arcomed ag Medical Systems	**Field Safety Notice** FSCA identifier: CH20200601_AIL_PP Date: 01.06.2020

Affected Devices Volumed µVP7000 with PP lines

Concern: Air in Line Detection

Problem description

Arcomed AG has been informed that in some rare cases und under particular conditions (cold devices with high residual sensor transmission) the Volumed µVP7000 would not consistently detect air in line when using PP (polypropylene) lines.

Background

The air in line detection of the Volumed µVP7000 has been proven to be very reliable and Arcomed AG has to date no reports or indications from clinical applications that air bubbles have not been correctly detected. The sensing system is based on a piezoelectric recognition of air bubbles in fluids used successfully over decades also by similar infusion devices. The air in line detector is continuously tested internally for correct function.
The inconsistent air bubble detection was observed during tests that were performed at an initial checkup of devices in a bioengineering lab with PP lines.

The concerned devices were returned to Arcomed AG and investigations showed that a combination of particular conditions could lead to the reported effect:

- The devices are cold and the tests were performed immediately after starting the devices.
- PP lines were used and air bubbles were introduced right at the beginning of the test.
- The sensitivity of the sensors were within limits but had higher transmission signals.

Arcomed AG could only reproduce these effects by cooling down the devices to temperatures well below normal operating temperatures immediately after startup.

- Under standard conditions (>22°C) also the devices with higher transmission signals would consistently detect air in line. Cold devices rapidly warm up when used on mains or when connected to the UniqueDoc docking station and the effect could not be further reproduced.
- Devices that reach their normal operating temperature would consistently detect air in line even with cooled fluids.
- The effect could only be reproduced with PP lines. It was found that PP lines show a higher residual transmission of the signal when cooled down significantly by inserting it into a cold device.
- The same tests were performed with PVC and silicone lines and showed consistent air in line detection.

Risk considerations:

The occurrence of this effect of inconsistent air in line detection could only be reproduced under particular conditions (cold devices) and with PP lines. Once the devices operated on mains reached normal operating temperature or if operated under standard temperature conditions the effect could not be reproduced. Arcomed AG has no reports of inconsistent air in line detection in clinical environments. Each pump is checked for correct air in line detection during production prior to

delivery and this check is repeated during the PPM (periodic preventive maintenance), this however under standard temperature conditions. An internal check also supervises the correct function of the sensor.

Nevertheless it can't be excluded that a poor priming of the line combined with a device taken from a cold room or being used in a very cold environment shows the described effect. Air in line in larger quantities **can lead to air embolism**.

Important: Most customers request lower sensitivity of the air in line detection to avoid nuisance alarms. Typically the limit for individual air bubbles is set to 200 – 300 µl. Hence it is normal that smaller bubbles of the length of 3 – 5 cm will pass without an alarm depending on the settings.

Solution and Actions:
Arcomed AG has developed two solutions:

- An attenuation foil that reduces the signal for PP lines. This attenuation foil can be easily applied on the piezoelectric plate on the door. This solution however is limited on the range of temperatures and increases the sensitivity of the air in line alarm.
- An upgrade of the software combined with a modification on the display PCB that enables an additional check of the air in line signals for this particular case of cold devices and PP lines.

Based on the results of the investigations Arcomed AG therefore recommends:

- Make sure lines are always correctly primed, bags properly handled, the venting is correctly set and the VTBI (volume to be infused) is adjusted according the volume in the bag.
- If you are using PVC or silicone lines, *no further actions are required*.
- If the devices with PP lines are operated exclusively in docking stations connected to mains power supply at normal temperatures (> 22°C) *no further actions are required*. The attenuation foils can be applied if temperatures may vary or pumps are sometimes taken out of a cold room prior to startup.
- If pumps with PP lines are used in colder environments (< 22°C), apply the attenuation foils or use for these particular cases PVC lines instead of PP lines until the upgrade of the software combined with the update of the display PCB is applied.
- If you are already a customer of PP lines it is recommended to upgrade the pumps during the next PPM. If colder environments are involved, contact Arcomed AG for an earlier update (see below for revision and ordering numbers).
- If you are planning to switch to PP lines contact Arcomed AG to check what needs to be ordered to upgrade the pumps.

The attenuation foil can be ordered at Arcomed AG and applied according to Arcomed AG instructions. The upgrade of the software and display PCB is carried out by specially trained personnel.

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:

Volumed µVP7000: All devices (Chroma & Premium) used with PP lines delivered prior to June 2020*.

***Arcomed AG will apply the update on all pumps ordered with PP lines starting June 2020.**

The attenuation foil can be ordered free of charge: Parts number 75099.
The update is SW release is 6.1013, HW release 2.13 (both must be installed)

Contact reference person:

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

Stefan Appel
Quality Management Representative

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Important Information

Concern: Volumed *µ*VP7000 (Chroma & Premium) – Air in Line Detection with PP lines

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 Signature:_____

Place:_____ Date: _____

Please return as letter, scan to email or facsimile