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INSTALLATION TEST PROTOCOL LGK MODEL 23004

PROJECT No.:

HOSPITAL:

CITY:

ORIENTATION MANUFACTURER:

ORIENTATION SITE:

PERFORMED BY:

PARTICIPANTS FROM HOSPITAL:

Action	Approved	Not Appr.	Date
Quality Control of Installation Test Protocol (Service Manager)			

ELEKTA INSTRUMENT AB, LINKÖPING, SWEDEN		TEST PROTOCOL
Project No:	Hospital:	

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1. INTRODUCTION

1.1. Summary

This document is a form which is used at the site to perform the Installation Test, which is performed, together with the customer, prior to acceptance.

1.2. Terminology

This document includes a number of acronyms and special terms, their meaning are as follows:

TERM	MEANING
LGK	Leksell Gamma Knife

1.3. Applicable Documents

Function Test LGK Model 23004

Commissioning Test LGK Model 23004/SITE TEST

1.4. Revision History

Issue	Date	Resp.	Description
1	November 30, 1994	JOL	First version, issue 1
2	March 16, 1995	EL	See "ÄM" No 0342
3	June 9, 1995	EL	See "ÄM" No 0378
4	January 16, 1996	EL	See "ÄM" No 0517
5	May 13	PF	See "ÄM" No 0618

1.5. Instructions

- * Initials shall be put in the space for approved/not approved.
- * Every test must be dated
- * If something is not approved or approved with a deviation, a remark of this must be made on the last page of the function test (item no 7)
- * The remark shall refer to the test no. and to the report that is to be written on the remark.
- * When action has been taken and the test has been redone and approved this shall be noted below the remark, signed and dated.

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2. LABELING

2.1. Identity of Parts

	Part	Id. no.	Approved	Not Appr.	Date
a	Radiation Unit				
b	Couch				
c	Frame Assembly				
d	Helmet Table				
e	Helmet with Collimator Diameter 4				
f	Helmet with Collimator Diameter 8				
g	Helmet with Collimator Diameter 14				
h	Helmet with Collimator Diameter 18				
i	Helmet Hoist				
j	Test Tool				
k	Adjustment Ring				
l	Control Panel				
m	Monitor				
n	Electrical Cubicle				
o	Camera				

2.2. Signs

2.2.1. Signs

	Action	Approved	Not Appr.	Date
a	<p>Check that all signs are properly attached according to drawings 301559, 301560 and 301561.</p> <p>For LGK Units installed in the US, signs should be checked against drawing 303088 instead of 301559.</p>			

✓
✓
✓

3. TREATMENT POSITIONING PROCEDURE

3.1. Check Helmet Switches with the Test Tool and the Test Box

3.1.1. Helmet with Collimator Diameter 4

	Action	Approved	Not Appr.	Date
a	Test tool attached. "green signal"			
b	Test tool and shims 0.1 mm attached. "red signal"			

3.1.2. Helmet with Collimator Diameter 8

	Action	Approved	Not Appr.	Date
a	Test tool attached. "green signal"			
b	Test tool and shims 0.1 mm attached. "red signal"			

3.1.3. Helmet with Collimator Diameter 14

	Action	Approved	Not Appr.	Date
a	Test tool attached. "green signal"			
b	Test tool and shims 0.1 mm attached. "red signal"			

3.1.4. Helmet with Collimator Diameter 18

	Action	Approved	Not Appr.	Date
a	Test tool attached. "green signal"			
b	Test tool and shims 0.1 mm attached. "red signal"			

3.2. Check Helmet Hoist Positioning

3.2.1. Operate the Couch

Attach helmet with collimator diameter 4, helmet cap and helmet angle connectors.
Connect the helmet hoist to the frame.

	Action	Approved	Not Appr.	Date
a	Try to operate the couch from the helmet hoist. Not possible.			
b	Try to operate the couch from the control panel. Not possible.			

3.2.2. Cap removed

Remove the cap on fixated helmet.

	Action	Approved	Not Appr.	Date
a	Check that it is possible to make the couch go in, operating from the helmet hoist.			
b	Check that it is not possible to make the couch go out, operating from the helmet hoist.			

3.2.3. Disconnected Helmet Angle Connectors

Disconnect helmet angle connectors.

