Elekta

September 22, 2017

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555-0001

RE: Elekta Inc. 10 CFR 21 Notification for the Applicator Modeling measured source path error

Dear Document Control,

Pursuant to 10 CFR 21.21(d)(4) Elekta Inc. Is providing the required written notification and final report of the identification of a defect Oncentra Brachy Applicator Modeling software when using a measured source path. This information was initially reported to the Nuclear Regulatory Commission Operations Center on August 25, 2017 via Event Notification #52926.

The enclosure to this letter provides information required by 10 CFR 21.21(d)(4). Appendices from section ***vi*** are submitted under 10 CFR 2.390; the Justification for Proprietary Information Affidavit is also enclosed.

If there are any questions pertaining to this communication , please contact Debra Bensen, RSO, at 770-670-2518 or via email debbie.bensen@elekta.com.

Sincerely,

Debra L Bensen

Debra Bensen
RSO – Elekta, Inc.

Enclosures: As stated

IE20
NRR

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Elekta

10 CFR 21.21(d)(4) Report

i. ***Name and address of the individual or individuals informing the Commission.***

Debra Bensen
Radiation Safety Officer
Elekta Inc.
400 Perimeter Center Terrace, Suite 50
Atlanta, GA 30346

ii. ***Identification of the facility, the activity, or the basic component supplied for such facility***

The issue occurs when using Applicator Models with a measured source path in combination with a specific afterloader configuration. Table 1 shows for which configurations the issue occurs.

Table 1. Combinations that cause the issue

Oncentra Brachy	Versions 4.5, 4.5.1 and 4.5.2
	Applicator Modeling with a measured source path
	RDStore default step size 5.0 mm, 10.0 mm
In Afterloader	microSelectron HDR/PDR V2, V3/Digital
With Applicators	Ring applicator Sets
	Ring CT/MR Applicator sets
	Interstitial CT/MR Rings
	Vienna CT/MR Rings
	Advanced Gynecological Applicator – Venezia™ with Lunar-shaped ovoids.

iii. ***Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.***

Nucletron B.V
Waardgelder 1
3905 TH Veenendaal
The Netherlands

iv. ***Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.***

Nature of the defect: Incorrect source step size may occur in Oncentra Brachy plans for Ring or Venezia applicator models with microSelectron

The issue is caused by the measured source paths for the applicators listed in ***ii*** above, which always have a source step size of 2.5 mm for the microSelectron afterloader. The default step size of the afterloader is 5.0; therefore, if such an applicator model is used to create a plan, the

step size in the ring or lunar-shaped ovoids will be incorrect. They will be shown as 2.5 mm, while the afterloader will deliver at 5.0 mm if the error is not detected during plan approval.

Clinical Impact: If such a plan is exported to the microSelectron Treatment Control System (TCS) and delivered, the treated dwell positions in the ring will be incorrect. When loading the plan in TCS, only the dwell position numbers and the source step size are taken over from the Oncentra Brachy plan. This leads to a shift of the treated dwell positions in the ring due to the incorrect step size.

v. ***The date on which the information of such defect or failure to comply was obtained.***

On July 13, 2017, a user in France notified Elekta, in The Netherlands, that they discovered a software issue during their Quality Assurance checks of Elekta's Oncentra Brachy Software. Elekta investigated and determined that a software issue exists in Oncentra software versions 4.5, 4.5.1 and 4.5.2.

vi. ***In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.***

Appendix A – Accounts with Applicator Modeling lists all US customers that have purchased the applicator modeling software.

Appendix B – Accounts with Applicable Configuration Confirmed lists the customers that have confirmed they have the equipment and configurations where the defect was able to occur.

Appendices submitted under 10 CFR 2.390.

vii. ***The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.***

Corrective Action #1: Release of Important Field Safety Notice

An Important Field Safety Notice, 806-01-BTP-001, was created to inform users of the issue and the workaround until a permanent solution has been developed and implemented (**IFSN 806-01-BTP-001 attached).**

Elekta sent the Important Field Safety Notification (IFSN) to all customers with the Applicator Modeling software license concerning the use of ring source paths with applicator modeling on 8/11/17

The review period for the Important Field Safety Notice is reduced to ensure safety information reaches customers as quickly as possible. The notice informs users of the specific product and version numbers affected by the issue, and any work arounds that can be used to avoid the issue.

