- Do not place the NIBP cuff over a wound, as this can cause further injury.
- Do not place the NIBP cuff on the same or adjacent arm to a mastectomy, or where the lymph nodes were removed, or if a shunt is on that arm. This can lead to bruising, inaccurate readings, or negatively impact the drainage of fluids because of temporary interference to blood flow.

! CAUTION

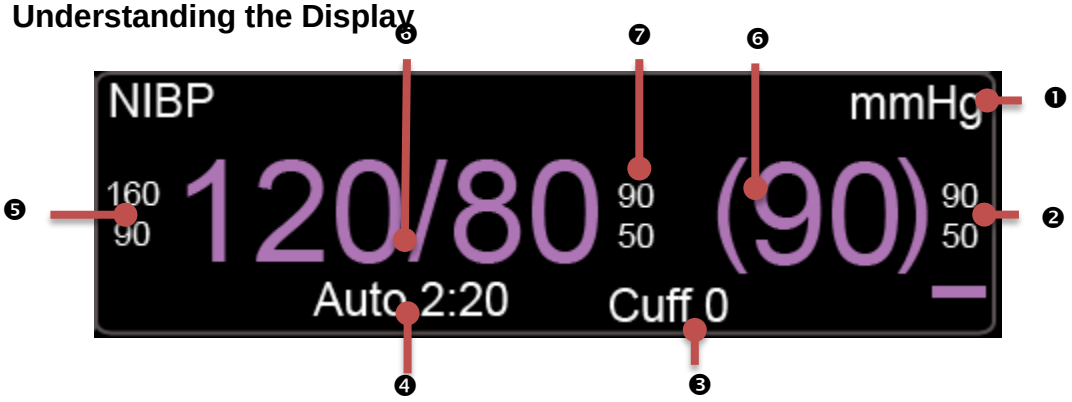
- Only use recommended MRI NIBP cuffs and tubing identified in section 9.2.
- In AUTO Mode, the monitor displays results of the last measurement until another measurement starts. If a patient's condition changes during the time interval between measurements, the monitor will not detect it.
- Excessive patient motion may cause inaccurate measurements. Minimize motion to improve blood pressure measurements.
- Avoid crimping or undue bending, twisting, or entanglement of the NIBP hose.

6.4.1.1. Limitations

The following factors may affect the accuracy of measurement:

- Heart rate extremes of less than 40 bpm or greater than 240 bpm
- A regular arterial pressure pulse is hard to detect
- Cardiac arrhythmias
- Physical movement (patient or imposed)
- Rapid blood pressure changes
- Severe shock or hypothermia that reduces blood flow to the peripheries
- Obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery
- Edematous extremity

6.4.2. Understanding the Display



1. Measurement Unit (mmHg or kPa)
2. Current Mean Pressure upper and lower alarm limits
3. NIBP cuff pressure when inflating
4. Time until next NIBP Measurement (minutes : seconds or manual)
5. Current Systolic Pressure upper and lower alarm limits
6. Most recent NIBP reading
7. Current Diastolic Pressure upper and lower alarm limits

6.4.3. NIBP Patient Application

When positioning the patient, routine NIBP measurements (including for the condition hypertension) require the patient to remain silent, still and relaxed, with legs uncrossed and arms supported. Note that during MRI procedures, patients are typically lying down with their legs uncrossed and arms supported as needed for the MRI scan. A five minute waiting period is recommended before starting readings. Ensure that the cuff is at the level of the right atrium of the heart.

1. Verify that the patient type is correct. Change it if necessary.
2. Ensure tubing is connected to the 3880 monitor
3. Select a correct sized cuff and then apply it as follows:
    a. Determine the patient's limb circumference.
    b. Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb.
    c. Apply the cuff to an upper arm or leg of the patient and make sure the marking on the cuff matches the artery location. Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities. Make sure that the cuff edge falls within the marked range. If it does not, use a larger or smaller cuff that will fit better.
4. Connect the cuff to the air tubing and make sure that the bladder inside the cover is not folded and twisted
5. Press the START/STOP button to initiate a blood pressure reading. Hold TART/STOP button down for three seconds to initiate a STAT burst of three successive NIBP readings.

NOTE

- Automatic NIBP readings will not cycle when the monitor is in Standby

6.4.3.1. Setup Checklist

- The hose is correct.
- The connector is firmly pushed inside the cuff tube.
- The NIBP hose is properly connected to the module and will not detach if pulled.
- The NIBP cuff is correct for the patient's limb size.

- There are no holes or cracks in the cuff bladder or cuff tube.
- All residual air is squeezed out of the cuff before wrapping it around the arm.
- The symbol indicating the center of the bladder is over the artery.
- The cuff is not loose.
- The cuff is at heart level.
- The cuff tubes or NIBP tube are not kinked or squeezed together.
- Non-invasive blood pressure is selected to be displayed through Monitor Setup patient parameters menu.

6.4.4. Changing Frequently Used NIBP Settings

6.4.4.1. Manual NIBP Mode

To adjust the NIBP mode between manual and automatic follow these steps:

1. Touch the NIBP vital sign numerical box to bring up the NIBP menu
2. For manual mode set the “Auto Cycle Time” to OFF
3. Touch Back button to close the menu

6.4.4.2. Automatic NIBP Interval Mode

To adjust the NIBP intervals for the Automatic settings follow these steps.

1. Touch the NIBP vital sign numerical box to bring up the NIBP menu
2. Select “Auto Cycle Time” to show drop down: OFF, 3 min, 5 min, 8 min, 10 min, 15 min, 30 min
3. Make your selection
4. Touch Back button to close the menu

6.4.5. NIBP Alarm Limits

	Low Limit Range	Default Low	Default High	High Limit Range
Adult				
systolic	Off, 30-270	90	160	30-270, Off
diastolic	Off, 10-245	50	90	10-245, Off
mean	Off, 20-255	60	110	20-255, Off
Pediatric /Infant				
systolic	Off, 30-270	70	120	30-270, Off
diastolic	Off, 10-245	40	70	10-245, Off
mean	Off, 20-255	50	90	20-255, Off
Neonatal				
systolic	Off, 30-130	40	90	30-130, Off
diastolic	Off, 10-100	20	60	10-100, Off
mean	Off, 20-120	25	70	20-120, Off

6.4.6. NIBP Messages

Message	Trigger Condition
NIBP Inop	Hardware or software failure detected
NIBP Over Press	Pressure exceeds 300 mmHg for Adult / Ped or 150 mmHg for Neonatal patients -or- 15 mmHg remains in the line for Adult / Ped or 5mmHg for Neo for greater than 90 seconds
NIBP Time Out	Pressure remains the same for more than 30 seconds or if measurement exceeds 180 seconds
NIBP Leak	Air leak is detected
Wrong Cuff	Displayed if the NIBP system detects an incorrect cuff size for the selected patient mode
NIBP Occlusion	Occlusion is detected
NIBP Cal Error	Calibration error detected
NIBP Delayed	NIBP reading start has been delayed to allow blood flow to resume

6.5. Temperature Monitoring

6.5.1. Temperature Overview

The 3880 system features a unique and innovative temperature measurement system supporting surface temperature readings.

6.5.1.1. Temperature Sensor

The fiber-optic temperature sensor is used for the measurement of patient body temperature using axillary sensing tip placement.

! WARNING

- Frequent medical attention to the sensor axilla site for possible pressure tissue necrosis should be given during longer term monitoring sessions (4 hours or more), especially on tender skin of neonatal patients.

! CAUTION

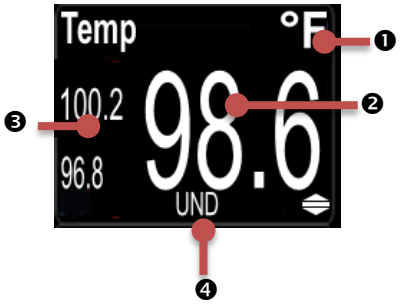
- The fiber-optic temperature sensors are constructed of fiber-optic glass and must always be handled with care to prevent damage. Improper handling can result in inaccurate readings.

6.5.1.2. Limitations

The following factors may influence the accuracy of measurement:

- Sensors access to ambient temperature or drafts
- Do not bend the fiber optic sensor in a radius of less than 15 mm
- Do not expose to temperature above 50°C
- Do not pull or apply tension to the fiber-optic cable
- Do not alter or modify the accessories

6.5.2. Understanding the Display



1. Measurement Unit
2. Current Vital Sigh
3. Alarm Limits
4. OVR/UND for Temp extended range <30.0 °C or >44.0 °C(<86.0°F or >111.2°F), accuracy ± 0.4 °C

6.5.3. Temperature Patient Application

6.5.3.1. Surface Temperature Application

Perform the following procedure to apply the fiber-optic temperature sensor to a patient:

1. Carefully uncoil the sensor, avoid knotting or kinking the fiber optic cable
2. Inspect sensor for damage, including tears or deformations
3. Thoroughly clean and dry the axilla or groin application site
4. Position the sensor tip at the application site
5. Secure sensor with some medical tape
6. Cover application site to block air drafts

! WARNING

- Avoid the use of any metalized foil temperature probe covers, or hydrogel backed probe covers, as excessive RF heating could occur resulting in inaccurate temperature measurements and/or burns.

NOTE

- There is a temperature difference between surface temperature and patient body (core) temperature.
- When monitoring temperature during MRI procedures, the radio frequency (RF) energy may normally increase the patient's body temperature.

6.5.3.2. Setup Checklist

- Temperature cable is properly inserted into the 3880 system
- Temperature sensor is applied and positioned correctly
- Temperature sensor is not damaged in any way

6.5.4. Changing the Temperature Settings

6.5.4.1. Units

The temperature format can be in Celsius or Fahrenheit. To adjust the units follow these steps:

1. Touch the Temperature vital sign box
2. Select "Unit"
3. Make your selection
4. Touch Back button to close menu

6.5.5. Temperature Alarm Limits, Celsius

	Low Limit Range	Default Low	Default High	High Limit Range
Adult Temp	Off, 25-40	36	39	25-40, Off
Pediatric Temp	Off, 25-40	36	39	25-40, Off
Neonatal Temp	Off, 25-40	36	39	25-40, Off

6.5.6. Temperature Messaging

Message	Trigger Condition
Temp Inop	Hardware or software failure detected
Temp Probe Fail	Broken sensor detected or a sensor is not attached properly
OVR / UND	Indicating Temp extended range < 30.0 °C or > 44 C°(<86.0°F or >111.2°F) accuracy ± 0.4 °C

6.5.7. Connecting the Sensor

The fiber optic temperature sensor utilizes a keyed twist locking connector to securely mate to the temperature connection port on the right side of the 3880 Monitor unit. Rotate the sensor connection while gently pushing into the mating connection on the monitor. Once the keyway has slide into the mating slot, turn the outer shell ≈30° to lock into place.

6.5.8. Temperature reference measurement

A baseline temperature measurement should be made once the fiber optic temperature sensor is applied and before starting the MR image scan, which should be used as a reference for the temperature measured during the scan.

7. Using the Recorder

The optional 3885-B Base Station recorder provides hard copies of up to two waveforms and trend information.

NOTE

- The 3880 MRI Patient monitor does not have an internal recorder. Printing can only be done if the system is communicating with the optional 3885-B Base Station. The Base station unit houses and drives the strip chart recorder in response to Record or Print requests from the 3880 Monitor or 3885-T Remote Tablet hard (Record) and soft (Print) keys.

7.1. Loading Paper

To load paper into the recorder review section 2.2.9 for details.

7.2. Recorder Setup Menu

7.2.1. Trace 1

The optional recorder can print one or two waveforms of ECG, SpO_2, CO_2 waveforms. When Trace 1 and 2 are selected to print, Trace 1 will appear on the top of the paper. To adjust which waveform you want to print when the Print button is pressed follow these steps:

1. Press the SETTINGS button
2. Select “Recorder Setup”
3. Select “Trace 1”
4. Select desired waveform to print
5. Touch Back button to close the menu

7.2.2. Trace 2

The optional recorder can print one or two waveforms of ECG, SpO_2, CO_2 waveforms. When trace 1 and 2 are selected to print, Trace 2 will appear on the bottom of the paper. To adjust which waveform you want to print when the Print button is pressed follow these steps:

1. Press the SETTINGS button
2. Select “Recorder Setup”
3. Select “Trace 2”
4. Select desired waveform to print or select OFF to print a single waveform
5. Touch Back button to close the menu
   NOTE : Each vital sign parameter must be set ‘ON’ to allow recording of its trace. Also, with ECG, two leads must be on display (display Trace A and B) and set for recording, to record ECG Trace 2.

7.2.3. Waveform Trace delay

Trace delay allows users to set a time delay before the waveform data is sent to the recorder. This can account for the time delay between when a user decides to print and when they actually depress the button. The delay options are 0, 4, 8 and 16 seconds.

To adjust the trace delay follow these steps:

1. Press the SETTINGS button
2. Select “Recorder Setup”

3. Select “Trace Delay”
4. Select desired delay
5. Touch Back button to close the menu

7.2.4. Auto Strip

Auto strip allows the automatic report feature of the recorder to be switched ON and OFF. The auto strip will automatically print when a clinical alarm is detected.

