Safety Notice
Technical Bulletin No. 30

GS Elektromedizinische Geräte
G. Stemple GmbH
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info@corpuls.com
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No.	Target audience	Date	Number of pages
030	Affected users	2025-07-17	5

Affected products	Serial numbers / Lot identification	Software / Firmware
corpuls3 / corpuls3 Touch	n/a	n/a

Dear sir or madam,

with this letter, we would like to inform you about a voluntary safety notice concerning corpuls3 / corpuls3 Touch daily function checks.

As part of our ongoing post-market surveillance and commitment to patient safety and device performance, we are issuing information about important updates in the IFU regarding device operation and user response. These updates are reflected in a forthcoming revision of the device's Instructions for Use (IFU) or additional IFU supplement pages.

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. Details of issue Importance of Daily Check Execution and Appropriate Response to identified defects

Failure to perform appropriate checks may result in undetected device readiness. It has been observed during post-market surveillance activities that the *Daily Checks of the Device* are not performed consistently or the results of the tests are not being reviewed by users as per the recommended procedure. This deviation from the IFU can result in undetected device readiness issues and may compromise emergency response effectiveness.

Measures taken by the manufacturer:

To address this, the following corrective measures will be implemented:

- The IFU will be updated to clearly communicate that execution and verification of the *Daily Checks of the Device* is mandatory for ensuring the device remains in a ready-for-use condition.

- Users will be instructed that failure to perform and document the daily check constitutes non-compliance with the manufacturer's operating instructions and may result in delayed or ineffective therapy delivery.

In the event of a failed self-test, immediate action must be taken, as described in IFU chapter 11 *Procedure in Case of Malfunctions* including temporary removal from service, replacement with a backup device, and escalation to your responsible sales and service partner.

Potential Risk

If the *Daily Checks of the Device* are not performed consistently or the results of the tests are not being reviewed by users as per the recommended procedure, the result of undetected device readiness issues and may compromise emergency response effectiveness can occure.

There have been no reported adverse events associated with these issues in the EEA.
These updates are being issued as a precautionary measure to enhance user awareness and ensure proper device operation in all clinical scenarios.

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2. Corrective Measures by this notice

This safety information will be sent to all affected users by 2025-07-31:

a. Read and understand the contents of this notice. Ensure that all relevant personnel are aware of the content of this notice.

b. If you have supplied the affected products to third parties, forward a copy of this information to them.

c. Return the response form attached in Appendix A (for authorised sales and service partners) or Appendix B (for users) by **2025-09-30**.

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.

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Appendix A

Response Form

To be completed by authorised sales and service partners:

- We have read and understood the safety instructions of GS Elektromedizinische Geräte G. Stemple GmbH and understood it.
- We have informed our customers in an appropriate manner about the content of this safety notice.

Organisation:	
Address:	
place:	Country:
name:	Pre name:
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
E-Mail: md-vigilance@corpuls.com

Manufacturer's contact person for queries:

Christian Fischer
Director Customer Success

Tel.: +49 8191 65722-598
E-Mail: md-vigilance@corpuls.com

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Appendix B

Response Form

To be completed by users:

- We have read and understood the safety instructions of GS Elektromedizinische Geräte G. Stemple GmbH and understood it.
- We have informed our users in an appropriate manner about the content of this safety notice.

Organisation:	
Address:	
place:	Country:
name:	
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:

Christian Fischer
Director Customer Success
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