

# Leksell Gamma Knife® 4C



## System Description



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# Leksell Gamma Knife<sup>®</sup> 4C

## System Description

Leksell Gamma Knife<sup>®</sup> 4C is a complete system for radiosurgery marketed worldwide by Elekta. The effective non-invasive treatment is made by beams of ionizing radiation that have sufficient penetration to reach even the most deep seated tumors. The surgery is achieved by delivering prescribed doses (shots) of radiation, in compliance with a pre-prepared treatment plan to the exact site of the intracranial target. The tissue in the target is thus treated by radiation while sparing surrounding tissue.

Ionizing radiation is obtained from a total of 201 cobalt-60 sources arranged in a hemispherical pattern and embedded within the shielded, dome-shaped radiation unit. The beams of gamma radiation that emanate from the cobalt sources coincide at a fixed focal point within the radiation unit. The delivered dose is shaped to the precise contour of the target by combination of shots using different collimator sizes and plugs.

During irradiation there are no moving parts within Leksell Gamma Knife<sup>®</sup> 4C and therefore safety, stability and accuracy are inherent features.

The system basically consists of the radiation unit with the patient couch and collimator helmets, the control panel and auxiliary systems.

### **Leksell Stereotactic System<sup>®</sup>**

Detailed diagnostic images of the head of the patient form the basis for treatment planning and these can be obtained by employing one or more imaging techniques: Magnetic Resonance (MR), Computerised Tomography (CT) and/or Angiography (AI) of the relevant anatomy.

As part of the imaging process it is essential to provide exact points of reference by means of which the shape and position of the targets can be ascertained with respect to the patient's skull. Moreover, during the following radiosurgery session, the head of the patient must be entirely immobilized to maintain the accuracy of the treatment.

Components of Leksell Stereotactic System<sup>®</sup> are used for these purposes and are thus an integral part of Leksell Gamma Knife<sup>®</sup> 4C concept. They are:

- Leksell<sup>®</sup> Coordinate Frame which provides spatial references and immobilizes the patient's head;
- MR, CT or AI indicators which impose reference fiducials during image acquisition.

### **Leksell GammaPlan<sup>®</sup> 4C**

Leksell GammaPlan<sup>®</sup> 4C is an integrated computer system for the planning and implementation of stereotactic radiosurgery. The planning is based on the dimensions, shape and location of the target defined from any stereotactic MR, CT, AI and PET, MEG, MR, CT non stereotactic images. The images are then processed and analyzed to obtain the correct treatment protocol for the patient.

The algorithms embedded within Leksell GammaPlan<sup>®</sup> 4C provide accurate calculations that support the treatment planning phase. Thus the configuration of the collimator helmet and the isodose necessary to implement radiosurgery are calculated.

### **Treatment**

The treatment includes couch movements and distribution of the radiation dose. All actions are controlled from the operator console and the associated supervisory system. A TV and intercom provide direct audio-visual communication between the patient and the operator.



1. **Localization;** Leksell Stereotactic System® with Leksell® Coordinate Frame G and associated CT, MR and AI indicators used for target localization.

2. **Treatment planning;** Leksell GammaPlan® 4C for 3-dimensional presentation and dose calculation.

3. **Treatment;** Operator Console with intercommunication system, patient supervisory monitor, treatment view monitor and control panel.

Photo 1 & 2: Courtesy of Bodo Lippitz, Priv. Doz. Dr. Med., Gamma Knife Clinic H.M. Queen Sophia Hospital, Stockholm, Sweden.

### Treatment room

- Leksell Gamma Knife® 4C with two integrated LCD screens;
- four helmet trolleys each with one collimator helmet;
- TV camera (wall mounted, not shown)
- storage cabinet and special tools (not shown)



Helmet Trolley with collimator helmet



# Leksell Gamma Knife® 4C

Leksell Gamma Knife® 4C is installed in a dedicated suite which essentially consists of a radiation-shielded treatment room, and separate control room. The treatment room is a clean but not necessarily sterile environment. The room must be shielded to contain scattered radiation.

The treatment room serves as preparation area to prepare the patient for treatment. The room also contains the collimator helmet trolleys, collimators for the helmets and all accessories needed for use of Leksell Gamma Knife® 4C.

## Radiation Unit

The ionizing radiation is emitted by cobalt-60 sources in the radiation unit. The sources are heavily shielded within a cast iron body with shielding doors. When the shielding doors

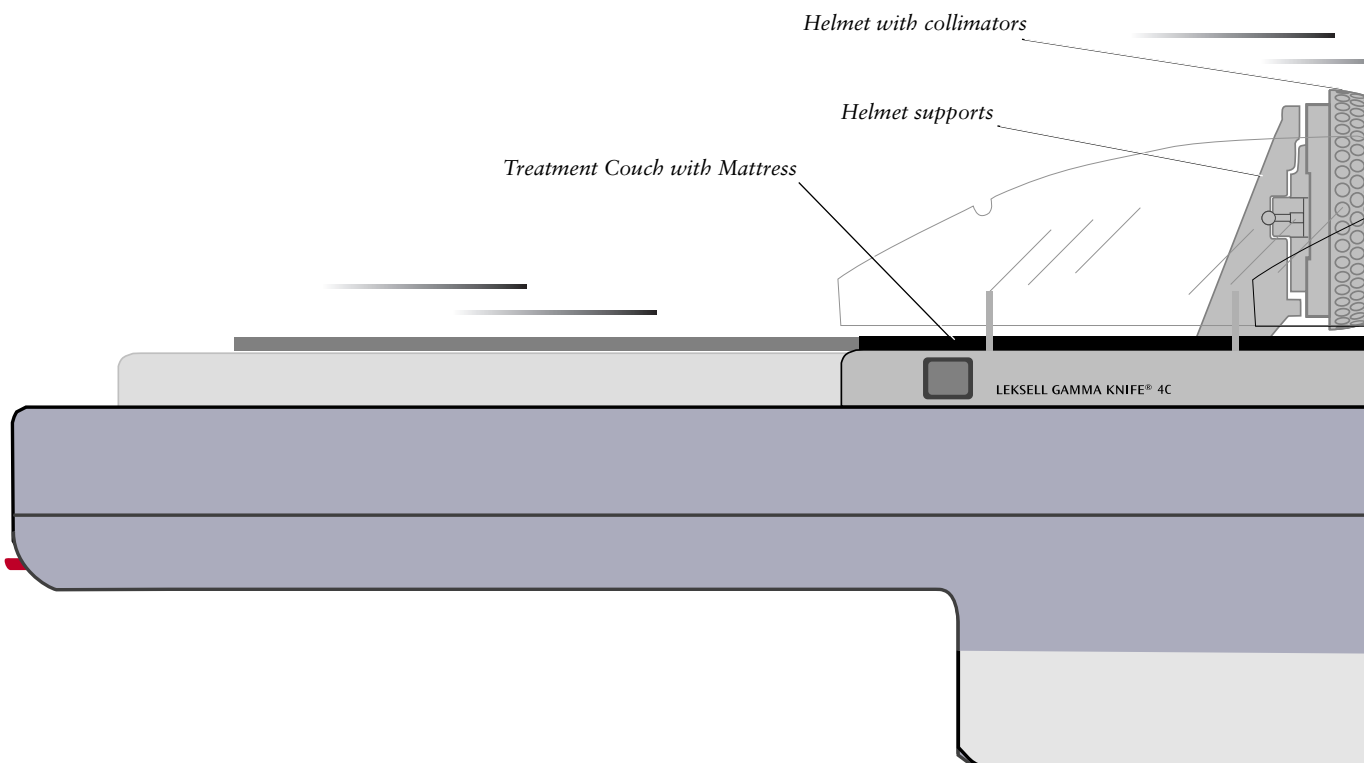
are closed the patient and the hospital staff are completely protected from radiation.

During the treatment session the shielding doors open and the patient is automatically moved into the treatment position. In this position the collimators in the helmet coincide with the beam channels in the radiation unit whereby the ionizing radiation is focused at the target. After the treatment the patient is automatically moved back to the initial position and the shielding doors are closed. During the treatment session yellow “Radiation On” warning indicators show that no-one, except the patient, is allowed to be in the treatment room.

