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License No.: 45-09001-01
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MSK
K-8

Response from email dated 5/6/2006:

- a) The documents accompanying this cover letter are John Freshcom's Gamma Knife training documentation which include a copy of the installation test protocol completed on-site with the Elekta representative and letter from UVA's Gamma Knife Center documenting his training in device operation and clinical use .

CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER—NAME AND TITLE	SIGNATURE	DATE
Sandra M. Snapp Riverside and University of Virginia Radiosurgery Center Administrator	<i>Sandra M Snapp</i>	5/9/2006

138787

NMCG/RGM MATERIALS-002



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May 8, 2006

Gamma Knife Training Documentation Letter for
John Freshcom, MS, Radiation Physicist

On May 8th, 2006, John Freshcom, MS, observed and participated in on-site training for Gamma Knife device operation and clinical use at University of Virginia's Gamma Knife Center.

Respectfully,

Abdul Rashid, PhD

Assistant Professor

Medical Physicist

- 4/8/06

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ELEKTA INSTRUMENT AB

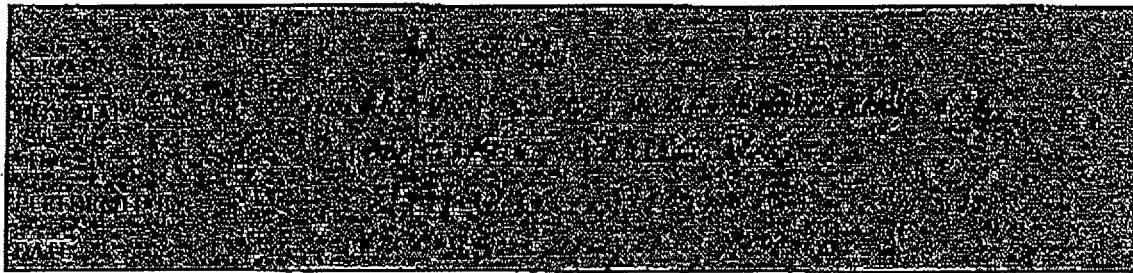
Test Protocol LGK C

☐ Incoming Inspection ☒ Other Inspection

Issued by Rolf Spaak/Sara Söderholm		Date 2004-09-07	Traceability <input checked="" type="checkbox"/> individual <input type="checkbox"/> batch <input type="checkbox"/> none	Edition 2	Page (Pages) 1(26)
Article No 912800 912762		Article LGK C 1.2/4C LGK model B upgrade to C 1.2/4C		Classification Yes No critical <input checked="" type="checkbox"/> <input type="checkbox"/> perishables <input type="checkbox"/> <input checked="" type="checkbox"/>	Doc. No. KI 01176
Approved (R&D) <i>[Signature]</i>		Date 2004-09-27	Approved (S&S) <i>[Signature]</i>	Remark -	Directory DOC_STYR
Date 2004-10-02					



INSTALLATION TEST PROTOCOL

ARTICLE: ☒ LGK C 1.2/4C☐ LGK upgrade to C 1.2/4C

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

John F. Fubner Jr. Radiation Physicist 5/5/06
Sandra U. Snapp Radiation Therapy Administrator 5/5/2006

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No.	Doc. No.	Edition	Page (Pages)
912800, 912762	KI01176	2	2(26)

Table of Contents

1	Summary	3
1.1	Revision History	3
1.2	Instructions	3
2	Inventory	4
3	Ocular Inspection	5
4	Identity	7
4.1	Identity of Parts	7
4.2	Signs	7
5	Helmet Switches and Positioning	8
5.1	Helmet switch with 4 mm Helmet	8
5.2	Helmet switch with 8 mm Helmet	8
5.3	Helmet switch with 14 mm Helmet	8
5.4	Helmet switch with 18 mm Helmet	8
5.5	Helmet position with 4 mm Helmet	9
5.6	Helmet position with 8 mm Helmet	9
5.7	Helmet position with 14 mm Helmet	9
5.8	Helmet position with 18 mm Helmet	10
6	APS	11
6.1	APS QA test tool	11
6.2	APS Coordinate Accuracy	11
6.3	APS G-frame and Frame Extender	11
6.4	APS - LGP interface	11
6.5	APS - PDI reading of all gamma angels	11
6.6	APS 50-step-treatment	12
7	LGP	13
8	Safety switches	14
9	UPS	15
9.1	Medical UPS	15
9.2	Office UPS	16
10	Couch and shielding door motors	17
11	Safety & timers	18
11.1	Emergency Safety	18
11.2	Timers Safety	18
11.3	Calibration of treatment timer	19
11.4	Treatment Stop	20
12	Installation remarks	21
13	Attachments	22
13.1	Accuracy test with precision instrument	22
13.2	Patient docking and undocking of APS	23
13.3	APS - LGP interface	24
13.4	The Patient Docking Indicator	25
13.5	50-step-treatment	26

