EDANUSA

X8/X10/X12
Patient Monitor
Product Specifications

A Product Specification

NOTE:

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

A.1 Classification

Anti-electroshock type	Class I equipment and internal powered equipment
Anti-electroshock degree	CF
Ingress Protection	IPX1
Disinfection/sterilization method	Refer to Chapter Care and Cleaning for details.
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

A.2.1 Size and Weight

Product	Size	Weight	
X8	236±2 mm (W)×236±2 mm (H)×147±2 mm (D)	< 2.4 kg	Standard configurations, no battery or accessories
X10	261±2 mm (W)×246±2 mm (H)×146±2 mm (D)	< 2.8 kg	
X12	306±2 mm (W)×309±2 mm (H)×151±2 mm (D)	< 3.5 kg	

A.2.2 Function Configuration

Product	Standard Configuration	Optional Configuration
X8	ECG (3 electrodes), ECG (5 electrodes), RESP, TEMP (T1), SpO_2, NIBP	ECG (6 electrodes), ECG (10 electrodes), CO_2, Wi-Fi, Recorder
X10	ECG (3 electrodes), ECG (5 electrodes), RESP, TEMP (T1, T2), SpO_2, NIBP	ECG (6 electrodes), ECG (10 electrodes), IBP, CO_2, Wi-Fi, Recorder
X12	ECG (3 electrodes), ECG (5 electrodes), RESP, TEMP (T1, T2), SpO_2, NIBP	ECG (6 electrodes), ECG (10 electrodes), IBP, CO_2, C.O., Wi-Fi, Recorder

A.2.3 Environment Specification

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.

Temperature		
Working	+0 °C to +40 °C (32 ℉ ~104 ℉) When the battery is charged: +0 °C to +35 °C (32 ℉~95 ℉)	
Transport and Storage	-20 °C to +55 °C (-4 ℉ ~131 ℉)	
Humidity		
Working	15%RH ~ 95%RH (non-condensing)	
Transport and Storage	15%RH ~ 95%RH (non-condensing)	
Altitude		
Working	86 kPa ~ 106 kPa	
Transport and Storage	70 kPa ~ 106 kPa	
Power Supply	100 V-240 V~, 50 Hz/60 Hz	
	X8	Current=1.0 A-0.5 A;
	X10/X12	Current=1.4 A-0.7 A.

A.2.4 Display

Product	Display	Messages
X8	Display screen: 8-inch color TFT, supporting touch screen Resolution: 800×600 A maximum of 13 waveforms	One power LED Two alarm LED One charge LED
X10	Display screen: 10.1-inch color TFT, supporting touch screen Resolution: 800×480 A maximum of 13 waveforms	
X12	Display screen: 12.1-inch color TFT, supporting touch screen Resolution: 800×600 A maximum of 13 waveforms	

A.2.5 Battery Specification

Operating Time	2550 mAh (standard)	≥ 4 h
	5100 mAh (optional)	≥ 8 h
Condition	At 20 °C ~30 °C, with (a) new fully charged battery/batteries, continuous SpO_2 measurement and NIBP automatic measurement mode at interval of 15 minutes, brightness set to "1".	
Charge Time	2550 mAh (standard)	≤ 3.5 h, 90% charge
	5100 mAh (optional)	≤ 6.5 h, 90% charge
Condition	Environment temperature: 20 °C ~30 °C. And the monitor is off.	

A.2.6 Recorder

Record Width	48 mm, 50 mm
Paper Speed	12.5 mm/s, 25 mm/s, 50 mm/s
Trace	3
Recording types	Continuous real-time recording 8 seconds real-time recording 20 seconds real-time recording Time recording Alarm recording Trend graph recording Trend table recording NIBP review recording Arrhythmia review recording Alarm review recording Drug calculation titration recording Hemodynamic Calculation result recording 12-lead analysis recording C.O. measurement recording ST view recording QT view recording

A.2.7 Data Management

Data Review

Trend graph/trend table review	3 hrs, at 1 Second Resolution

	120 hrs, at 1 min. Resolution
Alarm/Monitoring Event data	Up to 200 sets
NIBP Measurement Review	1200 sets
Arrhythmia events	Up to 200 sets
12-lead analysis Review	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:

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 electrodes/5 electrodes/6 electrodes: 48 hours 10 electrodes: 35 hours

The following storage capacity for the standard extended space is for reference:

Continuous parameter data	5400 hours, resolution: 1 min
NIBP data	At least 510000 sets
Physiological alarm event	At least 33750 sets
Arrhythmia event	At least 33750 sets
Full disclosure waveforms	225 hours

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

A.3 Wi-Fi (Optional)

A.3.1 Wi-Fi Technical Specifications

IEEE	802.11a/b/g/n
Frequency Band	2.4 GHz ISM band & 5 G ISM band
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Maximum Transmit Power (±2 dBm)	2.4 G:

	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 17 dBm for 802.11g OFDM 16 dBm for 802.11n OFDM 5 G: 10 dBm for 802.11a OFDM 9 dBm for 802.11n OFDM

A.3.2 Wi-Fi Performance Specifications

System Capacity and Resistance to Wireless Interference	When the following conditions are present, ■ Quantity of the monitors supported by a single AP: ≤ 8. ■ Each monitor can communicate with MFM-CMS. ■ Each monitor supports bed view function, which allows users to view its information from another bed or view other bed's information from its screen. ■ The AP signal strength of the monitor should be stronger than -65 dBm. ■ When the distance between the interfering devices and the monitor is more than 30 cm, and there are a co-channel interference Wi-Fi network (at least -85 dBm weaker than the monitor's network) and an adjacent-channel Wi-Fi network (at least -50 dBm weaker than the monitor's network) at the same time. Note: Excluding the Wi-Fi devices, the interfering devices include but are not limited to: ◆ 2.4 G or 5G wireless devices (excluding Wi-Fi devices) ◆ Cellular mobile communication networks ◆ Microwave ovens ◆ Interphones ◆ Mobile phones ◆ ESU equipment The wireless network function of all monitors

	works normally and meets the following requirements: ■ Total delay time for data transmission from the monitors to MFM-CMS: ≤ 2 s. ■ Total delay time of data transmission from one monitor to other monitors: ≤ 2 seconds. ■ Effective time of alarm reset configured on another monitor ≤ 2 s. ■ Effective time for monitor-related settings configured on the MFM-CMS: ≤ 2 s. ■ No communication loss between all the monitors.
Wi-Fi Network Stability	When the following conditions are present, ■ Quantity of the monitors supported by a single AP: ≤ 8. ■ Each monitor can communicate with MFM-CMS. ■ Each monitor supports bed view function, which allows users to view its information from another bed or view other bed's information from its screen. ■ The AP signal strength of the monitor should be stronger than -65 dBm. The following requirements must be met: ■ Within 24 hours, the time percentage of failing to transmit data from any monitor to the MFM-CMS does not exceed 0.1%. When the connected 8 monitors roam for 30 times, the time percentage of failing to transmit data from any monitor to the MFM-CMS does not exceed 0.1%.
Distinct Vision Distance	The distinct vision distance between the monitor and the AP: ≥ 50 meters.

A.4 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 corresponding 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, 50 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 *Changing the ECG Filter Settings*)
☆CMRR (Common Mode Rejection Ratio)	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)
☆ Differential Input Impedance	> 5 MΩ
☆Input Signal Range	±10 mV PP
☆ Accuracy of 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	±800 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 mV PP, 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: 0.077uV/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.
Minimum Input Slew Rate (Lead II)	> 2.5 V/s
☆Baseline Reset Time	< 3 s
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 to2.0 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 to 100 μs
Pace Pulse Detecting Lead: one among I, II, III, AVR, AVL, AVF, V1, V2, V3,V4, V5, V6	

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
Pauses/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	200ms ~ 800 ms
Resolution	1 ms
ΔQTc measurement	
Range	-600 ms ~ 600 ms
Resolution	1 ms
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 1200 ms, 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	
Ventricular Tachycardia	The interval of 5 consecutive ventricular beats is less than 600 ms
Ventricular Rhythm	The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms
Ventricular Bradycardia	The interval of 5 consecutive ventricular beats is more than 1000 ms
V-Tach	The interval of 5 consecutive ventricular beats is less than 600 ms
Vent Rhythm	The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms
VBRADY	The interval of 5 consecutive ventricular beats is more than 1000 ms

