid is available to identify needle holes on the separate template during transfer tube attachment. Consisting of: Qty # Part 1 189175 Grid Face Plate, B&K 6 Grid Face Plate Screws 1 598028 Screwdriver Grid Face Plates 1 189207 Grid L-frame for B&K

Prostate Stepper Template Accessories

Qty	Article number	Description
1	189167	**Eccentric Axle**
1	189170	**Assembly Bolt Template consisting of:** Bolt for use with the Prostate Stepper Template.
1	189205	**Assembly Screwdriver**
4	504910R	**LBB Screw 2.5 x 4R** Compatible with the Prostate Stepper template 189069.
1	189036	**CT Marker Set, 240mm, Black (package of 18)** The CT-Markers are designed to indicate source positions on CT images. The markers fit the ProGuide needle with diameters from 4F to 6F. During imaging, the marker is kept in place by means of a built-in spring mechanism. The curve of the CT marker acts as a spring to prevent the CT marker from shifting in the applicator. Consisting of: Qty # Part 18 189086 CT Marker, 240mm black
3	189604	**ProGuide Sharp Needle Set, 5F x 240mm consisting of:** This type of flexible implant needle is specifically manufactured for the Elekta remote afterloader. The disposable plastic needle has a sharp integrated closed tip to enable easy penetration of the skin surface. The needle tip is hollow to allow for a more distal source position. ProGuide Sharp Needle Set includes 3 pouches of 6 needles (total 18 Needles), 6 ProGuide obturators, User

Qty	Article number	Description
		Guide and Sterilization Advice.
1	089636	**Handle For Insertion Obturator** This stainless steel handle can be clamped on any Elekta needle or insertion obturator knob and provides a 10cm long grip for easy manipulation. It can quickly be attached and detached by pushing the proximal button.
1	090695ENG	PROGUIDE NEEDLE
1	189168	**Fixation Bolt Template**

Qty	Article number	Description
1	170021	**WACOM Digitizer Tablet consisting of:** The Cintiq 21UX with an Interactive Pen Display. A highly advanced drawing tablet for 3D contouring and Image fusion.
1	594839	**Uninterruptable Power Supply (110V) consisting of:** The Uninterruptable Power Supply (UPS) is a device which protects your data in case of power loss. The system secures data loss during power failures for servers, hubs and data centers in an optimal way.
1	170008	ONCENTRA PC PLATFORM HP Z8

Qty	Article number	Description
1	170698	**New OCB 4.5 or 4.6 server license** Provides the server license and also contains the USB HASPkey needed for license checks.
1	170223A04	**Oncentra Brachy Advanced 3D** Oncentra Brachy Advanced 3D includes 3D+HIPO+IPSA+Applicator Modelling. It is the full package with all 'state of the art' tools for Image registration, applicator modeling as well as optimization. This is a built up license, consisting of: Oncentra Brachy 3D (170243A04), IPSA (170233), HIPO (170332) and Applicator Modeling (170283).
1	170360	**Implant Modeling** A state of the art modeling tool for highly accurate modeling of implants that can be reconstructed once and reused in similar cases. This tool helps me to save time enabling me to fully focus on creating the best possible treatment plan.
1	170018	NEW CUSTOMER KIT ONCENTRA OCB 4.6.2 OCEB 4.5.3

Qty	Article number	Description
1	199171	**Installation For Oncentra External Beam and/or Oncentra Brachy** Installation, configuration and on-site testing of the Oncentra Brachy and/or Oncentra External Beam planning system by an Elekta engineer. Estimated installation time 1 day. Travel, accommodation and subsistence expenses will be itemized and charged separately unless travel and accommodation are included in this quotation.

Oncentra Prostate Real Time Planning System for HDR

Qty	Article number	Description
1	131030	**ECRM (EndoCavity Rotational Mover) consisting of:** Rotational Mover (ECRM) which is a computer- controlled, motor-driven rotational device used to rotate an Ultrasound probe, a sagittal imaging device. The ultrasound probe is fixed in a probe cradle. The ECRM rotates an endocavity probe around its long axis. In combination with the longitudinal array on a bi-plane rectal Ultrasound probe, the EndoCavity Rotational Mover (ECRM) can create automatically "fanned" data sets.

1	132046	**OncoSelect Stepper, Table Mount System + Stepper Encoder**
		The stepper encoder enables the user to automatically import large series of the transversal ultra sound images into Oncentra Prostate™. The inter slice steps can be set from 1 to 5 mm with a one-millimeter increment. Part of the set are the mechanical adaptations to the OncoSelect Stepper Unit and the necessary electronics and cabling.
		
		Consisting of the following items:
		• Stepping Head
		• Column + Stand on wheels
		• Encoder
		
		Features:
		• Head Rotation of 360º
		• Elevation of the column by quick action of a side handle
		• Left and Right travel Knob
		• Continuous in-out movement by the right- or left-side hand-wheel
		  • Setting of zero reference plane at the base of the prostate
		  • Five millimeter stepping mode and continues stepper (probe) movement
		  • Stable floor fixation structure
		  • Precision and user-friendly controls

1	131381	**Adapter Set OncoSelect Stepper - B-K Medical UltraSound probe (8848 andE14CL4b(9048)** This adapter is used to fix the UltraSound probe, together with the EndoCavity Rotational Mover (ECRM) onto the OncoSelect Stepper. Consising of: • An interface baseplate • A probe cable • A probe holder (black ring)
1	132001A02	**Oncentra Prostate 4.x** Oncentra Prostate™ enables the user to determine the optimal implant geometry, based upon live ultrasound information. It guides the user during the implantation of the treatment needles and performs the treatment planning, optimization and evaluation of the implant while the patient is still in the operating theater. The first fraction of the treatment can be given directly thereafter in the operating theatre or after the patient leaves the operating theatre. Basic package Oncentra Prostate, including all functionalities for transversal and sagittal imaging during image acquisition and live imaging, contouring, unique needle navigation, inverse planning (Advanced HIPO: inverse planning and calculating the number and place of needles) and manual planning, plan evaluation, Prostate model (sector definition of the prostate, for optimization and evaluation), RTOG export, image fusion for HDR prostate treatment planning. Consisting of: • Virtual, live and post planning options • Imaging modalities supported: US (color Doppler), CT and MR • Contouring: Pre-defined prostate, Free-hand, Segmental, Continuous, Pearl, automatic contouring, 3D contouring, path contouring • Dose prescription: normalized dose, prescribed dose • Normalization: MDPTV, MDP, MTD, absolute dose, on box or point • Catheter placement: template based, automatic, manual, inverse planning with HIPO • Optimization methods, geometrical, manual, graphical, optimization history • Evaluation: dose points, point list, DVH, Monitoring, volume evaluation

Qty	Article number	Description

		Equipped with mobile laptop cart:
		• Ergonomic and mobile cart with a high resolution 22 inchmonitor and laptop:
		  • Laptop with Intel Pentium Processor, with Windows 10 IoT operating system
		  • Mouse and Keyboard
		  • Manuals
		• All electronic components and connections for operating Oncentra Prostate
		• Prepared for upgrade to Oncentra Seeds Treatment planning
		Note:
		* Requires:
		• Any ultra sound scanner system and rectal probe with transversal image possibility and (s)VHS-PAL or (s)VHS-NTCS video output
		• Stepper Unit with encoder
		• ECRM for sagittal imaging (131030)

1	131030	**ECRM (EndoCavity Rotational Mover) consisting of:** Rotational Mover (ECRM) which is a computer- controlled, motor-driven rotational device used to rotate an Ultrasound probe, a sagittal imaging device. The ultrasound probe is fixed in a probe cradle. The ECRM rotates an endocavity probe around its long axis. In combination with the longitudinal array on a bi-plane rectal Ultrasound probe, the EndoCavity Rotational Mover (ECRM) can create automatically "fanned" data sets.

Advanced Imaging & Advanced Optimization

Qty	Article number	Description
1	132732	**Advanced Imaging consisting of:** Software package for Oncentra Seeds & Prostate, containing the modules sector analysis and advanced cube. Sector analysis is offering the opportunity to optimize and evaluated the treatment plan based on the definition of sectors according the biopsy method of the urologist. Advanced cube displays the 3D ultrasound image in a cube models that provide the possibility to extract part of the content of the cube to visualize the needles or organs at risk in an optimized way. Requires: Oncentra Seeds (131001) or Oncentra Prostate (132001)
1	132733	**Advanced Optimization consisting of:** Software package for existing Oncentra Seeds & Prostate, (MIPE & Multi Evolutionary DVHOE), All Multi-Optimization Functionalities. Includes DVH shaper.

Oncentra Prostate Team Training On-Site (3-Day)

Qty	Article number	Description
1	200743	**Oncentra Prostate New-user team training course** 3 days of on-site clinical applications training of the OCP- system, provided for the medical team. The sessions address the procedural and functional aspects of the system with the Physicians (Radiation Oncologists, Urologists, Oncologists), Medical Physicists, Dosimetrists, OR nurses and technicians (6 persons max. at training sessions). The training is directed and presented by an Elekta Application Specialist. The tariff is per person. The price does not include travel and accommodation costs of the Application Specialist. These will be itemized and charged separately at actual costs.
1	998USTC1DAY	**Travel and Accommodation 1 day**
2	998USTCPERDAY	**Travel and Accommodation additional day**

Oncentra Prostate Installation

Qty	Article number	Description
1	199134	**Oncentra Prostate® / Seeds - Installation** Installation of the Oncentra Prostate® system on site. Estimated installation time is one day. Any alterations to the local network are not included. Travel, accommodation and subsistence expenses will be itemized and charged separately unless travel and accommodation are included in this quotation.
1	199135	**Installation OncoSelect Stepper** Installation of the OncoSelect Stepper by an Elekta trained and qualified Service Engineer. Total estimated installation time is ½ day. This includes the testing and acceptance with the appropriate Elekta prostate devices. Travel accommodation and subsistence expenses will be itemized and charged separately unless travel and accommodation are included in this quotation.
1	998USTCINSTALL	**Travel and Accommodation for Installation 4 days**

Oncentra Prostate Stepper Template, 6F

Qty	Article number	Description
1	189074	**Grid Face Plate Set, B&K consisting of:** The B&K Grid Face Plate Set is used in combination with a Stepper Holder and a Prostate Stepper Template and indicates template grid coordinates according to B&K rectal ultrasound systems. The Grid Face Plate is screwed to the front of the Stepper Holder. An additional L-frame grid is available to identify needle holes on the separate template during transfer tube attachment. Consisting of: Qty # Part 1 189175 Grid Face Plate, B&K 6 Grid Face Plate Screws 1 598028 Screwdriver Grid Face Plates 1 189207 Grid L-frame for B&K
2	189067	**Prostate Stepper Template, 6F** The Prostate Stepper Template is designed for guidance and fixation of Proguide plastic needles and can be used with stainless steel needles as well. The square lightweight template has a universal grid array and an advanced needle fixation with a disposable plate that locks up to 30 needles in a movement. Compatible with wide range of stepper devices and ultrasound grid resolutions. Template holders and Grid faceplates need to be ordered separately. Consisting of: Qty # Part 1 189158 Base Plate Stepper, 6F 1 189161 Front Plate Stepper, 6F 1 189166 Fixation Plate Support assy 1 189165 Set of 10 Disposable Fixation Plates, 6F (5x2) 1 189167 Eccentric Axle 1 2 189170 Assembly Bolt Template 1 189205 Assembly Screwdriver 1 189173 Fixation Screwdriver 1 189041 Cleaning Brush Ø3 x 100, Set of 3 1 189043 Cleaning Brush Ø6.5 x 100, Set of 3
2	189072	**Stepper Holder Set, OncoSelect consisting of:** The OncoSelect Stepper Holder is designed for fixation of a Prostate Stepper Template on an OncoSelect stepper. It is normally used in combination with the Grid Face Plate Set that corresponds to the ultrasound system that is applied. Consisting of: Qty # Part 1 189076 OncoSelect Stepper Holder Assembly 6 189168 Fixation Bolt Template 1 598027 Allen Key Screwdriver 3mm 1 Sterile. Advice Chart Stepper Holder/Grid Faceplate
1	189074	**Grid Face Plate Set, B&K consisting of:** The B&K Grid Face Plate Set is used in combination with a Stepper Holder and a Prostate Stepper Template and

