

Concern: Syramed μ SP6000 and Volumed μ VP7000 Special TCI Protocol Greenblatt Midazolam

Problem description

Arcomed AG has been informed in case that the TCI protocol Greenblatt Midazolam has been used in combination with other TCI protocols the output rate might be too low. However the probability is very low as only under special condition this can occur. To the knowledge of Arcomed AG only two customers are known to have installed that particular protocol. Both customers are already informed. This is a preventive information in case the protocol will be installed later at customer site.

Conditions for the problem to occur

1. The pump has to be equipped with the TCI option
2. The pump has to be ordered or configured by Arcomed AG technician with the TCI Greenblatt Midazolam protocol in addition to other TCI protocols.
Note: The protocol can not be installed by the users, an external configuration software and configuration hardware is needed.
3. TCI Greenblatt Midazolam has to be used.
4. TCI Greenblatt Midazolam has to be used in combination with other TCI protocols on the same device.

Only if all above listed conditions are met simultaneously the problem might occur.

Problem occurrence

The problem has been identified as follows:

When the TCI protocol Greenblatt Midazolam is used the rate is correct. However if the next TCI infusion is performed with another TCI protocol the rate might be calculated too low.

Workaround

After ending a TCI Greenblatt Midazolam infusion switch the pump completely off. If the pump was used on battery, this will be completed automatically and no actions are needed. If the pump was used on mains or in a docking with an active unique concept box, disconnect the pump from mains and the docking and wait for one minute until the pump is completely powered down. After a complete power cycle the following TCI infusions are correct.

Concerned pumps: Syramed μ SP6000 and Volumed μ VP7000 pumps with TCI Greenblatt Midazolam configured, SW releases 4.1020 - 6.1001.

Actions

No action is needed under the following conditions:

- If your pump has been configured with the standard TCI protocols without TCI Greenblatt Midazolam, no action is needed.
- If your pump has been configured with the special TCI Greenblatt Midazolam protocol only no action is needed. Note: Standard ml/h, drug dose calculation or PCA modes are no problem in combination with TCI Midazolam.

A software update to release 6.1002 or later is necessary

- If your pump has been configured with the special TCI Greenblatt Midazolam protocol **and** other TCI protocols use the workaround above and update you pump as soon as possible to the SW release 6.1002 or later.

Please contact Arcomed AG for SW updates.

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

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Important Information

Concern: TCI Greenblatt Midazolam

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: _____