

# 3880

## PORTABLE MRI

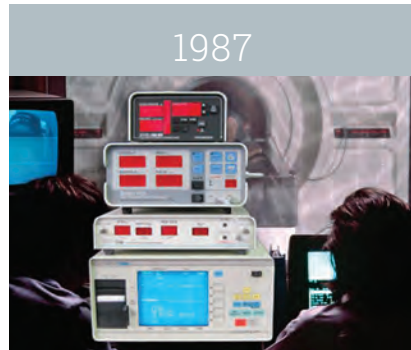
### MONITORING SYSTEM



# WE ARE MRI Patient Care

IRadimed is a leader in MRI patient care with vast experience in MRI innovation. Roger Susi, our president and CEO, is the founder of Invivo Research where he pioneered the world's first and best selling MRI patient vital signs monitoring brand, as well as founding IRadimed Corporation, the world's first and best selling non-magnetic MRI infusion pumps and patient monitors.

The leadership team at IRadimed has a deep history in developing and advancing MRI patient care and is proud to introduce the world's first and only portable, MRI multi-parameter vital signs monitor that maintains the continuum of care throughout the patient's entire MRI care cycle. Below are a few of this team's most notable contributions to MRI patient care.



## FIRST MRI MONITOR

The 3100 Omni-Trak was the world's first MRI patient monitor to receive FDA clearance. The 3100 opened the doors for patients to receive a MRI that would have been previously turned away.



## FIRST WIRELESS USE

Roger Susi and his team pioneered the use of wireless technology in MRI with the 3150 Omni-Trak. The simple setup of the wireless display expanded the benefits of MRI monitoring to a global scale.



## FIRST MRI IV PUMP

The MRidium is the world's first non-magnetic IV infusion system. This unique infusion pump allows the delivery of fluids at the MRI bore safely for I.V. sedations and critical care patients.



## FIRST AT MOBILITY

The IRadimed 3880 is a non-magnetic patient monitoring solution, designed to move with the patient between their care unit and the MRI suite while safely maintaining the 'continuity of care'.

## WHAT DOES NON MAGNETIC MEAN TO YOU?



### CLINICIANS

"I have the freedom to use this monitor on the MRI patient table which keeps both the monitor and the cables off the floor. I now have more room to work and less tangling of lines making me more efficient."



### MRI SAFETY OFFICER

"It means safety. Being non-magnetic gives me piece of mind knowing that patients arrive to MRI on a monitor that will not create any hazard should hospital staff use it in too strong of a magnetic field."



### MRI MANAGEMENT

"There are certain economic realities that I must face everyday. Having the IRadimed monitor allows us to stay on schedule and meet clinical standards of care without straining my capital or operating budgets."





## “Finally, an efficient way to transport our critical patients to the MRI”

The days of transferring a patient from a traditional transport monitor to the MRI monitor in the hallway outside of the MRI suite is now a thing of the past. The IRadimed 3880 MRI patient monitor is a small, lightweight, and easy to use, designed to travel with the patient between the MRI and their care unit. These unique transport attributes increase MRI efficiency while decreasing the amount of time critically ill patients are away from their care unit.

**10**

Minute Reduction in time slots would open capacity for more MRI cases each day.

**2**

Additional MRI Slots per day can equal more than 500 additional MRI exams annually.

### HAVE A SAFE TRIP

Patient safety is increased when you provide uninterrupted vital sign monitoring from their care unit to MRI and back. IRadimed partners with your team to evaluate your current procedural workflow and will recommend strategies on how our MRI patient monitor and IV infusion pump will improve your overall patient workflow and staff efficiency.

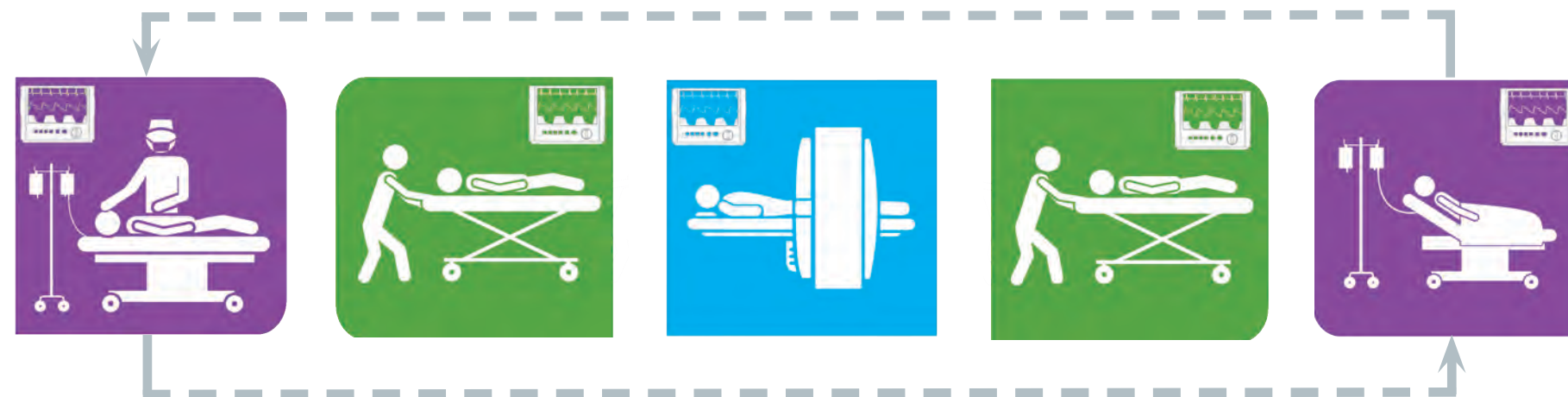
## All in a day's WORK [FLOW]

