

To all users of the medical device mint Lesion versions 3.5.0 to 3.7.1 with reading profiles LI-RADS v2018, Esophageal/Gastric cancer (TNM 8.0), Colorectal cancer (TNM 8.0/ESGAR)

-Heidelberg, July 15, 2020

Urgent Field Safety Notice for all users of the medical device mint Lesion (Versions 3.5.0 up to Version 3.7.1)

Dear valued mint Lesion users,

We would like to inform you about a software defect related to the following reading templates and mint Lesion product versions.

Details on affected medical devices

Reading template	Affected product versions
LI-RADS v2018	3.7.1 / 3.7.0 / 3.6.0 / 3.5.2 / 3.5.1 / 3.5.0
Colorectal cancer (TNM 8.0/ESGAR)	3.7.1 / 3.7.0 / 3.6.0
Esophageal/Gastric cancer (TNM 8.0)	3.7.1 / 3.7.0

All mint Lesion product versions 3.5.0 up to and including 3.7.1 are affected. You can view your product version in the login screen or via the general application menu, menu item "About".

Description of the problem

The malfunction is caused by a software error that is present in product versions 3.5.0 up to and including 3.7.1. Affected are reading templates for which the following conditions apply

1. Based on user input mint Lesion automatically calculates an (intermediate) result and at the same time calculates a textual explanation of the result
2. The calculated result affects the visibility of other case report form fields

These conditions are fulfilled in the above-mentioned report templates. All other reading templates are not affected.

Effects of the problem

If the malfunction occurs, user input into case report form fields will be discarded by the system. The user input will be missing in the generated final PDF report. After a restart of the application, the user input will also be unavailable in the user interface.

Detailed problem description for each affected reading template:

Reading template	Problem description
LI-RADS v2018	The problem occurs in follow-up examinations if the question "LI-RADS v2018 category" was automatically answered by the system in the previous examination. All user input in the follow-up examination will be lost. The content of the prior examinations is not affected. Initial examinations using the LI-RADS v2018 reading template are not affected.
Colorectal cancer (TNM 8.o/ESGAR)	The problem occurs in follow-up examinations (re-staging) if the question about the depth of infiltration of the primary tumor was answered with "Adjacent organ" in a previous examination. All user input in the follow-up examination will be lost. The content of the prior examinations is not affected. Prior and initial staging examination using the colorectal cancer reading template are not affected.
Esophageal/Gastric cancer (TNM 8.o)	The problem occurs at any diagnostic time-point (initial staging and re-staging) once a primary tumor has been defined and its exact location in the esophagus or stomach has been specified. All user input will be lost.

Advise on action to be taken by the user

Please do not use the listed reading templates in the affected product versions or use them exclusively under the conditions stated below:

Reading template	Safety measure
LI-RADS v2018	Do not use the LI-RADS reading template for follow-up examinations. You can still use the LI-RADS reading

	template for initial examinations, since the problem does not occur in this situation.
Colorectal cancer (TNM 8.o/ESGAR)	If the primary tumor infiltrates a neighboring organ, do not answer the question about the depth of infiltration. Instead, answer the question "Extension beyond organ" positively and mark affected organs according to the template. The determination of the T-category (in this case T4a or T4b) will still be carried out correctly in this way. If the primary tumor does not infiltrate adjacent organs, the problem does not occur, and the template can be used without restrictions.
Esophageal/Gastric cancer (TNM 8.o)	Do not use the Esophageal/Gastric cancer (TNM 8.o) reading template in the affected product versions.

How Mint Medical will resolve this problem

The error will be corrected with a software update. This will also automatically recover the answers that had been given but became invisible due to the software defect. Mint Medical will contact you when the update is available to schedule the installation of the update on your system.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization. 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 maintain awareness on this notice and resulting actions and precautions until a software update has been applied to ensure effectiveness of the corrective action. Please keep this information with your mint Lesion instructions for use.

If you need further information or have further questions, please contact Mint Medical support via phone (+49 6221 647976 9) or via e-mail (support@mint-medical.com).

A copy of notice has been sent to the appropriate Regulatory Agency.

We thank you for your understanding and your cooperation in this important safety notice.

Yours faithfully,

