Date: 2025-12-23
FSCA-Ref: FSCA-0015

Urgent Field Safety Notice

For the Attention of: All users of mint Lesion™ versions from 3.4.0 up to 3.11.1

Dear mint Lesion™ user,

We would like to inform you about a malfunction that may occur when using **mint Lesion™** in one of the versions listed below.

Information on affected devices

Affected medical device	mint Lesion™
Basic UDI-DI	426049588MINTLESIONSM

Affected mint Lesion™ device versions

Device Version	UDI-DI	UDI-PI
mint Lesion 3.4.0	04260495880341	(01)04260495880341(10)3.4.0(11)171220
mint Lesion 3.4.1	04260495880341	(01)04260495880341(10)3.4.1(11)180109
mint Lesion 3.4.2	04260495880341	(01)04260495880341(10)3.4.2(11)180116
mint Lesion 3.4.3	04260495880341	(01)04260495880341(10)3.4.3(11)180418
mint Lesion 3.4.4	04260495880341	(01)04260495880341(10)3.4.4(11)181128
mint Lesion 3.4.5	04260495880341	(01)04260495880341(10)3.4.5(11)190128
mint Lesion 3.4.6	04260495880341	(01)04260495880341(10)3.4.6(11)190502
mint Lesion 3.5.0	04260495880358	(01)04260495880358(10)3.5.0(11)190701
mint Lesion 3.5.1	04260495880358	(01)04260495880358(10)3.5.1(11)190711
mint Lesion 3.5.2	04260495880358	(01)04260495880358(10)3.5.2(11)190905
mint Lesion 3.6.0	04260495880365	(01)04260495880365(10)3.6.0(11)191024
mint Lesion 3.7.0	04260495880372	(01)04260495880372(10)3.7.0(11)200226
mint Lesion 3.7.1	04260495880372	(01)04260495880372(10)3.7.1(11)200422
mint Lesion 3.7.2	04260495880372	(01)04260495880372(10)3.7.2(11)200730
mint Lesion 3.7.3	04260495880372	(01)04260495880372(10)3.7.3(11)200930
mint Lesion 3.7.4	04260495880372	(01)04260495880372(10)3.7.4(11)210625
mint Lesion 3.8.0	04260495880389	(01)04260495880389(10)3.8.0(11)210525

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Device Version	UDI-DI	UDI-PI
mint Lesion 3.8.1	04260495880389	(01)04260495880389(10)3.8.1(11)210831
mint Lesion 3.8.2	04260495880389	(01)04260495880389(10)3.8.2(11)211122
mint Lesion 3.8.3	04260495880389	(01)04260495880389(10)3.8.3(11)220121
mint Lesion 3.8.4	04260495880389	(01)04260495880389(10)3.8.4(11)220203
mint Lesion 3.8.5	04260495880389	(01)04260495880389(10)3.8.5(11)220311
mint Lesion 3.8.6	04260495880389	(01)04260495880389(10)3.8.6(11)220414
mint Lesion 3.9.0	04260495880396	(01)04260495880396(10)3.9.0(11)230216
mint Lesion 3.9.1	04260495880396	(01)04260495880396(10)3.9.1(11)230502
mint Lesion 3.9.2	04260495880396	(01)04260495880396(10)3.9.2(11)231102
mint Lesion 3.9.3	04260495880396	(01)04260495880396(10)3.9.3(11)240227
mint Lesion 3.9.4	04260495880396	(01)04260495880396(10)3.9.4(11)240424
mint Lesion 3.9.5	04260495880396	(01)04260495880396(10)3.9.5(11)240528
mint Lesion 3.10.0	04260495883106	(01)04260495883106(10)3.10.0(11)240911
mint Lesion 3.10.1	04260495883106	(01)04260495883106(10)3.10.1(11)241031
mint Lesion 3.10.2	04260495883106	(01)04260495883106(10)3.10.2(11)250113
mint Lesion 3.10.3	04260495883106	(01)04260495883106(10)3.10.3(11)250131
mint Lesion 3.11.0	04260495883113	(01)04260495883113(10)3.11.0(11)250321
mint Lesion 3.11.1	04260495883113	(01)04260495883113(10)3.11.1(11)250602

Summary

If the connection between a mint Lesion workstation and the mint Lesion server is interrupted while performing a read, in rare cases some information may be lost or incorrectly linked to other patients. On occurrence, this is observable in mint Lesion as well as all exports, e.g. PDF reports.

Problem description

The malfunction is caused by a software error that is present in product versions 3.4 until 3.11.1. The malfunction can occur in the following use scenario (**all** steps must apply):

1. mint Lesion is deployed in a client-server configuration*
2. While a user performs radiological reads in the mint Lesion client application, the connection between client and server is temporarily interrupted e.g., caused by a network connectivity issue or by a server restart
3. The user continues entering data into mint Lesion while and after the network connection interruption. This must include entering a data value and then changing the same data value.

When all three steps occur multiple times, data corruption** may occur. How often the scenario needs to occur before data corruption occurs, depends on the usage pattern and the specific data fields that get edited during the connection interruption.