Mount it on an anesthesia cart, patient table, stretcher or freestanding pedestal and get rolling toward a more efficient workflow.

## WORK SMARTER NOT HARDER

Portability is at the heart of the IRadimed 3880 MRI patient monitoring system. Transferring the patient to the MRI monitor in the originating department such as an Intensive Care Unit, Emergency Department or Anesthesia induction room reduces the need for unnecessary equipment transfers providing the following benefits:

- More efficient use of the MRI scanner and staff can improve throughput
- Continuity of care during intradepartmental patient transports
- Reduces the time that critical patients are away from the ICU



### PRE MRI SET-UP

Connecting the MRI patient care devices to the patient within the ‘safety-net’ of their care unit insures patient stability prior to their MRI appointment.

### TRANSPORT

The lightweight 3880 monitor allows a single staff member to easily transport the patient to the MRI without the need to transfer monitors again once they arrive.

### MRI EXAM

With its 30,000 gauss rating and small footprint, clinicians have the freedom to position the 3880 monitor where it best enhances patient care for the required procedure.

### TRANSPORT

Using the 3880 monitor for the entire care cycle helps streamline patient transitions and maintains patient care without a lapse in monitoring during equipment transfers.

### POST MRI

Whether it is the patient’s originating department or a recovery area, the IRadimed 3880 is with you and your patient every step of the way to ensure continuity of care.



# SHAPING THE FUTURE OF MRI MONITORING

Slim, lightweight, with enough battery life to go the distance, this patient-side monitor has been meticulously engineered to meet the needs of today's complex MRI workflow. From bedside through transport, the 3880 non-magnetic monitor is mountable anywhere: wall, roll-stand, bed rail, or anesthesia cart and can quickly be detached for immediate mobility. IRadimed 3880 provides MRI safety and full functionality in a compact, non-magnetic package.

• 8 channel direct wireless communication allows simultaneous monitoring in both the MRI and control room.

• Combining a simple, single level menu structure with an intuitive touch screen makes this one of the easiest monitors to use.

• Integrated POD charging bays eliminate the need to find space for external chargers and managing battery swaps.

• Trusted Masimo® based Perfusion Indicator provides confidence in patient assessment and setup.

• Dynamic messaging system with color coded severity and user acknowledgment puts you in control of what messages to see.

• Advanced anesthetic agent monitoring featuring continuous MAC and color coded gases.

• Frequently used activities receive a physical button activation helping preserve the screen for patient information.



• Multicolor, severity-based dome lights are visible from all sides of the monitor.

• Smart battery management system for the monitor, PODS and Tablet provides full status of all system components.

• Wireless ECG with IRadimed dynamic gradient filtering helps increase patient comfort and safety.

• Wireless SpO<sub>2</sub> monitoring feature industry trusted Masimo® algorithms.

• Non-Magnetic EtCO<sub>2</sub> with waveform fill ensure the magnetic field doesn't alter the accuracy or reliability.

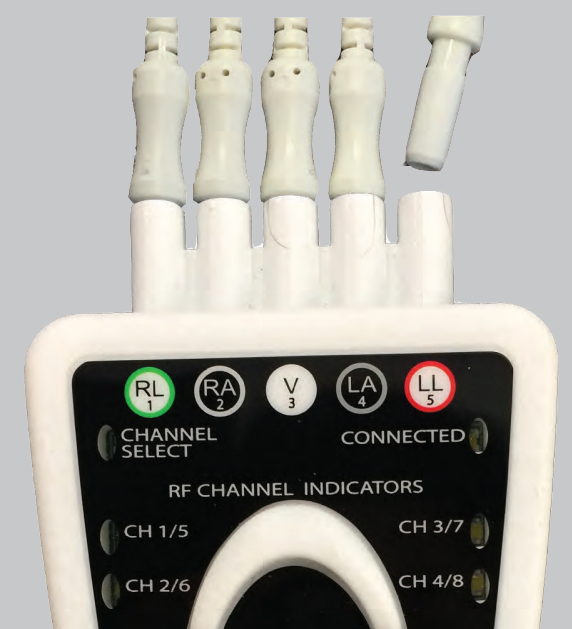
• Industry first Non-Magnetic blood pressure ensures accurate readings and long term reliability.

