EDANUSA

iM20 Patient Monitor

Product Specifications

Product Specifications

NOTE:

The performance of the equipment with ☆ mark is determined to be essential performance.

A.1 Classification

Anti-electroshock type	Class II equipment and internal powered equipment
Anti-electroshock degree	ECG (RESP), TEMP, IBP, C.O. CF SpO_2, NIBP, CO_2 BF
Ingress Protection	IP44 (protected against splashing water and solid foreign objects ≥ 1.0 mm diameter)
Working system	Continuous operation equipment
Compliant with Standards	IEC 60601-1: 2005+A1 :2012; IEC 60601-1-2: 2014; EN 60601-1: 2006+A1 :2013; EN 60601-1-2: 2015; IEC 60601-2-49: 2011

A.2 Physical Specifications

Product	Dimension	Max Weight	Comments
iM20	185 mm (W) ×116 mm (H) × 85.3 mm (D)	< 1.5 kg	Including battery, without accessories
EFM	207 mm (W) ×116 mm (H) × 93.4 mm (D)	< 0.58 kg	Including sidestream CO_2 module.

A.3 Function Configuration

Product	Standard Configuration	Optional Configuration
iM20	ECG (3- Electrode, 5- Electrode), RESP, SpO_2 (EDAN), NIBP (EDAN), TEMP, Wi-Fi, USB interface	ECG (6- Electrode, 10-Electrode), SpO_2 (Nellcor), NIBP (SunTech), IBP, C.O.
EFM	/	CO_2 (Respironics LoFlo)

Note: There is only one configuration for EFM module.

A.4 Environmental Specifications

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Main unit	
Temperature	
Working	+0 °C to +40 °C (32 ℉ ~ 104 ℉)
Transport and Storage	-30 °C to +70 °C (-22 ℉ ~ 158 ℉)
Humidity	
Working	15%RH to 95%RH (non-condensing)
Transport and Storage	15%RH to 95%RH (non-condensing)
Altitude	
Working	61.5 kPa to 106 kPa
Transport and Storage	61.5 kPa to 106 kPa

EFM	
Temperature	
Working	+0 °C to +35 °C (32 ℉ ~ 95 ℉)
Transport and Storage	-30 °C to +70 °C (-22 ℉ ~ 158 ℉)
Humidity	
Working	15%RH to 95%RH (non-condensing)
Transport and Storage	15%RH to 95%RH (non-condensing)
Altitude	
Working	61.5 kPa to 106 kPa
Transport and Storage	61.5 kPa to 106 kPa

NOTE:

The time required for the patient monitor to warm from the minimum storage temperature between uses until it is ready for intended use is at least 2 hours; the time required for the patient monitor to cool from the maximum storage temperature between uses until it is ready for intended use is at least 2 hours.

A.5 Out-Of-Hospital Transport Requirements

The monitor can be used in transport environments such as a road ambulance. For this purpose, the monitor meets the following requirements:

- EN 1789: 2007+A1: 2010 Road ambulances (Chapter 6 – Medical Devices).
- IEC/EN 60529 IP44 Specification for degrees of protection provided by enclosures.
- Radiated susceptibility 20 V/m according to Complies with ISO 80601-2-61: 2011. (SpO_2) and ISO 80601-2-55: 2011 (CO_2).

A.6 Power Supply

Voltage	DC 11.1 V – 19.8 V
Current	1.27 A – 2.3 A

A.7 Display

Display	Messages
Display screen: 5-inch color TFT, touch screen is configurable Resolution: 800 ×480	One power on/off LED One battery charge LED One DC power LED One physiological alarm LED One technical alarm LED One alarm mute LED

A.8 Battery

Number	1
Battery Type	Lithium battery
Capacity	11.1 V, 2400 mAh
Operating Time	5.5 hrs (At 25 ℃±2 ℃, with (a) new fully charged battery, ECG (RESP)/TEMP/SpO_2 module connected, NIBP automatic measurement mode at interval of 15 minutes, brightness set to “1”.)
Charging Time	≤ 14 hrs (The monitor is on or in standby mode, 100% charge)
	≤ 12.6 hrs (The monitor is on or in standby mode, 90% charge)
	2.5 hrs (The monitor is off, 100% charge)
	2.3 hrs (The monitor is off, 90% charge)

