

WEINMANN Emergency Medical Technology GmbH + Co. KG
PO Box 57 01 53 · 22770 Hamburg · GERMANY

Firma
Name
Adresszeile 1
Adresszeile 2
PLZ Ort
Land (SELEKTION: ALLE BETROFFENE GERÄTE-
KUNDEN DACH + IS, KOMMT VOM CS)

Hamburg, February 2017

Important safety notice: corrective measure to a medical device on the market

Modification of the battery pack for MEDUCORE Easy

Dear Sir or Madam,

Quality and safety are our top priority, which is why we would like to act swiftly and transparently as usual and **ask you for your support in implementing a corrective measure which will further increase the quality of the MEDUCORE Easy battery pack.**

From

WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee

Users and owner/operators of MEDUCORE Easy in combination with a battery pack; also specialist dealer partners.

Medical devices affected

Battery pack for MEDUCORE Easy (WM 40155) with serial numbers below 20000.

The rechargeable battery pack for MEDUCORE Easy (WM 40150) is **not** affected and can continue to be used without restriction!

Description of problem

In the course of our service processes, we have found that in very rare cases, the battery pack may fail.

We have received no information to date that this behavior has been observed when the product is in use.

Risk to the patient

In the fault situation described above, it would no longer be possible to administer a shock to the patient.

Remedy

We can provide you with an overhauled battery pack from Week 15/2017 onwards which will no longer display this behavior.

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Company Headquarters
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Frohbösestraße 12 • 22525 Hamburg • GERMANY
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F: +49 40 88 18 96-480
www.weinmann-emergency.com

Center for Production, Logistics, Service
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Siebenstücken 14 • 24558 Henstedt-Ulzburg
GERMANY

Business Management
Dipl.-Volksw. Marc Griefahn
Dipl.-Kfm. Philipp Schroeder
Dipl.-Volksw. André Schulte

Registration Court
Hamburg Municipal Court
Dept. A # 115967
V.A.T. # DE288367727
WEEE Reg. # DE 47913245

Creditor ID
DE35ZZZ00000353971

General Partner
WEINMANN Emergency
Management GmbH, Hamburg

Registration Court
Hamburg Municipal Court
Dept. B # 38144

Certified QM System meeting
EC directive 93/42/EEC, Annex II
(EN ISO 9001/EN ISO 13485)

Banking Connections

Deutsche Bank AG Hamburg
IBAN DE87 2007 0000 0646 9639 00
SWIFT DEUTDEHH

Hamburger Sparkasse AG
IBAN DE44 2005 0550 1032 2626 67
SWIFT HASPDEHHXXX

Commerzbank AG Hamburg
IBAN DE14 2004 0000 0632 0071 00
SWIFT COBADEHHXXX

As an owner/operator, user, or specialist dealer, this is what you must do now:

- We recommend that you replace battery packs with serial numbers below 20000 with a new battery pack.
- Please ensure that you carry an alternative replacement device when on professional duty (emergency service) until you receive a replacement battery pack.
- If the device displays the fault described above when you are on duty, continue first-aid measures in line with ERC Guideline 2015.
- We will replace battery packs with serial numbers 15148 to 19999 free of charge. To do this, please send us the relevant proof of purchase with the serial number of the battery pack.
- We will replace older battery packs with serial numbers 10756 to 15147 at a discounted price. To enable us to issue a quotation at a discounted price, please send us the relevant proof of purchase with the serial number of the battery pack.
- Once the old battery pack has been replaced, please make sure it is disposed of properly via local recycling facilities. We do not need the affected battery pack back.
- Within your organization, please ensure that this **safety information** is brought to the attention of all users of the MEDUCORE Easy (where it is operated with a battery pack and **not** with a rechargeable battery pack) and of other people who need to be informed. If you have passed these products on to third parties, **please forward a copy of this information on to them.**
- Please use the attached reply form **to confirm receipt of this letter and that it has been passed on.**

As a specialist dealer you must now also:

- If you have passed the above-mentioned products on to third parties, **please also forward a copy of this information on to your customers.**

Contact

If you have any questions, please contact your local specialist dealer or ourselves directly. We will be happy to answer any questions you may have. If required, please contact our Customer Service, telephone: +49 40 88 18 96 - 120, e-mail: CustomerService@weinmann-emt.de

Yours faithfully,

for WEINMANN Emergency
Medical Technology GmbH + Co. KG

Organizational information

Please note: WEINMANN Emergency Medical Technology GmbH + Co. KG is the legal successor of the Emergency business unit of WEINMANN Geräte für Medizin GmbH + Co. KG, which originally launched the devices on the market. WEINMANN Emergency has retained all the customers' addresses and delivery territories of the Emergency business unit in order for this "safety information" to be addressed to all users of MEDUCORE Easy.

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Report to WEINMANN Emergency

on safety information "Battery pack for MEDUCORE Easy" dated February, 2017

Original letter sent to:

ADRESSATENFELD wie auf Seite 1 des Anschreibens einfügen

Firma

Name

Anschrift

PLZ Ort

LAND

Please complete this reply form in full and send it by fax, e-mail or post to:

Fax: +49 40 88 18 96 - 25492

e-mail: vigilance@weinmann-emt.de

WEINMANN Emergency Medical Technology GmbH + Co. KG

Safety Officer for Medical Devices

Frohbösestraße 12

22525 Hamburg, Germany

GERMANY

Please complete in full in block capitals:

Company details are identical to those of the addressee above.

Company details differ from those of the addressee above as follows:

Your customer no.:

Company + address:

I hereby confirm receipt of this letter and that I have read and understood its contents. This letter has been brought to the attention of all users of the product and other people in my organization who need to be informed.

If the products have been passed on to third parties (applies to specialist dealers, for example), a copy of this information has been passed on to them.

Date, signature

Name (in block capitals)

Position (in block capitals)

e-mail (in block capitals)