• Fiber Optic patient temperature measurements provide real time status of your anesthetized patients.

## LIFELONG AFFORDABILITY

IRadimed understands the challenges that are facing healthcare providers and has designed the 3880 MRI patient monitoring system around today's sensitive budgets. Consideration was taken into every aspect of the monitor design to lower acquisition cost and reduce the cost of ownership burden traditionally associated with MRI monitors in the following areas:

- Start up cost
- Per patient case cost
- Service & maintenance cost
- Hardware and software upgrades extending life
- Individual lead replacement instead of 'whole cable'



# THE 3880 MRI MONITOR

The IRadimed 3880 non-magnetic patient monitoring system combines a legacy of proven performance with the ultimate fusion of both form and function.



3880

## MRI PATIENT MONITOR

The 3880 non-magnetic patient side monitor is used to acquire, process, and display all vital sign measurements during patient intradepartmental transport as well as during the MRI procedure.



3885T

## EXTENDED RANGE REMOTE TABLET

The non-magnetic wireless Remote Tablet has industry leading wireless technology that allows for remote monitoring that can go the distance inside the MRI control room.



3885B

## BASE STATION CONTROL CENTER

The Base Station is the control room communication hub that facilitates the printing and wireless communication through the MRI shielding between the Patient Monitor and the Tablet.



3881



3882

## LONG LIFE WIRELESS ECG AND SPO2 PODS

IRadimed non-magnetic PODs feature extended battery life lasting greater than 12 hours. This simplifies operation and eliminates the need for managing external battery chargers and batteries.



3886

## WIRELESS MULTIGAS MODULE

The 3886 multigas module preserves patient mobility by residing on the anesthesia machine and wirelessly communicating patient gas information to 3880 MRI monitor.



# YES, IT'S SMALL AND NON-MAGNETIC

The non-magnetic design allows the 3880 to operate safely in a 30,000 gauss magnetic field without the need for a heavy roll cart used by traditional MRI monitors.



 **IRADIMED**

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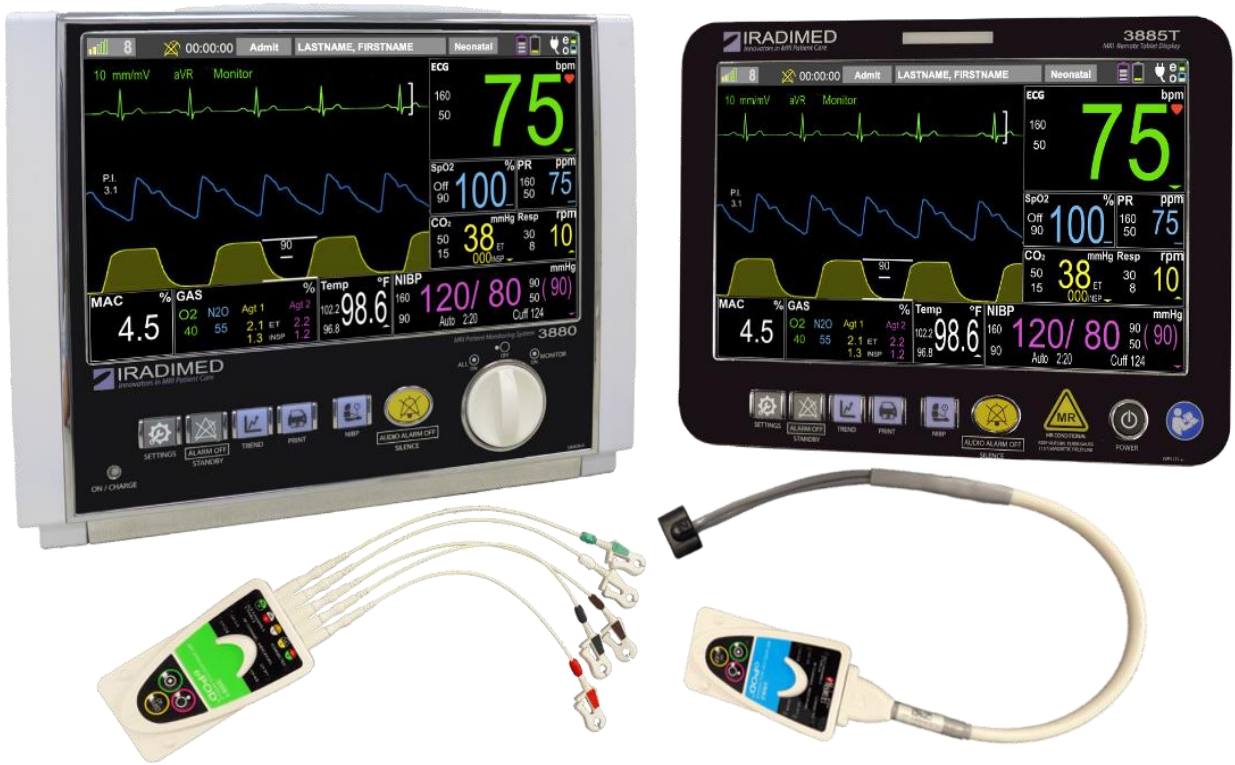






