

URGENT Field Safety Notice

MultiDiagnost Eleva

MultiDiagnost Eleva intermittently does not load license files

17-Dec-2021

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use

Dear Customer,

A problem has been identified in the MultiDiagnost Eleva IITV (MD-Eleva IITV) and MultiDiagnost Eleva FD (MD-Eleva FD) systems with software version R6.1.1sp2 and R6.1.2. that could pose a risk for patients. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

In the MD-Eleva systems, software license keys are used to enable functionality.

Philips has discovered that in the MD-Eleva systems with software releases R6.1.1sp2 and R6.1.2. intermittently two software keys are not loaded completely during the system start up:

- The License Key for Spectral Filter. Within the MD-Eleva system the spectral filter is used to ensure that the low mode for Reference Air Kerma Rate does not exceed 50% of the value for the normal mode. When the license file is not loaded, the low mode for Reference Air Kerma Rate will not be reduced to 50% of the value for the normal mode but reduction will be lower resulting in approximately 70-80% of the value for the normal mode.

The actual filter selection is displayed on the "Exposure presettings" tab of the examination monitor in the in the control room as shown in Figure 1:

- item "a" indicates the exposure setting
- item "e" indicates the fluoroscopy setting.

If Item "a" can be changed manually, the License Key for Spectral Filter is correctly loaded. If item "a" cannot be changed manually, the License Key for Spectral Filter is not correctly loaded.

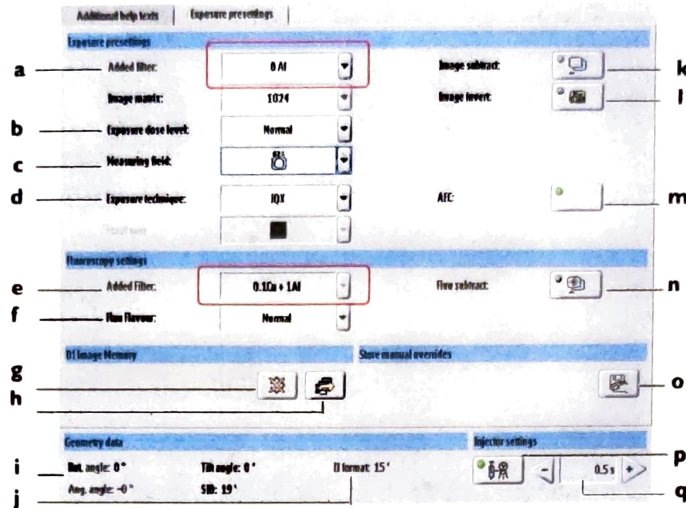


Figure 1: Exposure setting is indicated by “a” on the "Exposure presettings" tab on the Examination Console in the Control Room

- The License Key for Full Table Tilt Range. This license key is needed to enable full table tilt range. When the license file is not correctly loaded the table tilt range is restricted to -20 till +90 degrees instead of full range -90 till +90 degrees. In such a case not all desired image projections are possible.

To date, Philips has not received any reports of patient harm related to this issue.

2. What the hazard/harm associated with the issue is

- License key for spectral filter not loaded: If the problem occurs, this will lead to a higher patient dose than expected.
- License key for full table tilt range not loaded: If the problem occurs, there could be a delay in procedure.

3. The Affected products and how to identify them

Four MultiDiagnost Eleva systems with software version R6.1.1sp2 and R6.1.2. are affected:

Model number	Serial number(s)
708036	4
708037	113, NL73 and 95

The system product name and model number can be found in the System Basic Label located on the back side of the stand as shown in Figure 2. The software version of the MultiDiagnost Eleva system can be identified during the start-up. If the system has software version R6.1.1sp2 or R6.1.2. installed, it is affected by the problem.

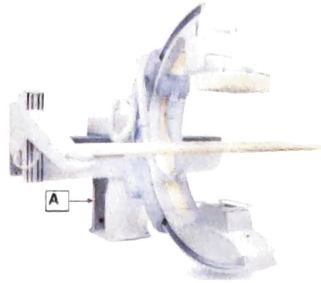


Figure 2: "A" shows the location of the System Basic Label

Philips will contact customers directly with affected systems.

4. The actions that should be taken by the user to prevent risks for patients

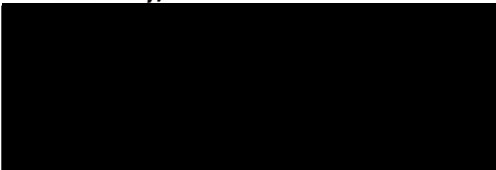
- The License Key for Spectral Filter: Confirm that the License Key for Spectral Filter is correctly loaded after system start up by checking the exposure setting on the "Exposure presets" tab on the examination monitor in the Control Room. If the License Key for Spectral Filter is not correctly loaded, perform a system restart. If the restart does not solve the problem, perform another restart.
- The License Key for Full Table Tilt Range: If all desired image projections are not possible, perform a system restart. If the restart does not solve the problem, perform another restart.
- Circulate this notice to all users of the system so that they are aware of the issue.
- Place this Field Safety Notice with the documentation of the MultiDiagnost Eleva system until Philips installs the software update.
- Return the attached reply form to Philips to confirm that the users of the system have reviewed and understood this Field Safety Notice.

5. The actions planned by Philips IGT Systems to correct the problem

Philips will install a software update in all affected systems to resolve the problem. You will be contacted by your local Philips representative to schedule the software update for your system.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information, please contact your local Philips representative (reference to FCO70800161 for MultiDiagnost Eleva IITV and FCO70800162 for MultiDiagnost Eleva FD).

Sincerely,



Philips' proprietary information. Unauthorized use is prohibited.

URGENT Field Safety Notice RESPONSE FORM

Reference: 2021-IGT-BST-014: MultiDiagnost Eleva intermittently does not load license files

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- The License Key for Spectral Filter: Check if the License Key for Spectral Filter is correctly loaded after system start up by checking the exposure setting on the "Exposure presets" tab on the examination monitor in the Control Room. If the License Key for Spectral Filter is not correctly loaded, perform a system restart. If the restart does not solve the problem, perform another restart.
- The License Key for Full Table Tilt Range: If not all desired image projections are possible, perform a system restart. If the restart does not solve the problem, perform another restart.
- Circulate this notice to all users of the system so that they are aware of the issue.
- Place this Field Safety Notice with the documentation of the MultiDiagnost Eleva system until Philips installs the software update.
- Return the reply form to Philips to confirm that the users of the system have reviewed and understood this Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the MultiDiagnost Eleva system.

Name of person completing this response form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date
(DD/MM/YYYY): _____

Please send this confirmation form to:
<provide instructions here for the customer regarding returning the form to Philips, e.g. fax #, email address. For example, "Please fax this completed form to Philips at (xxx)xxx-xxxx">.