

Medset Medizintechnik GmbH
Carsten Florian
Safety Officer Medical Devices
Curslacke Neuer Deich 66
D-21029 Hamburg

Urgent safety information

LiveECG Driver Update

concerning

PADSY-Holter with the Holter-ECG Systems Sirius and Antares with LiveECG Recorder

25.3.2019

Sender:

Medset Medizintechnik GmbH
Carsten Florian, Safety Officer Medical Devices
Curslacke Neuer Deich 66
D-21029 Hamburg

Addressee:

PADSY-Holter operators who use more than one LiveECG recorder or want to use several LiveECG recorders in the future.

Speciality retailers who have sold their customers PADSY-Holter with LiveECG recorders

Identification of the affected medical devices:

PADSY-Holter long-term ECG system Sirius or Antares together with the LiveECG recorder

Description of the problem including the identified cause:

- *If, during the reading process of a LiveECG long-term ECG recorder, the reading process is interrupted by opening the locking flap on the reader, the previous patient is displayed when a new LiveECG recorder is directly inserted.*
- *The previous patient's display may cause the recording in the recorder to be assigned to this previous patient instead of the actual one. Confusing the long-term ECG data can lead to the wrong treatment of the patient.*
- *This is a FSCA (Field Safety Corrective Action) message, there are no known occurrences of a recording confusion. This message is meant to prevent future patient confusion.*
- *An incorrect or, in the reverse case, no medication could cause significant damage to the patient.*

What measures should be taken by the addressee?

- *A new software driver is being developed that will fix this problem. In the meantime, unless this driver is already installed in your computer, you should definitely not interrupt the reading process of the LiveECG Recorder and complete it.*
- *By adhering to this measure, patient risk **can be excluded**.*
- *Do not interrupt the reading process, neither by pressing the cancel button nor by opening the locking flap!*
- *The development of the new driver for reading the LiveECG Recorder will take about 4-6 weeks. You will be informed immediately after completion. You will receive the new driver with an installation instruction.*

Distribution of the information described here by resellers

Please make sure in your organization that all users of the a.m. products and other persons to be informed receive this Urgent Safety Information. If you have given the products to third parties, please forward a copy of this information to these persons or inform the contact person listed below.

Please send us a list of your affected customers!

Please retain this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this "Urgent Safety Information".

Contact person:

Carsten Florian

Safety Officer of Medset Medizintechnik GmbH

E-Mail: C.Florian@medset.com

Phone: +49-(0)40-725822-25

Fax: +49-(0)40-725822-11

Mobile: +49-(0)172-9693953