3880

*MRI Patient Monitoring System*



3880Q Technical Data Sheet

LB035-A



# 1. Display (3880Q / 3885T)

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

## 1.1. User Interface

### 1.1.1. Monitor (3880Q)

Technical Parameters	Technical Detail
Power	Rotary On, Off
Feature Hard Keys	Trend, Record, NIBP (start stop) and Audio Alarm Off / Silence
Setup Hard Keys:	Settings and Alarm Off / Standby
Soft Keys	Touchscreen

### 1.1.2. Tablet (3885T)

Technical Parameters	Technical Detail
Power	Push Button On, Off
Feature Hard Keys	Trend, Record, NIBP (start stop) and Audio Alarm Off / Silence
Setup Hard Keys	Settings and Alarm Off / Standby
Soft Keys	Touchscreen

### 1.1.3. PODS (3881/3882/3883)



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

#### 1.1.4. Base Station (3885B)

Technical Parameters	Technical Detail
Power	Toggle
Hard Keys	Channel Selection

## 1.2. Application Features

### 1.2.1. 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 <sub>2</sub> , NIBP, EtCO <sub>2</sub> , Resp, Temp, MAC, O <sub>2</sub>

### 1.2.2. 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

### 1.2.3. Safety Standards

Technical Parameters	Technical Detail
IEC	60601-1, 60601-1-2, 60601-1-8, 60601-2-27, 60601-2-34, 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	Up to 5 KV
Defibrillator Recovery Time	During a defibrillation procedure, the ECG waveform will saturate then recover in less than 5 seconds, and the IBP waveform will saturate then recover in less than 8 seconds.

## 2. Physical Specifications

## 2.1. Height

Technical Parameters	Technical Detail
3880Q Monitor	23 cm (8.8 inches)
3885T Remote Tablet	19.6 cm (7.7 inches)
3885B Base Station	18.8 cm (7.4 inches)
3881/3882/3883 Wireless PODs	9.5 cm (3.8 inches)
3886 Multi-Gas Unit	8 cm (3.13 inches)

## 2.2. Width

Technical Parameters	Technical Detail
3880Q Monitor	29 cm (11.4 inches)
3885T Remote Tablet	26.7 cm (10.5 inches)
3885B Base Station	38 cm (15 inches)
3881/3882/3883 Wireless PODs	2.0 cm (0.8 inches)
3886 Multi-Gas Unit	14.7 cm (5.8 inches)

## 2.3. Depth

Technical Parameters	Technical Detail
3880Q Monitor	12.7 cm (5 inches)
3885T Remote Tablet	4.5 cm (1.8 inches)
3885B Base Station	12 cm (4.8 inches)
3881/3882/3883 Wireless PODs	5.7 cm (2.3 inches)
3886 Multi-Gas Unit	10.2 cm (4.1 inches)

## 2.4. Weight

Technical Parameters	Technical Detail
3880Q Monitor	4 kg (8.9 lbs)
3885T Remote Tablet	1.6 kg (3.6 lbs)
3885B Base Station	2.1 kg (4.6 lbs)
3881/3882/3883 Wireless PODs	73 g (0.16 lbs) (without sensors/leads)
3886 Multi-Gas Unit	1.04 kg (2.3 lbs)

## 3. Electrical Specifications



	Technical Parameters	Technical Detail
<i>Power Requirements</i>	Voltage Range: (All 3880Q system components)	85 - 264 VAC
	Frequency Range:	50 - 60 Hz
	Max Consumption: 3880Q Monitor 3885B Base Station 3886 Multi-Gas Unit	< 40 VA during charging < 65 VA during charging, 3885B < 10 VA
<i>Battery Capacity</i>	3880Q Monitor	14.8 V at 6 Ah Lithium Polymer
	3885T Remote Tablet	7.4 V at 6 Ah Lithium Polymer
	3881/3882/3883 Wireless PODs	3.7 V at 1200 mAh Lithium Polymer
<i>Battery Operation Time</i>	3880Q Monitor	>8 hours with NIBP readings every 5 minutes
	3885T Remote Tablet	> 10 hours
	3881/3882/3883 Wireless PODs	> 12 hours
<i>Battery Charge Time</i>	3880Q Monitor	< 5 hours to 90% capacity
	3885T Remote Tablet	< 5 hours to 90% capacity
	3881/3882/3883 Wireless PODs	< 3 hours to 90% capacity
<i>Power On</i>	Boot Time	< 4 seconds