## Treatment Couch

The treatment couch comprises a steel framework which supports a sliding cradle and houses the electromechanical drive for the cradle. An electric motor and drive system move the sliding cradle into, and withdraw it from, the treatment position in the radiation unit.

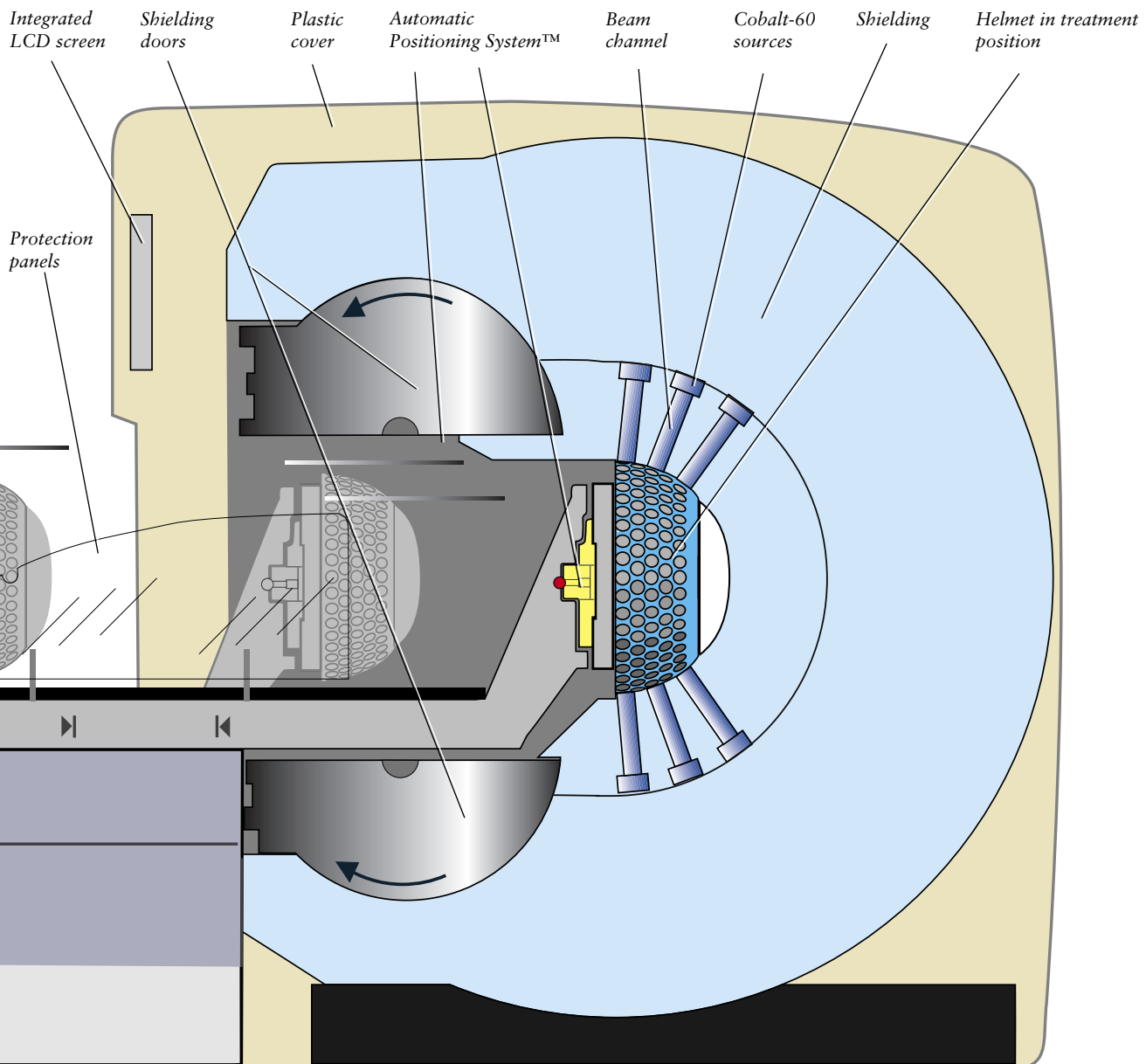
An adjustable sliding mattress is placed on the sliding cradle. By adjusting the position of the mattress, the operator can maneuver the patient horizontally and vertically when fitting the coordinate frame to the helmet.



During the patient docking procedures movements of the couch and Automatic Positioning System™ sequences are controlled by a hand-held control. The manual control has easy to read push-button for each operation.

**Automatic Positioning System™**  
Automatic Positioning System™ (APS) is controlled by target data from the Leksell GammaPlan® 4C treatment plan. The APS moves the patient's head to a number of target coordinates defined in the

treatment plan by means of two automatic positioning units, attached on each side of the helmet. Alternatively, trunnions can be used in place of the APS when required by the treatment plan.



### Radiation System

The dome shaped radiation unit houses the cobalt-60 sources. Each source is mounted at the head of a collimator channel which guides the radiation from the source to the focus point.

At the front of the radiation unit are two shielding doors, an upper door and a lower door. The doors are connected through gears to ensure that they both rotate through the same angle and that they are balanced.

As the doors open, pivots allow the doors to roll and house within the radiation unit.

The “Radiation On” warning indicators are mounted on the cover of the radiation unit, duplicating the function of the Radiation indicator on the operator console.

