



نقدم بثقة
Moving Forward
with Confidence



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 179 dated 24/8/23 Regarding NCMDR
FSN of Essenta DR Compact Systems from (mfr: Philips Medical Systems).

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



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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dgpa_dc Email: dg-padc@moh.gov.om



Circular No. 179 / 2023

08 -02-1445 H

24 -08-2023

Field Safety Notice of Essenta DR Compact Systems from Philips Medical Systems

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19667
Product	Essenta DR Compact Systems.
Description	Digital radiography.
Manufacturer	Philips Medical Systems.
Local Agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Ref. number: 712072 All Essenta DR Compact systems are impacted.
Reason	There is a potential cybersecurity issue with Essenta DR Compact Systems, which could result in unauthorized disclosure or modification of patient data.
Action	1. Please refer to the action to be taken by the customer / user in the attachment which is included installation of a firewall to ensure a secure communication when utilizing FTP to transfer data. 2. Contact the local agent for remedial action.
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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General





URGENT Field Safety Notice

Essenta DR Compact potential for data mismatch during file transfer protocol (FTP)

11-August-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 potential cybersecurity issue with Essenta DR Compact Systems, which could result in unauthorized disclosure or modification of patient data. This URGENT Field Safety Notice is intended to inform you about:

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

There is a potential cybersecurity issue with Essenta DR Compact Systems, which could result in unauthorized disclosure or modification of patient data. This issue may occur if a firewall is not in place, the file transfer protocol (FTP) is utilized, and the following sequence of events occurs:

- Unauthorized personnel gains physical access to your facility
- Your facility does not have a firewall and/or network segregation to isolate medical devices, and
- The unauthorized person connects their device to the Essenta DR Compact system network at the specific time data is transferred (data is not continuously transferred).

Under these conditions unauthorized access or modification of patient data is possible.

2. Hazard/harm associated with the issue









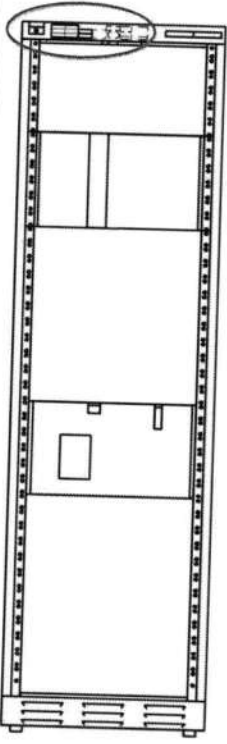




If unauthorized access occurs, the risk to users and patients includes potential for a mix up of patient images and/or patient names resulting in misdiagnosis. The issue may also result in the need to re-scan the patient.

3. Affected products and how to identify them

Identification of Impacted Systems:

All Essenta DR Compact systems are impacted. The systems can be identified by the model name, which can be found on the system label (see red boxes in Figure 1).

PHILIPS

Essenta DR Compact Label Example	Label Location (System Cabinet Generator)	Model	REF number						
<table border="1"> <tr> <td data-bbox="395 444 619 517">  PHILIPS </td> <td data-bbox="624 451 842 526">  Philips Medical Systems DMC GmbH Röntgenstraße 24 22335 Hamburg GERMANY </td> </tr> <tr> <td data-bbox="395 522 619 583"> type 9890-010-8738. SN: xxxxxx Essenta DR </td> <td data-bbox="624 539 842 592"> see generator:  </td> </tr> <tr> <td data-bbox="395 592 619 665">  Class I - TYPE B IEC 60601-1 </td> <td data-bbox="624 599 842 672"> Associated equipment IEC 60601-2-32:1994 </td> </tr> </table>	 PHILIPS	 Philips Medical Systems DMC GmbH Röntgenstraße 24 22335 Hamburg GERMANY	type 9890-010-8738. SN: xxxxxx Essenta DR	see generator: 	 Class I - TYPE B IEC 60601-1	Associated equipment IEC 60601-2-32:1994		Essenta DR Compact	712072
 PHILIPS	 Philips Medical Systems DMC GmbH Röntgenstraße 24 22335 Hamburg GERMANY								
type 9890-010-8738. SN: xxxxxx Essenta DR	see generator: 								
 Class I - TYPE B IEC 60601-1	Associated equipment IEC 60601-2-32:1994								

Intended Use:

The Essenta DR is a digital multifunctional X-ray system, suitable for all routine radiographic exams, including special areas like trauma or pediatric work, excluding mammography.

It is designed for radiographic examination of the standing or seated patient or the recumbent patient in combination with a mobile x-ray table (trolley).

The system is intended for direct digital imaging using the built in flat panel detector and in addition for free exposures on radiographic cassettes.

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

- Install a firewall to ensure a secure communication when utilizing FTP to transfer data. Philips does not recommend using the system without a firewall.
- Refer to Appendix A for network protection recommendations and attach this notice as an addendum to the Essenta DR Compact IFU provided with the system for future reference.
- Circulate this notice to all users of this device and to your IT security department so that they are aware of the issue.
- Customers can continue using affected systems in accordance with the intended use.
- 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 Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

PHILIPS

5. Actions planned by Philips to correct the problem

Philips is providing this Field Safety Notice which contains recommendations for network protection described in Appendix A.

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,

Karmen Greunert
Head of Quality Diagnostic X-Ray (DXR)