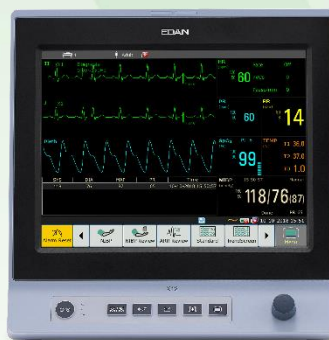


# X12

## 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<br>5100 mAh ≥ 8 h                             |
| Charge Time    | 2550 mAh ≤ 3.5 h, 90% charge<br>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 | Continuous real-time recording<br>8-second real-time recording<br>20-second real-time recording<br>Time recording<br>Alarm recording<br>Trend graph recording<br>Trend table recording<br>NIBP review recording<br>Arrhythmia review recording<br>Alarm review recording<br>Drug calculation titration recording<br>Hemodynamic Calculation result recording<br>12-lead analysis recording<br>C.O. measurement recording<br>ST view recording<br>QT view recording |

### 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<br>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<br>MFM-CMS / GW1 Gateway Software |

### ECG

|                     |                                                                                                                                                                                          |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Lead Mode           | 3-Electrodes: I, II, III<br>5-Electrodes: I, II, III, aVR, aVL, aVF, V<br>6-Electrodes: I, II, III, aVR, aVL, aVF, Va, Vb<br>10-Electrodes: I, II, III, aVR, aVL, aVF, V1-V6<br>AHA, IEC |
| Electrode Standard  |                                                                                                                                                                                          |
| 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                                                                                                                                                   |

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|                                    |                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bandwidth (-3 dB)                  | Diagnosis: 0.05 Hz to 150 Hz<br>Diagnosis 1: 0.05 Hz to 40 Hz<br>Monitor: 0.5 Hz to 40 Hz<br>Surgery: 1 Hz to 20 Hz<br>Enhanced: 2 Hz ~18 Hz<br>Customized: High-pass Filter and Low-pass Filter                                                                                                                                          |
| <b>CMRR</b>                        | Diagnosis: > 95 dB<br><b>Diagnosis 1: &gt; 105 dB (when Notch is turned on)</b><br><b>Monitor: &gt; 105 dB</b><br><b>Surgery: &gt; 105 dB</b><br><b>Enhanced: &gt; 105 dB</b><br><b>Surgery 1: &gt; 105 dB (when Notch is turned on)</b><br><b>Customized: &gt; 105 dB</b> (Low-pass Filter < 40 Hz)<br>> 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 Defibrillation | < 5 s (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)                                                                                                                                                                                                                                                    |
| ESU Protection                     | Cut mode: 300 W<br>Coagulation mode: 100 W<br>Restore time: ≤10 s                                                                                                                                                                                                                                                                         |
| <b>Pace Pulse Detecting Lead</b>   | <b>one among I, II, III, aVR., aVL, aVF, V1-V6</b>                                                                                                                                                                                                                                                                                        |

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

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

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

|                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <b>Arrhythmia analysis</b>                                                                                                                                                                                                                                                                                                                                                                                      |  |
| 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>               |                                                                                                                                        |
| Method                    | Impedance between RA-LL, RA-LA                                                                                                         |
| Measurement lead          | Options are lead I and II. The default is Lead II.                                                                                     |
| <b>RR Measuring Range</b> | <b>Adult: 0 rpm to 120 rpm</b><br><b>Ped/Neo: 0 rpm to 150 rpm</b>                                                                     |
| Resolution                | 1 rpm                                                                                                                                  |
| Accuracy                  | Adult: 6 rpm to 120 rpm: ±2 rpm<br>0 rpm to 5 rpm: not specified<br>Ped/Neo: 6 rpm to 150 rpm: ±2 rpm<br>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, 25.0 mm/s, 50.0 mm/s         |
| Apnea Delay | 10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s |

|                                        |                                                                                                       |
|----------------------------------------|-------------------------------------------------------------------------------------------------------|
| <b>NIBP</b>                            |                                                                                                       |
| Method                                 | Oscillometry                                                                                          |
| Mode                                   | Manual, Auto, Continuous, Sequence                                                                    |
| <b>Measuring Interval in Auto Mode</b> | <b>1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 min, and User Define</b>                              |
| Continuous                             | 5 min, interval is 5 s                                                                                |
| Measuring Type                         | SYS, DIA, MAP, PR                                                                                     |
| Measuring Range                        |                                                                                                       |
| <b>Adult Mode</b>                      | <b>SYS: 25 mmHg to 290 mmHg</b><br><b>DIA: 10 mmHg to 250 mmHg</b><br><b>MAP: 15 mmHg to 260 mmHg</b> |
| <b>Pediatric Mode</b>                  | <b>SYS: 25 mmHg to 240 mmHg</b><br><b>DIA: 10 mmHg to 200 mmHg</b><br><b>MAP: 15 mmHg to 215 mmHg</b> |
| <b>Neonatal Mode</b>                   | <b>SYS: 25 mmHg to 140 mmHg</b><br><b>DIA: 10 mmHg to 115 mmHg</b><br><b>MAP: 15 mmHg to 125 mmHg</b> |

|                                                         |                                                |
|---------------------------------------------------------|------------------------------------------------|
| <b>Cuff Pressure</b>                                    |                                                |
| <b>Measuring Range</b>                                  | <b>0 mmHg to 300 mmHg</b>                      |
| Pressure Resolution                                     | 1 mmHg                                         |
| Maximum Mean Error                                      | ±5 mmHg                                        |
| Maximum Standard Deviation                              | 8 mmHg                                         |
| Maximum Measuring Period                                | Adult/ Pediatric: 120 s<br>Neonate: 90 s       |
| Typical Measuring Period                                | 20 s to 35 s (depend on HR/motion disturbance) |
| <b>Dual Independent Channel Overpressure Protection</b> |                                                |
| <b>Adult</b>                                            | <b>(297±3) mmHg</b>                            |
| <b>Pediatric</b>                                        | <b>(245±3) mmHg</b>                            |
| <b>Neonatal</b>                                         | <b>(147±3) mmHg</b>                            |

