IRADIMED

3880

MRI Patient Monitoring System

TECHNICAL SPECIFICATION SHEET

REVISION A

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If you have questions or require additional information that is not covered in this booklet, please contact an IRadimed representative at: **1-866-677-8022**

1. Technical Specifications

1.1. Display

Technical Parameters	Technical Detail
Type:	Color TFT resistive touchscreen
Screen Size:	25.7 cm (10.1 inches) diagonal
Pixels:	800 by 480
Backlight:	LED
Screen Update Rate	2 Hz
Waveform Display Mode:	Moving Waveform
Waveform Display Width:	~145 mm
Waveform Display Height:	
ECG Single Waveform:	~48mm max
ECG Dual Waveform:	~20mm max
All other Waveforms:	~25mm max

1.2. User Interface

1.2.1. Monitor

Technical Parameters	Technical Detail
Power:	Rotary On, Off
Feature Hard Keys:	Trends, Print, NIBP Start/Stop and Alarm Silence
Setup Hard Keys:	Setup and Standby
Soft Keys:	Touchscreen

1.2.2. Tablet

Technical Parameters	Technical Detail
Power:	Push Button On, Off
Feature Hard Keys:	Trends, Print, NIBP Start/Stop and Alarm Silence
Setup Hard Keys:	Setup and Standby
Soft Keys:	Touchscreen

1.2.3. PODS

Technical Parameters	Technical Detail
Power:	Push Button On, Off
Hard Keys:	Channel Selection

1.2.4. Base Station

Technical Parameters	Technical Detail
Power:	Toggle
Channel Select:	Button

1.3. Application Features

1.3.1. Trend Reports

Technical Parameters	Technical Detail
Types:	Tabular
Trend Memory:	50 readings
Tabular Intervals:	3, 5, 8, 10, 15, 30, Auto NIBP
Data Types:	HR, SpO_2, NIBP, $EtCO_2$, Resp, Temp, MAC, O_2

1.3.2. Alarms

Technical Parameters	Technical Detail
Indication:	Audible & Visual
Levels:	High, Medium, Low and Information Messages
Volume:	User Adjustable, 50 to 85 dba, or OFF
Silence:	Permanent or 2 minutes timed hold

1.3.3. Safety Standards

Technical Parameters	Technical Detail
IEC:	60601-1, 60601-1-2, 60601-1-8, 60601-2-27, 60601-2-49, 80601-2-30, 80601-2-55, 80601-2-56, 80601-2-61
Med Device Directive:	93/42/EEC, 2007/47/EEC
Defibrillator Protection: Defibrillator Recovery Time:	Up to 5 KV During a defibrillation procedure, the ECG waveform will saturate then recover in less than 5 seconds

1.4. Physical Specifications

1.4.1. Height

Technical Parameters	Technical Detail
3880 Monitor:	23 cm (8.8 inches)
3885-T Remote Tablet:	19.6 cm (7.7 inches)
3885-B Base Station:	18.8 cm (7.4 inches)
3881/3882 Wireless PODS:	9.5 cm (3.8 inches)
3886 Multi-Gas Unit	8 cm (3.13 inches)

1.4.2. Width

Technical Parameters	Technical Detail
3880 Monitor:	29 cm (11.4 inches)
3885-T Remote Tablet:	26.7 cm (10.5 inches)
3885-B Base Station:	38 cm (15 inches)
3881/3882 Wireless PODS:	2.0 cm (0.8 inches)
3886 Multi-Gas Unit	14.7 cm (5.8 inches)

1.4.3. Depth

Technical Parameters	Technical Detail
3880 Monitor:	12.7 cm (5 inches)
3885-T Remote Tablet:	4.5 cm (1.8 inches)
3885-B Base Station:	12 cm (4.8 inches)
3881/3882 Wireless PODS:	5.7 cm (2.3 inches)
3886 Multi-Gas Unit	10.2 cm (4.1 inches)

1.4.4. Weight

Technical Parameters	Technical Detail
3880 Monitor:	4 kg (8.9 lbs)
3885-T Remote Tablet:	1.6 kg (3.6 lbs)
3885-B Base Station:	2.1 kg (4.6 lbs)
3881/3882 Wireless PODS:	73 g (0.16 lbs) (without sensors/leads)
3886 Multi-Gas Unit	1.04 kg (2.3 lbs)

