Safety Notice
Technical Bulletin No. 016

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 group	Date	Number of pages
016	Affected users	09-01-2017	6

Affected products	Affected parts numbers	Software / Firmware
corpuls 08/16 BI **corpuls 08/16 S BI** **corpuls 08/16 E BI**	**03101** **03101.11** **03101.50; 03101.51**	-/-

Dear Ladies and Gentlemen,

We are sending you this safety notice to inform you about a potential malfunction of our biphasic version of the corpuls 08/16 model series.
This safety notice concerns all biphasic corpuls 08/16 devices currently in use in the field.

If a biphasic corpuls 08/16 ready to deliver a shock is applied to a patient with internal defibrillator (ICD) and the internal defibrillator of the patient releases a shock at that time, an error message is displayed on the corpuls 08/16. In this error status, further shock delivery by the corpuls 08/16 is no longer possible. Once the device is restarted, the defibrillator is fully functional once again.

The error was reported to us in individual cases from the field. We have decided to inform you herewith about this error for reasons of patient safety.

According to our documents, your organisation has at least one of the affected devices in service.

Please read this safety notice attentively then fill out the confirmation letter enclosed as Appendix A and return it to us by 28-Feb-2017.

Our corpuls 08/16 monophasic defibrillators are **not** affected by this problem.

The competent supervisory authorities of the affected countries and their competent service and distribution partners have been informed about this FSN (Field Safety Notice).

1. Description of the error

If the therapy energy (e.g. 200 joule) is selected on the biphasic corpuls 08/16 in defibrillator mode, the therapy electrodes/paddles are applied to a patient having an implanted defibrillator and the implanted defibrillator releases a shock at this time, it may lead to an error message "**ERROR IN BIPHASIC MODULE"** on the corpuls 08/16. In this error status, shock delivery is no longer possible. Once the device is restarted, the defibrillator is fully functional once again.

2. Preconditions for occurrence of the error

1. The patient to be treated has an implanted defibrillator (ICD)
2. The corpuls 08/16 biphasic is in defibrillation mode and the therapy energy has been set
3. The therapy electrodes/paddles are attached to the patient
4. The patient's implanted defibrillator releases an internal shock during contact with the therapy electrodes/paddles of the corpuls 08/16

3. Potential risk

The patient therapy may be delayed, because the therapy functions of the corpuls 08/16 will not be available until the device is restarted.

4. Safety notices

Please notify your users promptly about

- errors that may potentially occur and their remedial actions

5. Fault elimination for devices that have become suspect

If the error message "**ERROR IN BIPHASIC MODULE"** appears under the circumstances described above, the corpuls 08/16 defibrillator must be **restarted**. Thereupon the device will be fully functional once again.

If the error message "**ERROR IN BIPHASIC MODULE"** continues to appear constantly after restart of the device, the device must be taken out of service as described in the instructions for use. (Instructions for use of corpuls 08/16 and corpuls 08/16 S – Software version 3.5 Status 02.08 page 10-1; Instructions for use of corpuls 08/16 E – Software version 3.5 Status 02.08 page 10-1)

6. Immediate actions

Please make sure in your organisation that all users of the above-mentioned products and other persons that must be informed are made aware of this safety notice.

If you have delivered the products to third parties, please forward a copy of this information and inform the contact person indicated below.

Please file a copy of this safety notice in your instructions for use of the devices listed above.

7. Manufacturer's actions

This safety notice will be sent to all affected service partners by 22-Jan-2017. They will inform the affected operators of the affected devices as soon as possible.

The German Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this safety notice.

All affected national authorities have also been informed.

8. Deadline

The users should be notified immediately by appropriate means (e.g. e-mail, conspicuous posting of this letter and filing of this letter in the instructions for use).

Please fill out the confirmation letter enclosed as Appendix A and return it to us by 28-Feb-2017.

9. Manufacturer's contact person for further inquiries:

Carsten Fuchs,
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 your understanding in implementing this corrective action and apologise for the resulting inconvenience. Please direct inquiries to your authorised corpuls® service partner (see also Appendix B or www.corpuls.com).

Best regards

GS Elektromedizinische Geräte G. Stemple GmbH

Dr Christian Klimmer

Geschäftsführer Marketing & Vertrieb/Finanzen
General Manager Sales & Marketing/Finance

Klaus Stemple

General Manager R&D/Production
Geschäftsführer F&E/Fertigung

Safety Notice
Technical Bulletin No. 016

Appendix A

Response form

Please tick ALL boxes applicable for your company.

- ☐ We have read and understood the safety notice of GS Elektromedizinische Geräte G. Stemple GmbH dated 09-Jan-2017.

- ☐ We have informed our users appropriately about the content of this safety notice and the fault elimination that may be necessary.

To be filled out by the customer (in block capitals, please):

Organisation:	
Address:	
City:	Country:
Surname:	Name:
Title:	Fax:
Telephone:	Company stamp:
E-mail address:	
Date/Signature:	

Please fill out this response form and send it by 28-Feb-2017 to:
GS Elektromedizinische Geräte G. Stemple GmbH, Hauswiesenstrasse 26, D-86916 Kaufering
Fax: + 49 8191 65722 - 22

Or as a scanned PDF attachment with subject line:

Response form to Safety Notice TB016

to: md-vigilance@corpuls.com

Appendix B

Authorised **corpuls®** Service Partners

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

Manufacturer:

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
web: **www.corpuls.com**