



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**  
Division of Health Service Regulation

ROY COOPER • Governor  
MANDY COHEN, MD, MPH • Secretary  
MARK PAYNE • Director

June 18, 2018

Jeffrey Shovelin  
Vidant Health  
PO Box 6028  
Greenville, NC 27835-6028

**No Review**

**Record #:** 2616  
**Facility Name:** Vidant Medical Center  
**FID #:** 933410  
**Business Name:** Pitt County Memorial Hospital, Inc.  
**Business #:** 1443  
**Project Description:** Replace existing Gamma Knife radiation source and upgrade  
**County:** Pitt

Dear Mr. Shovelin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of May 21, 2018 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.

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

It should be noted that this determination is binding only for the facts represented in your correspondence. 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 this office. 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.


NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603  
MAILING ADDRESS: 2704 Mail Service Center, Raleigh, NC 27699-2704  
www.ncdhs.gov/dhsr/ • TEL: 919-855-3873

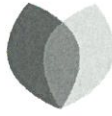
Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,

  
Jane Rhoe-Jones  
Project Analyst

  
Martha J. Frisone, Chief  
Healthcare Planning and Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR  
Construction Section, DHSR  
Radiation Protection Section, DHSR  
Amy Craddock, Assistant Chief, Healthcare Planning, DHSR



VIDANT HEALTH™



May 21, 2018

Ms. Jane Rhoe-Jones  
Certificate of Need Section  
Division of Health Service Regulation  
NC Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704

RE: Request for “No Review” for the Radiation Source Reload and Additional Upgrades of an Existing Gamma Knife at Pitt County Memorial Hospital d/b/a Vidant Medical Center

Dear Ms. Rhoe-Jones:

Pitt County Memorial Hospital, Inc. d/b/a/ Vidant Medical Center (VMC) plans to replace the radiation source for its existing Leksell Gamma Knife Perfexion unit. The radiation source is well past its half-life and is recommended to be replaced every five years. The radiation source is the original source from when VMC replaced the unit entirely in 2013 (CON Project ID Q-8445-12).

In addition, at the same time while the unit is down, VMC is planning to upgrade the current unit by installing the Leksell Gamma Knife Icon Package. The upgrade basically adds a C-arm and enhanced HD motion management systems to the existing unit. Today, all patients are required to have a fixation device attached to their head using a minimally invasive procedure. The C-arm upgrade will allow some patients to avoid the fixation process entirely. The enhanced HD motion management system allows for better precision and accuracy, greatly reducing damage to healthy cells surrounding brain and head tumors. In addition, the upgrade, coupled with the reload, allows VMC to provide the most advanced and current Gamma Knife technology without incurring the cost of fully replacing the unit. The total capital costs for the proposed reload and upgrade is estimated to be \$1,895,700. These costs include all expenses associated with the equipment reload and upgrade. The project will be funded through accumulated reserves and is anticipated to be complete by November 2018.

The proposed project does not meet the definition of replacement equipment since the project is not for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In fact, the proposed project does not meet any of the definitions for a new institutional health services found in G.S. 131E-176. VMC believes the proposed project is exempt from CON review because:

1. The proposed project does not meet the definition of a new institutional health service,
2. The proposed project is less than \$2,000,000 (see attached capital cost sheet and quotes),
3. The proposed project is for a source reload and upgrade to a previously approved and existing piece of equipment (see attached CON certificate and License Application)
4. The upgrades will not result in any new services or capabilities other than Gamma Knife (see attached equipment specifications)

5. The source reload and upgrades will be implemented on an existing unit in its current location on VMC's main campus (see attached site and floor plans)
6. VMC is an existing licensed healthcare facility (see attached license)

Therefore, VMC requests approval of a no review status for the proposed project. If you require additional information or clarification, please contact me at (252)-847-3631.

Sincerely,



Jeffrey Shovelin  
*Administrator, Corporate Planning*  
*Vidant Health*  
*PO Box 6028, Greenville, NC 27835-6028*  
*252-847-3631*  
*jshoveli@vidanthealth.com*

## PROJECT CAPITAL COSTS

### A. Site Costs

(1) Full Purchase Price of Land	\$	-	
Acres_____ \$/Acre_____			
(2) Closing Costs	\$	-	
(3) Site Inspection and Survey	\$	-	
(4) Legal Fees and Subsoil Investigation	\$	-	
(5) Site Preparation [Include]			
Soil Borings			
Clearing and Grading			
Roads and Parking			
Sidewalks			
Water and Sewer			
Excavation and Backfill			
Termite Treatment			
<b>Subtotal Site Preparation Costs</b>	\$	-	
(6) Other (Testing)	\$	-	
<b>(7) Subtotal Site Costs</b>			<b>\$ -</b>

### B. Construction Contract

(8) Cost of Materials [Include]			
General Requirements			
Concrete/Masonry			
Woods/Doors & Windows/Finishes			
Thermal & Moisture Protection			
Equipment/Specialty Items			
Mechanical/Electrical			
<b>Subtotal Cost of Materials</b>	\$	104,200	
(9) Cost of Labor	\$	100,000	
(10) Other (Contingency)	\$	30,000	
<b>(11) Subtotal Construction Contract</b>			<b>\$ 234,200</b>

### C. Miscellaneous Project Costs

(12) Building Purchase	\$	-	
(13) Equipment/Furniture Lease/Purchase	\$	-	
(14) Equipment Purchase	\$	1,597,000	
(15) Furniture	\$	-	
(16) Landscaping	\$	3,000	
(17) Consultant Fees			
Architect/Engineering Fees	\$	41,500	
Legal Fees	\$	-	
Market Analysis	\$	-	
Other (Underwriter Fees & Other Fees)	\$	-	
<b>Subtotal Consultant Fees</b>	\$	41,500	
(18) Financing Costs (e.g. Bond, Loan, etc.)	\$	-	
(19) Interest During Construction	\$	-	
(20) Other (IS / Security / BioMed / Signage)	\$	20,000	
<b>(21) Subtotal Miscellaneous Project Costs</b>			<b>\$ 1,661,500</b>

### D. Total Capital Cost of Project (Sum A-C Above)

**\$ 1,895,700**



Oncology | Brachytherapy | Neuroscience | Software | Services

Elekta is pioneering significant innovations and clinical solutions for treating cancer and brain disorders.

We provide intelligent and resource-efficient technologies that improve, prolong and save patient lives.



## Purchase and License Agreement

<b>Customer</b> (the "Customer")	<b>Site</b> (the "Site")	<b>Supplier</b> (the "Supplier")
Chuck Danneker	Same as Customer	Elekta Inc.
Vidant Medical Center.		400 Perimeter Center Terrace
2100 Stantonsburg Rd.		Suite 50
Greenville, North Carolina 27834-2818		Atlanta, Georgia 30346
US		(t) 800-535-7355
(t) (252) 847-5742		(f) 770-670-2323
Currency: USD		

Elekta, Inc. ("Elekta"), a Georgia corporation, is pleased to submit the following offer to sell/license the services, hardware and/or software described in the Scope of Supply (collectively referred to as the "Deliverables") at the prices and terms stated in this Purchase and License Agreement, which consists of this Cover Page and all exhibits attached hereto.

This offer is valid until February 28, 2018 and no agreement shall exist between the Customer and Supplier (jointly referred to as the "Parties" and each a "Party") until this Agreement is signed by both Parties.

	<b>Description</b>	<b>Currency</b>	<b>Price/License Fee</b>
<b>List Price</b>	Leksell Gamma Knife® Icon™ Upgrade	USD	\$1,175,378.90
<b>Discount</b>		USD	-\$413,378.94
<b>Offer Price</b>		<b>USD</b>	<b>\$762,000.00</b>
<b>List Price</b>	Leksell Gamma Knife® Perfexion™ Re-load	USD	\$936,700.00
<b>Discount</b>		USD	-\$101,699.95
<b>Offer Price</b>		<b>USD</b>	<b>\$835,000.00</b>
<b>Total List Price</b>		USD	\$2,112,078.90
<b>Discount</b>		USD	-\$515,078.89
<b>Total Contract Price*</b>		<b>USD</b>	<b>\$1,597,000.00</b>

\*plus applicable taxes

<b>Contract description</b>	<b>Service Level</b>	<b>Total service fee (in USD)</b>	<b>Annual service fee (in USD)</b>
Leksell Gamma Knife® Maintenance and Support	Platinum	\$1,439,800.00	\$287,960.00

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 Price Payment Schedule**

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

- a ) An amount equal to 5% of the Contract Price shall be paid within 14 days of execution of this Agreement;
- b ) 80% of the Contract Price shall be paid upon shipment (delivery to carrier for shipment to Customer) of the Hardware (excluding cobalt sources, if any);
- c ) The remaining 15% of the Contract Price shall be payable upon the date that the Acceptance Test Protocol has been successfully completed.

**Hardware Maintenance and Support Service Fee**

The Customer agrees to pay to Supplier the annual Hardware Maintenance and Support Service Fee set out in the Cover Page. The Service Fee is payable 30 days in advance of the contract renewal period and on each succeeding anniversary date of the contract renewal period while this Agreement remains in force.

**Contract Renewal Period: March 4, 2019 to March 3, 2025.**

**Contractual Delivery Date**

**The Contractual Delivery Date is: October 2018**

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.

