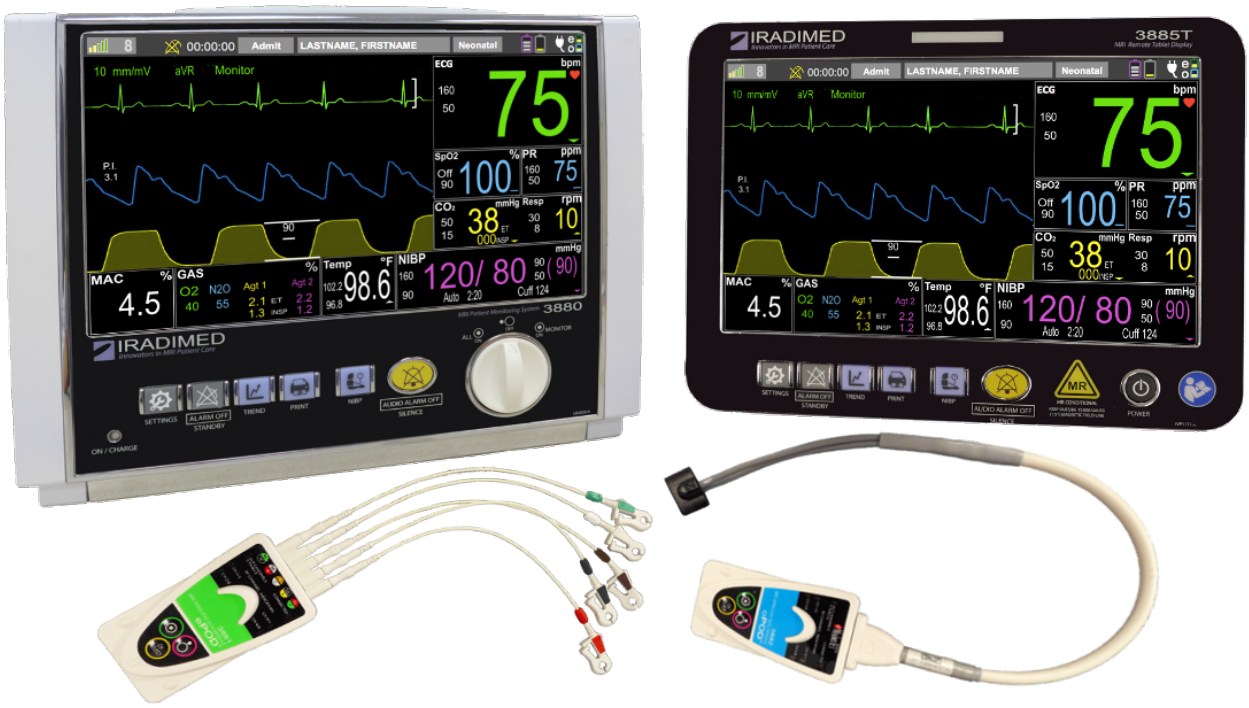
IRADIMED

3880

MRI Patient Monitoring System



Operation Manual REF 1200

Non-Magnetic Patient Monitoring System, Model 3880
Operation Manual, Part Number 1200 Release 03/01/2017

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IRADIMED CORPORATION

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1. Preface

1.1. About 3880 Non-Magnetic Patient Monitoring Systems

1.1.1. Intended Use

The IRadimed Corporation's 3880 MRI Patient Monitoring System is intended to monitor a single patient's vital signs for patients undergoing Magnetic Resonance Imaging (MRI) procedures.

The 3880 MRI Patient Monitoring System is intended for use by healthcare professionals.

The 3880 MRI Patient Monitoring System is intended for use in Adult, Pediatric, and Neonatal populations for monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Temperature, Pulse Oximetry (SpO_2), Respiration, Capnography (CO_2), Oxygen, and Anesthetic Agents.

Patient types as identified herein regard pediatric patient types as not including neonates. The definitions of pediatric patient types and associated ages is as below and per FDA guidance:

- Neonates: from birth through the first 28 days of life
- Infants: 29 days to less than 2 years
- Children: 2 years to less than 12 years
- Adolescents: aged 12 through 21 (up to but not including the 22nd birthday)

The 3886 Multi-Gas unit is intended for use in adult and pediatric populations, not including neonates.

1.1.2. Intended Audience

This manual is intended for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for radiology and the monitoring of high acuity patients.

The 3880 MRI Patient monitoring system, the pulse oximeter oPOD and ECG ePOD are to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

1.1.3. Equipment Classification and System Items

The 3880 MRI Patient Monitor System includes the following items:

3880 Monitor Unit
3881 ePOD ECG telemeter unit
3882 oPOD SpO2 telemeter unit
1120 Charger with cords and cable
1200 Operation Manual

Optional equipment includes:

3885-T Remote Control Tablet, Wireless (must be used with 3885-B)
3885-B Base Unit, Mains powered, Wireless Connect (must be used with 3885-T)
3886 Multi-Agent Gas Unit

Classification according to IEC 60601-1

Type of protection against electrical shock	Class I ME Equipment – 3880, 3886 Note: 3881 and 3882 are Internally powered Body Worn
Degree of protection against electrical shock	Type CF (defibrillator-proof) equipment for use in Patient Environment - 3880, 3886, 3881 ePOD, 3882 oPOD
Degree of protection against harmful ingress of water and particulate matter	IPX1 enclosed equipment protected against harmful effects of dripping water per IEC 60529 Note: Optional 3885-B Base Station, 3885-T Remote Tablet and 3886 Multi-Gas Unit are Ordinary Equipment (enclosed equipment without protection against ingress of water) used outside of Patient Environment
Methods of Sterilization or disinfection	Non-Sterilizable, Use of liquid surface disinfectants only
Mode of Operation	Continuous Operation
Equipment not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.	

1.1.4. Product Compliance

The 3880 Patient Monitor is classified in the following categories for compliance:

- This equipment is RoHS and WEEE compliant.
- This equipment is suitable for connection to public mains as defined in CISPR 11.
- This Monitor conforms to general safety standard for medical devices to IEC 60601-1.
- This Monitor conforms to EMC safety standard to IEC 60601-1-2.
- This Monitor conforms to usability safety standard for medical devices to IEC 60601-1-6 and IEC 62366.
- Software is developed in accordance with IEC 60601-1-4 and IEC 62304.
- The application of risk management analysis to medical device conforms to ISO 14971.
- The SpO_2 Parameter conforms to IEC 80601-2-61.
- The TEMP parameter conforms to IEC 80601-2-56.
- The CO_2 parameter conforms to IEC 80601-2-55.
- This Monitor conforms to particular safety standard for multifunction patient monitoring equipment to IEC 60601-2-49.
- The ECG parameter conforms to IEC 60601-2-27, ANSI/AAMI EC13.
- The NIBP parameter conforms to IEC 80601-2-30
- The alarm systems of the Monitor conform to IEC 60601-1-8.

Radio Compliance

INDUSTRY CANADA COMPLIANCE STATEMENT:

- This device complies with Industry Canada license‐exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
- Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

FCC COMPLIANCE STATEMENT:

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warning: Changes or modifications not expressly approved could void your authority to use this equipment.

1.1.5. Intellectual Property

This device is covered under one or more of the following U.S. patents:
7,267,661 B2, 7,404,809 B2 and International Equivalents
7,553,295, 7,553,882, 8,105,282 B2 and International Equivalents
7,753,882; 8,150,493; 8,690,829; 8,262,642; 8,469,932; 8,105,282; 8,500,694 EP1530440; 1802362; 4597970; 5001845 International Patents; Other U.S. and International patents pending.
Masimo Patent information and citations can be found at: www.masimo.com/patents.htm

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

1.1.6. Design Life Time

The design lifetime of the 3880 MRI Patient Monitoring System units is six years.

1.2. About this manual

1.2.1. Intellectual Property

1.2.1.1. Trademarks

1.2.1.2. Copyright

1.2.2. Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation which ensures patient and operator safety.

This manual is based on the full configuration (including all optional features) and therefore some content may not apply to your product. If you have any questions, please contact us.

This manual is an integral part of the product. It should always be kept close to the 3880 monitor so that it can be obtained conveniently when needed.

1.2.3. Illustrations

All images in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your 3880 patient monitor.

1.2.4. Printing History

New editions of this document will incorporate all material updated since the previous edition. Update packages may be issued between editions and contain replacement and additional pages. Note that pages which are rearranged due to changes on a previous page are not considered revised.

The documentation part number and revision indicate the current edition. The printing date changes when a new revision is printed. (Minor corrections and updates which are incorporated at reprint will not cause the date to change.) The document revision letter changes when extensive technical changes are incorporated.

NOTE

- Specific menu screens may vary depending on software release being used.

1.2.5. Conventions

1.2.5.1. Symbols

-  MR Conditional: An item that poses no known hazards in a specified MRI environment with specified conditions.
-  MR Unsafe: An item that is known to pose hazards in all MRI environments.
-  MRI Safe: An item that poses no known hazards in all MRI environments.
-  Settings button: Access monitor setup menus
-  ALARM OFF - Standby button: Indefinitely pauses all alarms and terminates automatic NIBP measurements
-  Trend button: Trend Screen access and adjustment
-  RECORD button: Starts strip chart recorder for hard copy printout at recorder in the optional 3885-B Base Station
-  NIBP START/STOP button: Initiates a NIBP measurement when one is not in progress, or stops an NIBP in progress. Holding START/STOP button for 3 seconds initiates STAT readings.

-  AUDIO ALARM OFF – Alarm Silence button: multi-function audible alarm control, resets sounding of alarm, pauses for 120 seconds the alarm sound, or re-enables alarm sound capability.
-  3885-T Remote Tablet battery life
-  3880 Vital Signs Monitor battery life
-  ECG ePOD battery life
-  SpO_2 oPOD battery life
-  Wireless signal strength at 3880 Monitor, 3885-B Base Station, and 3885-T Remote Tablet
-  Alarm sound system is capable of audio sound triggered by alarms/alerts
-  “Audio Alarm Off” ; ALARM conditions can visually indicate, if ALARM not OFF
-  “Audio Alarm is Paused, with time countdown to reactivation indication
-  ALARM condition is occurring
-  ALARMS OFF, alarm conditions will NOT be indicated
-  Heart beat detected

See Section F for more symbols and meanings

1.2.5.2. Definitions

- DSP – Digital Signal Processing is the manipulation of signals with the intention to remove gradient induced noise on the vital sign waveforms.
- FOV – Imaging field of view
- Gating – Synchronizing the scanner image acquisition with the patients vital signs
- Latching – Alarm that, once activated requires deliberate user action to be deactivated.
- MAC - Minimum Alveolar Concentration is the alveolar concentration (end-tidal) of the agent(s) at which 50% of individuals fail to *move* in response to a noxious or surgical stimulus
- MRI Zones – American College of Radiology has defined four safety zones within MRI facilities which correspond with levels of increasing magnetic field exposure.
- P.I. – Perfusion Index is a relative assessment of the pulse strength at the monitoring site.
- RoHS – Restriction of Hazardous Substances directive on the restriction of the use of certain substances in electronic equipment.
- WEEE – Waste Electrical and Electronic Equipment directive on the collection, recycling and disposal of electronic equipment.

1.2.6. Product Availability

Some of the products mentioned in this manual may not be available in all countries. Please, consult your local representative for the availability.

1.2.7. Warranty

IRadimed provides this document without warranty of any kind, implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

IRadimed has taken care to ensure the accuracy of this document. However, IRadimed assumes no liability for errors or omissions and reserves the right to make changes without further notice to any products herein to improve reliability, function, or design. IRadimed may make improvements or changes in the products or policies described in this document at any time.

Refer to section 8.7 for detailed warranty information.

1.3. Warnings and Safety Precautions

1.3.1. General

The accuracy of the measurements can be affected by the position of the patient, the patient's physiological condition, and other factors. Always consult a physician for interpretation of measurements made by this monitor.

Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

To avoid patient monitor fall, secure the monitor on a shelf or bracket outside of the 30,000 gauss magnetic field. Do not place the components of the 3880 MRI Patient monitoring system, including pulse oximeter oPOD, ECG ePOD or accessories in any position that might cause it to fall on the patient.

To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.

Explosion hazard: Do not use the 3880 MRI Patient monitor system including the pulse oximeter oPOD, ECG ePOD, or accessories in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

The operator should read and thoroughly understand this manual (Part Number 1200) completely before attempting to operate the system.

Care should be taken when using the 3880 monitor with pregnant patients to ensure that the device specifications are appropriate for the patient's vital signs and anatomy. This device is not intended for use with pre-eclamptic patients.

Fetal heart rates may be detected when monitoring pregnant patients.

Do not make modifications to this system. Modifications to the monitoring system and its components which are not authorized by IRadimed Corporation can present a hazard to the patient or user. Do not adjust, repair, open, disassemble, or modify the 3880 MRI Patient monitor system components, including the pulse oximeter oPOD, ECG ePOD, or accessories. Injury to personnel or equipment damage could occur. Return the device or its components for servicing if necessary.

Use only accessories specifically designed and approved for use with the IRadimed 3880 system. Refer to section 9 for a complete list of available accessories.

- To protect against injury, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Do not attempt to sterilize the device.
  - Use cleaning solutions only as instructed in this operator's manual.

    Do not attempt to clean the device while monitoring a patient.

    Do not submerge the pulse oximeter oPOD or ECG ePOD in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter oPOD or ePOD.

    Contraindication: Use of ECG monitoring is contraindicated on patients with conductive or active implant devices, including pacemakers or electrical stimulators.

1.3.2. MRI Monitor

Perform operational checkout before each use. If monitor fails to function properly, refer to qualified service personnel.

