Information on a field measure
Technical Bulletin No. 31

GS Elektromedizinische Geräte
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Nr.	Zielgruppe	Datum	Anzahl der Seiten
031	Limited number of affected customers	2026-02-11	5

Betroffene Produkte	Charge	Software / Firmware
corpuls1	board batch CH25/00037630	

Dear Sir or Madam,

We are writing to inform you about a field safety corrective action (FSCA) affecting a limited range of corpuls1 device serial numbers.

A trusting relationship with our customers and the consistently high quality of our products are of paramount importance to us. Through our established quality management system and regular monitoring measures, we ensure that our products meet our own high standards.

As part of our ongoing market monitoring, we have identified an anomaly in connection with the high-voltage unit of the corpuls1. In order to ensure our high quality and safety standards in the long term, we have decided to issue a Field Safety Corrective Action (FSCA) as a precautionary measure.

Although no safety-related incidents have been reported to date, we would like to take early action to continue to ensure the reliable functioning of our products.

The competent supervisory authorities in the affected countries and your authorized corpuls® sales and service center have already been informed about this safety notice.

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Description

During a quality-assured material changeover, it was discovered that a specific batch of circuit boards for the corpuls1 product deviated from the approved circuit board specifications. These boards are part of the high-voltage assembly and play a role in the defibrillator's energy delivery.

Internal technical investigations have shown that this deviation leads to reduced electrical voltage resistance. Under certain operating conditions, especially after repeated high-voltage shock cycles, degeneration of the insulation within the high-voltage assembly may occur, subsequently leading to a defect in the high-voltage assembly.

Potential risk

In the event of a fault, this may lead to functional impairment or failure of the high-voltage unit, meaning that shock delivery may not be available or may not be reliable. In the worst-case scenario, this could result in a failure of therapy, whereby the intended defibrillation/cardioversion cannot be performed.

At the time of writing this safety information, no adverse events or incidents related to this deviation are known. The measures described are being taken as a precautionary measure to eliminate potential risks and ensure product safety.

Measures taken by the manufacturer

Immediately after the deviation was identified, the affected production batch of corpuls1 circuit boards was blocked to prevent further delivery of non-compliant devices. The batch was comprehensively analyzed internally and devices that had already been delivered were systematically identified.

As a corrective measure, the circuit boards of all devices containing non-approved material will be replaced by the manufacturer with circuit boards that comply with the approved specifications in order to ensure the long-term conformity, safety, and performance of the product.

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Managing Bboard:
Dr. C. Brönnimann, DR. F. Kuhn, K. Stemple,
M. Heller, M. Leber
Court of Registry Augsburg HRB 3373
USt-Id. DE 128 668 535

Bank Account:
Volksbank Kaufering
IBAN DE20 7009 3200 0008 6801 24
BIC GENODEF1STH

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Required measures for customers and distribution partners

If you are using one of the devices listed below (see page 5: Appendix B, Affected Serial Numbers), you are hereby requested to discontinue use of the device in question and return it to the manufacturer immediately.

Please contact your corpuls® service or sales partner to arrange for the return and refurbishment of the device.
To maintain continuous patient care, a loaner device will be provided if necessary.

These measures serve to ensure compliance with the approved specifications, maintain product safety, and minimize risks to users and patients.

Remedial measures through this security notice

This security notice will be sent to all affected users by **February 25, 2026.**

a. Read and understand the content of this notice. Ensure that all affected employees have taken note 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 by **2026-03-25** at the latest to confirm completion of the measures.

The Federal Institute for Drugs and Medical Devices 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 users:

- ☐ We have read and understood the safety instructions provided by GS Elektromedizinische Geräte G. Stemple GmbH.
- ☐ All users have been informed of the contents of these safety instructions in an appropriate manner.
- ☐ The affected device serial numbers located on the premises (see page 5: Appendix B) have been sent to the manufacturer for revision.

organization:	
adress:	
city:	country:
name:	First name:
phone number:	company stamp:
email address:	
date/ signature:	

Please complete this response form by **March 25, 2026**, and send it electronically to the following email address:

Michael Schmidt
Vice President Quality Management, Regulatory Affairs, Design Assurance

Tel.: +49 8191 65722-120
E-Mail: **md-vigilance@corpuls.com**

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Appendix B

Affected (device) serial numbers

25300920	25300972	25300984	25300995	25301018	25301034
25300958	25300973	25300985	25300996	25301019	25301035
25300961	25300974	25300986	25301007	25301020	25301036
25300962	25300975	25300987	25301008	25301021	25301040
25300963	25300976	25300988	25301009	25301022	
25300964	25300977	25300989	25301010	25301023	
25300965	25300978	25300990	25301011	25301026	
25300969	25300980	25300991	25301013	25301027	
25300970	25300981	25300992	25301014	25301028	
25300971	25300982	25300994	25301015	25301031	

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