## 4. Environmental Specifications

	Technical Parameters	Technical Detail
<i>Operating</i>	All 3880Q 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 3,000 meters (equivalent pressure of 760 mmHg to 525 mmHg)
<i>Storage</i>	All 3880Q 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)

## 5. MRI Conditions

	Technical Parameters	Technical Detail
<i>3880Q Monitor</i>	MR Environment Safety:	MRI Conditional
	Magnetic Field Limit	30,000 Gauss
	MRI System	0.5 to 3.0 Tesla MRI Systems
<i>3881/3882/3883 Wireless PODS</i>	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
<i>3885T Remote Tablet</i>	MR Environment Safety	MRI Conditional
	Magnetic Field Limit	15,000 Gauss
<i>3885B Base Station</i>	MR Environment Safety	MRI Unsafe
<i>1812 Hextrodes</i>	MR Environment Safety	MRI Conditional
	Magnetic Field Limit	30,000 Gauss
	MR Environment Safety	1.5T and 3.0Tesla MRI Systems
<i>Accessories</i>	MR Environment Safety	MRI Safe as listed in Section 9.1-9.7
<i>3886 Multi-Gas Unit</i>	Magnetic Field Limit	MR conditional 600 gauss

## 6. Recorder (3885B)

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

## 7. Gating (1881)

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

## 8. Vital Signs

### 8.1. ECG (3881)



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)
Electrode Contact Impedance	≤ 20K ohms @ 10 Hz
Heart Rate	30 - 250 bpm
Heart Rate Accuracy	± 1% or ± 1 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 99BPM  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

## 8.2. SpO<sub>2</sub> (3882)

Technical Parameters	Technical Detail
Technique	Masimo SET®
Saturation Range	1% - 100%
Saturation Accuracy	+/- 3% (i.e. +/- 3 digits) 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)
SpO <sub>2</sub> averaging time	6 seconds

## 8.3. NIBP (3880Q)

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 Measurable Pressure Range	Adult/Pediatric: 40 - 270 mmHg (5.3 - 36 kPa) Neonatal: 30 - 130 mmHg (4 - 17 kPa)
Diastolic Measurable Pressure Range	Adult/Pediatric: 25 - 245 mmHg (3.3 - 32 kPa) Neonatal: 10 - 100 mmHg (1.3 - 13 kPa)
Mean Measurable 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 - 280 mmHg (0 - 37.3 kPa)
Transducer Accuracy	The greater of ± 2 mmHg or 2% of the reading

Technical Parameters	Technical Detail
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 $\pm$ 15 mmHg (2 kPa)
STAT Mode	3 consecutive NIBP Readings
Minimum Time Between Readings	Auto: 30 seconds (non STAT) Manual: 5 seconds
3880Q Automatic Intervals	1, 3, 5, 8, 10, 15, 30 minutes

#### 8.4. CO<sub>2</sub>-Only, Internal System (3880Q-3/3880Q-4)

See Section E3 below for more detail specifications

Technical Parameters	Technical Detail
Technique	Sidestream, Non-dispersive infrared absorption technique
Range	0-15% CO <sub>2</sub> , or partial pressures at STP: 0-115 mmHg, or 0 - 16 kPa
Accuracy	0-10% $\pm$ 0.43 Vol% +8%, or $\pm$ 3.75 mmHg +8%, or $\pm$ 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 $\pm$ 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: $ET=80Et(nom)/RR$

#### 8.5. Respiration (3880Q-3/3880Q-4/3886)

Technical Parameters	Technical Detail
Source	Capnogram
Range	3 - 120 rpm (respirations per minute)
Accuracy	1 rpm
Resolution	1 rpm

#### 8.6. Multi-Gas, Agents (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 (Negligible)
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 10.1.1.11.5 above
N <sub>2</sub> O Range	0 - 100 vol%
N <sub>2</sub> O Accuracy	± 2 vol% + 2%
N <sub>2</sub> O 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%

## 8.7. O2 (3886)

Technical Parameters	Technical Detail
Resolution	1%
Range	0 to 100 %
Accuracy 0 to 100%	+/- (1 vol% ± 2 % of reading)

### 8.8. Temperature (3880Q-2/3880Q-4)

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

### 8.9. Invasive Blood Pressure (3883)

Technical Parameters	Technical Detail
Pressure Channels (P1 and P2)	1 or 2
Pressure Measurement Range	-30 to 250 mmHg
Pressure Display Resolution	1 mmHg
Frequency Bandwidth	0 to 12 Hz (-3dB)
Sensitivity	5 uV/V/mmHg
Gain Accuracy	+/- 0.5%
Range of IBP Zero Feature	+/- 300 mmHg
Zero Accuracy	+/- 1 mmHg
Time to Zero	Within 1 second
Pressure Waveform Display Scales	-30 to 50, -20 to 75, 0 to 150, 0 to 200, 0 to 300 mmHg
Pressure Channel Labels	ART (Arterial), CVP (Central Venous Pressure), ICP (Intra-Cranial Pressure), or UA (Umbilical Artery)
IBP Pulse Rate Range	30 to 250 BPM
IBP Pulse Rate Accuracy	± 2%
IBP Pulse Rate Resolution	1 BPM

