Elekta

Product Data

Elekta Esprit

Protect the mind
Protect the person

Elekta Esprit–
a Leksell Gamma Knife®
Protect the mind
Protect the person

Based on decades of unrivalled Leksell Gamma Knife development, Elekta Esprit evolves to the next level, providing exceptional accuracy that spares healthy tissue in a seamless integrated system.

Submillimeter precision enables Esprit to target the smallest and most challenging intracranial tumors and lesions with minimal effect on healthy tissue.

With over 50 years of real-world Leksell Gamma Knife evidence, Esprit is trusted to lead the way in intracranial radiosurgery - transforming treatment protocols and relentlessly driving the standard of care forward.

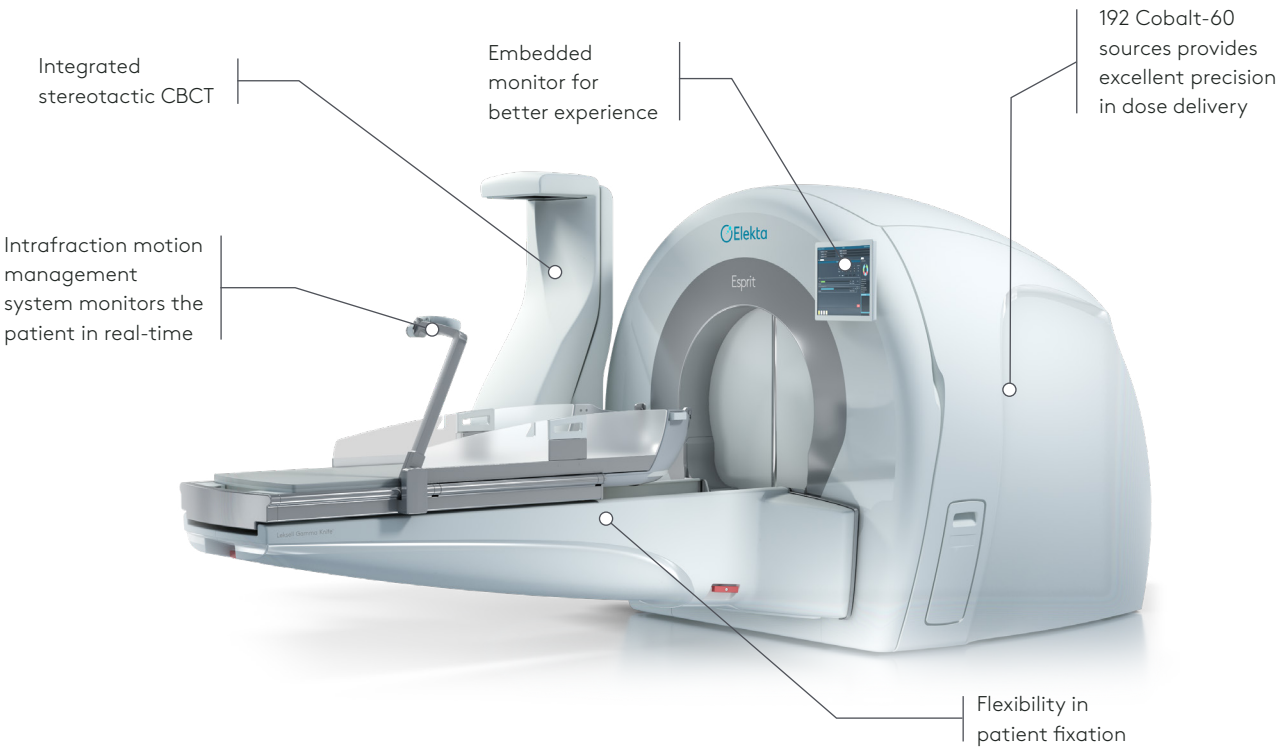
System Overview

About Elekta Esprit

Elekta Esprit is a dedicated radiosurgery system used in stereotactic irradiation of intracranial structures. Surgery is achieved by delivering a prescribed dose as one or several shots of ionizing radiation to the exact site of the target. Gamma Knife Radiosurgery is the most precise form of radiation therapy with an accuracy of 0.3 mm guaranteed over the lifetime of equipment*.

Esprit treats a broad range of brain disorders with the lowest dose to normal tissue. Esprit is equipped with integrated stereotactic Cone Beam CT (CBCT) imaging and High-Definition Motion Management (HDMM) to continuously control the dose delivery. Esprit provides several workflow options and adaptation possibilities to personalize each individual treatment.

The system enables multiple or single sessions, frameless and frame-based immobilization—always with the same high level of accuracy. Elekta Esprit is a platform for the future, ready to support new innovations through improvements to hardware and software.



For more information on the technical specification and overview of Elekta Esprit, please see Appendix A, Table 1.

Description of Elekta Esprit

The Esprit system consists of several parts, physically separated into a treatment room and a control room:

- The treatment room contains the Gamma Knife, including the radiation unit, a patient positioning system, a gantry for CBCT, and a set of covers. The real-time High Definition (HD) Motion Management system is attached to the patient positioning system. The treatment room also houses the patient surveillance system, a treatment view monitor, and a radiation warning lamp.
- The control room contains an operator console and an office cabinet. The treatment session is controlled and monitored by the operator from the control room. The control room also contains the primary GammaPlan workstation.

The system is electrically separated into an office side and a medical side.