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

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

|                         |                                                                  |
|-------------------------|------------------------------------------------------------------|
| <b>TEMP</b>             |                                                                  |
| Channel                 | 2                                                                |
| Sensor type             | YSI-10K and YSI-2.252K                                           |
| Technique               | Thermal resistance                                               |
| Measure Parameter       | T1, T2, TD                                                       |
| Position                | Skin, oral cavity, rectum                                        |
| Unit                    | °C , °F                                                          |
| <b>Measuring Range</b>  | <b>0°C to 50°C (32 °F to 122 °F)</b>                             |
| <b>Resolution</b>       | <b>0.1°C (0.1 °F)</b>                                            |
| Accuracy                | ±0.3 °C (±0.54 °F)<br>[±0.1 °C (±0.18 °F), exclude sensor error] |
| Transient Response Time | ≤ 30 s                                                           |

|           |  |
|-----------|--|
| <b>PR</b> |  |
|-----------|--|

|                                      |                                                                                                                                                       |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PR (SpO<sub>2</sub>)</b>          |                                                                                                                                                       |
| Measuring range                      | EDAN: 25 bpm to 300 bpm                                                                                                                               |
| Accuracy                             | EDAN: ±2 bpm                                                                                                                                          |
| Resolution                           | EDAN: 1 bpm                                                                                                                                           |
| <b>PR (NIBP)</b>                     |                                                                                                                                                       |
| Measuring range                      | EDAN: 40 bpm to 240 bpm                                                                                                                               |
| Accuracy                             | EDAN: ±3 bpm or 3.5%, whichever is greater                                                                                                            |
| Resolution                           | EDAN: 1 bpm                                                                                                                                           |
| <b>PR (IBP)</b>                      |                                                                                                                                                       |
| Measuring range                      | EDAN: 20 bpm to 300 bpm                                                                                                                               |
| Accuracy                             | EDAN: 30 bpm to 300 bpm: ±2 bpm or ±2%, whichever is greater;<br>20 bpm to 29 bpm: undefined                                                          |
| Resolution                           | EDAN: 1 bpm                                                                                                                                           |
| <b>IBP</b>                           |                                                                                                                                                       |
| Channel                              | 2                                                                                                                                                     |
| Technique                            | Direct invasive measurement                                                                                                                           |
| Measuring range                      | Art: 0 mmHg to +300 mmHg<br>PA: -6 mmHg to +120 mmHg<br>CVP/RAP/LAP/ICP: -10 mmHg to +40 mmHg<br>P1/P2: -50 mmHg to +300 mmHg                         |
| Resolution                           | 1 mmHg                                                                                                                                                |
| Accuracy                             | ±2% or ±1 mmHg, whichever is greater (not including sensor)                                                                                           |
| Unit                                 | kPa, mmHg, cmH <sub>2</sub> O                                                                                                                         |
| <b>CO<sub>2</sub></b>                |                                                                                                                                                       |
| Intended patient                     | Adult, Pediatric, Neonatal                                                                                                                            |
| Measure Parameters                   | EtCO <sub>2</sub> , FiCO <sub>2</sub> , AwRR                                                                                                          |
| Unit                                 | mmHg, %, kPa                                                                                                                                          |
| Measuring Range                      | EtCO <sub>2</sub> : 0 mmHg to 150 mmHg (0% to 20%)<br>FiCO <sub>2</sub> : 0 mmHg to 50 mmHg<br>AwRR: 2 rpm to 150 rpm                                 |
| Resolution                           | EtCO <sub>2</sub> : 1 mmHg<br>FiCO <sub>2</sub> : 1 mmHg<br>AwRR: 1 rpm                                                                               |
| EtCO <sub>2</sub> Accuracy           |                                                                                                                                                       |
| 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) mmHg | ±8% of reading, 71 mmHg to 100 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                                                                                                      |
| AwRR Accuracy                        | ±1 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 2 m gas sampling tube, sample gas flowrate: 100 ml/min/70 ml/min)<br>< 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                     | Support                                                                                                                                               |
| 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                                                                                                     |
| <b>C.O.</b>                          |                                                                                                                                                       |
| Technique                            | Thermidilution Technique                                                                                                                              |

|                    |                                                                                                                           |
|--------------------|---------------------------------------------------------------------------------------------------------------------------|
| Measure Parameters | C.O., TB, TI                                                                                                              |
| Measuring Range    | C.O.: 0.1 L/min to 20 L/min<br>TB: 23°C to 43° C(73.4 °F to 109.4 °F)<br>TI: -1° C to 27° C(30.2 °F to 80.6 °F)           |
| Resolution         | C.O.: 0.1 L/min<br>TB, TI: 0.1° C (+0.1 °F)                                                                               |
| Accuracy           | C.O.: ±5% or ±0.2 l/min, whichever is greater<br>TB: ±0.1° C (not including sensor)<br>TI: ±0.1° C (not including sensor) |

#### Safety Specifications

|                          |                                                                                                                      |
|--------------------------|----------------------------------------------------------------------------------------------------------------------|
| 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: 2018 |
| Anti-electroshock Type   | Class I equipment and internal powered equipment                                                                     |
| Anti-electroshock Degree | CF                                                                                                                   |
| Ingress Protection       | IPX1                                                                                                                 |

#### Environmental Specifications

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