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).

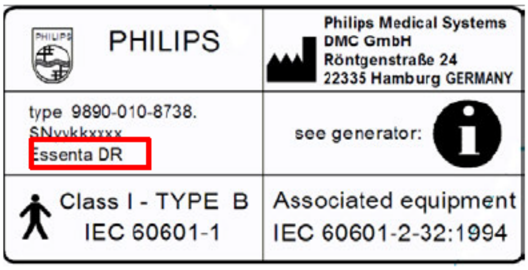
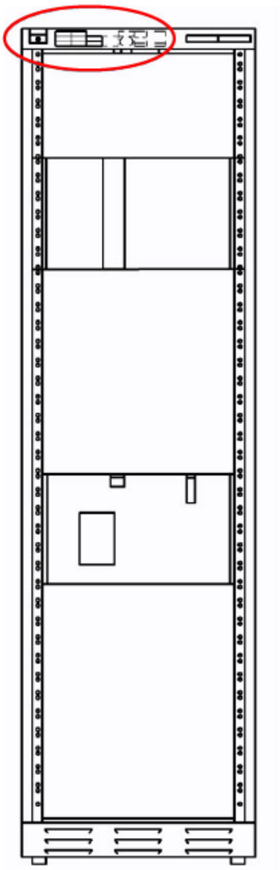
Under these conditions unauthorized access or modification of patient data is possible.

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).

Essenta DR Compact Label Example	Label Location (System Cabinet Generator)	Model	REF number
 PHILIPS Philips Medical Systems DMC GmbH Röntgenstraße 24 22335 Hamburg GERMANY type 9890-010-8738. SNyykkxxxx Essenta DR see generator: Class I - TYPE B IEC 60601-1 Associated equipment IEC 60601-2-32:1994		Essenta DR Compact	712072

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.

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,

[redacted]

Head of Quality Diagnostic X-Ray (DXR)

URGENT Field Safety Notice Response Form

Reference: Essenta DR Compact FTP Security Vulnerability (2023-PD-DXR-009)

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 this URGENT Field Safety Notice .

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.

Appendix A: Essenta DR Compact System IFU Addendum

Firewall

A properly configured firewall can help to reduce the vulnerability risk via the network. A firewall is designed to block unauthorized network access while permitting authorized communications. Philips does not recommend system operation without a firewall. Additionally, it is recommended to assign the system to a separated network segment, for example, a separate VLAN
for medical devices.

Eleva based systems run a built-in pre-configured software firewall. The systems can be ordered with and without an external (hardware) firewall. The firewall is configured during system installation via Philips service application.

Users with questions regarding their specific Philips Essenta DR Compact Systems solution are advised by to contact their local Philips service support team, or regional service support. Philips contact information is available at the following location.

https://www.philips.com/productsecurity

If the hospital chooses to install their own firewall, below list of ports are required to be configured.

Port	Transport Layer Protocol	Fixed	Inbound	OutBound	Usage
3010	TCP	No	Y	N	DICOM
80, 4440	TCP	Yes	Y		Remote Service FSF for AWS
5900	TCP	Yes	Y		Remote Service via VNC for AWS
17991	TCP	Yes	Y		legacy Fuji control protocol which replaces the RS232 control line
18015 - 18020, 18030, 18050	TCP	Yes	Y		PCR Reader Integration
21	TCP	Yes	Y		FTP for PCR Reader integration
50123	TCP	Yes	Y		Remote Service: CDF Provider Server (for Logserver
80	TCP	Yes		Y	VirusGuard Updates (EPO / distribution server / http)
443, 8086, 9006, 9900	TCP	Yes		Y	Remote service.
5104	TCP	No		Y	To RIS
6104	TCP	No		Y	To PACS
104	TCP	No		Y	To Printer
445	TCP	Yes		Y	DosePRN_445
9100	TCP	Yes		Y	DosePRN_JETDIRECT
515	TCP	Yes		Y	DosePRN_LPR
137 - 139	TCP&UDP	Yes		Y	DosePRN_SYSCO
123	UDP	Yes		Y	Time Synchronization
514	UDP	No		Y	Audit Trial
80, 104, 443, 6464	TCP	Yes		Y	iSite
>1023	TCP	Yes		Y	FTP RIS
514	UDP	No		Y	Dicom Print
80, 23	TCP	Yes		Y	PCR READER_CONF
18018	TCP	Yes		Y	PCR READER_FRUP
>1023	TCP	Yes		Y	PCR READER_FTPDATA