<table>
<tr><td colspan="4">Maximum Start-up Alarm Time for Tachycardia</td></tr>
<tr><td>V-Tach
1 mV 206 bpm</td><td colspan="3">Gain 0.5: 10 s
Gain 1.0: 10 s
Gain 2.0: 10 s</td></tr>
<tr><td>V-Tach
2 mV 195 bpm</td><td colspan="3">Gain 0.5: 10 s
Gain 1.0: 10 s
Gain 2.0: 10 s</td></tr>
<tr><td>Response Time of Heart Rate Meter to Change in HR</td><td colspan="3">HR range: 80 bpm to 120 bpm
Range : Within 11 s
HR range: 80 bpm to 40 bpm
Range : Within 11 s</td></tr>
<tr><td>☆Tall T-wave Rejection</td><td colspan="3">Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude</td></tr>
<tr><td>Accuracy of Heart Rate Meter and Response to Irregular Rhythm</td><td colspan="3">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</td></tr>
<tr><td>Time to Alarm for Heart Rate alarm conditions</td><td colspan="3">Asystole alarm: ≤ 10 s
HR low alarm: ≤ 10 s
HR high alarm: ≤ 10 s</td></tr>
<tr><td rowspan="7">Arrhythmia analyses</td><td>ASYSTOLE</td><td>VFIB/VTAC</td><td>COUPLET</td></tr>
<tr><td>VT > 2</td><td>BIGEMINY</td><td>TRIGEMINY</td></tr>
<tr><td>VENT</td><td>R on T</td><td>PVC</td></tr>
<tr><td>TACHY</td><td>BRADY</td><td>MISSED BEATS</td></tr>
<tr><td>IRR</td><td>VBRADY</td><td>PNC</td></tr>
<tr><td>PNP</td><td></td><td></td></tr>
<tr><td rowspan="7">12-Lead ECG Synchronization Analysis</td><td colspan="3">Average parameters of heart beat</td></tr>
<tr><td colspan="3">Heart rate (bpm)</td></tr>
<tr><td colspan="3">Time limit of P wave (ms)</td></tr>
<tr><td colspan="3">PR interval (ms)</td></tr>
<tr><td colspan="3">QRS interval (ms)</td></tr>
<tr><td colspan="3">QT/QTC (ms)</td></tr>
<tr><td colspan="3">P-QRS-T AXIS</td></tr>
</table>

A.5 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
Baseline Impedance Range	200 Ω to 2500 Ω (with ECG cables of 1 KΩ resistance)
Measuring Sensitivity	Within the baseline impedance range: 0.3 Ω
Waveform Bandwidth	0.2 Hz to 2.5 Hz (-3 dB)
Respiration Excitation Waveform	Sinusoid, 45.6 kHz (±10%), < 350 μA
☆RR Measuring Range	
☆Adult	0 rpm to120 rpm
☆Neo/Ped	0 rpm to150 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, 50 mm/s
☆No RR Detected Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.

A.6 NIBP

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

Technique	Oscillometry
Mode	Manual, Auto, Continuous, Sequence
Measuring Interval in AUTO Mode (unit: minutes)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 and User Define
Continuous	5 min, interval is 5 s
Measuring Parameter	SYS, DIA, MAP, PR

Pressure Unit	kPa, mmHg, cmH_2O
☆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
☆Alarm Type	SYS, DIA, MAP, PR (NIBP)
☆ 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
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	Range: 80/100/120/140/150/160/180/200/220/240 mmHg
Pediatric Mode	Range: 80/100/120/140/150/160/180/200 mmHg
Neonatal Mode	Range: 60/70/80/100/120 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

A.7 SpO_2

Complies with ISO 80601-2-61: 2017.

Measuring Range	0% 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

NOTE:

The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A.8 TEMP

Complies with ISO 80601-2-56:2017+A1:2018.