- The medical side includes the Gamma Knife unit in the treatment room that is powered and controlled by a medical cabinet, placed inside the rear cover of the radiation unit. A treatment room monitor on the covers of the Gamma Knife unit is also a part of the medical side.
- The office side consists of the equipment in the control room, the patient surveillance system and the radiation warning lamp in the treatment room. The office side is powered and controlled by the office cabinet. The office cabinet contains the MCU, the primary GammaPlan workstation, a network router, and an Uninterruptible Power Supply (UPS) unit for the office side of the system (Office UPS).

The office side and the medical cabinet in the treatment room are categorized as the control systems and electronics of Elekta Esprit.

Radiation unit

The radiation unit contains the delivery system (lead and tungsten) with the 60Co sources and radiation protection (cast iron). It houses 192 cobalt-60 (60Co) sources and the tungsten collimator system that directs the radiation to the focus point. The sources are fixed in 8 independently movable sectors mounted on the collimator body, and contain collimators of 4, 8, and 16 mm.

Servo-controlled motors in the sector mechanism position the sources to achieve one of the conditions for Beam On (the sources are aligned with the collimators) or Beam Off (the sources are positioned and locked in the sector home position). When the treatment target is repositioned between shots, the sources are placed in the shielded sector off position between the collimators of 4 and 8 mm.

The shielding doors move horizontally to the left and right to open the radiation unit and allow the patient positioning system to move the couch to the treatment position inside the radiation cavity. A thin cylinder-shaped collimator cap covers and protects the collimator apertures.

Glass fiber covers are suspended on attachment points around the radiation unit, and they cover the radiation unit.

Illustration of the radiation unit with the moveable sectors (left) and the source collimation system (right).

For technical specification on the radiation unit, see Appendix A, Table 2

Patient positioning system

The patient positioning system is a highly accurate electromechanical system for positioning the patient couch with the patient in the desired position. The patient reclines on the patient couch during treatment. The couch is part of the patient positioning system.

The patient positioning system is automatically repositioned inside the radiation unit, moving the patient to the target coordinates as defined in the treatment plan.

The 3-axis positioning system consists of a steel framework, housing the electromechanical drive for the patient couch. An adjustable mattress is placed on the couch. The mattress has a strap that can be used to secure the patient's arms.

The operator can maneuver the patient vertically for comfort, when fitting the mask or coordinate frame (and the patient) to its respective docking device, by adjusting the position of the mattress with the manual control (one unit on each side).

Two integrated protection panels are fitted on each side of the patient positioning system. The panels are made of transparent plastic and can be folded up or down to facilitate easy patient loading and unloading on the couch. Friction hinges hold the side panels and allow controlled movement of the panels.

For technical specification on the patient positioning system, see Appendix A, Table 3

Stereotactic CBCT

The unique stereotactic Cone Beam CT (CBCT) is an integrated part of the Esprit treatment unit. Calibrated to the patient positioning system, it determines stereotactic coordinates in 3D, using bony anatomy. By co-registration to MR and/or CT images it can be used as a stereotactic reference for treatment planning and automatic correction of treatment delivery. The CBCT gantry contains the CBCT imaging components. The C-arm contains an x-ray tube and an image detector. The C-arm moves the head of the x-ray tube and the image detector in a circular path around the patient to capture projections which are used to create the CBCT image.

The C-arm is attached to a tilt arm, which is attached to the radiation unit. The tilt arm moves the C-arm from the parked position to the scan position.

Because the gantry is mounted on the radiation unit, a fixed relation can be established between the coordinate system of the images and the radiation focus.

The complete gantry consists of the C-arm and the tilt arm fully assembled with sensors, cabling, motor, and transmission. It also includes the kV generator and the actuator for the tilt arm—both located inside the radiation unit covers.

For further technical information, see Appendix A, Table 4 for full specifications

Online Dose Evaluation

Thanks to the unique dose delivery attributes of Elekta Esprit, the system can automatically adapt the delivery of the plan according to the current patient position from CBCT to account for patient rotation and translation—contributing to the highest accuracy.

Online Dose Evaluation enables users to compare the dose distribution about to be delivered to the planned dose right at the console.

Real-time HDMM

With Esprit, the same precision can be achieved with frameless and frame-based immobilization. The High Definition Motion Management (HDMM) system monitors the patient in real time during treatment with 0.15 mm accuracy. If a patient moves out of the selected threshold during treatment the system's gating functionality instantly blocks the dose delivery.

The HDMM system is used to monitor movements of the patient during setup and treatment when immobilized by a mask fixation system and can also be used with Leksell Vantage head frame.

The HDMM system uses an infrared (IR) camera that, in combination with IR reference markers and a reflecting marker on the patient's nose, can detect movements. The reflecting marker is placed on the nose, as the skin is relatively thin in this area - providing good correlation between nose and skull movement as well as an advantageous line of sight.

A graph in the graphical user interface (GUI) shows the patient's movements when HDMM is on. The axis of the graph shows movements in mm and duration in seconds. During treatment (gamma radiation) and when HDMM Active mode is enabled, if the patient moves out of position the system pauses the dose delivery in a controlled manner. If the patient returns the position, the system resumes dose delivery after three seconds. In addition, if the camera cannot see the reference markers for more than two seconds, a treatment pause is activated.

The following table describes the technical specifications of the HDMM system.

Accuracy	< 0.15 mm
User selectable motion gating threshold	0.5 – 3.0 mm

Control Systems and Electronics

The control systems control all Esprit electromechanics based on treatment data.

Operator console

The operator console, the Function Keypad, in the control room is the interface between the operator and Elekta Esprit.

