Safety Notice
Technical Bulletin No. 017

GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstraße 26
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Tel. +49 8191 65722-0
Fax +49 8191 65722-22
info@corpuls.com
www.corpuls.com

No.	Target audience	Date	Number of pages
017	Affected users	2019-08-23	6

Affected products	Serial numbers / Lot identification	Software / Firmware
corpuls[1]	No relation	Software Version 1.0.1

Dear sir or madam,

with this letter we would like to inform you about the recall of software versions 1.0.1 that have been installed to a limited number of **corpuls1** devices.

Due to a malfunction in the software, corPatch easy defibrillation electrodes with revision status >= BA00000001 are not recognised and no therapy can be performed on the patient.

We decided to recall all **corpuls1** devices that are operating with the affected software version and to install a different software version.

According to our records, your organisation has purchased at least one of the affected devices.

Please do read this safety information attentively and send back the filled-in confirmation form attached in Annex A until 2019-09-20.

So far, we do not have information that other software versions for **corpuls1** devices are also 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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Management board:
G. Stemple, K. Stemple,
Dr. C. Klimmer, I. Klimmer
Registergericht Augsburg HRB 3373
USt-Id. DE 128 668 535

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

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1. Error description

If the following incompatible defibrillation electrodes are connected to the **corpuls1**, the alarm "Therapy electrode cable invalid" is generated. In addition, the message "Wrong therapy electrodes" appears in defibrillation- and pacer mode. Therapy on the patient is not possible.

Part number		Revision
05120.1	corPatch easy pre-connected	>= BA00000001
05120.2	corPatch easy Pediatric, product life 18 months	>= BA00000001
05120.3	corPatch easy Pediatric extended	>= BA00000001

Defibrillation electrodes with the revision level >=AA00000001 can be connected to and used with the **corpuls1** without restrictions.

2. Prerequisite for the Occurrence of the Error

The software version identified as problematic, 1.0.1, is installed on your **corpuls1** device and an incompatible defibrillation electrode is connected.

3. Potential Risk

No therapy can be performed on the patient with an incompatible defibrillation electrode.

4. Safety information

Please do notify your users as soon as possible about possible malfunctions that can occur and relevant corrective measures.

5. Troubleshooting for Conspicuous Devices

A correction of the malfunction is only possible by exchanging the affected software version 1.0.1.

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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 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 2019-09-10.

Maintenance for each device will be promptly arranged. A different software version 1.1.0 or higher will be installed to your device, so you will soon have a fully operational device. We recommend to upgrade to the latest software version 2.0.0. The incompatible defibrillation electrodes are then recognised as valid defibrillation electrodes and therapy can be performed.

For the duration of the maintenance a replacement device will be supplied.

All affected national authorities have been informed.

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 confirmation form (Annex A) to GS by 2019-09-20 at the latest.

The exchange will be carried out within 4 weeks after the return of the filled-in confirmation form. The implementation of this corrective action will have taken place by 2019-10-25 at the latest.

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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 (see also Annex B or www.corpuls.com).

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 2019-08-23.
- ☐ We have informed our users in an appropriate way about the contents of this safety information and the amendment to the user manual.
- ☐ We are attaching Annex B with the affected devices in our company.

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 2019-09-20 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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Annex B

Serial numbers of affected **corpuls1** devices with software version 1.0.1 in our company:

Serial numbers of devices affected with software version 1.0.1 installed

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