# Safety information
# Technical Bulletin No. 011

GS Elektromedizinische Geräte
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| No. | Target audience | Date: | Number of pages |
|---|---|---|---|
| 011 | Affected users | 03-02-2014 | 8 |

| Affected products | Serial numbers / Lot identification | Software / Firmware |
|---|---|---|
| Defibrillator/pacer SLIM **corpuls³** | from 12800103 to 13851242<br>Delivery date: between 07/2012 and 12/2013 | -/- |

Dear sir or madam,

with this letter we would like to inform you about the recall of defibrillator/pacer SLIM units bearing the serial numbers from **12800103 to 13851242 which have been delivered between 07/2012 and 12/2013**. This recall only applies to a limited number of **corpuls³** devices which have been delivered to the end customer in the mentioned period of time.

Due to a too little distance between a circuit board and the housing, there is the possibility that one component on that circuit board could be damaged mechanically. This impairs the radio connection between the modules. The user can recognise this, if a respective error message is displayed.

The error was discovered in a few devices in the field after longtime use. We decided to recall all **corpuls³** devices that were delivered with the affected defibrillator/pacer SLIM unit. In these affected defibrillator/pacer SLIM units we will mount a new circuit board which guarantees a bigger distance to the housing.

According to our records, your organisation has purchased at least one of the affected devices.

Please do read this safety information attentively and send back the filled-in confirmation form attached in Annex B until February 28th, 2014.

So far, we do not have information that other **corpuls³** devices are also affected by this problem.

The responsible supervisory authorities of the involved countries and your local distributor have been informed about this FSCA (Field Safety Corrective Action).

## 1. Error description

In rare cases it may happen that the radio connection between the modules is impaired due to damage in the radio module, and then it is no longer possible to:

- perform full patient monitoring
- correctly adjust and operate a therapy function of the device

## 2. Prerequisite for the Occurrence of the Error

Your device is equipped with a radio module that was identified by us as problematic and your device has been produced and delivered to you between 07/2012 and 12/2013.

Vibrations promote the occurrence of this malfunction.

## 3. Potential Risk

Diagnosis and therapy are delayed, because the measurement- and therapy functions cannot perform without problems.

## 4. Safety information

Please do notify your users as soon as possible about:

- possible malfunctions that can occur and relevant corrective measures

## 5. Troubleshooting for Conspicuous Devices

If there are malfunctions in the radio connection of the separate modules of the **corpuls$^3$**, connect the modules mechanically to form a compact device. Then, operation is possible without problems.
A permanent correction of the error is only possible by replacing the affected radio module.

The following error messages indicate the problem:

**"No connection to defibrillator unit"**
A description and recommended measures can be found in Table 10-3 "Network malfunctions" in the user manual (ENG - Version 2.1 - P/N 04130.2) on page 251 and in chapter 10 "Procedure in case of malfunctions" on page 268.

**"No connection to P-Box"**
A description and recommended measures can be found in chapter 10 "Procedure in case of malfunctions" on page 268 in the user manual (ENG - Version 2.1 - P/N 04130.2).

## 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 products to third parties, please forward a copy of this safety information to them and also inform the below mentioned contact person.

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 February 17th, 2014.

Maintenance for each device will be promptly arranged. A different radio module will be installed to your device, so you will soon have a fully operational device.
For the duration of the maintenance a replacement device will be supplied.

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 confirmation form (Annex B) to GS by February 28th, 2014 at the latest.

The exchange will be carried out within 12 weeks after the return of the filled-in confirmation form. The implementation of this corrective action will have taken place by May 31st, 2014 at the latest.

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

Carsten Fuchs,
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 national sales and service partner (see also Annex C or www.corpuls.com).

Sincerely,

GS Elektromedizinische Geräte G. Stemple GmbH

Dr. Christian Klimmer

Geschäftsführer Marketing & Vertrieb/Finanzen
General Manager Sales & Marketing/Finance

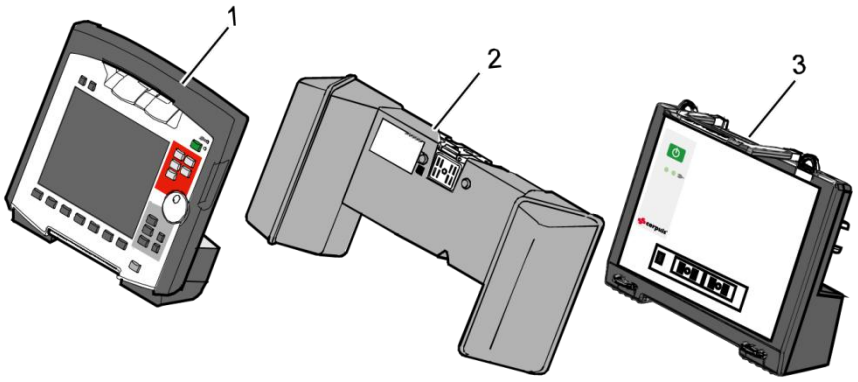
Klaus Stemple

General Manager R&D/Production
Managing Director R&D/Production

## Annex A

Illustration of the device combination **corpuls³**

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





*Rating plates with position of the serial numbers*

## 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 2014-02-03.
- ☐ We have informed our users in an appropriate way about the contents of this safety information.
- ☐ We are attaching Annex D with the serial numbers of the affected devices in our company.

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

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

Please return this confirmation form until 2014-02-28 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

## Annex C

Authorised corpuls® sales and service partners

**Germany**

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**Manufacturer**

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www.corpuls.com

## Annex D

Serial numbers of **corpuls$^3$** devices that are affected in our company:

| Serial numbers of devices affected | | |
|---|---|---|
| Monitoring unit | Patient box | **Defibrillator** |

Organisation: _____

Company stamp: _____

Date/Signature: _____