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No.	Doc. No.	Edition	Page (Pages)
912800, 912762	KI01176	2	3(26)

1 Summary

This document is used for installation verification and validation of LGK C 1.2/4C or upgrade to C 1.2/4C.

1.1 Revision history

Issue	Date	Resp	Description
1	2003-06-05	RSP	First version, update of KI00753 Verification Protocol Pj48P330 Review minute Pj48P337
2	2004-09-07	SaS	Updated for 4C and addition of values for 100 VAC Office UPS.

1.2 Instructions

- Initials and date shall be put in the space for approved/not approved.
- If something is not approved or approved with a deviation, a remark of this must be made.
- The remark shall refer to the test number 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.
- If the test is not valid for the installed system the term N/A (Not Applicable) shall be used. If N/A is used an explanation shall always be written telling why the test is not performed.

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 4(26)
-------------------------------	---------------------	--------------	-----------------------

2 Inventory

Parts checked	Action, Check the following:	Appr.	Not Appr.	Date
Long Allen key	• In place, condition	JM		5/4/06
APS release tool	• In place, condition	JM		5/4/06
Trunnion release tool	• In place, condition	JM		5/4/06
Emergency routines	• In place, condition	JM		5/5/06

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 5(26)
-------------------------------	---------------------	--------------	-----------------------

3 Ocular Inspection

Subsystem checked	Action, Check the following:	Appr.	Not Appr.	Date
Couch	<ul style="list-style-type: none"> Mattress covers and belt No parts are loose 	<i>RM</i>		5/5/06
Side protections	<ul style="list-style-type: none"> Condition 	<i>RM</i>		5/5/06
Cover RU	<ul style="list-style-type: none"> Functionality (open/close) of front doors. Functionality (open/close/locking) of side panels. Radiation lights 	<i>RM</i>		5/5/06
Cover Couch	<ul style="list-style-type: none"> Paint/color and surface finish 	<i>RM</i>		5/5/06
APS	<ul style="list-style-type: none"> Paint/color and surface finish Cabeling, flexcables and connectors Visual scales All parts are fasten enough No scratches on surface at IR sensors in PDI 	<i>RM</i>		5/5/06
Helmet changer	<ul style="list-style-type: none"> Paint/color and surface finish. 	<i>RM</i>		5/5/06
Helmet Trolley no 1	<ul style="list-style-type: none"> Paint/color and surface finish All wheels are well fasten 	<i>RM</i>		5/5/06
Helmet Trolley no 2	<ul style="list-style-type: none"> Paint/color and surface finish All wheels are well fasten 	<i>RM</i>		5/5/06
Helmet Trolley no 3	<ul style="list-style-type: none"> Paint/color and surface finish All wheels are well fasten 	<i>RM</i>		5/5/06
Helmet Trolley no 4	<ul style="list-style-type: none"> Paint/color and surface finish All wheels are well fasten 	<i>RM</i>		5/5/06
Manual Control -Helmet Changer	<ul style="list-style-type: none"> Mounting mechanism No parts are loose 	<i>RM</i>		5/5/06
Manual Control - APS / couch	<ul style="list-style-type: none"> Mounting mechanism No parts are loose 	<i>RM</i>		5/5/06
CCS Operator Console	<ul style="list-style-type: none"> Paint and surface finish No parts are loose 	<i>RM</i>		5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 6(26)
-------------------------------	---------------------	--------------	-----------------------

