

Concern: .Syramed μ SP6000 and Volumed μ VP7000

- Safety alarm (acoustic and display)

- Time & date display

Problem description

Arcomed AG has been informed that in some rare cases the Syramed μ SP6000 and Volumed μ VP7000 would signal a safety alarm. During the alarm the devices stop the infusion until restarted by the user. Some reports indicate that on some pumps the display of the time and date was not correct. This is only an informative display and has no influence on the function of the pump.

Background

The Syramed μ SP6000 and Volumed μ VP7000 have a very strict and advanced safety monitoring system. Any discrepancy detected during the internal safety checks will signal the users with a safety alarm to prevent any risks for the patient.

These safety alarms can occur statistically once or twice in a lifetime of a pump. Pumps can be powered down and will continue to work without any need for repair if these alarms are not persistent.

Some of these rare alarms were triggered by an internal display check depending on the display options and operation state of the pumps. Customers with very large pumps pools might notice these alarms due to the large amount of devices in operation. Most customers however will not notice these alarms due to the very low occurrence.

The latest software releases 6.1006 implements an intelligent algorithm that reduces alarms to the greatest extent possible to reduce the occurrence of these rare safety alarms.

The time and date display is retrieved from a real time clock chip which is backed up by a lithium battery. If the voltage of the lithium battery is out of range, the date and time is not correctly displayed. This is only an informative display and has no influence on the function of the pump. This can be solved by replacing the lithium battery. On some batches of PCB's a diode with a slightly higher reverse current can cause a shorten time until the battery has to be replaced. Arcomed AG has developed an update that can be fitted with the battery to improve the replacement time.

Solution and Actions:

The occurrence of the alarm with code 0, 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 and visual alarm and can by switching the pump off and on restart and continue the infusion. However, we recommend the following procedure in the sense of a high availability.

If you notice the display of safety alarms (continuous audible alarm), check the status and help windows as indicated in the user manual. If these alarms have the code 0 it is recommended to update your device to the latest software release as soon as possible. This concerns pumps with software releases prior to 6.1005 or earlier. The update can also be performed easily with the Arcomed AG update stations as a preventive measure. Software updates are done by staff that is trained to perform these updates.

It is recommended to keep your pumps up to date and perform this update during the periodic preventive maintenance.

Field Safety Notice

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Date: 29.12.2017

On pumps displaying time and date wrong replace the lithium battery as indicated in the maintenance manuals. Note: small time differences can be updated by resetting the time with an update station. On pumps with serial numbers xxxx1506 or later (main PCB with super capacitor near to the lithium battery) use the update for the lithium battery. Pumps delivered after 11.11.2017 do not need to be updated. The battery update can be ordered with the number 73135 and installed by your technical support in the lithium battery holder.

After the updates check the correct software release and time and date display. The checks for the periodic preventive maintenance do not have to be repeated for this update. Always handle the pumps with great care and follow the instructions of the user and maintenance manuals.

Note: The software update will not eliminate all safety alarms. Proceed as indicated in the maintenance manuals when alarms are displayed after the update.

If you need assistance for the software and lithium battery 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.

Field Safety Notice

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Date: 29.12.2017

Contact reference person:

Harald Hofpeter
Quality Management
Arcomed AG,
Althardstrasse 150
CH-8105 Regensdorf
e-mail: info@arcomed.com

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

Harald Hofpeter
Quality Management

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Important Information

Concern: Syramed μ SP6000 and Volumed μ VP7000 - Safety alarm displays and time & date display

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: _____