1.5. Electrical Specifications

	Technical Parameters	Technical Detail
Power Requirements	Voltage Range: (All 3880 system components)	85 - 264 VAC
	Frequency Range:	50 - 60 Hz
	Max Consumption: 3880 Monitor 3885-B Base Station 3886 Multi-Gas Unit	 < 40 VA during charging < 65 VA during charging, 3885-B < 10 VA
Battery Capacity	3880 Monitor:	14.8 V at 6 Ah Lithium Polymer
	3885-T Remote Tablet:	7.4 V at 6 Ah Lithium Polymer
	3881/3882 W ireless PODS:	3.7 V at 1200 mAh Lithium Polymer
Battery Operation Time	3880 Monitor:	>8 hours with NIBP readings every 5 minutes
	3885-T Remote Tablet:	>10 hours
	3881/3882 Wireless PODS:	>12 hours
Battery Charge Time	3880 Monitor:	< 5 hours to 90% capacity
	3885-T Remote Tablet:	< 5 hours to 90% capacity
	3881/3882 Wireless PODS:	< 3 hours to 90% capacity
Power On	Boot Time:	< 4 seconds

1.6. Environmental Specifications

	Technical Parameters	Technical Detail
Operating	All 3880 system components	
	Temperature Range:	+10° to + 40° C (+50° to + 104° F)
	Humidity Range:	5% to 85% RH, non-condensing
	Altitude Range:	Sea level to 5,000 meters (equivalent pressure of 760 mmHg to 405 mmHg)
Storage	All 3880 system components	
	Temperature Range:	-20° to + 50° C (-4° to + 122° F)
	Humidity Range:	5% to 95% RH, non-condensing
	Altitude Range:	Sea level to 5,000 meters (equivalent pressure of 760 mmHg to 405 mmHg)

1.7. MRI Conditions

	Technical Parameters	Technical Detail
3880 *Monitor*	MR Environment Safety:	MRI Conditional
	Magnetic Field Limit:	30,000 Gauss
	MRI System:	0.5 to 3.0 Tesla MRI Systems
3881/3882 Wireless *PODS*	MR Environment Safety:	MRI Conditional
	SAR:	≤4 W/kg whole body average SAR
	Magnetic Field Limit:	30,000 Gauss
	MRI System:	0.5 to 3.0 Tesla MRI Systems
3885-T Remote *Tablet*	MR Environment Safety:	MRI Conditional
	Magnetic Field Limit:	15,000 Gauss
3885-B Base *Station*	MR Environment Safety:	MRI Unsafe
Accessories	MR Environment Safety:	MRI Safe as listed in Section 9.1-9.7
3886 Multi-Gas Unit	Magnetic Field Limit:	MR conditional 600 gauss

1.8. Recorder

Technical Parameters	Technical Detail
Technique:	Thermal line recorder at 3885-B Base Station
Data Type:	Single or Dual Waveform; Tabular
Paper Speed:	25mm/s or 50mm/s

1.9. Gating

Technical Parameters	Technical Detail
Technique:	Cardiac
Digital Pulse:	3.3 p-p signal with a pulse duration of 10ms ± 3ms
Analog:	1V / mV ECG < 12mS delay, < 2.5 mS jitter

1.10. Vital Signs

1.10.1. ECG

Technical Parameters	Technical Detail
Lead Set Configuration:	3 and 5 lead
Lead Color:	AAMI/AHA and IEC
Lead Configurations:	I, II, III, V, AVF, AVR, AVL
Lead Fail:	Sensing imbalance using 10 nA DC Current applied to each electrode
Input Impedance:	> 2.5MΩ (according to IEC 60601-2-27, 50.102.3)
Electrode Contact Impedance:	≤ 20K ohms @ 10 Hz
Heart Rate:	30 - 250 bpm
Heart Rate Accuracy:	± 10% or ± 5 BPM, whichever is greater as tested in Monitor Filter Mode and in the absence of MR gradients. With MRI gradients, accuracy of indicated HR may be affected.
Heart Rate Resolution:	1 beat per minute (BPM)
Heart Rate T-Wave Rejection:	1.3 mV with a 1mV QRS amplitude
Cardiotach Sensitivity:	200 µV minimum
Cardiotach Bandwidth:	0.5 - 40 Hz
Heart Rate (HR) Averaging Method:	Five point Mean filter
Heart Rate Meter Accuracy and Response to Irregular Rhythm:	A1: Ventricular bigeminy: 40 BPM A2: Slow alternating ventricular bigeminy: 30 BPM A3: Rapid alternating ventricular bigeminy: 59 BPM A4: Bidirectional systoles 60 BPM
Response Time of Heart Rate Meter to Change in Heart Rate:	HR change from 80 to 120 BPM: 6 sec HR change from 80 to 40 BPM: 14 sec
Time to Alarm for Tachycardia:	B1 - Vent Tachycardia 1 mVpp, 206 BPM: Time to 99BPM Gain 0.5 (12.03, 11.04, 14.1, 11.8, 11.4) Average: 13 sec (The monitoring system may temporarily exit the alarm condition during the arrhythmia waveform duration.) Gain 1.0 (11.9, 11.6, 9.2, 9.6, 10.9) Average: 13 seconds Gain 2.0 (8.8, 9.1, 10.3, 9.4, 12.1) Average: 12 seconds B2 - Vent Tachycardia 2 mVpp, 195 BPM: Time to 99 BPM Gain 0.5 (9.0, 10.4, 12.3, 8.1, 10.4) Average: 10 seconds Gain 1.0 (8.4, 7.7, 12.5, 7.7, 8.3) Average: 3 seconds Gain 2.0 (9.7, 12.6, 8.9, 11.8, 8.3) Average: 4 seconds

