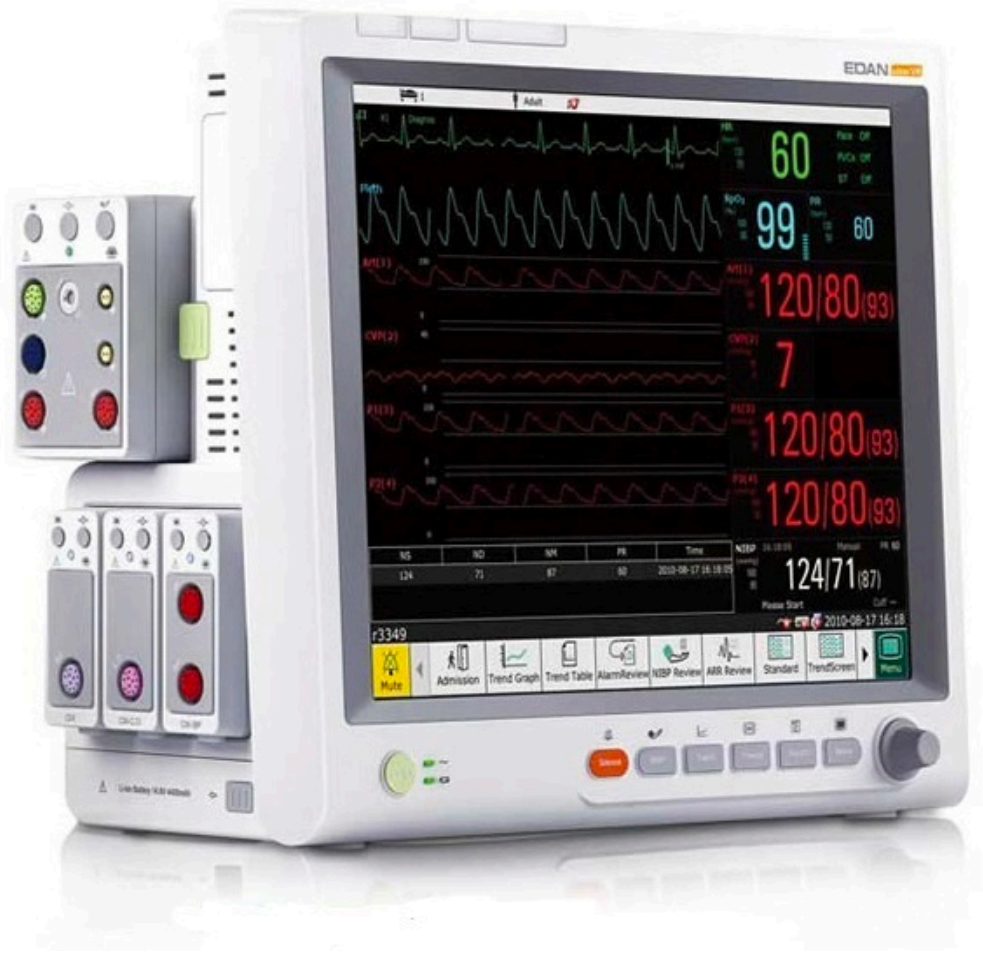
EDANUSA



Elite Series Patient Monitor

Product Specifications

Product Specifications

A.1 Classification

Anti-electroshock type	Class I equipment and internal powered equipment
EMC type	Group I, Class A
Anti-electroshock degree	ECG (RESP), TEMP, IBP, C.O. CF SpO_2, NIBP, CO_2, AG BF
Ingress Protection	IPX1
Disinfection/sterilization method	Refer to Chapter Care and Cleaning for details.
Working system	Continuous operation equipment
Compliant with Safety Standards	IEC 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 60601-1-2:2001+A1, ISO 9919, ISO 21647, IEC/EN 60601-2-27, IEC/EN 60601-2-30, IEC/EN 60601-2-34, IEC/EN 60601-2-49, ANSI/AAMI SP10, IEC/EN 60601-2-25, AAMI/ANSI EC13, EN12470-4 EN1060-1 EN1060-3, EN1060-4

