Safety Notice
Technical Bulletin No. 014

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
014	Affected users	2014-11-17	8

Affected products
04324.2 corPatch easy(Neonates)- defibrillation/pacing electrodes with cable (hard shell)
04325.2 corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips
05120.2 corPatch easy Pediatric

Serial numbers / Lot identification
see the Recall Letter of the company Leonhard Lang (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 defibrillation electrodes of the following types:

- *„DF 60 – GS: 04324.2 corPatch easy(Neonates)- defibrillation/pacing electrodes with cable (hard shell) Lots affected:* **30215-0770, 21213-0770, 21109-0773**
- *„DF 61 – GS: 04325.2* corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips*“ Lots affected*: **21127-0773**
- *„DF 68 – GS: 05120.2 corPatch easy Pediatric“*
  Lots affected: **30219-0778, 30325-0778, 30521-0776**

Internal investigations of the manufacturer "**Leonhard Lang GmbH"** have yielded results that make it necessary to reduce the shelf life of those electrodes to 18 months.

The electrodes are being used in connection with the defibrillators **corpuls 08/16, corpuls[1]** and **corpuls[3]**.

According to our records, your organisation 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/C until December 14th, 2014.

According to the company Leonhard Lang GmbH, other defibrillation electrodes manufactured for the corpuls® defibrillators are not affected by this problem.

The responsible supervisory authorities of the involved countries will informed about this FSCA (Field Safety Corrective Action) directly by Leonhard Lang GmbH.
Affected distributors and customers of GS Elektromedizinische Geräte G. Stemple GmbH will be 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
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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 organisation that all users of the above mentioned products and all other persons who need to know are informed about the **Urgent Safety Notice** of the 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.

According to the manufacturer of the electrodes the following interims solution could be applied:

“If no pediatric defibrillation electrodes are available, standard adult electrodes may be used for defibrillation of patients <25kg.”

Attention:
Please ensure the correct energy selection as the automatic selection / limitation to 100J is not carried out with this electrode type.

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7. Corrective Measures of the Manufacturer

Recall:
The electrodes

- *„DF 60 – GS: 04324.2 corPatch easy(Neonates)- defibrillation/pacing electrodes with cable (hard shell) Lots affected:* **30215-0770, 21213-0770, 21109-0773**
- *„DF 61 – GS: 04325.2* corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips*“ Lots affected*: **21127-0773**
- *„DF 68 – GS: 05120.2 corPatch easy Pediatric“ Lots affected*: **30219-0778, 30325-0778, 30521-0776**

must no longer be used.

For detailed information see the attached Safety Notice by Leonhard Lang GmbH.

As of December 1st, 2014 the authorised sales and service partners of the company GS Elektromedizinische Geräte G. Stemple GmbH will be able to supply a sufficient quantity of electrodes to ensure the operation of your devices in the field.
Please notify your sales and service partners about the quantity you need.

As of December 10th, 2014, electrodes with a new production status will be available. These can then gradually replace all electrodes with the lot numbers mentioned in this letter.

In order to complete this FSCA successfully, it is necessary for you to return all the not-used electrodes to your sales and service partner as soon as you have received a sufficient quantity of replacement electrodes.
Alternatively, you may confirm in writing that you have disposed of those electrodes. Please use for this option the corresponding remark on the confirmation form Annex B/C.
The delivery of replacement electrodes will correspond to the amount indicated in the Annex.

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

Also, all affected national authorities will directly be informed by the manufacturer of the electrodes (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/C) to GS by December 14th, 2014 at the latest.

The exchange will be carried out as soon as possible after the return of the filled-in confirmation form. By January 1st, 2014 at the latest the replacement of all electrodes from the lots affected by this recall will have taken place.

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9. Contact person at GS Elektromedizinische Geräte GmbH for questions:

Carsten Fuchs,
Vice President, Customer Support
Head of Customer Service

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 partner (see also Annex D or www.corpuls.com).

Sincerely,

GS Elektromedizinische Geräte G. Stemple GmbH

Dipl.-Ing. Klaus Stemple

CEO/CTO

GS Elektromed. Geräte
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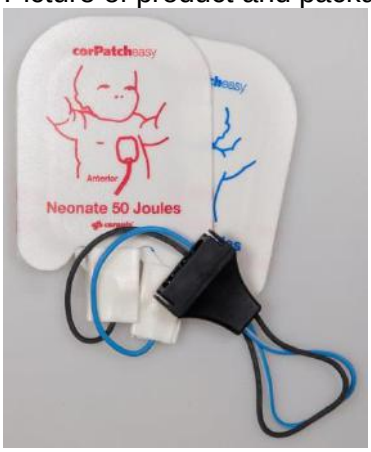
Annex A

List of product numbers affected:

04324.2 corPatch easy(Neonates) - defibrillation/pacing electrodes with cable (hard shell)

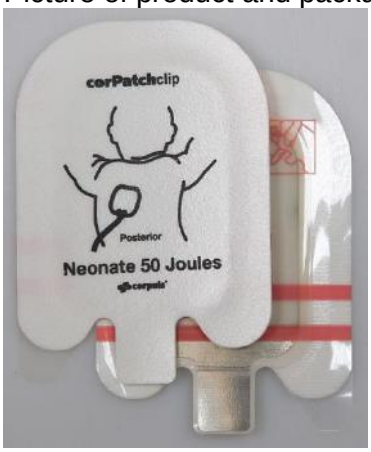
Picture of product and package



Position of the lot number

04325.2 corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips

Picture of product and package



Position of the lot number

05120.2 corPatch easy Pediatric

Picture of product and package

Position of the lot number

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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 Leonhard Lang GmbH of November 11th, 2014.
- ☐ 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 C with the lot numbers and quantity of the affected electrodes in our company.
- ☐ The affected electrodes indicated in Annex C have been taken out of commission and have been replaced by other lots. The affected electrodes will be marked and retained.
- ☐ **We declare under our sole responsibility that the affected lots will not be used on patients and will be destroyed.**

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 2014-12-14 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

Lot numbers and quantity of affected electrodes in our company:

04324.2 corPatch easy(Neonates) - defibrillation/pacing electrodes with cable (hard shell)		
Lot numbers	**Quantity**	**Remarks**
30215-0770		
21213-0770		
21109-0773		

04325.2 corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips		
Lot numbers	**Quantity**	**Remarks**
21127-0773		

05120.2 corPatch easy Pediatric		
Lot numbers	**Quantity**	**Remarks**
30219-0778		
30325-0778		
30521-0776		

The affected electrodes indicated in Annex C have been taken out of commission and will be retained.

☐ **We declare under our sole responsibility that the affected lots will not be used on patients and will be destroyed.**

Organisation: _____

Company stamp: _____

Date/Signature: _____

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Annex D

Your local authorized **corpuls®** sales and service partner:

Please consult our homepage for international authorized sales and service addresses:

www.corpuls.com

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