

Date: 2024-06-27

Field Safety Notice

For defibrillation electrodes:
 REF 04324.3 corPatch easy
 REF 05120.1 corPatch easy pre-connected
 REF 05120.3 corPatch easy pediatric

For Attention of: User of electrodes REF 04324.3 corPatch easy, REF 05120.1 corPatch easy pre-connected, REF 05120.3 corPatch easy pediatric with expiry date 2025-10-13 or earlier (see Figure 1).

Contact details of local representative (name, e-mail, telephone, address etc.)*
Manufacturer: Leonhard Lang GmbH: Thomas Recheis (Deputy Head of Quality), vigilance@leonhardlang.at, Tel. +43 512 33425, Archenweg 56, 6020 Innsbruck
Distributor: corpuls GS Elektromedizinische Geräte G. Stemple GmbH, Tel. +49 8181 65722-0, Hauswiesenstraße 26, 86916 Kaufering / Germany



Figure 1 Identification of potentially affected product based on REF and expiry date on the label by the means of 2025-10-13 or earlier (for sample see red frames, REF 05120.1 also represents REF 05120.3, both pre-connect in pouches, and REF 04324.3 in hardshell).

1. Information on Affected Devices*	
1.	1. Device Type(s)* Electrodes for Defibrillation
1.	2. Commercial name(s)* corPatch easy / corPatch easy pre-connected / corPatch easy pediatric
1.	3. Unique Device Identifier(s) (UDI-DI) 19005531505299 / 19005531505305 / 19005531001562
1.	4. Primary clinical purpose of device(s)* Defibrillation, Monitoring, Cardioversion
1.	5. Device Model/Catalogue/part number(s)* 04324.3 / 05120.1 / 05120.3
1.	6. Software version n.a.
1.	7. Affected serial or lot number range See Attachment I
1.	8. Associated devices corpuls1, corpuls3, corpuls3 SLIM, corpuls aed

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* Possible contact failure between electrode cable connector with defibrillator.
2.	2. Hazard giving rise to the FSCA* Electrode is not recognized by defibrillator, no shock delivery. Delay of therapy due to application of replacement electrodes.
2.	3. Probability of problem arising 1:40.000.000 – One incident per 40.000.000 therapies (worst-case scenario)
2.	4. Predicted risk to patient/users Risk for patient only; severity very high, occurrence of hazardous situation considering presence of shockable situation and no replacement electrode.
2.	5. Further information to help characterise the problem If defibrillator does not recognize electrode (Message "Connect therapy electrodes" is displayed on the device when therapy electrodes are connected.) immediately apply replacement electrode.
2.	6. Background on Issue Contacting process (crimping) of coding element within electrode connector (providing information of electrode presence and type) not stable enough.
2.	7. Other information relevant to FSCA The corpuls1 and corpuls3 display the message "Connect therapy electrodes" when therapy electrodes are connected in defibrillator mode.



Figure 2 message "Connect therapy electrodes" corpuls1

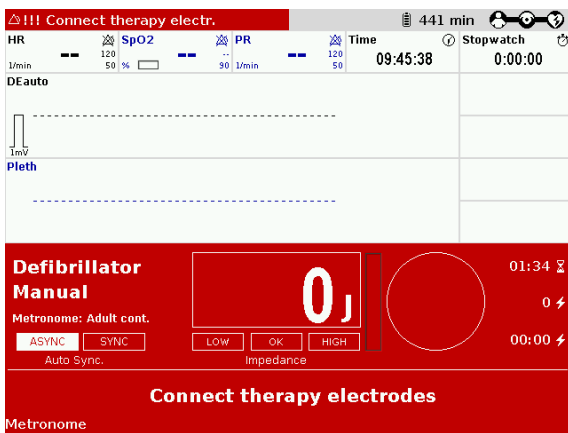


Figure 3 message "Connect therapy electrodes" corpuls3/corpuls3 SLIM

Immediately disconnect potentially affected electrode and connect defibrillator with replacement electrode. Withdraw affected electrode, cross check with batch list (Attachment I) and contact your local dealer for compensation product. Please always have a replacement electrode available for use.

For REF 05120.1 corPatch easy pre-connected: Failure is detected by automated daily self-check of the defibrillator corpuls aed for pre-connected electrodes

3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

- Identify Device Quarantine Device Return Device Destroy Device

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.