Qty	Article number	Description
		indicates template grid coordinates according to B&K rectal ultrasound systems. The Grid Face Plate is screwed to the front of the Stepper Holder. An additional L-frame grid is available to identify needle holes on the separate template during transfer tube attachment. Consisting of: Qty # Part 1 189175 Grid Face Plate, B&K 6 Grid Face Plate Screws 1 598028 Screwdriver Grid Face Plates 1 189207 Grid L-frame for B&K
2	189628	**ProGuide Obturator Bulk Set, 6F x 240mm** The obturator is a rigid tungsten alloy tool to maintain the needle stability during insertion. The obturator prevents kinking or breaking of the needles during insertion. The curve in the obturator is intentional and prevents the obturator from shifting within the needle during insertion. Consisting of 12 ProGuide obturators.
2	189616	**ProGuide Sharp Needle Bulk Set, 6Fx240mm consisting of:** This type of flexible implant needle is specifically manufactured for the Elekta remote afterloaders. The disposable plastic needle has a sharp integrated closed tip to enable easy penetration of the skin surface. The needle tip is hollow to allow for a more distal source position. Consisting of 55 ProGuide sharp needles (8 pouches of 6 needles and 7 pouches of single packed needles).
2	110583	**ProGuide Needle Set, 10 pcs (6F, 240mm, sharp, 10x1)** This type of flexible single use implant needle is specifically manufactured for the Elekta remote afterloaders. The disposable plastic needle has a sharp integrated closed tip to enable easy penetration of the skin surface. The needle tip is hollow to allow for a more distal source position. This Set includes 10 pouches of 1 needle (total 10 Needles), User Guide and Sterilization Advice.
1	090695ENG	PROGUIDE NEEDLE

Prostate Stepper Accessories

Qty	Article number	Description
1	189205	**Assembly Screwdriver**
1	189167	**Eccentric Axle**
2	189170	**Assembly Bolt Template consisting of:** Bolt for use with the Prostate Stepper Template.
4	504910R	**LBB Screw 2.5 x 4R** Compatible with the Prostate Stepper template 189069.
1	598028	**Screwdriver Grid Face Plates**
4	189168	**Fixation Bolt Template**
2	089636	**Handle For Insertion Obturator** This stainless steel handle can be clamped on any Elekta needle or insertion obturator knob and provides a 10cm long grip for easy manipulation. It can quickly be attached and detached by pushing the proximal button.

On-site Applications Support (1 of 3)

Qty	Article number	Description
1	200751	**Oncentra Prostate Clinical support by an Elekta Application specialist (1st treatment support)** On-site support during a clinical procedure by an Elekta Application specialist. The tariff is per day. The price does not include travel and accommodation costs of the Application Specialist. These will be itemized and charged separately unless travel and accommodation are included in this quotation.

Qty	Article number	Description
1	998USTC1DAY	**Travel and Accommodation 1 day**
1	998USTCPERDAY	**Travel and Accommodation additional day**

On-site Applications Support (2 of 3)

Qty	Article number	Description
1	200751	**Oncentra Prostate Clinical support by an Elekta Application specialist (1st treatment support)** On-site support during a clinical procedure by an Elekta Application specialist. The tariff is per day. The price does not include travel and accommodation costs of the Application Specialist. These will be itemized and charged separately unless travel and accommodation are included in this quotation.
1	998USTC1DAY	**Travel and Accommodation 1 day**
1	998USTCPERDAY	**Travel and Accommodation additional day**

On-site Applications Support (3 of 3)

Qty	Article number	Description
1	200751	**Oncentra Prostate Clinical support by an Elekta Application specialist (1st treatment support)** On-site support during a clinical procedure by an Elekta Application specialist. The tariff is per day. The price does not include travel and accommodation costs of the Application Specialist. These will be itemized and charged separately unless travel and accommodation are included in this quotation.
1	998USTC1DAY	**Travel and Accommodation 1 day**
1	998USTCPERDAY	**Travel and Accommodation additional day**

Imaging Ring Performance Package [2022-374739-BL]

Qty	Article number	Description
1	185001	**ImagingRing Performance** with large bore (121cm diameter) • X-ray tube 6 kW small focus and 25 kW large focus • X-ray generator max. 15 kW • Energy range 40-120 kV • Detector size 43x43 cm2 • Detector resolution max 2880 x 2880, 1440 x 1440 fast binning mode, 960 x 960 ultra fast binning mode • Min. space requirement (footprint) 1.59 m² (17.11 sqft) • 2.6 m² (22.99 sqft) in parking position with margin required due to moving components • Total weight 517kg (1139lbs) fully equipped with all options. **Includes the following options:** • ImagingRing motion & imaging software • ImagingRing User Interface & Control software • RingPad (HMI) - Wireless device used to safely control motion and X-ray exposures of the ImgagingRing. The handheld device provides a touchscreen embedded in an ergonomic, protective frame with hardware buttons and joysticks to remotely move all axes of the system. The software, which runs on a MS Surface 7 pro tablet under windows 10, allows the execution of all imaging workflows; user logon, select a patient, choose an imaging protocol, define the ROI and imaging center, position the device, acquire and review the images in 2D or 3D before export to a DICOM AET (PACS or TPS). Can be docked to the gantry on both sides. Any angle rotation possible. • External interlock interface - integration of room based interlock systems. • WiFi package - wifi extension (router and cable) • non-isocentric imaging - Allows flexible positioning of the ROI (in 2D and 3D) inside the large bore by (dynamic) offset adaption of source and detector. Includes support for dedicated imaging protocols and control unit capabilities which use adaption of the source and detector offset for free positioning of the ROI inside the bore of the imaging system. This package allows a flexible positioning of the ROI making repositioning of patient in vertical or lateral direction unnecessary. • short scans & reduced travel range to avoid obstacles - Protocols and reconstruction algorithms allowing short scans and dual short scans. Short scans are CBCT acquisitions with a reduced travel range of 180° (+ field divergency) and reduced acquisition duration of approx. 30 seconds in total. Apart from the reduced acquisition time and dose applied the reduced travel range can be used to avoid obstacles in the OR. Dual short scans allow acquisitions of large FOVs (cylinders of 48 cm diameter x 25 cm length) by performing two consecutive short scan segments in adverse direction, with a change in panel offset in between the two segments. • Large Field of View - 43x43x25 cm3 • Automatic stabilization function - Force sensors in the front wheels to support vibration-fee high resolution scans on uneven floors. • Source sided transaxial laser - Source sided trans axial laser pointing at the central axis of the detector (static). A rigid source sided trans axial line laser is provided to mark the central axis plane. Can be used to facilitate system positioning in patient´s longitudinal direction to image a defined ROI. • Scout supported 3D ROI definition - Includes a software wizard, guiding the user through the definition of the ROI for following CBCT acquisition by means of the acquisition of two orthogonal planar images wherein the user can precisely draw the center and extent of the region of interest for the CBCT acquisition (realized by dynamic collimation). Optimal field collimation reduces the dose applied to the patient to a minimum. Additionally, the image quality will be enhanced due to the reduced generation of scattered radiation from the object in the small FOV. • Faster acquisition and noise reduction - Silent gearboxes are assembled and built for system´s main axes to reduce the noise produced by the gearboxes about 10 dB.These gear boxes have higher mechanical efficacy and allow to increase the speed of rotation to a maximum of 20°/s, thus faster acquisitions can be made possible. • QA phantom - Consists of a Flexmap phantom, a dedicated Phantom mount to ensure a reproducible phantom positioning and dedicated software tools to perform system evaluation and calibration workflows. Corrects for mechanical flex of arms (source and detector) during a CBCT acquisition in 9 degrees of freedom (3 source translations, 3 detector offsets, 3 detector rotations).

Lasers & Cameras

Qty	Article number	Description
1	185040	**Detector sided lasers for 2D ROI definition** This package includes hardware components and software controls allowing to visualize the adjusted X-ray field at exit surface of patient, as it results from the current collimation on the source sided collimator. This is achieved by means of four detector mounted, independent moveable lasers, prior to imaging. The field is inversely

Qty	Article number	Description
		projected from the moveable and titlable line lasers alongside and laterally of the active area of the panel. Computer controlled laser lines are directed towards the focal spot. This enables the user to set a proper collimation of the imaged area at the first shot.
1	185041	**Detector mounted cameras** - integrated detector mounted cameras for patient monitoring. The package incorporates two cameras left and right side of detector arm. Cameras rotate with the detector and images (video stream) can be displayed in real time on the RingPad (HMI) / external workstation UI. Image pre-processing is done on the detector arm in a rotating camera control system board, video signals are then transferred to the internal computer and HMI via internal LAN. Main use case is supporting patient setup on couch and patient monitoring during image acquisition or treatment remotely from a control room. Cameras are mounted on a rigid internal frame and can be calibrated for stereoscopic applications, to capture 3D / 4D surface information or to track objects in the stereotactic coordinate system of the ring gantry without a need to crossregister with external tracking cameras. Cameras can also be used for collision avoidance purposes, e.g. when panel moves below patient couch.
1	185042	**Gantry mounted cameras** - integrated gantry mounted camers for patient monitoring Two stereoscopic gantry mounted cameras, to be used for surface scanning in case the patient is not in the field of view of the detector mounted cameras due to detector position. Camera signals are internally routed and video stream can be displayed in real time on HMI or processed on external workstation. Used for patient monitoring.
1	185017	**External Review workstation** - external workstation and required controls allowing image review from a control room. A fully equipped external workstation to be setup in a control room used for image review on a larger screen. The workstation provides a dedicated graphics card for parallel computing (CUDA) of computationally expensive calculations (e.g. reconstructions, registrations).

Fluoroscopy Package

Qty	Article number	Description
1	185024	**The fluoroscopy package** includes all hardware and software components allowing the use of the system as a fluoroscopic device, offering real time imaging capabilities and providing functions like last image hold (LIH), time averaging (motion) and recording of cine mode videos. With the fluoroscopy package comes a version of the RingPad (HMI) software to support required controls for fluoroscopic workflows, provides dedicated user information and real time image visualization. In addition, a wireless footswitch is provided, supporting hands free image acquisition and export.

Inclined Imaging

Qty	Article number	Description
1	185036	**Inclined imaging** - additional built in motor gear units allow tilting of the gantry for inclined 2D and 3D imaging.

High-Definition Image Quality Pack

Qty	Article number	Description
1	185011	**External viewing package** - a monitor which can be connected to the RingPad (HIMI) for image visualization on a large screen. The monitor can be mounted on a wall in the imaging room for real time review of images, e.g. In fluoroscopic mode.
1	185031	**High Definition Image Quality pack** includes; * detector perturbation - technique to reduce circular artifacts in low contrast imaging. * Bow-tie filter - the filter will automatically deploy if imaging protocol requests. Fluence modulation and dose rate dependent image corrections and calibration and reconstruction algorithms have been developed and optimized to be compatible with the built in bow tie filter. For improved dynamic range and low contrast soft tissue imaging.

Low Dose Package

Qty	Article number	Description
1	185033	**Low dose package** includes; * velocity modulations - dose modulation during acquisition * paediatric imaging - integration of a moveable filter wheel and provision of dedicated protocols to meet the needs of the paediatric imaging.

Crosshair View of X-Ray

Qty	Article number	Description
1	185037	**Laser Guided Imaging center definition - source sided** The package includes a first source sided, static transaxial line laser to mark the central axis plane and a second source sided, moveable laser to mark the sagittal/coronal plane. The moveable second line laser accomodates variable source - detector offsets in non-isocentric imaging. Buttons to manually adjust the lasers from the RingPad (HMI) are included.

Console for Workstation Motion Ctrl and Image

Qty	Article number	Description
1	185018	**Remote Control Console** - for motion control and image acquisition from a workstation located in a dislocated control room. In addition to the RingPad (HMI), image acquisitions can be started from an external workstation by means of hardwired buttons (e.g. reset, confirm, move/irradiate (execute), interrupt, terminate and e-stop) on the control console located in a radiation protected area. Software coordinates safe hand over of user control from the RingPad to the external workstation, and vice versa.

Qty	Article number	Description
1	185016	**Mobile Viewing Station** To display planar, fluoroscopic or 3D (CB)CT data of the ImagingRing and to provide a wireless connection to the ImagingRing through the docked RingPad. Display of the graphical user interface to enable control of image acquisition and viewing from a separate location in or outside the room where the imaging device is located. Included is a 27" monitor, a Logitec mouse and keyboard. On the Cart is a docking station for the RingPad which charges the RingPad when docked. The connections to the ImagingRing are through wifi, only a power outlet is needed in the room.