<b>Applies to this Agreement</b>	<b>List of Exhibits</b>	<b>Agreement Number</b>	<b>Date Executed</b>
Yes	Exhibit B: General Terms and Conditions	USBU00005765-3	10/17/2012
Yes	Exhibit C: Terms and Conditions for Hardware	USBU00005765-3	10/17/2012
No	Exhibit D: Terms and Conditions for Software	USBU00005765-3	10/17/2012
Yes	Exhibit E: Terms and Conditions for Compliance with Health Insurance Portability and Accountability Act (HIPAA)	USBU00005765-3	10/17/2012
Yes	Exhibit F: Terms and Conditions for Services	USBU00005765-3	10/17/2012
Yes	Exhibit G: Agreement Amendment	USBU00005765-3	10/17/2012
Yes	Exhibit H: Trademark License Agreement	USBU00005765-3	10/17/2012
No	Exhibit I: Surescripts Addendum		
No	Exhibit J: FDB Addendum		
No	Exhibit K: Terms and Conditions for METRIQ		
Yes	Exhibit L: Terms and Conditions for Leksell Gamma Knife® Reload	Attached Hereto	

**Customer:**

Signature: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

**Supplier:**

Signature: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_



## EXHIBIT A

### SCOPE OF SUPPLY

#### Leksell Gamma Knife® Icon™ Upgrade

Qty	Description
1	<p><b>Leksell Gamma Knife® Icon™ Configuration</b> Includes;</p> <ul style="list-style-type: none"> <li>• Covers - for Radiation Unit, Patient Position System™ and imaging gantry</li> <li>• CBCT Imaging Gantry               <ul style="list-style-type: none"> <li>◦ C-arm &amp; Tilt arm</li> <li>◦ Actuator</li> <li>◦ Image detector</li> <li>◦ X-ray tube</li> <li>◦ Electric cabling</li> </ul> </li> <li>• HD Motion Management System               <ul style="list-style-type: none"> <li>◦ IR camera</li> <li>◦ IR camera arm</li> <li>◦ Electric cabling</li> </ul> </li> <li>• Upgrade kit for Patient Positioning System</li> <li>• CATPHAN 503</li> <li>• Phantom baseplate</li> <li>• Icon QA tool</li> <li>• Icon Upgrade kit for Office cabinet               <ul style="list-style-type: none"> <li>◦ Icon MCU</li> <li>◦ Network Router</li> </ul> </li> <li>• CS Software 11.0.</li> </ul>
1	<p><b>kV Generator</b> kV generator for CBCT. 480 V</p>
1	<p><b>Mask adapter</b> With reference markers for HD Motion Management. Interfacing between mask fixation setup and Leksell Gamma Knife® Icon™.</p>
1	<p><b>Mask Nanor</b> Thermoplastic mask for patient fixation. 20 pcs.</p>
1	<p><b>Knee support</b> For patient comfort.</p>
1	<p><b>MR head support</b> For use in MR scanner for patients immobilized by mask. Separate interface for Philips MR scanners.</p>
1	<p><b>Patient marker</b> For HD Motion Management. 100 pcs.</p>
1	<p><b>Patient specific box</b> For storage of patient specific mask and head cushion. 5 pcs.</p>
1	<p><b>Leksell GammaPlan® Software for Leksell Gamma Knife® Icon™.</b></p>
2	<p><b>Drivers for ELD 3.20</b> Graphics and network drivers.</p>
1	<p><b>Drivers for ELD 3.20</b> Graphics and network drivers.</p>
1	<p><b>Standard Leksell GammaPlan® for Icon™</b> Includes one (1) Leksell GammaPlan® (LGP) license for creating new treatment plans for Leksell Gamma Knife® Icon™. This main license allows the addition, management and storage of an unlimited number patient records and treatment plans. LGP also allows the visualization of treatment plans created at other LGK units. Includes; 1016991 LGP - Preplanning /Retreatment License 1016993 Real Time Dose Planning</p>

1016990 LGP – Functional Planning License  
 1015989 LGP - ImageMerge License  
 1016992 LGP - Color PET License  
 1016994 LGP - DICOM RT License  
 1016650 LGP - Inverse Planning License  
 1016649 LGP - Convolution License  
 1518785 LGP – Mask License.

**2 HPZ640 Workstation Kit**

- HP Z640 Workstation
- Flat LCD Monitor 24 minimum
- External HD for Backup.

**1 HPZ640 Workstation Kit**

- HP Z640 Workstation
- Flat LCD Monitor 24 minimum
- External HD for Backup.

**2 Elekta Linux Distribution v3.2**

Computer Operating System.

**1 Elekta Linux Distribution v3.2**

Computer Operating System.

**1 Leksell GammaPlan® Atlas Space License**

This software add-on is an electronic brain atlas on the Atlas for Stereotaxy of the Human Brain by Schaltenbrand and Wahren to further enhance functional stereotactic planning. Requires Functional Planning License.

**1 Leksell Gamma Knife® Icon™ - Perfexion™ Upgrade Applications Training**

To introduce the clinical Gamma Knife team to the applications of Leksell Gamma Knife Icon. The training focuses on hands on applications, molding mask fixation, workflows with mask and G-frame and daily quality assurance. The training is given by an Elekta Applications Specialist and does not involve patient treatments.

**Support and Education & Training for Leksell Gamma Knife® Icon™**

- On-site System Start - the System Start is the third phase of the training for new installations and upgrades of Leksell Gamma Knife. Five days on-site application support with experienced consultant(s) is provided the first week of patient treatments. The objective of the System Start training is to provide confidence in daily practice.

For a new installation the support will be provided by a neurosurgeon and a physicist. For an upgrading site the support will be provided by a physicist. However, in cases where Elekta determines that it may be difficult to secure either the neurosurgeon and/or physicist to perform said On-site System Start, Elekta reserves the right to offer another substantially equivalent form of training to the relevant medical staff.

- 4 training slots in total selected between the following courses:

**1. Leksell Gamma Knife® Icon™ Clinical Introductory Program**

Participants will learn about principle and practice of Gamma Knife Surgery, clinical indications, treatment planning and observe patient treatments. Three to five (3-5) days training arranged by Elekta in collaboration with a Gamma Knife Center. Elekta pays for the tuition only at an approved Elekta training site.

**OR**

**2. Leksell Gamma Knife® Icon™ Applications Introductory Program** Participants will learn about radiation physics, dosimetry, stereotactic imaging, quality assurance (QA), technical information and treatment planning for different workflows using Leksell GammaPlan® with the aim to make users confident in the operation, care and maintenance of Leksell Gamma Knife Perfexion. Three (3) day training arranged at Elekta Stockholm, Sweden. Elekta pays for the tuition only.

1 **Leksell Gamma Knife® Icon™ - Perfexion™ Upgrade Applications Training**

To introduce the clinical Gamma Knife team to the applications of Leksell Gamma Knife Icon. The training focuses on hands on applications, molding mask fixation, workflows with mask and G-frame and daily quality assurance. The training is given by an Elekta Applications Specialist and does not involve patient treatments.

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Participants will learn about principle and practice of Gamma Knife Surgery, clinical indications, treatment planning and observe patient treatments. Three to five (3-5) days training arranged by Elekta in collaboration with a Gamma Knife Center. Elekta pays for the tuition only at an approved Elekta training site.
  - OR
  2. Leksell Gamma Knife® Icon™ Applications Introductory Program  
Participants will learn about radiation physics, dosimetry, stereotactic imaging, quality assurance (QA), technical information and treatment planning for different workflows using Leksell GammaPlan® with the aim to make users confident in the operation, care and maintenance of Leksell Gamma Knife Perfexion. Three (3) day training arranged at Elekta Stockholm, Sweden. Elekta pays for the tuition only.

2 **EN/LGK ICON/EMP**

Emergency procedure, English

1 **Leksell GammaPlan® language resources - Language not available**

1 **Leksell Gamma Knife® Site Kit**

1 **Leksell Gamma Knife® Installation Kit**

1 **CS SW 11.1 SUPPLIER ITEMS**

Leksell Gamma Knife® Control System, software and media

1 **DFM 2.1**

Data Flow Manager, software and media

1 **DFM 2.1**

Data Flow Manager, software and media

1 **Leksell Gamma Knife® Icon™ v11.1 Instructions for use**

1 **GS1 MATRIX ICON MANUFACT. SIGN**

1 **ICON PATIENT CUSHION KLARITY**

Head cushion

Used together with thermoplastic mask for patient fixation.

2 **LGP 11.0.2 SUPPLIER ITEMS**

Leksell Gamma Knife® Control System, software and media

1 **LGP 11.0.2 SUPPLIER ITEMS**

Leksell Gamma Knife® Control System, software and media

2 **LGP 11.0.3 PATCH**

Bug fix update for LGP 11.0

1 **LGP 11.0.3 PATCH**

Bug fix update for LGP 11.0

1 **Leksell GammaPlan® Upgrade**

Leksell GammaPlan upgrade includes an upgrade from a previous version. It can be performed during a PM visit, software visit or extra service visit.

Limitation: Installation and Training and required new hardware are not included.

1 **SPARE PART CLEARANCE CHECK TOOL**

1 **OFFICE UPS 1500VA 120V CPL**

1 **LGK Icon Signs, United States**

**Leksell Gamma Knife® Perfexion™ Reload – Serial #6172****Qty Description****1 Leksell Gamma Knife® Perfexion™ Reloading**

The Elekta specialist team will plan, manage and perform the reloading of Leksell Gamma Knife® PERFEXION™. The team will also remove old sources and take them back. The process takes approximately 14 days for the Elekta team and necessary materials are included.

