



Bluepoint Medical GmbH & Co. KG (Euro)

CID4864 Opera 00009300 Type:Company Supplier Customer
 Bluepoint Medical GmbH & Co. KG (Euro) An der Trave 15, ,
 23923 Selmsdorf, , Germany

Tel 0049 38823 5488020 Euro Distributor (0004)

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VAT DE246167530

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| Distributor Agreements | Documents Files | Linked Issues | Regulatory Agreements | | | | | |

BOX:899

Manufacturer RMA : 2023-0001/0002

☒ Repaired ☐ No Fault Found

[Returned Barcode](#)

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[Tick All Replaced](#)

Review	Stock Ref	Sup Ref	B/C	S/N	Fault	Replaced	No Fault Found	Repaired	Credited	Out Warranty	Returned Unrepaired
Review 4410520 Customer Stats	4410520	3090112007	1345935	A1711160004	Calibration check Reading low ETCo2 Country of Origin: Germany Customs Purpose 250 Euro	☐	☐	☐	☐	☐	☐
Review 4410520 Customer Stats	4410520	3090112007	1314888	A1809150028	Calibration check Reading low ETCo2 Country of Origin: Germany Customs Purpose 250 Euro	☐	☐	☒	☐	☐	☐

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Customer Failure Statistics

Start From 10/03/2021 End at 10/03/2023

Service protocol CapnoTrue AMP/ASP/MG

bluepoint MEDICAL

Customer error description:

Calibration check, Reading low ETCO2

Bluepoint service error analysis:

Name	H. Fiedlich		
Screw locking:	☒ yes	☐ No	Software version: V9.1 EU
Power supply connector:	☒ male, black 	☐ male, metal 	☐ female, black 
Gas outlet:	☐ back	☒ top	☐ no CapnoTrue® ASP
Analysis result:			
CO2 Module required zeroing. Upper case assembly required exchange → Menu button broken CO2 Module required fixation, was loose			

Actions for repair:

SW update to version: (regularly carried out from v5.9)	HW update: (ASP gas outlet is regularly moved to top housing: Mod.4)
24h load test performed (regularly carried out if main PCBA is replaced)	: ☐ yes ☐ no ☒ n/a
Actions for repair and replaced parts (Name, REF, SN):	
Ref: 9090512002 Upper Case assembly	
Perform Zeroing	
Fix screws of ISA Module	

Comment to customer:

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Test Result (detailed test see next pages)	☒ Pass AMP/MG: Step 1-5+7, ASP: Step 1-7	☐ Fail Don't use device to monitor patients!
Comments:		
21.2.2023	H. Fiedlich	
Date	Tester	

Model VM-2500-S	Device Serial Number A1809150028	RMA number 2023-0002	Date of analysis
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Service protocol CapnoTrue AMP/ASP/MG

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Test step	Acceptance criteria	Result	comment
1. Visual inspection			
1.1) Housing, Display, Keypad	No damages or defects	☒ pass ☐ fail	/
1.2) Sensors and cable	No exposed optical components, cables or other damages to the sensor	☒ pass ☐ fail	no Cables or Sensors returned
1.3) External power supply (cable+ connector)	- No damages or defects. - Output voltage: 5,6 – 6,2V. - Electrical test (e.g. SECUTEST VDE 0751) is passed.	☒ pass ☐ fail	no external supply returned
1.4) Label + transparent protective foil	Label and the transparent protective foil are fixed clean to the back of the device.	☒ pass ☐ fail	/
1.5) Screw lock	Fixed to upper right-hand screw	☒ pass ☐ fail	/
2. Power Supply Options (AA batteries, Li-Poly rechargeable battery, external power supply) Test procedure: switch on with each supply option (see test steps 2.1 - 2.5) >perform Measurements: SpO ₂ at finger; etCO ₂ by breathing through airway adapter > switch off			
2.1) Only 4xAA Batteries	Battery symbol is displayed. Proper operation (device is providing SpO ₂ & CO ₂ reading)	☒ pass ☐ fail	/
2.2) Only Li-Poly	Battery symbol is displayed. Proper operation (device is providing SpO ₂ & CO ₂ reading)	☒ pass ☐ fail	
2.3) Only ext. power supply	Power supply symbol is displayed. Proper operation (device is providing SpO ₂ & CO ₂ reading)	☒ pass ☐ fail	
2.4) ext. power supply + Li-Poly	Charging symbol is displayed. Proper operation (device is providing SpO ₂ & CO ₂ reading).	☒ pass ☐ fail	
2.5) No sensors are connected to the device. Switch on with 4xAA Batteries with <4.1V.	Low battery alarm (visual and audible)	☒ pass ☐ fail	
3. SpO₂-Function at simulator (Fluke Index 2, SpO₂ = 82%, Pulse rate = 75bpm, R-curve=BPM)			
3.1) SpO ₂ at simulator set point: 82%	82% SpO ₂ (+-2 digits)	☒ pass ☐ fail	reading SpO ₂ : 82
3.2) Pulse rate at simulator set point: 75bpm	75 beats/min (+-1 digits)	☒ pass ☐ fail	reading PR: 75
3.3) SpO ₂ low alarm (at default low limit setting: 85%)	Audible and visual	☒ pass ☐ fail	/
Model VM-2500-S	Device Serial Number A1809150028	RMA number 2023-0002	Date of analysis

