

**Safety Notice**
Technical Bulletin No. 020

GS Elektromedizinische Geräte
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No. 020	Target audience Affected users	Date 2020-09-17	Number of pages 7
Affected products Defibrillator/pacer corpuls3 SLIM	Serial numbers / Lot identification from 19850001 to 20850130	Software / Firmware -/-	

Dear sir or madam,

with this letter we would like to inform you about the safety measures for the defibrillator/pacer corpuls3 SLIM in the serial number range from 19850001 to 20850130. This safety information concerns a limited number of devices corpuls3.

Due to a potential combination of production tolerances of the injection moulded cases, which house the power and data contacts, there may be a loss of connection between the monitor unit and the defibrillator/pacer unit in compact mode. The Operator can recognize this by the connection status in the status/alarm line.

To meet our own expectation of quality we introduce this activity to improve all corpuls3 devices delivered with an affected defibrillator/pacer SLIM to improve the reliability of the contact for module detection.

According to our records, your organisation is using at least one of the affected devices.

Please do read this safety information attentively and send back the filled-in answer form attached in Annex B until 2020-11-15.

Other corpuls3 devices are not affected by this problem.

The responsible supervisory authorities of the involved countries and your authorised corpuls® sales and service centre have been informed about this FSCA (Field Safety Corrective Action).

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1. Error description

The device indicates in the graphical user interface the loss of connection between the monitoring unit (eye-shaped icon) and defibrillator/pacer unit (heart-shaped icon). This connection status can be identified by either a blinking wave or blinking bar symbol between the monitoring unit (eye-shaped icon) and the defibrillator/pacer unit (heart-shaped icon). Please refer to Figure 1 and 2 for the displayed information – the relevant section is highlighted with a red frame.



Figure 1: Interrupted connection in compact mode – optical connection indicator will blink when establishing the optical communication.



Figure 2: Interrupted connection in compact mode – wireless indicator will blink when establishing a wireless connection.

2. Prerequisite for the Occurrence of the Error

Your device contains a batch of injection moulded cases identified by us to potentially show this behaviour. The serial number of devices ranges between 19850001 and 20850130.

3. Potential Risk

If this was to occur during a resuscitation case, this behaviour may result in a potential delay in therapy of 30 seconds.

4. Safety information

Please do notify your users as soon as possible about:

- possible malfunctions that can occur and relevant corrective measures

Being aware of this safety information, allows to recognise the unintentional loss of connection assuredly and can be taken into account when using the corpuls3.

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5. Troubleshooting for Conspicuous Devices

In case of connection problems in compact mode (please refer to Figure 4 – reference number 1) or semi-modular mode (please refer to Figure 4 – reference number 2 and 3), disconnect the device as described in Figure 3. This establishes a stable radio connection between the units. Please note that establishing the connection may take around 10s. The connection status indicates a working radio connection by a solid (non-blinking) wave symbol.

Disconnecting the Monitoring Unit from the Defibrillator/Pacer:

1. Grasp the monitoring unit by the carrying handle and pull both snap locks simultaneously forwards and upwards with your thumbs (item A) or push them rearwards and downwards (item B).
2. Tilt the monitoring unit forwards (item C) and remove upwards (item D).

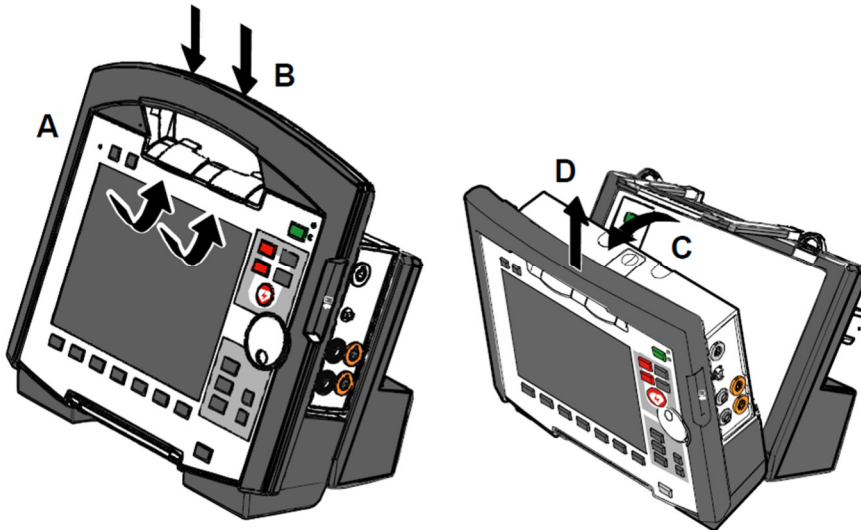


Figure 3 Disconnecting the monitoring unit from the defibrillator/pacer (illustration may differ)

Reference Number	Mode Description	Connection status	Meaning
1	compact mode		All three components are connected mechanically and communicate via the infrared optical interface.
2	semi-modular mode		Monitoring unit and defibrillator/ pacer are connected mechanically and communicate via the infrared optical interface. The patient box is disconnected mechanically, but there is a radio connection with the patient box.
3			Monitoring unit and patient box are connected mechanically and communicate via the infrared optical interface. The defibrillator/ pacer is disconnected mechanically, but there is a radio connection with the defibrillator/ pacer.
4	modular mode		All components have a radio connection.

Figure 4: Connection status

A permanent correction of the error is only possible by updating.

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6. Immediate Measures

Please ensure within your organisation that all users of the above mentioned products and all other persons who need to know are informed about this **urgent safety information**.

If you have supplied the affected products to third parties, please forward a copy of this safety information to them and also inform the contact person mentioned in point 9.

Please keep this information at least until the corrective measures have been completed.

