

Urgent Safety Information***Notes on continued safe use of the BEMER therapy system*****Date****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?

In patients who wear active medical implants which have a stimulatory effect (e.g., pacemakers, defibrillators, brain stimulators, muscle stimulators) there is a relative

contraindication for the use of the BEMER therapy system, i.e. continuation of the therapy must be dependent on a risk assessment by the treating physician.

Patients wearing active medical implants designed to deliver medication (e.g., medication pumps) have an absolute contraindication, i.e. the BEMER therapy system may no longer be used.

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,

Signature

Sandra Schwarzenberger, MBA
QMB