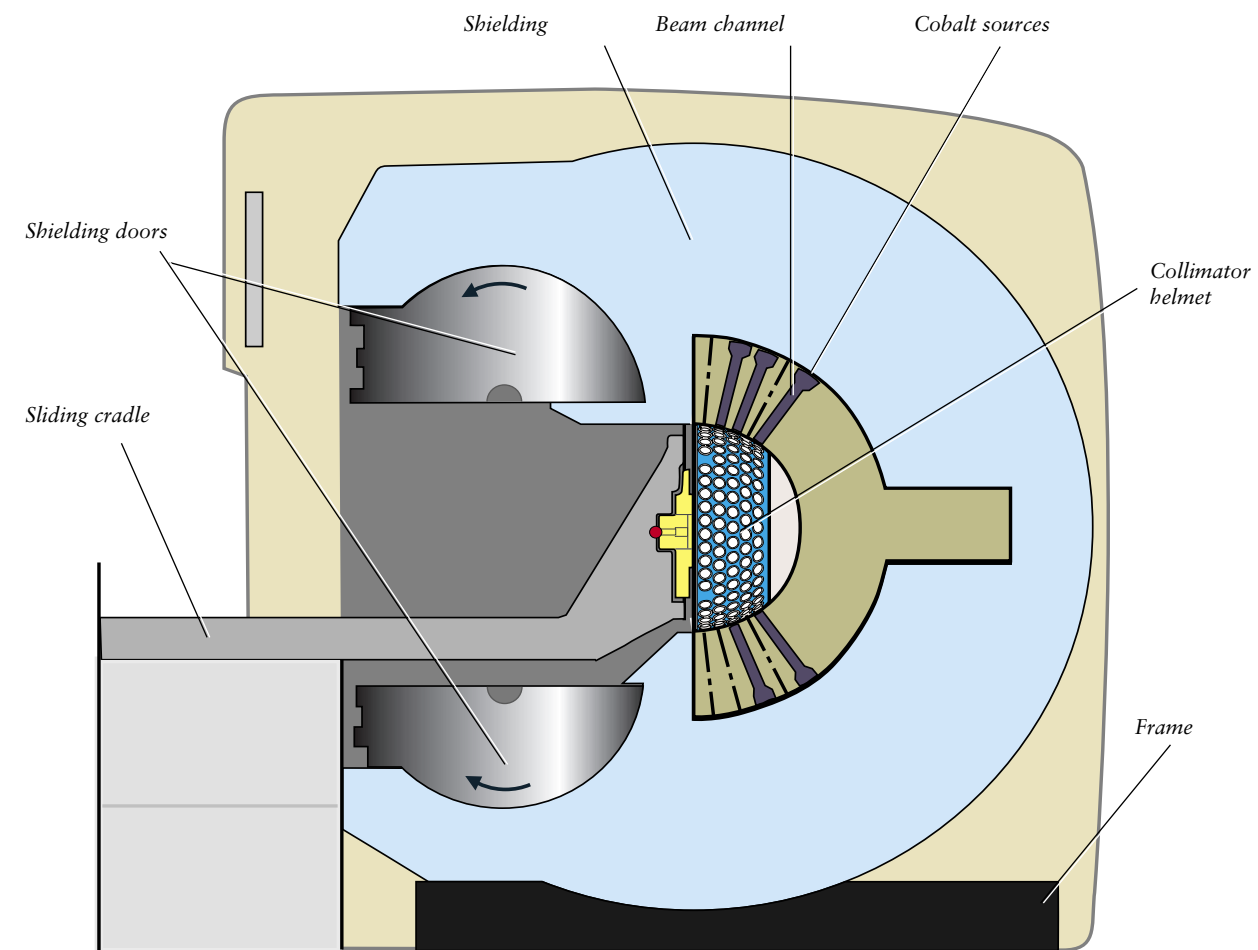
### Shielding

To allow hospital staff to work in the immediate vicinity of Leksell Gamma Knife® 4C for extended

periods of time, the radiation sources are heavily shielded.

The shield assembly encloses the source body with the cobalt sources, the collimating system, and a cavity into which the sliding cradle with helmet and patient are inserted during treatment.

The shielding of the radiation unit conforms to ICRP 33 radiation safety rules and regulations.



Radiation system

### Collimator System

Each beam channel consists of a stationary collimator located in the source body and an interchangeable final collimator located in the helmet.

When the helmet is in the treatment position the entire collimator system forms a conical channel with a circular cross-section. The shape of the channels are such that they diverge from the source towards the focus.

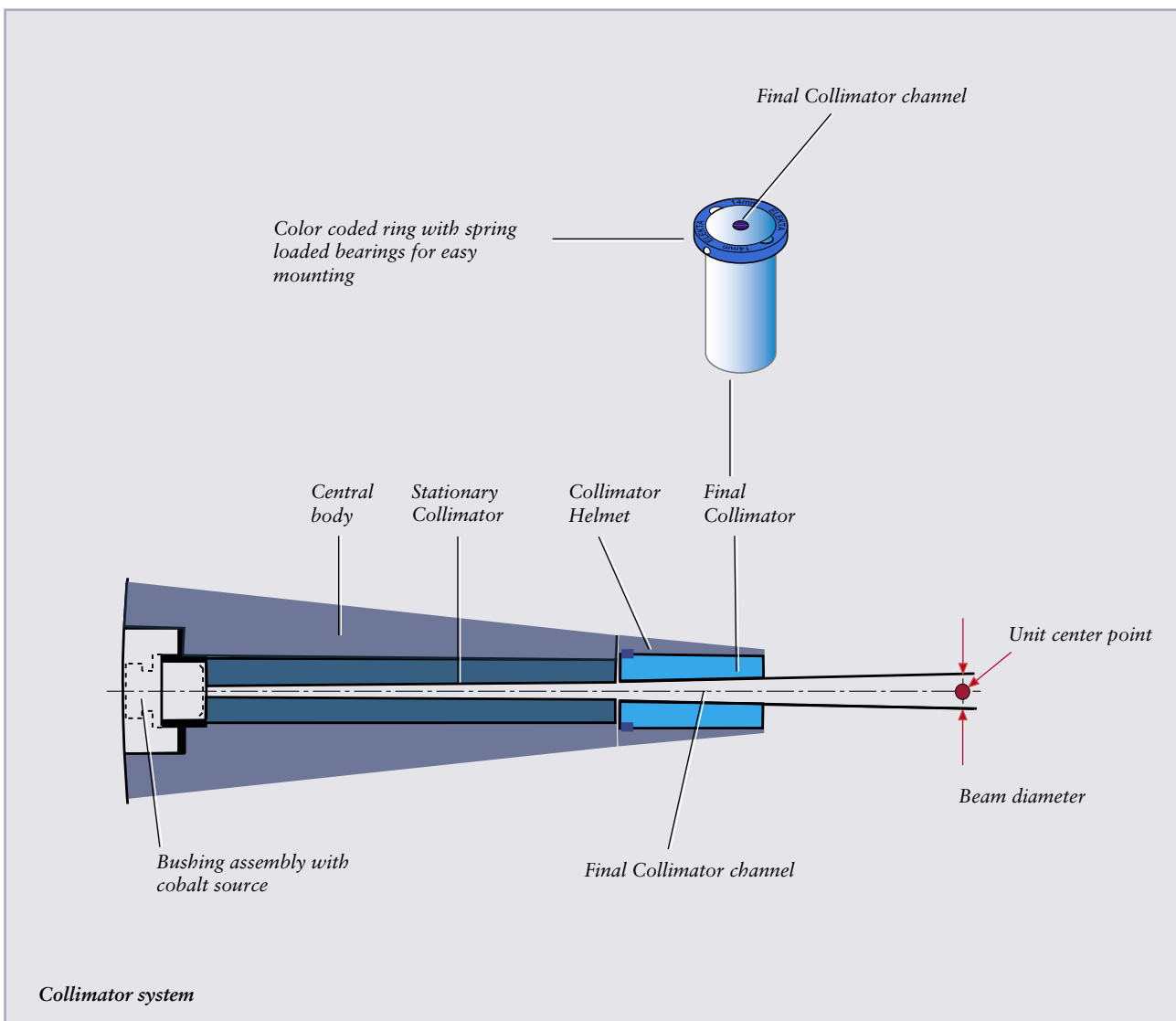
The unit center point (UCP) is located at the spherical center of the volume in space, where the axes of all radiation beams intersect. The radio-physical accuracy for Leksell Gamma Knife® 4C is guaranteed to less than 0.5 mm.

The size of the beams is determined by the collimator helmets with different collimator sizes.

Four alternative color coded collimator sets are included

with Leksell Gamma Knife® 4C yielding 4, 8, 14 or 18 mm beam diameter respectively at the UCP. The final collimator is locked into position in the collimator helmet by use of spring loaded bearings.

Collimators can also be replaced by solid plugs to optimize the dose gradient in specifically critical structures, to optimize the relationship between the shape of the cerebral target and dose distribution.



### Automatic Positioning System™

Automatic Positioning System (APS) moves the patient's head to the target coordinates defined in the treatment plan. There are two positioning units, one attached to each side of the helmet. Each positioning unit contains motor driven APS-x, APS-y and APS-z axis slides.

Each unit contains sensors to confirm correct mounting against the collimator helmet. The patient with the coordinate frame is secured in the APS by means of Leksell® Coordinate Frame and docking pins. Sensors automatically detect if the docking is accurate. The docking

position, defined in the treatment plan, is set when the coordinate frame is docked.

