Safety Notice
Technical Bulletin No. 018

GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstraße 26
D-86916 Kaufering
Tel. +49 8191 65722-0
Fax +49 8191 65722-22
info@corpuls.com
www.corpuls.com

No.	Target audience	Date	Number of pages
018	Affected users	2020-02-10	8

Affected products	Serial numbers / Lot identification	Software / Firmware
corpuls3	No relation	Software Version 3.1.0 Software Version 3.1.1 Software Version 3.1.2

Dear sir or madam,

with this letter we would like to inform you about the safety measure concerning corpuls3 software versions 3.1.0, 3.1.1, and 3.1.2 that have been installed to a limited number of devices.

When using the therapy functions (Manual and AED) the curve of the ECG lead DEauto may switch unexpectedly to lead IIauto, showing a faulty ECG signal (= malfunction), (see error description).

As a safety measure we decided to update all corpuls3 devices that are operating with the affected software version with a new software version.

According to our records, your organisation is using at least one of the affected devices.

Please do read this safety information attentively and send back the filled-in answer form attached in Annex B until 2020-03-31.

Other corpuls3 devices or software 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).

Safety Notice
Technical Bulletin No. 018

1. Error description

If two clips of the ECG cable not connected to the patient accidentally touch each other (e.g. in the accessory bag), the device may erroneously detect this as a valid ECG signal. This causes the display to switch from showing curve DEauto to curve IIauto. The pertaining symbol for the ECG lead is shown to the user in the respective curve area. This represents a faulty ECG signal (see following picture, Fig. 1).
An effective ECG analysis and patient therapy are thus not possible.
The ECG signal obtained by therapy electrodes can only be shown by manually changing the curve display in the configurable curve area.

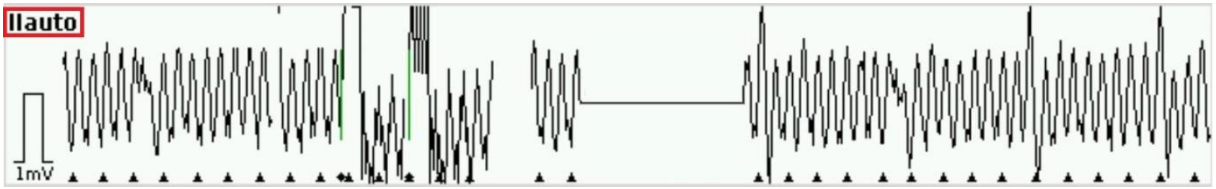


Fig. 1: corpuls3 with software version 3.1.0, 3.1.1 and 3.1.2 - unexpected switch to curve IIauto

2. Prerequisite for the Occurrence of the Error

One the software versions identified as problematic, 3.1.0, 3.1.1 or 3.1.2 is installed on your device.

Visible in the system info, main menu "System" ► "Info".

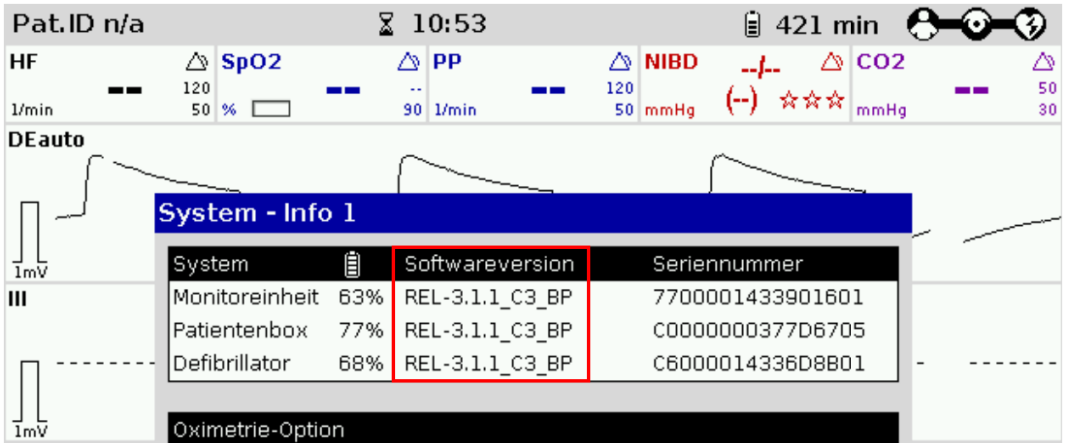


Fig. 2: system info - e.g. software version 3.1.1

corpuls | GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstr. 26 | 86916 Kaufering
Tel. +49 8191 65722-0 | Fax +49 8191 65722-22
E-Mail info@corpuls.com | www.corpuls.world

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

Safety Notice
Technical Bulletin No. 018

3. Potential Risk

The ECG is interpreted erroneously and the patient is treated wrong or therapy is delayed.

