IMPORTANT FIELD SAFETY NOTICE

PRODUCT: Digital Accelerator

Date: 05-2013 **FCO Ref:** 200 01 103 073

Electron Applicator Auto-Tracking Defaults

This Notice contains important information about the operation of your product. Elekta recommends that all users of the product follow the instructions or recommendations in this Notice.

This Notice must be put in the Important Notice section of the applicable manual.

If you have any queries about this Notice, contact your local Elekta office.

Scope: All Digital Accelerators with Electrons and Beam Modulator, MLCi/MLCi2, Agility or Asymmetric Heads.

Problem: It has been brought to the attention of Elekta that some Digital Accelerators have increased electron applicator auto-tracking settings in the field, to values greater than the factory-set defaults.

Increasing auto-tracking values from factory-set defaults goes against Elekta recommendations and can result in the system becoming non-compliant with IEC standards, in particular with the safety standard IEC 60601-2-1.

Clinical impact: Increasing auto-tracking values from factory-set defaults will generally increase the electron applicator radiation leakage in the patient plane, as well as around the applicator, which can cause leakage values to exceed the limits specified in the safety standard IEC 60601-2-1.

The factory-set defaults have been tested in the factory to adhere to these standards. Elekta cannot guarantee increased values are still compliant.

Solution: Please adhere to the instructions and advice given in manuals and system dialogues, which explicitly state that a change to auto-tracking values could compromise compliance with safety standards and can cause increased unwanted radiation dose to the patient.

All machines should be checked against the default settings attached. If the actual settings are greater than the default settings, then Elekta's recommendation is that the default settings should be re-applied and all relevant physics checks (e.g. beam uniformity, output factor) performed (note that these checks are required for any change of auto-tracking settings, whether an increase or a decrease) .

If however auto-tracking values are increased beyond their factory-set defaults, then electron applicator radiation leakage measurements should also be made to ensure that the system remains compliant to IEC safety standard 60601-2-1. Please contact Elekta for detailed instructions and test method.

This Notice has been notified to the appropriate Regulatory Authority

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There will be a number of changes in the next mandatory release of Integrity software that will affect electron and photon energy use as follows:

1. Any changes made to energy calibration block values will result in the energy being disabled for clinical use until authorized.
2. It will be possible to enable/disable individual electron applicators for clinical use.
3. It will NOT be possible to use any auto-tracking diaphragm values greater than a set limit of 3 cm greater than the default values.

Please note that the following default values have been confirmed as the correct values to be used and that they are to be used in preference to any values that may be defined in any other source.

Default Auto-tracking settings

Agility Default Auto-tracking Settings

Check that the primary foil and secondary filter hole positions set in the software are as per Table 1 and check that the auto-tracking settings correspond to the defaults in Table 2 and Table 3.

Primary foil and secondary filter hole positions		
E (MeV)	Primary foil	Secondary filter
4	2	4
6	3	3
8	4	3
9	3	4
10	3	4
12	4	4
15	6	4
18	4	1
20	5	1

Table 1: Primary foil and secondary filter hole positions set in the software for each electron energy in Agility.

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Applicator (cm × cm)		6 × 6		10 × 10		14 × 14		20 × 20		25 × 25	
Auto-tracking Axis		X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2
Agility Auto-tracking settings (cm)	Energy (MeV)										
	4	7.4	8.2	11.2	12.0	14.2	14.8	15.3	16.1	19.6	19.0
	6	7.4	8.1	10.2	10.9	12.3	12.9	14.3	15.1	17.3	18.0
	8	7.3	8.0	10.6	11.3	11.9	12.6	14.4	15.2	16.9	17.7
	9	7.0	8.0	10.0	11.0	10.7	11.7	13.0	14.0	15.7	15.7
	10	7.0	7.7	10.0	11.0	10.5	11.3	12.8	13.4	15.2	15.9
	12	7.0	7.7	8.9	9.6	9.9	10.6	12.7	13.3	15.4	16.3
	15	7.0	7.7	8.5	9.5	9.2	9.8	12.2	12.8	15.0	15.8
	18	7.0	7.7	8.2	8.9	8.8	9.5	11.5	12.4	14.3	14.8
	20	6.5	7.0	8.0	8.8	8.7	9.6	11.7	12.6	14.3	14.8

Table 2: Default auto-tracking settings for a selected number of energies/applicators in Agility. The primary and secondary hole positions set in the software as per Table1.

