

## URGENT IMPORTANT FIELD SAFETY MODIFICATION

**Subject:** Oncentra® Brachy v4.5.3 Installation Instructions

**Product:** Oncentra® External Beam Oncentra® Brachy

**Scope:** Oncentra Brachy v4.5, v4.5.1, v4.5.2

**Relates To:** 806-01-BTP-001 (IFSN), 806-05-BTP-011 (Product Bulletin)

**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 specific applicators, 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.

Technical Reference:	Not applicable
Manpower:	Depending on the current installation and database: average 2 hours
Tools & Test equipment:	Not applicable
Parts required:	<ul style="list-style-type: none"><li>• Oncentra Brachy v4.5.3 Installation Kit, part number 170537-07</li><li>• Applicable licenses</li></ul>
Installed by:	Elekta Service Personnel certified on Oncentra Systems training or Oncentra Brachy v4.5.x
Trained by:	Elekta trainers certified on Oncentra Brachy v4.5.x. See Section 9 for the training requirements.

# URGENT IMPORTANT FIELD SAFETY MODIFICATION

## Table of Contents

1	Details .....	2
2	Description .....	2
3	Related documents .....	3
4	Installation requirements.....	3
4.1	Installation kit.....	3
4.2	Licensing requirement.....	3
4.3	Supported operating systems .....	3
4.4	Separation of Oncentra Brachy and Oncentra External Beam .....	4
5	Upgrade procedure .....	4
6	Upgrade of Oncentra Brachy v4.3 to Oncentra Brachy v4.5.3 .....	4
6.1	Preparation for installation of Oncentra Brachy v4.5.3 .....	4
6.2	Upgrade to Oncentra Brachy v4.5.3 .....	5
6.3	Post-installation tasks .....	5
7	Upgrade of Oncentra Brachy v4.5.x to Oncentra Brachy v4.5.3 .....	6
7.1	Preparation for installation of Oncentra Brachy v4.5.3 .....	6
7.2	Upgrade to Oncentra Brachy v4.5.3 .....	6
7.3	Post-installation tasks .....	6
8	Verification of implementation.....	7
9	User training.....	7
10	Quality assurance .....	7

## 1 Details

This document contains the installation instructions for Oncentra Brachy v4.5.3 for all customers running v4.5.x. This bulletin also includes upgrade instructions for customers on v4.3.

Please refer to the Product Bulletin or Release Notes for detailed information on the changes in Oncentra Brachy v4.5.3.

## 2 Description

Oncentra Brachy v4.5.3 contains solutions for the reported issues listed in the Release Notes (777.00572MAN). Depending on the installed version and licensed Oncentra External Beam Oncentra Brachy modules, new licenses and/or a “separation” of Oncentra External Beam and Oncentra Brachy may be required. Please refer to Section 4 for the upgrade requirements.

## URGENT IMPORTANT FIELD SAFETY MODIFICATION

### 3 Related documents

Reference	Revision	Description
806-01-BTP-001	Latest*	Incorrect source step size may occur in Oncentra Brachy plans for Ring or Venezia applicator models with microSelectron
806-05-BTP-011	Latest*	Product Bulletin – Release of Oncentra Brachy v4.5.3
777.00298MAN	Latest*	Oncentra Brachy v4.5.3 System Administrator Manual
777.00572MAN	Latest*	Oncentra Brachy v4.5.3 Release Notes

\* Latest version can be downloaded from [www.ElektaMarketing.info](http://www.ElektaMarketing.info)

### 4 Installation requirements

#### 4.1 Installation kit

The Oncentra Brachy v4.5.3 Installation Kit (170537-07) is required to do the upgrade of Oncentra Brachy v4.x to v4.5.3.

#### 4.2 Licensing requirement

A new Oncentra Brachy Platform Server License (OTP\_SERVER\_BP) was introduced with Oncentra Brachy v4.5. Please make sure that this license is available before you start the upgrade to Oncentra Brachy v4.5.3. This license can be generated by certified Oncentra Brachy specialists.

**Note:**

*If you do the upgrade without the Oncentra Brachy v4.5 Server License, then Oncentra Brachy v4.5.3 will not start.*

#### 4.3 Supported operating systems

Oncentra Brachy v4.5.3 is validated on the operating systems listed in the table:

Supported Operating System	Service Pack	Environment	Installation
Windows 7 Professional	Service Pack 1	64-bit	Server/Client
Windows 7 Ultimate*	Service Pack 1	64-bit	Server/Client
Windows 7 Ultimate for Embedded Systems**	Service Pack 1	64-bit	Server/Client
Windows Server 2008 R2	Service Pack 1	64-bit	Server only
Windows Server 2012 R2	With latest patches installed	64-bit	Server only

\*) Windows 7 Ultimate is required for support of a display language other than English.

\*\*) Windows 7 Ultimate for Embedded Systems requires specific configuration and is only supported when system configuration is done by the Elekta service organization.

The required Windows Service Pack must be installed before Oncentra Brachy v4.5.3 is installed.

