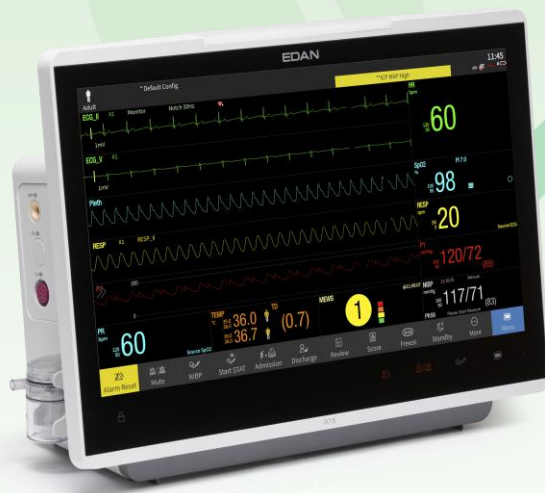


# iX15

## Patient Monitor

Version 1.0



## Main Unit Specification

### Physical Specifications

Dimension	385 mm (W) × 286 mm (H) × 162 mm (D)
Weight	< 4.9 kg (standard configuration, excluding battery, accessories, and recorder)

### Power Supply

AC Voltage	100 V to 240 V~
Input Current	1.6 A to 0.8 A
Frequency	50 Hz/60 Hz
Over Current Fuse Protection	Support

### Battery

Battery Type	Rechargeable lithium-ion battery
Operating Time	Two batteries (2×2500 mAh) ≥ 5 h Two batteries (2×5000 mAh) ≥ 10 h
Charge Time	Two batteries (2×2500 mAh) ≤ 5 h (monitor is off) ≤ 10 h (monitor is running or in standby mode) Two batteries (2×5000 mAh) ≤ 10 h (monitor is off) ≤ 20 h (monitor is running or in standby mode)

### Display

Display screen	15.6-inch color TFT, supporting touch screen
Resolution	1920 × 1080
Messages	A maximum of 12 waveforms

### Recorder

Record Width	48 mm
Paper Speed	12.5 mm/s, 25 mm/s, 50 mm/s
Channels	3
Recording types	Continual real-time recording 8-second real-time recording Trend graph recording Trend table recording C.O. measurement recording NIBP trigger recording ST VIEW recording QT VIEW recording

### Data Storage

Trend data	2400 hours @ 1 second
NIBP Measurement	1200 sets
Alarm Events	1000 sets

### Wi-Fi

IEEE	802.11a/b/g/n
Frequency Band	2.4 GHz ISM band & 5 G ISM band

### Interfaces and Others

Nurse Call / Analog Output/ Defibrillator Synchronization	1
USB Interfaces	4
HDMI Interface	1
RS232 Interface	1
Wired Network Interface	1

### ECG

Lead Mode	3 Electrodes: I, II, III 5 Electrodes: I, II, III, aVR, aVL, aVF, V 6 Electrodes: I, II, III, aVR, aVL, aVF, Va, Vb. 10 Electrodes: I, II, III, aVR, aVL, aVF, V1-V6
Electrode Standard	AHA, IEC
Display Sensitivity	×0.125, ×0.25, ×0.5, ×1, ×2, ×4, AUTO gain
Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
Bandwidth (-3 dB)	Diagnosis: 0.05 Hz to 150 Hz Diagnosis 1: 0.05 Hz to 40 Hz Monitor: 0.5 Hz to 40 Hz Surgery: 1 Hz to 20 Hz Enhanced: 2 Hz ~18 Hz Customized: High-pass Filter and Low-pass Filter
CMRR	Diagnosis: > 95 dB Diagnosis 1: > 105 dB (when Notch is turned on) Monitor: > 105 dB Surgery: > 105 dB Enhanced: > 105 dB Customized: > 105 dB (Low-pass Filter < 40 Hz) > 95 dB (Low-pass Filter > 40 Hz)
Hum Filter	In diagnosis, Diagnosis 1, monitor, surgery, enhanced and customized modes: 50 Hz/60 Hz (Hum Filter can be turned on or off manually)
Recovery Time After Defibrillation	<5 s
ESU Protection	Cut mode: 300 W Coagulation mode: 100 W Restore time: ≤10 s
Pace pulse detection	one among I, II, III, aVR, aVL, aVF, V1-V6