Subsystem checked	Action, Check the following:	Appr.	Not Appr.	Date
Office cabinet	<ul style="list-style-type: none"> Cabling and marking of electronics. Text / color printed at front plates. No parts are loose 	gm		5/5/06
Medical cabinet	<ul style="list-style-type: none"> Cabling and marking of electronics. Text / color printed at front plates. No parts are loose 	gm		5/5/06
Keyboard	<ul style="list-style-type: none"> Condition 	gm		5/5/06
PC Mouse	<ul style="list-style-type: none"> Condition 	gm		5/5/06
Helmet $\phi 4$ + collimators	<ul style="list-style-type: none"> Surface finish and markings 	gm		5/5/06
Helmet $\phi 8$ + collimators	<ul style="list-style-type: none"> Surface finish and markings 	gm		5/5/06
Helmet $\phi 14$ + collimators	<ul style="list-style-type: none"> Surface finish and markings 	gm		5/5/06
Helmet $\phi 18$ + collimators	<ul style="list-style-type: none"> Surface finish and markings 	gm		5/5/06
Helmet Cap	<ul style="list-style-type: none"> Functionality of magnets. Paint and surface finish. 	gm		5/5/06
Camera /s	<ul style="list-style-type: none"> Good finish. 	gm		5/5/06
Microphones	<ul style="list-style-type: none"> Finish of patient microphone & operator mic. Adhesiveness of tape for attachments on patient microphone, i.e. no loose parts 	gm		5/5/06
RU	<ul style="list-style-type: none"> Paint and surface finish. 	NA		5/5/06 gm
Shielding doors	<ul style="list-style-type: none"> Nickel coating and surface finish 	gm		5/5/06
Cabling	<ul style="list-style-type: none"> All external cables are in good condition. 	gm		5/5/06
Stereotactic Instrument	<ul style="list-style-type: none"> Condition of frames Condition of Y/Z slides Condition of frame extender Indicator boxes 	gm		5/5/06
Trunnion adapters	<ul style="list-style-type: none"> Condition 	gm		5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. K101176	Edition 2	Page (Pages) 7(26)
-------------------------------	---------------------	--------------	-----------------------

4 Identity

4.1 Identity of Parts

	Part	Serial/Version. no.	Approved	Not Appr.	Date
a	MCU computer	MCU-099	gm		5/1/06
b	MCU software	4.0.1.4	gm		5/1/06
c	APS mechanics left	476.00	gm		5/3/06
d	APS mechanics right	475.00	gm		5/3/06
e	APS software	5.1.2	gm		5/4/06
f	APS-5 phase detector board	TOE-0016	gm		5/1/06
g	LGP computer	SG52720067	gm		5/4/06
h	LGP software	LGR4C	gm		5/4/06
i	LGP scanner interface	4.7.2	gm		5/4/06
j	CU software (IC 14 at CUSS1)	LGR10205	gm		4/25/06
k	PLD treatment timer (IC 25 at CUSS1)	911660-2	gm		4/25/06
l	Address decoder (IC 7 at CUSS1)	911658-2	gm		4/25/06

4.2 Identity of Signs

	Action	Approved	Not Appr.	Date
a	Check that all signs at Cover and RU are attached according to drawing 712914 (for 1.2) or 716843 (for 4C).	gm		5/4/06
b	Check that all signs at Operator Console are attached according to drawing 712914 (for 1.2) or 716843 (for 4C).	gm		5/4/06
c	Check that all signs at Helmet Changer & Helmet Trolleys are attached according to drawing 106882.	gm		5/4/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 8(26)
-------------------------------	---------------------	--------------	-----------------------

5 Helmet Switches and Positioning

This procedure also verifies the performance of the helmet testing device.

5.1 Helmet switch with 4 mm Helmet

Action	Approved	Not Appr.	Date
a Adjustment ring attached. "green signal"	<i>GM</i>		5/5/06
b Adjustment ring & shims 0.1mm attached. "red signal"	<i>GM</i>		5/5/06
c Check that Helmet Id=1 and that helmet cap sensor is ok	<i>GM</i>		5/5/06

5.2 Helmet switch with 8 mm Helmet

Action	Approved	Not Appr.	Date
a Adjustment ring attached. "green signal"	<i>GM</i>		5/5/06
b Adjustment ring & shims 0.1mm attached. "red signal"	<i>GM</i>		5/5/06
c Check that Helmet Id=2 and that helmet cap sensor is ok	<i>GM</i>		5/5/06

