Patient Monitor

Version 1.2

Main Unit Specification

Physical Specifications

Dimension 306 ± 2 mm (W) \times 309 ± 2 mm (H) \times 151 ± 2 mm (D)

Max Weight

Standard configurations, no battery or accessories

Power Supply

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

Battery

2550 mAh, 5100 mAh Capacity

 $\geq 4 \text{ h}$ **Operating Time** 2550 mAh

> $\geq 8 \text{ h}$ 5100 mAh

≤ 3.5 h, 90% charge **Charge Time** 2550 mAh ≤ 6.5 h, 90% charge

5100 mAh

Display

Display screen 12.1-inch color TFT screen, touch screen available

 800×600 Resolution

A maximum of 13 waveforms can be displayed on the Waves

same screen

Recorder

Record Width 48 mm

Paper Speed 12.5 mm/s, 25 mm/s, 50 mm/s

Channels

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

3 hrs, at 1 s resolution Trend graph/trend



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

Full disclosure 3 electrodes/5 electrodes/6 electrodes: 48 hours

Waveforms 10 electrodes: 35 hours

Wi-Fi

HEIDE 802.11b/g/n

Frequency Band 2.4 GHz ISM band & 5 G ISM band

Interfaces and others

VGA output (optional)

USB interface

Nurse Call / Analog Output/ Defibrillator

Synchronization (optional) 1

Network Interface

Data Transmission

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

CMS-Lite **Data Management**

Central Monitoring

System MFM-CMS

HIS/EMR

connection MFM-CMS / GW1 Gateway Software

ECG

3-Electrodes: I, II, III **Lead Mode**

5-Electrodes: I, II, III, aVR, aVL, aVF, V

6-Electrodes: I, II, III, aVR, aVL, aVF,, Va, Vb 10-Elctrodes: I, II, III, aVR, aVL, aVF, V1-V6

1

2

Electrode Standard AHA, IEC

×0.125, ×0.25, ×0.5, ×1, ×2, ×4, AUTO gain **Display Sensitivity**

6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s Sweep



Diagnosis: 0.05 Hz to 150 Hz Bandwidth (-3 dB)

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

Diagnosis: > 95 dB **CMRR**

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)

In diagnosis, diagnosis 1, monitor, surgery, enhanced Hum Filter and customized modes: 50 Hz/60 Hz (Hum filter can

be turned on or off manually)

< 5 s (measured without electrodes as IEC60601-2-**Recovery Time After**

27:2011, Sect. 201.8.5.5.1 requires.) Defibrillation

Cut mode: 300 W ESU Protection Coagulation mode: 100 W

Restore time: <10 s

Pace Pulse Detecting

Lead one among I, II, III, aVR,, aVL, aVF, V1-V6

Heart Rate

Range ADU: 15 bpm to 300 bpm

PED/NEO: 15 bpm to 350 bpm

 $\pm 1\%$ or ± 1 bpm, whichever is greater Accuracy

Resolution

PVC

ADU: (0 to 300) PVCs/ min Range

PED/NEO: (0 to 350) PVCs/min

1 PVCs/min Resolution

ST value

-2.0 mV to +2.0 mVRange

 ± 0.02 mV or 10% (-0.8 mV to +0.8 mV), whichever is Accuracy

greater. Beyond this range: not specified.

0.01 mV Resolution

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) QRS interval (ms) Heart rate (bpm)

Time limit of P wave (ms) QT/QTC (ms)

P-ORS-T AXIS

RESP

Impedance between RA-LL, RA-LA Method

Options are lead I and II. The default is Lead II. Measurement lead

Adult: 0 rpm to 120 rpm RR Measuring Range Ped/Neo: 0 rpm to 150 rpm

Resolution

Adult: 6 rpm to 120 rpm: ±2 rpm Accuracy

0 rpm to 5 rpm: not specified Ped/Neo: 6 rpm to 150 rpm: ±2 rpm 0 rpm to 5 rpm: not specified

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

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

NIBP

Oscillometry Method

Manual, Auto, Continuous, Sequence Mode

(1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 min, Measuring Interval

and User Define in Auto Mode 5 min, interval is 5 s Continuous SYS, DIA, MAP, PR **Measuring Type**

