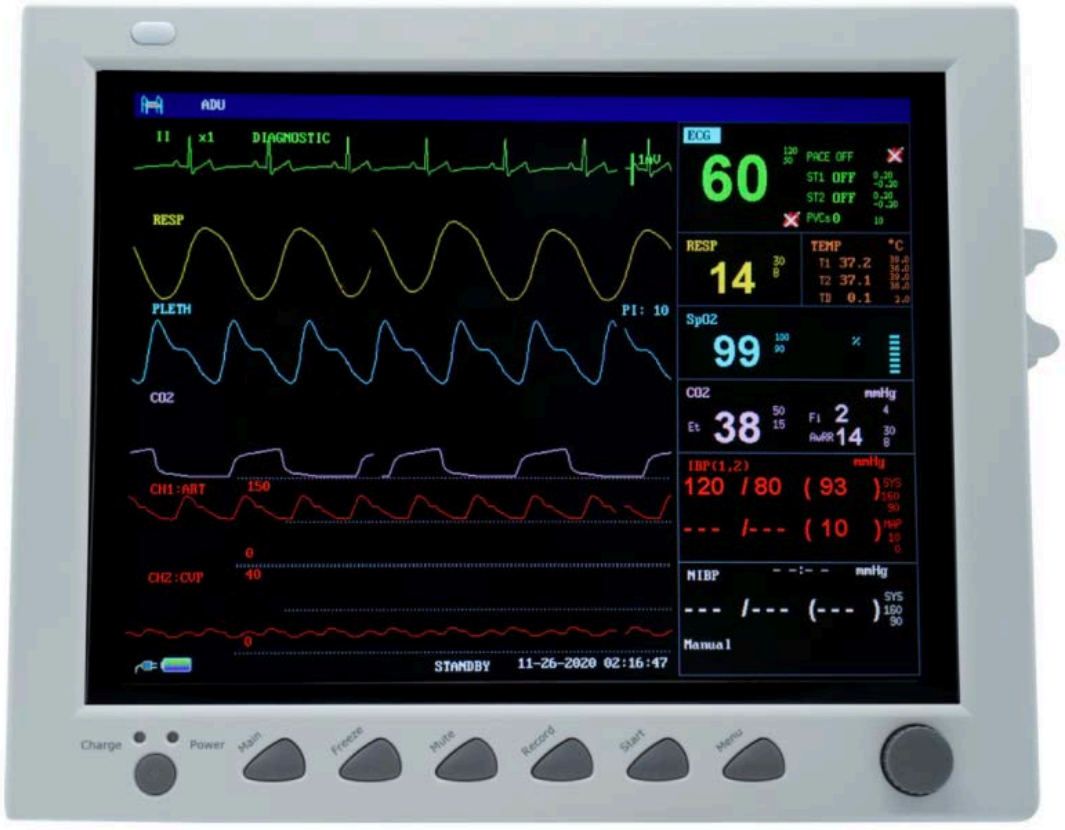
EDANUSA



iM8 Patient Monitor

Product Specifications

Digitally signed by Ermicev Alexandr
Date: 2021.05.27 12:41:18 EEST
Reason: MoldSign Signature
Location: Moldova

Product Specifications

A1.1 Classification

Anti-electroshock Type	Class I equipment and internal powered equipment
Anti-electroshock Degree	ECG (RESP), TEMP, IBP CF SpO_2, NIBP, CO_2 BF
Ingress Protection	IPX1
Disinfection/Sterilizing method	Refer to *Chapter 12 ~ Chapter 17* for details.
Working System	Continuous operation equipment
Compliant with Standards	IEC 60601-1: 1988+A1: 1991+A2: 1995; EN 60601-1: 1990+A1: 1993+A2: 1995; IEC 60601-1-2: 2001+A1: 2004; EN 60601-1-2: 2001+A1: 2006; IEC/EN 60601-2-27; IEC/EN 60601-2-30; IEC/EN 60601-2-34; IEC/EN 60601-2-49; ISO 9919; ISO 21647; EN 12470-4; EN 1060-1; EN 1060-3; EN 1060-4; ANSI/AAMI EC13; ANSI/AAMI SP10

A1.2 Specifications

A1.2.1 Size and Weight

Weight	< 5 kg (not including the battery and record)

A1.2.2 Environment

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	+5°C to +40°C
Transport and Storage	-20°C to +55°C
Humidity	

Working	25% to 80% (non-condensing)
Transport and Storage	25% to 93% (non-condensing)
Altitude	
Working	860hPa to 1060hPa
Transport and Storage	700hPa to 1060hPa
Power Supply	100V to 240V~, 50Hz/60Hz Current: 1.0-0.5A; FUSE T 1.6AL 250VP

A1.2.3 Display

Display Screen	10.1 inch /10.4 inch /12.1 inch, multicolour TFT LCD, 10.1-inch: Resolution 800×480; 10.4-inch /12.1-inch: Resolution 800×600.
Messages	A maximum of 11 waveforms
	iM8: One charge LED (Orange) One power LED (Green) One alarm LED (Yellow/Red)
	iM8A/iM8B: One charge LED (Orange/ Green) One alarm LED (Yellow/Red)
	Three indicator modes corresponding to alarm mode.