### APS Coordinates

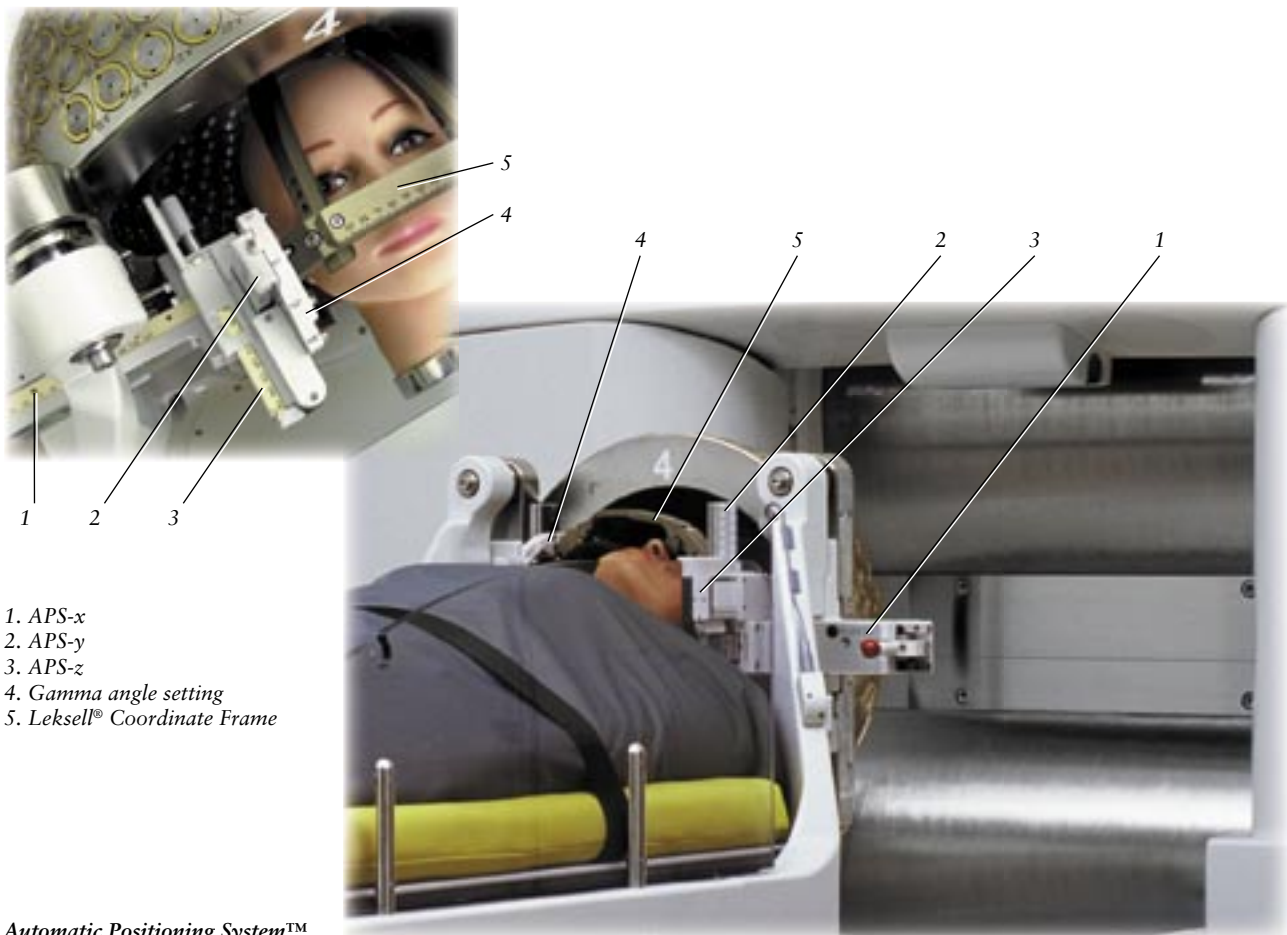
There are two automatic measuring systems on each axis of the APS. The movement of the APS-x, APS-y and APS-z is controlled by encoders on the motors which are calibrated to give very high accuracy. An independent measuring system with an even higher accuracy monitors the movement of the APS.

The APS computer continuously compares the readings from these two

measuring systems and checks for any error. Also comparison between the left and the right APS unit is continuously performed.

All the readings are displayed on the monitor in the Treatment View dialog in the control room. A treatment log file is generated from the monitoring system.

In addition to the automatic measuring systems a scale on each axis can be read manually, which allows the target coordinates to be read manually.



1. APS-x
2. APS-y
3. APS-z
4. Gamma angle setting
5. Leksell® Coordinate Frame

Automatic Positioning System™

### **Intercom**

The loudspeakers and the microphone together with TV system form the patient's intercom and utilizes direct contact with personnel in the control room. The speakers are located above the radiation shielding doors, pointing down towards the couch.

### **Collimator Helmets**

The Gamma Knife is provided with a set of four collimator helmets, providing collimator sizes of 4, 8, 14 and 18 mm respectively.

Each of the four helmets has a dedicated helmet storage trolley. A rack located in a drawer in the trolley provides storage space for collimators and plugs and the tools required for collimator/plug

exchange. Plugs provide beam shaping and protection for the patient's sensitive structures.

Accurate location of the helmet on the treatment couch is provided by screw bushings on the helmet which fit into bushings on the helmet supports. Each helmet has a unique identity for automatic detection of the helmet and of correct location in Leksell Gamma Knife® 4C.



*Helmet trolley with helmet*

### Helmet Changer

The helmet changer is used to move a helmet from its horizontal position on the helmet trolley to a vertical position on the helmet supports, or vice-versa. The helmet changer is fitted at either the left side or the right side of the couch depending on the local site design.

The helmet is lifted by the carrier which includes a locking

mechanism. The carrier moves along telescopic rails. The rails extend across the front of the shielding doors as the helmet carrier is moved toward the helmet docking position, and retract as the carrier is pulled towards the helmet trolley.

Apart from moving the helmet carrier along the rails, movement of the helmet changer is controlled by means of the

helmet changer manual control. When not in use, the helmet changer is covered by a hinged door, which also serves as storage for tools and the helmet changer manual control.

A guide rail on the side of the trolley ensures correct position adjacent to the couch when exchanging the helmet.



1. Positioning the helmet changer.



2. Detaching the helmet.



3. Sliding the helmet changer with helmet to the outer position.



4. Lowering the helmet onto the helmet trolley.



5. Releasing the helmet on the helmet trolley.

# Leksell Stereotactic System®

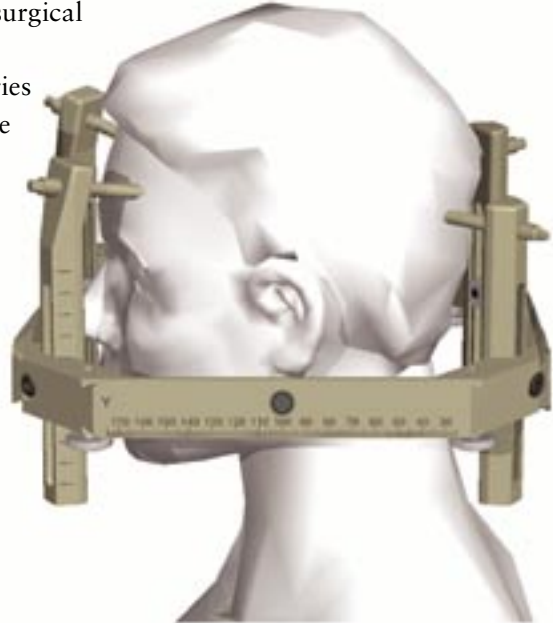
Leksell® Coordinate Frame model G is one essential component of Leksell Stereotactic System®. This coordinate is used for radiosurgical applications with Leksell Gamma Knife® 4C.

Its design is integrated with that of the collimator helmet to give maximum mobility of the patient's head inside the collimator helmet. It may thus be used throughout the whole operative procedure, from preoperative diagnostic imaging to the irradiation procedure.

The coordinate frame is supplied with quick fixation screws, which are used for both

the preoperative examination and the rest of the radiosurgical procedure.

A number of accessories are available, for instance an X-ray indicator and indicators for MR and CT localization of the target.



*Leksell® Coordinate Frame for frame fixation in the collimator helmet.*



*Leksell® Coordinate Frame with X-ray indicator for target localization using the x-ray films technique.*



*Leksell® Coordinate Frame with MR-indicator for target localization using the MR scanning technique.*

# Control System

## Operator Console

The operator console is the interface between the operator and Leksell Gamma Knife® 4C. To preserve security all users have to use a password at login.

The system computer running the Leksell Gamma Knife® 4C control software is placed in a computer cabinet which also includes an uninterruptable power supply unit (Office UPS). The control software is used to load, check and execute the treatment as stipulated in the treatment plan exported from Leksell GammaPlan® 4C.

The treatment view monitor provides a continuous display of the progress of the treatment session, including visual display of alarm conditions. The keyboard and mouse provide the user interface between the operator and the control software.