For safe and accurate operation and MRI compatibility, use only recommended IRadimed Corporation patient electrodes, cabling, lead wires, cuffs, hoses, sensors, tubing, etc. A listing of these can be found in the Accessory Listing within this manual, or by contacting IRadimed Corporation directly.

For continued operation, always connect the monitor to AC Main Power through the 1120 AC Power Supply when a Low Battery indication occurs. Failure to do this can lead to interruption of monitoring.

The system may not conform to all performance specifications if stored or used outside the environmental specifications identified in Exhibit A in the rear of this manual.

Do not apply any unnecessary pressure to the screen area of the monitor. Severe pressure applied to this portion of the monitor could result in damage or failure of this screen.

All equipment not complying with IEC 60601-1 should be placed outside the patient environment. Only connect IEC 60601-1 compliant equipment to this monitor. To avoid potentially hazardous leakage currents, always check the summation of leakage currents when several items of equipment are interconnected.

For proper equipment maintenance, perform the service procedures at the recommended intervals as described in the monitor’s service manual.

Single use devices should never be reused. Risk of infection or inaccurate readings may result.

Do not use this system or accessories inside a hyperbaric oxygen chamber.

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Monitor is not intended for long-term data storage.

Do not press on the buttons or touchscreen with sharp or hard objects which could damage the keys or screen. Use only finger tips with the buttons and screen. Do not place the 3880 MRI

Patient monitoring system or the pulse oximeter oPOD or ECG ePOD where the controls can be changed by the patient. In the case of the oPOD and ePOD, instruct the patient not to operate the controls.

Never connect a patients IV lines to any part of this monitor including gas and / or blood pressure connections.

Dropping, or shock to the monitor, PODs, Tablet, battery packs, or other accessories could result in damage and affect accuracy or safe operation. Refer the component to a qualified service personnel for proper checkout if any of these conditions occur.

1.3.3. Electrical Safety

Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.

To protect from electric shock, always remove the sensors and completely disconnect the pulse oximeter oPOD and ECG ePOD before bathing the patient.

ePOD and oPOD are not to be connected with any other equipment than the 3880 Monitor Unit POD charge bays. Patient connections cannot be maintained and must be disconnected when charging.

If monitor becomes wet or any fluid accidentally spills on the 3880 monitor, disconnect the power cord from the power supply, remove the battery pack, and have the 3880 monitor serviced by an authorized service representative.

Shock hazard exists if operated without chassis cover. Refer servicing to qualified service personnel only.

For continued protection against fire hazard, replace fuses with same type and rating only.

Do not use electrical power extension cords or additional Multiple Socket Outlets. Electrical power extension cords may create a safety hazard by compromising the grounding integrity of the monitor.

If the integrity of the earth conductor of the AC main power cable is in doubt, operate the monitor on internal battery power until proper earth connection is confirmed.

Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

Do not operate the 3880 MRI Patient Monitor without the 1133 Battery in place, as touching the patient and the circuitry in the battery compartment of the 3880 monitor simultaneously must be avoided.

This monitor and its listed accessories may be safely powered by the voltages 100-120VAC and 220-240 VAC having a frequency of 50 or 60 Hz.

To minimize radio interference, other electrical equipment that emits radio frequency

transmissions, other than the MRI machine, should not be in close proximity to the 3800 MR monitoring system or the pulse oximeter oPOD or ECG ePOD.

Connect only those 3880 system compatible items identified are section 1.1.3 and 9.

1.3.4. MRI Use Precautions

Certain components of this device will be affected by the magnetic and radio frequency fields present in your MRI System. Confer with your MRI physicist and/or Radiology staff to identify the proper placement and use areas for the monitor and its accessories, as defined on the monitor or accessory labeling. Failure to properly place the monitor and its accessories in the Magnet Room (Zone IV) may result in monitor failure, and possible patient or user injury. Always position the 3880 MRI Monitor at, or outside, the 30,000 Gauss (3.0T) magnetic field of the MRI system.

When using the 3885-T Remote Tablet always verify proper communication of the 3880 MRI Monitor with the 3885-T Remote Tablet prior to patient use. Should communication with the Remote Tablet be interrupted, maintain direct visual and audible contact with the 3880 monitor unit.

1.3.5. MRI Magnet Room (Zone IV) Placement

The 3880 MRI Monitor may be used in conjunction with an optional remote control. The 3880 MRI Monitor is specially designed not to interfere with MRI operations and may be used inside the MRI Magnet Room in any location at or outside the 30,000 Gauss (3.0T) Field of the MRI System.

Always place the 3880 MRI Monitor so that your view of the screen and alarm light will remain unobstructed during use.

Risk of RF burn. ECG Lead wires which become inadvertently looped during MRI act as conductive lines for RF induced currents. When lead cables or other cables form a conductive loop in contact with the patient's tissue, minor to severe burning can result.

The 3885-T Remote Tablet is not for use in Zone IV, though it can be exposed to up to a 15,000 Gauss field.

Avoid when possible and use care when using accessories inside the FOV. If artifact is present then re-position the oPOD, ePOD or accessories.

Keep cables clear from moving parts. Cables can get pinched and damaged between the MRI table and / or MRI bore causing a delay in monitoring.

1.3.6. MRI Compatibility

The MRI ECG electrode, and ECG Patient Lead Wires/Cable, are compatible with Magnetic Resonance Imaging (MRI) Systems within the following guidelines:

- MRI systems with static magnetic field strengths up to 3.0 Tesla.
- Usable within the MRI system bore with a Specific Absorption Ratio (SAR) of up to 4.0 W/Kg (whole body average). Use with a higher SAR greatly increases the risk of patient burns.
- Non-Magnetic materials are used in the construction of these assemblies.

- If scanned directly across the plane of the ECG electrode, a slight image distortion may be seen at the skin surface where the electrode is positioned.
- Keep the ECG ePod and SpO_2 oPOD out of the image Field of View (FOV). If scanned directly across the plane of either POD, image distortion may be seen where the POD(s) are positioned.

Perform the following to minimize risk of RF burn:

1. Keep ePOD and ECG lead wires from pressing against the bore of the MR magnet.
2. RF burn risk increases when multiple sensors/cables are in use. Such combinations are not recommended.
3. Should power levels greater than a SAR of 4 w/kg whole body average be used, the risk of patient heating or burn greatly increases. As a result, monitoring of ECG at power levels of greater than 4 W/Kg is not recommended for the general patient population. Such monitoring should only be attempted on conscious patients with good temperature reflex so they may warn the operator of excessive heat at the monitoring sites.
4. High RF energy may cause patient heating or burns. For scans with whole body average SAR >2 W/Kg, follow best practices such as limiting scan time to 5 minutes and pausing at least 3 minutes between scans to allow patient to cool.

1.3.7. Vital Sign Parameters

- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the 3800 MRI monitoring system is used.

1.3.7.1. ECG

For best ECG and Heart Rate monitoring, always select the optimum lead view which has the least artifact and largest QRS complex being detected for monitoring use.

Failure to respond to a Lead Fail alarm will cause a lapse in your patient's monitoring. Always respond promptly to this and any other alarms.

MRI induced gradient or radiofrequency artifact can sometimes cause inaccurate heart rates. Inspect the ECG waveform during MRI scanning if spurious heart rates are observed.

B0 (static) magnetic field artifact can present artificially-induced augmented T waves during ECG monitoring. Due to the effects of the magnetic field on the moving blood of the patient, follow the recommended ECG electrode placement to minimize this type of artifact.

An inoperative ECG is indicated by absence of an ECG trace. See section 2.2.12.4.2

Heart rate values may be adversely affected by cardiac arrhythmia, or by operation of electrical stimulators.

Ensure that the IRadimed MRI electrodes and / or ePOD wire set do not come in contact with any other conductive parts including Earth.

The 3880 patient monitor is not intended for use on patients with pacemakers or electrical stimulators.

1.3.7.2. NIBP

Use only NIBP accessories approved for MRI use (See MRI Accessory list in Section 9).

When using the NIBP portion of this instrument to measure blood pressure, remember that the patient's blood pressure readings are not continuous, but are updated each time a blood pressure measurement is taken. Set a shorter interval for more frequent updating of the patient's blood pressure.

Do not attach the NIBP cuff to a limb being used for infusion, therapy or an arterio-venous (A-V) shunt. Cuff inflation can block infusions, therapy or shunt bypass, possibly causing harm to the patient.

Frequent NIBP measurements can cause pooling of the blood in the limb (hemostasis), and peripheral tissue/nerve damage. Allow sufficient time for blood recirculation to prevent pooling of the blood in the limb.

Arrhythmic and/or erratic heart beats (or severe motion artifact, such as tremors or convulsions) can result in inaccurate readings and/or prolonged measurements. If questionable readings are obtained, re-check patient's vital signs by alternate means before administering medication.

To prevent possible nerve damage to the limb, apply the NIBP cuff as recommended by current American Heart Association (AHA) guidelines for blood pressure monitoring.

To ensure accurate and reliable measurements, use only recommended NIBP cuffs/hoses. For best accuracy, use the appropriate cuff size for each patient as recommended by the current American Heart Association (AHA) guidelines for blood pressure monitoring.

Always tighten the NIBP cuff air hose connections snugly into place for proper operation.

Avoid NIBP measurements on any limb with swelling (e.g. from lymphedema). Patient harm and/or inaccurate measurements could result.

Routinely inspect the NIBP cuff and hose assemblies for proper attachment and orientation. Replace any damaged cuff and/or hose assemblies with cracks, holes, tears, cuts, etc. that could cause leaks in the system. If cuff and/or hose assemblies with damage which could result in leaks are used, prolonged and/or inaccurate patient readings could result.

To prevent skin abrasion, apply and remove NIBP cuff carefully. Keep Velcro® (hook and latch) retention areas away from the skin.

Always use recommended NIBP cuffs and hoses. Avoid compression or restriction of NIBP hose.

1.3.7.3. SpO_2

The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

Do not start or operate the pulse oximeter unless the setup was verified to be correct.

Do not use the pulse oximeter if it appears or is suspected to be damaged.

Use only MRI compatible SpO_2 accessories (See MRI Accessory list in Section 9).

Use only the Fiber-optic SpO_2 sensors recommended by IRadimed Corporation. A listing of these can be found in the Accessory List within this manual, or by contacting IRadimed Corporation directly.

The Fiber-optic SpO_2 sensors are constructed of fiber-optic glass and should always be handled with care to prevent damage. Improper handling can reduce both the signal transmission quality and the SpO_2 measurement sensitivity. Improper handling can also shorten the SpO_2 sensor's useful life.

The pulse oximeter feature in this monitor is designed to display functional SpO_2 values.

SpO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

The pulse oximeter pulsatile waveform is not proportional to the pulse amplitude, but adjusts the waveform amplitude as needed for proper viewing.

Avoid placement of the SpO_2 probe on the same limb with an inflated blood pressure cuff. Cuff inflation could result in inaccurate readings and false alarm violations.

SpO_2 monitoring requires the detection of valid pulses to correctly determine SpO_2 and Heart Rate values. During conditions of gross artifact, or in the absence of valid pulses, the SpO_2 and / or pulse rate values may not be correct.

The SpO_2 monitoring portion of this monitor is intended to measure arterial hemoglobin oxygen saturation of functional hemoglobin (saturation of hemoglobin functionally available for transporting oxygen in the arteries). Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, may affect the accuracy of the measurement. Also, Cardiogreen and other intravascular dyes may, depending on their concentration, affect the accuracy of the SpO_2 measurement.

Always shield the SpO_2 sensor from extraneous incident light sources. Such extraneous light can cause SpO_2 reading or pulse detection errors.

Frequently inspect the SpO_2 sensor site for possible pressure tissue necrosis during prolonged monitoring. Reposition the sensor at least every 4 hours. Special care should be exercised when tape is used to secure the sensor, as the stretch memory properties of most tapes can easily apply unintended pressure to the sensor site.

The pulse oximeter is not an apnea monitor.

The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

The pulse oximeter should not be used for arrhythmia analysis.

If using pulse oximetry during full body irradiation, other than in MRI, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.

A functional tester cannot be used to assess the accuracy of the pulse oximeter.

High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.

At higher sensitivity settings, performance of the "SpO2 Probe Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

Do not loop the fiber optic sensor cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

1.3.7.4. CO_2 Only and Multi-Gas Systems

The 3880 MRI Patient Monitoring system offers two methods of gas monitoring, consisting of an integrated CO2/Respiration only option, and an external Multi-Gas (P/N 3886) option. The 3886 Multi-Gas Unit provides measurement of CO2/ Respiration, Fast ‘Parametric’ O2, N2O with automatic identification and measurement of a two gas mixture of five possible anesthetic agents. The unit is based upon the Masimo/Phasein ‘OR+’ sidestream gas analyzer. This unit is intended to be located in magnetic fields of less than 600 Gauss, such as direct mounting to an MR Anesthesia machine. See appendix E for more details of both methods of gas analysis.

The integrated CO2/Respiration only solution, utilizes a solid state gas detection system as well as a non-magnetic piezo sampling pump, for operation to 30,000 Gauss. This CO2 only unit is not for use with anesthetic agents.

The accessory items for the built in CO2/Respiration only option can be found in section 9.4, with the accessories for use with the 3886 Multi-Gas Unit in section 9.5. The accessories have different types of connections so that the Multi-Gas Unit accessories only can connect to the 3886 Multi-Gas Unit, while the CO2 only accessories can only mate with the built in CO2 only option.

Always select the appropriate CO_2 tubing set for the patient being monitored. Verify that the patient’s breathing efforts and timing coincide with the monitor’s waveform before completion of the patient set-up.

Frequently inspect the CO_2 patient tubing for proper gas flow. Avoid kinking of the CO_2 patient tubing that can result in leaking, reduction, or cut-off of the sample gas flow. Inaccurate gas measurements could result.