A.9 Power Adapter

AC Power Adapter	Input: 100 V - 240 Vac, 40VA; Output: 15 V±5%dc, 24 VA
DC Power Adapter	Input: 12.4 V - 15.1 Vdc or 24.8 V - 30.3 Vdc, 1.6 A max; Output: 15 Vdc, 1 A max

A.10 Data Management

Data Review

Trend data	1 hour, resolution: 1 s 150 hours, resolution: 1 min
Alarm events	Up to 200 sets
NIBP measurement data	1200 sets
Arrhythmia events	Up to 200 sets
12-Lead analysis result	Up to 50 sets

Refer to Chapter *Review* for more information about data review.

Data Storage

A single piece of patient data maximally contains the following information:

Patient information	MRN, name, date of birth, date of admission, gender, type, height, weight, blood type, pace, doctor, bed No., department
Trend graph and trend table	240 hours, resolution: 1 min
NIBP measurement review	1200 sets
Alarm review	200 sets
Arrhythmia event	200 sets
12-lead analysis review	50 sets
Full disclosure waveforms	3-lead/5-lead: 48 hours 12-lead: 35 hours

Refer to Section *Storing Data in the Storage Device* for more information about storing data in the storage medium.

A.11 ECG

Complies with IEC 60601-2-25: 2011, IEC 60601-2-27: 2011.

Lead Mode	3 Electrodes: I, II, III 5 Electrodes: I, II, III, aVR, aVL, aVF, V 6 Electrodes: I, II, III, aVR, aVL, aVF, and leads responding to Va Vb. 10 Electrodes: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Electrode Standard	AHA, IEC
☆Display Sensitivity (Gain Selection)	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/mV (×4), AUTO gain
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s
Bandwidth (-3dB)	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 (Refer to Section *Changing the ECG Filter Settings*)
☆CMRR (Common Mode Rejection Ratio)	Diagnosis: > 95 dB Monitor: > 105 dB Surgery: > 105 dB Enhanced: > 105 dB Diagnosis 1: > 105 dB (when Notch is turned on) Customized: > 105 dB (Low-pass Filter < 40 Hz) > 95 dB (Low-pass Filter > 40 Hz)
Hum Filter	In diagnosis, Diagnosis 1, monitor, surgery, enhanced modes: 50 Hz/60 Hz (Hum Filter can be turned on or off manually)
☆ Differential Input Impedance	> 5 MΩ
☆Input Signal Range	±10 mV PP
☆Accuracy of Input Signal Reproduction	An error of ≤ ±20% of the nominal value of the output or ±100 μV, whichever is greater. The total error and frequency response comply with IEC 60601-2-27: 2011, Sect. 201.12.1.101.1.

☆ Electrode Offset Potential Tolerance	±500 mV
Auxiliary Current (Leads off detection)	Active electrode: < 100 nA Reference electrode: < 900 nA
☆ Recovery Time After Defibrillation	< 5 s (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)
Leakage current of patient	< 10 μA
Scale signal	1 mVPP, accuracy is ±5%
☆System Noise	< 30 μVPP
☆Multichannel Crosstalk	≤ 5% of the input signal Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.5.
☆Frequency and Impulse Response	Frequency response: Input a 5 Hz, 1 mV sine wave signal, and the output signal amplitude remains within the range of 71% to 110% at 0.67 Hz and 40 Hz. Input a 1 Hz, 1.5 mV 200 ms triangular wave input signal, and the output shall be within 11.25 mm~15 mm. Impulse response: Displacement value: ≤ 0.1 mV Slope: ≤ 0.3 mV/s following the end of the pulse. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.8.
Sampling frequency	1000 Hz
Sampling channel switch time	< 80 μS
A/D precision	24 Bits (Minimum resolution: 0.07533 uV/LSB)
☆ESU Protection	Cut mode: 300 W Coagulation mode: 100 W Restore time: ≤ 10 s
Electrosurgical Interference Suppression	Test according to ANSI/AAMI EC13:2002, Sect. 5.2.9.14. Complied with ANSI/AAMI EC13:2002, Sect. 4.2.9.14.