### Heart Rate

Range	ADU: 15 bpm to 300 bpm
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	PED/NEO: 15 bpm to 350 bpm
Accuracy	±1% or ±1 bpm, whichever is greater
Resolution	1 bpm

#### PVC

Range	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min
Resolution	1 PVCs/min

#### Pause/min

Range	ADU/PED/NEO: (0 to 30) pauses/min
Resolution	1 pause/min

#### ST value

Range	-2.0 mV to +2.0 mV
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV

#### QT measurement

Range	200 ms ~ 800 ms
Resolution	4 ms
Accuracy	± 30 ms

#### QTc measurement

Range	200 ms ~ 800 ms
Resolution	1 ms

#### ΔQTc measurement

Range	-600 ms ~ 600 ms
Resolution	1 ms

#### Arrhythmia analysis

Asystole, Sustain VT, V-Fib/V-Tach, ExtremeTachy, ExtremeBrady, V-Tach, Vent Brady, Tachy, Brady, Wide QRS Tachy, Non-Sustain VT, Afib, Vent Rhythm, Acc. Vent Rhythm, Pause, Pauses/min High, PVCs High, R on T, PVC Bigeminy, PVC Trigeminy, Pacer not Pacing, Pacer not Capture, Missed Beat, VEB, PVC, Couplet, Run PVCs, IPVC, Irr Rhythm, PAC Bigeminy, Multiform PVCs, PAC Trigeminy, Low Voltage (Limb)

#### 12-lead ECG Synchronization Analysis

Average parameters of heart beat	PR interval (ms)
Heart rate (bpm)	QRS interval (ms)
Time limit of P wave (ms)	QT/QTc (ms)
P-QRS-T AXIS	

#### RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is lead II.
Measuring range	0 rpm to 200 rpm
Resolution	1 rpm
Accuracy	6 rpm to 200 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Sweep	6.25 mm/s, 12.5 mm/s, 25.0 mm/s, 50.0 mm/s
Apnea Alarm Time	10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s

#### NIBP

Method	Oscillometry
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Mode	Manual, Auto, Continuous, Sequence
Measuring Interval in Auto Mode	1/2/2.5/3/4/5/10/15/30/60/90/120/180/240/360/480 min and User Define
Continuous	5 min, interval is 5 s
Measuring Type	SYS, DIA, MAP, PR

Measuring Range	
Adult Mode	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg
Pediatric Mode	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg
Neonatal Mode	SYS: 25 mmHg to 140 mmHg DIA: 10 mmHg to 115 mmHg MAP: 15 mmHg to 125 mmHg

Cuff Pressure	
Measuring Range	0 mmHg to 300 mmHg
Pressure Resolution	1 mmHg
Maximum Mean Error	±5 mmHg
Maximum Standard Deviation	8 mmHg
Maximum Measuring Period	Adult/ Pediatric: 120 s Neonatal: 90 s
Typical Measuring Period	iCUFS measurement: 20 s to 35 s iFAST measurement: 15 s
Dual Independent Channel Overpressure Protection	Adult: (297±3) mmHg Pediatric: (245±3) mmHg Neonatal: (147±3) mmHg

#### CNBP

Measuring Range (Adult)	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg
Measuring Range (Pediatric)	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg
Alarm Type	SYS, DIA
Pressure Resolution	1 mmHg
Maximum Mean Error	±5 mmHg
Maximum Standard Deviation	8 mmHg

#### BPVI

Measuring Range	0~100%
Resolution	1%
Update Frequency	5 s

#### EDAN Module SpO<sub>2</sub>

Measuring Range	0% to 100%
Resolution	1%
Data update period	1 s
Accuracy	Adult/Pediatric: ±2% (70% to 100% SpO <sub>2</sub> ) Undefined (0% to 69% SpO <sub>2</sub> ) Neon: ±3% (70% to 100% SpO <sub>2</sub> ) Undefined (0% to 69% SpO <sub>2</sub> )

