iM 12 & iM 15

Technical Specifications

Product Specifications

1 Safety Specifications

1.1 Product Classification

Components	Type of Protection Against Electric Shock	Level of Protection Against Electric Shock	Liquid Intake Protection Grade	Level of Protection Against Explosion	Operating Mode
Host	Ⅰ	Non-nominal	General Equipment	Unsuitable	Continuation
ECG (Resp) Module	NA	CF(*)			
IBP Measuring Module (Optional)					
NIBP Measuring Module					
C.O. Measuring Module					
Temp Measuring Module					
SpO_2 Measuring Module					
CO_2 Measuring Module (Optional)		BF(*)			
AG Module (Optional)					

1.2 Environment Specifications

Equipment Environment (Host, Recorder, C.O. Module and IBP Module)			
Item	Temperature	Humidity (Non-Condensing)	Atmospheric Pressure
Operating	0℃～40℃ （32℉～104℉）	15%～80%	442.5 mmHg～805.5 mmHg （59 kPa～107.4 kPa）
Storage&Transport	-20℃～55℃ （-4℉～140℉）	10%～93%	165 mmHg～805.5 mmHg （22 kPa～107.4 kPa）
AG Module			
Item	Temperature	Humidity (Non-Condensing)	Atmospheric Pressure
Operating	0℃～40℃ （32℉～104℉）	10%～95%	393.8 mmHg～900 mmHg （52.5 kPa～120 kPa）
Storage&Transport	-40℃～75℃ (-40℉～167℉)	5%～100%	375 mmHg～900 mmHg （50 kPa～120 kPa）

1.3 Power Specifications

(AC) Input Voltage	100 V～240 V

Input Power	75 VA
Frequency	50 Hz/60 Hz (Allowable frequency error ±1Hz)
Fuse	3.15A/250V
Security Level	Category I ,Type BF, CF

2 Physical Specifications

Host		
	12 inches monitor	*15 inches monitor*
Weight	Approx. 4.5 kg	Approx. 5.0 kg
Size (L×W×H)	310 mm×163 mm×285 mm	370 mm×187 mm×313 mm

3 Hardware Specifications

Display	
Type	TFT LCD Screen
Dimensions	12.1 inches（12 inches monitor），15 inches（*15 inches monitor*）
Resolution	800×600 pixels（12 inches monitor），1024×768 pixels（*15 inches monitor*）
Screen Brightness	10-level, adjustable
LCD View Angle	Horizontal / vertical view angle at least 150°/120°
Recorder	
Type	Thermal array recorder
Horizontal Resolution	16 dots/mm (Paper Speed: 25.0 mm/s)
Vertical Resolution	8 dots/mm
Printing Paper Size	50 mm×20 m
Paper Speed	12.5 mm/s; 25.0 mm/s; 50.0 mm/s
Waveform	Max. 3 waveforms
Battery	
Dimensions	182 mm×71 mm×25.5 mm
Weight	0.3 kg
Type	Rechargeable lithium battery
Rated voltage	14.8 V
Battery Capacity	4.4 Ah
Length of Power Supply	In environment temperature ranging from 20 ℃ to 30 ℃ and under standard configuration, the continuous working time of a single battery is not less than 5 hours.
Time for recharging battery to 90% from zero power state	In environment temperature ranging from 20 ℃ to 30 ℃ and with the machine turning off, the charging time is not more than 8 hours to charge the battery to 90%.
Shutdown Delay	0 s, 0.5 s, 1 s, 1.5 s, 2 s
Host LED	
Physiological Alarm Indicator Lamp	1 (Dual color yellow & red)

Technical Alarm Indicator Lamp	1 (Blue)
Power Switch Indicator Lamp	1 (Green)
AC Power Indicator Lamp	1 (Green)
Battery Power Indicator Lamp	1 (Green)
Battery Charging Indicator Lamp	1 (Green)（Only for 12 inches monitor）
Keypad Backlight	5 (White)
Alarm Pause Key Backlight	1 (Red)
Speaker	Give out alarm sound (45 dB～85 dB), keystroke sound and QRS sound. Alarm sound complies with IEC 60601-1-8
Interface	
Power	1 AC power port
Network	Standard RJ45 network port, which can network with the central monitoring system and transmit all the patient monitored data to the central monitoring system.
USB	USB disk supported. For the manufacturer to upgrade and service the application software, and export data (Structurally 2 USB host interfaces supported)
VGA	Supported, for connection of external display
Analog Output Port	1 piece. It can be connected to oscilloscope for output of the analog signals.
Nurse Call System Port	1 piece. It can be connected to port of the nurse call system.
Equipotential Terminal Port	1 piece
ECG Analog Signal Output	
Bandwidth (-3 dB, reference 10Hz)	Surgery mode: 1 Hz～15 Hz Monitor mode: 0.5 Hz～40 Hz Diagnose mode: 0.05 Hz～150 Hz
Max. Transmission Delay	25ms (Wave filter closed under diagnose mode)
Sensitivity	1 V/mV ±5%
Accuracy of input signal reproduction	Using the method described in 4.2.7.1 of AAMI EC11 to test the overall system error, which is within ±5%; Using method A and D described in 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between sample rate and signal rate of the ECG module, digital systems may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings. This phenomenon, which is not physiologic, shall be clearly described in the operator's and service manuals.
IBP Analog Signal Output	

Bandwidth (-3 dB, reference 10Hz)	0 Hz～50 Hz
Max. Transmission Delay	30 ms (Filter closed)
Sensitivity	0.01 V/mmHg±5%