To enable the Auto Strip follow these steps:

1. Press the SETTINGS button
2. Select “Recorder Setup”
3. Toggle “Auto Strip” ON and OFF
4. Touch Back button to close the menu

7.2.5. Run Time

Recorder Run Time allows users to adjust the length of time the recorder prints when activated. The options are 8, 12, 16, 20 and 30 seconds.

To adjust the waveform Record Run Time follow these steps:

1. Press the SETTINGS button
2. Select” Recorder Setup”
3. Select “Run Time“
4. Select desired time
5. Touch Back button to close the menu

7.2.6. Recorder Sweep Speed

The Sweep Speed switches the recorder speed between 25 and 50 mm/second.

To adjust recorder Sweep Speed follow these steps:

1. Press the SETTINGS button
2. Select “Recorder Setup”
3. Select “Speed”
4. Select desired speed
5. Touch Back button to close the menu

7.2.7. To manually start a strip chart recording

Press the front panel “Record” hard key at either the 3880 Monitor or 3885-T Remote Tablet.

7.2.8. Recorder Output

The strip chart recorder output will be the waveform Trace or Traces selected in the Record Setup along with the selected delay and run time, with the text printout of all active vital signs values. The vital signs, such as HR, SpO2, Blood Pressure, GAS measurements, and Temperature print on the paper in a table at conclusion of the strip run time.

7.3. Printing

The term “Printing” is used herein to refer to using the strip chart recorder as a printer of text and numeric information, such as the Tabular Trend table. Strip “Recording” is a specialized print out of waveform data as described in 7.2.7 and 7.2.8 above. See section 5.5 for instruction to print Trends.

8. Pre-Use Operator Verification, Troubleshooting and User Maintenance

8.1. Overview

Check the following items prior to monitoring to ensure completion of all essential preparations. Items that are broken, missing, plainly worn, distorted, or contaminated must be replaced immediately. The 3880 system must not be repaired other than in accordance with written instructions provided by IRadimed. The device shall not be altered without written approval of 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 personnel.

! WARNING

- For proper equipment performance, maintenance and service procedures should be performed at the recommended intervals as described in the monitor's service manual.

NOTE

- The IRadimed software design controls include performance of a risk analysis using methods consistent with ISO 14971 Medical devices - Application of risk management to medical devices. The 3880 system employs watchdog timers, self-monitoring activities (memory, communication and sensor checks and so on), and power-on self-diagnostics (for example, memory checksums).

8.1.1. Battery Life Expectancy

Life expectancy of a battery depends on how frequent and how long it is used. For properly maintained and stored batteries, the life expectancy is about 2 or 3 years respectively. For more aggressive and non-traditional use models, the life expectancy maybe less. IRadimed recommends replacing batteries every 2 to 3 years or when signs of wear or operation are noticeably different.

To get the most out of your batteries observe the following guidelines:

- The battery performance test must be performed every year, before monitor repairs, or whenever the battery is suspected as being the source of the problems.
- Take out the battery before the monitor is shipped or will not be used for more than 3 months.
- The shelf-life of a Lithium Polymer battery is about 6 months when the battery is stored with the battery power being 50% of the total power.

8.1.2. Checking a Battery

The user replaceable battery packs utilized in the 3880 patient monitor can be checked outside of the monitor. This feature allows facilities with multiple batteries to proactively select a battery that has a desired charge level prior to inserting it into the system. To check a batteries charge follows these steps:

1. Locate the button on the rear corner of the battery (1)
2. Depress the button and the LED indicators will momentarily show the charge status. (2)

8.2. Performance Checks

8.2.1. Daily in between tasks

- Check that system components and accessories do not have any visual defects such as cracks or loose parts.
- Check that the system components as described in the Care and Cleaning 8.4 part of this section were cleaned properly after the previous use.
- All supplies and accessories are not passed their expired date.
- Check that batteries are properly inserted and charged.
- Ensure all system components are wirelessly communicated
- Wipe the monitor, PODs and accessory surfaces
- Change all airway patient accessories.
- Ensure that you are using correct accessory sizes for each patient and that they are properly connected.
- Check that all accessories, cables and monitor parts are clean and working properly.
- Check that you have selected desired parameters to be displayed in digit and waveform fields.
- Check that the trends of the previous patient are erased.
- Monitor patient type mode and alarm limits are suitable for the patient.
- Check the compatibility of the 3880 monitor, sensors and cables before use

8.2.2. Regular Inspection and Verification

Wireless Communication

- Place the PODs and 3880 Monitor inside the MRI room suite with the door shut. Place the 3885-T Remote Tablet in the control room in its desired location and check that the communication performance is acceptable.

ECG

- Check that the message 'Leads Off' disappears and the waveforms are displayed when the lead wires are connected to the patient.

Pulse Oximetry

- Check that the Red Light is visible in the sensor
- Check that the SpO_2 value is displayed and the message “Probe Off” disappears when the sensor is connected to the patient

CO_2 (CO2 only or 3886 Multi-Gas system)

- Occlude the sampling line and check that the message “Occlusion” appears within 30 seconds

NIBP

- Check that the pressure values are displayed for all cuff sizes

Temperature

- Check that the temperature value is displayed when the cable is connected

Recorder

- Check that the strip chart recorder is functional

Alarms

- Turn the monitoring system on and check that the Red, Amber and blue Tri-Color Tri-Color Alarm Dome Light are lit momentarily
- Check that the speaker gives and audible tones at the desired level
- Use a conventional patient simulator and / or test gasses to verify alarm functionality. When a problem with the alarm system is suspected, always refer the monitor to a qualified service personnel.

Battery

- The battery pack should be inspected anytime the battery pack is removed. Look for signs of physical damage, shock and swelling. Check that the battery pack is holding sufficient operating capacity.
- Check that the battery is communicating with the monitor by observing the battery icon on the display.

! CAUTION

- Any failure of the inspection of the battery pack will require discontinuance of use and replacement will be needed.
- If any cells swollen greater than 8 mm thick or cause the plastic case to bulge discontinue use and contact your support personnel for proper disposal.

8.2.3. Every Twelve Months

Preventative Maintenance Check

- Calibration check of temperature, NIBP and CO_2/ Multi-Gas Agents Unit

NOTE

- The annual check according to detailed instructions of the Service Manual requires trained service personnel and appropriate testing tools and equipment.
- Verify all calibration / test gas mixture containers are empty before disposal.
- Use only MRI compliant calibration / test gas mixture containers suitable for use in the MRI environment for verification of gas readings inside of zone IV.

8.3. Service Setup Menu

8.3.1. Software Version

To check the current revision of software in the 3880 system, PODs and Tablet follow these steps:

1. Press the SETTINGS Button
2. Select “Service Mode”
3. Enter password
4. Select “Device Information”
5. Check software version
6. Touch Back button to close the menu

8.4. Care and Cleaning

8.4.1. Introduction

For safe and reliable function and operation of the monitor, regular care has to be carried out in accordance with manufactures guidelines. Use only manufactures approved substances and methods to clean and disinfect your equipment. The warranty does not cover damage caused by unapproved substances or methods.

IRadimed makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection.

NOTE

- If the monitoring system does not function as it should and troubleshooting cannot solve the problem, contact your service representative.
- Detailed cleaning instructions provided with any accessory should be followed.

8.4.2. General Guidelines

Keep your equipment and accessories free of dust, dirt and contaminants. To avoid damage to the 3880 monitor follow these rules:

- Always dilute liquid cleaning agents according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the 3880 monitor into liquid.
- Do not pour or use pressurized spray liquid onto the 3880 monitor or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials, solvent or corrosive cleaners.
- Clean the 3880 monitor in a well-ventilated area before and after each patient use.
- Allow components to dry completely prior to use.
- A soft bristled brush may be used to clean narrow areas.
- Do not use hard or pointed objects to clean any part of the monitor.

! WARNING

- Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the 3880 monitor.
- Do not use unspecified cleaners, materials or methods as they may damage the device, labels or cause failures.
- Do not use conductive solutions or materials to clean the system.
- Do not reuse sensors intended for single patient use.

! CAUTION

- If liquid is spilled on the 3880 monitor or accessories and may have entered the system immediately contact your service personnel.
- Do not use solvent based cleaning agents as damage to the plastic parts could occur.

NOTE

- Before cleaning any equipment, consult your hospital's regulations for cleaning
- Refer to any superseding instructions accompanying any accessories or options.

8.4.3. Cleaning & Disinfecting

The 3880 system should be cleaned on a regular basis. If there is heavy pollution and/or lots of dust and sand at/in your facility, the 3880 monitor should be cleaned more frequently.

Recommended cleaning agents are:

- Mild Soap (diluted)
- Ammonia (diluted)
- Isopropanol (70%)
- Chloramine (5%)
- Glutaraldehyde (2%)
- Ethyl Alcohol Based (60-95%)
- Chlorine/Bleach Based (4-6%)
- Iodine Based (0.5-5%)
- Phenols (0.2-3%)
- Quaternary Ammonium Compounds (2%)
- Hydrogen Peroxide (<3%)

To clean the 3880 monitor, follow these rules:

1. Shut down the patient monitor and disconnect it from power.
2. Clean the displays using a soft, clean cloth dampened with glass cleaner.
3. Clean the exterior surface of the 3880 monitor using a soft cloth dampened with an approved cleaner.
4. Wipe the cleaning solution off the 3880 monitor with a dry cloth.

NOTE

- Disinfection may cause damage to the 3880 monitor and is therefore not recommended unless otherwise indicated in your hospital's policy. Cleaning the 3880 monitor prior to disinfecting is recommended.

8.4.4. Sterilizing

Sterilization may cause damage to the 3880 monitor and is therefore not recommended. The decision to sterilize components must be made per your institution's requirements with an awareness of the effects on the integrity of the cables and potential hazards that it may cause.

8.4.5. Cleaning the Recorder Printhead

After the recorder has been used for a long time, deposits of paper debris may collect on the printhead compromising the print quality and shortening the lifetime of the roller. Follow this procedure to clean the printhead:

1. Open the Recorder door
2. Gently wipe around the printhead using cotton swaps dampened with alcohol.
3. After the alcohol has complete dried, reload the paper and close the door.

! CAUTION

- Do not use anything that may destroy the thermal print head.
- Do not add unnecessary force to the thermal print head.

8.5. User Maintenance

8.5.1. Overview

Before every use, a thorough inspection should be performed.
Follow these guidelines when inspecting the 3880 monitor:

- Make sure that the environment and power supply meet the requirements.
- Inspect the 3880 system and its accessories for mechanical damage.
- Inspect all power cords for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Inspect if the alarm system functions correctly.
- Make sure that the recorder functions correctly and the recorder paper meets the requirements.
- Make sure that the patient monitor is in good working condition, and batteries have sufficient charge.

In case of any damage or abnormity, do not use the patient monitor. Contact the hospital's biomedical engineers or your authorized IRadimed service personnel immediately.

8.5.2. Updating Software

As revisions of the software become available, the 3880 can be updated, see service manual for detail procedure.

8.6. Troubleshooting Problems With No Onscreen Message

The following section is for troubleshooting the 3880 system when there is no corresponding message displayed on the screen. If a message is displayed on the screen please review Exhibit B of the operators manual. Please contact IRadimed Technical support at (407) 677-8022 if you need assistance troubleshooting or are unable to resolve any issues.

8.6.1. Troubleshooting Power Related Problems

	Problem	Possible Cause	Solution
1	3880 will not turn on.	Power dial is not in the correct position	1) Turn 3880 ON by rotating the power dial to the ON position.
		No AC power/battery depleted.	1) Plug AC Adapter power cord into a working AC outlet immediately. 2) Plug AC Adapter into the circular power receptacle on the rear of the device. 3) Optional Swap low battery with a fully charged battery.

	Problem	Possible Cause	Solution
		Blown Fuse(s).	1) Replace the fuse in the power supply box (P/N 1120). Refer to the service manual for proper fuse type and procedure.
		AC power source has incorrect voltage.	1) Switch AC power cord to a power receptacle with sufficient voltage. Refer to the service manual for voltage requirements.
		Screen Damaged.	If an audible alarm is heard and the alarm dome light changes when the power ON button is pressed. 1) Investigate the LCD display screen for failure. 2) Contact IRadimed technical support.
2	3885-T will not turn on.	Power ON [I] key not pressed.	1) Turn 3885-T ON by firmly pressing the ON button firmly. Listen and feel for the tactile feedback to confirm the button has been properly pressed.
		Battery depleted.	1) Plug AC Adapter power cord into an AC outlet immediately. 2) Plug AC Adapter into the circular power receptacle on the rear of the device. 3) Optional: Swap low battery with a fully charged battery.

	Problem	Possible Cause	Solution
3	3885-B will not turn on.	Power ON key not pressed.	1) Toggle the power switch to the ON position. Listen and feel for the tactile feedback to confirm the button has been properly pressed.
		Blown Fuse(s).	1) Replace the fuse in the rear of the 3885-T Refer to the service manual for proper fuse type and procedure.
		No AC power	1) Plug AC Adapter power cord into a working AC outlet immediately.
		AC power source has incorrect voltage.	1) Switch AC power cord to a power receptacle with sufficient voltage. Refer to the service manual for voltage requirements.
4	3886 will not turn on.	Power ON key not pressed.	1) Toggle the power switch to the ON position. Listen and feel for the tactile feedback to confirm the button has been properly pressed.
		Blown Fuse(s).	1) Replace the fuse in the rear of the 3885-T Refer to the service manual for proper fuse type and procedure.
		No AC power	1) Plug AC Adapter power cord into a working AC outlet immediately.