Pace Pulse	
Pulse indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs
Pulse Rejection	Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to100 μs
Pace pulse detecting lead: one among I, II, III, aVR, aVL, aVF, V1 to V6	
Minimum input slew rate (lead II)	> 2.5 V/S
☆Baseline Reset Time	< 3 s
Heart Rate	
HR Calculation	
☆Range	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm
☆Accuracy	±1% or 1 bpm, whichever is greater
Resolution	1 bpm
Sensitivity	≥ 300 μVPP
☆QRS Detection Range	The detection range has exceeded the requirement described in the standard: Width: 70 ms~120 ms for adult, 40 ms~120 ms for Pediatric/neonate. Amplitude: 0.5 mv~5 mv In adult mode, these two signals are not responded: 1. when QRS amplitude of 0.15 mV or less is applied; 2. when QRS duration of 10 ms and QRS amplitude of 1 mV or less is applied. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.15.

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
HR Averaging Method	
Method 1	Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.
Method 2	If each of three consecutive RR intervals is greater than 1200ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
Normal	Adult: 0.5 s < RR interval for 5 consecutive QRS complex < 1.5 s. Pediatric/neonatal: 0.375 s < RR interval for 5 consecutive QRS complex < 1 s.
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.
Range of Ventricular Rhythm	
V-Tach	5 consecutive ventricular beats and ventricular HR ≥ 100 bpm.

Vent Rhythm	Basic: 5 consecutive ventricular beats, and 40 bpm ≤ ventricular HR < 100 bpm. Advanced: 5 consecutive ventricular beats, and 20 bpm ≤ ventricular HR < 40 bpm.
Vent Brady	Basic: 5 consecutive ventricular beats, and ventricular HR < 40 bpm. Advanced: 5 consecutive ventricular beats, and ventricular HR < 20 bpm.
Maximum start-up alarm time for Tachycardia	
V-Tach 1 mV 206bpm	Gain 1.0: 10 s Gain 0.5: 10 s Gain 2.0: 10 s
V-Tach 2 mV 195bpm	Gain 1.0: 10 s Gain 0.5: 10 s Gain 2.0: 10 s
Response time of Heart Rate Meter to Change in HR	HR range: 80 bpm to 120 bpm Range : Within 11 s HR range: 80 bpm ~ 40 bpm Range : Within 11 s
☆Tall T-wave Rejection	Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude
Accuracy of Heart Rate Meter and Response to Irregular Rhythm	Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy: 80 bpm ±1 bpm Slow alternating ventricular bigeminy: 60 bpm ±1 bpm Rapid alternating ventricular bigeminy: 120 bpm ±1 bpm Bidirectional systoles: 91 bpm ±1 bpm
Time to Alarm for Heart Rate alarm conditions	Asystole alarm: ≤ 10 s HR low alarm: ≤ 10 s HR high alarm: ≤ 10 s

Arrhythmia analyses	Asystole	V-Fib/V-Tach	Couplet
	Vent Rhythm	PVC Bigeminy	PVC Trigeminy
	Tachy	R on T	PVC
	Irr Rhythm	Brady	Missed Beat
	Pacer not Pacing	Vent Brady	Pacer not Capture
	VEB	Run PVCs	Acc. Vent Rhythm
	IPVC	Non-Sustain VT	Multiform PVCs
	Pauses/min High	Pause	Afib
	PAC Bigeminy	PVCs High	Low Voltage(Limb)
	ExtremeBrady	PAC Trigeminy	Wide QRS Tachy
	Sustain VT	ExtremeTachy	V-Tach
12-lead ECG Synchronization Analysis	Average parameters of heart beat		
	Heart rate (bpm)		
	Time limit of P wave (ms)		
	PR interval (ms)		
	QRS interval (ms)		
	QT/QTC (ms)		
	P-QRS-T AXIS		

A.12 RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is lead II.
Calculation Type	Manual, Automatic
Respiration excitation waveform	Sinusoid, 45.6 kHz (±10%), < 500 μA
Measuring Sensitivity	Within baseline impedance range: 0.3 Ω
Waveform bandwidth	0.2 Hz to 2.5 Hz (-3 dB)
Baseline Impedance Range	200 Ω to 2500 Ω (leads cables 1 KΩ resistance)
☆RR Measuring Range	

☆Adult	0 rpm to 120 rpm
☆Neo/Ped	0 rpm to 150 rpm
Resolution	1 rpm
☆Accuracy	
☆Adult	6 rpm to 120 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
☆Neo/Ped	6 rpm to 150 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 mm/s
☆Apnea Alarm Time Setup	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.

