Safety information
Technical Bulletin No. 010

GS Elektromedizinische Geräte
G. Stemple GmbH
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www.corpuls.com

No.	Target audience	Date	Number of pages
010	Affected users	2013-01-21	8

Affected products	Serial numbers / Lot identification	Software / Firmware
corpuls³	from 12600158 to 12603530 Delivery date: between 07/2012 and 12/2012	-/-

Dear sir or madam,

with this letter we would like to inform you about the recall of the monitoring units bearing the serial numbers from **12600158 to 12603530 which have been delivered between 07/2012 and 12/2012**. 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.

As we have changed our supplier of TFT-displays, there is a risk of a short circuit between one component and the rear panel of the TFT display. If this happens, the screen of the monitoring unit becomes white. The user no longer sees curves, vital parameters or operating elements on the screen of the **corpuls³**.
In this condition, however, the device still reacts to keys being pressed.
Furthermore, minimal monitoring is possible via the display of the patient box.

This defect has been discovered in our internal quality assurance department. We decided to recall all **corpuls³** devices that were delivered with the affected TFT display. The affected monitoring units will be equipped with TFT displays that do no longer have this defect.

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 by February 28th, 2013.

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 display becomes white, 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 TFT display that was identified by us as problematic and your device has been produced and delivered to you between 07/2012 and 12/2012.

Vibrations promote the occurrence of this malfunction.

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

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.

A permanent correction of the malfunction is only possible by exchanging the affected TFT display.

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 January 31st, 2013.

Maintenance for each device will be promptly arranged. A different TFT display 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, 2013 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, 2013 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).

Kind regards,

GS Elektromedizinische Geräte
G. Stemple GmbH

[redacted]

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

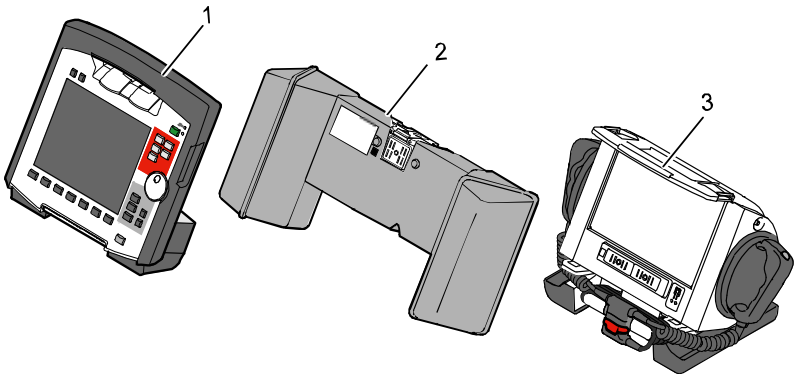
[redacted]

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

Annex A

Illustration of the device combination **corpuls³**

1 – Monitoring Unit
2 – Patient box
3 – Defibrillator



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 2013-01-21.
- ☐ 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 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 2013-02-28 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 C

Authorised corpuls® sales and service partners

Germany
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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: _____