Löwenstein Medical Technology • Postfach 54 02 68 • 22502 Hamburg • Germany

«Name»
«Kontaktperson»
«Straße»
«PLZ» «Ort»
«Land»

Hamburg, Monday, July 30, 2018

Important safety notice
Field service corrective action on power supply units for the sleep therapy devices SOMNObalance, SOMNOsoft 2, prisma SOFT and prisma SMART

Dear Sir or Madam,
Quality and safety are our highest priority, which is why we consider it important to implement the following corrective action linked to the potential risk due to overheating of external power supply units of the sleep therapy devices SOMNObalance, SOMNOsoft 2, prisma SOFT and prisma SMART.

From
Löwenstein Medical Technology GmbH + Co. KG

Addressee
Users and operators of sleep therapy devices of the type SOMNObalance, SOMNOsoft 2, prisma SOFT and prisma SMART.

Identification of the medical devices affected
SOMNObalance, SOMNObalance e
Article numbers: WM27410, WM27410HL0, WM27410CN0, WM29707
Serial numbers affected: See list of serial numbers attached.
Power supply units: WM 24480 with serial numbers: See list attached.

SOMNOsoft 2, SOMNOsoft2 e
Article numbers: WM29810HL0, WM29880
Serial numbers affected: See list of serial numbers attached.
Power supply units: WM 24480 with serial numbers: See list attached.

prisma SOFT
Article numbers: WM31630-1110, WM31631-1110, WM31631HL-4110, WM31630HL-4110
Serial numbers affected: See list of serial numbers attached.
Power supply units: WM 24480 with serial numbers: See list attached.

Prisma SMART:
Article numbers: WM31600-1110, WM31601-1110, WM31601HL-4110, WM31600HL-4110
Serial numbers affected: See list of serial numbers attached.
Power supply units: WM 24480 with serial numbers: See list attached.

Löwenstein Medical Technology GmbH + Co. KG
Kronsaalsweg 40 • 22525 Hamburg • Germany
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info@loewensteinmedical.de
www.loewensteinmedical.de
Receiving Department
Doerriesweg 3 • 22525 Hamburg • Germany

Registration Court
Hamburg Municipal Court
Dept. A, # 67 698
Excise Tax ID DE 118051598
Certified QM System meeting EC directive 93/42/EWG, Annex II (EN ISO 13485 / EN ISO 9001)

General Partner
Löwenstein Medical Technology Verwaltungs GmbH, Hamburg
Registration Court
Hamburg Municipal Court
Dept. B, # 8678
Creditor ID
DE25ZZZ00000353957

Business Management
Benjamin Löwenstein
Sascha Löwenstein

Banking Connection
Deutsche Bank AG Hamburg
BIC DEUTDEHH
IBAN DE61200700000640305900
Commerzbank AG Hamburg
BIC DRESDEFF200
IBAN DE68200800000507338800

Description of the problem including the cause identified
Routine quality testing on our products discovered that particular batches of external power supply units with article number WM 24480 overheat, leading to a potential risk to patients or users.
Following extensive analysis, we discovered that the manufacturer of the power supply unit had used defective components in production; in certain load ranges, these components exhibited excessive power loss, leading to the power supply units overheating.
It was possible to achieve overheating under certain trial conditions. No overheating during use of the devices in sleep therapy has been observed to date.

What measures should be taken by the addressee?
Under certain circumstances, power supply units WM 24480 from the batches mentioned may get too hot and present a risk to patients and users. Please inform your staff and affected customers accordingly about the potential risk from excessive temperature.

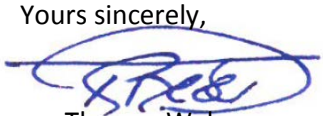
Measure for customers / operators
Check items in stock and quarantine affected power supply units. You may continue using power supply units not listed in this letter. The sleep therapy devices mentioned do not have faults and can likewise continue to be used once the power supply unit has been replaced.
Löwenstein Medical Technology GmbH + Co. KG will provide you with new power supply units in time for you to replace them without you needing to request them.
After you have received the new power supply units, use them to replace those already supplied to patients. Return the replaced power supply units from the affected lot to Löwenstein Medical Technology GmbH + Co. KG.

Acknowledgment
Please use the attached reply form to confirm receipt of this letter/that it has been forwarded.

Passing on the information given here
Please ensure that this safety information is brought to the attention of all users of the above-mentioned products and other people to be informed in your organization. If you have passed these products on to third parties, please forward a copy of this information on to them or inform the point of contact given below.

This measure will be reported to the relevant authority and the course of action agreed on.
Löwenstein Medical Technology GmbH + Co. KG apologizes for the inconvenience and disruption to your operational processes.

Yours sincerely,



pp. Thomas Weber
Director Quality Management and Regulatory Affairs

REPLY

To the safety notice “Field service corrective action on power supply units for the sleep therapy devices SOMNObalance, SOMNOsoft 2, prisma SOFT and prisma SMART”

Original letter sent to:

«Name»
«Kontaktperson»
«Straße»
«PLZ» «Ort»
«Land»

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

Fax: **+49 40 547 02-476**

e-mail: customerservice@loewensteinmedical.de

Löwenstein Medical Technology GmbH + Co. KG
Safety Officer for Medical Devices
Kronsaalsweg 40
22525 Hamburg, Germany
Germany

Please complete in full in block capitals:

☐ **Company details are identical to the above address field**

☐ **Company details are different from the above address field. The company details are as follows:**

Your customer number: _____

Company + address: _____

_____

_____

☒ **I hereby confirm receipt of this safety information** 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 have to be informed**.

Where we have passed on these products to third parties, a **copy of this letter has been forwarded to them.**

_____ _____

Name (in capitals) **Date, signature**

_____

Position