5.3 Helmet switch with 12 mm Helmet

Action	Approved	Not Appr.	Date
a Adjustment ring attached. "green signal"	<i>GM</i>		5/5/06
b Adjustment ring & shims 0.1mm attached. "red signal"	<i>GM</i>		5/5/06
c Check that Helmet Id=3 and that helmet cap sensor is ok	<i>GM</i>		5/5/06

5.4 Helmet switch with 15 mm Helmet

Action	Approved	Not Appr.	Date
a Adjustment ring attached. "green signal"	<i>GM</i>		5/5/06
b Adjustment ring & shims 0.1mm attached. "red signal"	<i>GM</i>		5/5/06
c Check that Helmet Id=4 and that helmet cap sensor is ok	<i>GM</i>		5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 9(26)
-------------------------------	---------------------	--------------	-----------------------

5. Helmet position with 4 mm helmet

Action	Approved	Not Appr.	Date
a Mount and check Trunnions pair 1 with helmet test tool. Center coordinate left, right.	gm		5/5/06
b Optionally, check Trunnions pair 2 with helmet test tool. Center coordinate left, right.	gm		5/5/06
c Select timer-run. First select wrong collimator helmet then correct. Verify helmet checking on MCU.	gm		5/5/06
d Start treatment, door opening time 7 ± 2 seconds. 7 sec	gm		5/5/06
e Start treatment, couch in to correct position. Green treatment field at MMI.	gm		5/5/06
f Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position. No Green treatment field at MMI.	gm		5/5/06

6. Helmet position with 8 mm helmet

Action	Approved	Not Appr.	Date
a Mount and check Trunnions pair 1 with helmet test tool. Center coordinate left, right.	gm		5/5/06
b Optionally, check Trunnions pair 2 with helmet test tool. Center coordinate left, right.	NA		gm 5/5/06
c Select timer-run. First select wrong collimator helmet then correct. Verify helmet checking on MCU.	gm		5/5/06
d Start treatment, couch in to correct position. Green treatment field at MMI.	gm		5/5/06
e Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position. No Green treatment field at MMI.	gm		5/5/06

7. Helmet position with 12 mm helmet

Action	Approved	Not Appr.	Date
a Mount and check Trunnions pair 1 with helmet test tool. Center coordinate left, right.	gm		5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 10(26)
-------------------------------	---------------------	--------------	------------------------

Action	Approved	Not Appr.	Date
b Optionally, check Trunnions pair 2 with helmet test tool. Center coordinate left, right.	NA		5/5/06
c Select timer-run. First select wrong collimator helmet then correct. Verify helmet checking on MCU.	JM		5/5/06
d Start treatment, couch out transport time 30 ± 5 seconds.	JM		5/5/06
e Start treatment, couch in to correct position. Green treatment field at MMI.	JM		5/5/06
f Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position. No Green treatment field at MMI.	JM		5/5/06

Helmet position with 18 mm helmet

Action	Approved	Not Appr.	Date
a Mount and check Trunnions pair 1 with helmet test tool. Center coordinate left, right.	JM		5/5/06
b Optionally, check Trunnions pair 2 with helmet test tool. Center coordinate left, right.	JM		5/5/06
c Select timer-run. First select wrong collimator helmet then correct. Verify helmet checking on MCU.	JM		5/5/06
d Start treatment, couch in to correct position. Green treatment field at MMI.	JM		5/5/06
e Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position. No Green treatment field at MMI.	JM		5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 11(26)
-------------------------------	---------------------	--------------	------------------------

6 APS

6.1 APS QA test tool

Action	Approved	Not Appr.	Date
a Start the QA-test-run from operator room. Check the two positions are reached within accepted limits ($\pm 0.5\text{mm}$)	gm		5/4/06

6.2 APS Coordinate Accuracy

Action	Approved	Not Appr.	Date
a Mount APS and verify coordinate accuracy according to <i>attachment 1</i> "Precision Instrument".	gm		5/4/06

6.3 APS G-frame and Frame Extender

Action	Approved	Not Appr.	Date
a Verify the docking and undocking of G-frame and Frame Extender according to <i>attachment 2</i> "Patient docking and undocking of APS".	gm		5/5/06

