

Safety information

Technical Bulletin No. 013



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- No. 013	Target audience Affected users	Date 2014-07-29	Number of pages 9
Affected products corpuls³	Serial numbers / Lot identification No relation	Software / Firmware Software Version 2.2.2	

Dear sir or madam,

with this letter we would like to inform you about the recall of software versions 2.2.2 that have been installed to a limited number of **corpuls³** devices.

During the recording of an D-ECG for diagnostic purposes, a non-intended, technical distortion of the R-spike or the ST-segment may occur.

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 2014-08-22.

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 authorized **corpuls[®]** sales and service partner have been informed about this FSCA (Field Safety Corrective Action).

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Ersteller Name:	Markus Raab	Freigabe Name:	Klaus Stemple



1. Error description

If a drifting ECG signal is present at input, the ECG signal will be kept in the display area by means of an correction mechanism. This correction mechanism is performed in the affected software version (SW 2.2.2) at too close intervals.

If this technically necessary zero re-adjustment occurs at the same time as the R-spike or the ST-segment, it may not be interpreted as distortion or correction - see **Fig. 1** with a current example from SW 2.2.2.

Therefore, it is possible that the user may misinterpret the curve.



Fig. 1: corpuls³ with SW 2.2.2 - Drifting ECG, the zero re-adjustment is marked in yellow

2. Prerequisite for the Occurrence of the Error

One the software versions identified as problematic, 2.2.2, is installed on your device.

If the heart rate and the interval for zero re-adjustment (dependent on the drifting speed) are almost identical, it is particularly difficult to identify the correction as such.

3. Potential Risk

The ECG may be misinterpreted and this may lead to a wrong therapy or therapy preparations (e.g. catheter lab).

4. Safety information

Please do notify your users as soon as possible about:

- possible malfunctions that can occur and relevant corrective measures

If this effect is known to the user, the regular correction intervals can be competently identified and taken into account when interpreting the ECG.

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5. Troubleshooting for Conspicuous Devices

It is possible to avoid or suppress this zero re-adjustment effect by positioning the patient and the ECG cable differently and by avoiding patient movement during a diagnostic ECG recording.

The probability that this error occurs is lessened as well when quick-response electrode are used and the recommendations of the electrode manufacturer on how to pre-treat the patient's skin are complied with.

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 - chapter 9 - 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 2014-08-08.

Maintenance for each device will be promptly arranged. A different software version 2.2.4 or higher will be installed to your device, so you will soon have a fully operational device. The zero re-adjustment will be performed at larger intervals – see **Fig. 2** Example with the planned SW 2.2.4.

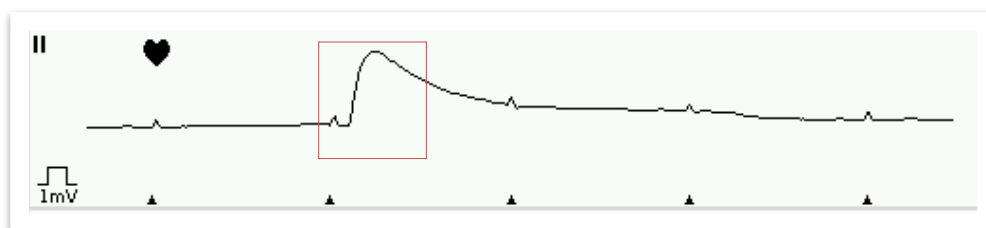


Fig. 2: corpuls³ with SW 2.2.4 - Drifting ECG, the zero re-adjustment in the red frame

For the duration of the maintenance a replacement device will be supplied.

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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 until 2014-08-22 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 2014-09-26 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 local authorized **corpuls**[®] sales and service partner (see also Annex C or www.corpuls.com).

Kind regards,
GS Elektromedizinische Geräte G. Stemple GmbH

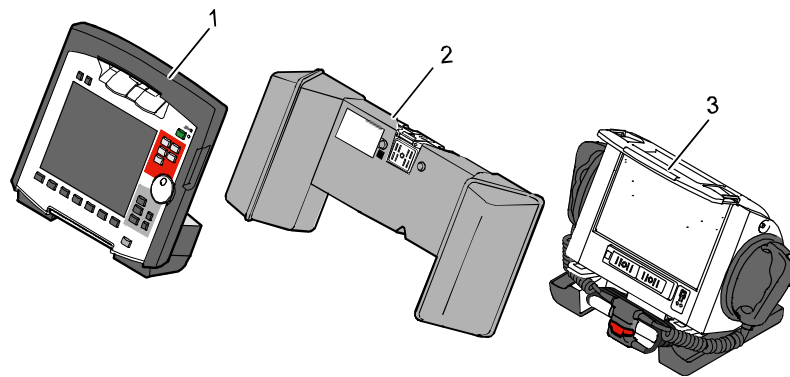
Klaus Stemple
Dipl.-Ing., Electrical- and Computer Engineering
CEO/CTO
R&D, Production, Product Safety
Safety representative for medical products pursuant to § 30 MPG

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Annex A

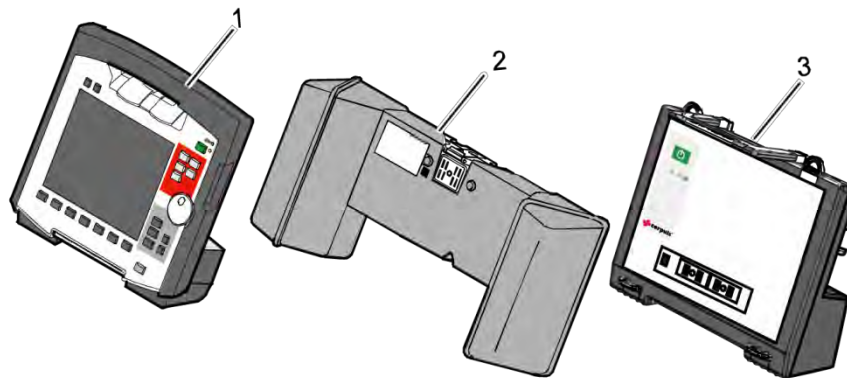
- Illustration of the device combination **corpuls³**

- 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



- actual 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 2014-07-29.

- 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 2014-08-22 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

Your local authorized **corpuls**[®] sales and service partner:

Please consult our homepage for international authorized 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) by the problem with software version 2.2.2:

Serial numbers of devices with installed software version 2.2.2

Monitoring Unit

Patient box

Defibrillator

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