Amendment No. 10

# MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

| Licensee | In accordance with letters dated September 30, 1996 and November 1, 1996 |
|---|---|
| 1. Columbia HCA Health Services of Oklahoma, Inc. dba Columbia Presbyterian Hospital<br>2. 700 N.E. 13th Street Oklahoma City, Oklahoma 73104 | 3. License number 35-12091-02 is amended in its entirety to read as follows: |
| | 4. Expiration date July 31, 2002 |
| | 5. Docket or Reference No 030-17190 |

| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
|---|---|---|
| A. Cobalt-60 | A. Sealed sources (General Electric Company AB Elekta Model 43047) | A. 14,500 curies (402 sources of not more than 36 curies each) |

9. Authorized storage:

A. For use, installation, source replacement and temporary storage of a Leksell Gamma System Model 23004 Type B (a.k.a Gamma Knife or Cerebral Stereotactic Radiosurgical Unit) radiation therapy unit for the treatment of humans.

## CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 700 N.E. 13th Street, Oklahoma City, Oklahoma.

11. The Radiation Safety Officer for this license is Clifford W. Richter, Ph.D.

12. Licensed material shall be used by, or under the supervision of, Clinton A. Medbery, III, M.D., John R. Taylor, M.D., or Astrid Morrison, M.D.

13. Gamma Knife Physicist: Clifford W. Richter, Ph.D.

14. A. The Gamma Knife shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.



OFFICIAL RECORD COPY

ML40

B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

C. The test sample shall be taken from selected accessible surfaces of the Gamma Knife. The selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used helmets. A minimum of a single wipe of the entire surface of the collimator will be taken.

D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

E. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.

15. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.

16. A. Access to the Gamma Knife room shall be controlled by a door at each entrance. Such doors shall be normally closed.

B. Each entrance to the Gamma Knife room shall be equipped with an electrical interlock system that will remove the patient from the focus beam of radiation upon opening of any entrance door. The interlock system shall be connected in such a manner that the patient cannot be returned to the focus beam until all treatment room entrance doors are closed and the control is reset at the control panel.

C. Electrical interlocks on entrance doors to the Gamma Knife room shall be tested for proper operation at least once every 6 months. Records of test results shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. In the event of malfunction of any door interlock, the Gamma Knife control shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

17. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the Gamma Knife unit that could result in increased radiation levels in areas outside the Gamma Knife treatment room shall be evaluated by a radiation survey made in accordance with Condition 18 and reported to the Commission within 30 days following completion of the change(s).

B. Relocation of the Gamma Knife unit to a new facility is not permitted without prior approval of the plans and details by the commission. Following such approval and relocation, a radiation survey shall be made in accordance with Condition 18. and reported to the Commission within 30 days after completion of the move.

18. Before initiation of a treatment program, and subsequent to each installation of a Gamma Knife source, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(i) The Gamma Knife source housing, with the shielding door closed. The maximum and average radiation levels at 1 meter from the Gamma Knife housing in the closed position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.

(ii) All areas adjacent to the treatment room with the Gamma Knife shielding door in the open position. The survey shall be performed with a phantom in the focus beam of radiation and shall clearly establish:

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201.

(b) The quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.

B. Tests shall be made to determine proper operation of:

(i) Electrical interlocks on entrance doors to the Gamma Knife treatment room.

(ii) The Gamma Knife treatment timing device.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
35-12091-02

Docket or Reference Number
030-17190

Amendment No. 10

C. A report of the results of the above surveys and tests shall be sent to the U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety not more than 30 days after each installation of a teletherapy source.

19. The following shall be performed by the manufacturer or persons specifically licensed by the Commission or an Agreement State to perform such services:

A. Installation, relocation, or removal of Gamma Knife units containing sources.

B. Source exchange.

C. Any maintenance or repair operations on the Gamma Knife unit involving a mechanism that could expose the source, reduce the shielding around the sources, or compromise the safety of the unit and result in increased radiaiton levels.

20. The licensee shall comply with the provisions of Title 10, Code of Federal Regulation, Part 35, "Human Uses of Byproduct Material," Sections 35.600 through 35.647, except Section 35.~~62~~632(b)(2), (3), and (6) and Section 35.634(a)(3) and (4).

21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated April 21, 1996
B. Letters dated September 30, 1996
C. Letter dated November 1, 1996

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Original Signed By
Vivian H. Campbell

Date NOV 5 1996

By _____
Nuclear Materials Licensing Section
Region IV
Arlington, Texas 76011

COLUMBIA
Presbyterian Hospital

700 Northeast 13th Street
Oklahoma City, Oklahoma 73104-5070
Phone (405) 271-5100
COLUMBIA's home page is http://www.columbia.net

11-1-96

# Fax Cover Sheet

To: Vivian Campbell
Senior Health Physicist
Nuclear Materials Licensing Branch

817-860-8263

From: Clifford W. Richter
RSO

Please find enclosed our response to your check list. It looks as if the questions were minor.

Thank you for your help-

Clifford W. Richter

405-271-3867 or 271-6445
405-271-3868 Fax

Mailed 11-1-96

Faxed
6:30 AM 11-1-96
+ 9:30 AM

COLUMBIA
Presbyterian Hospital

700 Northeast 13th Street
Oklahoma City, Oklahoma 73104-5070
Phone (405) 271-5100
COLUMBIA's home page is http://www.columbia.net

November 1, 1996

Vivian H. Campbell, Health Physicist
Nuclear Materials Licensing Section
Region IV
U. S. Nuclear Regulatory Commission
611 Ryan Plaza Dr., Suite 1000
Arlington, Texas 76011

Re: License #: 35-120391-02
Docket #: 030-17190
Control #: 466078

Response to your request for added information dated October 31, 1996

Dear Ms. Campbell:

Please find enclosed a detailed response to your request for additional information. This response will follow your module detailing the request.

Quality Management Program

Due to the complexity of the gamma knife written directive, we have elected to used the Treatment Planning Protocol as the written directive. This protocol is derived by an authorized user. It contains:

a. the target coordinates
b. the collimator size
c. the plug pattern
d. the total dose
e: the treatment time

The written directive will be signed by the authorized user. In order to assure that the treatment parameters are in accordance with the written directive, it will be verified and signed by a medical physicist.

Verification will be performed by an authorized user and another qualified individual to assure that the stereotactic frame coordinates on the patients skull match those on the treatment plan (written directive) and that the films used to determine frame coordinates positively and unambiguously identify the right and left hemispheres.

Dose calculations will be checked by a medical physicist or an authorized user who did not perform the original caiculations.

The treatment planning protocol will be signed or initialed at the end of each target treatment. When the treatment is completed, the authorized user will review, sign and make a notation that the treatment was delivered as

prescribed.

Our program review for the QMP incudes review of all written directives. This verifies compliance and effectiveness of the program. When deviations occur, all recordable facts will be preserved to determine the cause of the deviation. Then corrective action, if indicated, will be implemented to prevent recurrence. The program will be evaluated at least annually. Records of relevant facts, corrective actions, and annual reviews will be maintained for at least three years.

Item 5:

Our current source strength is 6208 Curies of Co-60 on 7-1-96. I believe that 6700 Curies (less that 10% more than we received) plus the decayed sources to be removed would be more than adequate.

Item 9.3:

Record of training of individuals will contain the date, duration of training, and the topics covered.

Item 10.2:

Calibration of survey meters will be completed annually. The report will be dated with the result of the calibration and the name of the organization providing the service. These records will be maintained for at least three years.

Item 10.6:

The Leksell Gamma Knife comes complete with a color CCTV and intercom. We has installed an additional CCTV and intercom in the room (a total of two). Patients will not be treated unless there is a functional CCTV and intercom. There is no viewing window.

Item 10.7:

The Gamma Knife suite is in radiation therapy, which is locked when not occupied. The door to the treatment unit is posted with a 'Caution Radioactive Material' and a 'Caution Radiation Area' sign. Currently there is a red beam on warning light over the door (this is to be changed to another type radiation warning sign that lights when the beam is 'on'). Warning lights are also on the unit and the control console.

We have a remote area monitor installed at the control console. The door is interlocked to the unit in a conventional fashion.

We have enclosed a copy of our response to tests required after installation of a teletherapy unit required by 10 CFR 35.645 dated 10-25-96. This was mailed this week.

Item 10.8:

As noted in the previous paragraph, surveys have been completed to insure

compliance with Parts 19 and 20.

Since the gamma knife suite is located in radiation oncology, controls exist to insure that the department is locked when not occupied. Only trained employees in this area are issued keys. The gamma knife control is locked when not in use.

Except for the treatment room during use, and during emergency situations, there are no restricted areas.

Clearly visible 'Caution Radioactive Materials' and 'Caution Radiation Area' sign are posted at the entry door to the gamma knife suite.

In order to address the possibility of a worker exceeding the limits in 10 CFR 19.12 (100 mrems) during an emergency, all employees working with the gamma knife will be instructed and issued monitoring devices.

The surveys required by 10 CFR 20.1501 and 35.641 dated 10-25-96 are enclosed.

Item 11.1:

We have adopted Appendix D of RG 10.8, Rev. 2.

Item 11.2:

We have adopted Appendix F of RG 10.8, Rev. 2.

Item 11.3:

We have adopted Appendix G of RG 10.8, Rev. 2.

Item 11.4:

We have adopted Appendix H of RG 10.8, Rev. 2 and/may use a licensed commercial source to provide leak testing services.

Item 11.21:

Enclosed with our report of required tests dated 10-25-96, we have enclosed an Emergency Procedure. These items are addressed.

Item 11.23.1:

The GSR unit may be operated for testing and measurements by a trained medical physicist. When used for patient treatment and authorized user and a medical physicist will be present.

The unit will only be used for required tests and measurements that are needed to insure regulatory/safety purposes in preparation for and to treat human disease processes.

Item 11.23.2:

Safety device checks will be done following manufacturers recommendations.

Test frequency on some items are day of use, others weekly/monthly.

If any malfunction is noted that would affect clinical use, the unit will not be used until it has been serviced or otherwise cleared by the manufacture as safe for clinical use.

Item 11.23.3:

The periodic spot check will be performed once each calendar month of use by a medical physicist. If the spot check is not performed by the GSR physicist, it will be reviewed and signed by the GSR physicist within 15 days of being conducted. The monthly spot check for the month of the annual calibration will be incorporated into that report.

Item 11.23.4:

Elekta will perform routine preventative maintenance to ensure that systems that deteriorate from use are identified and replaced.

Item 11.23.6:

Reports of surveys will be done after source changes, modification of the GSR unit or treatment room, or any other time that it would be suspected there would be a change in the radiation levels around the unit or room.

Certain reports are required to be send to the NRC per 10 CFR 35.641.

Enclosed is a copy of the report dated 10.25-96.

Item 11.23.8:

The Radiation Safety Officer maintains all records relating to the license and supporting documents, personnel dosimetry records, survey instrument calibrations/day of use checks, day of use beam monitor checks, day of use checks of audible alarm personal dosimeters, calibration of dosimetry systems used for the full calibration, calibration/intercomparison of dosimetry systems used for spot check measurements and training of new personnel and the annual refresher courses.

Item 11.23.9:

Enclosed with our report of 10-25-96 is the Emergency Procedure posted at the console, along with the notification list.

The Emergency Procedure will be practiced at least once per year. A record of that drill will be maintained.

As we discussed, we have a team from Elekta Sweden here next week (November 4) to assist us in treating patients (starting Wednesday), provided we have our license. If you need any additional information and cannot get in touch with me, please call 405-271-6445 and have me paged.

I appreciate you help in this endeavor and would like to invite you up to view

patient treatment. Thanks again for your help.

Sincerely,

Clifford W. Richter, PhD

Clifford W. Richter, Ph. D.
Radiation Safety Officer

COLUMBIA
Presbyterian Hospital

700 Northeast 13th Street
Oklahoma City, Oklahoma 73104-5070
Phone (405) 271-5100
COLUMBIA's home page is http://www.columbia.net

October 25, 1996

Vivian H. Campbell, Health Physicist
Nuclear Materials Licensing Section
Region IV
U. S. Nuclear Regulatory Commission
611 Ryan Plaza Dr., Suite 1000
Arlington, Texas 76011

Re: License #: 35-120391-02
Control #: 466078

Reports of teletherapy surveys, checks, tests, and measurements (35.645)

Dear Ms. Campbell:

Please find enclosed reports required after the installation of our Leksell Gamma Knife teletherapy unit.

The unit is a Leksell Gamma Knife Model 23004 ('B' model), containing 6208 Curies of Co-60 on July 1, 1996. The installation was completed on October 17, 1996 by Elekta personnel.

1) The following safety features were tested and were found to function properly:

   a) The electrical interlocks at the entry door.
   b) The beam condition indicators on the treatment unit, over the door, and at the treatment console.
   c) The patient viewing system (CCTV) and two way communication system.
   d) The proper opening and closing of the electrically assisted door from both inside and outside the room.

   These items demonstrate compliance with 10 CFR 35.634(d).

2) The enclosed report of the survey of the teletherapy head partially completed on August 23 and completed on October 2, 1996. The maximum value (2.3 mR/hr) was measured in a small area directly in front of the shielding doors. The average value was 0.68 mR/hr.

   This survey demonstrates compliance with 10 CFR 35.641(1). S/N 122209

3) The radiation survey was completed on October 16, 1996, with a Ludlum 14C GM survey meter calibrated on October 1[illegible], 1996.

   The survey was conducted with the helmet in the maximum out position. This resulted in the highest radiation exposure in all areas.

Dr. Richter

The locations are noted on the enclosed drawing. The measured radiation levels were measured at one foot from the barrier. Recorded levels and locations are the maximum observed for that barrier. The background was measured at 0.03 mR/hr.

| Location | Occupancy | Exposure Rate | Exposure per week |
|---|---|---|---|
| 1) Control area | 1 | 0.03 mR/hr | 0 mR |
| 2) Entry door | 1 | 0.04 mR/hr | 0.1 mR |
| 3) West wall | 1/4 | 0.03 mR/hr | 0 mR |
| 4) North wall | 1/16 | 0.12 mR/hr | 0.1 mR |
| 5) East wall | 1/16 | 0.05 mR/hr | 0 mR |
| 6) Roof | 1/16 | 0.5 mr/hr | 0.3 mR |

The February 13, 1996 Radiation Protection Design calculated a maximum beam "on" time of 9 hours per week. This beam "on" time and occupancy factors were used to evaluate the weekly/annual exposure values.

There is no area where an individual could receive more than 2 mR in any hour or more than 100 mR in a year, considering occupancy and the design use factor of the gamma knife.

This survey demonstrates compliance with 10 CFR 20.1301 and 10 CFR 35.641.

4) The output of the unit was measured on October 16, 1996 with a Capintec PR-05P ionization chamber. This chamber was calibrated by K & S Associates, Nashville, Tennessee on October 15, 1996 (an AAPM Accredited Dosimetry Calibration Laboratory).

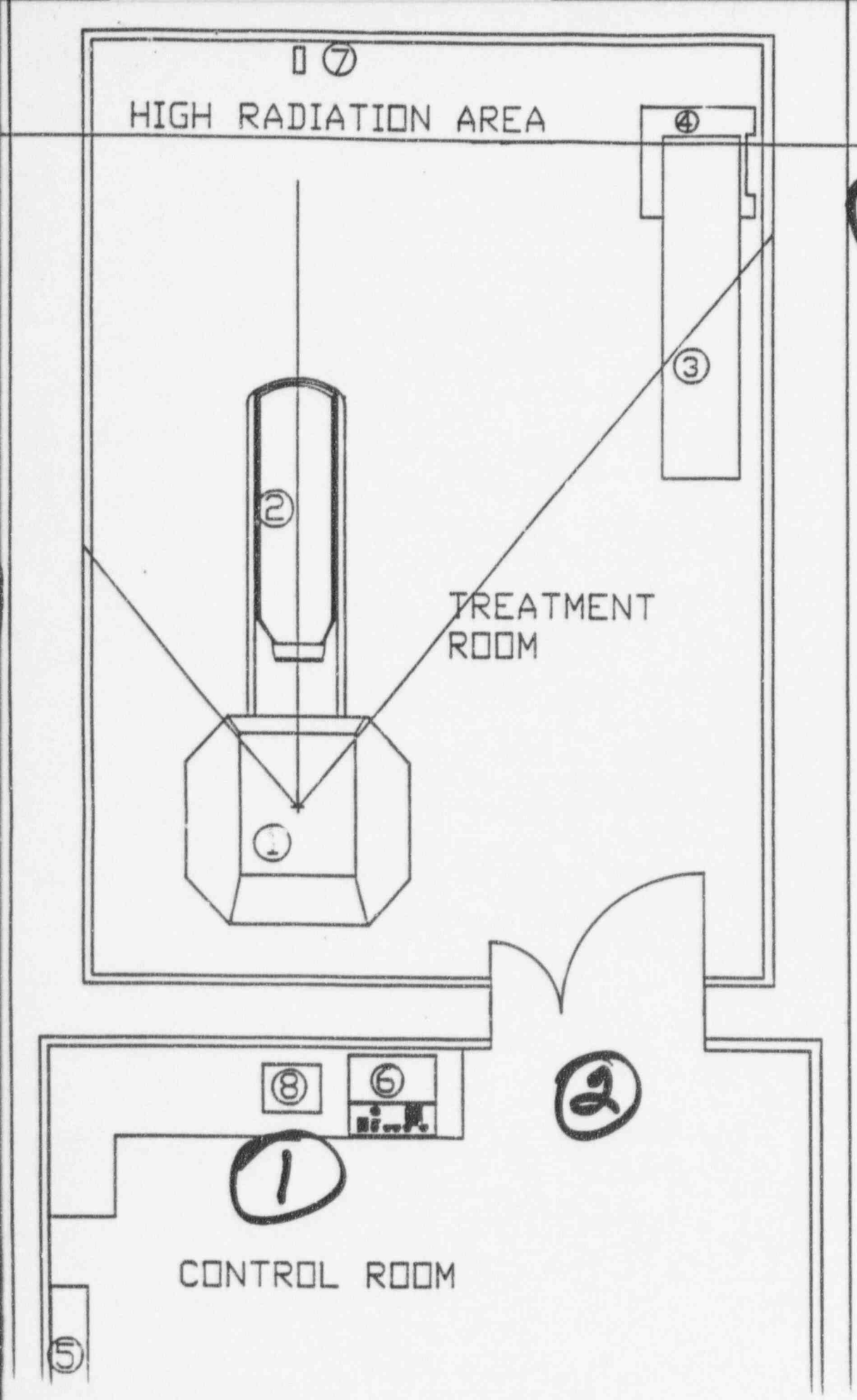
The output the unit at the focus of radiation with the 18 mm helmet was measured to be 368 rads per minute (3.68 Gy/min) at the center of a 16 cm spherical phantom of water equivalent plastic, per Elekta procedures. Dose was calculated using the AAPM TG-21 protocol.

If you have question concerning the results of this survey, or need other information, please contact us.

Sincerely,

Clifford W. Richter, Ph.D.

Clifford W. Richter, Ph. D.
Radiation Safety Officer
Director of Medical Physics




3. HEL
4. HEL
5. ELE
6. CON
7. CAI
8. MO

5

North

1/4" = 1'

Wall thicknesses are not scaled.

| Supply | Quality | Datum/Date | Dok ref/Doc no |
|---|---|---|---|
| | | 95-01-19. | 0095 |
| Avsnitt/Ra: Radioation Protection Survey | | | Directory: E:\DOC_STYR |

| Project No | Customer | Hospital | City |
|---|---|---|---|
| 495 | | COLUMBIA PRESBYTERIAN | OKLAHOMA CITY |

- Measuring distance from the sources: 1m, i.e. appr. 60 cm from the surface of the radiation unit.
- The measurement is performed in accordance with NCRP 33
- Use drawing 43824 for the LGK 23016 and 43834 for LGK 23004 as instruction for where to measure.
- If the measurement is done on LGK 23004, the plastic hood must be removed.
- A calibrated instrument shall always be used for the measurement.

| Measure point number | Measured dosrate ~~uSv/hr~~ mR/hr | Measure point number | Measured dosrate ~~uSv/hr~~ mR/hr |
|---|---|---|---|
| 01 | 0.7 | 14 | 0.4 |
| 02 | 1.4 | 15 | 0.2 |
| 03 | 2.3 | 16 | 0.6 |
| 04 | 0.6 | 17 | 0.8 |
| 05 | 0.2 | 18 | 0.6 |
| 06 | 0.6 | 19 | 1.0 |
| 07 | 0.4 | 20 | 0.6 |
| 08 | 0.8 | 21 | 0.3 |
| 09 | 1.1 | 22 | 0.5 |
| 10 | 0.5 | 23 | 0.3 |
| 11 | 0.4 | 24 | 0.8 |
| 12 | 0.8 | 25 | 0.6 |
| 13 | 0.9 | 26 | 0.2 |

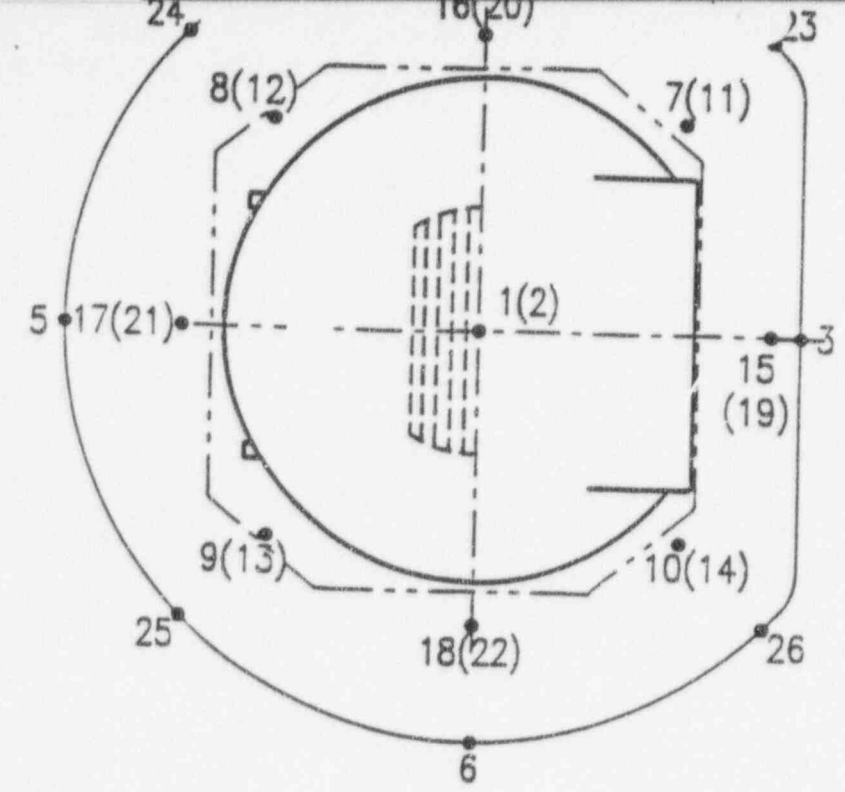
REG. KOPIA

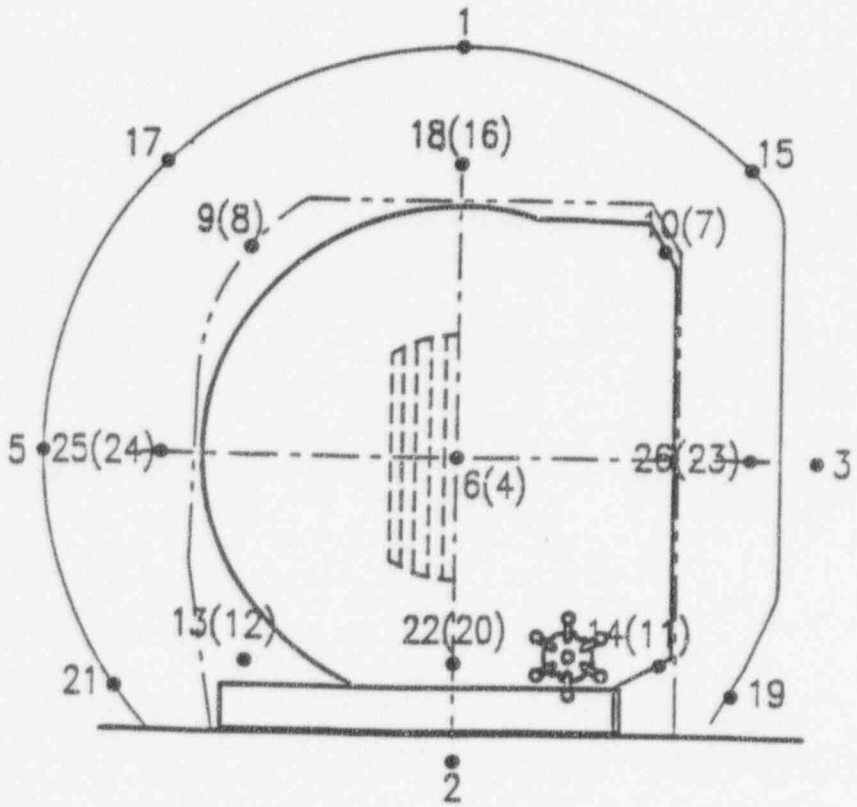
Total average measured: 0.68 ~~uSv/h~~ mR/hr

| Measuring instrument No: Type: | Date of Measurement | Measured by |
|---|---|---|
| Ludlum 14C GM | 10-2-96 | Clifford W. Richter, PhD. |

Calibrated 10-1-96

S/N 122209




REG. KOPIA

96-02-12

92-04-07

43834

LEKSELL GAMMA KNIFE, type B (23004)
Measurement points according to NCRP 33

General Operator Safety Instructions

1) The operator shall insure that only the patient is in the room when the unit is operated. The operator will be the last person out of the room and close the entry door.

2) The unit shall not be operated without a means to see and communicate with the patient.

3) If the radiation monitor in not operational, any individual entering the treatment room must use a survey instrument or audible alarm personal dosimeter to monitor the room for any malfunction of the source exposure mechanism. The monitor shall be promptly repaired or replaced if it is inoperable.

# EMERGENCY PROCEDURE-GAMMA KNIFE

Due to the complexity of this procedure and significant risk of radiation exposure, only trained individuals may enter the room during an emergency.

The emergency will be noted by indications on the control, CCTV, intercom, patient monitors, etc. The shielding doors of the unit take approximately one minute to close (with retraction of the patient from the treatment position). Entry into the treatment room in most emergency situations will result in radiation exposure to personnel.

1) Avoid the area of the maximum radiation as much as possible. The high radiation area is noted on the floor. Patient safety is the primary concern.

2) Follow the detailed instructions for removal of the patient and closing the shielding doors of the unit. The instructions are attached.

3) Try to estimate the time and your location in the room during the emergency.

4) If the shielding doors of the unit can not be closed, lock the entry door and post a notice of the situation. Immediately notify the R.S.O.

5) Notify the Radiation Safety Officer of the emergency.

6) If the emergency involved a malfunction of the unit, do not use the unit until Elekta has been notified.

Emergency Call List:

| | | | | |
|---|---|---|---|---|
| Cliffford W. Richter, Ph. D.<br>Radiation Safety Officer | 271-3867<br>627-4854 | office<br>cellular | 340-1195<br>636-8478 | home<br>pager |
| Clinton Medbery, M. D.<br>Radiation Oncologist | 271-3866<br>820-3056 | office<br>cellular | 524-4163 | home |
| Max D'Souza, Ph. D.<br>Medical Physicist | 271-6445<br>833-2396 | office<br>cellular | 528-1313<br>967-4862 | home<br>pager |

The hospital operator (271-5477) can page these or other staff.

| | | | |
|---|---|---|---|
| Timer | accuracy | 60 sec | 60.0 |
| | linearity | 180 sec | 180.0 |
| | | 240 sec | 240.0 |
| | | 600 sec | 601.0 |

Timer reproducability 180 sec set = 180.0, 180.0, 180.0

Dose calculation

| | | | |
|---|---|---|---|
| | Average electrometer 3 minute reading | x | 2.3053 |
| x | TG-21 total | x | $4.672 \times 10^{8}$ G/C |
| x | TPCF | x | 1.043 |
| x | timer correction | x | 60/185.2 |
| | | = | 3.639 G/minute |
| | | | 363.9 rads/min dose to muscle |

old method check

$$2.3053 \times 1.043 \times 477.4 \times \frac{60}{185.2} \times 0.957$$

($N_x$ = 477.4)

= 356 rads/m

Clifton W. Rietz PhD
11-5-96

**K&S Associates, Inc.**
1926 Elm Tree Drive Nashville, Tennessee 37210-3718
Voice 615-883-9760 Fax 615-871-0856 Schedule 800-522-2325

ACCREDITED DOSIMETRY CALIBRATION LABORATORY

# CALIBRATION REPORT

SUBMITTED BY: COLUMBIA PRESBYTERIAN HOSPITAL
700 NORTHEAST 13TH STREET
OKLAHOMA CITY, OKLAHOMA 73104-5070

INSTRUMENT: CAPINTEC PR-05P #CII.078460
KEITHLEY 35614 #17942

REPORT NO.: 6073

TEST NO.: 96690

REPORT DATE: OCTOBER 15, 1996

Geoffrey W. Ritchie, Ph.D.

The *CALIBRATION FACTORS* contained in this report were obtained by intercomparison with instruments calibrated by, or directly traceable to, the National Institute of Standards and Technology (NIST). K & S Associates, Inc. is licensed by the State of Tennessee (R-19075-G97, R-19136-B00) to perform calibrations, and is recognized by the American Association of Physicists in Medicine (AAPM) as an *ACCREDITED DOSIMETRY CALIBRATION LABORATORY* with special accreditation for the calibration of brachytherapy sources and well chambers. As part of the accreditation K & S participates in a measurement assurance program conducted by the AAPM and NIST.

The *CALIBRATION FACTORS* stated herein are valid under the conditions specified. It is the instrument user's responsibility to perform the appropriate constancy tests prior to shipment and after return from calibration. It is also the responsibility of the user to assure that the interpretation of the information in this report is consistent with that intended by K & S Associates, Inc.

## IONIZATION CHAMBER CALIBRATION

DATE: 10/12/96

SUBMITTED BY: Columbia Presbyterian Hospital
Oklahoma City, Oklahoma

CHAMBER:

| | |
|---|---|
| Mfgr: | Capintec |
| Model No.: | PR-05P (0.07 ml, C552) |
| Serial No.: | CII.078460 |

ORIENTATION / CONDITIONS:

white stripe toward source;
with polystyrene Co-60 build-up cap

ION COLLECTION EFFICIENCY ($A_{ion}$): 0.998

POLARIZING POTENTIAL: -359 V on thimble CHAMBER LEAKAGE: $<1 \times 10^{-15}$ A

| BEAM QUALITY HVT (mm) | H.C. | kVp | EXPOSURE RATE | SCD (cm) | CALIBRATION FACTOR | CLASS |
|---|---|---|---|---|---|---|
| Co-60 | -- | -- | 25 R/min | 80 | **$N_x = 4.774 \times 10^{10}$ R/C**<br>*$N_k = 4.197 \times 10^{8}$ Gy/C* | II |

COMMENTS: $N_{gas} / (N_x \cdot A_{ion}) = 8.60 \times 10^{-3}$ Gy/R

Calibrated by: Larry Bryson B.S. Reviewed by: Thomas A. Gowey

Title: Supervisor Title: Director

Checked by: LVD Prepared by MD Log C-32 Page 301

## ELECTROMETER CALIBRATION

DATE: 10/12/96

SUBMITTED BY: Columbia Presbyterian Hospital
Oklahoma City, Oklahoma

INSTRUMENT:
Manufacturer: Keithley
Model No.: 35614
Serial No.: 17942

SCALES, SWITCH POSITIONS, CONDITIONS:

BIAS: 100%, + (other settings good);
CURRENT SUPPRESS: OFF; RANGE ..

POLARIZING POTENTIAL: -359 V LEAKAGE: $+2.3 \times 10^{-14}$ A

LINEARITY: within +/-0.1 % or the precision of the reading, whichever is greater, except as noted.

CALIBRATION FACTOR:

| FUNCTION | UNITS | CALIBRATION FACTOR |
|---|---|---|
| $10^{-8}$ C | N/A | 1.006 C/rdg |

COMMENTS:

Calibrated by: Larry Bryson B.S. Reviewed by: Thomas J. Dowey

Title: Supervisor Title: Director

Checked by: LVD Prepared by MD Log E-22 Page 130

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

October 31, 1996

Columbia HCA Health Services of Oklahoma, Inc.
dba Columbia Presbyterian Hospital
ATTN: Clifford W. Richter, Ph.D.
RSO
700 N.E. 13th Street
Oklahoma City, Oklahoma 73104

SUBJECT: GAMMA KNIFE

We have reviewed your application dated April 21, 1996, and your letter dated September 30, 1996, requesting an amendment to your byproduct material license to use gamma stereotactic radiosurgery. Before further action can be taken, we shall need the information identified in the attached checklist. **Specific items that should be addressed are indicated as the shaded areas in the checklist.** (No additional information is necessary for the items marked with an "X.") Review the information provided in your application and compare it to that outlined in the draft Gamma Stereotactic Radiosurgery Module, the applicable items in Regulatory Guide 10.8, Revision 2, and the corresponding NRC regulations. Additionally, you should update operating and emergency procedures and the radiation safety manual to reflect changes implemented as a result of changes made to the application.

In order to continue review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please reply in duplicate and refer to the license, docket, and control number specified above. If you have questions or require clarification on any of the information stated above, we encourage you to contact us at (817) 860-8100.

Sincerely,

Vivian H. Campbell
Senior Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-17190
License: 35-12091-02
Control: 466078

Enclosure:
1. Checklist

GAMMA STEREOTACTIC RADIOSURGERY MODULE
Dated September 7, 1995

NOTE: Licensee should address the general information requested in Regulatory 10.8

Licensee/Applicant: Columbia HCA Health Services of Oklahoma, Inc.
License Number: 35-12091-02
Docket Number: 030-17190
Control Number: 466078

Date of Application: April 21, 1996
Application Signed [X] Yes [] No
James O'Loughlin, Ph.D, President & CEO

## REGULATORY PERFORMANCE

[] Review of last three inspections reveals no major regulatory considerations.

| DATE | INSPECTOR | VIOLATIONS |
|---|---|---|
| ■ | | |
| ■ | | |
| ■ | | |

[] Major violations/repeat violations:

[] Reviewer and inspector concerns:

## QUALITY MANAGEMENT PROGRAM

QMP on file: [X] YES [] NO
Date of submittal: September 30, 1996

[] Authorized for gamma stereotactic radiosurgery

A review of the written QMP was performed to determine whether your described policies and procedures appear to meet the objectives of the rule. Based on the review of the above submission, there are questions regarding the potential for failure of your QMP to meet the objectives in 10 CFR 35.32. You should review your QMP with regard to these questions and determine if additions or modifications are necessary.