During gas monitoring, a water vapor evacuating tubing (Nafion) which is included in the gas sample circuit, reduces water vapor content of the patient's exhaled breath.

For proper operation, check the CO_2 calibration during routine service. Routine calibration

should not be required, but if the specified operation does not occur, have a qualified service person recheck the calibration. Proper re-calibration can only be performed during factory service.

Gas sampling patient tubing and associated components are intended for single-patient use only. Avoid cleaning or disinfecting these items for reuse. Inaccurate gas measurements or cross contamination could result.

To prevent inaccurate or missed readings, keep the CO_2 patient tubing clear of any moving mechanisms which may kink, cut or dislodge the patient tubing.

Avoid connecting the CO_2 calibration gas canister to the monitor by any method other than with the designated calibration tubing. Connecting by any other method could invalidate the calibration, and/or damage the monitor.

The gas measurements are displayed within 1 second of when the gas was sampled internally to the associated analyzer.

1.3.7.5. Other

When positioned upon an IV pole or mobile cart, always secure the wheel locks when placed within the MRI Magnet Room (Zone IV).

This product, or any of its parts, should not be repaired other than in accordance with written instructions provided by IRadimed Corporation, or altered without prior written approval of IRadimed Corporation.

No parts of the 3880 Patient Monitoring System shall be serviced while they are in use with a patient.

The user of this product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than IRadimed Corporation, or its authorized service personnel.

This monitor is equipped with a demonstration mode which displays simulated electronic patient data for training or demonstration purposes. Do not attach a patient to the monitor whenever this simulation is present on the monitor display (“SIMULATION” can also be seen in the screen center).

All monitor alarms are categorized as medium priority, unless otherwise specified.

The patient connector inputs for all parameters are protected against the use of a defibrillator by internal circuitry, and when the recommended patient cables or accessories are used. Though not intended for use with High Frequency Surgical Equipment, the use of this circuitry and the recommended cables and accessories provided in section 9 protect against the hazards resulting from use of high frequency surgical equipment.

This monitor should not be synchronized with a defibrillator.

There are no known electromagnetic or other hazardous interference between the monitor and other devices. However, care should be taken to avoid the use of cellular phones or other unintended radio-frequency transmitters in the proximity of the monitoring system.

This monitor is not intended to be used with exposure to Linear Accelerator beam.

This monitor, ECG ePOD(s), SpO_2 oPOD(s), and the 3885-T Remote Tablet use lithium polymer rechargeable batteries, which must be recycled, or disposed of properly. For proper disposal methods, contact your local IRadimed Corporation representative or distributor.

1.3.8. USER RESPONSIBILITY

This product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided.

This product must be checked periodically for proper operation. A defective or questionable product should not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately.

Should such repair or replacement become necessary, IRadimed Corporation recommends that a telephone call or written request for service be made to the factory or nearest service center. IRadimed's toll free number is: 866-677-8022 or 407-677-8022, ask for technical assistance.

This product or any of its parts should not be repaired other than in accordance with written instructions provided by IRadimed Corporation or altered without the prior written approval of IRadimed.

The user of the product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than IRadimed Corporation or IRadimed Corporation authorized service provider.

Users must confirm the intended values are displayed on the screen during setup and after any changes.

1.3.9. Manufacturer's Responsibility

This product will perform as intended only if:

- The 3880 MRI monitoring system is used in accordance with the manufacturer's specification, recommendations, warnings and precautions.
- The 3880 MRI monitoring system is installed, maintained and serviced in accordance with the instructions provided in the related technical manuals.
- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by IRadimed.

1.3.10. Safety Warnings Designation

1.3.10.1. Warning

! WARNING

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

1.3.10.2. Caution

! CAUTION

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor injury or product/property damage.

1.3.10.3. Note

NOTE

- Provides application tips or other useful or important information.

1.3.11. Disposal

! WARNING

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate appropriately before disposing of it in accordance with local laws.

1.3.11.1. Waste

At the end of lifetime, the product and its accessories must be disposed of in compliance with the guidelines regulating the disposal of such products. Never dispose of waste electrical and electronic equipment as unsorted municipal waste. Remove potentially dangerous materials (for example batteries) before disposal. Collect materials separately, so that it can be safely and properly reused, treated, recycled, or recovered. If you have questions concerning disposal of the product, please contact IRadimed Corporation or your local IRadimed representatives.

Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.

1.3.11.2. Batteries

When a battery has visual signs of damage, or no longer holds 50% of rated capacity, it should be replaced. Follow local laws for proper disposal of batteries.

! WARNING

Do not disassemble batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, leak or heat up causing personal injury.

1.3.11.3. Electronics

The 3880 monitoring system, radio, and accessories are subject to strict disposal regulations for user and environmental safety. Observe and adhere to all local regulations when disposing of any electronic component.

1.3.11.4. Calibration Gases and Patient-Related Materials

The 3880 Monitoring System and its accessories are subject to strict disposal regulations for user and environmental safety. Observe and adhere to all local regulations when disposing of any containers of calibration gases, patient scavenged gases, and any other patient-related accessories used during monitoring.

2. Getting Started

2.1. About 3880

2.1.1. Introduction

The 3880 system is a Non-Magnetic multi-parameter patient monitor to continuously monitor patients throughout the entire MRI care cycle. The 3880 monitor is comprised of the 3880 MRI Monitor, 3881 ePOD, 3882 oPOD and an optional 3885-T Remote Tablet with 3885-B Base Station. Further options include, CO2, Temperature, and the 3886 Multi-Gas unit. The wireless 3880 solution is designed to be small, simple and light weight making it a practical intra-department patient transportation monitor for the MRI suite. This system is not intended for patient transportation between hospitals. The 3880 system is equipped to support an entire nursing shift with greater than 8 hours of typical battery operation. The 3880 monitor is Non-Magnetic* and its MRI specific accessories are intended for the harsh MRI examination procedures and environment including ultra-high-field applications.

The 3880 patient monitoring solution utilizes non-magnetic wireless technology which improves safety, usability and data connectivity. The system utilizes wireless ECG and SpO_2 PODs which simplify patient workflow and setup by reducing the potential for loops and sensor damage.

- **Standard Features**
    1. Small portable design weighing approximately 8.9 lbs (4 Kg)
    2. Non-Magnetic and MRI conditional multi-parameter monitor up to 30,000 Gauss and 4 W/Kg whole body average SAR
    3. 10 inch color touchscreen user interface to simplify operation and cleanliness
    4. Integrated wireless ECG and SpO_2 POD charging
    5. Wireless ECG and SpO_2 POD enabled
    6. 2.4 GHz wireless communication enabled for optional remote viewing
    7. Integrated non-invasive blood pressure monitoring
    8. Masimo SET SpO_2 monitoring
    9. Integrated MRI system gating enabled
    10. Tri-Color Alarm Dome Light
    11. ECG waveform gradient removal algorithms
    12. Minimum of 8 hour battery operation
    13. Instant On system start (< 4 seconds)

* Magnetic field ≤ 30,000 Gauss (3.0T)

- **Optional Features**
    1. Integrated Sidestream Capnography monitoring
    2. Integrated Sidestream Capnography or external 3886 Multi-Gas CO2/Anesthetic Agent monitoring
    3. O2 monitoring, with Agent Unit
    4. Integrated temperature monitoring
    5. 10 inch color Touchscreen Tablet
    6. Base station
    7. Thermal Strip Chart Recorder
    8. HDMI output
    9. Mount for pole and bedrail operation

2.1.2. System Hardware Overview

2.1.2.1. System Hardware Components (accessories not shown)

3880 Non-Magnetic patient monitor

MR conditional to 30,000 Gauss
For use in MR magnet room

3885-T Remote Tablet (Optional)

MR conditional to 15,000 Gauss
For use outside MR magnet room

3882 Wireless SpO_2 oPOD

For patient monitoring in bore

MR conditional
to 30,000 Gauss

3881 Wireless ECG ePOD

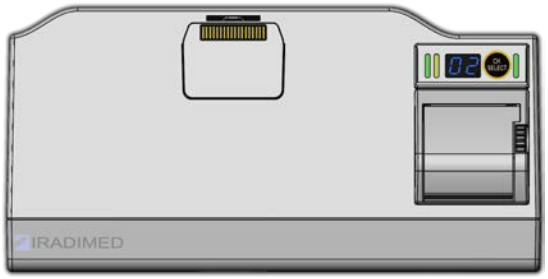
For patient monitoring in bore

3886 Wireless Multi-Gas Unit (Optional)

MR conditional to 600 Gauss
For use in MR magnet room

The 3880, 3881, 3882, and 3886 can be used in all zones. See section 2.1.8.

3885-B Base Station (Optional)



Base Unit acts as wireless repeater link between 3880 monitor and 3885-T remote tablet. Base also hosts the strip chart recorder/printer.

MR “unsafe” for use outside MR magnet room.

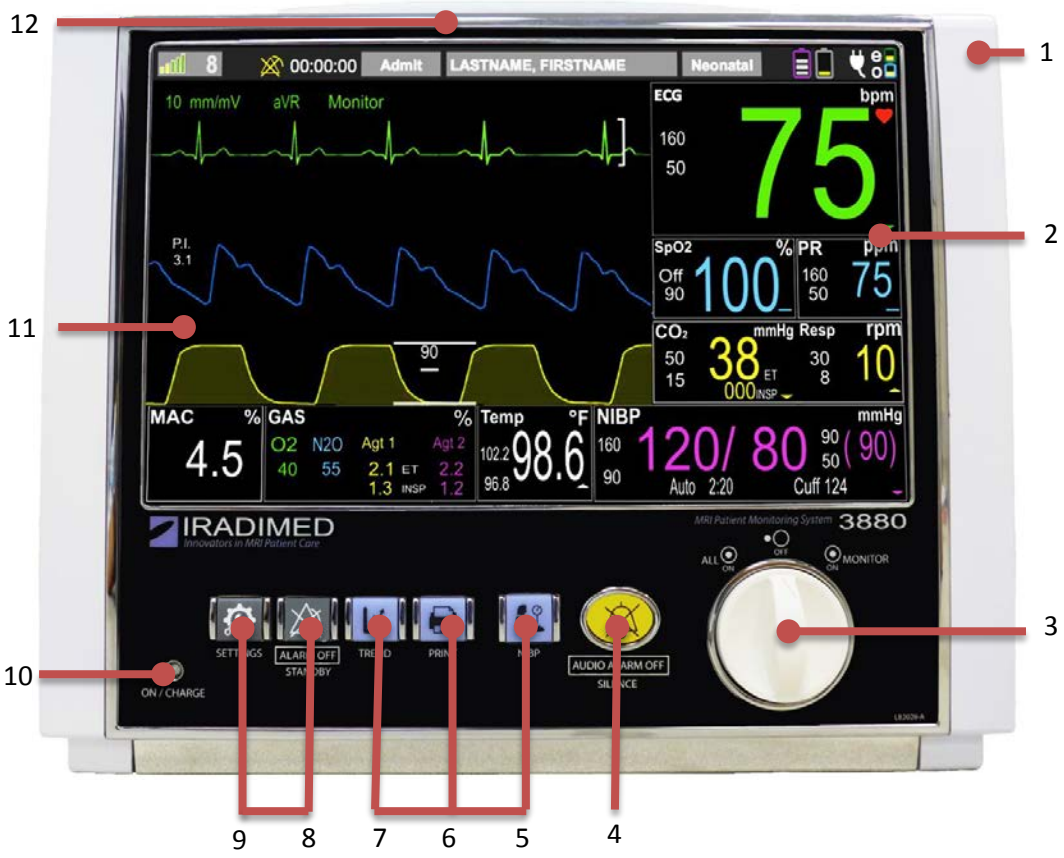
The 3885-B is for use only in Zone III. See section 2.1.8.

2.1.3. 3880 Monitoring System Components

2.1.3.1. 3880 Multi-Parameter Monitor

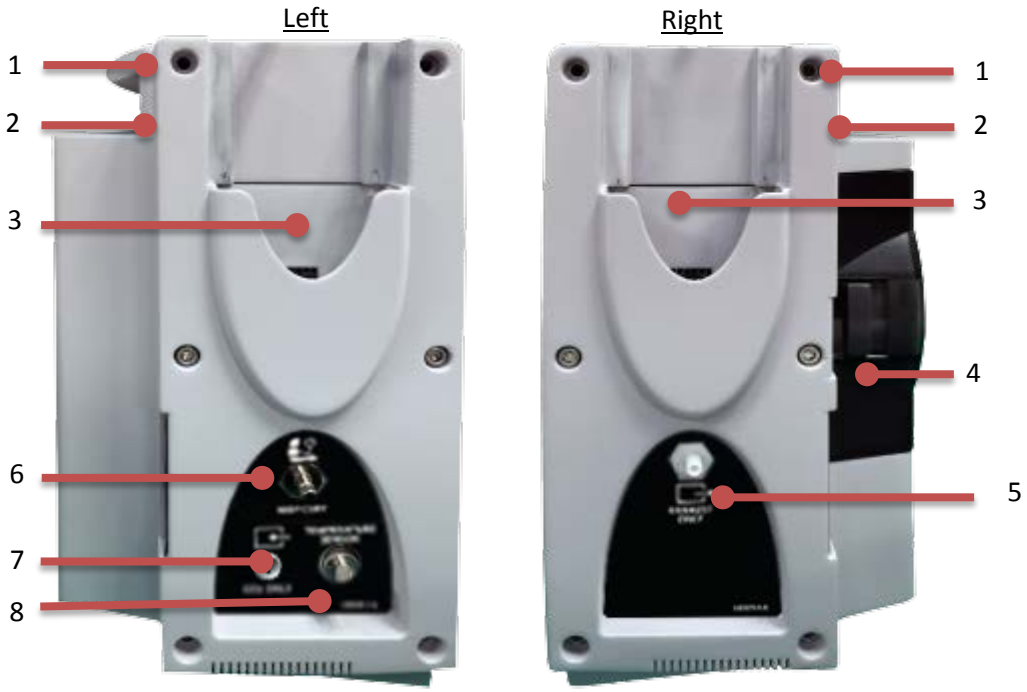
The 3880 system is a small and portable Non-Magnetic multi-parameter patient monitor designed for use when a large magnetic field such as a MRI system will be present during the patient's care cycle. The 3880 system is used to acquire, process, and display all vital sign measurements during patient transport and during the MRI procedure.

