

Service protocol CapnoTrue AMP/ASP/MG

bluepoint MEDICAL

Customer error description:

For calibration Check

Bluepoint service error analysis:

Name	DR		
Screw locking:	☐ yes	☒ No	Software version:
Power supply connector:	☐ male, black	☒ male, metal	☐ female, black
Gas outlet:	☐ back	☒ top	☐ no CapnoTrue®ASP
Analysis result:	All ports are working well		

Actions for repair:

SW update to version: <i>nu</i>	HW update: <i>nu</i>
(regularly carried out from v5.9) (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):	
Calibration Check	

Comment to customer:

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:		
22.03.2021	<i>[Signature]</i>	
Date	Tester	

Model VM 2500-S	Device Serial Number 81040-152	RMA number 2021-0045	Date of analysis 22.03.2021
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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	
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	
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 bpm
3.3) SpO ₂ low alarm (at default low limit setting: 85%)	Audible and visual	☒ pass ☐ fail	
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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: Main Menu > Service > Maintenance > Check gas accuracy 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 4.7% / 0.2% Zeroing? ☒ yes ☐ no
4.2) Breath per minute	10 (+-1 bpm)	☒ pass ☐ fail	reading RR:
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 „SpO ₂ 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. 1.14
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. 8.8 Model VM 2500-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 81040152	RMA number 2021-0045	Date of analysis 22.03.2021
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