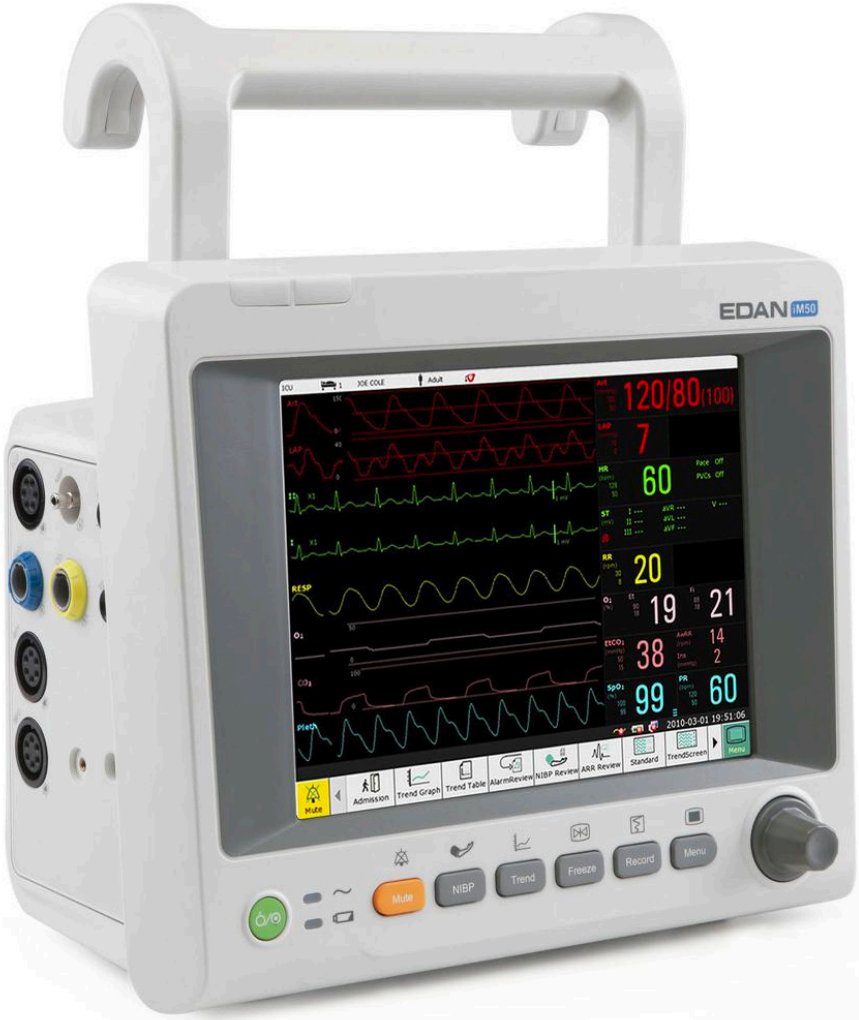
EDANUSA



iM50/iM60/iM70/iM80 Patient Monitor

Product Specifications

Product Specification

A.1 Classification

Anti-electroshock type	Class I equipment and internal powered equipment
Anti-electroshock degree	ECG (RESP), TEMP, IBP, C.O., Quick Temp CF SpO_2, NIBP, CO_2, AG BF
Ingress Protection	IPX1 (No protection against ingress of water if configured with Quick TEMP module)
Disinfection/sterilization method	Refer to Chapter Care and Cleaning 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; 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, AAMI/ANSI EC13, EN12470-4 EN1060-1 EN1060-3, EN1060-4, IEC/EN 60601-2-25*, IEC/EN 60601-2-51* (Symbol * means this standard only applicable to iM80)

A.2 Physical Specifications

A.2.1 Size and Weight

Product	Size	Weight (standard configuration, without battery)
iM50	261 mm (L) × 198 mm (W) × 215 mm (H)	<3.6 kg
iM60	303mm(L) × 161mm(W) × 254mm(H)	<4.5 kg
iM70	328mm(L) × 158mm(W) × 285mm(H)	<5.5 kg
iM80	370 mm (L) × 175 mm (W)× 320 mm (H)	<7 kg

A.2.2 Environment Specification

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 ~ +40°C	
Transport and Storage	-20°C ~ +55°C	
Humidity		
Working	25% ~ 80% (non-condensing)	
Transport and Storage	25% ~ 93% (non-condensing)	
Altitude		
Working	860hPa ~ 1060hPa	
Transport and Storage	700hPa ~ 1060hPa	
Power Supply	100V-240V~, 50Hz/60Hz	
	iM50	Current=1.0A-0.5A; Fuse: T 1.6AL, 250V
	iM80	Current=1.4A-0.7A; Fuse: T 1.6AL, 250V
	iM60/iM70	Current=1.4A-0.7A; Fuse: T3.15AH, 250V