A written directive for a gamma sterotactic radiosurgery radiation dose, as defined in 10 CFR 35.2, must include the target coordinates, the collimator size, plug pattern, and total dose, Your written directive for administration of a gamma sterotactic radiosurgery radiation dose does not contain:

a. the target coordinates,
b. the collimator size,
c. the plug pattern,
d. the total dose.

Your submittal for gamma sterotactic radiosurgery administration does not adequately describe procedures to ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Examples of acceptable procedures include:

a. verification, before administering each gamma sterotactic radiosurgery dose, to assure that the treatment parameters are in accordance with the written directive, should be performed by at least one qualified person (e.g., an oncology physician, radiation therapy physicist, or radiation therapy technologist) other than the individuals who dated and signed the written directive and plan of treatment. The prescribed target coordinates, collimator size, plug pattern, and the total dose should be confirmed by the person administering the treatment to verify agreement with the written directive and treatment plan.

b. verify that the sterotactic frame coordinates on the patient's skull match those of the plan of treatment, and that films used to determine frame coordinates positively and unambiguously identify right and left hemispheres.

c. check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations) by an authorized user or a qualified person under supervision of an authorized user who whenever possible did not make the original calculations.

d. prompt recording of the treatment parameters, and sign or initial the patient's chart or appropriate record.

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

ITEM 1: AMENDMENT TO LICENSE NO 35-12091-02

ITEM 2: NAME AND MAILING ADDRESS OF APPLICANT

Columbia HCA Health Services of Oklahoma, Inc.

dba Columbia Presbyterian Hospital
700 N.E. 13th Street
Oklahoma City, OK 73104

**ITEM 3: LOCATION OF USE**

Same address as above

**ITEM 4: NAME OF PERSON TO BE CONTACTED ABOUT APPLICATION**

Clifford W. Richter, Ph.D.
405-271-3867

**ITEM 5: RADIOACTIVE MATERIAL**

| Byproduct Material | Chemical/Physical Form | Maximum Amount of Possession |
|---|---|---|
| Cobalt-60 | Sealed sources (General Electric Company AB Elekta Model 43047 | Specify the maximum amount to be possession. Your application states 6700 curies, plus de[illegible]ayed sources at source exchange. |

**ITEM 6: PURPOSE FOR WHICH MATERIAL WILL BE USED**

| Authorized use: |
|---|
| For use, installation, source replacement and temporary storage of a Leksell Gamma System Model 23004 Type B (a.k.a. Gamma Knife) radiation therapy unit for the treatment of humans. |

**ITEM 7: AUTHORIZED USERS**

A. [illegible] A. Medbery, III, M.D.
B. [illegible] Taylor, M.D.
C. [illegible] rison, M.D.

**ITEM 8: INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY**

Item 8.4 GSR Physicist [35.961(a) & (b)]

(X) Full Name: Clifford W. Richter, Ph.D.

(X) Training and Experience
  (X) Authorized on NRC/Agreement State license as medical physicist. License No.35-13058-02 (authorizes Co-60 teletherapy)

**ITEM 9: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**

Item 9.1: Training Program

Item 9.1.1 Training Program for Individuals Responsible for GSR Treatment of Patients

(X) Description of procedure for "team approach"
  (X) Minimum, includes qualified medical physicist and physician.
  (X) Manufacturer's training
  (X) Commitment to instruct personnel
    (X) Before assuming duties
    (X) Annual refresher
    (X) Significant changes in duties

Item 9.1.2 Training for Nursing Staff

(X) Instruction includes following topics:
  (X) Basic radiation biology
  (X) Basic radiation physics (time, distance, shielding)
  (X) Risk estimates
  (X) ALARA
  (X) Posting req.
  (X) Personnel dosimetry
  (X) QM Program
  (X) Emergency procedures
  (X) Occupation dose limits (20.1207)
  (X) Embryo/fetus dose limits (declaration of pregnancy) (20.1208)
  (X) Public dose limits (20.1301)
  (X) Right to be informed of exposure (19.13)
  (X) Report unsafe conditions to RSO (19.12)
  (X) Regs, License conditions, IN, Bulletins
  (X) Location of regs, license, etc.
  (X) Record keeping
  (X) Case Histories regarding incidents
  (X) Q/A

Item 9.1.3 Training for the Medical Physics Staff
(medical physicist, therapists, and dosimetrists)

(X) Instruction includes following topics:

(X) Topics covered for nursing staff
(X) Appropriate surveys
(X) Leak testing
(X) Emergency procedures
(X) Operating procedures (daily PM, patient treatment)
(X) Computerized treatment planning system
(X) Dosimetry protocol

Item 9.1.4 Training for Ancillary Personnel (Housekeeping, dietary services, security, etc.)

(X) Instruction includes following topics:
(NA) May choose to prohibit ancillary personnel from entering restricted area.
(X) Posting/labeling
(X) Precautions

Item 9.1.5 Training for Contractors

(X) Instruct as employees according to appropriateness

Item 9.3 Records

(X) Date
(X) Duration of training
(X) Topics covered
(X) Instructor
(X) Attendees
(X) Maintained for 3 years

**ITEM 10: FACILITIES AND EQUIPMENT**

Item 10.1 Facility Diagram

(X) Annotated drawings for:
(X) GSR suite (X) remote loading device
(X) Scale
(X) Direction of north
(X) Principal use of each room
(X) Location of GSR unit and source within the treatment room
(X) Type, thickness, and density of shielding materials (walls, floor, and ceiling)
(X) Location of doors, windows, conduits, and other penetrations
(X) Adjacent areas- uses of and distances to
(X) Height of earth against outside walls, if applicable

Item 10.2 Survey Instruments and Radiation Monitors

(X) Portable survey instrument meeting (35.620)
(X) Beam-on radiation monitor permanently mounted in suite [35.615(d)]
  (X) backup emergency power supply
  (X) provides visible indication of exposed source
  (X) visible indicator must be readily observable by any person entering suite
(X) Dosimetry system (35.630)
(X) Instrument sufficiently sensitive for counting leak-test samples.
(X) Calibration of instruments
  (X) By manufacturer
  (X) By person authorized by NRC or Agreement State
    (X) Name: HCA Health Services of Oklahoma, Inc.
    (X) License No.35-12091-01
  (X) Frequency of calibration: annually
  (X) Maintain records for 3 years
    (X) Date
    (X) Results
    (X) Name of organization providing service

Item 10.5 Temporary Hot Cell Construction and Source Loading
**(Self-shielded loader used instead of a temporary hot cell)**

(X) Name of service company: Elekta Radiosurgery, Inc. and Alpha Omega Services
(X) Copy of NRC or Agreement State license
(X) Copy of operating procedures
() Copy of agreements regarding radiation safety procedures that will be used during source installation procedures.

Item 10.6 Viewing System (only 1 system required, either/or)

() Viewing window
  () Thickness
  () density
  () Type of material
(X) Closed circuit TV
  (X) Describe backup system, or backup CCTV + intercom
  () Procedure to be used in case electronic system malfunction, or
  (X) Specify treatments will be suspended until electronic system is repaired.

There appears to be inconsistency within your application regarding the viewing system. While you indicate that you plan on a backup CCTV and intercom, Item 10.6 states that treatments will not be done unless CCTV

system is operational. Item E.5.2 C. of Appendix 11.23.9 seems to infer that if the CCTV ceases to work, the patient will be observed visually. Please clarify. If you plan on using a viewing window as backup, provide the applicable information. If you will have a backup CCTV and intercom, please describe.

Item 10.7 Warning Systems and Access Controls (35.615)

() Describe warning systems (e.g.,locks, signs, warning lights and alarms, interlock systems) for each GSR suite
(X) Describe methods for controlling occupancy for each restricted area.
(NA) If 2 radiation-producing units occupy same room, describe steps to ensure both units cannot be operated simultaneously.

Item 10.8 Adequacy of Shielding

(X) Identify each area adjacent to treatment room as restricted or unrestricted.
(X) Submit calculations of maximum radiation levels
  (X) Maximum anticipated workload data
  (X) Value of each parameter used in your calculations
  (X) Contribution from primary, leakage(w/source "on") and scattered radiation
  (X) Calculation for each area adjacent to suite (exclude areas not excavated)
  (X) "Worst case" situations for exposure in adjacent areas
  (X) Consideration of continuous occupancy (factor of unity) for unrestricted areas (except if you request authorization for higher radiation levels)
  (X) Results of calculations in mrem in any 1 hour and mrem in any 1 day, or milliSieverts in any 1 hour and milliSieverts in any 1 day
(X) For each unrestricted area, state how you will meet 10 CFR 20.1301, or
(NA) Request authorization for higher levels by providing information required by 10 CFR 20.1301(c)
✓ For each unrestricted area, describe you program for meeting Parts 19 and 20
  ✓ Physical and administrative controls used to restrict access to restricted area
  ✓ Number, wording, size, and location of warning signs for restricted area
  ✓ Program for ensuring that personnel entering restricted area are instructed in accordance with 10 CFR 19.12
  ✓ Program for ensuring that personnel entering restricted area are monitored.
  ✓ Surveys performed per 10 CFR 20.1501 and 35.641.

**ITEM 11: RADIATION SAFETY PROGRAM**

Item 11.1 Personnel Monitoring Program

(✓) Appendix D of RG 10.8, Rev.2 implemented and followed

() Equivalent procedures implemented and followed

Item 11.2 Radiation Safety Committee (RSC)/Radiation Safety Officer (RSO)

(✓) Appendix F of RG 10.8, Rev.2 implemented and followed

() Equivalent procedures submitted

Item 11.3 ALARA Program

(✓) Appendix G of RG 10.8, Rev.2 implemented and followed

() Equivalent procedures submitted

Item 11.4 Leak Test

(✓) Appendix H of RG 10.8, Rev.2 implemented and followed

() Equivalent procedures submitted

Item 11.21 Emergency Instructions

(✓) Submit copy of procedures, minimum to include

(X) When procedures are to be followed

(X) Step-by-step actions to be taken and by whom

(X) 1st consideration should be minimizing exposure to patient (usually by removing patient)

(✓) Instruct staff to act quickly and calmly and avoid primary beam

(X) Require room to be secured as soon as staff and patient are out of room

(✓) Specify who will be notified. (Names of at least 2 individuals and on- and off-duty telephone numbers)

Item 11.22 GSR Survey Reports

(X) 10 CFR 35.641 report

(X) Name, address, and license no. of organization providing service

(X) Name, address of each person conducting survey

(X) Describe reason for survey (installation, relocation)

(X) Date work completed
(X) Date survey conducted
(X) Info about radiation detection instrument used
  (X) Manufacturer's name and model number
  (X) Date of last calibration
  (X) Standard and procedures used in calibration
(X) Manufacturer's name and model name and number of GSR unit
(X) Manufacturer's name and model number of GSR sources
(X) Activity of each source and assay date
(X) Intensity of primary beam at isocenter and date measured
(X) Maximum and average radiation levels measured at 1 meter from sources in off position
  (X) Describe location of the 14-26 points and levels measured at each point
(X) Describe phantom used when measuring radiation levels in adjacent areas, including composition of phantom and size.
(X) Plan and elevation drawings of GSR facility (reference Item 10.1)
  (X) Identify location at which radiation levels were measured
(X) Describe tests conducted and results of tests to ensure proper operation of safety systems
  (X) GSR treatment room door interlock (35.615)
  (X) GSR treatment timing device
(X) If GSR unit or sources removed provide:
  (X) Date of removal
  (X) Name, address, and license no. of person who took possession of unit/sources.
(X) Describe recommendations of surveyor to improve safety operations and your response to recommendations.

Item 11.23 Operating Procedures for GSR

Item 11.23.1 Use of the GSR Unit
( ) Who may operate the unit
( ) How unit may be used
( ) How unit is to be operated (sequence of steps to follow)
(X) Who must be present during treatment
(X) Ensure that only patient is in the room when the primary beam on
(X) Specify daily checks to ensure proper operation

Item 11.23.2 Safety Device Checks
( ) Instructions for making checks Follow manufacturers recommended procedures
( ) Recommended frequency - once a week
( ) Prompt correction of malfunction or defects noted
(X) Record of check made (can use a simple checklist)

(✓) In event of malfunction, steps that personnel will follow should delay in correction occur

Item 11.23.3 Periodic Spot-Check Measurements of GSR Units (35.634)

(X) Performed once each calendar month

(X) Properly calibrated dosimetry system required (35.630)

(✓) Specify when, how, and by whom the spot-check measurements will be made

We understand that this procedure will be performed by the GSR physicist.

(NA) Procedures established by GSR physicist

(✓NA) GSR physicist to review and initial spotcheck results within 15 days of being conducted.

Item 11.23.4 Inspection and Servicing of the GSR Unit (35.641)

(X) Fully inspected and serviced during source replacement, or at intervals not to exceed 5 years

(✓) Preventative maintenance to ensure that systems that deteriorate from use are identified and repaired. Manufacturer will perform

Item 11.23.5 Limitations on Work Done on GSR Unit

(X) Work limited to authorized persons (35.605)

(X) Install, relocate, remove sealed source or unit

(X) Maintenance, adjustment, repair of unit that involve mechanisms that could expose source, etc.

() Operating procedures sufficient to ensure compliance

Item 11.23.6 Survey Reports (Reference Item 11.22)

(X) Who will perform formal surveys

(✓) How and when surveys will be conducted

(✓) When and to whom copies formal report will be sent

Please provide copies of reports of surveys, checks, tests, and measurements required by 10 CFR 35.645

Item 11.23.7 Relocation of GSR Unit (35.606)

(X) Operating procedures ensure compliance (amendment request required)

Item 11.23.8 Recordkeeping

(X) OP identifies individual responsible for maintaining records

() Records consist of:

(✓) License, and supporting licensee documents

(X) Results of safety device checks

(✓) Personnel dosimetry records

- Survey instrument calibrations and daily check
- Daily checks of beam-on monitor
- Daily checks of audible-alarm personal dosimeter
- Calibration of dosimetry system used for full calibration
- Calibration/intercomparison of dosimetry system for spot-check measurements
- (X) Full calibration measurements
- (X) Spot-check measurements
- (X) Leak-test results
- Training of new personnel and annual refresher
- (X) Full inspection and servicing of unit
- (X) Reports of surveys
- (X) Receipt and disposal records

Item 11.23.9 Safety Instructions (35.610)

- (X) Written emergency instructions established (Item 11.21)
- Posted at console
- Practice drills at least once a year
- (X) OP specified categories of occurrences that require notification
- Names and telephone numbers to be notified

**ITEM 12: WASTE DISPOSAL**

Item 12.3 Returning Sources (20.2001-20.2007)

- (X) Transfer to authorized recipient (20.2001(a)(1)

DOCUMENT NAME: G:\HCAgamma.ltr

To receive a copy of this document, indicate in the box "C" - Copy without attachment/enclosure "E" - Copy with attachment/enclosure "N" - No Copy

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| RIV:NMLB | N | | | | | | |
| VHCampbell | | | | | | | |
| 10/31/96 | | | | | | | |

OFFICIAL RECORD COPY

N.K. Campbell

$I = I_0 e^{\frac{-.693\ x}{HVL}}$ where: $I_0$ = initial dose rate

$\frac{I}{I_0} = e^{\frac{-.693}{HVL}x}$ $I$ = final dose rate

$x = \frac{-\ln(I/I_0)}{.693/HVL}$ HVL = half value layer

$x$ = thickness of shielding

$n_{TVL} = -\log I/I_0$ where: $I$ = final dose rate

$I_0$ = initial dose rate

$n_{TVL}$ = number of tenth value layers

## Control Area Wall (south)

Assume: 1) Control room will be occupied during working hours (40 hours/week) This area is controlled and public does not have general access. No need to consider 7 day/week exposure

2) Using Elekta drawing #43834 (leakage points @ 1 meter according to NCRP 33), consider measurement points 5, 24, +25 for source activity of 6600 Ci of Co-60. [.77 mrem/h]

3) According to licensee, distance from leakage point to occupancy point equal to 1.22 meters

Leakage calculation:

$(0.77\ mrem/h)(40\ h/wk) \div (1.22\ m)^2 = 20.7\ mrem/wk$

$x = \frac{-\ln(2\ mrem/wk / 20.7\ mrem/wk)}{.693/6.2}$

$HVL_{concrete} = 6.2\ cm$

final dose rate = 2 mrem/wk

$x = 20.9\ cm$ [thickness of concrete]

$= 8.2283$ inch

$2.54\ cm = 1$ inch

$10\ \mu Sv\ h^{-1} = 1\ mrem\ h^{-1}$

Scatter calculation:

Using Elekta drawing # 43818: maximum scatter occurs when patient is transitioning into and out of TX position. [6 mrem/h]

Beam on time determined by licensee using following assumptions

1) 1 patient Tx per day
2) dose at focus = 5000 rads [range 1800 - 8000 rads]
3) dose rate at loading assumed @ 300 rads/min for 6000 Ci Co-60
4) # foci per patient = 5 [range 1-8]
5) Transition time = 1 min going into Tx position and 1 min going out of Tx position.
6) Physics use = 1 h/wk

$5000 \text{ rads} / 300 \frac{\text{rad}}{\text{min}} = 16.7 \text{ min}$

16.7 min + 2 min (door open during transition) = 18.7 min

(18.7 min)(5 foci/patient)(5 patients/wk) = 466.7 min beam on/wk

466.7 min = 7.8 h

Total beam on time = 7.8 h + 1 h physics use

= 8.8 h (~ 9 h/wk)

(6 mrem/h)(9 h/wk) = 54 mrem/wk

$$\gamma = \frac{-\ln[2 \text{ mrem/wk} / 54 \text{ mrem/wk}]}{.693/4.4 \text{ for } 120^\circ \text{ scatter}}$$

$= 20.9259 \text{ cm} / 2.54 \text{ cm}$

$= 8.2386 \text{ inches}$

$n_{(TVL)} = -\log[2 \text{ mrem/wk} / 54 \text{ mrem/wk}]$

$n_{(TVL)} = 1.4314$

$(1.4314)(14.5 \text{ cm}_{TVL}) = 20.7548_{cm}$

$= 8.1712 \text{ inches}$

* Licensee recommended 12 inches of concrete

Entry Door: (lead)

Licensee assumed:

1) Area in front of door 1/2 occupied (occupancy factor)
2) Using Elekta drawing # 43834, measurement point 25 used
3) Distance from measurement point to occupied area = 2.13 meters
4) Angle of scatter = 45°

Leakage calculation:

$$\frac{(1.09\ \text{mrem/h})(40\ \text{h/wk})(.5\ \text{occupancy factor})}{(2.13\text{m})^2} = 4.805\ \text{mrem/wk}$$

$$\mu = \frac{-\ln(2/4.805)}{.693/0.87_{(Pb)}}$$

$$= 1.1004\ \text{cm (Pb)}$$

$$n_{(TVL)} = -\log(2/4.805)$$

$$= .3807$$

$(.3807)(2.9_{(Pb)}) = 1.104\ \text{cm (Pb)}$ for 45°

$(.3807)(4.0_{(Pb)}) = 1.52\ \text{cm Pb}$ for primary

Scatter calculation:

licensee assumed:

1) According to Elekta drawing # 43818, maximum scatter 5 mrem/h

$(5\ \text{mrem/h})(9\ \text{h/week})(.5\ \text{occupancy factor}) = 22.5\ \text{mrem/wk}$

$$\mu = \frac{-\ln(2/22.5)}{.693/.2}$$

$\mu = .6985\ \text{cm Pb}$ for 120° scatter

$$n_{(TVL)} = -\log(2/22.5)$$

$$= 1.05$$

$(1.05)(0.65) = 0.6825\ \text{cm Pb}$ for 120° scatter

licensee recommended 1/2 inch Pb doors (1.27 cm)

## East Wall

Licensee assumed:

1) occupancy factor = 1 (potential for fulltime occupancy in future)
2) measurement point 6 used for leakage calculation
3) Distance from point 6 to occupied area = 3.66 meters

Leakage calculation:

$$\frac{(.64\ \text{mrem/h})(168\ \text{h/wk})}{(3.66\ \text{m})^2} = 8.025\ \text{mrem/wk}$$

$$T = \frac{-\ln(2/8.0265)}{(.693/6.2)}$$

$= 12.4322$ cm

$= 4.8946$ inches concrete

$n = -\log(2/8.0265)$

$= .6035$

$(.6035)(20.6\ \text{cm}) = 12.4383$ cm

$= 4.897$ inches

## Scatter calculation:

Using Elekta drawing # 43818, primary radiation is maximum during transition stage and is 120 mrem/h

$(120\ \text{mrem/h})(9\ \text{h/wk}) = 1080\ \text{mrem/wk}$

$$T = \frac{-\ln(2/1080)}{.693/6.2}$$

$= 56.2882$ cm

$= 22.1607$ inches concrete

$n = -\log(2/1080)$

$= 2.7324$

$(2.7324)(20.6\ \text{cm}) = 56.2873$ cm

$= 22.1604$ inches

* Licensee assumes that the scattered radiation strikes the wall at a 50 degree angle. They used the cosine 45°

(cosine 45°)(22.1604)

$(.7071)(22.1604) = 15.6698$ inches concrete

licensee added 1 HVL for buildup factor = 17.4 inches

Licensee recommended 18 inches of concrete

North Wall

① licensee used an occasional occupancy factor of 1/16 because there is a driveway outside the North wall.

2) Using Elekta drawing # 43819, exposure = 100 mrem/h.

Leakage calculation:

1) According to Elekta, the maximum air kerma rate is located at the lower part of the lower shielding door. At 5cm distance from that surface, maximum dose rate measured is 50 mrem/h. at 60 cm, the maximum reading is 5 mrem/h.

2) The licensee measured 5.3 meter from the 5 mrem/h distance to the North Wall.

$$\frac{(5)(1/16)(168)}{(5.3)^2} = 1.869 \text{ mrem/wk}$$

? + no shielding needed for leakage according to licensee

$$\frac{(50)(1/16)(168)}{(5.4)^2} = 15.0819 \text{ mrem/wk}$$

~~Scatter calculation~~

$$\alpha = \frac{-\ln(2/15.0819)}{.693/6.2}$$

$\alpha = 18.0753$ cm
$= 7.1162$ inches

$$n = \frac{-\log(2/15.0819)}{}$$

$n = .8774$

$(.8774)(20.6) = 18.07$ cm
$= 7.1141$ inches

Scatter calculation

1) according to Elekta drawing 43819, dose rate at wall = 100 mrem/h

(100 mrem/h)(9h/wk)(1/16 occupancy factor) = 56.25 mrem/wk

$n = -\log(2/56.25)$
$= 1.4491$

(100 mrem/h)(10h/wk)(1/16) = 62.5 mrem/wk

$n = -\log_{}(2/62.5) = 1.4949$

$(1.4491)(20.6) = 29.8513$ cm
$= 11.7525$ inches

$(1.4949)(20.6) = 30.7939$ cm $= 12.12$ inches

licensee recommended 14 inches of concrete

## West Wall

1) Using Elekta drawing, measurement point 4
2) Distance = 1.8 meters
3) Occupancy factor = 1

$$\frac{(.62\ \text{mrem/h})(1)(40\ \text{hrs/wk})}{(1.8\text{m})^2} = 7.65$$

Leakage calculation:

$$x = \frac{-\ln(2/7.65)}{.693/6.2}$$

$= 12.0$ cm
$= 4.7$ inches concrete.

$n = -\log(2/7.654)$
$n = .58$
$(.58)(20.6) = 12.0$ cm
$= 4.7$ inches concrete

Scatter calculation:

Elekta drawing - max exposure = 400 mrem/h

$(400\ \text{mRem/h})(9\text{h/wk})(1) = 3600$ mrem/wk

$$x = \frac{-\ln(2/3600)}{.693/6.2}$$

$= 67.06$ cm
$= 26.4$ inches

$n = -\log(2/3600)$
$= 3.255$
$(3.26)(20.6) = 67.16$ cm
$= 26.44$ inches
$(\text{cosine } 45)(26.4) = 18.7 + 1\text{HVL}$
$= 21.1$ inches

Licensee recommended 42" concrete because of location of linear accelerator.

Ceiling — N H Campbell

licensee assumed occupancy factor of 1/16 – roof

Leakage calculation:

measurement point 1 = .67 mrem/h

distance = 1.49 m

$$\frac{(.67)(168\ h/w)(1/16)}{(1.49)^2} = 3.17\ \text{mrem/wk}$$

$$x = \frac{-\ln(2/3.17)}{.643/6.2}$$

$= 4.12$ cm

$= 1.62$ inches

$n = -\log(2/3.17)$

$= .1999$

$(.1999)(20.6) = 4.12$ cm

$= 1.62$ inches

Scatter calculation:

1) Elekta drawing states dose rate at 120 mrem/h, 4 meters off floor.

2) licensee assumed dose rate of 100 mrem/h because ceiling is 5.2 meters.

$(100\ \text{mrem})(9)(1/16) = 56.3$ mrem/wk

$(120\ \text{mrem})(9)(1/16) = 67.50$ mrem/wk

$n = -\log(2/67.5)$

$= 1.53$

$(1.53)(20.6) = 31.48$ cm

$= 12.4$ inches

$(\cos 45°)(12.4) = 8.8$

$n = -\log(2/56.3)$

$= 1.45$

$(1.45)(20.6) = 29.9$ cm

$= 11.8$ inches

$(\cos 45°)(11.8) = 8.3$ inches

licensee recommend 10 inches concrete

ELEKTA

LEKSELL GAMMA KNIFE

# TECHNICAL PROGRAM


This binder belongs to:

_____


Art. No. 001057/00. Jan. 95

# Caution

The Leksell Gamma Knife is a sophisticated medical instrument designed exclusively for treatment of the human brain. This instrument must not be used for treatment of any part of the human body other than the brain.

Any procedures performed using the equipment must be done by validly licensed (depending on requirements of the user's state and country regulations) and qualified neurosurgeons, radiation oncologists, and radiation physicists, who are trained and experienced in stereotactic techniques and Gamma Knife radiosurgical procedures.

While every effort has been made to make this Manual understandable, certain sections may be difficult to understand, depending upon the user's background and experience. Do not use the equipment if there is any instruction, direction, precaution or note which you do not understand or which is unclear. Contact an authorized Elekta representative for further information and clarification before proceeding to use the equipment.

It's very important that all personnel working with, and around, the Leksell Gamma Knife have read the User's Manual.

Neither Elekta Instrument S.A. nor any of its affiliates represent that the Gamma Knife will be useful for the treatment of any particular condition or in any set of circumstances. The neurosurgeon using the Gamma Knife is responsible for assessing each situation, based on the patient's condition and the neurosurgeon's experience. While experience has shown that the Gamma Knife is useful in treating certain conditions, no representation or warranty has been, or will be made, that the Gamma Knife will be useful in treating any particular person or condition. The only warranties related to the Gamma Knife are those explicitly set forth in the Purchase Agreement between the Purchaser of the Gamma Knife and the Elekta Instrument S.A. or Elekta Instruments Inc.

# Technical Training Manual Conventions

To make the user of this Technical Training Manual aware of especially important instructions or consequences, the following indications are used.

**Danger:** Dangers are marked red and used when there is risk of serious injury or death for the patient.

**Warning:** Warnings are marked orange and used when a mistake in the procedure may have serious danger or harmful consequences for the patient.

**Caution:** Cautions are marked yellow and used when the operator can choose an alternative to the normal procedure. This alternative may cause harmful consequences for the patient if the operator is not absolutely sure of his actions.

**Note:** Notes are used when the consequences involve only the equipment and there is no danger to the patient.

ELEKTA

1

# General Principles of Stereotaxy

*This chapter gives the reader an introduction and description of the principles of stereotaxy and Gamma Knife surgery.*

# CONTENTS

# Definition of Stereotaxy

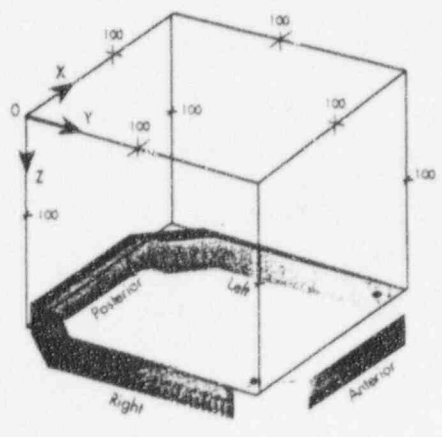
The spelling of the word stereotactic is derived from the Greek word *stereo* for three-dimensional and the Latin word *tactus* meaning to touch. Stereotactic surgery involves more than merely displaying the brain in three dimensions. It also makes it possible to touch structures deep within the brain, without visual control (Ph. L. Gildenberg in L. D. Lunsford, 1988).

# Cartesian Coordinate System

The principles of stereotactic surgery are based on the use of either a rectilinear or polar coordinate system.

It was observed early that it is possible to define the location of an individual point in space by relating it to three planes intersecting each other at right angles. To define a point, one must define three coordinates, each corresponding to the distance between the point and one of the intersecting planes (Gildenberg in Lunsford, 1988), along a line perpendicular to that plane.

The rectilinear coordinate system of the Leksell frame has its origin outside the frame, superior, posterior and lateral to its right side. It conforms with the X-, Y- and Z-nomenclature used in CT- and MR-scanning. The coordinate scales on the frame indicates positive values only.




*The coordinate system with its origo.*

# Arc Centre Principle

Stereotactic instrument are of different designs. The four basic designs include the burr-hole mounted systems, the translational and the interlocking arc instruments, and finally, the arc-centre systems. Of these, the most frequently used are the two latter types.

Although most instruments in use today have similar capabilities, they nonetheless have different characteristics which mainly translate into differences in their practical use. There is little doubt that the arc centre principle, pioneered by Leksell in 1949, coupled with a rectilinear or Cartesian coordinate system, makes the instrument more intuitive and easier to use.

The arc centre design is based on two conditions:

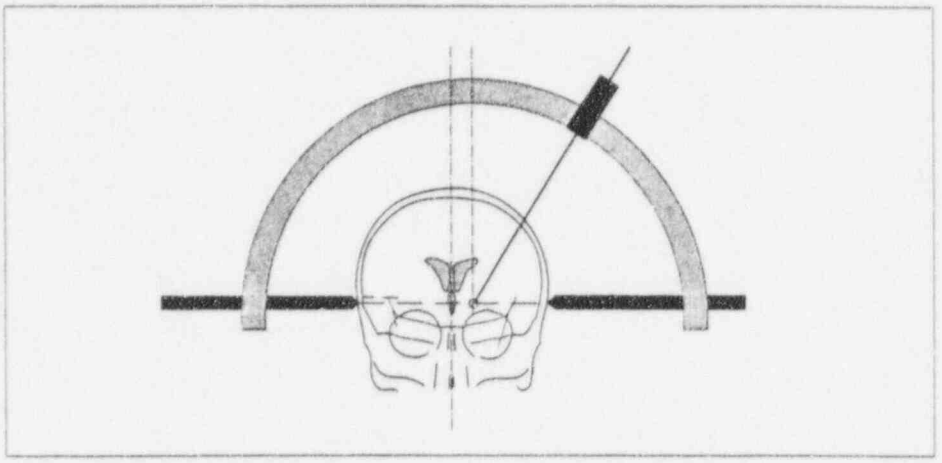
1. That the stereotactic arc represents a segment of a perfect circle.
2. That all instruments, i.e. electrodes, biopsy forceps etc., that are passed through the arc have a known and fixed length which must equal the radius of the arc.

Given these two requirements, the surgical procedure is easily described and the benefits of the arc centre principle easily understood:

By applying the coordinate frame to the patient, the surgical target is encompassed by a well defined three-dimensional space, i.e. the stereotactic space.

The localization procedure has the purpose of assigning a numerical value to each one of the three axes of the coordinate system (X, Y, Z). The target point is thereby defined by the point of intersection of all three axes.

By attaching the semicircular arc to the frame, its centre is brought to exactly coincide with the point, X, Y and Z described above. Since the probe to be used has the same length as the arc radius, its tip will always be on the target when it is inserted to its full length.



*The arc centre principle.*

In addition, since the arc can be tilted back and forth and since the instrument holder slides along the whole arc, the target can be approached from an infinite number of points, limited only by the anatomy of the patient.

When applied to the collimator helmet of the Gamma Knife, the basic principle of the stereotactic arc remains unchanged. The only difference is that, in the case of the Gamma Knife, we deal with a segment of a perfect sphere, rather than a segment of a circle.

# Bibliography

Philip L. Gildenberg General concepts of stereotactic surgery referred in: L. Dade Lunsford: Modern Stereotactic Surgery, Martinus Nijhoff Publishing, Boston, 1988.

