Health Hazard Evaluation 148655, v 1.0

Date: January 16th, 2025

I. Product Data

1. Device Information:

Device Name	Model/ Catalog Number	Quantities Distributed
RayStation	4.5-2024B	See separate sheet

2. Marketing Status (selected markets):

Canada License Number: 83471

China NMPA Certificate: 20193210441 <only for RayStation>

Europe – EC Certificate: 41314834-04 (MDD) and 28620117938-01 (MDR)

US 510(k) Number and Clearance Date: K160093, January 26, 2016; K170355, February 10, 2017; K14536, May 31, 2017; K180379, February 15, 2018; K190387, June 19th, 2019; K200569, September 24th, 2020; K210645, June 29th, 2021; K211867, June 29th, 2021; K220141, April 15th, 2022; K222312, March 29th, 2023.

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, ablation therapy* and medical oncology. Based on user input, RayStation visualizes and 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.

* Ablation therapy is only available in EU, UK, Switzerland, Thailand, Philippines and New Zealand.

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

II. Problem Definition and Analysis

4. **Description of Adverse Event:** No event occurred. There is only a potential health hazard discovered by the manufacturer.
5. **Number of Similar of Identical Reported Adverse Events:** 0
6. **Number of Alleged Deaths:** 0
7. **Number of Alleged Serious Injuries:** 0
8. **Number of Alleged Malfunctions:** 0
9. **Source of Reports of Deaths, Serious Injuries, or Malfunctions:** N/A no such reports
10. **Description of the Reported Adverse Event and the Actual or Potential Health Hazard:**

A treatment planning system, TPS, such as RayStation calculates estimated radiation dose in a patient model based on patient CT images acquired prior to treatment. The accuracy of this estimate depends on how well the patient model corresponds to the patient at the time of treatment. If, e.g., the patient anatomy at the time of treatment differs from the pre-treatment CT images, the delivered dose will differ from the nominal dose estimated by the TPS.

Tools for evaluating plan robustness are used to investigate how the dose distribution may differ from the nominal dose due to inaccuracies in the patient model. In RayStation, Robust evaluation can be used to investigate the effects of uncertainties in patient setup, density interpretation from the CT, and organ motion. Robust optimization can be used to create plans with the intention to be robust with respect to such variations.

Dose cannot be calculated directly on CT image data. Calibration curves are used for converting the image data to values appropriate for dose calculation. For ion dose computation, CT images can be converted either to mass densities, MD images, or to stopping power ratios, SPR images.

During internal testing, an inconsistency in the use of density uncertainty was found. In Robust optimization and when using Robust evaluation for SPR images, the selected density uncertainty results in the same uncertainty in the ion range along the beam path. This is likely what a user would expect from this functionality. However, in Robust evaluation for MD images, when specifying a density uncertainty, the resulting uncertainty in ion range will typically be lower than what a user may expect.

The Robust evaluation Implementation for MD images is not incorrect, and is in line with what is written in the UI, but it may not be what a user expects, and it is not consistent with the other use cases.

Range uncertainty evaluation is only relevant for ion planning. Other treatment modalities are not 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:

The issue will not lead to an incorrect treatment plan, but potentially to a plan that could have been improved with respect to robustness. Worst-case scenario is that Robust evaluation using density uncertainty is performed and results in a lower range uncertainty than the user intended, leading to a Robust evaluation result that appears acceptable although the proposed treatment plan is less robust than the clinic's requirement. This could lead to acceptance of a plan that is less robust than what is considered acceptable. Such a plan would not be harmful if the patient model used for the nominal dose calculation accurately represents the patient at the time of treatment. However, if there is a significant difference in density compared to what was used for the nominal dose calculation, there is an increased risk of delivered dose not matching the intended dose.

The impact will depend on the plan setup and patient anatomy. For example, for a prostate case with a distal depth of 240 mm, a density change of -3.5% will lead to an increased range of about 6 mm. This is 2.4 mm less than the 8.4 mm given by a -3.5% change in stopping power that the user may expect.

Probability:
The likelihood of the issue occurring at all is very high as it occurs always in Robust evaluation of density uncertainty for MD images, and this is a common use case for ion treatments.
The likelihood of the issue occurring in a way that could cause serious harm is low. This would require planning on a patient model where there is an actual error in density that leads to a deviation in range which is significantly larger than the range uncertainty used in Robust evaluation or Plan Evaluation. In that case, there is an increased risk of an unintended dose distribution. The impact will depend on the plan setup and patient anatomy.
Detectability (= If Device failure occurs, is it easily recognized by the User?):
Detectability is low. The implementation differs between the RayStation use cases and this is not described in labeling. Users cannot be expected to realize this.
Use Related and User/Human Performance Contributing Factors:
Robust evaluation is commonly used as an auxiliary evaluation tool for ion treatments. The primary evaluation tools, i.e., physical dose and RBE dose calculated on the nominal patient model, are unaffected by this issue. Even if the Robust evaluation result is misleading, this will not lead to a plan where the nominal dose is unacceptable since review of the nominal dose is always performed.
Health/Risk Index:
Based on the low probability of harm there is **Minor** risk of **Serious** harm resulting from the error.
Risk class III

Investigation details:

11. **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. An inconsistency in the software implementation has been identified.

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

    N/A

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

    In the event that a clinical decision is based on robust evaluation where the user assumes that the density uncertainty specified leads to the same uncertainty in ion range, this could lead to the approval of dose plan that is less robust against range variations than intended. With a less robust plan, there is an

increased risk of the delivered dose not fulfilling the treatment prescription in case the patient density differs from what was used when calculating the expected dose in RayStation. The magnitude of the deviation depends on how much the actual patient density at delivery differs from the input data used to dose calculation and the effect will depend on the patient anatomy and plan setup.

14. 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.

15. 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.

16. 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 workflow 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 April 2025 (subject to market clearance in some markets).