4 Data Storage

Trend Data	Short Trend (Trend Window Time 4 min, 40 min, 2 h) Resolution of Trend Chart 5 s, 30 s, 1 min, 10 min): Max. storage time: 72h. Long trend (Trend Window Time 4 h, 16 h, 32 h, 48 h) Resolution of Trend Chart 15 min, 30 min, 1 h, 2 h, 3 h): Max. storage time: 480h.
Parameter Alarm Event	700 parameter alarm events and manual events, as well as the parameter waveform related to the occurring time, wave length 10s
NIBP Measuring Result	Max. 1000 groups
Single-Channel ECG Waveform	Max. 2h
Holographic Waveform	Max. 2 min (Power cutoff storage not supported)

5 Wireless Network

Applicable Standard	IEEE 802.11b/g, compatible with wifi
Safe to use distance	20 cm
Frequency Range	2.412 GHz～2.472 GHz
Signal Path	1-13 (China)
Transmission Distance	30 m (Open area without obstruction)

6 Measuring Specifications

6.1 ECG Monitoring

Input Mode	3-Lead ECG input (Optional) 5-Lead ECG input (Standard) 12-Lead ECG input (Optional)
Lead Selection	Ⅰ, Ⅱ, Ⅲ(Optional) Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V1～V6 (Optional)
Lead Standard	AHA, IEC
Measuring Range of Heart Rate	Adult: 15 bpm～300 bpm Pedi: 15 bpm～350 bpm Neonate: 15 bpm～350 bpm

Heart Rate Display Tolerance	±1% or ±1 bpm, whichever is higher
Sensitivity	1.25 mm/mV (×1/8), 2.5 mm/mV (×1/4), 5.0 mm/mV (×1/2), 10.0 mm/mV (×1), 20.0 mm/mV (×2), 40.0 mm/mV (×4), Auto. Error: ±5%
Resolusion Stability	The resolusion change 1 minute after the instrument is powered on does not exceed 0.66% per minute. The total change within 1h does not exceed any available fixed gain setting by ±10%.
Sweep Speed	6.25 mm/s, 12.5 mm/s, 25.0 mm/s, 50.0 mm/s. Error: ±10%
Noise Level	≤30 μV_{p-p}
Input Circuit Current	≤0.1 μA
Input Impedance	≥2.5 MΩ
Patient Leakage Current	< 10μA
ESU Proof	Cutting Mode: 300 W Coagulation Mode: 100 W Recovery Time: ≤10 s
ESU Noise Inhibition	Tested acc. to 5.2.9.14 of ANSI/AAMI EC 13:2002: 1) The ECG signal track does not disappear; 2) Change in heart rate does not exceed 10% of the heart rate when the electrosurgical knife is not activated.
CMRR	Diagnose Mode: ≥89 dB Surgery & Monitor Mode: ≥100 dB
Time Constant	Monitor Mode: ≥0.3 s Diagnose Mode: ≥3.2 s
Frequency Response	Surgery Mode: 1 Hz-15 Hz; Monitor Mode: 0.5 Hz-40 Hz; Diagnose Mode: 0.05 Hz-150 Hz.
ECG Parameter Frequency Characteristics	Surgery Mode: Meet (+0.4 dB ～ (-3.0 dB)) requirements at 15 Hz. Monitor Mode: Meet (+0.4 dB ～ (-3.0 dB)) requirements at 0.5 Hz ～40 Hz. Diagnose Mode: Meet (+0.4 dB ～ (-1.0 dB)) requirements at 0.05 Hz ～60 Hz. Meet (+0.4 dB ～ (-3.0 dB)) requirements at 61 Hz ～150 Hz.
Notch	Monitor & Surgery Mode: notch filter automatically activated at 50 Hz/60 Hz Diagnose Mode: Notch filter manually activated or deactivated at 50 Hz/60 Hz
Range of Electrode Polarized Voltage	±300 mV d.c.
Lead Fall Testing Current	Measuring Electrode: < 0.1 μA Drive Electrode < 1 μA
Pacemaker Pulse	
Pacemaker Pulse Display Capacity	Pace-making mark can be displayed for the following pacemaker pulses: Pulse Amplitude: ±2 mV ～ ±100 mV Pulse Width: 0.1 ms ～ 2 ms Pulse Rise Time: 10 μs～ 100 μs Pacemaker pulse should be no overshoot
Pacemaker Pulse	The monitor can inhibit the pacemaker pulse that conforms to the following conditions:

Suppression Capacity	Pulse Amplitude: ±2 mV ～ ±100 mV Pulse Width: 0.1 ms ～ 2 ms Pulse Rise Time: 10μs～ 100 μs Pacemaker pulse should be no overshoot
Alarm Limit Specifications	**Range**
Upper Limit of ECG Heart Rate	Alarm upper limit for adult: (Lower limit+2) bpm～300 bpm Alarm upper limit for pedi: (Lower limit+2) bpm～350 bpm Alarm upper limit for neonate: (Lower limit+2) bpm～350 bpm
Lower Limit of ECG Heart Rate	Alarm lower limit for adult: 15 bpm～ (Upper limit-2)bpm Alarm lower limit for pedi: 15 bpm～ (Upper limit-2)bpm Alarm lower limit for neonate: 15 bpm～ (Upper limit-2)bpm
Resolution	±1 bpm
Accuracy	The tolerance of alarm limit setting is ±1 bpm. In addition, the ECF signal alarm below the publicized lower limit of the alarm will not fail. If the alarm is not disabled, the alarm will not fail if you enter the ECG input signal higher than the upper limit of alarm up to 300 bpm (350 bpm for neonate and pedi).
HR	
Heart Rate Testing Amplitude	±0.3 mV～±5 mV
Resolution	1 bpm
Alarm Time for Tachycardia	Acc. to ANSI/AAMI EC13:2002 Part 4.1.2.1 g). 4ah-Range: 11 s 4a-Range: 11 s 4ad-Range: 11 s 4bh-Range: 11 s 4b-Range: 11 s 4bd-Range: 11 s
Heart Rate Average	Acc. to ANSI/AAMI EC13:2002 Part 4.1.2.1 g). The average heart rate is obtained by the method below: If the interval of the last continuous 3 RR is higher than 1200ms, the heart rate is averaged based on the most recent 4 RR intervals; otherwise, the heart rate is averaged based on the most recent 12 RR intervals. The heart rate displayed on the screen is refreshed every second.
Response to Irregular Rhythm of the heart	Acc. to ANSI/AAMI EC13:2002 Part 4.1.2.1 e). The heart rate displayed after 20s stabilizing period is: 3a (Ventricular bigeminy)～ 80±1bpm 3b (Slow alternating ventricular bigeminy)～ 60 bpm±1 bpm 3c (Rapid alternating ventricular bigeminy)～ 120 bpm±1 bpm 3d (Bidirectional systoles)～ 90 bpm±1 bpm
Response Time to Heart Rate Change	Acc. to ANSI/AAMI EC13:2002 Part 4.1.2.1 f). Increase of heart rate: response time ≤11 s Decrease of heart rate: response time ≤11 s

