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URGENT Field Safety Notice

ProxiDiagnost N90 1.1 and ProxiDiagnost Upgrade

Software Defects causing imaging issues during Radiography and Fluoroscopy examination

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 this letter for your records.

05-December-2023

Dear Customer,

Philips has identified multiple issues with certain models of ProxiDiagnost systems that could pose risks for patients and users. This URGENT Field Safety Notice is to inform you about:

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

   Issue 1: Mixed Images: Philips has identified that the Radio Fluoroscopy (RF) viewer may also display a previous patient's radiography (RAD) images when starting the next patient scan while the previous patient image export is still processing. If the issue occurs, there is a potential for incorrect patient data to be displayed in the image.

   Issue 2: Detector Access point: Philips has identified a security vulnerability specific to the Wireless Portable Detector configuration items in Philips Support Connect (PSC). Due to this vulnerability it is possible, with physical access to the system and knowledge of specific settings, to modify and export data to removable media (example: USB).

   Philips has identified additional software defects that may impact clinical workflow. Detailed descriptions and recommendations to customers pertaining to these issues are provided in Appendix A.

   There have been no reports of adverse events reported to Philips regarding the issues included in this letter as of October 2023.

2. **Hazard/harm associated with the issue**

   Issue 1: Mixed Images: There is a potential for misdiagnosis or wrong treatment if images of the same anatomical region are mixed up with a different patient.

   Issue 2: Detector Access point: If unauthorized access occurs, the risk to users and patients includes potential for a mix up of patient images and/or patient names resulting in misdiagnosis. The issue may also result in the need to re-scan the patient.

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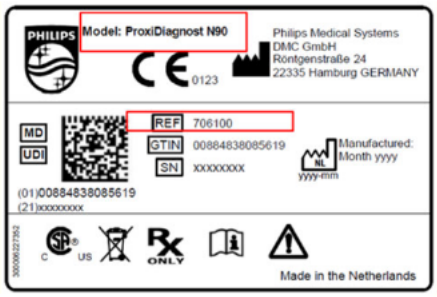
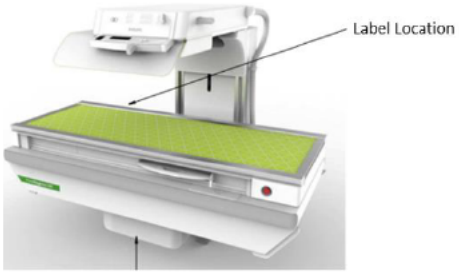
3. Affected products and how to identify them

Identification of Impacted Systems:
Refer to Figure 1 for the list of impacted model names and model numbers (REF). The model name and model number (REF) can be found on the system label.

Figure 1. Impacted Systems

Sample System Label Example	Label Location	Model	Model (REF) Number
		ProxiDiagnost N90	706100 706110
		ProxiDiagnost upgrade	706150

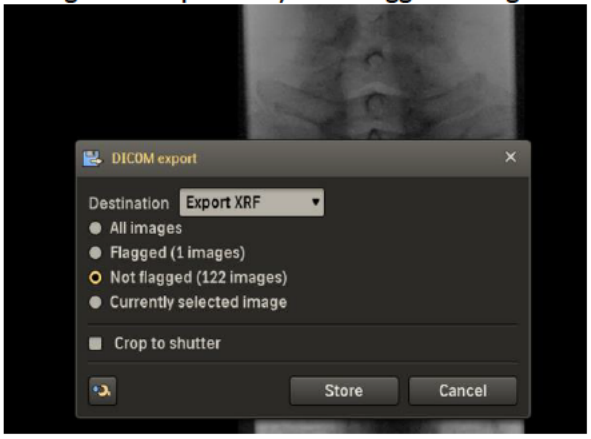
Intended Use:
ProxiDiagnost N90 is a multi-functional general Radiography and Fluoroscopy (R/F) system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.

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

For Issues 1 and 2:

- To avoid previous patient data from being represented as current patient data, ensure all images have been exported from the previous RAD exam before starting a new examination.
- Correct images will be square shape and wrong images can be recognized by a different patient anatomy and rectangular shape. If you identify a wrong image, flag the incorrect images and only export "not flagged" images for the current examination to PACS (See figure 2 below).