A1.2.4 Battery

Capacitance	2.1 Ah/4.2Ah
Working Period	2.1Ah ⩾80 min 4.2Ah ⩾180 min

	At 25℃, with a new fully charged battery, in continual SpO_2 measuring mode and NIBP automatic measuring mode with the operating interval of 15 minutes; ECG/TEMP module connected; the recording interval of 10 minutes.
Rechargeable Period	2.1Ah ≤180 min 4.2Ah ≤360 min
	Monitor is on or in standby mode.

A1.2.5 Recorder (Optional)

Record Width	48 mm
Paper Speed	25 mm/s, 50 mm/s
Channels	3
Recording Types	Continuous real-time recording 8 second real-time recording Automatic interval recording Physiological alarm recording Frozen waveform recording Trend graph/table review recording NIBP review recording Alarm event review recording Arrhythmia review recording Titration table recording

A1.2.6 Recall

Trend Recall	1 hrs, 1-second resolution
	96 hrs, 1-min. resolution
Recall	500 sets NIBP measurement data

A1.2.7 ECG

Lead Mode	3-Lead: I, II, III 5-Lead: I, II, III, aVR, aVL, aVF, V
Waveform	3-Lead: 1-channel waveform 5-Lead: 2-channel waveform, max. seven waveforms;
Lead naming style	AHA, IEC
Display Sensitivity	1.25mm/mV (×0.125), 2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2), 40mm/mV (×4), AUTO gain
Sweep	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s
Bandwidth (-3dB)	Diagnosis: 0.05Hz to 150Hz Monitor: 0.5Hz to 40Hz Surgery: 1Hz to 20Hz
CMRR (Common Mode Rejection Ratio)	Diagnosis: >95dB (the Notch filter is off) Monitor: >105dB (the Notch filter is on) Surgery: >105dB (the Notch filter is on)
Notch	50Hz/60Hz (Notch filter can be turned on or off manually)
Differential Input Impedance	>5MΩ
Input Signal Range	±10mV PP
Accuracy of Input Signal Reproduction	The total error and frequency response comply with ANSI/AAMI EC13:2002, Sect. 4.2.9.8.
Electrode Offset Potential Tolerance	±500mV
Auxiliary Current (Leads off detection)	Active electrode: <100nA Reference electrode: <900nA

Recovery time after Defibrillation	<5s
Leakage current of patient	<10μA
Scale signal	1mVPP, accuracy is ±5%
System noise	<30μVPP (RTI)
ESU Protection	Restore time: ≤10s Meets the requirements of ANSI/AAMI EC13-2002: Sect. 4.1.2.1 a)
Noise Suppression of Electrotome	Tested according to the test method in EC13: 2002 Sect.5.2.9.14, it accords with the standard.
Pace Pulse	
Pulse indicator	Pulse is marked if the requirements of ANSI/AAMI EC13:2002, Sect. 4.1.4.1 are met: Amplitude: ±2 mV ~ ±700 mV Width: 0.1 ms ~2.0 ms Ascending time: 10 μs ~ 100 μs
Pulse Rejection	Pulse is rejected if the requirements of ANSI/AAMI EC13-2002: Sect. 4.1.4.1 are met: Amplitude: ±2 mV ~ ±700 mV Width: 0.1 ms ~2 ms Ascending time: 10 μs ~100 μs
Minimum input slew rate	>2.5V/S
Heart rate	
Range	ADU: 15 bpm ~ 300 bpm PED/NEO: 15 bpm ~ 350 bpm
Accuracy	±1% or 1 bpm, whichever is greater
Resolution	1 bpm
Sensibility	≥300 μVPP
PVC	
Range	ADU: 0~300 PVCs/ min PED/NEO: 0~350 PVCs/ min
Resolution	1 PVCs/min
ST value	