Technical Parameters	Technical Detail
Pressure Transducer Compatibility	<p>TruWave® Transducers (by Edwards Lifesciences), and Transpac IV® Transducers (by ICU Medical)</p> <p>Note: Pressure transducers are sold separately. Contact the transducer manufacturer for the appropriate transducer kit for your intended application.</p>
Transducer Adapter Cable Compatibility	<p>Invasive pressure adapter cables compatible with Iradimed's 1861 Dual 6-pin "MS 3106" type of invasive pressure connection must mate with:</p> <ul style="list-style-type: none"> <li>- Amphenol connector type MS-3106A 14S-6P, and</li> <li>- TruWave® Transducers (by Edwards Lifesciences), or Transpac IV® Transducers (by ICU Medical).</li> </ul>

Technical Specifications are from the Operators Manual 1200 REV N. Specifications are subject to change.





# 38800Q

**NON-MAGNETIC**  
MRI PATIENT MONITOR



 **IRADIMED**



# THE IRADIMED 3880Q

## WORLD'S ONLY NON-MAGNETIC MRI MONITOR

This one of a kind, lightweight, portable monitor has been meticulously engineered to meet the needs of today's complex MRI workflow. **From bedside through transport, the 3880Q non-magnetic monitor is mountable patient-side, on a wall, roll-stand, bed rail, or an anesthesia cart.** The 3880Q can be quickly detached for immediate mobility and provides MRI safety with full functionality in a compact, non-magnetic package.



### NON-MAGNETIC DESIGN

- 30,000 Gauss Field Line safety
- Zone IV piece of mind
- Eliminates projectile risks

### IMPROVED WORKFLOW

- 10 lbs (4.5kg), small, lightweight design
- Familiar bedside monitor look and feel
- Flexible mounting: cart, IV pole & bed

### CONTINUOUS MONITORING

- Interdepartmental transfer ease
- Uninterrupted vital sign monitoring
- Patient safety is enhanced

## ROADMAP TO A SEAMLESS WORKFLOW



### 1. 3880Q PATIENT SETUP

Connecting the 3880Q MRI Patient Monitor to the patient within the 'safety-net' of their care unit **improves patient stability** prior to their MRI appointment.



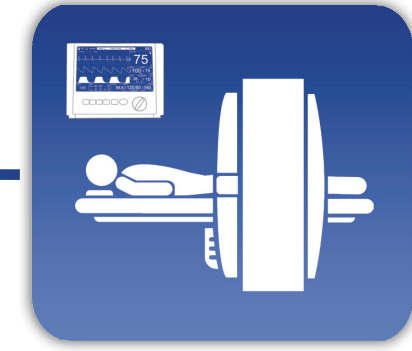
### 2. PATIENT TRANSPORT TO MRI

The lightweight design of the 33880Q MRI Patient Monitor allows minimal members to **easily transport the patient to the MRI** without the need to transfer monitors again upon arrival.



### 4. RECOVERY OR CRITICAL CARE

Whether the patient's post MRI transfer is to their originating department or a recovery area, the 3880Q MRI Patient Monitor is with the patient every step of the way, **standardizing continuity of care.**



### 3. MRI EXAM

With its 30,000 gauss rating and small footprint, clinicians have the freedom to ergonomically position the 3880Q MRI Patient Monitor **where it best enhances patient care** and throughput.



# MODERN PROBLEMS REQUIRE MODERN SOLUTIONS



## WIRELESS ECG WITH DYNAMIC GRADIENT FILTERING

- Industry exclusive "Convertible ECG" supports 3, 4, and 5 leads setups giving clinicians flexibility on patient application.
- Single lead wire replacement instead of whole cable reduces replacement cost.



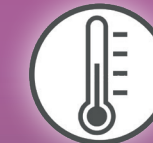
## WIRELESS MASIMO® PULSE OXIMETRY

- More than 100 studies have shown that Masimo® SET provides best in class performance with patients with low perfusion.
- Integrated motion tolerance provides stability during transport results in more reliable readings.



## WIRELESS INVASIVE BLOOD PRESSURE MONITORING

- Intuitive design and setup keeps lines on the patient's bed and off the floor.
- Reduces the risks of tripping hazards on long IBP lines.



## UNINTERRUPTED PATIENT TEMPERATURE

- Fiber optic thermometer provides real time and reliable readings.
- Precision results within 0.3° C instills confidence during clinical decisions.



## LOW FLOW END TIDAL CO<sub>2</sub>

- Magnetic field doesn't alter accuracy or reliability giving clinicians peace of mind.
- Cross contamination is controlled by the enclosed design, eliminating the need for a water-trap.



