

URGENT - Field Safety Notice

**Pinnacle³ Radiation Therapy Planning System
Digital Imaging and Communications in Medicine (DICOM) Radiation Therapy (RT) Dose
Export Incorrect**

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

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy of this notice near the affected Pinnacle³ Radiation Therapy Planning System(s) for ease of reference.

October 2022

Dear Customer,

A problem has been identified in the Philips Pinnacle³ Radiation Therapy Planning System that could pose a risk for patients undergoing radiation therapy treatment. This Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

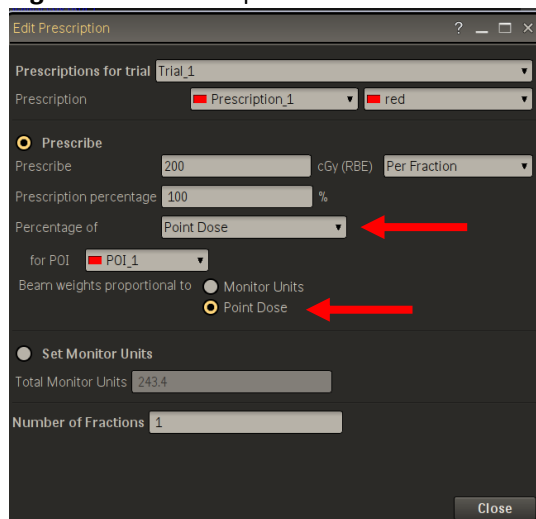
When computing a radiation dose in the Pinnacle³ Radiation Therapy Planning System, the exported DICOM-RT dose is incorrect when there is more than one beam attached to the prescription and the following options are selected on the Edit Prescription screen (see Figure 1):

- **Percentage of** is selected as **Point Dose**
- **Beam weights proportional to** is selected as **Point Dose**

Any new treatment plans created by importing the exported DICOM-RT dose will be incorrect and any downstream system using the DICOM-RT dose file will receive incorrect data.

The issue only affects the dose information when it is exported as detailed above. The dose displayed on the Pinnacle system is correct. Radiation Therapy (RT) Plan Information sent to your record and verify system is correct.

Figure 1: Edit Prescription screen



Philips has not received any reports of adverse events associated with this issue.

Intended use of affected product:

The Pinnacle³ Radiation Therapy Planning System is a software package that provides planning support for the treatment of disease processes, utilizing photon, electron and brachytherapy techniques. Pinnacle³ Radiation Therapy Planning System assists the clinician in formulating a treatment plan that maximizes the dose to the treatment volume while minimizing the dose to the surrounding normal tissues. The system is capable of operating in both the forward planning and inverse planning modes. Plans generated using this system are used in the determination of the course of a patient’s radiation treatment. They are to be evaluated, modified, and implemented by qualified medical personnel.

2. Describe the hazard/harm associated with the issue

Using the incorrect exported DICOM-RT dose information when creating new treatment plans could lead to an overdose or underdose of radiation.

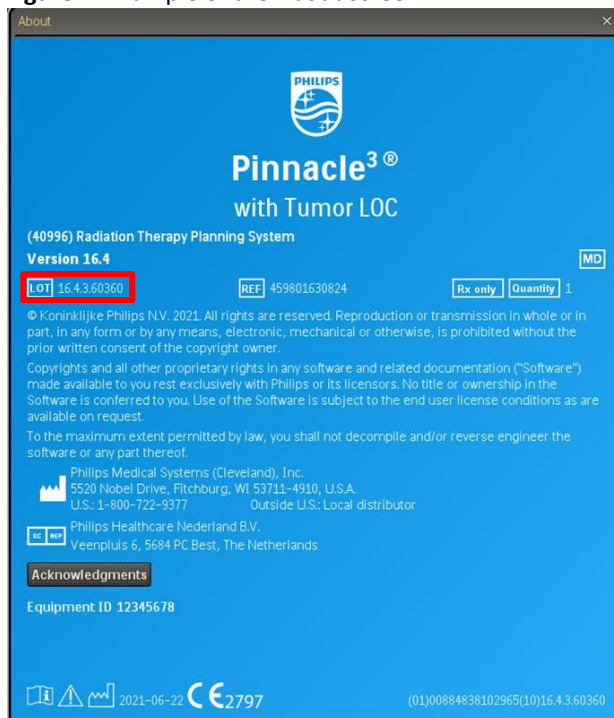
- A radiation overdose could potentially result in permanent tissue damage and/or radiation burns.
- An underdose of radiation could potentially result in progression of a disease, such as expansion of the disease locally and/or metastasis.

3. Affected products and how to identify them

Product Name	Model Number	Software Version
Pinnacle ³ Radiation Therapy Planning System	870231	16.4.2, 16.4.3 16.0.4 (China only)
	870237	18.0.1 16.4.6 (China only)

To identify if your product is impacted, check the software version in the About screen of the system (See Figure 2). The full software version is included in the lot number.

Figure 2: Example of the About screen.



4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients.

- A. To avoid exporting an incorrect DICOM-RT dose, do not prescribe to Percentage of Point Dose. Only prescribe plans using one of the following options until the software solution is provided by Philips:
 - Max Dose
 - Region of Interest (ROI)
 - ROI Min
 - ROI Max
 - ROI Mean
 - ROI Volume
 - Set Monitor Units
- B. Circulate this notice to the Head of Medical Physics in your Radiation Oncology Department or your Department Director with specific instructions that this notice be distributed to all users of the Pinnacle³ Radiation Therapy Planning System, so that they are aware of the product issue and associated hazard/harm.
- C. Post this notice near the affected Pinnacle³ Radiation Therapy Planning System(s) for ease of reference.
- D. Please complete and return the attached response form to Philips promptly and no later than 3 days from receipt via email to: FCO.Nordic@philips.com

5. Describe the actions planned by Philips to correct the problem

Philips is currently developing a correction which will be released in the future. Once the correction is released, Philips will contact your site to schedule installation of the software solution to resolve the issue.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative:

Telephone 80 30 30 35
Email philips.service@philips.com

Sincerely,

Kenneth Revenaugh
Quality Director, Precision Diagnosis Solutions (PDS)

Field Safety Notice RESPONSE FORM

Reference: Pinnacle³ Radiation Therapy Planning System – Incorrect Dose Export
Software versions 16.0.4/16.4.2/16.4.3 (FCO87000100), 18.0.1 (FCO87000101), and 16.4.6 (FCO87000102).

Instructions: Please complete and return this form to Philips promptly and no later than 3 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- To avoid exporting an incorrect DICOM-RT dose, only prescribe plans using one of the options listed in Section 4 of the Field Safety Notice.
- Circulate this notice to the Head of Medical Physics in your Radiation Oncology Department or your Department Director with specific instructions that this notice be distributed to all users of the Pinnacle3 Radiation Therapy Planning System, so that they are aware of the product issue and associated hazard/harm.
- Post this notice near the affected Pinnacle³ Radiation Therapy Planning System(s) for ease of reference.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this letter has been properly distributed to all users of the affected systems.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD/MM/YYYY): _____

Please complete and return this form to Philips promptly upon receipt and no later than 3 days from receipt via email to FCO.Nordic@philips.com