A copy of the IFSN is to be kept with the most current labelling and all personnel working with the product should be made aware of the content of the letter.

The customers are instructed to complete and return the IFSN Acknowledgement form to their local Elekta representative as soon as possible but no longer than 30 days from receipt.

Elekta Inc. has personally contacted each facility representative to review the IFSN and discuss the work-around. Those that could not be contacted after several attempts were sent the IFSN a second time via FedEx delivery.

Corrective Action #2: Oncentra Brachy Software Upgrade

The problem will be resolved in a software upgrade to Oncentra Brachy 4.5.

The fix is currently being developed and is estimated to be released for installation in the field by the end of February 2018. Once released, Elekta Service teams will pro-actively reach out to all affected customers to organise a time to install the fix as soon as possible.

The target time for completion is 12 months from date solution is made available.

viii. ***Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.***

The IFSN provides a work around until an upgraded version of Oncentra Brachy is available; whereby, facilities are strongly recommended to only use a default source step size of 2.5 mm for microSelectron afterloaders in RDStore.

Beyond all advice provided in the IFSN (806-01-BTP-001), affected customers will be informed when the software patch is made available that solves the issue.

ix. ***In the case of an early site permit, the entities to whom an early site permit was transferred.***

N/A

Elekta

Field Corrective Action Reference: **FCA-NU-0004**
This notice reference: 806-01-BTP-001

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: **Incorrect source step size may occur in Oncentra Brachy plans for Ring or Venezia applicator models with microSelectron.**

Product: **Oncentra® Brachy.**

Scope: **Oncentra Brachy versions 4.5, 4.5.1, 4.5.2.**

Notification Released: August 2017

Description of Problem:

The default step size set in RDStore is typically used during the planning process. The measured source paths for a ring-type applicator always have a source step size of 2.5 mm for the microSelectron afterloader. When creating an Oncentra Brachy plan for a Ring applicator with a measured source path, the step size of the measured source path will be used for the entire plan.

The issue is caused by the measured source paths for the applicators listed below, which have a source step size of 2.5 mm for the microSelectron afterloader. If you use such an applicator model to create a plan, while the default step size of the afterloader is 5.0, the step size in the ring or lunar-shaped ovoids will be incorrect. They will be shown as 2.5 mm, while the afterloader will deliver at 5.0 mm if the error is not detected during plan approval.

Details:

This issue occurs when using Applicator Models with a measured source path in combination with a specific afterloader configuration. Table 1 shows for which configurations the issue occurs.

Table 1. Combinations that cause the issue

Oncentra Brachy	Version 4.5, 4.5.1, 4.5.2
	Applicator Modeling with a measured source path
	RDStore default step size 5.0 mm, 10.0 mm
Afterloader	microSelectron HDR/PDR V2, V3/Digital
Applicators	Ring Applicator Sets
	Ring CT/MR Applicator sets
	Interstitial CT/MR Rings
	Vienna CT/MR Rings
	Advanced Gynecological Applicator - Venezia™ with Lunar-shaped ovoids

In this bulletin the Ring applicator will be used to represent all applicable applicators. Where ring is mentioned also lunar-shaped ovoids apply (Advanced Gynecological Applicator). Where 5.0 mm is used as a default step size this could also be 10.0 mm.

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

When using an applicator model, the default step size set in RDStore is always used during the planning process. When an applicator with a measured source path is used, the step size of the measured source path will be used for the entire plan instead. For a microSelectron afterloader the step size of a measured source path is always 2.5 mm.

However, that doesn't happen if the user selects a microSelectron afterloader during planning which is setup in RDStore with a default step size of 5.0 mm.

In such a case the override of the default step size by the step size of the measured source path is incorrectly performed. The Case Explorer shows a step size of 5.0 mm, while this should be 2.5 mm, see Figure 1.