**Scope**

- Project planning
- New Cobalt Supply
- Rental of loading equipment and transportation casks for the Old Cobalt Supply and for the New Cobalt Supply including packing of the equipment.
- Transportation of the loading equipment to the Site
- Dismantling of the Leksell Gamma Knife®
- Supervision during unloading and loading
- Unloading of Old Cobalt Supply and loading of the Leksell Gamma Knife® with the New Cobalt Supply according to the reloading procedure.
- Inspection and cleaning of the Leksell Gamma Knife® before loading
- Acceptance Test after reloading with New Cobalt supply.
- Transportation of the loading equipment and the Old Cobalt Supply from the Site
- Disposal of the of Old Cobalt Supply at a licensed facility
- Travel expenses and loading team

**Limitation**

Rigging arrangements and rigging personal is the responsibility of the Leksell Gamma Knife® site. Local transport licenses including double cobalt license and other local licenses are the responsibility of the Leksell Gamma Knife® site. The reloading and time planning are performed in close cooperation with the Leksell Gamma Knife® site. The reloading schedule and procedure may however change due to specific site requirements, unforeseen difficulties, special site requirements or not fulfilled obligations from the Leksell Gamma Knife® site.

## EXHIBIT A-1

### Elekta Care™ Platinum for Leksell Gamma Knife® - 6172

Vidant Medical Center  
2100 Stantonsburg Rd.  
Greenville, NC 27834  
Site: 30000171-002

#### Maintenance & Support Service Fee

Annual Hardware Maintenance & Support Fee offer price:	USD	\$287,960.00**
Term in months:		60
Contract Start Date:		3/4/2019
Contract End Date:		3/3/2025
<b>Total Hardware Maintenance &amp; Support Service Fee</b>	<b>USD</b>	<b>\$1,439,800.00</b>
Price is based on invoice schedule:		Annually

\*\*Note: upon expiration of Warranty period for the Icon™, the first year annual fee of \$287,960.00 will be pro-rated to align with existing renewal period for the Perfexion which is March 4 to March 3.

Payment Schedule	Periodic Payment		Annual Amount	
Annual Payment (IN ADVANCE)	USD	\$287,960.00	USD	\$287,960.00
Bi-Annual = 2%	USD	\$146,859.60	USD	\$293,719.20
Quarterly = 4%	USD	\$74,869.60	USD	\$299,478.40
Monthly = 6%	USD	\$25,436.47	USD	\$305,237.60

#### Service Hours and Response Time

Remote services accepted:	Yes
Estimated Spare part response time:	Next flight out or <24 hours (excluding weekends and holidays)
Estimated onsite response time	Within 24 working hours
Uptime Guarantee:	98%

Note: the Uptime Guarantee module shall only be applicable if Elekta Remote systems, including IntelliMax, are installed and available for use on the Site and Unique Components Coverage is chosen as a module.

Unless otherwise agreed in writing between the Parties, Third Party Products and consumables are not included in the scope of this Agreement.

#### Covered products:

Qty	Part Number	Description	Serial #
1	SN-ICON-Z	ICON - Platinum - Including Frame(s) with serial SH01169, SH01172 - Including Workstation(s) with serial TBD, TBD	

#### Optional services selected:

Qty	Part number	Description
1200	TRAINING0000001	ELEKTA LEARNING CREDITS - ELEKTA CARE

**Elekta Care™ Platinum for Leksell Gamma Knife®**

<b>Labor and parts coverage</b>	
Management Service Reviews	•
Hardware and Software Safety Releases	•
Genuine Elekta Parts Availability	•
Spare Parts	•
Unique Spare Parts Coverage	•
Corrective Maintenance (Emergency Support)	•
Planned Maintenance	•
Site Kit Management	•
Guaranteed Accuracy (LGK Icon only)	•
<b>Software support</b>	
Software Updates	•
Software Upgrades	•
New Licensable Software Modules	•
<b>System availability</b>	
Uptime Guarantee	•
Technical support (Email/Phone)	•
Application support (telephone)	•
Technical Information Supply	•
Scanner Interface Support (LGK Icon only)	•
Cobalt Management during repair (LGK)	•
<b>Technology Refresh</b>	
Technology Refresh	•
<b>Remote services</b>	
Remote Services Technical Online Support	•
Remote Services Application Online Support	•
<b>Education services</b>	
Customer Training Review	•
Elekta Care Learning Credits	•
<b>Business services</b>	
Physics Support (Telephone/Remote)	•
Data Server & IT Networking Support / Elekta interface support/Interconnectivity support	•
Online Customer Portal (SupportPlus™)	•

**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

Neuro-Gamma Knife

[08:00 - 17:00] Monday to Friday excluding holidays

**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 by 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**

**MEMORIAL DAY**

**INDEPENDENCE DAY**

**LABOR DAY**

**THANKSGIVING DAY**

**DAY AFTER THANKSGIVING**

**CHRISTMAS EVE**

**CHRISTMAS DAY**



## Exhibit A-2

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 Exhibit A-1.

### 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 Unique Components Coverage

Unique Components are spare parts not covered under the general Spare Parts Module. The same terms as applicable to the Spare Parts module above are applicable to this module. 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 Unique Component.

The Unique Components are:

- All Imaging panels
- Motor Assembly Systems for the Leksell Gamma Knife® Perflexion™ and Icon™ sector drives
- kV Generators for Leksell Gamma Knife® Icon™

#### 1.6 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.

#### 1.7 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.

#### 1.8 Site Kit Management

Elekta delivers and refurbishes a predefined kit, excluding consumables, for immediate replacement of defective parts of the Hardware on Site, provided contents and use of the kit are at Elekta's discretion from time to time.

Ownership of the kit shall pass to the Customer on delivery to Site, provided Customer is up-to-date on all payments due to Elekta. Customer shall store the kit safely on site and have adequate insurance in place for loss or damage of the kit.

#### 1.9 Guaranteed Accuracy (for LGK Icon Only)

A guarantee that the system has an accuracy of 0.3 mm or better.

The accuracy is verified using the Installation Diode Tool (IDT) at each PM.

### 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.

**2.3 New Licensable Software Modules**

This includes supply and installation of any new licensed software features.

**2.4 General Conditions**

Updates/Upgrades do not include the supply of any new licensed software modules should they exist in the Update or Upgrade being provided.

Updates/Upgrades/New Licensable Software may only be installed as part of this module if the customer is on the most current software release at the time this Agreement is entered into.

Updates/Upgrades/New Licensable Software installation will be scheduled at times convenient to both the Customer and Elekta, but within Normal Office Hours. The responsibility for installation may be that of Elekta or Customer, depending which Software is being installed.

The supply and/or installation of any necessary hardware or software to run any Updates/Upgrades/New Licensable Software is not included, unless required by local laws or regulations, or if the Update/Upgrade/New Licensable Software falls within the description of the Hardware/Software Safety Releases module, in which case the provisions of the Hardware/Software Safety Release module apply.

The Customer shall ensure adequate personnel are present on Site at the time of (remote) installation to assist with the installation of the Updates/Upgrades/New Licensable Software. Elekta may install the Updates/Upgrades/New Licensable Software remotely, in which case the Customer shall give Elekta sufficient access to the relevant systems and Products.

On-site training is not included, unless specifically agreed otherwise, for Updates and Upgrades. The duration of any training and whether this is performed remotely or on site will depend upon the specific features and will be agreed between the Parties. On-site application training for the new features (New Licensable Software) is included and shall take place at the time of installation.

**3. SYSTEM AVAILABILITY**

**3.1 Uptime Guarantee**

Elekta hereby guarantees that the Hardware will achieve an annual Uptime listed in the 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:

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

For the purposes of the Uptime calculation, Agreed Available Time shall be as noted in the 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 prerequisites 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		Elekta Care					
From	To	Platin	Gold	Platin	Gold	Platin	Gold
		um	LGK	um	Linac	um	Brach
						y	y
99	100	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
98	99	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
97	98	5.0%	0.0%	2.0%	0.0%	2.0%	0.0%
96	97	10.0%	0.0%	3.0%	3.0%	3.0%	3.0%
95	96	20.0%	0.0%	4.0%	4.0%	4.0%	4.0%
94	95	50.0%	20.0%	5.0%	5.0%	5.0%	5.0%
93	94	50.0%	30.0%	6.0%	6.0%	6.0%	6.0%
92	93	50.0%	40.0%	7.0%	7.0%	7.0%	7.0%
91	92	50.0%	50.0%	8.0%	8.0%	8.0%	8.0%
90	91	50.0%	50.0%	9.0%	9.0%	9.0%	9.0%
< 90	90	50.0%	50.0%	10.0%	10.0%	10.0%	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.

### 3.5 Scanner Interface Support (for LGK Icon Only)

This service provides the customer with a new MR adapter or CT Table Fixation if needed during update of their scanner.

### 3.6 Cobalt Management During Repair

Applicable to the Leksell Gamma Knife only.

This option covers the Customer against the costs associated with the unloading and reloading of the existing Co-60 sources from Radiation Unit should a fault occur requiring their removal.

The activities covered include:

- Rigging and the usage of any cranes and trucks as necessary,
- Transportation and usage of loading machine for unloading/and reloading of the Co-60 sources,
- Transportation and usage of cask for storing Co-60 sources,
- Any reasonable and necessary repairs once the Co-60 sources have been removed,
- Reloading of the same Co-60 sources and any necessary functional tests thereafter.

## 4. TECHNOLOGY REFRESH

Elekta will provide the necessary Hardware Upgrades (as selected from the list defined below) to the Hardware components 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 listed in the Scope of Supply 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 Leksell Gamma Knife:

- The Leksell GammaPlan® (LGP) computer
- The Leksell® Coordinate Frame (LCF)
- The Leksell Gamma Knife® Perfexion™ and Icon™ Control System main control unit, (MCU)
- The Leksell Gamma Knife® Icon™ X-ray kV generator

## 5. REMOTE SERVICES

In order to benefit from Remote Services and to ensure uptime guarantees, equipment must be connected to an IntelliMax Agent where available or WebEx where Elekta IntelliMax™ is not available.

