Field Safety Notice

GS Elektromedizinische Geräte
G. Stemple GmbH
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Nr.	Affected audience	Date	Number of pages
FSN-034	Users, operators, and holders of affected devices	2026-08-25	6

Affected products	Serial numbers / batch designation	Software / Firmware
Li-Ion Rechargeable Battery	A240400001 - A240400216	N/A

Dear Sir or Madam,

A trusting relationship with our customers and the consistently high quality of our products are of paramount 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 these monitoring activities and internal investigations, we have identified a potential issue related to the rechargeable battery of the corpuls CPR, which may increase the risk of an unexpected device failure.

Below, you will find detailed background information and instructions regarding the necessary actions.

Please read this Field Safety Notice carefully and follow the required actions. We kindly ask you to complete and return the attached response form within 14 days.

Field Safety Notice

Description of the issue

We are reaching out with an important safety notice because, according to our records, you are in possession of, operate, maintain, or are responsible for one or more affected devices. As part of our ongoing market monitoring, we were informed by the battery manufacturer (Ansmann) about a recall of a specific batch of the batteries used in our CPR products. Based on further investigations, it was determined that some of your batteries may be affected and have an increased risk of unexpected failure. According to the manufacturer, approximately 3% of the listed batteries may develop an electrical defect. The issue is caused by improperly soldered joints that can lead to sudden battery failure.

The affected batch number is: A1075843. The following serial numbers are affected:

A240400001	A240400044	A240400087	A240400130	A240400173
A240400002	A240400045	A240400088	A240400131	A240400174
A240400003	A240400046	A240400089	A240400132	A240400175
A240400004	A240400047	A240400090	A240400133	A240400176
A240400005	A240400048	A240400091	A240400134	A240400177
A240400006	A240400049	A240400092	A240400135	A240400178
A240400007	A240400050	A240400093	A240400136	A240400179
A240400008	A240400051	A240400094	A240400137	A240400180
A240400009	A240400052	A240400095	A240400138	A240400181
A240400010	A240400053	A240400096	A240400139	A240400182
A240400011	A240400054	A240400097	A240400140	A240400183
A240400012	A240400055	A240400098	A240400141	A240400184
A240400013	A240400056	A240400099	A240400142	A240400185
A240400014	A240400057	A240400100	A240400143	A240400186
A240400015	A240400058	A240400101	A240400144	A240400187
A240400016	A240400059	A240400102	A240400145	A240400188
A240400017	A240400060	A240400103	A240400146	A240400189
A240400018	A240400061	A240400104	A240400147	A240400190
A240400019	A240400062	A240400105	A240400148	A240400191
A240400020	A240400063	A240400106	A240400149	A240400192
A240400021	A240400064	A240400107	A240400150	A240400193
A240400022	A240400065	A240400108	A240400151	A240400194
A240400023	A240400066	A240400109	A240400152	A240400195
A240400024	A240400067	A240400110	A240400153	A240400196
A240400025	A240400068	A240400111	A240400154	A240400197
A240400026	A240400069	A240400112	A240400155	A240400198
A240400027	A240400070	A240400113	A240400156	A240400199
A240400028	A240400071	A240400114	A240400157	A240400200
A240400029	A240400072	A240400115	A240400158	A240400201
A240400030	A240400073	A240400116	A240400159	A240400202
A240400031	A240400074	A240400117	A240400160	A240400203
A240400032	A240400075	A240400118	A240400161	A240400204
A240400033	A240400076	A240400119	A240400162	A240400205
A240400034	A240400077	A240400120	A240400163	A240400206

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Geschäftsführung:
Dr. C. Brönnimann, Dr. F. Kuhn,
M. Heller, M. Leber
Registergericht Augsburg HRB 3373
USt-Id. DE 128 668 535

Bankdaten:
Volksbank Kaufering
IBAN DE20 7009 3200 0008 6901 24
BIC GENODEF1STH

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A240400035	A240400078	A240400121	A240400164	A240400207
A240400036	A240400079	A240400122	A240400165	A240400208
A240400037	A240400080	A240400123	A240400166	A240400209
A240400038	A240400081	A240400124	A240400167	A240400210
A240400039	A240400082	A240400125	A240400168	A240400211
A240400040	A240400083	A240400126	A240400169	A240400212
A240400041	A240400084	A240400127	A240400170	A240400213
A240400042	A240400085	A240400128	A240400171	A240400214
A240400043	A240400086	A240400129	A240400172	A240400215
				A240400216

(manufactured between March 2024 and December 2024).

1. Potential risk

An unexpected battery failure can cause the CPR resuscitation aid to be temporarily unavailable during use. This may result in interruptions or delays in life-saving treatment during emergency situations and, in the worst case, lead to serious health consequences for patients.

Based on the current assessment, this is a preventive safety measure. We have received no reports of serious incidents resulting in patient harm related to this issue. Nevertheless, due to the clinical significance of using the CPR device, a precautionary Field Safety Corrective Action (FSCA) is required.

2. Required actions for holders of affected devices

- Identify all batteries in your facility that belong to the corpuls CPR resuscitation aid.
- Check whether any battery belongs to batch A1075843 and has a serial number between A240400001 and A240400216.
- Take all identified affected batteries out of service immediately and clearly label them as "Do not use / Recall".
- Make sure that ready-to-use replacement batteries are available for all affected devices to ensure the operational readiness of your CPR resuscitation aids.
- Do not use the affected batteries. Your responsible service partner has been informed about the affected serial numbers at your site and will contact you directly to coordinate the replacement.

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3. Corrective measures implemented by the manufacturer

To ensure uninterrupted operation, we will proactively replace all affected batteries from this batch free of charge for you.

The replacement will be carried out by our authorized service partner. As part of the process, the service partner will provide you with a replacement certificate. Please make the affected batteries available for replacement.

Please sign the replacement certificate provided or sent by the service partner and return the form along with the old batteries to be replaced.

The replaced batteries meet the current specifications and, in our assessment, fulfill the requirements for safety and performance.

4. Additional information

This Field Safety Corrective Action (FSCA) has been reported to the relevant authorities in accordance with applicable regulatory requirements. The action is being carried out in close coordination with the battery manufacturer Ansmann and is based on our internal risk assessments.

5. Distribution of this Field Safety Notice

Please ensure that all relevant stakeholders in your organization are informed about this Field Safety Notice.

If you have passed on affected devices to third parties, please forward a copy of this letter to them.

6. Feedback

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

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7. Manufacturer's contact person for queries:

Michael Schmidt
Vice President
Quality Management & Regulatory Affairs

Tel.: +49 (0) 81 91 6 57 22 309
Fax: +49 (0) 81 91 6 57 22 22 (Entrance)
E-Mail: md-vigilance@corpuls.com

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

Signiert von:

Michael Schmidt
Vice President
Quality Management & Regulatory Affairs

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Annex A

Response form

Please check ALL boxes that apply:

- ☐ 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 measures specified in the notice.

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

To be completed by the holder of the affected device(s):

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

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

support@corpuls.com