schwarzer cardiotek
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74076 Heilbronn
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Field Safety Notice

Software – Update for evolution core
Date: 16.02.2021

Dear Ladies and Gentlemen, customer and partner,

we hereby inform you about a Field Safety Corrective Action for evolution core.

Details on affected devices:

All evolution core (80EVL00) devices which are used in an evolution system are affected:

- 80EVL-XX
- 88EVL-XX

All software versions released for evolution starting with 4.3.0 up to 4.3.9 are affected.

Description of the problem:

The ECG waveforms are received as a stream from the amplifier by the online application. There the assignment to the individual channels is made. Apparently the entries for aVR and aVF were made in the wrong order, thus the channels got assigned to the other label and position.

This effects only the live signals, the online ST – Evaluation works as intended with correct label position.

In the offline application the analysis, reports and printouts are not affected by this issue.

For typical hemodynamic programs using lead I, II or III the issue has no effect. Heartrate and heart beat detection for hemodynamic analysis are not affected by this issue.

The issue is apparent only if the aVR/aVF leads are displayed e.g. if you use the 12 Lead ECG display for an ECG lead overview of the patient. In that case the swapped channels are visible and must be interpreted accordingly.

Actions to be taken by the user:

An updated software version, where the problem was identified and corrected, is already released (4.3.10.1133).

The online view shows wrongly assigned entries for aVR and aVF until the updated software version is installed. Assessments of the corresponding ECG leads in an ECG overview can be done using recordings and printouts from the offline application, further action is not needed.

As the ECG overview is intended only for general assessment purposes where the problem is immediately apparent the impact on the procedure and patient's health is negligible.

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Actions to be taken by the manufacturer:
Software updates take place with every service action, at the latest with regularly preventive maintenance once a year.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

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

Contact person:
Anna Held
QM & RA
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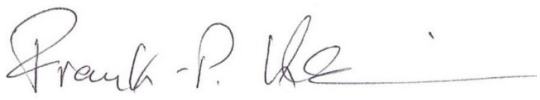
Fax: +49 7131 2774 590
Mail: helpdesk@schwarzercardiotek.com

The signing person confirms that this notice has been transmitted to the appropriate regulatory agency.



Frank-Peter Klein
Safety Officer for Medical Devices