PHILIPS

URGENT - Field Safety Notice

CombiDiagnost R90
System software update

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.

August 2021

Dear Customer,

A problem has been identified in the Philips CombiDiagnost R90 that could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

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

   Philips CombiDiagnost R90 has a lock-in feature which is used only during fluoroscopy. When this feature is switched ON, the current radiation parameters, i.e. kV and mA values, are retained to keep a consistent image impression. This feature is relevant for examinations of anatomies such as knee or shoulder, where the amount of dose at the detector is strongly influenced by the amount of direct radiation.

   Philips has become aware of a software issue, where the kV and mA values are not locked but change when the collimator shutter position is changed directly after the Lock-In command. This software issue leads to an over or under exposed image. However, if the user stops and restarts fluoroscopy, then the Lock-In works as specified.

   There have been no adverse events reported to Philips as of June 2021.

2. **Describe the hazard/harm associated with the issue**

   If kV and mA values are not locked, image quality may not be as expected (over or under exposure); therefore, it may be necessary to repeat the scan resulting in an additional radiation exposure to the patient.

3. **Affected products and how to identify them**

Product	Model Number	Software Version
CombiDiagnost R90	706100	R1.0 R1.1

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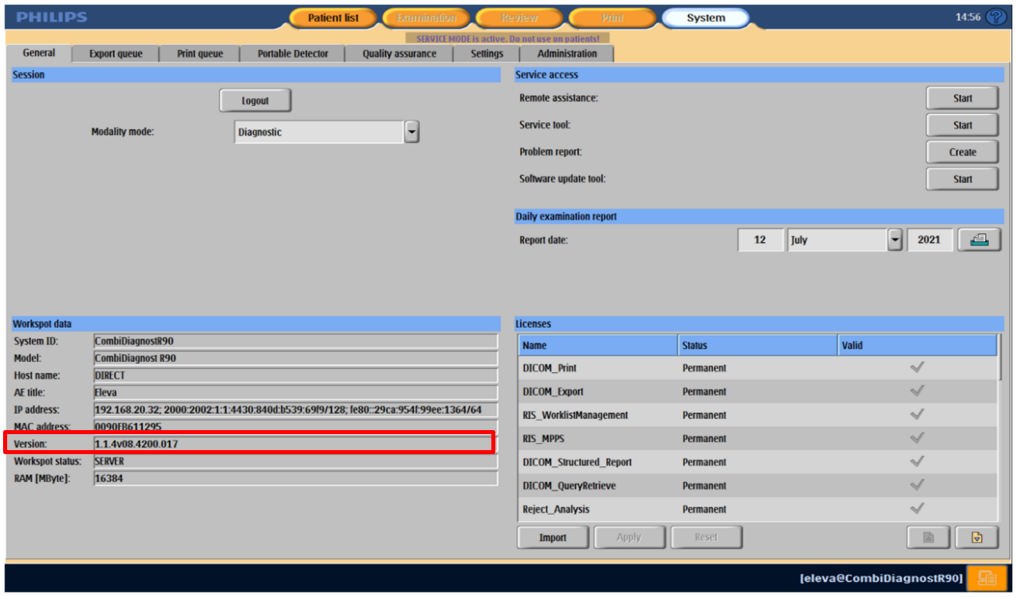
Instructions for How to determine the software version of your CombiDiagnost R90 system:

1. Power up the system and allow it to complete the boot sequence.
2. At the login screen, input your username and password.
3. Once the system starts, click **OK** for any pop-up messages that may appear.
4. Under the **system tab**, locate **Workspot Data**.
5. The software version is listed in the **version** section.



4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients or users

Because the software issue can cause the kV and mA values to shift, please take the following steps:

1. After lock-in selection is made, stop fluoroscopy before changing collimation. Collimation can also be changed on the Last Image Hold (LIH) image.
2. Following Lock-in selection, monitor kV and mA. If the values change, then unlock and lock kV-mA again.

If the user stops and restarts fluoroscopy, then the Lock-In works as specified.

Please complete and return the attached acknowledgment form to Philips DXR promptly upon receipt and no later than 30 days from receipt via email to: DIFCO@philips.com.

5. Describe the actions planned by Philips DXR to correct the problem

A Philips Field Service Engineer (FSE) will visit your site and will update the system software to resolve the software issue.

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This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this issue, please contact your local Philips representative and reference FCO70900051:

0800 80 3000

Sincerely,

David Hanly
Head of Quality Diagnostic X-Ray (DXR)

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: System software update, CombiDiagnost R90, FCO70900051

Instructions: Please complete and return this form to Philips promptly upon receipt 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:

Because the software issue can cause the kV and mA values to shift, please take the following steps:

1. After lock-in selection is made, stop fluoroscopy before changing collimation. Collimation can also be changed on the Last Image Hold (LIH) image.
2. Following Lock-in selection, monitor kV and mA. If values change, then unlock and lock kV-mA again.

If the user stops and restarts fluoroscopy, then the Lock-In works as specified.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this notice has been properly distributed to all CombiDiagnost R90 users.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please complete and return the attached acknowledgment form to
dach.cs.pmplanning.gbs@philips.com