Usually the treatment plan is transferred from Leksell GammaPlan® 4C via a direct serial connection to the system computer. Alternatively, the diskette drive on the system computer can be used to load a treatment plan utilizing a standard diskette.

## Patient Supervisory System

An intercom system is used for communication with the patient. The patient is observed through the color TV system.

A camera is mounted in the treatment room overlooking the patient in the treatment position. The color video monitor provides continuous visual monitoring of the patient, the treatment couch and the Leksell Gamma Knife® 4C shielding doors.

## Electronic Cabinet

The electronic cabinet contains the control electronics and the power supply system for Leksell Gamma Knife® 4C. Operation and monitoring of Leksell Gamma Knife® 4C is performed by modules in the electronic cabinet:

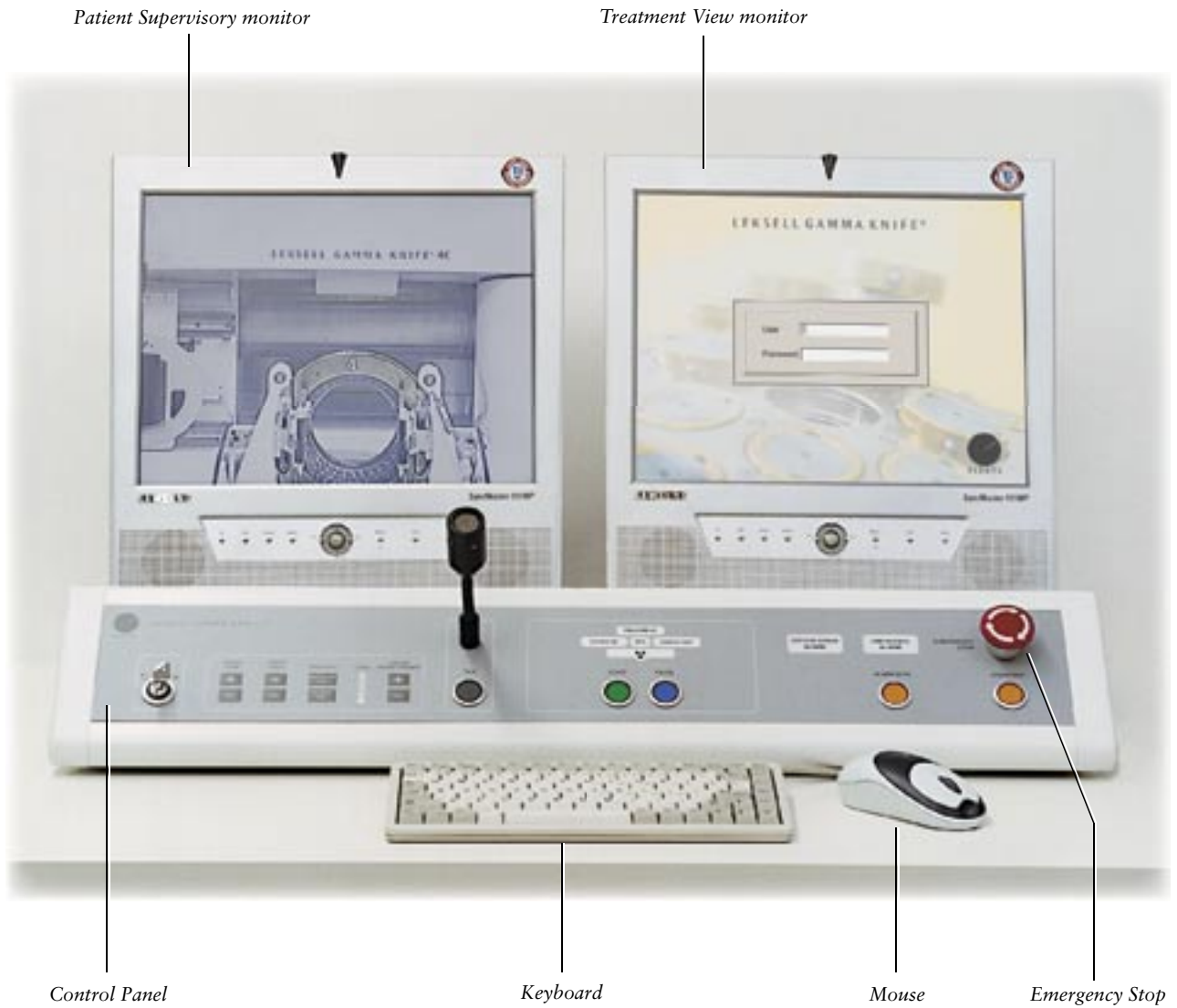
- the Control Unit module
- the Safety System module
- the Automatic Positioning System™ module
- the Uninterruptable Power Supply module.

**The control unit** controls the movements of the couch, shielding doors and monitors information from sensors in the system. Two independent timers in the control unit display the planned and the elapsed treatment time as a backup.

If an irregularity is detected in the system or its sequence of operations, an alarm is signalled to **the safety system module**. Once an alarm has been initiated, interlocks incorporated into the system prevent a treatment from being started until the alarm condition is cleared.

**The APS module** controls and monitors the highly accurate movements of the patient's head to the target coordinates.

**The uninterruptable power supply** (Medical UPS) provides power to the system for at least 20 minutes if there is a failure in the mains supply. If a power failure is longer than one minute a treatment pause sequence is automatically initiated. The power system contains rechargeable batteries which are maintained in a charged state by built-in chargers.



*Operator console – computer cabinet underneath table (not shown)*

# Treatment Planning System

## Leksell GammaPlan® 4C

Leksell GammaPlan® 4C with MultiView Extension is a dedicated treatment planning system for Leksell Gamma Knife® 4C.

Its ability to process all forms of imagery is combined with sophisticated functionality, enabling you to visualize and analyze a wide range of surgical approaches – all in three dimensions and real time.

- Designed to facilitate presurgical tentative planning and post-operative follow-up by co-registration of image studies from CT, MR, PET and MEG
- Any frameless image study can be matched with a Leksell® Coordinate Frame scanned image
- AtlasSpace™, Schaltenbrandt & Wahren brain atlas, can be overlaid any data set
- Automatic calculation of multiple treatment steps and necessary gamma angles
- Surface and volumetric rendered 3D representation
- Real time dose calculation
- Inverse planning with Leksell GammaPlan® Wizard™
- DICOM transfer via network or CD-ROM
- Direct communication link to Leksell Gamma Knife® 4C or by diskette.

### Procedure

Diagnostic stereotactic images (CT, MR and AI), are transferred into the system. A fiducial recognition routine scales the images to the coordinate frame of Leksell Stereotactic System®.

The intracranial target is manually or semiautomatically outlined by thresholding algorithms. Subsequently the target can be displayed on the imported images in all directions and orientations. Leksell GammaPlan® 4C Wizard™ – the optional automatic planning routine uses the identified target to offer a treatment plan that the operator can further refine.

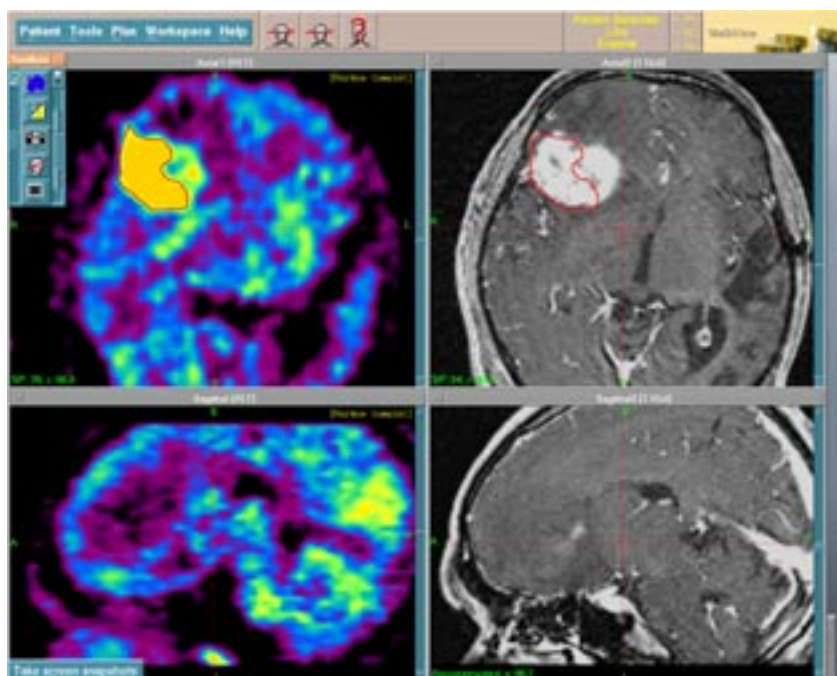
Irradiation to critical anatomical structures is avoided by use of multiple isocenters. Leksell GammaPlan® 4C features

an automatic field shaping routine utilizing Leksell Gamma Knife® 4C selective beam blocking (plugging).