7. Corrective Measures of the Manufacturer

This security information will be sent to all affected users by 2020-10-05.

Maintenance for each device will be promptly arranged. During this process the contact area of your corpuls3 will be modified by one of our authorized sales and service partners. So you will soon have a fully operational device.

The Federal Institute for Drugs and Medical Products („Das Bundesinstitut für Arzneimittel und Medizinprodukte“) has received a copy of this safety information.

All affected national authorities have been informed.

8. Deadline

Briefing the users should be effected immediately by appropriate measures (e.g. via e-mail or by posting this letter at the bulletin board and depositing a copy with the user manual).

Please return the filled-in answer form (Annex B) to GS by 2020-11-15 at the latest.

The update will be performed after consultation with your authorised sales and service partner. The implementation of this corrective action will have taken place by 2021-05-31 at the latest.



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9. Contact person of the manufacturer (for questions):

Daniel Rampp,
Vice President, Customer Support
Head of Customer Support

Tel.: +49 (0) 81 91 6 57 22 30
Fax: +49 (0) 81 91 6 57 22 22
E-Mail: md-vigilance@corpuls.com

We thank you for understanding and apologise for any inconvenience you may have in connection with this corrective action. Questions concerning this matter will be answered by your authorised corpuls® sales and service centre.

With kind regards
GS Elektromedizinische Geräte G. Stemple GmbH

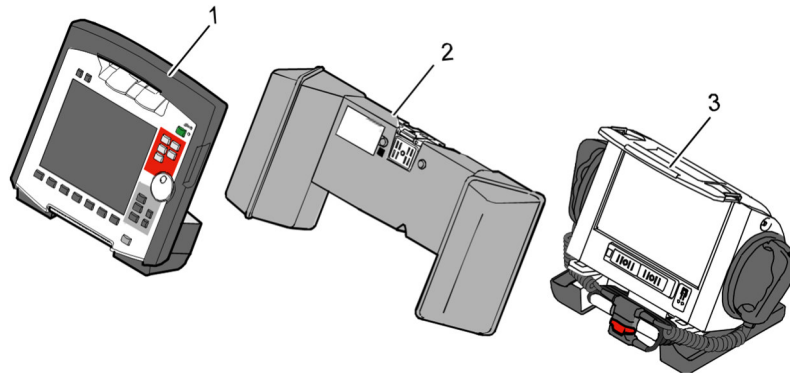
Klaus Stemple
Dipl.-Ing., Electrical engineering and Information technology
CEO/CTO
R&D, Production, Product Safety
Safety officer for medical devices (acc. §30 MPG)

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Annex A

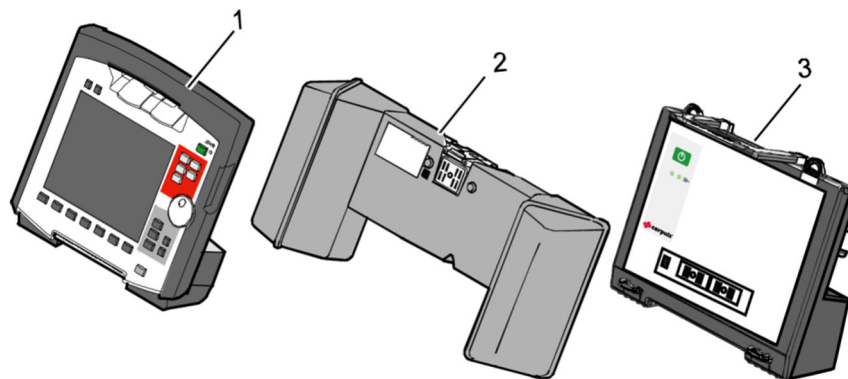
- Illustration of the device combination corpuls³

- 1 – Monitoring Unit
- 2 – Patient box
- 3 – Defibrillator



- Illustration of the device combination corpuls³ with defibrillator SLIM

- 1 – Monitoring unit
- 2 – Patient box
- 3 – Defibrillator SLIM



- Current rating plates with position of the serial numbers

GS Elektromedizinische Geräte G. Stemple GmbH Hauswiesenstraße 26, 86916 Kaufering, Germany	GS Elektromedizinische Geräte G. Stemple GmbH Hauswiesenstraße 26, 86916 Kaufering, Germany	GS Elektromedizinische Geräte G. Stemple GmbH Hauswiesenstraße 26, 86916 Kaufering, Germany	GS Elektromedizinische Geräte G. Stemple GmbH Hauswiesenstraße 26, 86916 Kaufering, Germany
Display Unit corpuls ³ 12 V = 30 W REF 04100 04100-00-01004 SN 20600001	Patient Box corpuls ³ 12 V = 30 W REF 04200 04200-00-01070 SN 20700001	Defib corpuls ³ SLIM 12 V = 74 W REF 04301 04301-00-01000 SN 20850001	Defib Unit corpuls ³ 12 V = 74 W REF 04300 04300-00-01001 SN 20800001

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Annex B

Confirmation form

Please mark with a cross ALL fields that apply to your company:

- We have read and understood the safety information of GS Elektromedizinische Geräte G. Stemple GmbH of 2020-09-17.

- We have informed our users in an appropriate way about the contents of this safety information and the amendment to the user manual.

To be filled in by the customer (please print):

Organisation: _____	
Address: _____	
City: _____	Country: _____
Name: _____	First name: _____
Mr/Ms/Title: _____	Fax: _____
Phone: _____	Company stamp: _____
E-Mail address: _____	
Date/Signature: _____	

Please return this confirmation form until 2020-11-15 at the latest to:

GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstrasse 26
D-86916 Kaufering
Fax: + 49 8191 65722 - 22

Or scanned as PDF attachment to:
md-vigilance@corpuls.com