A.2 Physical Specifications

Product	**Dimension**	**Max Weight**	**Comments**
elite V8	425 mm (L) × 245 mm (W)× 382 mm (H)	<14 kg	Including batteries, XM module and recorder, without options
XM module	188 mm (L) × 81.5 mm (W)× 120 mm (H)	<1 kg	Without accessories
V-IBP module	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories
V-C.O. module	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories

Product	Dimension	Max Weight	Comments
V-CO_2 module (mainstream)	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories
V-CO_2 module (sidestream)	134 mm (L) × 84 mm (W)× 102 mm (H)	<0.65 kg	Without accessories
V-AG module (mainstream)	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories
V-AG module (sidestream)	134 mm (L) × 84 mm (W)× 102 mm (H)	<0.65 kg	Without accessories
V-SpO_2 module	134 mm (L) × 38 mm (W)× 102 mm (H)	<0.2 kg	Without accessories
PAM	503 mm (L) × 170 mm (W)× 148 mm (H)	<2.5 kg	Without accessories

A.3 Environmental Specifications

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.

Main unit, PAM, XM module, V-SpO_2 module, V-IBP module, V-C.O. module, Recorder	
Temperature	
Working	+0°C ~ +40°C
Transport and Storage	-20°C ~ +55°C
Humidity	
Working	15% ~ 95% (non-condensing)
Transport and Storage	15% ~ 95% (non-condensing)
Altitude	
Working	860hPa ~ 1060hPa

Transport and Storage	700hPa ~ 1060hPa
Power Supply	100V-240V~, 50Hz/60Hz, 1.8A~0.75A. Pmax=180VA FUSE: T3.15AH250VP

V-CO_2 module (sidestream)	
Temperature	
Working	+5°C ~ +35°C
Transport and Storage	-20°C ~ +55°C
Humidity	
Working	10% ~ 90% (non-condensing)
Transport and Storage	10% ~ 90% (non-condensing)
Altitude	
Working	530hPa ~ 1066hPa
Transport and Storage	530hPa ~ 1066hPa

V-CO_2 module (mainstream)	
Temperature	
Working	+0°C ~ +40°C
Transport and Storage	-20°C ~ +55°C
Humidity	
Working	10% ~ 90% (non-condensing)
Transport and Storage	10% ~ 90% (non-condensing)
Altitude	
Working	530hPa ~ 1066hPa
Transport and Storage	530hPa ~ 1066hPa

V-AG module (sidestream)	
Temperature	
Working	+5°C ~ +40°C
Transport and Storage	-20°C ~ +55°C
Humidity	

Working	10% ~ 95% (non-condensing)
Transport and Storage	10% ~ 95% (non-condensing)
Altitude	
Working	525hPa ~ 1200hPa
Transport and Storage	500hPa ~ 1200hPa

V-AG module (mainstream)	
Temperature	
Working	+10°C ~ +40°C
Transport and Storage	-20°C ~ +55°C
Humidity	
Working	10% ~ 95% (non-condensing)
Transport and Storage	10% ~ 95% (non-condensing)
Altitude	
Working	525hPa ~ 1200hPa
Transport and Storage	500hPa ~ 1200hPa

A.4 Leakage Current

	Applied Part	**Normal Condition**	**Single Fault Condition**
Earth Leakage Current		<0.5 mA	<1 mA
Enclosure Leakage Current		<0.1 mA	<0.5 mA
Patient Leakage Current	CF	AC: <0.01 mA DC: <0.01 mA	AC: <0.05 mA DC: <0.05 mA
	BF	AC: <0.1 mA DC: <0.01 mA	AC: <0.5 mA DC: <0.05 mA
Patient Leakage Current (Mains on Applied Parts)	CF		<0.05 mA
	BF		<5 mA
Patient Auxiliary Current	CF	AC: <0.01 mA DC: <0.01 mA	AC: <0.05 mA DC: <0.05 mA
	BF	AC: <0.1 mA DC: <0.01 mA	AC: <0.5 mA DC: <0.05 mA

A.5 Display

Display	**Messages**
Display screen: 17 inch color TFT, touch screen is configurable Resolution: 1280 × 1024	A maximum of 12 waveforms One power LED One physiological alarm LED One technical alarm LED One alarm mute LED One charge LED

