X10

Patient Monitor

Version 1.2

Main Unit Specification

Physical Specifications

Dimension 261±2 mm (W) × 246±2 mm (H) × 146±2 mm (D)

Max Weight < 2.8 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

 $\begin{tabular}{lll} \textbf{Capacity} & 2550 \text{ mAh} \ , 5100 \text{ mAh} \\ \textbf{Operating Time} & 2550 \text{ mAh} & $\geq 4 \text{ h} \\ \end{tabular}$

5100 mAh ≥ 8 h

Charge Time $2550 \text{ mAh} \leq 3.5 \text{ h}, 90\% \text{ charge}$

 $5100 \text{ mAh} \leq 6.5 \text{ h}, 90\% \text{ charge}$

Display

Display screen 10.1 inch color TFT screen, touch screen available

Resolution 800×48

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 Continuous real-time recording

8-second real-time recording

20-second 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

Data Storage

Internal Temporary Memory

Trend graph/trend 3 hrs, at 1 s resolution



table 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

Non-volatile Memory (internal or external storage device)

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 3 electrodes/5 electrodes/6 electrodes: 48 hours

Waveforms 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)

Network Interface

Data Transmission

Data Export Ethernet / USB / Wi-Fi (Optional)

Data Management CMS-Lite

Central Monitoring

System MFM-CMS HIS/EMR HL7

connection MFM-CMS / GW1 Gateway Software

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 $\times 0.125, \times 0.25, \times 0.5, \times 1, \times 2, \times 4$, 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

EMRR Diagnosis: > 95 dB
Diagnosis 1: > 105 dB (when Notch is turned on)

$$\begin{split} & Monitor: > 105 \; dB \\ & Surgery: > 105 \; dB \\ & Enhanced: > 105 \; dB \end{split}$$

Surgery 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 and customized modes: 50 Hz/60 Hz (Hum filter can

be turned on or off manually)

Recovery Time After < 5 s (measured without electrodes as IEC60601-2-**Defibrillation** 27:2011, Sect. 201.8.5.5.1 requires.)

ESU Protection 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

Heart Rate

RangeADU: 15 bpm to 300 bpmPED/NEO: 15 bpm to 350 bpmAccuracy $\pm 1\%$ 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

ST value

Range -2.0 mV to +2.0 mV

Accuracy $\pm 0.02 \text{ mV} \text{ or } 10\% \text{ (-0.8 mV to +0.8 mV), whichever is}$

greater. Beyond this range: not specified.

Resolution 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)

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 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 $\times 0.25, \times 0.5, \times 1, \times 2, \times 3, \times 4, \times 5$

 Sweep
 6.25 mm/s, 12.5 mm/s, 25.0 mm/s, 50.0 mm/s

 Apnea Delay
 10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s

NIBP

Method Oscillometry

Mode Manual, Auto, Continuous, Sequence

 Measuring Interval in Auto Mode
 1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 min and User Define

 Continuous
 5 min, interval is 5 s

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
 Adult: 120 s

 Measuring Period
 Neo/Ped: 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

SpO₂

Measuring Range0% to 100%Resolution1%Data update period1 s

Accuracy Adult/Pediatric: ±2% (70% to 100% SpO₂)

Undefined (0% to 69% SpO₂)
Neonate: ±3% (70% to 100% SpO₂)
Undefined (0% to 69% SpO₂)

PI (Perfusion Index)

Measuring Range 0-10, invalid SI value is -?-.

Resolution 1

TEMP

Channel

Sensor type YSI-10K and YSI-2.252K
Technique Thermal resistance

Measure Parameter T1, T2, TD

Position Skin, oral cavity, rectum

Unit °C, °F



Measuring Range 0°C to 50°C (32 °F to 122 °F)

Resolution 0.1°C (0.1 °F) Accuracy ±0.3 °C (±0.54 °F)

[± 0.1 °C (± 0.18 °F), exclude sensor error]

Transient Response

Time < 30 s

PR

PR (SpO₂) Measuring range EDAN: 25 bpm to 300 bpm

EDAN: ±2 bpm Accuracy Resolution EDAN: 1 bpm

PR (NIBP)

EDAN: 40 bpm to 240 bpm Measuring range

EDAN: ±3 bpm or 3.5%, whichever is greater Accuracy

Resolution EDAN: 1 bpm

PR (IBP)

Measuring range EDAN: 20 bpm to 300 bpm

Accuracy EDAN: 30 bpm to 300 bpm: ± 2 bpm or $\pm 2\%$,

whichever is greater;

20 bpm to 29 bpm: undefined

EDAN: 1 bpm Resolution

IBP

Channel

Technique Direct invasive measurement Measuring range Art: 0 mmHg to +300 mmHg

PA: -6 mmHg to +120mmHg

CVP/RAP/LAP/ICP: -10 mmHg to +40 mmHg

P1/P2: -50 mmHg to +300 mmHg

Resolution 1 mmHg

±2% or ±1 mmHg, whichever is greater Accuracy

(not including sensor)

Unit $kPa, mmHg, cmH_2O$

CO₂

Adult, Pediatric, Neonatal **Intended patient**

EtCO2, FiCO2, AwRR **Measure Parameters**

Unit mmHg, %, kPa

Measuring Range EtCO₂: 0 mmHg to 150 mmHg (0% to 20%)

FiCO₂: 0 mmHg to 50 mmHg

AwRR: 2 rpm to 150 rpm

EtCO₂: 1 mmHg

FiCO₂: 1 mmHg AwRR: 1 rpm

EtCO₂ Accuracy

Resolution

Typical conditions: ± 2 mmHg, 0 mmHg to 40 mmHg

Ambient temperature: ±5% of reading, 41 mmHg to 70 mmHg $(25 \pm 3) \, ^{\circ}\text{C}$

Barometric pressure:

 $\pm 8\%$ of reading, 71 mmHg to 100 mmHg ±10% of reading, 101 mmHg to 150 mmHg

 (760 ± 10) mmHg Balance gas: N2

Sample gas flowrate:

100 ml/min

All conditions $\pm 12\%$ of reading or ± 4 mmHg, whichever is greater

AwRR Accuracy $\pm 1~\mathrm{rpm}$

Sample Gas Flowrate 50 ml/min, 70 ml/min or 100 ml/min(default),

accuracy: ±15 ml/min

Warm-up time Display waveform within 20 s, reach the design

accuracy within 2 minutes.

Response time < 4 s (with m;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)

Barometric pressure compensation

Automatic (The change of barometric pressure will not add additional errors to the measurement values.)

Zero Calibration

Calibration Support (It is recommend to be operated by trained

personal.)

Apnea delay 10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40s

Safety Specifications

Compliant with IEC 60601-1: 2005+A1 :2012: IEC 60601-1-2: 2014: Standards

EN 60601-1: 2006+A1:2013; EN 60601-1-2: 2015; IEC 60601-2-49: 2018

Anti-electroshock

Class I equipment and internal powered equipment Type

Anti-electroshock

CF Degree IPX1 **Ingress Protection**

Environmental Specifications

Working: $+0^{\circ}$ C to $+40^{\circ}$ C (32 °F ~ 104 °F) When the Temperature

battery is charged: +0 °C to +35 °C (32 °F~95 °F) Transport and Storage: -20°C to +55°C (-4 °F ~131 °F)

Humidity Working: 15%RH to 95%RH (non-condensing)

Transport and Storage: 15%RH to 95%RH (non-

condensing)

Altitude Working: 86 kPa to 106 kPa

Transport and Storage: 70 kPa to 106 kPa