1.10.2. SpO_2

Technical Parameters	Technical Detail
Technique:	Masimo SET®
Saturation Range:	1% - 100%
Saturation Accuracy:	+/- 3% at 70% - 100% (full scale) <70% oxygen accuracy is unspecified
Saturation Resolution:	1%
Pulse Rate Range:	30 - 240 ppm
Pulse Rate Accuracy:	± 3 ppm
Pulse Rate Resolution:	1 pulse per minute (PPM)
Wavelength Range:	660 nm / 905 nm Note: Wavelength range can be especially useful to clinicians
Emitted Light Energy	< 1.2mW maximum average at 905nm
Calibration Range:	70 - 100%
Minimum sensor Bend Radius	4 cm (1.6 inches)
SpO2 averaging time:	6 seconds

1.10.3. NIBP

Technical Parameters	Technical Detail
Technique:	Oscillometric, step type deflation
Modes:	Manual, Automatic and STAT
Measurement Time:	< 60 seconds typical; standard adult cuff, deflation rate approx. 4mmHg/Sec, in steps.
Systolic Measureable Pressure Range:	Adult/Pediatric: 40 - 270 mmHg (5.3 - 36 kPa) Neonatal: 30 - 130 mmHg (4 - 17 kPa)
Diastolic Measureable Pressure Range:	Adult/Pediatric: 25 - 245 mmHg (3.3 - 32 kPa) Neonatal: 10 - 100 mmHg (1.3 - 13 kPa)
Mean Measureable Pressure Range:	Adult/Pediatric: 30 - 255 mmHg (4 - 34 kPa) Neonatal: 15 - 120 mmHg (2 - 16 kPa) Note: MAP not displayed in USA configurations
Pressure Accuracy:	Max. Std. Deviation: <8 mmHg (1.1 kPa) Max. Mean Error: within ± 5mmHg (±0.7 kPa)
Pressure Resolution:	1 mmHg (0.1 kPa)
Pulse Rate Range:	Adult/Pediatric 30-220 ppm, Neonatal 30-240 ppm
Pulse Rate Accuracy:	± 1% or ± 5 BPM, whichever is greater
Max Cuff Inflation Pressure:	Adult/Pediatric: 270 mmHg Neonatal: 140 mmHg
Pressure Transducer Range:	0 - 300 mmHg (0 - 40 kPa)
Transducer Accuracy:	The greater of ± 2 mmHg or 2% of the reading
Overpressure Protection:	Adult: 300 mmHg (40 kPa) < 2 seconds Pediatric: 300 mmHg (40 kPa) < 2 seconds Neonatal: 150 mmHg (20 kPa) < 2 seconds
Initial Pressure:	Adult: 165 mmHg (22 kPa) Pediatric: 165 mmHg (22 kPa) Neonatal: 100 mmHg (13.3 kPa) All initial pressures ± 15 mmHg (2 kPa)

STAT Mode:	3 consecutive NIBP Readings
Minimum Time Between Readings:	Auto: 30 seconds (non STAT) Manual: 5 seconds

1.10.4. CO_2 Only, Internal System

Technical Parameters	Technical Detail
Technique:	Sidestream, Non-dispersive infrared absorption technique
Range:	0-15% CO2, or partial pressures at STP: 0-115 mmHg, or 0 - 16 kPa,
Accuracy:	± 0.43 Vol% +8%, or ± 3.75 mmHg +8%, or ±0.5kPa +8%
Resolution:	1 mmHg, 0.1%, 0.1 kPa
Warmup Time:	< 10 seconds (concentrations reported and full accuracy)
Response Time:	< 5 seconds for sample, 150mS waveform response
Flow Rate:	80 ± 20 ml/min
Calibration:	Automatic
Accuracy degradation with rate	Above 80 RPM, end-tidal agent measurements will typically decrease below the nominal value in proportion to the respiration rate as follows: ET=80Et(nom)/RR