The Function Keypad is used to control the treatment procedure and communicate with the patient. The treatment view monitor provides a continuous display of treatment session progress, including a visual display of alarm conditions.

Mouse and keyboard provide the user interface between operator and control system software that runs on the office computer—the Main Computer Unit (MCU). The control system software is used to load, check, and execute the treatment as stipulated in the treatment plan exported from Leksell GammaPlan.

Isolation and Patient Surveillance Unit (IPSU)

The IPSU ensures that all interconnections between the office and the medical sides (safety signals and the CAN bus to the ECU) respect the required isolation.

The IPSU also handles the mains power for the office side and distributes the interruptible power (via Power On control) to the devices that can be shut down (mainly the monitors).

It finally manages all of the indicators and the buttons on the operator panel.

The following signals are accessible via relay contacts from the IPSU on the back panel of the console:

- Emergency alarm
- Radiation On (not Beam Off)
- In treatment (Beam On)

A music source, such as a music streaming device or CD player, can be connected to the IPSU to play music in the treatment room.

Patient Surveillance System (PSS)

The Patient Surveillance System is included in the operator console as a separate unit, this consists of a video and intercom system used to observe and communicate with the patient.

A camera mounted in the treatment room overlooks the patient in treatment position, providing continuous visual monitoring of patient, treatment couch and the shielding doors of the radiation unit.

The video system, loudspeakers and microphone form a patient intercom, allowing direct contact with control room personnel. The speakers are located in the treatment couch and the microphone is close to the patient's head, next to the manual control.

User interface

The control software of Esprit runs on the office computer and is displayed on the operator console's treatment view monitor. The treatment room monitor shows a copy of the information displayed on the treatment view monitor.

There are two operating modes (versions) of the control software—a clinical mode for treatment sessions and a service mode for service activities (for service personnel) only. The current operating mode is clearly identified in the title bar when running the software. To preserve security a password is required for all users at login.

Together, the control panel and graphical user interface show treatment status and different treatment flow states.

During treatment, control panel information is reduced to one green light and one yellow light, with green representing beam off. Yellow can alter between blinking when there is movement (such as shielding door opening), and a steady light when beams are on.

The GUI presents these states in more detail, with icons explaining the different states and movements using a yellow color in activated icons.

The application window includes:

- Title bar, containing patient information
- Main tab displaying available functions
- Status tab, which displays important system status
- Indicator area, which displays the system's physical status
- Command buttons for the main functions

Office cabinet

The office cabinet is a standard 19″ cabinet that holds the MCU, the office UPS, a network router, and the primary GammaPlan workstation.

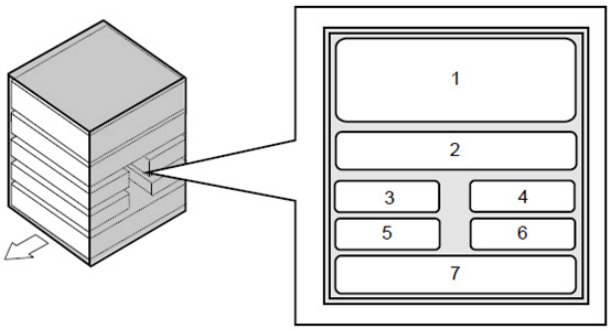
Main Control Unit (MCU)

The MCU, or office computer, is an industrial grade rack PC. The patient's treatment plan is sent from the GammaPlan database to the MCU via the network router. The MCU then communicates to the electronic control unit the part of the treatment that is to be performed and updates the treatment status after each performed part.

In addition, the MCU monitors the status of the Esprit system and the office UPS.

Office Uninterruptible Power Supply (UPS)

- The office UPS is a standard rack battery backup powered by the mains inlet. It produces the same alternating voltage on its outputs as on the input (and the same frequency).
- The office UPS comes in different configurations to meet country-specific requirements.



	Office cabinet units	Description
1	**LGP primary workstation**	Runs the LGP application used for treatment planning
2	**Office computer (MCU)**	Runs the system application
3	**Network router**	Connects to the local network
4	**IPSU (Isolation and Patient Surveillance Unit)**	Interface between control room and treatment room
5	**Agent PC**	Runs the IntelliMax client application
6	**Network switch**	Connects to the local network
7	**Office UPS**	Supplies the units in the control room with electrical power in case of failure in the mains supply. Also supplies the camera, patient speakers, and patient microphone in the treatment room.

Network router

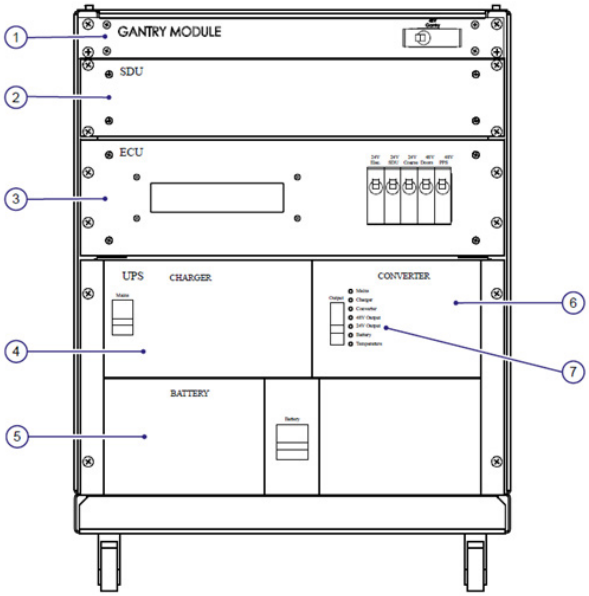
The Ethernet gateway provides secure and reliable access to the database. It also delivers secure and reliable high-speed interconnection between the different subsystems of Elekta Esprit.

