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For all users of mint Lesion™ versions 3.9.0, 3.9.1, 3.9.2, 3.9.3, 3.9.4, 3.9.5, 3.10.0 and 3.10.1

2024-11-13

Urgent Field Safety Notice

For the Attention of: All users of mint Lesion™ versions from 3.9.0 up to 3.10.1

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™ 3.9.0	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

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Problem description

The malfunction is caused by a software error that is present in product versions 3.9.0, 3.9.1, 3.9.2, 3.9.3, 3.9.4, 3.9.5, 3.10.0 and 3.10.1. The malfunction can possibly occur in the following use scenario:

1. Import an image series in DICOM format where the DICOM tag "Image Orientation Patient" tag differs per frame.

   > The problem was reported for nuclear medicine (NM) multi-detector whole-body bone-scans in multi-frame DICOM format (i.e., one DICOM file that includes multiple image frames). We cannot rule out that other modalities may produce similar DICOM files that lead to the same malfunction.
   >
   > Please refer to the mint Lesion™ DICOM Conformance Statement for more information.

2. Open the image series in mint Lesion™ in the Read screen.

Effects of the problem

mint Lesion™ shows patient orientation markers (L,R,A,P,H,F) for each image in a DICOM series. They describe how the patient is positioned in the image. When the malfunction occurs, these orientation markers may be wrong. For example, the left (L) and right (R) markers may be transposed (see Figures 1 and 2). If not noticed, this could lead to a user assuming a wrong anatomical location of a finding.

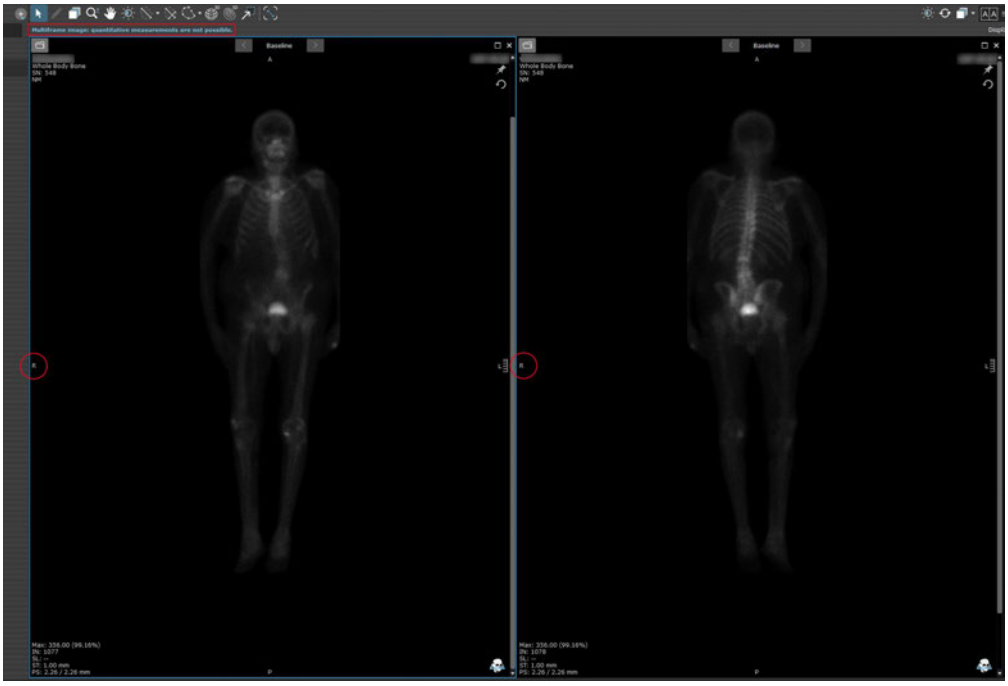

Figure 1: Whole-body bone-scan images with two projections. The left/right (L/R) orientation markers in the left anterior projection are correct while the L/R orientation markers in the right posterior projection are transposed.

