

Field Safety Notice

MobileDiagnost wDR

Expiration of Software Certificate Validity Preventing Users from System Log In

May 18, 2023

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.

Dear Customer,

Philips has identified a software login issue associated with specific models of MobileDiagnost wDR systems running on Windows 10 operating system. This Field Safety Notice is intended to inform you about:

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

Philips has become aware of a software login issue associated with specific models of MobileDiagnost wDR systems running on Windows 10 operating system preventing use of the system. This issue occurred because the software certificate protecting the Eleva user login expired on May 15, 2023. Therefore, if you log out or reboot your system, you will be prevented from logging in.

2. Hazard/harm associated with this issue

Please be assured that this issue is not related to a security breach. There is no impact on the security credentials of your system and no impact on the data privacy of your system.

Rebooting or logging out of your system will result in the system becoming inoperable which will potentially result in delay in diagnosis.

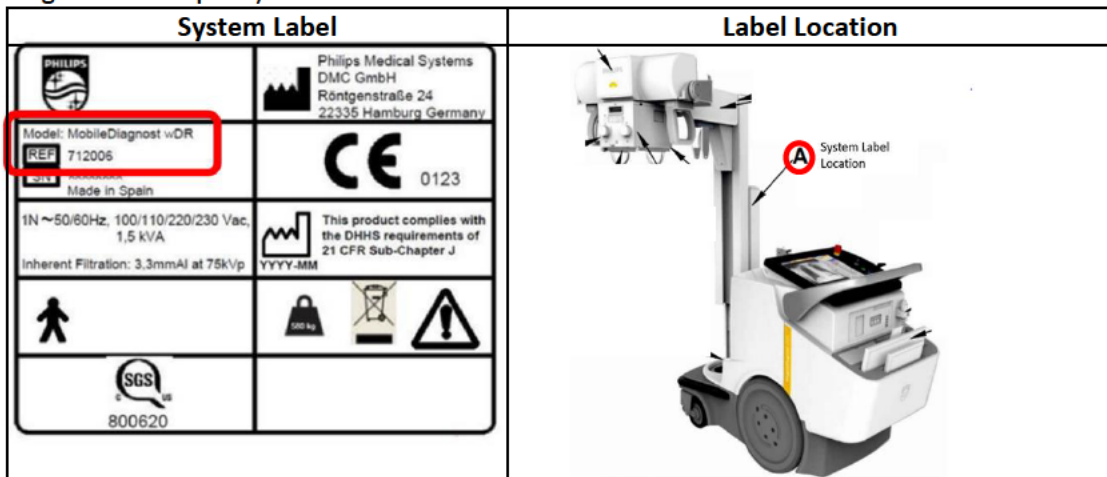
3. Affected products and how to identify them

Refer to Table 1 for the list of impacted model names, model numbers (REF), and software versions. The model name and model number (REF) can be found on the system label, as indicated in Figure 1.

Table 1. Impacted Systems

Model Name	Model Number (REF)	Software Version
MobileDiagnost wDR	712007	2.2.0, 2.2.1, 2.2.2, 2.2.3
	712006	2.2.0, 2.2.1, 2.2.2, 2.2.3
	712004	2.1 with Windows 10 Upgrade
	712002	2.1 with Windows 10 Upgrade

Figure 1. Example System Label



Intended Use:

The MobileDiagnost wDR is suitable for all routine radiographic exams, including specialty areas such as intensive care, trauma, operating room, or pediatric work. Standard radiography procedures are, for example:

- X-ray examinations of the skeleton including skull, chest, spine, pelvis, upper extremities, lower extremities, etc.
- X-ray examinations of the lung
- X-ray examinations of soft tissue such as abdomen

The user has the following exposure methods available.

- Free exposure technique for two differently sized wireless portable detectors.
- Free exposure technique for film cassettes and or CR systems

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

- To prevent the system from becoming inoperable, do not reboot or log out of your system until Philips has implemented the software correction.
- Circulate this notice to all users of the device so that they are aware of the issue.
- 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 Field Safety Notice, understanding of the issue, and required actions to be taken.


5. Actions planned by Philips to correct the problem

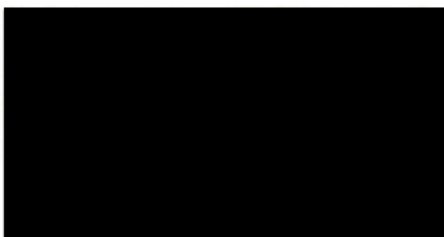
A Philips representative will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site and implement a software solution to resolve the issue (Reference FCO71200226 for Australia and New Zealand and FCO71200228 for all other impacted countries)

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 representative.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,


 Head of Diagnostic X-Ray (DXR) Quality



Field Safety Notice Response Form

Reference: MobileDiagnost wDR - Expiration of Software Certificate Validity (FCO71200226, FCO71200228)

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:

- To prevent the system from becoming inoperable, do not reboot or log out of your system until Philips has implemented the software correction.
- Circulate this notice to all users of the device so that they are aware of the issue.
- Complete and return the attached response form to Philips promptly and no later than 30 days from receipt.

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

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 via email to PD.CNR@Philips.com