# 2

# Design and Construction

*This chapter describes the construction of the Leksell Gamma Knife (LGK) type 23004, the main parts will be shown, and their names will be given.*

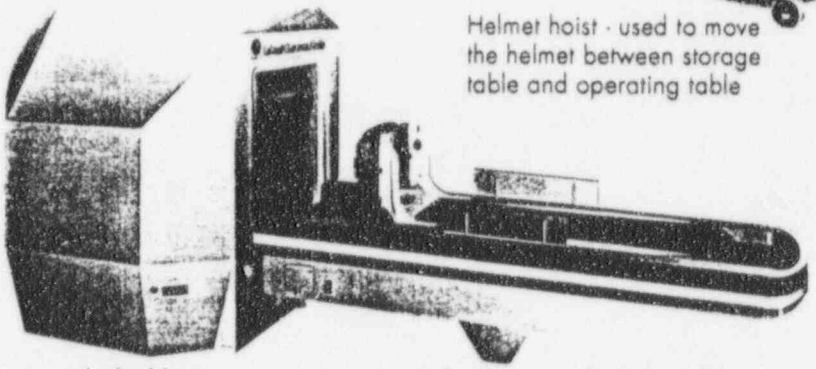
# Contents

# General Description of the Leksell Gamma Knife and Auxiliary Equipment

Control panel - from this the Leksell Gamma Knife is operated

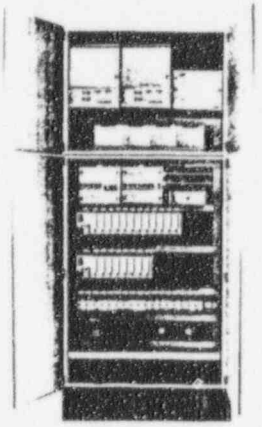
TV camera

Helmet hoist - used to move the helmet between storage table and operating table

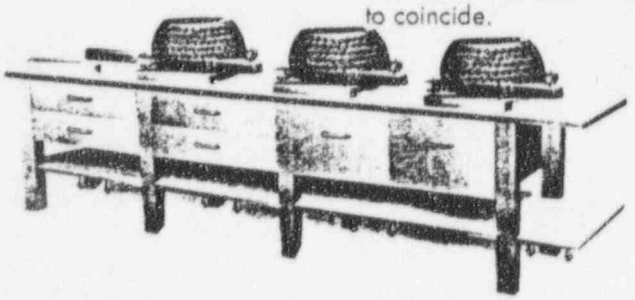


Radiation unit with shielding for the $^{60}$Co-sources.

Operating table with mobile couch



Helmet with collimator used to get the gamma radiation from each individual source to coincide.

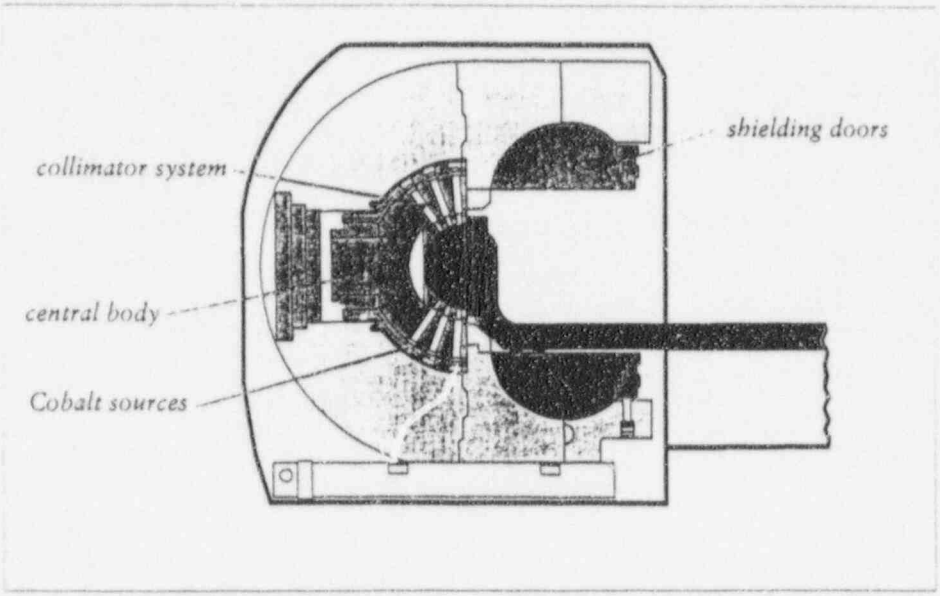


Helmet Storage Table

Electrical cabinet - distributes power and controls the Leksell Gamma Knife functions, connected to the control panel

*General view of the Leksell Gamma Knife package main parts.*

# Radiation Unit

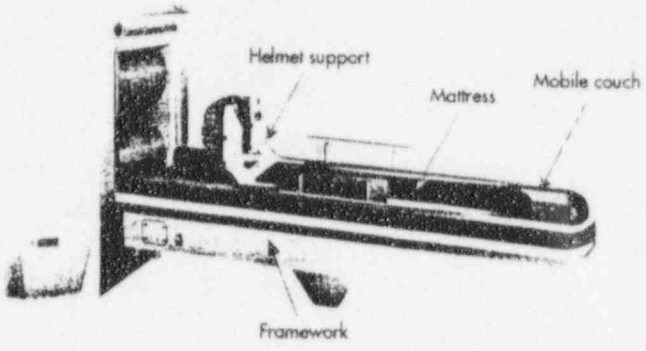



*Cross-section of the Leksell Gamma Knife*

The radiation unit contains 201 $^{60}$Cobalt sources distributed about a hemispherical central body. These sources are heavily shielded in order to provide adequate radiation protection for the patient and hospital staff.

During treatment the shielding doors open, allowing the patient to be moved into treatment position by the operating table. The doors are electrically driven.

# Operating Table

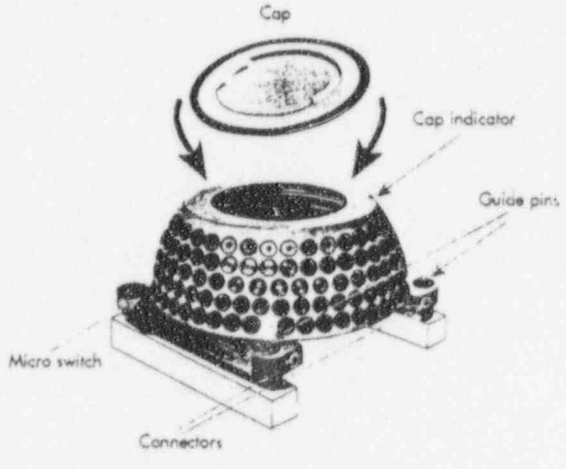



*View of the operating table.*

The operating table consists of a framework and a mobile couch with a helmet support. The mobile couch constitutes the movable patient couch and is driven by an electrical motor system.

# Helmets

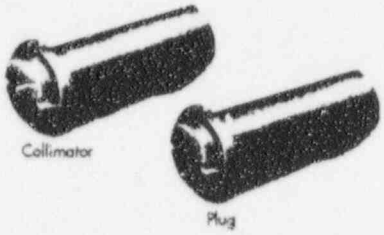
The Leksell Gamma Knife is provided with four helmets made of cast iron and perforated with 201 precision drilled holes for the collimators.




*The helmet has 201 precision drilled holes, where collimators are mounted .*

## Collimator System

There are four different sizes of collimators and each helmet has a dedicated set of 201 openings of the same size. These collimators are placed in the 201 perforations in the helmet. A collimator can be replaced by a plug and thereby radiation beam may be blocked.



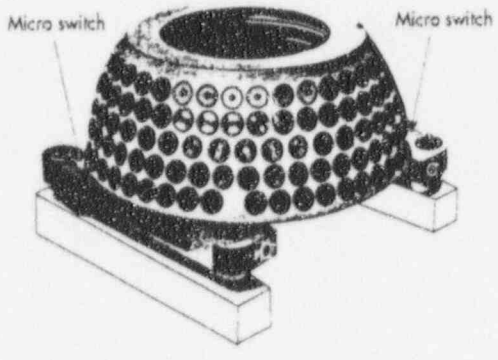

*Final collimator and plug*

The collimators and plugs are made of tungsten.

# Micro Switches

To verify that the helmet is in the correct treatment position in the radiation unit, each helmet is provided with two micro switches.

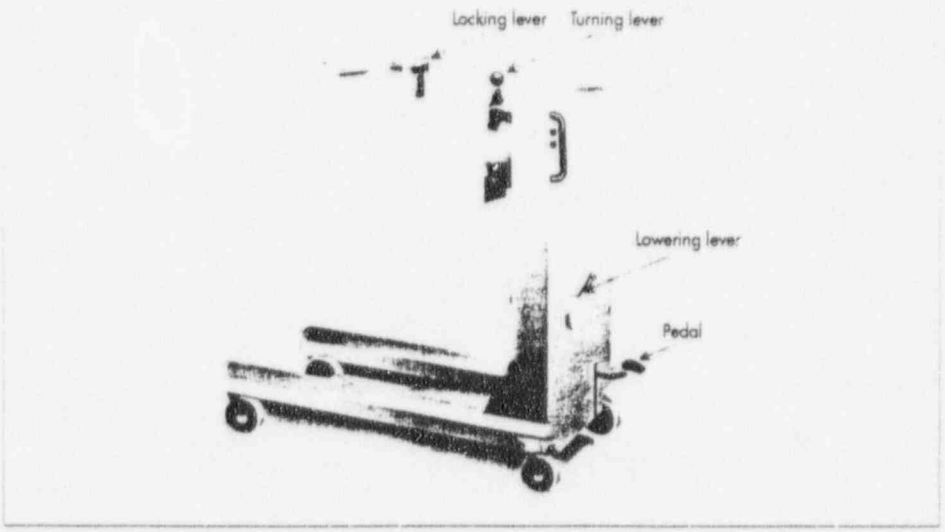
When the micro switches are in contact with the central body, correct position is verified.




*Helmet micro switches are used to verify that the helmet is in correct treatment position.*

# Helmet Hoist

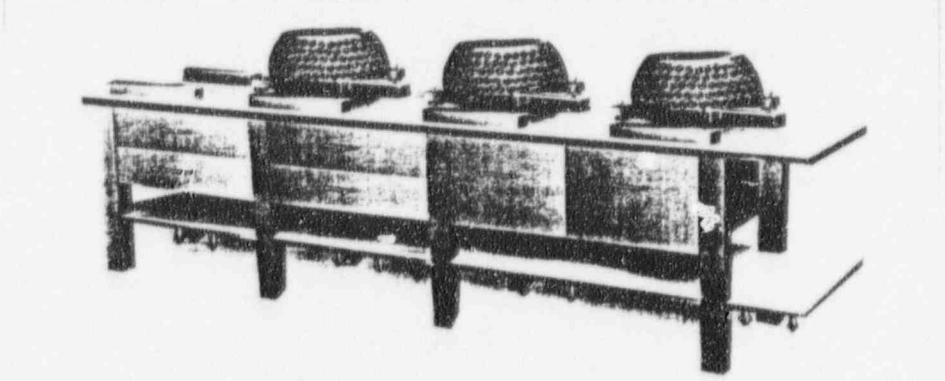
The helmet hoist is operated manually and is used to handle the helmets when moving them between the helmet storage table and the Leksell Gamma Knife.




*Helmet hoist and its different parts.*

# Helmet Storage Table

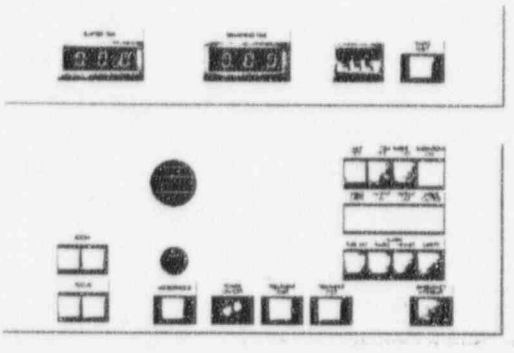
The Leksell Gamma Knife is delivered together with a helmet storage table where the helmets, tools and collimators are kept.



*The helmet storage table can store four helmets, collimators and the different tools needed for mounting and testing.*

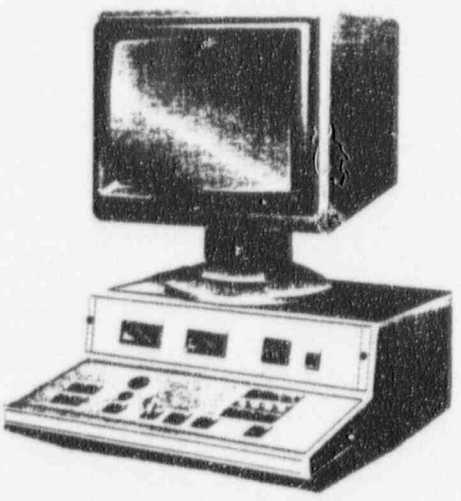
# Control Panel and Audio System

The control panel is located in an adjacent area separated from the treatment room. The Leksell Gamma Knife is operated from this panel.



*Control panel.*

A camera is mounted in the treatment room so that the patient can be supervised on a monitor, and an intercom system enables conversation between the doctor and the patient.

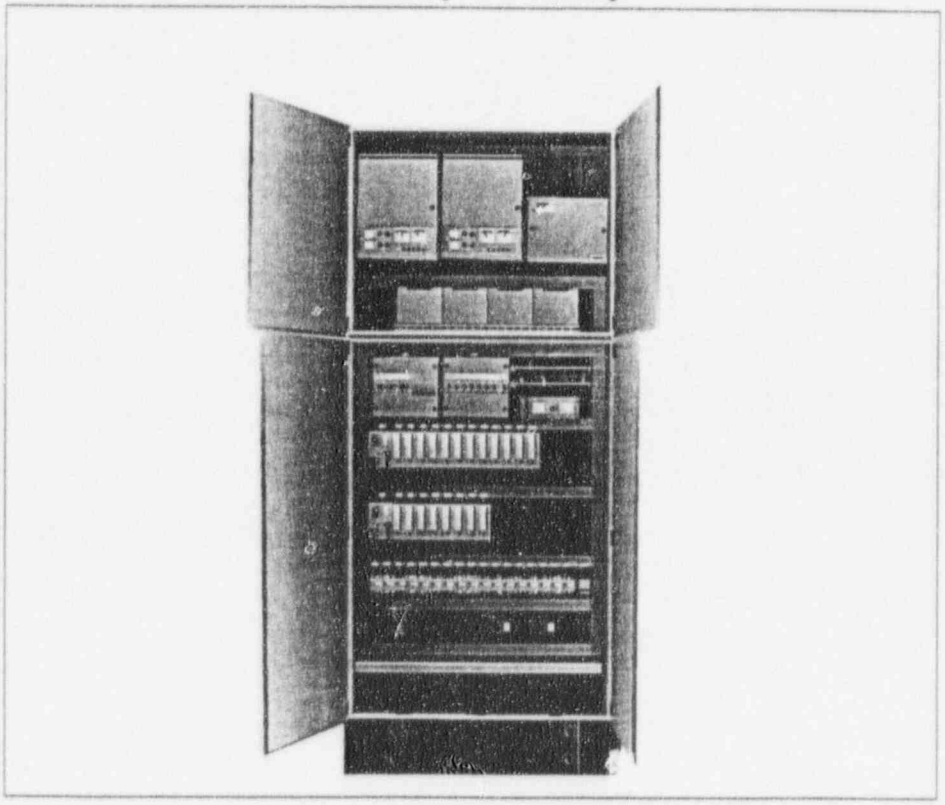


*The patient can be viewed on a monitor placed on the control panel.*

# Electrical Cabinet

Note that the cabinet among other things contains the following:

- conversion and distribution of power.
- Control system with two Programmable Logic Control (PLC) units (one for backup) which initiates the treatment procedures
- batteries for electrical power backup.



*Electrical cabinet*

# 3

# Functions

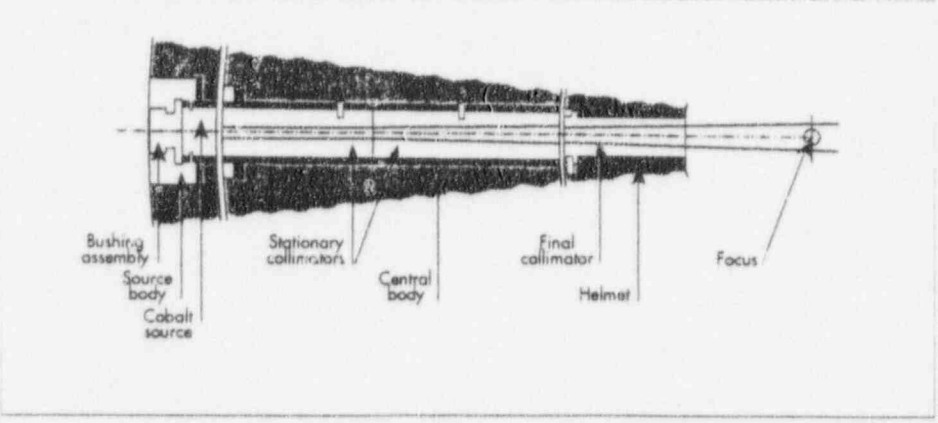
*This chapter describes the functions of the Leksell Gamma Knife (LGK), model 23004, and it's control panel.*

# Contents

# Collimator System

The central body contains 201 $^{60}$Cobalt sources. The beam from each individual source is collimated and converged to the common focal point at the centre of the radiation unit.

The helmet with collimators constitutes the final segment of the beam channel.



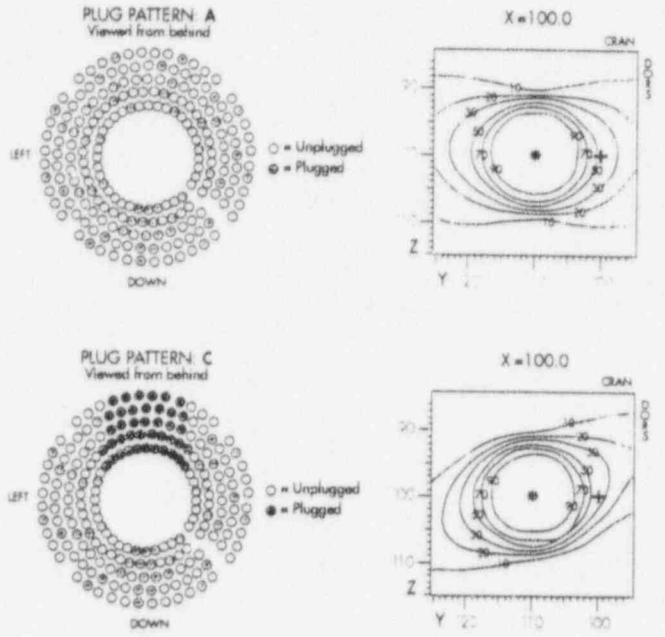

*Cross-section of the collimator system.*

The configuration of the dose distribution can be varied in a number of ways. The dose may be delivered as a single "shot" through one helmet or several shots may be used with any combination of collimator helmets.

The number of shots and dosage is a clinical matter to be decided by the operating team.

The Leksell Gamma Knife is delivered with four different collimator sizes; 4 mm, 8 mm, 14 mm, 18 mm. These sizes refer to the diameter of the 50% isodose in the X-Y plane.

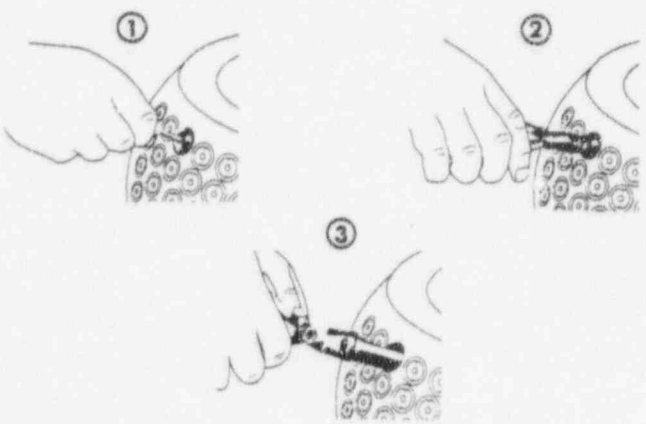
In addition, collimators may be plugged for one or more shots to give extra accuracy of dose distribution.




*When using plugs instead of collimators the isodose can be shaped.*

## Plugging

When it is necessary to use plugging, a given radiation beam may be blocked by replacing the relevant tungsten collimator with its central channel with a solid plug with no channel. This is illustrated below.

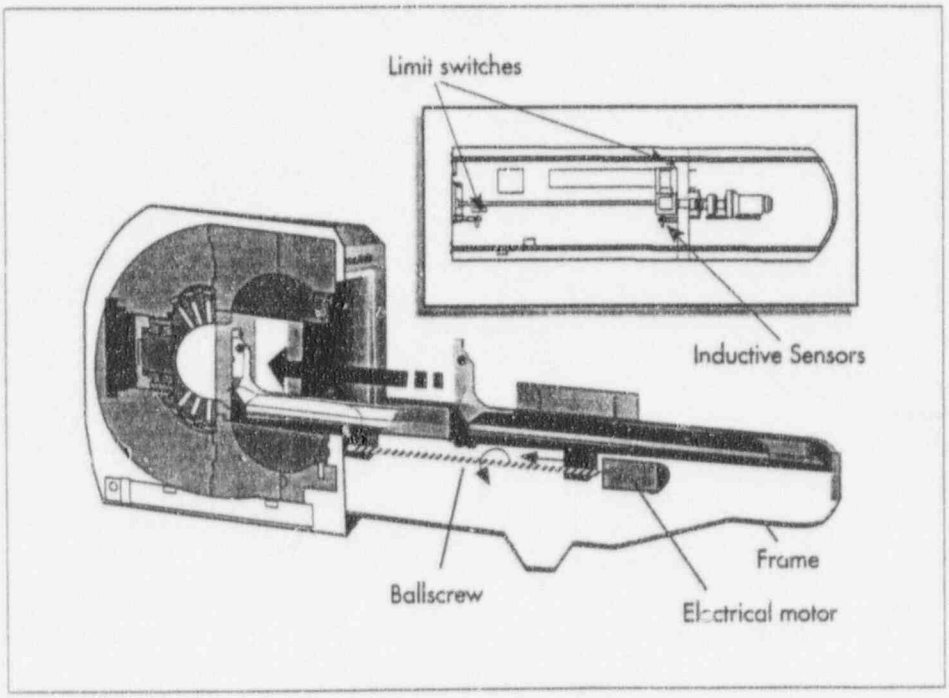



*Use special screwdriver to turn the collimator to release position, use thereafter the special tong to withdraw the collimator.*

Thereafter mount the selected plug or collimator, using the same tools.

**Note:** Do not forget to secure the mounted plug or collimator.

# Couch with Framework



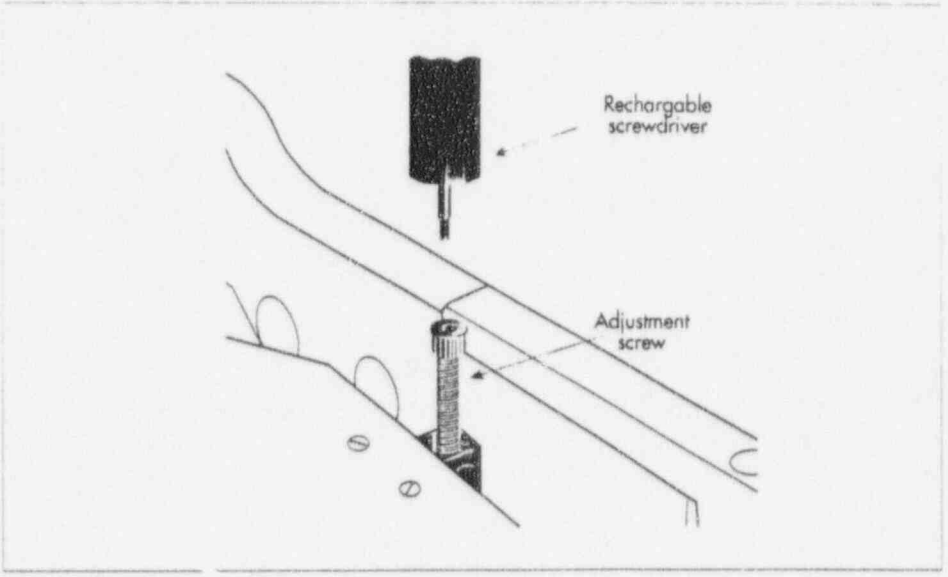

*Cross-section of the framework*

To indicate the position of the couch, there are several sensors and limit switches mounted on the framework of the operating table. The limit switches stop the couch when it is in its outer or inner position. Inductive sensors are placed near the limit switches in order to slow down the movement of the couch just before it reaches the end positions. Moreover, the limit switches and the sensors indicate the treatment cycle status on the control panel.

# Check the Couch Adjustment

The couch is mobile and provided with a pad, adjustable in height in order to give the patient a comfortable position during treatment, and to enable the patient's head with its attached stereotactic frame, to be placed correctly for fitting into the helmet.

Be sure to adjust gradually when shifting between the left and the right adjustment screws.

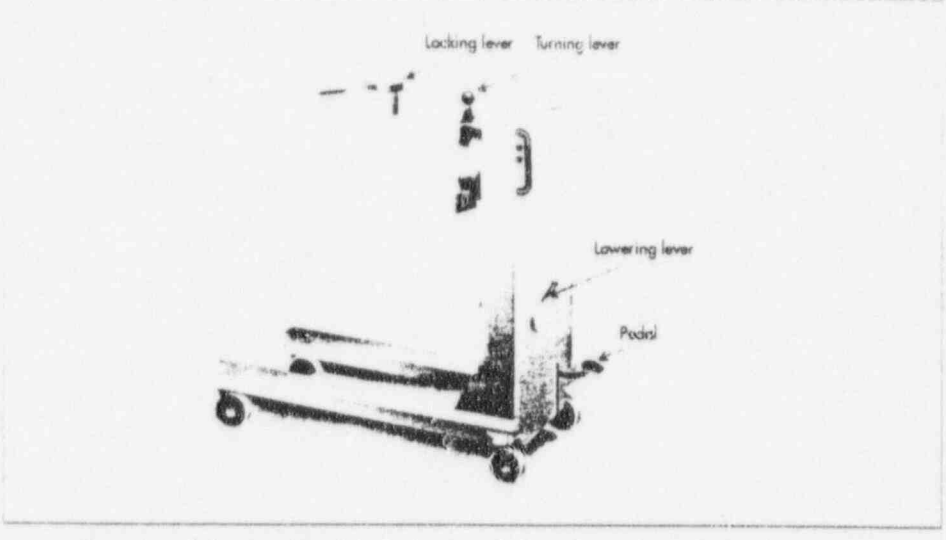



*Use the rechargeable screwdriver to achieve the correct height on the couch.*

Minor adjustments may be done when the patient is in place.

# Helmet Hoist

When a helmet is not in use, it is placed on the Helmet Storage Table. The helmet hoist is used to transport and to mount the helmet on the mobile couch.



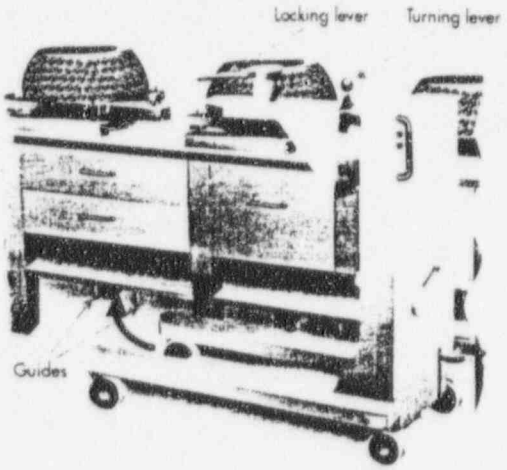

*Because of the weight of the helmets a helmet hoist must be used when transporting and mounting the helmet on the mobile couch.*

The helmet shelf is lifted by pumping the pedal, and lowered by turning the lever.

**Caution:** Never attempt to lift the helmet manually.

## Mounting and Dismounting Helmet

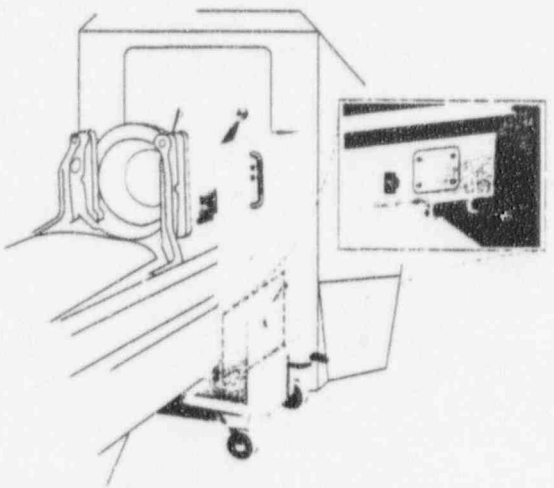
1. Push the hoist correctly into the table by using the guides under the table (see illustration on next page).
2. Lower the helmet shelf towards the helmet.
3. Secure the helmet to the shelf with the locking lever when it is in position.




*The helmet hoist must be pushed correctly into the helmet storage table when getting a helmet for transportation.*

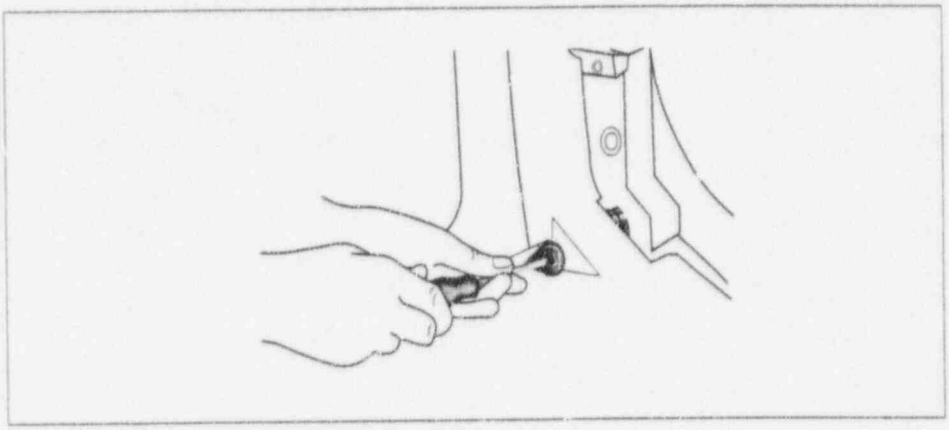
4. Lift the helmet up and pull the hoist out from the table. Tilt the shelf and lift it to its upper position.

**Note:** It is important that the tilted shelf is lifted to its upper position before pushing the hoist to the couch.

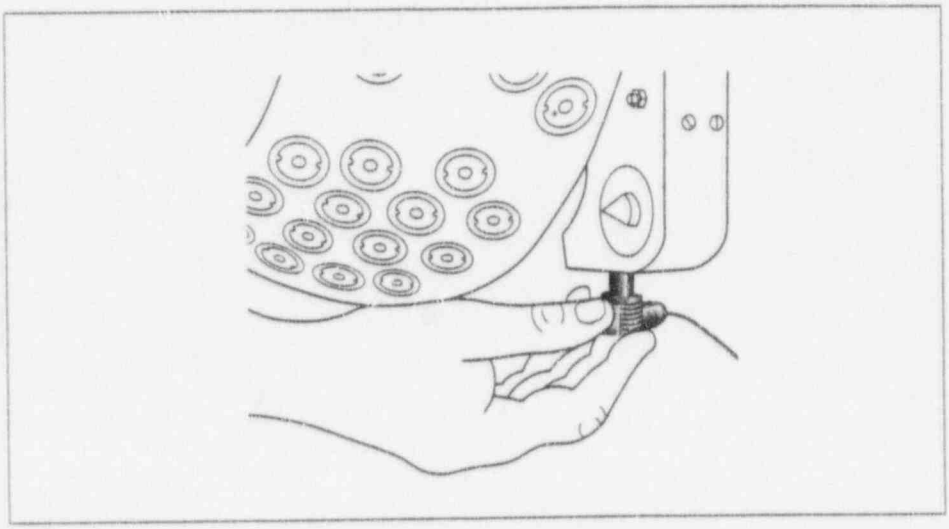


*Push the hoist to the couch and use the guides on the framework to get it in correct position.*

5. Secure the helmet to the helmet support and connect the two plug-in connectors.



*The helmet must be secured to the helmet support.*

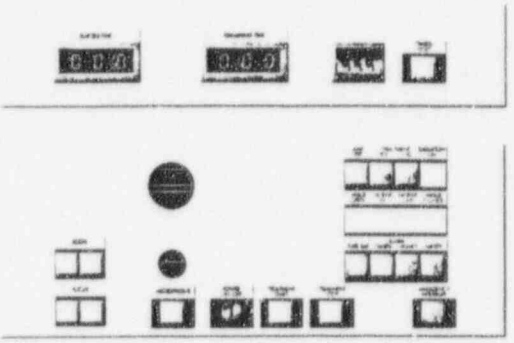


*Don't forget to connect the two plug-in connectors.*

When dismounting a helmet, perform the above sequence in the reverse order.

**Note:** Disconnect the two plug-in connectors before dismounting the helmet, and be sure that the shelf is in its upper position when you move the helmet hoist out from the helmet.

# Control Panel Functions



*The control panel*

The treatment is initiated and surveyed from the control panel. Here the course of the treatment is indicated by a number of indicator lamps. These lamps and their functions are described in the section Control Panel during treatment on page 11.

There are several push buttons on the panel to start and stop the treatment. The push buttons have the following functions:

## Power ON/OFF

A key-operated master switch controls all power supply to the Gamma Knife.

## Treatment Start

This push button starts the treatment cycle. A normal treatment is described later on in this section.

## Treatment Stop

Initiates the treatment stop cycle. This means that the couch moves out to its outer position and the shielding doors close.

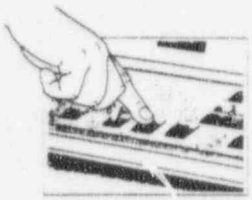
## Emergency Interrupt

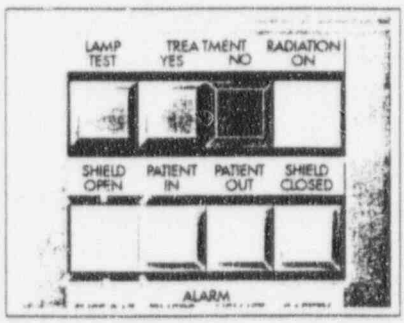
This button is used to stop any movement. It affects both the shielding doors and the couch.

With one push of the button the emergency interrupt is activated and all movement is stopped simultaneously, while the emergency interrupt button starts to blink to indicate the activation.

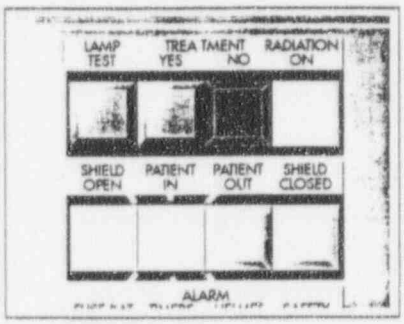
The treatment stop cycle is initiated when the push button is released.

