Field Safety Notice To Customers

Fred Easyport

FSCA-identifier: 26.02.2016

Type of action: FSCA

Date: 08.03.2016

Attention: Schiller subsidiaries and customers

Details on affected devices:
Product: FRED Easyport sold from 2004 to 2016
Article number: 0.900000

Description of problem:

We have received an incident report of Fred easyport where the ECG trace showed a ventricular fibrillation. Fred easyport decided for a shock delivery correctly. During the loading of capacitor Fred easyport analyzed further and due to the short change of rhythm Fred easyport diverted the shock internally and asked the user to resume CPR (cardiopulmonary resuscitation) immediately. The Fred easyport in question had as special feature automatic analysis every 2 minutes; however, the standard Fred easyport analyses upon pressing "Analysis" button, i.e. 1st and 2nd categories (for detail, see below). The user is prompted to do so every 2 minutes.

In the present case the user got confused and did not allow for the further automatic rhythm analysis after 2 minutes. He continued with CPR, so the Fred easyport noted motion artefacts and thus could not analyze the trace anymore. The patient was successfully rescued and left the hospital without impairment.

The Fred easyport in question was thoroughly investigated by Schiller AG in cooperation with the rescue organization. The analysis of the device and the recorded device-data of the incident showed the Fred easyport in question worked according to its specification.

Since the analysis in the Fred easyport in question is performed automatically every 2 minutes and delivers the message "Do not touch the patient analyzing", the user might disregard this message and continue with CPR; thus, impeding Fred easyport to do rhythm analysis (device detects motion artefacts) and therefore, no shock is possible. With the new software version 3.14 in contrast to the current version there will be no automatic re-analysis during charging of capacitor; therefore, this potential risk will be eliminated.

Actions to be taken by Schiller subsidiaries and distributors:

Fred easyport according to its configuration can be categorized into three categories. The 1st category of Fred easyport has manual mode of analysis and can override the analysis in order to shock based on user's decision. The 2nd category of Fred easyport has manual mode of analysis and shock delivery by user, if suggested by the device. Analysis can't be overridden but initiated again at any time. The 3rd category of Fred easyport does automatic analysis every 2 minutes which can't be overridden by user. The Fred easyport in question falls into the 3rd category. Based on the cause investigation and risk assessment Schiller AG advises:

- The 1st and 2nd categories of Fred easyport: you can use your Fred easyport without any restriction; no immediate precautionary action is to be taken. However, Schiller recommends new software upgrade to ver. 3.14 at the next service of device. Please note software update can only be made by FredCo and together with its adaptor.

- The 3rd category of Fred easyport: new software upgrading shall be completed upon receipt from Schiller of the new software version 3.14.

- Fred easyport with the serial number of defi-board (3.2628BA, 3.2628BB and 3.2628DA): these devices are older than the designated device lifetime 10 years. For this reason, Schiller recommends replacing the devices that are still in use with the latest version. Please contact Schiller Sales responsible for an offer on a device exchange. The list of these devices' serial number is attached.

- Complete acknowledgement form and return to Schiller AG's contact person a.m. below.

- Inform your local competent authority about this field safety notice.

- Translation of this letter into the necessary local languages.

Publication of the information described in this statement:

Please make sure that all users of the aforementioned products and other relevant person within your organization will be aware of this field safety notice. If you have passed the devices to third parties, please forward a copy of this information or inform the below mentioned contact person.

The obligation for regular monitoring of functions and safety devices by users is maintained.
Always follow the prescribed intervals for preventive maintenance and safety checks.

Please keep this information at least until the action has been completed.

The responsible Swiss Health Authority Swissmedic has a copy of this field safety notice.

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