Technique	Thermal resistance
Position	Skin, oral cavity, rectum
Measure Parameter	T1, T2, TD(the absolute value of T2 minus T1)

Channel	X8: 1 X10/X12: 2
Sensor Type	YSI-10K and YSI-2.252K
Unit	°C, °F
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 to 10 minutes
Measuring Mode	Direct Mode
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.9 PR

	Measuring range	Accuracy	Resolution
PR (SpO_2)	25 bpm to 300 bpm	± 2 bpm	1 bpm
PR (NIBP)	40 bpm to 240 bpm	±3 bpm or 3.5%, whichever is greater	1 bpm
PR (IBP)	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.10 IBP

Complies with IEC 60601-2-34: 2011.

Technique			Direct invasive measurement
Channel			2 channels
IBP Measure	☆Measuring Range	Art	(0 to +300) mmHg
		PA/PAWP	(-6 to +120) mmHg
		CVP/RAP/LAP/ICP	(-10 to +40) mmHg
		P1/P2	(-50 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 Range		300 Ω 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		7.4 x 10^4 mm^3 / 100 mmHg

A.11 CO_2

Complies with ISO 80601-2-55: 2011.

Intended Patient	Adult, pediatric, neonatal		
Measure Parameters	$EtCO_2$, $FiCO_2$, AwRR		
Unit	mmHg, %, kPa		
☆ Measuring Range	$EtCO_2$	0 mmHg to 150 mmHg (0 % to 20%)	
	$FiCO_2$	0 mmHg to 50 mmHg	
	AwRR	2 rpm to 150 rpm	
Resolution	$EtCO_2$	1 mmHg	
	$FiCO_2$	1 mmHg	
	AwRR	1 rpm	
☆Accuracy	$EtCO_2$	± 2 mmHg, 0 mmHg to 40 mmHg	Typical conditions: Ambient temperature: (25 ± 3) °C Barometric pressure: (760 ± 10) mmHg Balance gas: N_2 Sample gas flowrate: 100 ml/min
		± 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 or ± 4 mmHg, whichever is greater	All conditions
	AwRR	± 1 rpm	
Drift of Measure Accuracy	Meets the requirements of the measure accuracy		
Sample Gas Flowrate	70 ml/min or 100 ml/min (default), accuracy: ±15 ml/min		
Warm-upTime	Display reading within 20 s; reach to the designed accuracy within 2 minutes.		
Rise Time	< 400 ms (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)		
	< 500 ms (with 2 m gas sampling tube, sample gas flowrate: 70 ml/min)		
Response Time	< 4 s (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min/70 ml/min)		
Work Mode	Standby (default), measure		
O_2 Compensation	Range: 0% to 100% Resolution: 1% Default: 16%		
N_2O Compensation	Range: 0% to 100% Resolution: 1% Default: 0%		
AG Compensation	Range: 0% to 20% Resolution: 0.1% Default: 0%		
Humidity Compensation Method	ATPD (default), BTPS		
Barometric Pressure Compensation	Automatic (The change of barometric pressure will not add additional errors to the measurement values.)		
Zero Calibration	Support		
Calibration	Support (It is recommend to be operated by trained personal.)		
☆Alarm	$EtCO_2$, $FiCO_2$, AwRR		
☆ No RR Detected 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		

$EtCO_2$ Change[1]	AwRR ≤ 80 rpm, meet the accuracy mentioned above; AwRR > 80 rpm, $EtCO_2$ descends 8%; AwRR > 120 rpm, $EtCO_2$ descends 10%;	with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)
	AwRR ≤ 60 rpm, meet the accuracy mentioned above; AwRR > 60 rpm, $EtCO_2$ descends 8%; AwRR > 90 rpm, $EtCO_2$ descends 10%; AwRR > 120 rpm, $EtCO_2$ descends 15%;	with 2 m gas sampling tube, sample gas flowrate: 70 ml/min)

Note 1: Use a test device equivalent to EN ISO 80601-2-55 fig 201.101 to measure at 1:2 I/E ratio. Respiration rate accuracy is determined by frequency of device, and end-tidal reading change refers to the nominal value.