## Control Panel During Treatment

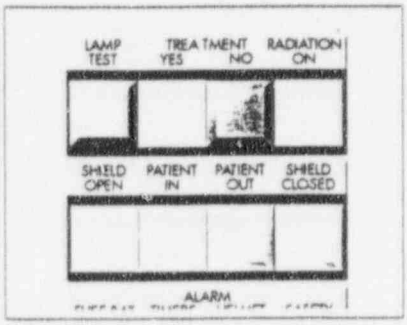




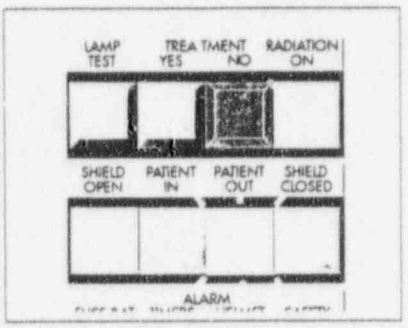

The indicator lamp **Radiation On** immediately lights up and remains on until treatment stops. The **Shield Open** light blinks until shielding doors are completely open. The **Treatment No** light is on without blinking.



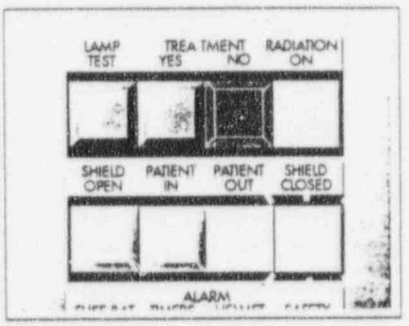

When the shielding doors are completely open, the **Shield Open** light stops blinking and the **Patient In** light starts to blink and continues blinking as long as the couch is moving to its inner position.



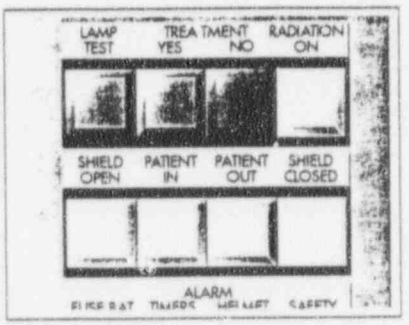

When the couch is in its inner position, the **Patient In** light stops blinking and remains on while the timers start to count. The **Treatment No** light goes out and the **Treatment Yes** light goes on without blinking.




When the treatment time is over, the **Patient Out** light starts to blink and the **Patient In** light turns off. The couch starts to move out from the radiation unit. The **Treatment Yes** light goes out and the **Treatment No** light goes on without blinking.




When the couch reaches its outer position, the **Patient Out** light remains on but stops blinking. The **Shield Open** light goes out and the **Shield Closed** lamp starts blinking.




The shielding doors close and the lamp **Shield Closed** remains on but stops blinking. At the same time the **Radiation On** light goes out.

# Safety Functions

## Treatment Start-up

To start a treatment the following conditions must be met:

- the Gamma Knife is supplied from the electric grid, not the battery backup
- the PLC units are working normally
- the couch is in its outer position
- no alarm lamps are on
- the battery voltage is over a preset limit.

If any of the above conditions are not met, a treatment start will not be possible.

When you have pushed **Treatment Start** button, the shielding doors start to open. The shielding doors must be completely open before the couch starts to move.

The couch movement is secured by timers in the safety system. If the couch has not reached its inner position within 90 seconds, the Treatment Stop cycle is activated and the couch moves out again. If the couch does not reach the Patient Out position in another 90 seconds, the external flashlight starts blinking.

## Treatment

- Two timers keep independent control of treatment time. Each timer is connected to one of the PLC units.
- If the main power supply fails, the standby battery backup is immediately activated and allows the treatment to continue.
- Failure in the backup PLC unit – treatment is completed but no new treatment is possible.
- Failure in the main PLC unit activates the treatment stop cycle and no new treatment is possible until the fault is repaired.

There are several ways in which the treatment may be interrupted manually. See more in section Stop Treatment Functions on page 14.

## After Treatment

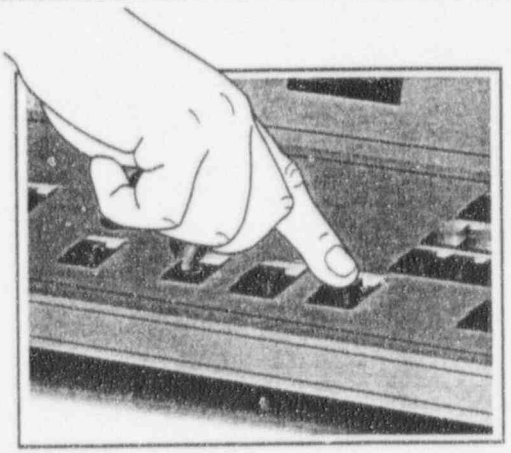
When the couch is ordered out (by time or by push button), the safety functions will check that:

- the couch has left the Patient In position within 7 seconds, otherwise the external flashlight will start flashing.
- the shielding doors closed position is reached within 90 seconds, otherwise the external flashlight will start flashing.

## Stop Treatment Functions

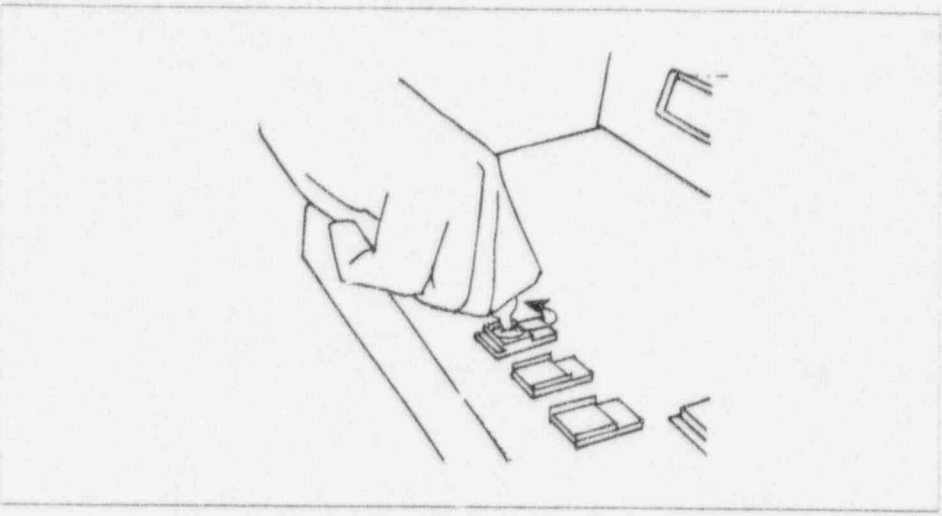
Treatment is normally stopped automatically when the treatment time has elapsed.

However, there are three other ways of interrupting the treatment:



*Activate* Treatment Stop *push button*

Activate the Treatment Stop push button. The treatment stop cycle is activated and the couch immediately starts to return to its outer position and the shielding doors close.



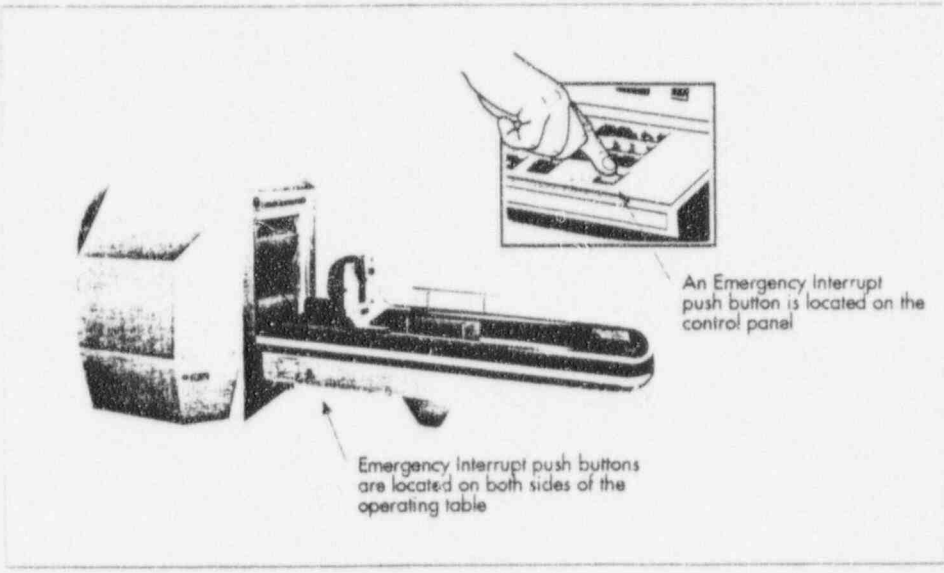
*Turn the main switch key off and on.*

**Warning:** Turning the main switch key off and on will also initiate the treatment stop cycle.

Emergency Treatment push buttons, that are supplied and installed by the hospital, activate the treatment stop cycle.

## Other Safety Functions

- If anyone either accidentally or intentionally enters the treatment room during treatment, micro switches - containing photocells - on the doors, activate the treatment stop cycle.
- Emergency Interrupt push buttons are located on the Leksell Gamma Knife and on the control panel. These are used to stop any movement of the shielding doors or couch.



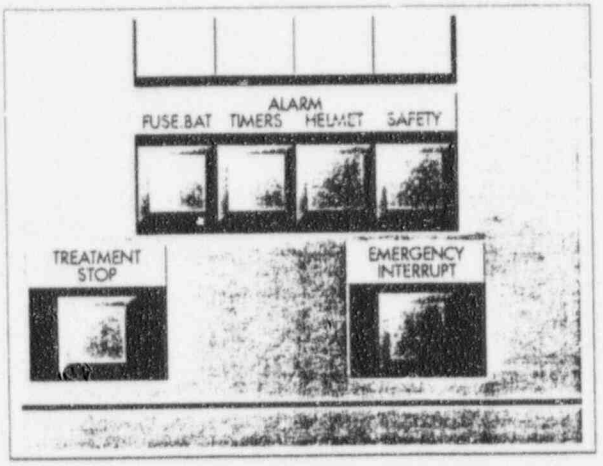

*Emergency Interrupt push buttons.*

**Note:** The emergency interrupt has no immediate effect on an ongoing treatment. The timers continue counting until the treatment time has elapsed. Then the couch moves out from the treatment position (approx. 5 cm) which is enough to get the helmet out of the point where the rays coincide. Thereafter an external flashlight is activated.

The couch or the shielding doors are not able to return until the Emergency Interrupt push button is released.

# Alarm Lamps

There are four alarm lamps mounted on the control panel to indicate malfunction of the equipment.




*Alarm lamps on the control panel.*

All alarm lamps indicate a malfunction that is preventing the start of treatment. While one of these indicator lamps is lit, no treatment can start.

If an alarm lamp lights up during treatment no interrupt will be initiated. The treatment continues. However, no new treatment start is possible, until the relevant fault has been corrected.

## FUSE BAT

This red lamp indicates that the power is supplied by the batteries, due to power failure or a tripped fuse. The treatment continues as planned.

## TIMERS

There are three cases when the alarm lamp **TIMERS** is lit:

- when a fuse is blown and there is an alarm from the back-up PLC unit
- if the timers have counted down to zero, but the couch is still in its inner position

- Patient Out is ordered but has no effect and the couch is still in the radiation unit.

### HELMET

This indicator lamp turns on when the cap on the top of the helmet is not in position, or if one of the angle connectors on the helmet is not properly connected.

### SAFETY

This lamp is lit when a safety switch or emergency interrupt push button is activated.

### External Flashlight

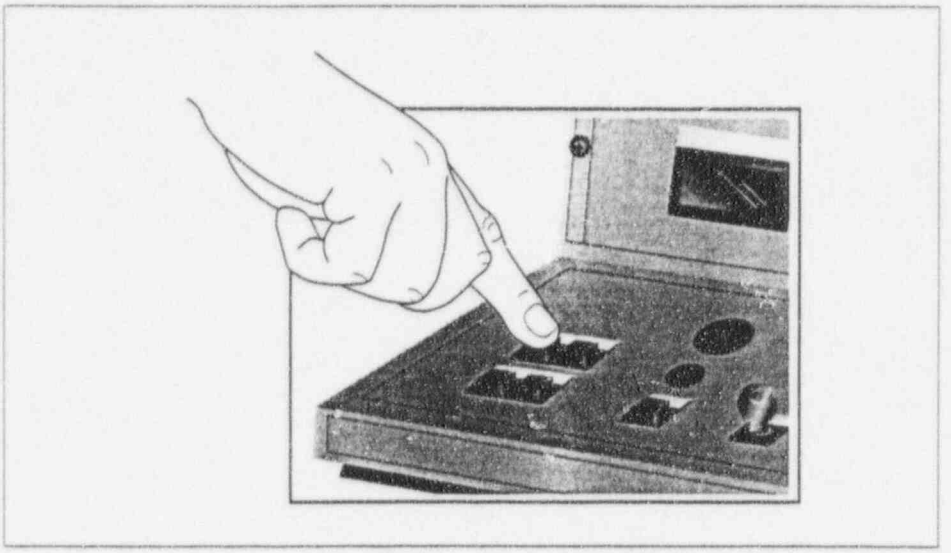
There is an external flashlight to make hospital staff aware of equipment malfunction .

The flashlight is lit if:

- the PLC II malfunctions
- the door switch is activated
- the couch has not reached the Patient In position within 90 seconds
- Treatment stop is ordered and the Shield Closed position for the door is not reached within 90 seconds
- the correct position of the helmet in the central body has not been reached within two seconds following the Couch In indication
- the couch is ordered out from treatment position and has not left the Patient In position within 7 seconds.

### Audio and Monitor System

The TV-camera to monitor the patient is maneuvered by the zoom and focus buttons.



*Push the zoom and focus button to control the monitor.*

The microphone on the control panel which is activated with a push button, enables the operator to communicate with the patient.

Both the monitor and the audio system are automatically operating when the main power is turned on.

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4

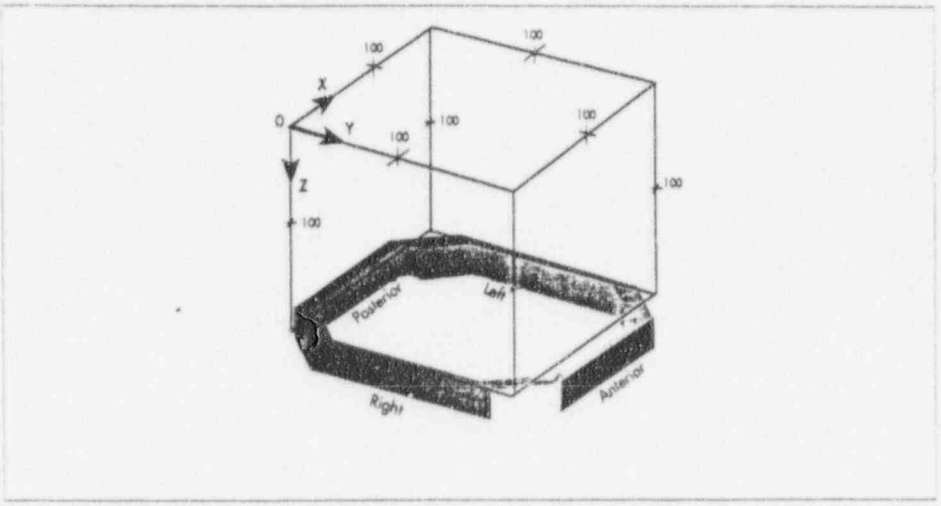
# Coordinate Frame and Frame Fixation

*This chapter explains the various parts of the Leksell stereotactic frame, how to prepare the frame for Gamma Knife Surgery and frame fixation. (Some of the auxiliary equipment described in this chapter, such as film holder, CT-, and MR-scales, are excluded from the standard delivery of the LGK.)*

# CONTENTS

# Coordinate Frame

The coordinate frame is engineered and manufactured in a way which enables ease of use in conjunction with all presently available imaging techniques. It has the shape of a rectangle which is 25 mm high, 206 mm wide and 236 mm long. It is made of light weight aluminum and has four feet which connect it to various imaging equipment. The rectilinear coordinate system has its origin outside the frame. It is located on the right side superiorly, posteriorly and laterally (see illustration below). It conforms with the X-, Y- and Z-nomenclature used in CT- and MR-scanning. The coordinate scales on the frame indicate positive values only. Thus, for instance, confusion between right and left is precluded.



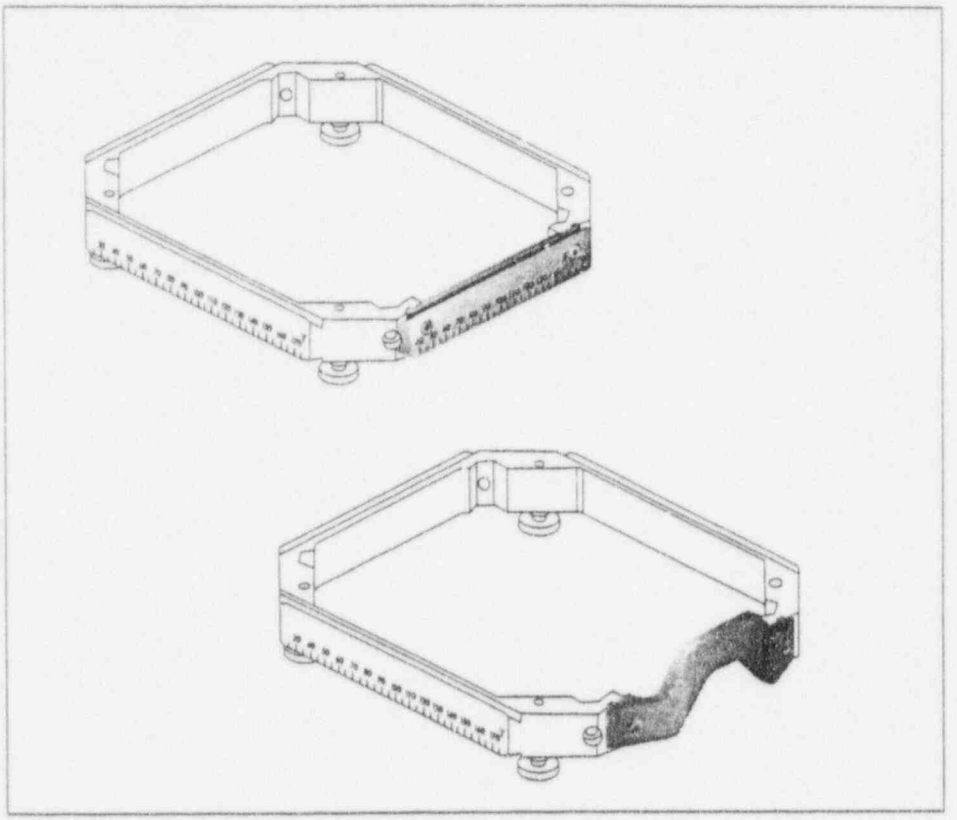

*The frame with its coordinate system.*

**Caution:** The numeric coordinate values engraved on the frame, represent millimeters.

The X-, Y- and Z-scales are filled with color as an adjunct for the preoperative setting of the coordinate.

The anterior part of the frame is removable. There are two alternative front pieces. One is a straight aluminum bar with an engraved X-scale. The other is a curved, non-engraved bar

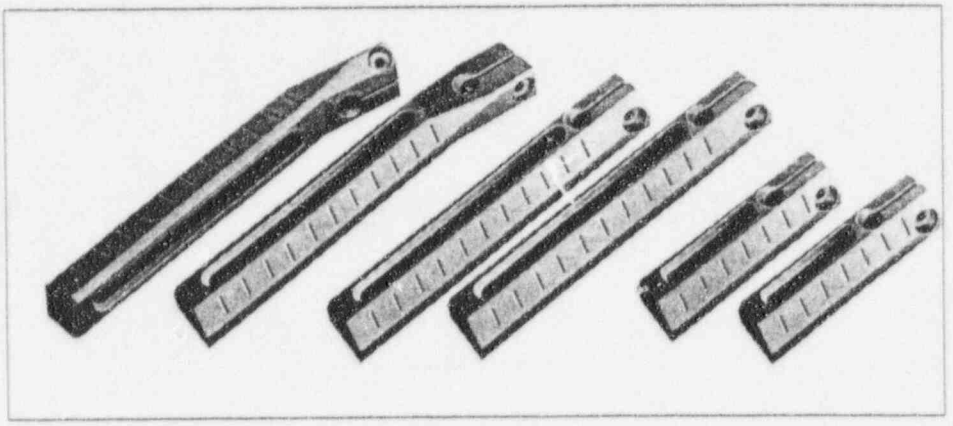
which provides extra space within the frame. It is U-shaped and it can be reversed.



*The two different front pieces of the coordinate frame.*

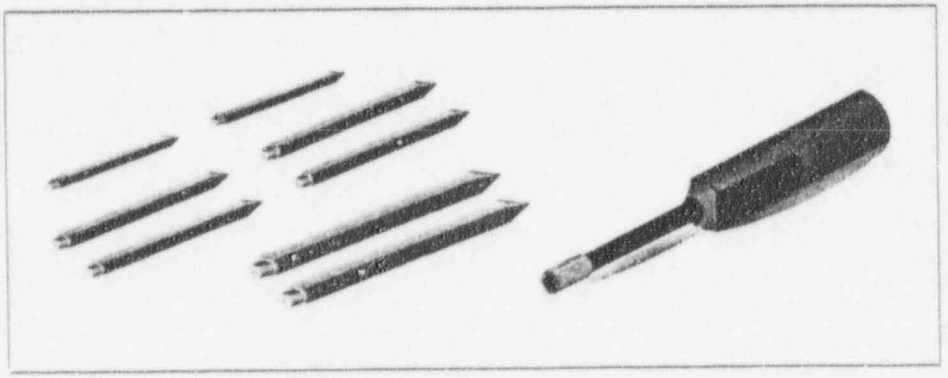
The design and material in the frame has been chosen in order to exclude artefacts in CT- and MR-imaging. In spite of this, the frame is also used for localization of a target from conventional x-ray films by means of the x-ray indicator. The frame is also devoid of magnetic materials allowing it to be used in conjunction with MRI.

The frame is provided with six posts for fixation to the patient. Two are long and angled at the top, two are long and straight and two are short.



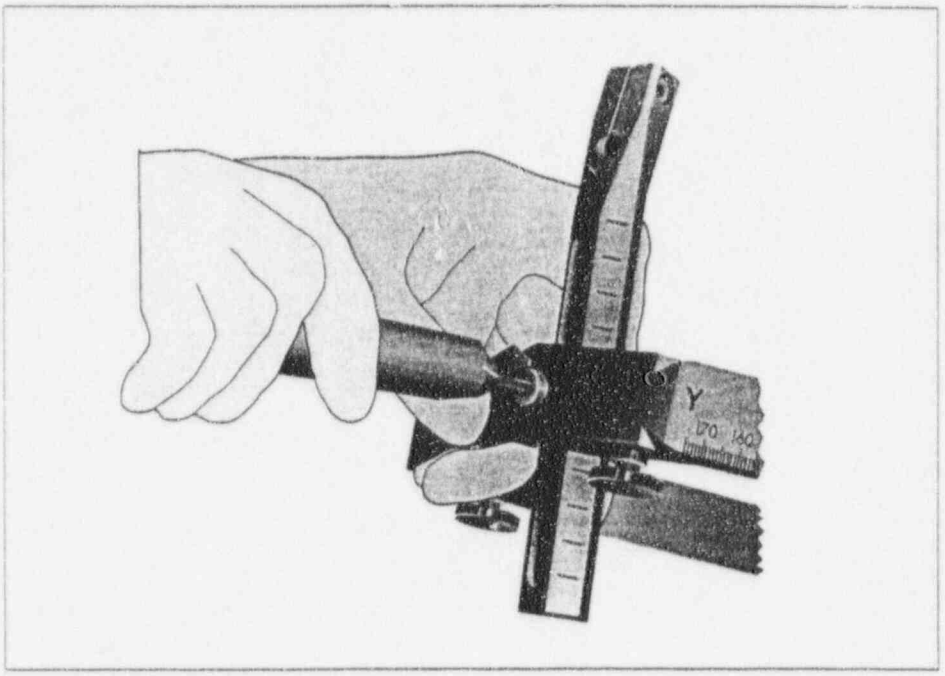
*Fixation posts.*

The long angled posts are used in the front. The threaded hole is used with the tapered screws to attach the frame to the head. The long straight posts are used posteriorly. They have the same two holes at their top as the angled anterior posts. The short posts are also used posteriorly. A further difference between the two sets of posterior posts is that the threaded hole is perpendicular to the post in the long ones while it is angled upwards in the short ones.



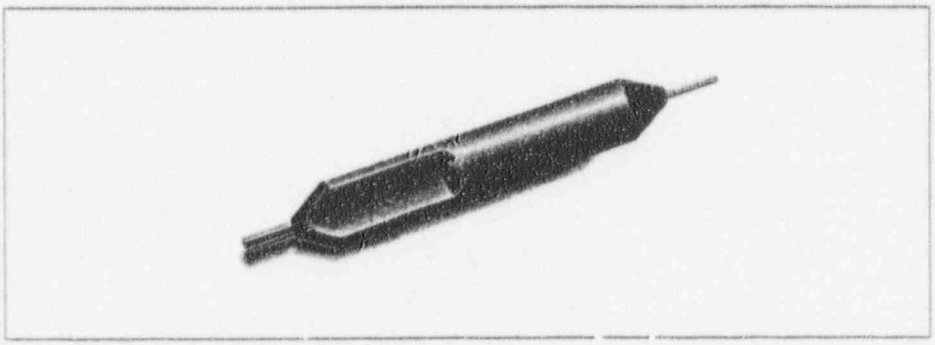
*Tapered fixation screws and socket wrench.*

Each post is attached to the frame by first inserting the correct screw through the hole in the corner of the frame. Next the appropriate nut is inserted into the slot of the post from inside. The post and nut are now brought together with the screw and the post is secured to the frame.



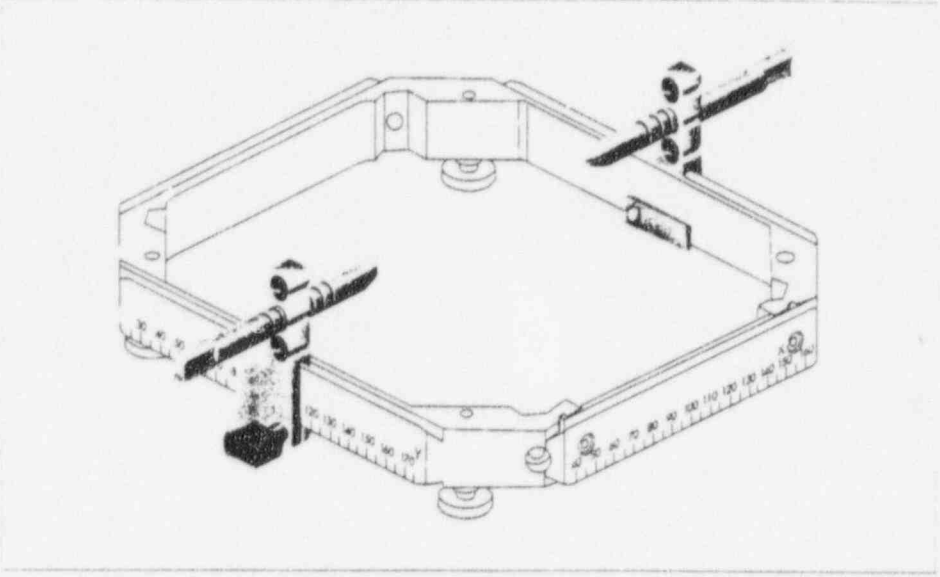

*Securing the post to the frame.*

The position of the posts is adjustable. By slightly loosening the locking screws, each post slides up and down and the optimal position can be selected. The posts are locked in position using the instrument screw driver.



*Instrument screw driver.*

The frame is provided with two ear plugs which are used as an aid for the orientation of the frame on the patient's head prior to its fixation. They sit in their own ear plug holders which slide onto the right and left sides of the frame. Each earplug holder has three holes, the use of which determines the height at which the frame will be attached to the head.



*Earplug holders and earplugs attached to the frame.*

## Preparation of the Coordinate Frame

1. Select and mount the front piece to the frame. The possibility to choose between the straight and curved front piece should be kept in mind when planning the frame application.

**Caution:** The selection between the straight and curved front piece and its fixation to the frame must be performed before frame fixation. Once the frame is fixed to the patient's head, it will be impossible to exchange the front piece.

2. Mount the fixation posts in four corners of the frame as previously described.
3. Secure the earplug holders to the frame at an appropriate Y-value which should be the same on both sides and insert the earplugs. The exact placement of the earplug holders is not critical and will vary from patient to patient.

4. Insert the fixation screws into each fixation post so that the tip of the screw barely protrudes the hole. The length of the chosen fixation screw should be as short as possible.

**Note:** Damaged or broken fixation screws must be replaced.

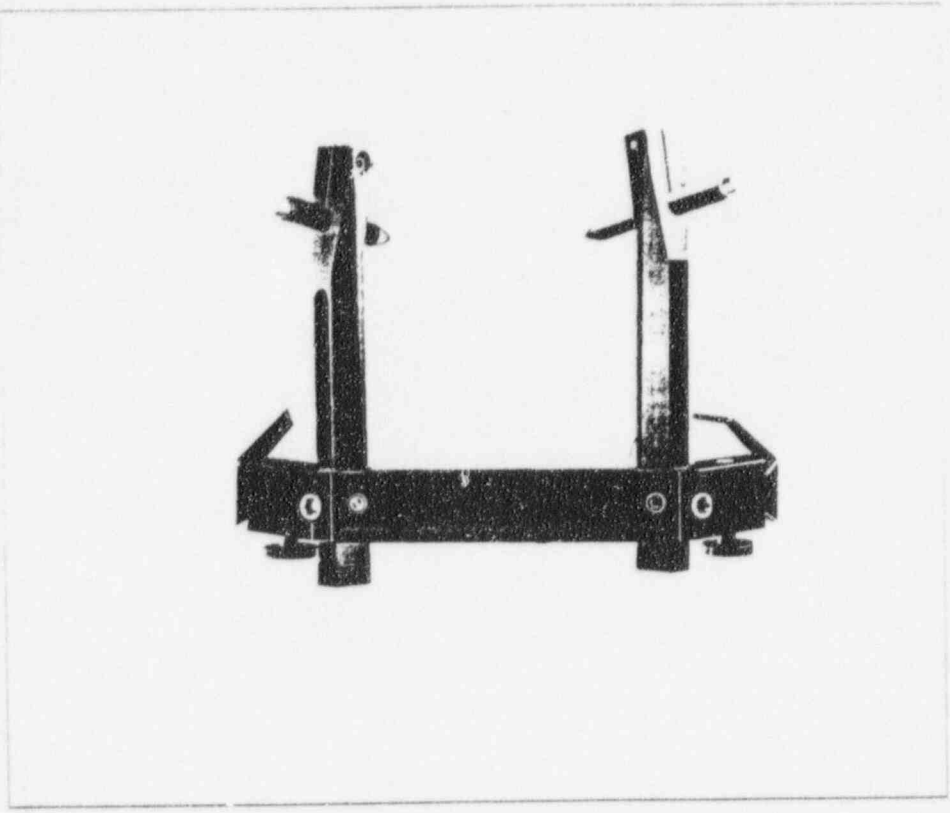
# Frame Fixation

Attachment of the frame is greatly aided by the use of the ear plugs. These ensure that the frame is indeed in the intended position when frame fixation is completed. The frame application also becomes much more cumbersome when the ear plugs are not used.

The head of the patient is scrubbed and the coordinate frame is aligned on the patient's head with the aid of the ear plugs. Since the width of the frame is ample for most cases it can be placed either symmetrically on the head or displaced towards the right, the left, backwards or forwards or any feasible combination of these directions.

1. If the target is in the midline the frame can be adjusted to a symmetrical position by symmetrical adjustment of the two ear plugs.
2. If, on the other hand, the target is somewhere between the midline and the skull, the frame should be placed asymmetrically on the head.

   The centre of the frame should be on the same side as the surgical target. This extra precaution during the application of the frame will maximize accessibility during the subsequent surgical procedure.



*Shifting of the frame centre.*

The height of the frame on the head is determined by selection of one of the three holes in the ear plug holders.

The highest position is achieved by using the lowermost holes.

**Note:** The ear plugs must be inserted into the outer canals past their cartilaginous portion. This means that the tip of each plug is on or beyond the junction between cartilage and bone. The bony canal is normally quite sensitive and all unnecessary pushing or pulling on the frame should be avoided while it is supported by the ear plugs.

If the frame is placed very low and/or inclined backwards, it may be necessary to use long fixation posts also at the back of the head. Two additional long posts are delivered with the frame for this purpose.

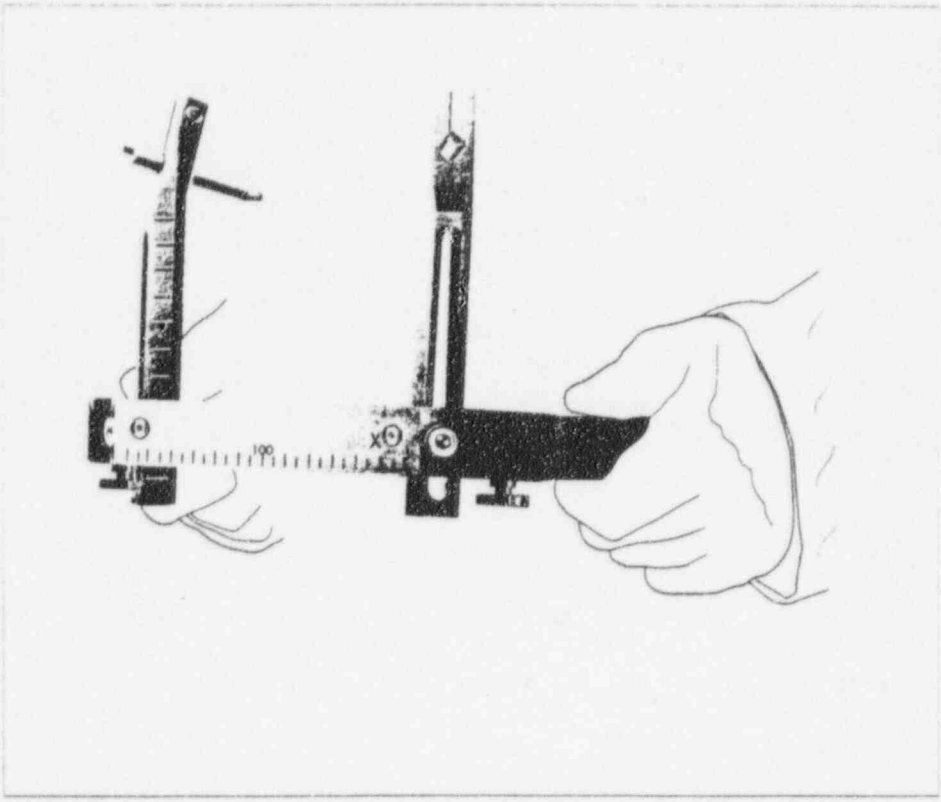
Once the frame is held to the head by means of the ear plugs, it swivels around these and it is easy to select an angle which gives the desired relationship to the canto-meatal plane.