2.1.3.1.1 Front View



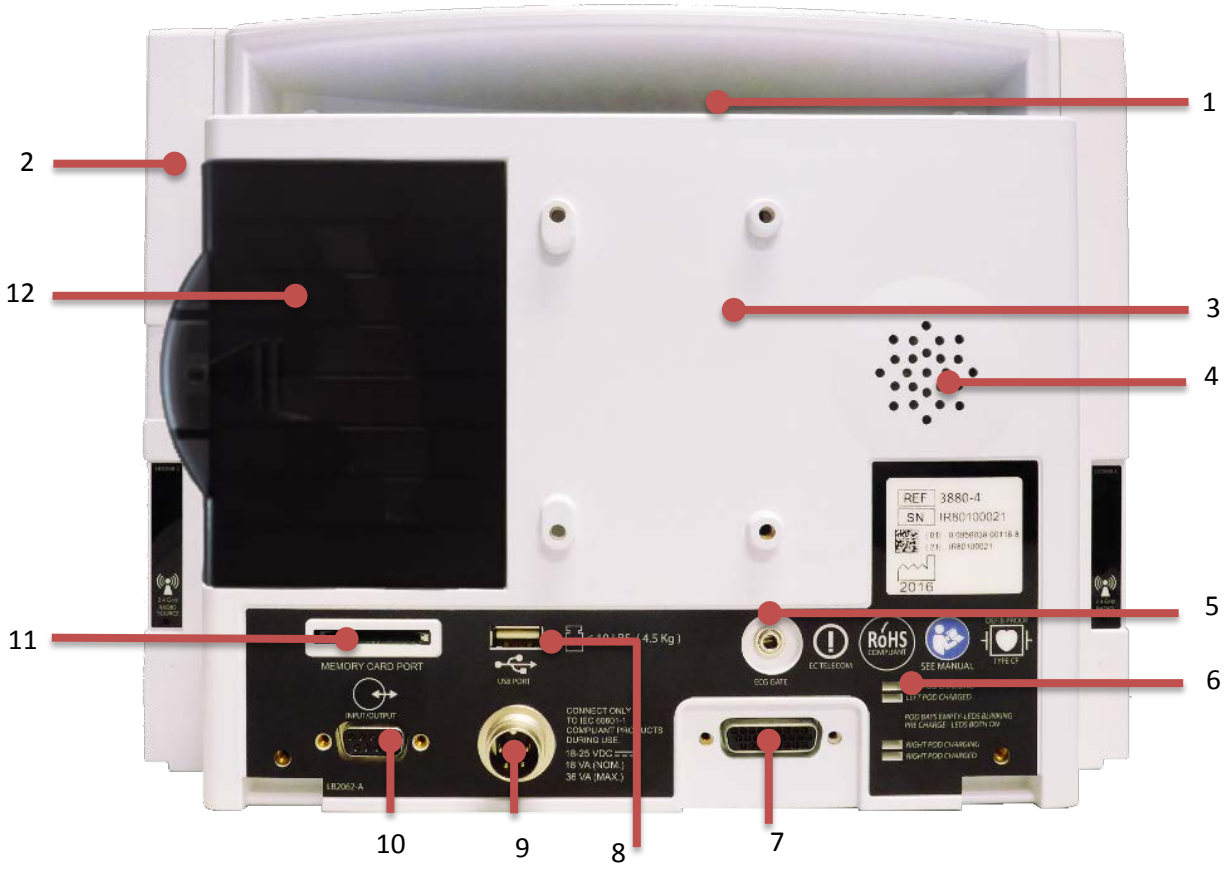
1. Lightweight, Nonmagnetic Case
2. Vital Sign Numerical Information Boxes
3. Power ON/OFF Dial, Clockwise Monitor only ON, Center Off, Counter clockwise All On for Monitor and future Option Expansion Connector power on
4. Audio Alarm Off - Alarm Silence Button [AUDIO ALARM OFF]
5. Case Management Button: NIBP Start/Stop (Hold down to initiate STAT readings)
6. Case Management Button: Recorder Start/Stop (recorder optional with 3885-B)
7. Case Management Button: Trend Quick Access
8. Configuration Button: Monitor Standby [ALARM OFF] Mode ON/OFF
9. Configuration Button: Monitor Settings (Menus)
10. Mains Power/Charging LED Status
11. Touchscreen Display Interface
12. Tri-Color Alarm Dome Light

2.1.3.1.2 Side View



1. Handle
2. Cable Management Clip
3. ECG ePOD or SpO_2 oPOD charging bay
4. User Replaceable Battery
5. Exhaust Scavenge Connection, Gas Outlet
6. Patient Vital Sign Connections: NIBP Port
7. Patient Vital Sign Connections: Built in CO_2 Only Port, Gas Inlet
8. Patient Vital Sign Connections: Fiber optic Temperature Connector

2.1.3.1.3 Rear View



1. Handle
2. Cable Management Clip
3. Flex Mount IV Pole / Bed Rail Mount
4. Speaker
5. Gating Output
6. POD Charging Status Indicator,
   Blinking = No connection, Amber = Charging, Green = Charged
7. Future Option Expansion Connector
8. USB Port
9. Power Input, 19 VDC
10. Input / Output Connector, serial RS232
11. SD memory card slot
12. User Replaceable Battery

! WARNING

- Data I/O ports on the 3880 rear panel are not a PC-compatible computer format. Do not connect any non-IRadimed accessory to these ports during patient use. Improper monitoring operation could result. Refer to the service manual for specific port use.

NOTE

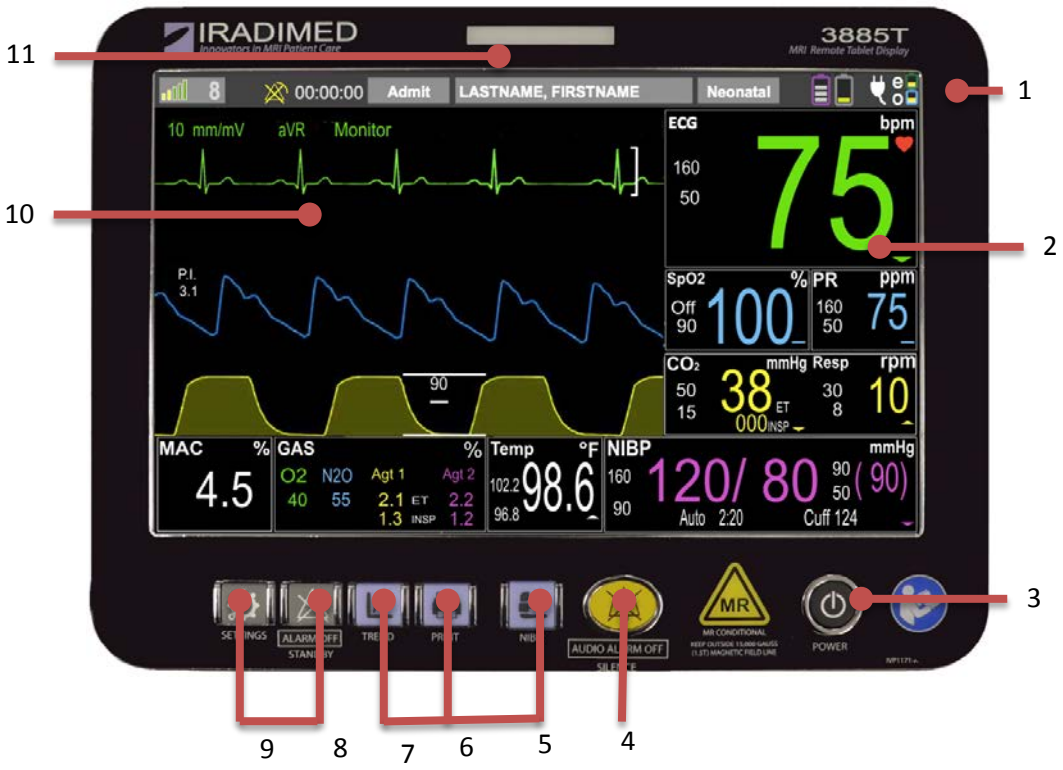
- Do not connect any non-IRadimed supplied devices or cabling to the connections on the back of the 3880 as these connections do not provide electrical isolation.
- Any peripherals or serial cables connected to the data ports must be IEC 950 or IEC 60950 compliant.
- The 3880 uses a serial port (DB-9 female) for the external data output port. The monitor uses a proprietary RS232 communication protocol.

- Remove any protective port covers prior to use.

2.1.3.2.3885-T Remote Tablet

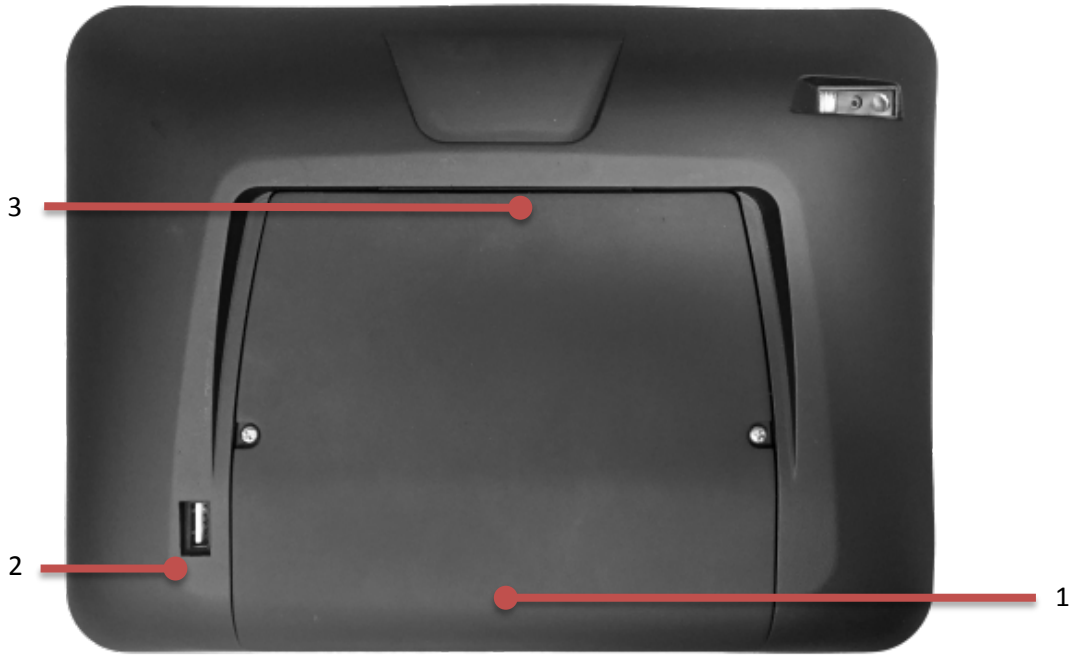
The 3885-T optional Remote Tablet is a convenient user interface mirroring the 3880 Monitor unit, to display, monitor, control and document the patient case. The 3885-T Remote Tablet is non-magnetic up to 15,000 Gauss, but is not RF shielded for use inside of zone IV during imaging. The 3885-T Remote Tablet has the following hardware features.