A.13 NIBP

Complies with IEC 80601-2-30: 2009+A1: 2013.

EDAN Module

Technique	Oscillometry
Mode	Manual, Auto, Continuous, Sequence
Measuring interval in AUTO Mode(unit: minute)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 and User Define (default is 2.5)
Continuous	5 min, interval is 5 s
Measuring Parameter	SYS, DIA, MAP, PR
Pressure Unit	kPa, mmHg, cmH_2O
☆Measuring Range (Applicable for CE registration area)	
☆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

☆Measuring Range (Applicable for FDA registration area)	
☆Adult Mode	SYS: 40 mmHg ~ 270 mmHg DIA: 10 mmHg ~ 215 mmHg MAP: 20 mmHg ~ 235 mmHg
☆Pediatric Mode	SYS: 40 mmHg ~ 230 mmHg DIA: 10 mmHg ~ 180 mmHg MAP: 20 mmHg ~ 195 mmHg
☆Neonatal Mode	SYS: 40 mmHg ~ 135 mmHg DIA: 10 mmHg ~ 100 mmHg MAP: 20 mmHg ~ 110 mmHg
☆Alarm Type	SYS, DIA, MAP
☆ Cuff Pressure Measuring Range	0 mmHg ~ 300 mmHg
Pressure Resolution	1 mmHg
☆Maximum Mean Error	±5 mmHg
☆Maximum Standard Deviation	8 mmHg
Maximum measuring period	
Adult/Pediatric	120 s
Neonate	90 s
Typical Measuring Period	20 s to 35 s (depend on HR/motion disturbance)
Dual Independent Channel Overpressure Protection	
Adult	(297±3) mmHg
Pediatric	(245±3) mmHg
Neonatal	(147±3) mmHg
Pre-inflation Pressure	
Adult Mode	80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 240 mmHg Default: 160 mmHg
Pediatric Mode	80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg Default: 140 mmHg
Neonatal Mode	60 mmHg, 70 mmHg, 80 mmHg, 100 mmHg, 120 mmHg Default: 100 mmHg

Venipuncture pressure	
Adult	Default: 60 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 110 mmHg, 120 mmHg
Pediatric	Default: 40 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg
Neonatal	Default: 30 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg

SunTech Module

Method	Oscillometric
Mode	Manual, Auto, Continuous and Sequence
Measuring Interval in AUTO Mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/240 and User Define
☆Measuring Parameter	SYS, DIA, MAP, PR
☆Measuring Range	
☆Adult Mode	SYS: 40 mmHg ~ 260 mmHg DIA: 20 mmHg ~ 200 mmHg MAP: 26 mmHg ~ 220 mmHg
☆Pediatric Mode	SYS: 40 mmHg ~ 230 mmHg DIA: 20 mmHg ~ 160 mmHg MAP: 26 mmHg ~ 183 mmHg
☆Neonatal Mode	SYS: 40 mmHg ~ 130 mmHg DIA: 20 mmHg ~ 100 mmHg MAP: 26 mmHg ~ 110 mmHg
☆Alarm Type	SYS, DIA, MAP
Pressure Resolution	1 mmHg
☆Maximum mean error	±5 mmHg
☆Maximum standard deviation	8 mmHg
Maximum measuring period	
Adult	130 s

Adult (Sports Mode)	120 s
Pediatric	90 s
Neonate	75 s
Overpressure protection	
Adult/Pediatric	< 300 mmHg
Neonate	< 150 mmHg
Pre-inflation Pressure	
Adult Mode	120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 240 mmHg, 260 mmHg, 280 mmHg Default: 160 mmHg
Pediatric Mode	80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 250 mmHg Default: 140 mmHg
Neonatal Mode	60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 120 mmHg, 140 mmHg Default: 90 mmHg

A.14 SpO_2

Complies with ISO 80601-2-61: 2011.