## WIRELESS ANESTHESIA GAS MONITORING

- Operating Room workflow supported by mounting on the anesthesia machine.
- Multiple 3880Q patient monitors supported by a single multi-gas module.



## NIBP WITH ecQ-TEK

- Quick inflation cycles.
- Energy efficient ecQ-TEK pump technology extends battery run time.
- Quiet and smooth operation enhances reliability and comfort.

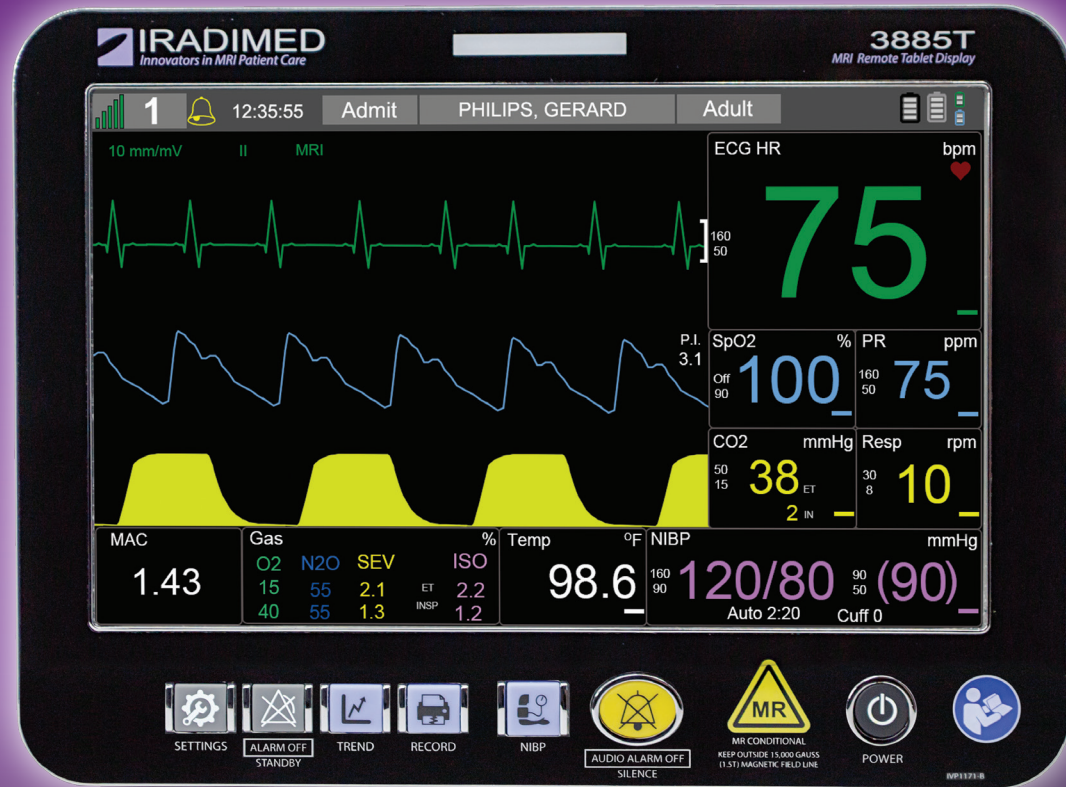


## INTEGRATED BATTERY CHARGING

- No external Zone III battery chargers required to manage.
- Assures wireless PODS always have a charge and are ready for immediate use.



# PERFECTLY PORTABLE: WIRELESS MONITORING BY REMOTE CONTROL



## EXTENDED RANGE WIRELESS REMOTE

- Remotely monitor patients inside the MRI Zones III & IV with minimal interruptions.
- Tablet wirelessly controls the 3880Q with full audio and visual alarm functionality.



## E.M.R CONNECTIVITY THAT SAVES TIME

- HL7 and RS232 simultaneous output options allows integration to both legacy and future EMR systems.

