

**URGENT - Field Safety Notice
Essenta DR**

Patient and image data can be exchanged

Dear Customer,

A problem has been detected on our Radiography system Essenta DR.

This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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 a copy with the equipment Instruction for Use.

If you need any further information or support concerning this issue, please contact your local Philips representative:

<Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>

<Name>

<Function>



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AFFECTED PRODUCTS	Essenta DR Release 1.0
PROBLEM DESCRIPTION	When patient is selected in patient list and examination tab pressed with background query running at the same time there is a risk that the wrong patient is selected.
HAZARD INVOLVED	See details above.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Essenta DR systems with release 1.0.3 and below.
ACTION TO BE TAKEN BY CUSTOMER / USER	The clinical user shall verify the selected patient before releasing an exposure
ACTIONS PLANNED BY PHILIPS	Current systems need to be upgraded to latest release with FCO71200031.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

