

SAFETY INFORMATION
Technical Bulletin No. 007



GS Elektromedizinische Geräte
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 info@corpuls.com
 www.corpuls.com

No. 007	Target audience All users	Date 2010-10-11	Number of pages 8
Affected products corpuls³	Serial numbers / Lot identification see Annex D	Software / Firmware independent of the SW-version	

Dear Sir or Madam,



we would like to inform you via this letter about a sporadic malfunction of the communication line during the use of the **corpuls³** as a compact device.

Because of customer complaints we noticed a minor number of malfunctions of the IrDa-communication between the connected modules. The malfunction is caused by a defective part of a circuit board of the **corpuls³**. We were able to identify the source of the problem in a specific incoming lot of these circuit boards. We then commissioned a laboratory investigation of the defective components which yielded the following results:

The affected components sustained initial damage during the production process at our component supplier. Due to this initial damage the components have an increased risk of malfunction in the first months of using the device.

We have decided to recall all devices affected by the damaged components and to change the defective component as a preventive action.

Please read this customer information carefully and return the filled-in and signed confirmation letter (Annex B) to GS until 2010-10-30 at the latest.

Document name and location:	U:\Allgemein\Technische Bulletins\TB_007_eng.doc	Page	1 of 8	 
translation date:	2010-10-07	Release date.:	2010-10-11	
Translator name:	Dr. Anke Bader	Release name:	Klaus Stemple	

1. Error Description

The communication between the modules of the **corpuls³** is suddenly faulty.

Identification of the problem:

- ECG curves are failing permanently
- Pairing of new modules is not possible
- Permanent display of the message : „No connection to ...“ (See User Manual chapter 10 Procedure in case of malfunctions, Table 10-6 Network alarms)

Important!

The malfunction **cannot** be corrected by restarting the device.

If you restart your device and the malfunction is still persisting, the error messages can be assigned to the malfunction of the communication components.

2. Precondition for the Occurrence of the Error

The circuit boards in your device originate from the identified lot of incoming goods with defective communication components.

3. Potential Risk

The device does not work correctly during use as a compact device. A delay of max. 20 sec is possible until the device has switched to wireless communication (modular use).

4. Safety Information

In case of a malfunction of the IrDa communication during the use of the **corpuls³** as a compact device, separate the device to the individual modules and change to wireless communication (see User Manual chapter 4.4 Disconnecting and Connecting Modules).

Now you can use the device without limitations until the mission is finished. You can use all monitoring, diagnostic and therapeutic functions in the modular operating mode.

Do not connect “new” modules during an ongoing mission. In case of the malfunction of communication the connection authorisation (pairing) is not carried out correctly (see User Manual chapter 3 Introduction). When testing the radio connection, the wireless communication is not established and the device issues an alarm (“No connection to...”).



Devices like this are not functioning correctly and must not be used.

Combine “new” modules only at the EMS headquarters or in a clinic.

5. Troubleshooting for Conspicuous Devices

Troubleshooting is possible only indirectly by separating the modules and changing to wireless communication (see User Manual chapter 4.4 Disconnecting and Connecting Modules).

Now you can use the device without limitations until the mission is finished. You can use all monitoring, diagnostic and therapeutic functions in the modular operating mode.

Document name and location:	U:\Allgemein\Technische Bulletins\TB_007_eng.doc	Page	2 of 8		
translation date:	2010-10-07	Release date.:	2010-10-11		
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SAFETY INFORMATION

Technical Bulletin No. 007



6. Immediate Measures

Please instruct the user again on:

- Error messages and corrective measures
- Correct actions in case of malfunction of the IrDa communication during the use of the **corpuls³** as a compact device
- Informing your sales and service partner.
- Combining “new” modules only at the EMS headquarters or in a clinic.

7. Corrective Measures of the Manufacturer

This security information will be sent to all affected users until October 15th, 2010.

Our service team will exchange all affected boards in the devices as soon as possible.
For the time period of this procedure you will be supplied with a loaned device.

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 October 30th, 2010 at the latest.

The exchange of the affected boards will be carried out within 6 months after the return of the filled-in confirmation letter. The implementation of this corrective action has to take place until 2011-05-01 at the latest.

Document name and location:	U:\Allgemein\Technische Bulletins\TB_007_eng.doc	Page	3 of 8		
translation date:	2010-10-07	Release date.:	2010-10-11		
Translator name:	Dr. Anke Bader	Release name:	Klaus Stemple		

SAFETY INFORMATION
Technical Bulletin No. 007



9. Contact person of the manufacturer (for questions)

Carsten Fuchs,
Vice President, Customer Support
Kundendienstleiter

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 (www.corpuls.com).

Kind regards
GS Elektromedizinische Geräte G. Stemple GmbH

Günter Stemple
Managing Director
Geschäftsführer

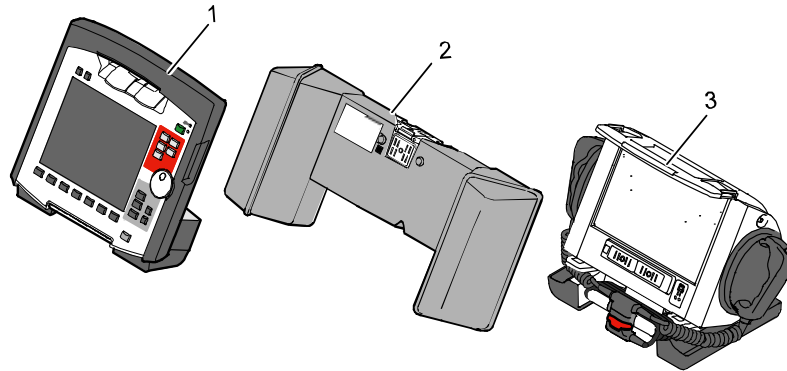
Klaus Stemple
General Manager R&D/Production
Geschäftsführer F&E/Fertigung

Document name and location:	U:\Allgemein\Technische Bulletins\TB_007_eng.doc	Page	4 of 8	
translation date:	2010-10-07	Release date.:	2010-10-11	
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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

SAFETY INFORMATION
Technical Bulletin No. 007



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 2010-10-11.

- 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 2010-10-30 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 attachement to:

md-vigilance@corpuls.com

Document name and location:	U:\Allgemein\Technische Bulletins\TB_007_eng.doc	Page	6 of 8		
translation date:	2010-10-07	Release date.:	2010-10-11		
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SAFETY INFORMATION
Technical Bulletin No. 007



Annex C

Authorised **corpuls**® sales and service partners

Please consult our homepage for international sales and service addresses:

www.corpuls.com

Document name and location:	U:\Allgemein\Technische Bulletins\TB_007_eng.doc	Page	7 of 8		
translation date:	2010-10-07	Release date.:	2010-10-11		
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SAFETY INFORMATION
Technical Bulletin No. 007



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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Document name and location:	U:\Allgemein\Technische Bulletins\TB_007_eng.doc	Page	8 of 8	
translation date:	2010-10-07	Release date.:	2010-10-11	
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