Installation / Training / Travel

Qty	Article number	Description
1	199185	**Installation of the ImagingRing.** Estimated installation time is 2 days. One day installation, configuration, calibration, connectivity. Second day customer acceptance. Structural alterations are not included. Travel, accommodation & subsistence expenses will be itemized and charged separately at actual cost unless travel and accommodation are included in this quotation.
2	200734	**Operator training** This 1 day on-site training addresses the user aspects of the ImagingRing and is intended to familiarize hospital staff with operating the system and handling the safety issues. The course consists of demonstrations, discussions and hands-on cases for practical use. The maximum number of participants is 4. The price does not include travel and accommodation costs of the trainer. These will be itemized and charged separately unless travel and accommodation are included in the quotation.
1	998USTCINSTALL	**Travel and Accommodation for Installation 4 days**

Qty	Article number	Description
1	998USTC1DAY	**Travel and Accommodation 1 day**
1	998USTCPERDAY	**Travel and Accommodation additional day**

Qty	Article number	Description
1	200760	**Clinical Training (US) consisting of:** 1-day on-site clinical assistance by an Elekta Applications Specialist (up to two people from clinical site maximum attendance, otherwise additional cost will apply). This on-site visit requires pre-scheduling with Elekta Training Department. (Up to 3-4 weeks lead time may be required). Elekta will provide written confirmation of date and time of on-site Applications Specialist clinical support visit. Includes travel, accommodation and expenses for trainer.

Qty	Article number	Description
1	185500	**3D mobile Imaging Table,Biodex-820, 115VAC** **Designed for use with 3D C-Arm, O-Arm and Mobile CT Scanners** Compare TablesDesigned and equipped for use with 3D C-Arm for seed implantation, urology, thoracic/vascular and other general C-Arm and O-Arm applications. The narrow, low-attenuation carbon-fiber tabletop is cantilevered to accommodate portable 3D C-Arms. The functional design provides unrestricted access with minimal radiation exposure to clinicians. **Power Motions** The table features motorized actuation of height, X-Y, lateral roll and Trendelenburg motions of the tabletop. The hand-held and foot-operated controllers can be positioned for access from any point around the table and ensure quick and safe tabletop positioning during any phase of a procedure. The "Level" feature returns the table to 0° tilt and 0° lateral roll, bringing the table quickly to a level position. Both controllers can be used for motorized X-Y positioning of the tabletop and feature proportional speed control. **More Adjustments and Features…** The table comes equipped with a lightweight, non-imaging patient transfer extension and a radiolucent extension. A standard OR accessory rail located at the foot end of the table makes stepper positioning quick and easy. Select from knee crutches or the PAL Stirrups, standard or Dura Board arm boards, the choice is yours…configure to your exact specifications. Both AC and battery power are standard. When operating on battery, there are no power cords to hinder movement or block casters. Battery charging can be accomplished during off hours by plugging in the AC adapter cord. An optional battery with separate charging unit can provide continuous cordless operation.applications. The narrow, low-attenuation carbon-fiber tabletop is cantilevered to accommodate portable 3D C-Arms.
1	185502	**Stirrups, PAL with boot (pair) for Biodex table, US rails** PAL Stirrups represent the gold standard in lithotomy positioning. They allow for easy adjustment of abduction and lithotomy while maintaining the sterile field. The boot design reduces pressure under the popliteal fossa and the superficial peroneal nerve. The stirrup enables safe and easy positioning while providing enhanced surgical site access.
1	185504	**Rail Mounted Arm boards (pair), US rails** Detachable Arm Boards with Pads
1	185505	**Adjustable Height Mounted IV Pole**

Biodex-820 Table [2023-386522-BL]

Qty	Description
1	**3D mobile Imaging Table,Biodex-820, 115VAC** **Designed for use with 3D C-Arm, O-Arm and Mobile CT Scanners** Compare TablesDesigned and equipped for use with 3D C-Arm for seed implantation, urology, thoracic/vascular and other general C-Arm and O-Arm applications. The narrow, low-attenuation carbon-fiber tabletop is cantilevered to accommodate portable 3D C-Arms. The functional design provides unrestricted access with minimal radiation exposure to clinicians. **Power Motions** The table features motorized actuation of height, X-Y, lateral roll and Trendelenburg motions of the tabletop. The hand-held and foot-operated controllers can be positioned for access from any point around the table and ensure quick and safe tabletop positioning during any phase of a procedure. The "Level" feature returns the table to 0° tilt and 0° lateral roll, bringing the table quickly to a level position. Both controllers can be used for motorized X-Y positioning of the tabletop and feature proportional speed control. **More Adjustments and Features…** The table comes equipped with a lightweight, non-imaging patient transfer extension and a radiolucent extension. A standard OR accessory rail located at the foot end of the table makes stepper positioning quick and easy. Select from knee crutches or the PAL Stirrups, standard or Dura Board arm boards, the choice is yours…configure to your exact specifications. Both AC and battery power are standard. When operating on battery, there are no power cords to hinder movement or block casters. Battery charging can be accomplished during off hours by plugging in the AC adapter cord. An optional battery with separate charging unit can provide continuous cordless operation.applications. The narrow, low-attenuation carbon-fiber tabletop is cantilevered to accommodate portable 3D C-Arms.
1	**Stirrups, PAL with boot (pair) for Biodex table, US rails** PAL Stirrups represent the gold standard in lithotomy positioning. They allow for easy adjustment of abduction and lithotomy while maintaining the sterile field. The boot design reduces pressure under the popliteal fossa and the superficial peroneal nerve. The stirrup enables safe and easy positioning while providing enhanced surgical site access.
1	**Rail Mounted Arm boards (pair), US rails** Detachable Arm Boards with Pads
1	**Adjustable Height Mounted IV Pole**

EXHIBIT A-1
Scope of Supply for Services

Elekta Care ImagingRing - Gold

Atrium Health Levine Cancer Institute
1021 Morehead Drive
Charlotte, NC 28204
Site Number: TBD

Maintenance & Support Service Fees

Annual Maintenance & Support Fee (*)	USD	$76,411.62
Discount		9.96 %
Annual Maintenance & Support Fee offer price (*)	USD	$68,800.00
Term in months		60
Contract Start Date		Upon execution of this Agreement
Total Maintenance & Support Service Fee (*)	USD	$344,000.00
Price is based on invoice schedule		Annually

(*) Excluding applicable CPI increase

Payment / invoicing options		Please indicate selected Invoicing Option
Annual Invoicing (IN ADVANCE)	No additional charge	_____
Bi-Annual invoicing	Additional 2% fee	_____
Quarterly invoicing	Additional 4% fee	_____
Monthly invoicing	Additional 6% fee	_____

Service Hours and Response Time

Remote Services Accepted	No
Estimated spare parts response time	Within 24 hours (excluding weekends and holidays)
Estimated Onsite response time	Within 12 working hours
Uptime guarantee	97%

Covered Products

Qty	Part Number	Description	Serial #
1	SBIRM-FLUOR-Y	Fluoroscopy pack - Gold	
1	SBIRM-PERFORM-Y	ImagingRing m Performance - Gold	
1	SBIRM-INCLIMG-Y	Inclined Imaging - Gold	
1	SBIRM-LOWPACK-Y	Low dose package - Gold	
1	SBIRM-X-XRAY-Y	Crosshair view of Xray Cax - Gold	
1	SBIRM-DET-CAM-Y	Detector mounted cameras - Gold	
1	SBIRM-DET-ROI-Y	Detector sided lasers for ROI - Gold	
1	SBIRM-EXTVIEW-Y	External view package - Gold	
1	SBIRM-GNT-CAM-Y	Gantry mounted cameras - Gold	
1	SBIRM-REMCON-Y	Remote Control Console - Gold	

Optional services selected

Qty	Part Number	Description
1	OB-IRM-TROPTWKS	ImagingRing-Technology Refresh Optional Workstation
1	OB-IRM-TRHMI	ImagingRing-Technology Refresh RingPad

Elekta Care ImagingRing - Gold

LABOR AND PARTS COVERAGE

- Management Service Reviews
- Hardware and Software Safety Releases
- Genuine Elekta Parts Availability
- Spare Parts
- Corrective Maintenance (Emergency Support)
- Planned Maintenance

SOFTWARE SUPPORT

- Software Updates
- Software Upgrades

SYSTEM AVAILIBILITY

- Uptime Guarantee
- Technical Support (Email/Phone)
- Application Support (telephone)
- Technical Information Supply

TECHNOLOGY REFRESH

- Technology Refresh

REMOTE SERVICES

- Remote Services Technical Online Support
- Remote Services Application Online Support

BUSINESS SERVICES

- Elekta Care™ Community

Elekta Care Flexitron - Gold

Atrium Health Levine Cancer Institute
1021 Morehead Drive
Charlotte, NC 28204
Site Number: TBD

Maintenance & Support Service Fees

Annual Maintenance & Support Fee (*)	USD	$77,977.23
Discount		35.86 %
Annual Maintenance & Support Fee offer price (*)	USD	$50,010.88
Term in months		60
Contract Start Date		Upon expiry of the Warranty period
Total Maintenance & Support Service Fee (*)	USD	$250,054.39
Price is based on invoice schedule		Annually

(*) Excluding applicable CPI increase

Payment / invoicing options		Please indicate selected Invoicing Option
Annual Invoicing (IN ADVANCE)	No additional charge	_____
Bi-Annual invoicing	Additional 2% fee	_____
Quarterly invoicing	Additional 4% fee	_____
Monthly invoicing	Additional 6% fee	_____

Service Hours and Response Time

Remote Services Accepted	No
Estimated spare parts response time	Within 24 hours (excluding weekends and holidays)
Estimated Onsite response time	Within 12 working hours
Uptime guarantee	97%

Covered Products

Qty	Part Number	Description	Serial #
1	SBFL-40CH-IR-Y	Flexitron 40Channels Iridium - Y	
1	SBFL-REM-CAM-Y	Remote Controlled Camera - Y	

Optional services selected

Qty	Part Number	Description
20	OBFL-SRC-10CI	Selected optional coverage for Flexitron® Source HDR 10Ci
20	OB-SHIP-HNDLNG	Selected optional coverage for Shipping and handling Costs
20	OBFL-IR-CHCKCBL	FLEXITRON IRIDIUM CHECK CABLE
1	OB-AFT-HWOBS	AFTERLOADER, HARDWARE TECHNOLOGY REFRESH (DESKTOP)

Elekta Care Flexitron - Gold

LABOR AND PARTS COVERAGE

- Management Service Reviews
- Hardware and Software Safety Releases
- Genuine Elekta Parts Availability
- Spare Parts
- Corrective Maintenance (Emergency Support)
- Planned Maintenance

SOFTWARE SUPPORT

- Software Updates
- Software Upgrades

SYSTEM AVAILIBILITY

- Uptime Guarantee
- Technical Support (Email/Phone)
- Application Support (telephone)
- Technical Information Supply

TECHNOLOGY REFRESH

- Technology Refresh

REMOTE SERVICES

- Remote Services Technical Online Support
- Remote Services Application Online Support

BUSINESS SERVICES

- Elekta Care™ Community
- Sources (Brachytherapy)

Elekta Care Oncentra Brachy - Gold

Atrium Health Levine Cancer Institute
1021 Morehead Drive
Charlotte, NC 28204
Site Number: TBD

Maintenance & Support Service Fees

Annual Maintenance & Support Fee (*)	USD	$32,481.06
Discount		30.76 %
Annual Maintenance & Support Fee offer price (*)	USD	$22,489.12
Term in months		60
Contract Start Date		Upon expiry of the Warranty period
Total Maintenance & Support Service Fee (*)	USD	$112,445.61
Price is based on invoice schedule		Annually

(*) Excluding applicable CPI increase

Payment / invoicing options		Please indicate selected Invoicing Option
Annual Invoicing (IN ADVANCE)	No additional charge	_____
Bi-Annual invoicing	Additional 2% fee	_____
Quarterly invoicing	Additional 4% fee	_____
Monthly invoicing	Additional 6% fee	_____