Service protocol

CapnoTrue AMP/ASP/MG

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Test step	Acceptance criteria	Result	comment
4. CO₂-Measurement (CO ₂ values at breath simulator: CapnoCheck Program 1, 10 breath per minute) Select Mode at CapnoTrue: <i>Main Menu > Service > Maintenance > Check gas accuracy</i> Calibration gas (5% ±0.1vol% CO ₂ , 20.9% O ₂ balance N ₂)			
4.1) 5vol% CO ₂ calibration gas + airway adaptor	EtCO ₂ : 4.7 – 5.3 vol% FiCO ₂ : 0.0 – 0.3vol%	☒ pass ☐ fail	value: EtCO ₂ / FiCO ₂ 4,9 Zeroing? ☐ yes ☒ no
4.2) Breath per minute	10 (+-1 bpm)	☒ pass ☐ fail	reading RR:: 10
5. Alarms und Data Download (switch on device, SpO ₂ Sensor at finger, breath through airway adapter)			
5.1) Remove SpO ₂ Sensor from finger	Alarm sound and message „SpO2 Probe off !“	☒ pass ☐ fail	
5.2) Breath 3x through airway adapter and wait 20s	Alarm sound and message „Apnoea !!“	☒ pass ☐ fail	
5.3) Download data to PC with CapnoTrue PC-Software	Successful data download to PC	☒ pass ☐ fail	PC-SW version: V 1.11
5.4) Delete all data	All stored data in the device are deleted	☒ pass ☐ fail	
6. Leakage test – ISA module (Only for sidestream capnograph CapnoTrue® ASP)			
6.1) Perform leakage test (see Technical Support Manual)	CO ₂ drop <0.5vol% in 1 Min.	☒ pass ☐ fail	
7. Packaging and accessories			
7.1) Latest FW on the device?	See server	☒ pass ☐ fail	Ver. 9.1 Model VM-S Language EU
7.2) Time (accuracy RTC)	Same as test PC	☒ pass ☐ fail	
7.3) Remove Li-ion battery	Battery case empty	☒ pass ☐ fail	
7.4) SN on device back label	SN like label in battery case	☒ pass ☐ fail	
7.5) Protective sheet on label	Implemented	☒ pass ☐ fail	
7.6) Screw locking	Implemented	☒ pass ☐ fail	
7.7) Final check	Device and parts clean & no damages	☒ pass ☐ fail	

Attachments:

Model VM-2500-S	Device Serial Number A1809150028	RMA number 2023-0002	Date of analysis
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Service protocol CapnoTrue AMP/ASP/MG

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bluepoint medical GmbH & Co. KG - An der Trave 15 - 23923 Selmsdorf

Viamed
Steve Nixon
15 Station Road, Cross Hills
BD20 7DT KEIGHLEY - WEST YORKSHIRE
GROßBRITANNIEN

Proforma invoice

Number: 2023-00054
Date: 28.02.2023
Customer No. 10247
Contact: Anja Mertens
phone: 038823-548-818

Shipment	UPS	Our VAT No.	DE246167530
Delivery cond.	Pick up	Our Tax No.	
Reference	Delivery note 2023-20402	Ausländ. StNr	
Cust. Ref.	Cathy Green	Your VAT No.	
Cust.Doc.	RTS1100899		

Pos.	Article No.	Description	date of deliv	Qty. Pqty	Price	Amount
1	99993	RMA 2023-0002 VM-2500-S SN: A1809150028 *** Commercial value for customs purposes only ***	28.02.2023	1 pcs	0,00	0,00
2	9090512002	Upper case assembly VM-2500-S +VM Keypad+VM-2500-S display window+buzzer 4400010	28.02.2023	1 pcs 1 pcs	15,00 15,00	15,00
3	99995	anteilige Reparaturzeit 1/4 stündlich	28.02.2023	3 pcs.	22,50	67,50
					Subtotal EUR	82,50
plus VAT					0 0,00 % of	82,50 0,00
					Total amount EUR	82,50

Steuerfreie Ausfuhr ins Drittland nach § 4 Nr. 1.a in Verbindung mit § 6 UStG.

A member of the bluepoint group

bluepoint medical
GmbH & Co. KG

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Bank accounts:

Commerzbank AG, BLZ/bankcode: 130 400 00 €-Kto./acct.: 35 3399 9 BIC(Swift Code) COBADEFF131 IBAN DE66 1304 0000 0353 3999 00	HypoVereinsbank AG, BLZ/bankcode: 200 300 00 €-Kto./acct.: 638 00 68 66 BIC(Swift Code) HYVEDEMM300 IBAN DE91 2003 0000 0638 0068 66	HypoVereinsbank AG, BLZ/bankcode: 700 202 70 \$-Kto./acct.: 879 533 139 BIC(Swift Code) HYVEDEMMXXX IBAN DE62 7002 0270 0879 5331 39
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Ust-Nr./VAT-No. DE 246 167 530

Trade register: Schwerin Reg.-No.: HRA 2600