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iM 8

Technical Specifications

Product Specifications

1.Safety Specifications

1.1Product Classification

Class	Specification
Type of protection against electric shock	Class I, with internal power supply
Degree of protection against electric shock	Anti-defibrillation: CF type
Degree of protection against ingress of water as detailed in the current edition of IEC 529	Ordinary equipment (sealed equipment without liquid proof)
Degree of protection against hazards of ignition of flammable anesthetic mixtures with air, oxygen or nitrous oxide	Not suitable for use in the presence of a flammable anesthetic mixtures with air, oxygen or nitrous oxide
Mode of operation	Continuous

1.2 Environment Specifications

Runtime Environment Requirements	
Temperature	5 ~ 40°C (41°F ~ 104°F)
Relative humidity	≤95% (non-condensing)
Air pressure	70kPa ~ 106kPa
Other	Drafty and without corrosive gas
Transportation and Storage Environment Requirement	
Temperature	-40°C ~ 55°C (-40°F ~131°F)

Relative humidity	≤95% (non-condensing)
Air pressure	16.5kPa ~ 106kPa
Other	Drafty and without corrosive gas

1.3 Power Specifications

AC power supply	
Input Voltage	100V~240V (±10%)
Frequency	50/60Hz(±3Hz)
Power	≤40VA
Internal battery input	
Type	Rechargeable Lithium battery
Output Voltage	6.4V~8.4V
Capability	2200mAh
Charge time	Less than 6 hours when the monitor is on
DC power input	
Input Voltage	9V~15V

2. Physical Specifications

Instrument	Size	180mm × 250mm × 180mm
	Weight	2.0 kg (with battery)
Package	Size	310mm × 320mm × 235mm

	Weight	3.7 kg

3. Hardware Specifications

Display	
Type	LED+TFT LCD
LCD Dimensions	3.2 inches
LCD Resolution	320X240
Recorder	
Type	Thermal array recorder
Recording speed	25mm/s
Waveform	Maximum 3 waveforms
Paper width	50mm

4. Data Storage

NIBP Measuring Result	4000 groups of NIBP results at most
Patient data	120 groups
Alarm	4000 groups
Trend review	1500 hours

5. Measuring Specifications

5.1ECG Monitoring

ECG

Lead	3 leads(RA,LA,LL) / 5 leads(RA,RL,LA,LL,V)
Lead system option	monitoring lead / standard lead
Gain	5mm/mv, 10mm/mv
Sweep speed	12.5mm/s, 25mm/s, 50mm/s
Wave gain	5%
Range of heart rate	Adult: 20~300bpm Neonate/Pediatric: 20~350bpm
Resolution	1 bpm
Precision	20~200bpm: 5% or ±5bpm whichever is greater 201~350bpm: 10%
Alarm setting	the limit of alarm (setup range: 20～350 bpm), and leads-off alarm display.
Aalarm method	Alarm with sound and lights, and record the data during alarm for the review.
Input resistance	≧5 MΩ
CMRR	≧89 dB
S-T detecting range	-2.00~2.00mv
Heart disorder analysis	No
Anti-polarized voltage	±500 mV
Baseline renewing time	<5 s after the defibrillation
ECG filter mode	mode 1(diagnostic), mode 2(monitoring), mode 3(operation)

Frequency characteristic	0.67Hz~40Hz
Safeguard	4000V high voltage isolation, anti-defibrillation,

5.2NIBP Monitoring

NIBP (Biocare)	
Method	Oscillometric
Application	Neonatal, pediatric and adult patients
Measurement Modes	
Manual	Adaptive or preset cuff inflation
Automatic	Host controlled (1-90 minutes as selected by host)
STAT	Restarts a new measurement after 5 or 10 second pause (host selectable); terminates after 5 minutes
Test Mode	Provides continuous output of system pressure
Data unit	mmHg / kPa optional
Data storage/review	4000 blood pressure value at most
Alarm setup	The range is the same as parameter measurement range of SYS、DIA、MAP
Alarm method	Sound light alarm， and record the alarm status for review
Measuring range	
Adult Mode	
SYS	40~260 (mmHg)