Leksell GammaPlan workstation

The primary Leksell GammaPlan workstation is an HP workstation hosting the central patient database and servers for all Leksell GammaPlan workstations in the system.

Note: Although the primary Leksell GammaPlan workstation is shipped with Elekta Esprit, the Leksell GammaPlan workstation (as well as optional external units) has its own registration.

	Medical cabinet units
1	Gantry module
2	Sector Drive Unit (SDU)
3	Electronic Control Unit (ECU)
4	Medical UPS, charger (AC/DC converter)
5	Medical UPS, battery section
6	Medical UPS, converter (DC/DC converter)
7	Medical UPS, indicators



Medical cabinet

The medical cabinet is located inside the radiation cover behind the radiation unit. It contains the control electronics and the power supply system for the medical side of the system:

- The Electronic Control Unit (ECU)
- The Sector Drive Unit (SDU)
- The gantry module
- The medical UPS

It is a bespoke Elekta-made cabinet designed fit into the back of the radiation unit.

Sector Drive Unit (SDU)

The SDU contains eight servo drivers (one for each sector). When the servo drivers are disabled (either by the ECU or in case of Emergency Stop or Emergency Exit), the sector motors are completely disconnected from the drivers.

In case of Emergency (Stop or Exit), a fixed voltage is applied directly to the sector motors, pulling them back to a locked shielded position.

Electronic Control Unit (ECU)

The ECU contains the control system interacting with the system software and executing the treatment sequence ordered from the operator console. It consists of two complete Power PCs (PPC) with peripherals (RAM, ROM, inputs, outputs, and CAN interfaces).

PPC1 controls all movements of the Esprit system via CAN messages to the other subsystems. PPC2 monitors all CAN traffic and the PPC1 commands. If any failure or error is detected, the PPC2 activates the safety system.

In order to always display the planned and elapsed treatment times, the ECU cannot be shut down by the MCU. Nevertheless, in power off mode the microprocessors are reset, and all outputs are inactivated.

The FPGA (field programmable gate array) handles the reading of the redundant scales of all moving axes and makes this information available to both PPC1 and PPC2. In the FPGA, an independent timer measures the Beam On time.

The treatment time is read by the PPCs. PPC1 decides when to stop the treatment and if it fails, PPC2 will terminate the treatment. Information from both PPC1 and PPC2 are shown on the ECU display. Typical information is treatment time and run number.

The following signals are accessible from the back panel of the ECU:

- External pause
- External emergency stop
- Treatment room door sensor

Patient fixation

The patient's head must be entirely immobilized during the radiosurgery session, to maintain treatment accuracy. Esprit offers two methods of immobilization—frameless and frame-based fixation—that provide mechanical interfaces to the treatment equipment's docking device.

Frame-based fixation

Detailed stereotactic images of the patient's brain form the basis for treatment planning. Stereotactic images can be obtained by employing one or more imaging techniques: computed tomography (CT), magnetic resonance (MR), and/or angiograms (AI), together with a stereotactic system. Two different frame-based stereotactic systems, the Leksell Stereotactic System, and the Leksell Vantage Stereotactic System, are available for use with Esprit.

Dedicated indicator boxes for MRI, CT, and AI are used to impose reference fiducials in the images during image acquisition. These reference fiducials define the location of the Leksell Coordinate System in relation to the patient brain and are used during the planning to derive stereotactic coordinates of the targets to be treated. Alternatively, the integrated CBCT on Esprit can be used to set the stereotactic reference.

The new stereotactic Leksell® Vantage™ Head Frame has been designed to provide free access to mouth, nose, and eyes during the procedure. The Vantage head frame and imaging accessories were developed to allow unrestricted MR imaging sequences in 1.5 T and 3 T MR scanners. The head frame is fixed to the head using FirmFix screws to assure a rigid attachment without coordinate frame displacement. Vantage FirmFix screws are delivered sterile and the frame itself does not need to be sterilized. With the Vantage system it is also possible to make use of the HD Motion Management system of Esprit as an additional safety measure for frame-based treatment.

Frameless mask fixation setup

The frameless solution of Esprit includes a thermoplastic mask, a head cushion, and a mask adapter. To provide fixation, the mask and the head cushion are carefully shaped to the patient's head and then left to harden to ensure rigidity of fixation. For patient comfort, a knee support is used.

The patient can be undocked and re-docked using mask immobilization. This means that mask based (frameless) fixation can be used to facilitate fractionated treatments, re-using the same fixation throughout the course of treatment. The stereotactic reference is always set using the integrated CBCT when employing mask immobilization.

Leksell GammaPlan®

For Elekta Esprit, the seamless integration between Leksell GammaPlan, the stereotactic CBCT and the delivery unit makes GammaPlan more than a treatment planning system—it is a treatment management system. With Leksell GammaPlan a full treatment plan can take just minutes to complete—even for complex cases—thanks to a range of highly responsive inverse and forward planning tools tailored for the system's unique dose characteristics. Leksell Gamma Knife Lightning dose optimization enables precise handling of complex targets and protection of critical structures.

Leksell GammaPlan is fully integrated with Elekta Esprit and specialized for intracranial radiosurgery. It provides tools that make full use of the advanced technology incorporated into the system, while ensuring safe and efficient treatment workflows.