Installation of Oncentra Brachy on any other operating system is not supported.

For maximum performance we recommend customers to upgrade their system to the latest supported computer platform. Please contact the Product Supply Center (PSC) for more details.

## **URGENT**

### **IMPORTANT FIELD SAFETY MODIFICATION**

#### **4.4 Separation of Oncentra Brachy and Oncentra External Beam**

With the release of Oncentra Brachy v4.5 and Oncentra External Beam v4.5, installing and using Oncentra Brachy and Oncentra External Beam on the same physical system is no longer supported. This is valid both for the application server and the clients.

Therefore, customers that use their system for both external beam and brachytherapy planning must “separate” their configuration and use two application servers. For multi-client installations a separation of the application clients could also be required.

The instructions to separate an Oncentra External Beam Oncentra Brachy system are not covered in this document. The separation can only be done by a selected number of certified specialists.

#### **5 Upgrade procedure**

Oncentra External Beam Oncentra Brachy v3.2 to v4.1 SP1 must first be upgraded to Oncentra Brachy v4.3.

The instructions for a new installation are not in the scope of this document. Please refer to the System Administrator Manual.

Two different upgrade paths are possible:

- Upgrade of Oncentra Brachy v4.3 to Oncentra Brachy v4.5.3 (see Section 6)
- Upgrade of Oncentra Brachy v4.5.x to Oncentra Brachy v4.5.3 (see Section 7)

#### **6 Upgrade of Oncentra Brachy v4.3 to Oncentra Brachy v4.5.3**

This section describes the steps to upgrade from v4.3.x to v4.5.3. You can find detailed instructions in the System Administrator Manual.

##### **6.1 Preparation for installation of Oncentra Brachy v4.5.3**

**Note:**

---

*Make sure that you log in with an account with the necessary administrative privileges for the upgrade.*

1. Perform a system disk backup.
2. Back up the site-specific settings and licenses (see the System Administrator Manual).
3. Back up the “**peisoline.xml**” file located in **C:\Program Files\Nucletron\OTP\Isolines\**
4. Back up the Oncentra Brachy v4.3 databases (see the System Administrator Manual).
5. Uninstall Oncentra Brachy v4.3 via the Control Panel on the Oncentra Brachy server and the clients.

**Note:**

---

*During removal of the old version of Oncentra Brachy the system will ask to select which additional items to remove. Make sure that the two items shown in the figure below are unchecked, because the data cannot be recovered. When selecting the option “Delete temporary folder”, the complete OTP\_DATA folder will be removed. Selecting the option “Delete all files in Program folder” will remove the Oncentra Brachy installation directory. This will also remove the isoline settings.*

## URGENT IMPORTANT FIELD SAFETY MODIFICATION

Please specify additional items to remove

Delete temporary folder

Delete all files in program folder

**Note:**

Do not uninstall the *Mimer* application.

6. Check the local firewall rules to allow connections over TCP port 19998 for use by OTP-ServicesBrachy (previously OTP-Services used TCP port 19999).
7. Check the local anti-malware software to make sure that the proper TCP port is opened to allow communication for OTP-ServicesBrachy.

### 6.2 Upgrade to Oncentra Brachy v4.5.3

1. Insert the Oncentra Brachy v4.5.3 DVD at the Oncentra server.
2. Upgrade the Mimer database.
3. Install Oncentra Brachy v4.5.3, including the automatic database upgrade.

**Note:**

To be able to continue with the current patient and physics database, make sure to select the existing *OTP\_DB* and *OTP\_DATA* locations during installation of Oncentra Brachy v4.5.3.

4. Install the new *OTP\_SERVER\_BP* license.
5. Remove the old *OTP\_SERVER* license.
6. If present, replace the *OTP\_EM* license by the *OTP\_PA* and *OTP\_PE* license.
7. Remove the old *OTP\_EM* license.
8. Install any new purchased licenses.
9. Install the local language.

**Note:**

In certain countries it is mandatory to install the local language on all the Oncentra Brachy systems. Please make sure that the correct local language(s) is installed.

10. Share the client kit with the Oncentra Brachy clients.
11. Start the client kit on the Oncentra Brachy clients.
12. Upgrade the Mimer database.
13. Install Oncentra Brachy v4.5.3.
14. Install the local language.

### 6.3 Post-installation tasks

1. If needed, restore any site-specific settings.
2. Copy the backed up 'peisolines.xml' file to the new location:  
**C:\Program Files\Nucletron\Brachy\Isolines\**
3. Rename the copied 'peisolines.xml' to 'isolines.xml'.
4. Update the Oncentra Brachy Backup configuration.
5. Back up the Oncentra Brachy v4.5.3 database.
6. Make a system backup.