A.6 Battery

Number	2	
Capacity	4.2 Ah	
Nominal Voltage	14.8 V DC	
Operating Time	120 min	with 2 new, fully charged batteries, at 25°C, typical configuration (continuous SpO_2 measurement and NIBP automatic measurement mode at interval of 15 minutes, ECG/TEMP module connected, recording at interval of 10 minutes, brightness set to "1")
	90 min	with 2 new, fully charged batteries, at 25°C, typical configuration (continuous SpO_2 measurement and NIBP automatic measurement mode at interval of 15 minutes, ECG/TEMP module connected, sidestream CO_2 and sidestream AG modules connected, recording at interval of 10 minutes, brightness set to "1")
Charge Time	4.2 Ah 350 min (Monitor is on or in standby mode.)	

A.7 Recorder

Record Width	48 mm
Paper Speed	12.5mm/s, 25 mm/s, 50 mm/s
Trace	1/2/3 optional
Recording types	Continuous real-time recording 8 second real-time recording Parameter alarm recording Trend recording Titration table recording Frozen waveform recording

A.8 Review

Trend Review	
Short	1 hr, at 1 second resolution
Long	150 hrs, at 1 min. resolution
Review	1200 sets of NIBP measurement data

A.9 ECG

Lead Mode	3-Lead: I, II, III 5-Lead: I, II, III, aVR, aVL, aVF, V 12-Lead: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
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 ~ 150Hz Monitor: 0.5Hz ~ 40Hz Surgery: 1Hz ~ 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	In diagnosis, monitor and surgery modes: 50Hz/60Hz (Notch filter can be turned on or off manually)
Differential Input Impedance	>5MΩ
Input Signal Range	±8mV 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
Input Offset Current	≤0.1μA
Recovery time after Defibrillation	<5s
Leakage current of patient	<10μA
Scale signal	1mVPP, accuracy is ±5%
System noise	<30μVPP
Sampling frequency	1000Hz
Sampling channel switch time	<80μS
A/D precision	24 Bits
ESU Protection	Incision mode: 300W Congelation mode: 100W 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 complies with ANSI/AAMI EC13:2002 Sect.4.2.9.14.
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 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 (lead II)	>2.5V/S
Heart Rate	
HR Calculation	
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	-0.8 mV ~ +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
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 beats is less than 600 ms
Ventricular Rhythm	The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms
Ventricular Bradycardia	The interval of 5 consecutive ventricular beats is more than 1000 ms
Startup 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">Complied with ANSI/AAMI EC13-2002 Sect.4.1.2.1 e), the HR value after 20 seconds of stabilization is displayed as follows:
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>

12-lead ECG Synchronization Analysis	Average parameters of heart beat
	Heart rate (bpm)
	Time limit of P wave (ms)
	PR interval (ms)
	QRS interval (ms)
	QT/QTC (ms)
	P-QRS-T AXIS

A.10 RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is lead II.
Respiration excitation waveform	Sinusoid, 62.8kHz(± 10%), <300μA
Measuring Sensitivity	200 to 4500 baseline impedance: 0.3Ω
Differential input impendence	> 2.5MΩ
Waveform bandwidth	0.2Hz ~ 2.5Hz (-3dB)
Baseline Impedance Range	200Ω ~ 2500Ω (no leads cables resistance)
	2200Ω ~ 4500Ω (leads cables 1KΩ resistance)
Noise	<0.1 Ω (3/ 5-lead monitoring)
	<0.2 Ω (12-lead monitoring)
Maximum dynamic range	Baseline impedance: 500Ω Variable impedance: 3Ω No clipping
RR Measuring Range:	
Adult	0 rpm ~120rpm
Neo/Ped	0 rpm ~150rpm
Resolution	1 rpm
Accuracy	±2 rpm
Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Apnea Alarm Time Setup	10s, 15s, 20s, 25s, 30s, 35s, 40s

