Safety information
Technical Bulletin No. 012

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
012	Affected users	2014-05-02	8

Affected products	Serial numbers / Lot identification	Software / Firmware
05120.1 **corPatch**easy pre-connected	See attached letter of Leonhard Lang GmbH (Innsbruck / Austria)	-/-

Dear sir or madam,

with this letter we would like to inform you about the recall issued by the manufacturer Leonhard Lang GmbH concerning the defibrillation electrodes of the type: „**DF53C GS corPatcheasy pre-connected with 1.3m cable**“
LOTs affected: 30917-0770, 31014-0774, 31121-0773, 40121-0776, 40205-0776, 40220-0771, 40319-0776, 40414-0778, 40415-0770.
The electrodes are being used with the defibrillators **corpuls³** and **corpuls¹**.

With many thousand electrodes in the field there has been a reported incident of a flashing arc during therapy use. Analysis of the case showed that the isolation of the electrode cable was damaged when the user pulled apart the twin cable of the electrode before placing it on the patient.

According to our records, your organization has purchased at least one of the affected electrodes.

Please do read the attached safety information of the manufacturer Leonhard Lang GmbH attentively and send back the filled-in confirmation form attached in Annex B until May 21th, 2014.

We do have information that other defibrillation electrodes manufactured by Leonhard Lang GmbH for the **corpuls®** defibrillators are not affected by this problem.

The responsible supervisory authorities of the involved countries will been informed about this FSCA (Field Safety Corrective Action) directly by Leonhard Lang GmbH.
Affected distributors and customers of GS Elektromedizinische Geräte G. Stemple GmbH are informed by this letter.

GS Elektromed. Geräte
G. Stemple GmbH
Hauswiesenstr. 26
D-86916 Kaufering

Managing Board:
G. Stemple, K. Stemple, Dr. C. Klimmer, I. Klimmer
Registergericht: Augsburg HRB 3373
USt-Id.: DE 128 668 535

Bankverbindung:
IBAN DE20 7009 3200 0008 6801 24
BIC GENODEF1STH

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1. Error description

- See attached Safety Notice by Leonhard Lang GmbH.

2. Prerequisite for the Occurrence of the Error

- See attached Safety Notice by Leonhard Lang GmbH.

3. Potential Risk

- See attached Safety Notice by Leonhard Lang GmbH.

4. Safety information

- See attached Safety Notice by Leonhard Lang GmbH.

5. Troubleshooting for defective electrodes

- See attached Safety Notice by Leonhard Lang GmbH.

6. Immediate Measures

Please ensure within your organization that all users of the above mentioned products and all other persons who need to know are informed about this **urgent safety information** issued by Leonhard Lang GmbH.

If you have supplied the products to third parties, please forward a copy of this safety information to them and also inform the below mentioned contact person.

Please keep this information at least until the corrective measures have been completed.

7. Corrective Measures of the Manufacturer

Recall:
Electrodes **corPatcheasy pre-connected** (Part Nr. 05120.1)
of the affected LOTs 30917-0770, 31014-0774, 31121-0773, 40121-0776, 40205-0776, 40220-0771
shall not be used as soon as replacement electrodes get available.

Safety Information:
Electrodes **corPatcheasy pre-connected** (Part Nr. 05120.1)
of the affected LOTs 40319-0776, 40414-0778, 40415-0770 can be used safely under the precondition that the twin cable is not separated further by pulling apart the electrode cables.

For detailed information See attached Safety Notice by Leonhard Lang GmbH.

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Replacement for affected electrodes will be promptly arranged. By May 26th 2014 your local distributors will have sufficient replacement electrodes available to ensure the operation of your devices. Please report the quantities needed to your local distributor.

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

All affected national authorities will be informed by Leonhard Lang GmbH.

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 B) to GS by May 21th 2014 at the latest.

The exchange will be carried out shortly after the return of the filled-in confirmation form. The implementation of this corrective action will have taken place by June 30th 2014 at the latest.

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9. Contact person of the manufacturer (for questions):

Carsten Fuchs,
Vice President 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 national sales and service partner (see also Annex C or www.corpuls.com).

Sincerely,

GS Elektromedizinische Geräte G. Stemple GmbH

Klaus Stemple

CEO/CTO

GS Elektromed. Geräte
G. Stemple GmbH
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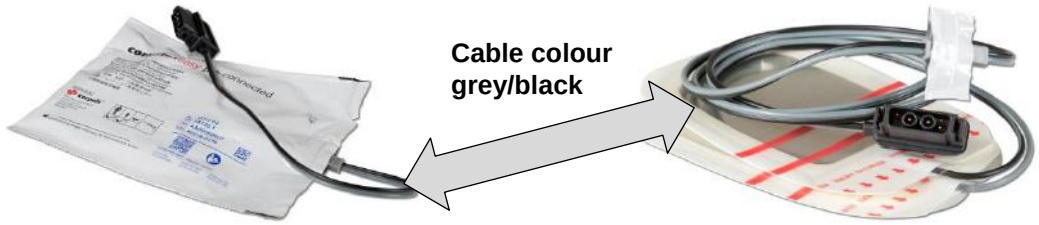
Annex A

Anhang A

Affected electrode 05120.1 "**corPatch**easy pre-connected"

corPatcheasy pre-connected - defibrillation/pacing electrodes with cable
(Artikel Nr. 05120.1) **with grey/black colored cable**



Location of LOT-number printed on pouch

GS Elektromed. Geräte
G. Stemple GmbH
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Annex B

Confirmation form

Please mark ALL fields that apply to your organization with a cross.

- ☐ We have read and understood the safety information of Leonhard Lang GmbH of 2014-02-03.
- ☐ We have informed our users in an appropriate way about the contents of this safety information.
- ☐ We are attaching Annex D with the LOT numbers of the affected products in our organisation.

To be filled in by the customer (please print):

Organisation:	
Address:	
Location:	Country:
Name:	First name:
Mr/Ms/Title:	Fax:
Phone:	Company stamp:
E-Mail address:	
Date/Signature:	

Please return this confirmation form until 2014-05-21 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

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Annex C

Authorised **corpuls®** sales and 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

Please consult our homepage for international sales and service addresses:

www.corpuls.com

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Annex D

LOT numbers and quantity of affected electrodes within our organisation.

Lot-/Chargennummern	Quantity	Comment
30917-0770		
31014-0774		
31121-0773		
40121-0776		
40205-0776		
40220-0771		
40319-0776		
40414-0778		
40415-0770		

Organisation: _____

Company stamp:

_____

_____

Date/Signature: _____

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