Applicator (cm × cm)		20 × 10		16 × 8		14 × 6		10 × 6		20 × 6		Tubular (5, 4, 3, 2)	
Auto-tracking Axis		X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2
Agility Auto-tracking settings (cm)	Energy (MeV)												
	4	11.2	16.1	9.3	15.2	7.4	14.8	7.4	12.0	7.4	16.1	5.0	5.0
	6	10.2	15.1	9.0	12.5	7.4	12.9	7.4	10.9	7.4	15.1	5.0	5.0
	8	10.6	15.2	9.5	12.0	7.3	12.6	7.3	11.3	7.3	15.2	5.0	5.0
	9	10.0	14.0	9.0	11.5	7.0	11.7	7.0	11.0	7.0	14.0	5.0	5.0
	10	10.0	13.4	9.0	11.0	7.0	11.3	7.0	11.0	7.0	13.4	5.0	5.0
	12	8.9	13.3	9.0	10.5	7.0	10.6	7.0	9.6	7.0	13.3	5.0	5.0
	15	8.5	12.8	9.0	10.5	7.0	9.8	7.0	9.5	7.0	12.8	5.0	5.0
	18	8.2	12.4	9.0	10.0	7.0	9.5	7.0	8.9	7.0	12.4	5.0	5.0
	20	8.0	12.6	8.0	10.0	7.0	9.6	7.0	8.8	7.0	12.0	5.0	5.0

Table 3: Default auto-tracking settings for a selected number of energies/applicators in Agility. The primary and secondary hole positions set in the software are as per Table 1.

MLCi/MLCi2 Default Auto-tracking Settings

For electron energies 4-15 MeV, check that the primary foil and secondary filter hole positions set in the software are as per Table 4 and check that the auto-tracking settings correspond to the defaults in Table 5 and Table 6.

Primary foil and secondary filter hole positions		
E (MeV)	Primary foil	Secondary filter
4	2	3 OR 4
6	3	3
8	4	3
9	2 OR 3	4
10	3	4
12	4	4
15	5 OR 6	4

Table 4: Primary foil and secondary filter hole positions set in the software for electron energies 4-15 MeV in MLCi/MLCi2.

Applicator (cm × cm)			**6 × 6**		**10 × 10**		**14 × 14**		**20 × 20**		**25 × 25**	
Auto-tracking Axis			X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2
MLCi/MLCi2 auto-tracking settings (cm)	**Energy (MeV)**	**4**	7.4	8.2	11.2	12.0	14.2	14.8	15.3	16.1	19.6	19.8
		6	7.4	8.1	10.2	10.9	12.3	12.9	14.3	15.1	17.3	18.0
		8	7.3	8.0	10.6	11.3	11.9	12.6	14.4	15.2	16.9	17.7
		9	7.0	8.0	10.0	11.0	10.7	11.7	13.0	14.0	16.5	17.8
		10	7.0	7.7	10.0	11.0	10.5	11.3	12.8	13.4	15.2	15.9
		12	7.0	7.7	8.9	9.6	9.9	10.6	12.7	13.3	15.4	16.3
		15	7.0	7.7	8.5	9.5	9.2	9.8	12.2	12.8	15.0	15.8

Table 5: Default auto-tracking settings for a energies 4-15 MeV and a selected number of applicators in MLCi/MLCi2. The primary and secondary hole positions set in the software are as per Table 4.

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Applicator (cm × cm)			20 × 10		16 × 8		14 × 6		10 × 6		20 × 6		Tubular (5, 4, 3, 2)	
Auto-tracking Axis			X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2
MLCi/MLCi2 auto-tracking settings (cm)	Energy (MeV)	**4**	11.2	16.1	9.3	15.2	7.4	14.8	7.4	12.0	7.4	16.1	5.0	5.0
		6	10.2	15.1	9.0	12.5	7.4	12.9	7.4	10.9	7.4	15.1	5.0	5.0
		8	10.6	15.2	9.5	12.0	7.3	12.6	7.3	11.3	7.3	15.2	5.0	5.0
		9	10.0	14.0	9.0	11.5	7.0	11.7	7.0	11.0	7.0	14.0	5.0	5.0
		10	10.0	13.4	9.0	11.0	7.0	11.3	7.0	11.0	7.0	13.4	5.0	5.0
		12	8.9	13.3	8.0	10.0	7.0	10.6	7.0	9.6	7.0	13.3	5.0	5.0
		15	8.5	12.8	8.0	9.5	7.0	9.8	7.0	9.5	7.0	12.8	5.0	5.0

Table 6: Default auto-tracking settings for a energies 4-15 MeV and a selected number of applicators in MLCi/MLCi2. The primary and secondary hole positions set in the software are as per Table 4.

