Nightingale PPM3 Technical Data

General	
Dimensions	11.3”W x 7.2”H x 2.4”D (288 mm x 182 mm x 60 mm)
Weight	4.5 lb (2.0 g), 5.0 lb w/ Oridion Microstream® CO_2 (2.3 kg)
Finish	PC/ABS
Power Requirements	100 – 240 VAC, 1.2 A max
Mains Frequency Range	50 – 60 Hz
Power Consumption	12W nominal, 30W (when charging battery)
Standards Conformance	IEC 60601-1:2005 (General Safety) AAMI ES60601-1:2005 (General Safety) CSA C22.2#60601-1:2008 (General Safety) IEC 60601-1-2:2007 (Class B) (EMC) IEC 60601-1-4:2000 (General Safety) IEC 60601-1-8:2006 (Alarms) IEC 60601-2-27:2011 (ECG Monitoring) AAMI SP10:2002/A1:2003 (Non-Invasive Blood Pressure) ISO 80601-2-30:2009 (Non-Invasive Blood Pressure) IEC 60601-2-34:2011 (Invasive Blood Pressure) ISO 80601-2-55:2011 (CO_2 Respiratory Gas Monitoring) ISO 80601-2-56:2009 (Temperature) ISO 80601-2-61:2011 (SpO_2) IEC 62366:2007 (Usability) IEC 62304:2006 (Software)
Patient Risk Current (IEC 60601-1)	Electromedical Apparatus with Isolated Patient Connection. Meets the following limits: Enclosure Risk Current < 100 µA Patient-applied Risk Current < 10 µA Patient Isolation Risk Current < 50 µA Earth Risk Current < 500 µA
Type of Protection (Electrical)	Class I
Degree of Protection (Electrical)	Type CF, Defibrillation-proof
Degree of Protection (Water)	Ordinary Equipment (IPX1)
Disinfecting Method	Per the instructions in the Cleaning chapter
Degree of Safety (Flammable Anesthetic Mixture)	Not suitable for use in the presence of a Flammable Anesthetic Mixture
Mode of Operation	Continuous

PPM3 Device Markings	
CE 0123	European CE Mark according to Council Directives 93/42/EEC
	For indoor-use only
	Consult accompanying documents before using this device.
 06/2013	Manufacture date (month/year)
	Type CF Equipment (Defibrillation-proof)
REF	Zoe Medical Part Number
SN	Serial Number
	Do not dispose as unsorted municipal waste. European Union Directive 2002/96 on Waste Electrical and Electronic Equipment (WEEE) requires separate handling for waste disposal according to national requirements
IPX1	Indicates device has been tested for safety from vertically dripping water; specifically, it indicates DRIP PROOF, a higher than ordinary level of protection from drips, leaks, and spills.
REF 725-0037-X	External AC/DC power supply; only use Zoe Medical P/N 725-0037-X
	Local Area Network interface
IOIO A	Interface for Nightingale MPC central station
IOIO B	Interface for Other Medical Devices – Reserved for future use
	Recorder interface
ECG	3 and 5 wire ECG connector
SpO_2	Pulse Oximetry connector
NBP	Non-Invasive Blood Pressure connector
P1/P2	Invasive Blood Pressure (dual) connector for P1 and P2

TEMP	Temperature connector
Microstream® $ETCO_2$ 	Oridion CO_2 input connector
	Oridion CO_2 exhaust connector
$ETCO_2$	Masimo CO_2 module connector
Battery	
Type	Lithium-Ion Rechargeable
Discharging Time	4 hours (minimum)
Charging Time	5 hours
Charging Method	Battery is charged while monitor is connected to AC main
Environmental	
Cooling	Convection (no fan)
Operating Temperature	32 to 104 °F (0 to 40 °C)
Storage Temperature	-4 to 140 °F (-20 to 60 °C)
Operating Humidity	15% to 90% non-condensing
Storage Humidity	15% to 95% non-condensing
Operating Altitude	0 to 15,000' (0 to 4572 m)
Storage Altitude	0 to 40,000' (0 to 12,192 m)
Alarm Signal Sound Pressure	45 to 80 dB(A)
Display	
Type	Active Matrix LCD
Size	8.4 inches (diagonal)
Matrix	800 x 600 pixels
Number of Waveform Channels	Up to 5
Sweep Speed	6.25, 12.5, 25 mm/s
Display Mode	Eraser Bar

