

# X12

## Patient Monitor

Version 1.2



## Main Unit Specification

### Physical Specifications

Dimension	306±2 mm (W) × 309±2 mm (H) × 151±2 mm (D)
Max Weight	< 3.5 kg
	Standard configurations, no battery or accessories

### Power Supply

Line Voltage	100 V to 240 V~
Current	1.4 A to 0.7 A
Frequency	50 Hz/60 Hz

### Battery

Capacity	2550 mAh , 5100 mAh
Operating Time	2550 mAh ≥ 4 h
	5100 mAh ≥ 8 h
Charge Time	2550 mAh ≤ 3.5 h, 90% charge
	5100 mAh ≤ 6.5 h, 90% charge

### Display

Display screen	12.1-inch color TFT screen, touch screen available
Resolution	800 × 600
Waves	A maximum of 13 waveforms can be displayed on the same screen

### Recorder

Record Width	48 mm
Paper Speed	12.5 mm/s, 25 mm/s, 50 mm/s
Channels	3
Recording Types	<ul style="list-style-type: none"> <li>Continuous real-time recording</li> <li>8-second real-time recording</li> <li>20-second real-time recording</li> <li>Time recording</li> <li>Alarm recording</li> <li>Trend graph recording</li> <li>Trend table recording</li> <li>NIBP review recording</li> <li>Arrhythmia review recording</li> <li>Alarm review recording</li> <li>Drug calculation titration recording</li> <li>Hemodynamic Calculation result recording</li> <li>12-lead analysis recording</li> <li>C.O. measurement recording</li> <li>ST view recording</li> <li>QT view recording</li> </ul>

### Data Storage

Internal Temporary Memory	
Trend graph/trend	3 hrs, at 1 s resolution

review	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 Diagnosis Review	Up to 50 sets
<b>Non-volatile Memory (internal or external storage device)</b>	
A single piece of patient data maximally contains the following information:	
Trend graph and trend table	240 hours, at 1 min resolution
NIBP measurement review	1200 sets
Alarm review	200 sets
Arrhythmia event	200 sets
12-lead diagnosis review	50 sets
Full disclosure Waveforms	3 electrodes/5 electrodes/6 electrodes: 48 hours 10 electrodes: 35 hours

### Wi-Fi

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

### Interfaces and others

VGA output (optional)	1
USB interface	2
Nurse Call / Analog Output/ Defibrillator Synchronization (optional)	1
Network Interface	1

### Data Transmission

Data Export	Ethernet / USB / Wi-Fi (Optional)
Data Management	CMS-Lite
Central Monitoring System	MFM-CMS
HIS/EMR connection	HL7 MFM-CMS / GW1 Gateway Software

### ECG

Lead Mode	<ul style="list-style-type: none"> <li>3-Electrodes: I, II, III</li> <li>5-Electrodes: I, II, III, aVR, aVL, aVF, V</li> <li>6-Electrodes: I, II, III, aVR, aVL, aVF, Va, Vb</li> <li>10-Electrodes: I, II, III, aVR, aVL, aVF, V1-V6</li> </ul>
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

<b>Bandwidth (-3 dB)</b>	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
<b>CMRR</b>	Diagnosis: > 95 dB Diagnosis 1: > 105 dB (when Notch is turned on) Monitor: > 105 dB Surgery: > 105 dB Enhanced: > 105 dB Surgery 1: > 105 dB (when Notch is turned on) Customized: > 105 dB (Low-pass Filter < 40 Hz) > 95 dB (Low-pass Filter > 40 Hz)
<b>Hum Filter</b>	In diagnosis, diagnosis 1, monitor, surgery, enhanced and customized modes: 50 Hz/60 Hz (Hum filter can be turned on or off manually)
<b>Recovery Time After Defibrillation</b>	< 5 s (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)
<b>ESU Protection</b>	Cut mode: 300 W Coagulation mode: 100 W Restore time: ≤10 s

**Pace Pulse Detecting Lead** one among I, II, III, aVR., aVL, aVF, V1-V6

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

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

<b>ST value</b>	
<b>Range</b>	-2.0 mV to +2.0 mV
<b>Accuracy</b>	±0.02 mV or 10% (-0.8 mV to +0.8 mV), whichever is greater. Beyond this range: not specified.
<b>Resolution</b>	0.01 mV

**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)

<b>12-Lead ECG Synchronization Analysis</b>	
Average parameters of heart beat	PR interval (ms)
Heart rate (bpm)	QRS interval (ms)
Time limit of P wave (ms)	QT/QTc (ms)
<b>P-QRS-T AXIS</b>	