High T-wave Suppression Capacity	Acc. to ANSI/AAMI EC13:2002 Part 4.1.2.1 c). The heart rate moniter inhibits all T-waves with amplitude lower than 1.2 mV, 100msQRS wave groups, T-wave period 180 ms and QT period 350ms.
Arrhythmia Type	a) Monitoring type: Asystole, VFib / VTac, VTac, Ventricular bradycardia, Extreme-Tachy, Extreme-Brady, Non-Sustained VT, PVC, Tachycardia, Bradycardia, VR, V-Bigeminy, V-Trigeminy, Irr.Rhythm, PVCs/min, Run PVCs＞2, Couplet, R on T, Multiform, HeartBeat Pause, Missed Beats. b) Pace-making: Pacemaker not captured (PNC), Pacemaker not paced (PNP).
ST Interval Measuring	
Range	(-2.0 mV)～(+2.0 mV)
Accuracy	Measuring Tolerance: measuring tolerance within (-0.8 mV)～(+0.8 mV) is ±0.02 mV or ±10%, whichever is higher. It not defined for other ranges.
ST Interval Updating Interval	A single heart beat interval or 1s, whichever is higher.

6.2 Respiration (Resp) Monitoring

Measuring Method	Chest Impedance Method
Measuring Lead	Lead I and II for selection. Lead I defaulted.
Respiration Exciting Waveform	< 300 μA, Sine signal, 62.8 kHz (±10%)
Range of Respiration Impedance	0.5 Ω～3 Ω
Range of Base Impedance	250 Ω-2000 Ω (Use of ECG cable with 1kΩ resistor)
Differential Input Impedance	> 2.5 MΩ
Brandwidth	0.2 Hz～2 Hz (-3 dB)
Waveform Sensitivity	×1/4, ×1/2, ×1, ×2, ×4, Auto
Sweep Speed	6.25 mm/s; 12.5 mm/s; 25.0 mm/s
Resolution	1 rpm
Accuracy	±2 rpm
Asphyxia Alarm	Off, 10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s
RR	
Range	Monitoring Range for adult: 0 rpm～120 rpm Monitoring Range for pedi: 0 rpm～150 rpm Monitoring Range for neonate: 0 rpm～150 rpm
Resolution	1 rpm
Respiration Monitoring Tolerance	Within 7 rpm～150 rpm, the measuring error is ±2 rpm or ±2%, whichever is higher. The tolerance is not defined for other ranges.
Asphyxia Alarm Tolerance	Within 10 s～40 s (Increase/decrease by 5s for each rotation of the knob), the asphyxia alarm tolerance is ±5 s.
Alarm Limit Specifications	**Range**

RR Upper Limit	Alarm upper limit for adult: (Lower limit+2) rpm～100 rpm Alarm upper limit for pedi: (Lower limit+2) rpm～100 rpm Alarm upper limit for neonate: (Lower limit+2) rpm～100 rpm
RR Lower Limit	Alarm lower limit for adult: 0 rpm～ (Upper limit-2) rpm Alarm lower limit for pedi: 0 rpm～ (Upper limit-2) rpm Alarm lower limit for neonate: 0 rpm～ (Upper limit-2) rpm

6.3 SpO_2 Monitoring

Alarm Limit Specifications	**Range**
SpO_2 Upper Limit	(Lower limit+1)%～100%
SpO_2 Lower Limit	80%～ (Upper limit-1)%
Accuracy Tolerance	±1% of the setting
Sensing element	Optical power <15 mW Red light wavelength: 658 nm~664 nm, infrared light: 897 nm~915 nm Information on the wavelength range is particularly useful for clinicians (e.g. in optical dynamic therapy)

SpO_2 Module

Monitoring Parameters	SpO_2 and Pulse Rate (PR)
Range	0%～100%
Resolution	1%
Data update peiriod	1 s
Accuracy	Within 70%～100%, the measuring tolerance is ±2%. Within 0%～69%, the measuring tolerance is not defined.

Masimo Oximeter Module

Monitoring parameter	Pulse oximetry (SpO_2) and pulse rate (PR)
Range	1%~100%
Resolution	1%
Accuracy	Adult and pedi:in the range of 70%~100%, the measurement error is ±2%; Neonate:in the range of 70%~100%, the measurement error is ±3%; In the range of 0%~69%, the measurement error is not defined.
Average time	2 s-4 s,4 s-6 s,8 s,10 s,12 s,14 s,16 s
Data update peiriod	1 s
Weak perfusion condition	Pulse amplitude: >0.02%; Light transmittance: >5%.
Weak perfusion SpO_2 accuracy	Adult and pedi:±2% Neonate:±3%.