ECG	
Accessories	3-lead cable, 5-lead cable
Input Connector	7-pin connector
Displayable Leads	3-lead cable: I, II, III, AVL, AVR, AVF 5-lead cable: I, II, III, AVL, AVR, AVF, V
HR Resolution	1 bpm (beats per minute)
Measurement Range	15 to 300 bpm
Measurement Accuracy	±2 bpm or ±1%, whichever is greater
Response Time	Per IEC 60601-2-27, change from 80 to 120 bpm: < 7 seconds Per IEC 60601-2-27, change from 80 to 40 bpm: < 11 seconds
Report Interval	1 second
HR Averaging Scheme	Average of the 10 most recent, valid R-R intervals, discarding the shortest and longest interval
Time To Alarm - Tachycardia	IEC 60601-2-27, ECG Complex B1: < 10 sec (5 sec typical) IEC 60601-2-27, ECG Complex B2: < 10 sec (9 sec typical)
Notch Filter Frequency	50Hz, 60 Hz, Off
Filter Bandwidth	Monitor Mode: 0.67 Hz to 40 Hz (-3 dB) Diagnostic Mode: 0.05 to 40 Hz (-3 dB)
Dynamic Range AC	±5 mV, per IEC 60601-2-27
Dynamic Range DC	±300 mV, per IEC 60601-2-27
Electrode Impedance	>2.5 MOhm , per IEC 60601-2-27
Defibrillation Protection	Complies with IEC 60601-2-27
Pacer Pulse Detection	Lead II, I and V
Pacer Pulse Rejection	Rejects all pulses of amplitude ±2mV to ±700mV and duration 0.1 to 2 ms, per IEC 60601-2-27, Clause 201.12.1.101.13
Tall T-Wave Rejection	Rejects T-Waves less than or equal to 120% of a 1mV QRS and a Q-T interval of 350 ms, per IEC 60601-2-27, Clause 201.12.1.101.17
HR Response to Irregular Rhythm	IEC 60601-2-27, ECG Complex A1: HR is 80 bpm IEC 60601-2-27, ECG Complex A2: HR is 65 bpm IEC 60601-2-27, ECG Complex A3: HR is 120 bpm IEC 60601-2-27, ECG Complex A4: HR is 91 bpm
Active Noise Suppression	RL drive (< 5 µA)
Pulse Tone	Yes

Respiration	
Method	Impedance Pneumography
Input Connector	Same as ECG
Sensing Lead	II
RR Resolution	1 bpm (breaths per minute)
Measurement Range	0 to 120 bpm
Measurement Accuracy	±3 bpm
Measurement Sensitivity	0.25 ohms (minimum)
Report Interval	1 second
Bandwidth	0.17 to 3.3 Hz (-3dB)
Impedance Measuring Current	40 µA @ 28 kHz square wave across Lead II
Pulse Oximetry	
Method	Absorption – Spectrophotometric (dual wavelength) (Functional oxygen saturation of arterial hemoglobin)
Input Connector	9-pin connector
SpO_2 / PR Resolution	SpO_2: 1 O_2% PR: 1 bpm (beat per minute)
Measurement Range	SpO_2: 20 to 100% PR: 30 to 240 bpm
Measurement Accuracy	SpO_2: from 70 to 100%: ±2% (O_2%), < 70%: unspecified PR: ± 3 bpm
Measurement Test Method	Comparison versus co-oximeter, per ISO 80601-2-61
Report Interval	1 second. Numeric values held < 30 seconds
Pulse Tone	Yes (pulse tone pitch tied to SpO_2 parameter value)
Alarm Signal Generation Delay	< 0.5 sec

