Safety Notice
Technical Bulletin No. 019

GS Elektromedizinische Geräte
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No.	Target audience	Date	Number of pages
019	Affected users	2020-04-09	5

Affected products	Serial numbers / Lot identification	Software / Firmware
Battery corpuls cpr P/N 09120	No relation	Each firmware version up to and including 1.3-004

Dear sir or madam,

with this letter we would like to inform you about the safety measure concerning the battery of the corpuls cpr firmware versions up to and including 1.3-004 that have been installed to a limited number of batteries.

An abrupt drop in voltage of the battery of the corpuls cpr may lead to an unintended switch off of the corpuls cpr. (see error description).

As a safety measure we decided to update all batteries that are operating with the affected firmware versions with a new firmware version.

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

Please do read this safety information attentively and send back the filled-in answer form attached in Annex A until 2020-05-31.

Other batteries of the type battery corpuls cpr and firmware versions are not affected by this problem.

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. Error description

Due to a faulty balancing of individual battery cells, the detection of cell voltage and cell capacity may be faulty. This triggers the safety mechanism of the battery and switches the battery off.
An effective therapy with the corpuls cpr is thus not possible and the CPR measures must be continued manually without the corpuls cpr.

2. Prerequisite for the Occurrence of the Error

Your battery corpuls cpr has installed one of the firmware versions up to and including 1.3-004 that we have identified as problematic.

This can be seen on the rating plate of the battery corpuls cpr.

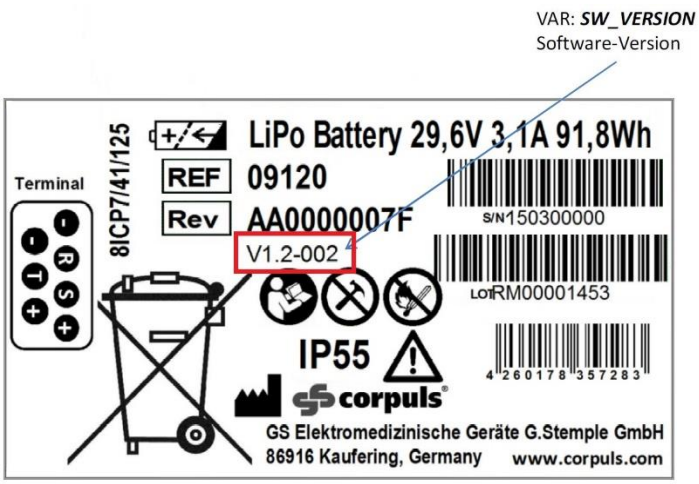

Illustration 1: Rating plate battery corpuls cpr - e.g. firmware version 1.2-002

3. Potential Risk

Due to the abrupt switch off of the corpuls cpr device and the resulting need to continue CPR manually without the corpuls cpr there may be a therapy delay.

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Management board:
G. Stemple, K. Stemple,
Dr. C. Klimmer, I. Klimmer
Registergericht Augsburg HRB 3373
USt-Id. DE 128 668 535

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

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4. Safety information

Please do notify your users as soon as possible about:

- possible malfunctions that can occur and relevant corrective measures

Being aware of this safety information allows to safely handle the abrupt drop in voltage of the battery corpuls cpr and can be taken into account when using the corpuls cpr.

5. Troubleshooting for Conspicuous Batteries

Insert a fully charged backup battery or continue CPR manually without the corpuls cpr.

A permanent correction of the malfunction is only possible by updating the affected firmware version up to and including 1.3-004.

6. Immediate Measures

Please ensure within your organisation that all users of the above mentioned products and all other persons who need to know are informed about this **urgent safety information.**

If you have supplied the affected products to third parties, please forward a copy of this safety information to them and also inform the contact person mentioned in point 9.

Please keep this information at least until the corrective measures have been completed.

7. Corrective Measures of the Manufacturer

This security information will be sent to all affected users by 2020-04-30.

Maintenance for each battery will be promptly arranged. A new firmware version 1.4-000 or higher will be installed on your battery corpuls cpr by our authorised sales and service partners. So you will soon have a fully operational corpuls cpr.

All affected national authorities have been informed.

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8. Deadline

Briefing the users 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 GS by 2020-05-31 at the latest.

The firmware update will be performed after consultation with your authorised sales and service partner. The implementation of this corrective action will have taken place by 2020-10-31 at the latest.

9. Contact person of the manufacturer (for questions):

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

Tel.: +49 (0) 81 91 6 57 22 30
Fax: +49 (0) 81 91 6 57 22 22
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

Klaus Stemple
Dipl.-Ing., Electrical engineering and Information technology
CEO/CTO
R&D, Production, Product Safety
Safety officer for medical devices (acc. §30 MPG)

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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 information of GS Elektromedizinische Geräte G. Stemple GmbH of 2020-04-09.

- ☐ We have informed our users in an appropriate way about the contents of this safety information and the amendment to the user manual.

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

Organisation:	
Address:	
City:	Country:
Name:	First name:
Mr/Ms/Title:	Fax:
Phone:	Company stamp:
E-Mail address:	
Date/Signature:	

Please return this confirmation form until 2020-05-31 at the latest to:

GS Elektromedizinische Geräte G. Stemple GmbH
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Or scanned as PDF attachment to:
md-vigilance@corpuls.com

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