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

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

Customer acknowledges and agrees that notwithstanding the provisions contained in Customers Elekta Purchase and License Agreement, Elekta shall have the ability to remotely monitor Elekta supplied systems on the Customers network via Elekta IntelliMax™ to gain information and aid in diagnosis and correction of system issues. Remote Access/screen sharing, 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.

### 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.

### 5.3 Remote Services Remote Access

The ability to allow screen sharing of your own devices. Ideal for self-maintainers or customers with satellite sites who wish to provide remote assistance to their own staff.

Remote Access is available at any time when the Elekta system is running and connected to Elekta IntelliMax™.

## 6. EDUCATION SERVICES

### 6.1 Customer Training Review

On an annual basis, Elekta staff will, together with the hospital contact person, conduct an assessment of the ongoing training needs of the department. This will be based on the current and

planned clinical techniques within the department and any gaps in knowledge preventing the Customer from maximizing the clinical use of the Elekta equipment.

Following the visit, a report will be submitted to the Customer detailing the recommended training.

This option does not cover the actual training which must be provided for via an "Application Support – Onsite" option or purchased separately.

#### **6.2 Elekta Care Learning Credits**

Set number of Elekta Care Learning Credits provided per each coverage year. Number of credits provided depends on product selected. The credits can be used towards any training offered by Elekta. See course catalogue on [www.elekta.com/elektacare](http://www.elekta.com/elektacare) or contact your local Elekta representative for training options.

Elekta Care Learning Credits are valid for two years; they will expire two years after the start of the Service Agreement in which they were purchased.

Travel and accommodation is not included and cannot be paid for with Elekta Care Learning Credits. Travel needs to be managed by the responsible local Elekta office or responsible local distributor representative.

### **7. BUSINESS SERVICES**

#### **7.1 Physics Support (Telephone/Remote)**

Direct access to Elekta Physicists to provide expert phone support.

Support is typically related to questions around dosimetry, radiation shielding and treatment planning, but can be of any physics-related nature.

Physics support is only available during Normal Office Hours.

Despite any advice given by Elekta, the Customer must still take full responsibility for any on-site QA and appropriate sign-off prior to clinical use of the equipment.

#### **7.2 Online Customer Portal (Support Plus)**

Access to the Elekta Customer Portal providing a range of useful system and product information.

Information on the portal 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.

**EXHIBIT L**  
**TERMS AND CONDITIONS FOR RELOAD OF LEKSELL GAMMA KNIFE®**

## 1. DEFINITIONS

The following words and terms shall have the meaning set forth opposite them in this Section 1:

- 1.1 Alpha-Omega shall mean Alpha-Omega Services Corporation, a corporation organized under the laws of California.
- 1.2 Installation Test Protocol means Supplier's standard protocol for testing the LGK, as revised from time to time by Supplier.
- 1.3 Estimated Date of Delivery means the estimated date of delivery of the New Cobalt Supply to the Site, which is indicated on the Executive Summary. Customer and Supplier agree that the Estimated Date of Delivery is a target date only, and the Supplier shall not be liable for deviations of the actual date of delivery that are beyond the Supplier's reasonable control of the New Cobalt supply from the Estimated Date of Delivery.
- 1.4 LGK means the certain equipment used for stereotactic radiosurgery known as Leksell Gamma Knife® that Customer heretofore has purchased from Supplier.
- 1.5 Licenses are defined in Section 3.1.
- 1.6 New Cobalt Supply means the new supply of Cobalt-60 sources to be installed in the LGK.
- 1.7 Old Cobalt Supply means the supply of Cobalt-60 sources in the LGK as of the date hereof to be removed by Supplier.
- 1.8 Reloading Fee means the price payable by Customer relating to the Reloading Services as set out in the Executive Summary.
- 1.9 Reloading Services means the services to be provided by Supplier hereunder as described in Section 2 hereof.
- 1.10 Replacement Parts are defined in Subsection 2.3 hereof.
- 1.11 Specification refers to the technical standards with which the LGK shall comply as described on Exhibit A hereto, and as hereafter modified pursuant to Subsection 34.7 hereof.
- 1.12 Subcontractor Services are defined in Section 7 hereof.

## 2. SCOPE OF RELOADING SERVICES

- 2.1 Supplier shall remove the Old Cobalt Supply from the LGK and dispose of the Old Cobalt Supply at a licensed facility in accordance with federal, state and local laws and regulations
- 2.2 Supplier shall arrange and pay for the delivery of the New Cobalt Supply to the Site at the risk and cost of Supplier and by personnel of Supplier's choosing. Title to, and risk of loss of, the New Cobalt Supply shall pass to Customer when Supplier effects proper installation of the New Cobalt Supply and Customer provides written acceptance of the proper installation at the Site to Elekta..
- 2.3 Supplier shall install the New Cobalt Supply in the LGK. Supplier shall also perform any required maintenance on, and if applicable, shall replace necessary parts for the LGK (the "Replacement Parts").
- 2.4 A detailed description of the Reloading Services is included in Exhibit A hereto.

## 3. RELOADING

- 3.1 Customer shall obtain all licenses, permits, approvals, consents, and authorizations which may be required of Customer by any local, state or federal governmental or other regulatory agency for the receipt and possession of the New Cobalt Supply in the LGK at the Site, and the continued use by Customer of the LGK (hereinafter collectively the "Licenses"). Supplier or its subcontractors shall obtain all licenses, permits, approvals, consents and authorizations which may be required of Supplier or its subcontractor for the removal of the Old Cobalt Supply and its disposal per Subsection 2.1 hereof, from the LGK and the installation of the New Cobalt Supply in the LGK at the Site.

- 3.2 Each party shall, no later than sixty (60) days before the Estimated Date of Delivery or as otherwise mutually agreed upon in writing between the Parties, submit to the other party a copy of the licenses, permits, approvals, consents and authorizations described in Subsection 3.1 hereof.
- 3.3 Customer shall provide such access to the Site as may be required by Supplier for the performance of the Reloading Services. Customer shall also provide a secure area for equipment of Supplier and its subcontractors and parking for all personnel of Supplier and its subcontractors.
- 3.4 Customer shall be responsible for securing the site and such areas adjacent to or in the vicinity of the site as may be designated by Supplier or its subcontractors, at all such times as Supplier or its subcontractors may reasonably require in order to perform the Reloading Services.
- 3.5 Customer shall, at its own expense, prepare the Site as necessary for the performance of the Reloading Services. Customer shall also be responsible for the positioning and rigging of the LGK on its foundation.
- 3.6 In case of Customer's delay in obtaining the licenses, permits, approvals, consents or authorizations described in Subsection 3.1 hereof, or if for any other reason Customer is unable to receive the New Cobalt Supply at the Site or otherwise perform its obligations under the Agreement (including sections 3.3 and 3.4 hereof), either at the time the New Cobalt Supply arrives at the Site or thereafter, upon mutual agreement, Supplier may elect not to perform the Reloading Services and instead to transport and to store the New Cobalt Supply or to defer its initial shipment from the hot cell from which it originates until such time as the Customer is ready to receive the New Cobalt Supply and to perform its obligations hereunder. In case of Supplier's delay in obtaining and providing to the Customer a copy of permits, approvals, consents or authorizations described in Subsection 3.1 hereof or otherwise perform its obligations under the Agreement, Customer may elect to postpone the Reloading Services until such time as the Supplier is ready to perform its obligations hereunder.
- 3.7 In the event of an election by Supplier pursuant to Subsection 3.6 hereof:
- (a) the Specification shall be modified to reflect the reduction in minimum activity of the New Cobalt Supply corresponding to the time of the storage and transportation thereof;
  - (b) Customer shall reimburse Supplier for Supplier's reasonable incremental expenses incurred as result of such delay, including without limitation, reasonable storage and insurance costs.
- 3.8 Upon completion of the installation of the New Cobalt Supply in the LGK, in the presence of Customer and under the supervision of the radiation safety officer of the Customer, Supplier shall perform the Installation Test Protocol. The Reloading Services shall be deemed to have been satisfactorily completed after the Installation Test Protocol has been completed and has demonstrated that the LGK complies with Specification and Supplier has completed the performance of the Reloading Services. Any noncompliance with the Specification revealed during performance of the Installation Test Protocol shall be remedied by Supplier at Supplier's costs, unless such noncompliance is caused by the Customer or the failure of the Site to meet the Site Planning Criteria specified in the purchase Agreement between Customer and Supplier pursuant to which Customer purchased the LGK. Immediately after the Installation Test Protocol has been completed to the mutual satisfaction of Supplier and approved by the Customer, they shall sign a certificate prepared by Supplier to the effect that the Installation Test Protocol has been successfully completed. After Supplier has commenced the Reloading Services, Customer shall not run, operate, or otherwise use the LGK except for the purpose of conducting the Installation Test Protocol, until the Installation Test Protocol has been successfully completed and completion certificate signed.

#### 4. WARRANTY; LIMITATION OF LIABILITY

- 4.1 Supplier warrants that the Replacement Parts and New Cobalt Supply will be free from defects in materials and workmanship causing noncompliance with the Specification, as amended, for a period of one (1) year, but this warranty shall not apply in any form with respect to:
- (a) defects arising out of Replacement Parts provided, modified or designed by Customer;
  - (b) defects caused by Customer's improper use or maintenance;
  - (c) normal deterioration or normal wear and tear, including radioactive decay of the New Cobalt Supply, or
  - (d) defects resulting from repairs or service of the LGK supplied other than by Supplier or its authorized representative.