Complete and accurate modeling of Elekta Esprit and patient immobilizations enables accurate dose calculations and simulation of all geometries to ensure safety in treatment delivery. A range of highly responsive forward and inverse planning tools tailored for the system's unique dose characteristics allows for interactive dose sculpting and makes it possible to complete plans in minutes— even for complex and multiple targets. Convolution provides optional heterogeneity correction for targets near bone and air cavities. Manual and automatically calculated dose statistics are available for efficient plan review.

Leksell GammaPlan supports several workflows for treatment planning and delivery with Esprit. For frameless treatments, a fully integrated and guided workflow is provided for automatic correction and online evaluation of dose delivery based on the current patient position from stereotactic CBCT images. For frame-based treatments, CBCT may be used as an optional quality assurance for patient positioning. Replanning tools with optional dose summation are provided to facilitate plan adaptation for single session or fractionated treatments. Retreatment functionality provides tools for efficient management of recurring disease—particularly metastases. Pre-planning makes it possible to plan on non-stereotactic images.

Leksell GammaPlan supports DICOM image studies obtained from MR, CT, CBCT, and PET scans as well as x-ray angiograms (AI). MR and CT images acquired with Leksell Vantage Head

Frame or Leksell G Frame can be stereotactically defined, and other tomographic image studies can be co-registered and fused to other image studies based on mutual information. The patient outline can be automatically segmented from MR or CT images, and regions of interests can be delineated on both tomographic images and projective x-ray angiograms. The fully configurable image workspace allows for simultaneous display and exploration of multiple image studies while planning.

Functional planning is supported with the optional AtlasSpace® brain atlas, and functional targeting can be defined relative to the intercommisural line.

Thanks to a client-server architecture, multiple GammaPlan workstations have instant access to all patient data recorded in the online database shared with Elekta Esprit. Connectivity with external systems is provided via standard DICOM interfaces. DICOM images and DICOM RT Structure Sets can be imported from and exported to external systems over the network. It is also possible to export DICOM RT Dose. For DICOM conformance statements, visit:

https://www.elekta.com/products/oncology-informatics/dicom-conformance-statements/

Optional Leksell GammaPlan add-ons

Leksell Gamma Knife® Lightning allows users to create plans quickly and automatically for one or more targets through optimization based on dose constraints for targets and organs at risk, together with controls to minimize beam-on time and overall low dose to surrounding tissue.

Leksell GammaPlan Remote makes it possible to access Leksell GammaPlan workstations from remote clients within the hospital network for the purpose of plan review and collaboration.

- MOSAIQ® Connectivity provides seamless integration with MOSAIQ Oncology Information System and enables scheduling and recording of treatments in the Electronic Health Record (EHR) for patients in MOSAIQ shared with other departments and treatment modalities.
- Convolution offers increased dose calculation accuracy near heterogeneous tissues
- Inverse Planning is a legacy inverse planner capable of optimizing the dose conformity for an individual target.
- AtlasSpace® brain atlas Schaltenbrand and Wahren brain atlas.

Treatment with Elekta Esprit

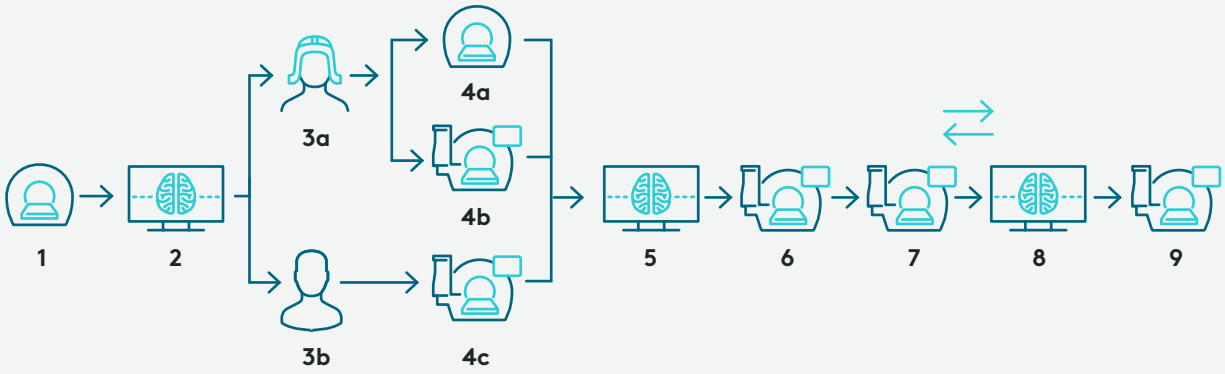
The treatment workflow can be divided into two main steps, treatment planning and treatment. Treatment planning is done in Leksell GammaPlan®. The purpose of the treatment plan is to define the target that is to be treated, and to determine the positions of the shots during the treatment. When the treatment plan is approved in Leksell GammaPlan, it is exported to Leksell Gamma Knife for execution and treatment.

Esprit provides several workflows, with stereotactic reference defined from either MR/CT indicator box fiducials or stereotactic CBCT. This brings flexibility, patient centricity, and adaptation to clinic logistics.

For fiducial-based workflows, the integrated CBCT system in Esprit adds an additional imaging modality, visualizing the treatment quality. The versatile workflow enables several possibilities to adapt the procedure to the clinical needs based on options in patient immobilization, when to perform planning imaging and defining stereotactic reference, and on which day tasks are performed.