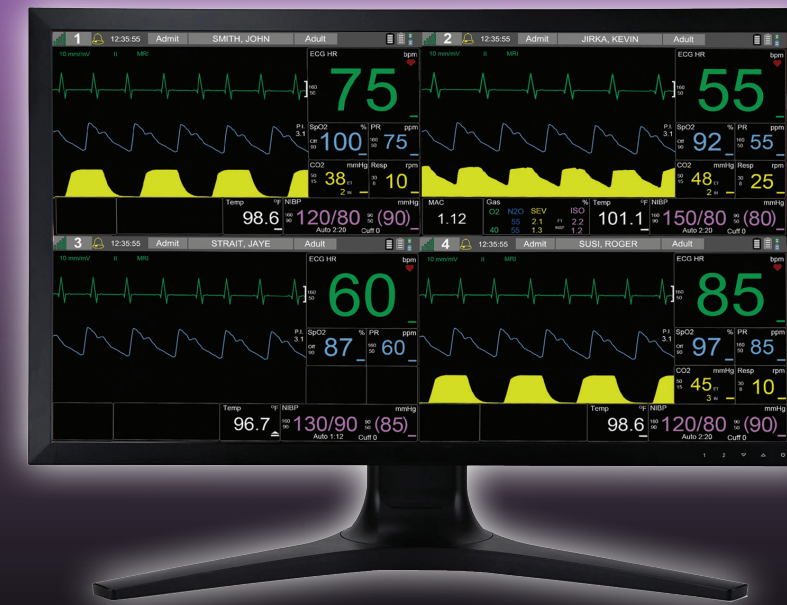
## TOUCH SCREEN TECHNOLOGY

- Every step of the patient's MRI care cycle has been simplified with an intuitive touch screen user interface.



## SECURE 4K REMOTE VIEWING

- The Remote Viewing Station allows for clinicians to oversee up to four patients on a single screen.



# SERVICE BEYOND REPAIR!

## DEPOT SERVICE GETS YOU BACK TO PATIENT CARE FAST!

IRadimed depot service combined with our priority equipment loaner program is the most effective way to ensure MRI cases are resumed promptly when unexpected service is needed.



No one knows MRI patient care devices like IRadimed. IRadimed technical support and medical device service engineers are expert problem solvers with deep product knowledge. Our dedicated team of professionals are eager to manage the end-to-end care of your 3880Q MRI Patient Monitor System and accessories.



Scan for Training Videos



[www.IRadimed.com](http://www.IRadimed.com)



## UPGRADE YOUR PATIENT CARE BY GOING NON-MAGNETIC!

Start moving forward by replacing your magnetic, bulky, outdated equipment with a portable, lightweight, MRI monitor. From patient preparation to recovery, the 3880Q MRI patient-side monitor provides your facility with more reliability, and functionality, in a compact, non-magnetic package.

\*Not all features are available in all markets.

 **IRADIMED**

1025 Willa Springs Drive  
Winter Springs, FL 32708  
(407) 677-8022



**DECLARATION OF CONFORMITY**

**The object of this declaration is in conformity with the following EU Council Directive:**

- MDD 93/42/EEC concerning medical devices as amended by 2007/47/EEC, including the requirements of Annex I

**Product Name:** 3880 MRI Patient Monitoring System

**Product Model Numbers:** 3880 MRI Patient Monitor (configurations 1-4)  
3881 MRI Wireless ECG e-POD  
3882 MRI Wireless SpO2 o-POD

**Product Options:** 3883 MRI Wireless IBP ip-POD (configurations 1-3)  
3885T MRI Remote Tablet Display  
3885B Base Station  
3886 Multi-Gas Unit

**Product Accessories:** Listed by the manufacturer in product accompanying documentation

**Control Indicator:** All devices manufactured from the Date of Issue: 12 December 2019

**Device Classification:** IIb, per Annex IX, Rule 10 of 93/42/EEC

**Global Medical Device Nomenclature Code:** 61161, MRI Patient Physiologic Monitoring System

**Manufacturer:** Iradimed Corporation, 1025 Willa Springs Drive, Winter Springs, FL 32708 USA, [www.iradimed.com](http://www.iradimed.com)

**Authorized EU Representative:** Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany, [www.mdssar.com](http://www.mdssar.com)

**Notified Body:** Ente Certificazione Macchine (ECM) SRL, Via Ca' Bella, 243 - Loc. Castello di Serravalle, 40053 Valsamoggia (BO), Italy, [www.entecerma.it](http://www.entecerma.it) (CE Notified Body Identification Number: 1282)

**Conformity Assessment Route:** The notified body identified, ECM, performed an assessment per MDD 93/42/EEC Annex II, excluding clause 4 and issued EC Certificate No. ECM19MDD012 rev. 1

**Additional Information:** The product has been tested in the fully optioned system as described in the manufacturer's accompanying documentation. Additionally, the accessories listed in the accompanying documentation have been tested and found to be compatible with the product. All supporting documentation is retained under the premises of the manufacturer. The product is compliant with the relevant harmonized standards as listed below.


**Harmonized Standards to which Conformity is Declared:** IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-2-27, IEC 80601-2-30, IEC 60601-2-34, IEC 60601-2-49, ISO 80601-2-55, ISO 80601-2-56, ISO 80601-2-61, ISO10993, IEC 62366, IEC 62133, IEC 62304, IEC 10993 ISO, 13485, ISO 14971, ISO 15223

**We, Iradimed Corporation, the manufacturer, declare under our sole responsibility that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices, as amended by Directive 2007/47/EC.**

**Place of Issue:** Iradimed Corporation, Winter Springs, FL, USA

**Date of Issue:** 22 June 2021

**Signature:**

  
Steven J Kachelmeyer  
Vice-President, Q.A. & Regulatory Affairs