Important physical and geometrical aspects of the treatment plan can be calculated and displayed in comprehensive statistical routines.

Prior to Gamma Knife® surgery the patient's treatment plan must be approved (signed) by the physician. For this purpose you can choose to print the treatment plan, anatomical images with overlaid graphics, geometric measurements, dose statistics and the physics protocol on a printer.

The treatment plan can be transferred to the Leksell Gamma Knife® 4C system computer via a direct serial link or by diskette.



Screen capture of Leksell GammaPlan® 4C

# Cobalt Sources and Radiation Protection

## Sources

Each of the 201 radiation sources located in the radiation unit is composed of Cobalt-60 pellets which are encapsulated in double stainless steel capsules with welded closures.

The sources are licensed and meet the ANSI standard N-542 for medical radiotherapy sources. At the time of loading Leksell Gamma Knife® 4C has a total activity of approximately  $2.22 \times 10^{14}$  Bq.

The cobalt sources are delivered to the site in a specially designed

protective cask. Once loaded into the radiation unit the sources are maintenance free. They are handled again only when it is necessary to reload the radiation unit with new sources.

### Source Loading

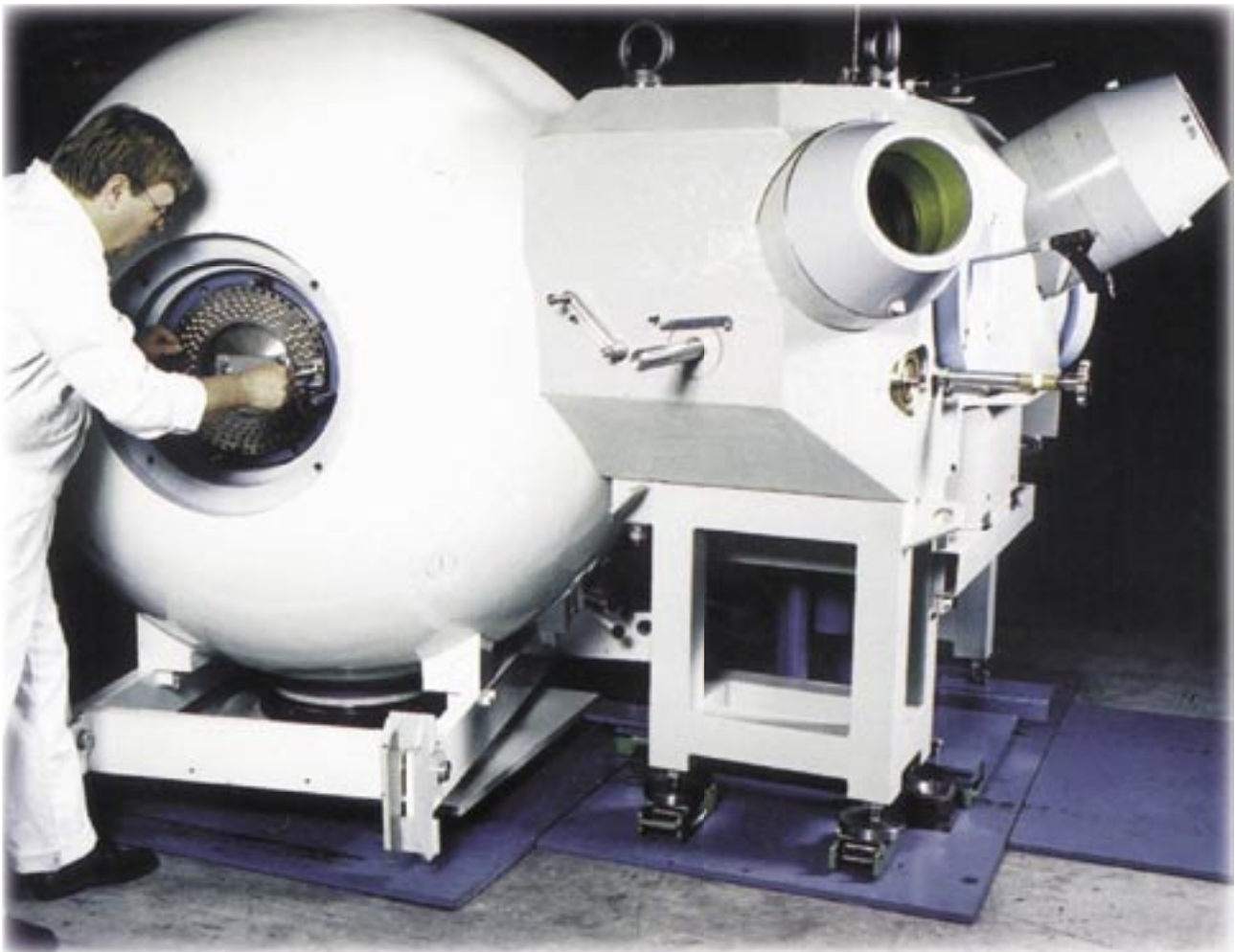
The sources are loaded into the positions within the radiation unit by use of a loading machine. The loading machine is specifically designed to transfer sources from the shipping cask to the radiation

unit with full radiation safety. It is built almost entirely of lead and weights approximately 12,000 kg.

Due to the heavy weight of the equipment, radiation unit, loading machine and cask, the room floor must withstand a total weight of 38,000 kg. A certain working area is also required.

Assembling the loading machine and performing the loading procedure are carried out by certified Elekta personnel.

*Loading of cobalt sources into Leksell Gamma Knife® 4C*



## Radiation Protection and Site Layout

Installation of the equipment should be in accordance with the instructions and drawings for the actual site. The user is responsible for the dimensions of walls, floor and ceiling of the site. Recommendations for site planning will be supplied by Elekta.

Recommendations for the installation room: Length 6.5 m., Width 4.7 m. and Height 2.75 m.

During the installation the radiation unit is tested to comply with the applicable recommendations for radiation protection.

The protective housing of the radiation unit is designed and manufactured in accordance with ICRP 33 rules and recommendations.

# Service & Support

## Service & Support Programs

Elekta Service & Support Programs are designed to deliver maintenance, repairs and availability of spare parts to ensure high performance and reliability.

The buyer can choose between three Service & Support Programs with Elekta who then guarantees swift service and spare part deliveries, i.e. Basic, Full and Advanced Service & Support.

## Mechanical and Electrical Components

All mechanical and electrical components must be serviced on site. Service after and outside the warranty commitment and the warranty period is done by Elekta at current prices.

### Spare Parts

Only Elekta original components are used for the mechanical and electrical systems. Spare parts are supplied at current prices or as part of the agreed Service & Support program. The most frequent spare parts are available in stock.

### Elekta Technical Assistance Group (TAG)

TAG combines technical and field service experience to offer the most comprehensive support either on-site or by remote support.

## Modifications

Elekta reserves the right to make changes to the product specifications and equipment covered thereby, especially where such changes are anticipated to improve performance of the product or parts thereof, or are required in order to satisfy the product specifications, or are expected to improve reliability, quality or value of the product.