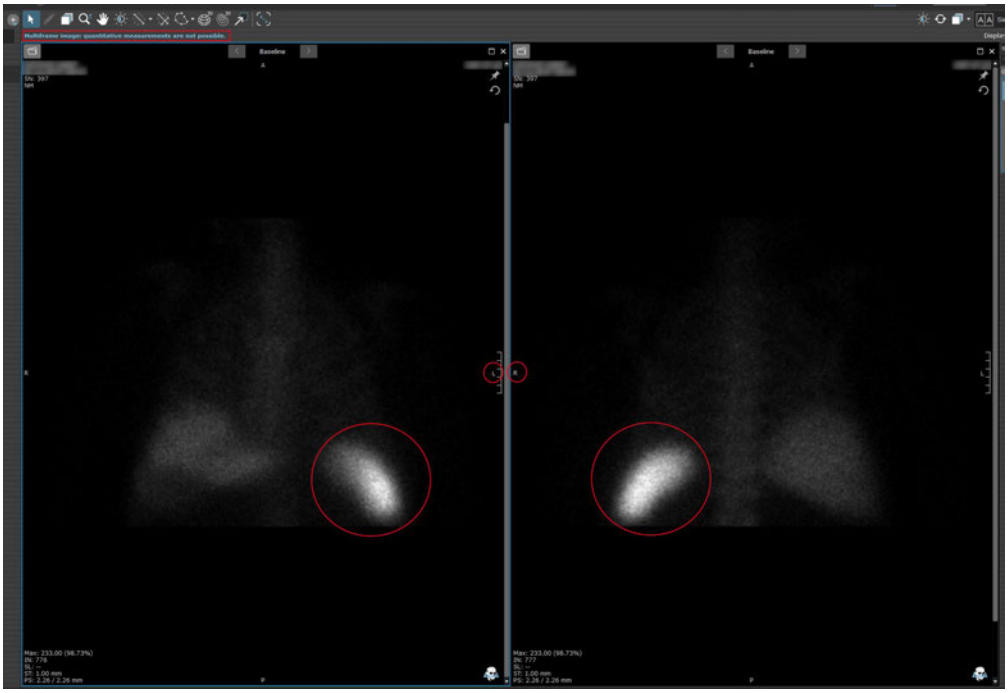

Figure 2: Chest bone-scan images with two projections. The L/R orientation markers in the left projection are correct while the ones in the right projection are transposed.

Actions to be taken by the user

Please read this information carefully and assess whether you are using an affected product version and if DICOM series with differing patient orientation may be used in your organization (Note: mint Lesion™ shows a notice above the images when multi-frame images are displayed (see Figures 1 and 2). If that is the case, the malfunction may occur in your system. Please be aware that displayed orientation markers may indicate a wrong patient orientation.

Verify the patient orientation based on anatomical landmarks that you can see in the images, when you rely on patient orientation for reporting findings (e.g., "anomaly in left kidney").

If possible, do not assess DICOM data that may lead to the malfunction with mint Lesion™ .

If you suspect that your organization uses DICOM files with the described parameters and that they have already been read using mint Lesion™ , you can contact Mint Medical support (support@mint-medical.com) to request analysis of your mint Lesion™ instance.

If you believe that this failure could have occurred in past use of mint Lesion™ , please review the potentially affected radiological reports in your reporting application and take the necessary steps to correct them. Please inform Mint Medical if this may have led to any patient harm in your organization.

Actions being taken by the manufacturer

The error will be corrected with a software update. Mint Medical Support will contact you when the update is available to schedule the installation of the 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
	Address	Mint Medical GmbH Burgstr. 61 69121 Heidelberg Germany
	Manufacturer Email	info@mint-medical.de
	Manufacturer Phone	+49 6221 64 79 76 0
	EUDAMED Single Registration Number (SRN)	DE-MF-000020202

	Person responsible for regulatory compliance (PRRC)	[redacted]
	PRRC Email	[redacted]
	PRRC Phone	[redacted]

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

Transmission of this Field Safety Notice

This notice needs to be passed 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, 2024-11-13

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