



## Information on a field measure Technical Bulletin No. 31

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|                                 |  |                     |                        |
|---------------------------------|--|---------------------|------------------------|
| Nr.<br>031                      | Zielgruppe<br>Limited number of affected customers | Datum<br>2026-06-11 | Anzahl der Seiten<br>5 |
| Betroffene Produkte<br>corpuls1 | Charge<br>board batch CH25/00037630                | Software / Firmware |                        |

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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### **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: _____    |                      |
| address: _____         |                      |
| 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](mailto: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 |          |