A.11 NIBP

Technique	Oscillometry
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
Measuring Range	
Adult mode	SYS: 40 mmHg ~ 270 mmHg DIA: 10 mmHg ~ 215 mmHg MAP: 20 mmHg ~ 235 mmHg
Pediatric mode	SYS: 40 mmHg ~ 200 mmHg DIA: 10 mmHg ~ 150 mmHg MAP: 20 mmHg ~ 165 mmHg
Neonatal mode	SYS: 40 mmHg ~ 135 mmHg DIA: 10 mmHg ~ 100 mmHg MAP: 20 mmHg ~ 110 mmHg
Alarm Type	SYS, DIA, MAP
Cuff pressure measuring range	0 mmHg ~ 300 mmHg
Pressure resolution	1mmHg
Maximum mean error	±5mmHg
Maximum standard deviation	8mmHg
Maximum measuring period	
Adult/Pediatric	120s
Neonate	90s
Typical measuring period	30s ~ 45s (depend on HR/motion disturbance)
Overpressure protection (Dual 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

A.12 SpO_2

Measuring Range	0 ~ 100 %	
Alarm Range	0 ~ 100 %	
Resolution	1 %	
Accuracy		
Adult /Pediatric	±2 % (70%~100% SpO_2)	
	Undefined (0~69% SpO_2)	
Neonate	±3 % (70%~100% SpO_2)	
	Undefined (0~69% SpO_2)	
Pulse Rate		
Measuring Range	25 bpm ~ 300 bpm	
Alarm Range	30 bpm ~ 300 bpm	
Resolution	1 bpm	
Accuracy	±2bpm	
Data update period	1s	
Wave length		
Red light	660±3 nm	
Infrared light	905±5 nm	
Emitted light energy	Less than 15 mW	
Nellcor module		
Measuring Range		1% ~ 100%
Alarm Range		1% ~ 100%
Resolution		1%
Data update period		1s

Accuracy	Sensor Type	Accuracy
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST	± 2 (70% ~ 100% SpO_2)
	OxiCliq A, OxiCliq P, OxiCliq N (Adult), OxiCliq N (Neonate), OxiCliq I	± 2.5 (70% ~ 100% SpO_2)
	D-YS (Infant to Adult), DS-100A, OXI-A/N, OXI-P/I	± 3(70% ~ 100% SpO_2)
	D-YS (including D-YSE ear clip), D-YS (including D-YSPD spotclip)	± 3.5(70% ~ 100% SpO_2)
* When the sensor is used on neonates as recommended, the specified accuracy range increases by ±1 compared with that used on adults.		
Pulse Rate		
Measuring Range		20bpm ~ 300bpm
Resolution		1bpm
Accuracy		± 3bpm (20bpm ~ 250bpm)
Sensor		Wave length: approximately 660 and 900nm
		Emitted light energy: <15mW

A.13 TEMP

Channel	2
Sensor type	YSI-10K and YSI-2.252K
Technique	Thermal resistance
Position	Skin, oral cavity, rectum
Measuring Range	0 °C ~ 50 °C(32 ºF ~ 122 ºF)
Resolution	0.1°C (0.1 ºF)
Accuracy (Without sensor)	±0.1°C or ±0.2 ºF
Refresh Time	Every 1s ~ 2s

A.14 IBP

Technique	Direct invasive measurement
Pressure measuring range	-50 to +300 mmHg
Resolution	1 mmHg
Accuracy (without sensor)	± 2 % or ±1 mmHg, whichever is greater
Pressure sensor	
Sensitivity	5 (μV/V/mmHg)
Impedance	300 to 3000 Ω
Frequency response	d.c. to 12.5 or 40 Hz
Zero	Range: ±200 mmHg
	Accuracy: ±1 mmHg
Measuring range	
Art	0 mmHg to +300 mmHg
PA	-6 to +120mmHg
CVP/RAP/LAP/ICP	-10 to +40 mmHg
P1/P2	-50 to +300 mmHg
Volume displacement of MSI	4.5 x 10^{-4} in^3 / 100 mmHg

A.15 CO_2

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

$EtCO_2$ Accuracy	± 2 mmHg, 0 to 40 mmHg
	± 5 % of reading, 41 to 70 mmHg
	± 8 % of reading, 71 to 100 mmHg
	± 10 % of reading, 101 to 150 mmHg
AwRR Accuracy	± 1 rpm
Sample Gas Flowrate	50 ±10 ml/min
O_2 Compensation	
Range	0 ~ 100%
Resolution	1%
Default	16%
Stability	
Short Term Drift	Drift over 4 hours < 0.8 mmHg
Long Term Drift	120 hours
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) 3s (Sidestream)
Calibration	Not required.
Barometric pressure compensation	User setup
Alarm Type	$EtCO_2$, $FiCO_2$, AwRR
Apnea Alarm Delay	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.