	Action	Approved	Not Appr.	Date
a	Check that it is possible to make the couch go out, operating from the helmet hoist.			

3.3. Check Helmet Positioning

3.3.1. Helmet with Collimator Diameter 4

	Action	Approved	Not Appr.	Date
a	Trunnions pair 1. Center coordinate left, right.			
b	Trunnions pair 2. Center coordinate left, right.			
c	Start treatment, couch in to correct position. "Treatment yes" lights.			
d	Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position. "Treatment no" lights.			

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3.3.2. Helmet with Collimator Diameter 8

Action	Approved	Not Appr.	Date
a Trunnions pair 1. Center coordinate left, right.			
b Trunnions pair 2. Center coordinate left, right.			
c Start treatment, couch in to correct position. "Treatment yes" lights.			
d Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position. "Treatment no" lights.			

3.3.3. Helmet with Collimator Diameter 14

Action	Approved	Not Appr.	Date
a Trunnions pair 1. Center coordinate left, right.			
b Trunnions pair 2. Center coordinate left, right.			
c Start treatment, couch in to correct position. "Treatment yes" lights.			
d Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position. "Treatment no" lights.			

3.3.4. Helmet with Collimator Diameter 18

Action	Approved	Not Appr.	Date
a Trunnions pair 1. Center coordinate left, right.			
b Trunnions pair 2. Center coordinate left, right.			
c Start treatment, couch in to correct position. "Treatment yes" lights.			
d Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position. "Treatment no" lights.			

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3.4. Time Measuring

Action	Approved	Not Appr.	Date
a Couch in to correct positioning. Time = seconds. (60s \pm 5s) acceptable			
b Couch out to correct position. Time = seconds. (60s \pm 5s) acceptable			
c Opening radiation shield. Time = seconds. (10s \pm 2s) acceptable			
d Closing radiation shield. Time = seconds. (10s \pm 2s) acceptable			

3.5. Check Slow Speed of Radiation Shield

Action	Approved	Not Appr.	Date
a Slow speed when opening.			
b Slow speed when closing.			

4. SUPERVISION FUNCTIONS

4.1. Power Failure

Terms within brackets are positions according to old version.

4.1.1. Power failure before treatment

Shut off main switch -A31Q1 [HB1] on electrical cubicle.

Action	Approved	Not Appr.	Date
a Push "Treatment start". Start of treatment not possible.			

4.1.2. Power failure during treatment

Shut off main switch -A31Q1 [HB1] during treatment..

Action	Approved	Not Appr.	Date
a Treatment interrupted.*			
b Normal function operating table checked.			
c Battery power checked.			

* For LGK units delivered and installed before 960601 the treatment shall be completed.

4.1.3. Power failure during couch in

Push "Treatment start" and shut off main switch -A31Q1 [HB1] when couch is moving in.

Action	Approved	Not Appr.	Date
a Ingoing couch stops and moves out *			

* For LGK units delivered and installed before 960601 the treatment shall be completed

4.2. PLC1 Computer, -A31A1A11 [R6=1], Failure

4.2.1. Circuit breaker off, during treatment

Shut off circuit breaker -A31W2F1 [R2=1] in the electrical cubicle during treatment.

Action	Approved	Not Appr.	Date
a Treatment stop cycle is initiated.			

4.2.2. Power failure when circuit breaker off, during treatment

Shut off main switch -A31Q1 [HB1] and circuit breaker -A31W2F1 [R2=1] during treatment

Action	Approved	Not Appr.	Date
a Treatment stop cycle is initiated.			

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4.2.3. Circuit breaker off, before treatment

Shut off circuit breaker -A31W2F1 [R2=1]

Action	Approved	Not Appr.	Date
a Push "Treatment start". Start of treatment not possible.			

4.3. PLC2 Computer ,-A31A2A11 [R7=1], Failure

4.3.1. Circuit breaker off, during treatment

Shut off circuit breaker -A31W2F5 [R2=5] in the electrical cubicle during treatment.

Action	Approved	Not Appr.	Date
a Treatment interrupted.*			

* For LGK units delivered and installed before 960601 the treatment shall be completed.

4.3.2. Power failure when circuit breaker off, during treatment

Shut off main switch -A31Q1 [HB1] and circuit breaker -A31W2F5 [R2=5] during treatment

Action	Approved	Not Appr.	Date
a Treatment interrupted.*			

* For LGK units delivered and installed before 960601 the treatment shall be completed.