Flexible workflows aid efficiency

Treatment workflows



1. Non-stereotactic imaging MR/CT (optional for Frame workflows)

2. Pre-planning on non-stereotactic images

3. Fixation for mask or frame workflow

3a) Frame fixation (Vantage or G-frame)

3b) Mask fixation

4. Stereotactic imaging (required for plan approval)

4a) by Stereotactic MR/CT (Vantage and G-frame only)

4b) by Stereotactic CBCT (Mask)

5. Treatment planning

6. Prepare for treatment

7. Stereotactic CBCT for treatment

8. Treatment delivery evaluation

9. Treatment delivery (print operators report)

Cobalt Sources

Sources

Each of the 192 radioactive sources located in the radiation unit is composed of Cobalt-60 (60Co) 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. The total activity at the time of loading of Elekta Esprit is a maximum of 6600 Ci.

The cobalt sources are delivered to the site in a specially designed and approved protective container, called a cask. Once loaded into the radiation unit, the sources are maintenance free and handled again only when necessary to reload the unit with new sources.

Source loading

Sources are loaded into positions within the radiation unit using a loading machine 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 weighs approximately 13,000 kg.

Due to the heavy weight of the equipment (radiation unit, loading machine, cask), the treatment room floor and its access way must be able to support a load of 20,000 kg/m2. The treatment room in its entirety must withstand a total load of 37,000 kg. A certain working area is also required.

The assembly of the loading machine and the loading procedure are carried out by certified Elekta personnel.

Radiation Protection and site layout

The control room contains:

- Treatment view monitor/ Patient surveilance monitor (1)
- Control panel (2)
- Leksell GammaPlan workstation(3)
- Office cabinet (4)
- Operator's position (A)

The treatment room (B) contains:

- Radiation warning lamp (5)
- Patient surveillance camera (6)
- Leksell Gamma Knife unit (7)
- Medical cabinet (8)
- Treatment room monitor (9)
- Patient speakers and microphone (integrated with the patient positioning system (10))

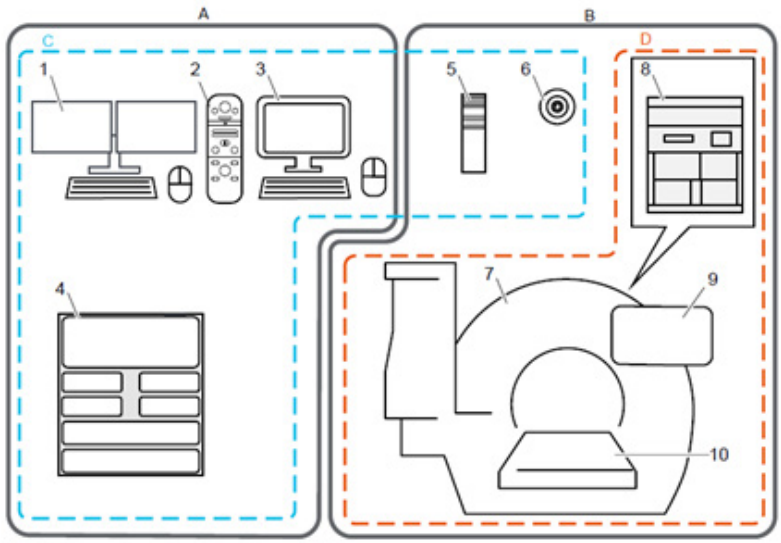


Figure 3.1 Control room and treatment room

Installation of the equipment is performed in accordance with the installation instructions and specific site drawings.

Recommendations for site planning such as the creation of room foundation, room layout, and electrical layout of the site are supplied by Elekta as part of the sales commitment. However, the user is responsible for the dimensions of walls, floor, and ceiling of the particular site.

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

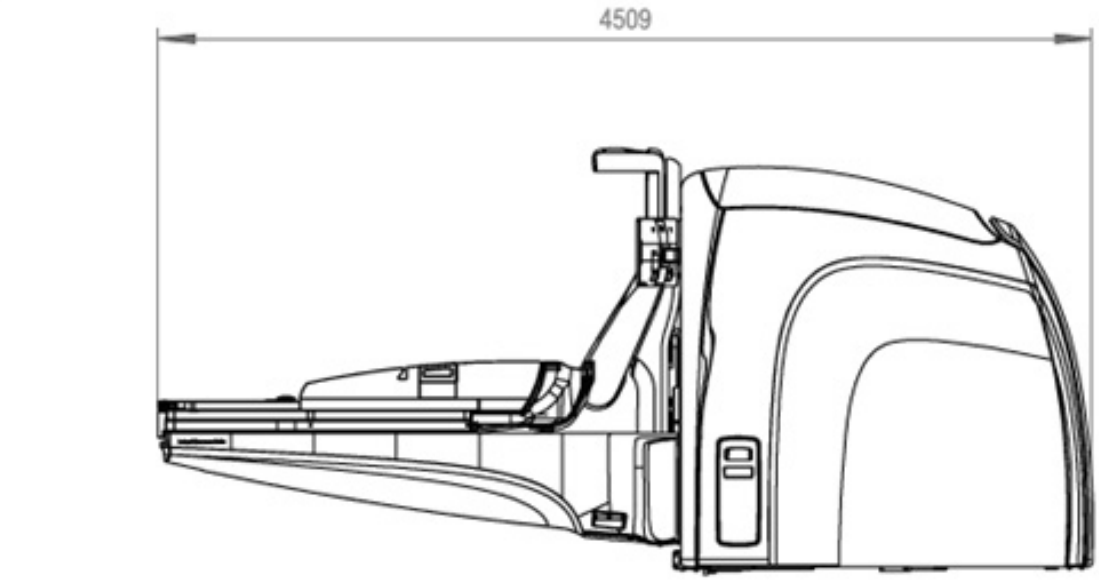
The protective housing of the radiation unit is designed and manufactured in accordance with ICRP 60, NCRP 102, and IEC 60601-2-11 rules and recommendations.

