

## Field Safety Notice

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|                                                         |                                                                      |                                   |                 |
|---------------------------------------------------------|----------------------------------------------------------------------|-----------------------------------|-----------------|
| Nr.                                                     | Affected audience                                                    | Date                              | Number of pages |
| <b>FSN-034</b>                                          | <b>Users, operators, and holders of affected devices</b>             | 2026-08-25                        | 6               |
| Affected products<br><b>Li-Ion Rechargeable Battery</b> | Serial numbers / batch designation<br><b>A240400001 - A240400216</b> | Software / Firmware<br><b>N/A</b> |                 |

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 |

## Field Safety Notice

|            |            |            |            |            |
|------------|------------|------------|------------|------------|
| 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.

## Field Safety Notice

### 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.

## Field Safety Notice

### 7. Manufacturer's contact person for queries:

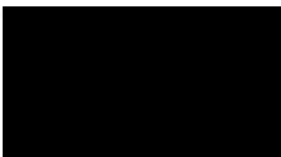


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We thank you for your understanding regarding the implementation of this corrective measure and apologize for any inconvenience caused. If you have any questions, please contact your authorized corpuls® sales and service center.

Kind regards,  
GS Elektromedizinische Geräte G. Stemple GmbH



Vice President  
Quality Management & Regulatory Affairs

## Field Safety Notice

## 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](mailto:support@corpuls.com)