#### PI (Perfusion Index)

Measuring Range	0 to 20%, invalid PI value is -?.
Resolution	1% (10% to 20%) 0.1% (1.0% to 9.9%) 0.01% (0.00% to 0.99%)

#### Nellcor Module SpO<sub>2</sub>

<b>Measuring Range</b>	1% to 100%
<b>Resolution</b>	1%
<b>Data Update Period</b>	1 s
<b>Accuracy</b>	
DS-100A, OXI-A/N (Adult)	
D-YS (Adult and Pediatric)	
OXI-P/I (Pediatric)	±3% (70% to 100% SpO <sub>2</sub> )
MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±2% (70%~100% SpO <sub>2</sub> )
MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±3% (60%~80% SpO <sub>2</sub> )

## PR

### PR (SpO<sub>2</sub>)

<b>Measuring range</b>	EDAN: 25 bpm to 300 bpm Nellcor: 20 bpm to 300 bpm
<b>Accuracy</b>	EDAN: ±2 bpm Nellcor: ±3 bpm (20 bpm to 250 bpm)
<b>Resolution</b>	EDAN: 1 bpm Nellcor: 1 bpm

### PR (NIBP)

<b>Measuring range</b>	EDAN: 40 bpm to 240 bpm
<b>Accuracy</b>	EDAN: ±3 bpm or 3.5%, whichever is greater
<b>Resolution</b>	EDAN: 1 bpm

### PR (IBP)

<b>Measuring range</b>	EDAN: 20 bpm to 300 bpm
<b>Accuracy</b>	EDAN: 30 bpm to 300 bpm: ±2 bpm or ±2%, whichever is greater; 20 bpm to 29 bpm: undefined
<b>Resolution</b>	EDAN: 1 bpm

## TEMP

<b>Channel</b>	2
<b>Sensor Type</b>	YSI-10K and YSI-2.252K
<b>Technique</b>	Thermal resistance
<b>Measure Parameter</b>	T1, T2, TD (the absolute value of T2 minus T1)
<b>Position</b>	Skin, oral cavity, rectum
<b>Unit</b>	°C, °F
<b>Measuring Range</b>	0°C to 50°C (32°F to 122°F)
<b>Resolution</b>	0.1°C (0.1°F)
<b>Accuracy</b>	±0.3 °C (± 0.1 °C exclude sensor error)
<b>Transient Response Time</b>	≤30 s

## IBP

<b>Channel</b>	4
<b>Technique</b>	Direct invasive measurement
<b>Measuring Range</b>	
ART, Ao, UAP, BAP, FAP, LV, P1-P4	(-50 mmHg to +400) mmHg
PA	(-6 mmHg to +120) mmHg
CVP, ICP, LAP, RAP, UVP	(-10 mmHg to +40) mmHg
<b>Resolution</b>	1 mmHg
<b>Accuracy</b>	±2% or ±1 mmHg, whichever is greater
<b>(not including sensor)</b>	ICP: 0 mmHg to 40 mmHg: ±2 % or ±1 mmHg, whichever is greater; -10 mmHg to -1 mmHg: undefined
<b>Unit</b>	kPa, mmHg, cmH <sub>2</sub> O