**Caution:** If the frame is tilted backwards excessively, it might later become difficult to return the frame to the vertical position required for CT- or MR-scanning. Keep in mind that the patient can only flex his neck until the chin hits the sternum.

Before finally securing the frame to the head, some consideration should be given to the fixation posts. They may be raised or lowered to any suitable position.

When attaching the frame to the head the screws are first turned down towards the skin. This is done by hand preferably in a diagonal fashion by using the two supplied wrenches.

The earplugs and their supports are removed and firm attachment of the coordinate frame is checked by grasping the frame from above and gently lifting it.



*Checking the attachment of the frame.*

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5

# CT-localization and Target Coordinate Determination

*This chapte gives technical information about the equipment used together with the Leksell coordinate frame for CT-imaging. It also describes various techniques for target coordinate determination, using both manual and software based methods.*

# CONTENTS

# Principles for Target Definition

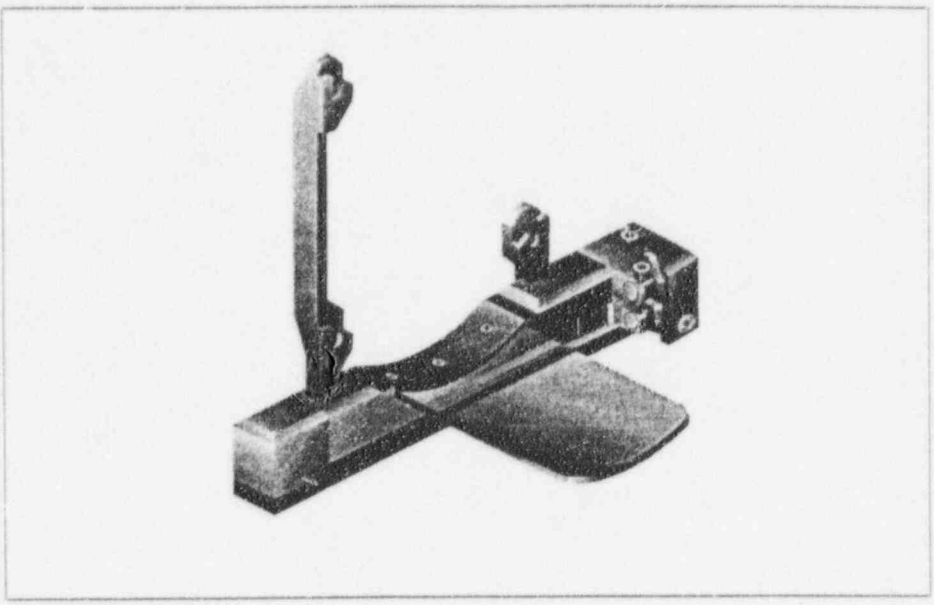
The principle for target definition in CT and MRI is based on the determination of the frame center on the scanner picture and the target's distances from that center in the X- and Y-direction.

**Note:** The method of localization is depending on the clinical indications. Thus a clinical decision has to be made by the physician or by the operating team.

# Equipment for CT-localization

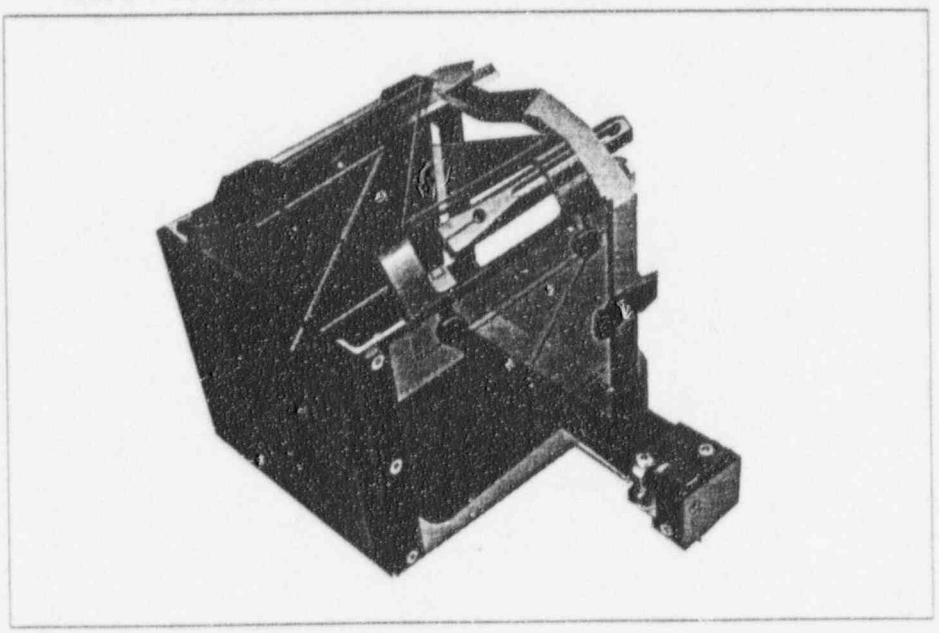
The Leksell stereotactic frame allows CT-scans to be made parallel to the coordinate frame. This in turn provides repeatability, the scans can be superimposed on each other and the images can be compared with those of an atlas. In order to achieve this, the frame has to be perpendicular to the gantry during scanning. Such precise perpendicularity is obtained by means of an adapter, which acts as an interface between the patient and the scanner, i.e. the patient lies in a fixed position during the whole imaging procedure. This position remains unaltered even if, for any reason, imaging has to be interrupted. An added advantage of this system is that the patient's head is comfortably supported throughout the scanning procedure.

A consequence of this technique is that the adapter has to be properly adjusted prior to being used the first time, see Preparation.



*The CT-adapter.*

The illustration shows the adjustable CT-adapter which links the stereotactic coordinate frame to the tabletop of any CT-scanner. The adapter firmly attaches to the table, replacing the table's standard headrest.



*CT-adapter attached to the table.*

The adapter is designed to maximize patient safety. It gives firm fixation but also allows easy detachment in case of an involuntary movement of the patient. The frame attaches to the adapter by means of slots which accommodates the feet of the frame.

A Perspex plate is attached to the base of the adapter. This plate, which is easily removable, can be used to support the occiput of the patient when in the supine position. A small inflatable rubber cushion is then placed underneath the patient's head and sufficiently inflated to relieve pressure from the sub-occipital screws.

---

**Note:** Over inflation of the cushion may raise the head and possibly disconnect the frame from the adapter.

---

For target localization in the CT, coordinate indicators are used. These are three square plastic plates, two of which fit onto each side of the frame. The two lateral plates are held together by a plastic piece which connects to both lateral plates. The third plate is placed in front of the patient and attaches to the two side plates. The lateral plates are marked "left" and "right".

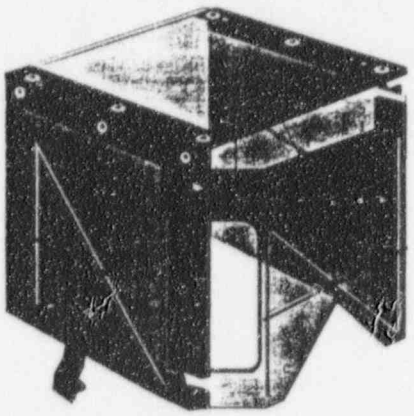
The indicators are locked to the frame with the snap-on locking mechanism. In the plastic, several thin radio-opaque bars are embedded. These bars are reproduced as fiducials on the CT-images.

Each lateral indicator plate contains two vertical bars parallel to their anterior and posterior margins respectively. Between them is a diagonal bar, descending from the patients posterior-superior to anterior-inferior. The two lateral indicator plates are mirror-images of each other, but otherwise identical.

The frontal plate is characterized by its opening for the patients nose. It also has two vertical bars, one on the left and one on the right side. Between these is the diagonal bar which runs from the upper right to the lower left corner.

A thin cross-line is engraved on all indicators, one horizontal and one vertical. The cross-lines correspond to the mid planes of the coordinate system.

**Caution:** If it is difficult to attach the indicator to the frame, check that the indicator not has been damaged in any way.



*The CT indicator box.*

## Preparation of the Equipment

After receipt of the equipment, the following preparations are necessary:

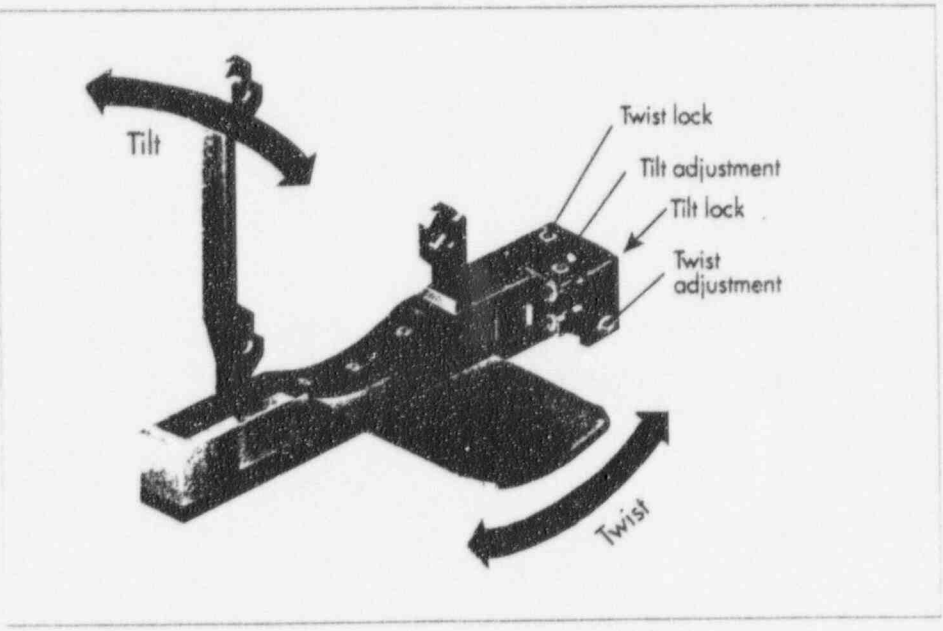
The CT-adapter is attached to the table top of the scanner, replacing its standard headrest. The coordinate frame with the three CT-indicators is coupled to the adapter with the removable front piece facing upwards. The aim is now to adjust the adapter in such a way that the frame rests perpendicular to the gantry. The laser light and its relationship to the vertical cross-lines on the indicators gives a preliminary rough indication of correct or incorrect positioning. The vertical cross-lines on the indicators, which represent the mid plane of the frame in the transaxial plane, are aligned perfectly with the laser light of the scanner.

To check frame/gantry alignment more precisely, a scan is made at any level that crosses the diagonal bars. The scan will then include the frontal diagonal indicator as well as the diagonals on the left and right sides on the frame.

**Warning:** The gantry must be at 0 degree tilt when doing this scan. Under no circumstances may the gantry be tilted when doing a stereotactic CT-examination with the Leksell instrument.

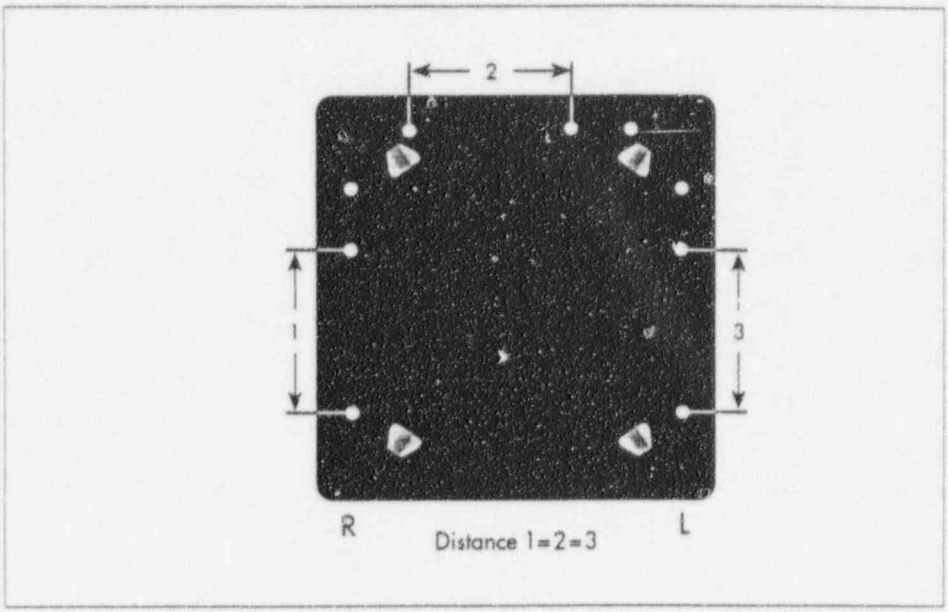
If there is a misalignment between the frame and the scanner, i.e. if the frame is not perpendicular to the gantry, this can now be seen on the CT-scan as described below.

Corrections can be made on the adapter which provides two manual adjustment possibilities. One adjusts the frame towards left or right. The other corrects for sagging of the table, i.e. it adjusts any angular deviation between the frame and the horizontal plane.




*The CT-adapter has two manual adjustment possibilities.*

On the test scan a total of nine fiducials will appear. There will be three fiducials on the left and three on the right side of the patient. In addition there will be three fiducials anteriorly. The right and left fiducials serve for localization of the target. The anterior three are only for assessment of correct positioning of the frame in the scanner.




*In a correct scanned CT-image, nine fiducial points will appear and the distances 1, 2 and 3 are the same.*

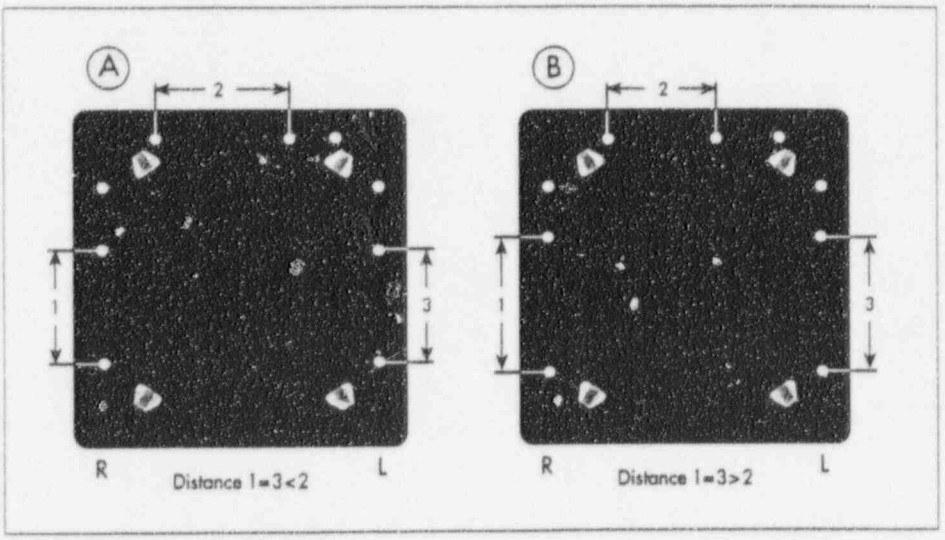
In the example above the scan is made at a low level (caudal) in the frame. Since the origin of the coordinate system is at the superior posterior corner on the patient's right side and since the diagonals run from superior posterior to inferior anterior (upper right to lower left for the frontal plate), the three diagonals will show up as indicated in the illustration above.

When the frame is correctly aligned with the gantry (as it is in the example above) the distances 1, 2 and 3 in the illustration are the same.

The different misalignments and their adjustments are described in the following section.

# Misalignments

If the frame is tilted downwards or upwards with respect to the horizonta' plane, the image will appear as in the illustration below.




*CT-image with the frame tilted downwards or upwards with respect to the horizontal plane, when the image was taken.*

In example A, the table of the CT-scanner may be sagging (heavy patient), the frame may not be correctly attached to the adapter or the adapter may be grossly maladjusted. In any event the frame is not horizontal, the head is hanging down and must be raised.

The adjustment screw on the adapter (see above) allows the frame to be easily raised. Normally the misalignments that occur are of the magnitude of a few degrees only and consequently one needs to turn the adjustment screw very little.

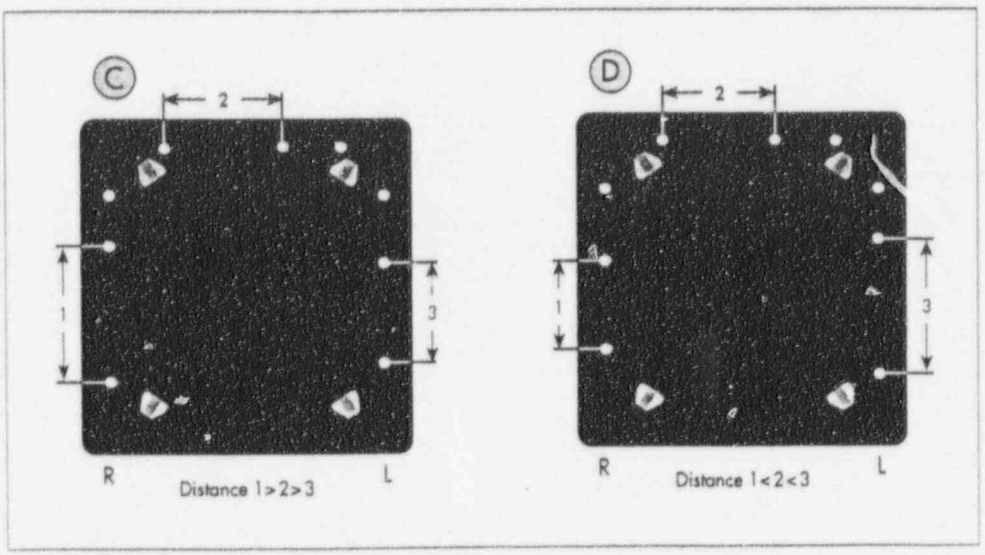
When the measured distance between the frontal vertical fiducial on the right side of the frame and the centre of the frontal diagonal (2) equals the distance between the posterior vertical fiducials and the lateral diagonals (1 and 3), the frame will be correctly positioned in the horizontal plane. At this time the lever locking the horizontal adjustment screw should be tightened.

In example B, the cranial aspect of the frame is raised with respect to the horizontal plane. The distance between the posteri-

or vertical fiducials and the lateral diagonals (1 and 3) is greater than that between the frontal vertical on the right side and the frontal diagonal (2), i.e. the frontal diagonal is closer to the frame centre than the lateral ones. The frame must be lowered. This is accomplished with the same adjustment screw as in example A, only it has to be turned in the opposite direction. Once the position of the frame is perpendicular to the gantry, the locking lever is tightened.

If the frame cannot be adjusted by adjusting the adapter, the patient's body is moved a tiny amount in the appropriate direction in the long axis of the CT-table, to reduce the amount of angling within the adapter. It will then be a simple matter to "fine tune" the position of the adapter to obtain alignment. During this adjustment, much time will be saved if both sides of the indicator are checked to avoid rotation in the coronal plane.

If the frame is angulated sideways with respect to the longitudinal axis of the table, the image as illustrated on next page may appear. In example C, the frame is angulated towards the patient's left side. The opposite is illustrated in example D.




*CT-image with the frame angulated sideways with respect to the longitudinal axis of the table, when the image was taken.*

The second adjustment screw on the adapter allows the frame to be easily adjusted for left/right angulation.

**Note:** In a pure sagging misalignment, the two lateral diagonals will remain in position. Only the anterior diagonal will appear in a wrong position. On the other hand, if there is a sideways tilt, not only will the lateral diagonal fiducials shift but the anterior one too. Consequently, when misalignment occur in both planes, it is easier to adjust first the sideways tilt. Once the frame is aligned with the longitudinal plane of table, it is easy to make it concur with the horizontal plane.

A rotation of the whole image on the screen, i.e. the nose is turned right or left, does not affect localization. The position of the diagonal fiducials is not affected by rotation.

Once the preparations outlined above have been made, the position of the frame in the CT-scanner aperture usually remains unchanged as long as the scanner is not modified or its parts displaced.

The method described above usually indicates that any relevant displacement of the frame occurring between procedures will be seen on any scan traversing the three indicator plates. If the first scan of a new patient shows discrepancies in the distances between diagonal fiducials as illustrated above, the surgeon can easily verify the distances by using the MEASURE DISTANCE function of the scanner and, if needed, he can make the necessary adjustments on the CT-adapter.

It should be noted that such adjustments are made without need to detach the patient from the adapter.

**Note:** With some CT-scanners it may be necessary to enlarge the field of view in order to visualize the fiducials from the anterior plate. With very large fields of view the image quality (resolution) is compromised.

The magnification factor must be known to the operating team before each treatment.

If the field of view necessary to visualize the anterior fiducials with a particular CT-scanner is so large that image quality is unacceptable, the anterior indicator plate may have to be disregarded. Since it represents a means of quality control and is not part of the localization itself, its exclusion does not compromise the execution of the surgical procedure.

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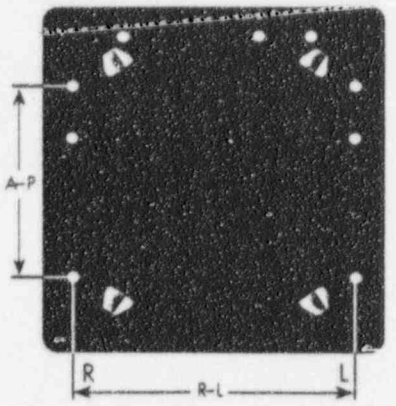
If it is difficult to obtain a properly quadratic image of the frame, this is usually due to inaccuracies in the photographic equipment (multiformat camera) of the scanner, which should then be adjusted by the scanner or camera service representative.

A way of checking squareness of the image can be made through two simple equations as follows:

$$\frac{R - L}{190} \quad \text{and} \quad \frac{A - P}{120}$$

The real distance between the lateral indicator plates is 190 mm. The real distance between the anterior and posterior vertical bars on each plate is 120 mm. The distance between the left and right vertical fiducials on the image (R-L) is measured and divided by 190. The procedure is repeated for the distance (A-P) between the anterior and posterior vertical fiducials on one side of the image and this number is divided by 120.




*The squareness of an CT-image can be calculated by dividing the distance (A-P) with 120 and the distance (R-L) with 190.*

The two quotients should coincide as closely as possible. Differences of more than 5 % should not be accepted and will also make it difficult to align the film with the coordinate scale. An adjustment of the photographic equipment of the CT-scanner is then called for.

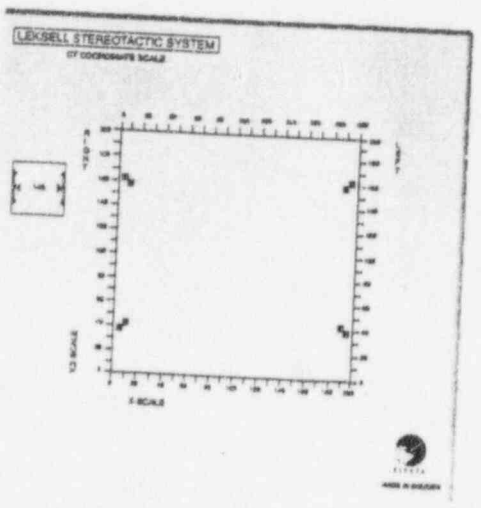
**Caution:** To check that no patient movement has occurred during the course of the CT examination, the cursor is placed over each of the four vertical fiducials in the lateral plates in turn. Then the first and last films of the series are inspected in turn. The relationship of the cursor to fiducial should remain unchanged. If not, then some frame movement will have occurred during the examination, which will have to be repeated.

# Target Coordinate Determination – Manual Technique

## Equipment

For target coordinate determination from CT-images, a special scale is used. The CT-scale consists of a square semi-transparent Perspex sheet with an engraved projection of the coordinate frame.

The scale is made individually for each customer and the degree of magnification of the printed coordinate scale is selected according to the size of the CT-images that the surgeon chooses to work with. The user is required to send a good quality CT-image of the frame with the indicators to the manufacturer or its supplier. As a rule, it is more convenient to localize from big images than from small. The target is better defined on a larger image and target coordinates are therefore easier and more precisely obtained from such an image.

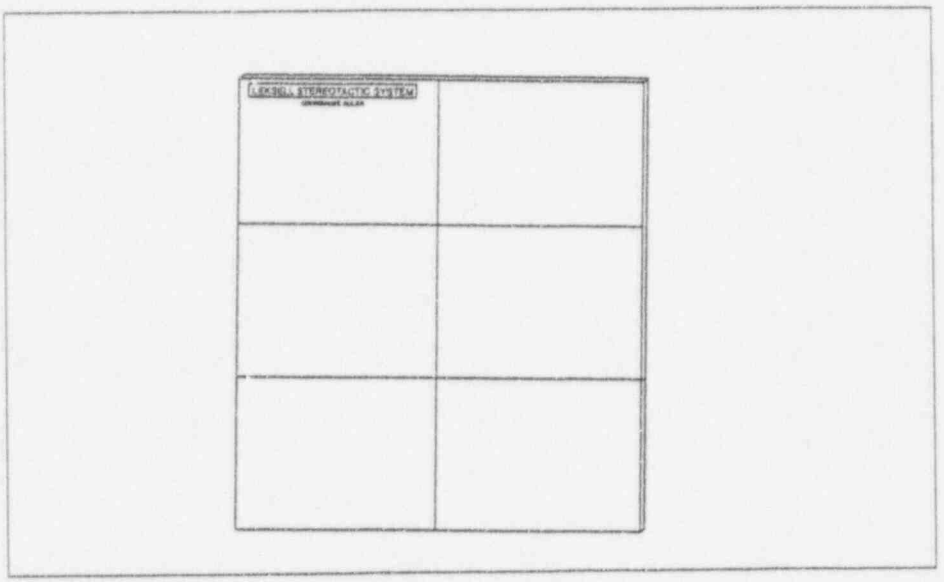



*The CT coordinate scale.*

The four "double boxes" on the scale are aligned with the anterior and posterior fiducials that appear on the right and left sides of the image. These are generated by the vertical bars

embedded at the anterior and posterior margins of each lateral indicator plate. The fiducials appearing on the upper part of the images, i.e. in front of the patient, are generated by the third, frontal, indicator plate. They have nothing to do with the actual localization of the target.

To read off the correct target coordinates, a ruler is used. This is a transparent sheet of plexiglass with thin cross-lines engraved on one side. For X-, Y- and Z-coordinate determination, the ruler is superimposed on the film and the coordinate scale.



*A ruler is used to read off the correct target coordinates.*

## Method

Only the late. indicator plates are important for the actual localization of the target. The frontal plate is used merely as a means of verifying correct positioning of the frame within the gantry of the scanner. Therefore, only the lateral plates are mentioned in what follows. Each coordinate indicator plate incorporates two vertical and one diagonal indicator bar. The middle of the diagonal bar represents the centre of the coordinate frame (Y = 100, Z = 100). The diagonal bar always descends from the posterior to the anterior side of the frame. Thus all CT-images will include three fiducials on each side. Scans above the Z = 100 (i.e. Z < 100) level will show the middle (diagonal) fiducial closer to the posterior vertical one.

The X-, Y- and Z-coordinates of the target can be read off directly from the CT-image using the CT-scale.

1. The CT-scale is first placed on the viewing box.
2. The CT-image is superimposed on the scale and oriented so that the four vertical fiducials coincide symmetrically with their respective "double boxes" on the scale. The film is now secured to the scale with adhesive tape.

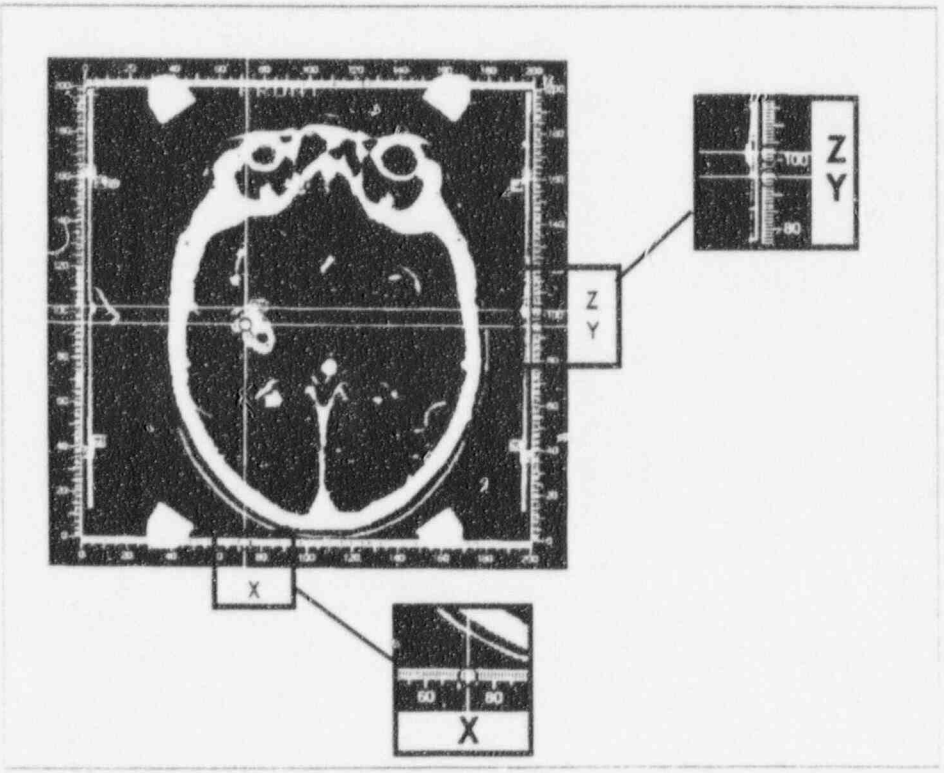
**Caution:** Each vertical fiducial should be placed at the point where the corners of the two boxes in each of the four couples meet.
If the fiducials, with the film symmetrically placed on the scale, enter the inner or outer "boxes" this indicates either incongruous magnification of the scale with respect to the image or distortion of the image which is then not properly quadratic.

Each line in the boxes represents 1 % decreased or increased magnification. Variance of more than 5 % should not be accepted. If the fiducials do not coincide with the point of intersection between the two boxes in their respective couple, there are two possible explanations:

- The image is too small or too large. All four fiducials will be off the scale to the same extent and in the same direction. In this case, the image magnification is incorrect and has to be adjusted or a new scale has to be ordered, corresponding to the new image size being used.
- The size of the image is correct but one or more fiducials are not in the correct position. In this case, the image is distorted and the multiformat camera needs to be serviced by the manufacturer.

**Warning:** With a distorted image it may be tempting to rotate the film on the scale in order to get a better fit between the fiducials on the film and the boxes on the scale. This may look better but must not be done since in such case the film and scale will not be parallel to each other and the localization will thereby be inaccurate.

3. The transparent ruler is placed on the film and two intersecting lines are placed on the target point. The X- and Y-coordinates are read off directly from the point of intersection between the two cross-lines and the coordinate scale. The Z-coordinate is defined as the point where a line through the centre of both the middle fiducials, intersects the coordinate scale.




*Manual target coordinate determination.*

As an example, in the illustration above, the target coordinates are:

X = 72.5

Y = 95

Z = 102.5

**Note:** The vertical and horizontal cross lines of the ruler must be parallel to the printed scale when the coordinates are read off. Read off the X- and Y- coordinates on both X- and Y-scales.

# Target Coordinate Determination - Software Based Techniques

In quite a few centres it has become customary to use standard scanner software for the determination of target coordinates. The accuracy of the localization then depends on the performance of the software of the particular scanner being used.

**Caution:** Elekta AB, the manufacturer of the Leksell Micro-Stereotactic System and the Leksell Gamma Knife, does not recommend or endorse the use of any scanner software which has not been specifically designed for use with the Leksell Micro-Stereotactic System and approved by Elekta AB.

Software options on currently available CT-scanners differ between manufacturers. However, simple distance measurements by means of a cursor are usually available. A simple alternative method for coordinate determination involves using the computer's standard scanner software to obtain the X-, Y-, and Z-coordinates of the target. The basic principle of the Leksell Stereotactic Instrument should be remembered in the sense that the definition of a target point always refers to the centre of the coordinate frame (X = 100, Y = 100, Z = 100). The target point

can therefore be specified in terms of a left-right distance from the centre of the frame (X-coordinate), an anterior-posterior distance from the centre of the frame (Y-coordinate), and a superior or inferior distance from the centre of the frame (Z-coordinate). The coordinate system of the stereotactic instrument conforms to that used in CT- and MR-scanners.

**Caution:** It is important to remember that CT-scan images are normally read from below. The patient's left side is therefore on the right of the CT-image and vice versa.

## Scanner Console Method (GE 8800)

The following descriptions are based on experiences with the General Electric 8800 and 9800 CT-scanners but similar procedures can probably be adopted for other CT-scanners.

To determine the stereotactic coordinates from the CT-image, the user must first identify the centre of the stereotactic frame on the CT-image. The centre of the stereotactic frame is identified by defining the centre of the rectangle formed by the four fiducials created by the vertical radio-opaque bars in the coordinate indicator plates which are attached to the frame during CT-imaging. The centre of the frame can be identified by placing the cursor first on one of the anterior fiducials and then on the contra lateral posterior one, depositing the cursor at each point and then depressing the MEASURE DISTANCE key. This is repeated for the two remaining fiducials. Both sets of fiducials will now be connected by the diagonal lines drawn by MEASURE DISTANCE and the intersection of these two lines will represent the centre of the frame (X = 100, Y = 100). The cursor should then be moved to rest over the intersection of these two lines, the ERASE GRAPH key is depressed to eliminate the diagonal lines, and the centre of the frame where the cursor now rests should be redeposited (press CURSOR DEPOSIT key).

