# ACCUCAP 911®

## Digital Capnograph

PARSIAN MEDICAL Co.


### Technical Specification:

- Digital capnograph with selectable Mainstream or Microstream sensor
- Ability to select $EtCO_2$ measurement unit (mmHg, kPa, or %)
- Selectable patient type (Adult, Pediatric, and Neonate) with the related airway adapter
- Accurate monitoring in the presence of anesthetic agents
- Automatic measurement of ambient (atmospheric) pressure for higher $EtCO_2$ accuracy
- Record and save measured parameters (Trend) per patient
- Ethernet output complying with HL7 protocol
- USB connection with relevant computer software
- Internal rechargeable Li-ion battery, with a lifetime of 5 hours of continuous monitoring
- 7.8" widescreen LCD with capacitive touch with vertical and horizontal orientation
- Audible and visual alarms consistent with IEC standard


### Digital Capnograph including following parameters:

- Exhaled End-tidal $CO_2$ ($EtCO_2$)
- Respiration Rate (RR)
- Inspired Fraction of $CO_2$ ($FiCO_2$)
- $CO_2$ Waveform

| Electrical Characteristic | |
|---|---|
| Power Requirement | 80~264 VAC |
| Frequency Range | 47~63 Hz |
| Rated Power | 45 W |
| Fuse | 2 x 500 mA/250 VAC, 5 x 20 mm |

| Internal Battery | |
|---|---|
| Type | Li-Ion 7.4 V, Rechargeable, Maximum Protection |
| Operating Time | 5 hours |
| Charging Time | 3 hours |

| Physical Dimension | |
|---|---|
| Dimensions (WHD) | 25 x 8 x 22 cm |
| Weight | 1 Kg |

| Display | |
|---|---|
| Type | TFT Liquid Crystal Display (LCD), 400 x 1280 pixels, 7.8 inches |
| Data Displayed | $EtCO_2$, Respiration Rate, $FiCO_2$, Capnography Waveform, Alarms and Status Message |

| Specifications of Sensors | | | | |
|---|---|---|---|---|
| Transducer Type | CAPNOSTAT® 5: Mainstream<br>LoFlo®: Microstream | | | |
| Principle of Operation | Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts | | | |
| Initialization Time | Less than 15 seconds for CAPNOSTAT® 5 and less than 20 seconds for LoFlo® at an ambient temperature of 25°C, full specifications within 2 minutes | | | |
| $CO_2$ Measurement Range | 0 to 150 mmHg<br>0 to 19.7%<br>0 to 20 KPA (at 760 mmHg) | | | |
| $CO_2$ Rise Time | Less than 60 msec | | | |
| $CO_2$ Resolution | 0.1 mmHg 0 to 69 mmHg<br>0.25 mmHg 70 to 150 mmHg | | | |
| $CO_2$ Accuracy (Temperature at 35° C) | 0 - 40 mmHg ± 2 mmHg<br>41 - 70 mmHg ± 5% of reading<br>71 - 100 mmHg ± 8% of reading<br>101 - 150 mmHg ± 10% of reading | | | |
| $CO_2$ Stability | Short Term Drift: Drift over four hours shall not exceed 0.8 mmHg maximum.<br>Long Term Drift: Accuracy specification will be maintained over a 120 hour period. | | | |
| $CO_2$ Noise | RMS noise of the sensor shall be less than or equal to 0.25 mmHg at 7.5% $CO_2$ for CAPNOSTAT® 5 and at 5% for LoFlo®. | | | |
| Respiration Rate | Range: 0 to 150 respirations per minute (RPM) | | | |
| Respiration Rate Accuracy | ± 1 breath | | | |
| Inspired $CO_2$ Measurement | Range: 3 to 50 mmHg | | | |
| Calibration | No routine user calibration required. An airway adapter zero is required when changing to a different style of airway adapter | | | |
| Compensations | Expired $O_2$, balance gas ($N_2$, $N_2O$, He) and anesthetic agents | | | |
| Total Pressure (Barometric plus Airway pressure) | Range: 400-850 mmHg | | | |
| Cross-sensitivity Compensation Error | 0-40 mmHg: ± 1 mmHg additional error<br>41-70 mmHg: ± 2.5% additional error<br>71-100 mmHg: ± 4% additional error<br>101-150 mmHg: ± 5% additional error | | | |
| Physical characteristics | CAPNOSTAT® 5 | Weight: 25 gr | Size (WHD): 43 × 33 × 23 mm | Cable length: 3 meters |
| | LoFlo® | Weight: 272.16 gr | Size (WHD): 66.0 × 38.1 × 88.9 mm | Cable length: 55.88 cm |

| List of Relevant Standards | |
|---|---|
| IEC 60601-1:2020 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2014 | Medical electrical equipment - Part 2-1: General requirements for safety - Collateral standard: Electromagnetic disturbances - Requirements and tests |
| IEC 60601-1-8:2006 | Medical electrical equipment - Part 8-1: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| ISO 80601-2-55:2018 | Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors |
| IEC 62304:2006 | Medical device software - Software life cycle processes |
| ISO 14971:2019 | Medical devices - Application of risk management to medical devices |

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Certificate Number: XXXX
Catalog Version: 25.01