4.3.3. Circuit breaker off, before treatment

Shut off circuit breaker -A31W2F5 [R2=5]

Action	Approved	Not Appr.	Date
a Push "Treatment start". Start of treatment not possible.			

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4.4. Couch Position Failure

4.4.1. Motor off during couch movement

Push "Treatment start". Disconnect couch motor drive board, -A31A3 [R30], during couch movement.

Action	Approved	Not Appr.	Date
a When the couch does not reach correct position within 80 seconds* "Patient in" is off and "Patient out" on.			
b When the shielding doors are not closed within 80 seconds* the flashlight is on.			

* For LGK Units delivered and installed before 1996-06-01, the time limit shall be 90s.

4.4.2. "Emergency Interrupt" during treatment

Push "Emergency interrupt" when "Treatment yes" lights.

Action	Approved	Not Appr.	Date
a When elapsed time is completed the couch is ordered out. The couch stops at "Patient almost in". Flashlight starts.			
b Release "Emergency interrupt" and the couch is ordered out.			

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4.5. Shielding Doors Position Failure

4.5.1. "Emergency Interrupt"

Push "Emergency interrupt" during shielding doors movement to closed position.

Action	Approved	Not Appr.	Date
a When the "shield closed" position is not reached within 80 seconds* then flashlight will start.			

* For LGK Units delivered and installed before 1996-06-01, the time limit shall be 90s.

4.5.2. "Treatment Start"

Push "Treatment start" and shut off "power off/on" key when shielding doors are open.

Action	Approved	Not Appr.	Date
a Check that timers light.			
b Check that flashing light starts.			

4.5.3. "Radiation On"

Action	Approved	Not Appr.	Date
a Check that "Radiation on", on the control panel, is on whenever the shielding doors are not closed.			
b Check that the lamp on the radiation unit (-A1H1) is on whenever the shielding doors are not closed. *			

* Only for LGK Units installed in the US.

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5. SAFETY

5.1. System Interlocks

5.1.1. Fuse bat

For LGK units installed after 1996-06-01

Disconnect A31U2:J6 in electrical cubicle.

Action	Approved	Not Appr.	Date
a Warning lamp "Fuse bat" lights on the control panel. Treatment start is not possible.			

For LGK units installed after 1996-06-01

Disconnect A31U3:J6 in electrical cubicle.

Action	Approved	Not Appr.	Date
b Warning lamp "Fuse bat" lights on the control panel. Treatment start is not possible.			

For LGK units installed before 1996-06-01

Shut off circuit breakers -A31W1F1 [R1=1] in electrical cubicle.

Action	Approved	Not Appr.	Date
c Warning lamp "Fuse bat" lights on the control panel. Treatment start is not possible.			

5.1.2. Timers

Shut off "off/on switch" on -A31A2A11 [R7=1] in electrical cubicle.

Action	Approved	Not Appr.	Date
a Warning lamp "Timers" lights on the control panel. Treatment start is not possible.			
b Reset "Power off/on", the timers lights. Reset the key switch and check that treatment is possible.			

5.1.3. Safety

Open treatment room door.

Action	Approved	Not Appr.	Date
a Warning lamp "Safety" lights on the control panel. Treatment start is not possible.			

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Open treatment room door during treatment.

Action	Approved	Not Appr.	Date
b Treatment stop is initiated. Warning lamp "Safety" lights on the control panel.			

Close the door again.

Push "Emergency treatment stop"

Action	Approved	Not Appr.	Date
c Warning lamp "Safety" lights on the control panel. Treatment start is not possible.			

Push "Emergency treatment stop" during treatment

Action	Approved	Not Appr.	Date
d Treatment stop is initiated. Warning lamp "Safety" lights on the control panel.			

5.1.4. Helmet

Remove the cap on fixated helmet.

Action	Approved	Not Appr.	Date
a Treatment is not possible. Warning lamp "Helmet" lights on the control panel.			

Disconnect helmet angle connectors.

Action	Approved	Not Appr.	Date
b Treatment is not possible. Warning lamp "Helmet" lights on the control panel.			