# Technical Data

## Leksell Gamma Knife® 4C

### Physical Data

Overall length including hood .....	4,640 mm
Overall width including hood .....	2,000 mm
Overall height .....	1,935 mm
Total weight (approximate) .....	20,000 kg
Maximum load on couch .....	180 kg

### Radio-physical Data

Total Cobalt-60 activity at loading (approximate) .....	6,600 Curie (<math>2.44 \times 10^{14}</math> Bq)
Single source activity deviation .....	<10% of average source activity
Number of radiation sources .....	201
Dose rate measured in calibration conditions .....	>3 Gy/min

### Accuracy Data

APS positioning accuracy .....	<0.2 mm
Mechanical isocenter radius .....	<0.3 mm
Helmet positioning accuracy .....	<0.1 mm
Treatment timer .....	<0.2%

### Electrical Data

Power consumption (approximate) .....	1.4 kVA
Mains power supply, Office section	
Office UPS in Computer Cabinet .....	700 VA
Input .....	100–120 ( $\pm 10\%$ ) V AC, 50/60 Hz, T10 A/250 V
(According to country mains voltage and frequency.)	or
	220–240( $\pm 10\%$ ) V AC, 50/60 Hz, Circuit breaker 5A
Operator Console (powered by Office UPS) .....	100–240 ( $\pm 10\%$ ) V AC, 50/60 Hz, 2xT3.15 AH/250 V
Mains power supply, Medical section	
Medical UPS in Electronic Cabinet .....	700 VA
Input .....	100–120 ( $\pm 10\%$ ) V AC, 50/60 Hz, 2xT6.3 A/250 V
(According to country mains voltage and frequency.)	or
	220–240 ( $\pm 10\%$ ) V AC, 50/60 Hz, 2xT6.3 A/250 V
Output .....	24 V DC and 48 V DC

### Environmental Data

Ambient temperature .....	+10 °C to +40 °C
Relative humidity .....	30 to 75 %
Atmospheric pressure range .....	700 to 1,060 hPa

### Video System

PAL, NTSC .....	Two LCD screens at the operator console. Two integrated LCD screens in the cover of Leksell Gamma Knife® 4C.
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# Standards Approval

## EN/IEC 60601-1

Medical Electrical Equipment - General Requirements for Safety.

## EN/IEC 60601-1-2

Collateral Standard: Electromagnetic Compatibility.

## UL 2601

Medical Electrical Equipment - General Requirements for Safety.

## CAN.CSA-C22.2 No 601.1-M90

Medical Electrical Equipment, Part 1: General Requirements for Safety.

## EMC

Potential electromagnetic or other interference between the equipment and other devices can occur even though the device fulfills the legal requirements. To avoid such problems the possible interfering equipment could be removed from the treatment room or placed somewhere else in the room. The user should take extra care if the patient uses a pacemaker or similar device.

## Interconnecting requirements

All interconnected equipments must be connected to the system in accordance with the requirements of IEC/EN 60601-1-1.

All equipments placed inside the patient area must fulfill the requirements in IEC/EN 60601-1.

All other interconnected equipments must fulfill applicable safety standards e. g. IEC/EN 61010-1 and IEC/EN 60950.

# Leksell GammaPlan® 4C

## Configuration

- Workstation: High End HP Visualize workstation
- Operating system: HP-UXHP
- Processor: HP PA-RISC
- Monitor: TFT HP monitor with superior ergonomic design
- Printer: Color and B&W HP LaserJet business range
- Storage: HP DAT drive and HP Magneto-Optical drive
- Interface: Ethernet, CD-ROM, serial link and diskette.

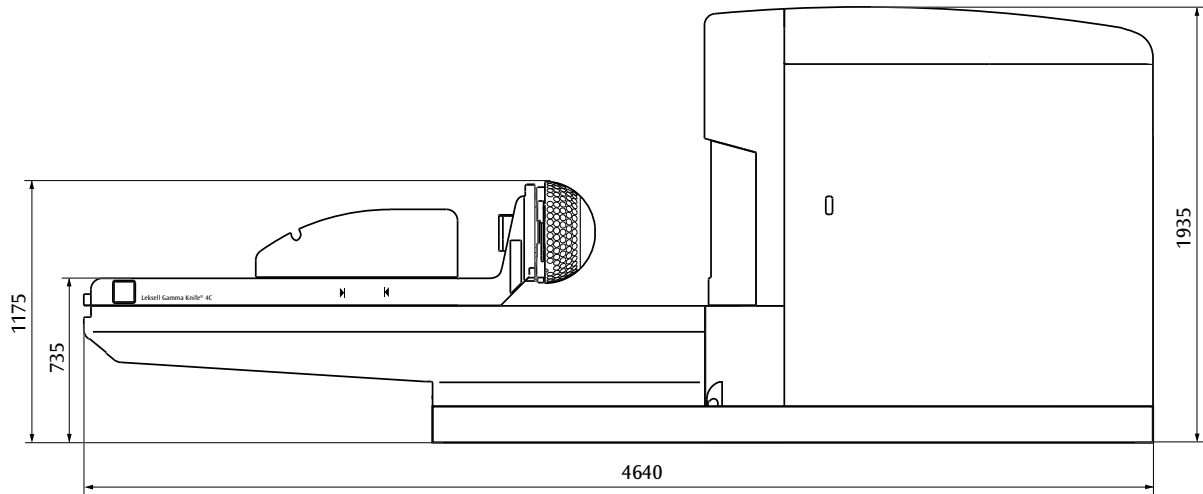
## Declaration of Conformity

The devices comply with the requirements of the Medical Device Directive 93/42/EEC. The products are marked with the CE mark.

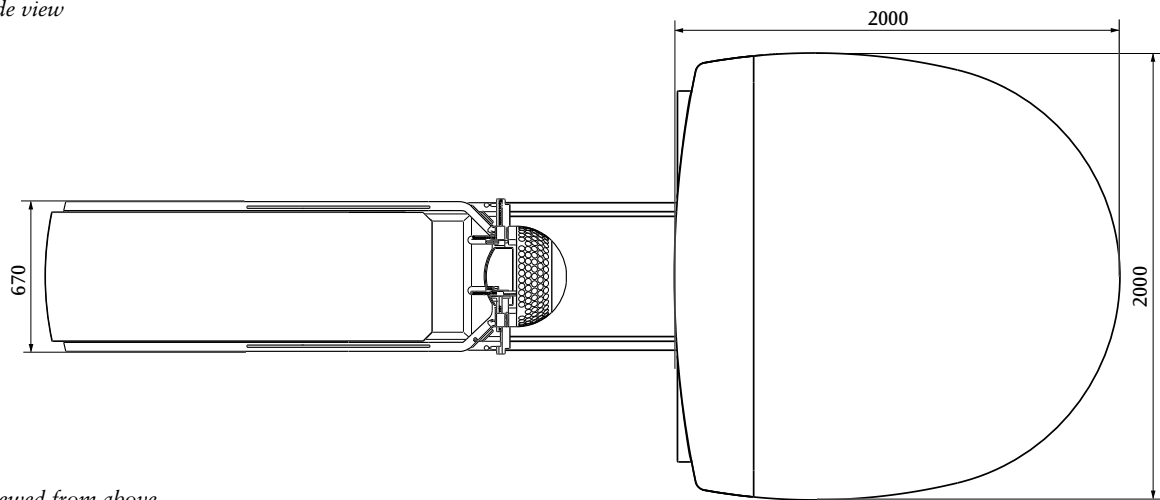
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# Dimensional Drawings (all dimensions expressed in mm)