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 recognise the unintentional switch to curve IIauto assuredly and can be taken into account when using the corpuls3.

5. Troubleshooting for Conspicuous Devices

If the described device behaviour occurs, one has to keep in mind which ECG lead is active in curve II/DEauto. Please point this out to users in your organisation.

If the curve shows the symbol of the IIauto lead, this can be remedied by disconnecting the ECG cable from the patient box. So, the lead obtained by the therapy electrodes is displayed automatically (Fig. 3).

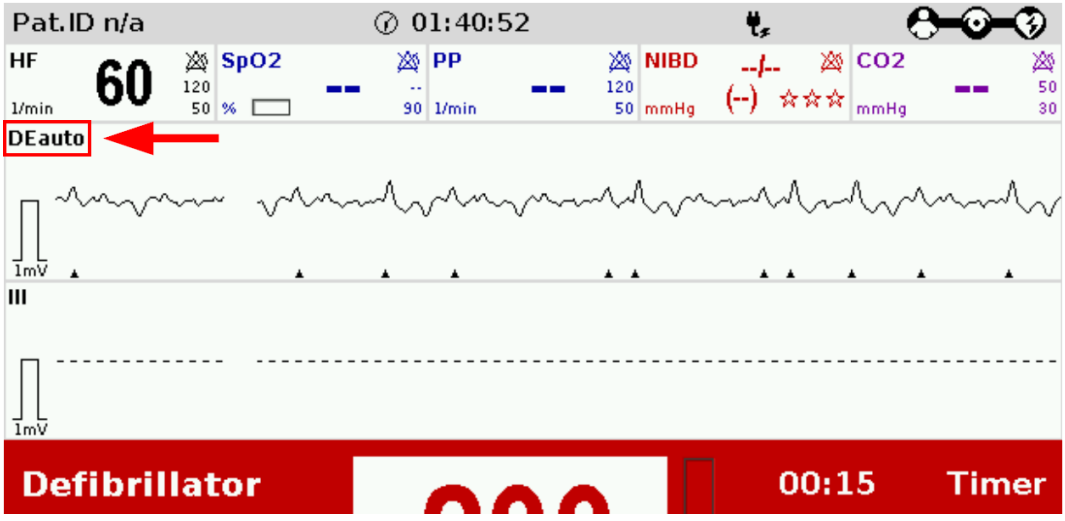


Fig. 3

A permanent correction of the error is only possible by updating the affected software version 3.1.0, 3.1.1 and 3.1.2.

corpuls | GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstr. 26 | 86916 Kaufering
Tel. +49 8191 65722-0 | Fax +49 8191 65722-22
E-Mail info@corpuls.com | www.corpuls.world

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

Safety Notice
Technical Bulletin No. 018

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 2020-02-29.

Maintenance for each device will be promptly arranged. A new software version 3.1.3 or higher will be installed on your corpuls3 by our authorised sales and service partners. So you will soon have a fully operational device.

The Federal Institute for Drugs and Medical Products („Das Bundesinstitut für Arzneimittel und Medizinprodukte“) has received a copy of this safety information.

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 answer form (Annex B) to GS by 2020-03-31 at the latest.

The software update will be performed after consultation with your authorised sales and service partner. The implementation of this corrective action will have taken place by 2021-03-31 at the latest.

corpuls | GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstr. 26 | 86916 Kaufering
Tel. +49 8191 65722-0 | Fax +49 8191 65722-22
E-Mail info@corpuls.com | www.corpuls.world

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

Safety Notice
Technical Bulletin No. 018

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 C or www.corpuls.com).

With kind regards
GS Elektromedizinische Geräte G. Stemple GmbH

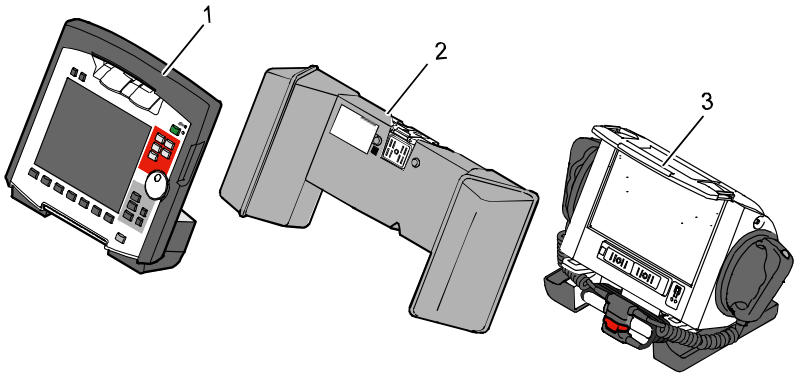
Klaus Stemple
Dipl.-Ing., Electrical engineering and Information technology
CEO/CTO
R&D, Production, Product Safety
Safety officer for medical devices (acc. §30 MPG)