* Client-server configuration: systems where mint Lesion services runs on a central server and the client application is installed on local workstations where users start the mint Lesion client application directly. The problem may arise if LesionClient runs on a different computer than the database.

** Data corruption: incorrect or missing information in the radiological report.

> **i   Notice**
>
> Temporary connection interruption does not usually occur in regular product use. However, it may occur if the internal network that hosts your mint Lesion installation has failures or not-well managed servicing activities that cause interruptions. Longer outages are unlikely to cause this issue as this will prevent working with mint Lesion altogether. Short outages in the time frame of seconds to few minutes may be relevant as this is the time frame where a user may conduct a radiological read in the read screen of the client application without triggering the need to load new data from the server.

Effects of the problem

The effects are different in different version of mint Lesion.

In versions starting from v3.4.0 until and including v3.9.5:

Effect 1:

On repeated occurrences of the malfunction scenario above, a lesion may get inadvertently removed from all time-points of a random assessment case. If a user opens this case later (e.g. to assess the next time-point) the situation appears to the user as if the lesion was never defined. This applies to the mint Lesion application (Read screen, report screen) and to all exported reports. In previously generated reports for prior time-points, the lesion will still be present.

Effect 2:

Entered attribute data for lesions (see Figure 1) may inadvertently overwrite the same attribute value in a random other assessment case. This may occur for attributes such as

- Lesion Category (see Figure, 1, Box 1)
- Location (see Figure, 1, Box 2)
- PET-State
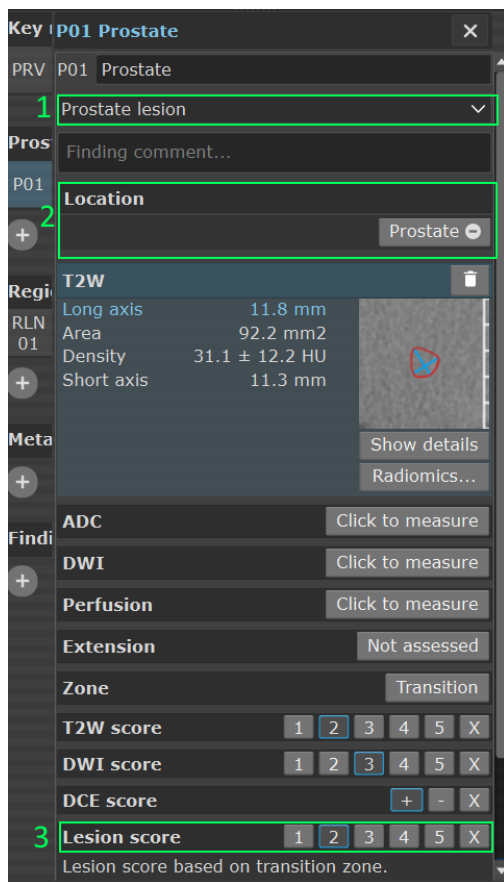- PI-RADS score (see Figure, 1, Box 3)

Figure 1: Lesion attributes

<u>In versions 3.10.0 until 3.11.1:</u>

When the network connection between client application and server is interrupted, the client application will terminate. In this event, the last data entered will not be stored and will be lost.

Please note:

- If you mint Lesion system was running a version prior to 3.10.0, the malfunction may have occurred at that time and the described data corruption may be present in the database, even though the malfunction cannot recur any more.
- The effect is a change in the stored data for an assessment case. When another time-point is added to the case and is assessed (e.g., when new images of the patient become available), the changed data of one of the prior timepoints may influence calculation of results of the new timepoint.

Actions to be taken by the user

Please read this information carefully and assess whether you are using or have been using an affected product version in a client-server deployment. If that is the case, the malfunction may have occurred and may occur in your system. Please be aware that the malfunction may occur.

Your IT department must ensure that no temporary network interruptions occur in your clinical network. Also, your IT department must ensure that the mint Lesion server is not restarted while users work with mint Lesion application (i.e., the server may be restartet, but only outside of working hours).

Please verify correctness of the information of prior time-points. Be attentive to potential inconsistencies in lesion attributes when opening existing cases for follow-up. Cross-check lesion location and categorization with prior radiological reports and image data.

If you suspect that the problem may have occurred on your mint Lesion system, please contact Mint Medical support via support@mint-medical.com or any other contact details for technical analysis and investigation.

Mint Medical Support will analyze if the malfunction appeared at your mint Lesion system in the past.

If you believe that this failure has occurred, please review the potentially affected radiological reports in your reporting application and take the necessary steps to correct them.

Actions being taken by the manufacturer

The error will be corrected with a software update to mint Lesion 3.11.2 or later. This version is already available. Mint Medical Support will contact you to schedule the installation of the software update on your system.

General Information

FSN Type	New Field Safety Notice
Further advice or information already expected in follow-up FSN	Not planned

Manufacturer information	Legal manufacturer name	Mint Medical GmbH
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	Manufacturer Phone	+49 6221 64 79 76 0
	EUDAMED Single Registration Number (SRN)	DE-MF-000020202

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Transmission of this Field Safety Notice

Pass this notice on to all users of mint Lesion™ within your organization. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Heidelberg, 2025-12-23