	Problem	Possible Cause	Solution
		AC power source has incorrect voltage.	1) Switch AC power cord to a power receptacle with sufficient voltage. Refer to the service manual for voltage requirements.
5	ePOD or oPOD will not turn on	Power ON key not pressed.	1) Toggle the power switch to the ON position. Listen and feel for the tactile feedback to confirm the button has been properly pressed.
		Insufficient battery life	1) Plug 3880 system into AC power. 2) Ensure the POD is correctly docked and seated into a charging bay on the 3880 monitor. 3) Allow to charge a minimum of 4 hours. 4) Contact IRadimed Technical Support
6	3880 will not operate on battery.	Battery not properly charged.	1) Plug AC Adapter power cord into an AC outlet immediately. 2) Plug AC Adapter into the circular power receptacle on the rear of the device. 3) Wait until battery is fully charged. 4) Press the button on the exterior of the battery pack. If no LED's illuminate replace the battery pack before use.

	Problem	Possible Cause	Solution
		Aged battery won't hold charge.	1) Plug AC Adapter power cord into an AC outlet immediately. 2) Plug AC Adapter into the circular power receptacle on the rear of the device. 3) Wait until battery is fully charged. 4) Press the button on the exterior of the battery pack. If no LED's illuminate replace the battery pack before use.
		Battery is in sleep mode.	When the battery test button is pressed and no lights illuminate. 1) Insert the dead battery into a 3880 or 3885-B that is already turned on and connected to AC power. 2) If battery doesn't wake up after 1 hour of charge dispose of it according to policy. 3) Replace the battery prior to putting the 3880 back in use.
7	Short battery run time.	Battery not charged long enough.	1) Plug AC Adapter power cord into an AC outlet immediately. 2) Plug AC Adapter into the circular power receptacle on the rear of the device. 3) Check battery by pressing the test button on the battery (1133 battery only). Note: The batteries will charge at a faster rate when the 3880 is turned off.

	Problem	Possible Cause	Solution
		Aged battery will not hold charge.	1) Plug AC Adapter power cord into an AC outlet immediately. 2) Plug AC Adapter into the circular power receptacle on the rear of the device. 3) For 1133 batteries only. After a few hours of charge check battery by pressing the test button on the battery. 4) If problem persists dispose of the battery according to policy. 5) Replace battery or POD with a new one. 6) If problem persists, contact IRadimed technical support.
8	Battery is hard to remove.	Swollen Battery Cells.	Return the device to IRadimed for battery removal.

8.6.2. Troubleshooting Alarm Related Problems

	Problem	Possible Cause	Solution
1	No Audible alarm tone heard.	Alarm volume set too low for the use environment.	1) Press the Settings Button. 2) Select Alarms Function 3) Adjust alarm volume for the intended use environment.
		Faulty alarm speaker.	1) Contact IRadimed Technical Support.
2	Continuous alarm tone after alarm silence is pushed.	Faulty hardware.	1) Note any onscreen messages. 2) Contact IRadimed technical support.

	Problem	Possible Cause	Solution
3	The unit is in Alarm mode with lights flashing but no audible alarms can be heard.	The 2 minute Alarm Silence button is activated.	1) Press the ALARMSILENCE button to re-engage alarm volume. 2) Or wait for two minutes. After two minutes, alarm tones will automatically re-engage.
		Audible volume set too low to be heard.	1) Press the Settings Button. 2) Select Alarms Function 3) Adjust alarm volume for the intended use environment.

8.6.3. Troubleshooting Operation Related Problems

	Problem	Possible Cause	Solution
1	Buttons will not function.	Key not pressed firmly.	1) Repeat key press more firmly. Listen for audible and feel for the tactile feedback to confirm the button has been properly pressed.
		Faulty key panel.	If the above 2 solutions are acceptable contact IRadimed Technical Service.
2	Programmed settings are restored to default on power up.	3880 turned off for longer than 30 seconds between uses.	1) Train appropriate personnel that turning off the 3880 for more than 30 seconds resets settings.
		Volatile memory may not store due to internal Coin cell battery problem.	1) Replace CR2032 coin cell battery. 2) Contact IRadimed Technical Service.
3	Clock is not correct.	Clock not properly adjusted to local time after receipt.	1) Adjust clock time as described in manual.
		Internal coin cell battery has become depleted.	1) Replace CR2032 coin cell battery. 2) Contact IRadimed Technical Service.
		Summer/Winter time change.	1) Adjust clock as described in service manual.

	Problem	Possible Cause	Solution
4	3885-T Remote will not communicate to a selected 3880 or drops out.	3880 is not turned ON.	1) Ensure the 3880 is turned on and is operational.
		3880 is not within wireless range.	1) Verify 3880 and 3885-T within 90 ft (30 m) of 3885-B and that no other devices are blocking the wireless signal. 2) Reposition 3880 to establish communication as needed.
		Software incompatibility.	1) Ensure the software revisions for the 3880 and 3885-T are equal.
		Incorrect Channel.	1) Ensure that both the 3885-T, 3885-B and 3880 are operating on the same wireless network channel. 2) Record wireless network from the 3880. 3) Select matching wireless channel on 3885-T 4) Select matching wireless channel on 3885-B.
		Multiple system components on the same wireless network channel.	1) Ensure that each 3880 in your facility are on separate, unique channels (or not used simultaneously).
		Loose or damaged antenna.	1) Ensure that the antennas on the 3885-B are in good working order and are attached tightly.
		Local radio interference prevents communication.	1) Ensure other wireless equipment is greater than 3 feet away from the 3880 system components.
			1) Try using a different wireless network channel for the 3880 system to communicate on.

	Problem	Possible Cause	Solution
		MRI Room Attenuation.	1) Ensure the high gain antenna is attached to the correct receptacle on the 3885-B 2) Position the high gain antenna so it has a direct line of sight to the 3880. 3) Try a different wireless channel 4) Contact IRadimed Technical Service.
5	ePOD or oPOD will not communicate with a 3880	3880 is not turned ON.	1) Ensure the 3880 is turned on and is operational.
		3880 is not within wireless range.	1) Verify PODS are within 9 ft (3 m) of 3880 and that no other devices, walls or doors are blocking the wireless signal. 2) Reposition 3880 to have a line of sight to the PODS as needed
		Incorrect Channel.	1) Ensure that the ePOD, oPOD and 3880 are operating on the same wireless network channel. 2) Record wireless network from the 3880. 3) Select matching wireless channel on 3881 ePOD 4) Select matching wireless channel on 3882 oPOD.
		Multiple system components on the same wireless network channel.	1) Ensure that each 3881 and 3882 in your facility are on separate, unique channels that match a corresponding 3880 (or not used simultaneously).
6	Printer will not print	Wireless communication to the 3885-B	1) Ensure wireless connection is established to a 3885-B equipped with a recorder

	Problem	Possible Cause	Solution
		Printer out of paper or paper jam	1) Review section 7 of the operators manual

8.6.4. Troubleshooting MRI Related Problems

	Problem	Possible Cause	Solution
1	Artifact on MR images.	Loose connection to cord when running on AC power.	Tighten AC cord connection to Monitor and power supply.
		Faulty Hardware.	1) Switch to battery power. 2) Disconnect the power cable from the 3880 monitor. 3) Disconnect AC power cord from the AC outlet in the MRI room. 4) Inspect components damage. 5) Remove all power cables from the room. 6) If artifact disappears then replace faulty hardware. 7) If artifact is still present repeat steps for the 3886. 8) If artifact still appears contact IRadimed technical service.

8.6.5. Troubleshooting Vital Sign Related Problems

	Problem	Possible Cause	Solution
1	ECG Vital Signs are not performing as expected		1) Ensure the ePOD is on the same wireless network channel as the 3880. 2) Ensure the ECG parameter is enabled. 3) Inspect all ECG components for damage and replace as necessary. 4) Review section 6.1 of the operators manual 5) Contact your local representative to schedule applications training.

	Problem	Possible Cause	Solution
		Incompatible lead view for the MRI scan and/or electrode placement	Change the ECG lead view to select the best performing view for the sequence.
		Poor skin preparation	Re-prep the patient according the application procedure found in section 6.
		Poor electrode placement	Reposition/replace electrodes according to the application procedure found in section 6.
		Poor electrode quality	Replace the electrode with an IRadimed approved electrode.
		Weak radio link	Verify radio channel setting and signal level. Reposition antenna for improved reception.
		QRS amplitude is less than 10 mm/mv	Change the lead view and / or reprep and reposition the electrodes.
		Faulty ECG ePOD	Replace ECG module, or refer to qualified technical service representative.
		Incorrect ECG Mode selected	Select the appropriate ECG filter mode for the application. Refer to section 6 of the operators manual.
		Patient motion	Ensure that the patient is not shivering or moving.
		ECG lead not properly inserted into the ePOD	Ensure each ECG leadwire is inserted completely into the ePOD.
		Damaged ECG lead	Replace ECG lead with an IRadimed approved ECG lead.

	Problem	Possible Cause	Solution
		All other issues	1) Ensure the ePOD is on the same wireless network channel as the 3880. 2) Ensure the ECG parameter is enabled. 3) Inspect all ECG components for damage and replace as necessary. 4) Review section 6.1 of the operators manual 5) Contact your local representative to schedule applications training.
2	SpO2 not functioning	SpO2 sensor is not attached to the patient.	Ensure SpO2 sensor is securely attached.
		Poor SpO2 sensor placement	Reposition/replace SpO2 sensor according to section 6.
		Weak radio link	Verify radio channel setting and signal level. Reposition antenna for improved reception.
		Faulty SpO2 oPOD	Replace SpO2 oPOD, or refer to qualified technical service representative.
	SPO2 readings are unstable or poor	Sensor positioning	Check the P.I. value and try repositioning the sensor correctly on the patient according to section 6.
			Ensure the SpO2 cable is correctly inserted into the SpO2 applicator / grip.
		Averaging time	Try adjusting the SpO2 averaging time.
		Patients specific anatomy	Skin pigment and certain anatomy ailments can cause inconsistent SpO2 readings.
			Check that there is no nail polish on the patients digit impeding the readings.
		Cool temperature is affecting patients perfusion	Check the P.I. value and ensure the patient is not shivering and that their digits are warm to the touch.

	Problem	Possible Cause	Solution
		interference from NIBP cuff or arterial catheter.	Move the SpO2 sensor to an application site and limb that is not being utilized for other medical functions.
		Excessive ambient light	Limit the amount of ambient light entering the sensors. Cover with a cloth as needed.
		Excessive patient motion	Ensure that the patient is not shivering or moving.
		Circulation is reduced because of excess pressure	Position the sensor at a different site and ensure it is not applied to tightly to the patients digit.
		Finger was removed from the sensor	Check that the appropriate sized sensor is being used and reapply according to section 6.
	SpO2 Vital Signs are not performing as expected	All other issues	1) Ensure the SpO2 parameter is enabled. 2) Inspect all SpO2 components for damage and replace as necessary. 3) Review section 6.2 of the operators manual. 4) Contact your local representative to schedule applications training.
3	CO2 not functioning	Sampling line hose is not connected	Attach sampling line hose.
		Leaking sampling line hose	Re-check fittings to ensure they are tight. Replace sampling line hose.
		Sampling line filter is wet or clogged	Verify proper drying tubing is in position. Re-check filter to ensure it is clear. Replace sampling line hose filter.
		Monitor has an internal leak	Refer to qualified technical service representative.
	Values are too low or unstable	Monitor has an internal failure	Refer to qualified technical service representative.

	Problem	Possible Cause	Solution
	EtCO2 Vital Signs are not performing as expected	All other issues	1) Ensure the EtCO2 parameter is enabled. 2) Inspect all EtCO2 components for damage and leaks and replace as necessary. 3) Review section 6.3 of the operators manual. 4) Contact your local representative to schedule applications training.
4	NIBP values seem unstable	Compromised hose or cuff	Check that tubing is not stretched, bent, compressed or loose.
			Ensure the patient is not shivering or moving.
			Ensure the correct sized cuff is being used and applied correctly.
			Replace Hose or cuff if a leak is suspected.
		Monitor has an internal leak	Refer to qualified technical service representative.
		Patients Arm Position	Ensure that the patients arm is at heart level.
	Cuff comes off patient limb	Inappropriate sized cuff	Determine correct cuff size and apply to patient according to section 6.
		Cuff applied inside out	Reapply cuff according to section 6.
	NIBP not functioning	NIBP hose or cuff is disconnected	Ensure NIBP hose is securely connected.
		Monitor has an internal failure	Refer to qualified technical service representative.
	NIBP Vital Signs are not performing as expected	All other issues	1) Ensure the NIBP parameter is enabled. 2) Inspect all NIBP components for damage and leaks and replace as necessary. 3) Review section 6.4 of the operators manual. 4) Contact your local representative to schedule applications training.