6.4 APS - LGP interface

Action	Approved	Not Appr.	Date
a Verify a correct interface towards the valid LGP edition according to <i>attachment 3</i> "APS - LGP interface".	gm		5/5/06

6.5 APS - PDI reading of all gamma angels

Action	Approved	Not Appr.	Date
a Verify a correct reading from PDI of all gamma angels according to <i>attachment 4</i> "The patient docking indicator".	gm		5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No.	Doc. No.	Edition	Page (Pages)
912800, 912762	KI01176	2	12(26)

5.6 APS 50-step treatment

Action	Approved	Not Appr.	Date
a Verify a long 50-step treatment process according to <i>attachment 5</i> "50-step-treatment", using a frame with no posts mounted.	<i>gm</i>		5/4/06

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 13(26)
-------------------------------	---------------------	--------------	------------------------

7 LGP

This test also verifies that all extreme coordinates can be reached. Make sure that the gamma angle is set to 90 degrees when creating the dose plans in LGP. To avoid collisions use a Leksell frame with "straight" frontpiece to perform the tests.

Action	Approved	Not Appr.	Date
a Create a dose plan on LGP with all skull radii set to 200 mm and one shot in $X=59.0$, $Y=40.0$, $Z=58.0$ and export to LGK using diskette transfer.	<i>gm</i>		5/4/06
b Import the dose plan and complete the treatment.	<i>gm</i>		5/4/06
c Create a dose plan on LGP with all skull radii set to 200 mm and at least two shots in $X_{max}=141.0$ $Y_{min}=40.0$, $Z_{max}=142.0$ $X_{min}=59.0$ $Y_{max}=160.0$, $Z_{min}=58.0$ and export to LGK using serial connection.	<i>gm</i>		5/4/06
d Import the dose plan and complete the treatment.	<i>gm</i>		5/4/06

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 14(26)
-------------------------------	---------------------	--------------	------------------------

8 Safety switches

This procedure also verifies the performance of the helmet changer, helmet trolleys and if applicable installed room door switch.

Action	Approved	Not Appr.	Date
a Check that it is not possible to start a treatment when the cap is removed.	JM		5/5/06
b Check that it is not possible to start a treatment when left patient protection panel is removed.	JM		5/5/06
c Check that it is not possible to start a treatment when right patient protection panel is removed.	JM		5/5/06
d Check that it is not possible to start a treatment when the helmet changer is elsewhere than in stored position.	JM		5/5/06
e Check that it is not possible to start a treatment when the treatment room door is open.	JM		5/5/06
f Check that it is not possible to start a treatment if emergency release handle on couch is pulled.	JM		5/5/06
g Check that the helmet screw-sensor at helmet console works properly, i.e., helmet cannot be released from changer if this is disengaged	JM		5/5/06
h Check that the helmet changer "in" sensor works properly, i.e. Press "Couch In". Pull Helmet Changer. Couch Stops.	JM		5/5/06
i Check that the helmet trolley sensor works properly, i.e., helmet can only be lowered to the helmet trolley if this sensor is activated.	JM		5/5/06
j Check that the helmet changer "down" sensor works properly, i.e., helmet cannot be released from changer if this is not in down position even when helmet table is in position.	JM		5/5/06
k Check that mattress slide lock/unlock works and that the squeeze protection works at front, middle and back on both right and left side.	JM		5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. K101176	Edition 2	Page (Pages) 15(26)
-------------------------------	---------------------	--------------	------------------------

