arcomed ag
Medical Systems

Field Safety Notice

FSCA identifier: CH-20191004

Date: 4.10.2019

Affected Devices **Syramed µSP6000 and Volumed µVP7000**

Concern: **Safety alarm and stop of infusion**

Problem description

Arcomed AG has been informed that in some rare cases the Syramed µSP6000 and Volumed µVP7000 would signal a safety alarm. During the alarm the devices stop the infusion until reset and restarted by the user.

Background

Investigation of the concerned devices revealed that one capacitor on the main PCB was assembled with reverse polarity. Since the capacitor is used more than ten times below its rated voltage, the capacitor operates as desired, but may age faster than expected. This has no immediate impact on the device and all functions will perform normally. This assembly has however an accelerated aging effect on that particular component which can after some time (reports showed that these rare cases of affected devices worked normally for over one to three years prior to the alarms) interfere with the microcontroller on the main PCB. Arcomed's infusion devices implement a double processor technology, where one processor system continuously checks the other and vice versa. These checks detect the accelerated aging of the component and trigger the safety alarm. The LED display stops displaying the running pictogram and might only display frozen data on the LCD while emitting a distinct audible alarm (safety alarm).
Since the effect is delayed or does not occur at all, this problem was not detected in the production and test of the devices and also was not apparent until users reported it years later.

If the safety alarm is triggered, the pump can be switched off as described in the user manual by holding the Off button for 15 seconds while the pump is disconnected from mains power. After restarting, SW releases 6.1007 and later will trigger an additional safety alarm that is recorded also in the history file (code 0).
Once the alarms are cleared by an Off/On cycle, the pumps can be operated as usual.

Risk considerations:

The occurrence of this safety alarm, as such, does not pose a significant hazard to the patient, but the infusion will be stopped as indicated in the user manual until restarted by the user. The user is notified by an audible alarm and visual indications. By switching the pump off/on the infusion can be restarted and continued. Even though the pumps can be restarted, it is recommended to use a replacement pump instead, in particular for critical infusions. As soon as the infusion is finished, make sure the pump is checked and updated by your technical support prior to further use in order to minimise the risk of a re-occurrence of this alarm.

Solution and Actions:

Arcomed AG recommends the following procedures in the sense of a high availability.

- As advised in the user manual, advise the clinical personnel that the internal safety system continuously supervises all functions and might trigger a safety alarm anytime and the infusion will be interrupted thereafter. To avoid any risk for the patient make sure replacement equipment is available and the procedures are in place for an exchange in case a technical defect should happen on a device.
- If you had devices that displayed safety alarms and in particular could only be switched off with the 15 seconds reset function, make sure these devices are not used until checked and updated by your technical support.
- For critical infusions that are particularly time sensitive make sure to update the affected devices as soon as possible as a preventive measure. Arcomed AG will assist your technical support with the needed updates (replacement of the main PCB).
- It is recommended to keep your pumps up to date and perform this update during the periodic preventive maintenance.

The maintenance is carried out by specially trained personnel.

The update consists of either replacing the concerned capacitor or replacing the main PCB and re-initialization of the settings and loaded drug libraries.

Note: The update will not delete or affect safety alarms. The supervision system will continue to monitor the functions of the device. Proceed as indicated in the maintenance manuals when alarms are displayed after the update.

If you need assistance for the update do not hesitate to contact Arcomed AG. We kindly ask you to report back to Arcomed AG if you were concerned by one of the above problems.

Concerned devices:

Syramed µSP6000 produced from May 2016 (serial number ending with xxxx1605 and higher) or production date till 10/2019.
Volumed µVP7000: Production date 201907 - 201909

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Contact reference person:

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The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Harald Hofpeter
Quality Management Representative

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Important Information

Concern: Syramed *µ*SP6000 and Volumed *µ*VP7000 - Safety alarm (main PCB)

Company: _____ Address: _____

Name: _____ PC/City: _____

Country: _____

Herewith I confirm that I have received, read and understood this field safety notice and that I will follow the recommendation of Arcomed AG as soon as possible.

Place:_____ Date: _____ Company stamp and Signature:_____

Please return as letter, scan to email or facsimile