	Problem	Possible Cause	Solution
5	Temperature error or intermittent function	Temperature sensor is not securely attached to the patient.	Re-attach Temperature sensor.
		Poor Temperature sensor placement	Reposition/replace Temperature sensor.
		Faulty Temperature sensor	Replace Temperature sensor, or refer to qualified technical service representative.
	Temperature Vital Signs are not performing as expected	All other issues	1) Ensure the Temperature parameter is enabled. 2) Inspect all Temperature cable for damage or kinking and replace as necessary. 3) Review section 6.4 of the operators manual. 4) Contact your local representative to schedule applications training.
6	Respiration and Gases from 3886 are not performing as expected		1) Ensure the 3886 is turned ON 2) Ensure the Gas parameter is enabled on the 3880. 3) Inspect all EtCO2 components for damage and leaks and replace as necessary. 4) Review section 6.3.8 of the operators manual. 5) Contact your local representative to schedule applications training.

8.7. Repair

8.7.1. Overview

All repairs on components under warranty must be performed by authorized IRadimed service personnel. If the 3880 system fails to function properly or requires maintenance, contact your IRadimed representative.

! CAUTION

- Decontaminate all equipment prior to performing any repair or before sending to IRadimed.
- No repair should ever be attempted by anyone not having a thorough knowledge of the 3880 system.
- Only replace damaged components with parts manufactured and authorized by IRadimed.

NOTE

- Unauthorized repairs will void the warranty.
- The user of this product shall have sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alterations by anyone other than authorized IRadimed service personnel.

8.7.2. Changing Fuses

1. Remove the power cord if used.
2. Remove the fuse holder by pulling the holder out with screwdriver.
3. If a fuse is blown, replace it with the IRadimed HE14 fuse which is the correct type and rating.

8.7.3. Removing a Paper Jam

If the recorder works incorrectly or produces unusual sounds, check if there is a paper jam. If a jam is detected follow these steps to remove it:

1. Open the Recorder Door
2. Remove the paper and tear off any damaged paper
3. Reload the paper and close the recorder door.

8.8. Warranty

IRadimed Corporation warrants the major components of the 3880 system (e.g. 3880, 3885-T Remote Tablet and 3885-B Base Station) to be free from defects in materials and workmanship for a period of twelve (12) months from the date of original delivery to the buyer or to buyer's order, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed. A ninety (90) day warranty applies to limited-life parts and accessories (e.g.1133 MRI Compatible Battery Pack, gating cable, SpO_2, ECG, NIBP, CO_2, Temperature patient accessories). A thirty (30) day warranty applies to all parts and accessories not listed above.

This warranty will become null and void if product has been repaired other than by IRadimed Corporation, or its authorized representative, or if the product has been subject to misuse, accident, negligence, or abuse.

IRadimed Corporation's sole obligation under this warranty is limited to repairing a product which has been reported to IRadimed Corporation's Technical Service Center during normal business hours and shipped transportation prepaid. IRadimed Corporation is not liable for any damages including, but not limited to, incidental damages, consequential damages or special damages.

This warranty is in lieu of any other warranties, guarantees or conditions, including merchantability or fitness for a particular purpose. The remedies under this warranty are exclusive and IRadimed Corporation neither assumes nor authorizes anyone to assume for it any other obligation in connection with the sale or repair of its products.

A purchased Maintenance Extension agreement provides for an additional 1, 2, or 3 years of authorized repair for major products. The maintenance extension period will begin at the end of the standard warranty period, and continue until the end of the maintenance extension period purchased. The extended maintenance does not apply to equipment which has been subject to abuse or neglect.

Maintenance Extensions purchased after the standard warranty has expired shall require a physical inspection by IRadimed Corporation prior to purchase of any Maintenance Extension. An additional service fee may also be required to bring the out of warranty product(s) within specifications before any maintenance extension can be activated. (Cost of such inspection and possible repair to the product will be communicated to customer at that time). We reserve the right to refuse the sale of Maintenance Extension to any Product.

IRadimed Corporation warrants any such product subject to a Maintenance Extension agreement shall, other than its expendable parts, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed; be repaired by IRadimed and restored to full operational specification as where applicable at the time of original manufacture. Any Maintenance Extension will become null and void if product has been repaired other than by IRadimed Corporation, or its authorized representative, or if the product has been subject to misuse, accident, negligence or abuse.

Should a unit perform outside of IRadimed specifications and cannot be corrected by on site technicians with instruction and support from IRadimed and unit must be returned to IRadimed for repair, a loaner unit, if available, may be provided.

9. Accessories

The packaging of the accessories is color coded to help identify which accessories are most likely appropriate for your particular patient.

- Gray – All patient sizes
- Neonatal (Birth to one month of age) – Purple
- Infant (One month to two years of age) – Orange
- Child (Two to Twelve years of age) – Green
- Adult (Above twelve years of age) – Blue

NOTE

- All materials that come in contact with patients and users comply with ISO 10993-1.

To order replacement parts contact your IRadimed representative or call 1-866-677-8022

9.1. SpO_2

Part Number	Description	Image	Use Type
1171	**Reusable Sensor Grip Kit (Pack of 3)** *Reusable Sensors Grip come in 3 sizes (Grips only)*		Multiple Use
1821	**Fiber Optic oPOD SpO2 Cable** *Fiber optic SpO2 cable for use with IRadimed oPODs.*		Multiple Use
3882	**8 Channel Wireless oPOD** *Wireless MRI SpO2 module featuring Masimo technology. For use with the IRadimed 3880.*		Multiple Use

9.2. NIBP

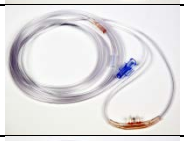
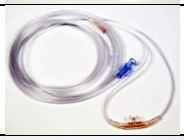
Part Number	Description	Image	Use Type
1832LA	**Large Adult Reusable Cuff (34-44cm)** *Reusable Non-Invasive blood pressure cuff are constructed of an extremely soft, easy to clean material to provide a long usable life and support multiple patient use.*		Multiple Use
1832A	**Adult Reusable Cuff (27-35cm)** *Reusable Non-Invasive blood pressure cuff are constructed of an extremely soft, easy to clean material to provide a long usable life and support multiple patient use.*		Multiple Use
1832SA	**Small Adult Reusable Cuff (20.5-28.5cm)** *Reusable Non-Invasive blood pressure cuff are constructed of an extremely soft, easy to clean material to provide a long usable life and support multiple patient use.*		Multiple Use

Part Number	Description	Image	Use Type
1832P	**Pediatric Reusable Cuff (14-21.5cm)** *Reusable Non-Invasive blood pressure cuff are constructed of an extremely soft, easy to clean material to provide a long usable life and support multiple patient use.*		Multiple Use
1832I	**Infant Reusable Cuff (9-15cm)** *Reusable Non-Invasive blood pressure cuff are constructed of an extremely soft, easy to clean material to provide a long usable life and support multiple patient use.*		Multiple Use
1833N4-10	**Neonatal Size 4 Cuff (7-13cm) (Box of 10)** *Single Use Non-Invasive blood pressure cuffs are constructed of soft fabric material that conform to the tiniest of patients.*		Single Use
1833N3-10	**Neonatal Size 3 Cuff (6-11cm) (Box of 10)** *Single Use Non-Invasive blood pressure cuffs are constructed of soft fabric material that conform to the tiniest of patients.*		Single Use
1833N2-10	**Neonatal Size 2 Cuff (4-8cm) (Box of 10)** *Single Use Non-Invasive blood pressure cuffs are constructed of soft fabric material that conform to the tiniest of patients.*		Single Use
1833N1-10	**Neonatal Size 1 Cuff (3-6cm) (Box of 10)** *Single Use Non-Invasive blood pressure cuffs are constructed of soft fabric material that conform to the tiniest of patients.*		Single Use
1831	**NIBP Swift Connect NIBP Hose** *Single lumen non-invasive blood pressure hose featuring simple connections*		Multiple Use

9.3. ECG

Part Number	Description	Image	Use Type
1813-3	**ECG Skin Prep Gel (Box of 3)** *Package of 3 tubes of skin prep gel to prepare patients skin for MRI ECG electrodes.*		Multiple Use
1811	**9” Five Lead ePOD MRI Leadwire (AAMI)** *ECG leadwire for 3 and 5 lead ECG applications with AAMI color coding. For Use with IRadimed ePOD only.*		Multiple Use
1811E	**9” Five Lead ePOD MRI Leadwire (IEC)** *ECG leadwire for 3 and 5 lead ECG applications with IEC color coding. For Use with IRadimed ePOD only.*		Multiple Use
3881	**8 Channel Wireless ePOD** *Wireless MRI ECG module for use with the IRadimed 3880*		Multiple Use

9.4. CO2/Respiration Monitoring

Part Number	Description	Image	Use Type
1842A-25	**Adult Nasal Cannula (Pack of 25)** *Single use standard nasal cannula*		Single Use
1842P-25	**Pediatric Nasal Cannula (Pack of 25)** *Single use standard nasal cannula*		Single Use
1842I-25	**Infant Nasal Cannula (Pack of 25)** *Single use standard nasal cannula*		Single Use
1841-25	**Coextruded Sample Line (Pack of 25)** *Sample line for use with capnography and anesthetic agent gas monitoring. For use with P/N 1849.*		Single Use

9.5. Multi-Gas (Agents) Monitoring

Part Number	Description	Image	Use Type
1849-25	**Nomoline Agent Sample Line (2m) (Pack of 25)** *For use with IRadimed's 3886 Wireless Multigas Module only*		Single Use
1846-25	**Scavenge Hose (Pack of 25)** *For use with IRadimed's 3886 Wireless Multigas Module only*		Single Use
1848	**Verification Check Gas** *For use with IRadimed's 3886 Wireless Multigas Module only*		Multiple Use

9.6. Temperature

Part Number	Description	Image	Use Type
1851	**Optical Temperature Sensor** *Multiple use Fiber Optic temperature sensor*		Multiple Use

9.7. Gating

Part Number	Description	Image	Use Type
1881	**Universal Gating Interface** Non-Magnetic gating interface cable for use with MRI Systems equipped with cardiac gating leads		Multiple Use

9.8. Power Supply

Part Number	Description	Image	Use Type
1133	**3880 Battery** Non-Magnetic battery used with the 3880		Multiple Use
1188	**3885T Battery** Non-Magnetic battery used with the 3885T		Multiple Use
1122	**DC Power Cable, 10 feet (3m)** *Replacement power cable used to interface the 3880 with the 1120 power supply*		Multiple Use
1120	**Power Supply / Charger** *Replacement power cable used with the 1122 cable*		Multiple Use
1128	**North America AC Power Cord, 10 feet (3m)** *Replacement power cable used with 3885 and 3886*		Multiple Use
1121	**North America AC Power Cord, 3 feet (1m)** *Replacement power cable used to interface the 3880 with the 1120 power supply*		Multiple Use

9.9. Recorder

Part Number	Description	Image	Use Type
1882-3	**3885B Recorder Paper (Pack of 3)** *3 Rolls of printer paper for the 3885B recorder*		Multiple Use

10. Exhibits

A. Specifications

10.1. Overview

Standard System Components

- 3880 MRI Patient Monitor
- Wireless ECG POD
- Wireless SpO_2 POD
- Non- Invasive Blood Pressure
- Accessories

Optional System Components

- 3885-T Remote Tablet 'Extended Range' Control Room Display
- 3885-B Base Station with recorder
- CO_2 and Respiration vital signs
- Temperature vital sign
- 3886 Multi-Gas Anesthetic Agent , 3886 Unit

Clinical Parameters

- Dual Channel, 5 Lead ECG
- Pulse Oximetry
- Perfusion Index
- Non – Invasive Blood Pressure
- Sidestream Capnography, Et CO_2 and CO_2
- Respiration Rate
- Fiber Optic Temperature
- Dual Anesthetic Agents
- Inspired N_20
- Inspired O_2
- MAC

10.1.1. Technical Specifications

10.1.1.1. Display

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

10.1.1.2. User Interface

10.1.1.2.1. Monitor

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

10.1.1.2.2. Tablet

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

10.1.1.2.3. PODS

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

10.1.1.2.4. Base Station

Technical Parameters	Technical Detail
Power:	Toggle
Channel Select:	Button

10.1.1.3. Application Features

10.1.1.3.1 Trend Reports

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

10.1.1.3.2 Alarms

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

10.1.1.4. Safety Standards

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

10.1.1.5. Physical Specifications

10.1.1.5.1. Height

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

10.1.1.5.2. Width

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

10.1.1.5.3. Depth

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

10.1.1.5.4. Weight

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

10.1.1.6. Electrical Specifications

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

10.1.1.7. Environmental Specifications

	Technical Parameters	Technical Detail
Operating	All 3880 system components	
	Temperature Range:	+10° to + 40° C (+50° to + 104° F)
	Humidity Range:	5% to 85% RH, non-condensing
	Altitude Range:	0 – 5000 meters, Pressure: 1010hPa – 540hPa
Storage	All 3880 system components	
	Temperature Range:	-20° to + 50° C (-4° to + 122° F)
	Humidity Range:	5% to 95% RH, non-condensing
	Altitude Range:	0 – 5000 meters, Pressure 1010hPa – 540hPa

10.1.1.8. MRI Conditions

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

10.1.1.9. Recorder

Technical Parameters	Technical Detail
Technique:	Thermal line recorder at 3885-B Base Station
Data Type:	Single or Dual Waveform; Tabular
Paper Speed:	12.5 or 25mm/sec continuous