Nellcor Oximeter Module

Monitoring parameter	Pulse oximetry (SpO_2) and pulse rate (PR)
Range	1%~100%
Resolution	1%
Data update peiriod	1 s
Accuracy	Adult:in the range of 70%~100%, the measurement error is ±2%; Neonate: in the range of 70%~100%, the measurement error is ±3%; Insufficiency:in the range of 70%~100%, the measurement error is ±2%; In the range of 0%~69%, the measurement error is not defined.

6.4 PR Specifications

Alarm Limit Specifications	**Range**
PR Upper Limit	Alarm upper limit for adult: (Lower limit+2) bpm～250 bpm Alarm upper limit for pedi: (Lower limit+2) bpm～250 bpm Alarm upper limit for neonate: (Lower limit+2) bpm～250 bpm
PR Lower Limit	Alarm lower limit for adult: 25 bpm～ (Upper limit-2)bpm Alarm lower limit for pedi: 25 bpm～ (Upper limit-2)bpm Alarm lower limit for neonate: 25 bpm～ (Upper limit-2)bpm

PR from SpO_2 Module

Range	30 bpm～250 bpm
Resolution	1 bpm
Measuring Tolerance	±2 bpm
Average Time	8 s

PR from Masimo SpO_2 Module

Range	25 bpm～240 bpm
Resolution	1 bpm
Measuring Tolerance	The measuring tolerance is ±3 bpm or ±1%, whichever is higher.
Average Time	2 s-4 s,4 s-6 s,8 s,10 s,12 s,14 s,16 s

PR from Nellcor SpO_2 Module

Range	20 bpm～300 bpm
Resolution	1 bpm
Measuring Tolerance	Adult and Neonate: 20 bpm～250 bpm: ±3 bpm Insufficiency: 251 bpm～300 bpm: not defined.

PR from IBP

Range	30 bpm～350 bpm
Resolution	1 bpm
Measuring Tolerance	30 bpm～200 bpm: ±1 bpm or ±1%, whichever is higher; 201 bpm～350 bpm: ±2%.

6.5 NIBP Monitoring

Measuring Method	Automatic oscillometric method				
Safety Requirements	Acc. to ANSI/AAMI SP-10 Non-invasive Automated Blood Pressure Monitor, Part 4.4				
Work Mode	Manual, Auto, STAT Measuring				
Measuring Time under Continuous Mode	5 min				
Measuring Interval under Auto Mode	1 min, 2 min, 3 min, 4 min, 5 min, 10 min, 15 min, 30 min, 60 min, 90 min, 2 h, 3 h, 4 h, 8 h, Timer interval error: < 10 s				
Resolution	1 mmHg (0.133kPa)				
Nominal Range of Monitoring	Blood Pressure (unit)		Adult	Pedi	Neonate
	Systolic Pressure	mmHg	40～270	40～200	40～135
		kPa	5.3～35.9	5.3～26.6	5.3～18.0
	Mean Pressure	mmHg	20～230	20～165	20～110
		kPa	2.7～30.6	2.7～22.0	2.7～14.7
	Diastolic Pressure	mmHg	10～210	10～150	10～100
		kPa	1.3～27.9	1.3～20.0	1.3～13.3
Range of Initial Inflation Pressure Setting	Adult: 80 mmHg, 100 mmHg, 120 mmHg,140 mmHg,160 mmHg,180 mmHg, 200mmHg,220 mmHg,240 mmHg Pedi: 80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 160 mmHg, 180 mmHg,200 mmHg Neonate: 60 mmHg, 80 mmHg, 100 mmHg, 120 mmHg, 145 mmHg				
Default of Initial Inflation Pressure	Adult: 160 mmHg (21.3 kPa) Pedi: 140 mmHg (18.6 kPa) Neonate: 100 mmHg (13.3 kPa)				
Measuring Tolerance of Pressure Source Testing	±3 mmHg (±0.4 kPa)				
Overpressure Protection	Adult state: when the pressure in cuff exceeds 297 mmHg (39.5 kPa)±3 mmHg (0.4 kPa), the control valve shall relieve the pressure. Pedi state: when the pressure in cuff exceeds 240 mmHg (31.9 kPa)±3 mmHg (0.4 kPa), the control valve shall relieve the pressure. Neonate state: when the pressure in cuff exceeds 147 mmHg (19.6 kPa)±3 mmHg (0.4 kPa), the control valve shall relieve the pressure.				

Alarm Limit Specifications	**Range**
Upper Limit of Systolic Blood Pressure	Adult: (Lower limit+5)mmHg～270 mmHg ((Lower limit+0.7)kPa～35.9 kPa) Pedi: (Lower limit+5)mmHg～200 mmHg ((Lower limit+0.7)kPa～26.6 kPa) Neonate: (Lower limit+5)mmHg～135 mmHg ((Lower limit+0.7)kPa～18.0 kPa)
Lower Limit of Systolic Blood Pressure	Adult: 40 mmHg～ (Upper limit-5)mmHg (5.3 kPa～ (Upper limit -0.7)kPa) Pedi: 40 mmHg～ (Upper limit-5)mmHg (5.3 kPa～ (Upper limit-0.7)kPa) Neonate: 40 mmHg～ (Upper limit-5)mmHg (5.3 kPa～ (Upper limit-0.7)kPa)
Upper Limit of Mean Blood Pressure	Adult: (Lower limit+5)mmHg～230 mmHg ((Lower limit+0.7)kPa～30.6 kPa) Pedi: (Lower limit+5)mmHg～165 mmHg ((Lower limit+0.7)kPa～21.9 kPa) Neonate: (Lower limit+5)mmHg～110 mmHg ((Lower limit+0.7)kPa～14.6 kPa)
Lower Limit of Mean Blood Pressure	Adult: 20 mmHg～ (Upper limit-5)mmHg (2.7 kPa～ (Upper limit-0.7)kPa) Pedi: 20 mmHg～ (Upper limit-5)mmHg (2.7 kPa～ (Upper limit-0.7)kPa) Neonate: 20 mmHg～ (Upper limit-5)mmHg (2.7 kPa～ (Upper limit-0.7)kPa)
Upper Limit of Diastolic Blood Pressure	Adult: (Lower limit+5)mmHg～210 mmHg ((Lower limit+0.7)kPa～27.9 kPa) Pedi: (Lower limit+5)mmHg～150 mmHg ((Lower limit+0.7)kPa～20.0 kPa) Neonatev: (Lower limit+5)mmHg～100 mmHg ((Lower limit+0.7)kPa～13.3 kPa)
Lower Limit of Diastolic Blood Pressure	Adult: 10 mmHg～ (Upper limit-5)mmHg (1.3 kPa～ (Upper limit-0.7)kPa) Pedi: 10 mmHg～ (Upper limit-5)mmHg (1.3 kPa～ (Upper limit-0.7)kPa) Neonate: 10 mmHg～ (Upper limit-5)mmHg (1.3 kPa～ (Upper limit-0.7)kPa)

