Von Ardenne Institut für
Angewandte Medizinische Forschung
GmbH

Zeppelinstraße 7 · 01324 Dresden

BIOMEDIZINISCHE TECHNIK
HYPERTHERMIETECHNIK
SAUERSTOFF-MEHRSCHRITT-THERAPIE
KREBS-MEHRSCHRITT-THERAPIE

To the customers of the:
Von Ardenne Institut für
Angewandte Medizinische Forschung GmbH

Ihre Nachricht	Unser Zeichen	Durchwahl	Datum
	BMT/Günther	489	09. Apr. 2019

Urgent safety information

Safety-relevant measure, concerning IRATHERM®1000 with IRAcom® transducer

Sender / Contact person:

Manufacturer: Von Ardenne Institut für Angewandte medizinische Forschung GmbH
Zeppelinstraße 7
01324 Dresden - Germany

Security administrator: Gerrit Günther
Zeppelinstraße 2
03124 Dresden
Tel.: 0351/2637489
E-Mail: Guenther@ardenne.de

Adressat:
Users and operators of IRATHERM®1000 whole-body hyperthermia systems with IRAcom® instrument transducer.

Identification of the medical devices concerned:
All systems with serial numbers 001/01/94 to 118/12/15 are affected.

Description of the problem, including the cause identified:
During commissioning and the associated introductory seminar, users and operators of the IRATHERM®1000 whole-body hyperthermia systems with IRAcom® transducer were informed that a special infrared thermometer (hand pyrometer) with adjustable ε value (emissivity) of the skin can be used as an optional aid. This could be used in addition to the visual observation of the irradiated skin surface to determine the skin temperature. However, the said infrared thermometer (hand pyrometer) is not approved as a medical device. Therefore, further use of the infrared thermometer (hand pyrometer) is not permitted.
For patients whose skin temperature will be measured with the infrared thermometer (hand pyrometer) in the future, there is a risk that the skin temperature cannot be reliably identified, and thus thermal tissue damage can be caused.
There is no risk for patients who have already been treated with the infrared thermometer.

At this point it must be expressly pointed out again that the current operating manual is correct. In order to improve and to avoid irritations, only an addition and concretization of point 4, appendix 2 and appendix 3 is made.

What measures are to be taken by the addressee?
Since the use of the above mentioned infrared thermometer (hand pyrometer) is not permitted, we advise those users who use such an infrared thermometer (hand pyrometer) for skin temperature measurement against further use.
The monitoring of the body core temperature and the skin temperature of the IRATHERM®1000 whole-body hyperthermia systems with IRAcom® transducer is not carried out by an electronic, i.e. automatic control circuit, but exclusively by the treating therapist.
The treating therapist is provided with rectal and axillary temperature information (in °C) as well as the set thermal radiation output (in %). This temperature information and the power of the thermal radiation are recorded with the aid of the IRAcom® transducer and displayed to the therapist on a large screen.
In order to avoid thermal tissue damage, the treating therapist has to find out in a permanent conversation with the patient whether the patient feels a "burning sensation on the skin" and, if "yes", reduce the performance of the thermal radiation locally/regionally. In addition, by observing the degree of redness of the skin with the eye of the treating therapist, the local/regional stress on the skin reported by the patient can be confirmed. If the degree of redness is higher, the skin can be protected and the skin temperature reduced by using panthenol or water spray.
It should be noted that if the user instructions described in the operating instructions are followed, thermal tissue damage of a higher degree in the context of moderate whole body hyperthermia (body core temperature ≤ 40.5°C) occurs extremely rarely but cannot be excluded.

Under point 4, "Course of mild and moderate hyperthermia", the operating instructions are corrected for the prohibition of deep intravenous anaesthesia and general anaesthesia in accordance with the current "Guidelines for whole-body hyperthermia" of the German Society for Hyperthermia.

The table in Appendix 2 of the instruction manual has been graphically corrected.

The contraindications listed in Appendix 3 of the Instructions for Use have been supplemented by the terms "deep intravenous anaesthesia and general anaesthesia".

Disclosure of the information described here:
The concrete operating instructions and the FSN are made available to all users electronically. Receipt will be confirmed electronically by the user / operator. If electronic delivery is not possible, this will be done by post.
Delivery will take place by 30.04.2019.
The Federal Institute for Drugs and Medical Devices will receive a copy of this "Urgent Safety Information".

Best regards

Gerrit Günther