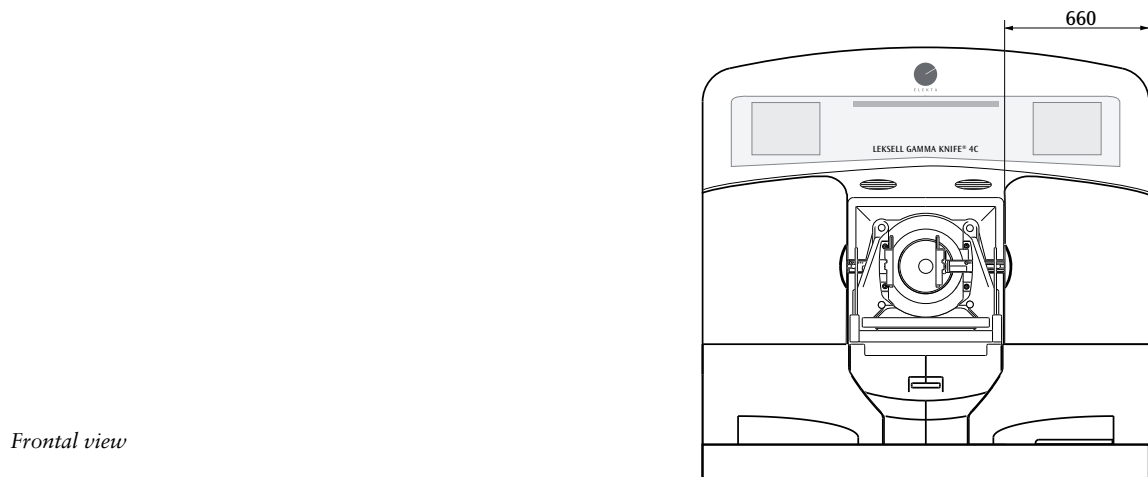
*Leksell Gamma Knife® 4C*



*Side view*

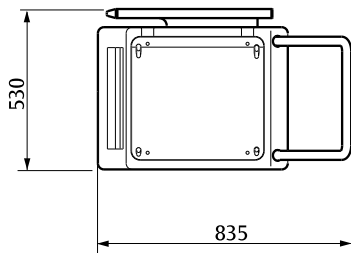
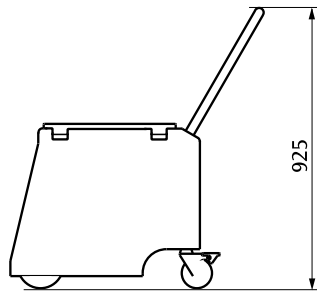
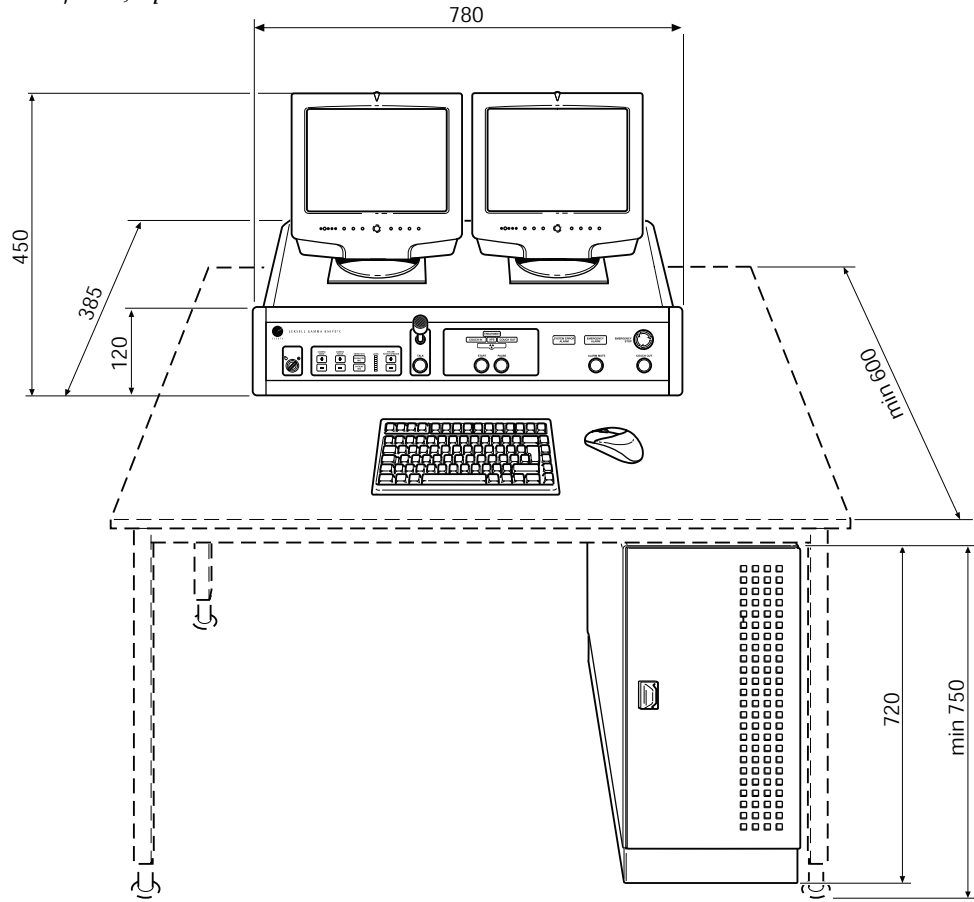


*Viewed from above*

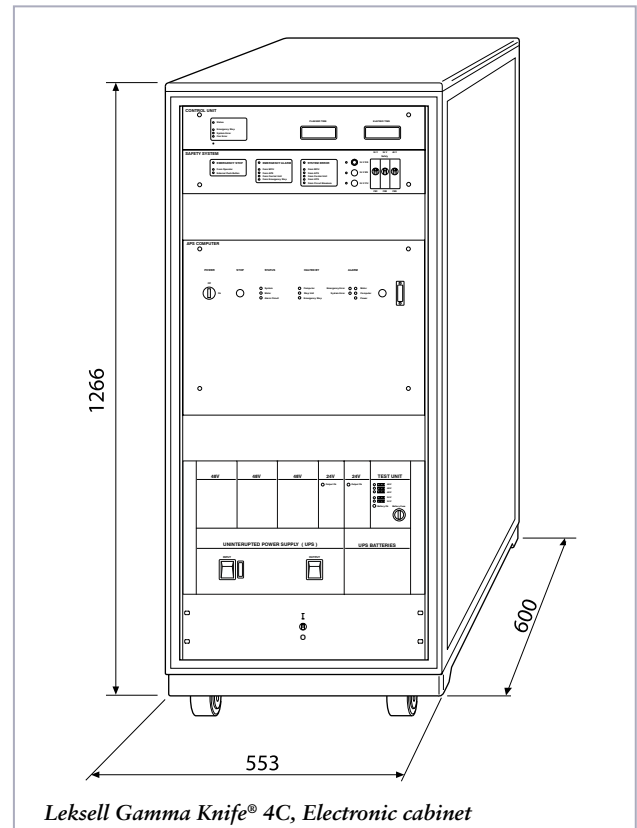


*Frontal view*

*Leksell Gamma Knife® 4C, Operator Console*



*Leksell Gamma Knife® 4C, Helmet Trolley*



*Leksell Gamma Knife® 4C, Electronic cabinet*



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**Corporate Head Office**  
Stockholm, Sweden  
Tel +46 8 587 254 00  
Fax +46 8 587 255 00  
[info@elekta.com](mailto:info@elekta.com)

**Worldwide Product  
Support Center**  
Tel +46 8 587 254 00  
Fax +46 8 587 255 00  
[info.neuro@elekta.com](mailto:info.neuro@elekta.com)

**North America**  
Atlanta, USA  
Tel +1 770 300 9725  
Fax +1 770 448 6338  
[info.america@elekta.com](mailto:info.america@elekta.com)

**Europe, South America,  
Africa & Middle East**  
Tel +44 1293 654 068  
Fax +44 1293 654 655  
[info.europe@elekta.com](mailto:info.europe@elekta.com)

**Japan**  
Kobe, Japan  
Tel +81 78 241 7100  
Fax +81 78 271 7823  
[info.japan@elekta.com](mailto:info.japan@elekta.com)

**Asia**  
Hong Kong, China  
Tel +852 2891 2208  
Fax +852 2575 7133  
[info.asia@elekta.com](mailto:info.asia@elekta.com)