A.2.3 Display

Product	Display	Messages
iM50	Display screen: 8.4 inch color TFT, supporting touch screen Resolution: 800×600	A maximum of 11 waveforms One power LED Two alarm LED One charge LED
iM60	Display screen: 10.4 inch color TFT, supporting touch screen Resolution: 800×600	A maximum of 11 waveforms One power LED Two alarm LED One charge LED
iM70	Display screen: 12.1 inch color TFT, supporting touch screen Resolution: 800×600	A maximum of 11 waveforms One power LED Two alarm LED One charge LED

iM80	Display screen: 15 inch color TFT, supporting touch screen Resolution: 1024 × 768	A maximum of 13 waveforms One power LED Two alarm LED One charge LED

A.2.4 Battery Specification

Operating Time	iM50	2.1Ah	180 min or longer
		4.2Ah	420 min or longer
	iM80	One battery (4.2Ah)	120 min or longer
		Two batteries (2*4.2Ah)	240 min or longer
	iM60/iM70	2.1Ah	150 min or longer
		4.2Ah	300 min or longer
Condition	At 25°C, with (a) new fully charged battery/batteries, 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"		
Charge Time	iM50	2.1Ah	200 min or shorter
		4.2Ah	380 min or shorter
	iM80	One battery (4.2Ah)	320 min or shorter
		Two batteries (2*4.2Ah)	560 min or shorter
	iM60/iM70	2.1Ah	200 min or shorter
		4.2Ah	360 min or shorter
Condition	Monitor is on or in standby mode.		

A.2.5 Recorder

Record Width	48 mm
Paper Speed	25 mm/s, 50 mm/s
Trace	3
Recording types	Continuous real-time recording 8 seconds 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

A.2.6 Data Storage

Trend graph/trend table review	1 hour, at 1 Second Resolution by default 120 hrs, at 1 min. Resolution by default
Alarm/Monitoring Event data	Up to 60 sets
NIBP Measurement Review	1200 sets
Arrhythmia events	Up to 60 sets
12-lead Diagnosis Review	Up to 50 sets

A.3 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
Waveform	3-Lead: 1-channel waveform; 5-Lead: 2-channel waveform, max. seven waveforms; 12-Lead: 2-channel waveform, a maximum of 13 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
Waveform Speed	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	In diagnosis, monitoring, surgery mode: 50Hz/60Hz (Notch filter can be turned on or off manually)
Differential Input Impendance	>5MΩ
Input Signal Range	±10mV (peak-to-peak value)
Accuracy of Input Signal Reconstruction	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	1mV(peak-to-peak value), accuracy is ±5%
System noise	<30μVPP
ESU Protection	Recovery time: ≤10s
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	>2.5V/S
Heart rate	
Measurement Range	ADU: 15 bpm ~ 300 bpm PED/NEO: 15 bpm ~ 350 bpm
Accuracy	±1% or ±1 bpm, whichever is greater
Resolution	1 bpm
PVC	
Measurement Range	ADU: 0~300 PVCs/ min PED/NEO: 0~350 PVCs/ min
Resolution	1 PVCs/min
ST value(only applicable to adult）	
Measurement 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: undefined
Resolution	0.01 mV
HR averaging method	
Method 1	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

