Safety note
Technical Bulletin No. 029

GS Elektromedizinische Geräte
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Nr.	Target group	date	Number of pages
029	Affected users	2025-06-13	4

Affected products	Serial numbers / batch designation	Software / Firmware
corpuls3 , corpuls3 SLIM, corpuls3 Touch, corpuls3 MAX, corpuls3 SLIM MAX, corpuls3 Touch MAX	No dependency	Software-Version 4.4.1

Dear Sir or Madam

With this letter we would like to inform you about a security notice of the corpuls3 software version 4.4.1, which has been installed on a limited number of devices. Please read this security notice carefully and complete and return the response form attached in Appendix A (for authorised sales and service partners) or Appendix B (for users) **by 2025-09-30.**

Please ensure that all users of the above-mentioned products and other persons to be informed are made aware of this urgent safety notice. If you have passed on the affected products to third parties, please forward a copy of this safety notice and inform the contact person indicated. Please keep this information until the action has been finalised.

The responsible supervisory authorities of the countries concerned and your responsible, authorised corpuls® sales and service centre have been informed about this FSCA (Field Safety Corrective Action).

We thank you for your understanding in implementing this corrective action and apologise for any inconvenience this may cause. Please direct any queries to your responsible, authorised corpuls® sales and service centre.

Yours sincerely

GS Elektromedizinische Geräte G. Stemple GmbH

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1. Description of the error and prerequisite for its occurrence

When using one of the therapy electrodes offered by GS (active DE-ECG), no alarm is triggered if the heart rate exceeds or falls below the set limit values. The behaviour is independent of an additionally connected monitoring ECG. As soon as the therapy electrodes are disconnected, the alarm messages are displayed again as usual. This behaviour only occurs when using software version 4.4.1, other software versions are not affected.

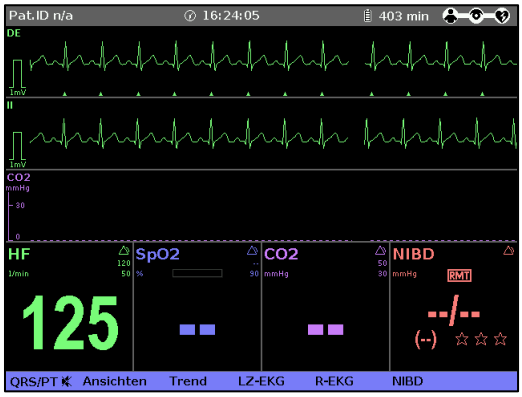

Figure 1: No alarm if the limit values are exceeded

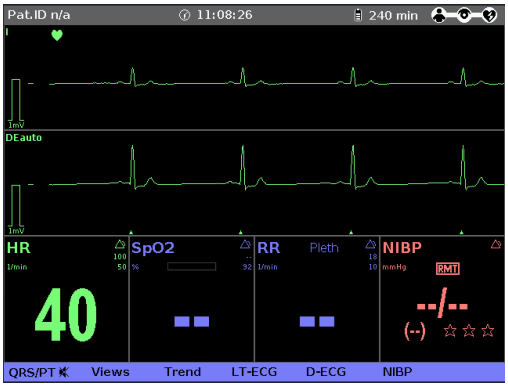

Figure 2: No alarm if the limit values are not reached

Figure 3: Alarm (top left) and inverted parameter field

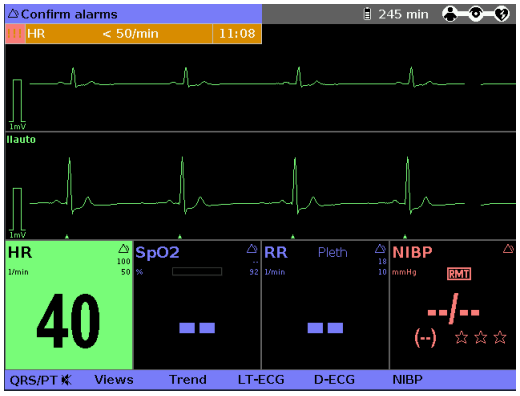

Figure 4: Alarm confirmation request

2. Potential risk and risk minimising measures

Reliable patient monitoring of the heart rate can no longer be ensured due to the absence of an alarm if the heart rate exceeds or falls below the set limit values. Patient monitoring is still possible, the displayed heart rate parameter is correct. We therefore recommend permanent visual monitoring of the heart rate on the monitor in order to be able to react promptly to changes in the patient parameters.

3. Troubleshooting

If you have installed the software version 4.4.1 affected by this behaviour on your device, please contact your authorised sales and service partner immediately to update the software version on your device. The subsequent version of the software (REL- 4.4.2) was developed as a corrective measure to eliminate this behaviour.

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Court of Registry Augsburg HRB 3373
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Appendix A

Response Form

To be completed by authorised sales and service partners:

o We have read and understood the safety instructions of GS Elektromedizinische Geräte G. Stemple GmbH and understood it.

o We have informed our users in an appropriate manner about the content of this safety notice and the necessary troubleshooting.

o The necessary troubleshooting has been carried out for all affected customers.

Organisation:	
Address:	
place:	Country:
name:	Pre name:
titel:	Fax:
Phone number:	Company stamp:
E-mail address:	
Date/Signature:	

Please complete this reply form by 2025-09-30 and return it to:

GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstrasse 26
D-86916 Kaufering
Fax: + 49 8191 65722 - 22
E-Mail: md-vigilance@corpuls.com

Manufacturer's contact person for queries:

Christian Fischer
Director Customer Success
Tel.: +49 8191 65722-598
Fax: +49 8191 65722 - 22
E-Mail: md-vigilance@corpuls.com

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Appendix B

Response Form

To be completed by the user:

o We have read and understood the safety instructions of GS Elektromedizinische Geräte G. Stemple GmbH and understood it.

o The necessary troubleshooting has been carried out (in consultation with the authorised sales and service partner).

Organisation:	
Address:	
place:	Country:
name:	Pre name:
titel:	Fax:
Phone number:	Company stamp:
E-mail address:	
Date/Signature:	

Please complete this reply form by 2025-09-30 and return it to:

- Insert contact person of the authorised sales and service partner -

Manufacturer's contact person for queries:

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