1.10.5. Respiration

Technical Parameters	Technical Detail
Source:	Capnogram
Range:	3 - 120 breaths per minute
Accuracy:	1 bpm
Resolution:	1 bpm

1.10.6. Multi-Gas, Agents, P/N 3886

Technical Parameters	Technical Detail
Technique:	Sidestream, Non-dispersive infrared (NDIR) absorption technique
Warmup Time:	< 20 seconds (concentrations reported and full accuracy)
Response Time:	≤ 5 seconds
Flow Rate:	50 ± 10 ml/min
Calibration:	Automatic
Drift of Measurement	None
Accuracy degradation with rate	Above 80 RPM, end-tidal agent measurements will typically decrease below the nominal value in proportion to the respiration rate as follows: ET=80Et(nom)/RR
CO2 and Respiration	Ranges and accuracy same as 10.1.1.11.4 and 5 above
N_2O Range:	0 - 100 vol%
N_2O Accuracy:	± 2 vol% + 2%
N_2O Resolution:	1%
Primary Agent ID	0.15 vol%
Secondary Agent ID	0.20 vol% + 10% of total agent concentration
Multiple Agent (>2) Detect	0.20 vol % +/- 10% of total agents concentration
Sev Range:	0 - 10 vol%, accuracy ±0.15vol% +5%
ISO, HAL, ENF Range:	0 - 8%, accuracy ±0.15vol% +5%
Des Range:	0 - 22%, accuracy ±0.15vol% +5%

Sev, ISO, HAL, ENF, DES Accuracy:	± 0.15 vol% + 5%
Sev, ISO, HAL, ENF, DES Resolution:	0.1%
Interfering Gas Effects	**Tested according to IEC 80601-2-55**
Nitrous Oxide	No effect at 60%
Halothane	No effect at 4%
Enflurane	No effect at 8%
Isoflurane	No effect at 8%
Sevoflurane	No effect at 8%
Xenon	-10 % of reading @ 80 vol%
Helium	-6 % of reading @ 50 vol%
Desflurane	+12 % of reading @ 15 vol%
Ethanol	No effect at 0.3 vol%
Isopropanol	No effect at 0.5 vol%
Acetone / Metabolic Ketones	No effect at 1 vol%
Methane	No effect at 3 vol%
Carbon Monoxide	No effect at 1 vol%
Nitrogen Monoxide	No effect at 0.02 vol%
Oxygen	No effect at 100 vol%

1.10.6.1.O2 (Part of 3886)

Resolution	1%
Range	0 to 100 %
Accuracy 0 to 59%	+/- (1 vol% + 2 % of reading)

1.10.7. Temperature

Technical Parameters	Technical Detail
Technique:	Direct Fiber-Optic
Range:	33 - 44° C (91.4 – 111.2° F)
Accuracy:	± 0.3° C (±0.54° F)
Extended Range:	10° C to 50° C (50° F to 122° F)
Extended Range Accuracy:	±0.4° C (±0.72° F)
Resolution:	0.1°
Response Time:	< 20 seconds
Application Type:	Axillary or skin surface

1.10.8. Invasive Blood Pressure

Technical Parameters	Technical Detail
PRESS Channels (IBP1 and IBP2)	1, or 2 simultaneous pressure channels
PRESS Frequency Response (-3dB)	0 to 12 Hz
PRESS Range/Resolution	-10 to +250 mmHg with maximum offset of +/- 300 mmHg
PRESS Sensitivity	5 uV/V/mmHg
PRESS Gain Accuracy	+/- 1 % + 1 mmHg, whichever is greater
PRESS Auto Zero Feature Available	Yes, Zeroes with +/- 300 mmHg offset to 0+/- 2 mmHg within 1 second
PRESS Waveform Display Scales	-30 to 50, -20 to 75, 0 to 150, 0 to 200, 0 to 300 mmHg
PRESS Channel Labels Display	ART (default, arterial SYS/DIA), CVP (Central Venous Pressure MEAN), ICP (Intra-Cranial Pressure MEAN), or UA (Umbilical Artery SYS/DIA)
Pressure Resolution:	1 mmHg
Pulse Rate Range:	Adult/Pediatric and Neonatal: 30-300 ppm
Pulse Rate Accuracy:	± 1% or ± 5 BPM, whichever is greater
Pressure Transducer Type:	Edwards PX3 series, or equivalent