Service Hours and Response Time

Remote Services Accepted	No
Estimated spare parts response time	Within 24 hours (excluding weekends and holidays)
Estimated Onsite response time	Within 12 working hours

Covered Products

Qty	Part Number	Description	Serial #
1	SBOB-APPL-MOD-Y	Oncentra Brachy, Applicator Modeling - Y	
1	SBOB-EXP-FLT-Y	Oncentra Brachy, Export float - Y	
1	SBOB-HIPO-Y	Oncentra Brachy, HIPO - Y	
1	SBOB-HW-PLFM-Y	Oncentra Brachy, Hardware Platform - Y	
1	SBOB-IPSA-FLT-Y	Oncentra Brachy, IPSA float - Y	
1	SBOB-IR-FLT-Y	Oncentra Brachy, Image Registration float - Y	
1	SBOB-IMP-FLT-Y	Oncentra Brachy, Import float - Y	
1	SBOB-PA-FLT-Y	Oncentra Brachy, Plan Analysis float - Y	
1	SBOB-BP-FLT-Y	Oncentra Brachy, float - Y	

Optional services selected

Qty	Part Number	Description
1	OB-OCB-HWOBS	OCENTRA BRACHY, HARDWARE TECHNOLOGY REFRESH (WORKSTATION)

Elekta Care Oncentra Brachy - Gold

LABOR AND PARTS COVERAGE

- Management Service Reviews
- Hardware and Software Safety Releases
- Genuine Elekta Parts Availability
- Spare Parts
- Corrective Maintenance (Emergency Support)
- Planned Maintenance

SOFTWARE SUPPORT

- Software Updates
- Software Upgrades

SYSTEM AVAILIBILITY

- Technical Support (Email/Phone)
- Application Support (telephone)
- Technical Information Supply

TECHNOLOGY REFRESH

- Technology Refresh

REMOTE SERVICES

- Remote Services Technical Online Support
- Remote Services Application Online Support

BUSINESS SERVICES

- Elekta Care™ Community

Elekta Care Oncentra Prostate - Gold

Atrium Health Levine Cancer Institute
1021 Morehead Drive
Charlotte, NC 28204
Site Number: TBD

Maintenance & Support Service Fees

Annual Maintenance & Support Fee (*)	USD	$29,702.13
Discount		36.70 %
Annual Maintenance & Support Fee offer price (*)	USD	$18,800.00
Term in months		60
Contract Start Date		Upon expiry of the Warranty period
Total Maintenance & Support Service Fee (*)	USD	$94,000.00
Price is based on invoice schedule		Annually

(*) Excluding applicable CPI increase

Payment / invoicing options		Please indicate selected Invoicing Option
Annual Invoicing (IN ADVANCE)	No additional charge	_____
Bi-Annual invoicing	Additional 2% fee	_____
Quarterly invoicing	Additional 4% fee	_____
Monthly invoicing	Additional 6% fee	_____

Service Hours and Response Time

Remote Services Accepted	No
Estimated spare parts response time	Within 24 hours (excluding weekends and holidays)
Estimated Onsite response time	Within 12 working hours

Covered Products

Qty	Part Number	Description	Serial #
1	SBOP-ECRM-Y	ECRM (EndoCavity Rotational Mover) - Y	
1	SBOP-Y	Oncentra Prostate - Y	
1	SBOP-ADVIMG-Y	Oncentra Prostate Advance Imaging - Y	
1	SBOP-ADVOPT-Y	Oncentra Prostate Advance Optimization - Y	
1	SBOP-TBLENCDR-Y	Oncentra Prostate OncoSelect Tbl Mnt Step+Enc - Y	
1	SBOP-ENC-SLCT-Y	Stepper encoder -- OncoSelect Stepper - Y	

Optional services selected

Qty	Part Number	Description
1	OB-OCP-HWOBS	ONCENTRA PROSTATE, HARDWARE TECHNOLOGY REFRESH (LAPTOP)

Elekta Care Oncentra Prostate - Gold

LABOR AND PARTS COVERAGE

- Management Service Reviews
- Hardware and Software Safety Releases
- Genuine Elekta Parts Availability
- Spare Parts
- Corrective Maintenance (Emergency Support)
- Planned Maintenance

SOFTWARE SUPPORT

- Software Updates
- Software Upgrades

SYSTEM AVAILIBILITY

- Technical Support (Email/Phone)
- Application Support (telephone)
- Technical Information Supply

TECHNOLOGY REFRESH

- Technology Refresh

REMOTE SERVICES

- Remote Services Technical Online Support
- Remote Services Application Online Support

BUSINESS SERVICES

- Elekta Care™ Community

Agreed Available Time: In consideration for the Service Fee above the Services shall be provided during the Agreed Available Time, as defined below:

Agreed Available Time consists of Normal Office Hours plus any Agreed Overtime Hours, if any are listed below.
Additional Hours are any hours worked outside of the Agreed Available Time and will be charged at applicable time and material rates.

Note: All times, dates and holidays are those observed by the local Elekta office of the country in which the Site is located.

Normal Office Hours:
08:00 - 17:00 Monday to Friday excluding holidays.

Agreed Available Time:

ImagingRing Performance		
	08:00 - 17:00	Monday to Friday excluding holidays
Flexitron		
	08:00 - 17:00	Monday to Friday excluding holidays
Oncentra Brachy		
	08:00 - 17:00	Monday to Friday excluding holidays
Oncentra Prostate and/or Seeds		
	08:00 - 17:00	Monday to Friday excluding holidays

Agreed discounts on:

Standard Spare Parts:

ImagingRing Performance
100.00 %
Flexitron
100.00 %
Oncentra Brachy
100.00 %
Oncentra Prostate and/or Seeds
100.00 %

End of Life and Guaranteed Support: The supply of Services is subject to the End of Life and End of Guaranteed Support policy.

Removed Parts: Any part removed from the Products and replaced by a replacement part or on behalf of Elekta under this agreement shall become the property of Elekta upon removal. Elekta shall be free to dispose of or use any removed parts at its discretion.

ELEKTA, INC. HOLIDAY SCHEDULE
NEW YEAR'S DAY
MLK DAY
MEMORIAL DAY
INDEPENDENCE DAY
LABOR DAY
THANKSGIVING DAY
DAY AFTER THANKSGIVING
CHRISTMAS EVE
CHRISTMAS DAY

EXHIBIT A-2
ELEKTA CARE COVERED MODULES

The following section describes all the Elekta Care™ service modules available. Each section shall only apply where it is specifically referred as an included module in the Service Scope of Supply.

1. LABOR AND PARTS COVERAGE

1.1 Management Service Reviews
The local Elekta service manager will conduct a periodic management meeting. This will take place either in person or remotely as agreed between the Parties, with the intention of reviewing the performance of both Elekta and the Products, and to mutually plan any activities or changes needed for the period ahead.

1.2 Hardware/Software Safety Releases
The supply, and, where the Customer is unable to do so itself, installation of all software and hardware releases declared by Elekta, via the publication of a mandatory Field Change Order, as necessary to maintain the safe operation of the Products.

1.3 Genuine Elekta Parts Availability
Availability of Unique Elekta product spare parts, Field Replaceable Units or modification kits by Elekta's Lifecycle Stock Control Management System to ensure availability throughout the expected system lifetime.

1.4 Spare Parts
Should any Product or part be defective in material or workmanship and/or does not perform according to the Product's Specifications, Elekta shall supply and deliver at its cost any replacement spare parts necessary to restore compliance with the Specifications. Consumable parts, and Unique Components, or those parts required to be replaced as part of the planned maintenance are not covered by this module.

Elekta may use refurbished parts and components to replace any defective parts or component.

Customer's rights under this module shall not apply if the Product or part is a Third Party Product or is defective as described above due to (a) accident or negligence or intentional act or omission of customer or customer's representative (b) if the Product or parts have been used or stored in a manner not authorized by Elekta, (c) lack of routine care or maintenance as indicated by Elekta, (d) modification of the Product not performed by a certified Elekta engineer, (e) the Product or part being declared End of Guaranteed Support or End of Life.

1.5 Corrective Maintenance (Emergency Support)
On-site technical support by Elekta-certified engineers to resolve urgent technical issues.

The service includes a report detailing any actions undertaken and any additional work the engineer recommends needs to be addressed.

Emergency Support is carried out during the Agreed Available Time. Any activity undertaken by Elekta engineers outside of the Agreed Available Time will be charged at applicable overtime rates.

The response time to guarantee an on-site visit is as specified in exhibit A-1 of this Agreement.

Any spare parts needed for the repair are not included in this option. Inclusion of travel time and costs are only included if specifically agreed between the Parties in writing.

1.6 Planned Maintenance
Elekta shall perform site visits for the purposes of planned maintenance ("PM"). The number and duration of the visits required shall vary according to the products covered and will be in accordance with the Elekta planned maintenance schedules published at the time.

Unless specifically agreed otherwise, all planned maintenance will be carried out during Normal Office Hours.

Elekta will make available the recommended schedule including the duration of visits, time between visits and general scope of work at the beginning of each agreement year. Mutually convenient dates will then be agreed upon between Elekta and the Customer. Should additional work be required over the agreed planned activity, this will be charged at Elekta's current rates.

The cost of supply of spare parts or consumables other than those identified by Elekta as being part of the standard planned maintenance and found to be required during the planned visits are not included in this module.

Elekta shall issue a report detailing the actions undertaken during the planned maintenance visits and any additional recommended work.

2. SOFTWARE SUPPORT

There are various possible Software Support modules depending on your selected service agreement level: Software Updates, Software Upgrades and New Licensable Software, as defined below. To each module, the "General Conditions" below shall apply.

2.1 Software Updates
Updates are minor improvements, patches, or service pack releases to a version of software, but do not upgrade the software to the next major version (if one exists).

2.2 Software Upgrades
Upgrades are major software releases of feature enhancements and performance improvements to existing licensed software functionality. This option does not cover the transition onto alternative or next generation platforms.

3. SYSTEM AVAILABILITY

The Customer will respond to any alerts provided by the Products or Elekta and will take appropriate action to manage any such alerts. Information on actions can be found in Instructions for Use or as otherwise notified to the Customer by Elekta from time to time.

The Customer will inform Elekta in a timely manner and in advance of any planned power outages.

3.1 Uptime Guarantee
Elekta hereby guarantees that the Hardware will achieve an annual Uptime listed in the Service Scope of Supply for the duration of this Agreement.

Uptime statistics will be evaluated for each successive twelve (12) month period from the Effective Date ("Contract Year").

Uptime percentage will be calculated using the following formula:

$$\text{UPTIME} = \frac{\text{Agreed Available Time - Downtime}}{\text{Agreed Available Time}}$$

For the purposes of the Uptime calculation, Agreed Available Time shall be as noted in the Service Scope of Supply and shall exclude time set aside by the customer or in mutual agreement between the customer and Elekta for planned activities such as planned maintenance, system modifications, improvements and/or updates or customer-initiated treatment shutdowns.

Downtime, with the exclusions set out below, means the aggregate hours within the Agreed Available Time during a Contract Year, when the Product(s) are inoperable solely due to system failure in the Product(s) which, as a result thereof, cannot be used for patient treatment. For the avoidance of a doubt, if a specific system component is inoperable but a patient can still be treated, the Product(s) will be classified as degraded and will not constitute Downtime.

Downtime begins when a Customer calls Elekta Care Support during the Agreed Available Time notifying that, due to an unplanned event, the Customer is no longer able to treat patients and the Product(s) is available for immediate servicing. Downtime continues during the Agreed Available Time period until repair has been completed and the Elekta engineer returns access to the Product(s) back to the customer for them to initiate QA procedures and thereafter allow clinical use to recommence. Start and end of Downtime shall be as documented within the Elekta service management system.

Any repair time or inoperability that occurs outside the Agreed Available Time is excluded from the Downtime calculation.

All system failures, damage or malfunction of the Product(s) caused by the Customer or a third party either through act or failure to act (e.g. through misuse, operator error) or by breach of the Customer's undertakings under the Agreement (including failure to act according to manuals and handbooks) or by external causes beyond Elekta's control (e.g. power failure or failure of environmental systems) are excluded from the downtime calculation.

Where applicable, enabled Remote Services and Unique Component Coverage, as defined in this Agreement, are pre-requisites for any uptime guarantee commitment.