Non-Invasive Blood Pressure	
Method	Oscillometric
Input Connector	Single Lumen Hose (Quick-Disconnect fitting)
Cuff	Infant, Child, Small Adult, Adult, Large Adult
Derived Parameters	Systolic, Mean, Diastolic
Resolution	1 mmHg
Measurement Range	Systolic: 30 to 250 mmHg Mean: 20 to 230 mmHg Diastolic: 10 to 210 mmHg
Measurement Accuracy	Complies with AAMI SP10
Transducer Accuracy	± 3 mmHg
Pulse Rate Range	30 to 240 bpm
Pulse Rate Accuracy	± 5% or ± 2 bpm, whichever is greater
Update Interval	Upon measurement completion
Measurement Time	30 seconds (typical) < 135 seconds (maximum)
Initial Cuff Pressure	160 mmHg (user-selectable)
Repeated Cuff Pressure	Previous systolic + 40 mmHg
Static Cuff Pressure Accuracy	± 3 mmHg
Overpressure Cutoff	290 ± 3 mmHg (normal means), 300 ± 10 mmHg (back-up)
Measurement Modes	Single Measurement or Auto (Interval) Measurement
Auto Measurement Settings	Off, 3, 5, 10, 15, 30, 60, 120 minutes

Oridion CO_2 / Capnography	
OEM Board	Oridion miniMediCO_2
Method	Sidestream (Non-dispersive IR)
Units	mmHg
Parameters	$ETCO_2$, $FICO_2$, RRc, IPI
CO_2 Measurement Range	$ETCO_2$ & $FICO_2$: 0 to 150 mmHg
CO_2 Measurement Accuracy	$ETCO_2$ & $FICO_2$: 0 to 38 mmHg: ± 2 mmHg > 38 to 150 mmHg: ± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12 % of reading whichever is greater, for $ETCO_2$ values exceeding 18 mmHg. This is tested according to and is compliant with ISO 21647. To achieve the specified accuracies for breath rates above 60 bpm, the Microstream FilterLine H Set for Infant/Neonatal (p/n 006324) must be used. Above 55℃ module temperature, ±1mmHg or ± 2.5% (whichever is greater) has to be added to the tolerance of the accuracy specs.
CO_2 Resolution	$ETCO_2$ & $FICO_2$: 1 mmHg
RRc (Resp. Rate) Measurement Range	0 to 120 bpm
RRc Measurement Accuracy	0 to 70 bpm: ± 1 bpm 71 to 120 bpm: ± 2 bpm $ETCO_2$, $FICO_2$, and Respiration accuracy tested according to ISO21647 using a mixture of gases (5% CO_2, 21% O_2, N_2 balance) supplied via function generator and breath simulator application. Respiration rates from 10-60 bpm for adults/pediatrics as measured in 10 bpm discrete steps were tested for 1 minute before moving forward to the next value and at the end of this one minute period modules readings were taken.
RRc Resolution	1 bpm
IPI Range	0 to 10
Barometric Pressure Range	430 to 795 mmHg
Barometric Pressure Compensation	Automatic
Report Interval	1 second
Flow Rate	50 ml / min (-7.5 to +15 ml / min), flow measured by volume
Warm-up Time Required to Meet Accuracy Specifications	Typical: 30 seconds Max: 180 seconds (No readings until warm-up completed)
Total System Response Time	3.5 sec (typical) using standard Microstream FilterLine ®

Drift of Measurement Accuracy	Meets accuracy specifications when the calibration schedule is followed in the General Care & Maintenance section
Measurement Accuracy for Gas Mixture	Meets ISO 21647 Clause 51.101.3 (Tables 101 and 103): ± (volume fraction of 0.43% + 8% of gas level)
Measurement Accuracy in the Presence of Interfering Gases	Meets ISO 21647 Clause 101.1 (Tables 101 and 105): ± (volume fraction of 0.43% + 8% of gas level)

