tricumed
Medizintechnik GmbH

Field Safety Notice

Product name	Programmer for implantable infusion pump Siromedes®
Reference No.	Intern No. 100D103 BfArM – No. 01945/20 and 22826/20
Type of measure	Software update of all programming devices to version 3.06b

Date: 2020/02/19

Address data: all users

Description

This information is provided to ensure the correct use of the date for refilling an implanted Siromedes® infusion pump.

After reading the current pump status from an implanted infusion pump, the programming device shows, among other things, the date for the next refill.
The program calculates this date from the current fill level of the pump, the set flow rate and the current date of the programming device.

When calling up a data record stored in the programming device (function "Load data record" in the main menu), the programming device displays an incorrect date for the next refilling.For the calculation of the date, the program does not use the date of the saved data record but the current date of the programming device. This then leads to an incorrect date for the refill appointment.

To eliminate the error, the software must be updated to version 3.06b.

[redacted]

This safety information applies to programming devices with the following REF numbers.

Description	REF	SW Version
Programming device for the Siromedes® implantable infusion pump	210V0000020W0	All versions < 3.06b

Potential clinical effects

When using an appointment for refilling from a loaded data record, it can happen that patients are called in too late for refilling and thus the pump can run dry and the patient is withdrawn from the medication.
If the correct refilling date has been transferred from the programming device immediately after the filling process, there is no risk of the infusion pump running empty prematurely and the patient being withdrawn from the medication when using this date documented in the patient passport and in the patient file for refilling.

Recommended action

Until your programming device has been updated, we recommend that you generally refrain from calling up stored data records in the programming device.
As the date for the refilling, please only use the date determined on the day of refilling and documented in the patient passport and in the patient file.
This can be checked at any time based on the data of the last filling (date, filled amount of medication and flow rate).

Implementation of the update process

To carry out the update to version 3.06b, a Tricumed employee will contact you and replace the programming device in your house with a replacement device for the period of the update.
After the update, you will receive your programming device with the current software version 3.06b in exchange for the replacement device.

[redacted]

tricumed
Medizintechnik GmbH

More resources

We are committed to answering your questions.
You can obtain further information from your Tricumed employee or sales partner.
Patient safety is the highest priority for Tricumed Medizintechnik GmbH.
We appreciate your assistance in this matter and apologize for any inconvenience this may cause you.

Forwarding the security information

Please ensure in your facility that all users of the programming device for the Siromedes® implantable infusion pump are made aware of this safety information.
Please also inform all persons who fill pumps and other groups of people who are treating patients with Siromedes® pumps.
If you have given the products to third parties, please forward a copy of this information.

With best regards

[redacted]

[redacted]

tricumed
Medizintechnik GmbH

Confirmation of acknowledgment of the safety information

Reference No. 100DO103

BfArM – No. 01945/20 and 22826/20

I hereby confirm that I have received the safety information in connection with the programming device for the Siromedes® implantable infusion pump.

Date: _____

Name (Pamphlet): _____

Signature: _____

Hospital name: _____

City, country: _____

Please return the completed and signed confirmation form to your local Tricumed representative or fax it to:
Tricumed Medizintechnik GmbH, Kiel: *+49 431 70 99 099*

[redacted]