If the Hardware fails to achieve the specific Uptime criteria on average over a Contract Year, then Customer shall benefit from a discount, applicable to the agreed service for the applicable Product for the Contract Year following that in which the Uptime has not been met. This discount shall be the sole and exclusive remedy for any failure to meet the Uptime Guarantee.

Percentage Uptime		Brachy
From	To	Gold
99	100	0.0%
98	99	0.0%
97	98	0.0%
96	97	3.0%
95	96	4.0%
94	95	5.0%
93	94	6.0%
92	93	7.0%
91	92	8.0%
90	91	9.0%
<90	90	10.0%

3.2 Technical Support - Email/Phone
Access to the Elekta Care Support line or an Elekta Care representative, providing technical assistance and advice to ensure optimal system uptime. Access to Elekta Care Support is provided during Normal Office Hours only.

3.3 Application Support - Telephone
Direct access to the Elekta Care Support line, providing clinical and applications expertise to ensure optimal use of the system.

Access to Elekta Care Support is provided during Normal Office Hours only.

3.4 Technical Information Supply
Includes provision of technical information and bulletins designed to keep the Customer up-to-date with regards to the covered products.

Typical information includes, but is not limited to:
- Current and pending software updates & upgrades,
- Upcoming events and training opportunities,
- Important service announcements.

4. TECHNOLOGY REFRESH

Elekta will provide the necessary Hardware Upgrades to the Hardware components (as selected from the list below in this section) of the Products if an End of Life is published for such components during the term of this Agreement. Consequential upgrades to other components are not included.

The components (as defined and listed below in this section) will from time to time be replaced at least once during the term of this Agreement irrespective whether an End of Life date has been published.

The installation of any new component covered by this module is provided free of charge if performed during the Agreed Available Time and at a time and date mutually agreed by the Parties.

Any applications or technical training deemed necessary following an upgrade is not included in this module.

Unless specifically agreed otherwise, the systems containing the covered products must be at the most current release levels at the start of this Agreement.

This module shall only apply if the Service Agreement is for a minimum duration of 3 years or has been in existence and renewed in the 3 years preceding the replacement of the hardware component.

For Brachytherapy products:
- ImagingRing m (Optional Workstation)
- ImagingRing m (HMI)

5. CONNECTIVITY, MONITORING AND REMOTE ACCCESS

For all other products not using Elekta IntelliMax®

In order to benefit from Remote Services and to ensure uptime guarantees, equipment must be connected to allow Elekta approved remote access solution (for example WebEx).

Remote Access/screen sharing, if permitted, is configurable separately and can be set to only allow visibility of the customer's screens when initiated by the customer.

5.1 Remote Services Technical Online Support
Secure remote access and phone communication for quick problem resolution, pre-checks prior to on-site visits and over the shoulder support.

This option is a prerequisite for any Uptime Guarantee unless otherwise agreed.

Technical Online Support is only available during Normal Office Hours.

For Leksell Gamma Knife
The service, except over the shoulder support, which will not be supported, will be included when available.

5.2 Remote Services Application Online Support
Secure controlled remote access and phone communication for guided application advice to safeguard clinical availability and enable refresher training.

Applications Online Support is only available during Normal Office Hours.

6. BUSINESS SERVICES

6.1 Elekta Care™ Community
Access to the Elekta Care™ Community providing a range of useful system and product information.

Information on the community changes all the time, but typically includes:
- Proactive & preventive information and articles
- Frequently Asked Questions
- Knowledge bases
- Documentation
- Useful training information

END OF LIFE AND END OF GUARANTEED SUPPORT POLICY

Elekta uses 3 distinct Lifecycle Categories for products that have either been superseded by a newer model or have reached the limit of their declared service life.

The 3 Lifecycle Categories are as follows:

1. End of Sales: is the date after which the product will be removed from the Sales Catalogue

- Elekta will no longer market or offer the product for general sale.
- Elekta will no longer develop new features or functionality for this product.
- Education and training will still be available for the product.
- Elekta will discontinue the manufacture of this product, but will continue to make available stocks of spare parts for repairs of the product under its existing maintenance and support agreements with Customers until End of Guaranteed Support is announced.

2. End of Guaranteed Support: is the date after which Elekta will be unable to guarantee normal servicing of hardware or software products.

- After this date, the availability of the product, component or spare parts can no longer be guaranteed.
- Elekta's obligation under its maintenance and support agreements may be subject to the limited availability of parts and knowledge and this may affect Elekta's ability to provide solutions in a timely manner. Uptime guarantees under the maintenance and support agreement for the product will cease.
- Where the hardware or software product or component part forms part of a larger host system, Elekta will continue to provide maintenance and support for the host system, however, Elekta will not be responsible for any downtime of the host system as a result of a failure of any hardware or software product or component part that is subject to an End of Guaranteed Support Notice.
- In the event that Elekta is unable to supply replacement parts after End of Guaranteed Support, circumstances may exist where, following a failure, Elekta is not able to restore the product to operation. The only course of action would then be for Customer to purchase an upgrade to restore the system functionality.
- Safety investigations, notifications and fixes will continue.
- Customers may continue to use systems at End of Guaranteed Support but in doing so acknowledge that there is an increased risk of extended or even permanent downtime following a failure.

3. End of Life is the date after which Elekta will no longer support the Product.

- Elekta will typically release an End of Life Notice no less than 12 months after the date of End of Guaranteed Support, however there may be circumstances where this date is reached earlier.
- From the date of End of Life, Elekta shall not:
    - Enter into any maintenance and support agreements or any other contractual relationship with respect to products at End of Life.
    - Provide spare parts, technical support, training or other fixes relating to the product.
- Where the hardware or software product or component part forms part of a larger host system, Elekta will continue to provide maintenance and support for the host system, however, Elekta will not be responsible for any downtime of the host system as a result of a failure of any hardware or software product or component part that is subject to an End of Life Notice.
- Should the hardware or software product fail following the declared End of Life date, Elekta will only provide a solution based on Customer's upgrade to a currently supported platform at the Customer's expense.
- Customer's continued use of a product after End of Life is at Customer's own risk and Customer acknowledges that there is a significant risk of permanent downtime following a failure.
- Elekta will continue to investigate potential safety issues and may from time to time issue safety notices. Elekta will, however, no longer develop, or resolve issues with hardware or software product or component parts which are at End of Life.

With the exception of End of Sales, Elekta will construct a lifecycle announcement to formally declare the End of Guaranteed Support or End of Life date and to clarify the implications to any affected customer or end user.

The lifecycle announcements will be issued to affected customers with as much notice as possible before the declared dates take effect. This notice period will typically be 12 months but cannot be guaranteed.

With regards to customers in Elekta's distributor markets, the lifecycle announcements will be issued to the Elekta distributor who will then be responsible for onward communication to the customer or end user.

Attachment D

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CMC Brachytherapy Equipment Replacement

Provider/Company: Atrium Health

(1)	Purchase price of land	$0
(2)	Closing costs	$0
(3)	Site Preparation	$0
(4)	Construction/Renovation Contract	$1,359,600
(5)	Landscaping	$0
(6)	Architect/Engineering Fees	$175,000
(7)	Medical Equipment	$1,385,874
(8)	Non Medical Equipment	$0
(9)	Furniture	$0
(10)	Consultant Fees (CON Fees, Legal Fees)	N/A
(11)	Financing Costs	N/A
(12)	Interest During Construction	N/A
(13)	Other (IS, Security, Internal Allocation)	$379,526
(14)	**Total Capital Cost**	$3,300,000

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

03/10/23

(Signature of Licensed Architect or Engineer) *DATE*

WILLIAM MICHAEL MUMFORD
LICENSED ARCHITECT
8284
NORTH CAROLINA
CHARLOTTE, N. C.

Sales taxes have been included in these equipment costs. However, because Atrium Health is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that Atrium Health initially incurs for this medical equipment purchase will be refunded to Atrium Health, and thus will reduce the capital costs that Atrium Health actually incurs for the equipment by $ 93,766 .

Attachment E

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

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

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

July 2, 2009

F. Del Murphy, Vice President
CHS Management Company
Carolinas HealthCare System
P.O. Box 32861
Charlotte, NC 28232-2861

RE: No Review/ Carolinas Medical Center/ Acquisition of a dedicated HDR CT Scanner/ Mecklenburg County
FID #943070

Dear Mr. Murphy:

The Certificate of Need (CON) Section received your letters of June 24, 2008 and January 15, 2008 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request,** the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,

Carol L. Hutchison, Project Analyst
Certificate of Need Section

Lee B. Hoffman, Chief
Certificate of Need Section

Attachment F

Elekta

Product Technical Specifications

Flexitron®

Brachytherapy afterloading platform

Performance you can rely on

With Flexitron®, we have created a new way of working, setting the new standard in treatment delivery.

Features like source position reference zero at the entrance of the applicator, metric dwell position numbering, forward stepping technology, standard transfer length and a time-saving, intuitive user interface support a logical workflow and ease-of-use system operation. Flexitron provides performance you can rely on for brachytherapy treatments.

This product datasheet is applicable for the Flexitron HDR afterloader with an Iridium-192 source.

The Flexitron system consists of three main components:

Treatment Delivery Unit (TDU)
The Treatment Delivery Unit houses the radioactive source, stored in a shielded safe. For treatment delivery, applicators are connected through transfer tubes or adapters. The TDU delivers the radiation dose based on the treatment plan that is transferred to it.

Treatment Communication Console (TCC)
The Treatment Communication Console holds the dedicated Flexitron software to operate the Flexitron platform. The intuitive layout of the software leads you through the treatment preparation and delivery workflow. During treatment, a color scheme shows the position of the source and the exact status of the treatment progress.

Treatment Control Panel (TCP)
A touch screen interface controls the treatment delivery. The TCP is directly connected to the TDU.

Treatment Delivery Unit (TDU)

Treatment Communication Console (TCC)

Treatment Control Panel (TCP)

Treatment Delivery Unit

- Mobile treatment delivery unit with built-in source container for approved storage of up to 444 GBq (12 Ci) Ir-192
- Dose equivalent rate at a 50 mm distance from the surface of the Treatment Delivery Unit (TDU): ≤ 100 µSv x h-1 storing a source with a strength of 444 GBq (or 12.0 Ci or 48.44 mGy x m2 x h-1) of Ir (conform IEC 60601-2-17)
- Source storage container material: tungsten
- Forward stepping source technology
- Source position accuracy: +/-2.0 mm: conform IEC 60601-2-17*
- Source position reproducibility: within 0.5 mm*
- Dwell times: from 0.1 to 999.9 seconds
- Source movement: by stepper motor with incremental encoder. Maximum speed: 500 mm/s
- 10, 20 or 40 channels
- Dwell positions: from 0 to 400 mm in 1 mm steps
- Maximum treatment length: 400 mm
- Reference point zero at the end of the Transfer tube
- Height and floor space: 975 mm (height), 631 mm (depth), 445 mm (width)
- Weight: 98 kg (216 lbs)
- Power requirements: max. 250 W
- Line voltage: 220–240 VAC, 50/60 Hz 100–120 VAC, 50/60 Hz
- Uninterruptable Power Supply (UPS)
- Cable drive for check cable
- Integrated back-up battery
- Low maintenance modular drive system with low friction and touchless sensors

*Every time the source is sent out to a set position it has to arrive within a 2 mm range (according to the official regulations). The source can have a discrepancy within this 2 mm window—this could come from its environment, temperature or other aspects. The discrepancy becomes the new fixed position (as long as the source hasn't been (re-)calibrated) and under the same unchanged circumstances the source accuracy is now 0.5 mm. Calibration will correct the position of the source at the set, e.g., 200 mm position.

