

To all users of the medical device
mint Lesion

September 13, 2017

**Subject: Important safety information for all users of the medical device
mint Lesion (version 3.0 up to version 3.3.2)**

**Multiparametric magnetic resonance imaging of the prostate -
PI-RADS PDF-report possibly shows wrongly numbered identifiers in the schematic
overview graphic of the prostate**

Dear valued mint Lesion users,

We would like to inform you about a software defect related to the assessment of MRI prostate images according to the PI-RADS classification in the software versions mentioned above.

Identification of the affected medical devices

The affected product versions of mint Lesion are from 3.0 up to and including 3.3.2. You can check your product version in the login screen or in the basic application menu (menu item „About“).

Description of the malfunction including the identified cause and its occurrence

Due to a programming error, the PI-RADS PDF-report may show wrongly numbered lesion identifiers in the schematic overview graphic of the prostate. This malfunction only occurs if the following two conditions are fulfilled:

- Between two and five (maximum according to PI-RADS) prostate lesions are captured and they were marked in the overview graphic by the user.
- After that, the user manually changes the order of at least one prostate lesion in the lesion list by a drag and drop interaction.

A typical scenario for the described malfunction is listed below:

1. The user defines a lesion and marks it in the overview graphic. The lesion will automatically be named as „Po1“.

2. The user defines and marks another lesion. Then the user rearranges the order of the lesions in the lesion list so that the new lesion is listed as Po1 (possible by mouse interaction / drag and drop). The new lesion will get the name „Po1“ and the existing lesion will be named „Po2“ in the user interface.
3. The user or a third person accesses the corresponding PDF-report. The report outlines both lesions as „Po1“.

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Under certain circumstances, it is possible that some lesion identifiers in the schematic overview graphic refer to other lesions. Textual information in the PDF-report and PI-RADS scores are not affected. The malfunction can be identified by comparing the selected prostate region with the representation in the overview graphic.

If the issue remains unidentified, it may have an effect on the subsequent diagnosis and therapy (e.g. biopsy).

Which actions have to be taken by the user?

In order to ensure a precise PI-RADS classification, please verify that for every region in the overview graphic a correct lesion identifier is used. In case of doubt you can ignore the schematic overview graphic.

Corrective actions by Mint Medical

The described failure will be corrected by an update to version 3.3.3. As soon as the update becomes available, Mint Medical will inform you and plan the installation of the update on your system.

Please ensure that all users of mint Lesion including all staff involved in the work with mint Lesion will receive knowledge of this safety information. Please keep this information in your mint Lesion instructions for use.

If you need further information or have further questions, please contact the Mint Medical GmbH hotline (Phone: +49 62 21 64 79 76 9) or write an E-Mail (support@mint-medical.com).

We thank you for your understanding and your cooperation in this important hint for the customers.

Yours faithfully,

signed Dr. Matthias Baumhauer