Measuring Range

SYS: 25 mmHg to 290 mmHg Adult Mode

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

1 mmHg **Pressure Resolution**

Maximum Mean

Error ±5 mmHg

Maximum Standard

Deviation 8 mmHg

Adult/ Pediatric: 120 s Maximum Measuring Period Neonate: 90 s

Typical Measuring

Period 20 s to 35 s (depend on HR/motion disturbance)

Dual Independent Channel Overpressure Protection

(297±3) mmHg Adult Pediatric (245±3) mmHg Neonatal (147±3) mmHg

SpO₂

0% to 100% Measuring Range

1% Resolution Data update period

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

Undefined (0% to 69% SpO₂) Neonatal: $\pm 3\%$ (70% to 100% SpO₂) Undefined (0% to 69% SpO₂)

PI (Perfusion Index)

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

Resolution

TEMP

Channel

YSI-10K and YSI-2.252K Sensor type Thermal resistance Technique T1, T2, TD Measure Parameter

Skin, oral cavity, rectum Position

°C,°F

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

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

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

Transient Response

Time $\leq 30 \text{ s}$



PR (SpO₂) Measuring range EDAN: 25 bpm to 300 bpm EDAN: ±2 bpm Accuracy EDAN: 1 bpm Resolution PR (NIBP) EDAN: 40 bpm to 240 bpm Measuring range EDAN: ±3 bpm or 3.5%, whichever is greater Accuracy EDAN: 1 bpm Resolution PR (IBP) EDAN: 20 bpm to 300 bpm Measuring range EDAN: 30 bpm to 300 bpm: ± 2 bpm or $\pm 2\%$, Accuracy whichever is greater; 20 bpm to 29 bpm: undefined Resolution EDAN: 1 bpm **IBP** Channel **Technique** Direct invasive measurement Art: 0 mmHg to +300 mmHg Measuring range 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** mmHg, %, kPa EtCO₂: 0 mmHg to 150 mmHg (0% to 20%) Measuring Range FiCO₂: 0 mmHg to 50 mmHg AwRR: 2 rpm to 150 rpm EtCO₂: 1 mmHg Resolution FiCO₂: 1 mmHg AwRR: 1 rpm EtCO₂ Accuracy Typical conditions: ±2 mmHg, 0 mmHg to 40 mmHg Ambient temperature: $\pm 5\%$ of reading, 41 mmHg to 70 mmHg (25 ± 3) °C $\pm 8\%$ of reading, 71 mmHg to 100 mmHg Barometric pressure: ±10% of reading, 101 mmHg to 150 mmHg (760 ± 10) mmHg Balance gas : N2 Sample gas flowrate: 100 ml/min All conditions ±12% of reading or ±4 mmHg, whichever is greater AwRR Accuracy $\pm 1 \text{ rpm}$ 50 ml/min, 70 ml/min or 100 ml/min(default), Sample Gas accuracy: ±15 ml/min **Flowrate** Display waveform within 20 s, Reach the design Warm-up time accuracy within 2 minutes. < 4 s (with 2 m gas sampling tube, sample gas Response time flowrate: 100 ml/min/70 ml/min) < 5.5 s (with 2 m gas sampling tube, sample gas flowrate: 50 ml/min) Automatic (The change of barometric pressure will not Barometric pressure compensation add additional errors to the measurement values.) Zero Calibration Calibration Support (It is recommend to be operated by trained

C.O., TB, TI **Measure Parameters**

C.O.: 0.1 L/min to 20 L/min **Measuring Range**

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)

C.O.: 0.1 L/min Resolution

TB, TI: 0.1° C (+0.1 °F)

C.O.: ±5% or ±0.2 l/min, whichever is greater Accuracy

TB: ±0.1° C (not including sensor) TI: ±0.1° C (not including sensor)

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;

Class I equipment and internal powered equipment

IEC 60601-2-49: 2018

Anti-electroshock Type

Anti-electroshock

Humidity

Degree

CF **Ingress Protection**

IPX1

Environmental Specifications

Working: +0°C to +40°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) Working: 15%RH to 95%RH (non-condensing)

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

condensing)

Working: 86 kPa to 106 kPa Altitude

Transport and Storage: 70 kPa to 106 kPa



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

Thermodilution Technique

Apnea delay

Technique

C.O.