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PIERENKEMPER GmbH

Urgent safety information

Software-Update

concerning

StimaWELL® 120MTRS (Art.-Nr. 200199-G)

Ehringshausen, April 5th, 2016

Sender:

Pierenkemper GmbH
Am Geiersberg 6
35630 Ehringshausen
Germany

Addressee:

Distributors of the medical device StimaWELL® 120MTRS (Art.-Nr. 200199-G)

Identification of concerning medical products:

- StimaWELL® 120MTRS Series A (Item No. 200199-G) serial number 001000 to 001250
- StimaWELL® 120MTRS Series B (Item No. 200199-G) serial number 002000 to 002177

Description of the problem including the determined cause:

During operation of the product StimaWELL® 120MTRS overheating of the skin in the lower back was found in a case of a patient. As a result of thermal overheating, there was an approximately 2 cm square skin damage.
The cause of the high temperature was a contact of the patient with a part of the stimulation base of the StimaWELL® stimulation mat, that was not meant for skin contact. The contact with this part of the base of the StimaWELL® stimulation mat was possible because the patient had large skin folds, which were pressed between the individual electrode pads of the base. Removing the heat through the interstices of the electrode pads was due to the constitution of the patient no longer possible.
Since it is not excluded that there may be a similar unfavorable contact location in obese patients, we decided to reduce the maximum temperature of StimaWELL® stimulation mat by a software update, to avoid further cases. The software update results in a thermal reduction of total StimaWELL® stimulation mat and hence also the removal of the "hot spots" in the area not meant for skin contact.

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AMTSGERICHT WETZLAR
HRB 734

GESCHÄFTSFÜHRUNG
Waltraud Pierenkemper

By installing this software update the risk of overheating due to unfavorable patient positioning can be virtually ruled out.

Furthermore, the application product safety information has been added to the following points:

- Particular attention must be paid to the central positioning of the patient on the stimulation mat. The spinous process must be placed in the vertical mat cleft.
- For safety reasons, application with the StimaWELL® should be carried out under repeated monitoring of patient and device.
- Pay particular attention when treating patients with sensory disturbances or sensory loss in the application area.
- Moisten the whole underlay well and evenly with water prior to the treatment to ensure sufficient and constant current flow.

What measures should be taken by the addressee?

In order to avoid the repetition of above described case, please perform a software update to our software version 2.8 respectively 3.4, now available.
The instruction to perform the software update can be found in the operating manual in chapter "Software Update".
Until the software update it is necessary to ensure that during the treatment of patients there will be no skin contact with the interstices of the base of the StimaWELL® stimulation base and that removal of heat is possible.

Forwarding of the described information:

Please make sure that in your organization all users and any person concerned with above mentioned products are aware of this Field Safety Notice. If you have passed the products to third parties, please forward a copy of this information or inform the below mentioned contact person.

Please keep 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:

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