URGENT - Field Safety Notice

MultiDiagnost Eleva FD R6.1.1

Incorrect Skin dose calculation. SW update

Dear Customer,

We have noticed an issue with the Philips MultiDiagnost systems that, if it were to re-occur, could potentially pose a risk for patients.This Field Safety Notice notification 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.

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>

[redacted]
Sr. Director Q&R iXR

AFFECTED PRODUCTS	System: MultiDiagnost Eleva FD, Productcode: 708037 Software release: PBL 6.1.1

URGENT - Field Safety Notice

MultiDiagnost Eleva FD R6.1.1

Incorrect Skin dose calculation. SW update

PROBLEM DESCRIPTION	Investigation of a remark / feedback from the field showed that the displayed Air Kerma (AK) is using an incorrect point of reference. This is a defect per 21 CFR 1003, system design. The system must be calibrated according to AK and AKR per 21 CFR 1020.32(d). Air Kerma is to express the radiation delivered to a point, such as the entrance surface of a patient's body. The Air Kerma Rate means the air kerma per unit time. The DAP (Dose Area Product) value is correct. Through the DAP meter the user aware of any given –higher- dose to the patient.
HAZARD INVOLVED	Due to an incorrect algorithm the Air Kerma and Air Kerma Rate values are not calculated correctly. This programming error does not affect the dose control loop and the 88mGy/min (10R/min) limit. As such, the dose as received by the patient is not affected, but AK and AKR as displayed and stored in the patient record are too low. The DAP (Dose Area Product) value is correct. The user can monitor and measure the dose through the DAP meter and is so aware of any given –higher- dose to the patient. The DAP reading is also used for reporting purposes.
HOW TO IDENTIFY AFFECTED PRODUCTS	All MultiDiagnost systems as mentioned above. The affected systems will be clearly identified by the local Philips Organisation.
ACTION TO BE TAKEN BY CUSTOMER / USER	Incorrect values are visible for the user. User might notice a deviant AK rate value, up to 41%. DAP value is correct. No action to be taken by the customer/user.
ACTIONS PLANNED BY PHILIPS	A mandatory Field Safety Corrective Action will be issued to solve this problem. This FCO will be identified as FCO70800124 and will be free of charge. This FCO consists of a Software update. The expected date of this FCO will be Q1, 2012
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>