

**Safety Notice
Technical Bulletin No. 022**

GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstraße 26
D-86916 Kaufering
Tel. +49 8191 65722-0
Fax +49 8191 65722-22
info@corpuls.com
www.corpuls.com

No.	Target audience	Date	Number of pages
022	Affected users	2021-07-30	8
Affected products Defibrillator-/pacer unit corpuls3 SLIM P/N 04301 Defibrillator-/pacer unit corpuls3 Touch SLIM P/N 04302	Serial numbers / Lot identification See Annex C	Software / Firmware -/-	

Dear sir or madam,

with this letter we would like to inform you about the safety measure with regard to the defibrillator-/pacer unit corpuls3 SLIM (P/N 04301) as well as to defibrillator-/pacer unit corpuls3 Touch SLIM (P/N 04302), produced from January 2020 until April 2021. Detailed serial numbers see Annex C.

Other corpuls3 devices, in particular the defibrillator-/pacer series corpuls3 with the P/N 04300 are not affected by this problem.

Due to a too high mechanical strain on the defibrillator-/pacer unit corpuls3 SLIM or the defibrillator-/pacer unit corpuls3 Touch SLIM, caused e.g. by the device falling down, can result in rare cases in malfunction or failure of the high voltage unit. Shock release may then no longer be possible. When using the device within the specified range, complete functionality can be guaranteed.

To satisfy our concept of quality in our products, we are introducing a preventive safety measure. The measure should include all affected devices produced in the period mentioned above. By implementing this improvement, the reliability of the devices will be guaranteed.

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 2021-09-30.

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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).

1. Description of the Error

When performing a defibrillation, the device shows the alarm message "Shock aborted" as well as the message in the message line of the monitoring unit (see Fig. 1). Due to this, no therapy can be performed on the patient.



Fig. 1: Screenshot – Alarm message "Shock aborted"

2. Prerequisite for the Occurrence of the Error

The device was exposed to high mechanical strain, e.g. by falling down or being hit. The device was produced in the period between January 2020 and April 2021 and contains the affected high voltage unit.

3. Potential Risk

After being exposed to a high mechanical strain, the device can exhibit the described error and consequently, therapy on a patient may be unsuccessful. If resuscitation is needed, therapy cannot be performed.

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4. Safety information

Please do notify your users as soon as possible about:

- possible malfunctions that can occur and relevant corrective measures.
- the importance of the daily check which must be performed at least once a day or when starting a shift.

Being aware of this safety information allows to recognise a defective high voltage unit and can be taken into account when using the corpuls3.

5. Troubleshooting for Conspicuous Devices

In case of high mechanical strain, we recommend to perform the function test immediately, as described in the user manual chapter 10.2.1 "Daily Checks of the Device".

Daily check		
Description	Measures by the User	Correct result
Function check of the defibrillator/ pacer SLIM	<p>For the function check the testbox (P/N 04310), the testload (P/N 04312) or the corpuls simulator (P/N 04311) is needed:</p> <ul style="list-style-type: none"> ▪ Make sure that a 1.5 V battery is inserted in the testbox/corpuls simulator. ▪ Switch on testbox/corpuls simulator. ▪ Connect testbox/testload/ corpuls simulator to the therapy socket. ▪ Confirm the message "Mark mission as test mission?" by pressing the softkey [Yes]. ▪ Select the manual mode of the defibrillator. ▪ For the testload, select an energy of 50 J (max. 100 J). For the testbox/ corpuls simulator, select an energy of 200 J. ▪ Charge energy. ▪ Deliver shock. ▪ On the printout of the shock protocol is the message Test successful or Test failed. ▪ After performing the function check, switch off testbox/testload/ corpuls simulator and remove it from the defibrillator/pacer SLIM. 	<ul style="list-style-type: none"> ▪ Energy is internally discharged via the testbox/testload/ corpuls simulator. ▪ No error message is issued.

Fig. 2: Excerpt from User Manual, chapter 10.2.1

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If the described alarm message is issued during the function check, the measures in chapter 11 of the user manual "Procedure in Case of Malfunctions" have to be performed.

Alarm message	Priority	Explanation/Measure
Shock aborted	System alarm High priority	The shock could not be delivered. Check correct position of therapy electrode. Repeat shock delivery if necessary. The event is documented in the protocol. If the message persists, contact your authorised sales and service partners, there could be a hardware defect. In this case, the device has to be taken out of commission.

Fig. 3: Excerpt from User Manual, chapter 11

A permanent correction of the malfunction is only possible by exchanging the affected high voltage unit by an authorised sales and service partner.

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 2021-08-20.

The corrective measure will be applied to each affected defibrillator-/pacer unit corpuls3 SLIM or defibrillator-/pacer unit corpuls3 Touch SLIM as soon as possible.

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.



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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 2021-09-30 at the latest.

Your authorised sales and service partner will implement the corrective measure. The implementation of this corrective action will have taken place by 2022-07-31 at the latest.

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, Product Safety

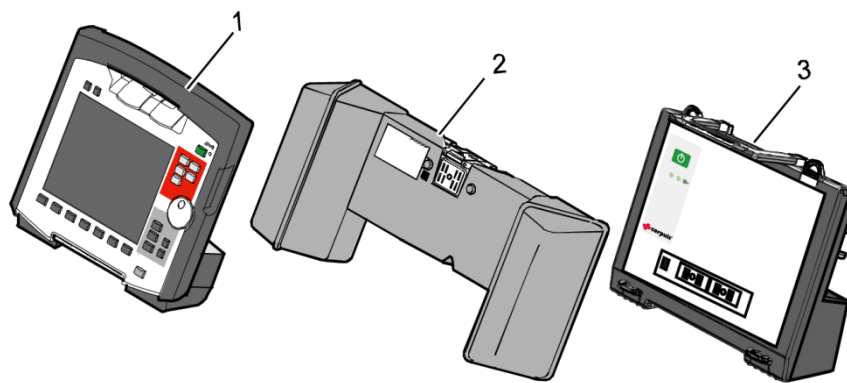


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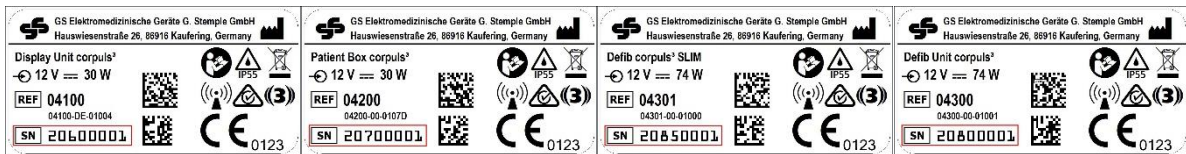
Annex A

- 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





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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 2021-07-30.
- 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 2021-09-30 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



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Annex C

Serial numbers of the affected defibrillator-/pacer units corpuls3 SLIM P/N 04301

20852085

Serial numbers of the affected defibrillator-/pacer units corpuls3 Touch SLIM P/N 04302

20852103, 20852137, 20852164, 20852168