

Safety information
Technical Bulletin No. 009



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- No. 009	Target audience Affected users	Date 30-11-2012	Number of pages 9
Affected products corpuls³	Serial numbers / Lot identification No relation	Software / Firmware Software Version 2.0.0 and 2.0.2	

Dear sir or madam,

with this letter we would like to inform you about the recall of software versions 2.0.0 and 2.0.2 that have been installed to a limited number of corpuls3 devices.

Due to a malfunction of the software, the display on the monitoring unit may sporadically freeze and stop being operable, after a diagnostic ECG has been started (see User Manual chapter 6.3). The error manifests as extremely slow curve build-up or lack of curves in the D-ECG preview. In this condition, the device no longer reacts to keys being pressed.

We decided to recall all **corpuls³** devices that are operating with the affected software version and to install a different software version.

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 December 20th, 2012.

So far, we do not have information that other software versions for **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).

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1. Error description

The software malfunction may cause a variety of sporadic, not always reproducible errors, in particular:

- Failure of the D-ECG preview
- possibly in combination with softkey failure
- possibly in combination with defibrillator key failure

2. Prerequisite for the Occurrence of the Error

One the software versions identified as problematic, 2.0.0 or 2.0.2 is installed on your device.

You have started a D-ECG preview and additionally:

- immediately prior to that, you have changed the connection status (see chapter 3.2 of the user manual) and the new connection is not yet stable (status display at the monitoring unit see table 4-2 of the User Manual)
- you are changing the connection status when the device is in D-ECG mode
- you are entering data with the insurance card reader when the device is in D-ECG mode
- you are performing an NIBP measurement at the same time

3. Potential Risk

Diagnosis and therapy are delayed, because the measurement- and therapy functions are not available until the monitoring unit has been re-started.



4. Safety information

Please do notify your users as soon as possible about:

- possible malfunctions that can occur and relevant corrective measures

If you want to record or send a D-ECG with a device that has software version 2.0.0 or 2.0.2 installed, try to avoid:

- to change the connection status when the device is in D-ECG mode (also immediately prior to that)
- Do NOT enter data with the insurance card reader when the device is in D-ECG mode
- Do NOT perform an NIBP measurement at the same time

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5. Troubleshooting for Conspicuous Devices

Re-start the monitoring unit.

Please note that in case of the occurrence of the described malfunction the monitoring unit has to be re-started separately, that is in modular operation. (see also chapter "4.2.2 Switching Off" of the User Manual). To do so, hold down the green On/Off key until the device shuts down (at least 8 seconds). After that the monitoring unit can be re-started by pressing the same key.

Switching off in case of system crash	In case of a system crash of one of the modules or of the compact device, these can be switched off individually by holding down the On/Off key at the respective module for 8 seconds. Counting the seconds is recommended to make sure the button is held down for the correct amount of time. It is not necessary to remove the battery.
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A permanent correction of the error is only possible by installing a different software version.

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 until December 7th, 2012.

Maintenance for each device will be promptly arranged. A different software version 1.9.0 or 2.0.3 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.



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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 confirmation form (Annex B) to GS until December 20th, 2012 at the latest.

The exchange will be carried out within 4 weeks after the return of the filled-in confirmation form. The implementation of this corrective action will have taken place until February 13th, 2012 at the latest.

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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).

Kind regards,
GS Elektromedizinische Geräte
G. Stemple GmbH

Günter Stemple
Managing Director
Geschäftsführer

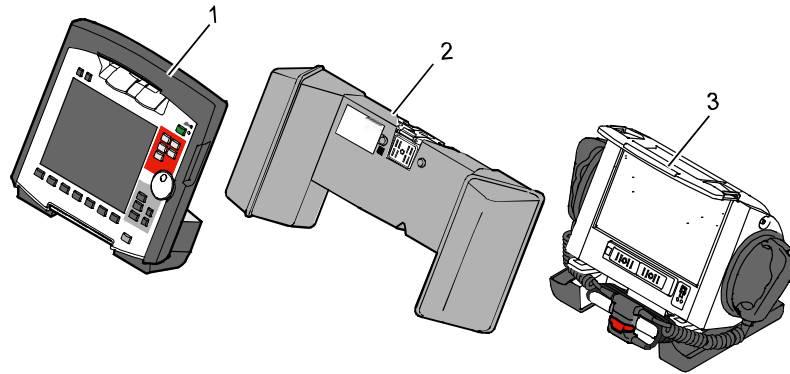
Klaus Stemple
General Manager R&D/Production
Geschäftsführer F&E/Fertigung

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Annex A

Illustration of the device combination corpuls3

- 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 2012-11-30.
- 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 organisation _____

Company stamp: _____

E-Mail address _____

Date/Signature: _____

Please return this confirmation form until 2012-12-20 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

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 corpuls3 that are affected in your company (according to our records):

Serial numbers of devices affected

Monitoring Unit

Patient box

Defibrillator

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