Safety Notice
Technical Bulletin No. 023

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No.	Target audience	Date	Number of pages
023	Affected users	2023-02-20	8

Affected products	Serial numbers / Lot identification	Software / Firmware
corpuls3	No relation	Software Version 3.2.x Software Version 4.0.x Software Version 4.1.x Software Version 4.2.x Software Version 4.3.0

Dear sir or madam,

with this letter we would like to inform you about a safety notice concerning corpuls3 software versions 3.2.x, 4.0.x, 4.1.x, 4.2.x and 4.3.0 that have been installed on a limited number of devices.

When using therapy functions in AED mode in combination with the activated function "Auto Analyse" and a particular setting of the metronome, in very rare cases the operability of the defibrillator function may fail (see description of the error). The monitoring function of the device is not affected and patient monitoring is still possible.

Please do read this safety information attentively and send back the filled-in answer form attached in Annex A by 2023-04-30.

Other corpuls3 devices or software versions are not affected by this problem.

The responsible supervisory authorities of the involved countries and your authorised **corpuls**® sales and service centre have been informed about this FSN (Field Safety Notice).

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1. Description of the Error

When using therapy functions in AED mode in combination with the settings "Auto Analyse", "Metronome" and a particular CPR frequencies, which deviate from the factory settings can in very rare cases, cause the operability of the defibrillator function to fail. When the error occurs, the screen shows an energy level of 0 Joules and a time since the last shock (also shown on the pie chart) of 1:54 (see the following illustration, Fig. 1). The ECG lead incl. parameters is obtained correctly.

Manual ECG analysis and monitoring are still possible.

Therapy and shock release is only possible after rebooting the device.

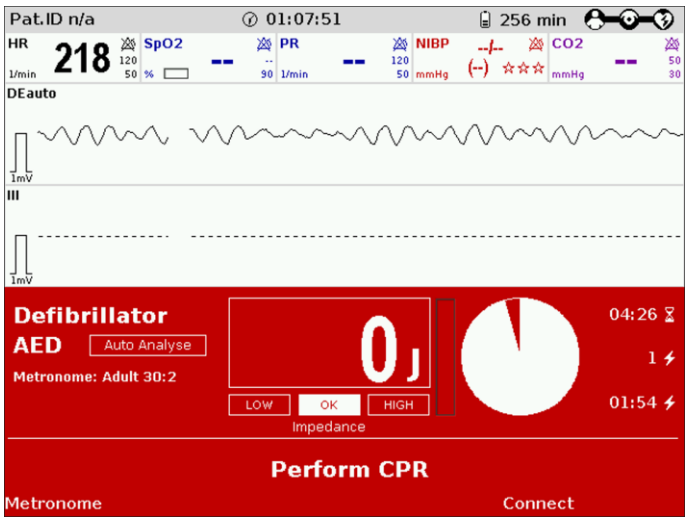

Fig. 1: corpuls3 with software versions 3.2.x, 4.0.x, 4.1.x, 4.2.x and 4.3.0 – In case of the error, the screen freezes

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2. Prerequisite for the Occurrence of the Error

With the following configuration, the error may occur:

- Software versions 3.2.x, 4.0.x, 4.1.x, 4.2.x or 4.3.0
- Activated function „Auto Analyse“
- AED mode is activated
- Metronome activated with the following settings:

Metronome modes	Compression rate	Duration of ventilation phase
30:2	110 /min	3 s
	100 /min	6 s

Software version – this can be seen in the system info, main menu "System" ► "Info".

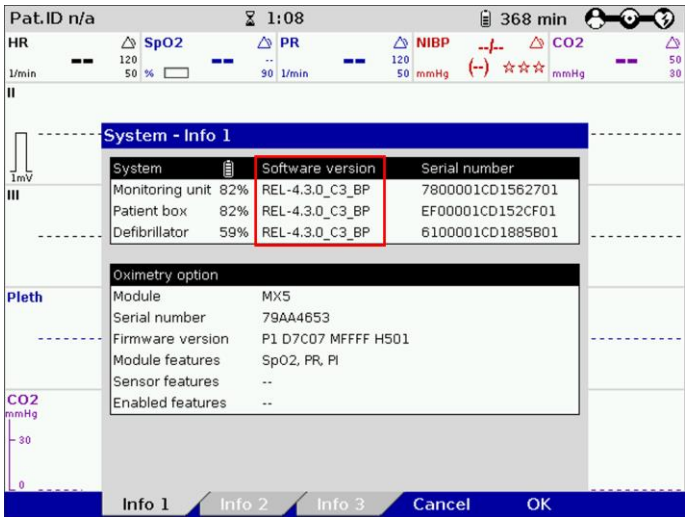

Fig. 2: System info - e.g. Software version 4.3.0

Auto Analyse – can be seen in the system info, main menu "Defib" ► "Settings".