## EDAN G2 Sidestream Module CO<sub>2</sub>

<b>Intended patient</b>	Adult, pediatric, neonatal
<b>Measure Parameters</b>	EtCO <sub>2</sub> , FiCO <sub>2</sub> , AwRR
<b>Unit</b>	mmHg, %, kPa
<b>Measuring Range</b>	EtCO <sub>2</sub> : 0 mmHg to 150 mmHg (0% to 20%) FiCO <sub>2</sub> : 0 mmHg to 50 mmHg AwRR: 0 rpm to 150 rpm
<b>Resolution</b>	EtCO <sub>2</sub> : 1 mmHg FiCO <sub>2</sub> : 1 mmHg AwRR: 1 rpm
<b>EtCO<sub>2</sub> Accuracy</b>	
Typical conditions:	±2 mmHg, 0 to 40 mmHg
Ambient temperature: (25±3) °C	±5% of reading, 41 to 70 mmHg
Barometric pressure: (760±10) mmHg	±8% of reading, 71 to 100 mmHg
Balance gas: N <sub>2</sub>	±10% of reading, 101 to 150 mmHg
Sample gas flowrate: 100 ml/min	
All conditions	±12% of reading or ±4 mmHg, whichever is greater
<b>AwRR Accuracy</b>	±1 rpm
<b>Sample Gas Flowrate</b>	50 ml/min, 70 ml/min or 100 ml/min (optional), accuracy: ±15 ml/min
<b>Warm-up Time</b>	Display reading within 20 s; reach to the designed accuracy within 2 minutes.
<b>Response Time</b>	< 4 s (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min&70 ml/min) < 5.5 s (with 2 m gas sampling tube, sample gas flowrate: 50 ml/min)
<b>Barometric Pressure Compensation</b>	Automatic (The change of barometric pressure will not add additional errors to the measurement values.)
<b>Zero Calibration</b>	Support
<b>Calibration</b>	Support
<b>Apnea Alarm Delay</b>	10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s

## Responics Sidestream and Mainstream Module CO<sub>2</sub>

<b>Applicable Patient Type</b>	Adult, pediatric and neonatal patients
<b>Method</b>	Infra-red Absorption Technique
<b>Measure Parameters</b>	EtCO <sub>2</sub> , FiCO <sub>2</sub> , AwRR
<b>Unit</b>	mmHg, %, kPa
<b>Measuring Range</b>	EtCO <sub>2</sub> : 0 mmHg to 150 mmHg FiCO <sub>2</sub> : 3 mmHg to 50 mmHg AwRR: 2 rpm to 150 rpm (Sidestream) 0 rpm to 150 rpm (Mainstream)
<b>Resolution</b>	EtCO <sub>2</sub> 1 mmHg FiCO <sub>2</sub> 1 mmHg AwRR 1 rpm
<b>EtCO<sub>2</sub> Accuracy</b>	±2 mmHg, 0 mmHg to 40 mmHg ±5% of reading, 41 mmHg to 70 mmHg ±8% of reading, 71 mmHg to 100 mmHg ±10% of reading, 101 mmHg to 150 mmHg ±12% of reading, RR is over 80 rpm (Sidestream) There will be no degradation in performance due to respiration rate. (mainstream)
<b>AwRR Accuracy</b>	±1 rpm
<b>Apnea Alarm Delay</b>	10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s
<b>Zero Calibration</b>	Support
<b>Sample Gas Flow Rate (Sidestream)</b>	(50 ±10) ml /min
<b>Barometric Pressure Compensation</b>	User setup
<b>CO<sub>2</sub> Rise Time/Response Time (Mainstream)</b>	< 60 ms
<b>Sensor Response Time (Sidestream)</b>	< 3 seconds, includes transport time and rise time

### Masimo Sidestream Module CO<sub>2</sub>

Ambient CO <sub>2</sub>	≤ 800 ppm (0.08 vol%)
Sampling Flow Rate	(50 ± 10) sml/min
Respiration Rate	0 to 150 ± 1 breaths/min.
Calibration	No span calibration is required.
Warm-up Time	< 10 seconds
CO <sub>2</sub> Rise Time At 50sml/min Sample Flow	≤ 200 ms
NomoLine ISA CO <sub>2</sub> System Response Time	< 3 seconds
Apnea Alarm Delay	15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s
AwRR Range	0 rpm to 150 rpm
AwRR Accuracy	± 1 rpm
CO <sub>2</sub> Accuracy	
Standard Conditions	±(0.2 vol% + 2% of reading), (0 to 15) vol% Unspecified, (15 to 25) vol%
All Conditions	±(0.3 kPa + 4% of reading)

