Safety information
Technical Bulletin No. 008

GS Elektromedizinische Geräte
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Number	Target audience	Date	Number of pages
008	Affected users	17.08.2011	8

Affected products	Serial numbers / Lot identivication	Software / Firmware
corpuls^3	See Annex D	Independent of the SW-version

Dear Sir or Madam,

Herewith we would like to inform you about 122 potentially faulty processor boards that are integrated in a limited number of **corpuls^3** devices.

An error in the processor supply voltage can sporadically lead to non-reproducible bugs. The errors range from false-positive alarms to the temporary breakdown of measurement- and therapy functions.

The malfunction was identified in our regularly held quality assurance tests. A connection with malfunctions reported from the field has not yet been determined.

We have decided to recall all **corpuls^3** devices equipped with the component that has been identified as problematic, and perform a preventive replacement of the affected component.

According to our records, your organisation has purchased at least one of the affected devices. The affected serial numbers are listed in Annex D of this letter.

We kindly request to read this safety information carefully and return the filled-in and signed confirmation letter, Annex B, to GS until 30/09/2011 at the latest.

So far we have no further information that other devices of the type **corpuls^3** are 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).

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1. Error description

The faulty processor boards can produce a variety of sporadic, non-reproducible errors, which are in particular:

- Loss of measurement functions (the ECG measurement function is not affected).
- Fax transfer is not possible, the GSM module is not recognised correctly.
- Communication via the **Bluetooth®-Data-Interface (Option)** is no longer possible.
- Health insurance card reader does not work (new option; not yet delivered to any customer).
- Communication in the Defibrillator/Pacer unit is impaired, the message „no connection to defibrillator“ appears sporadically.
- While booting the **corpuls³**, one of the modules does not respond or one of the modules stops working during operation.
- During maintenance: It may occur that a software update is not completed correctly.

2. Precondition for the Occurrence of the Error

One of the identified problematic processor boards are installed in your device.

Low temperatures (< 0 °C) favor the occurrence of the error.

3. Potential Risk

There will be delays in diagnosis and therapy, as measurement and therapy functions are temporarily not available.

A software update can fail (only affects the service access).

4. Safety information

Restart the affected module.

Note that a faulty communication interface could lead to individual re-starts of each module (see also chapter 4.2.2 Switching off of the user manual).

5. Troubleshooting for Conspicuous Devices

A permanent correction of the error is only possible by replacement of the affected processor boards.

6. Immediate Measures

Please instruct the user again on:

- Possibly occuring error messages and their corrective actions

Please ensure within your organisation that all users of the above mentioned products and all other necessary persons 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 until 31.08.2011.

Maintenance for each device will be promptly arranged. A new processor board with Revision BA0000000F or higher is going to be installed, so you will shortly have a fully operable unit. For the duration of this procedure 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 and the user manual amendment at the bulletin board).

Please return the filled-in confirmation letter (Annex B) to GS until 30.09.2011 at the latest.

The exchange of the affected boards will be carried out within 2 months after the return of the filled-in confirmation letter. The implementation of this corrective action has to take place until 01.12.2011 at the latest.

9. Contact person of the manufacturer (for questions)

Carsten Fuchs,
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).

With kind regards,

GS Elektromedizinische Geräte G. Stemple GmbH

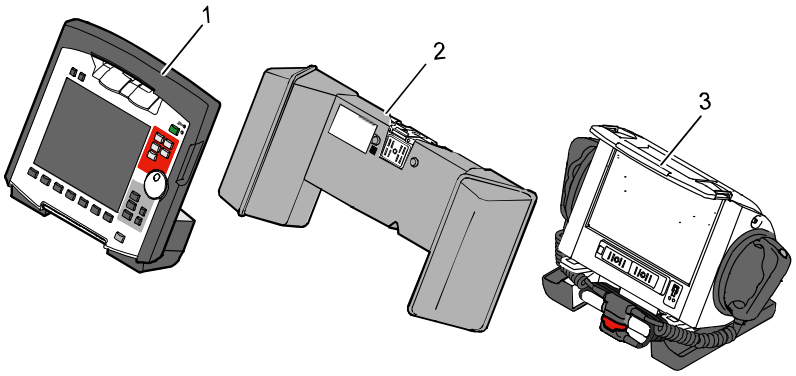
Günter Stemple
Managing Director
Geschäftsführer

Klaus Stemple
General Manager R&D/Production
Geschäftsführer F&E/Fertigung

Annex A

Illustration of the device combination **corpuls^3**

1 – Monitoring unit
2 – Patient box
3 – Defibrillator



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 2011-08-17.

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

- ☐ We are attaching Annex D (if necessary with corrected serial-no.) 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:	
Date/Signature:	

Please return this confirmation form until 2011-09-30 at the latest to:
GS Elektromedizinische Geräte G. Stemple GmbH, Hauswiesenstrasse 26, D-86916 Kaufering
Fax: + 49 8191 65722 - 22

or scanned-in as PDF attachemend to:
md-vigilance@corpuls.com

Annex C

Authorised **corpuls®** sales and service partners

Please consult our homepage for international sales and service addresses:

www.corpuls.com

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Annex D

Serial numbers of **corpuls^3** that are affected in your company (according to our records):

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