9 UPS

9.1 Medical UPS

Action	Approved	Not Appr.	Date
a Check that mains has been set correctly (100 – 120V or 220 – 240V).	<i>gM</i> <i>4/26/06</i>		<i>4/26/06</i> <i>gM</i>
b Check the fuse rating and note your result. Installed fuse: <i>6.3</i> 6,3A accepted	<i>gM</i> <i>4/26/06</i>		<i>4/26/06</i> <i>gM</i>
c Measure the phase to neutral on the primary side and note your result. (Input on UPS backside) Phase to neutral: <i>116</i> V (Nominal voltage $\pm 10\%$) accepted	<i>gM</i> <i>5/3/06</i>		<i>5/3/06</i> <i>gM</i>
d Check the ambient temperature. Measure inside the medical electrical cabinet after at least 2 hours of normal operation and note your result. Ambient temp.: <i>22</i> °C (max 60°C) accepted	<i>gM</i> <i>5/3/06</i>		<i>5/3/06</i> <i>gM</i>
e Check that the connections are properly connected	<i>gM</i> <i>4/26/06</i>		<i>4/26/06</i> <i>gM</i>
f Measure the output voltage and note your result. 48 VDC UPS: <i>54.0</i> V (54 VDC V $\pm 6V$) (UPS backside)	<i>gM</i>		<i>5/3/06</i>
24 VDC UPS: <i>23.4</i> V (24 VDC V $\pm 2V - 1V$) (UPS backside)	<i>gM</i>		<i>5/3/06</i>
g Measure the UPS battery capacity. 1) Switch off the Main switch on the backside of the UPS. 2) Measure voltage on 48V output on backside after 20 minutes and note your results. Measured voltage: <i>49.7</i> V (> 44 V) Switch on the Input switch on UPS backside.	<i>gM</i>		<i>5/3/06</i>

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 16(26)
-------------------------------	---------------------	--------------	------------------------

Office UPS

Action	Approved	Not Appr.	Date
a Check that the UPS for the correct mains voltage has been selected.	<i>gm</i>		4/26/06
b Check the ambient temperature. Measure inside the office electrical cabinet (PC box) after at least 2 hours of normal operation and note your result. Ambient temp.: 24 °C (max 60°C) accepted	<i>gm</i>		5/3/06
c Check that the connections are properly connected	<i>gm</i>		4/26/06
d Measure the output voltage and note your result. (Use RMS voltage meter for 230V) 230/120/100 VAC: 120.3 V (230/120/100 VAC ± 10%) (UPS backside)	<i>gm</i>		5/3/06
e Check the UPS battery capacity. 1) Break Mains to UPS. 2) Check battery indicator at UPS front after 20 minutes and note your results. Number of green LED: 3 (at least 2) Switch on the Input switch on UPS.	<i>gm</i>		5/3/06

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No.	Doc. No.	Edition	Page (Pages)
912800, 912762	KI01176	2	17(26)

10 Couch and shielding door motors

Not to be tested for LGK C 1.2/4C.

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 18(26)
-------------------------------	---------------------	--------------	------------------------

11 Safety & timers

11.1 Emergency Safety

Action	Approved	Not Appr.	Date
a Switch on mains. Start treatment. Shut off mains to Medical UPS . Treatment interrupted after 1 minute.	JM		5/5/06
b Switch on mains. Start treatment. Shut off mains to Office UPS . Treatment interrupted after 1 minute.	JM		5/5/06
c Start a treatment. Cut power to couch after reaching treatment position. (Release CUSS out cable C4 MT3-cable 133) System error will start after planned treatment time. Couch out activated automatically after less than 5 sec. Elapsed time is still counting as long as Green Treatment Field at MMI is lit.	JM		5/5/06

11.2 Timer safety

Action	Approved	Not Appr.	Date
a. Verify timer correctness by measuring using stop watch or connect a timer to C5 pin 7-8. 30.00 min.: 29:59:86 min. (accepted 30.00 min \pm 5 sec) 1.00 min.: 59.82 sec min. (accepted 1.00 min \pm 1 sec)	JM JM		5/2/06 5/4/06

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 19(26)
-------------------------------	---------------------	--------------	------------------------

1.3 Calibration of treatment time

Action	Approved	Not Appr.	Date
<p>Intro:</p> <p>Calibration of the timer is done to compensate for the mechanical delay from:</p> <ul style="list-style-type: none"> -signal to couch to leave treatment position until -the time when the couch leaves treatment position and the helmet sensors go low. <p>The system has a built in automatic calibration function. At shipment this function is set to dynamic (adaptive) mode i. e. new compensation time is calculated continuously. At delivery to customer this adaptive mode shall be disabled.</p>	<i>gm</i>		5/4/06
<p>a After performing a 50 step run (see other cases in this KI) check configuration file:</p> <p>\\LGK\systemfiles\CCS_Conf.cfg.</p> <p>Parameter:</p> <ul style="list-style-type: none"> -LGKCU_COMPENSATION_TIME_SEC less than 1.2 s - LGKCU_COMPENSATION_VALUE_ARRAY less than 0.5 s between max and min value. <p>2)</p> <p>If OK, set the parameter:</p> <ul style="list-style-type: none"> - LGKCU_COMPENSATION_USE_DYNAMIC to NO i. e. dynamic (adaptive) mode is disabled. 	<i>gm</i>		5/4/06
<p>b Perform an APS test run and check that performed treatment time is equal to planned treatment time</p>	<i>gm</i>		5/4/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 20(26)
-------------------------------	---------------------	--------------	------------------------

