

[HOFFRICHTER GmbH, Mettenheimer Straße 12/14, 19061 Schwerin, Germany](http://www.hoffrichter.de)

To all customers and partners

HOFFRICHTER GmbH
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Germany

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URL: www.hoffrichter.de

Schwerin, 13 May 2015

Urgent Field Safety Notice

Replacement of power cords of HOFFRICHTER GmbH respiratory therapy devices TREND II, point and VECTOR et

Our Reference: 1503_01

Sender:

HOFFRICHTER GmbH
Mettenheimer Str. 12/14
19061 Schwerin
GERMANY

Recipient:

This Field Safety Notice (Field Safety Corrective Action, FSCA) is addressed to users, operators and distributors of HOFFRICHTER respiratory therapy devices TREND II, point und VECTOR et.

Identification of the affected medical devices:

The HOFFRICHTER GmbH respiratory therapy devices TREND II, point and VECTOR et which were manufactured and sold from January 2007 until December 2013 and include a power cord with a two-piece device socket manufactured by SELF MAN or Yung Li (see embossing).

The power cord has the HOFFRICHTER GmbH item number 31100015.

Please find attached a list of all medical devices you have received from HOFFRICHTER GmbH according to our database in the time from January 2007 until December 2013 and which include the affected power cord.



HRB 4571 Amtsgericht Schwerin, Geschäftsführer: Frank Franzen, Markus Gross; USt.-IdNr.: DE 122950345

Deutsche Bank
Konto: 30 16 607 00
BLZ: 130 700 00
BIC: DEUTDEBRXXX
IBAN: DE40 1307 0000 0301 6607 00

Commerzbank
Konto: 02 564 671 00
BLZ: 140 800 00
BIC: DRESDEFF140
IBAN: DE25 1408 0000 0256 4671 00

Description of the problem:

In the recent past the HOFFRICHTER GmbH received a small amount of complaints about defective power cords from TREND II respiratory therapy devices. The affected power cords showed a pulled off protective insulation at the device socket (see Figure 3) resulting in an uncovering of the inlying electrical contacts. This creates a potential hazard of an electric shock because the electrical contacts could accidentally be touched by the user while the power cord is still connected to the mains.

The affected power cords were used from January 2007 until December 2013 with the HOFFRICHTER GmbH respiratory therapy devices TREND II, point and VECTOR et and feature a two-parted and bipolar device socket. This socket is composed from two parts: The insert to hold the inlying electrical contacts and the main part or base body. During manufacturing the base part is covered by a second material during overmolding, generating a thin seam between the base part and the tip of the socket (see Figure 1). In some circumstances it is possible that the tip gets pulled off if high mechanical loads affect the socket at the seam during the use of the device. Apart from this it can't be excluded that recurrent mechanical stress and environmental conditions can facilitate an early and faster aging of the device socket.

Advice on action to be taken by the user:

All affected power cords with two-parted device socket should be replaced immediately by a power cord with a one-piece device socket (cf. Figure 1 and Figure 2). This is the only way to substantially decrease the risk of an electrical shock. Please note that you are only allowed to use power cords approved by HOFFRICHTER GmbH. Of course you will receive the appropriate cables from us free of charge and on request. Just use the enclosed answering form to order the amount of cables you need.

Above this we would like to ask you to take the following actions and consider the additional safety notes thereafter.

- First of all please ensure that the power cord is disconnected from the mains! After that please examine the power cord of your breathing therapy device for any damages or defects. Especially pay attention to the seam of the two-parted device socket.
- If the power cord does not show any damages or defects you are allowed to continue using the cable. Anyhow please request a replacement power cord immediately by using the attached answering form.
- If the power cord shows any kind of damage or defect – especially at the device socket – you should not use the cable any more.
- The damaged or defective cable should urgently be disposed of or send back to HOFFRICHTER GmbH (see contact information below). Please ensure that this cable cannot be used by anyone else. This is also applicable for any replacement or secondary power cords.



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- According to our database you have received one or more affected devices (and eventually further replacement power cords). These devices are listed in the attached table of devices. We kindly ask you to inform us about the whereabouts and status of the affected power cords by filling out this attached table.

Additional safety information:

- Please ensure the power cord is disconnected from the mains during the following operations:
 - Change of installation site
 - Storing away or packing the device into the device case.
 - Examination or inspection of the device, its accessories and power cord for damages or defects
 - Cleaning, maintenance and repair of the device
- Avoid any mechanical loads on the power cord by
 - Placing the cable without any kinks or bends.
 - Not wrapping the power cord around the device; Store the cable separately from the device.
 - Examine the power cord regularly for any damages or defects (visual control).
- Do not use damaged or defective power cords!

By consequent consideration of the safety information and by taking all measures you can still use the device without any limitations or risk. If you still have any questions about the product, the safety information or how to proceed please do not hesitate to contact us (see contact information below).

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

This urgent field safety notice has been notified the appropriate Regulatory Agency.