10.1.1.10. Gating

Technical Parameters	Technical Detail
Technique:	Cardiac or Peripheral
Digital Pulses:	3.3 p-p signal with a pulse duration of 10ms ± 3ms

10.1.1.11. Vital Signs

10.1.1.11.1. ECG

Technical Parameters	Technical Detail
Lead Set Configuration:	3 and 5 lead
Lead Color:	AAMI/AHA and IEC
Lead Configurations:	I, II, III, V, AVF, AVR, AVL
Lead Fail:	Passive, sensing signal imbalance
Input Impedance:	> 2.5MΩ (according to IEC 60601-2-27, 50.102.3)
Electrode Contact Impedance:	≤ 20K ohms @ 10 Hz
Heart Rate:	30 - 250 bpm
Heart Rate Accuracy:	± 1% or ± 5 BPM, whichever is greater
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 90 – 110 BPM
Response Time of Heart Rate Meter to Change in Heart Rate:	HR change from 80 to 120 BPM: 5 sec HR change from 80 to 40 BPM: 9 sec
Time to Alarm for Tachycardia:	B1 - Vent Tachycardia 1 mVpp, 206 BPM: Gain 0.5 (12.03, 11.04, 14.1, 11.8, 11.4) Average: 6.25 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: 2.59 seconds Gain 2.0 (8.8, 9.1, 10.3, 9.4, 12.1) Average: 3.93 seconds B2 - Vent Tachycardia 2 mVpp, 195 BPM: Gain 0.5 (9.0, 10.4, 12.3, 8.1, 10.4) Average: 3.99 seconds Gain 1.0 (8.4, 7.7, 12.5, 7.7, 8.3) Average: 1.82 seconds Gain 2.0 (9.7, 12.6, 8.9, 11.8, 8.3) Average: 4.01 seconds

10.1.1.11.2. SpO_2

Technical Parameters	Technical Detail
Technique:	Masimo SET®
Saturation Range:	1% - 100%
Saturation Accuracy:	± 2.1% at 70% - 99% (full scale) < 70% oxygen saturation is unspecified
Saturation Resolution:	1%
Pulse Rate Range:	30 - 240 ppm
Pulse Rate Accuracy:	± 3 ppm
Pulse Rate Resolution:	1 pulse per minute (PPM)
Wavelength Range:	660 nm / 905 nm Note: Wavelength range can be especially useful to clinicians
Emitted Light Energy	< 1.2mW maximum average at 905nm
Calibration Range:	70 - 100%
Minimum sensor Bend Radius	4 cm (1.6 inches)
SpO2 averaging time:	6 seconds

10.1.1.11.3. NIBP

Technical Parameters	Technical Detail
Technique:	Oscillometric
Modes:	Manual, Automatic and STAT
Measurement Time:	< 60 seconds typical; standard adult cuff
Systolic Measureable Pressure Range:	Adult/Pediatric: 40 - 270 mmHg (5.3 - 36 kPa) Neonatal: 30 - 130 mmHg (4 - 17 kPa)
Diastolic Measureable Pressure Range:	Adult/Pediatric: 25 - 245 mmHg (3.3 - 32 kPa) Neonatal: 10 - 100 mmHg (1.3 - 13 kPa)
Mean Measureable Pressure Range:	Adult/Pediatric: 30 - 255 mmHg (4 - 34 kPa) Neonatal: 15 - 120 mmHg (2 - 16 kPa)
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:	30-240 ppm
Pulse Rate Accuracy:	± 1% or ± 5 BPM, whichever is greater
Max Cuff Inflation Pressure:	Adult/Pediatric: 270 mmHg Neonatal: 140 mmHg
Pressure Transducer Range:	0 - 300 mmHg (0 - 40 kPa)
Transducer Accuracy:	The greater of ± 2 mmHg or 2% of the reading
Overpressure Protection:	Adult: 300 mmHg (40 kPa) < 2 seconds Pediatric: 300 mmHg (40 kPa) < 2 seconds Neonatal: 150 mmHg (20 kPa) < 2 seconds
Initial Pressure:	Adult: 165 mmHg (22 kPa) Pediatric: 165 mmHg (22 kPa) Neonatal: 100 mmHg (13.3 kPa) All initial pressures ± 15 mmHg (2 kPa)
STAT Mode:	3 consecutive NIBP Readings
Minimum Time Between Readings:	Auto: 30 seconds (non STAT) Manual: 5 seconds

10.1.1.11.4. CO_2 Only, Internal System

Technical Parameters	Technical Detail
Technique:	Sidestream, Non-dispersive infrared absorption technique
Range:	0-15% CO2, or partial pressures at STP: 0-115 mmHg, or 0 - 16 kPa,
Accuracy:	± 0.43 Vol% +8%, or ± 3.75 mmHg +8%, or ±0.5kPa +8%
Resolution:	1 mmHg, 0.1%, 0.1 kPa
Warmup Time:	< 10 seconds (concentrations reported and full accuracy)
Response Time:	< 5 seconds for sample, 150mS waveform response
Flow Rate:	80 ± 20 ml/min
Calibration:	Automatic

10.1.1.11.5. Respiration

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

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

Technical Parameters	Technical Detail
Technique:	Sidestream, Non-dispersive infrared (NDIR) absorption technique
Warmup Time:	< 20 seconds (concentrations reported and full accuracy)
Response Time:	≤ 5 seconds
Flow Rate:	50 ± 10 ml/min
Calibration:	Automatic
Drift of Measurement	None
Accuracy degradation with rate	Above 80 RPM, end-tidal agent measurements will typically decrease below the nominal value in proportion to the respiration rate as follows: ET=80Et(nom)/RR
CO2 and Respiration	Ranges and accuracy same as 10.1.1.11.4 and 5 above
N_2O Range:	0 - 100 vol%
N_2O Accuracy:	± 2 vol% + 2%
N_2O Resolution:	1%
Primary Agent ID	0.15 vol%
Secondary Agent ID	0.20 vol% + 10% of total agent concentration
Multiple Agent (>2) Detect	0.20 vol % +/- 10% of total agents concentration
Sev Range:	0 - 10 vol%, accuracy ±0.15vol% +5%
ISO, HAL, ENF Range:	0 - 8%, accuracy ±0.15vol% +5%
Des Range:	0 - 22%, accuracy ±0.15vol% +5%
Sev, ISO, HAL, ENF, DES Accuracy:	± 0.15 vol% + 5%
Sev, ISO, HAL, ENF, DES Resolution:	0.1%
Interfering Gas Effects	**Tested according to IEC 80601-2-55**
Nitrous Oxide	No effect at 60%
Halothane	No effect at 4%
Enflurane	No effect at 8%
Isoflurane	No effect at 8%
Sevoflurane	No effect at 8%
Xenon	-10 % of reading @ 80 vol%
Helium	-6 % of reading @ 50 vol%

Desflurane	+12 % of reading @ 15 vol%
Ethanol	No effect at 0.3 vol%
Isopropanol	No effect at 0.5 vol%
Acetone / Metabolic Ketones	No effect at 1 vol%
Methane	No effect at 3 vol%
Carbon Monoxide	No effect at 1 vol%
Nitrogen Monoxide	No effect at 0.02 vol%
Oxygen	No effect at 100 vol%

10.1.1.11.7. O2 (Part of 3886)

Resolution	1%
Range	0 to 100 %
Accuracy 0 to 59%	+/- 3%
Accuracy 60 to 100%	+/- 5%

10.1.1.11.8. Temperature

Technical Parameters	Technical Detail
Technique:	Direct Fiber-Optic
Range:	30 - 44° C (86 – 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

B. Messages, Alerts, Alarm Priority

Message	Trigger Condition	Priority
Apnea	Respiration detection system (CO2 / Multi-Gas) reports Apnea	High
Agent Unit Connecting	Indicates 3880 attempting to make connection with 3886 Multi-gas Unit	N/A
Check Print Door	Printer door is not fully closed	N/A
CO2 Occlusion	Gas sampling line is occluded	Med
CO2 Overscale	Co2 measurement exceeds range of the display scale	Low
CO2 Zeroing	Performing a Zero reference in gas system	N/A
COMM LOSS	Wireless communication loss with 3885-B for more than 4 seconds	Low
Crit Mon Batt	≤ 5% of battery capacity in 3880 monitor	Med
Crit Tab Batt	≤ 5% of battery capacity in 3885-T Remote Tablet	Med
Data Delay	Display update error or delay possible	High
ECG Batt Crit	Battery level in ECG transmitter POD at extreme low level	Med
ECG Inop	Hardware or software failure detected	Med
ECG Lead Fail	Lead wire has no electrical connection to the patient or ECG level over-scale	Low
EtCO2 Cal Error	Calibration error detected	Med

Gas System Inop	Hardware or software failure detected in a gas measurement system	Med
Gas System Warmup	CO2/Multi-Gas unit warming up	N/A
LAN Conn Error	LAN connection errors preventing communication	Low
Low ECG Batt	≤ 15% of battery capacity left in ePOD	Low
Low Mon Batt	≤ 15% of battery capacity left in 3880 monitor	Low
Low SpO2 Batt	≤ 15% of battery capacity left in oPOD	Low
Low Sig IQ	SpO2 unit reports Signal IQ Low	Low
Low Tab Batt	≤ 15% of battery capacity left in 3885-T Remote Tablet	Low
Low Perfusion	Low perfusion detected by SpO2	Low
Mag Field High	Agent bench magnetic field limitations surpassed	Med
Multi Agent MAC	The MAC value consists of more than one agent	Med
Mixed Agents	More than two agents may be present	Med
NIBP Cal Error	Calibration error detected	Med
NIBP Delayed	NIBP reading start held for blood flow	N/A
NIBP Inop	Hardware or software failure detected	Med
NIBP Leak	Air leak is detected	Low
NIBP Occlusion	Occlusion is detected	Med
NIBP Over Press	Pressure exceeds 300 mmHg for Adult / Ped or 150 mmHg for Neonatal patients -or- 15 mmHg remains in the line for Adult / Ped or 5mmHg for Neo for greater than 90 seconds	Low
NIBP Time Out	Pressure remains the same for more than 30 seconds or if measurement exceeds 180 seconds	Low
No Sample Line	CO_2 sampling line disconnected, 3886 Only	Low
Out of Paper	Recorder paper has run out at Base	Low
POST Fail	Power on self-test failure	Med
Recorder Inop	Hardware or software failure detected in Base recorder	Low
Recorder Off Line	Print head is too hot or communication loss to the recorder/Base	Low
Radio Inop	Radio failure detected with comm to 3885 Base/Tablet	Med
SEE MESSAGES!	Critical message area full	High
Sp02 Batt Crit	Battery level in SpO2 transmitter POD at extreme low level	High
SpO2 Noisy	SpO2 unit reports noisy signals from sensor	Low
SpO2 Hi Light	SpO2 unit reports high ambient light at sensor	Low
SpO2 Bad Probe	SpO_2 sensor damaged or not compatible	Low
SpO2 Inop	Hardware or software failure detected	Med
SpO2 No Probe	SpO_2 sensor is disconnected from the oPOD	N/A
SpO2 Probe Off	SpO_2 sensor is not properly attached to the patient	Med
SpO2 Searching	Searching for patient pulse	N/A
SW Mismatch	Software version difference between 3880 components	Low
Temp Inop	Hardware or software failure detected	Med
Temp Probe Fail	Broken sensor detected or a sensor is not attached properly	Low
Wrong Cuff	NIBP system detects an incorrect cuff size for the selected patient mode	Low

All vital signs with alarm limits use high priority indication for violations.

Priority is indicated with visual and audible indications:

Low – Blue, Medium – Yellow, High – Red. See section 4.1.4

Watch Dog Fail Safe timeout indicated by continuous audio alarm tone and flashing red alarm dome.

C. Repair

All repairs on products under warranty must be performed by Iradimed Corporation personnel, or an authorized Iradimed Corporation Service and Repair Center.
Unauthorized repairs will void the warranty.

If a device fails to function properly or requires maintenance, contact Iradimed Corporation Technical Service at 1-407-677-8022 within the U.S., +001-407-677- 8022 from outside the U.S.(during normal business hours EST), or by E-mail at techsupport@iradimed.com. Iradimed Corporation Technical Service will advise you of the corrective action required. If you are advised to return the device to Iradimed Corporation for repair, please do the following:

a. Obtain a Return Authorization Number. This will ensure proper routing and facilitate timely repair of your monitoring device.

b. Clean monitoring device prior to shipment. Do not ship contaminated product to IRadimed Corporation for repair.

c. Package the monitoring device with adequate protection. If available, use the original carton and packing materials in which the monitoring device was shipped from Iradimed Corporation.

d. Include a brief description of the problem as well as the name, address and phone number of the person to be contacted for additional information.

e. Include a purchase order with the monitoring device being returned if it is out of warranty; Iradimed Corporation Technical Services can advise you of your monitoring device's warranty status if need be. Repairs will be made at Iradimed Corporation's current list price for the replacement part(s) plus a reasonable labor charge.

f. Ship the monitoring device transportation prepaid, to the location specified by your Iradimed Corporation Service Representative with the Return Authorization Number written on the outside of the shipping carton. Repairs will be made, normally, within two (2) weeks and the monitoring device will be returned to you prepaid.

