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To all users of the medical device mint Lesion
versions 3.5 to 3.6 with reading template LI-RADS v2018

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**Subject: Important safety information for all users of the medical device
mint Lesion (version 3.5 up to version 3.6)**

Dear valued mint Lesion users,

We would like to inform you about a software defect related to the reading template
“LI-RADS v2018” for the evaluation of CT and MRI scans of the liver.

Identification of the affected medical devices

The issue affects all mint Lesion product versions from 3.5 to 3.6. You can identify
your product version in the login screen or via the general application menu, item
“About”.

Description of the malfunction including the identified cause and its occurrence

The malfunction is due to a software defect present in product versions 3.5 and 3.6.
It can only occur in follow-up examinations with activated LI-RADS classification
profile. The LI-RADS classification needs to consider whether liver lesions have
grown beyond a certain threshold since the prior exam.

In the English product version, the software wrongly assumes threshold growth in
all follow-up exams, which can erroneously lead to an upgrade of LR-3 to LR-4 or of
LR-4 to LR-5 given that other lesion characteristics are present; in some cases, no LI-
RADS category is determined at all.

In the German product version, threshold growth is not considered at all. If the liver
lesion actually grows beyond the growth threshold, the software does not upgrade

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the LI-RADS category, and report LR-3 instead of the correct category of LR-4 or LR-5, or report LR-4 instead of the correct category of LR-5.

In addition to threshold growth, other parameters contribute to determining the LI-RADS category. All other parameters are used correctly by the software.

Users can manually override the automatically calculated LI-RADS category and thus are able to correct the error once observed.

Which actions have to be taken by the user?

When using the LI-RADS reading template in a follow-up situation, please verify the automatically determined LI-RADS category and manually override the category using the LI-RADS CT/MRI diagnostic table if necessary:

Arterial phase hyperenhancement (APHE)		No APHE		Nonrim APHE		
Observation size (mm)		< 20	≥ 20	< 10	10-19	≥ 20
Count additional major features: • Enhancing "capsule" • Nonperipheral "washout" • Threshold growth	None	LR-3	LR-3	LR-3	LR-3	LR-4
	One	LR-3	LR-4	LR-4	LR-4 LR-5	LR-5
	≥ Two	LR-4	LR-4	LR-4	LR-5	LR-5



Observations in this cell are categorized based on one additional major feature:

- LR-4 – if enhancing "capsule"
- LR-5 – if nonperipheral "washout" **OR** threshold growth

Figure 1: LI-RADS v2018 CT/MRI diagnostic table¹

LI-RADS v2018 defines threshold growth as follows:

≥ 50% threshold growth of lesion diameter in ≤ 6 months

Please also consider the presence of malignant or benign ancillary features, and further adjust the LI-RADS category as necessary according to the following diagram:

¹ [LI-RADS](#) by American College of Radiology is licensed under CC BY-NC-ND 4.0

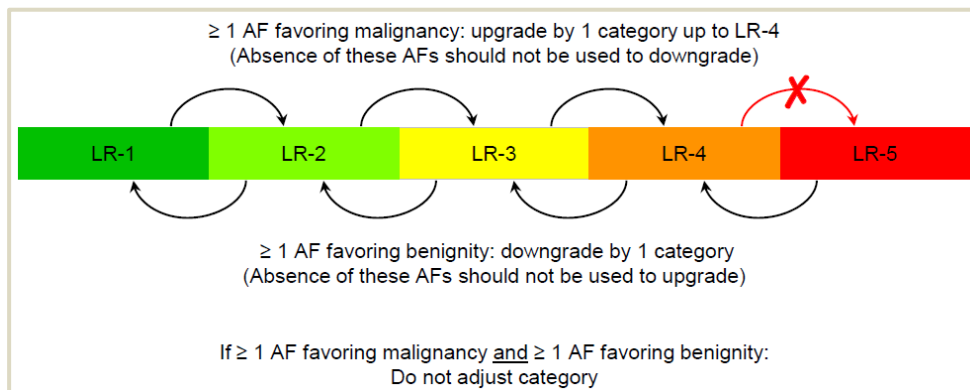


Figure 2: Ancillary Features category adjustment¹

Corrective actions by Mint Medical

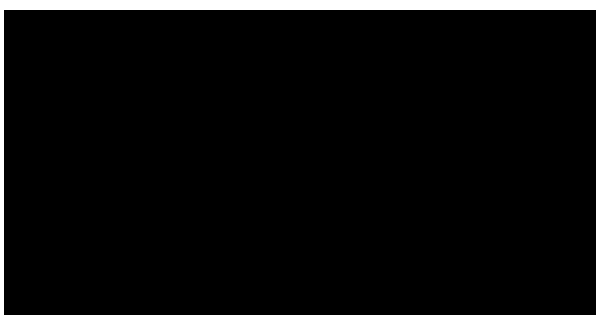
The described malfunction will be corrected by an update to version mint Lesion 3.7. As soon as the update becomes available, Mint Medical will inform you and plan the installation of the update on your system.

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 with your mint Lesion instructions for use.

If you need further information or have further questions, please contact the Mint Medical GmbH hotline (Phone: +49 6221 647976 9) or write an E-Mail (incidents@mint-medical.com).

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

Yours faithfully,



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