**Note:** Identifying the frame center should be carried out using the "bone window" to ensure accurate cursor placement.

The cursor is then moved to the selected target on the axial CT-image. What the user wishes to know at this point is how far to the left or right and how far anterior or posterior the target is from the centre of the frame.

This information can be obtained in the following way:

1. The centre of the frame (as described above) is deposited by placing the cursor over the centre of the frame and depressing the CURSOR DEPOSIT key.
2. The cursor is then moved to the target and the CURSOR DEPOSIT key is depressed again.
3. The MEASURE DISTANCE key is depressed; at this point the computer console will display the scanner's X- and Y-coordinates of the target and the scanner's X- and Y-coordinates of the centre of the frame (these X- and Y-coordinates thus represent the position of these points referable to the X = 0, Y = 0 point of the CT computer system).
   The user is interested only in the difference between the X-value of the frame centre and the X-value of the target, and similarly the Y-value of the frame centre and the Y-value of the target.
4. The signs given to the X- and Y-coordinates reflect the quadrant of the CT coordinate system in which they are located. For example, if the target is located anterior and to the right side of the frame centre both values will be positive provided that the coordinates of the frame centre are also in the right upper quadrant on the CT-image.

However, the following rules can be followed to obtain the actual stereotactic X- and Y-coordinates from the two X- and Y-coordinates provided on the CT-monitor:

When the signs of the two X- or Y-values are different, the actual stereotactic coordinate will represent the sum of the two values regardless of their signs; when the signs of both the X- or the Y-values are the same, the actual stereotactic X- or Y-coordinates will represent the difference between these two values (disregarding their signs).

The X- and Y-values obtained represent the true left/right (X) and anterior/posterior (Y) distances from the frame centre. The final X- and Y-frame coordinates can now be obtained by adding or subtracting the above distances from X = 100, Y = 100 (frame centre) knowing the target position in relation to the frame centre and the origin of the frame coordinate system.

The Z-coordinate (superior/anterior) is obtained by moving the cursor to the lateral side of the image, on the same side as the target. The distance between the middle (diagonal) and the posterior (vertical) fiducial is measured by means of MEASURE DIST. It should now be kept in mind that the lateral posterior fiducial on the CT-image represents a Z-value of 40 millimeters. Therefore by adding 40 to the measured distance the true stereotactic Z-coordinate is obtained.

If the measured distance is called D, the Z-coordinate can be obtained by the formula:

$$Z = 40\ mm + D$$

**Note:** When measuring the distance from which the Z-coordinate will be calculated, use the "bone-window" on the CT. This facilitates accurate placement of the cursor and thus improves the accuracy of the measurement.

**Caution:** Some scanners display distances in number of pixels or in centimeters. In these cases the measured distances must by translated to millimeters.

# Scanner Console Method (GE 9800)

1. Select the proper slice for the target.
2. The image must now be positioned on the monitor so that the geometrical centre of the frame coincides with the centre of the scanner's grid system. To accomplish this, two diagonal lines between the anterior and posterior fiducials on opposite sides have to be drawn. This will reveal the centre of the frame which will be represented by the point of intersection of the two diagonals. These diagonals are drawn by using the keyboard as follows:

   A. Press ANNOT DISPLAY, select "Draw a line". Place the cursor at the posterior vertical fiducial on one side and press DEPOS CURSOR. Move the cursor to the anterior vertical fiducial on the opposite side of the frame and press DEPOS CURSOR again. Two diagonal lines have now been drawn.

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**Note:** Identifying the frame centre should be carried out using the "bone window" to ensure accurate cursor placement.

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   B. Place the cursor at the point of intersection of the two diagonal lines, i.e. at the frame centre. Press MAG CURSOR and select the desired magnification. The computer will now shift the image so that perfect alignment between the frame centre and the centre of the scanner's grid system will be obtained.

   C. Press GRID. Place the cursor at the selected target. By means of MEASURE DIST two perpendicular lines, one horizontal and one vertical, are drawn from the target to the X- and Y-axes of the grid. The X- and Y- coordinates of the target are now read off directly from the grid, paying attention to the numerical X- and Y-values of the origin of the grid, X and Y = 100 mm.

The cursor is now moved to the lateral side of the image, on the same side as the target, and the distance between the middle (diagonal) and the posterior (vertical) fiducials is measured by means of MEASURE DIST. A distance figure will appear in the lower right hand corner of the screen.

If the distance is called D, the Z-coordinate is easily obtained by the formula:

$$Z = 40 \text{ mm} + D$$

**Note:** When measuring the distance from which the Z-coordinate will be calculated, use the "bone window" on the CT. This facilitates accurate placement of the cursor and thus improves the accuracy of the measurement.

**Caution:** Some scanners give distances in number of pixels or in centimeters. In these cases the measured distances must be translated to millimeters.

This section described how it was possible to obtain the X-, Y- and Z-coordinates of a target from an image produced by the General Electric 8800 and 9800 CT scanners. The two examples may overlap and partly be applied to one scanner or the other. Similar procedures can in most cases be used also with CT-scanners other than GE, although they may have to be performed in different ways.

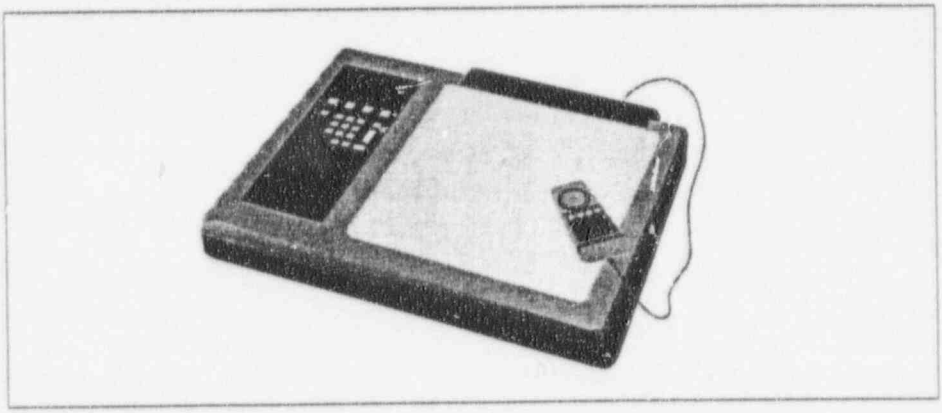
# Leksell Localizer Method

The Leksell Stereotactic System has relied on a variety of localizing techniques for a long time. Different techniques have been used for CT and for MRI and there has been more than one technique for different studies involving conventional x-rays.

In an effort to simplify the localization of targets from different kinds of images, the Leksell Localizer was designed. This instrument provides the user with an integrated, reliable and self-explanatory method of determining target coordinates. It can be used with images produced by all currently available techniques.

The Leksell Localizer consists of a digitizing table, pointing device and a small keyboard with LED-display. All components are built into an easy-to-use transportable tabletop unit which incorporates adequate lighting for viewing of images.

For further information on the Leksell Localizer, see the separate User's Manual.



*The Leksell Localizer.*

ELEKTA

6

# MR-localization and Target Coordinate Determination

*Here you will find technical information about the equipment used together with the Leksell coordinate frame for MR-imaging. This chapter also describes techniques for target coordinate determination, using both manual and software based methods.*

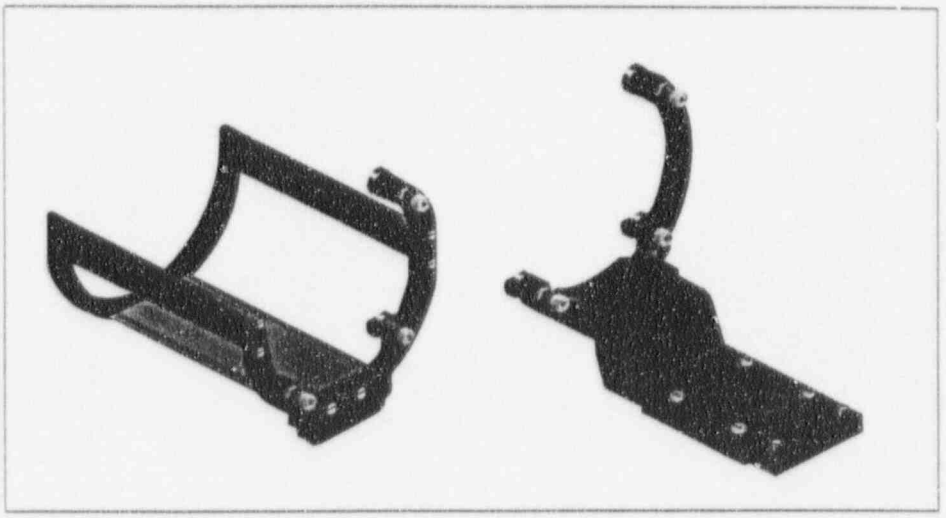
# CONTENTS

# Principles for Target Definition

The principle for target definition in CT and MRI is based on the determination of the frame center on the scanner picture and the target's distances from that center in the X- and Y-direction.

# Equipment for MR-localization

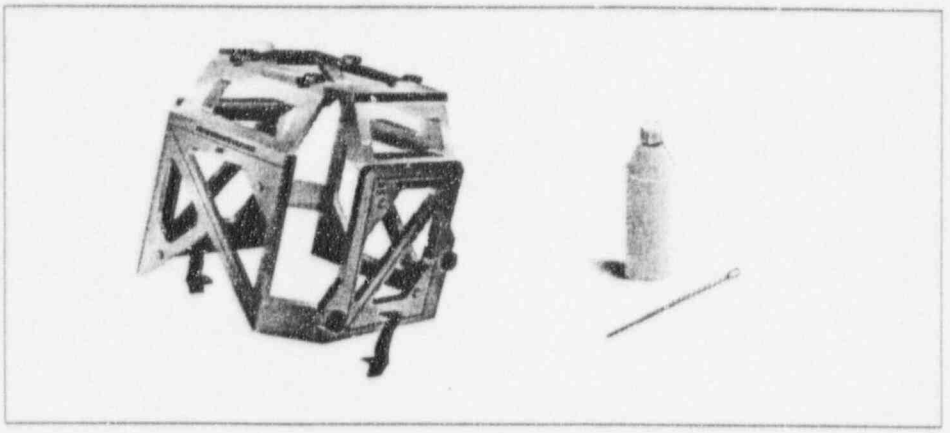
For MR-scanning a non-magnetic adapter is available.



*To different kinds of MR-adapters.*

This adapter will fit into any MR-scanner with a head-coil system having an inner diameter of 30 centimeters or more. The stereotactic frame is attached to the MR-adapter in the same way as with the CT-adapter (see Equipment for CT-Localizations, page 5–4).

For target localizations an MR coordinate indicator box is used. The principle for the box is based on the same principles as the CT coordinate indicators (see Equipment for CT-Localizations, page 5–5) but instead of a radio-opaque material, the indicator contains multiple channels which are filled with a liquid. The channels in each plate communicate with each other and the channel system is sealed by two small screws which are used when refilling the system.



*An MR indicator box is used for target localizations from MR images. It can be used with or without a fifth posterior indicator plate. The indicator box is delivered with an extra long cannula to fill the liquid into the indicator plates.*

The two lateral indicators are attached to the frame in the same way as with the CT-indicators. The lateral indicator plates are marked "left" and "right side anterior". In addition to the lateral indicator plates, there is a third one which is placed on top of the frame. This serves for localizations from sagittal films and the top plate is attached to the lateral indicators by means of two screws. There is also a fourth indicator plate which attaches to the front, much in the same manner as the frontal indicator plate in CT. A fifth posterior indicator plate secures sagittal localizations. In MR the frontal plate serves two purposes: It aids localizations from sagittal scans and it makes possible the assessment of correct positioning of the frame. The thin cross-lines engraved on the outer surface of all plates correspond to the mid planes of the coordinate system. They are also used when checking the position of the frame against the laser alignment light in the MR-scanner.

To fill the indicators with the included liquid, both the sealing screws are removed. The supplied syringe, with its extra long cannula, is filled with the liquid and inserted into the most distal corner. The liquid is now injected (if necessary, more than 20 ml may have to be used) until a solid flow comes from the second opening in the plate. It must be ascertained that no air bubbles remain in the channels. While holding the filling holes upwards and horizontal, the channel system is sealed again with the two screws. Due to the plastic material being some-

what hygroscopic, bubbles of air tend to appear in the channels with time. This is obviated by refilling the system whenever necessary.

**Note:** Inspect the plates once a week to check for bubbles or other irregularities.

The MR-indicators also include channels on the upper and lower margins of the plate. These are necessary for coordinate determination from coronal MR-scans. For localizations from sagittal scans the frontal and vertex indicator plates are used.

**Warning:** If it is difficult to attach the indicator to the frame, check that the indicator has been correctly aligned in the groove.

## Preparation of the Equipment

After receipt of the equipment the following preparations are necessary to obtain a permanent installation:

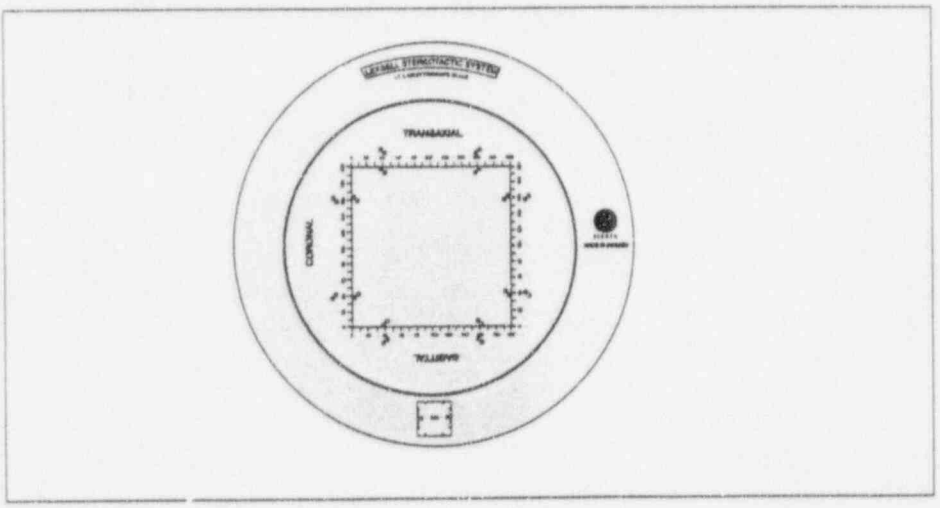
The adapter is attached to the MR-scanner in the way indicated in the instructions included with the adapter. The technique for this varies with different makes of scanners. As with CT-scanning, it is important to obtain a perpendicular position of the coordinate frame in the head coil.

## Misalignments

Misalignment of the frame in the coil is verified in the same manner as in CT-scanning. A transaxial MR-scan will show the same fiducials as those seen on a CT-scan. For instructions on the verification of proper positioning in the axial plane, see CT-localization and Target Coordinate Determination, Equipment for CT-localization, Misalignments. For position verification from coronal scans, the distances from the interior fiducials (right and left side) to the middle (diagonal) fiducials just above them, should be the same. If they are not, it means that the head is *tilted* right

to use reasonably sized films, as described in Target Coordinate Determination – Manual Technique, on page 5-14.

The scale is made individually for each customer and the degree of magnification of the printed coordinate scale is selected according to the size of the MR-images that the user chooses to work with. The user is required to send a good quality MR-image of the frame with the indicators to the manufacturer or its supplier.




*The MR-scale is used for manual target coordinate determination from MR-images.*

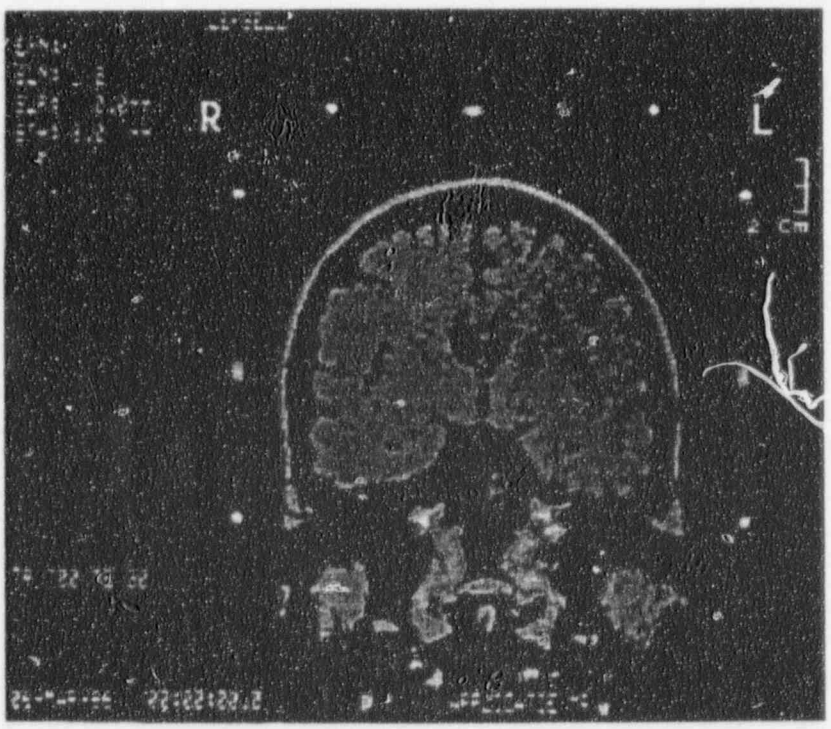
For reading off the target coordinates, the same cross-line ruler which is used in CT-localization is employed.

## Localization from Transaxial MR-images

When localizing a target from a transaxial image the coordinate scale is rotated so that the text TRANSAXIAL is read on top of the scale, i.e. the origin of the engraved scales (the 0-point) should be on the image's bottom left-hand corner (with patient viewed from below). The transaxial MR-image is aligned with the scale in exactly the same way as already described when using transaxial CT-scans. The procedure for reading off the target coordinates by means of the cross-line ruler is also described in CT-localization and Target Coordinate Determination, Target Coordinate Determination – Manual Technique, Equipment.

# Localization from Coronal MR-images

When the localization is done from coronal MR-scans the scale is rotated until the text CORONAL at the top, i.e. the origin of the engraved scales (the 0-point) should be on the image's upper left-hand corner (with patient viewed from the front). Once again the film is aligned to the scale in the same fashion as previously described in the CT-localization chapter. The only difference is that the fiducials which are to be aligned with the scale are located above and below instead of anteriorly and posteriorly with respect to the image of the brain.




*A coronal MR-image.*

There are also three fiducials on the top of the image. The lateral ones are also aligned with their own boxes.

The X-coordinate is now read off from the point where the vertical cross-line from the target intersects the upper scale.

The Z-coordinate is represented by the horizontal cross-line from the target which intersects the scale on the right and/or left side of the image.

The Y-coordinate is obtained from the point where a horizontal line traversing the centre of the middle (diagonal) fiducials intersects the coordinate scale. In this case, a vertical line originating from the horizontal one and traversing the upper (centre) diagonal fiducial, should give the same value for Y on the upper scale as on the right and left ones.

In summary, the X-coordinate of the target is obtained in the same way from both transaxial and coronal scans while the middle (diagonal) fiducial will represent the Z-coordinate in transaxial scans and the Y-coordinate in coronal scans.

## Localization from Sagittal MR-images

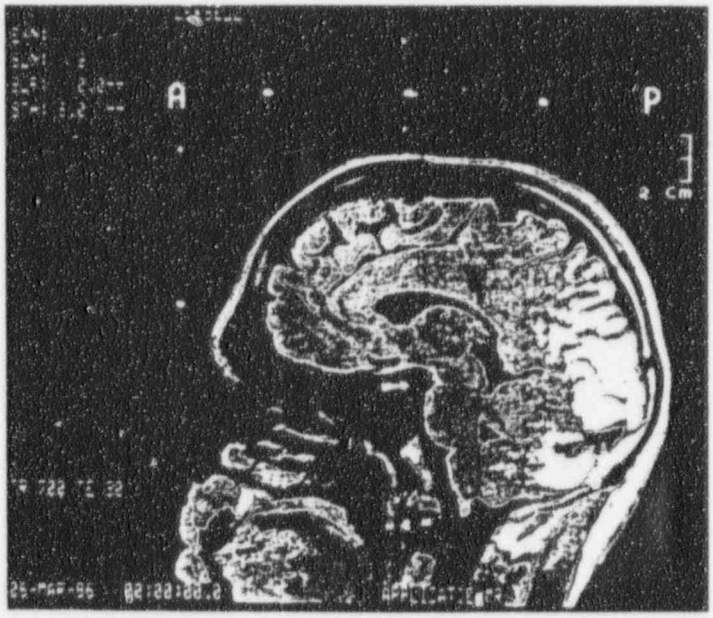
Sagittal scans may also be used for *a gross* target coordinate determination, provided that the frontal and vertex plates and, if possible, the posterior plate, have been attached to the frame. The scale is rotated so that the text SAGITTAL is at the top. The film is aligned with the scale by placing the anterior and posterior fiducials which are seen above the head in their respective boxes on the scale.

---

**Note :** The nose of the patient must point towards the left.

---

Anterior to the head there are two fiducials. One originates from the frontal diagonal. The second, which is above the diagonal, originates from a channel running from left to right in the frontal plate. Because of the nose of the patient, no such channel exists below the frontal diagonal. This means that there are a total of five fiducials in a sagittal scan (or eight with attached posterior plate), two of which are diagonals (three with posterior plate). The remaining fiducials are used to align the film to the scale.




*A sagittal MR-image.*

The cross-line ruler is now placed on the target and the X-coordinate is read off at the intersection between the scale and a vertical line crossing the midpoint of the upper diagonal fiducial.

The Y-coordinate is represented by the point where a vertical cross-line from the target intersects the scale.

The Z-coordinate is read off at the point where the horizontal cross-line through the target intersects the scale.

**Warning:** MR-scanning is known to be affected to a variable extent by distortions of different kinds. These distortions may be difficult or impossible to detect from the images. It may therefore be advisable, for the time being, to confirm target coordinates obtained from MR-images with those obtained by CT.

It is not recommend that a stereotactic procedure is based exclusively on MRI.

# Target Coordinate Determination – Software Based Techniques

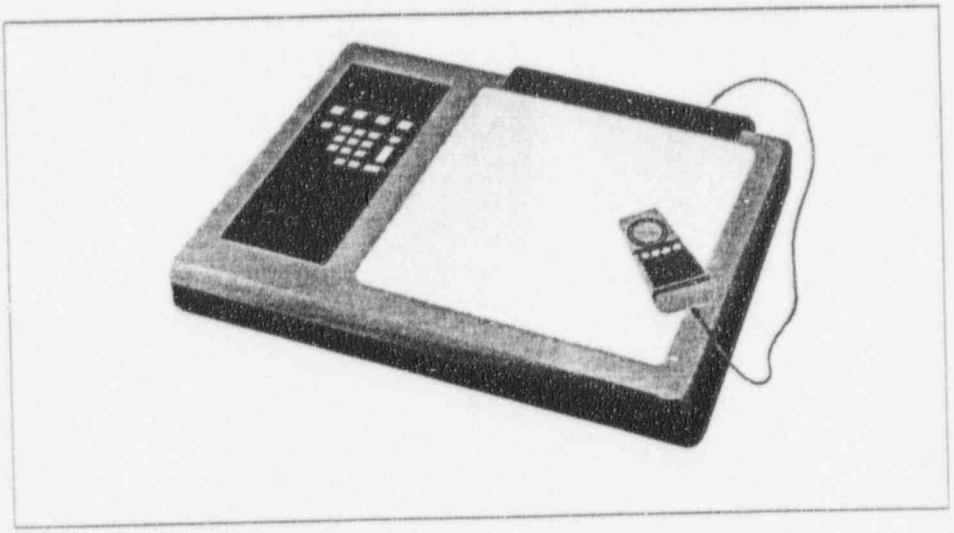
## Leksell Localizer Method

The Leksell Stereotactic System has relied on a variety of localizing techniques for a long time. Different techniques have been used for CT and for MRI and there has been more than one technique for different studies involving conventional x-rays.

In an effort to simplify the localization of targets from different kinds of images, the Leksell Localizer was designed. This instrument provides the user with an integrated, reliable and self-explanatory method of determining target coordinates. It can be used with images produced by all currently available techniques.

The Leksell Localizer consists of a digitizing table, pointing device and a small keyboard with and LED-display. All components are built into an easy-to-use transportable tabletop unit which incorporates adequate lighting for viewing of images.

For further information on the Leksell Localizer, see the separate User's Manual.



*The Leksell Localizer.*

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# X-ray Localization and Target Coordinate Determination

*The equipment for x-ray localization is technically described in this chapter, together with methods for manual and software based target coordinate determination. The chapter covers target coordinate determination of both visible and invisible targets.*

# CONTENTS

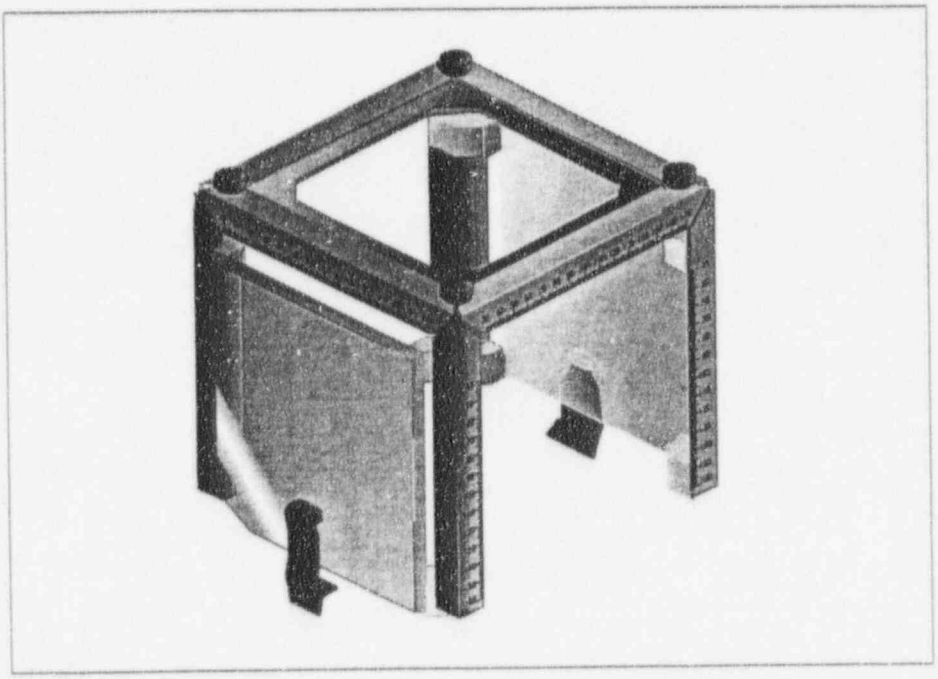
# Principles for Target Definition

The principle for X-ray target definition is based on that the target coordinates defined by direct measurements on a visible scale system depicted on the lateral and A-P films.

# Equipment for X-ray Localization

## X-ray Indicator

The Leksell Stereotactic x-ray equipment allows x-ray exposures to be made with the tube head at a very short distance from the film. For target localization using conventional x-rays, a special x-ray indicator is used.



*The x-ray indicator.*

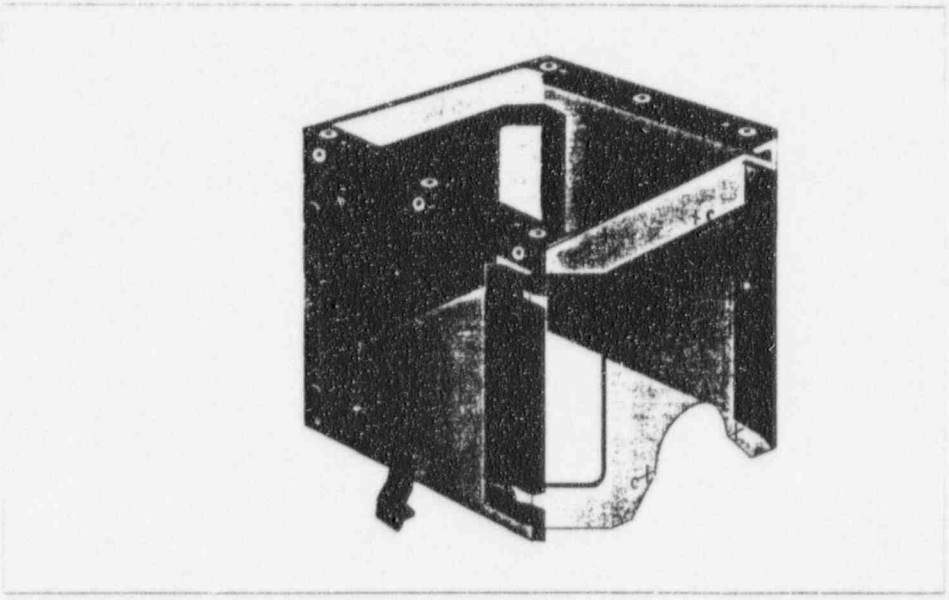
This indicator incorporates radio-opaque X-, Y- and Z-coordinate scales. It attaches to the coordinate frame in the same way as the CT- and MR-indicators. The Z- and Y-scales on the right side are reversed. The same applies to the posterior X-scale. The word RIGHT is engraved in reverse on the anterior Z-scale on the right side. The reason for this is explained below.

**Caution:** When localizing a target the lateral exposures should be made with the tube-head on the left side of the patient. Those scales which are engraved in reverse on the x-ray indicator will then appear correct on the films. The reversed RIGHT engraved on the anterior Z-scale on the right side of the indicator will of course also appear correct on the lateral films. It serves as a means of checking that the frame and indicator have been correctly placed on the head. On the film the word RIGHT will thus appear on the smaller (less magnified) scale, i.e. on the distal one (on the patient's right side).

**Caution:** A-P films should be taken with the x-ray tube in front of the patients, in order to see the posterior X-scale on the indicator correctly on the films. It is advisable to make a habit of the above since this allows any error of placement of the frame or x-ray indicator to be seen on the localization films before the surgical procedure is started.

## Indicator for Computer Based X-ray Localization

In addition to the above x-ray indicator a special indicator box with incorporated reference fiducials is available to be used with various computerised planning systems and/or the Leksell Localizer.



*Indicator for computer based x-ray localization.*

The lateral as well as the anterior and posterior panels have embedded reference marks with known coordinates. These marks are shaped as "+" on the anterior and left indicator panels and as "x" on the posterior and right indicator panels in order to identify respective side on the A-P and lateral films.

For target coordinate calculation using the indicator for computer based localization, please see the separate User's Manual for the Leksell Localizer or for respective computer planning system.

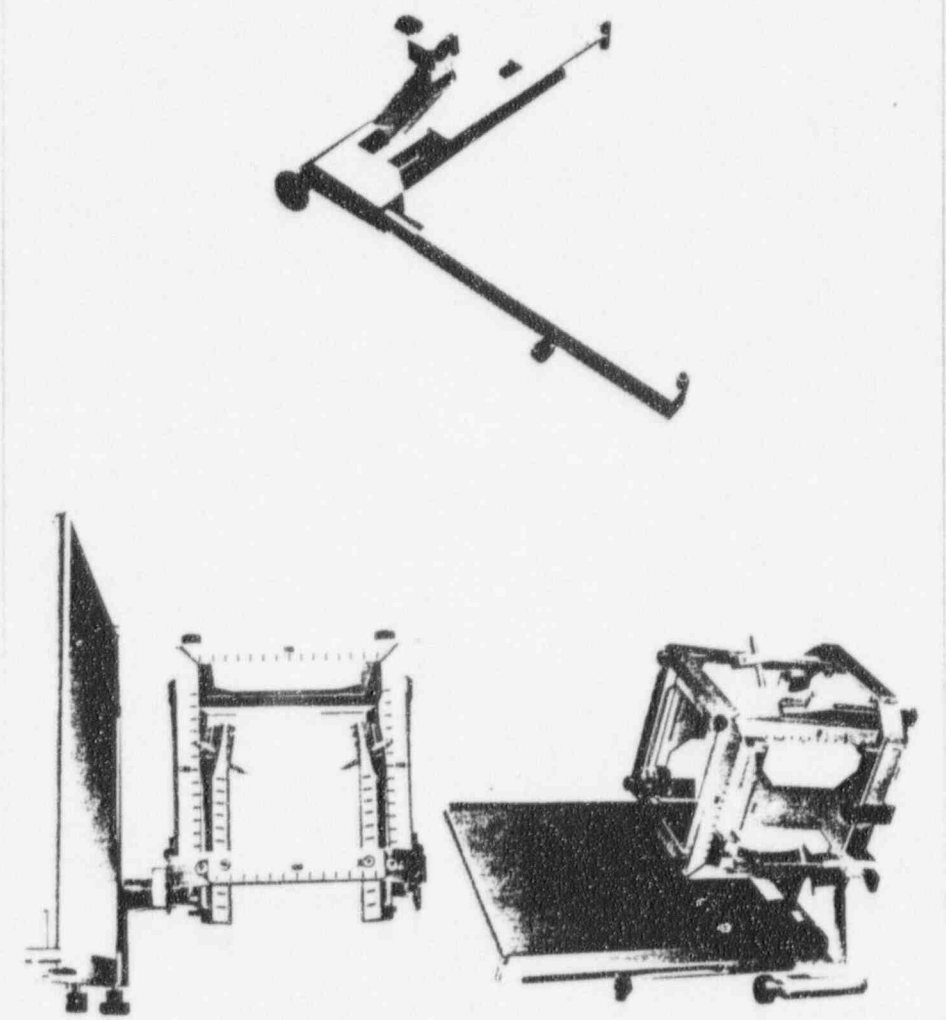
## Equipment for Use with Existing Mobile and/or Fixed X-ray Units

**Warning:** Whenever any existing mobile and/or fixed x-ray unit is used in combination with the Leksell Stereotactic System in order to obtain intraoperative verifications and/or preoperative target coordinate calculations, it is essential for the accuracy of the localization, that the frame and the cassette are positioned in an absolute parallel fashion.

The x-ray cassette holder is designed to hold a cassette in any size parallel to the frame, both in the A-P direction as well as in

the lateral. The cassette holder can be attached to any side of the frame, thus permitting the x-ray unit to be positioned on any suitable side of the patient.