<table>
<tr><td>Ventricular Rhythm</td><td colspan="3">The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms</td></tr>
<tr><td>Ventricular Bradycardia</td><td colspan="3">The interval of 5 consecutive ventricular beats is more than 1000 ms</td></tr>
<tr><td colspan="4">Maximum Start-up alarm time for Tachycardia</td></tr>
<tr><td>Ventricular Tachycardia
1 mV 206bpm</td><td colspan="3">Gain 1.0: 10 s
Gain 0.5: 10 s
Gain 2.0: 10 s</td></tr>
<tr><td>Ventricular Tachycardia
2 mV 195bpm</td><td colspan="3">Gain 1.0: 10 s
Gain 0.5: 10 s
Gain 2.0: 10 s</td></tr>
<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">Complies with 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="6">16 different arrhythmia analysis classification
(applicable to adult and pediatric)</td><td>ASYSTOLE</td><td>VFIB/VTAC</td><td>COUPLET</td></tr>
<tr><td>VT>2</td><td>BIGEMINY</td><td>TRIGEMINY</td></tr>
<tr><td>VENT</td><td>R on T</td><td>PVC</td></tr>
<tr><td>TACHY</td><td>BRADY</td><td>MISSED BEATS</td></tr>
<tr><td>IRR</td><td>VBRADY</td><td>PNC</td></tr>
<tr><td>PNP</td><td colspan="2"></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
ECG Analog Output	
Bandwidth (-3dB; reference frequency: 10Hz)	Diagnosis: 0.05Hz ~ 100Hz Monitor: 0.5Hz ~ 40Hz Surgery: 1Hz ~ 20Hz
Maximum transmission delay	500ms (in diagnostic mode, and with notch off)
Sensitivity	1V/mV ±10%
PACE rejection/enhancement	Without Pace enhancement or pace rejection
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.
Defib Sync Pulse	
Output wave	Square pulse
Output impedance	<500 Ω
Maximum Time Delay	35mS (R-wave peak to leading edge of pulse)
Amplitude	High level: 3.5 to 5 V, providing a maximum of 1 mA output current; Low level: < 0.5V, receiving a maximum of 5 mA input current.
Minimum required R wave amplitude	0.3mV
Pulse width	100ms ± 10%
Limited current	15 mA rating
Rising and falling time	< 1 ms

A.4 RESP

Measurement method	Trans-thoracic impedance
Measurement lead	Lead Options are lead I and II. The default lead is lead II.
Waveform amplitude	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Waveform speed	6.25mm/s, 12.5mm/s, 25.0mm/s, , 50mm/s
Respiration excitation waveform	< 300 μA, sinusoid, 62.8 kHz (± 10%)
Measuring sensitivity	0.3 Ω (base impedance 200 to 4500 Ω)
Base impedance range	200 to 2500 Ω (cable resistance = 0 K)
	2200 to 4500 Ω (leads cables 1KΩ resistance)
Maximum dynamic range	500 Ω base impedance, 3 Ω variable impedance
Waveform bandwidth	0.2 to 2.5 Hz (-3 dB)
Differential input impedance	>5 MΩ
RR measuring range	
Adult	0 to 120 rpm
Neo/Ped	0 to 150 rpm
Resolution	1 rpm
Accuracy	
Adult	6 to 120 rpm: ±2 rpm 0 to 5 rpm: not specified
Neo/Ped	6 to 150 rpm: ±2 rpm 0 to 5 rpm: not specified
Apnea Alarm delay	10s, 15s, 20s, 25s, 30s, 35s, 40s. The default value is 20s.

A.5 NIBP

EDAN Module

Measurement 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
Measurement 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
Cuff pressure measuring range	0 mmHg ~ 300 mmHg
Accuracy	
Maximum mean error	±5mmHg
Maximum standard deviation	8mmHg
Pressure resolution	1mmHg
Maximum measuring period	
Adult/Pediatric	120s
Neonate	90s
Typical measuring period	30s ~ 45s (depend on HR/motion disturbance)
Overpressure protection	
Adult	297±3mmHg
Pediatric	240±3mmHg
Neonatal	147±3mmHg

PR	
Measurement range	40 bpm ~240bpm
Accuracy	±3bpm or 3.5%, whichever is greater

Omron Module

Method	Oscillometric
Mode	Manual, Auto, Continuous
Measuring Interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90 min, 2/4/8h
Continuous	5min, interval is 5s
Maximum measurement period	Adult/ Pediatric: 160s Neonatal: 80s
PR Measurement Range	Adult/ Pediatric mode: 40bpm ~ 200bpm
	Neonatal mode: 40 bpm ~ 240bpm
PR Accuracy	± 2 bpm or 2% of the readings
Measurement Range	
Adult/ Pediatric Mode	SYS: 60 mmHg ~ 250 mmHg DIA: 40 mmHg ~ 200 mmHg MAP: 45 mmHg ~ 235 mmHg
Neonatal Mode	SYS: 40 mmHg ~ 120 mmHg DIA: 20 mmHg ~ 90 mmHg MAP: 30 mmHg ~ 100 mmHg
Cuff pressure measuring range	0 mmHg ~ 300 mmHg
Pressure Resolution	1mmHg
Accuracy	
Maximum Mean Error	±5mmHg
Maximum Standard Deviation	8mmHg

A.6 SpO_2

EDAN Module

Measurement Range	0 ~ 100 %
Resolution	1 %
Accuracy	
Adult (including 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	25bpm ~ 300bpm
Resolution	1bpm
Accuracy	±2bpm
Data update period	1s
Sensor	Wave length: Red light: 660±3 nm; Infrared light: 905±5 nm
	Emitted light energy: <15mW