Range	-2.0 mV ~ +2.0 mV
Accuracy	±0.02 mV or 10% (-0.8 mV ~ +0.8 mV), whichever is greater.
Resolution	0.01 mV
HR averaging method	
Method 1	Normally, 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 1200ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	ADU: 120 bpm ~ 300 bpm PED/NEO: 160 bpm ~ 350 bpm
Normal	ADU: 41 bpm ~ 119 bpm PED/NEO: 61 bpm ~159 bpm
Brady	ADU: 15 bpm ~ 40 bpm PED/NEO: 15 bpm ~ 60 bpm
Range of Ventricular Rhythm	
Ventricular Tachycardia	The interval of 5 consecutive ventricular wave is less than 600 ms
Ventricular Rhythm	The interval of 5 consecutive ventricular wave ranges from 600 ms to 1000 ms
Ventricular Bradycardia	The interval of 5 consecutive ventricular wave is more than 1000 ms
Maximum Start-up time for Tachycardia	
Ventricular Tachycardia 1 mV 206bpm	Gain 1.0: 10 s Gain 0.5: 10 s Gain 2.0: 10 s
Ventricular Tachycardia 2 mV 195bpm	Gain 1.0: 10 s Gain 0.5: 10 s Gain 2.0: 10 s

<table>
<tr><td>Response time of Heart Rate Meter to Change in HR</td><td colspan="3">HR range: 80 bpm ~ 120 bpm
Range : 7s ~ 8s, average is 7.5s
HR range: 80bpm ~ 40bpm
Range : 7s ~ 8s, average is 7.5s</td></tr>
<tr><td>Tall T-wave Rejection</td><td colspan="3">Exceeds ANSI/AAMI EC13-2002 Sect. 4.1.2.1 C) minimum recommended 1.2mV T-Wave amplitude</td></tr>
<tr><td>Accuracy of Heart Rate Meter and Response to Irregular Rhythm</td><td colspan="3">Complies with ANSI/AAMI EC13-2002 Sect.4.1.2.1 e)
The HR value displays after a stable period of 20s:
Ventricular bigeminy: 80bpm±1bpm
Slow alternating ventricular bigeminy: 60bpm±1bpm
Rapid alternating ventricular bigeminy: 120bpm±1bpm
Bidirectional systoles: 91bpm±1bpm</td></tr>
<tr><td rowspan="8">Arrhythmia analyses</td><td colspan="2">Non-Paced Patient</td><td>Paced Patient</td></tr>
<tr><td>ASYSTOLE</td><td>R on T</td><td>ASYSTOLE</td></tr>
<tr><td>VFIB/VTAC</td><td>PVC</td><td>TACHY</td></tr>
<tr><td>COUPLET</td><td>TACHY</td><td>BRADY</td></tr>
<tr><td>VT>2</td><td>BRADY</td><td>PNC</td></tr>
<tr><td>BIGEMINY</td><td>MISSED BEATS</td><td rowspan="3">PNP</td></tr>
<tr><td>TRIGEMINY</td><td>IRR</td></tr>
<tr><td>VENT</td><td>VBRADY</td></tr>
</table>

A1.2.8 RESP

Method	Trans-thoracic impedance: R-F(RA-LL), R-L (RA-LA)
RR measuring range	Adult: 0 to 120 rpm
	Neo/Ped: 0 to 150 rpm
	Resolution: 1 rpm
	Accuracy: ±2 rpm
Gain selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Sweep	6.25mm/s, 12.5mm/s, 25.0mm/s, 50.0mm/s

Measurement lead	Options are lead I and II. The default is lead II.
Calculation Type	Manual /Automatic
Measuring sensitivity	0.3 Ω (baseline impedance 200 to 4500 Ω)
Maximum dynamic range	Baseline impedance: 500Ω Variable impedance: 3Ω No clipping
Baseline Impedance Range	200Ω ~ 2500Ω (no leads cables resistance) 2200Ω ~ 4500Ω (leads cables 1KΩ resistance)
Waveform bandwidth	0.2 to 2.5 Hz (-3 dB)
Apnea Alarm Time	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.

A1.2.9 NIBP

Method	Oscillometric
Mode	Manual, Auto, Continuous
Measuring Interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90/120/240/480 min
Continuous	5min, interval is 5s
Measuring Type	SYS, DIA, MAP, PR
Alarm Type	SYS, DIA, MAP
Measuring Rang	
Adult Mode	SYS: 40 mmHg to 270 mmHg DIA: 10 mmHg to 215 mmHg MAP: 20 mmHg to 235 mmHg
Pediatric Mode	SYS: 40 mmHg to 200 mmHg DIA: 10 mmHg to 150 mmHg MAP: 20 mmHg to 165 mmHg

Neonatal Mode	SYS: 40 mmHg to 135 mmHg DIA: 10 mmHg to 100 mmHg MAP: 20 mmHg to 110 mmHg
Cuff Pressure Measuring Range	0 mmHg to 300 mmHg
Pressure Resolution	1mmHg
Maximum Mean Error	±5mmHg
Maximum Standard Deviation	8mmHg
Maximum Measuring Period	
Adult/ Pediatric	120s
Neonatal	90s
Typical Measuring Period	30s to 45s (depend on HR/motion disturbance)
Overpressure Protection	
Adult	297±3mmHg
Pediatric	240±3mmHg
Neonatal	147±3mmHg
PR	
Measuring range	40 bpm ~240bpm
Accuracy	±3bpm or 3.5%, whichever is greater