### Masimo Mainstream Module CO<sub>2</sub>

Respiration Rate	0 to 150 ± 1 breaths/min.
Calibration	No span calibration required for the IR bench.
Warm-up Time	< 10 seconds
Rise Time (@ 10 l/min)	≤ 90 ms
Total System Response Time	Total system response time
Apnea Alarm Delay	15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s
AwRR Range	0 rpm to 150 rpm
AwRR Accuracy	± 1 rpm
CO <sub>2</sub> Accuracy	
Standard Conditions	±(0.2 vol% + 2% of reading), (0 to 15) vol% Unspecified, (15 to 25) vol%
All Conditions	±(0.3 kPa + 4% of reading)

### C.O.

Technique	Thermodilution Technique
Measure Parameters	C.O.: TB, TI
Measuring Range	C.O.: 0.1 L/min to 20 L/min TB: 23°C to 43°C (73.4°F to 109.4°F) TI: -1°C to 27°C (30.2°F to 80.6°F)
Resolution	C.O. : 0.1 L/min TB, TI : 0.1°C (+0.1°F)
Accuracy	C.O.: ±5% or ±0.2 L/min, whichever is greater TB: ±0.1°C (±0.18 °F) (not including sensor) TI : ±0.1°C (±0.18 °F) (not including sensor)

### EDAN G7 (Sidestream) AG

Intended Patient	Adult, pediatric, neonatal
Measure Parameters	Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), CO <sub>2</sub> , O <sub>2</sub> , N <sub>2</sub> O, AwRR, and MAC
Unit	HAL, ISO, ENF, SEV, DES, N <sub>2</sub> O: %; CO <sub>2</sub> , O <sub>2</sub> : mmHg, %, kPa, default is %; AwRR: bpm;
Measuring Range	
CO <sub>2</sub>	0~15 vol%
N <sub>2</sub> O	0~100 vol%
Halothane/ Enflurane/ Isoflurane	0~8 vol%
Sevoflurane	0~10 vol%

Desflurane	0~22 vol%
O <sub>2</sub>	0~100%
Resolution	N <sub>2</sub> O, O <sub>2</sub> : 1% CO <sub>2</sub> , AG: 0.1%
AwRR	Measurement range: 2 ~ 150 rpm Measuring accuracy: ±1 bpm (120 bpm and below), Not specified (120 bpm above) Resolution: 1 rpm
Sampling Flow Rate	150 ml/min, accuracy ±15 ml/min
Warm-up Time	Display reading within 20 s; reach to the designed accuracy within 2 minutes
Response Time	< 4 s (with 2 m gas sampling tube, sample gas flowrate: 150 ml/min)

### Masimo ISA Analyzer AG

Module Type	
ISA AX+	Displaying the concentration of CO <sub>2</sub> , N <sub>2</sub> O, and two anesthesia agent and identifying the anesthesia agent automatically (built-in module)
ISA OR+	Displaying the concentration of CO <sub>2</sub> , O <sub>2</sub> , N <sub>2</sub> O, and two anesthesia agent and identifying the anesthesia agent automatically (built-in module)
Measurement Parameters	CO <sub>2</sub> , N <sub>2</sub> O, O <sub>2</sub> , Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), AwRR, MAC
Measurement Principle	CO <sub>2</sub> , N <sub>2</sub> O, Anesthesia Agent: Infra-red absorption characteristic; O <sub>2</sub> : Paramagnetic method
Sampling Flow Rate	50 ± 10 ml/min
Compensations	Automatic compensation for pressure, temperature and broadening effects on CO <sub>2</sub> .
Warm-up Time	< 20 s
Measurement Range	CO <sub>2</sub> : 0 to 25 vol% O <sub>2</sub> : 0 to 100 vol% N <sub>2</sub> O: 0 to 82 vol% HAL, ENF, ISO, SEV, DES: 0-25 vol% AwRR: 0 rpm to 150 rpm
Resolution	CO <sub>2</sub> : 0.1% HAL, ENF, ISO, SEV, DES: 0.1% N <sub>2</sub> O: 1% O <sub>2</sub> :1% AwRR: 1 rpm
Accuracy(Standard Conditions)	
CO <sub>2</sub>	± (0.2 vol% + 2% of reading), 0 to 15 vol% Unspecified, 15 to 25 vol%
N <sub>2</sub> O	± (2 vol% + 2% of reading), 0 to 82 vol%
HAL, ENF, ISO	± (0.15 vol% + 5% of reading), 0 to 8 vol % Unspecified , 8 to 25 vol %
SEV	± (0.15 vol% + 5% of reading), 0 to 10 vol % Unspecified, 10 to 25 vol %
DES	± (0.15 vol% + 5% of reading), 0 to 22 vol % Unspecified, 22 to 25 vol %
O <sub>2</sub>	± (1 vol% + 2% of reading), 0 to 100 vol %
Accuracy(All Conditions)	
CO <sub>2</sub>	±(0.3 kPa + 4% of reading)
N <sub>2</sub> O	±(2 kPa + 5% of reading)
Agents	±(0.2 kPa + 10% of reading) (The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set)
O <sub>2</sub>	±(2 kPa + 2% of reading)
AwRR Accuracy	±1 rpm
Apnea Alarm Delay	20 s (Default), 25 s, 30 s, 35 s, 40 s