Figure 2. Export only "not flagged" images



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- Refer to Appendix A for specific details regarding the other issue descriptions and advice on actions to be taken.
- Customers can continue using affected systems in accordance with the intended use.
- Circulate this notice to all users of this device so that they are aware of the issue.
- Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

5. The actions planned by Philips to correct the problem

A Field Service Engineer (FSE) will contact you to schedule a time to visit your site and install the software upgrade to resolve the issues (Reference FCO70600110). Philips plans to start implementing the solution in Q2 2024.

The software upgrade will also include software enhancements to improve clinical experience.

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

Philips regrets any inconvenience caused by this problem.

Sincerely

[redacted]

Head of DXR Quality

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URGENT Field Safety Notice Response Form

Reference: Software Defects causing imaging issues during Radiography and Fluoroscopy examination (Reference FCO70600110).

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 URGENT 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:

Follow the instructions provided in Section 4 and Appendix A of the Urgent Field Safety Notice letter.

We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice and confirm that the information from this notification has been properly distributed to all users of the affected systems.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please complete and return the response form to Philips promptly and no later than 30 days from receipt via email to: pd.cnr@philips.com.

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Appendix A

The following table summarizes the issues identified, the impact to the customer/patient, and Philips recommendations for continued use where applicable.

Issue #	Issue Description	Impact to Clinical Workflow	Recommendations
1	**Grey Image exported to PACS** This issue occurs under the following sequence of events: 1. User selects the registration device Fluoro & Spot images. 2. User selects single shot for exposure. However, subtraction is not available for single shot. 3. User selects the exposure subtraction on the Eleva UI or Scopo UI. 4. After exposure, Image is displayed normal in the RF-Viewer. 5. Export to PACS and the image is completely grey	The exported image is completely grey and not usable.	In case a homogeneous grey image appears in PACS, perform the following steps: 1. Open the image on the system. 2. Open the Subtraction Dialog switch on the roadmap function and pull the slider to 100%. 3. Resend image to PACS.
2	**RF-Viewer: Annotation rotated in PACS** When a patient is examined in prone position, acquired images will be flipped before export to PACS. In case annotations are added to the flipped image, these annotations will appear on the User interface in horizontal orientation. During export the annotations will be rotated by 90° and appear rotated in PACS.	The annotation does not appear on the image in the desired orientation since the relevant anatomy orientation is changed during export.	In case the rotated annotation covers relevant anatomy: 1. Move the annotation on the system to another more suitable position. 2. Re-send the image to PACS.
3	**Stitching editor crashed** This issue occurs under the following sequence of events: 1. User performs stitching exam to a patient and an error message appears “failed to stitch automatically”. 2. User ignores the message and moves to new patient and auto stitching was successful. 3. The user goes back to the previous patient tries to perform manual stitching.	Once the images of the stitching series are disconnected from the patient, stitching of these images is not possible anymore.	During stitching exams ensure the stitching ruler is always properly displayed inside the collimated area with the numbers pointing towards the patient. This allows the stitching algorithm to create the composite automatically. In case the automatic stitching of the composite fails, open the stitching editor and stitch the images before performing a 2nd

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Issue #	Issue Description	Impact to Clinical Workflow	Recommendations
	4. Eleva Stitching editor crashes.		stitching run or performing stitching on another patient.
4	**A white blank screen appears at PACS for RF image** When XRF images are sent to PACS with the polarity negative (bones are displayed white) and the export node is configured in the PSC to burn the electronic shutters into the image and the Export parameter "increase virtual bit depth" is selected on the system TAB of the Eleva UI the exported images will appear in PACS plain white.	The plain white image in PACS is not usable.	In case a white XRF image appears in PACS the function "increase virtual bit depth" can be disabled on the Eleva User interface under "System/Quality assurance/Export" and the image can be re-sent.
5	**QA-mode no patient available for AEC-test** Per the IFU, an optional User Routine Check called "Checking the AEC Function" is described. This Routine Check cannot be executed since switching to QA mode does not show the respective QA patient (dummy patient) for "AEC function check" as indicated in the IFU. The QA patient (dummy patient) is missing in the Service EPX database.	The AEC-function check cannot be performed as described in the IFU.	Perform the AEC function check in Diagnostic mode following the below steps: 1. Select kV-mA technique (AEC on) 2. Set Values 40 kV, 25 mA, small focal spot 3. SID=100 cm 4. Added Filtration: non (0Al) 5. Release an exposure and note the exposure time. 6. Select added Filtration 0,1 mmCu +2 mmAl 7. Release an exposure again and note the exposure time Note: the exposure time of the 2nd exposure must be at least twice as long as the exposure time of the first exposure.