## **URGENT**

# **IMPORTANT FIELD SAFETY MODIFICATION**

**Note:**

---

*If the TCP port OTP-ServicesBrachy in the firewall or virus scanner is not corrected, it is possible that your clients cannot connect to the server anymore.*

**Note:**

---

*Due to a folder name change in the installation kit, the Oncentra Brachy Backup will not run if the configuration is not updated. To do this update, change the scheduled time by 1 minute and click the Apply button again.*

### **7 Upgrade of Oncentra Brachy v4.5.x to Oncentra Brachy v4.5.3**

This section describes the steps to upgrade from v4.5.x to v4.5.3. You can find detailed instructions in the System Administrator Manual.

**Note:**

---

*Make sure that you log in with an account with the necessary administrative privileges for the upgrade.*

#### **7.1 Preparation for installation of Oncentra Brachy v4.5.3**

1. Make a system disk backup.
2. Back up the site-specific settings and licenses (see the System Administrator Manual).
3. Back up the Oncentra Brachy v4.5.x databases (see the System Administrator Manual).

#### **7.2 Upgrade to Oncentra Brachy v4.5.3**

1. Insert the Oncentra Brachy v4.5.3 DVD at the Oncentra server.
2. Upgrade the Mimer database.
3. Upgrade to Oncentra Brachy v4.5.3, including automatic database upgrade.
4. Install the local language.
5. Share the client kit with the Oncentra Brachy clients.
6. Start the client kit on the Oncentra Brachy clients.
7. Upgrade the Mimer database.
8. Upgrade to Oncentra Brachy v4.5.3.
9. Install the local language.

**Note:**

---

*In certain countries it is mandatory to install the local language on all of the Oncentra Brachy systems. Please make sure that the correct local language(s) is installed.*

#### **7.3 Post-installation tasks**

1. If needed restore any site-specific settings.
2. Back up the Oncentra Brachy v4.5.3 database.
3. Make a system backup.

## URGENT IMPORTANT FIELD SAFETY MODIFICATION

### 8 Verification of implementation

Description	Checked
1 Start Oncentra Brachy and check that all user accounts are there.	
2 Verify that patient data is there and can be opened.	
3 Check if data can still be received from the CT and MR scanners and import them.	
4 Verify if the DICOM destinations can be reached.	
5 If used, verify if the TCS/TCC folder can be reached.	
6 Create a test plan and verify that the parameters can send and execute.	
7 Verify that menus are displayed in the local language (if required).	

### 9 User training

Make the user aware of the changes and the solved issues. Refer to the Release Notes for an overview of the changes and solved cases. Please see the table below to check if training is required for this upgrade.

Upgrade from version	Training required?
v4.5.x	No
v4.3.x (microSelectron user)	No
v4.3.x (Flexitron user)	Yes
Earlier versions than v4.3.x	Yes

**Note:**

*The table only refers to the training requirements as part of this FCO process. In case a customer purchases the upgrade (as of version v3.x) or new licenses or extra training, then this is part of the sales process and this might require extra training.*

**Note:**

*When a customer upgrades from v4.3 or earlier versions, make sure that the Oncentra Brachy trainer has the required certifications on the older version. This will allow the trainer to adequately explain the differences between the software versions.*

### 10 Quality assurance

Please request the local physics department to perform quality assurance as required by local regulations before going clinical with the new version(s). In Appendix A of the User Manual the user can find a Treatment Plan Approval Checklist that we strongly recommend to fill in for every treatment.

# **URGENT IMPORTANT FIELD SAFETY MODIFICATION**

— Blank page —



## URGENT IMPORTANT FIELD SAFETY MODIFICATION

### MODIFICATION ACKNOWLEDGEMENT

If the solution detailed in this Field Safety Modification is being implemented by an Elekta Service Partner (Distributor or Self Maintainer), the implementer is required to complete the details in the boxes below and sign to confirm completion. If implementation is refused by the customer, the implementer must obtain the customer's signature in the refusal section. Please return this report to the local Elekta Office or Representative.

Classification: Important Field Safety Modification	FCO Reference Number: 806-02-BTP-001
Description: Installation Instructions Oncentra® Brachy v4.5.3	
Product: Oncentra® External Beam Oncentra® Brachy	
Hospital:	
Device Serial No(s): (if applicable)	Location or Site:
<p>Action on this unit/device was (<i>select one</i>):</p> <p><input type="checkbox"/> Completed as per instructions on date day/month/year:</p> <p><input type="checkbox"/> Not completed because the unit/device is in storage (<i>if applicable</i>):</p> <p><input type="checkbox"/> Not completed because (<i>give reasons</i>):</p> <p><input type="checkbox"/> Delayed by customer because (<i>give reasons</i>):</p> <p><input type="checkbox"/> Refused by customer because (<i>give reasons</i>):</p>	
<p><small>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.</small></p>	
<p><b>Modification not Completed / Refused by customer because:</b> This section to be completed by the customer. <b>Reason:</b></p> <p>Name: _____ Title: _____</p> <p>Signature: _____ Date: _____</p>	
<p><b>Acknowledgement by non-Elekta installing engineer:</b> This section to be signed by the installing engineer only when being performed by a third party representative or hospital employee</p> <p>Name: _____ Title: _____</p> <p>Signature: _____ Date: _____</p>	