Nellcor Module

Measuring Range		1% ~ 100%
Resolution		1%
Data update period		1s
Accuracy	Sensor Type	Accuracy
	DS-100A, OXI-A/N	± 3%(70% ~ 100% SpO_2)
* When the sensor is used to neotate as recommendation, the specified accuracy range of the neotate is always higher ±1 than adult.		
Pulse Rate		
Measuring Range		20bpm ~ 300bpm
Resolution		1bpm
Accuracy		± 3bpm (20bpm ~ 250bpm)
Sensor		Wave length: approximately 660 and 900nm
		Emitted light energy: <15mW

A.7 TEMP

Measurement method	Thermal resistance
Channel	2
Sensor type	YSI-10K and YSI-2.252K
Measuring Range	0 °C ~ 50 °C
Resolution	0.1°C
Accuracy (Without sensor)	±0.1°C
Unit	℃, ℉
Refresh Time	1s ~ 2s

A.8 Quick TEMP

Measuring Range	25°C ~ 45°C(monitoring mode) 35.5℃～42℃(prediction mode)
Operating Temp	10°C ~ 40°C
Sensor Type	Oral/Axillary sensor, Rectal sensor
Resolution	0.1°C
Accuracy(without sensor)	±0.1°C (25°C ~ 45°C) (monitoring mode)
Response time	< 60s
Update time	1s ~ 2s
Warm-up time	Less than 10 seconds
Prediction time	Less than 30 seconds

A.9 IBP

Measurement method	Direct invasive measurement
Channel	iM80: 4 channels iM50/iM60/iM70: 2 channels
Pressure sensor	
Sensitivity	5 (μV/V/mmHg)
Impedance range	300 to 3000 Ω
Frequency response	d.c. to 12.5 or 40 Hz
Zero	Range: ±200 mmHg

Unit	kPa, mmHg
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 (without sensor)	± 2 % or 1 mmHg, whichever is greater

A.10 CO_2

EDAN Module

<table>
<tr><td>Intended patient</td><td colspan="3">Adult, pediatric, neonatal</td></tr>
<tr><td>Measurement method</td><td colspan="3">Non-dispersive infrared gas analysis (NDIR)</td></tr>
<tr><td>Unit</td><td colspan="3">mmHg, %, kPa</td></tr>
<tr><td rowspan="2">Measuring Range</td><td>CO_2</td><td colspan="2">0 mmHg ~ 150 mmHg (0 % ~ 20%)</td></tr>
<tr><td>AwRR</td><td colspan="2">2 rpm ~ 150 rpm</td></tr>
<tr><td rowspan="3">Resolution</td><td>$EtCO_2$</td><td colspan="2">0.2mmHg (0 mmHg~ 70mmHg), 0.5mmHg (70 ~ 100mmHg)</td></tr>
<tr><td>$FiCO_2$</td><td colspan="2">0.2mmHg</td></tr>
<tr><td>AwRR</td><td colspan="2">1rpm</td></tr>
<tr><td rowspan="6">Accuracy</td><td rowspan="5">$EtCO_2$</td><td>± 2 mmHg, 0mmHg ~ 40 mmHg</td><td rowspan="4">Typical conditions:
Ambient temperature: 25± 3℃
Barometric pressure: 760± 10 mmHg
Balance gas: N_2
Respiratory rate: not exceed 60rpm
Sample gas flowrate: 100ml/min</td></tr>
<tr><td>± 5% of reading, 41 mmHg ~ 70 mmHg</td></tr>
<tr><td>± 8% of reading, 71 mmHg ~ 100 mmHg</td></tr>
<tr><td>± 10% of reading, 101 mmHg ~ 150 mmHg</td></tr>
<tr><td>±12% or ± 4 mmHg of reading, whichever is greater</td><td>All conditions</td></tr>
<tr><td>AwRR</td><td colspan="2">± 1 rpm</td></tr>
<tr><td>Sample gas Flowrate</td><td colspan="3">70ml/min or 100ml/min, optional (±15ml/min)</td></tr>
</table>

Stability	Short term drift: drift over 4 hours < 0.8 mmHg Long term drift: 120 hours
Warm-up time	Display reading within 20s; reach to the designed accuracy within 2 minutes.
Rise time	400ms (typical value, using water trap, sample gas flowrate:100ml/min
Response time	<4s (water trap) with 2m gas sampling tube, sample gas flowrate: 100ml/min
Work mode	Standby, measure; default: measure
Respiratory inspection	The value of concentration change is greater than 1 vol%.
O_2 compensation	Range: 0%~100% Resolution: 1% Default: 16%
N_2O compensation	Range: 0%~100% Resolution: 1% Default: 0%
AG compensation	Range: 0%~20% Resolution: 0.1% Default: 0%
Humidity compensation method	ATPD, BTPS (default)
Calibration	Support
Alarm	$EtCO_2$, $FiCO_2$, AwRR
Apnea alarm delay	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.