In the event that any of the Replacement Parts or the New Cobalt Supply fail to comply with this warranty obligation, Supplier shall repair or replace such defective Replacement Part or New Cobalt Supply.

## **5. PARTIES IN INTEREST**

- 5.1 The Agreement shall inure to the benefit of each of the parties hereto as well as to their respective representatives, successors and permitted assigns.

## **6. SUBCONTRACTORS, AFFILIATES**

- 6.1 Customer acknowledges and agrees that Supplier may subcontract to Alpha-Omega (the performance of certain portions of the Reloading Services which may include the services listed on Exhibit C hereto).

## **7. DELIVERY AND INSTALLATION**

- 7.1 Supplier shall deliver any Hardware to the Customer CIP Site (as defined in Incoterms 2000). Notwithstanding the preceding sentence, the Customer agrees to pay all sales or use taxes levied by any state or political subdivision thereof, which are the responsibility of Customer, as a result of this Agreement. The Customer shall also be responsible for payment of all customs and otherwise reasonable charges with respect to the importation of the Deliverables.



# Leksell Gamma Knife<sup>®</sup>

## Icon<sup>™</sup>

Shaping a new era in  
intracranial radiosurgery



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Helping clinicians  
improve patients' lives

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 Elekta

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# New possibilities evolve for more personalized treatments

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**The current environment presents significant growth potential for advanced brain programs, and Icon is designed to meet the demand.**

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The demand for stereotactic intracranial radiosurgery is increasing, propelled by many factors:

- Rise in cases among aging populations
- Higher expectations on quality of life
- Trend toward more personalized treatment strategies

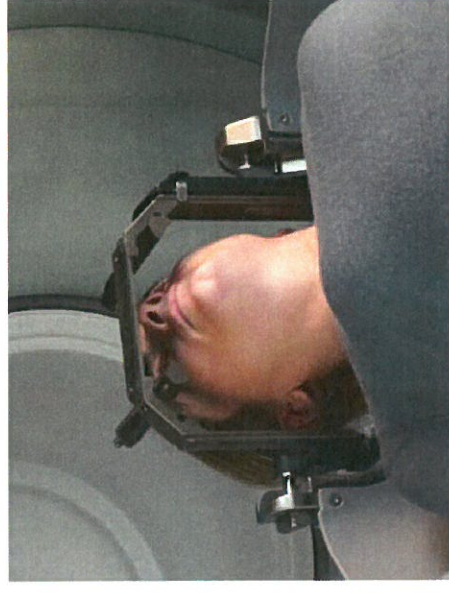
In this environment, advanced brain programs are poised for significant growth, and Leksell Gamma Knife<sup>®</sup> Icon<sup>™</sup>, the latest generation Gamma Knife system, is designed to meet the demand.

Building on Gamma Knife precision and adding new technology, Icon gives clinicians the option to perform single or fractionated frame-based or frameless treatments, allowing for more individualized delivery—without sacrificing precision and accuracy.

“It’s a new paradigm in SRS with Icon, where we have flexibility in fractionation, workflow, the lowest integral dose, sharp dose gradients and all with the patient comfortable in a mask.”

**Arjun Sahgal, MD, FRCPC**

Radiation Oncologist, Odette Cancer Centre  
Sunnybrook Health Sciences Centre  
Toronto, Canada



# Precision care for the brain

**Leksell Gamma Knife Icon is a truly integrated system with all components built on the same rigid structure and calibrated to one another. This tight integration improves precision. It also contributes to an assured uptime standard of 98 percent.\***

## **High therapeutic dose with maximum precision**

During Gamma Knife radiosurgery, up to 192 low-intensity radiation beams from cobalt-60 sources converge with high accuracy on the target. At isocenter where the beams merge, radiation dose is concentrated powerfully at the target, sparing healthy brain. Target mass and shape determines the number of beams used, and beams can be individually modulated, further enhancing accuracy.

## **Stereotactic cone-beam CT**

Integrated stereotactic cone-beam CT, calibrated to the robust patient positioning system, determines the stereotactic coordinates in 3D.

## **Online Adaptive DoseControl™**

Online Adaptive DoseControl confirms accuracy and ensures precise treatment delivery during every fraction of treatment. Integrated with the control system, it permits clinical decision making during the treatment process.

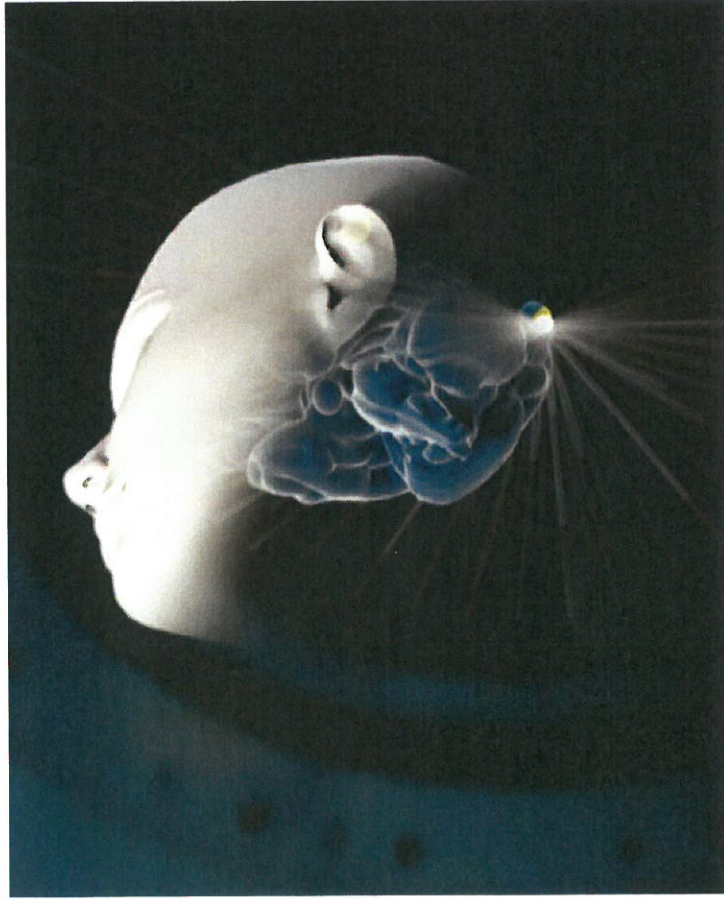
The automatic dose correction is made possible by the unique design of Leksell Gamma Knife. Since Leksell Gamma Knife uses up to 192 non coplanar beams instead of shaped beams, it is possible to move some or all of the shots to compensate for smaller patient movements. If the patient has shifted, the shots will follow the anatomy. We call this virtual 6D couch since it adapts for movement.

The online dose evaluation is the last step prior to treatment, and gives the physician an opportunity to look at the plan to be delivered each day and compare with the dose that was originally planned. If needed, the physician has the choice of adjusting the delivery.

## **Real-time motion management**

High Definition Motion Management monitors the patient during treatment, with a resolution of 0.15 mm. If the patient moves outside a pre-set limit, beam delivery automatically turns off. The result: the highest possible accuracy for both frameless and frame-based treatment.

\*With valid service contract



Elekta guarantees the accuracy of Leksell Gamma Knife for its entire lifetime—no other radiosurgery system does the same\*

\* With a Platinum service contract. The supported lifetime of Icon is 10 years.

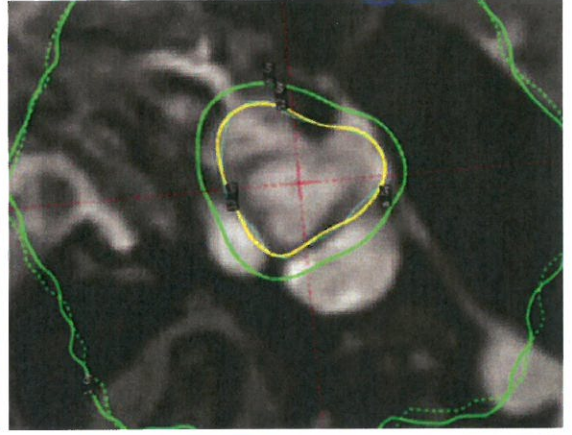


Gamma Knife  
delivers lower dose  
to healthy tissue  
than other systems:

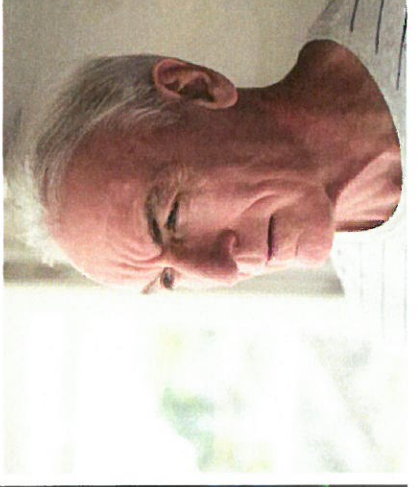
2-4X

lower dose to normal brain

Ma L, Nichol A, Hossain S, et al. Variable dose interplay effects across radiosurgical apparatus in treating multiple brain metastases. *Int J CARS*. Published online: 20 April 2014. doi:10.1007/s11548-014-1001-4



Leksell Gamma Knife Icon enables frameless or frame-based treatments with uncompromising accuracy



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## Clinical decisions determine the workflow

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**No patient or radiosurgery treatment is exactly the same as another. Gamma Knife Icon offers new freedom to adapt and optimize treatment to the needs of patients and to everyday clinical logistics.**

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### **Clinical and workflow flexibility for intracranial SRS**