**Warning:** Due to the extra weight from the cassette holder and cassette, it is essential that the frame is securely fixed to the operation or examination table via the Mayfield clamp or table fixation before the weight is applied to the frame. Failure to observe this precaution may cause the frame to be twisted off the patient's head.



*The x-ray cassette holder is designed to hold a cassette parallel to the frame both in lateral as well as in the A-P direction .*

For target coordinate determination from conventional x-rays, several methods are available, using manual and software based techniques. Each has its merits and are described below.

# Manual Techniques – Visible Targets

## Graphic Method

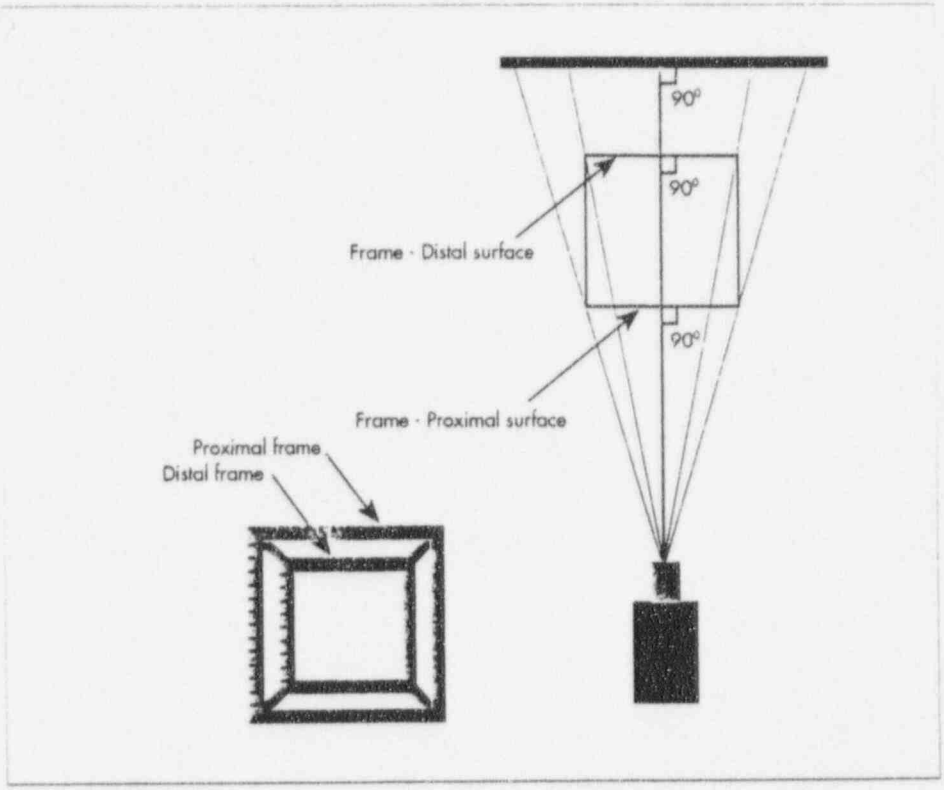
As in CT- or MR-scanning, it is desirable to be able to localize a target manually, also from conventional x-ray films. A manual technique for localization ensures that a procedure can be completed, regardless of computer malfunctioning.

The graphic method for target coordinate determination involves the use of two or three graphs which are essentially projections of the Leksell coordinate system in different planes.

One depicts the coordinate system (frame) in the axial projection, the second in the lateral view and the third in a frontal view. Information from the x-ray films is transferred to these grids from which the X-, Y- and Z-coordinates can be read.

This technique is used in conventional x-ray imaging, angiography and encephalography. The method works regardless of the distance between the x-ray tube and the frame. The position of the central beam is not critical. It is recommended to adjust the central beam to correspond as closely as possible to the centre of the coordinate system (X, Y, Z = 100). This makes it very simple to identify the frame centre during dose planning, which, while not essential, nonetheless facilitates accuracy (see illustration below). In addition, it may be mentioned that it is generally easier to achieve better visualization on the lateral than on the A-P films.

The x-ray equipment may be either one of the Leksell units or any other suitable x-ray machine.




*Short distance x-rays produce an image of the frame where the proximal part of the frame differs in magnification as compared to the distal part.*

This is easy with the Leksell units since they are designed to hold the cassettes in a fixed position. However, with other units it is also fairly easy to accomplish. It should be noted, that with short distance projections, there is a variable degree of magnification. In addition the proximal indicator scale, i.e. the one

closest to the x-ray tube, is more magnified than the distal one. This is important to keep in mind when doing the exposures. With the x-ray tube on the left side of the patient the left indicator scale will be more magnified than the right. The same applies to the anterior indicator scale if the x-ray tube is in front of the patient.

The graphs used are the same for visible and invisible targets. When the coordinates are read off the films they are transferred to the LOCALIZATION DATA sheet is used. Once it has been compiled it may serve as a record of the localization, together with the graphs.

---

**Note:** The AXIAL GRAPH is used to determine the target X- and Y-coordinates, while either one of the LATERAL or FRONTAL GRAPHS are used depending on whether the Z-values are read off from the A-P or lateral film.

---

It is advisable to determine the true Z-coordinate using the x-ray projection most clearly visualizing the target. If the A-P and lateral films are equal in this respect, the Z-coordinate may be determined based on each and an average value used.

However, it should be remembered that differences in the Z-coordinates imply differences in target selection on the A-P and lateral projections or misalignment of frame/indicator, film or x-ray tube.

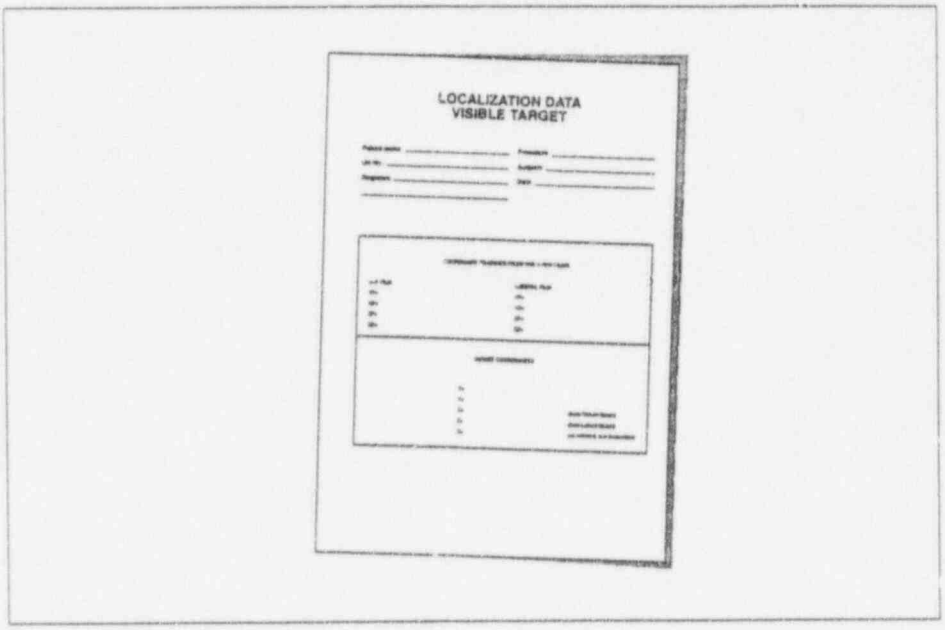
This difficulty can be largely avoided by having the centre beam of the x-ray concordant with the X, Y, Z, 100, 100, 100 point. If this is not possible, the centre point can still be defined if there is excellent visualization of all the scales on the films.

For determination of the stereotactic coordinates of a visible target using conventional skull x-ray, use the following step-by-step instruction. The technique takes a great deal less time to perform in practice than it does to describe:

## A. Reading the A-P and lateral skull films

**Note:** The proximal scale has the larger magnification.

1. Read the A-P film and mark the position of the target.
2. Draw a line from the target perpendicular to the X-scales of the indicator.
3. Read X on the proximal (XP) and distal (XD) scales.
4. Make a note of the XP and XD on the LOCALIZATION DATA sheet.



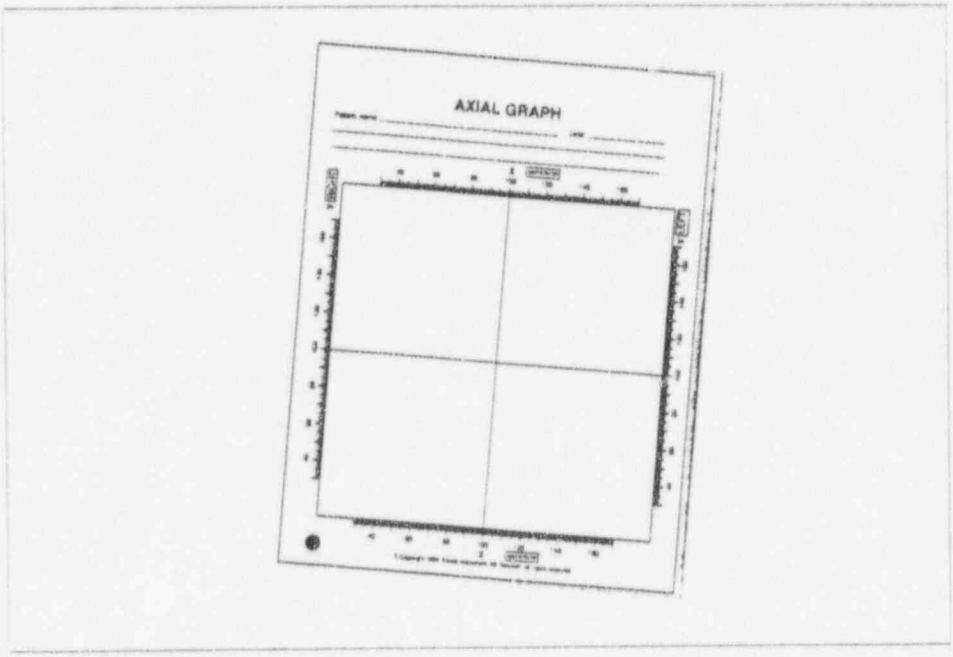

*Localization data sheet for visible targets.*

5. Draw a line from the target perpendicular to the Z-scales of the indicator.
6. Read Z on the proximal (ZP) and distal (ZD) scales.
7. Make a note of ZP and ZD on the LOCALIZATION DATA sheet.
8. Read the lateral film and mark the position of the target.
9. Draw a line through the target perpendicular to the Y-scales of the indicator.

10. Read Y on the proximal (YP) and distal (YD) scales.
11. Make a note of the YP and YD on the LOCALIZATION DATA sheet.
12. Draw a line through the target perpendicular to the Z-scales of the indicator.
13. Read Z on the proximal (ZP) and distal (ZD) scales.
14. Make a note of the ZP and ZD on the LOCALIZATION DATA sheet.

## B. Calculation of the target coordinates using the graphs

1. Start by using the AXIAL GRAPH.




*The axial graph.*

2. Plot the position of YP on the Y-scale marked LEFT, if the x-ray tube was on the patient's left side when the lateral film was obtained.

**Caution:** If the x-ray tube was on the patient's right side, YP should be plotted on the Y-scale of the graph marked RIGHT.

**Note:** When plotting, use an H or 2H pencil to ensure maximum accuracy.

3. Mark the position of the YD on the Y-scale marked RIGHT, if the x-ray tube was on the patient's left side when the lateral film was obtained.

**Caution:** If the x-ray tube was on the patient's right side, YD should be plotted on the Y-scale marked LEFT.

4. Draw a straight line on the AXIAL GRAPH between the points YP and YD on the left and right Y-scales.
5. Plot the position of XP on the X-scale marked ANTERIOR, if the x-ray tube was anterior to (facing) the patient when the A-P film was obtained.

**Caution:** If the x-ray tube was posterior to the patient when the A-P film was obtained, XP should be plotted on the X-scale marked POSTERIOR.

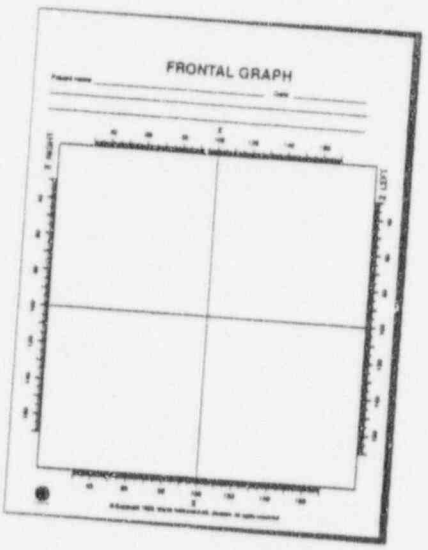
6. Plot the position of XD on the X-scale marked POSTERIOR, if the x-ray tube was anterior to (facing) the patient when the A-P film was obtained.

**Caution:** If the x-ray tube was posterior to the patient when the A-P film was obtained, XD should be plotted on the X-scale marked ANTERIOR.

7. Draw a straight line on the AXIAL GRAPH between the points XP and XD on the anterior and posterior X-scales.
8. Read the X- and Y-coordinates of the point of intersection between the lines YP-YD and XP-XD in the axial graph. These are the true X- and Y-coordinates of the target.
9. Write down the true X- and Y-coordinates of the target on the LOCALIZATION DATA sheet.

**Note:** The following (10 - 17) describes the use of the FRONTAL GRAPH, used when ZP and ZD are obtained from the lateral film.

10. Use the FRONTAL GRAPH to caiculate the Z-coordinate for the target.




*The frontal graph.*

**Note:** When plotting, use an H or 2H pencil to ensure maximum accuracy.

11. Mark the position of the true X-coordinate just obtained (see B:9 above) on the upper and lower X-scales of the FRONTAL GRAPH.
12. Draw a straight line between the points marked on the upper and lower X-scales of the graph.
13. Plot the position of ZP from the lateral film on the Z-scale marked LEFT, if the x-ray tube was on the patient's left side when the lateral film was obtained.

**Caution:** If the x-ray tube was on the patient's right side, ZP should be plotted on the Z-scale marked RIGHT.

14. Plot the position of ZD from the lateral film on the Z-scale marked RIGHT, if the x-ray tube was on the patient's left side when the lateral film was obtained.

**Caution:** If the x-ray tube was on the patient's right side, ZD should be plotted on the Z-scale marked LEFT.

15. Draw a straight line on the FRONTAL GRAPH between the points ZP and ZD on the left and right Z-scales.
16. Read the Z-coordinates of the point of intersection between the X-line and the ZP-ZD line in the FRONTAL GRAPH. **This is the true Z-coordinate of the target.**
17. Write down the true Z-coordinate for the target on the LOCALIZATION DATA sheet.

---

**Note:** The following (18 - 25) describes the use of the LATERAL GRAPH used when ZP and ZD are obtained from the A-P film.

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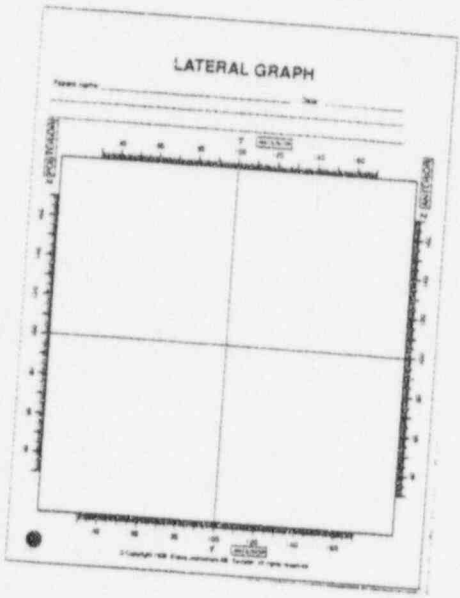
18. Use the LATERAL GRAPH to calculate the Z-coordinate of the target.




*The lateral graph.*

**Note:** When plotting, use an H or 2H pencil to ensure maximum accuracy.

19. Plot the position of the true Y-coordinate just obtained (see B:17 above) on the upper and lower Y-scales of the LATERAL GRAPH.
20. Draw a straight line between the points marked on the upper and lower Y-scales of the graph.
21. Plot the position of ZP from the A-P film on the Z-scale marked ANTERIOR, if the x-ray tube was facing the patient when the A-P film was obtained.

**Caution:** If the x-ray tube was behind the patient, ZP should be plotted on the Z-scale marked POSTERIOR.

22. Plot the position of ZD from the A-P film on the Z-scale marked POSTERIOR, if the x-ray tube was facing the patient when the A-P film was obtained.

**Caution:** If the x-ray tube was behind the patient ZD should be plotted on the Z-scale marked ANTERIOR.

23. Draw a straight line on the LATERAL GRAPH between the points ZP and ZD on the anterior and posterior Z-scales.

24. Read the Z-coordinates of the point of intersection between the Y-line and the ZP-ZD line in the LATERAL GRAPH. This is the true Z-coordinate of the target.

25. Write down the true Z-coordinate of the target on the LOCALIZATION DATA sheet.

26. Select the Z-coordinate to be used considering the accuracy in target determination on the A-P and lat al film.

27. Write down the selected Z-coordinate on the LOCALIZATION DATA sheet.

28. The X-, Y- and Z-coordinates of the target point have now been determined.

# Mathematical Method

Usually, the stereotactic coordinates of a target point, as well as the magnification of image planes, are determined by a graphic method. An alternative mathematical method is described below which may be more accurate than the graphic one. The formulas that are used for the calculations can easily be stored in a pocket calculator or alternatively executed by suitable computer worksheet programs.

The same three constraints which apply to the graphic method also apply to the mathematical method. Geometrical errors of uncertain dimensions may be introduced if the radiological examinations are not correctly performed. The important factors are:

1. X-ray film and frame must at all times be aligned at a right angle to the central ray of the diagnostic beam.
2. The frame must be so positioned in relation to the x-ray tube and the film that all proximal and distal scales are visible.
3. The position of the x-ray tube in relation to the head (in front, behind on the A-P series, or on the right or the left in the lateral series) must be known, in order to know which are the proximal and which are the distal scales on the films used in dose planning.

## Calculation of the Coordinates of a Point

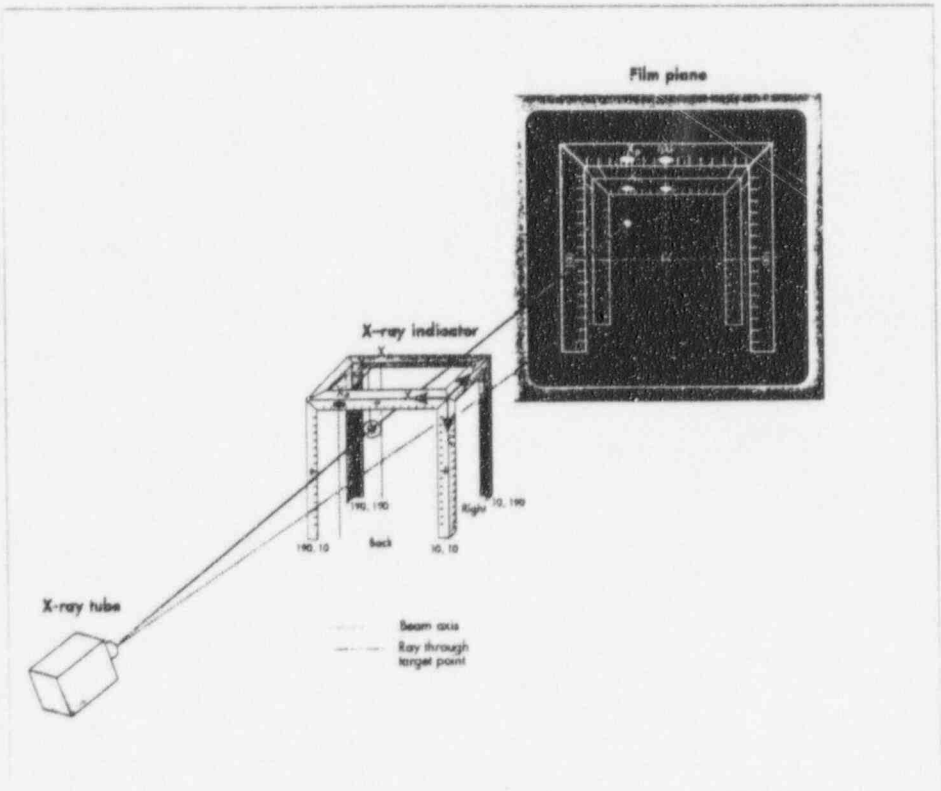
In the following examples it is assumed that the x-ray tube is either located at the right side of the patient or behind the patient. For the calculations we need to read six figures. From the lateral film (Figure 2) the $Y_R$, $Y_L$, $Z_R$ and $Z_L$ are read and $X_A$ and $X_P$ are read from the AP-film (Figure 1).

If we solve $X_T$, $Y_T$ and $Z_T$ by using equations ( 1 ), ( 2 ) and ( 3 ), we have the tools and the data to calculate the coordinates of a point that is located within the space of the Leksell Stereotactic System.

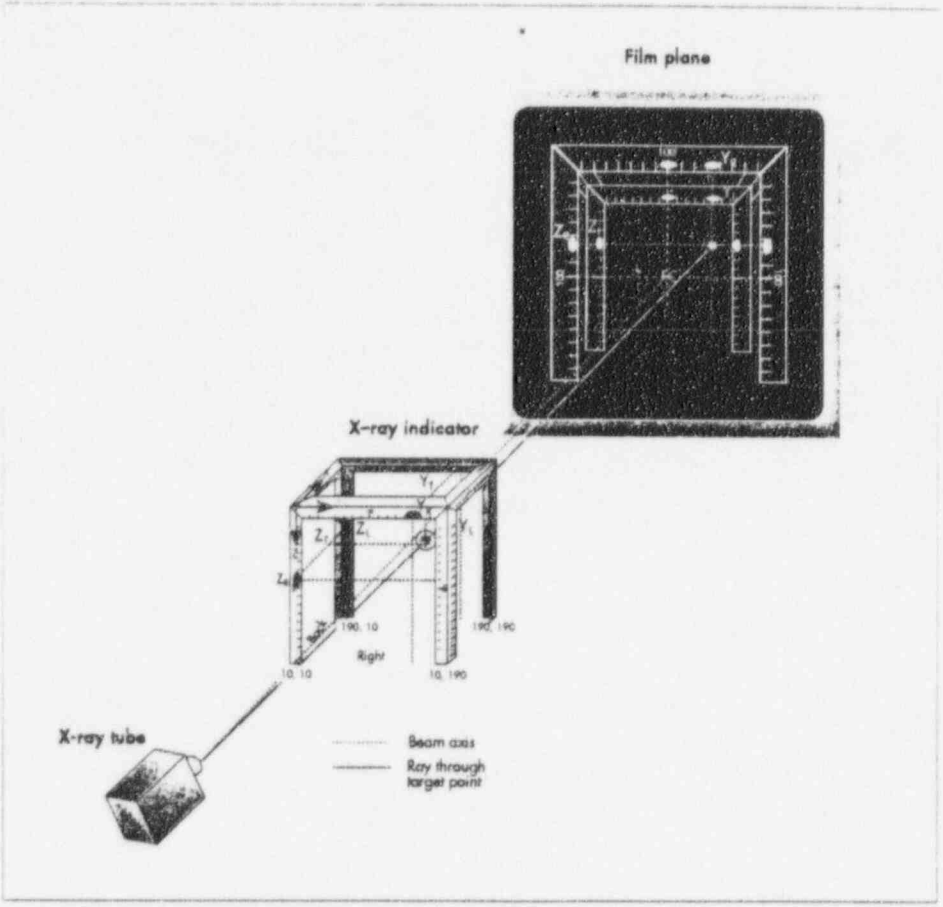
$$(1) \qquad X_T = X_p + \frac{180(190 - Y_R) - (Y_L - Y_R)(X_p - 10)}{(X_A - X_p)(Y_L - Y_R) - 180^2} (X_A - X_p)$$

$$(2) \qquad Y_T = Y_R + \frac{(X_A - X_p)(190 - Y_R) - 180(X_p - 10)}{(X_A - X_p)(Y_L - Y_R) - 180^2} (Y_L - Y_R)$$

$$(3) \qquad Z_T = Z_R + \frac{(X_A - X_p)(190 - Y_R) - 180(X_p - 10)}{(X_A - X_p)(Y_L - Y_R) - 180^2} (Z_L - Z_R)$$




*Projection of the three dimensional Angio box and a target point T on a film plane, as seen from behind the patient.*




*Projection of the three dimensional Angio box and a target point T on a film plane, as seen from the patient's right side*

In this example, we have assumed that $Z_T$ is determined from the lateral film. This is most often the case because the shape of the head results in a generally better picture quality in the lateral films as compared to the A-P films. If for some reason the AP-films should be used, then the formula used to calculate $Z_T$ must be rewritten.

## Magnification of Image Planes

In any view of the films, there are an infinite number of planes directed at a right angle to the beam axis. Of these, at least three are of interest. Moreover, two of these planes are made visible, the planes containing the scales of the frame. In the A-P film, the Y-axis values are 10 for the plane closest to the x-ray

tube and 190 for the plane furthest from the tube. The third parallel plane, containing the centre of the target, has the Y value $Y_T$. Plane $Y_{10}$ has the larger magnification and the plane $Y_{190}$ has the smaller. The magnification of the YT will be intermediate between these two extremes, the actual magnification depending on its position. If the target has an elongated shape in the Y-direction, several planes with different magnification may be needed. The same principles apply when viewing the lateral films but this time in relation to the X-axis.

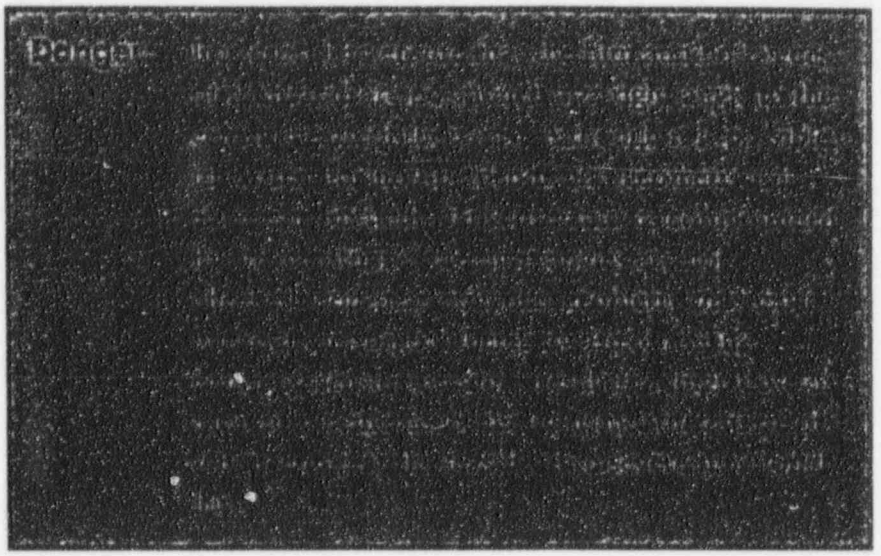
To calculate the magnification of lateral and A-P images planes, the coordinates of the target must be known. This is here assumed, for convenience, to have the previously determined coordinates $X_T$, $Y_T$, $Z_T$. In the A-P films, the magnification $M_P$ of the proximal plane ($Y_{10}$) is obtained from the scale as is $M_A$ the magnification of the distal plane ($Y_{190}$). In the same way, in the lateral films, $M_R$ the magnification of the proximal scale ($X_{10}$) and $M_L$ the magnification of the distal scale ($X_{190}$) are again read off the scales. With these values available, the magnifications $M_{AP}$ and $M_{LAT}$ may be derived for any A-P plane or lateral plane from the following two equations.

$$M_{LAT} = M_R + \frac{M_R (X_T - 10)}{M_L (190 - X_T) + M_R (X_T - 10)} (M_L - M_R)$$

$$M_{AP} = M_P + \frac{M_P (Y_T - 10)}{M_A (190 - Y_T) + M_P (Y_T - 10)} (M_A - M_P)$$

## Comment

In figures 1 and 2 we have assumed that the x-ray tube is aligned relative to the frame so that the beam axis passes through the frame centre (100, 100, 100). This geometrical arrangement helps when a radiosurgical procedure is planned with KULA because one of the fixed reference points of the isodose printouts from KULA is the frame centre, or its projection. To this end, it helps to use a large film size. With some of the smaller film sizes currently in use, it may be impossible both to centre the film at 100, 100, 100 and at the same time retain all the indicator scales in the picture. In this circumstance, there is no choice but to move the centre so as to ensure the scales are visible.



# Manual Technique – Invisible Targets

## Assumption

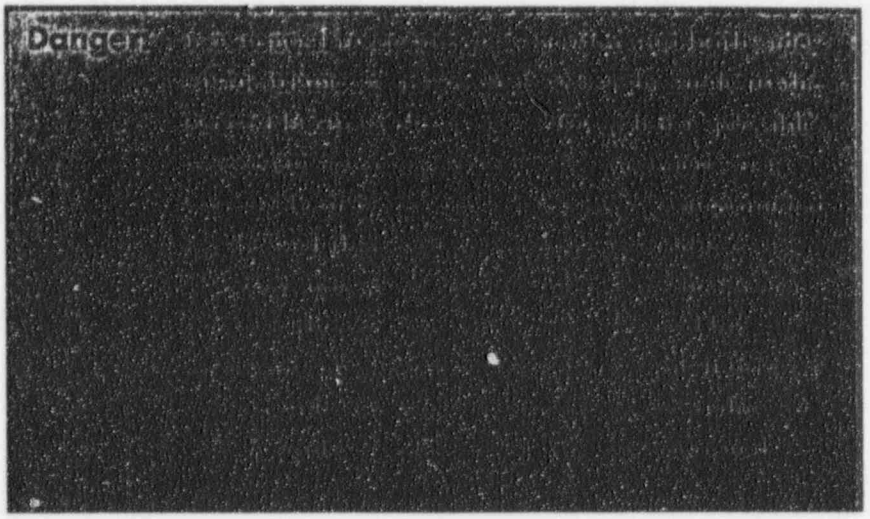
It is difficult or impossible to find the anterior and posterior commissures on an A-P x-ray film. It is therefore assumed that the Y-Z plane through the middle of the third ventricle also passes through the commissures. This assumption is a reasonable approximation unless the frame has been fixed to the skull in excessive rotation.

## Graphic Method

The graphic method for target coordinate determination of invisible targets involves the use of two graphs. These are essentially projections of the Leksell coordinate system in two planes, axial (X–Y) and frontal (X–Z). The technique is used in conjunction with conventional x-ray imaging, angiography and enchephalography. The method works regardless of the distance between the x-ray tube head and the frame. It is recommended to adjust the central beam to correspond as closely as possible to the centre of the coordinate system (X, Y, Z = 100).

This makes it very simple to identify the frame centre during dose planning, which, while not essential, nonetheless facilitates accuracy. In addition, it is generally easier to achieve better visualization on the lateral than on the A-P films.

The x-ray equipment may be either one of the Leksell units or any other suitable x-ray machine.




It should be noted that with short distance projections there is a variable degree of magnification. In addition the proximal indicator scale, i.e. the one closest to the tube head, is more magnified than the distal one. This is important to keep in mind when doing the exposures. With the tube head on the left side of the patient the left indicator scale will be more magnified than the right. The same applies to the anterior indicator scale if the tube head is in front of the patient and so on.

The graphs used are the same for visible and invisible targets. When the coordinates are read off the films the LOCALIZATION DATA sheet is used.

For determination of stereotactic coordinates of an invisible target in reference to the midpoint on the intercommissural line using stereotactic ventriculography, use the following step-by-step instruction:

**Warning:** Since the graphic method for invisible target co-ordinate determination cannot compensate for any frame rotation in the sagittal, coronal or transaxial plane, the accuracy of the method is in direct relation to the distance from the target to the frame centre.

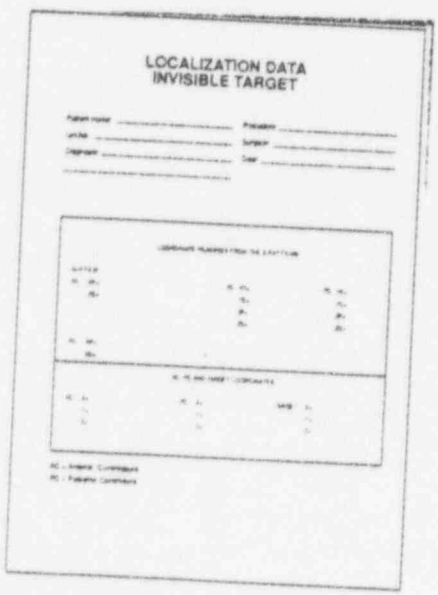
## A. Reading of the A-P and lateral ventriculograms

**Note:** The proximal scale has the larger magnification.

1. Read the A-P film and draw a line in the mid plane of the third ventricle perpendicular to the X-scales of the frame.

2. Read X on the proximal (XP) and distal (XD) scales.

3. Write down XP and XD on the LOCALIZATION DATA sheet.




*Localization data sheet for invisible targets.*

4. Read the lateral film and mark the position of the AC.

5. Draw a line through the AC perpendicular to the Y-scales of the frame.

6. Read Y on the proximal (YP) and distal (YD) scales.

7. Write down YP and YD for the AC on the LOCALIZATION DATA sheet.

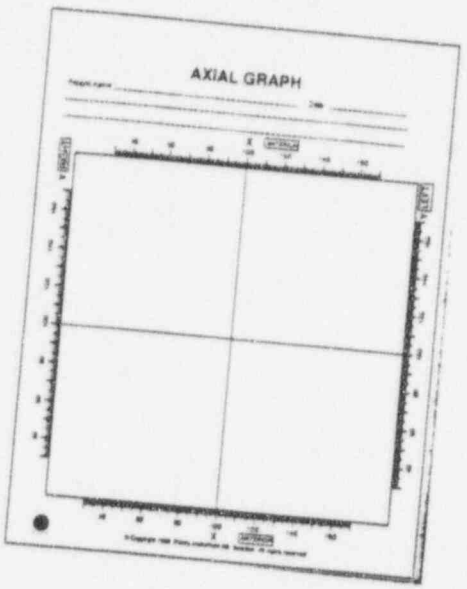
8. Draw a line through the AC perpendicular to the Z-scales of the frame.