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

Gas or vapor	Gas level (%)	Quantitative effect/Comments
Nitrous oxide Halothane Enflurane Isoflurane Sevoflurane Xenon Helium Desflurane	60 4 5 5 5 80 50 15	Dry and Saturated Gas 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. 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.

A.16 C.O.

Technique	Thermodilution Technique
Measuring range	
C.O.	0.1 L/min ~ 20L/min
TB	23°C ~ 43°C(73.4 º F ~109.4 º F)
TI	Auto: -1°C ~ 27°C(30.2 º F ~80.6 º F) Manual: 0°C ~ 27°C(32℉~80.6℉)
Resolution	
C.O.	0.1L/min
TB, TI	+0.1°C (+0.1 º F)
Alarm Range	23°C ~ 43°C (73.4℉~109.4℉)
Accuracy	
C.O.	±5% or ± 0.2 L/min
TB	±0.1°C
TI	±0.1°C
Output parameters	C.O.
	Hemodynamic Calculation

NOTE:

At least 90% of the C.O. data should reside inside the bounded region, and the lower 95% confidence interval should not exceed 85%.

A.17 AG

A.17.1 Sidestream

Module Type	ISA AX+ Analyzer	Displaying the concentration of CO_2, N_2O, and two anaesthesia agent and identifying the anaesthesia agent automatically (portable module)
	ISA OR+ Analyzer	Displaying the concentration of CO_2, O_2, N_2O, and two anaesthesia agent and identifying the anaesthesia agent automatically (portable module)

Measurement Parameters	CO_2 , N_2O , O_2, Halothane (HAL), Isoflurane(ISO), Enflurane(ENF), Sevoflurane(SEV) , Desflurane(DES), awRR, MAC	
Measurement Principle	CO_2, N_2O, Anaesthesia Agent: infra-red absorption characteristic; O_2: Paramagnetic method	
Sampling Flow Rate	50 ml/min	
Work Mode	Measurement, Standby	
Warm-up Time	< 20s	
Typical Rise Time	$CO_2 \leq 200ms$ $O_2 \leq 350ms$ $N_2O \leq 350ms$ $O_2 \leq 450ms$	
Primary Anaesthesia Agent Threshold	≤ 0.15 vol%	
Second Anaesthesia Agent Threshold	0.2 vol% + 10%	
Agent Identification Time	< 20 seconds (typically < 10 seconds)	
Response Time	< 3 seconds	
Standard Conditions		
GAS	Range	Accuracy
CO_2	0 to 15 vol% 15 to 25 vol%	±(0.2 vol% + 2% of reading) Unspecified
N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
HAL, ENF, ISO	0 to 8 vol % 8 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
SEV	0 to 10 vol % 10 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
DES	0 to 22 vol % 22 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
O_2	0 to 100 vol %	±(1 vol% + 2% of reading)
All Conditions		

Gas	Accuracy
CO_2	±(0.3kPa + 4% of reading)
N_2O	±(2kPa + 5% of reading)
Agents	±(0.2kPa + 10% of reading)
O_2	±(2kPa + 2 of reading)
Apnea Alarm Delay	20s~40s
Alarm	Providing alarms of $EtCO_2$, $FiCO_2$, EtO_2 , FiO_2 , EtN_2O , FiN_2O , EtAA , FiAA , awRR
Mechanical Robustness	Meets the shock and vibration requirements of SS-EN ISO 21647:2004 clause 21.101

Interfering gas and vapor effects:

Gas or Vapour	Gas Level	CO_2		Agents	N_2O
		ISA CO_2	ISA AX+		
N_2O[4)]	60 vol%	–[2)]	–[1)]	–[1)]	–[1)]
HAL[4)]	4 vol%	–[1)]	–[1)]	–[1)]	–[1)]
ENF, ISO, SEV[4)]	5 vol%	+8% of reading[3)]	–[1)]	–[1)]	–[1)]
DES[4)]	15 vol%	+12% of reading[3)]	–[1)]	–[1)]	–[1)]
Xe(Xenon)[4)]	80 vol%	-10% of reading[3)]		–[1)]	–[1)]
He(Helium)[4)]	50 vol%	-6% of reading[3)]		–[1)]	–[1)]
Metered Dose Inhaler Propellants[4)]	Not for use with metered dose inhaler propellants				
C_2H_5OH(Ethanol)[4)]	0.3 vol%	–[1)]	–[1)]	–[1)]	–[1)]
C_3H_7OH (Isopropanol)[4)]	0.5 vol%	–[1)]	–[1)]	–[1)]	–[1)]
CH_3COCH_3 (Acetone)[4)]	1 vol%	–[1)]	–[1)]	–[1)]	–[1)]
CH_4(Methane)[4)]	3 vol%	–[1)]	–[1)]	–[1)]	–[1)]
CO(Carbon monoxide)[5)]	1 vol%	–[1)]	–[1)]	–[1)]	–[1)]

NO(Nitrogen monoxide)	0.02 vol%	– [1]	– [1]	– [1]	– [1]
O_2 [5]	100 vol%	– [2]	– [2]	– [1]	– [1]

Note 1: Negligible interference, effect included in the specification "Accuracy, all conditions" above.

Note 2: Negligible interference with N_2O / O_2 concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06)*5.0 vol% =4.7 vol% CO_2.

Note 4: According to the EN ISO 21647 standard.

Note 5: In addition to the EN ISO 21647 standard.

A.17.2 Mainstream

Module Type	IRMA AX+	Displaying the concentration of CO_2, N_2O and two anaesthesia agent and indentifying two anaesthesia agent
Measurement Parameters	CO_2, N_2O, HAL, Isoflurane(ISO), Enflurane(ENF), Sevoflurane(SEV), Desflurane(DES), awRR, MAC	
Measurement Principle	CO_2, N_2O, anaesthesia agent: infra-red absorption characteristic	
Warm-up Time	Concentrations are reported and the automatic agent indentification is running within 10 seconds. Full accuracy within 20 seconds	
Rise Time	$CO_2 \leq 90$ms $N_2O \leq 300$ms HAL, ISO, ENF, SEV, DES ≤ 300ms	
Primary Agent Threshold	0.15 vol%	
Secondary Agent Threshold	0.2 vol% + 10% of total agent concentration	
Agent Identificaiton Time	< 20 seconds (typically < 10 seconds)	
Response Time	< 1 second	

Standard Conditions		
Gas	Range	Accuracy
CO_2	0 ~ 10 vol% 10 ~ 15vol% 15 ~ 25 vol%	±(0.2 vol% + 2% of reading) ±(0.3 vol% + 2% of reading) Unspecified
N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
HAL ISO ENF	0 to 8 vol% 8 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
SEV	0 to 10 vol% 10 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
DES	0 to 22 vol% 22 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
All Conditions		
GAS	Accuracy	
CO_2	±(0.3 vol% + 4 % of reading)	
N_2O	±(2 vol% + 4 % of reading)	
Agents	±(0.2 vol% + 10 % of reading)	
Apnea Alarm Delay	20s ~ 40s	
Alarm	Providing alarms of $EtCO_2$, $FiCO_2$, EtO_2 , FiO_2 , EtN_2O , FiN_2O , EtAA, FiAA, awRR	

Interfering gas and vapour effects:

Gas or vapour	Gas level	CO_2		Agents	N_2O
		IRMA CO_2	IRMA AX+		
N_2O[4)]	60 vol%	–[1&2)]	–[1&2)]	–[1)]	–[1)]
HAL[4)]	4 vol%	–[1)]	–[1)]	–[1)]	–[1)]
ENF, ISO, SEV[4)]	5 vol%	+8% of reading[3)]	–[1)]	–[1)]	–[1)]
DES[4)]	15 vol%	+12% of reading[3)]	–[1)]	–[1)]	–[1)]
Xe(Xenon)[4)]	80 vol%	-10% of reading[3)]		–[1)]	–[1)]

