

Safety Information

Marodyne-LiV:

Recall of supplied power supply units GlobTek Model GTM96600-6516-T3 (PN: TR9CT4060LCPCIMR6B)

Date: 29.07.2024

Sender:

BTT Health GmbH
Beurer Str. 25a
86926 Greifenberg
Germany

BTT Health contact person:

Mr Werner Reusch
Quality management
+49 8192 998 3937
+49 160 97666321

Addressees:

Distributors of BTT Health GmbH
NewMedX GmbH (Austria)
MedVib GmbH (Germany)
ValMedEx LLC (USA)
Copa Healthcare LLC (USA)
and their end customers

Target group:

Distributor and user of the medical device Marodyne-LiV

Identification of the medical devices concerned:

Marodyne-LiV medical devices in the production period 21/05/2024 to 19/07/2024

Versions:

- LiV-20000 / 3045-501 (Germany, Austria)
- LiV-10107 /3045-500 (USA)
- 113 affected serial numbers according to attachment "CASE 158 SN Tracking_20240729"

Description of the problem including the identified cause:

BTT Health has introduced a new external power supply unit from GlobTek Inc. for the Marodyne-LiV product, type GTM96600-6516-T3, BTT customer version TR9CT4060LCPCIMR6B, BTT part number 3045-133, in accordance with the specification.

Despite the extensive existing approvals in accordance with the electrical safety for medical devices of the power supply unit and successful functional tests by BTT Health, it became apparent shortly after its introduction that some power supply units in Austria and Germany had a voltage drop in the millisecond range, which led to a cancellation of the treatment and subsequent restart of the medical device. The treatment is only restarted by a step-off/step-on (step-on for activation).

The power supply behaviour is contrary to the BTT specification and also contrary to the manufacturer's specification.

For the patient, this can lead to an extension of the treatment time or exceeding the recommended treatment duration.

Corrective measures:

a) The entire stock of power supply units 3045-133 has been transferred into the quarantine storage.

b) The manufacturer GlobTek Inc. has been informed and has received sample devices and a LiV Medical Device for error analysis.

c) The faulty voltage drop is only recognisable and verifiable in products delivered in Austria and Germany. In the USA (grid voltage 110V), neither customers nor the power supply manufacturer have experienced any faults to date.

d) The case of a short-term voltage fluctuation (here in the millisecond range) is not mapped in the existing risk analysis but will be included in the RA. The following measures are taken:

- Batch tests requested from the manufacturer
- Sample tests per power supply unit batch of the medical device in combination with the power supply unit introduced

e) BTT Health has detected all devices delivered with this power supply unit in accordance with the delivery documents. There are 113 devices affected:

- 11 medical devices in Austria
- 40 devices in Germany
- 62 devices in USA

As a corrective action, all 3045-133 power supply units will be exchanged via the responsible distributors and replaced by the reliable power supply units of the previous power supply unit type from Eljintek (BTT part number 3045-033, Eljintek number GMPU70A-5), which have been delivered since 2019.

Risk for patients, users or third parties during further use of the product:

A possible risk for the patient is an increase or decrease in the duration of treatment.

The intended duration of 10 minutes could be exceeded in the event of multiple use after premature cancellation or shortened if the treatment is terminated after cancellation.

According to the risk analysis, increased treatment durations of more than one hour should be avoided.

If the duration is undercut, the success of the treatment may be reduced.

Due to the prompt replacement of the power supply units, there is currently no risk to the patient.

Risks for patients who have already been treated with affected products:

There are no risks as long as the treatment duration is not significantly (>1h) and permanently exceeded. If you have any questions, please get in touch with the contact person at BTT Health GmbH.

What measures are to be taken by the addressee?

Distributors will receive replacement devices and a serial number list of the devices affected in their deliveries.

The power supply units must be exchanged or replaced and the customer must be instructed to no longer use the previous power supply unit in combination with the medical device.