DIA	20~200 (mmHg)
MAP	26~220 (mmHg)
Pediatric Mode	
SYS	40~160(mmHg)
DIA	20~120(mmHg)
MAP	26~133(mmHg)
Neonate Mode	
SYS	40~130(mmHg)
DIA	20~100(mmHg)
MAP	26~110 (mmHg)
Resolution	1 mmHg
Transducer Accuracy	±3 mmHg, over full range
Max Average Error	±0.67kPa (±5 mmHg)
Max Standard Error	±1.067kPa (±8 mmHg)
Overpressure limit	Adult/Pediatric /Neonate Mode: 290/220/150 (mmHg)
Pulse Rate	30-220 BPM
Pulse Rate Accuracy	±2% or ±3 BPM, whichever is greater

NIBP (SunTech)	
Method of Measurement	Oscillometric. Diastolic values correspond to Phase 5 Korotkoff sounds.

Patients	Neonatal, pediatric and adult patients
Measurement Modes:	
Manual	Adaptive or preset cuff inflation
Automatic	Host controlled (1-90 minutes as selected by host)
STAT	Restarts a new measurement after 5 or 10 second pause (host selectable); terminates after 5 minutes
Test Mode	Cuff pressure will be hold after inflation for test
Data unit	mmHg / kPa optional
Data storage/review	4000 groups of NIBP results at most
Alarm setup	The range is the same as parameter measurement range of SYS, DIA, MAP
Alarm method	Alarm with sound and lights, and record the alarm status for review
Measuring range	
Adult Mode	
SYS	40~260 (mmHg)
DIA	20~200 (mmHg)
MAP	26~220 (mmHg)
Pediatric Mode	
SYS	40~160(mmHg)
DIA	20~120(mmHg)

MAP	26~133(mmHg)
Neonate Mode	
SYS	40~130(mmHg)
DIA	20~100 (mmHg)
MAP	26~110 (mmHg)
Resolution	1 mmHg
Pulse Rate Range	30 to 220 BPM (Beats Per Minute)
Pulse Rate Accuracy:	± 2% or ± 3 BPM, whichever is greater
Cuff Deflate Rate:	Deflation step size varies with heart rate, cuff pressure and cuff volume
Initial Inflation Pressure:	Adult: 160 mmHg (default),variable from 120 to 280 mmHg Pediatric: 120 mmHg (default), variable from 80 to 170 mmHg Neonate: 90 mmHg (default), variable from 60 to 140 mmHg
Clinical Accuracy	Meets accuracy requirements of ANSI/AAMI SP10: 1992 and 2002.
Transducer Accuracy	±3 mmHg between 0 mmHg and 300 mmHg for operating conditions between 0°C and 50°C.
Recommended Frequency of Pressure Transducer Calibration	The Pressure Transducer calibration should be verified on a yearly interval.
Operating Conditions	0°C to 50°C, 15% to 95% non-condensing humidity
Storage Conditions	-20°C to 65°C, 15% to 95% non-condensing humidity
Altitude	Measurement accuracy is not affected by altitude

Startup Initialization Period:	7 seconds
Patient Safety	Internal operating software ensures that: • Maximum cuff inflation time is limited to 75 seconds • Duration of blood pressure reading is limited to 130 seconds (Adult mode) 120 seconds (Adult Motion Tolerant mode) 90 seconds (Pediatric mode) 75 seconds (Neonate mode)
	Additional redundant safety circuitry oversees normal operation and will override to abort a reading if: • cuff pressure exceeds 300 mmHg (Adult &Pediatric modes) or 150mmHg (Neonate mode) at any time • the cuff has been inflated for 180 seconds (Adult & Pediatric modes) or 90 seconds (Neonate mode) The Module meets all relevant parts of the following Safety Standards: • IEC60601-1:1997 • IEC/EN60601-2-30:1999/2000 • AAMI SP10:1992/2002 • EN1060-1:1996 • EN1060-3:1997

5.3SpO2 Monitoring

SpO2 (Biocare)	
Measuring method	Dual wave length infrared wave
Measuring Range	0~100%

Alarm setup range	70~100%
Resolution	1%
Precision	±2% (70~100% adult/ Pediatric)
	±3% (70~100% neonate)
	Unspecified (0~69%)
Pulse rate	
Measuring Range	25~240bpm
Alarm setup range	25~240bpm
Precision	±3bpm (Geostationary) or ±5 bpm (Campaign)
Sweep speed	12.5mm/s, 25mm/s
Alarm setup	SPO2 overruns, pulse rate overruns
Alarm method	Alarm with sound and lights, and record the alarm status for review