Treatment stop

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

Action	Approved	Not Appr.	Date
a Check that couch returns.	JM		5/5/06
b Check that elapsed time have stopped.	JM		5/5/06
c Push "Treatment start" and check that treatment is continuing from existing elapsed time when the couch is in position.	JM		5/5/06
d Press Emergency stop. All movements stop. Emergency Alarm.	JM		5/5/06
e Restart treatment. Press Emergency stop in the treatment room while shielding doors are opening. Check that all movements stop.	JM		5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 21(26)
-------------------------------	---------------------	--------------	------------------------

12 Installation remarks.

	Remark	Item	Sign	Date	Report nr/id
a.					
	Approved: <input type="checkbox"/>				
b.					
	Approved: <input type="checkbox"/>				
c.					
	Approved: <input type="checkbox"/>				
d.					
	Approved: <input type="checkbox"/>				
e.					
	Approved: <input type="checkbox"/>				
f.					
	Approved: <input type="checkbox"/>				
g.					
	Approved: <input type="checkbox"/>				
h.					
	Approved: <input type="checkbox"/>				
i.					
	Approved: <input type="checkbox"/>				

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 22(26)
-------------------------------	---------------------	--------------	------------------------

13 Attachments

3.1 Accuracy test with precision instrument

Purpose:	To verify the accuracy of the APS & check correct calibration files are installed.		
Strategy:	A complete system (with APS). Run the "Precision Test" for the precision instrument. Verify with the gauge, that has two sides, one is 4.8 mm the other is 5.2 mm.		
Acceptance Criteria:	x-y-z are ok if deviation < 0.2 mm and not ok if deviation ≥ 0.2 mm. Note go/no go for all coordinates APS x, APS y, APS z. Go marked: 1 No go marked: 0 (See list below)		
	4.8 mm	5.2 mm	OK or NOT OK
	1	0	OK (<0.2mm)
	1	1	not ok (≥ 0.2 mm)
	0	0	not ok (≥ 0.2 mm)
Precondition:	A complete system (with APS) - 707658: Plate - 707669: Gauge (4.8 mm & 5.2 mm) - 707659: Docking Pin		
Procedure:	1. Start the "Precision Test" (a button at MMI) for the precision instrument. 2. The APS unit will be positioned at APS coordinates (100,100,60) 3. Dismount the Helmet and G-frame. Mount the Plate at APS & the Docking Pin at the place for G-frame. Confirm at Manual Control APS. -OK 4. Step through the six measuring points and at each points check the position with the Gauge in APS x,y,z. Press confirm in between the different steps. - Note go/no go in all directions APS x,y,z. -OK 5. Dismount the precision instrument and mount Helmet again.		

Action	APS	x	APS	y	APS	z	Comment	Appr.	Not Appr.	Date
Precision Gauge	4.8	5.2	4.8	5.2	4.8	5.2		--	--	--
Example point (x, y, z)	1	0	1	0	0	0	Not ok in z		.PF	981024
1 st point: (100.00,100.00,100.00)	1	0	1	0	1	0		g.m		5/4/06
2 nd point: (110.00,100.00,100.00)	1	0	1	0	1	0		g.m		5/4/06
3 rd point: (130.00,80.00,100.00)	1	0	1	0	1	0		g.m		5/4/06
4 th point: (70.00,80.00,100.00)	1	0	1	0	1	0		g.m		5/4/06
5 th point: (100.00,65.00,110.00)	1	0	1	0	1	0		g.m		5/4/06
6 th point: (110.00,65.00,110.00)	1	0	1	0	1	0		g.m		5/4/06