Radioactive Source

- Isotope type: Ir-192
- Nominal source strength for Iridium (Ir): 370 GBq (or 10.0 Ci)
- Source capsule: stainless steel, 0.86 x 4.6 mm
- Pellet construction: single solid Iridium rod, 0.6 x 3.5 mm
- Laser welded source to cable connection with additional protective collar for extra durability
- Mechanical expected service life of each source assembly: 30,000 runs or 100 obstructions (whichever comes first)
- Source cable: main part Ø 0.85 mm, ultraflex end part Ø 0.72 mm of 110 mm
- The minimum radii of curvature in applicators and transfer tubes are:
  - 11 mm for all applicators with a fixed geometry
  - 15 mm for flexible applicators with an inner diameter of 1.2 mm and outer diameter of 1.5 mm or more (such as all types of 6F flexible implants and 6F lumen catheters)
- Finished device test includes 100% visual inspection and dimensional verification
- Flexisource conforms to the following international standards: ISO 2919, ISO 9978, IAEA ST1
- Unique protective collar around source weld for extra durability

Quality Assurance

- Built-in QA components to ensure safe and reliable system operation
  - check cable to detect catheter obstructions in connected transfer tubes and applicators
  - modular precision source drives that permanently monitors all source steps made
  - channel selector that permanently monitors all transfer tube connections to afterloader
  - independent source retraction system with battery-powered DC motor source
  - detection of source retraction by proximity switches
  - detection of source retraction by optical encoder
  - integrated radiation detector for source return confirmation
  - manual source retraction option with drive motor disconnection mechanism
- Source position accuracy verification
  - using a source position check ruler and digital camera (see accessories list)
  - source position adjustable by user (+/- 2 mm)
- Source activity verification by well chamber for source calibration (see accessories list)
- Source wipe procedure for detection of radioactive contamination using the source exchange and wipe tool (see accessories list)
- Independent room radiation monitoring system with radiation warning lights column outside the treatment room to detect radiation in the treatment room (see accessories list)
- User ID and password protection

Treatment Communication Console (TCC)

- Time-saving intuitive user interface provides clear treatment delivery workflow guidance for operator
- Clear module selection
  - treatment
  - plan manager
  - maintenance
  - reports
  - QA
- Patient plan and system information at a glance
- Information bar shows system status and next steps in workflow
- System checklist provides continuously status and safety information
- Visual display of channels and dwell positions using a color scheme showing exact status of source and dwell positions
- Supports import of DICOM treatment plans and export of treatment records via network or external storage devices
- Connects seamlessly with MOSAIQ® and other DICOM unified worklist compliant oncology information systems. Requires MOSAIQ 2.5 or higher, MOSAIQ Connectivity Module for Elekta HDR [PN 45017-010001-IQRO], and access to MOSAIQ Radiation Oncology [PN 45000-000000-IQRO]
- Simple creation and editing of plans via Plan Manager module
- Pre- and post-treatment report generation
- Local database for patient plans and reports
- Individual user permission and password protection
- Can be used in combination with Oncentra® Brachy (v4.3 or higher) and Oncentra® Prostate (HDR) v4.1 or higher
- All TCC functionality is delivered on a standard desktop PC and Windows 10 IoT

Treatment Control Panel (TCP)

- Separate touch screen interface to control treatment delivery
- Powered by and connected to the treatment delivery unit
- Displays an alarm and code in alarm conditions
- Produces an audio alarm in alarm conditions
- Table top panel with emergency button and emergency reset switch with removable key
- During treatment, the remaining treatment time and radiation status are displayed
- Height: 219 mm
- Width: 195 mm
- Depth: 150 mm
- Weight: 5 kg (11 lbs)

Other

- Compatible with Elekta Brachytherapy applicators
- Multiple service options to support you and maintain your system for optimum reliability and safety
- An unprecedented range of brachytherapy training and education options that bring you up to speed with current practice and novel brachytherapy approaches
- Upgradable design to future innovations
- For HDR treatments with Iridium sources, approx. 40 cm (15.8") of high quality concrete (2.4 g/cm³) or 5 cm (2.0") of lead is required
- Even when a maze wall is used—which is recommended for treatment room shielding, especially for HDR treatment rooms—a shielded door is required at the entrance, with an option to open the door manually if an automatic opening and closing (lead) shielded door is used.

Environmental Requirements

Operating conditions

- Temperature: 10° C to 35° C (50° F to 95° F)
- Humidity: 20% to 75% relative humidity (non-condensing)
- Altitude: 0 to 4,000 meters (0 to 13,000 feet)

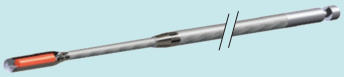
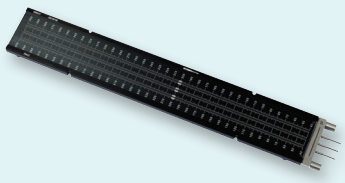
Transport and storage conditions

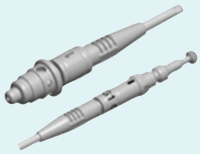
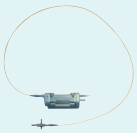
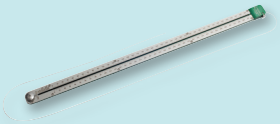
- Temperature: -20° C to 50° C (-4° F to 122° F)
- Humidity: 10% to 100% relative humidity (non-condensing)
- Atmospheric pressure range: 62 kPa to 110 kPa

Equipment Classification

- Type of protection against electric shock: Class I
- Degree of protection against electric shock: Type B
- Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC60 529: IPX0
- Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide
- Mode of operation: continuous

Flexitron HDR accessories

Item	Description	Type	Image	Part number
Flexisource Iridium-192 HDR, 370 GBq (10 Ci)	A stainless steel cable with a capsule containing an Iridium-192 source pellet. The source is shipped in a Flexisource transport container. It has an active length of 3.5 mm and steps through the applicator or implant with steps of 1 mm over a maximum length of 400 mm (401 dwell positions).	Required		136147
Check cable for Flexitron Iridium-192	Non-radioactive check cable used to automatically check if the source guiding channel is free from obstructions, before the radioactive source cable is steered out. This cable is used to verify the route to the most distal programmed dwell position for a programmed channel. The check cable is independently driven.	Required		136148
Flexitron HDR Transport Container for Iridium-192 sources	Internationally approved low weight tungsten transport and service container for the transportation of one Iridium-192 Flexisource. The transport container is shipped inside a plastic transport drum.	Required		136192
Flexitron HDR Emergency Set	Flexitron emergency set consisting of an emergency container, forceps and cutter. The emergency container can hold the source and applicator in the well in case of an emergency.	Required		136191
Flexitron HDR Source Exchange Tool for Iridium-192	Tool to load or unload sources from the Flexitron into the transport container.	Required		136164
Source Position Check Ruler	Quality control tool designed to measure and verify the correct treatment position of the sources and check cable and the length of each of the transfer tubes. The scale ranges from 40 to 400 mm. Adapter plates are available for the various transfer tube connectors. • #137.040 – SPCR adapter set to connect GYN titanium transfer tubes (#137.063) • #137.042 – SPCR adapter set to connect 5F catheter transfer tubes (#137.090, #137.091, #137.092, #137.093) (only compatible with catheter transfer tubes that were delivered after May 1 2014) • #137.043 – SPCR adapter set to connect 6F catheter transfer tubes (#137.094, #137.095, #137.096, #137.097) (only compatible with catheter transfer tubes that were delivered before May 1 2014) • #137.180 – SPCR adapter set to connect CT/MR GYN transfer tubes (#111.650) • #137.182 – SPCR adapter set to connect SS GYN transfer tubes (#111.680) . Default included in part number 136196 • #137.818 – metal needles connection block to connect SS GYN transfer tubes (#111.805, #111.816, #111.827 and #111.838)	Required		136196

Item	Description	Type	Image	Part number
Transfer Tubes	Transfer tubes and adaptors are used to connect applicators, needles, implant tubes and catheters to the Treatment Delivery Unit. They provide a fail-safe connection to ensure a clear path for the source to travel to the intended treatment positions.	Required		Depends on application
Room Radiation Monitor System	Independent room radiation monitoring system with radiation warning lights column outside the treatment room to detect radiation in the treatment room.	Recommend		077027
Treatment Status Indicator	Set of lamps located just outside the treatment room providing light signals that indicate basic treatment status information (alarm, radiation, ok to enter).	Recommend		136201
Remote Controlled Camera	High resolution patient surveillance CCTV camera located in the treatment room, that allows to monitor the patient as well as the the source position in combination with a source position check ruler. Includes a second monitor.	Recommend		136134
Start Enable Interlock	Interlock system in the treatment room to ensure all staff has left the treatment room.	Recommend		076059
Flexitron HDR Wipe and Exchange tool	The source exchange tool is required to load or unload sources from the Flexitron. Simultaneously and separately, the tool can be used to execute a wipe test as part of a QA check against radioactive contamination.	Optional		136595
Source Position Simulator	Independent QA tool to determine treatment positions and to measure the internal length of applicators. The ruler of the source position simulator indicates positions 1–400.	Optional		138200 or 138202 (country depended)
5kV insulation box	Safety switch box between external indicators and the Flexitron electrical system.	Optional		138050

For almost five decades, Elekta has been a leader in precision radiation medicine.

Our nearly 4,000 employees worldwide are committed to ensuring everyone in the world with cancer has access to—and benefits from—more precise, personalized radiotherapy treatments.

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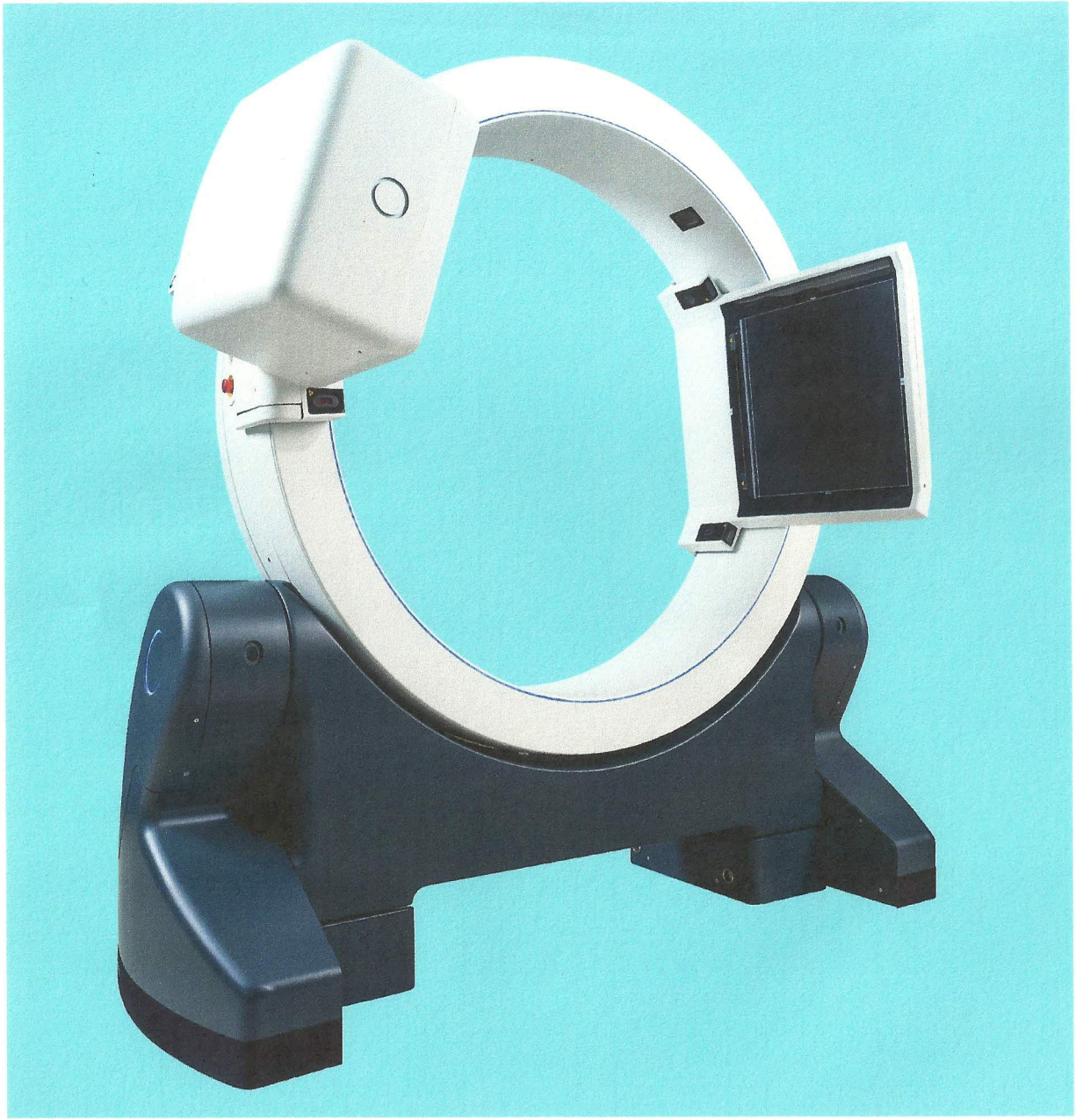