SpO2 (NELLCOR)	
Measuring method	Dual wave length infrared wave
Measuring Range	0~100%
Alarm setup range	70~100%
Resolution	1%
Precision	±2% (70~100% adult/ Pediatric)
	±3% (70~100% neonate)

	Unspecified (0~69%)
Pulse rate	
Measuring Range	25~240bpm
Alarm setup range	25~240bpm
Precision	±3bpm (Geostationary) or ±5 bpm (Campaign)
Sweep speed	12.5mm/s, 25mm/s
Alarm setup	SPO2 overruns, pulse rate overruns
Alarm method	Alarm with sound and lights, and record the alarm status for review

SpO2 (MASIMO)	
Display Range	0.0%-100.0%
Calibration Range	60%-80%, 70%-100%
Calibration Standard	Invasive Co-oximeter
No Motion Accuracy(RMS)	≤2.0%, ≤3.0%
Motion Accuracy(RMS)	≤3.0%
Resolution	≤0.1%
Time to Display	≤8, ≤10, ≤20 seconds
Asystole Detection Time	≤8 seconds
Delay	≤10 seconds
Response Time	≤20 seconds

Display Update Frequency	≥1 HZ
Averaging Time	2-4,4-6,82,10,12,14,16secs
Trend	Every 2secs for 72hrs

5.4 RESP Monitoring

RESP	
Measuring method	The thorax impedance method (used with ECG leads)
Measuring range	15 ~ 120rpm
Resolution	1 rpm
Precision	The bigger one between ±2 rpm or ±2 %
Alarm setup	Respiration rate overruns, asphyxiation
Alarm method	Alarm with sound and lights, and record the alarm status for review

5.5 TEMP Monitoring

TEMP (Thermal Probe)	
Channel	1
Measuring mode	Thermal
Measuring and Alarm Range	0 ~ 50°C (32~122°F)
Resolution	0.1 °C
Measurement accuracy	± 0.1 °C (25 ~ 45°C)
	± 0.2 °C (others)

Average measurement time	< 60 s
Data unit	°C/ °F

TEMP(Infrared Probe)	
Measurement range	34°c~42.2°c (93.2°F ~108°F)
Resolution	0.1°c
Measurement accuracy	35.5°c~42°c: ±0.2°c
	Other: ±0.3°c
Measurement time	≤1s
Power supply of module	Power supply: DC3V button lithium battery Power consumption: ≤20mW Auto power off time: 60s±10s
Module size	140mm×38mm×30mm
Module weight	about 70g

5.6 EtCO2 Monitoring

IRMA (Phasein mainstream)	
Genaral	
Description	Extremely compact infrared mainstream multi-gas probe. Available in various parameter configurations.
Dimensions (WxDxH)	IRMA CO2: 38 x37 x 34 mm (1.49x1.45x1.34 inch)
Cable length	2.50 m±0.02 m

Weight	<25 g (cable excluded)
Power supply	IRMA CO2: 4.5-5.5 VDC, max 1.0 W (power on surge@5 V less than 350 mA during 200 ms)
Surface temperature (at ambient temp 23°C)	IRMA CO2: Max 41°C/106°F
Interface	Modified RS-232 serial interface operating at 9600 bps
Airway adapters	Disposable adult/pediatric: Adds less than 6 ml dead space Pressure drop less than 0.3 cm H2O@30 LPM Disposable infant: Adds less than 1 ml dead space Pressure drop less than 1.3 cm H2O@10 LPM
Data output	
Breath detection	Adaptive threshold, minimum 1 vol. % change in CO2 concentration
Respiration rate	0~150 bpm. The respiration rate is displayed after three breaths and the average value is updated every breath
Fi and ET	Fi and ET are displayed after one breath and have a continually updated breath average. IRMA CO2: CO2
Waveforms	YES
Diagnostic parameters	Atmospheric pressure, software and hardware revision, serial number.
Flags	Breath detected, apnea, check adapter, unspecified accuracy and sensor error.

