



Schwarzer Cardiotek GmbH Im Zukunftspark 3 74076 Heilbronn

Customer / Partner name and address

[REDACTED]
17.02.2017

Field Safety Notice

**schwarzer evo and eco c
FSCA-identifier (2017-02-17)
Retrofit by purchaser of manufacturer's modification**

Dear Ladies and Gentlemen, customer and partner,

we hereby inform you about a Field Safety Corrective Action for the schwarzer evo-series and eco c.

Details on affected devices:

All schwarzer evo and eco c products manufactured between 27.12.2014 and 15.12.2016.

Each service partner will receive a list of affected devices (see "Feedback Form" for reporting of performed corrections).

Description of the problem:

During EMC testing according to EN 60601-1-2:2007 the following issues were discovered:

1. Emission testing: during testing the function keyboard radiated noise mainly at a frequency of 48 MHz and 82.8 MHz. These emissions are outside the frequency range of physiological signals. The emissions caused by the keyboard are not visible on the ECG and IBP signals in normal operation as the keyboard is located in the control room.
2. Immunity testing: during testing distortions of the ECG and IBP signals were noticed in the frequency range of 80-110 MHz (i.e. radio frequencies used by



police and radio stations). As the user can easily identify these distortions, they do not cause an unacceptable risk to the patient.

Retesting showed that both issues can be eliminated by mounting ferrite filters on the signal cables, function keyboard and mouse cables.

Advise on action to be taken by the user:

As we are not aware of any cases where these issues caused problems no immediate actions are required by the user. Customers can continue to use their devices.

Schwarzer Cardiotek will provide service material (ferrite filters and an assembly instruction) to all service partners for distribution to customers who received schwarzer evo and eco c products manufactured between 27.12.2014 and 15.12.2016.

The ferrite filters can be mounted directly by the customer according to the applicable assembly instruction.

If support with the service material is required, the local service partner can be contacted and the ferrite filters will be mounted during the next regular service.

Transmission of this Field Safety Notice:

Schwarzer Cardiotek will provide this service notice and the service materials (including ferrite filters and an assembly instruction) to all service partners. Our service partners will provide this notice together with the service material to all affected customers.

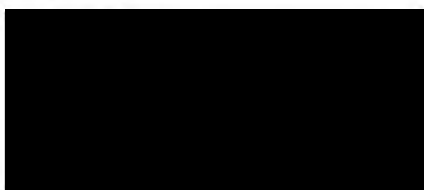
This notice needs to be passed on to all those who need to be aware within your organization.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Michael Grüttner
Director Service Worldwide
Schwarzer Cardiotek GmbH
+49 71 31 / 27 74 – 555
+49 71 31 / 27 74 – 590

The undersign confirms that this notice has been notified the appropriate Regulatory Agency





Feedback Form

Please return this form by fax or E-Mail:
E-Mail: Service@schwarzercardiotek.com
Fax: +49 7131 2774 590

Thank you for your support!

Customer name:	
Contact person:	
Contact person phone:	
Contact person E-Mail:	

**The ferrite filters have been mounted to the applicable devices
according to the provided assembly instruction.**

Hospital	City	Device	Serial	Date change implemented

Completed by:

Function	Name	Date	Signature