EDAN Module

Measuring Range	0% to 100%
Alarm Range	20% to 100%
Resolution	1%
☆Data Update Period	1 s
☆Accuracy	
☆Adult /Pediatric	±2% (70% to 100% SpO_2)
	Undefined (0% to 69% SpO_2)
☆Neonate	±3% (70% to 100% SpO_2)
	Undefined (0% to 69% SpO_2)
Sensor	
Red light	(660±3) nm
Infrared light	(905±10) nm

Emitted light energy	< 15 mW
PI	
Measuring Range	0-10, invalid PI value is 0.
Resolution	1

Nellcor Module

Measuring Range	1% to 100%	
Alarm Range	20% to 100%	
Resolution	1%	
☆ Data Update Period	1 s	
☆Accuracy	DS-100A, OXI-A/N(Adult) D-YS (Adult and Pediatric) OXI-P/I (Pediatric)	± 3% (70% to 100% SpO_2)
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±2% (70%～100% SpO_2)
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±3% (60%～80% SpO_2)
	If sensor is used for neonate as recommended, the accuracy will be larger greater than adult by ±1.	
Sensor	Wave length: approximately 660 nm and 900 nm	
	Emitted light energy: < 15 mW	

NOTE:
Information about the wave length range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A.15 PR

		Measuring range	Accuracy	Resolution
PR (SpO_2)	EDAN	25 bpm to 300 bpm	±2 bpm	1 bpm
	Nellcor	20 bpm to 300 bpm	± 3 bpm (20 bpm to 250 bpm)	1 bpm

		Measuring range	Accuracy	Resolution
PR (NIBP)	EDAN	40 bpm to 240 bpm	±3 bpm or 3.5%, whichever is greater	1 bpm
	SunTech	30 bpm to 220 bpm	±3 bpm or ±2%, whichever is greater	1 bpm
PR (IBP)	EDAN	20 bpm to 300 bpm	30 bpm to 300 bpm: ±2 bpm or ±2%,whichever is greater; 20 bpm to 29 bpm: undefined	1 bpm

A.16 TEMP

Complies with ISO 80601-2-56: 2009.

Channel	2
Sensor type	YSI-10K and YSI-2.252K
Technique	Thermal resistance
Measuring Mode	Direct Mode
Position	Skin, oral cavity, rectum
Measuring Range	0 °C to 50 °C(32 ℉ to 122 ℉)
Resolution	0.1 °C (0.1 ℉)
☆Accuracy[1]	±0.3 °C
Refresh Time	Every 1 s to 2 s
Temperature Calibration	At an interval of 5 minutes to 10 minutes
Transient Response Time	≤ 30 s

Note 1: The accuracy consists of two parts, as following:

- Accuracy (not including sensor): ±0.1 °C
- Sensor accuracy: ≤ ±0.2 °C

A.17 IBP

Complies with IEC 60601-2-34: 2011.

Technique	Direct invasive measurement
☆Measuring Range	
Art	0 mmHg to + 300 mmHg

PA		-6 mmHg to + 120 mmHg
CVP/RAP/LAP/ICP		-10 mmHg to + 40 mmHg
P1/P2		-50 mmHg to + 300 mmHg
Resolution		1 mmHg
☆Accuracy (not including sensor)		± 2% or ±1 mmHg, whichever is greater ICP: 0 mmHg to 40 mmHg: ±2% or ±1 mmHg, whichever is greater; -10 mmHg to -1 mmHg: undefined
Pressure Unit		kPa, mmHg, cmH_2O
Pressure sensor		
Sensitivity		5 (μV/V/mmHg)
Impedance		(300 to 3000) Ω
Filter		DC~ 12.5 Hz; DC~ 40 Hz
Zero		Range: ±200 mmHg
Pressure Calibration Range	IBP (excluding ICP)	80 mmHg to 300 mmHg
	ICP	10 mmHg to 40 mmHg
Volume displacement of MSI		7.4×10^4 mm^3/100mmHg

A.18 CO_2

Complies with ISO 80601-2-55: 2011.