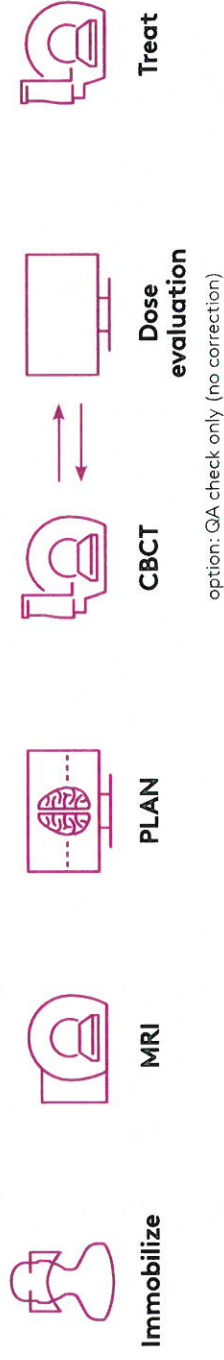
- Icon introduces flexible workflows for:
- Frameless or frame-based procedures
  - Single session or fractionated treatment

### **Treat more patients with improved efficiency**

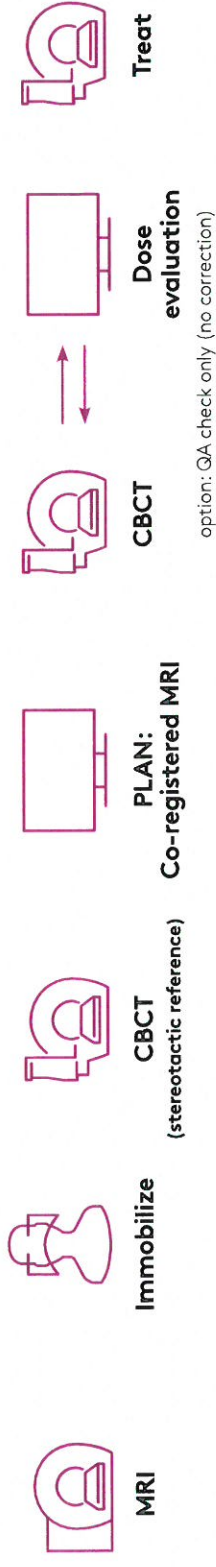
Streamlined Icon workflows contribute to efficient patient throughput. Icon treatment times are often shorter than those of linac-based systems, when considering all steps required, from planning and quality assurance to treatment.

# Flexible workflows aid efficiency

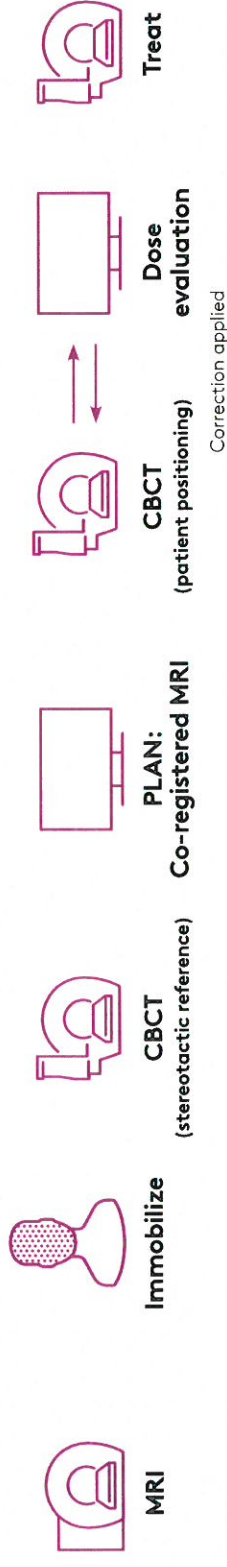
## Frame-based workflow with fiducial based registration



## Frame-based workflow with stereotactic CBCT based registration



## Mask-based workflow with stereotactic CBCT based registration





“What is amazing is the capability of the Icon system to adapt, very precisely, the planning to the new position of the patient. And this is really meeting our expectations in terms of real-time recalculation of the dose.”

**Jean Régis, MD**

Director, Stereotactic, Functional Neurosurgery and Radiosurgery  
Timone University Hospital, Marseille FR



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# Planning and QA— elegantly efficient even in complex cases

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**Leksell GammaPlan® is a sophisticated treatment planning and management software that is fully integrated with Icon and designed specifically for the needs of the brain. It provides specialized tools that make full use of the advanced technology incorporated into Icon, while providing safe and efficient workflows.**

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## **Optimal plans in your daily clinical practice**

A complete and accurate modelling of Icon and patient fixations enable both accurate dose calculations and simulation of all geometries to ensure you deliver exactly what you have planned efficiently and simply.

- WarpSpeed™ and Inverse Planning tools are tailored for Icon. They allow for interactive dose sculpting, and make it possible to complete plans in a matter of minutes, even for complex and multiple targets.
- The Convolution tool provides optional heterogeneity correction for targets near bone and air cavities.
- Both manual and automatically calculated dose statistics are available for efficient plan review.
- Re-Treatment™ functionality provides tools for efficient management of reoccurring diseases, in particular metastases.
- Pre-planning makes it possible to plan on frameless images.

## **Fast and easy quality assurance**

The QA procedure for Leksell Gamma Knife Icon is fast and fully automated. It is integrated in the system with no need for external QA tools (e.g. water phantoms). Special patient specific QA is not needed.

System Accuracy QA: Max. 10 min./day  
Treatment Plan QA (optional): 5 min./patient

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## Advancing new treatment paradigms

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**Icon achieves high accuracy regardless of the method of immobilization—frame-based or frameless. This unique capability opens up new paradigms for fractionation, enabling treatment of larger targets and targets close to critical structures. As a result, most cases in the brain, regardless of the size, location or number of targets, can be treated with Gamma Knife accuracy and confidence.**

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### **Performing ultraprecise radiosurgery**

Leksell Gamma Knife is the only technology capable of performing ultraprecise radiosurgery, enabling treatment of the most complex and critically located targets. For these types of indications, treatment must be optimized along many parameters: accuracy, conformity, selectivity, dose fall-off and integral dose. Only Leksell Gamma Knife can achieve such strict optimization across all parameters at the same time.

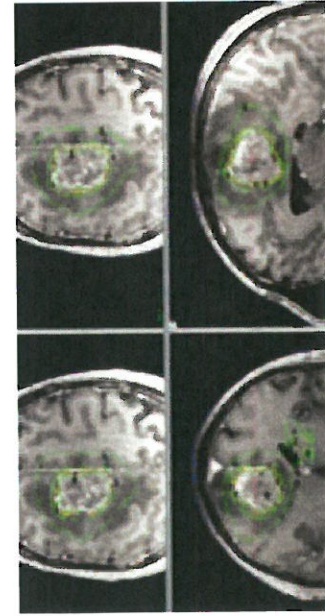
### **Fractionation with highest precision and dose distribution sparing healthy tissue**

Icon enables new methods of immobilization and the option to fractionate treatment, making the exceptional accuracy and precision of Leksell Gamma Knife radiosurgery a possibility for many more types of cases and many more patients.

Icon can be deployed in different treatment regimens and adaptive, mask-based approach ranges from single session treatments and hypo-fractionation to full fraction approaches.

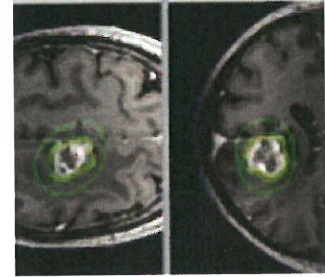
Typical frameless cases:

- Hypofractionation of larger volumes
- Ability to treat more complex targets
- Easier re-treatment of patients with brain metastases who present with new or recurring lesions

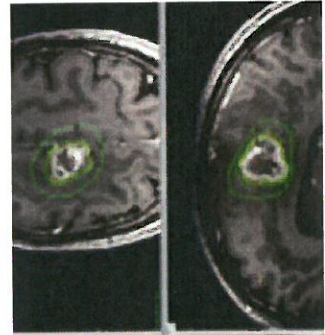


Fraction 1: volume 15.643 cm<sup>3</sup>

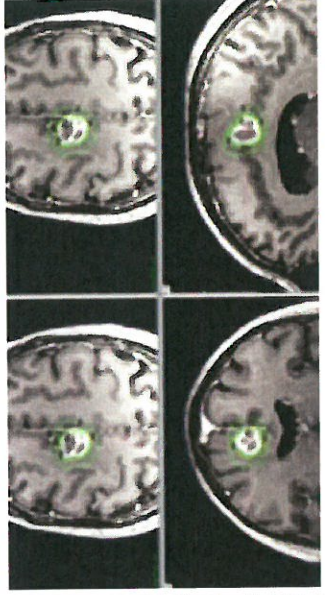
Images courtesy of Bristol Gamma Knife Centre, University Hospitals, Bristol