To ensure full reliability, it is recommended that all repairs be made by an Iradimed Corporation Authorized Service and Repair center. For repair at your facility, a competent individual experienced in the repair of monitoring device can repair the monitoring device only IF it is authorized by Iradimed Corporation Technical Service prior to the repair.

CAUTION: No repair should ever be attempted by anyone not having a complete knowledge of the repair of Iradimed Corporation monitoring device. Only replace damaged parts with components manufactured or sold by Iradimed Corporation. Contact the Iradimed Corporation Technical Service and Repair Center for service and technical assistance.

D. Masimo SET™ Technology

D.1. Masimo SET Principles of Operation

The Masimo SET® MS pulse oximeter is based on three principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
2. The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).
3. Arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse.

The Masimo SET® MS pulse oximeter as well as traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 905 nm:

- S(660) = AC(660)/DC(660)
- S(905) = AC(905)/DC(905)

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

- R = S(660)/S(905)

This value of R is used to find the saturation SpO_2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The Masimo SET® MS board pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. MS board decomposes S(660) and S(905) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

- S(660) = S1 + N1
- S(905) = S2 + N2
- R = S1/S2

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

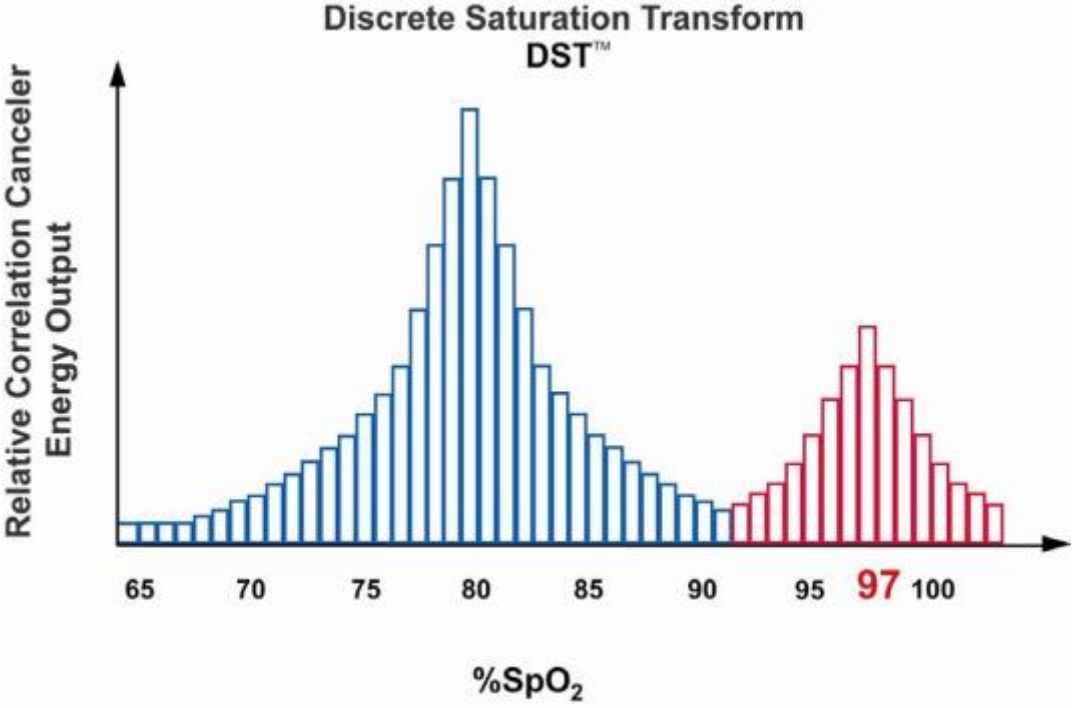
The above equations are combined and a noise reference (N') is determined:

- N' = S(660) - S(905) x R

If there is no noise N' = 0: then S(660) = S(905) x R which is the same relationship for the traditional pulse oximeter.

The equation for the noise reference is based on the value of R, the value being sought to determine the SpO_2. The MS board software sweeps through possible values of R that correspond to SpO_2 values between 1% and 100% and generates an N' value for each of these R-values. The S(660) and S(905) signals are processed with each possible N' noise reference

through an adaptive correlation canceler (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possibleSpO2 value as shown in the following figure where R corresponds to SpO_2 = 97%:



MEASURED A_{RMS} VALUES	
Range	A_{RMS}
90-100 %	1.30 %
80-90 %	1.78 %
70-80 %	2.80 %

Range	A_{RMS}
70-100 %	± 2.1 %
Overall Claimed Accuracy Value	

SpO2 Performance information of measured A(rms) accuracy shown in tabular form by range.

Graphic plots below of sampled points from blood study with Iradimed 1170 FO Sensor:

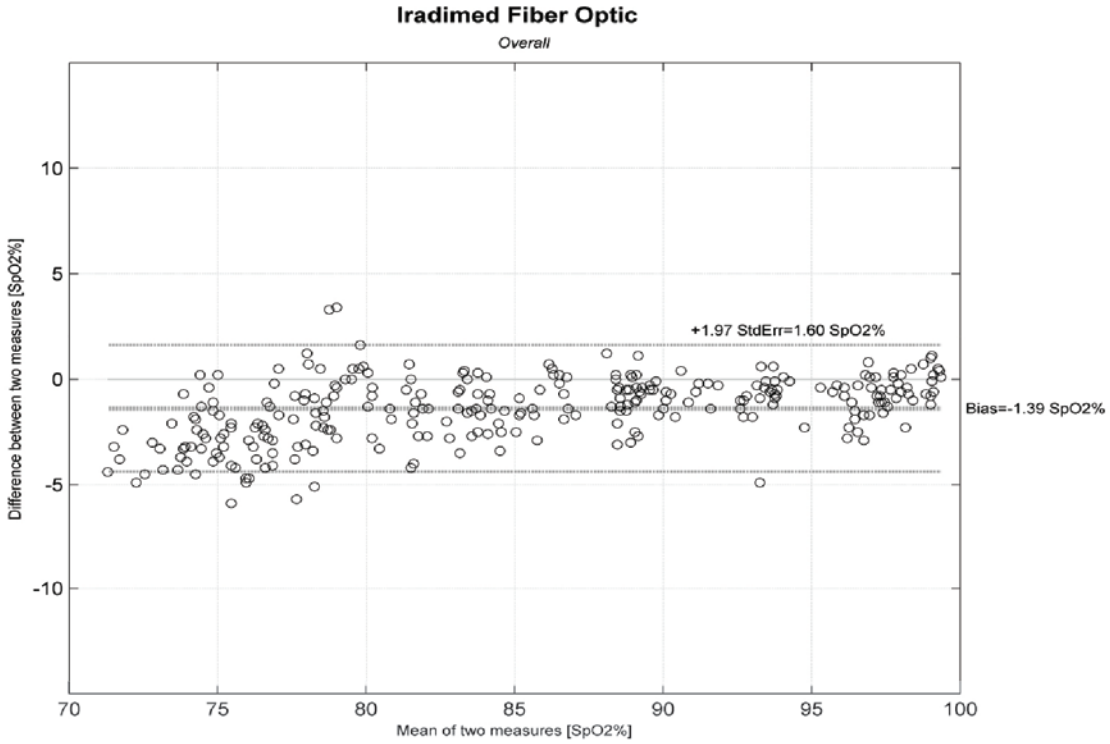
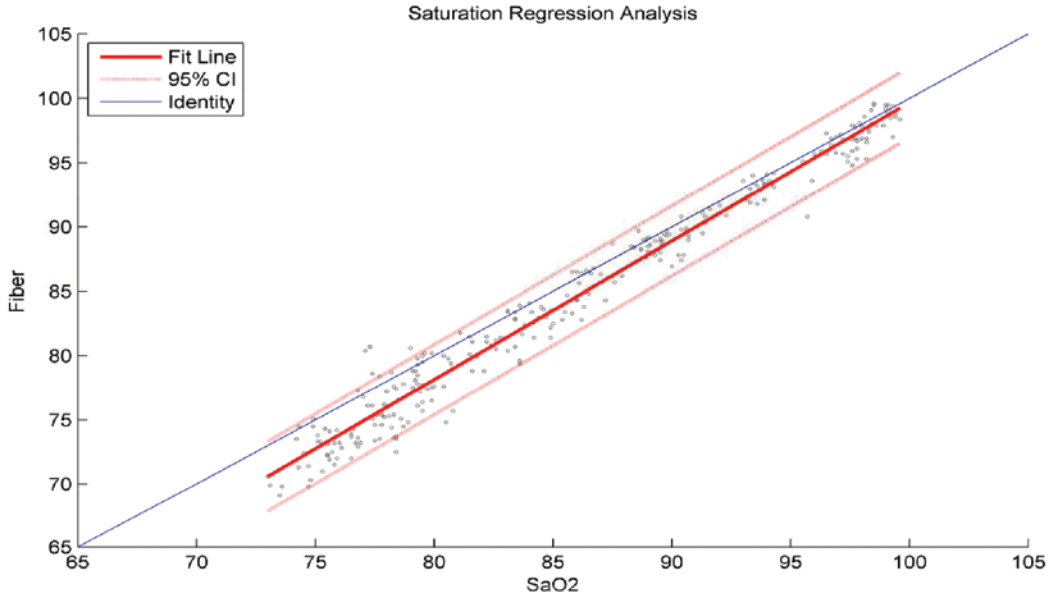


Figure 4



Test Instrument: Fiber

Y = -8.027 + 1.077 SaO2 R^2=0.97 MSE= 1.932

Bias= -1.39 Prec= 1.52 RMS= 2.06

Figure 6

E. Internal CO2 Only, and Masimo Multi-Gas Systems Detail Operation

The 3880 MRI Patient monitoring system has two options for gas measurement. There being a 'built in' CO2/Respiration only option and an externally packaged Multi-Gas option with full automatic anesthetic agent identification as well as 'fast' parametric O2, known as P/N 3886. The 'built in' CO2 only option is housed within the 3880 monitor unit and operable to the full magnetic limits of the 3880 monitor unit, 30,000 Gauss. Using the Parameter Setup menu, the user can select CO2 only which will activate this internal CO2 unit and display CO2 waveform, Et and Fi CO2 as well as respiration this internal unit measures.
Likewise, from the Parameters Setup menu the operator can select Agents which turns off the internal CO2 only unit and causes the 3880 monitor unit to communicate with the external 3886 Multi-Gas unit. The 3880 now displays CO2 waveform, Et and Fi CO2, respiration, anesthetic agents, N2O, and 02 from the 3886 unit. The core of the 3886 is the Masimo/Phasein ISA sidestream OR+ Multi-Gas system which includes the Servomex Pm1116 Fast Oxygen transducer. These devices have a long history of successful deployment in various non-MRI monitors. The 3886 unit, provides magnetic and RF shielding allowing use in MR with magnetic fields up to 600 Gauss, as such the 3886 is to be mounted on the MR gas machine or other fixed position below 600 Gauss.

Terms and definitions

Specific terms and definitions used in this manual and explained below:

Term	Explanation
AA	Anesthetic Agent
BTPS	Body Temperature and Pressure Saturated
delay time	The delay time is defined as the time required for a step function change at the sampling site to result in 10% of the final *value*
Et cone.	End-tidal (expired) concentration
Fi cone.	Inspired gas concentration
harmful substances	Substances introduced in the patient circuit to an amount that may cause harm to substances the patient
ICU	Intensive Care Unit
LEG!	Light Emitting Gas Inlet. Status indicator integrated in the gas sample inlet port
MAC value	1 MAC (Minimum Alveolar Concentration) is the alveolar concentration (end-tidal) of the agent at which 50% of individuals fail to *move* in response to a noxious or surgical stimulus
MOD	Medical Device Directive
MRI	Magnetic Resonance Imaging

	OR	Operating Room
	rise time	Time required to achieve a rise from 1O % to 90 % of final value when a step function change in concentration occurs at the sampling site
	sampling line config	A sampling line configuration consists of a Nomoline Family sampling line connected to either a patient breathing circuit or spontaneous breathing patient
	STP	Standard Temperature and Pressure: 101.3 ± 4 kPa atmospheric and gas pressure 22 ± 5 °C ambient temperature
	Total system response time	Time from a step function change in gas level at the sampling site to the achievement of 90% of the final gas reading of the gas monitor. Total system response time= Delay time+ Rise time
	USS	Universal Serial Bus
	zeroing	Ambient gas reference measurement used to establish zero concentration levels for CO_2, N_2O and Anesthetic Agents, as well as a calibration point for the oxygen measurements

E.1.1. Warnings and Cautions

To avoid water condensation inside the ISA module and the connecting tubings, ensure that the surrounding temperature of the ISA module and the connecting tubings does not fall below the ambient temperature of the Nomoline sampling line.

E.1.2. 3886 Multi-Gas Unit

ISA OR+

The 3886 Multi-Gas Unit contains the Masimo ISA OR+ which is a low-flow sidestream multigas analyzer designed to monitor respiratory concentrations of CO_2, N_2O and gas mixtures containing any two of the five anesthetic agents Halothane, Enflurane, lsoflurane , Sevoflurane and Desflurane in the OR and the ICU. Its low sampling flow and low agent identification threshold makes the ISA AX+ a perfect choice for adult and pediatric applications, as well as for the monitoring of infant patients with low tidal volumes and high respiratory rates .

