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Important Safety Notices (FSN)

No.	Affected audience	Date	Number of pages
FSN-035	☐ Users, operators, and owners of affected devices	2026-09-30	5

Affected products	Serial numbers	Software / Firmware
C3/C3T 04100, 04100.2, 04101	See local service information.	N/A

Dear Customer,

A trusted relationship with our customers and the consistently high quality of our products are of the utmost importance to us. Through our established quality management system and continuous post-market surveillance activities, we ensure that our products meet our high standards.

As part of our ongoing post-market surveillance and internal investigations, we have identified a potential correlation between printing a resting ECG and a temporary interruption of the monitor's Bluetooth connection, which may result in an unexpected, brief interruption of the display.

Detailed background information and instructions regarding the required actions are provided below.

Please read this Field Safety Notice carefully and follow the required actions.

We kindly ask you to complete and return the enclosed response form within 14 days.

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Important Safety Notices (FSN)

Description of the Issue

We are contacting you with this safety information because, according to our records, you are a user, operator, or owner of a corpuls3/corpuls3T device.

As part of our ongoing post-market surveillance activities, we have received reports of temporary interruptions of the display.

Based on further investigations, it has been determined that devices manufactured between January 2024 and March 2026 may, under certain conditions, be subject to this issue. The probability of occurrence is considered very low. In addition, the issue requires specific environmental conditions, such as low humidity or very dry printer paper.

The root cause is charge separation generated by the movement of the printer paper, which may lead to electrostatic charging of the metallic paper guide. This charge may discharge via a nearby test connection point. The resulting electrical interference can cause a temporary interruption of the Bluetooth connection to the monitor and consequently a temporary interruption of the display.

No additional failure modes were identified during the investigation. However, the occurrence of further failure modes cannot be completely excluded.

This safety action affects Article Number 04100, 04100.2, 04101.

1. Potential Risk

A temporary interruption of the display may result in users temporarily losing access to displayed patient information and being unable to operate the system for 5–25 seconds. Particularly in emergency situations, this may lead to an interruption or delay in life-saving treatment and, in the worst case, may result in serious adverse health consequences for patients. Based on our current assessment, this is a precautionary safety measure. To date, we have not received any reports of patient harm related to this failure mode. Nevertheless, due to the clinical relevance of the device application, a Field Safety Corrective Action (FSCA) is required.

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2. Required Actions

- Inform your personnel, users, **operators** and owners of the affected device about the possibility of a temporary interruption of the Bluetooth connection to the monitor, which may result in a temporary loss of the display. The interruption is limited in duration and the display will be restored automatically. The product can then continue to be used in accordance with its intended purpose.

- If the described issue occurs on your device, please contact your responsible service partner. The service partner will perform the necessary corrective measures to resolve the issue.

- If the issue does not occur on your device, no immediate action is required. Not all products on the market are affected. Your responsible service partner has already been informed and provided with all relevant information and will assess the local situation. Where applicable, the affected components will be replaced either on demand or as a precaution during the next scheduled maintenance visit or annual service.

3. Corrective Actions Implemented by the Manufacturer

To ensure uninterrupted operation, the relevant components in all devices manufactured during the specified production period will be replaced proactively and free of charge. The implementation of this measure will be carried out by an authorized service partner either after occurrence of the described issue or during the next scheduled maintenance visit or annual service.

4. Additional Information

This Field Safety Corrective Action (FSCA) has been reported to the competent authorities in accordance with applicable regulatory requirements. The measure is being conducted in close coordination with the competent authorities and is based on our internal risk assessments.

5. Distribution of this Field Safety Notice

Please ensure that all relevant persons within your organization are made aware of this Field Safety Notice. If affected devices have been transferred to third parties, please provide them with a copy of this Field Safety Notice.

6. Response

Please complete the enclosed response form and return it to your local service center.

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7. Manufacturer Contact Person:

Michael Schmidt
Vice President
Quality Management & Regulatory Affairs

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E-Mail: md-vigilance@corpuls.com

We thank you for your understanding and cooperation in implementing this corrective action and apologize for any inconvenience caused.
If you have any questions, please contact your authorized corpuls® sales and service center.

Kind regards,

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Annex A

Response Form

Please check ALL applicable boxes:

- ☐ We confirm that we have read and understood the Field Safety Notice issued by GS Elektromedizinische Geräte G. Stemple GmbH and have implemented all required actions described therein.

- ☐ We have informed all affected users and relevant personnel about the contents of this notice and the required actions.

To be completed by the owner/operator of the affected devices:

Organization:	
Adress:	
Location:	Country:
Name:	First name:
Salutation / Title:	Fax:
Telephone:	Company Stamp
E-Mail:	
Date/Signature:	

Please complete this response form and return it within 14 days of receipt to:

support@corpuls.com