6.6 Temperature (Temp) Monitoring

Range	0℃～50℃ (32℉～122℉)
Measuring Method	Thermal resistance method
Accuracy	The measuring tolerance is ±0.1℃ (exclusive of probe tolerance)
Updating Interval	1 s
Nominal Resistance of Temp. Sensor	2252 Ω (25℃)
Type of Temp. Sensor	YSI400 Sensor or its Compatible Sensor (Precision±0.1℃)
Channel Number	2 channels
Resolution	0.1℃
Alarm Indication	Audible & visual alarm, data and parameter blinking, alarm message displayed in the screen, 3 levels of alarm.
Alarm Limit Specifications	**Range (℃)**
Upper Limit	（Lower Limit +1）℃～50 ℃
Lower Limit	0 ℃～（Upper Limit -1）℃

6.7 IBP Monitoring

Measuring Method	Invasive direct measuring
Volume displacement (Abbott)	<0.04 mm^3/100mmHg
IBP	

Measuring Range		-50 mmHg～350 mmHg
Resolution		1 mmHg
Accuracy		±2% or ±1 mmHg，whichever is higher (exclusive of the sensor)
Updating Interval		1 s
Alarm Limit Specifications		**Range**
Art P1 P2	Upper Limit of Systolic Blood Pressure	(Lower limit+2) mmHg～350 mmHg （（Lower limit+0.3）kPa～46.7 kPa）
	Upper Limit of Mean Blood Pressure	
	Upper Limit of Diastolic Blood Pressure	
PA	Upper Limit of Systolic Blood Pressure	(Lower limit+2) mmHg～120 mmHg （（Lower limit+0.3）kPa～16.0 kPa）
	Upper Limit of Mean Blood Pressure	
	Upper Limit of Diastolic Blood Pressure	
Art	Lower Limit of Systolic Blood Pressure	0 mmHg～（Upper limit-2）mmHg （0 kPa～（Upper limit-0.3）kPa）
	Lower Limit of Mean Blood Pressure	
	Lower Limit of Diastolic Blood Pressure	
P1 P2	Lower Limit of Systolic Blood Pressure	-50 mmHg～（Upper limit-2）mmHg （-6.7 kPa～（Upper limit -0.3）kPa）
	Lower Limit of Mean Blood Pressure	
	Lower Limit of Diastolic Blood Pressure	
PA	Lower Limit of Systolic Blood	-6 mmHg～（Upper limit-2）mmHg （-0.8 kPa～（Upper limit-0.3）kPa）

	Pressure	
	Lower Limit of Mean Blood Pressure	
	Lower Limit of Diastolic Blood Pressure	
LAP RAP ICP CVP	Upper Limit of Mean Blood Pressure	（Lower limit+2）mmHg～40 mmHg （（Lower limit+0.3）kPa～5.3 kPa）
	Lower Limit of Mean Blood Pressure	-10 mmHg～（Upper limit-2）mmHg （-1.3 kPa～（Upper limit-0.3）kPa）

6.8 CO_2 Monitoring (Optional)

Measuring Mode	Sidestream type (support 50ml/min pumping rate), mainstream type
Measuring Method	Infrared radiation absorption technique

Phasein Sidestream ISA Module

Measuring Method	Infrared Spectrum Method
Measuring Mode	Sidestream
Range	0%～25%
Accuracy	At 0%～25%: ± (0.2%+2% of reading) At 15%～25%: undefined
Unit selection	%, mmHg, kPa
Operating temperature	0 ℃～50 ℃ (32 ℉～122 ℉)
Storage&Transport temperature	-40 ℃～70 ℃ (-40 ℉～158 ℉)
Operating humidity	10 %～95 % (non-condensing)
Storage&Transport humidity	5 %～100 % (non-condensing)
Operating atmospheric pressure	52.5 kPa～120 kPa（393.75 mmHg～900 mmHg）
Storage&Transport atmospheric pressure	20 kPa～120 kPa（150 mmHg～900 mmHg）
Preheating time	< 10 s (Report the concentration and reach the highest precision)
Total System Response Time	< 3 s (use of 2m sampling tube)
Primary agent threshold (ISA OR+/AX+)	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%
Secondary agent threshold (ISA OR+/AX+)	0.2 vol% + 10% of total agent concentration

Airway Leakage	≤0.5 ml/min
Range of Breathing Rate	0 rpm～150 rpm
Accuracy of Breathing Rate	±1 rpm
Asphyxia Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s, 45 s, 50 s, 55 s, 60 s
Sampling Flow Rate	50 ml/min ±10 ml/min
Automatic Pressure Compensation	yes
Alarm Limit Specifications	**Range**
$EtCO_2$ Upper Limit	（Lower Limit +2）mmHg～99 mmHg
$EtCO_2$ Lower Limit	0 mmHg～（Upper Limit -2）mmHg
$FiCO_2$ Upper Limit	0 mmHg～99 mmHg
awRR Upper Limit	(Lower limit+2) rpm～100 rpm
awRR Lower Limit	0 rpm～ (Upper limit-2) rpm