ISA OR+ sidestream analyzer offers the addition of oxygen measurement capabilities by means of an integrated paramagnetic O_2 sensor.

In the following information regarding the 3886 Multi-Gas Unit, the Masimo term “OR+” is used interchangeably.

E.2. Theory and design, 3886 Multi-Gas System

E.2.1. Gas measurements and identification

The measurement of CO_2, N_2O and anesthetic agents is based on the fact that different gases absorb infrared light at specific wavelengths. The analysis of respiratory gases by the ISA gas analyzers are therefore performed by continuously measuring the infrared light absorption in the gas flow through an infrared spectrometer. Oxygen, on the other hand, does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods.

The gas analysis

The heart of the ISA gas analyzer is the multi-channel spectrometer which uses a proprietary broadband infrared radiation source to transmit light through the gas sample. Before reaching the gas sample, the light path is intersected by narrowband optical filters that only allow light corresponding to selected wavelength peaks of the measured gases to pass. At the other end of the light path, a sensor detects the portion of the light that is not absorbed by the gas. The amplitude of the detector output is an inverse function of the gas concentration.
Thus, at a concentration of zero, the amplitude is at its maximum.

If the gas sample is a mixture of several components that absorb light at the same wavelength, such as a mixture of two anesthetic agents, the absorbed radiation will be the sum of the absorption of the agents. To determine the concentration of each of the individual gases, several filters have to be used. The ISA gas analyzers therefore uses the SIGMA spectrometer, which contains up to nine different narrowband filters to facilitate simultaneous measurement of CO_2, N_2O and a mixture of any two of the five anesthetic agents.

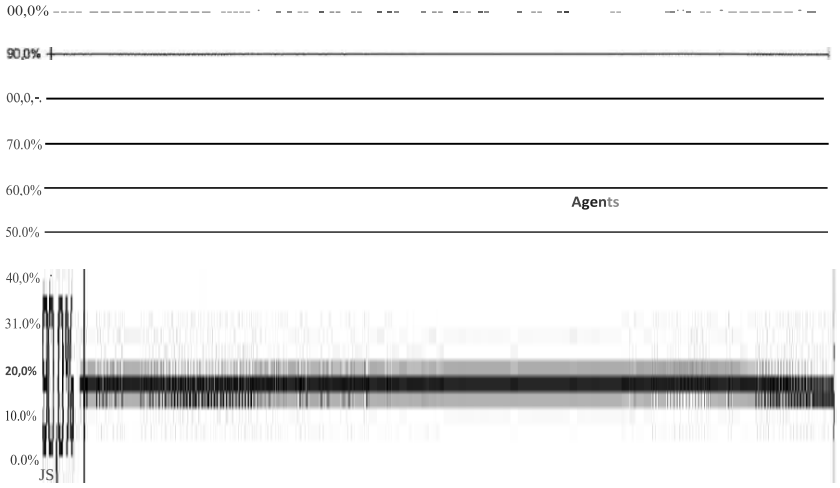


Figure 4-1. Gas absorption spectra.

The selection of the optical filters within the spectrometer is crucial to the characteristics and performance of the gas analyzers. The ISA spectrometer uses the strong absorption peaks at and 4.5 µm for CO_2 and N_2O measurements and five wavelengths in the 8 to 10 µm long wave infrared range (LWIR) for the anesthetic agent calculations. The LWIR contains strong absorption peaks for the anesthetic agents and negligible interference from other common respiratory gases, such as alcohol and acetone, which could degrade

measurement accuracy.

In addition to the measurement filters, two optical filters appropriately located within the 4 to 10 µm range are used as references.

E.2.2. Oxygen measurement, Paramagnetic

Oxygen does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods. The ISA OR+ analyzer is fitted with a paramagnetic oxygen sensor.

Paramagnetic oxygen analysis

Paramagnetic oxygen analysis is based on measurements of the attractive force exerted by a strong magnetic field applied to the oxygen molecules in a gas mixture. The paramagnetic analyzer distinguishes oxygen from other gases as a function of their magnetic susceptibility. Due to its paramagnetic nature, oxygen is attracted into the magnetic field, while most other gases are not. On a scale, where oxygen is assigned the value 100, most other gases have a magnetic susceptibility of close to zero.

The Servomex sensors

The oxygen sensor included in the 3886 Multi-Gas system as part of the ISA OR+ gas analyzer is the Pm1116 paramagnetic oxygen sensor from Servomex. In these sensors, a symmetrical non- uniform magnetic field is created. If oxygen is present, it will be attracted into the strongest part of this field. Two nitrogen-filled glass spheres are mounted on a rotating suspension within the magnetic field. Centrally on this suspension, a mirror is mounted. A light beam projected on the_mirror is reflected onto a pair of photocells. Oxygen attracted into the magnetic field will push the glass spheres from the strongest part of the magnetic field, causing the suspension to rotate.
When this rotation is detected by the photocells, a signal is generated and passed to a feedback system. The feedback system will pass a current around a wire mounted on the suspension, causing a restoring torque that keeps the suspension in its original position. The current flowing around the wire is measured. This current is directly proportional to the oxygen concentration.

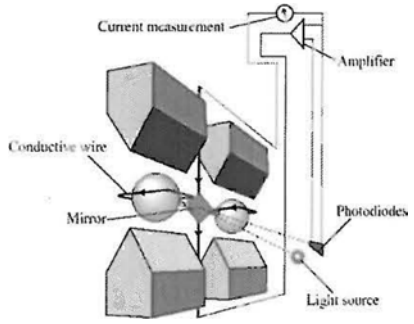


Figure 4-2. Oxygen measurement with Servomex paramagnetic oxygen sensors.

The most important benefits of the paramagnetic oxygen sensor are:

- Fast rise time
- High stability and accuracy
- No chemicals to replace or renew
- Low maintenance requirement

E.2.3. Sampling

A sidestream gas analyzer continuously removes a gas sample flow from the respiratory circuit, for example a nasal cannula, a respiratory mask or the Y-piece of an intubated patient. The gas sample is fed through a sampling line to the gas analyzer. The sampled gas is usually warm and humid, and cools down in contact with the wall of the sampling line. Water therefore condenses in form of droplets on the inner wall of the sampling line. These droplets could potentially occlude the sampling line and interfere with the gas measurement.

The Nomoline Family

To overcome the shortfalls of current gas sampling solutions, the Nomoline Family sampling lines have been developed for the ISA sidestream gas analyzers.

Unlike traditional solutions that remove water vapor and collect water in a container, the Nomoline Family sampling lines incorporates a unique water separation **(NO MO**isture) section, which removes condensed water. The NOMO section also has a bacteria filter which protects the gas analyzer from water intrusion and cross contamination.

Figure 4-3 . The NOMO section.

The Nomoline Family sampling lines are specially designed for 50 sml/min low sample flow applications. The Nomoline Family sample lines have a very low dead space that results in an ultra-fast rise time, making measurements of CO_2, N_2O and anesthetic agents possible even at high respiratory rates. ISA sidestream gas analyzers are therefore suitable for adult, pediatric and infant patients.

The Nomoline Family sampling lines are available in a wide variety of versions for both intubated and spontaneously breathing patients and in both disposable and ReSposable configurations - intubated patients can for instance be monitored using the disposable Nomoline Airway adapter Set or a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter.

The Nomoline Airway Adapter Set with integrated airway adapter can be used with intubated patients.

The Nomoline with a male Luer Lock type connector is compatible with any normal configuration that uses a female Luer Lock connector. When connecting to a T-adapter,

be sure to use a Masimo T-adapter that samples the gas from the center of the T-adapter (see below). See section 12 for ordering details.

Flow control

During normal operation, a sidestream gas analyzer is continuously fed with a small sample gas flow. To pull the gas through the sampling line and maintain a steady flo w, a high-precision flow control system is required. In !SA sidestream gas analyzers, the flow control system consists of an integrated micro pump, a zero valve and a flow controller. The pump is fitted with a low-power brushless motor incorporating three miniature ball bearings to ensure trouble free operation without the need for regular maintenance. Its balanced shaft design and integrated pneumatic filter virtually eliminates pressure and flow variations.

System response

In any sidestream gas analyzer, there are three major time parameters characterizing the system:

- Total system response time
- Delay time
- Rise time

When designing a sidestream gas monitoring system, the physical characterist ics of several components have to be considered. Parameters such as sampling line volume, tubing material and the physical design of the sampling interfaces play decisive roles in determining the responsiveness of the system.

Generally, the total system response time equals the delay time plus the rise time.

The rise time is defined as the time required for a step function change at the sampling site to bring about a rise from 10% to 90% of the final gas concentration value. The total numbers of gas fittings together with the physical design of the fittings are examples that effects the rise time. Fast rise times are important when monitoring infants with high breathing rates.

The delay time is defined as the time required for a step function change at the sampling site to result in 10% of the final value. Parameters affecting the delay time are the sample flow rate, tubing length and tubing inner diameter. In mainstream gas monitoring, where no tubing exist, the delay time is virtually zero, whereas a sidestream system has a sample delay time of a few seconds.

Leak test

1. Connect a Nomoline Adapter and a Nomoline Extension sampling line or equivalent to the ISA gas analyzer, with the analyzer connected to Masimo Gas Master.

2. Tightly block the gas inlet of the Nomoline sampling line.
   Check the field "Atm press - cuvette press [kPa]" in Masimo Gas Master - the pressure value will start to rapidly increase, until the internal pump stops.
   When the internal pump stops and while keeping the inlet blocked, quickly block the exhaust port tightly. *When blocked, the "Atm press - cuvette press [kPa]" in Masimo Gas Master shall be >6 kPa.*

3. Stop the pump by sending parameter "Stop pump" under "Installation & maintenance"

in Masimo Gas Master.

4. Wait about 1O seconds until the *"Atm press - cuvette press [kPa]"value* as shown by the Masimo Gas Master is stable. Note the value.

5. Wait additional 10 seconds.

6. Check that the *"Atm press - cuvette press [kPa]"value* has not changed more than 3 kPa in 10 seconds.

7. If the *"Atm press - cuvette press [kPa}"* value changes more than 3kPa in 10 seconds, check tubing and fittings for leakage. If the problem persists, return the analyzer to Masimo Sweden (see section 9).

Note: In step 5, if the *"Atm press - cuvette press [kPa]"* is less than 6 kPa, repeat steps 1 to 3 blocking the exhaust port quicker.

Gas span calibration

Only perform the gas span calibration if the gas span check fails repeatedly.

Before performing the gas span calibration, ensure that the SETO2 and SETN2O values are set (if applicable for your gas analyzer model) correctly to match the corresponding calibration gas.

Span calibration can be performed using gases within the ranges:

4.0% ≤ CO_2 ≤ 11.0%

45% ≤ O_2 ≤ 100% - for ISA Multigas with Servomex only

30% ≤ N_2O ≤ 100% - for ISA Multigas only

2.0% ≤ DES ≤ 12.0% - for ISA Multigas only

The accuracy of the individual components of the calibration gas mixture shall each have an accuracy of at least +/-0.03 vol% or +/-(0.02 vol% +0.1% of reading), whichever is greater.

Note: DES shall be used for span calibration of all 5 agents (HAL, ENF, ISO, SEV, DES).

Note: Gas span calibration should be performed only for the gas components that failed in the Gas span check.

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1. Warm up the ISA gas analyzer for at least 1 min

2. Send "Pre span calibration zeroing" and make sure that the surrounding gas is normal air (21% O_2 and 0% CO_2),

3. For each gas that failed the Gas span check, perform step 4 to 7. Always perform the span calibration with the gases in order O_2, N_2O , DES and CO_2

   Example: *Span calibration of O_2 and CO_2 only, start with O_2 then CO_2.*

4. Supply the calibration gas and wait for at least 30 seconds.

5. Send the corresponding span calibration command.

6. Wait until the gas span calibration is no longer in progress. The calibrationgas can be turned off when *"span calibration is in progress"* no longer is set, but the O_2 span calibration continues for about 40 s with a special zeroing during which the Servomex paramagnetic O_2 sensor is sensitive to mechanical movements.

7. Verify the gas readings

Notes: If the calibration process fails, the flag SPAN_ERR is set, and will stay active until the next successful calibration is passed.

As long as no sampling line is connected, an ISA gas analyzer stays in a low-power, sleep mode. Once the sampling line is connected, the ISA gas analyzer switches to measuring mode and starts delivering gas data.

E.2.4. Zeroing

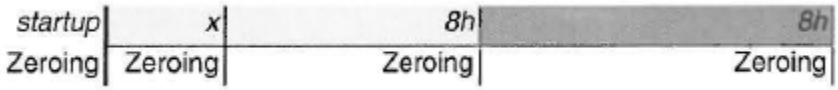
The infrared gas analyzer needs to establish a zero reference level for the CO_2, N_20 and anesthetic agent gas measurement. This zero calibration is here referred to as "Zeroing".

ISA sidestream gas analyzers perform Zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic Zeroing takes less than 3 seconds for ISA CO2 gas analyzers and less than 10 seconds for ISA multigas analyzers. If the ISA sidestream gas analyzer is fitted with an oxygen sensor, the automatic Zeroing will also include room air calibration of the oxygen sensor. Since a successful Zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the ISA is placed in a well-ventilated place.

