Urgent Safety Information

Notes on continued safe use

of the BEMER therapy system

2020-12-16

Sender:

BEMER Int. AG, Austrasse 15, 9595 Triesen, LIECHTENSTEIN

Addressee:

To all users and patients of the BEMER Classic and Pro therapy system.

Identification of the affected medical products:

The BEMER Classic and Pro therapy systems (Art. No. 410200, Art. No. 420200, Art. No. 410100, Art. No. 420100)

Description of the problem:

BEMER Int. AG has become aware of cases in which a causal link between the use of the BEMER therapy system and a technical defect in an insulin pump or a malfunction of a pacemaker (active medical implants) could not be ruled out with absolute certainty. It cannot be ruled out that the electromagnetic fields generated in the BEMER therapy system may have caused these disturbances.

For patients who wear active medical implants (e.g., pacemakers, defibrillators, brain stimulators, muscle stimulators) or implants intended for drug delivery (e.g., drug pumps), the use of the BEMER therapy system could lead to malfunctions in these devices.
On the basis of this information BEMER Int. AG has adapted the corresponding risk assessment and also the instruction manuals, and has included relative and absolute contraindications.

What measures should be taken by the addressee?

Patients who wear an active medical implant that leads to stimulation (e.g., pacemakers, defibrillators, brain stimulators, muscle stimulators) should not use the BEMER therapy system unless a specialist physician carries out a personal risk

assessment and subsequently expressly tells the patient that he/she can continue the treatment. If you are an affected patient, please stop using the BEMER therapy system immediately and consult your specialist physician. The specialist physician will then decide whether or not you can continue using the BEMER therapy system.

In the risk assessment, your specialist physician must estimate whether or not the BEMER therapy can cause possible interference at a maximum flow density of 150 µT (average flow density for total body treatment 21 µT), based on the individually set threshold values of the implant and under consideration of the distance between the applicator (coil) and the pacemaker with its electrodes.

If the specialist physician estimates that interference and therefore, operating safety, cannot be excluded, do not continue the BEMER therapy system treatment

Patients wearing active medical implants designed to deliver medication (e.g., medication pumps) have an absolute contraindication. In other words, they may no longer use the BEMER therapy system.

These contraindications must be observed by the user for future use.

Sharing this information:

If you have sold the affected products to a third party, please forward a copy of this information to them or inform the contact person listed below. Your competent national authority has received this safety information.

Contact person:

Ms. Kirsten Hübner
BEMER Int. AG
Austrasse 15
9495 Triesen
Liechtenstein

00423 399 39 70
sales@bemergroup.com

We apologize for any inconvenience and thank you for your cooperation!

Kind regards,

Sandra Schwarzenberger, MBA
QMB

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