

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.	 Primary clinical purpose of device(s)* 			
	Defibrillation, Monitoring, Cardioversion			
1.	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.	 Description of the product problem* 			
	Possible contact failure between electrode cable connector with defibrillator.			
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.			



X Alarm OFF ☉09:10 200:11 DEauto	:32 🕴 🗐 325 min	
1mV	25 Hz - 0,5 Hz	
111		
	25 Hz - 0,5 Hz	
Defib - AED Metronome off	₹ 0:00:06	
Connect therapy el	ectrodes	
Metronome	Monitor	
Figure 2 message "Connect thera		
△ !!! Connect therapy electr. HR		
100 % 50 % 50 1/min 50 DEauto	09:45:38 0:00:00	
Π		
រី _m ប្ Pleth		
Defibrillator Manual Metronome: Adult cont. ASYNC SYNC LOW OK HIGH	01:34 ½ 0 ¢ 00:00 ¢	
Auto Sync. Impedance Connect therapy ele	ctrodes	
Metronome Figure 3 message "Connect thera	py alastradas" as m	uls2/comuls2 SLIM
I Igure S message Commerci merc	py electiones colp	
		electrode and connect defibrillator with
(Attachment I) and contact		lectrode, cross check with batch list
Please always have a repla		
i leace allaye have a topia		
		cted: Failure is detected by automated da
self-check of the defibrillato	r 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	2025-10-13 for 05120.3 corPatch easy pediatric;		
	action be completed?	2025-05-03 for 04324.3 corPatch easy;		
		2025-09)-17 for 05120.1 corPa	tch easy pre-connected
3.	3. Action Being Taken by	3. Action Being Taken by the Manufacturer*		
	Design change and improvement of manufacturing process.			
3.	4. By when should the		improvements have b	
	action be completed?		duction (11/2022). Curi	rent batches are not
			cted.	
3.	5. Is the FSN required to be c	ommunic	cated to the patient	No
	/lay user?			
		Genera	I Information*	
4.	1. FSN Type*		New	
4.	2. Further advice or info		No	
	already expected in fo	ollow-up		
4	FSN? *			
4.	3. Manufacturer information (For contact details of local repre	contotivo	refer to page 1 of this ES	
	a. Company Name	Sentative	Leonhard Lang GmbH	
	b. Address		Archenweg 56	
	c. Website address		www.leonhardlang.at	
4.	4. The Competent (Regulator	N) Autho		s been informed about this
ч.	communication to custome		The of your country had	
	Yes			
4.	5. List of attachments/append	dices:	Attachment I List of af	fected batches
4.	6. Name/Signature			
			Thomas Recheis (Dep	outy 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				
Prod. Date	Expiry Date			
2022-01-03	2024-07-03			
2022-02-15	2024-08-15			
2022-02-19	2024-08-19			
2022-03-08	2024-09-08			
2022-03-09	2024-09-09			
2022-04-20	2024-10-20			
2022-04-25	2024-10-25			
2022-04-28	2024-10-28			
2022-05-30	2024-11-30			
2022-06-20	2024-12-20			
2022-09-07	2025-03-07			
2022-09-30	2025-03-30			
2022-11-02	2025-05-02			
2022-11-02	2025-05-02			
2022-11-03	2025-05-03			
	2022-01-03 2022-02-15 2022-02-19 2022-03-08 2022-03-09 2022-04-20 2022-04-25 2022-04-28 2022-04-28 2022-05-30 2022-05-30 2022-09-07 2022-09-30 2022-11-02 2022-11-02			

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