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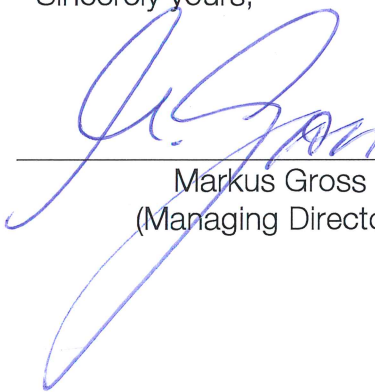
Commerzbank
Konto: 02 564 671 00
BLZ: 140 800 00
BIC: DRESDEFF140
IBAN: DE25 1408 0000 0256 4671 00

Contact information:

Mr. Ali Nehme (Product Manager)
HOFFRICHTER GmbH
Mettenheimer Str. 12/14
19061 Schwerin
GERMANY
Tel.: (+49) 0385 39925 - 0
FAX: (+49) 0385 39925 - 25
Mail: info@hoffrichter.de

Thank you for your understand and support.

Sincerely yours,



Markus Gross
(Managing Director)



Ali Nehme
(Product Manager)

Attachments: figures, answering form



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Attachment A: Figures

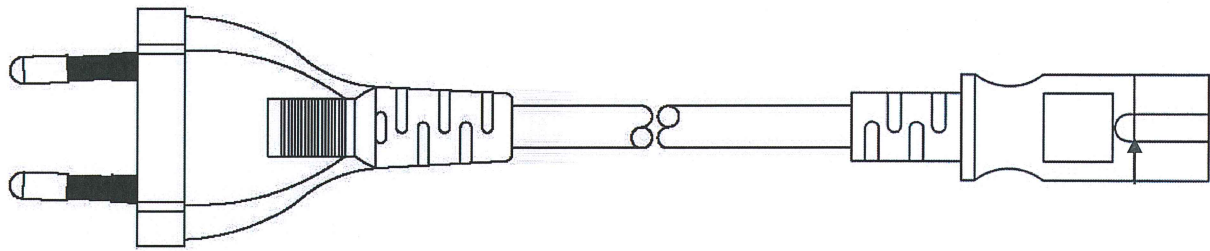


Figure 1: Power cord with mains plug (left) and two-parted device socket (right). Seam is indicated by arrow.

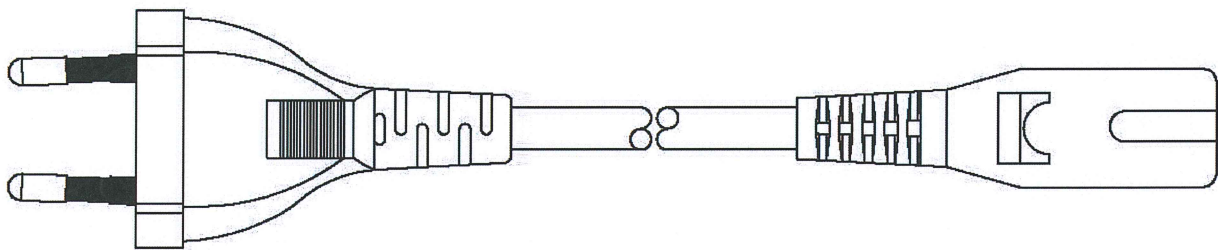


Figure 2: Power cord with mains plug (left) and one-piece device socket (right).

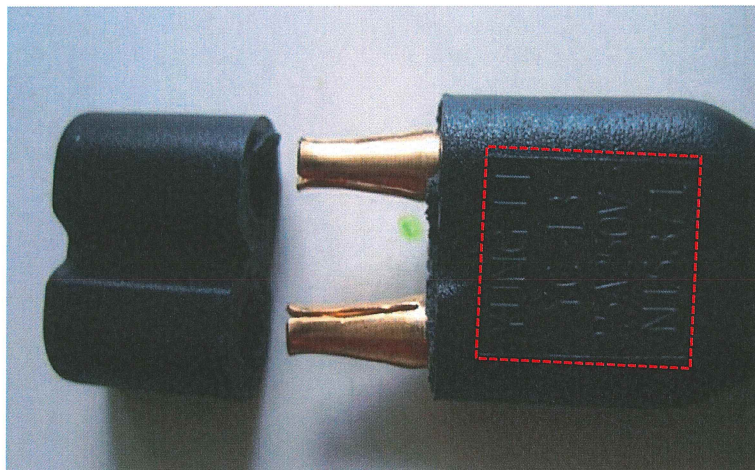


Figure 3: Pulled off tip of the two-parted device socket. The embossing (marked in red) can be seen on the right.



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Attachment B: Answering Form

For the Urgent Field Safety Notice about the replacement of power cords of the HOFFRICHTER GmbH breathing therapy devices TREND II, point and VECTOR et

Please fill out this answering form and send it to HOFFRICHTER GmbH as soon as possible.
Please use one of the following contact addresses:

By FAX: (+49) 0385 39925 - 25
By E-Mail: info@hoffrichter.de
By Mail: HOFFRICHTER GmbH
Keyword: Power Cord Replacement / SELF MAN, Yung Li
Mettenheimer Str. 12/14
19061 Schwerin
GERMANY

Sender

Customer ID _____

Company/Institution _____

Name _____

Address _____

- We herewith confirm that we received the Urgent Field Safety Notice about the replacement of power cords for the HOFFRICHTER GmbH breathing therapy devices TREND II, point and VECTOR et
- Please send us _____(pcs) replacement power cords free of charge.

Place, Date

Stamp/Signature



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