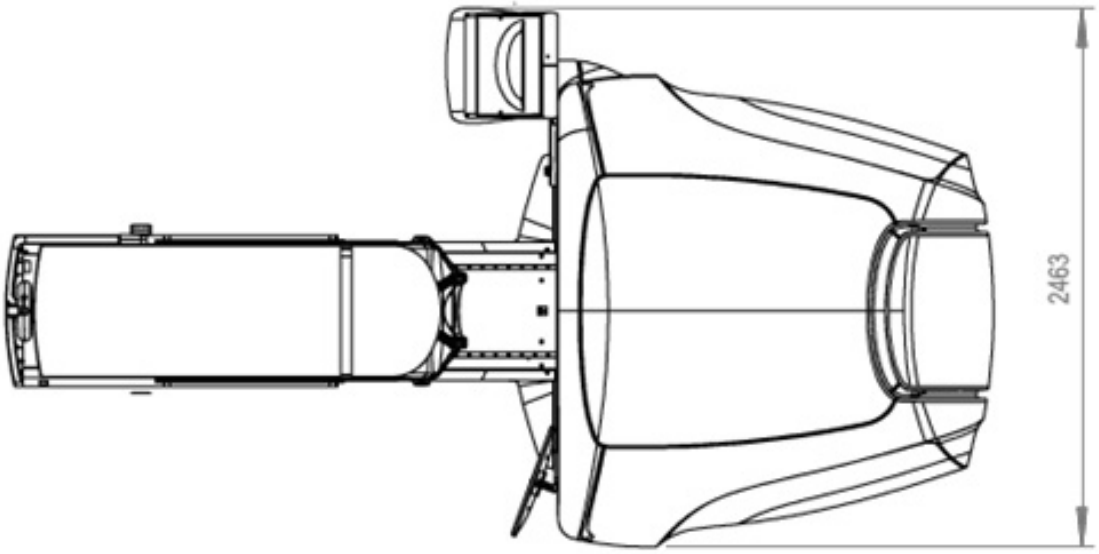
Radiation levels from a CBCT scan must be considered besides the 60Co radiation levels. In general, if the treatment vault is designed for 60Co radiation and does not have a window, the radiation levels from the CBCT system will have no implications for the design of the wall thickness. If a window is used, it must be made of lead glass.

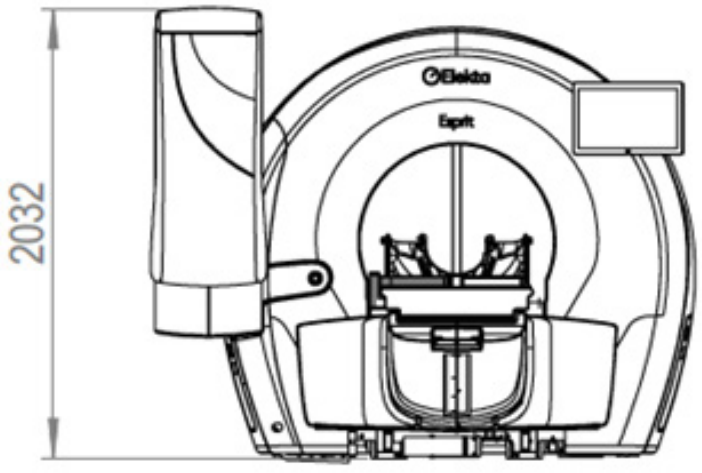
It is recommended that the treatment room have the following minimum dimensions:

- Length 6.5 m
- Width 4.65 m
- Height 2.5 m¨

Drawing of Elekta Esprit



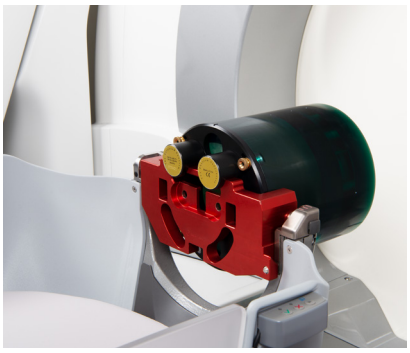




Quality assurance tools

The Quality Assurance tools are designed to maintain the Elekta Esprit system performance over time.

QA tool Plus or QA tool Vantage are used for QA of focus precision, CBCT precision, and clearance check tool (CCT). All three tests are integrated and performed within the control system software.



The CATPHAN 503 phantom is used to perform tests for spatial resolution, contrast to noise (CNR), and uniformity of the CBCT imaging.

The dosimetry phantom is a more advanced solution (built with high-end material and is more configurable) compared to the radiation phantom. The dosimetry phantom is compatible with both the Vantage frame and G-frame adapters.

The radiation phantom is used to perform standard dosimetry tests such as

- Dose-rate determination according to international code of practice e.g., IAEA-TRS-483, and AAPM TG-178
- Precision of the dose-distribution using film dosimetry

The Film holders are used to perform independent QA checking of the system accuracy. Versions exist for both the Vantage frame and G-frame adapters.