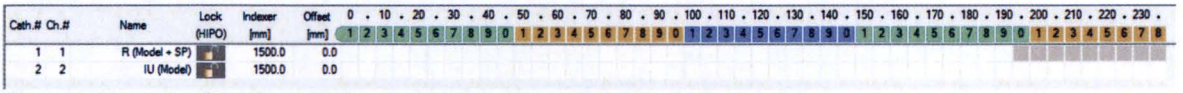

Figure 1. Example of the Case Explorer with the incorrect step size

The 3D view of the applicator will show a step size of 2.5 mm for the ring and 5.0 mm for the tandem, see Figure 2. When activating dwell positions in the Case Explorer, it seems a 5.0 mm step size is used, while the 3D view shows a 2.5 mm step size for the ring.

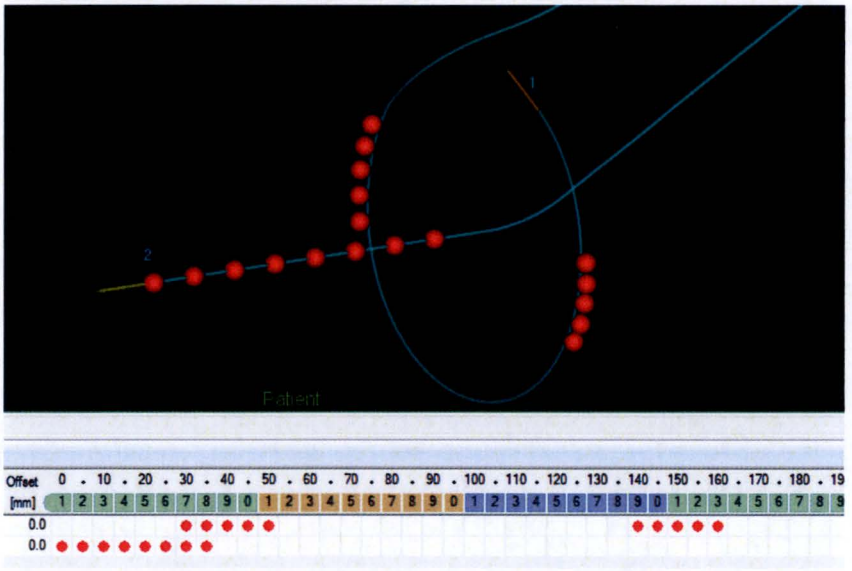

Figure 2. Example of the 3D reconstruction area with the differences in the step size.

The dose calculated for the plan will correspond to a 2.5 mm step size for the ring and a 5.0 mm step size for the tandem. The Oncentra Brachy Treatment Printout will show a 5.0 mm step size for both ring and tandem.

When this plan is exported, a step size of 5.0 mm will be sent to the microSelectron afterloader. The afterloader Pre Treatment Report will show a 5.0 mm step size as will be delivered by the afterloader.

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Clinical Impact:
If such a plan is exported to the microSelectron Treatment Control System (TCS) and delivered, the treated dwell positions in the ring will be incorrect. When loading the plan in TCS only the dwell position numbers and the source step size are taken over from the Oncentra Brachy plan. This leads to a shift of the treated dwell positions in the ring due to the incorrect step size.

Recommended User Action:
Until an upgraded version of Oncentra Brachy is available, it is strongly recommended to only use a default source step size of 2.5 mm for microSelectron afterloaders in RDStore.

If a larger default source step size is required in RDStore, a workaround is to reselect the same afterloader in the Prescription dialog in the Oncentra Brachy planning module. The source step size is then forced to the correct value of 2.5 mm.

It is strongly advised to perform proper Quality Assurance for all treatment plans before delivery of the first fraction to the patient.

This document contains important information for the continued safe and proper use of your equipment.

- Please post this notice in a place accessible to all users, e.g. Instructions for Use, until this action is closed.
- Advise the appropriate personnel working with this product the content of this letter

Elekta Corrective Actions:
The issue will be solved in the next version of Oncentra Brachy.

This notice has been provided to the appropriate Regulatory Authorities.

We sincerely apologize for any inconvenience this action may cause and thank you in advance for your cooperation.

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Acknowledgement Form

In order to meet regulatory requirements, you are required to complete this form and return it to Elekta immediately upon receipt but no later than 30 days.