He(Helium) [4)]	50 vol%	-6% of reading [3)]		– [1)]	– [1)]
Metered dose inhaler propellants[4)]	Not for use with metered dose inhaler propellants				
C_2H_5OH(Ethanol) [4)]	0.3 vol%	– [1)]	– [1)]	– [1)]	– [1)]
C_3H_7OH (Isopropanol) [4)]	0.5 vol%	– [1)]	– [1)]	– [1)]	– [1)]
CH_3COCH_3 (Acetone) [4)]	1 vol%	– [1)]	– [1)]	– [1)]	– [1)]
CH_4(Methane) [4)]	3 vol%	– [1)]	– [1)]	– [1)]	– [1)]
CO(Carbon monoxide) [5)]	1 vol%	– [1)]	– [1)]	– [1)]	– [1)]
O_2[5)]	100 vol%	– [1&2)]	– [1&2)]	– [1)]	– [1)]

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

Note 2: For probes not measuring N_2O and/or O_2 the concentrations shall be set from monitor. (IRMA CO_2 measures neither N_2O, nor O_2. IRMA AX+ does not measure O_2.)

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the measured CO_2 concentration will typically be (1-0.06)*5.0 vol% =4.7 vol% CO_2.

Note 4: According to the EN ISO 21647 standard.

Note 5: In addition to the EN ISO 21647 standard.

A.18 Wireless Network

Compliant with Standard and Directive	IEEE802.11b/g, R&TTE Directive (99/5/EEC)
Frequency Range	2.412 GHz ~2.462 GHz (America) 2.412 GHz ~2.484 GHz (Japan) 2.412 GHz ~2.472 GHz (ETSI)
Working frequency segment	Ch1 ~ 11 (America) Ch1 ~ 14 (Japan) Ch1 ~ 13 (ETSI)

A.19 Interfaces

A.19.1 Analog Output

Bandwidth (-3dB; reference frequency: 10Hz)	Diagnosis: 0.05Hz ~ 100Hz Monitor: 0.5Hz ~ 40Hz Surgery: 1Hz ~ 20Hz
Maximum Transmission Delay (Diagnosis Mode)	500ms
Sensitivity	1V/1mV ±10%
PACE Rejection/ Enhancement	Not applicable.
Waveform Display	Consistent with the calculation leads.
Compliant with Standard and Directive	Complies with the requirements in terms of short circuit protection and leakage current in EN60601-1.
Output Impedance	<500Ω
Interface Type	PJ-365 socket, 3.5mm audio plug

A.19.2 Defibrillator Synchronization

Output Impedance	<500Ω
Maximum Time Delay	35mS (R-wave peak to leading edge of pulse)
Waveform	Rectangular wave
Amplitude	High level: 3.5V ~ 5V, providing a maximum of 1mA output current; Low level: <0.5V, receiving a maximum of 5mA input current
Minimum Required R-wave Amplitude	0.3mV
Pulse Width	100mS±10%
Limited Current	15mA rating
Rising and Falling Time	<1mS
Interface Type	BNC-SR-2P connector

A.19.3 Nurse Call

Drive Mode	Voltage Output
Power Supply	≤12VDC, 200mA Max.
Contact Type	Normally open or contact (optional)
Interface Type	PJ-365 socket, 3.5mm audio plug

A.19.4 USB Interfaces

Number of USB Interfaces	Standard: 4; optional: 4
Drive Mode	HOST interface, USB1.0/2.0 protocol
Power Supply	5VDC, 500mA Max.
Interface Type	USB A-type port

A.19.5 VGA Interface

Number of VGA Interface	1
Horizontal Refreshing Rate	63.49KHZ
Video Signal	0.7 Vpp @ 75 Ohm, HSYNC/VSYNC signal TTL
Interface Type	DB-15 female receptacle

A.19.6 DVI Interface

*Auto drive is only applicable to DVI display. A HDMI-to-DVI tieline is required.

Clock Rate	108.0MHZ
DVI Video Signal	1280×1024@85HZ; 4:3;
Interface Type	HDMI A-type port

A.19.7 RS232 Interface

Level	RS232
Power Supply	+/-13.2V, 60mA Max.
Interface Type	DB-9 female receptacle

A.19.8 PAM Interface

*Only use link cable supplied by EDAN.

Level	RS422
Power Supply	≤24VDC, 2A Max.
Interface Type	POWER USB port

A.19.9 Network Interface

Bandwidth	10MHZ ~ 100MHZ
Interface Type	Standard RJ-45 network interface