# Safety Notice
# Technical Bulletin No. 025

GS Elektromedizinische Geräte
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| No. | Target audience | Date | Number of pages |
|---|---|---|---|
| 025 | All users, operators and service partners | 2024--11-04 | 5 |

Dear sir or madam,

with this letter we would like to inform you about the safety measure concerning the battery corpuls aed.

| **Battery corpuls aed** | **In medical device corpuls aed** |
|---|---|
| REF 06120 | REF 06100.10 corpuls aed semi-automatic with CPR |
| | REF 06101.10 corpuls aed semi-automatic |
| | REF 06100.11 corpuls aed (semi-autom.) with emergency call with CPR |
| | REF 06101.11 corpuls aed (semi-autom.) with emergency call |
| | REF 06100.20 corpuls aed fully automatic with CPR |
| | REF 06101.20 corpuls aed fully automatic |
| | REF 06100.21 corpuls aed (fully autom.) with emergency call with CPR |
| | REF 06101.21 corpuls aed (fully autom.) (multiling.) with emergency call |
| | REF 06100.22 corpuls aed (fully autom.) (ext.) with CPR |
| | REF 06101.22 corpuls aed (fully autom.) (multiling.) |

According to our records, your organisation is using at least one of the affected batteries with one corpuls aed.

Please do read this safety notice attentively and send back the filled-in answer form attached in Annex A by 2024-11-30.

The responsible supervisory authorities of the involved countries and your authorised corpuls® sales and service centre have been informed about this FSCA (Field Safety Corrective Action).

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## 1. Description of the Error and Prerequisite for the Occurrence

We are observing in the field a certain number of devices that perform an unplanned restart with self-test during operation. The cause for this is a loss of contact between the battery and the device. When there is pressure on one side of the device, the inserted battery is tilted to the maximum and the brief loss of contact leads to a restart of the device with self-test.

To meet our own quality requirements for our products, we have adjusted the production process for all batteries corpuls aed. All batteries will profit from this improvement and the functionality of the devices will reach our set standard.

## 2. Occurrence Probability and Potential Risk

Due to the feedback we received, we assume a failure rate of 1.82%.

If the error occurs immediately during the treatment of the patient, in rare cases there can be a delay of more than 3 minutes. Up to now, we are not aware of any serious incidents in connection with this error pattern.

## 3. Immediate Measures and Error Elimination

Briefing all the users with this urgent safety notice should be effected immediately by appropriate measures (e.g. via e-mail or by posting this letter at the bulletin board and depositing a copy with the user manual). Please return the filled-in answer form (Annex A) to us by 2024-11-30 at the latest.

- If this safety notice is known, affected batteries can be identified by performing the pressure point test - see No 7.
  If you have identified an affected product by means of the test procedure described below, decommission the affected battery and contact your authorised sales- and service partner.
- A permanent improvement of conspicuous devices can be achieved by exchanging the battery or by modifying the corpuls aed device in the area of the battery interface board.

Both solutions can be implemented independently to correct the faulty behaviour of the device. After consultation with your authorised sales- and service partner, one of the two solutions will be prepared for you.

Batteries that pass the described test process can still be used without any concerns. For remedying other error messages, please refer to the currently valid user manual.

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## 4. Identifying Affected Devices

To identify conspicuous corpuls aed batteries, please perform a pressure point test. This test checks the system stability of the device and makes sure that manipulation of the battery withing the housing does not lead to a restart of the device.

- Insert the battery firmly into the battery compartment of the corpuls aed. The battery lock on the rear side of the device must be completely snapped shut (Illustration 1).
- Now switch on the corpuls aed. Note: the edge of the battery housing is not level with the device housing (Illustration 2).