Phasein Mainstream IRMA Module

Measuring Method	Infrared Spectrum Method
Measuring Mode	Mainstream
Range	0%～25%
Accuracy	Range:0 %～15 %, Default: ±（0.2 %+ reading 2 %）; Range:15%～25%, Default: Undefined。
Resolution	1 mmHg (0.133 kPa)
Unit selection	%, mmHg, kPa
Operating temperature	0 ℃～40 ℃（32 ℉～104 ℉）
Storage&Transport temperature	-40 ℃～75 ℃（-40 ℉～167 ℉）
Operating humidity	10 %～95 % (non-condensing)
Storage&Transport humidity	5 %～100 % (non-condensing)
Operating atmospheric pressure	52.5 kPa～120 kPa（393.75 mmHg～900 mmHg）
Storage&Transport atmospheric pressure	50 kPa～120 kPa（375 mmHg～900 mmHg）
Total System Response Time	< 1 s
Primary agent threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.
Secondary agent threshold	0.2 vol% + 10% of total agent concentration
Range of Breathing Rate	0 rpm～150 rpm
Accuracy of Breathing Rate	±1 rpm

Asphyxia Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s, 45 s, 50 s, 55 s, 60 s
Automatic Pressure Compensation	yes
Alarm Limit Specifications	**Range**
$EtCO_2$ Upper Limit	（Lower Limit +2）mmHg～99 mmHg
$EtCO_2$ Lower Limit	0 mmHg～（Upper Limit -2）mmHg
$FiCO_2$ Upper Limit	0 mmHg～99 mmHg
awRR Upper Limit	(Lower limit+2) rpm～100 rpm
awRR Lower Limit	0 rpm～ (Upper limit-2) rpm

Respironics Sidestream LoFlo Module

Measuring Method	Infrared Spectrum Method
Measuring Mode	Sidestream
Preheating time	Max. length of waveform is 20s. Full accuracy requirements satisfied after 2min (environment temp.: 25℃)
Range	0%～19.7% (0 mmHg ～150 mmHg) (0 kPa～20 kPa)
Resolution	0.1 mmHg 0 mmHg～69 mmHg 0.25 mmHg 70 mmHg～150 mmHg
Stability	Short-term drift: ≤0.8 mmHg (0.1 kPa) within 4h Long-term drift: accuracy maintained within 120h.
Unit selection	%, mmHg, kPa
Operating temperature	0 ℃～40 ℃（32 ℉～104 ℉）
Storage temperature	-40 ℃～70 ℃（-40 ℉～158 ℉）
Operating humidity	10 %～90 % (non-condensing)
Storage humidity	10 %～90 % (non-condensing)
Storage atmospheric pressure	53.33 kPa～106.67 kPa（400 mmHg～800 mmHg）
Accuracy (Gas Temp. at 25℃)	0 mmHg～40 mmHg (0 kPa～5.3 kPa), ±2 mmHg (0.27 kPa) 41 mmHg～70 mmHg (5.5 kPa～9.3 kPa), ±5% of the reading 71 mmHg～100 mmHg (9.4 kPa～13.3 kPa), ±8% of the reading 101 mmHg～150 mmHg (13.4 kPa～20 kPa), ±10% of the reading (When the breathing rate is **>** 80 rpm, all ranges are ±12% of the reading)
Total System Response Time	**<** 3 s
Range of Breathing Rate	2 rpm～150 rpm
Accuracy of Breathing Rate	±1 rpm
Asphyxia Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s, 45 s, 50 s, 55 s, 60 s
Sampling Flow Rate	≥50 ml/min（100Hz）

Automatic Pressure Compensation	no
Alarm Limit Specifications	**Range**
$EtCO_2$ Upper Limit	（Lower Limit +2）mmHg～99 mmHg
$EtCO_2$ Lower Limit	0 mmHg～（Upper Limit -2）mmHg
$FiCO_2$ Upper Limit	0 mmHg～99 mmHg
awRR Upper Limit	(Lower limit+2) rpm～100 rpm
awRR Lower Limit	0 rpm～ (Upper limit-2) rpm

Respironics Mainstream CAPNOSTAT5 Module

Measuring Method	Infrared Spectrum Method
Measuring Mode	Mainstream
Preheating time	Max. length of waveform is 15s. Full accuracy requirements satisfied after 2min (environment temp.: 25℃)
Range	0%～19.7% (0 mmHg～150 mmHg) (0 kPa～20 kPa)
Resolution	0.1 mmHg 0 mmHg～69 mmHg 0.25 mmHg 70 mmHg～150 mmHg
Stability	Short-term drift: ≤0.8 mmHg (0.1 kPa) within 4h Long-term drift: accuracy maintained within 120h.
Rise Time	< 60 ms
Unit selection	%, mmHg, kPa
Operating temperature	0 ℃～45 ℃（32 ℉～113 ℉）
Storage temperature	-40 ℃～70 ℃（-40 ℉～158 ℉）
Operating humidity	10 %～90 % (non-condensing)
Storage humidity	0 %～90 % (non-condensing)
Storage atmospheric pressure	50 kPa～106 kPa（375 mmHg～795 mmHg）
Accuracy (Environment Temp. at 35℃)	0 mmHg～40 mmHg (0 kPa～5.3 kPa), ±2 mmHg (0.27 kPa) 41 mmHg～70 mmHg (5.5 kPa～9.3 kPa), ±5% of the reading 71 mmHg～100 mmHg (9.4 kPa～13.3 kPa), ±8% of the reading 101 mmHg～150 mmHg (13.4 kPa～20 kPa), ±10% of the reading
Range of Breathing Rate	0 rpm～150 rpm
Accuracy of Breathing Rate	±1 rpm
Asphyxia Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s, 45 s, 50 s, 55 s, 60 s
Sampling Flow Rate	100 Hz
Automatic Pressure Compensation	no
Alarm Limit	**Range**