Please always have a replacement electrode available when using the corpuls1 and corpuls3.

In case of message "Connect therapy electrodes" appears after connecting the electrode to the defibrillator, use a replacement electrode immediately.

3.	2. By when should the action be completed?	2025-10-13 for 05120.3 corPatch easy pediatric; 2025-05-03 for 04324.3 corPatch easy; 2025-09-17 for 05120.1 corPatch easy pre-connected
3.	3. Action Being Taken by the Manufacturer*	
	Design change and improvement of manufacturing process.	
3.	4. By when should the action be completed?	The improvements have been incorporated into production (11/2022). Current batches are not affected.
3.	5. Is the FSN required to be communicated to the patient /lay user?	No
4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Leonhard Lang GmbH
	b. Address	Archenweg 56
	c. Website address	www.leonhardlang.at
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	5. List of attachments/appendices:	Attachment I List of affected batches
4.	6. Name/Signature	Thomas Recheis (Deputy Head of Quality)

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Attachment I – List of potentially affected batches of REF 04324.3 corPatch easy, REF 05120.1 corPatch easy pre-connected and REF 05120.3 corPatch easy pediatric in the means of possible contact failure between electrode cable connector with defibrillator

REF 05120.1
corPatch easy pre-connected

Batch	Prod. Date	Expiry Date
210707-4017	2021-07-07	2024-07-07
210709-4018	2021-07-09	2024-07-09
210712-4019	2021-07-12	2024-07-12
210720-4012	2021-07-20	2024-07-20
210803-4017	2021-08-03	2024-08-03
210825-4017	2021-08-25	2024-08-25
210909-4013	2021-09-09	2024-09-09
210929-4016	2021-09-29	2024-09-29
211025-4016	2021-10-25	2024-10-25
211029-4016	2021-10-29	2024-10-29
211124-4018	2021-11-24	2024-11-24
211129-4019	2021-11-29	2024-11-29
211130-4012	2021-11-30	2024-11-30
211221-4015	2021-12-21	2024-12-21
220110-4011	2022-01-10	2025-01-10
220214-4011	2022-02-14	2025-02-14
220216-4012	2022-02-16	2025-02-16
220311-4012	2022-03-11	2025-03-11
220314-4013	2022-03-14	2025-03-14
220324-4015	2022-03-24	2025-03-24
220330-4016	2022-03-30	2025-03-30
220401-4017	2022-04-01	2025-04-01
220420-4013	2022-04-20	2025-04-20
220503-4014	2022-05-03	2025-05-03
220518-4012	2022-05-18	2025-05-18
220527-4015	2022-05-27	2025-05-27
220617-4018	2022-06-17	2025-06-17
220629-4011	2022-06-29	2025-06-29
220704-4012	2022-07-04	2025-07-04
220721-4011	2022-07-21	2025-07-21
220808-4017	2022-08-08	2025-08-08
220829-4019	2022-08-29	2025-08-29
220917-4014	2022-09-17	2025-09-17

REF 04324.3
corPatch easy

Batch	Prod. Date	Expiry Date
220103-3991	2022-01-03	2024-07-03
220215-3992	2022-02-15	2024-08-15
220219-3993	2022-02-19	2024-08-19
220308-3990	2022-03-08	2024-09-08
220309-3990	2022-03-09	2024-09-09
220420-3994	2022-04-20	2024-10-20
220425-3995	2022-04-25	2024-10-25
220428-3996	2022-04-28	2024-10-28
220530-3997	2022-05-30	2024-11-30
220620-3998	2022-06-20	2024-12-20
220907-3999	2022-09-07	2025-03-07
220930-3991	2022-09-30	2025-03-30
221102-3993	2022-11-02	2025-05-02
221102-3992	2022-11-02	2025-05-02
221103-3994	2022-11-03	2025-05-03

REF 05120.3
corPatch easy pediatric

Batch	Prod. Date	Expiry Date
210730-0772	2021-07-30	2024-07-30
210902-0775	2021-09-02	2024-09-02
211111-0774	2021-11-11	2024-11-11
220208-0774	2022-02-08	2025-02-08
220209-0775	2022-02-09	2025-02-09
220307-0773	2022-03-07	2025-03-07
220622-0779	2022-06-22	2025-06-22
220726-0771	2022-07-26	2025-07-26
220901-0774	2022-09-01	2025-09-01
221013-0777	2022-10-13	2025-10-13