The receipt of this letter and exchange of power supplies must be confirmed by the distributor.

Handling of affected products:

The affected power supply units must be returned to BTT Health and labelled and stored in the quarantine storage with reference C158.

The distributor is instructed to report the replacement of its affected serial number to BTT Health.

Description of safe use of the product until the measure is implemented:

The device can continue to be operated until it is replaced. If a treatment cycle is cancelled and continued after a restart, ensure that the intended total treatment time of maximum 10 minutes is adhered to and treatment is ended after the time has elapsed.

Timetable for the implementation of the measure:

- Dispatch of replacement power supply units to distributors by 30/08/2024.
- Completion of the end customer exchange by 30 September 2024 (planned)

Further information:

The field safety corrective action is reported to the health authorities concerned in accordance with European or country-specific regulations.

BTT Health GmbH deeply regrets any inconvenience caused by these measures and we thank you for your support in realising these actions.

Greifenberg, 29 July 2024

Werner Reusch
COO & Quality Management



Appendix CASE 158 SN Tracking_20240729:

MidVib GmbH

Produktion / Verpacken				UDI		Kunde / Customer				
Model	Country	Customer	Date Packaging	UDI Gerät / Device	UDI CountryKit	Name	Vorname	Strasse / Hausnummer	Postleitzahl	Ort
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05322711240430	010426065891401221S55345411240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05322811240430	010426065891401221S55349411240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05322911240430	010426065891401221S55348111240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323011240430	010426065891401221S55371411240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S0532311240430	010426065891401221S55371711240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323211240430	010426065891401221S55345011240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323311240430	010426065891401221S5534511240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323411240430	010426065891401221S55345311240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323511240430	010426065891401221S55349211240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323611240430	010426065891401221S55371211240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323711240430	010426065891401221S55350611240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323811240430	010426065891401221S55348211240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05323911240430	010426065891401221S55348311240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324011240430	010426065891401221S55344911240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324111240502	010426065891401221S55370311240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324211240502	010426065891401221S55350911240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324311240502	010426065891401221S55371311240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324411240502	010426065891401221S55349611240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324511240502	010426065891401221S55350711240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324611240502	010426065891401221S55349511240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324711240502	010426065891401221S5535111240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324811240502	010426065891401221S55350811240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05324911240502	010426065891401221S55350511240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325011240502	010426065891401221S55349811240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325111240502	010426065891401221S55349711240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325211240502	010426065891401221S55349111240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325311240502	010426065891401221S55348411240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325411240502	010426065891401221S55348511240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325511240502	010426065891401221S55370611240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325611240502	010426065891401221S55370911240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325711240502	010426065891401221S55371111240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325811240502	010426065891401221S55344811240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05325911240502	010426065891401221S55370811240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05326011240502	010426065891401221S55371011240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05326111240502	010426065891401221S55344611240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05326211240502	010426065891401221S55344511240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05326311240502	010426065891401221S55344711240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05326411240502	010426065891401221S55345211240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05326511240502	010426065891401221S55349311240617					
3045-501	DEU/AUT	MedVib	17.06.2024	010426065891001421S05326611240506	010426065891401221S55349011240617					

Confirmation of device exchange:

Date	Company	Name	Signature
------	---------	------	-----------

BTT Health GmbH - Beurer Str. 25a - 86926 Greifenberg - Germany - Managing Director: Ivo Simundic
 Phone +49 8192 998 2606 - E-Mail: info@btt-health.com
 VR Bank Landsberg-Ammersee eG Diessen - IBAN: DE78 7009 1600 0005 2722 70 - BIC-Code: GENODEF1DSS
 Munich Local Court HRB 186346 - VAT ID No. DE277526114



Appendix CASE 158 SN Tracking_20240729:

NewMedX GmbH

Produktion / Verpacken				UDI		Kunde / Customer				
Model	Country	Customer	Date Packaging	UDI Gerät / Device	UDI CountryKit	Name	Vorname	Strasse / Hausnummer	Postleitzahl	Ort
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05301311240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05301411240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05301511240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05301611240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05301711240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05301811240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05301911240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05302011240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05302111240416						
LiV-20000	DEU/AUT	New Medx	19.07.2024	010426065892000021S05302211240416						
3045-501	DEU/AUT	New Medx	19.07.2024	010426065891001421S05346511240702	010426065891401221S57355311240718					

Confirmation of device exchange:

Date	Company	Name	Signature
------	---------	------	-----------



Appendix CASE 158 SN Tracking_20240729:

ValMedX LLC

Produktion / Verpacken				UDI		Kunde / Customer				
Model	Country	Customer	Date Packaging	UDI Gerät / Device	UDI CountryKit	Name	Vorname	Strasse / Hausnummer	Postleitzahl	Ort
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05327911240506	010426065891400521S55362911240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328011240506	010426065891400521S55363011240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328111240506	010426065891400521S55361011240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328211240506	010426065891400521S55361311240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328311240506	010426065891400521S55361911240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328411240506	010426065891400521S55362111240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328511240506	010426065891400521S55361611240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328611240506	010426065891400521S55361511240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328711240506	010426065891400521S55361811240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328811240506	010426065891400521S55361211240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05328911240506	010426065891400521S55361711240624					
3045-500	USA	ValMedX	25.06.2024	010426065891001421S05329011240506	010426065891400521S55361411240624					

Confirmation of device exchange:

Date	Company	Name	Signature



Appendix CASE 158 SN Tracking_20240729:

Copa Healthcare LLC

Produktion / Verpacken				UDI		Kunde / Customer				
Model	Country	Customer	Date Packaging	UDI Gerät / Device	UDI CountryKit	Name	Vorname	Strasse / Hausnummer	Postleitzahl	Ort
3045-500	USA	COPA	17.06.2024	010426065891001421505321911240430	010426065891400521555370211240617					
3045-500	USA	COPA	17.06.2024	010426065891001421505322011240430	010426065891400521555370111240617					
3045-500	USA	COPA	17.06.2024	010426065891001421505322111240430	010426065891400521555379211240617					
3045-500	USA	COPA	17.06.2024	010426065891001421505322211240430	010426065891400521555371511240617					
3045-500	USA	COPA	17.06.2024	010426065891001421505322311240430	010426065891400521555370711240617					
3045-500	USA	COPA	17.06.2024	010426065891001421505322411240430	010426065891400521555370411240617					
3045-500	USA	COPA	17.06.2024	010426065891001421505322511240430	010426065891400521555370011240617					
3045-500	USA	COPA	17.06.2024	010426065891001421505322611240430	010426065891400521555379611240617					
LiV-10107	USA	COPA	21.05.2024	010426065891000721505336411240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505336511240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505336611240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505336711240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505336811240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505336911240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337011240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337111240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337211240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337311240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337411240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337511240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337611240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337711240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337811240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505337911240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338011240521						
LiV-10107	USA	COPA	21.05.2024	01042606589100072150533811240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338211240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338311240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338411240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338511240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338611240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338711240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338811240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505338911240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339011240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339111240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339211240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339311240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339411240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339511240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339611240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339711240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339811240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505339911240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505340011240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505340111240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505340211240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505340311240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505340411240521						
LiV-10107	USA	COPA	21.05.2024	010426065891000721505340511240521						

Confirmation of device exchange:

Date	Company	Name	Signature
------	---------	------	-----------

BTT Health GmbH - Beurer Str. 25a - 86926 Greifenberg - Germany - Managing Director: Ivo Simundic
 Phone +49 8192 998 2606 - E-Mail: info@btt-health.com
 VR Bank Landsberg-Ammersee eG Diessen - IBAN: DE78 7009 1600 0005 2722 70 - BIC-Code: GENODEF1DSS
 Munich Local Court HRB 186346 - VAT ID No. DE277526114