

SAFETY INFORMATION
Technical Bulletin No. 006



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No. 006	Target audience All users	Date 2010-04-06	Number of pages 7
Affected products corpuls³	Serial numbers / Lot identification User Manual	Software / Firmware Pertaining to software version 1.4.0 ; 1.5.0 und 1.6.0	

Dear Sir or Madam,

we would like to inform you via this letter about an amendment to the user manual of the **corpuls³** defibrillator/monitoring system.



This letter will contain information on:

- the reason for the amendment and on possible consequences,
- the measures you have to take as user of the device to reduce implications of the problem.

This applies to user manuals pertaining to the software versions 1.4.0 ; 1.5.0 and 1.6.0 of the **corpuls³** series, independent of the configuration of the devices.

Please find the amendment as a separate annex to this letter or on our homepage.

Please read this customer information carefully and return the filled in and signed confirmation letter (Annex B) to GS until **2010-04-30** at the latest.

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1. Error description

There has been one reported case that the user did not react correctly to the message „Pairing failed“ and that this faulty module combination was used on a patient. (Cause for the pairing request of the device was a new module combination after servicing the device).

Consequently, the patient box did not start correctly.

At the attempt to switch off the **corpuls³** as a compact device, the message „Check modules“ was not interpreted correctly neither.

There is no information available about the possible effects of this incident on the patient.

Missing instructions in the summary list of the user manual might be the cause for the wrong reaction of the crew to the warning messages.

2. Precondition for the Occurrence of the Error

When a new module is integrated into the device combination of the **corpuls³** (e.g. the patient box is transferred with the patient into another vehicle), device data have to be exchanged via the infrared interface so that the radio connection can function properly.

If this procedure was carried out correctly, the message „Pairing successful“ appears. If errors have occurred, (e.g. due to foreign bodies on the infrared interfaces) the message „Pairing failed“ is shown on the monitoring unit. Description in chapter „3.2.1 Connection Authorisation (Pairing)“ of the user manual.

If the error is not eliminated it may occur that the patient box or the defibrillator unit of the **corpuls³** is not switched off. The message „Check modules“ always appears if the patient box or the defibrillator unit are still in operation while the monitoring unit is already switched off. This is supposed to avoid unintended and unobserved draining of the batteries in the device. The measures to be taken in case of this error message are described below Fig. 4-10 (Fig. 4-11 in version 1.5) in chapter „4.2.2 Switching Off“ of the user manual.

These are necessary and correctly functioning error messages of the device. It is essential that the user either knows the necessary corrective actions or has quick access to these in the user manual.

3. Potential Risk

The device cannot be operated correctly due to the missing (or incorrectly transmitted) device data. The transmission of medical data to the monitoring unit is faulty.

4. Safety Information

The users should be trained in the exchange of modules if this is provided for in the mission procedure.

After the **corpuls³** has been serviced, the user should at least perform the daily check. Obviously, this has not been done as described in chapter „9 Maintenance and Tests“ of the manual. If the connection test of the modules had been performed (for details see Table 4-1 in chapter 4.1.2), the device would have requested a new, correctly performed pairing procedure.

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5. Troubleshooting Conspicuous Devices

If the message „Pairing failed“ is shown, repeat the pairing procedure. If this does not remedy the problem, check the infrared interfaces of the device for foreign bodies and start the pairing procedure again. Please take notice that the monitoring unit and the patient box have to be paired first. The pairing procedure is then repeated with the defibrillator unit and this module combination.

If the device shows the message „Check modules“ when switching off, separate the individual modules and check if all modules have been switched off correctly. If this is not the case, each module can be switched off correctly by keeping the green On/Off key depressed for 3 seconds. If this does not work, the switch-off can be forced by keeping the green On/Off key depressed for 8 seconds and thus interrupting the power supply of the module. However, a forced switch-off may result in data loss on the CF card.

6. Immediate measures

Please inform all users in your organisation once again about:

- The correct procedure when integrating new modules in the device combination,
- possible errors that can occur doing so and how to remedy them,
- the importance of the message „Check modules“ when switching off the **corpuls³** and
- the necessity to check the modules for correct switch-off, if the message was displayed.

For further improvement and to assist the user, the short manual should be carried along with the device.

7. Corrective Measures of the Manufacturer

Complementing the user manual in chapter „10 Procedure in Case of Malfunctions“ with the missing alarm messages, their meaning and possible corrective measures to be taken.

Please file this amendment into your user manual version 1.4.0 ; 1.5.0 and 1.6.0.

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 **2010-04-30** at the latest.

We thank you for your understanding for the realisation of these corrective measures and apologise for the inconveniences. For further questions, please contact your authorised **corpuls[®]** sales and service partner (see also annex C or www.corpuls.com).

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Contact person of the manufacturer for questions:

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Kind regards
GS Elektromedizinische Geräte G. Stemple GmbH

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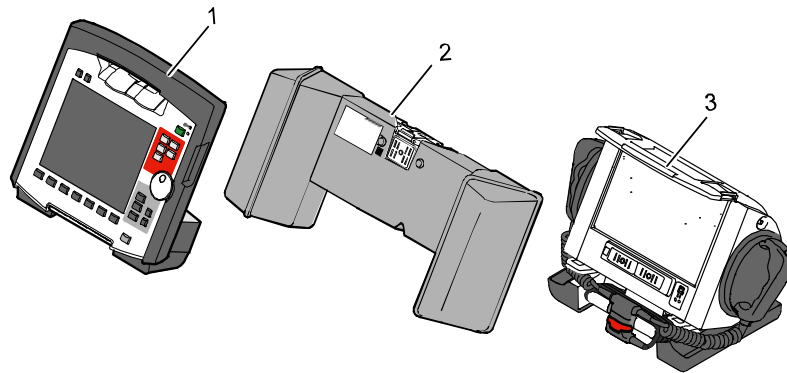
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Annex A

Illustration of the device combination **corpuls³**

- 1 – Monitoring unit
- 2 – Patient box
- 3 – Defibrillator



Rating plates with position of the serial numbers

System - Info 1		
System	Software Version	Serial Number
Monitoring Unit	REL-1.6.0_C3_BD	2000000036760305
Patient box	REL-1.6.0_C3_BD	D7000000366AD105
Defibrillator	REL-1.6.0_C3_BD	DA000000366E5A05

Info 1 Info 2 Cancel OK

System - Info 2		
Options	Software Version	Serial Number
Biphasic module	M:v2.00V/S:v2.00L	--
ECG	1K	--
SpO2	996/v0.3.14.5/v0.3.14.6	--
NIBP	LM3.390/SM V220/0829	--
CO2	--	--
IBP	v13/v7/v7	--
Temp	v3/v3/v4	--
GSM	MC55 04.00	--
ECG-Interpretation	18.24-03	--
Data Interface	0212	00:18:da:00:b4:bd

Info 1 Info 2 Cancel OK

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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 2010-04-06.

- We have informed our users in an appropriate way about the contents of this safety information and the amendment to the user manual.

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 2010-04-30 at the latest to:
 GS Elektromedizinische Geräte G. Stemple GmbH, Hauswiesenstrasse 26, D-86916 Kaufering
Fax: + 49 8191 65722 - 22

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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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