Safety Notice
Technical Bulletin No. 018

Annex A

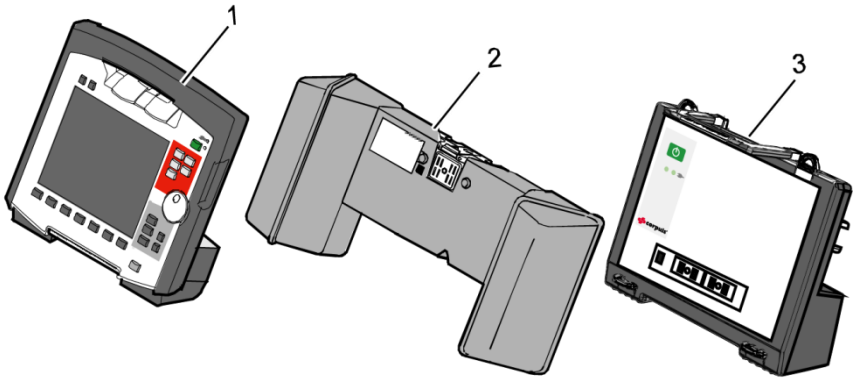
- Illustration of the device combination corpuls3

1 – Monitoring Unit
2 – Patient box
3 – Defibrillator

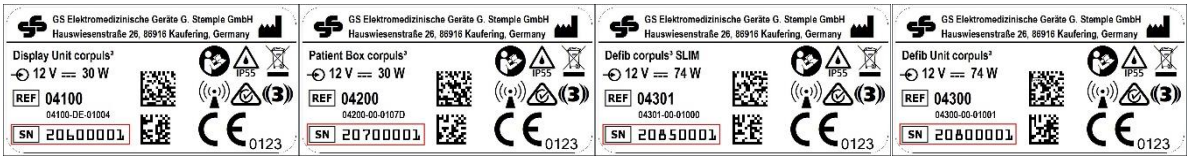


- Illustration of the device combination corpuls3 with defibrillator SLIM

1 – Monitoring unit
2 – Patient box
3 – Defibrillator SLIM



- Current rating plates with position of the serial numbers



corpuls | GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstr. 26 | 86916 Kaufering
Tel. +49 8191 65722-0 | Fax +49 8191 65722-22
E-Mail info@corpuls.com | www.corpuls.world

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

Safety Notice
Technical Bulletin No. 018

Annex B

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 2020-02-10.

- ☐ 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 2020-03-31 at the latest to:

GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstrasse 26
D-86916 Kaufering
Fax: + 49 8191 65722 - 22

Or scanned as PDF attachment to:
md-vigilance@corpuls.com

Safety Notice
Technical Bulletin No. 018

Annex C

Authorised **corpuls®** sales and service center:

Germany

GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstraße 26
D-86916 Kaufering
phone: +49 8191 65722-0
fax: +49 8191 65722-22
e-mail: info@corpuls.com

Hans Peter Esser GmbH
Cliev 4
D-51515 Kürten-Herweg
phone: +49 2207 7605
fax: +49 2207 4236
e-mail: info@defi-esser.de

Meßmer Medizintechnik GmbH
Albert-Einstein-Str. 11
D-76829 Landau
phone: +49 6341/95919-10
fax: +49 6341/95919-19
e-mail: info@messmer-medizintechnik.de

Hesto-Med Nord GmbH
Daimlerstr. 1
D-23617 Stockelsdorf
phone: +49 451 7078780
fax: +49 451 707878 91
e-mail: nord@hesto-med.de

RIEDEL & SCHULZ Medizintechnik GmbH
Wetzlarer Str. 36
D-14482 Potsdam
phone: +49 331/237878-0
fax: +49 331/237878-29
e-mail: info@riedel-schulz.de

Austria

Sanitas Gmbh
Holunderstraße 6
A-5071 Wals

phone: +43 662 852186 0
fax: +43 662 852186 70
e-mail: sanitas@sanitas.at

Switzerland

MK-MED Medizitechnik AG
Industriezone Basper 33
CH-3942 Raron
phone: +41 27 948 10 00
fax: +41 27 948 10 01
e-mail: info@mk-med.ch