Maintenance - Instructions
CapnoTrue AMP / ASP / MG

NOTE: CapnoTrue®AMP/ASP/MG monitors do not require a routine Safety Check - STK (§6) or routine Measurement Accuracy Check - MTK (§11) according to German regulation (Attachment 1 and 2 of MPBetreibV)

The Handheld capnograph and pulse oximeter CapnoTrue®AMP/ASP/MG with accessories is permanently factory calibrated. The maintenance and calibration-free technology (gas analyzer and SpO_2 Module) integrated in the CapnoTrue®AMP/ASP/MG ensures a robust measurement function throughout the lifetime of the monitor. No routine calibration is required however a basic maintenance plan is highly recommended.

The following maintenance tasks shall be performed:

1) Gas readings should be verified at regular intervals with a reference instrument or with calibration gas (5% ±0.1vol% CO_2, 20.9% O_2 balance N_2). The suggested interval for gas span check is once every year and whenever gas readings are questionable.

2) Perform a functional SpO_2 test using a SpO_2 simulator. However note that a functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor, only its functionality. The only reliable method of testing the SpO_2 measurement accuracy of the monitor is the clinical validation of the measurement data, indicated by the system monitor with SpO_2 sensor on the basis of a blood gas analysis. During extensive clinical studies, the monitor combined with the approved sensors evidenced the accuracy required. Verify SpO_2 readings at regular intervals with a reference instrument.

3) Test of the alarm system. In order to trigger an alarm for test purposes during monitoring set the upper alarm limit of SpO_2 or pulse rate below the currently indicated measurement value. The device will react with a visual and audible alarm.

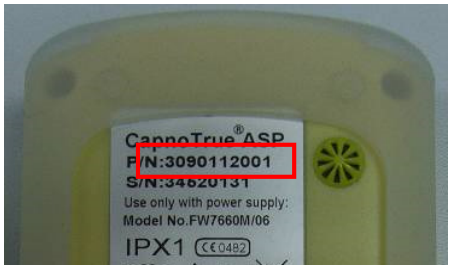
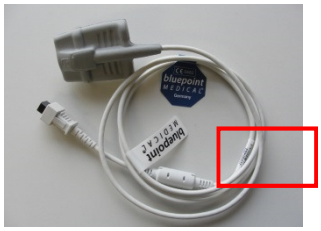
4) Check the data download function at a PC with the PC-software

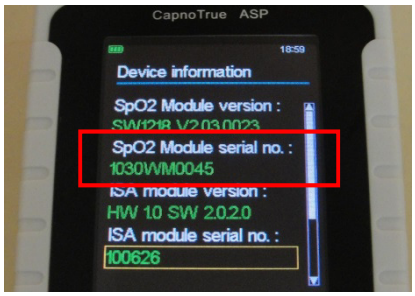
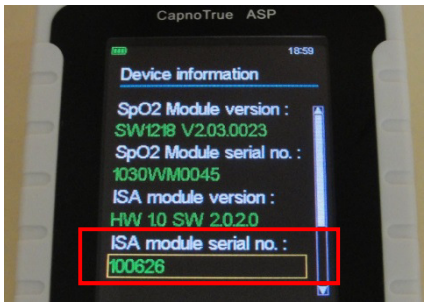
5) Perform a visual inspection of all cables accessories and housing parts

6) Perform a functional check of all power supply options (Li-Poly battery, Mignon AA battery, external power supply)

To document the maintenance, use the following checklist. All recommended test steps are described in detail in the document *CapnoTrue Maintenance instructions* and *Service Manual.*

Description of device components for documentation of the maintenance of the device and its components throughout the live time of the device.