9. Read Z from the proximal (ZP) and distal (ZD) scales.

10. Write down ZP and ZD for the AC on the LOCALIZATION DATA sheet.

## B. Calculation of the commissure coordinates using the two graphs

1. Start by using the AXIAL GRAPH.




*The axial graph.*

**Note:** When plotting, use an H or 2H pencil to ensure maximum accuracy.

2. Plot the position of YP on the Y-scale marked LEFT, if the x-ray tube was on the patient's left side when the lateral film was obtained.

**Caution:** If the x-ray tube was on the patient's right side, YP should be plotted on the Y-scale marked RIGHT.

3. Plot the position of YD on the Y-scale marked RIGHT, if the x-ray tube was on the patient's left side when the lateral film was obtained.

**Caution:** If the x-ray tube was on the patient's right side, YD should be plotted on the left Y-scale marked LEFT.

4. Draw a straight line on the AXIAL GRAPH between the points YP and YD on the left and right Y-scales.

5. Plot the position of XP on the X-scale marked ANTERIOR, if the x-ray tube was anterior to (facing) the patient when the A-P film was obtained.

**Caution:** If the x-ray tube was posterior to (behind) the patient when the A-P film was obtained, XP should be plotted on the X-scale marked POSTERIOR.

6. Plot the position of XD on the X-scale marked POSTERIOR, if the x-ray tube was anterior to (facing) the patient when the A-P film was obtained.

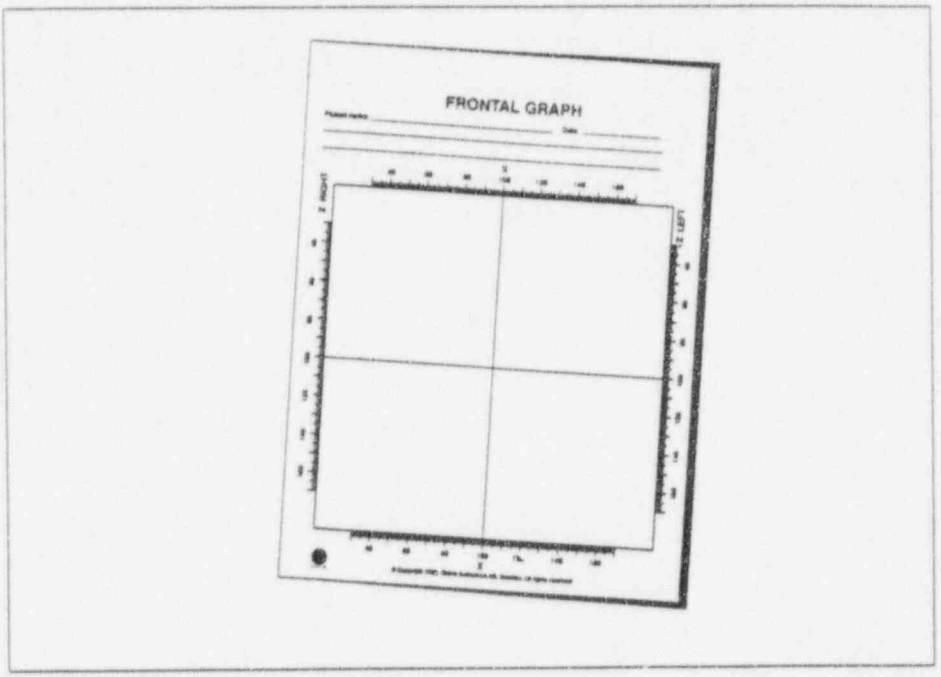
**Caution:** If the x-ray tube was posterior to (behind) the patient when the A-P film was obtained, the XD should be plotted on the X-scale marked ANTERIOR.

7. Draw a straight line on the AXIAL GRAPH between the points XP and XD on the anterior and posterior X-scales.

8. Read the X- and Y-coordinates of the point of intersection between the lines YP-YD and XP-XD in the AXIAL GRAPH. These are the true X- and Y-coordinates of the AC.

9. Write down the true X- and Y-coordinates of the AC on the LOCALIZATION DATA sheet.

10. Use the FRONTAL GRAPH to calculate the Z-coordinate for the anterior commissure (AC).




*The frontal graph.*

**Note:** When plotting, use an H or 2H pencil to ensure maximum accuracy.

11. Plot the position of the true X-coordinate just obtained (see B:9 above) on the upper and lower X-scales of the FRONTAL GRAPH.

12. Draw a straight line between the points marked on the upper and lower X-scales of the graph.

13. Plot the position of ZP (from the lateral film) on the Z-scale marked LEFT, if the x-ray tube was on the patient's left side when the lateral film was obtained.

**Caution:** If the x-ray tube was on the patient's right side, ZP should be plotted on the Z-scale marked RIGHT.

14. Plot the position of ZD on the Z-scale marked RIGHT, if the x-ray tube was on the patient's left side when the lateral film was obtained.

**Caution:** If the x-ray tube was on the patient's right side, ZD should be plotted on the Z-scale marked LEFT.

15. Draw a straight line on the FRONTAL GRAPH between the points ZP and ZD on the left and right Z-scales.

16. Read the Z-coordinates of the point of intersection between the XP-XD line and the ZP-ZD line in the FRONTAL GRAPH. **This is the Z-coordinate of the AC.**

17. Write down the X-, Y- and Z-coordinate for the AC on the LOCALIZATION DATA sheet.

## C. Marking the position of PC.

Repeat all steps from A:4 through B:17 to obtain the coordinates for the PC. Write down the X-, Y- and Z-coordinates for the PC on the LOCALIZATION DATA sheet.

## D. Target point coordinate determination.

For the target point coordinate determination follow the steps below:

1. The AC-PC line can now be drawn on the AXIAL GRAPH and its midpoint (IM) marked by dividing this line into equal halves.

2. The AC-PC line can also be drawn in the FRONTAL GRAPH and the midpoint (IM) marked (in the FRONTAL GRAPH the AC-PC line is a point if the frame has been positioned with its X-Y plane parallel to the transaxial plane through the commissures).

3. The midpoint on the intercommissural line (IM) is usually the reference point for the target. Since the position of IM is now marked on the AXIAL and FRONTAL GRAPHS, the target point (TP) can now also be marked in these graphs at the appropriate distance from IM.

---

**Note:** Corrections must be made for third ventricles of exceptional width.

---

4. Read the X- and Y-coordinates of the target point (TP) from the AXIAL GRAPH and write them down on the LOCALIZATION DATA sheet.

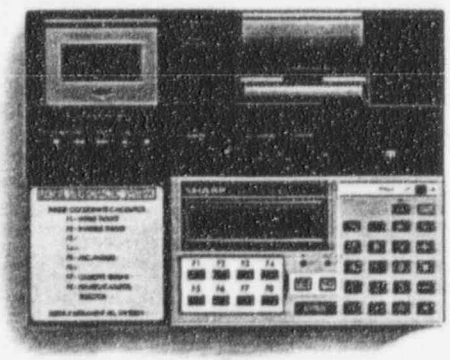
5. Read the Z-coordinate of TP from the FRONTAL GRAPH and make a note of it on the LOCALIZATION DATA sheet.

6. The true X-, Y- and Z-coordinates of the target point (TP) have now been determined.

# Target Coordinate Determination – Software Based Techniques

## Target Coordinate Calculator Method

An alternative for the manual target localization is to use the calculator which features a stereotactic software allowing X-, Y- and Z-coordinates to be determined from x-ray films regardless of the distance between tube head and coordinate frame. Visible as well as invisible targets are localized.



*The Target Coordinate Calculator.*

The use of the calculator involves the transfer of numerical values directly from the x-ray films to the calculator.

For further information on the use of the Target Coordinate Calculator, see the separate User's Manual

## Leksell Localizer Method

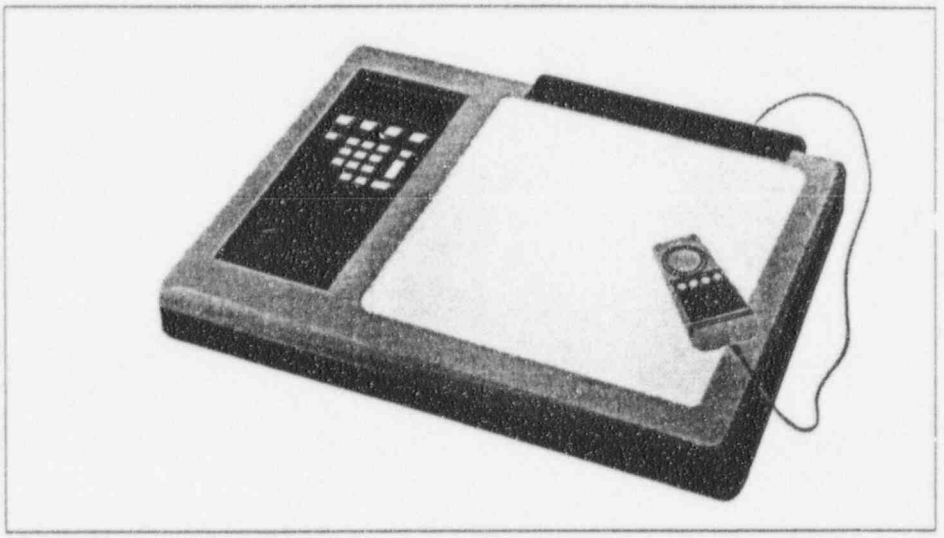
The Leksell Stereotactic System, has relied on a variety of localizing techniques for a long time. Different techniques have been used for CT and for MRI and there has been more than one technique for different studies involving conventional x-rays.

In an effort to simplify the localization of targets from different kinds of images, the Leksell Localizer was designed. This instrument provides the user with an integrated, reliable and self-

explanatory method of determining target coordinates. It can be used with images produced by all currently available techniques.

The Leksell Localizer consists of a digitizing table, pointing device and a small keyboard with and LED-display. All components are built into an easy-to-use transportable tabletop unit which incorporates adequate lighting for viewing of images.

For further information on the Leksell Localizer, see the separate User's Manual.



*The Leksell Localizer.*

ELEKTA

12

# Emergency Routines

*The following relevant actions are to be taken when the equipment is out of order.*

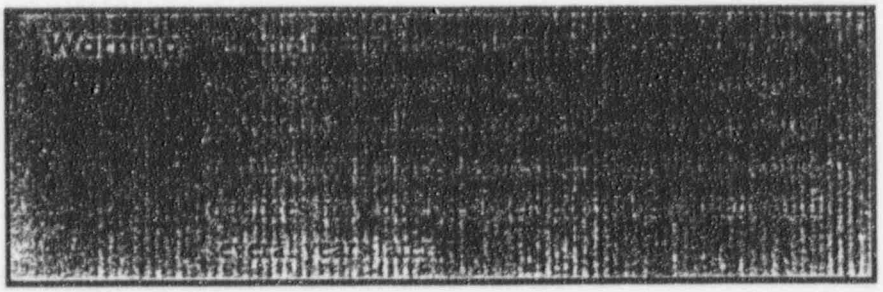
# Contents

# Safety

The Gamma Knife must only be maneuvered by personnel who have a full understanding of the operation of the unit, including procedures applicable in an emergency.

Prepare a check list that is followed during each procedure. This list of steps which can improve safety, depends to a large extent on local conditions. Some of the steps that should be included are outlined below.

1. At least two persons should be present during the preparation of the Gamma Knife for treatment, the positioning procedure of the patient and during treatment.
2. All procedures that affect the treatment such as selection of helmets, their plugging, the setting of stereotactic coordinates, the setting of the treatment timer etc. must be verified by a second person prior to treatment. This DOUBLE CHECK IS AN ABSOLUTE REQUIREMENT for safe treatments with the Gamma Knife.



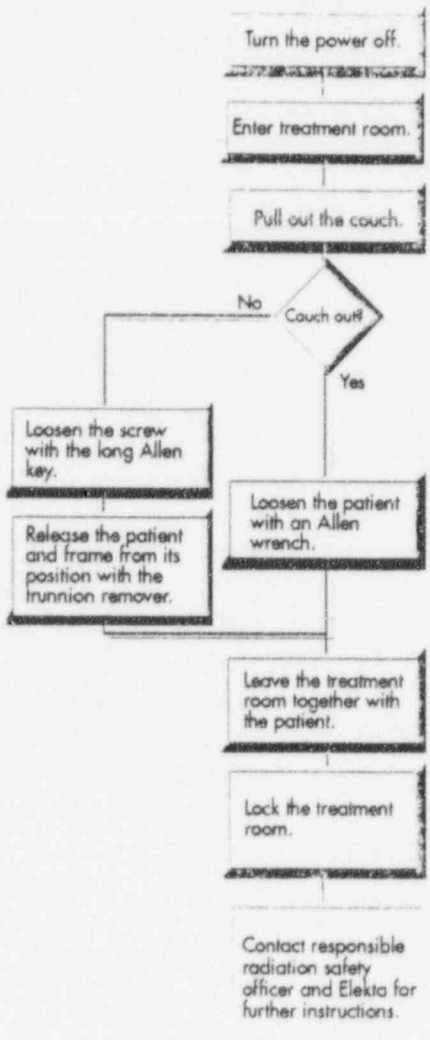
**Caution:** Check before accepting a treatment plan that the treatment time, and the coordinates for each irradiatiopnare reasonable as judged by your experience.

3. Before positioning the patient in the unit, estimate that the Y- and Z-coordinates set on the frame approximately correspond with the location of the target in the skull.
4. When the patient is positioned in the unit, ensure that the head of the patient is dislocated in the correct direction.

5. The person who is responsible for the procedure should be the last to leave the treatment room before treatment. At this moment he/she should have checked that no items such as collimators, tools etc. are left on the bed between the helmet and the unit. Check that everyone except the patient has left the treatment room.
6. The person who maneuvers the unit should frequently communicate with the patient via the audio-vision communication system.
7. Although the Gamma Knife is simple to operate and is reliable in its function, emergency situations may occur. It is therefore strongly recommended that procedures which are applicable in possible emergency situations are prepared and personnel trained at regular intervals.
8. It is helpful in emergency situations to have a checklist visible at the maneuver panel of the Gamma Knife.

# Emergency Routines for the Leksell Gamma Knife

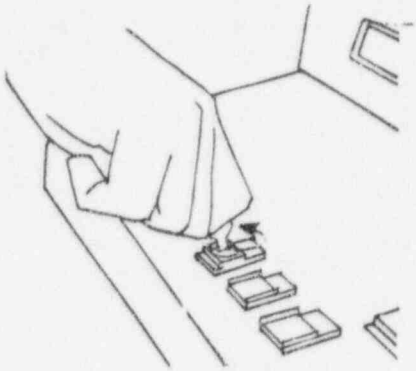
If the couch does not leave the treatment position when the treatment time has elapsed, proceed as follows:



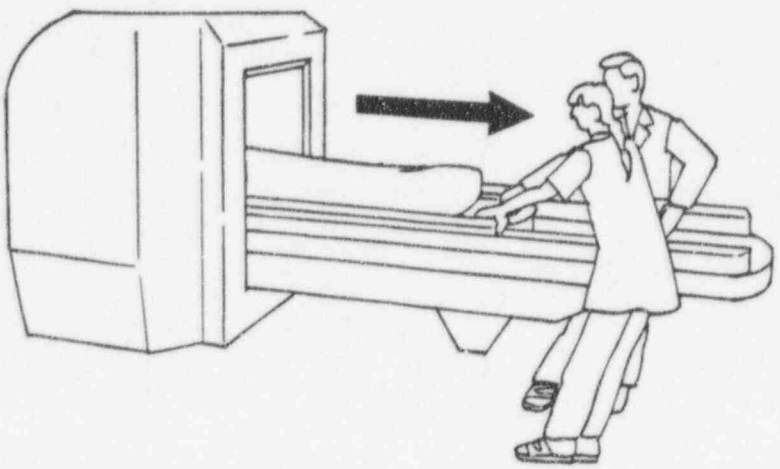

*The different actions in an emergency situation.*

# Couch not Returning Properly

(2 persons required)

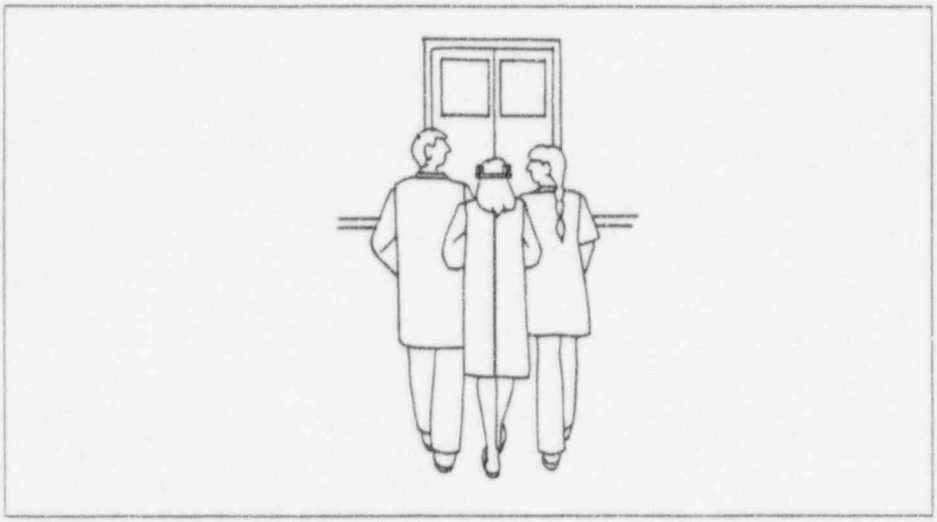


*Turn off the main power key and be sure to take the key with you.*



*Enter the treatment room and try to withdraw the couch manually.*

*Loosen the patient with an Allen key.*

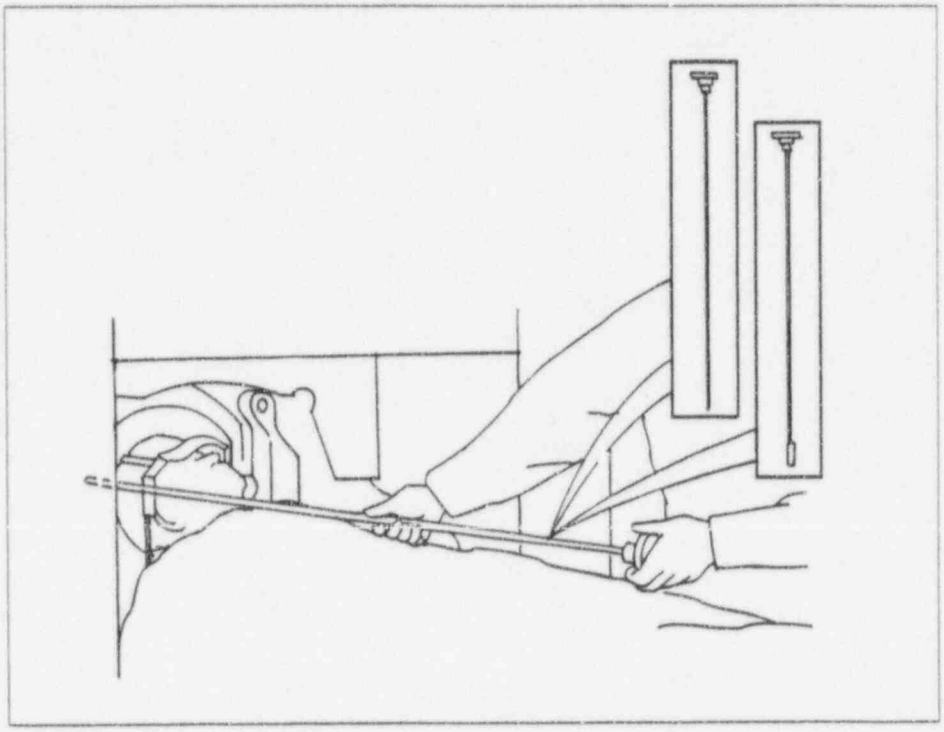


*Leave the treatment room together with the patient.*

Try to restart the equipment and to close the shielding doors from the control panel. If this does not succeed, close the shielding doors manually (see Shielding Doors Stuck).

**Note:** In order to close the shielding doors from the control panel, the couch must be withdrawn to its outer position.

## Couch Stuck in Treatment Position



*Loosen the patient with the long Allen key and release patient with trunnion remover. Help the patient out of the Gamma Knife.*

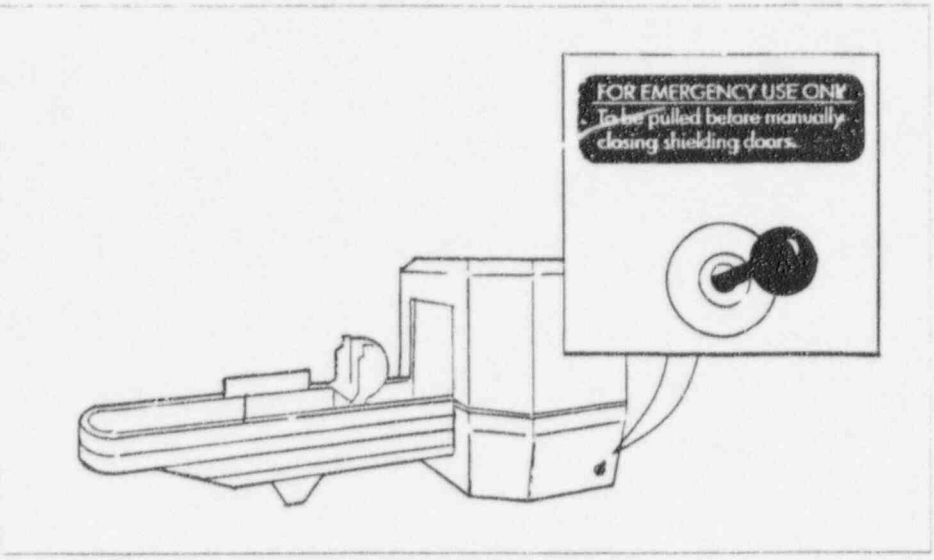
## Shielding Doors Stuck

Call authorized personnel for help. The procedure is as follows:

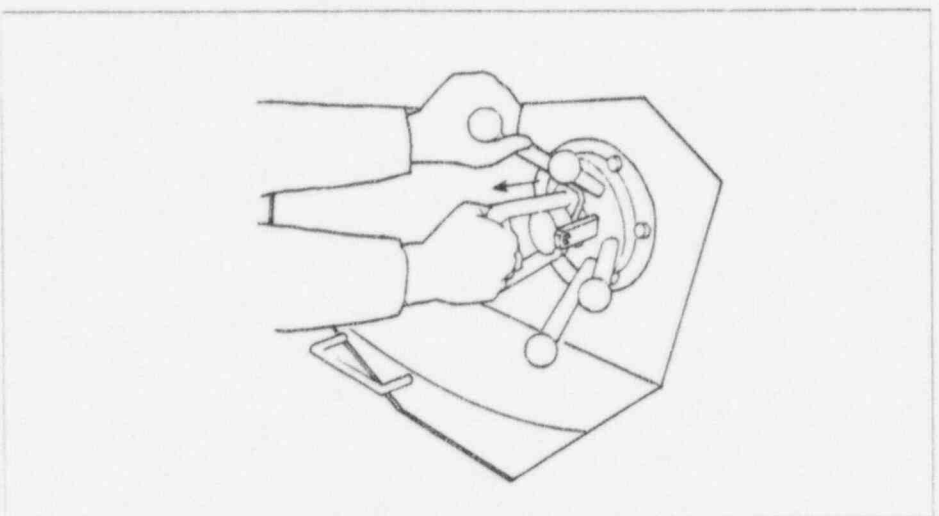
---

**Note:** Before starting, turn off the main switch key. Bring the key, which is needed to unlock the handwheel, into the treatment room.

---

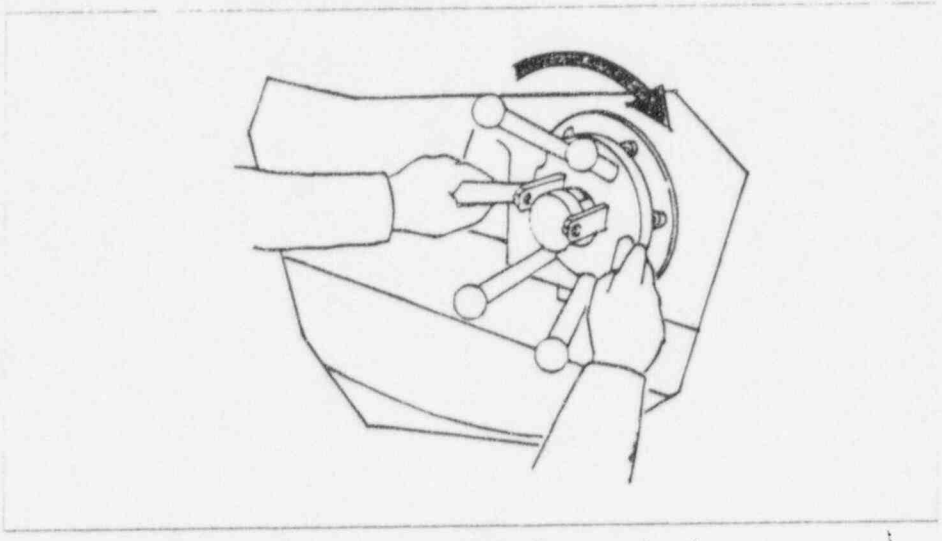



*Pull the brake release knob.*



*Remove the cover lid, unlock the handwheel (with the key that comes with the main switch key). Pull out the knob with the special tool.*

**Warning:** Ensure that no assisting personnel are near the shielding doors at this time.



*Rotate the handwheel clockwise until the doors are closed.*

**Caution:** Always hold the handwheel with both hands. Otherwise the doors can close with considerable force and may be damaged.

## After an Emergency Situation

Lock the doors to the treatment room and tape a warning on the doors.

Call without any delay for Elekta assistance for further information and instructions.





466223

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02240
Status Code: 0
Fee Category: 3P 2B
Exp. Date: 20020731
Fee Comments: 2 STAGES/PENDING HUM
Decom Fin Assur Reqd: N

1996 OCT 12 AM 6:12

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: COLUMBIA HCA HEALTH SERVICE OF OKLA
   Received Date: 961007
   Docket No: 3017190
   Control No.: 466223
   License No.: 35-12091-02
   Action Type: Amendment

2. FEE ATTACHED
   Amount: —
   Check No.: —

3. COMMENTS
   Continuation of MC # 466078

Signed Laura Sudley
Date 10/9/96

RECEIVED
OCT 17 1996
REGION IV

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 02 is entered in LTS)

FEE NOT REQUIRED

1. Fee Category and Amount: 3P 2B Cont 466078

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed Rita Messina
Date 10/12/96

RECEIVED BY LFMS
Date 10/12/96
Log Oct 2 IV
Rem
mpleted 10/12/96

COLUMBIA
Presbyterian Hospital

700 Northeast 13th Street
Oklahoma City, Oklahoma 73104-5070
Phone (405) 271-5100
COLUMBIA's home page is http://www.columbia.net



September 30, 1996

U. S. Nuclear Regulatory Commission
611 S. Ryan Plaza Drive, Suite 400
Arlington, Texas 76011

RE: License Amendment for Gamma Sterectactic Radiosurgery (GSR)
License number: 35-120391-02

Subject: Removal of Colbolt 60 Teletherapy Unit

Dear Ms. Campbell:

On August 23, 1996, Xray Equipment Company of Mansfield, Texas removed our AECL Theratron 80 Teletherapy Unit and source. We have enclosed the appropriately signed Transfer Certificate.

This effectively removes material identified in (6A Colbolt 60) and (6B Uranium, natural or depleted) from this license. You will recall that the license still contains material for the gamma stereotactic radiosurgery unit.

We do not plan on decommissioning this room, as this room is used to house our high dose rate unit as noted in license number 35-12091-01.

If you have questions regarding this notification, please do not hesitate to contact us.

Sincerely,

Clifford W. Richter, PhD

Clifford W. Richter, Ph.D
Radiation Safety Officer
Director of Medical Physics

# X-RAY EQUIPMENT COMPANY

## SOURCE DISPOSAL CERTIFICATE

THIS IS TO CERTIFY THAT A COBALT 60 SOURCE;

MODEL NUMBER: C-146

SERIAL NUMBER: S-3977

CATALOG NUMBER: _____

CONTAINING 6684 CI COBALT 60

MEASUREMENT DATE: 3 / 16 / 87

THE ABOVE SOURCE HAS BEEN DETERMINED BY WIPE TEST TO BE FREE OF REMOVABLE CONTAMINATION. THIS SOURCE HAS BEEN REMOVED FROM THE TELETHERAPY UNIT DESCRIBED AS FOLLOWS;

MANUFACTURER: AECL

MODEL NUMBER: T-80

SERIAL NUMBER: 139

THE ABOVE UNIT HAS [x] HAS NOT [ ] BEEN REMOVED FROM SERVICE.

AND IS HEREBY TRANSFERED TO:

X-RAY EQUIPMENT COMPANY
2214 HWY. 1187
MANSFIELD, TEXAS 76063

TEXAS RADIOACTIVE MATERIAL LICNESE L01485

FROM THE POSSESSION OF;

Columbia HCA Health Services - Columbia Presbyterian Hospital

700 N.E. 13th Street

Oklahoma City, OK 73104

RADIOACTIVE MATERIAL LICENSE NUMBER: 35-12091-02

REPRESENTIVE OF USER:

Clifton W. Butler BS
Radiat Safety Officer

DATE 8/23/96

X-RAY EQUIPMENT COMPANY

Dennis Tarker

DATE 8/23/96

COLUMBIA
Presbyterian Hospital

700 Northeast 13th Street
Oklahoma City, Oklahoma 73104-5070
Phone (405) 271-5100
COLUMBIA's home page is http://www.columbia.net



SEPTEMBER 30, 1996

Vivian H. Campbell, Health Physicist
Nuclear Materials Licensing Section
Region IV
U. S. Nuclear Regulatory Commission
611 S. Ryan Plaza Drive, Suite 400
Arlington, Texas 76011

RE: License Amendment for Gamma Stereotactic Radiossurgery (GSR)
License number: 35-120391-02
Control: 466078

Dear Ms. Campbell:

Please find enclosed the following information with regard to our gamma knife project:

A. An updated technical manual describing the model B Leksell Gamma Knife. This technical program's manual specifically addresses some of the items that you had questions about and includes in Chapter 12 at the latest updated version of the emergency procedures that we will use.

B. The quality management programs specifically developed for our gamma knife.

C. A schedule that outlines the required regulatory tests and their frequency.

As previously discussed, we are attempting to begin clinical operations early in November. Naturally, if you or your staff have questions concerning our request, please do not hesitate to call.

Sincerely,

Clifford W. Richter, Ph.D.

Clifford W. Richter, Ph.D
Radiation Safety Officer
Director of Medical Physics

466223

STEREOTACTIC RADIOSURGERY
QUALITY MANAGEMENT PROGRAM - GAMMA

I. Responsibility and authority: these procedures are established to meet the requirements of a Quality Management Program (QMP) identified in 10 CFR 35.32 for Gamma Stereotactic Radiosurgery.

II. Elements of the Program are based on a record keeping system, worker methodology regarding the procedures to follow relating to physician written directives, and verification that the patient and the treatment plan will be confirmed to establish agreement wih the written directive.

A. Records (i.e., written directives and other written instructions or records) relating to the medical use will be legible and written clearly, precisely, and in a manner to minimize the likelihood of misunderstanding.

B. All workers involved in medical usae will equest clarification from an authorized user or a physician under the supervision of an authorized user if any element of a written directive, and other written instruction or record is unclear, ambiguous, or apparently erroneous, before proceeding with the procedure.

C. Before medical use, the person administering the byproduct material will verify that the medical use is in accordance with the written directive and/or clinical procedures manual.

III. Specific Elements for gamma stereotactic radiosurgery applications.

A. Before writing a directive, the authorized user or the physician under the supervision of an authorized user (hereafter understood as the authorized user) will prsonally review the patient's case to establish that thd medical use is indicated for the patient.

B. Before administering gamma stereotactic radiosurgery , the authorized user will personally make, date and sign a written directive.

C. Any change in the written directive will be made by the authorized user, will be recorded in writing in appropriate record, and will be dated and signed.

D. Before administering gamma stereotactic radiosugery, the identity of the patient will be confirmed by more than one method as the individual named in the written directive, and the plan of treatment will be confirmed to establish agreement with the written directive.

E. For gamma stereotactic radiosurgery procedures qppropriate images of the treatment area (volume) will be completed to verify treatment area. For these images or from fixed geometry data, calculations will be performed to calculate, exposure time and/or dose (as required by the written directive).

F. The authorized user will date and sign or initial the calculations and record the administered dose.

G. After the completion of the gamma stereotactic radiosurgery proceeduare, the authorized user will make, date and sign a written record which describes the dosage administered, and will record the agreement, or lack thereof, between the actual dose administered.

IV. QMP review to evaluate patient administrations, recordable events, and all misadministrations will be established.

A. These reviews will be conducted at least annually. The purpose of review will be:

1. verify compliance with all aspects of the quality management program;
2. determine the effectiveness of the program, and if necessary, make modifications to assure that byproduct materials are administered as directed by the authorized user.

B. Records of each review will include evaluations and findings of the review and will be maintained for three years.

C. Recordable events will be evaluated within 30 days of discovery of the recordable event by:

1. assembling the recordable facts including the cause,
2. identifying what, if any corrective action is required to prevent recurrence; and
3. retaining a record of the relevant facts and any corrective actions for three years.

D. Records of each written directive and each administered gamma stereotactic radiosurgery dose will be maintained in an auditable form for three years from date of administration.

E. As needed, modifications will be made to increase the efficiency of the QMP program without reducing the program's effectiveness.

The above listed policies are to be implemented at this facility on or before clinicaL use of the LEKSELL GAMMA KNIFE.

Director of Radiation Oncology — Date 10/2/96

Radiation Safety Officer — Date 10-1-96

Hospital Administration — Date 10/3/96

REGULATORY TEST AND FREQUENCY
GAMMA STEREOTACTIC RADIOSURGERY

DAY OF USE:

- Door Interlock
- Area Monitor
- TV/Intercom
- Timer termination of exposure
- Survey meter (present)

MONTHLY:

- Output check
- Timer constancy/accuracy/linearity
- Shutter error
- Check of required postings

SEMI-ANNUAL:

- Demonstration of emergency proceedures
- Leak Tests of sealed sources

ANNUAL:

- Calibration