Push "Treatment start". Remove cap.*

Action	Approved	Not Appr.	Date
c Treatment interrupted. Warning lamp "Helmet" lights on the control panel.*			

* Not valid for LGK units delivered and installed before 1996-06-01.

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5.1.5. Emergency Interrupt, on control panel

Push "Emergency interrupt" on control panel during shielding doors opening.

	Action	Approved	Not Appr.	Date
a	Lamp starts blinking.			
b	The shielding doors are simultaneously stopped moving until the "Emergency interrupt" is released.			

Push "Emergency interrupt" on control panel during couch movement.

	Action	Approved	Not Appr.	Date
c	Lamp starts blinking.			
d	The couch is simultaneously stopped moving until the "Emergency interrupt" is released.			

5.1.6. Emergency Interrupt, on operating table

Push "Emergency Interrupt" on the left side of the operating table.

	Action	Approved	Not Appr.	Date
a	Lamp starts blinking on control panel.			

Push "Emergency Interrupt" on the right side of the operating table

	Action	Approved	Not Appr.	Date
b	Lamp starts blinking on control panel.			

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5.2. Emergency Safety

5.2.1. Couch stuck in treatment position

Disconnect motor and brake at X3:17 [KL3:1] and X1:3 [KL3:3] in electrical cubicle during "Treatment yes".

Action	Approved	Not Appr.	Date
a Flashlight will start 7 seconds after the time is out. Elapsed time is still counting as long as "Treatment yes" lights.			

5.2.2. Close down of shielding doors

Switch off "Power off/on" when shielding doors are open and the couch is in the outer position.

Action	Approved	Not Appr.	Date
a Check emergency close down of shielding doors by hand.			

5.2.3. Manual withdrawal of couch

Action	Approved	Not Appr.	Date
a Check the possibility to pull the couch by hand, when shielding doors are closed (two persons needed).			

5.2.4. Release of patient

Action	Approved	Not Appr.	Date
a Check the possibility to release patient from trunnion by hand when shielding doors are closed (use long Allen key and special trunnion release tool).			

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5.3. Timers Safety

5.3.1. Timers

	Action	Approved	Not Appr.	Date
a	Check elapsed time during treatment.			
b	Check remaining time during treatment.		/	
c	Check synchronization during treatment time, 30min.			

5.3.2. "Treatment Stop"

Push "Treatment stop" when couch is in treatment position.

	Action	Approved	Not Appr.	Date
a	Check that couch returns.			
b	Check that elapsed and remaining time have stopped.			
c	Push "Treatment start" and check that treatment is continuing from existing remaining time when the couch is in position.			

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6. MISCELLANEOUS

6.1. The Unit

Action	Approved	Not Appr.	Date
a Check paint and surface finish on the LGK operating table, helmet hoist and helmet table.			
b Check finish on plastic hood on the radiation unit.			
c Ensure correct function of helmet hoist.			
d Check that all collimators are included.			
e Check elbow rest.			
f Check camera.			
g Check couch insert fitting and function with rechargeable screwdriver.			
h Check nickel coating on the shielding doors.			
i Check the intercom system.			

6.2. No of completed cycles (for information only)

Action	No of cycles	Sign	Date
a During installation test			

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6.3 Set of Tools

	Action	Approved	Not Appr.	Date
a	1 Bits			
b	1 Bits holder			
c	1 El. screwdriver + charger			
d	1 Washer			
e	1 Thumb screw			
f	1 Pull handle			
g	4 Handles			
h	1 Special trunnion release tool			
i	1 Allen key 2,5 mm			
j	1 Allen key 3 mm			
k	1 Allen key 4 mm			
l	1 Allen key 6 mm			
m	1 Allen screwdriver 3 mm			
n	1 Allen screwdriver 5 mm			
o	1 Ring wrench 8mm			
p	1 Screwdriver			
q	2 Wall brackets			
r	1 Special long Allen key			
s	2 Special screwdrivers			
t	1 Socket wrench			
u	2 Special pairs of tongs			
v	1 Helmet test tool			
x	1 Helmet adjustment ring			

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7. REMARKS

Remark	Item	Sign	Date	Report nr/id
Approved: <input type="checkbox"/>	-----	-----	-----	-----
Approved: <input type="checkbox"/>	-----	-----	-----	-----
Approved: <input type="checkbox"/>	-----	-----	-----	-----
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