Interfering Gas Effects:

Gas	Gas Level (%)	Quantitative Effect/Comments
Nitrous oxide	60%	None
Halothane	4%	None
Enflurane	5%	None
Isoflurane	5%	None
Sevoflurane	5%	None
Xenon	Not applicable	Not applicable
Hehelium	Not applicable	Not applicable
Metered dose inhaler propellants	Not applicable	Not applicable
Desflurane	15%	None
Ethanol	0.1%	None
Isopropanol	0.1%	None
Acetone	0.1%	None
Methane	1%	None

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.12 C.O.

Only applicable to X12.

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.	0.01 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.13 Interfaces

A.13.1 Analog Output (Optional)

Bandwidth (-3 dB; reference frequency: 10 Hz)	Monitor: 0.5 Hz to 40 Hz Diagnosis/Diagnosis 1: 0.05 Hz to 40 Hz Surgery: 1 Hz to 20 Hz Enhanced: 2 Hz ~18 Hz Customized: When Low-pass Filter < 40 Hz, Bandwidth is High-pass Filter ~ Low-pass Filter; When Low-pass Filter > 40 Hz, Bandwidth is High-pass ~40 Hz.
Maximum Transmission Delay (Diagnosis Mode)	500 ms
Sensitivity	1 V/1 mV ±10%
PACE Rejection/ Enhancement	No PACE Rejection or Enhancement

Waveform Display	Consistent with the calculation leads.
Compliant with Standard and Directive	Complies with the requirements in terms of short circuit protection and leakage current in EN60601-1.
Output Impedance	< 500 Ω
Interface Type	PS2 connector

NOTE:

While using analog output, set the calculation lead as following:

1) In 3 Electrodes mode, set to Lead I, Lead II, or Lead III.
2) In 5 Electrodes mode, set to Lead I, Lead II, Lead III or Lead V.
3) In 6 Electrodes mode, set to I, II, III, and leads corresponding to Va, Vb.
4) In 10 Electrodes mode, set to Lead I, Lead II, Lead III or Lead V1~V6.

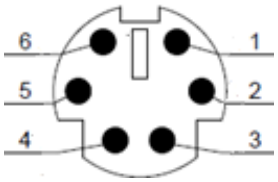
A.13.2 Defibrillator Synchronization (Optional)

Output Impedance	< 500 Ω
Maximum Time Delay	35 ms (R-wave peak to leading edge of pulse)
Waveform	Rectangular wave
Amplitude	High level: 3.5 V to 5.5 V, providing a maximum of 1 mA output current; Low level: < 0.5 V, receiving a maximum of 5 mA input current
Minimum Required R-wave Amplitude	0.3 mV
Pulse Width	100 ms ±10%
Limited Current	15 mA rating
Rising and Falling Time	< 1 ms
Interface Type	PS2 connector

A.13.3 Nurse Call (Optional)

Drive Mode	Voltage output
Power Supply	≤ 12.6 VDC, 200 mA Max.
Interface Signal	12 V power supply and PWM waveform
Interface Type	PS2 connector

PS2 connector Definition for Analog Output/Defibrillator Synchronization/Nurse Call

	PIN.NO.	Signal name	Signal Description
	1	ANALOG_OUT	Analog out signal
	2	GND	Ground
	3	SYS_OUT	Defibrillator Synchronization signal
	4	+12V	Nurse call power
	5	GND	Ground
	6	NURSE_OUT	Nurse call control signal

A.13.4 USB Interfaces

Number of USB Interfaces	Standard: 2
Drive Mode	HOST interface, USB 2.0 protocol
Power Supply	5 VDC ±5%, 500 mA Max.
Interface Type	USB A-type port

A.13.5 VGA Interface (Optional)

Number of VGA Interface	1
Horizontal Refreshing Rate	(30-94) KHZ
Video Signal	0.7 Vpp @ 75 Ohm, HSYNC/VSYNC signal TTL
Interface Type	DB-15 female receptacle

A.13.6 Wired Network Interface

Specification	100-Base TX (IEEE802.3)
Interface Type	Standard RJ-45 network interface