Specifications	
$EtCO_2$ Upper Limit	（Lower Limit +2）mmHg～99 mmHg
$EtCO_2$ Lower Limit	0 mmHg～（Upper Limit -2）mmHg
$FiCO_2$ Upper Limit	0 mmHg～99 mmHg
awRR Upper Limit	(Lower limit+2) rpm～100 rpm
awRR Lower Limit	0 rpm～ (Upper limit-2) rpm

Kingst KM7002-V33/KM7003-V40 **Sidestream Module**

Measuring Method	Non-scattering Infrared Gas Analysis
Measuring Technology	Non-dispersive Infrared Gas Analysis (NIDR)
Range	0%～20%　(0 mmHg～150 mmHg)　(0 kPa～20 kPa)
Protection Level / Type	BF
Preheating time	2 min at 25 ℃
Response Time	50 ml/min
Delay Time	50 ml/min
Fully-automatic Drift Calibration	Automated according to the time and temperature. Time 5 s～8 s
Operating temperature	5 ℃～50 ℃（41 ℉～122 ℉）
Storage temperature	-40 ℃～70 ℃（-40 ℉～158 ℉）
Environment humidity	30 %～75 % (non-condensing)
Environment pressure	80 kPa～106 kPa（600 mmHg～795 mmHg）
Airway Leakage	< 0.1% (within the flow range above)
Accuracy	When < 5.0%: ±0.3% (±2.0 mmHg) (0.27 kPa) When ≥5.0%: < 6% of the reading
Range of Breathing Rate	3 rpm～150 rpm
Accuracy of Breathing Rate	1% or ±1 rpm, whichever is higher.
Asphyxia Alarm Delay	30 s, 35 s, 40 s, 45 s, 50 s, 55 s, 60 s
Automatic Pressure Compensation	yes
Alarm Limit Specifications	**Range**
$EtCO_2$ Upper Limit	（Lower Limit +2）mmHg～99 mmHg
$EtCO_2$ Lower Limit	0 mmHg～（Upper Limit -2）mmHg
$FiCO_2$ Upper Limit	0 mmHg～99 mmHg
awRR Upper Limit	(Lower limit+2) rpm～100 rpm
awRR Lower Limit	0 rpm～ (Upper limit-2) rpm

6.9 C.O. Specifications(Optional)

Measurement method	Thermodilution method	
Measuring range	C.O.:	0.01～20L/min
	TB:	23～43℃
	TI:	0～27℃
Resolution	C.O.:	0.01L/min
	TB, TI:	0.1℃
Accuracy	C.O.:	±5% or ±0.1 L /min, whichever is greater
	TB, TI:	±0.1°C (without sensor)
Alarm Limit Specifications	Range	
TB Upper Limit	(Lower Limit＋1.1)～43℃ (Lower Limit＋2)～109.4℉	
TB Lower Limit	23～(Upper Limit－1.1)℃ 73.4～(Upper Limit－2)℉	

6.10 AG Specifications(Optional)

Measurement method	Infrared radiation absorption characteristics	
Warm-up time	30 s	
Measuring range	CO_2:	0%～25%
	O_2:	0%～100%
	N_2O:	0%～100%
	Des:	0%～25%
	Sev:	0%～25%
	Enf:	0%～25%
	Iso:	0%～25%
	Hal:	0%～25%
	awRR:	0 rpm～254 rpm
Resolution	CO_2: 1 mmHg awRR: 1 rpm	
Measurement accuracy drift	Meet the accuracy requirements within 6 hours	
Suffocation alarm delay	20 s、25 s、30 s、35 s、40 s、45 s、50 s、55 s、60 s	
Update time	1 s	
IRMA AX+	Primary agent threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.

	Secondary agent threshold	0.2 vol% + 10% of total agent concentration
ISA OR+/AX+	Primary agent threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.
	Secondary agent threshold	0.2 vol% + 10% of total agent concentration

Interfering gases and steam effect

gases and steam	Gas concentration	Carbon dioxide			
		IRMA CO_2、OR	IRMA AX+/OR+	Anesthetic gas	Nitrous oxide
N_2O[4)]	60 vol%	-[1&2)]	-[1&2)]	-[1)]	-[1)]
Hal[4)]	4	-[1)]	-[1)]	-[1)]	-[1)]
Enf，Iso，Sev[4)]	5	Reading of +8%[3)]	-[1)]	-[1)]	-[1)]
Des[4)]	15	Reading of +12%[3)]	-[1)]	-[1)]	-[1)]
Xe（Xenon）[4)]	80	Reading of -10%[3)]		-[1)]	-[1)]
He（Helium）[4)]	50	Reading of -6%[3)]		-[1)]	-[1)]
Quantitative spray 4）	Not for quantitative spray				
Ethanol[4)]	0.3	-[1)]	-[1)]	-[1)]	-[1)]
Isopropano[4)]	0.5	-[1)]	-[1)]	-[1)]	-[1)]
Acetone[4)]	1	-[1)]	-[1)]	-[1)]	-[1)]
Methane 4)	3	-[1)]	-[1)]	-[1)]	-[1)]
Carbon monoxide[4)]	1	-[1)]	-[1)]	-[1)]	-[1)]
Nitric oxide 5)	0.02	-[1)]	-[1)]	-[1)]	-[1)]
Oxygen 5)	100	-[1&2)]	-[1&2)]	-[1)]	-[1)]