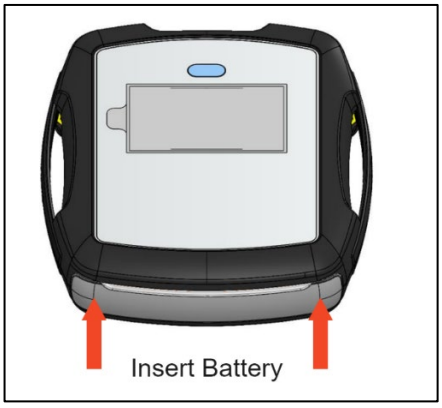

Illustration 1: Inserting the battery

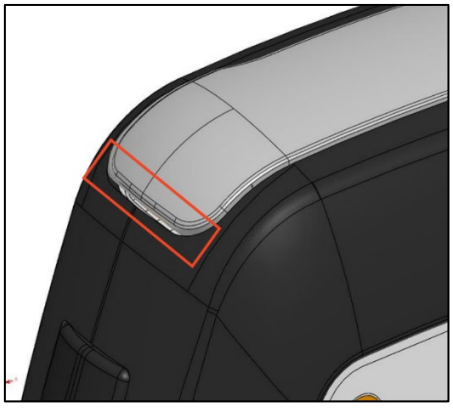
Illustration 2: Battery housing

- Apply pressure alternatingly at the outer areas of the battery at the test points 1 and 2 (Illustration 3).
- At the test point 1 the battery is pushed in deeply with both thumbs, the battery tilts and now is level with the device housing (Illustration 4). Hold this position at least 3 seconds. Repeat this procedure at test point 2.

If the corpuls aed switches off in step 1 and/or step 2 due to the applied pressure, this is the described error.

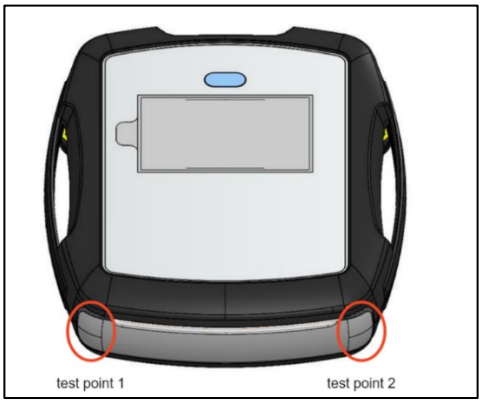

Illustration 3: ´Test points

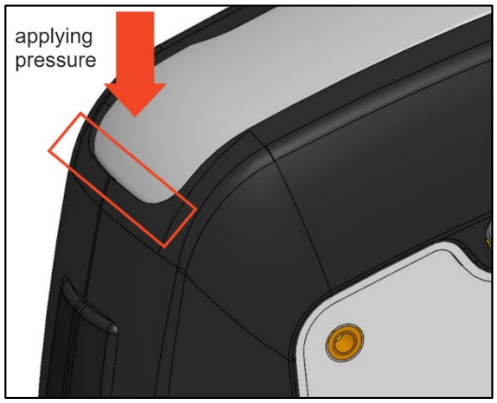

Illustration 4: Pressure on test points

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5. **Contact person of the manufacturer (for questions):**

Daniel Rampp,
Vice President, Customer Support
Head of Customer Support

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E-Mail: md-vigilance@corpuls.com

We thank you for understanding and apologise for any inconvenience you may have in connection with this corrective action. Questions concerning this matter will be answered by your authorised corpuls® sales and service centre.

With kind regards
GS Elektromedizinische Geräte G. Stemple GmbH

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## Annex A

### Confirmation form

Please mark with a cross ALL fields that apply to your company:

- ☐ We have read and understood the safety notice of GS Elektromedizinische Geräte G. Stemple GmbH.

- ☐ We have informed our users in an appropriate way about the contents of this safety notice and the identification of the affected batteries.

To be filled in by the customer (please print):

| | |
|---|---|
| Organisation: | |
| Address: | |
| City: | Country: |
| Name: | First name: |
| Phone: | Company stamp: |
| E-Mail address: | |
| Date/Signature: | |

Please return this confirmation form until 2024-11-30 at the latest to:

GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstrasse 26
D-86916 Kaufering

Fax: + 49 8191 65722 - 22

Or scanned as PDF attachment to: md-vigilance@corpuls.com