Device Identify device	Device Model (REF on back of label) ☐ CapnoTrue®AMP (3090112001) ☐ CapnoTrue®MG (3090112009) ☐ CapnoTrue®ASP (3090112002) 
External power supply documentation of revision	☐ black connector at cable and at device (Rev. 1) ☐ orange connector at cable , metal connector at device (Rev. 2) 
SpO_2-Sensor Sensor type is noted on the label fixed to the sensor cable	○ SC 6500 ○ SCP 6500 ○ W 6500 ○ SCA 6500 ○ SCPA 6500 ○ Disposable
Serial number Of the SpO2 module in the device menu: Service Menu> System information > Device information Changing the default start up settings of the device can seriously affect the functionality of the device and the alarms! Only suitably qualified personnel with the required technical and medical	**Device** (SN on rear device label):  **SpO_2-Sensor** (SN on cable): 

knowledge are allowed to change the default start up settings!	**SpO_2 Module** (SN in Service Menu): 
	CO_2 Modul (SN in Service Menu or on housing)**:**  
Firmware Version startin from v7.5 a software upgrade is available at bluepoint Medical	Version (Startup-Screen at switch on): 

Comment	Detailed description on repairs performed to pass the functional test etc.	
Result	☐ Pass **AMP/MG:** Test 1 – 5 **ASP:** Test 1 – 6 Tick if all tests successfully passed	☐ Fail **Don't use device to monitor patients! Perform repair.** Send device to SERVICE of bluepoint MEDICAL or trained and certified service partners
Date	Tester	

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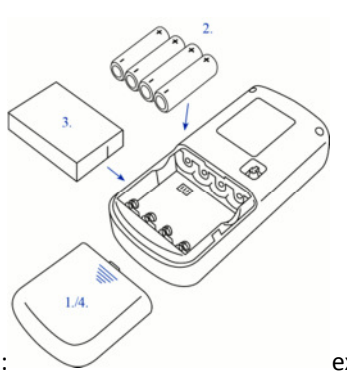
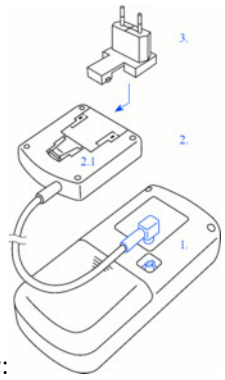
Test step	Target state	Result	comment
1. Visual inspection			
Housing, Display, Keypad	No damages or defects	☐ pass ☐ fail	
Sensors and cable	No exposed optical components or cables or other damages to the sensor	☐ pass ☐ fail	
external power supply (cable+ connector)	No damages or defects	☐ pass ☐ fail	
Label + transparent protective foil 	Label and the transparent protective foil are fixed clean to the back of the device.	☐ pass ☐ fail	
Screw lock	Fixed to upper right-hand screw	☐ pass ☐ fail	
2. Power Supply Options (AA batteries, Li-Poly rechargeable battery, external power supply) (switch on with each supply option >Measurements: SpO_2 at finger; etCO2 by breathing through airway adapter > switch off)			
only 4 AA Batteries	switch on> measurement> switch off	☐ pass ☐ fail	
only Li-Poly	switch on> measurement> switch off	☐ pass ☐ fail	
only ext. power supply	switch on> measurement> switch off	☐ pass ☐ fail	
ext. power supply + Li-Poly	switch on > measurement + charging > switch off	☐ pass ☐ fail	
Comments: (Pixel defects, etc.)			



4 x AA Batteries, or 1 x Li-Poly:



external power supply:

Before measurement ensure that AA batteries are full and Li-Poly charged

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Test step	Target state	Result	comment
3. SpO_2-Function at simulator			
SpO_2 at simulator setpoint 82% (BPM or Nellcor curve)  e.g. INDEX II simulator (Biotek, Fluke) select the SpO2 cal. Curve *BPM* or *NELLCOR* under MAKE	82% SpO_2 (+-2 digits) NOTE: SpO2 low alarm sounds, SpO2 measurement value turns yellow and is flashing.	☐ pass ☐ fail	value: write down displayed SpO2 value
Pulse rate at simulator setpoint 75bpm set pulse rate at simulator	75 beats/min (+-1 digits)	☐ pass ☐ fail	value: write down displayed pulse rate value
SpO_2 low alarm	Audible and visual	☐ pass ☐ fail	
Comments:			
4. CO_2-Measurement (use reference device as alternative means if no breath simulator is available) Select Mode at CapnoTrue: *Main Menu > Service > Maintenance > Check gas accuracy* Calibration gas (5% ±0.1vol% CO2, 20.9% O_2 balance N_2) Verify gas accuracy reading in Test Screen via SERVICE MENU: 1) Switch on device 2) connect new IRMA airway adapter (or sampling line for ASP), perform zeroing 3) Select at device: *Main Menu > Service > Maintenance > Check gas accuracy* 4) Apply calibration gas to airway adapter and verify reading			
5vol% CO_2 calibration gas + airway adaptor e.g. 	CO_2 should be Gas conc. (+- (0.2 vol%. + 2% of measurement value) At 5vol% CO_2 the limits are: $EtCO_2$:**4.7 – 5.3 vol%** $FiCO_2$: **0.0 – 0.3vol%**	☐ pass ☐ fail	value: $EtCO_2$ / $FiCO_2$ write down displayed CO_2 values
Breath per minute connect airway adaptor to adaptor of reference device. Breath uniformly through adaptors for 30 minutes. Compare values	reference value (+-1 digit) + tolerance of reference device	☐ pass ☐ fail	value: write down displayed respiration rate at CapnoTrue and reference device

