

# Service protocol CapnoTrue AMP/ASP/MG

bluepoint MEDICAL

| Test step                                                                                                                                                                                                                                                                                                    | Acceptance criteria                                                     | Result                                                                 | comment                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| 4. CO <sub>2</sub> -Measurement (CO <sub>2</sub> values at breath simulator: CapnoCheck Program 1, 10 breath per minute)<br>Select Mode at CapnoTrue: Main Menu > Service > Maintenance > Check gas accuracy<br>Calibration gas (5% ±0.1vol% CO <sub>2</sub> , 20.9% O <sub>2</sub> balance N <sub>2</sub> ) |                                                                         |                                                                        |                                                                                                             |
| 4.1) 5vol% CO <sub>2</sub> calibration gas + airway adaptor                                                                                                                                                                                                                                                  | EtCO <sub>2</sub> : 4.7 – 5.3 vol%<br>FiCO <sub>2</sub> : 0.0 – 0.3vol% | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail | value: EtCO <sub>2</sub> / FiCO <sub>2</sub><br>48% 0.2%                                                    |
| 4.2) Breath per minute                                                                                                                                                                                                                                                                                       | 10 (+-1 bpm)                                                            | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail | Zeroing?<br><input checked="" type="checkbox"/> yes<br><input type="checkbox"/> no<br>reading RR::<br>10bpm |
| 5. Alarms und Data Download (switch on device, SpO <sub>2</sub> Sensor at finger, breath through airway adapter)                                                                                                                                                                                             |                                                                         |                                                                        |                                                                                                             |
| 5.1) Remove SpO <sub>2</sub> Sensor from finger                                                                                                                                                                                                                                                              | Alarm sound and message<br>„SpO <sub>2</sub> Probe off !“               | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |
| 5.2) Breath 3x through airway adapter and wait 20s                                                                                                                                                                                                                                                           | Alarm sound and message<br>„Apnoea !!“                                  | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |
| 5.3) Download data to PC with CapnoTrue PC-Software                                                                                                                                                                                                                                                          | Successful data download to PC                                          | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail | PC-SW version:<br>V1.11                                                                                     |
| 5.4) Delete all data                                                                                                                                                                                                                                                                                         | All stored data in the device are deleted                               | <input checked="" 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 <sub>2</sub> drop <0.5vol% in 1 Min.                                 | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |
| 7. Packaging and accessories                                                                                                                                                                                                                                                                                 |                                                                         |                                                                        |                                                                                                             |
| 7.1) Latest FW on the device?                                                                                                                                                                                                                                                                                | See server                                                              | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail | Ver. Model Language<br>88 VM-2500-S Euro                                                                    |
| 7.2) Time (accuracy RTC)                                                                                                                                                                                                                                                                                     | Same as test PC                                                         | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |
| 7.3) Remove Li-ion battery                                                                                                                                                                                                                                                                                   | Battery case empty                                                      | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |
| 7.4) SN on device back label                                                                                                                                                                                                                                                                                 | SN like label in battery case                                           | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |
| 7.5) Protective sheet on label                                                                                                                                                                                                                                                                               | Implemented                                                             | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |
| 7.6) Screw locking                                                                                                                                                                                                                                                                                           | Implemented                                                             | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |
| 7.7) Final check                                                                                                                                                                                                                                                                                             | Device and parts clean & no damages                                     | <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail |                                                                                                             |

Attachments:

|                    |                                  |                         |                                |
|--------------------|----------------------------------|-------------------------|--------------------------------|
| Model<br>VM-2500-S | Device Serial Number<br>80640162 | RMA number<br>2025-0007 | Date of analysis<br>24.02.2025 |
|--------------------|----------------------------------|-------------------------|--------------------------------|