Safety Notice
Technical Bulletin No. 024

GS Elektromedizinische Geräte
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No.	Target audience	Date	Number of pages
024	Affected users	2024-07-31	6

Affected products	Serial numbers / Lot identification	Software / Firmware
Battery corpuls cpr (LiPo) REF 09120	150000207 to 241500195	Each firmware version up to and including 1.4-005

Dear sir or madam,

with this letter we would like to inform you about the safety measure concerning the battery corpuls cpr (LiPo) REF 09120 in the **serial number range from 150000207 to 241500195.**

We have observed a number of batteries corpuls cpr (LiPo) REF 09120 in the field that do not reach the specified life span, but are failing prematurely. This does not comply with our or our customers' quality standards.

To comply with the quality standard of our products, we have decided to implement a preventive safety measure and update all batteries corpuls cpr (LiPo) REF 09120 with the new firmware version 1.4-006 or higher. All batteries will profit from this improvement and the life span will reach our set standard.

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 by 2024-11-30.

Other batteries of the type battery corpuls cpr 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. Description of the Error

Sporadically, the specified life span of the battery corpuls cpr (LiPo) REF 09120 is not reached.
Cause for this is the cell voltage which falls below a certain voltage threshold due to deep discharging or longer storage periods if the battery is not charged regularly, as prescribed in the user manual. This promotes the progressive degradation of the electrode materials. This results in the battery going into error statuses and the life span is shortened.

For this reason, we have developed an improved battery firmware that improves the charging process, can recognise occurring error statuses and intervenes accordingly in the charging process. In contrast to the former version, the error behaviour as well as the alarm behaviour have been reworked and improved .

2. Prerequisite for the Occurrence of the Error

Your battery corpuls cpr (LiPo) REF 09120 is within the serial number range 150000207 to 241500195 and the new firmware version 1.4-006 or newer has not yet been installed.

The type designation and the serial number range can be found on the rating plate of the battery corpuls cpr.

Illustration 1: Rating plate of battery corpuls cpr (LiPo) REF 09120

The installed firmware version is shown after the update on the attached additional label.

1.4-006

Illustration 2: Labelling of the new firmware 1.4-006 after update

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3. Potential Risk

Premature failure of the battery corpuls cpr (LiPo).

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 a failure of the battery corpuls cpr (LiPo) and allows safe use of the battery if the preventive measures are taken.

5. Troubleshooting for Conspicuous Batteries

Always insert a fully charged battery into the corpuls cpr and keep a charged spare battery available. When the battery fails, continue CPR manually without the corpuls cpr.

A permanent improvement is only possible by updating the affected firmware versions.

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.

Please check your warehouse stock of batteries. The charging status of the battery is indicated by the battery-LED, independent from the operational status of the arm. The number of LEDs lit indicates the charging status of the battery. Error statuses are indicated by the LED 1 glowing orange and the LED 2 flashing green, as described in the alarm list in the user manual.

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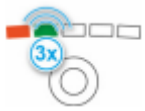
The following measures have to be taken, depending on the charging status of the battery:

Non-functional batteries (not even flashing status messages) are deeply discharged and must be replaced - Deeply discharged batteries must no longer be charged. Batteries with the error pattern "flashing 3x" must not be charged as well.

Status of the LEDs	Cause	Consequences	**Measure**
No display Non-functional batteries	Battery is deeply discharged	Battery does not start	1. **Do not start the charging process** 2. Battery exchange performed by service partner
	Battery voltage too low	Battery switches off	1. **Do not start the charging process** 2. Update performed by service partner

For remedying other alarm conditions, please refer to the currently valid user manual. Have batteries that still display an error message after being reinserted into the device be replaced by your service partner.

Insert batteries that show the correct charging status at the push of the button into the arm or the external charger to activate the battery and then check the charging status again. If the charging status is still displayed correctly, charge the battery as described in the user manual. These batteries can be used without problems and will get the newest firmware in the annual routine check.

Please make sure in the future as well to check the charging level of stored batteries regularly and recharge if necessary (< 20% or one illuminated LED). Check the battery after storage (before use) together with the corpuls cpr by means of the self-test.

7. Corrective Measures of the Manufacturer

This security information will be sent to all affected users by 2024-09-30.

Maintenance for each battery will be promptly arranged. A new firmware version 1.4-006 or higher will be installed on your battery corpuls cpr (LiPo) by our authorised sales and service partners. So you will soon have an improved battery corpuls cpr (LiPo).

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 2024-11-30 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 2025-11-30 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, Product Safety

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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 2024-07-31.

- ☐ 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 2024-11-30 at the latest to:

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Or scanned as PDF attachment to:
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