2.1.3.2.1 Front View



1. Non-Magnetic Case
2. Vital Sign Numerical Information Boxes
3. Power ON/OFF Button
4. Audio Alarm Off - Alarm Silence Button
5. Case Management Button: NIBP Start/Stop
6. Case Management Button: Recorder Start/Stop (recorder optional with 3885-B)
7. Case Management Button: Trend Quick Access
8. Configuration Button: Monitor Standby Mode ON/OFF
9. Configuration Button: Monitor Settings
10. Touchscreen Display Interface
11. Tri-Color Alarm Dome Light

2.1.3.2.2 Remote Tablet Rear View

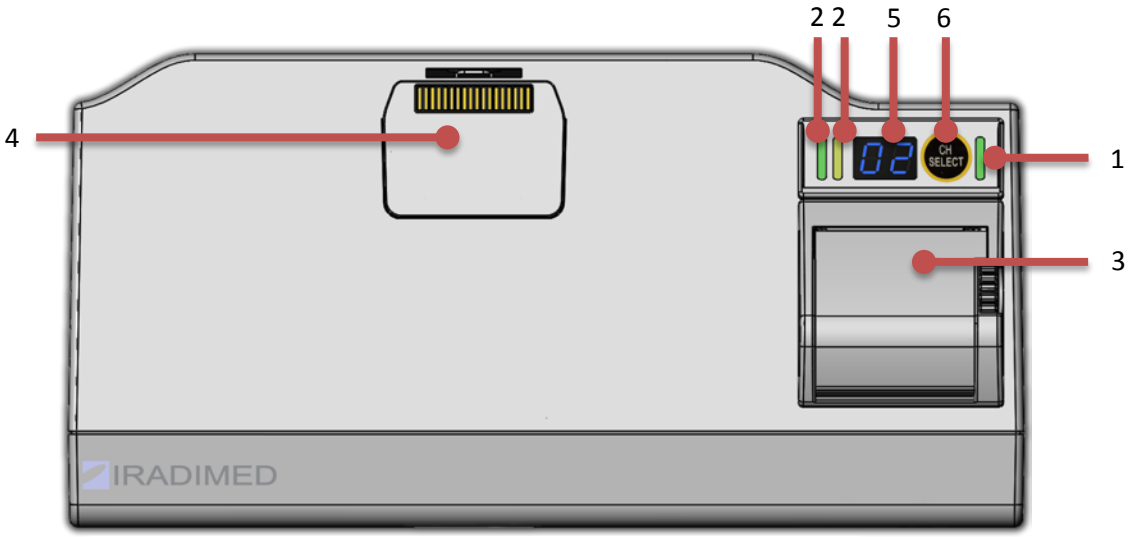


1. Replaceable Battery
2. USB Port
3. Base Station Dock

2.1.3.3.3885-B Base Station

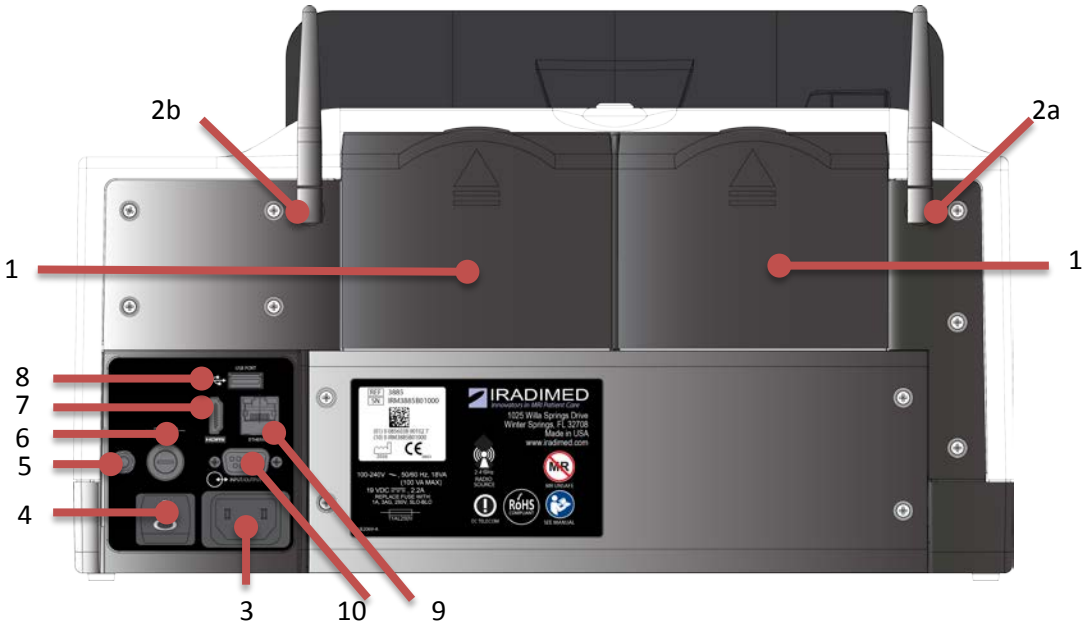
The 3885-B Base Station is the communication hub of the 3880 MRI Patient Monitoring System. The Base Station is facilitates transfer of data through the MRI shielding, enabling wireless communication between the 3880 Patient Monitoring System components during MRI procedures. The Base Station also serves as a MRI Control room charging and strip chart recording/printing station. Tablet and Base must always be on the SAME channel. To connect a complete wireless system with the 3880 Monitor unit and ePOD / oPOD, all devices should be on the same channel.

2.1.3.3.1 Front View



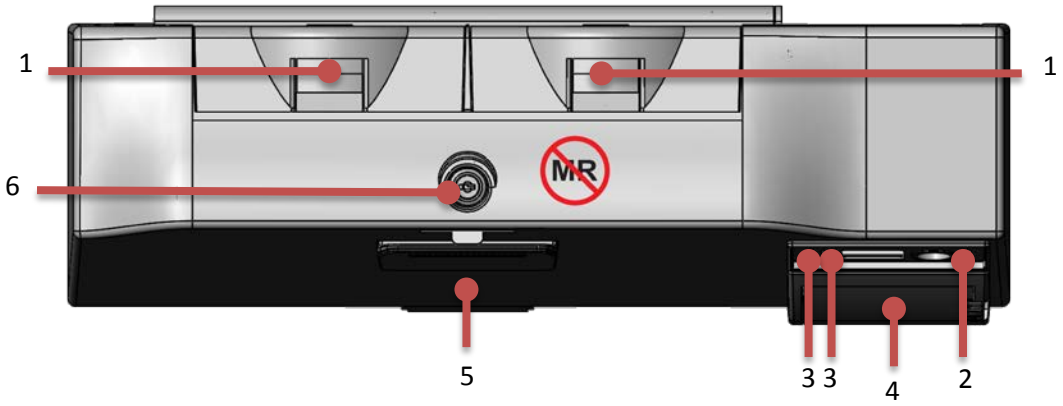
1. Power Status Indicator of the Base Station, Tablet Charge Indicator (Amber)
2. Charging Indicators for 1133 Battery Packs
3. Thermal Strip Chart Recorder/Printer
4. Tablet / Base Station Dock
5. Channel LED Indicator
6. Channel Select Button

2.1.3.3.2 Rear View



1. 3880 Monitor unit Battery charging bay
2. Antenna Connectors:
   2a MRI Room Zone IV antenna connection, Base/3880 monitor
   2b Zone II and III 3885-T Tablet / 3885-B Base Station antenna
3. AC Power Receptacle
4. ON/OFF Mains Power Switch
5. Ground Terminal
6. Fuse
7. HDMI Output
8. USB Port
9. Ethernet Connector
10. I/O Port

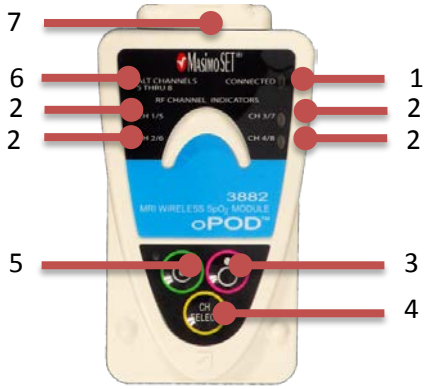
2.1.3.3.3 Top View



1. 3880 Monitor unit Battery Charging Bay
2. Power LED status of the Base Station
3. Charging Indicators for 1133 Battery Packs
4. Thermal Strip Chart Recorder
5. Tablet / Base Station Dock
6. Tablet Lock

2.1.3.4.3882 Wireless SpO_2 oPOD

The Wireless SpO_2 oPOD communicates the pulse waveform, heart rate and perfusion index to the 3880 monitor. The pulse waveform can be displayed and is output from the 3880 monitor as a MRI system gating input. The SpO_2 oPOD is powered by one battery that is charged when docked to the 3880 monitor. The wireless oPOD features internal temperature cutoff protection in the event that the operating temperature exceeds the designed limits. The wireless SpO_2 oPOD has the following hardware features.



1. RF Connection
2. RF Channel Indicators, 1 or 5, 2 or 6, 3 or 7, 4 or 8
3. OFF Button
4. RF Channel Selector
5. ON Button
6. Channel 5-8 Indicator – indicates channel indicator count 5 - 8
7. SpO_2 Sensor Connector

NOTE

- Turn off PODs when not in use

2.1.3.5. 3881 Wireless ECG ePOD

The Wireless ECG ePOD communicates two channels of ECG simultaneously to the 3880 monitor. These two channels of ECG can be displayed with lead of Trace A output from the 3880 monitor as a MRI system cardiac gating input. The ECG ePOD is powered by one battery that is charged when docked to the 3880 monitor. The wireless ePOD features internal temperature cutoff protection in the event that the operating temperature exceeds the designed limits. The wireless ECG ePOD has the following hardware features.

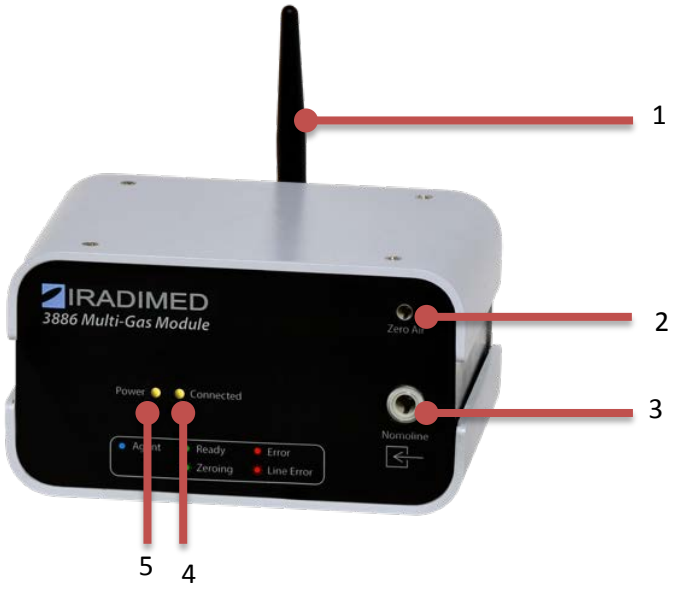
1. RF Connection
2. RF Channel Indicators, 1 or 5, 2 or 6, 3 or 7, 4 or 8
3. OFF Button
4. RF Channel Selector
5. ON Button
6. Channel 5-8 Indicator, indicate channel indications count 5 - 8
7. ECG Lead Wire Connector

NOTE.

- Turn off PODs when not in use

2.1.3.6. 3886 Wireless Multi-Gas Unit

The 3886 Multi-Gas unit removes the airway tether to the monitor by residing on the anesthesia machine and wirelessly communicating patient gas information to the 3880 MRI Monitor.

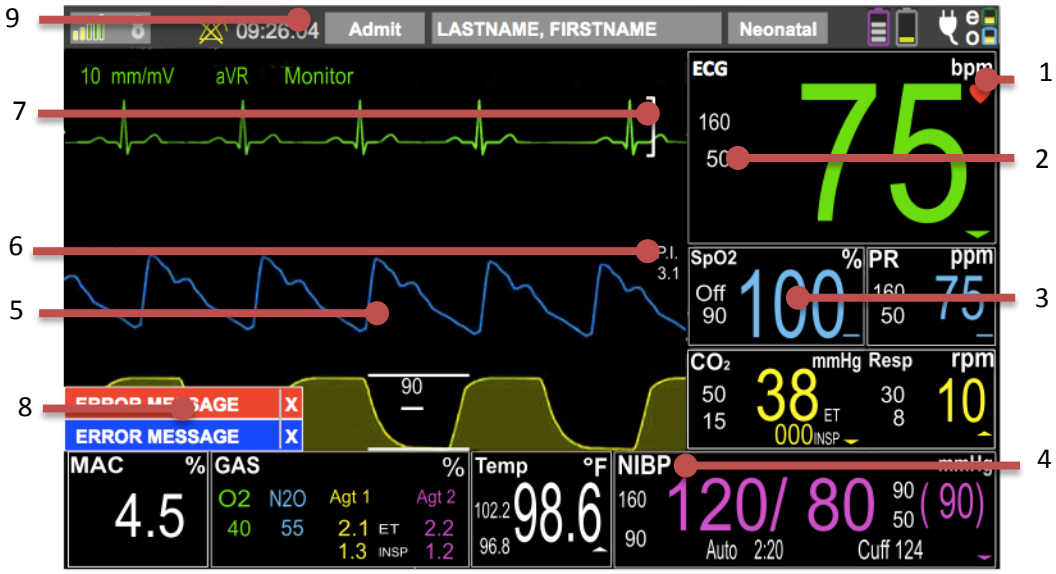


1. Antenna
2. Zero Port
3. Nomoline Sample line Receptacle
4. Wireless Communication LED
5. Power LED

2.1.4. User Interface Overview

2.1.4.1. Displayed Information (3880 and 3885-T Remote Tablet)

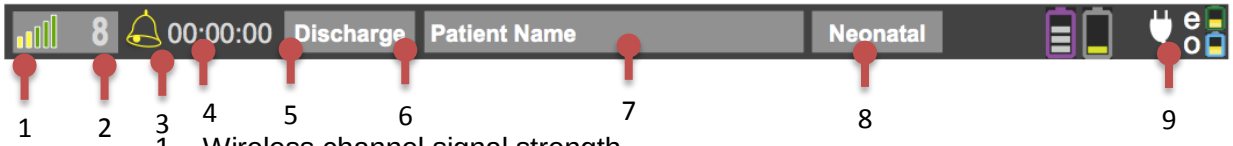
High resolution color graphics facilitate waveform analysis and vital sign numeric interpretation. Important display elements are designed to be legible at a distance of 1 meter. When using the 3880 system always adjust the viewing angle of the display to complement your line of sight and always ensure that your view remains unobstructed.



1. Vital Sign Unit of Measure
2. Alarm Upper and Lower Limits
3. Current Vital Sign Numerical Measurement
4. Vital Sign Description
5. Vital Sign Waveform
6. SpO_2 Perfusion Index
7. ECG Indicator
8. Message and Alerts Area
9. Information Bar

2.1.4.1.1 Information Bar

The information bar (located along the top of the screen) provides system, patient and monitoring information including access to case management, patient type and user setting functions.