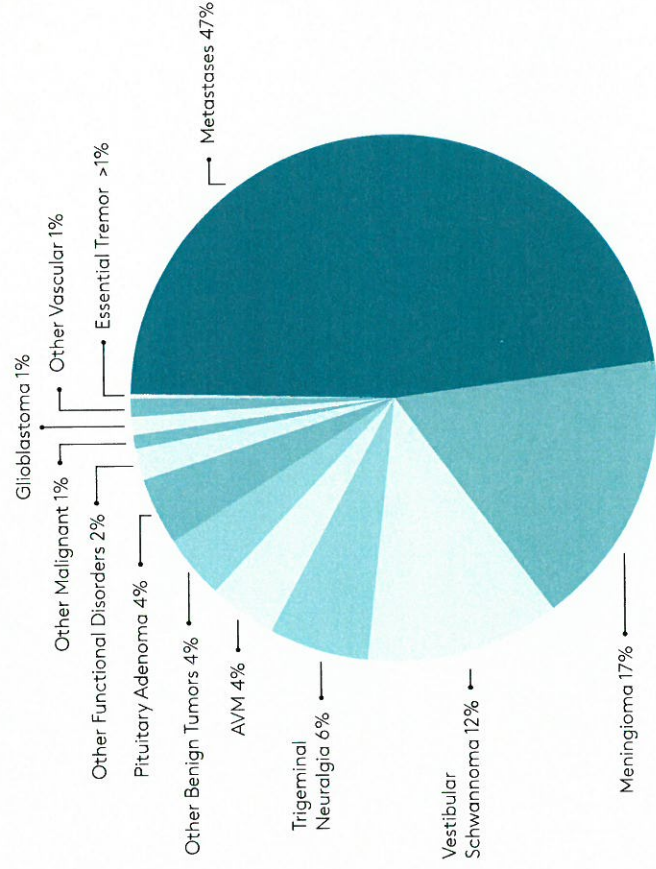
Fraction 2: volume 6.628 cm; 57.6% reduction at fraction 2



Fraction 3: volume 2.639 cm<sup>3</sup>; 83.1% reduction at fraction 3

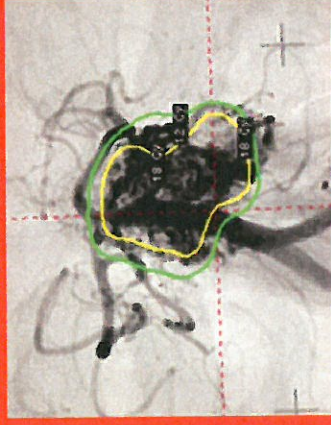


## Icon enables intracranial treatments for a broad case mix



Leksell Gamma Knife Treatment Statistics Report, 1966-2016 (published 2017) Leksell Gamma Knife Society

### Brainstem AVM



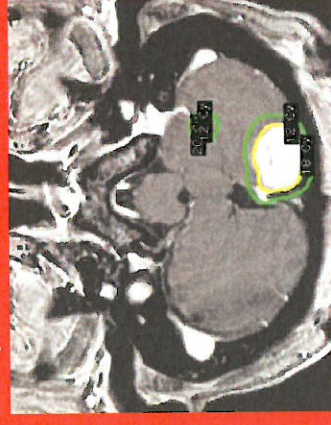
45 year old male, no prior OP; Embol, no hemorrhage, facial pain

### Pituitary adenoma



56 year old male, double vision, Prolactin level 1900

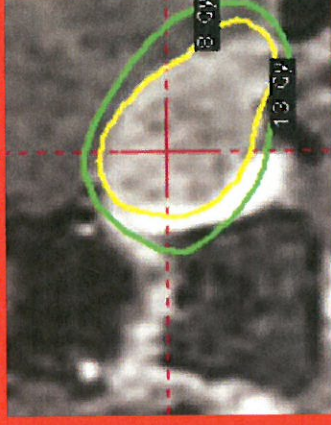
### Multiple mets



63 year old female, breast cancer, ER(+), PR(-), Her2/neu(+), bone and lung metastases (+), no prior WBRT

Images courtesy of Cleveland Clinic Foundation, USA

### Cavernous sinus meningioma



43 year old female, no prior surgical resection, Lt. CN 4, 6 palsy, Lt. facial numbness

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# Feature-benefit summary

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## Icon capabilities support system continuity for current and future needs

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### High therapeutic dose with maximum precision

- Effective tumor control sparing organs at risk
- 2-4x lower dose to normal brain
- Highest possible accuracy for both frame-based and frameless treatments

### Online Adaptive DoseControl

- Continuous quality control
- Delivers exactly what is planned efficiently and simply

### Cranial SRS flexibility

- Treatment options include frame/frameless, single session/fractionation, SRS/microradiosurgery

### System integration

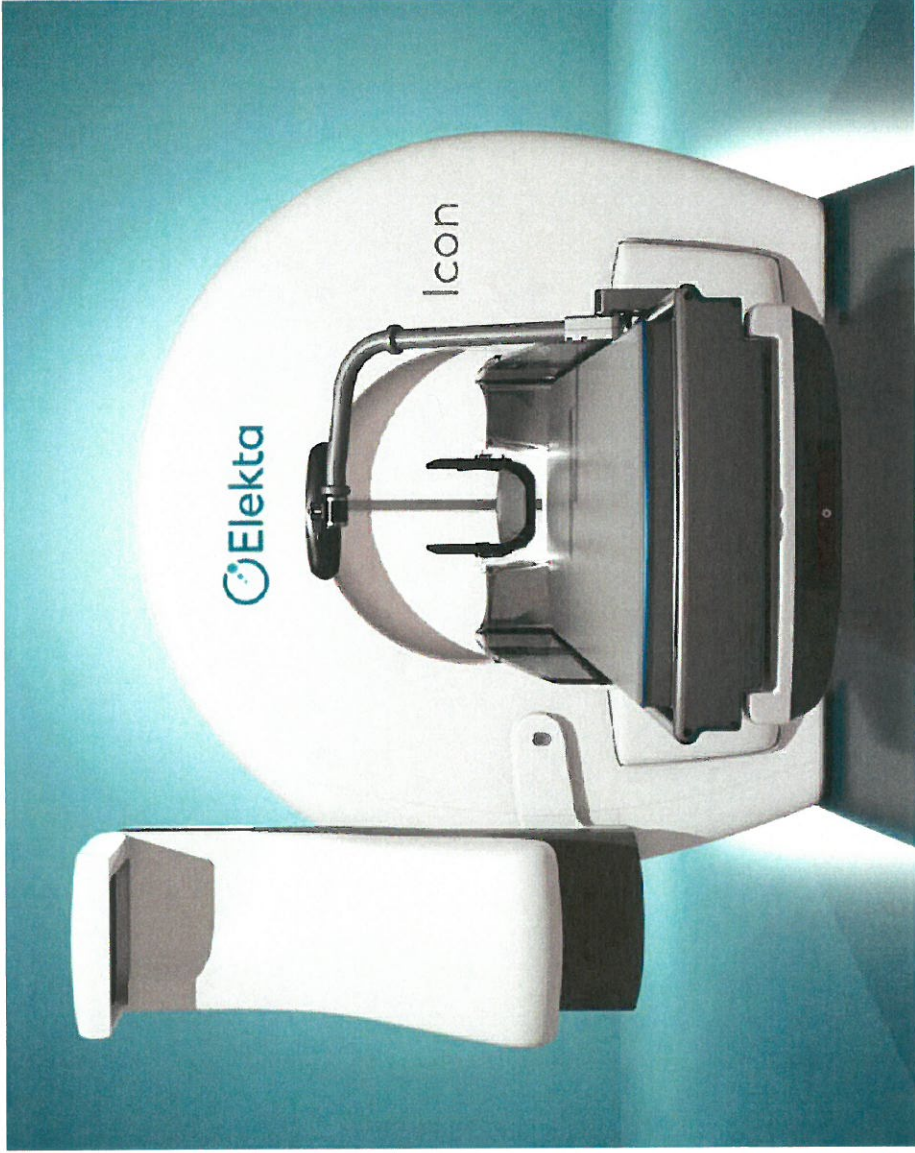
- Efficiency, safety, reliability

“We need Icon to cover all of the patients requiring Gamma Knife treatment. With Icon, we can expand the indications treated with Gamma Knife and treat 10 to 20 percent more patients.”

**Prof. Jung-Il Lee, Neurosurgeon**

Samsung Hospital  
Seoul, Korea





0.15

mm average accuracy



10

minutes QA



98

percent uptime



2,800

peer reviewed journal articles



>1,000,000

patients treated

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# Contact your Elekta representative for more information about Icon and the Gamma Knife experience.

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Choose Icon and gain access to a robust support system designed to help you get the most from your system.

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#### **Elekta Care**

Personal response, experiential learning and lifecycle management are ways we stay connected to help you improve patient care. Find out more at [elekta.com/elektacare](http://elekta.com/elektacare).



#### **SMART communications**

Online tools and templates support the promotion of your Gamma Knife clinic. Visit [elekta.com/smart](http://elekta.com/smart) for more information.



#### **Education and training**

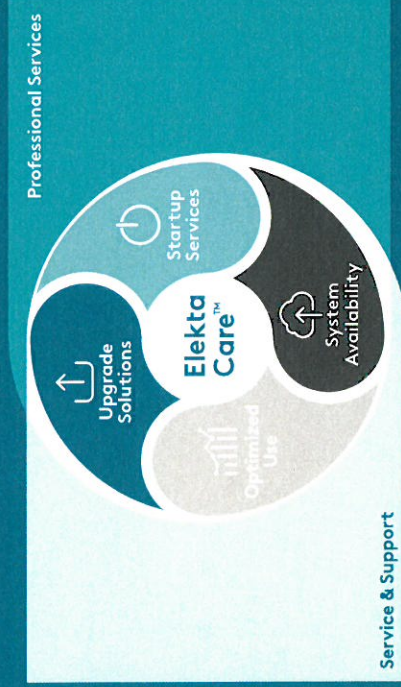
A comprehensive training package supports sustainable learning and inspires continuous development for Icon users. Find out more at [elekta.com/services/education-and-training](http://elekta.com/services/education-and-training).



#### **Leksell Gamma Knife Society**

As an Icon user, you become a member of Leksell Gamma Knife Society—a scientific community of more than 1,500 members sharing knowledge and driving the development of cranial SRS. Visit [LGKSociety.com](http://LGKSociety.com) for more information.

**Elekta Care™** supports you from startup through your product's lifecycle with comprehensive options from education, training and upgrades to solutions allowing you the highest uptime and improved operational efficiency.