Masimo ISA™ CO_2 / Capnography	
Method	Sidestream (Non-dispersive IR)
Units	mmHg
Parameters	$ETCO_2$, $FICO_2$, RRc
CO_2 Measurement Range	$ETCO_2$ & $FICO_2$: 0 to 150 mmHg
CO_2 Measurement Accuracy	As measured with dry single gases: 0 to 15 vol%: ±(0.2 vol% + 2% of reading) 15 to 25 vol%: unspecified
CO_2 Resolution	1 mmHg
RRc (Resp. Rate) Measurement Range	0 to 150 ± 1 bpm
RRc Resolution	1 bpm
Barometric Pressure Range	525 to 1200 hPa
Barometric Pressure Compensation	Automatic
Report Interval	Per breath
Flow Rate	50 ± 10 sml/min
Warm-up Time Required to Meet Accuracy Specifications	< 10 seconds (concentrations reported and full accuracy)
Total System Response Time	< 3 seconds (with 2m Nomoline sampling line)
Drift of Measurement Accuracy	Complies with EN ISO 21647:2004 standard
Measurement Accuracy for Gas Mixture	Complies with EN ISO 21647:2004 standard
Measurement Accuracy in the Presence of Interfering Gases	Complies with EN ISO 21647:2004 standard
Masimo IRMA™ CO_2 / Capnography	
Method	Mainstream
Units	mmHg
Parameters	$ETCO_2$, $FICO_2$, RRc
CO_2 Measurement Range	$ETCO_2$ & $FICO_2$: 0 to 150 mmHg
CO_2 Measurement Accuracy	Dry single gases at 22 ± 5°C and 1013 ± 40 hPa 0 to 15 vol%: ±(0.2 vol% + 2% of reading) 15 to 25 vol%: unspecified All conditions ±(0.3 kPa + 4% of reading)

CO_2 Resolution	1 mmHg
RRc (Resp. Rate) Measurement Range	0 to 150 bpm. RRc is displayed after 3 breaths and the average value is updated every breath.
RRc Resolution	1 bpm
Barometric Pressure Range	525 to 1200 hPa
Barometric Pressure Compensation	Automatic
Report Interval	Per breath
Warm-up Time Required to Meet Accuracy Specifications	< 10 seconds (concentrations reported and full accuracy)
Total System Response Time	< 1 second
Drift of Measurement Accuracy	Complies with EN ISO 21647:2004 standard
Measurement Accuracy for Gas Mixture	Complies with EN ISO 21647:2004 standard
Measurement Accuracy in the Presence of Interfering Gases	Complies with EN ISO 21647:2004 standard

Invasive Blood Pressure	
Transducer Type	Strain gauge
Transducer Excitation Voltage	5.00 VDC ± 1 %
Frequency Response	0-12 Hz
Measurement Units	mmHg
Parameters	Diastolic, Systolic, Mean for all except Mean-only for CVP
Measurement Range	-50 to 300 mmHg
Measurement Accuracy	± 1 mmHg or ± 1 %, whichever greater
IBP Resolution	1 mmHg
Pulse Rate Measurement Range	30 - 250 bpm
Pulse Rate Accuracy	± 2 bpm or ±2 %, whichever greater
Numeric Update Rate	Every 3 seconds
Temperature	
Compatibility	YSI 400-series probes
Measurement Mode	Direct (as defined in ISO 80601-2-56)
Input Connector	2-pin connector
Display Units	℉ and ℃ (user-selectable)
Measurement Resolution	0.1 ℉ (0.1 ℃)
Measurement Range	41.0 to 122.0 ℉ (5.0 to 50.0 ℃)
Measurement Accuracy	±0.2 ℉ (±0.1 ℃) plus probe tolerance
Transient Response	Within 30 seconds from 25 to 27 ℃