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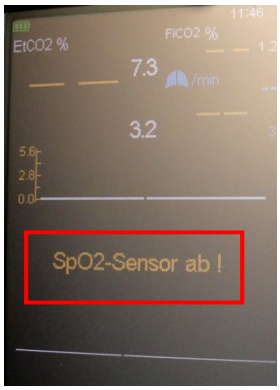
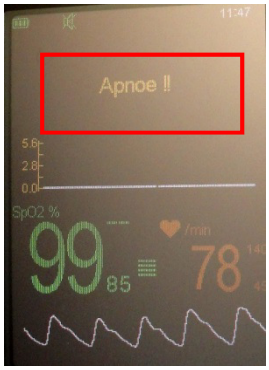
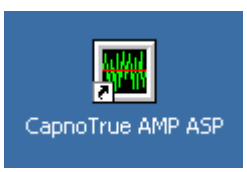
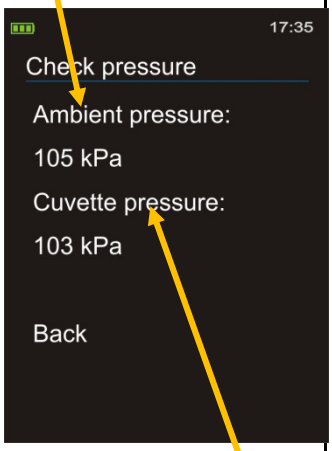
Test step	Target state	Result	comment
Comments::			
5. Alarms und Data Download (switch on device, SpO_2 Sensor at finger, breath through airway adapter)			
Remove SpO_2 Sensor from finger	Alarm sound and message „SpO2 Probe off !“  2 x beep every 16s	☐ pass ☐ fail	
Breath 3 X through airway adapter and wait 20s	Alarm sound and message „Apnoea !!“  3 x beep every 5s	☐ pass ☐ fail	
Download data to PC with CapnoTrue PC-Software 1. Connect device via USB to PC 2. Verify message “USB connected at device 3. Open CapnoTrue SW  4. download data according to instructions at “communication download”	Successful data download to PC Compare data in Tab Diagram and stored alarms in Tab Patient info with data at device - If errors occur during download check compatibility of versions (see page 3 of Instructions for Use) - check if correct COM port is selected - check if the USB drivers were installed according to the instructions	☐ pass ☐ fail	

S/N:_____

Test step	Target state	Result	comment
Delete all data Select *Delete all data* under: *Menu > data management > delete all data*	All stored data in the device are deleted	☐ pass ☐ fail	
Comments:			
6. Check pressure – ISA module (**Only** for sidestream capnograph CapnoTrue **ASP**) Select at device: *Main Menu > Service > Maintenance > Check pressure*			
Compare displayed ambient pressure value with the actual barometric pressure value at the local site 	actual barometric pressure ±5 kPa	☐ pass ☐ fail	
Compare displayed cuvette pressure with ambient pressure	cuvette pressure is 1 to 5 kPa smaller than displayed ambient pressure	☐ pass ☐ fail	Ambient pr. kPa Cuvette pr. kPa write down displayed values
Comments:			