Alarm Limit Specifications	**Range**
$EtCO_2$ Upper Limit	（Lower Limit +2）mmHg～99 mmHg
$EtCO_2$ lower limit	0 mmHg～（Upper Limit -2）mmHg
$FiCO_2$ Upper Limit	0 mmHg～99 mmHg
awRR Upper Limit	(lower limit+2) rpm~100 rpm
awRR lower limit	0 rpm~(upper limit-2) rpm
FiEnf Upper Limit	(lower limit+0.2)%~8%
FiEnf lower limit	0%~(upper limit-0.2)%

EtEnf Upper Limit	(lower limit+0.2)%~8%
EtEnf lower limit	0%~(upper limit-0.2)%
EtHal Upper Limit	(lower limit+0.2)%~8%
EtHal lower limit	0%~(upper limit-0.2)%
Filso Upper Limit	(lower limit+0.2)%~8%
Filso lower limit	0%~(upper limit-0.2)%
Etlso Upper Limit	(lower limit+0.2)%~8%
Etlso lower limit	0%~(upper limit-0.2)%
EtSev Upper Limit	(lower limit+0.2)%~10%
EtSev lower limit	0%~(upper limit-0.2)%
FiSev Upper Limit	(lower limit+0.2)%~10%
FiSev lower limit	0%~(upper limit-0.2)%
EtDes Upper Limit	(lower limit+0.2)%~22%
EtDes lower limit	0%~(upper limit-0.2)%
FiDes Upper Limit	(lower limit+0.2)%~22%
FiDes lower limit	0%~(upper limit-0.2)%
FiO_2 Upper Limit	(lower limit+16) mmHg~760 mmHg((lower limit+2.1) kPa~101.1 kPa)
FiO_2 lower limit	136 mmHg~(upper limit-16) mmHg(18.1 kPa~(upper limit-2.1) kPa)
EtO_2 Upper Limit	(lower limit+16) mmHg~760 mmHg((lower limit+2.1) kPa~101.1 kPa)
EtO_2 lower limit	136 mmHg~(upper limit-16) mmHg(18.1 kPa~(upper limit-2.1) kPa)
FiN_2O Upper Limit	(lower limit+2)%~100%
FiN_2O lower limit	0%~(upper limit-2)%
EtN_2O Upper Limit	(lower limit+2)%~100%
EtN_2O lower limit	0%~(upper limit-2)%

6.11 Recorder Specifications

Recorder	To record the patient information, the hospital information, waveform, parameters and others displayed in the screen
Method	Thermal array recorder
Printing Paper	Thermal paper

Print Resolution	8 dots/mm on Y-Axis
Delay Characteristics	≤0.5 mm
Amplitude-frequency Characteristics	Monitor Mode: 0.5 Hz～25 Hz; Diagnose Mode: 0.05 Hz～100 Hz.
Time Constant	≥0.3 s

Biocare

Care from hearts

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

Headquarters: 7/F, Block A, Shenzhen Mingyou Industrial Products Exhibition & Procurement Center, Baoyuan Road, Xixiang Sub-district, Bao'an District, 518102 Shenzhen, P.R. China

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E-mail: sales@biocare.com.cn

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

SHENZHEN BIOCARE BIO-MEDICAL EQUIPMENT CO., LTD.
#16-1，JINHUI ROAD, JINSHA COMMUNITY, KENGZI SUB-DISTRICT, PINGSHAN NEW DISTRICT, 518122 SHENZHEN, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:	*PATIENT MONITOR* *TYPE: IM 12, PM-900* *GMDN CODE: 33586*
CLASSIFICATION - *ANNEX IX*:	*CLASS IIB, RULE 10*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX VII.3*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	*G1 17 0565758 004*
EC REP EUROPEAN REPRESENTATIVE:	*SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)* *Eiffestraße 80, 20537 HAMBURG, GERMANY*

START OF CE-MARKING: *2012-08-02*

PLACE, DATE OF DECLARATION:	*SHENZHEN P.R.C., 2017-05-10*
SIGNATURE:	_____ *NAME: CHEN JUN* *POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)*

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 05 65758 004

Manufacturer:

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

#16-1
Jinhui Road,Jinsha Community,Kengzi Sub-District
Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Digital Electrocardiograph, Patient Monitor, B-Ultrasonic Diagnostic Equipment, Doppler Fetal Heart Rate Detector, Infusion Pump, Syringe Pump, Fingertip Pulse Oximeter, Handheld Pulse Oximeter, Fetal/Maternal Monitor, Fetal Monitor, Color Doppler Ultrasound System, Central Monitoring System, Ambulatory Electrocardiographs, Ambulatory blood pressure recorders, and associated software.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ16896041

Valid from: 2017-05-10
Valid until: 2020-03-19

Date, 2017-05-10

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 05 65758 004

Facility(ies):

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
#16-1, Jinhui Road,Jinsha Community,Kengzi Sub-District,
Pingshan New District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 17 02 65758 001

Holder of Certificate: **Shenzhen Biocare Bio-Medical Equipment Co., Ltd.**

#16-1
Jinhui Road,Jinsha Community,Kengzi Sub-District
Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
#16-1, Jinhui Road,Jinsha Community,Kengzi Sub-District, Pingshan New District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of Digital Electrocardiograph, B-Ultrasonic Diagnostic Equipment, Patient Monitor, Fetal Monitor, Doppler Fetal Heart Rate Detector, Infusion Pump, Syringe Pump, Fingertip Pulse Oximeter, Handheld Pulse Oximeter, Ambulatory electrocardiographs, Ambulatory blood pressure recorder and associated software, Fetal/Maternal Monitor, Color Doppler Ultrasound System, Central Monitoring System.

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ16896041

Valid from: 2017-04-01

Valid until: 2020-03-31

Date, 2017-03-29

Stefan Preiß

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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