Urgent safety information
Medication order

mesalvo
real-life applications

Manufacturer

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Addressee:
All customers with a major release version from 2024.07 are affected

Identification of the medical devices concerned:
MEONA Release V

Description of the problem including the identified cause:

As part of our internal quality assurance activities, we have become aware of a case that involves the following display behaviour:

The basic prerequisite for this behaviour to occur is that the profile option 'SHOW_ADDITIONAL_UNIT_PUMP' is set to TRUE in affected areas.

If a pain pump with a parenteral analgesic is used via the medication order and dosed at a basal rate that is to be calculated on a weight basis, the patient's curve will display incorrectly.

In addition to the correct basal rate, a supposed maximum run-rate limit of 24 or a multiple thereof (coming from the 24-hour calculation) and the corresponding dosing equivalent is now also displayed, suggesting to the user that this is a prescription with a run-rate range.

The further display of the run rate after the documentation of the start of the pain pump is not affected and the curve view then also shows the correct behaviour again.

What actions are to be taken by the addressee?

We ask all affected customers to set the profile option 'SHOW_ADDITIONAL_UNIT_PUMP' to FALSE until a corresponding solution can be provided to you via a service pack.
Please contact our support team if you notice any anomalies.

Passing on the information described here:

Please ensure in your organisation that all users of the above-mentioned products and other persons to be informed are aware of this Urgent Safety Information. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person specified below.
Please keep this information at least until the action has been completed.

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The Federal Institute for Drugs and Medical Devices has received a copy of this 'Urgent Safety Information'.

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Unterschrift

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