Respironics Module

Intended patient	Adult, pediatric, neonatal
Measurement method	Infra-red Absorption Technique
Unit	mmHg, %, Kpa
Measuring Range	
$EtCO_2$	0 mmHg ~ 150 mmHg
$FiCO_2$	3 mmHg ~50 mmHg
AwRR	2 rpm ~ 150 rpm(sidestream) 0 rpm ~ 150 rpm(mainstream)
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
	± 12 % of reading, RESP measurement value exceeds 80rpm (sidestream)
AwRR Accuracy	± 1 rpm
Sample Gas Flowrate (sidestream)	50±10ml/min
Stability	
Short Term Drift	Less than 0.8 mmHg over four hours
Long Term Drift	Accuracy specification will be maintained over a 120 hour period
O_2 Compensation	
Range	0 ~ 100%
Resolution	1%
Default	16%
GAS Compensation	
Range	0 ~ 20%
Resolution	0.1%
Default	0.0%
Zero	Support
Work Mode	Standby, Measurement
Barometric pressure compensation	User setup
Balance gas compensation	Including Helium, N_2O and room air
Apnea Alarm Delay	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.

Interfering Gas Effect 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.11 C.O.

Intended patient	Adult
Measurement method	Thermodilution Technique
Measuring range	
C.O.	0.1 L/min ~ 20L/min
TB	23°C ~ 43°C

TI	-1°C ~ 27°C
Resolution	
C.O.	0.1L/min
TB, TI	+0.1°C
Accuracy	
C.O.	±5% or 0.2 L/min, whichever is greater
TB	±0.1°C(without sensor)
TI	±0.1°C(without sensor)

A.12 AG

A.12.1 Phasein Sidestream

Temperature		
Working		+5°C ~ +40°C
Transport and Storage		-20°C ~ +55°C
Humidity		
Working		25% ~ 80% (non-condensing)
Transport and Storage		25% ~ 93% (non-condensing)
Altitude		
Working		860hPa ~ 1060hPa
Transport and Storage		700hPa ~ 1060hPa
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±10ml/min	
Work Mode	Measurement	
Warm-up Time	< 20s	
Typical Rise Time	CO_2 ≤ 200ms HAL, ISO, ENF, SEV, DES ≤ 350ms N_2O ≤ 350ms O_2 ≤ 450ms	
Primary Anaesthesia Agent Threshold	≤ 0.15 vol%	
Second Anaesthesia Agent Threshold	0.2 vol% + 10%	
Agent Identificaiton Time	< 20 seconds (typically < 10 seconds)	
Total System Response Time	< 3 seconds	
Data Update Time	1 second	
Accuracy(Standard Conditions)		
GAS	Measurement 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)
Apnea Alarm Delay	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.	
Zero	Support	
O_2 Compensation	Support	

N_2O Compensation	Support				
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: 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 2: In addition to the EN ISO 21647 standard.

A.12.2 Phasein Mainstream

Temperature		
Working		+10°C ~ +40°C
Transport and Storage		-20°C ~ +55°C
Humidity		
Working		25% ~ 80% (non-condensing)
Transport and Storage		25% ~ 93% (non-condensing)
Altitude		
Working		860hPa ~ 1060hPa
Transport and Storage		700hPa ~ 1060hPa
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. 20 seconds for IRMA AX+.	
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 less than 10 seconds)	
Response Time	< 1 second	
Data Update Time	1 second	
Accuracy(Standard Conditions)		

Gas	Range	Accuracy
CO_2	0 ~ 10 vol% 10 ~ 15 vol% 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
AwRR accuracy	±1rpm	
Real-time gas concentration monitoring	Support	
Zero	Support	
Work Mode	Measurement	
Apnea Alarm Delay	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.	

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)]
NO	0.02 vol%	– [1)]	– [1)]	– [1)]	– [1)]
O_2[5)]	100 vol%	– [1&2)]	– [1&2)]	– [1)]	– [1)]

Note 1: 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 2: 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 3: In addition to the EN ISO 21647 standard.