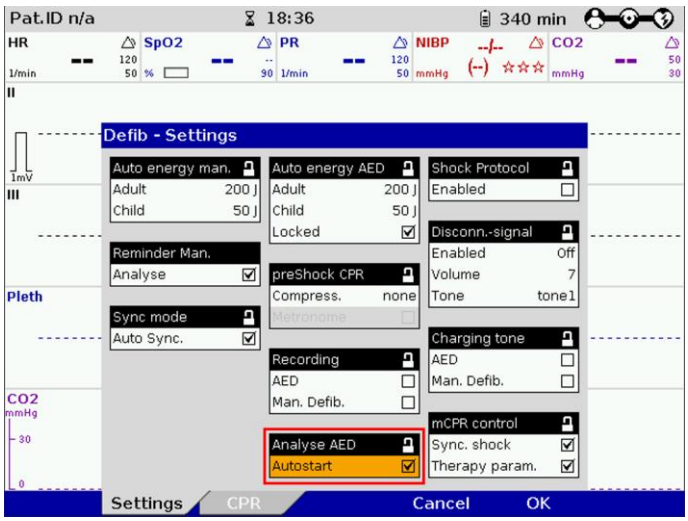

Fig. 3: Defib - Settings – Analyse AED

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CPR Settings – can be seen in the system info, main menu "Defib" ► "CPR".

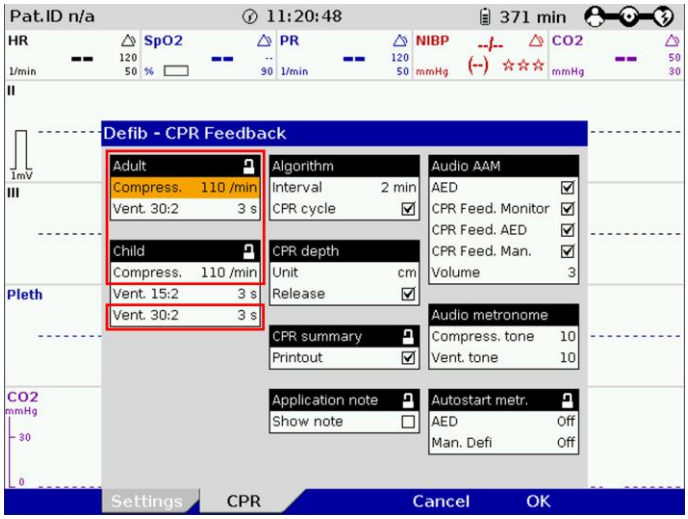

Fig. 4: Defib - CPR – Adult / Child

3. Potential Risk

In very rare cases, the device can exhibit the described error and consequently, therapy may be delayed. It is only possible to release a shock after rebooting the device.

4. Safety information

Please do notify your users as soon as possible about possible malfunctions that can occur and relevant corrective measures.

Awareness of this safety notice allows the user to deploy the device on the patient without limitations.

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5. Troubleshooting for Conspicuous Devices

If the described device behaviour occurs, the device needs to be rebooted.

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 affected products to third parties, please forward a copy of this safety information to them and also inform the contact person mentioned in point 9.

Please check the device settings in order to prevent the error from occurring.

The following combination of settings must not be used in combination with the activated "Auto Analyse" function and metronome:

Metronome modes	Compression rate	Duration of ventilation phase
30:2	110 /min	3 s
	100 /min	6 s

If this configuration is set, it must be adjusted by the user OPERATOR.

The procedure is described in the user manual, chapter 7.4.12 Configuration of the Metronome and CPR feedback (Persons Responsible for the Device)

It is recommended to use the factory settings of the device.

Excerpt - User manual Appendix D Factory Settings

Field	Value/Setting
Defib – CPR Feedback	
Adult	
Compress.	100 /min
Vent. 30:2	4 s
Child	
Compress.	100 /min
Vent. 15:2	4 s
Vent. 30:2	4 s

7. Corrective Measures of the Manufacturer

This security information will be sent to all affected users by 2023-03-15.

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 actioned 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 answer form (Annex A) to GS by 2023-04-30 at the latest.

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9. Contact person of the manufacturer (for questions):

Daniel Rampp,
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 authorised **corpuls**® sales and service centre.

With kind regards
GS Elektromedizinische Geräte G. Stemple GmbH

Klaus Stemple
Dipl.-Ing., Electrical engineering and Information technology
CEO/CTO
R&D, Product Safety

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Annex A

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 2023-02-20.
- ☐ We have informed our users in an appropriate way about the contents of this safety information and the amendment to the user manual.
- ☐ We have checked the device settings and adjusted them, if needed.

To be filled in by the customer (please print):

Organisation:	
Address:	
City:	Country:
Name:	First name:
Mr/Ms/Title:	Fax:
Phone:	Company stamp:
E-Mail address:	
Date/Signature:	

Please return this confirmation form until 2023-04-30 at the latest to:

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Or scanned as PDF attachment to:
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