<b>RESP</b>	
<b>Method</b>	Impedance between RA-LL, RA-LA
<b>Measurement lead</b>	Options are lead I and II. The default is Lead II.
<b>RR Measuring Range</b>	Adult: 0 rpm to 120 rpm Ped/Neo: 0 rpm to 150 rpm
<b>Resolution</b>	1 rpm
<b>Accuracy</b>	Adult: 6 rpm to 120 rpm: ±2 rpm 0 rpm to 5 rpm: not specified Ped/Neo: 6 rpm to 150 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
<b>Gain Selection</b>	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5

<b>Sweep</b>	6.25 mm/s, 12.5 mm/s, 25.0 mm/s, 50.0 mm/s
<b>Apnea Delay</b>	10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s

<b>NIBP</b>	
<b>Method</b>	Oscillometry
<b>Mode</b>	Manual, Auto, Continuous, Sequence
<b>Measuring Interval in Auto Mode</b>	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 min, and User Define
<b>Continuous</b>	5 min, interval is 5 s
<b>Measuring Type</b>	SYS, DIA, MAP, PR
<b>Measuring Range</b>	
<b>Adult Mode</b>	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg
<b>Pediatric Mode</b>	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg
<b>Neonatal Mode</b>	SYS: 25 mmHg to 140 mmHg DIA: 10 mmHg to 115 mmHg MAP: 15 mmHg to 125 mmHg
<b>Cuff Pressure</b>	
<b>Measuring Range</b>	0 mmHg to 300 mmHg
<b>Pressure Resolution</b>	1 mmHg
<b>Maximum Mean Error</b>	±5 mmHg
<b>Maximum Standard Deviation</b>	8 mmHg
<b>Maximum Measuring Period</b>	Adult/ Pediatric: 120 s Neonate: 90 s
<b>Typical Measuring Period</b>	20 s to 35 s (depend on HR/motion disturbance)
<b>Dual Independent Channel Overpressure Protection</b>	
<b>Adult</b>	(297±3) mmHg
<b>Pediatric</b>	(245±3) mmHg
<b>Neonatal</b>	(147±3) mmHg

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

<b>PI (Perfusion Index)</b>	
<b>Measuring Range</b>	0-10, invalid SI value is -?.
<b>Resolution</b>	1

<b>TEMP</b>	
<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
<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 (±0.54 °F) [±0.1 °C (±0.18 °F), exclude sensor error]
<b>Transient Response Time</b>	≤ 30 s

**PR**

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

<b>Measuring range</b>	EDAN: 25 bpm to 300 bpm
<b>Accuracy</b>	EDAN: ±2 bpm
<b>Resolution</b>	EDAN: 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

## IBP

<b>Channel</b>	2
<b>Technique</b>	Direct invasive measurement
<b>Measuring range</b>	Art: 0 mmHg to +300 mmHg PA: -6 mmHg to +120mmHg CVP/RAP/LAP/ICP: -10 mmHg to +40 mmHg PI/P2: -50 mmHg to +300 mmHg
<b>Resolution</b>	1 mmHg
<b>Accuracy</b>	±2% or ±1 mmHg, whichever is greater (not including sensor)
<b>Unit</b>	kPa, mmHg, cmH <sub>2</sub> O

## 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: 2 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 mmHg to 40 mmHg
Ambient temperature: (25 ± 3) °C	±5% of reading, 41 mmHg to 70 mmHg
Barometric pressure: (760 ± 10)	±8% of reading, 71 mmHg to 100 mmHg
mmHg Balance gas : N <sub>2</sub>	±10% of reading, 101 mmHg 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(default), accuracy: ±15 ml/min
<b>Warm-up time</b>	Display waveform within 20 s, Reach the design 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 (It is recommend to be operated by trained personal.)
<b>Apnea delay</b>	10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40s

## C.O.

<b>Technique</b>	Thermodilution Technique
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<b>Measure Parameters</b>	C.O., TB, TI
<b>Measuring Range</b>	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)
<b>Resolution</b>	C.O.: 0.1 L/min TB, TI: 0.1° C (+0.1 °F)
<b>Accuracy</b>	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)

## 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 60601-2-49: 2018
<b>Anti-electroshock Type</b>	Class I equipment and internal powered equipment
<b>Anti-electroshock Degree</b>	CF
<b>Ingress Protection</b>	IPX1

## Environmental Specifications

<b>Temperature</b>	Working: +0°C to +40°C (32 °F ~104 °F) When the battery is charged: +0 °C to +35 °C (32 °F~95 °F) Transport and Storage: -20°C to +55°C (-4 °F ~131 °F)
<b>Humidity</b>	Working: 15%RH to 95%RH (non-condensing) Transport and Storage: 15%RH to 95%RH (non- condensing)
<b>Altitude</b>	Working: 86 kPa to 106 kPa Transport and Storage: 70 kPa to 106 kPa