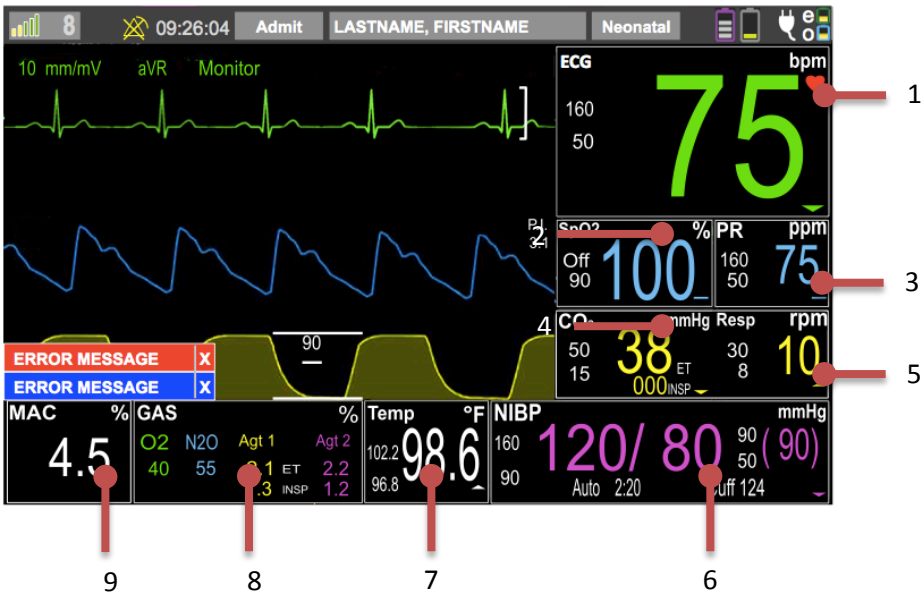
1. Wireless channel signal strength
2. Wireless channel (1-8)
3. Current state of the alarm sound: If alarm sounding, clapper swings and glows red
4. State of Alarm, indicates ALARMS OFF or ALARM Occurring
5. Clock: Current Time
6. Admit / Discharge Button
7. Current Patient Name
8. Patient Type Selection
9. Power Status: Battery, Charge and AC
    a. Purple Battery Symbol = 3885-T Remote Tablet
    b. Gray Battery Symbol = 3880 Monitor
    c. Green = 3881 ECG ePOD
    d. Blue = 3882 SpO_2 oPOD

    } display of POD battery icon also indicates communication link with POD

    e. White AC power connected at 3880 Monitor unit icon

2.1.4.2. Vital Sign Numerics

Vital sign numerical boxes (located in the right and bottom of the screen) are uniquely colored and labeled framed boxes that display the numeric measurements for each monitored vital sign parameter. The current alarm limits settings (where applicable), parameter-specific settings and associated messages may also be displayed within these boxes to alert for potential or detected problems. In addition, touching the vital sign box allows entry into the menu of the respective parameters.



1. Heart Rate Vital Sign Box – Electrocardiogram heart rate measurement
2. SpO_2 Vital Sign Box – Pulse Oximetry / Blood Oxygen Saturation measurement
3. PR Vital Sign Box – Pulse Rate from SpO_2
4. CO_2 Vital Sign Box – Capnography measurement
5. RESP Vital Sign Box – Respiration Capnography breath rate measurement
6. NIBP Vital Sign Box – Non-Invasive blood pressure measurement
7. Temp Vital Sign Box – Temperature measurement
8. Gas Vital Sign Box – Anesthetic Agent, Oxygen and N_2O measurements
9. MAC Vital Sign Box – Minimum Alveolar Concentration

NOTE

- Under certain conditions one or more vital sign numeric may display dashes, which indicate that no data is available.
- If a parameter is disabled or unavailable, the vital sign boxes will be empty.

2.1.4.3. Vital Sign Waveforms

Vital sign waveforms (located in the center of the screen) are uniquely colored waveforms for the ECG, SpO_2 and CO_2 parameters. These waveforms are fixed across the screen, adjustable and updated from left to right with an erase bar. The color of the waveform corresponds to the associated vital sign box numeric for that parameter.

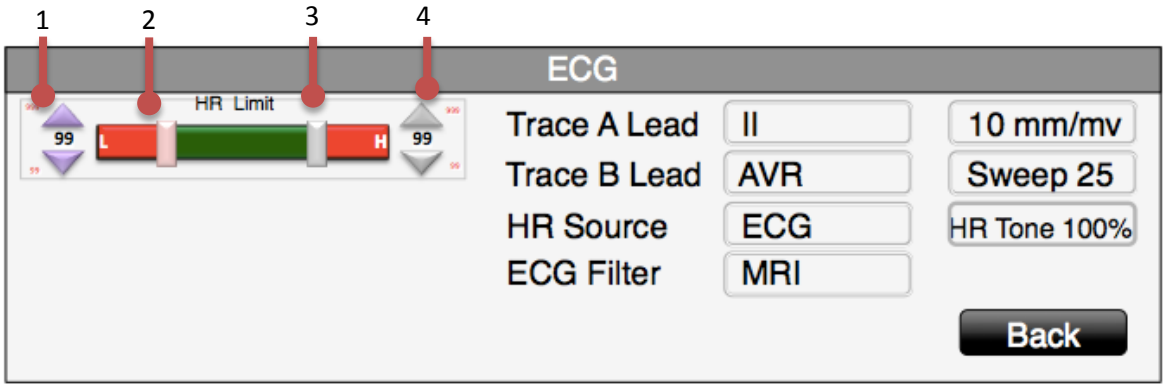
1. ECG Trace A Lead View
2. ECG Trace A
3. ECG Trace B
4. SpO_2 Waveform
5. CO_2 Waveform
6. ECG Trace B Scale Indicator
7. ECG Trace B Lead View
8. ECG Trace A Scale Indicator
9. ECG Scale

NOTE

- Under certain conditions one or more vital sign numeric may display dashes, which indicate that no data is available.
- Up to four waveforms can be displayed, but if a parameter is turned off or unavailable that waveform portion of the screen will be blank.

2.1.4.4. Alarm Example

Alarm adjustments can be made by touching the corresponding vital sign numerical box of the alarm that needs adjusting.



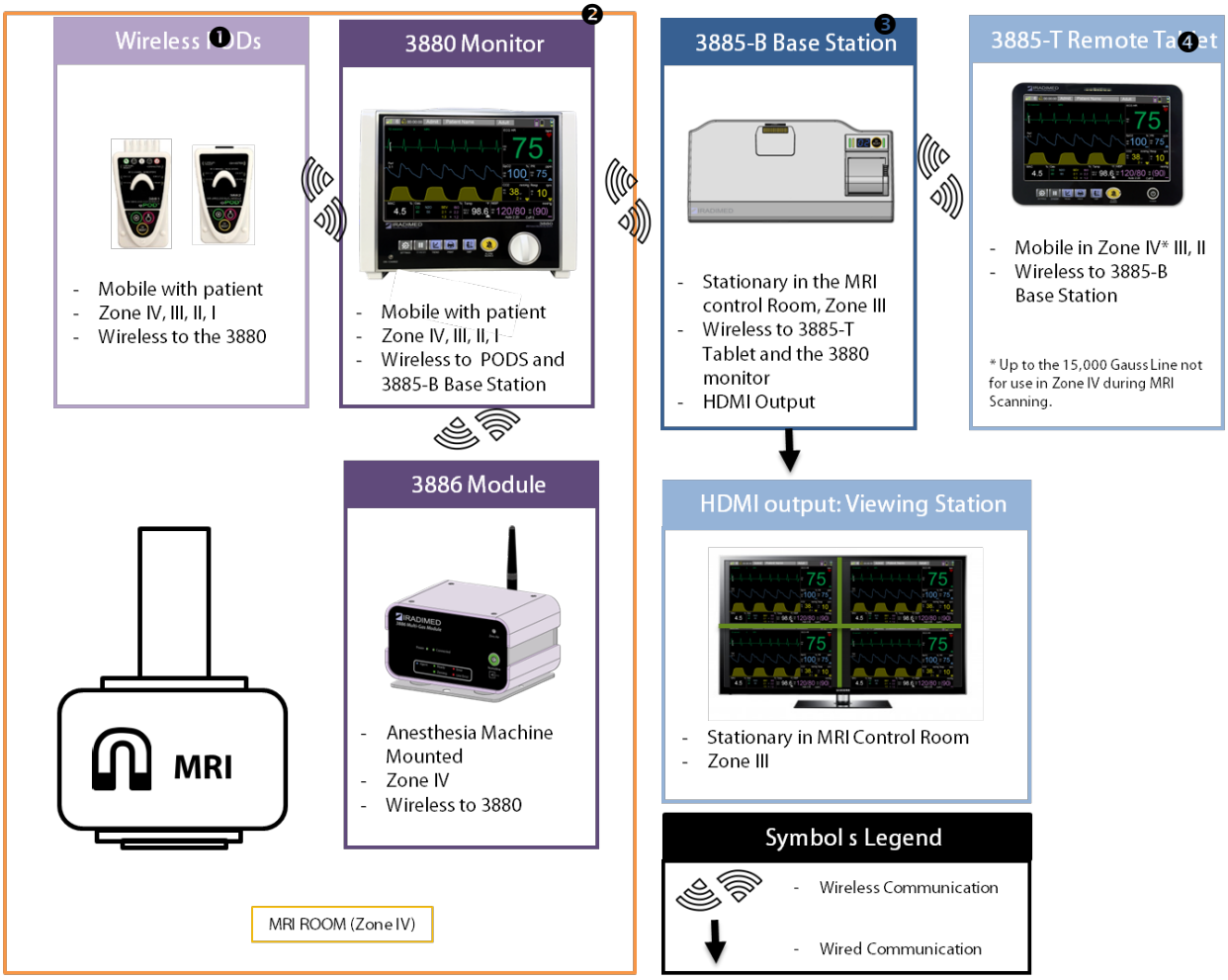
1. Lower Alarm Limit Fine Adjustment
2. Lower Alarm Limit Quick Slide Adjustment
3. Upper Alarm Limit Quick Slide Adjustment
4. Upper Alarm Limit Fine Adjustment

NOTE

- **Green:** range of numerical values that are inside the alarm limits and will not trigger an alarm.
- **Red:** range of numerical values that are outside the alarm limits and will trigger an alarm.

2.1.5. System Use Model

The diagram below illustrates an example of the 3880 system when used for MRI patient monitoring.



The 3880 non-magnetic patient monitor (2) is a multi-parameter vital sign monitor positioned near the patient during the procedure as well as transport. The 3880 acquires the patient vital sign measurements wirelessly from the ECG and SpO_2 PODs (1) as well as traditional connections for NIBP cuff, CO2, and fiber optic temperature probe.

The patient monitoring experience can be enhanced by utilizing the 3885-B Base Station (3). The 3885-B Base Station is a data consolidation hub, data router, battery charger and centralized recorder. The 3885-B Base Station enables remote monitoring in the control room by wirelessly connecting(repeater) the 3885-T Remote Tablet (4) with the 3880 monitor (2). The 3885-T Remote Tablet is intended to be used as a secondary display control interface for the 3880 monitor (2).

The 3885-B Base Station also enhances patient monitoring abilities by integrating a HDMI output enabling a remote viewing station utilizing standard Audio Visual components.

2.1.6. General Wireless Principles

There are 8 user selectable wireless channels utilized by the 3880 system. Once a user matches the desired wireless channels of the PODs, 3880 monitor, 3885-B Base Station, and 3885-T Remote Tablet the system will automatically communicate the information utilizing wireless technologies. The 3880 system utilizes a frequency hopping 2.4 GHz spread spectrum wireless technology (FHSS) with proprietary hopping durations and patterns.

The 3880 system is designed to work in the 2.4 GHz ISM Band and special frequency options are selectable to satisfy regulatory requirements for varying countries. This type of wireless technology has been utilized in MRI patient monitors for over 20 years.

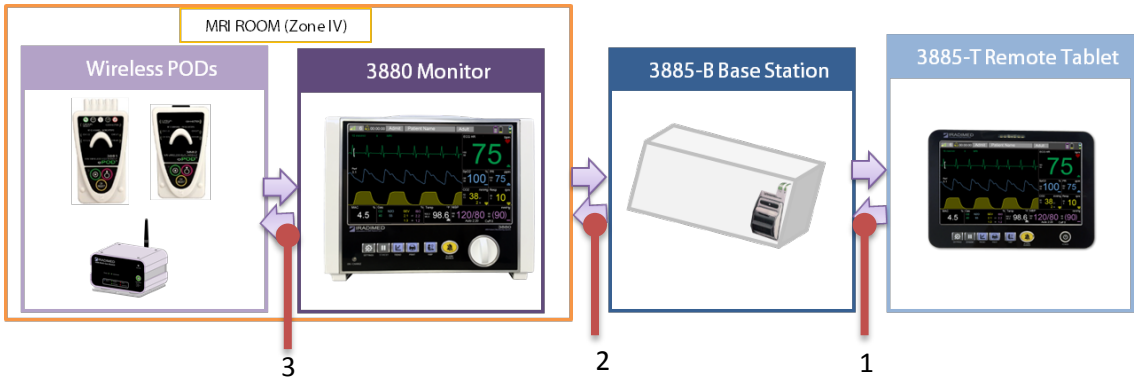
The 3880 system has 8 unpublished and secure dedicated wireless 'channels' which optimize various radio settings to produce the most robust communications possible under very difficult MR and RF environments. This 3880 non-magnetic monitor overcomes this problem when communicating with the 3885-B Base Station then to the Remote Tablet by hopping rapidly throughout the band in a pseudo-random pattern.

In addition to the 3880 system's ability to communicate with the 3885-B Base Station , the 3880 system features lower powered radios to communicate with the PODs. The Wireless ECG and SpO_2 PODs communicate directly with the 3880 patient monitor with 1 mW RF power which transmits in the 2.4 GHz band.

