

Field Safety Notice

Software – Update for evolution core

Date: 09.12.2019

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 devices which are used in a system together with an amplifier option 3. Thermodilution measurement is only possible with this option of the amplifier.

Description of the problem:

The determination of the cardiac output (CO) by means of thermodilution measurement in conjunction with the commonly used catheter depending correction factors, results in values which are about factor 2 too small.

The deviations of those values are that large that the error is obvious to the user. The values are either unrealistic, do not match to the general patient condition or contradict with other routinely collected parameters.

Actions to be taken by the user:

An updated software version, where the identified problem was corrected, is already available.

The CO measurement using thermodilution can result in incorrect values until the updated software version is installed. Therefore, this version of CO measurement should not be used until the updated software is installed.

The calculation of the CO values based on the Fick principle is still possible independent of the software version.

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:

Tatjana Nuber

QM & RA

Phone: +49 7131 2774 559

Fax: +49 7131 2774 590

Mail: helpdesk@schwarzercardiotek.com

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