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No. 912800, 912762	Doc. No. KI01176	Edition 2	Page (Pages) 23(26)
-------------------------------	---------------------	--------------	------------------------

13.2. Patient docking and undocking of APS

Purpose:	To verify the docking and undocking of G-frame and Frame extender.
Strategy:	
Acceptance Criteria:	See below.
Precondition:	<ul style="list-style-type: none"> - A complete system. - G-frame - Frame extender. - 10 kg test weight <u>or</u> manually apply the force on the frame by hand.
Procedure:	<ol style="list-style-type: none"> 1. Test that the Patient release knobs works correctly— OK 2. Dock G-frame at APS. Load the frame with 10 kg, no automatically undocking — OK 3. Release a G-frame from APS units — OK 4. Dock G-frame and Frame Extender at APS Load the frame with 10 kg, no automatically undocking — OK 5. Release the G-frame with frame extender from APS units — OK

The Patient release knobs at APSM-R & APSM-L works correctly. Not possible to unscrew knob. Space for patient Release Tool is approx. 10mm.	JM	5/5/06
Releasing a G-frame when ca 10 kg applied works fine.	JM	5/5/06
Releasing a G-frame + frame extender when ca 10 kg applied works fine.	JM	5/5/06

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No. 912800, 912762	Doc No. KI01176	Edition 2	Page (Pages) 24(26)
-------------------------------	--------------------	--------------	------------------------

3.3 APS - LGP interface

Purpose:	To verify a correct interface towards the valid LGP edition
Strategy:	Import a treatment from a diskette. Also check the serial line.
Acceptance Criteria:	See below.
Precondition:	Use an existing testfile on LGP or create a new file.
Procedure:	<ol style="list-style-type: none"> 1. Import a Treatment Test File. 2. Dock a G-frame at APS. 3. Verify the gamma angle with the PDI. 4. Make a Positioning check – OK 5. Press Start. 6. The couch moves into the RU. The different steps in the treatment are performed inside the RU (defocus). – OK

LGP diskette from valid LGP version works properly	QM			5/5/06
Serial link to MCU works properly	QM			5/5/06

ELEKTA INSTRUMENT AB

Instruction for Inspection

Article No. 912800, 912762	Doc No. KI01176	Edition 2	Page (Pages) 25(26)
-------------------------------	--------------------	--------------	------------------------

3.4 The Patient Docking Indicator

Purpose:	To verify that the connection to the PDI is correct.
Strategy:	Prepare a treatment with all docking positions (four gamma angles and high).
Acceptance Criteria:	See below.
Precondition:	-A complete system with APS. -G-frame -Two G-frame Extenders -A test file with at least using all different gamma angles and high docking
Procedure:	1. Load the Treatment Test File 2. Dock a G-frame at APS. 3. Make only the Position check (or Clearance) in each run for all different docking positions. Check a correct verification (dock and verify) of the docking codes with the PDI. – OK 4. Click at Cancel at MMI before treatment start. Go to next run.

G-frame with posts in LOW position:

	PD	PF
PDI works correctly for docking position 72° (no other sensors gives signal)	GM	5/5/06
PDI works correctly for docking position 90° (no other sensors gives signal)	GM	5/5/06
PDI works correctly for docking position 110° (no other sensors gives signal)	GM	5/5/06
PDI works correctly for docking position 125° (no other sensors gives signal)	GM	5/5/06
PDI works correctly for docking position high (no other sensors gives signal)	GM	5/5/06
Clearance Check works properly	GM	5/5/06

ELEKTA INSTRUMENT AB**Instruction for Inspection**

Article No.	Doc. No.	Edition	Page (Pages)
912800, 912762	KI01176	2	26(26)

1.5 50-step treatment

Purpose:	To verify a long 50-step treatment process, total 250s.
Strategy:	Make a whole treatment.
Acceptance Criteria:	See below.
Precondition:	- Use predefined test file PM test 50 s fast.
Procedure:	<ol style="list-style-type: none">1. Load Treatment Test File D2. Dock a G-frame at APS. Verify the gamma angle with the PDI.3. Make a Positioning check – OK4. Press Start.5. The couch moves into the RU. The 50 steps inside the RU are performed – OK

50 step treatment (250 s) works without any disturbances	JM	5/4/06
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