**We are healthcare technology innovators,  
specializing in radiotherapy treatments  
for cancer and brain disorders.**

**We help clinicians to improve patients'  
lives through our forward-thinking  
treatment solutions and oncology  
informatics, creating focus where it  
matters to achieve better outcomes.**

**Elekta AB**

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F +1 770 448 6338

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South America**

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F +55 11 5054 4568

**Asia Pacific**

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F +852 2575 7133

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F +81 3 6436 4231

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F +86 10 6970 4685



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**STATE OF NORTH CAROLINA**  
*Department of Health and Human Services*  
*Division of Health Service Regulation*

**CERTIFICATE OF NEED**

for

Project Identification Number #Q-8845-12

FID #933410

**ISSUED TO:** Pitt County Memorial Hospital, Incorporated  
d/b/a Vidant Medical Center  
P.O. Box 6028  
Greenville, NC 27835-6028

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

**SCOPE:** Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall acquire no more than one replacement gamma knife to operate on the existing hospital campus/ Pitt County

**CONDITIONS:** See Reverse Side


**PHYSICAL LOCATION:** Vidant Medical Center  
2100 Stantonsburg Road  
Greenville, NC 27834

**MAXIMUM CAPITAL EXPENDITURE:** \$4,671,700

**TIMETABLE:** See Reverse Side

**FIRST PROGRESS REPORT DUE:** February 28, 2013

This certificate is effective as of the 29<sup>th</sup> day of October, 2012

  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Health Service Regulation

**CONDITIONS:**

1. Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall materially comply with all representations made in its certificate of need application.
2. Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.
3. Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall de-install and use as trade-in the existing gamma knife equipment system prior to the acquisition of the new gamma knife system.
4. Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on October 8, 2012.

**TIMETABLE:**

Completion of preliminary drawings _____	January 18, 2013
Approval of final drawings by Construction Section, DHSR _____	April 10, 2013
25% completion of construction _____	June 7, 2013
75% completion of construction _____	June 17, 2013
Completion of construction _____	June 21, 2013
Occupancy/offering services _____	July 1, 2013
Operation of equipment _____	July 1, 2013

All responses should pertain to **October 1, 2016 through September 30, 2017.**

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

**Campus – if multiple sites:** \_\_\_\_\_

CPT Code	Description	# of Procedures
<b>Simple Treatment Delivery</b>		
77401	Radiation treatment delivery	
77402	Radiation treatment delivery (<=5 MeV)	
77403	Radiation treatment delivery (6-10 MeV)	
77404	Radiation treatment delivery (11-19 MeV)	
77406	Radiation treatment delivery (>=20 MeV)	
<b>Intermediate Treatment Delivery</b>		
77407	Radiation treatment delivery (<=5 MeV)	
77408	Radiation treatment delivery (6-10 MeV)	
77409	Radiation treatment delivery (11-19 MeV)	
77411	Radiation treatment delivery (>=20 MeV)	
<b>Complex Treatment Delivery</b>		
77412	Radiation treatment delivery (<=5 MeV)	
77413	Radiation treatment delivery (6-10 MeV)	
77414	Radiation treatment delivery (11-19 MeV)	
77416	Radiation treatment delivery (>= 20 MeV)	
<b>Other Treatment Delivery Not Included Above</b>		
77418	Intensity modulated radiation treatment (IMRT) delivery and/or CPT codes 77385 and/or 77386	
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator	
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	
G0339	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery in one session or first fraction	
G0340	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery, fractionated treatment, 2nd-5th fraction	
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the LINAC)	
	Pediatric Patient under anesthesia	
	Neutron and proton radiation therapy	
	Limb salvage irradiation	
	Hemibody irradiation	
	Total body irradiation	
<b>Imaging Procedures Not Included Above</b>		
77417	Additional field check radiographs	
<b>Total Procedures – Linear Accelerators</b>		
<b>Gamma Knife® Procedures</b>		
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of one session; multisource Cobalt 60 based (Gamma Knife®)	164
<b>Total Procedures – Gamma Knife®</b>		164



FACILITIES + ARCHITECTURE  
 200 EASTMAN DRIVE ROAD  
 GREENVILLE, NC 27602  
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VIDANT MEDICAL CENTER  
 GAMMA KNIFE SOURCE REPLACEMENT  
 GREENVILLE, NORTH CAROLINA  
 VIDANT MEDICAL CENTER  
 VIDANT MEDICAL CENTER

NO.	DESCRIPTION	DATE	BY

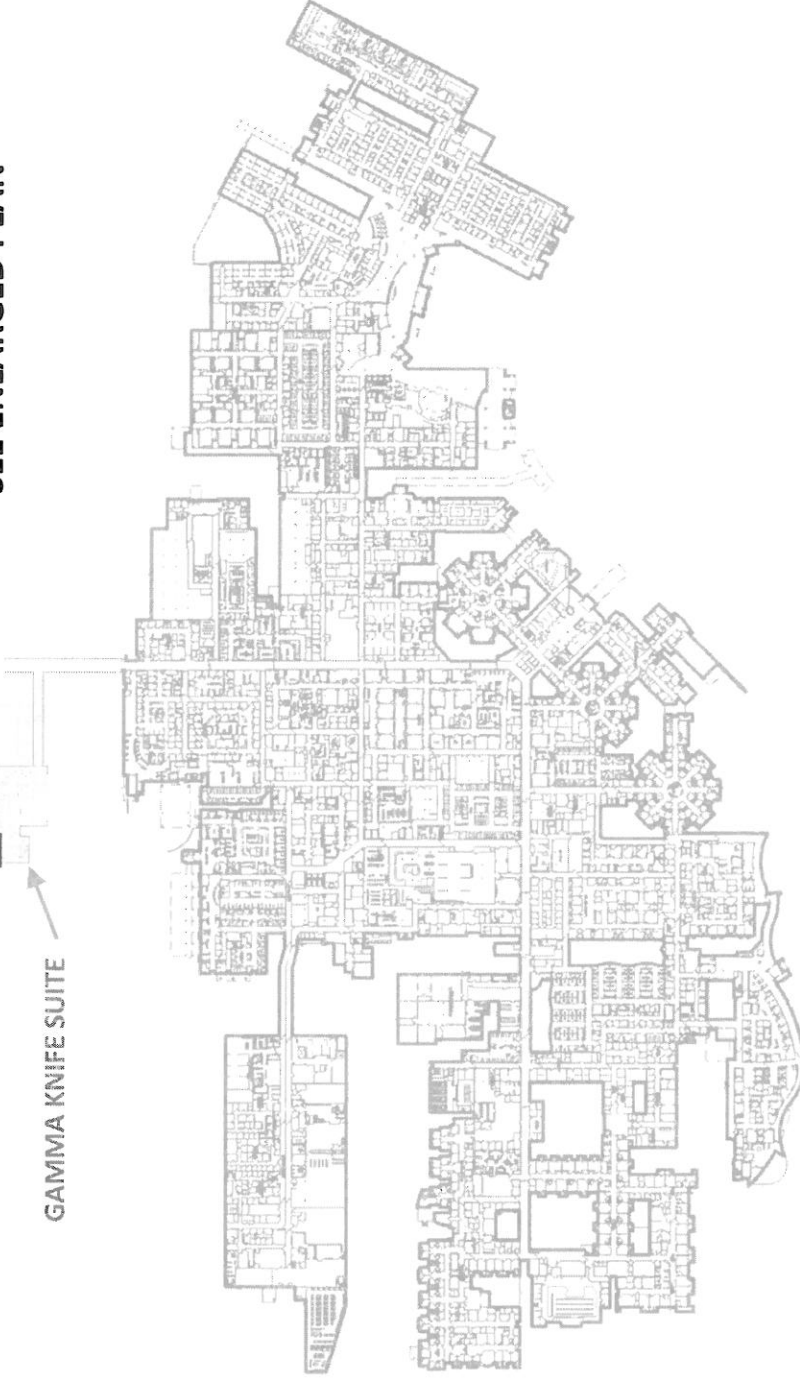
PROJECT NO.	14C-086
DATE	03/27/17
DRAWN BY	FOR
SHEET NO.	01 OF 03

**101**

VT-000-001-001

**GAMMA KNIFE ROOM,  
 SEE ENLARGED PLAN**

GAMMA KNIFE SUITE



**VIDANT MEDICAL CENTER  
 FIRST FLOOR PLAN  
 NO SCALE**



# State of North Carolina

## Department of Health and Human Services Division of Health Service Regulation

*Effective March 20, 2018, this license is issued to  
Pitt County Memorial Hospital, Inc.*

*to operate a hospital known as  
Vidant Medical Center  
located in Greenville, North Carolina, Pitt County.*

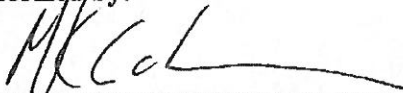
*This license is issued subject to the statutes of the  
State of North Carolina, is not transferable and shall remain  
in effect until amended by the issuing agency.*

*Facility ID: 933410  
License Number: H0104*

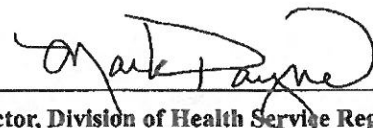
**Bed Capacity: 974**  
*General Acute 847, Rehabilitation 75, Psych 52,*

**Dedicated Inpatient Surgical Operating Rooms: 7**  
**Dedicated Ambulatory Surgical Operating Rooms: 0**  
**Shared Surgical Operating Rooms: 26**  
**Dedicated Endoscopy Rooms: 4**

Authorized by:



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



Director, Division of Health Service Regulation