The foil and secondary filter hole positions set in the software for 18, 20 and 22 MeV depends on the hardware installed (secondary filter part = 1006027). In order to get the correct auto-tracking default settings check the foil and secondary filter hole positions set in the software in Table 7, if not applicable check Table 10.

Primary foil and secondary filter hole positions		
E (MeV)	Primary foil	Secondary filter
18	4	1
20	5	1
22	6	1

Table 7: Primary foil and secondary filter hole positions set in the software for electron energies 18, 20 and 22 MeV in MLCi/MLCi2. (secondary filter Part #= 1006027)

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Applicator (cm × cm)			6 × 6		10 × 10		14 × 14		20 × 20		25 × 25	
Auto-tracking Axis			X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2
MLCi/MLCi2 Auto-tracking (cm)	Energy (MeV)	18	7.0	7.5	8.2	8.9	8.8	9.5	11.5	12.4	14.3	14.8
		20	7.0	7.5	8.0	8.8	8.7	9.6	11.7	12.6	14.3	14.8
		22	7.0	7.5	7.0	7.8	7.8	8.7	10.8	11.7	14.3	14.8

Table 8: Default auto-tracking settings for energies 18, 20 and 22 MeV and a selected number of applicators in MLCi/MLCi2. The primary and secondary hole positions set in the software are as per Table 7.

Applicator (cm × cm)			20 × 10		16 × 8		14 × 6		10 × 6		20 × 6		Tubular (5, 4, 3, 2)	
Auto-tracking Axis			X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2
MLCi/MLCi2 Auto-tracking (cm)	Energy (MeV)	18	8.2	12.4	8.0	9.0	7.0	9.5	7.0	8.9	7.0	12.4	5.0	5.0
		20	8.0	12.6	7.0	9.5	7.0	9.6	7.0	8.8	7.0	12.6	5.0	5.0
		22	7.0	11.7	6.8	9.7	7.0	8.7	7.0	7.8	7.0	11.7	5.0	5.0

Table 9: Default auto-tracking settings for energies 18, 20 and 22 MeV and a selected number of applicators in MLCi/MLCi2. The primary and secondary hole positions set in the software are as per Table 7.

For LINACs with secondary filter part #= 45133308961 the foil and secondary filter hole positions set in the software for 18, 20 and 22 MeV are defined in Table 10.

Primary foil and secondary filter hole positions		
E (MeV)	Primary foil	Secondary filter
18	3	1
20	4	1
22	5	1

Table 10: Primary foil and secondary filter hole positions set in the software for electron energies 18, 20 and 22 MeV in MLCi/MLCi2. (secondary filter Part #= 45133308961)

Applicator (cm × cm)			6 × 6		10 × 10		14 × 14		20 × 20		25 × 25	
Auto-tracking Axis			X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2
MLCi/MLCi2 auto-tracking (cm)	Energy (MeV)	18	7.0	7.5	8.2	8.9	8.8	9.5	11.5	12.4	16.2	16.8
		20	7.0	7.5	8.0	8.8	8.7	9.6	11.7	12.6	16.2	16.8
		22	7.0	7.5	8.0	8.8	8.8	9.7	11.8	12.7	16.2	16.8

Table 11: Default auto-tracking settings for energies 18, 20 and 22 MeV and a selected number of applicators in MLCi/MLCi2. The primary and secondary hole positions set in the software are as per Table 10.

Applicator (cm × cm)			20 × 10		16 × 8		14 × 6		10 × 6		20 × 6		Tubular (5, 4, 3, 2)	
Auto-tracking Axis			X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2	X1, X2	Y1, Y2
MLCi/MLCi2 auto-tracking (cm)	Energy (MeV)	18	8.2	12.4	8.0	9.0	7.0	9.5	7.0	8.9	7.0	12.4	5.0	5.0
		20	8.0	12.6	7.0	9.5	7.0	9.6	7.0	8.8	7.0	12.6	5.0	5.0
		22	8.0	12.7	6.8	9.7	7.0	9.7	7.0	8.8	7.0	12.7	5.0	5.0

Table 12: Default auto-tracking settings for energies 18, 20 and 22 MeV and a selected number of applicators in MLCi/MLCi2. The primary and secondary hole positions set in the software are as per Table 10.

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Beam Modulator Default Auto-tracking Settings

For electron energies 6-15 MeV, check that the primary foil and secondary filter hole positions set in the software are as per Table 13 and then check that the auto-tracking settings correspond to the defaults in Table 14.

