

Service protocol

CapnoTrue AMP/ASP/MG

Customer error description:

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Bluepoint service error analysis:

Name				
Screw locking:	<input type="checkbox"/> yes	<input type="checkbox"/> No	Software version:	
Power supply connector:	<input type="checkbox"/> male, black		<input type="checkbox"/> male, metal 	<input type="checkbox"/> female, black 
Gas outlet:	<input type="checkbox"/> back	<input type="checkbox"/> top	<input type="checkbox"/> no CapnoTrue®ASP	
Analysis result:				

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)	: <input type="checkbox"/> yes <input type="checkbox"/> no
Actions for repair and replaced parts (Name, REF, SN):	

Comment to customer:

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Test Result (detailed test see next pages)	<input type="checkbox"/> Pass AMP/MG: Step 1-5+7, ASP: Step 1-7	<input type="checkbox"/> Fail Don't use device to monitor patients!
Comments:		
Date	Tester	

Model	Device Serial Number	RMA number	Date of analysis
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Test step	Acceptance criteria	Result	comment
1. Visual inspection			
1.1) Housing, Display, Keypad	No damages or defects	<input type="checkbox"/> pass <input type="checkbox"/> fail	
1.2) Sensors and cable	No exposed optical components, cables or other damages to the sensor	<input type="checkbox"/> pass <input type="checkbox"/> fail	
1.3) External power supply (cable+ connector)	- No damages or defects. - Output voltage: 6,0V - 6,2V. - Electrical test (e.g. SECUTEST VDE 0751) is passed.	<input type="checkbox"/> pass <input type="checkbox"/> fail	
1.4) Label + transparent protective foil	Label and the transparent protective foil are fixed clean to the back of the device.	<input type="checkbox"/> pass <input type="checkbox"/> fail	
1.5) Screw lock	Fixed to upper right-hand screw	<input type="checkbox"/> pass <input type="checkbox"/> 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)	<input type="checkbox"/> pass <input type="checkbox"/> fail	
2.2) Only Li-Poly	Battery symbol is displayed. Proper operation (device is providing SpO ₂ & CO ₂ reading)	<input type="checkbox"/> pass <input type="checkbox"/> fail	
2.3) Only ext. power supply	Power supply symbol is displayed. Proper operation (device is providing SpO ₂ & CO ₂ reading)	<input type="checkbox"/> pass <input type="checkbox"/> fail	
2.4) ext. power supply + Li-Poly	Charging symbol is displayed. Proper operation (device is providing SpO ₂ & CO ₂ reading).	<input type="checkbox"/> pass <input type="checkbox"/> fail	
2.5) No sensors are connected to the device. Switch on with 4xAA Batteries with <4.1V.	Low battery alarm (visual and audible)	<input type="checkbox"/> pass <input type="checkbox"/> 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)	<input type="checkbox"/> pass <input type="checkbox"/> fail	reading SpO ₂ :
3.2) Pulse rate at simulator set point: 75bpm	75 beats/min (+-1 digits)	<input type="checkbox"/> pass <input type="checkbox"/> fail	reading PR:
3.3) SpO ₂ low alarm (at default low limit setting: 85%)	Audible and visual	<input type="checkbox"/> pass <input type="checkbox"/> fail	
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Test step	Acceptance criteria	Result	comment	
4. CO ₂ -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 – 0.3 vol%	<input type="checkbox"/> pass <input type="checkbox"/> fail	value: EtCO ₂ / FiCO ₂	Zeroing? <input type="checkbox"/> yes <input type="checkbox"/> no
4.2) Breath per minute	10 (+-1 bpm)	<input type="checkbox"/> pass <input type="checkbox"/> 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 !“	<input type="checkbox"/> pass <input type="checkbox"/> fail		
5.2) Breath 3x through airway adapter and wait 20s	Alarm sound and message „Apnoea !!“	<input type="checkbox"/> pass <input type="checkbox"/> fail		
5.3) Download data to PC with CapnoTrue PC-Software	Successful data download to PC	<input type="checkbox"/> pass <input type="checkbox"/> fail	PC-SW version:	
5.4) Delete all data	All stored data in the device are deleted	<input type="checkbox"/> pass <input type="checkbox"/> 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.	<input type="checkbox"/> pass <input type="checkbox"/> fail		
7. Packaging and accessories				
7.1) Latest FW on the device?	See server	<input type="checkbox"/> pass <input type="checkbox"/> fail	Ver.	Model Language
7.2) Time (accuracy RTC)	Same as test PC	<input type="checkbox"/> pass <input type="checkbox"/> fail		
7.3) Remove Li-ion battery	Battery case empty	<input type="checkbox"/> pass <input type="checkbox"/> fail		
7.4) SN on device back label	SN like label in battery case	<input type="checkbox"/> pass <input type="checkbox"/> fail		
7.5) Protective sheet on label	Implemented	<input type="checkbox"/> pass <input type="checkbox"/> fail		
7.6) Screw locking	Implemented	<input type="checkbox"/> pass <input type="checkbox"/> fail		
7.7) Final check	Device and parts clean& no damages	<input type="checkbox"/> pass <input type="checkbox"/> fail		

Attachments:

Model	Device Serial Number	RMA number	Date of analysis