Safety Notice
Technical Bulletin no. 005

GS Elektromedizinische Geräte
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Nr.	Target audience	Date	Nr of pages
005	all users	2008-12-12	8

Concerned products	Serial numbers / Lot identification	Software / Firmware
corpuls^3	all devices	each software version up to and including 1.4.2

Dear user,

With this letter we are informing you of a **corpuls^3** Defibrillator/Monitoring system series software issue.

This letter is intended to inform you about

- what the problem is and under what conditions it may appear,
- the measures, you as operator must take to minimize the effects of this problem,
- the measures scheduled by the manufacturer to sustainably fix this problem.

Affected are all **corpuls^3** devices independent of both configuration and software version up to and including software version 1.4.2. We kindly request you to read this Safety Notice carefully and return the completed and signed Confirmation Letter annex B not later than January 31, 2009.

1. Description of error

Under appearance of the below mentioned conditions the software may store data in a non-provided memory area. So far, thereupon the following malfunctions have been noticed:

- The message "Pairing failed" may appear after start pairing of the different device components Defibrillator Unit, Patient Box and Monitoring Unit.
- The printer may fail when the speed is changed.
- Temperature measurement may suddenly fail.

2. Precondition for the appearance of the error

The error may appear under simultaneous appearance of the below listed conditions:

1. The CompactFlash® memory card is full, almost full, damaged or being removed during operation.
2. Several diagnosis ECGs are being recorded.
3. Subsequently, configuration data (e. g. pairing data, alarm limits) are being modified.

3. Potential risk

The Monitoring Unit indicates the message „Pairing failed". The connection between the device components Defibrillator Unit, Patient Box and Monitoring Unit is interrupted. The device is not ready for use.

4. Safety information

Until installation of a new software version please consider the items below:

- Archive data periodically from the CompactFlash® memory card, than delete them completely; latest if the message "CF card capacity low" appears (see User Manual, page 203).
- Do not remove the CompactFlash® memory card from the device during operation.
- Do not generate further diagnosis ECGs after any error message concerning the CompactFlash® memory card has appeared during operation. Contact contact the technical customer service of an authorized sales and service partner.
- Do not change any configuration adjustments (User Manual chapter 7) during regular operation.
- Do not start a pairing process during regular operation.
- Perform the functional test according to the User Manual (chapter 9.2.1) periodically.

5. Trouble shooting at devices which caught attention

If the aforementioned error has already been noticed, we recommend the reinstallation of the software currently operated in your device until the advertised software version 1.4.3 is available. Contact the technical customer service of your authorised sales and service partner.

6. Immediate measures

Please instruct all users in your organisation without delay about the potential risk and measures. If doubts exist, the measures described in the User Manual, chapter 10.2 "Troubleshooting and remedying malfunctions" must be executed immediately.

7. Manufacturers measures

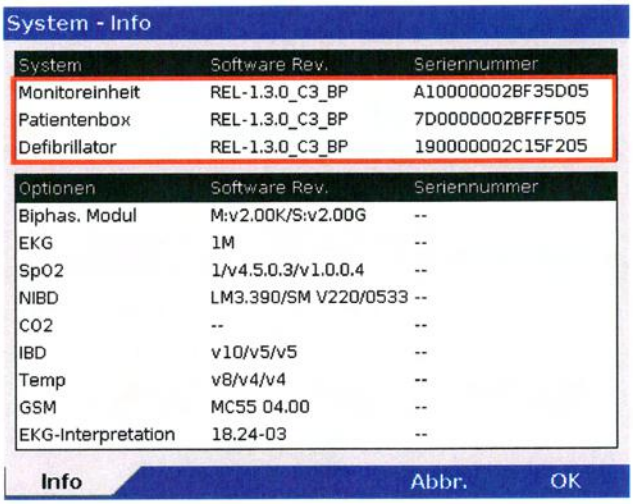
Starting with calendar week 02/2009 a new software version will be provided. The version number is 1.4.3.

The software installation is carried out by the manufacturer or by an authorised sales and service partner.

If you don't have any service contract with an authorised **corpuls®** sales and service partner, and your device is serviced by third party companies, please do not hesitate to immediately contact your national sales and service partner to make an appointment for software installation.

8. Deadline

The measures must be implemented not later than May 01, 2009. All **corpuls^3** devices with software version 1.4.2 or lower (indicated in the menu System – Info) are not allowed for operation as from this date.



Indication of software version

May we thank you for your 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 annex D or www.corpuls.com).

Contact person of the manufacturer for inquiry calls:

Mr. Carsten Fuchs,
Vice President, Customer Support

Phone: +49 81 91 6 57 22 30
Fax: +49 81 91 6 57 22 22
E-Mail: fuchs@corpuls.com

With kind regards
GS Elektromedizinische Geräte G. Stemple GmbH

Günter Stemple
Managing Director
Geschäftsführer

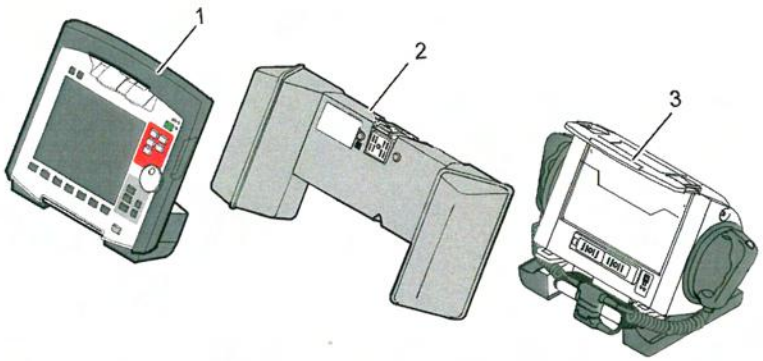
Klaus Stemple
General Manager R&D/Production
Geschäftsführer F&E/Fertigung

Carsten Fuchs
Vice President, Customer Support
Serviceleiter

Annex A

Figure of device combination **corpuls³**

1 – Monitoring Unit
2 – Patient Box
3 – Defibrillator



Type plates with positions of serial numbers

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corpuls®

Annex B

Reply form

Kindly mark all fields where applicable for your organization.

- ☐ We have read and understood the Safety Notice of GS Elektromedizinische Geraete G. Stemple GmbH from December 12, 2008.
- ☐ We operate the below listed devices of the **corpuls^3** series (pls. enter all serial numbers):

No.	Monitoring Unit	Patient Box	Defibrillator Unit
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

- ☐ All our employees have been conveniently informed about the content of this Safety Notice.
- ☐ We have discontinued the operation of the following **corpuls^3** whose serial number is listed in annex C of this document. Kindly specify what was done with this device; e.g. decommissioning, selling, other use. If available, please attach a cross reference.

_____

_____

_____

_____

To be completed by the customer (block letters please):

Organization: _____

Address: _____

City: _____ Country: _____

Name: _____ First name: _____

Title: _____ Fax: _____

Phone: _____ Company stamp:

e-mail-address: _____

Date / Signature: _____

Please complete this reply form and return by fax not later than 31-01-2009.
GS Elektromedizinische Geraete G. Stemple GmbH, Hauswiesenstrasse 26, D-86916 Kaufering
Fax: + 49 8191 65722 - 22

Annex C

National sales and service partners

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e-mail: ernst@schiller-reomed.ch

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Manufacturer:
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Annex D

Serial numbers

Ladies and Gentlemen,

According our records you're operating the **corpuls^3** device with the serial numbers as listed below (for position of serial number see annex A):

Monitoring Unit	Patient Box	Defibrillator		Monitoring Unit	Patient Box	Defibrillator