NOTE

- The 3885-T Remote Tablet can only operate if the 3880 patient monitor and 3885-B Base Station are turned on with all components on the same channel. All audible and visual information displayed on the main monitor is heard and seen on the remote unit within 1 second. A symbol displays in the upper right-hand corner of the screen to indicate both devices are connected and active. The 3885-T Remote Tablet has access to all the same functions as the 3880 except for the Service Menu and Option Configuration modes.
- The 3880 system is not wirelessly networked to other external systems

An illustration of the wireless technology utilized in the 3880 system is below:



1. FH Spread Spectrum 2.4 GHz Wireless Communication
2. FH Spread Spectrum 2.4 GHz Wireless Communication
3. Low Power 2.4 GHz Wireless Communication

! CAUTION

- 3880 system utilizes 8 independent channels. Always ensure all wireless components are on the same channel prior to monitoring a patient.
- Avoid having multiple 3880 systems operate on the same wireless channel.

- Locate the 3885-B Base Station antennas, the 3880 Monitor and 3885-T Remote Tablet and the PODs more than 1 meter (3 feet) from other sources of RF energy in the 2.4 GHz band. (ie: WiFi Hot Spot)

2.1.7. Wireless Commands

Menu commands that control the patient parameter and strip recorder/printing functions are communicated between the 3880 non-magnetic monitor and the 3885-T Remote Tablet.

Other operational control settings remain localized to each device and are not communicated.

- Alarm volume
- Pulse volume
- Display Brightness
- Click volume
- Wireless Channel
- Alarm sound on/off

2.1.8. MRI Conditions

All system components of the 3880 system except for the 3885-B Base Station are designed to be as non-magnetic as possible to help alleviate some of the hazards associated with magnetic operating environments. Having a non-magnetic design allows clinicians to place the 3880 system in the most efficient and optimal position for the highest possible patient care. Operation in magnetic fields greater than what is specified for each component may affect its operation and performance. Below are some of the conditions and general guidelines to follow for safe MRI operation.


3880 multi-parameter monitor

- Non-Magnetic design is capable of operation up to a 30,000 Gauss (3 Tesla) magnetic field.
- Use with Ultra-High Field MRI Systems up to 3 Tesla static field.
- Not for use inside a MRI system bore.


ECG and SpO_2 PODs

- Non-Magnetic RF shielded design with 30,000 gauss restriction, able to operate in the MRI system Bore during imaging.
- Use with Ultra-High Field MRI Systems up to 3 Tesla static field.
- Use with whole body average Specific Absorption Rates (SAR) up to 4.0 W/kg or less.


3885-T Remote Tablet

- Non-Magnetic design capable of operation up to a 15,000 Gauss (1.5 Tesla) magnetic field.
- Not RF shielded for use inside the MRI Exam Room (Zone IV) during imaging.


3885-B Base Station

- Contains Ferrous Materials and is designed to be operated in Zone III.
- Not for use inside the MRI Exam Room (Zone IV)


3880 Patient Worn Accessories

- Non-Magnetic design with unlimited gauss restriction able to operate in the MRI system bore during imaging.

3880 Patient Worn ECG Accessories

- Use with Ultra-High Field MRI Systems greater than 0.5 Tesla static field.
- Use with whole body average Specific Absorption Rates (SAR) up to 4.0 W/kg or less.

NOTE

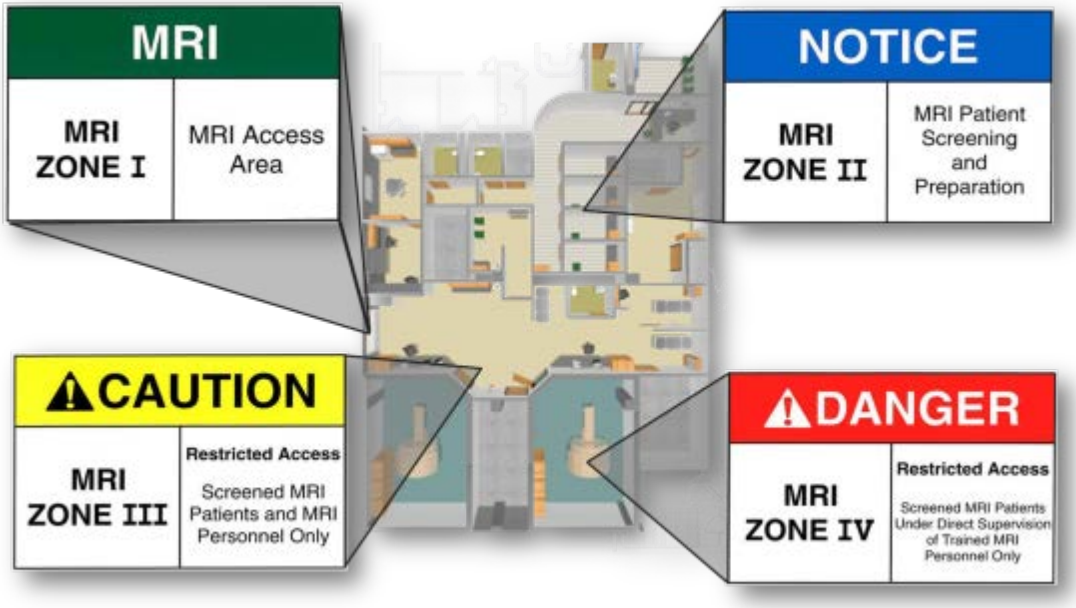
- When moving the 3880 monitor within high magnetic fields (>2,000 gauss) Eddy Current effects may be noticeable. These are forces generated in the device which resists motion through the intense magnetic field. Such effects are normal and present no risk of free magnetic movement of the unit.
- Scanning directly across the plane of the ECG electrode, a slight image distortion may be seen at the skin surface where the ECG electrode is positioned.
- Accessory cables and tubing shall be placed parallel to each other and aligned with the main center line of the MRI Bore.
- 3885-T Remote Tablet is non-magnetic to aid in the patient setup workflow. It is capable of operation up to 15,000 Gauss but is not intended for operation during scanning as artifacts may be noticeable on the image

! WARNING

- The 1120 AC Adapter is magnetic. Keep outside of the 1,000 Gauss line, or at least 10 feet (3 meter) from the MRI magnet. Secure with Velcro straps provided to the floor. NEVER Velcro, never secure the AC Adapter directly to the monitor or mobile cart.
- To ensure safety, always position the 1120 AC Adapter in a manner which allows for easy disconnection of the device from AC mains.
- The 3885-B Base Station contains ferrous material and should not be taken into the MRI room suite Zone IV.
- Use with higher SAR greatly increases the risk of patient burns.
- The high radio frequency (RF) power used in MRI scanning poses an ever-present risk of excessive heat at the monitoring sites and, therefore, the risk of RF burn. The risk of patient burn greatly increases if power levels greater than a whole body averaged specific absorption rate (SAR) of 4.0 W/Kg is used. Monitoring of the ECG based upon the whole body average SAR of 4.0 W/Kg may underestimate the actual SAR value at the ECG leads. When monitoring unconscious patients additional precautions maybe required.
- RF burn risk increases when metallic items and / or multiple conductive sensors/cables are in use such as ECG lead wires. Such combinations are not recommended. Always remove non IRadimed accessories prior to performing a MRI procedure.
- Patient lead cables which become inadvertently looped during an MRI examination may act as conductive lines for RF induced currents, resulting in excessive heating and possible burns. When patient lead cables or other cables form a conductive loop in contact with the patient's tissue, minor to severe burning can result.
- Position all cables in the center of the MRI bore and avoid contacting the internal side of the MRI bore during scanning.

! CAUTION

- High levels of RF energy may cause patient heating or burns. Inspect electrode sites for heating for scan times (i.e., per pulse sequence) greater than 15 minutes.
- Medical drug treatment can alter the sensitivity to skin heating.
- When using or repairing the equipment, do not bring any tools or components containing ferrous material into the magnet room (Zone IV). Risk of serious injury and/or damage to the equipment can result.



Typical MRI Facility Zones

2.1.9. Cleaning

For cleaning guidelines review the Care and Cleaning section 8.4 of this manual.

2.1.10. Repair

The 3880 System or any of its parts should be repaired in accordance with written instructions provided by the IRadimed. The user has the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than IRadimed-authorized service personnel.

For repair guidelines review Section 8 Pre-Use Operator Verification, Troubleshooting and User Maintenance of this manual.

2.2. Initial Setup

2.2.1. Safety Precautions

! WARNING

- The monitor and its components should not be used adjacent to or stacked with non IRadimed equipment. If adjacent or stacked use is necessary, the monitor and its components should be observed to verify normal operation in the configuration prior to use. Never install the monitor directly above the patient.
- To avoid risk of electric shock, this equipment must only be connected to properly grounded AC outlets with the power cord supplied by IRadimed.

! CAUTION

- If the monitor is going to be in storage and not used for more than 30 days, the battery pack should be removed from the devices if possible and charged to 50%.
- If the PODs are going into storage for more than 30 days they should be stored 50% charged and recharged at a minimum of 6 month intervals.

2.2.2. Unpacking the System

1. Confirm that the packing box is undamaged. If the box is damaged, contact the shipper.
2. Open the top of the box and carefully unpack all components.
3. Confirm that all components are undamaged. If any of the components are damaged, contact the shipper.
4. Confirm that all components are included. If any of the components are missing, contact your IRadimed representative.
    a. Standard Equipment:
        - 3880 Monitor
        - ECG and SpO_2 PODs
        - 1120 Power Supply and Cables(P/N 1121, 1122)
        - Operators & Service Manual
        - ECG, SpO_2 and NIBP accessories
    b. Optional Equipment:
        - 3885-T Remote Tablet and 3885-B Base Station
        - Hi-Gain Antenna
        - CO_2, Gas, Fiber Optic Temperature, and Recorder accessories
        - Gating Cable
        - Mounting Hardware and Stand

! CAUTION

- Never unpack or assemble items inside the MRI room suite (Zone IV).

2.2.3. Visual Inspection

Perform the following visual inspection to the installed monitoring system:

- Carefully inspect the patient monitor components for any damage.
- Verify that the patient monitor is properly mounted with specified mounting solutions.
- Verify that the cables between the patient monitor and the connected peripheral devices are intact and properly connected to the right connectors.
- Verify that the battery is intact and locked into the monitor.

The cleaning precautions, cleaning requirements, cleaning procedures, and recommended cleaning solutions for the monitor are described in Care and Cleaning section 8.4. For details about cleaning and disinfecting the accessories, see the instructions for use in the accessory package.

2.2.4. Functional Inspection

Start-up

Turn on the components of the 3880 system (3880 Patient Monitor, 3885-T Remote Tablet and wireless PODs).

Verify that the system components start up normally:

- The red, yellow and blue Tri-Color Alarm Dome Light on the 3880 Monitor and 3885-T Remote Tablet are lit momentarily.
- The speaker on the 3880 monitor and 3885-T Remote Tablet gives an audible beep.
- Check that the normal monitoring screen appears and that all text is readable and clear.
- Check wireless communication.
- Check that there are no error messages on either screen.

NOTE

- Before placing the patient monitor system into use for the first time, the battery should be fully charged. Keep the monitor system connected to the charger until the battery is fully charged.
- If multiple systems are ordered perform the start-up procedure on one device at a time.

2.2.5. Mounting

Mounting of monitor components to the roll stand (IV Pole) is described in the instruction sheet of the stand.

2.2.6. Choosing a location

Consider the following aspects:

- Lighting
- Patient and staff location during procedure
- MRI room visibility
- Space
- Electromagnetic and radio frequency interference
- Traffic flow

NOTE

- Careful consideration should be given when placing the 3880 system components near other equipment with wireless communication or near high traffic areas. Human traffic between the systems wireless components can reduce wireless signal power and lead to reduced quality of wireless service.

2.2.7. System Power

2.2.7.1. Battery Operation

The 3880 system utilizes Lithium Polymer 'smart' battery technology with self-monitoring. When all components of the system are turned on and communicating, the battery charge status is displayed on the 3880 Monitor and 3885-T Remote Tablet displays. The actual battery capacity will decrease over time and a full battery symbol may not indicate the same capacity and operating time as compared to a new battery.

The system's batteries each contain lithium-polymer cells and integral safety circuits. As these cells age, they can expand due to internal gas release, which is anticipated for this type of cell. However, if excessive expansion occurs, this can result in the battery case expanding (swelling), and possibly cause failure of the battery case, cells, or safety circuit. If this is observed, remove the Battery Pack or PODs from use and replace it as soon as possible.

! WARNING

- Avoid damage to the Battery Pack by impact, dropping, overheating, or mechanical abuse. Never compress, drop, shock, or strike the Battery Pack. Never use objects that could puncture the internal battery cells. Any of these actions can cause the battery cells to heat, smoke, or cause catastrophic battery failure, which could result in fire.
- Do not attempt to disassemble the Battery Pack. Damage caused by disassembly or tool use can result in catastrophic battery failure, which could result in fire.
- Under no circumstances should Battery Packs or the internal cells be incinerated as this can cause an explosion.
- If PODs or batteries are dropped, perform a physical and functional inspection before returning them to clinical use.

! CAUTION

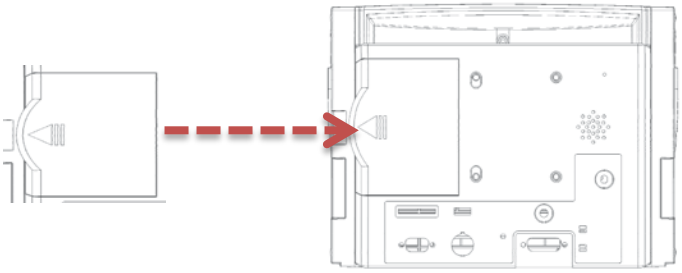
- The battery packs may contain slight magnetic properties. Use caution when removing or inserting the batteries near strong magnetic fields (30,000 Gauss).
- If the 1133 Battery Pack case begins to expand and/or swell, discontinue battery charging and use immediately, and replace the battery pack. Continued charging will cause further battery pack case expansion, with possible battery case fracture, and potential electrolyte leakage.
- Only operate the monitor with the battery pack installed.
- Immediately charge a device that has a low battery.