Applicable Patient Type	Adult, pediatric and neonatal patients	
Technique	Infra-red Absorption Technique	
Unit	mmHg, %, Kpa	
☆Measuring Range		
☆$EtCO_2$	0 mmHg ~ 150 mmHg	
☆$FiCO_2$	3 mmHg ~ 50 mmHg	
☆AwRR	2 rpm ~ 150 rpm (Sidestream)	
Resolution	$EtCO_2$	1 mmHg
	$FiCO_2$	1 mmHg
	AwRR	1 rpm

☆$EtCO_2$ Accuracy	±2 mmHg, (0 to 40) mmHg
	±5% of reading, (41 to 70) mmHg
	±8% of reading, (71 to 100) mmHg
	±10% of reading, (101 to 150) mmHg
	±12% of reading, RR is over 80 rpm (sidestream)
☆AwRR Accuracy	±1 rpm
Operation Mode	Measure, standby
Sample Gas Flowrate (sidestream)	(50 ±10) ml/min
O_2 Compensation	
Range	0%~ 100%
Resolution	1%
Default	16%
Barometric pressure compensation	User setup
Anesthetic Gas Compensation	
Range	0% ~ 20%
Resolution	0.1%
Default	0.0%
Balance Gas Compensation	Room air, N_2O, helium
Stability	
Short Term Drift	Drift over 4 hours < 0.8 mmHg
Long Term Drift	120 hours
Total System Response Time	4.7 s
Alarm Type	$EtCO_2$, $FiCO_2$, AwRR
Apnea Alarm Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.
Data Sample Rate	100 Hz
Sensor Response Time (sidestream)	< 3 seconds, including transport time and rise time

Interfering Gas and Vapor Affects on $EtCO_2$ Measurement Values:

Gas or vapor	Gas level (%)	Quantitative effect/Comments

Nitrous oxide	60	Dry and Saturated Gas
Halothane	4	(0 ~ 40) mmHg: ±1 mmHg additional error
Enflurane	5	(41 ~ 70) mmHg: ±2.5% additional error
Isoflurane	5	(71 ~ 100) mmHg: ±4% additional error
Sevoflurane	5	(101 ~ 150) mmHg: ±5% additional error
Xenon	80	*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.
Helium	50	
Desflurane	15	Desflurane:
		The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.
		Xenon:
		The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg.

Barometric Pressure on $EtCO_2$ Measurement Values:

Quantitative effect
Ambient Barometric, Operational
(0 ~ 40) mmHg: ±1 mmHg additional error
(41 ~ 70) mmHg: ±2.5% additional error
(71 ~ 100) mmHg: ±4% additional error
(101 ~ 150) mmHg: ±5% additional error
*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.

NOTE:

Respiration Rate accuracy was verified by using a solenoid test setup to deliver a square wave of known CO_2 concentration to the device. 5% and 10% CO_2 concentrations were used. Respiration rate was varied over the range of the device. Pass/Fail criteria was comparison of the respiratory rate output from the sensor to the frequency of the square wave.

A.19 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 ℉ to 109.4 ℉)
TI	-1 °C to 27 °C (30.2 ℉ to 80.6 ℉)
Resolution	
C.O.	0.1 L/min
TB, TI	0.1 °C (+0.1 ℉)
Accuracy	
C.O.	± 5% or ± 0.2 L/min, whichever is greater
TB	± 0.1 °C (not including sensor)
TI	± 0.1 °C (not including sensor)

NOTE:

At least 90% of the C.O. data should reside inside the bounded region, and the lower 95% confidence interval should not exceed 85%.

A.20 Wi-Fi

IEEE	802.11b/g/n
Frequency	2.4 GHz ISM band
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Typical Transmit Power (±2 dBm)	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM

A.21 Interface

A.21.1 USB Interface

Number of USB Interfaces	Standard: 1
Drive Mode	OTG, USB1.0/2.0 protocol
Power Supply	5 VDC±5%, 150 mA Max.
Interface Type	Micro USB-type port