Health Hazard Evaluation 56089, v 1.0

Date: March 4th, 2020

I. Product Data

1. Device Information:

Device Name	Model/ Catalog Number	Quantities Distributed
RayStation	4.0, 4.5, 4.7, 5.0, 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 event involving any patient has occurred. A potential health hazard was discovered by a user while testing the limits of the system.
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:** MidCentral Health, Palmerston, New Zealand
7. **Description of the Reported Adverse Event and the Actual or Potential Health Hazard:**

While testing the system limits for Siemens Virtual Wedge dose calculation, the user noticed a discrepancy between RayStation calculated dose and measured dose for very large field widths. Investigation showed that the difference is due to the y jaw overtravel limit of the LINAC. The machine model was set up with a 20cm overtravel limit. This is the correct overall maximum overtravel distance. However, when using Virtual Wedge, the overtravel limit is only 10cm.

When defining a field with Siemens Virtual Wedge that would require overtravel > 10cm, RayStation calculates dose as if the jaw could overtravel to the limit defined in the machine model, but if that limit is set to more than 10cm, this cannot be realized on the LINAC. The result is a high dose plateau region in the toe side of the virtual wedge field which is not reflected in the RayStation calculated dose.

Field sizes that trigger this behavior are outside the recommended specification per Siemens' labeling. However, there is no warning in RayStation that the dose calculation will be incorrect for such fields and there is no parameter in RayStation for Virtual Wedge overtravel limit.

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 a plan appears appropriate and is approved for treatment based on the calculated dose, but it is in fact inappropriate due to too high dose in the plateau region.
Probability:
The likelihood of the error occurring at all is moderate. Using Virtual Wedge for the affected fields sizes would not be common. If the error occurs, the likelihood of severe adverse effects is low. Although the local dose deviation could be ~15%, this would occur in the high dose region and is not likely to affect any critical avoidance regions.
Detectability (= If Device failure occurs, is it easily recognized by the User?):
Detectability is high if performing beam commissioning or plan QA measurements that cover the affected field sizes. There is no way of detecting the error in RayStation during planning.
Use Related and User/Human Performance Contributing Factors:
Field sizes that trigger this behavior are outside the recommended specification per Siemens' labeling. User should take extra care when using such fields sizes.

However, there is no warning in RayStation that the dose calculation will be incorrect for such fields and there is no parameter in RayStation for Virtual Wedge overtravel limit.
It is possible to limit the Virtual Wedge field sizes in RayPhysics in a way that avoids the issue, but this is not straightforward and is not described in labeling.
There will be a warning on the LINAC console that “Initial gap is >1cm”. However, this warning does not clearly convey that the field size is outside recommended specifications for the LINAC and it is possible to proceed without any further warnings by clicking “Y”.

Health/Risk Index:
Based on the low probability, there is **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 limitation in the software implementation has been 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 incorrect RayStation dose, this could lead to the approval of an inappropriate dose plan. This could lead to local over-dose in a risk organ from allowing too high of a dose in the treatment plan.

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) has been 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 May 2020.

Approval and Signature:

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