Field Safety Notice

Affected Devices   **Syramed μSP6000 Chroma Hyperbaric with Battery**

Volumed μVP7000 Chroma Hyperbaric with Battery

Concerns: **Pressure sensor of battery charging circuit**

Problem description

Arcomed AG has been noted that the first batch of pressure sensors would not reliably sense the pressure increase.

Background

The circuit called 'PressureGPIO' was developed as an additional security for hyperbaric pumps with batteries.

The Arcomed AG hyperbaric pumps have multiple security measures to prevent any overheating of the batteries when charging the batteries:

- The pump software supervises the charge of the battery. Once the battery is fully charged, the charging is interrupted to prevent overcharging the battery.
- The power supply of the hyperbaric pumps is specified to 12 VDC. Once the battery reaches full charge, the voltage increases also to 12 VDC, hence the battery current will also be reduced to 0 mA, even if the supervision of the charging (above) should not stop the charging.
- The charging current is limited by a charging resistor.
- A fuse is installed on the PCB that would stop the charge in case of excessive currents.
- A thermos-switch is installed in the battery packs. In case of excessive heat, the charging would be interrupted.
- Each battery cell is equipped with a pressure limiting valve to avoid any risk of damage of the battery cells in case of overheating.
- The battery type was chosen to be NiMeH which are extremely robust battery cells. These batteries have no known effects to overheat or even ignite such as LiPo cells. Over two decades of use of these batteries no reports have been sent to Arcomed AG of problems during charging.
- The specified range of use of the hyperbaric pumps is limited to 4 ATA. The batteries are specified to withstand up to 20 ATA (pressure limiting valve).
- In most clinically used hyperbaric chambers patients use oxygen masks, hence the oxygen level in the chamber itself is not particularly high.

As an additional precaution the hyperbaric pumps feature a sensor (PressureGPIO) to measure the ambient pressure and stop the charging when a hyperbaric environment is detected.

A hyperbaric chamber is pressurized, hence the ambient pressure increases. If the pressure sensor detects a pressure increase of approximately 0.1 bar, the supervision in the pump will also stop the charging as an additional measure.

However, the circuit does not function as intended: it reacts on relative pressure changes instead of an absolute pressure change of 0.1bar.

Risk considerations:

The implemented measures to prevent overheating will guarantee that the pumps can be operated safely in a hyperbaric environment, even if additional safety of the PressureGPIO will not disable the charging.

If the pumps are only used in battery mode in the hyperbaric chamber, it is recommended to upgrade the PressureGPIO during the next preventive service.

If the pumps are used with 12V power supply in the pressurized chamber, it is recommended to upgrade the pumps as soon as possible.

Please note: Hyperbaric pumps without battery are not affected by this upgrade.

Solution and Actions:

Arcomed AG has developed a new version of the PressureGPIO that measures an absolute pressure change of 0.1Bar and stops charging if that limit is reached.

Replacement:

The PressureGPIO printed circuit board is connected via a 10-pin flat ribbon cable with the main PCB. It can be easily replaced:

- Open the pump by removing the two screws in the clamp at the back of the pump. Make sure the pump is disconnected from mains power supply.
- If the sealing tape is installed between the two housings, remove it.
- Disconnect the flat ribbon cable from the PressureGPIO and remove the PressureGPIO PCB (mounted with double sided tape). Clean off the double-sided tape from the housing.
- Connect the replacement PressureGPIO PCB to the flat ribbon cable and place and fixate it with the double-sided tape in the same place.
- Put the housing together and secure it with the two screws in the clamp.
- Reinstall the sealing tape if it was installed previously.

Testing:

To test the operation of the PressureGPIO put the pump into the test mode:

- Startup the setup mode, set address 98 = 65
- Switch off the pump completely, switch on the pump.
- Connect the 230V power supply to the pump (outside of the hyperbaric chamber).

-> The reading in the DATA window should be around 850 (at sea level, lower at higher altitudes)

If the test is positive, set back address 98 = 1 in the setup mode.

Concerned devices:

Syramed µSP6000 Chroma HYP with battery: Art. No. 6T-HYBA-01 + 6T-HYBA-W-BA
Volumed µVP7000 Chroma HYP with battery: Art. No. 7T-HYBA-01 + 7T-HYBA-W-BA

The PressureGPIO can be ordered free of charge: Parts number 67150.

Contact reference person:

████████

Quality Management Representative
Arcomed AG,
Steinackerstrasse 29
CH-8302 Kloten
e-mail: qm@arcomed.com
fax +41 43 388 90 40

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

████████

Quality Management Representative

✂--

Important Information

Concerns: Syramed and Volumed Chroma Hyperbaric pumps with batteries

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.

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

Please return as letter, scan to email or facsimile.