Field Notice

GS Elektromedizinische Geräte
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SRN	UDI DI	Date
DE-MF-000007648		23.03.2026
Nr.	**Zielgruppe**	**Technical Devices**
032	affected users	0400, SLIM 04001, 04002
Affected products	**Serial numbers/ batch designation**	**Software / Firmware**
corpuls3 Product-family with Glasgow Full Scale or HES-License	99014-4.3.3 99014-4.4.2 99014-4.4.3	SW-REL-4.3.3 SW-REL-4.4.2 SW-REL-4.4.3

Dear Sir or Madam,

A trusted partnership with our customers and the consistently high quality of our products are of the highest importance to us. Through our established quality management system and routine monitoring activities, we ensure that our products continue to meet our stringent quality and safety requirements.

As part of our ongoing post-market surveillance activities, we have identified an anomaly related to the license file associated with the automatic ECG interpretation functionality (Glasgow Full Scale, HES). This functionality is available as a paid, optional upgrade.

To maintain our high standards for product quality and transparency, we are issuing this Field Notice to inform our customers about this observation.

At this time, no safety-related incidents or adverse events have been reported in connection with this matter. Based on the information currently available, there is no indication of an increased risk to patients or users. Nevertheless, we consider it important to proactively inform our customers and provide additional clarification.

Please ensure that all relevant personnel within your organization are informed about this Field Notice. This includes, in particular, device users, biomedical or clinical engineering departments, and any other staff responsible for the operation or management of the affected devices. If affected devices have been transferred or provided to third parties, please ensure that these recipients also receive a copy of this Field Notice.
Please retain this information for your records.

The following sections provide further details regarding the background of the identified anomaly and additional information for users.

Field Notice

1. Description of the error

In corpuls3 modules running software versions SW-REL-4.3.3, 4.4.2, or 4.4.3 in combination with a license for automatic ECG interpretation (Glasgow Full Scale or HES), an internal configuration file may, in very rare cases, be lost during the boot process. This behavior occurs randomly and cannot be influenced by the user.

If this condition occurs, the functions for automatic ECG interpretation and the specific ECG alarms (corpuls ACS) are not available. The basic device functions for ECG signal acquisition and display remain available. The alarm message “Possible acute STEMI” also remains available and is therefore not affected.

The following additional changes may occur:

- The serial number stored in the module is deleted (field displayed as empty)
- The STK or MTK dates stored in the modules are deleted
- In the patient module (PAM), the stored ECG license code is reset to the default value “Glasgow Basic”

The device does not generate an active warning or error message to indicate that this condition has occurred. The changed status can only be identified in the system information menu (page 2), where the “Glasgow” entry is displayed with a gray background.

2. Potential risk

Due to the reset of the ECG license code, the functions for automatic ECG interpretation and the associated ECG alarm notifications are no longer available. As the device does not provide an indication that this condition has occurred, the loss of this functionality may initially remain unnoticed by the user.

This may limit the availability of automated clinical decision support and the corresponding alerting for certain ECG-related events. The basic functions for ECG signal acquisition, display, and derivation remain fully available. Users can continue to visually assess the ECG signal and make clinical decisions based on their professional judgment.

Based on the information currently available, the manufacturer, GS Elektromedizinische Geräte G. Stemple GmbH, is not aware of any safety-related incidents or patient harm associated with this issue.

This behavior may occur in all three modules of the corpuls3 system; however, clinically relevant effects are limited to the patient module (PAM).

For the patient module (PAM), the described behavior may result in the automatic ECG interpretation and the associated alarm functions (corpuls ACS) being unavailable in rare cases.

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BIC GENODEF1STH

Field Notice

3. Risk-minimizing measures for the user

Operators and users are advised to take the following precautions:

- As part of routine device checks, verify the system information (page 2) on devices with an active Glasgow or HES license.
- Check whether the “Glasgow” entry is displayed with a gray background or whether the module’s serial number is missing (see Figure 1: Glasgow Basic).

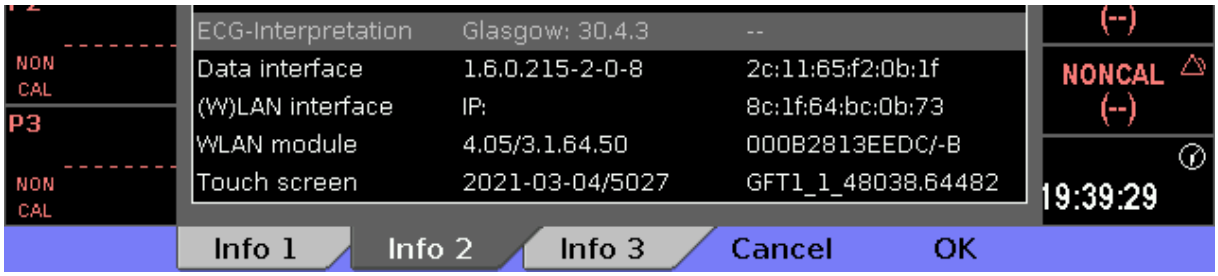

Figure 1: Glasgow Basic

The clinical use of the device for ECG monitoring and recording remains fully available.
If this condition is observed, please contact your authorized corpuls® sales and service center.

4. Troubleshooting

The manufacturer has investigated the described behavior as part of internal analyses and has initiated appropriate measures. A software modification is being developed to permanently address the root cause and prevent the potential loss of the internal configuration file during the boot process.

The manufacturer has already released a software update that fully resolves the issue. The new software version, SW-REL-4.4.4, will be available from 23 March 2026.

The software update will be provided through the regular service channels. Affected customers will be informed accordingly.

Until the corrected software becomes available, devices may continue to be used as intended. The core functions for ECG signal acquisition, display, and derivation remain fully available.

Field Notice

5. Manufacturer's contact person for queries

Michael Schmidt
Vice President
Quality Management & Regulatory Affairs

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We thank you for your understanding regarding the implementation of this corrective measure and apologize for any inconvenience caused. If you have any questions, please contact your authorized corpuls® sales and service center.

Kind regards,
GS Elektromedizinische Geräte G. Stemple GmbH
2026-03-23

Signiert von:
Michael Schmidt
89560392D8BD4EC...
Michael Schmidt
Vice President
Quality Management & Regulatory Affairs

Field Notice

Annex A

Response form

Please check ALL boxes that apply to your company:

- ☐ We have read and understood the field notice issued by GS Elektromedizinische Geräte G. Stemple GmbH.

- ☐ We have appropriately informed our users about the content of this Field Notice and any potential corrective actions that may be required.

To be completed by the customer:

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

Please return this form to your authorized corpuls® sales and service center by no later than **31 May 2026.**