Gas analyzer	
Probe	2~9 channel NDIR type gas analyzer measuring at 4–10µm. Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing Airway adapter. No span calibration required for the IR bench. Room air calibration of oxygen sensor performed automatically when changing airway adapter(<5 seconds)
Warm-up time	Full accuracy within 10 seconds for IRMA CO2
Rise time (@10 l/min)	CO2≤90 ms
Total system response time	<1 second

ISA (Phasein Sidestream)	
Genaral	
Description	Ultra-compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Dimensions (W·D·H)	ISA CO2/AX+: 33 x 78 x 49 mm (1.3" x 3.1" x 1.9")
Weight	ISA CO2/AX+: 130 g including cable
Ambient CO2	≤ 800 ppm
Power supply	4.5 to 5.5 VDC, ISA CO2: < 1.4 W (normal op.), < 1.8 W (peak @ 5 VDC)
Interface	USB or RS-232 serial interface. Software upgrade possible using the RS-232 serial interface.
Water handling	Sampling line with proprietary water removal tubing.

Sampling lines	2 ± 0.1 m and 3 ± 0.1 m versions
Sampling flow rate	50 ± 10 ml/min
Data output	
Breath detection	Adaptive threshold, minimum 1 vol % change in CO2 concentration.
Respiration rate	0 to 150 ± 1 breaths/min
Fi and ET	CO2
Waveforms	Up to five simultaneous gas concentration waveforms.
Diagnostic parameters	Atmospheric pressure, Cuvette pressure, Serial number, Software revision, Hardware revision
Flags	Breath detected, No breaths detected, Replace O2 sensor, Check sampling line, Unspecified accuracy, Sensor error
Gas analyzer	
Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 µm.
Compensations	ISA CO2: Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO2.
Calibration	No span calibration is required for the IR bench. An automatic zero reference calibration is performed at startup and then every 24 hours
Warm-up time	ISA CO2: < 10 seconds (Concentrations reported and full accuracy)
Typical rise time at 50 ml/min sample flow	CO2 ≤ 200 ms

Total system response time	< 3 seconds (with 2 m sampling line)

Accuracy and Interference Specification		
Accuracy		
Gas	**Range**	**Accuracy**
CO2	standard conditions: CO2: 0~15	±(0.2 vol%+2%of reading)
	standard conditions: CO2:15~25	Unspecified
	all conditions	±(0.3 vol%+4%of reading)
Note: The accuracy specification is valid for the operating temperature and humidity conditions specified, except for interference specified in the table “Interfering gas and vapour effects” below.		

Interfering Gas and Vapour Effects		
Gas or Vapour	**Gas level**	**IRMA CO2**
N2O 4)	60 vol%	- 1&2)
HAL 4)	4 vol%	- 1)
ENF,ISO,SEV 4)	5 vol%	+8%of reading 3)
DES 4)	15 vol%	+12%of reading 3)
Xe (Xenon) 4)	80 vol%	-10%of reading 3)
He(Helium) 4)	50 vol%	-6%of reading 3)
Metered dose inhaler propellants 4)	Not for use with metered dose inhaler propellants	
C2H5OH(Ethanol) 4)	0.3 vol%	- 1)
C3H7OH(Isopropanol) 4)	0.5 vol%	- 1)

CH3COCH3(Acetone) 4)	1 vol%	- 1)
CH4(Methane) 4)	3 vol%	- 1)
CO(Carbon monoxide) 5)	1 vol%	- 1)
NO(Nitrogen monoxide) 5)	0.02vo%	- 1)
O2 5)	100vol%	- 1&2)

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

Note 2: For probes not measuring N2O and/or O2 the concentrations shall be set from host. according to the instructions in section 4.2(SetN2O/SetO2),see also Appendix B. (IRMA CO2 measures neither N2O,nor O2.IRMA AX+ does not measure O2.)

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%.This means that if measuring on a mixture containing 5.0 vol% CO2 and 50 vol% Helium, the measured CO2 concentration will typically be (1-0.06)*5.0 vol%=4.7 vol% CO2.

Note 4: According to the EN ISO 21647:2004 standard.

Note 5: In addition to the EN ISO 21647:2004 standard.

Caution:

After being in a condensing atmosphere, the unit shall be stored for more than 24 hours in an environment equivalent to the operating humidity. The humidity range 50~100%is valid within the temperature range-40~40°C only.

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Care from hearts

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