



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 43..... dated 28/2/22 Regarding NCMDR FSCA of DigitalDiagnost C90 and CombiDiagnost R90 from (mrf: Philips Healthcare).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 43/2022

27-07-1443 H

28-02-2022

بمقدم بثقة
Moving Forward
with Confidence



Field Safety Corrective Action of DigitalDiagnost C90 and CombiDiagnost R90 from Philips Healthcare

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16037
Product	DigitalDiagnost C90 and CombiDiagnost R90.
Description	X-ray system, diagnostic, general-purpose, stationary, digital.
Manufacturer	Philips Healthcare.
Affected	DigitalDiagnost C90, Model numbers: 712034, 712035 CombiDiagnost R90, Model numbers: 709031
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
Reason	If a user touches the Eleva touch screen during start-up of the DigitalDiagnost C90 and CombiDiagnost R90system, the login screen may move to the background and then will not be visible to the user and the user will be unable to log into the system.
Action	1. Refer to “ The actions that you as a customer can take to minimize the effect of the problem” 2. Philips will provide a software update to resolve the issue. 3. Contact the local agent for remedial action.
Product Image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al-Rubaie
DIRECTOR GENERAL




- Home
- Published FSNs/Recalls
- About NCMDR
- Contact Us
- FAQ
- Login

NCMDR Recall

Reference Number: mdprc 025 02 22 000

[Back](#)

Date submitted: 2/17/2022

Manufacturer:	Philips Healthcare
Device Type:	DigitalDiagnost C90 and CombiDiagnost R90
Description:	X-ray system, diagnostic, general-purpose, stationary, digital
Medical Device Identifier:	DigitalDiagnost C90, Model numbers: 712034, 712035 CombiDiagnost R90, Model numbers: 709031
Reason of Field Safety Corrective Action:	If a user touches the Eleva touch screen during start-up of the DigitalDiagnost C90 and CombiDiagnost R90 system, the login screen may move to the background and then will not be visible to the user and the user will be unable to log into the system.
Remedy Action:	Refer to " The actions that you as a customer can take to minimize the effect of the problem" A Philips Field Service Engineer (FSE) will visit impacted customers to provide a software update to resolve the issue.
Athorized Representative/Importer/Distributor:	Philips Healthcare Saudi Arabia Ltd.
Report Source:	NCMDR
Source Ref. Number:	8ADD1A11571E9
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	 Philips Healthcare.pdf

[View History](#)

IMPORTANT PRODUCT NOTICE

DigitalDiagnost C90 and CombiDiagnost R90 Login screen software issue

20-DEC-2021

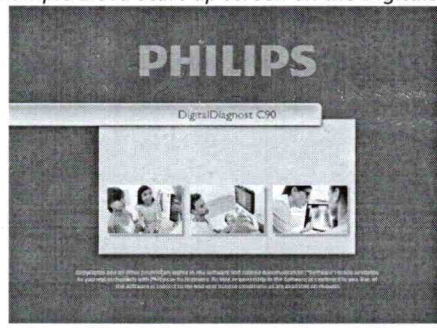
Dear Customer,

Philips has identified an issue with the Philips DigitalDiagnost C90 and CombiDiagnost R90, that, if it were to occur, could affect the performance of the DigitalDiagnost C90 and CombiDiagnost R90 system. This Important Product Notice is intended to inform you about:

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

If a user touches the Eleva touch screen during start-up of the DigitalDiagnost C90 and CombiDiagnost R90 system, the login screen may move to the background and then will not be visible to the user. The system will continue to display the screen shown in Figure 1, and the user will be unable to log into the system.

Figure 1. Example Eleva Start-up screen on the DigitalDiagnost C90



There is no safety risk to patients or users associated with this issue.

2. Affected products and how to identify them

System Label Example	Product	Models
	DigitalDiagnost C90	712034, 712035
	CombiDiagnost R90	709031

The user can identify this issue if they do not see the login screen or if it disappears after system start up.

3. The actions that you as a customer can take to minimize the effect of the problem

- A. Circulate this notice to all users of this device so that they are aware of the issues.
- B. Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt via email to: pd.cnr@philips.com
- C. To prevent the login screen issue, do not touch the Eleva touch screen during start up.
 - Mitigation: If a user touches the Eleva touch screen during start up and the login is not visible to the user, the user can complete one of the following mitigations:
 1. Press <Alt> + <Tab> simultaneously on the keyboard (Figure 3). The login screen will then come to the foreground and will be visible.

Figure 3. <Alt> + <Tab> on a keyboard



2. Complete a hard restart of the system. When the system re-boots, the user should ensure they do not touch the Eleva touch screen during start up.

4. The actions planned by Philips to correct the problem

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

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 and reference FCO71200210 for DigitalDiagnost C90 and FCO70900050 for CombiDiagnost R90.

Sincerely,

A handwritten signature in black ink, appearing to read 'Karmen Gruenert'.

Karmen Gruenert
Head of Diagnostic X-Ray (DXR) Quality and Regulatory

IMPORTANT PRODUCT NOTICE ACKNOWLEDGEMENT FORM

Reference: Login screen software issue (2021-PD-DXR-033)
FCO71200210 for DigitalDiagnost C90 and FCO70900050 for CombiDiagnost R90.

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 Important Product Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- A. Circulate this notice to all users of this device so that they are aware of the issues.
- B. Please perform the steps provided in Section 3 of the attached Important Product Notice if you experience the software issue.

We acknowledge receipt and understanding of the accompanying Important Product Notice and confirm that the information from this letter has been properly distributed to all users that handle the DigitalDiagnost C90 and CombiDiagnost R90.

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 Philips DXR via email to: pd.cnr@Philips.com.