Health Hazard Evaluation 83773, v 1.0

Date: 2021-09-06

I. Product Data

1. Device Information:

Device Name	Model/ Catalog Number	Quantities Distributed
RayStation, RayPlan	6-11	See separate sheet

2. Marketing Status (selected markets):

Canada License Number: 83471

China NMPA Certificate: 20193210441 <only for RayStation>

Europe – EC Certificate: 41314834-04

US 510(k) Number and Clearance Date: K210645, June 29, 2021

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

Description of Product:
RayStation is a treatment planning system for planning and analysis of oncology 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 staff trained in using the system.

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II. Problem Definition and Analysis

1. **Description of Reported Adverse Event:** No serious event occurred. A customer has reported a potential health hazard.
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:** 1
6. **Source of Reports of Deaths, Serious Injuries, or Malfunctions:** University of Wisconsin UW-Health, US
7. **Description of the Reported Adverse Event and the Actual or Potential Health Hazard:**

A user reported that they noticed an error during treatment planning. When optimization a Tomotherapy plan, they started with a rather coarse dose grid and then changed to a higher resolution dose grid for final fine-tuning. They noticed that the jaws were repositioned incorrectly for some segments. The issue was identified prior to patient treatment. No patient was affected.

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 the user starts optimization, edits the dose grid, and then continues without resetting the optimization, triggering incorrect jaw positions which may lead to unnecessary irradiation of regions outside the target.
Probability:
The likelihood of the error occurring at all high. Starting optimization with a low dose resolution and then changing the dose grid to a high resolution for the final fine-tuning is a common use case. The probability of the error resulting in a plan that would cause serious harm is however low.
Detectability (= If Device failure occurs, is it easily recognized by the User?):
Detectability is very high. The dose distribution is correctly calculated, and any unacceptable plans should be detected by the user in the mandatory plan review before approval and treatment.
Use Related and User/Human Performance Contributing Factors:
The dose distribution is correctly displayed in the different dose views, in the dose statistics and in the clinical goals, so any unwanted dose should be clearly visible when reviewing the plan before delivery. An issue that is highly detectable in the plan is normally considered low risk, as the user is required to review all plans before they are used for treating patients. This is communicated in the RayStation Instructions for Use, in accordance with the ISO 62083 safety standard for radiotherapy treatment systems. However, the use case where this bug can be triggered has been marketed as dose sparing by giving a sharper penumbra than other techniques. If the error is triggered, this expected dose sparing is not achieved. The user may think that the resulting dose is optimal, although a sharper penumbra could have been achieved without this error.
Health/Risk Index:
Based on the very high detectability, there is at the most **Minor** risk of **Serious** harm resulting from the error. **Risk class III**

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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):**

   A software implementation error has been identified.

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 an inappropriate plan is created and not identified as inappropriate during the mandatory plan review, the plan could be approved for treatment. The incorrect jaw positions may then lead to unnecessary irradiation of regions outside the target. This could lead to local over-dose in a risk organ.

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. A 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 October 2021.

Approval and Signature:

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