Classification:	Important Field Safety Notification	FCO Reference Number:	806-01-BTP-001
Description	Incorrect source step size may occur in Oncentra Brachy plans for Ring or Venezia applicator models with microSelectron.		

Hospital:	
Device Serial No(s): (if applicable)	Location or Site:

I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations.

Name: Title:

Customer Signature: Date:

New installation confirmation to be signed by the installing Elekta engineer or Representative employee when the installed product has a physical IFU/manual:

I acknowledge that the customer is informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual or added to the record with the applicable User Manual:

Name: Title:

Signature: Date:

JUSTIFICATION FOR PROPRIETARY INFORMATION AFFIDAVIT

I, Susan Himmer, Senior Legal Counsel for Elekta Inc. hereby affirm and state:

(1) I have been specifically delegated the function of reviewing the information sought to be withheld as confidential and am authorized to apply for its withholding on behalf of Elekta Inc.

(2) Elekta Inc. is providing the NRC with the documents *"Appendix A – Accounts with Applicator Modeling"* and *"Appendix B – Accounts with Applicable Configuration Confirmed"* as part of the Elekta Inc. 10 CFR Part 21(d)(4) Report concerning the Applicator Modeling measured source path error.

(3) The information includes sensitive and proprietary customer information and is sought to be withheld pursuant to the provisions of paragraph (a)(4) of 10 CFR 2.390 are the documents, *"Appendix A – Accounts with Applicator Modeling"* and *"Appendix B – Accounts with Applicable Configuration Confirmed"*, marked as follows, "Proprietary information submitted under 10 CFR 2.390 to be withheld from public disclosure under 10 CFR 2.390".

(4) Pursuant to the provisions of paragraph (b)(4) of Section 2.390 of the Commission's regulations, the documents, *"Appendix A – Accounts with Applicator Modeling"* and *"Appendix B – Accounts with Applicable Configuration Confirmed"*, should be held in confidence by the NRC, because:

i. The information is for Elekta internal use only and it has been held in confidence by Elekta Inc.

ii. The information is of a type customarily held in confidence by Elekta Inc. and not disclosed to the public. Elekta Inc. has a rational basis for determining the types of information customarily held in confidence by it and, in that connection, uses a uniform method to determine when and whether to hold certain types of information in confidence.

Under Elekta's approach, information is held in confidence if it falls in one or more of several types of information, the release of which might result in the loss of an existing or potential competitive advantage and/or be used to damage Elekta's reputation or business position as follows:

a. The information reveals Elekta Inc.'s customer base;

b. The information reveals which customers have specific Elekta software and the applicator modeling application.

c. The information reveals which customers have used specific configurations of Elekta's applicator modeling application.

iii. This information is being transmitted to the Commission voluntarily to aid in its investigation and, under the provisions of 10 CFR 2.390, it is to be received in confidence by the Commission.

iv. This information is not available in public sources.

v. Public disclosure of this information is likely to cause substantial harm to the competitive position and the reputation of Elekta Inc. because of the reasons outlined below.

a. Unrestricted disclosure would jeopardize the position of Elekta Inc. in the world market, and thereby give a market advantage to the competition in those countries.

b. Unrestricted disclosure would jeopardize the confidentiality of Elekta's customer base, including the confidentiality of how Elekta's customers use treatment tools, including application modeling.

(5) Accordingly, Elekta Inc requests that the designated information be kept confidential and withheld from public disclosure pursuant to paragraph (a)(4) of CFR 10.239.

AFFIDAVIT, STATE OF GEORGIA, COUNTY OF Dekalb

Before me, the undersigned authority, personally appeared, Susan Himmer, who, being by me duly sworn according to law, deposes and says that she is authorized to execute this Affidavit on behalf of Elekta Inc. and the averments of fact set forth in this Affidavit are true and correct to the best of her knowledge, information and belief:

Signature

Susan Himmer
Name

Sr. Counsel, Elekta Inc.
Title

SWORN TO AND SUBSCRIBED before me this 25th day of September, 2017

Erin Melville
Notary Public

Printed Name: Erin Melville

Personally Known X or produced identification ____

My Commission Expires:

01.12.2021

Seal: