Urgent Safety Notice

VERIQA RT MonteCarlo 3D module of VERIQA software (S070031)

Date: December 19, 2023

Attention: If the user excludes voxels from the Gamma calculation that are below a dose threshold (Suppress gamma calculation), the Gamma Passing Rate (GPR) calculated for individual ROIs is not correct. The GPR calculated by VERIQA overestimates the correct GPR. The evaluation can therefore show false positive results.
To date, PTW has received no reports of adverse events or patient injuries in this regard and is acting out of an abundance of caution.

Details of affected medical devices:
All VERIQA versions of the RT MonteCarlo 3D module are affected.

Description of the problem:
Under the assumption that:
- V corresponds to the number of all voxels within a ROI,
- V_s corresponds to the number of voxels within a ROI for which the gamma calculation is suppressed,
- $V_e = V - V_s$ corresponds to the number of voxels within a ROI for which a gamma calculation is performed,
- $V_{f,e}$ corresponds to the number of voxels within V_e for which gamma > 1,
- $V_{p,e}$ corresponds to the number of voxels within V_e for which gamma $\leq$ 1,

the GPR is calculated as follows in the current VERIQA implementation:

$$GPR_{incorrect} = (V_{p,e}+V_s) / V * 100$$

However, the correct GPR calculation should only refer to the number of voxel V_e for which a gamma calculation was performed and ignore all voxel V_s:

$$GPR_{correct} = (V_{p,e} / V_e) * 100$$

$GPR_{incorrect}$ is used for the GPR calculation of individual ROIs.
The deviation of the GPR calculation is particularly large for ROIs that have a high proportion of V_s compared to V.

$GPR_{correct}$ is used for the GPR calculation of the entire dose volume (VERIQA *Total*). *VERIQA Total* is therefore not affected by the problem described.

If a deviation in the dose recalculation relevant to the QA result occurs, this is signaled to the user by a deviation in the *VERIQA Total* GPR calculation and other comparison parameters (e.g. Dose Volume Histogram).

Advice for users:
PTW recommends not using the *Suppress gamma calculation* function for ROIs where a high proportion of voxels are to be suppressed in the gamma calculation.
Since the malfunction is limited to the GPR calculation of ROIs and does not affect the GPR calculation of the *VERIQA Total* volume, it is recommended to rely on the comparison based on *VERIQA Total.*

Measures undertaken by the manufacturer:
PTW will correct the malfunction in the next software version. The corrected version will be made available to all VERIQA users. The above information should be taken into account by the customer until the installed VERIQA version has been updated.

Communicating this Safety Notice:
Pass this information on to all persons in your facility/hospital or in another facility/hospital where the software is located who need to know about it.
DISTRIBUTORS: Because PTW sells this product through distributors, including your organization, we may not have the information to contact all users. Therefore, please send a copy of the attached Field Safety Notice to any customer to whom you have distributed any of the affected product.

PTW regrets any inconvenience caused by this problem.

Sincerely

Persoonsgegevens

PTW Freiburg
Bedrijfsgevoelige informatie