Elekta

ImagingRing

Specification sheet

System	ImagingRing m
Mounting	medPhoton robotic platform
Benefits	✓ Flexibility
	✓ Ultra-large gantry bore (121 cm) for extra-large field of view (FOV)
	✓ Brachytherapy, IORT, IGRT, IGPT, Radiology, Forensics
	✓ Battery powered maneuverability
	✓ Wireless remote control
	✓ Robotic movements
	✓ Non-isocentric imaging and dynamic collimation
	✓ Movable lasers to define scan range
CE	EN ISO 13485, EN ISO 14971, EN 62304, EN 62366, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-28, IEC 60601-2-43, IEC 60601-2-54, EN 1041:2008, EN ISO 15223-1:2016, ANSI/AAMI ES60601-1, CAN/CSA-C22.2 No. 60601-1

Imaging Capabilities	
Customizable Protocols	✓
Isocentric Imaging	✓
Non-Isocentric Imaging	✓
Adaptive Protocols	✓
X-ray Techniques and Protocols **Note:** Not all protocols may be available in standard configuration. Some protocols may be subject to a license option.	2D (planar) Radioscopy (immediate imaging) - live (last image hold) - record (save film sequence) 2D (planar) Radiography (projection) - single (iso. 25.4cm) - double stitched (iso. max. 52.1cm—0 cm overlap) - triple stitched—sequence (AP, LAT) 2D Topogram (scout view) - single slit - longitudinal extension (reduced travel) 3D (volumetric scan) small field of view (SFOV iso. 25.1 cm) - short scan short-scan (180° + divergency) - full scan full-scan (360°) - tomosynthesis (limited angle) 3D (volumetric scan) large field of view (LFOV iso. max. 49.1 cm at 0 cm overlap radius) - dual short-scan (2 x 180° + div., circular) - full offset scan (360° circular)

2D imaging	
2D Single Images	✓
2D FOV (in Isocentre) [cm]	25.4 x 25.4
2D Extended FOV (in isocentre) [cm]	25.4 x ca. 48 stitched (optional)
Scout View (Topogram)	✓ (optional)
2D Fluoroscopy (Radioscopy) incl. footswitch	✓ (optional)
2D Scatter Correction	✓ (scatter glare)
Last Image Hold	✓
Resolution	max. 3.4 LP/mm
Fluoro Frame integration	✓ (configurable averaging time)
Virtual Collimation	✓
Automatic Exposure Control (AEC) in Fluoroscopic Mode	✓
2D Flip / Rotate option	✓

3D imaging	
CBCT	✓
Full Scan (360°)	✓
Short Scan (180° + field divergency)	✓
Dual Short Scan (2 x 180°)	✓
CBCT Acquisition	LFOV dual short scan: min 45 s exposure time + 12 s switch SFOV: min. 11.6 s, typical 22–40 s (spine)
Reconstruction times (inline, typical, after exposure is finished, excl. iterative / MAR and DICOM export)	LFOV dual short scan: low resolution min 18 s, medium resolution min 28 s SFOV: low resolution min 17 s, medium resolution min 28 s limFOV: low resolution min 14 s, medium resolution min 19 s, high resolution min 35 s (all figures for normal quality mode)
High Quality Mode	✓ (internal resolution for reconstruction doubled)
Metal Artefact Reduction (MAR)	✓
3D Automatic Exposure Control (AEC)	✓ (based on previously acquired scout 2D images)
Multiplanar reconstruction (MPR)	✓ Free Navigation in 3D Volume by shifting / rotating (orthogonal) planes 3D
3D Field of View [cm]	Depends on non-isocentric offset from gantry center. All variable sizes of non-circular (elliptic) trans-axial FOVs are individually adjustable per patient scan
LFOV (large field of view) [cm^3]	max. 49.1 x 49.1 x 25.4 cm^3 (0 cm overlap)
SFOV (small field of view) [cm^3]	25.1 x 25.1 x 25.4 cm^3
Spine FOV (spine field of view) [cm^3]	12 x 12 x 20 cm^3
LimFOV (limited field of view) [cm^3]	12 x 12 x 12 cm^3

3D imaging continued	
miniFOV (mini field of view) [cm]	6 x 6 x 6 cm
USFOV (ultra-small field of view) [cm]	3 x 3 x 3 cm
3D Limited Field of View (Dynamic Collimation)	✓ (elliptic FOV)

Image Characteristics	
Pixel pitch	150 µm (binned to larger pixels for specific protocols)
Matrix	Configurable, user selectable resolution Maximum volume supported by GPU memory: 1024x1024x512x2 Byte = 1 GB [Ultra-Low (181^3 Voxels = 11 MB)] configurable Low (256^3 Voxels = 32 MB) Medium (362^3 Voxels = 90 MB) High (512^3 Voxels = 256 MB) [Ultra-High (724^3 Voxels = 724 MB)] configurable (for cubic volume, isotropic resolution)
Voxel aspect ratios	customizable per image protocol and anatomical region range from 1:1:1 (isotropic spacing) to 1:5:1 (longitudinal binning)
Voxel Size	Dynamic Voxel size adapted to FOV dimension isotropic spacing (ultralow-medium-ultrahigh resolution): LFOV 1.99—1.00v0. 50 mm SFOV 1.40—0.70—0.35 mm spine FOV 1.05—0.40—0.20 mm limFOV 1.05—0.40—0.17 mm miniFOV 1.05—0.40— 0.15 mm USFOV 1.05—0.40— 0.15 mm
Line pair resolution	max. 21 LP/cm (with Catphan, small focal spot, limited FOV collimated to Line Pair insert (values in brackets correspond to theoretically achievable resolution, function of voxel size)) LFOV 2.5—5.0—10.0 LP/cm SFOV 3.6—7.1—14.3 LP/cm spFOV 4.8—12.6 LP/cm limFOV 4.8—12.6 LP/cm miniFOV 4.8—12.6 LP/cm USFOV 4.8—12.6 LP/cm
Low Contrast Detectability	1 mm at 1% 2 mm at 0.5% 5 mm at 0.3% (Catphan 515, 5 mm long. binning, collimated to low contrast insert)
HU Uniformity (SFOV CBCT phantom conditions)	2% CatPhan
Geometrical Accuracy	iso. SFOV < 0.5 mm (95% confidence interval at gantry 0°, inherent deflection compensated) < 1 mm (with external tracking)
Mechanical Flex Correction	✓ 9 + 3 DOF 3 source translations (x, y, z) 3 detector translations (x, y, z) 3 detector rotations (rx, ry, rz) 2 source central axes tilts

Imaging Geometry	
Source Axis Distance (SAD) [cm]	74.3
Detector Axis Distance (DAD) [cm]	51.7
Source Detector Distance (SDD) [cm]	126.0 (opposing)
Patient Entrance Reference Point (Reference Air KERMA measurement point)	Isocenter (due to non-isocentric capabilities)

X-ray Generator	
Inverter	IMD HF1 GMX-350/S2
Monobloc	HF1 R/23 ORB
Power Rating [kW@100 kVp]	max. 15 kW (typical < 2 kW)
Current range (continuous) [mA]	0.2–8
Energy Range [kV]	60–120 typical (X-ray system is capable of 40 kV min.)
Continuous Mode	✓ (2D and 3D)
Current Range (pulsed) [mA]	Small Focal Spot: 5–30 mA Large Focal Spot (3D): 40–80 mA (clinically used range, X-ray tube is capable of 150 mA—may require warmup of tube before exposure)
Pulsed Mode	✓ (2D and 3D)
Pulse Length [ms]	typical range used 10 ms–28 ms (technical range 2–35 ms @ 12 Hz)
Velocity Dose Modulation During Acquisition	✓
Cooling system	Monotank filled with dielectric oil—fan assisted cooling control (no turbulent airflow in the surgical environment)
Exposure Time in Fluoroscopic Mode	After 5 min (warning buzzer), max. 10 min in one exposure (regulatory limit)
Automatic Exposure Control (AEC)	✓

X-ray Tube Anode	
Type	IAE RTM 780H 0.3/0.6
Maximum Output [kW]	Small focus: 6kW Large focus: 25 kW max (typical < 2 kW)
Heat Capacity Anode [kJ]	225
Heat Capacity System [kJ]	X-ray: 610; Total:(incl. electronic) 910
Cooling Anode [W]	750
Cooling System [W]	75
Focal Spot Size [mm]	0.3 / 0.6 mm depending on preset (both focal spots available in radiographic and fluoroscopic imaging)
X-ray Primary Aperture [degrees]	55 (asymmetrical)
Anode Angle	10° (the effective emission angle may be larger due to the mounting angle of the x-ray housing)
Tube power rating (kW@100 kVp)	max. 5.2 kW (Small focus), 22 kW (Large focus) (typical < 2 kW)
Frequency [Hz]	0–30 (depending on chosen detector setting, typical 12/15/30)

Collimator	
Dynamic Collimation	✓ Asymmetric, 4 independent jaws
Fixed Filtration	4.4 mm Al eq. @75 kVp (inherent filtration + 0.1 mm Cu sheet always in beam path)
Additional Filtration	**Filter Wheel and Filter Carriage Inserts** (motorized) **Variable filter wheel position for:** - 0.5 mm Cu (13.0 mm Al eq. @75 kVp) - 1.5 mm Al - no additional filtration (air) - 0.2 mm Cu (5.2 mm Al eq. @75 kVp) **Variable filter carriage position for:** - no additional filtration (air) - 1.5 mm Cu (31.3 mm Al eq. @75 kVp)
Bow-Tie Filter	1 motorized bow-tie filter with 0.3–3 mm Cu optimized for pelvis configuration

Detector System	
Detector Type	Varex XRD4343RF
Scintillator	CsI(Tl)
Panel Size [cm²]	43.2 x 43.2
Flat Panel Resolution	max. 2880 x 2880 px @150 µm 1440 x 1440 px fast binning mode 960 x 960 px ultra fast binning mode
Internal Data Transmission	Glass Fiber

Motion	
Wireless System Positioning	✓
Wireless Region-of-Interest (ROI) Definition	✓
Patient Positioning System (PPS) Compatibility	any (radiotransparent)
Table Top Indexing	any
Gantry Clearance [cm]	121 (ring bore size), 101.2 (detector)
Gantry Width [cm]	28.5
Travel Range Source [degrees]	683,3° (1.90 turns)
Travel Range Detector	688,5° (1.91 turns)
Max. Rotational Speed [degree/s] (source, detector)	16°/s, 7°/s typical fastest isocentric short scan 11.6 s
Longitudinal Motion Range	Unlimited
Gantry Tilt and Rotation	tilt +90° / -90° (±30° for 360° CBCT, +45° for short scan CBCT source below, +60° for 2D source 180° detector 0°), Nx 360° free yaw rotation
Battery uptime [min]	~ 30 (depends on the motion type and temperature, 48 V) ~ 40 without motion (24 V)
Remote Control Panel Battery uptime [min]	~ 60 without docking / charging

Guidance	
Source-sided Trans-axial Lasers (Class 1)	✓ (optional)
Source-sided Motorized Sagittal Lasers	✓ (optional)
Detector-sided Adaptive Lasers (Class 1)	✓ (optional)
Laser Field-size Mode FOV Planning	✓ (optional)
Two Cameras inside gantry	✓ (optional)
Two Cameras inside detector arm	✓ (optional)

Ports and Power	
Interfaces	Ethernet—For navigation (length 5 m) Ethernet—For hospital network (length 10 m) Ethernet—For WiFi extension (length 10 m) Power Supply (length 4 m) Potential Equalization Conductor (length 8 m) 2x Multifunctional interfaces (to connect CC2 / Footswitch / Room doors / Warning lamp)
Network	IEEE 802.3ab 1000BASE-T (internal) IEEE 802.11ac WiFi-5 1300 Mbps (HMI) IEEE 802.11n WiFi-4 450 Mbps (PACS)
Input Voltage	230 V +/- 10%, 50-60 Hz, 2 kVA (4 kVA Peak) Main fuse 13 A or 10 A (configurable) 120 V +/- 10%, 50-60 Hz, 2 kVA (4 kVA Peak) Main fuse 25 A or 20 A (configurable) Line Impedance ≤ 2 Ω @ 230 V / ≤ 0.43 Ω @ 120 V
Integrated Uninterruptable Power Supply	Only for motion (up to 40 min without mains)
External Uninterruptable Power Supply	✓ (optional, external 6000 W power capacity, 208/220/230/240 VAC output, 40–70 Hz, 16x 12V/7Ah batteries)
Protection class	Class 1