A1.2.10 SpO_2

Measuring Range	0 % to 100 %
Alarm Range	0 % to 100 %
Resolution	1 %
Data Update Period	1s

Accuracy	
Adult (including Pediatric)	±2% (70% to 100% SpO_2)
	Undefined (0% to 69% SpO_2)
Neonatal	±3% (70% to 100% SpO_2)
	Undefined (0% to 69% SpO_2)
Pulse Rate	
Measuring Range	25bpm to 300bpm
Alarm Range	30bpm to 300bpm
Resolution	1bpm
Accuracy	±2bpm
Sensors	
Wave Length	Red Light: 660±3 nm
	Infrared Light: 905±5 nm
Emitted Light Energy	<15 mW

A1.2.11 TEMP

Channel	2
Sensor Type	YSI-10K and YSI-2.252K
Technique	Thermal resistance
Measuring Range	0 °C to 50 °C
Resolution	0.1°C
Accuracy (not including sensor)	±0.1°C
Refresh Time	Every 1 to 2s

A1.2.12 IBP (Optional)

Technique	Direct invasive measurement
Measuring range	
Art	0 to +300 mmHg
PA	-6 to +120mmHg
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
Unit	kPa、mmHg
Zero calibration range	±200 mmHg
Filter	DC～12.5Hz; DC～40Hz
Pressure sensor	
Sensitivity	5 (μV/V/mmHg)
Impedance	300 to 3000 Ω

A1.2.13 CO_2 (Optional)

Applicable Patient Type	Adult, pediatric and neonatal patients	
Method	Infra-red Absorption Technique	
Unit	mmHg/ %/ kPa	
Measuring Range	$EtCO_2$	0 mmHg to 150 mmHg
	$FiCO_2$	3 to 50 mmHg
	AwRR	2 to 150 rpm (Sidestream) 0 to 150 rpm (Mainstream)
Resolution	$EtCO_2$	1 mmHg
	$FiCO_2$	1mmHg
	AwRR	1rpm
Measuring Accuracy		

$EtCO_2$	±2 mmHg, 0 mmHg to 40 mmHg
	Reading ±5%, 41 mmHg to 70 mmHg
	Reading ±8%, 71 mmHg to 100 mmHg
	Reading ±10%, 101 mmHg to 150 mmHg
	Reading ±12%, RR is over 80 rpm (Sidestream)
AwRR	± 1 rpm
Sample Gas Flow Rate (Sidestream)	50±10 ml /min
O_2 Compensation	
Range	0 to 100%
Resolution	1%
Default	16%
Anesthetic Gas Compensation	
Range	0 to 20%
Resolution	0.1%
Default	0.0%
Balance Gas Compensation	Options: N_2O, helium, room air
Barometric pressure compensation	User setup
Operation Mode	Measure, standby
Stability	
Short Term Drift	< 0.8 mmHg over 4 hours
Long Term Drift	Accuracy specification will be maintained over 120 hours period

Initialization time	It displays the value within 15s and meets the requirement for measurement accuracy within 2min. (Mainstream)
	It displays the value within 20s and meets the requirement for measurement accuracy within 2min. (Sidestream)
Response time	60ms (Mainstream)
Calibration	Not required.
Alarm	$EtCO_2$, $FiCO_2$ and AwRR alarm
Apnea Alarm Delay	10, 15, 20, 25, 30, 35, 40s; 20s by default

Interfering Gas and Vapor Effect on $EtCO_2$ Measurement Values:

Gas or vapor	Gas level (%)	Quantitative effect/Comments
Nitrous oxide	60	Dry and Saturated Gas
Halothane	4	0 – 40 mmHg: ± 1 mmHg additional error
Enflurane	5	41 – 70 mmHg: ± 2.5% additional error
Isoflurane	5	71 – 100 mmHg: ± 4% additional error
Sevoflurane	5	101 – 150 mmHg: ± 5% additional error
Xenon	80	*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.
Helium	50	
Desflurane	15	
		Desflurane:
		The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38mmHg.
		Xenon:
		The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38mmHg.

Barometric Pressure on $EtCO_2$ Measurement Values:

Quantitative effect
Ambient Barometric, Operational
0 – 40 mmHg: ± 1 mmHg additional error
41 – 70 mmHg: ± 2.5% additional error
71 – 100 mmHg: ± 4% additional error

101 – 150 mmHg: ± 5% additional error

*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.