Health Hazard Evaluation 60564, v 1.0

Date: May 18th, 2020

I. Product Data

1. Device Information:

Device Name	Model/ Catalog Number	Quantities Distributed
RayStation	4, 4.5, 4.7, 5, 6, 7, 8A, 8B, 9A, 9B, including all service packs	See separate sheet

2. Marketing Status (selected markets):

Canada License Number: 83471

China NMPA Certificate: 20193210441

Europe – EC Certificate: 41314834-04

US 510(k) Number and Clearance Date: K190387: June 19th, 2019

3. Device Description and Its Intended Use(s):

Description of Product:
RayStation is a treatment planning system for planning and analysis of radiation therapy treatment plans. It has a modern user interface and is equipped with fast and accurate dose and optimization engines.

Indications for Use:
RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments.

The system functionality can be configured based on user needs.

The intended users of RayStation shall be clinically qualified radiation therapy staff trained in using the system.

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II. Problem Definition and Analysis

1. **Description of Reported Adverse Event:** No serious adverse event reported. An issue with the proton Pencil Beam dose engine was found during investigation of a report of an unexpected behaviour when using the proton Monte Carlo dose engine.
2. **Number of Similar of Identical Reported Adverse Events:** 0
3. **Number of Alleged Deaths:** 0
4. **Number of Alleged Serious Injuries:** 0
5. **Number of Alleged Malfunctions:** 0
6. **Source of Reports of Deaths, Serious Injuries, or Malfunctions:** N/A, no such reports
7. **Description of the Reported Adverse Event and the Actual or Potential Health Hazard:**

A software error in the proton pencil beam (PB) dose engine has been found. Spots for which the central axis does not go through the External ROI (i.e. the region of interest that defines the volume where dose calculation shall be performed) are not included in the PB proton dose calculation even if parts of the spot fall inside the External ROI.This leads to an underestimation of the dose that would be delivered in volumes affected by such spots.

The Monte Carlo (MC) proton optimization dose engine contains the same bug, but the final MC dose calculation is correct. A customer reported significant discrepancy between optimized and final MC dose. This is what lead to the dicovery of the safety related PB dose error.

Risk analysis:

Background:

We define the following levels of potential harm:

Potential Harm	Description
Catastrophic	Death due to device malfunction or use error
Serious	Serious injury due to device malfunction or use error
Marginal	Unintended deviation from the “correct” treatment without expected significant clinical consequences
None	No harm

Risk assessment is based on potential severity, probability to cause harm and detectability.

We define the following risk levels (risk classes):

Risk class	Description
I	Severe public health threat - the possibility of multiple deaths occurring at short intervals
II	Significant risk – significant probability of Catastrophic or Serious harm
III	Minor risk – very low probability of Catastrophic or Serious harm
IV	Negligible risk – only Marginal harm could occur or sequence of events leading to harm cannot be expected to occur
V	No risk

Severity:
Worst case scenario is that spots with significant dose distribution are generated with central axis just outside external, leading to local underestimation of expected dose in volumes affected by these spots. The magnitude of error will depend on the MU of the affected spot(s), but we assess that serious harm could occur. Local deviations up to 20% has been seen in a generated example plan.
Probability:
The likelihood of the error occurring in a way that would lead to harm is relatively low. RayStation will not automatically assign spots with central axis outside external, except in robust optimization, where such spots can be used to compensate for expected movement of the target.
It is possible to generate spots outside of the external without robust optimization, e.g. by manually adding/moving spots, or moving the isocenter, and subsequently running Continue optimization, but these scenarios are not very likely.
For most beam directions, even robust planning would not generate spots that trigger the error. This could only be the case for tangential fields, which are, at least in some regions, less commonly used for proton treatment.
When using Monte Carlo (MC) proton dose, detectability of the error would be very high, since there would be a significant discrepancy between optimized and final dose. Since most clinics use MC, which is known to be more accurate, and we have until now never had any reports of such a discrepancy, we think the bug has rarely been triggered to give a significant effect
Detectability (= If Device failure occurs, is it easily recognized by the User?):
Detectability is very low when using robust optimizaton and PB dose. For manual spot placement, users could potentially notice that an added spot does not contribute to dose. However, when following best practise, detectability is high, see **Use Related**... below.
Use Related and User/Human Performance Contributing Factors:
MC dose is known to be more accurate. Few clinics are currently still using PB dose.

We have discussed the issue with many potentially affected proton clinics and it appears they are not really worried about mistreatment from this bug. Most if not all customers use the Robust Evaluation module (or the Compute Perturbed Dose function for older versions where this module was not available) to evaluate the robustness. When performing this evaluation, the bug would be highly visible. This is recommended in the RayStation Instructions for Use.

Health/Risk Index:

Although probablity of harm is low and the detectability is relatively high, there is still the potential for significant deviations in clinics that do not follow the best practices outlined in the **Use Related**... section above. To err on the safe side, this issue is classified as **Significant** risk of **Serious** harm resulting from the error. **Risk class II**

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Investigation details:

8. **Factors That May Have Caused or Contributed to the Adverse Event and the Actual or Potential Health Hazard (e.g., Design Defect or Manufacturing Defect):**

   There has been no adverse event reported for the PB dose error. However, during investigation of a reported discrepancy when using the MC dose engine, a software implementation error was identified. The cause of the software error is currently not known. Root cause analysis is in progress.

9. **Population at Greater Risk (e.g., Children, the Elderly, Pregnant Women and Immunocompromised Patients):**

   N/A

10. **Immediate and/or Long-Range Health Consequences of the Actual or Potential Health Hazard:**

    In the event that a clinical decision is based on the incorrectly calculated dose, this could lead to the approval of an inappropriate dose plan. This could lead to local over-dose from allowing too high of a dose in volumes affected by spots with central axis outside the External ROI.

11. **Internal immediate action until final determination of cause / problem is made (stop shipment, quarantine raw materials, stop production, etc.):**

    Distribute a field safety notice to all affected users.

11. **Corrective actions and residual risk**

    The issue relates to an error that is triggered only for certain conditions in a well-defined use case. There is an acceptable workaround that can be easily understood by users and adhered to in order to avoid harm.

    The issue will therefore be corrected by means of updated labeling. An urgent Field Safety Notice (FSN) will be distributed to all affected customers. For future installations of the affected versions, the description of the error and the workaround shall be included in the product installation as an additional release note.

    Residual risk after correction: With the correction in the form of updated labeling, the residual risk is Acceptable. The RayStation Instructions for Use requires users to study the Release Notes carefully, as these notes provide final instructions on how to use the RayStation system. When following the instructions in the updated labeling, the affected work flow will be safely avoided and there is no risk of harm.

    The long term solution is to release a new version of the RayStation system eliminating the problem. The release is planned for June 2020.

Approval and Signature:

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Medical Device Safety Officer

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