Built-in computer	
Processor	Intel® Xeon® Processor E3-1275 v5 (8M Cache, 4.0 GHz) or equivalent in performance
Memory	32 GB DDR4-2133 MHz
Graphics	NVIDIA® Quadro RTX 5000 or equivalent in reconstruction performance (16 GB GPU RAM)
Built-in Storage	4 TB SSD ≙ ca. 2000 3D scans (medium resolution incl. projection data) or 37000 CBCT volumes medium resolution +256 GB internal SSD

Physical Specifications	
Total Weight	520 kg (1146 lbs) fully equipped with all options, excl. accessories and disconnected wireless controls
Remote Control Panel Weight	2.6 kg (5.7 lbs)
Gantry Weight w/o Carrying Structure	203 kg (447.54 lbs)
Transformer Weight	21.5 kg (47.4 lbs)
Surface Load (Under Wheels)	< 245 N/cm2 (51169.3 lbf/sqft) in balanced parking position
Wheels (Diameter, Width, Hardness)	4 x 125 mm, 40 mm, 75°A
Minimum Space Requirement (Footprint)	Min. 1.59 m² (17.11 sqft) 2.6 m² (22.99 sqft) in parking position with margin required due to moving components
Floor Pressure (weight / space required in parking position with additional space required for moving components)	193.46 kg/m² (39.62 lbs/sqft)
Dimensions (Width x Length x Height) [cm]	182 x 87 x 189

Environmental Conditions	
Temperature (Operation)	15°C–32°C
Temperature (Storage)	-10°C–50°C
Temperature (Transport)	-10°C–50°C
Relative Humidity (Operation)	30%–70% (no condensation)
Relative Humidity (Storage)	10%–95% (no condensation)
Relative Humidity (Transport)	10%–95% (no condensation)
Peak Heat Output	250 W Standby 1600 W during CBCT acquisition

Accessories	
Remote Control—wireless control, handheld with joysticks to control the motion of system and buttons to start/stop pre-planned motion and irradiation, with tablet Microsoft Surface Pro 7 touch screen	✓ Microsoft Surface Pro 7+ Display: 12.3" at 2736 x 1824 px (267 PPI) 10-Point Multi-Touch Intel® Core™ i5-1135G7 Quad-Core Processor 16 GB LPDDR4x RAM 256 GB SSD
Interfaces on Remote Control Panel	1 x USB-C (+ additional Hub to connect monitor and input devices)
Wireless Footswitch	✓ (optional) (up to 10 m with a direct line of sight)
External Workstation—desktop PC with monitor, keyboard and mouse, storage, CPU and GPU graphics card performance sufficient for image acquisition and visualization tasks. PC can be used in a radiation protected area as a viewing console for images	✓ (optional) (requires IRm online and connected)
Wired Control Console—wired control console with buttons to start / stop motion and exposures, including a wired safe emergency stop button to be used in radiation protection areas in connection with the desktop PC	✓ (optional)
Cylinder Phantom for Flexmap Calibration—to be used by service engineers or physicists in system calibration or QA	✓
Monitor cart for Remote Control with charging function, including 27" touch screen monitor and control function with separate computer client, holder for mouse and keyboard, with power supply	✓ (optional) charging function UPS optional

Disclaimer

Technical specifications are subject to change without notice and may be dependent on version/serial number of the system. Some options may not be available on all systems and require a specific license.

This specification sheet has been created based on available information from R&D at the time being. Continuous progress in research and developments, test conditions and phantoms, performed test cases, risk assessment, safety- and regulatory requirements which may be dependent on the country of operation and which may change from time to time may have an impact on system specifications and constrain the intended usage.

The user is requested to retrieve the latest specification sheet and manuals from the manufacturer for a specific product/version/serial number before setting the system in operation.

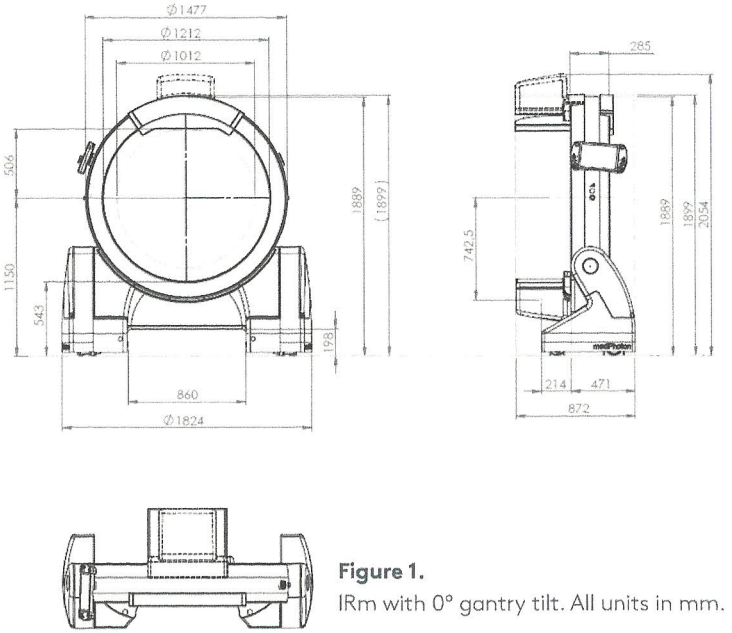

Figure 1.
IRm with 0° gantry tilt. All units in mm.

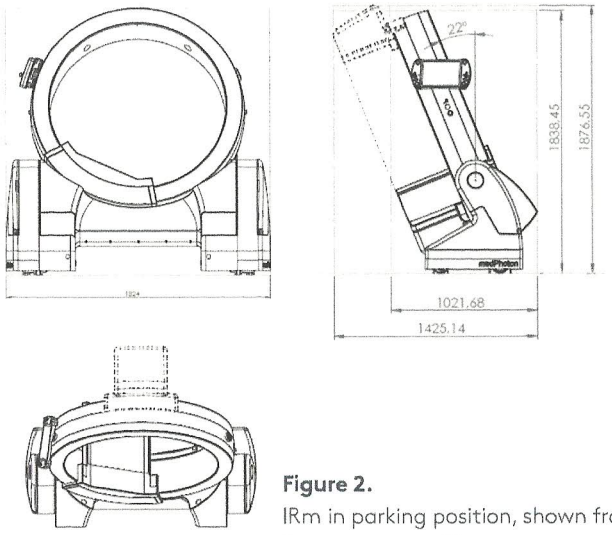

Figure 2.
IRm in parking position, shown from 3 perspectives. All units in mm.

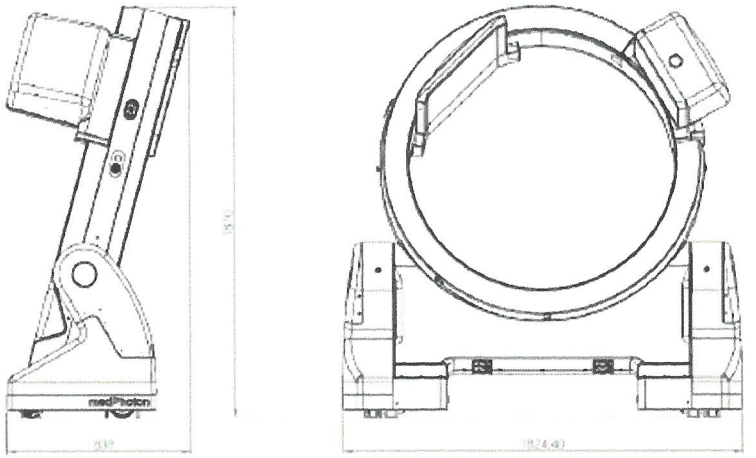

Figure 3.
IRm minimal dimensions for narrow doors 15° gantry tilt, source arm 60°, detector arm 45°. All units in mm.

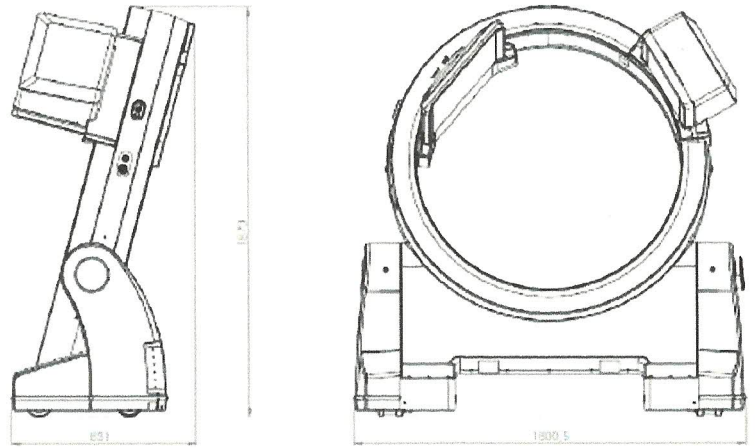

Figure 4.
Loop-X minimal dimensions for narrow doors 15° gantry tilt, source arm 60°, detector arm 50°. All units in mm.

As a leader in precision radiation therapy, Elekta is committed to ensuring every patient has access to the best cancer care possible. We openly collaborate with customers to advance sustainable, outcome-driven and cost-efficient solutions to meet evolving patient needs, improve lives and bring hope to everyone dealing with cancer. To us, it's personal, and our global team of 4,700 employees combine passion, science, and imagination to profoundly change cancer care.

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ImagingRing-m may not yet be available in all markets.

LLFBX201116_v2.0

Attachment G

EQUIPMENT COMPARISON – CMC (LCI Morehead) Brachytherapy Equipment Replacement

	EXISTING EQUIPMENT	**REPLACEMENT EQUIPMENT**
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, etc.)	Brachytherapy Equipment (Afterloader and CT scanner)	Brachytherapy Equipment (Afterloader and ImagingRing)
Manufacturer	Varian / GE	Elekta
Model name/number	Varian VariSource iX HDR Afterloader GE Goldseal Lightspeed Plus CT scanner	Flexitron HDR 40CH Afterloader ImagingRing
Other method of identifying the equipment (e.g., Serial Number, VIN #)	H600450 / 317559CN3	Not Available Until Installed
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2006 (Afterloader) / 2009 (CT scanner)	2023
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project	NA	$3,300,000
Total cost of the equipment	Not available due to system transition	$1,062,563
Location of the equipment	CMC (LCI Morehead), Room #1410	CMC (LCI Morehead), Room #1410
Document that the existing equipment is currently in use	Existing equipment performed 306 brachytherapy procedures from February 2022 to January 2023	NA
Will the replacement equipment result in any increase in the **average charge per procedure**?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the **average operating expense per procedure**?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment	Brachytherapy Procedures	NA
Type of procedures the replacement equipment will perform	NA	Brachytherapy Procedures

Attachment H

CMC Brachytherapy Volume by Month	
Month	**Volume**
Feb-22	19
Mar-22	13
Apr-22	29
May-22	30
Jun-22	22
Jul-22	25
Aug-22	25
Sep-22	37
Oct-22	26
Nov-22	24
Dec-22	35
Jan-23	21
Total	**306**

From:	Waller, Martha K
To:	Stancil, Tiffany C
Subject:	FW: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center
Date:	Friday, April 21, 2023 6:48:03 AM
Attachments:	2023 CMHA dba CMC Brachytherapy Equipment Replacement Exemption.pdf

From: Huber, Brighid K <Brighid.Huber@atriumhealth.org>
Sent: Thursday, April 20, 2023 6:19 PM
To: Hunt, Tiffany C <Tiffany.C.Hunt@dhhs.nc.gov>; Waller, Martha K <martha.waller@dhhs.nc.gov>; Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Subject: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center

Good afternoon,

Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Carolinas Medical Center to replace existing brachytherapy equipment.

Thank you very much, and please let me know if you have any questions.

Best,

Brighid

Brighid Knoll Huber, MHA, ATC
Enterprise Strategy Partners
Mobile: 724-986-6214

Atrium Health
Carolinas HealthCare System is Atrium Health

2709 Water Ridge Parkway, Suite 200, Charlotte, NC 28217