NOTE

- The operating time depends on the configuration and operation of the 3880 system. For example, measuring NIBP more frequently will shorten the operating time.
- Review the Battery Maintenance in Section 8 of this manual prior to initial use.
- The 3880 monitor utilizes a user replaceable battery pack which enables continuous monitoring. The Wireless PODs and 3885-T Remote Tablet feature integrated batteries so backup devices maybe necessary for continuous monitoring longer than 10 hours.
- If the system is power cycled during a case always confirm settings and patient name prior to resuming monitoring activities.

3880 multi-parameter monitor
The 3880 system has a user replaceable battery located on the rear of the device.

1. Insert the user replaceable battery pack into the battery bay on the rear of the 3880 monitor as shown. The battery pack will lock into place if inserted properly.
2. Connect the system to AC power. Reference the Charging Instructions section 2.2.7.2 in this manual for additional details.
3. Verify that a green or yellow LED is present on front panel indicating mains power (Green) and charging (Yellow).
4. Allow to charge for a minimum of 5 hours prior to initial use.



3881 ECG and 3882 SpO_2 PODs
The 3880 PODs have an integrated battery that is not user serviceable. Additional PODs maybe added to this system to allow for continuous operation on battery. The 3880 Non-Magnetic patient monitor has the ability to charge 2 PODs simultaneously.

1. Disconnect the Patient and insert the PODs with the labels facing outward into the charging bays located on either side of the 3880 monitor.
2. Connect the system to AC power. Reference the Charging Instructions section 2.2.7.2.1 in this manual for additional details.
3. Verify associated charge indicator LEDs on rear panel.
4. Allow to charge for a minimum of 4 hours prior to initial use.

3885-T Remote Tablet and 3885-B Base Station

The 3885-T Remote Tablet has an integrated battery that is user serviceable. The Remote Tablet is charged by docking it to a 3885-B Base Station that is connected to AC power.

1. Connect the 3885-B Base Station to AC power. Reference the Charging Instructions section 2.2.7.2 in this manual for additional details.
2. Lower the 3885-T Remote Tablet onto the 3885-B Base Station Charging Dock.
3. Verify that a green or yellow light is present on the right most 3885-B Base Station LED.
4. Allow to charge for a minimum of 5 hours prior to initial use.

3885-B Base Unit, Charger and Wireless Repeater Link for 3885-T Remote Tablet

2.2.7.2. Charging Instructions

2.2.7.2.1. Connecting and Disconnecting AC Power

Always connect the 1120 AC power supply to a properly grounded 3-wire power receptacle. If the quality of the earth grounding is in question, use battery power for the monitoring system. Avoid the use of extension cords. The 3880 Monitor and 3885-T Remote Tablet will automatically switch to battery power when disconnected from AC Power. Always check the battery charge level prior to disconnecting AC power to ensure there is sufficient battery power for the procedure. If disconnected from AC power without a battery installed or a dead battery installed, the 3880 Monitor will revert to factory default settings.

To connect the power supply, follow these steps:

3880 Monitor

1. Locate
    - 3880 Power Input (1)
    - 1122 - 3M (~10 ft) Shielded DC Cable (2)
2. 1120 MRI Power Supply (3)
3. Country Specific Power Cord (4)
4. Screw the male end of the 1122 Shielded Cable (2) directly into the 1120 MRI Power Supply (3)
5. Attach the Country Specific Power Cord (4) to the MRI Power Supply (3)
6. Position the 1120 MRI Power Supply (3) outside the 1,000 Gauss line, or 10 feet (3 meters) from the MRI system when placed inside the MRI exam suite Zone IV.
7. Place the Country Specific Power Cord (4) into the designated AC power outlet.
8. Screw the female end of the 1122 Shielded Cable (2) directly into the power input receptacle (1) on the rear of the 3880 Monitor
9. Check for a green /yellow power/charging indicator LED light on the front of the 3880 Monitor

3885-B Base Station, Optional

1. Locate the power cord (P/N 1128 in US) and ensure the Base Station power switch is in the OFF position. (1)
2. Locate a suitable location in the control room that enables access and wireless communication. See 2.2.8 for antenna connection.
3. Attach the power cord to the 3885-B Base Station (2)
4. Place the power cord into the designated AC power outlet.
5. Turn the 3885-B Base Station power switch to the ON position (1)
6. Check for green LED light on the front of the 3885-B Base Station.

! WARNING

- The 1120 power supply contains magnetic properties. Keep outside the 1,000 Gauss line, or 10 feet (3 meters) from the MRI system.
- Never Velcro or attach the power supply directly to the monitor, monitor mounting solution, or IV pole.
- The 3885-B Base Station contains ferrous materials that are attracted to magnetic fields. DO NOT install or place the 3885-B Base Station or its components in the MRI room (Zone IV).

2.2.8. Antenna Strategies

The 3880 system uses 2.4 GHz bidirectional communication to communicate between the 3880 monitor and the 3885-T Remote Tablet. There are different antenna options to support various environments and workflow scenarios. Please contact your IRadimed representative for information regarding one of the optional antenna options.

2.2.8.1. Omni Directional Antenna

The Omni Directional Antenna ❶ is the standard antenna that is included with the 3880 Monitor and 3885-B Base Station. This bidirectional broadcast antenna is the easiest to use and provides patient workflow flexibility in typical MRI environments.

! CAUTION

- Locate the 3885-B Base antennas, the 3880 and 3885-T and the PODs more than 1

meter (3 feet) from other sources of RF energy in the 2.4 GHZ band. (ie: WiFi Hot Spot).

2.2.8.3.1 LED Power Indicator

The power indicators located on the 3880 Monitor and optional 3885-B Base Station are two color LEDs and the PODs are a single color LED that provides a visual indication of the power status as indicated below. Reference the System Hardware Components (accessories not shown) section 2.1.2 of the operation manual for specific LED locations.

3880 Monitor and 3885-BBase Station:

- **Solid Green:** A solid green light indicates that the device is connected to AC power and the batteries are fully charged.
- **Solid Yellow:** A solid yellow light indicates that the device is connected to AC power and the batteries are being charged.
- **No Light:** A blank LED light indicates that the device is disconnected from AC power.

Wireless PODS:

- **Solid Green:** A solid green light indicates that the device is powered ON.
- **No Light:** A blank LED light indicates that the device is powered OFF.

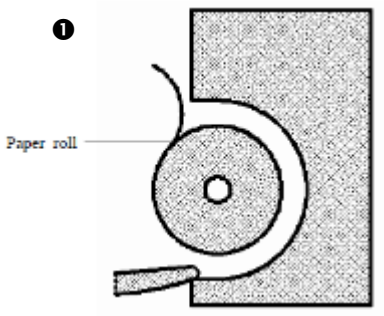
NOTE

- No Light: indicates that the device is not connected to AC power and the system will need to be powered on to check the battery charge status on the display.
- Charge status of each communicated component is visible on the 3880 system's displays.

2.2.9. Loading Recorder Paper

When equipped with the optional Strip Chart Recorder, the 3885-B Base Station is capable of providing hard copies of up to two waveforms and/or trend information. To load paper into the recorder, follow the following procedure:

1. Press the release button to open the door on the recorder
2. Insert a new roll of paper into the compartment so the paper end is on the bottom ❶
3. Pull approximately 2 inches (50 mm) of paper from the roll then extend it over the top of the door
4. Close the recorder door
5. Tear off the paper to complete the loading
6. Confirm that the paper is loaded correctly by printing a sample



! CAUTION

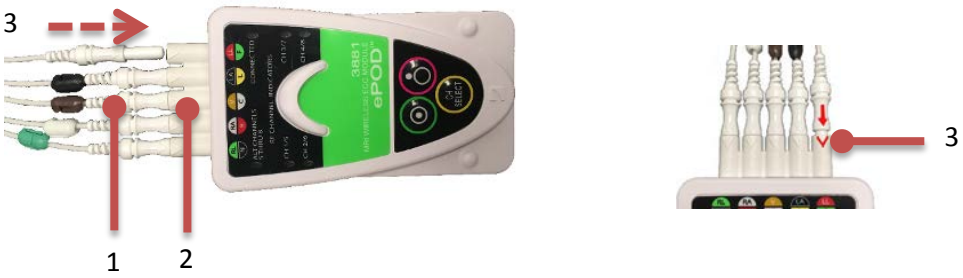
- Use only specified thermal paper. Otherwise, it may cause damage to the recorder's print head, the recorder may be unable to print, or poor print quality may result.
- Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.

- Do not leave the recorder door open.

2.2.10. Connecting Patient Accessories

2.2.10.1. 1811 ECG Wires and 3881 ePOD

The wireless ECG POD “3881 ePOD” and lead wires are constructed of special material to reduce the amount of radio frequency (RF) energy that can flow through the components. The ECG ePOD and lead wires are designed for use in the MRI system bore but should remain outside of the MRI procedure Field of View (FOV) where possible.



To connect the ECG Lead wires to the ECG ePOD:

1. Locate the 1811 ECG Lead wires (1) and the 3881 ECG ePOD (2)
2. Position the ECG Lead wires with the ECG ePOD so the colors and letters align
3. Firmly insert the ECG Lead wires into the corresponding ECG ePOD receptacle
   NOTE: Align the molded arrow on the lead wire with the top side chevron “V” molded in to the receptacle. (3)
4. Ensure that ECG Lead wires are secure into the ECG ePOD and not loose
5. Verify operation of the MRI cable by connecting it to an ECG simulator or test subject if one is not available

NOTE

- The ECG Leads are intended specifically for MRI use.

! CAUTION

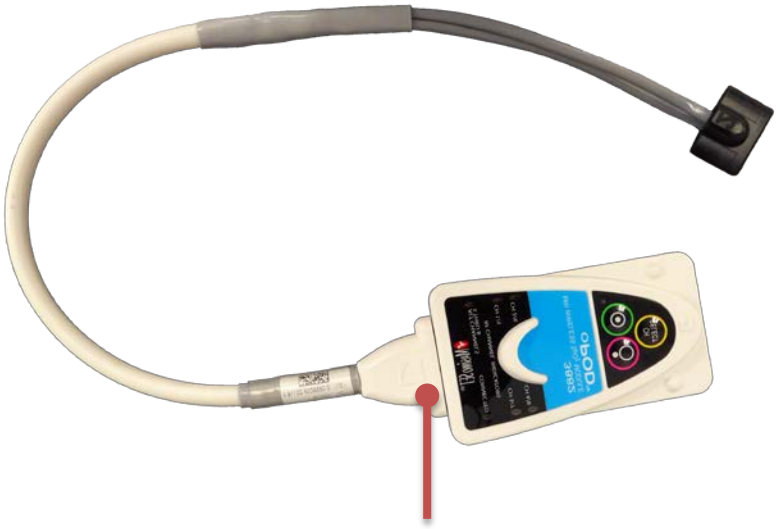
- Use only ECG Lead wires specifically designed and approved for use with the IRadimed ECG ePOD. Refer to section 9 for a complete list of available accessories.

! WARNING

- Avoid contact with the MR system bore as this may cause heating of the lead wires or the patient electrodes.

2.2.10.2. SpO_2 1821 Cable and 3882 oPOD

The wireless SpO_2 POD "3882 oPOD" and accessories are constructed of special material to reduce the amount of radio frequency (RF) energy that can flow through the components. The SpO_2 oPODs and accessories are designed for use in the MRI system bore but should remain outside of the MRI procedure field of view (FOV), where possible.



The SpO_2 Sensor cable, P/N 1821 is fiber optic (glass), and mated to the SpO_2 oPOD

1. The 1821 SpO_2 sensor (1) is mechanically attached to the 3882 SpO_2 oPOD.
2. Assure that the SpO_2 sensor is firmly connected to the SpO_2 oPOD
3. Replacing the sensor requires removal to two screws which are non-magnetic, insert the replacement SpO_2 sensor into the corresponding SpO_2 oPOD receptacle and re-apply the non-magnetic screws. See Service manual for details.
4. Ensure that SpO_2 sensor is secure into the SpO_2 oPOD and not loose
5. Verify sensor operation by connecting it to a SpO_2 simulator or test subject if one is not available

NOTE

- The SpO_2 sensor is a fiber optic assembly intended specifically for MRI use.

! CAUTION

- Use only SpO_2 accessories specifically designed and authorized for use with the IRadimed SpO_2 oPOD. Refer to section 9.1 for a complete list of available accessories.
- The SpO_2 sensors are constructed of fiber-optic glass and must always be handled with care to prevent damage. Improper handling can result in inaccurate readings.
- Use only SpO_2 sensors specifically designed for use with the SpO_2 oPOD (part number 1821)
- Do not use magnetic tools inside of zone IV

2.2.10.3. 3886 Multi-Gas / Agent Sampling Lines

The optional CO2/ Multi-gas Anesthetic Agent unit (P/N3886) provides sidestream measurement of End-Tidal CO_2, anesthetic agents, fast O2, respiration with a continuous real-time CO_2 waveform display. This Multi-gas option will also identify and display any two of five anesthetic agent concentrations. This feature will perform automatic zeroing at periodic intervals or upon user demand.

To connect the sampling circuit:

1. Attach the country specific AC power cord to the Mains inlet on the rear of the 3886 Multi-Gas unit and switch on the Mains power switch located next to the inlet. The Green power indicator will light.
2. Locate the sampling line (1) and the CO_2 receptacle on the Multi-gas unit (2)
3. Position the sampling line with the light emitting Gas inlet receptacle (LEGI) so they