## Masimo IRMA Module AG

<b>Module Type: IRMA AX+</b>	Displaying the concentration of CO <sub>2</sub> , N <sub>2</sub> O and two anesthesia agent and identifying two anesthesia agent
<b>Measurement Parameters</b>	CO <sub>2</sub> , N <sub>2</sub> O, HAL, Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), AwRR, MAC
<b>Measurement Principle</b>	CO <sub>2</sub> , N <sub>2</sub> O, anesthesia agent: infra-red absorption characteristic
<b>Barometric Pressure Compensation</b>	Automatic
<b>Warm-up Time</b>	<20 seconds
<b>Measurement Range</b>	CO <sub>2</sub> : 0 to 25 vol% N <sub>2</sub> O: 0 to 82 vol% HAL, ENF, ISO, SEV, DES: 0 to 25 vol% AwRR: 0 to 150 rpm
<b>Resolution</b>	CO <sub>2</sub> : 0.1% HAL, ENF, ISO, SEV, DES: 0.1% N <sub>2</sub> O: 1% AwRR: 1 rpm
<b>Accuracy(Standard Conditions)</b>	
CO <sub>2</sub>	± (0.2 vol% + 2% of reading), 0 to 15 vol%
N <sub>2</sub> O	± (2 vol% + 2% of reading), 0 to 82 vol%
HAL, ENF, ISO	± (0.15 vol% + 5% of reading), 0 to 8 vol %
SEV	± (0.15 vol% + 5% of reading), 0 to 10 vol %
DES	± (0.15 vol% + 5% of reading), 0 to 22 vol %
<b>Accuracy(All Conditions)</b>	
CO <sub>2</sub>	±(0.3 kPa + 4% of reading)
N <sub>2</sub> O	±(2 kPa + 5% of reading)
Agents	±(0.2 kPa + 10% of reading) (The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set)
<b>AwRR Accuracy</b>	±1 rpm
<b>Apnea Alarm Delay</b>	20 s (Default), 25 s, 30 s, 35 s, 40 s

## Safety Specifications

<b>Compliant with Standards</b>	IEC 60601-1: 2005+A1 :2012; IEC 60601-1-2: 2014; EN 60601-1: 2006+A1 :2013; EN 60601-1-2: 2015; IEC 80601-2-49: 2018
<b>Anti-electroshock Type</b>	Class I equipment and internal powered equipment
<b>Anti-electroshock Degree</b>	CF
<b>Ingress Protection</b>	IP22

## Environmental Specifications

<b>Temperature</b>	Working: +0°C to +40°C (32°F ~ 104°F) Transport and storage: -20°C to +60°C (-4°F ~ 140°F)
<b>Humidity</b>	Working: 15%RH to 95%RH (non-condensing) Transport and storage: 10%RH to 95%RH (non-condensing)
<b>Altitude</b>	Working: 57 kPa to 107.4 kPa Transport and storage: 16 kPa to 107.4 kPa