Appendix A

Table 1: Technical overview of Elekta Esprit

The following tables describes selected components within Elekta Esprit. All components are chosen from well-recognized suppliers to secure reliability to ensure optimal product performance.

Workflow	
Automatic positioning system	Couch integrated
Typical repositioning time	< 3 s
Typical collimator size setup time	< 3 s
Blocked collimation setup time	< 3 s
Mixed collimation setup time (Composite shot)	< 3 s
Check and verify	100%
QA procedure	Automatic
Accuracy	
Radiological accuracy	< 0.5 mm (< 0.3 mm with Platinum service contract)
Positioning repeatability	< 0.05 mm
CBCT image accuracy	< 0.5 mm
Treatment planning	
Treatment planning system	PC/Linux based
Mechanical treatment range X/Y/Z	160/180/220 mm
Shape of accessible volume	Cylindrical
Real collimator sizes	4, 8, 16 mm diameter
Radiation data	
Maximum cobalt-60 activity at loading	< 6600 Curie (244 TBq)
Number of radiation sources	192
Radiation dose rate at focal point at loading	> 3 Gy/min
CBCT dose presets	2.5, 6.3 mGy
Physical Data	
Overall length, including cover	4.50 m
Overall length, including cover and gantry	4.50 m
Overall width, including cover	2.23 m
Overall width, including cover and gantry	2.46 m
Overall height, including cover	1.94 m
Overall height, including cover and gantry	2.03 m
Total weight (approx.)	20,000 kg

Table 2: Technical specification for Radiation unit

Collimator body with radiation shielding	
Collimator body	Tungsten body with 576 collimator channels
Outer shielding	Cast iron
Inner shielding	Tungsten and lead
Shielding doors	Steel
Servo Controller	High precision, fully digital servo drive with embedded intelligence
Sector units: 8 source carrying sector units with 24 Cobalt-60 sources each	
Sector	Aluminum: 24 source housings
Shafts	Induction hardened stainless steel
Bearings	Graphite bushings
Motor	24V DC motor
Encoder	500 impulses/turn
Linear guide unit	Repeatability: ±0.003 mm
Linear encoder	Absolute linear encoder
Accuracy grade ±5 µm	
Solenoid	Photo-micro sensor
Servo card	Intelligent servo card

Table 3: Technical specification for patient positioning system

Couch framework with X/Y/Z drive	
Maximum load on patient couch	210 kg (460 pounds)
Framework	20 mm zinc chromated steel
Motors	DC motors with 2000-line encoders
Linear encoders	Absolute linear
	Accuracy grade ±5 µm
Servo controller	High precision, fully digital servo drive, with embedded intelligence
Frame fixation	Hardened stainless steel
Comfort system	
Mattress support	Sandwich structure with aluminum honeycomb core and steel sheets
Covers	
Radiation unit and couch covers	3 layers glass reinforced polyester. Meets ASTM E84 with flame spread index less than 75. Flammability rating V-0 according to UL 94.

Table 4: Technical specification for CBCT Gantry and CBCT

CBCT Gantry	
Framework	Zinc chromated steel plates in various dimensions
Motors	DC motors with 8196 line encoders
Motors	DC motors with 2000 line encoders
Gear C-arm	Worm gear 82:1
Tilt arm	Actuator with trapezoid screw
Bearings	Preloaded angular contact bearings on both axis
Absolute encoder C-arm	Optical touchless 26 bits
Absolute encoder tilt arm	25 bits
Servo controllers	High precision, fully digital servo drive, with embedded intelligence
CBCT	
kV generator instantaneous power	3 kVA (normal use), 25 kVA (calibration)
Charge/projection	0.4, 1.0 mAs
Tube current	0.1, 0.25 mA
Energy	90 kVp
Pulse length	40ms
Volume size	448x448x448 voxels
Voxel size	0.5 mm
Spot size	0.6 mm
Detector pixel size	0.368 mm
Apodization filter, cut off frequency	Hamming, 0.63

Appendix B

Applicable international standards

EN/IEC 60601-1
Medical electrical equipment, Part 1:
General requirements for safety.

EN/IEC 60601-1-2
Collateral standard:
Electromagnetic compatibility.

IEC 60601-2-11
Medical electrical equipment, Part 2:
Particular requirements for the safety of gamma beam therapy equipment.

AAMI ES60601-1
Medical electrical equipment:
General requirements for safety.

C22.2 No 601.1:08
Medical Electrical Equipment, Part 1:
General Requirements for safety.

IEC 60601-1-3
Radiation protection in diagnostic x-ray equipment.

IEC 60601-2-28
Particular requirements for the basic safety and essential performance of x-ray tube assemblies for medical diagnosis.

IEC 60601-2-68
Particular requirements for basic safety and essential performance of x-ray based Image Guided Radiotherapy Equipment for use with electron accelerators, light ion beam therapy systems and radionuclide beam therapy systems.

IEC classification

Elekta Esprit is classified as follows:

- IEC 60601-1 Type of protection against electric shock
- IEC 60601-1 Degree of protection against electric shock
- IEC 60601-1 Methods of disinfection recommended by the manufacturer
- IEC 60601-1 Degree of application safety in the presence of flammable anesthetic mixture with air or with oxygen, or with nitrous oxide
- Class I equipment
- Type B applied parts
- Disinfectant safe equipment (or elements)
- Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide

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, or are required to satisfy the product specifications, or are expected to improve reliability, quality or the value of the product.

Elekta

We don't just build technology, **we build hope**

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