Primary foil and secondary filter hole positions		
E (MeV)	Primary foil	Secondary filter
6	3	3
8	4	3
9	2 OR 3	4
10	3	4
12	4	4
15	5 OR 6	4
18	3 OR 4	1
20	4 OR 5	1
22	5 OR 6	1

Table 13: Primary foil and secondary filter hole positions set in the software for electron energies 6-22 MeV in Beam Modulator.

Applicator (cm × cm)		6x6				6x10				10x10			
Auto-tracking Axis		X1	X2	Y1	Y2	X1	X2	Y1	Y2	X1	X2	Y1	Y2
BeamModulator auto-tracking (cm)	**Energy (MeV)**												
	6	8.0	7.6	8.0	8.0	8.0	7.6	8.8	9.0	*	*	*	*
	8	8.0	7.6	8.0	8.0	8.0	7.6	8.8	9.0	*	*	*	*
	9	8.0	7.6	8.0	8.0	8.0	7.6	8.0	8.4	*	*	*	*
	10	8.0	7.6	7.7	7.7	8.0	7.6	8.0	8.4	8.0	7.6	8.0	8.4
	12	8.0	7.6	7.7	7.7	8.0	7.6	7.4	7.6	8.0	7.6	7.4	7.6
	15	8.0	7.6	7.7	7.7	8.0	7.6	7.0	7.4	7.6	7.2	7.0	7.4
	18	7.2	6.8	7.2	7.2	7.2	6.8	6.6	7.0	7.6	7.2	6.6	7.0
	20	7.2	6.4	7.2	7.2	7.2	6.4	6.4	7.0	7.6	7.2	6.4	7.0
	22	7.2	6.4	7.2	7.2	7.2	6.4	6.4	7.0	7.6	7.2	6.4	7.0

Table 14: Default auto-tracking settings for energies 6-22 MeV and a selected number of applicators in Beam Modulator. The primary and secondary hole positions set in the software are as per Table 13.

For LINACs with the primary foil and secondary filter hole positions set in the software for 4 MeV as per Table 15 check that default auto-tracking settings are as per Table 16.

Primary foil and secondary filter hole positions		
E (MeV)	Primary foil	Secondary filter
4	2	3

Table 15: Primary foil and secondary filter hole positions set in the software for electron energies 4 MeV in Beam Modulator.

Applicator (cm × cm)			6x6				6x10			
Auto-tracking Axis			X1	X2	Y1	Y2	X1	X2	Y1	Y2
Beam Modulator auto-tracking (cm)	E (MeV)	**4**	8.0	7.6	8.0	8.0	8.0	7.6	9.2	9.4

Table 16: Default auto-tracking settings for energies 6-22 MeV and a selected number of applicators in Beam Modulator. The primary and secondary hole positions set in the software are as per Table 15.

For LINACs with the primary foil and secondary filter hole positions set in the software for 4 MeV as per Table 17 check that default auto-tracking settings are as per Table 18.

Primary foil and secondary filter hole positions		
E (MeV)	Primary foil	Secondary filter
4	2	4

Table 17: Primary foil and secondary filter hole positions set in the software for electron energies 4 MeV in Beam Modulator.

Applicator (cm × cm)			6x6				6x10			
Auto-tracking Axis			X1	X2	Y1	Y2	X1	X2	Y1	Y2
Beam Modulator auto-tracking (cm)	E (MeV)	**4**	8.0	7.6	8.0	8.0	8.0	7.6	10.5	10.5

Table 18: Default auto-tracking settings for energy 4 MeV and a selected number of applicators in Beam Modulator. The primary and secondary hole positions set in the software are as per Table 17.

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FCO ACTION NOTIFICATION REPORT

<Give this Notice to the customer, and then complete and return this report to your local Elekta Office or Representative for the Configuration Database.>

Classification:	Important Field Safety Notice	**FCO Ref:**	200 01 103 073
FCO description:	Electron Applicator Auto-Tracking Defaults		
Scope:	All Digital Accelerators with Electrons and Beam Modulator, MLCi/MLCi2, Agility or Asymmetric Heads		

Hospital:	
Device Serial No: (e.g. linac - if applicable)	**Location or** **Site No:**

Action on this unit/device was: (*select one*)

Note: If you use a work-order in the CLM configuration database, then you do not have to complete this section. The work-order will be used to add the information to the system.

☐ Completed as per instructions on: <date day/month/year]>

☐ Not completed because: **(***give reasons*)

☐ Not completed because the unit/device is in storage *(if applicable).*

☐ Refused by customer because: **(***give reasons*)

Acknowledgement by customer:
This notification to be signed by the customer.

The REASON and PURPOSE of this notice has been explained.

Name: _____ Title: .....

Signature: _____ Date: .....

This Notice has been notified to the appropriate Regulatory Authority

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