

DXR

Quality Management System DXR

## DXR Field Safety Notice

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FSN MA-FCO 71200193

2019-May-15

# URGENT - Field Safety Notice *Digita/Diagnost*

## ***Software Upgrade to Digita/Diagnost Rel 4.2.7***

<Hospital/Clinic Name>

cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

A problem has been detected in the Philips DigitalDiagnost, that, if it were to re-occur, could pose a risk for patients or users. 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, please contact your local Philips representative:

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,

  
Michael Mizrachi  
Head of Q&R DXR Hamburg

DXR

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## **URGENT - Field Safety Notice**

### ***DigitalDiagnost***

#### ***Software Upgrade to DigitalDiagnost Rel 4.2.7***

|  |   |
|--|---|
| <b>AFFECTED PRODUCTS</b>                     | All DigitalDiagnost systems with Software 4.2.x delivered to Switzerland in 2018 and 2019   |
| <b>PROBLEM DESCRIPTION</b>                   | The unit of DAP (Dose Area Product) is currently displayed by the System in $\mu\text{Gym}^2$ or $\text{mGym}^2$ . Due to a recent change in Swiss law, this information must be displayed in $\text{mGy}\cdot\text{cm}^2$  |
| <b>HAZARD INVOLVED</b>                       | No hazard associated with this issue for patients or operators.<br>Should you have any questions about this notice, please contact Philips.   |
| <b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>     | All DigitalDiagnost systems with Software 4.2.x delivered to Switzerland in 2018 and 2019   |
| <b>ACTION TO BE TAKEN BY CUSTOMER / USER</b> | No action required by the customer. Customers may continue to use the device according to its intended use.<br>Should you feel uncertain regarding these instructions, please contact Philips.  |
| <b>ACTIONS PLANNED BY PHILIPS</b>            | Philips plans to install a system software version upgrade in affected systems, which will eliminate this issue.<br>A Philips Service Engineer will contact you when the FCO Kit is available for implementation.<br>Should you need to communicate with Philips with regard to this program, please reference Field Change Order 71200193. |
| <b>FURTHER INFORMATION AND SUPPORT</b>       | If you would like any further information or support concerning this issue, please contact your local Philips representative.   |