HOMOTH
Homoth Medizinelektronik GmbH & Co. KG
Leibnizstr. 13-15
24568 Kaltenkirchen

Urgent safety information

Conversion (exchange power supply)

concerning

Air Calorisator

15th November 2019

Dear Sir or Madam,

As a part of our repair evaluation, Homoth Medizinelektronik has detected that, due to a possible production error, the medical devices listed below (2012 to present year, blue LC displays) may not match with the relevant safety standard (DIN EN ISO 60601-1) in regards to fault safety. Potentially it is possible that an unfavorable defect of a component (short circuit of the circuit breaker to control the heating coil) may causes impermissible temperatures of the air flow and / or the handpiece.

To our current knowledge the protective circuit designed for this case is not fully functional in all devices due to a faulty production. This event can lead to impermissible temperatures (> +51° C) with permanent activation of the heating coil.

A potential danger exists that the user (contact with probe housing / handpiece too hot) or the patient (contact with excessively hot airflow) may is damaged if the circuit breaker fails in the manner described above. Due to measure regarding hardware component (exchange of power supply against new power supply with attached protective circuit) a risk for user / patient is effectively avoided in the event described above.

Identification of the affected medical devices:

Affected air calorisator produced from 2012 up today (with blue LC display).

Action taken by the addressee

• After switching on the device and before treatment of patient, the user must check the actual temperature display. The value range must be within the preselected setpoints. Temperatures above 50 ° C are to be regarded as errors, the device must be switched off immediately and disconnected from the power supply. The customer service of Homoth Medizinelektronik GmbH & Co.KG must be informed immediately.

• Please check before treatment of the patient, if the pump is active (The pump causes a weak audible noise)

• Carefully check the temperature of the handpiece (there must be no relevant noticeable heating detectable)

• After activating the warm or cold stimulus, the device emits an acoustic signal. Please check the temperature of the airflow, e.g. by hand before starting the irritation on the patient (distance hand to handpiece: approx. 5 cm).

• In case of any odor development, the device must be switched off immediately and disconnected from the power supply. Do not put the device back into operation. The customer service of the company Homoth Medizinelektronik GmbH & Co.KG must be informed immediately.

• The service technicians of the company Homoth Medizinelektronik GmbH & Co.KG will get in contact with you and coordinate the further procedure (coordination of the installation / replacement of the power supply). In a concrete handling instruction all necessary steps are described in detail. The exchange will start approx. From week 48/2019.

• Place the old power supply unit into the box of the delivery, we will then have the package collected by UPS Retriever.

Passing of this information described here:

Please make sure in your organization that all users of the a.m. Products and other related persons have been informed of this "Urgent safety information". If you have given the products to third parties, please forward a copy of this information and inform the contact person listed below.

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

The Federal Institute for Drugs and Medical Devices, the competent state authority and also our notified body (MedCert Certification and Audit Company for Medical Devices) have received a copy of this "Urgent Safety Information".

Contact persons:

Fa. Homoth Medizinelektronik GmbH & Co.KG

Petra Semmelmann Phone: +49 4191-272620 / Fax: +49 4191-2726222

Jakob Hoffmann Phone: +49 4191-272620

Email: j.hoffmann@homoth.de / p.semmelmann@homoth.de

We apologize to you and your staff for any inconvenience this action may cause.

With best regards

Jakob Hoffmann

(Managing Director of Homoth Medizinelektronik GmbH & Co.KG)