During Zeroing, if ISA's exhaust gas is returned to the patient circuit, the returned gas level will be different from the gas level at the sampling site

ISA OR+ Multigas analyzers normally perform Zeroing directly at startup (with or without Nomoline attached), when a steady operating temperature is achieved and thereafter *every* 8 h from start up. A Zeroing is also performed when the operating mode is changed from sleep mode to measurement mode.

Additional automatic Zeroing can however be performed if the system consider it necessary.



E.2.5. Flow reference zeroing

Addition to the Zeroing the ISA sidestream gas analyzer also perform an automatic flow reference zeroing 1h from startup and thereafter *every* 96h. During a flow reference zeroing the ISA sidestream gas analyzers switch from gas sampling from the respiratory circuit to ambient air while the pump is switched off. Hence no flow will be drawn from the reference inlet. During the automatic flow reference zeroing , which takes less than 8 seconds , the LEGI will be blinking with a green light.

E.2.6. Gas data considerations

Gas measurement units

$$\%gas = \frac{Partial\ pressure\ of\ gas\ component}{Total\ pressure\ of\ gas\ mixture} * 100$$

Effects of humidity

The partial pressure and the volume percentage of CO_2, N_2O , O_2 and anesthetic agents depend on the amount of water vapor in the measured gas. The O_2 measurement will be calibrated to show 20.8 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure. 20.8 vol% O_2 corresponds to the actual O_2 concentration in room air with 0.7 vol% H20 concentration (at 1013 hPa this equals for example 25°C and 23% RH). The measurement of CO_2, N_2O, and anesthetic agents (e.g. all gases measured by the IA-bench) will always show the actual partial pressure at the current humidity level.

In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS). When the breathing gas flows through the sampling line, the gas temperature will adapt to ambient before reaching the gas analyzer. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.

If CO_2 values at BTPS are required, the following equation can be used:

$$EtCO2(BTPS) = EtCO2 * \left(1 - \left(\frac{3.8}{Pamb}\right)\right)$$

where :
EtCO2 = $EtCO_2$ value sent from ISA [vol %]
Pamb = Ambient pressure sent from ISA [kPa]
3.8 = Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa)
EtC02(BTPS) = $EtCO_2$ gas concentration at BTPS [vol%]

Spectral broadening

The presence of oxygen and nitrous oxide can cause some interference in the CO_2 measurement. This is known as spectral broadening.

Nitrous oxide, N_2O:

ISA sidestream analyzers automatically compensates for spectral broadening caused by nitrous oxide.

Below is the typical effect if using the default value (0 *vol%* N20) when measuring on gas mixtures with different N20 concentrations:

N_2O concentration in gas mix	**Effect on gas reading**	**Displayed value if true concentration is 5.0 vol% CO_2**
0 vol%	0 % relative	5.0 vol%
30 vol%	5.17 % relative	5.3 vol%
60 vol%	10.34 % relative	5.5 vol%
82 vol%	14.14 % relative	5.7 vol%

Oxygen, O_2:
ISA OR+ sidestream units automatically compensates for spectral

broadening caused by oxygen

Below is the typical effect if using the default value (21 vol% 0_2) when measuring on gas mixtures with different O_2 concentrations:

O_2 concentration in gas mix	**Effect on gas reading**	**Displayed value if true concentration is 5.0 vol% CO_2**
21 vol%	0 % relative	5.0 vol%
50 vol%	-2.76 % relative	4.9 vol%
70 vol%	-4.67 % relative	4.8 vol%
95 vol%	-7.05 % relative	4.7 vol%

E.3. Specifications

E.3.1. Intended use

The ISA OR+ product is intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

ISA OR+: CO_2, O_2, N_2O ,Halothane, lsoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+ is intended to be connected to a patient breathing circuit for monitoring of inspired /expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

Nomoline sampling cannulas are intended to be used as accessories to the ISA gas analyzers. They are connected to the nostrils or to the nostrils and mouth on spontaneously breathing patients for sampling of CO_2. Some models are also used to deliver O_2 in parallel with CO_2 sampling. The intended patient population is adult, pediatric and infant patients.

E.3.2. Gas Analyzer

Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 µm. Data acquisition rate 10 kHz(sample rate 20 Hz/channel)
Compensations	ISA OR+: Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO_2
Calibration	No span calibration is required for the IR bench. An automatic Zeroing is performed typically 1 to 3 times per day.
Warm-up time	ISA OR+: <20 seconds (Concentrations reported, automatic agent identification enabled and full accuracy)
Rise time[1] At 50 sml/min sample flow	ISA OR+ CO_2 ≤ 300 ms N_2O, O_2, ENF, ISO, SEV, DES < 400 ms HAL < 400 ms
Primary agent threshold (ISA OR+)	0.15 vol% When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected
Secondary agent threshold (ISA OR+)	0.2 vol% + 10% of total agent concentration
Agent identification time (ISA OR+)	< 20 seconds (typically < 10 seconds)
Total system response time	ISA OR+ < 4 seconds (with 2 m Nomoline Airway Adapter Set sampling line)

[1] Measured according to EN ISO 80601-2-55

E.3.3. Accuracy - standard conditions

The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:

Gas	Range [1]	Accuracy
CO_2	0 to 15 vol%	±(0.2 vol%+ 2% of reading)
N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
HAL, ENF, ISO	0 to 8 vol%	±(0.15 vol% + 5% of reading)
SEV	0 to 10 vol%	±(0.15 vol% + 5% of reading)
DES	0 to 22 vol%	±(0.15 vol% + 5% of reading)
O_2	0 to 100 vol%	±(1 vol%+ 2% of reading)

E.3.4. Accuracy - all conditions

The following accuracy specifications are valid for all specified environmental conditions except for interference specified in section E3.5 (effects from water vapor partial pressure on gas readings) and section E3.6 (interfering gas effects).

Gas	Accuracy
CO_2	±(0.5 kPA + 8% of reading) ±(3.75 mmHg + 8% of reading)
N_2O	±(2 kPA + 5% of reading) ±(15 mmHg + 5% of reading)
Agents[2]	±(0.2 kPA + 10% of reading) ±(1.5 mmHg + 10% of reading)
O_2	±(2 kPA + 2% of reading)

1 All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

2 The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

E.3.5. Effects from water vapor partial pressure on gas readings

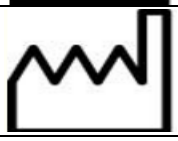
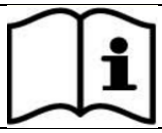
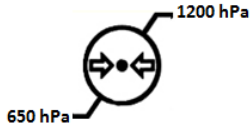
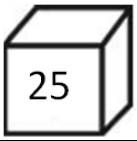
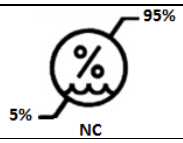
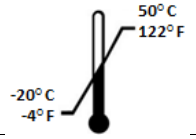
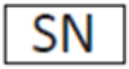
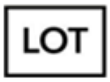
When the breathing gas through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The measurement of all gases will always show the actual partial pressure at the current humidity level in the gas sample. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. However reading will typically be 6% lower than corresponding partial pressure after removal of all water.

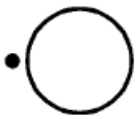
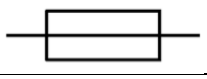
E.3.6. Interfering gas effects

Gas	Gas level	CO2		Agents of 3886	N2O of 3886
		CO2 only option	3886 ISA OR+		
N^2O [4]	60 Vol%	- [2]	- [1]	- [1]	- [1]
HAL [4]	4 Vol%	- [6]	- [1]	- [1]	- [1]
ENF, ISO, SEV [4]	5 Vol%	- [6]	- [1]	- [1]	- [1]
DES [4]	15 Vol%	- [6]	- [1]	- [1]	- [1]
Xe (Xenon) [4]	80 Vol%	-10% of reading [3]		- [1]	- [1]
He (Helium) [4]	50 Vol%	-6% of reading [3]		- [1]	- [1]
Metered dose inhaler propellants [4]	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol) [4]	0.3 Vol%	- [1]	- [1]	- [1]	- [1]
C_3H_7OH (Isopropanol) [4]	0.5 Vol%	- [1]	- [1]	- [1]	- [1]
CH_3COCH_3 (Acetone) [4]	1 Vol%	- [1]	- [1]	- [1]	- [1]
CH_4 (Methane) [4]	3 Vol%	- [1]	- [1]	- [1]	- [1]
CO (Carbon monoxide) [5]	1 Vol%	- [1]	- [1]	- [1]	- [1]
O2 [5]	100 Vol%	- [2]	- [2]	- [1]	- [1]

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.
Note 2: Negligible interference with N_2O / O_2 concentrations correctly set, effect included in the specification “Accuracy, all conditions” above.
Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO_2.
Note 4: According to the EN ISO 80601-2-55:2011 standard.
Note 5: In addition to the EN ISO 80601-2-55:2011 standard.
Note 6: CO2 Only internal option is contra-indicated for use with anesthetic agents, no interfering gas testing or specification per EN ISO 80601-2-55 standard.

F. Symbol Conventions and meanings

Symbol	Used for	Symbol	Used For
	Manufacturer		CE Mark
	Manufacturer/ Date of Manufacture		Do Not Reuse
	Use by date; do not use after the year (YYYY), month (MM)		Federal Communications Commission radio certification
	Consult Instructions for Use		Authorized EU Representative
	Non sterile		MR Safe: Completely safe for use with no potential for interaction with the MR field.
	MR Conditional: Use in the MR environment is restricted to certain conditions of use to ensure patient and operator safety		MR Unsafe: Must not be used in an MRI environment
	Fragile	RxOnly	Prescription Only
	Atmospheric Pressure Limits		Quantity in Package
	Humidity Limits, non-condensing		Part Number
	Temperature Limits		Serial Number
 (01) 0 0856038 00102 7 (10) 0 IRM388001000	QR Code, Unique Device Identifier		Lot Number
	Instructions for Use must be consulted		Defibrillator-proof type CF equipment (IEC 60601-1) protection against

			Shock
	Radio Source		Not for General Waste
	Gas Inlet		Gas Outlet
	Power On		Power Off
–	Battery, negative contact	+	Battery, positive contact
	Direct Current		Alternating Current
	Universal Serial Bus (USB)	**IPX1**	Protected against harmful effects of dripping water per IEC 60529
	Alarm sound system is capable of audio sound triggered by alarms/alerts		Audio Alarms Off; ALARM conditions can visually indicate, if ALARM not OFF
	Audible Alarms Paused (includes 120 second countdown timer adjacent to symbol)		Alarm condition is occurring
	All Alarms Off: Indefinitely pauses all alarms and terminates automatic NIBP measurements		Wireless Signal Strength
	Connected to AC mains		3885-T Remote Tablet battery life
	3880 Patient Monitor battery life		3881 ECG ePOD battery life
	3881 SpO_2 oPOD battery life		No Battery, or Battery unable to communicate remaining life
	Heartbeat Detected		Fuse
	Settings button: Access monitor setup menus		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.

G. Manufactures Technical Declaration

EMC Information Tables as required by EN 60601-1-2:2007 Clause 5

In accordance with EN 60601-1-2:2007 Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic Compatibility – Requirements and tests

1. "Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents" (the following tables).
2. "Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment".
3. "The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it is used".

The following tables (as required in EN 60601-1-2:2007) provide information regarding the Electromagnetic Compatibility (EMC) of this product and its accessories.

Table 201—Guidance and manufacturer's declaration— electromagnetic emissions—for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration—electromagnetic emissions		
The 3880 System is intended for use in the electromagnetic environment specified below. The customer or the user of the 3880 System should assure that it is used in such an		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The 3880 System must emit electromagnetic energy in order to perform its intended function (remote communications within an specific band for WLAN; i.e. 2.431 to 2.474 GHz). Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The 3880 System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 202—Guidance and manufacturer's declaration— electromagnetic immunity—for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration—electromagnetic immunity			
The 3880 System is intended for use in the electromagnetic environment customer or the user of the 3880 System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 3880 System requires continued operation during power mains interruptions, it is recommended that the 3880 System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE—UT is the a.c. mains voltage prior to application of the test level.

Table 203—Guidance and manufacturer's declaration— electromagnetic immunity—for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration—electromagnetic immunity			
The 3880 System is intended for use in the electromagnetic environment customer or the user of the 3880 System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the 3880 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 V	d = 1.17 ¥ P
	10 Vrms 150 kHz to 80 MHz outside ISM bands[a]	10 V	d = 1.20 ¥ P
Radiated RF IEC 61000-4-3	10 Vrms 80 MHz to 2.5 GHz	10 V/m	d = 1.20 ¥ P 80 MHz to 800 MHz d = 2.33 ¥ P 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: IEC 60417, No. 417-IEC5140, "Source of Non-Ionizing Radiation" Symbol

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 3880 System is used exceeds the applicable RF compliance level above, the 3880 System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 3880 System.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m

Table 205—Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM—for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the 3880 System

The 3880 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 3880 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 3880 System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = 1.17 \sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.77
1	1.17	1.2	1.17	2.33
10	3.8	3.8	3.8	7.67
100	11.67	12	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3—An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Recommended separation distances between the 3880 System components and local radio frequency devices, such as WiFi AP devices, for wireless coexistence: Maintain a 2 meter (6') separation.

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