Operators Manual

TIR-1™ Thermometer



MASIMO

These operating instructions provide the necessary information for proper operation of all models of the TIR-1. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of TIR-1 are prerequisites for its proper use. Do not operate TIR-1 without completely reading and understanding these instructions.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH AAMI ES60601-1, IEC 60601-1 & ISO 80601-2-56. Certified to STD C22.2 #60601-1 Standards for which the product has been found to comply by Intertek.

Patents: ***www.masimo.com/patents***

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About this Manual

This manual explains how to set up and use TIR-1™ Thermometer. Important safety information relating to general use of TIR-1 appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Features and Intended Use

Product Description

The TIR-1™ Thermometer is a noninvasive, infrared, clinical thermometer that can be used as a standalone device or with Masimo devices. This device is an adjusted mode thermometer.

Features

Features of TIR-1 include:

- Fast measurement that meets ASTM and ISO standards.
- Simple 1-button operation, no scanning required.
- Audible and visual indication of completed temperature.
- Backlit LCD display and Low Battery indication.
- Long Battery Life of more than 10,000 temperatures (typical).
- Memory recall of up to 30 temperature readings (with date and time stamp).
- Can communicate via Bluetooth LE to Masimo devices.

Intended Use

TIR-1™ Thermometer is an infrared thermometer intended for the measurement of human body temperature in people of all ages without contact to the body and is to be used by medical professionals.

Safety Information, Warnings and Cautions

The manual, accessories, directions for use, all precautionary information, and specifications should be read before use. Refer to Masimo Operator's Manuals for additional safety information, warnings, and cautions.

Safety Warnings and Cautions

WARNING: Do not use TIR-1 during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Do not place TIR-1 or accessories in any position that might cause it to fall on the patient.

WARNING: Do not use TIR-1 during defibrillation.

WARNING: Do not use TIR-1 during electrosurgery.

WARNING: Do not use TIR-1 in the presence of flammable anesthetics or other flammable substances, oxygen-enriched environments, or nitrous oxide to avoid the risk of explosion.

WARNING: Do not leave the TIR-1 unattended around children. Small items such as the battery door, battery, and lanyard may become choking hazards.

Performance Warnings and Cautions

WARNING: TIR-1 should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Do not use TIR-1 if it appears or is suspected to be damaged. Damage to internal parts can result in no or inaccurate readings.

WARNING: Do not repair, open, or modify TIR-1. Damage to internal parts can result in no or inaccurate readings.

WARNING: Do not use the TIR-1 if the internal parts have been exposed to liquids. Damage to the internal parts may result in no or inaccurate readings.

CAUTION: Remove perspiration and excess oil from the forehead as this may affect the accuracy of the reading.

CAUTION: Do not use on patients with the following as they may affect the accuracy of the readings:

- Scarred tissue or tissue compromised by skin disorders or trauma in the vicinity of the forehead measurement area.
- Patients treated with certain drug therapies that may affect normal body temperature or use on patients while skin is exposed to external sources of heat or cold such as direct sunlight, fireplace heat, cold compress therapies, air conditioner flow, etc.

CAUTION: Keep the TIR-1 away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.

CAUTION: When using the TIR-1 Thermometer connected via Bluetooth, keep both devices within the recommended 8 to 10 feet range of each other; moving outside of this range may cause a loss in connection.

CAUTION: When paired to a Masimo device, the time and date of the Masimo device is used as the time stamp.

CAUTION: When paired to a Masimo device, the temperature unit of measure of TIR-1 and the Masimo device is are not synchronized.

Note: If coming from a warmer or cooler environment or after a period of exertion, allow the patient and thermometer to acclimate to room temperature for 20 minutes prior to taking temperature.

Note: Replace protective sensor cap when not in use.

Cleaning and Service Warnings and Cautions

WARNING: Properly use and dispose of Alkaline batteries or they may leak or explode.

WARNING: Remove alkaline batteries when the TIR-1 will not be in use for more than 30 days to avoid damage to the device due to batteries that may leak.

WARNING: Replace both batteries at the same time to avoid mixing fully and partially charged batteries. These actions may cause the batteries to leak; resulting in possible damage to the device.

CAUTION: Use only AA alkaline batteries. Use of non-alkaline batteries may affect the accuracy of the battery status indicator.

CAUTION: Only perform maintenance procedures specifically described in the manual; otherwise, return TIR-1 for servicing. Improper maintenance may result in damage to the internal parts. Damage to internal parts may result in no or inaccurate readings.

CAUTION: Do not clean TIR-1 with any chemical other than those specified in Maintenance and Cleaning of this manual. These substances may affect the device's materials and damage internal parts.

CAUTION: Do not submerge TIR-1 in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

CAUTION: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in Maintenance and Cleaning of this manual. Permanent damage to TIR-1 may occur if other unspecified solutions are used.

CAUTION: Never submerge TIR-1 in water or any other liquid solution this may cause permanent damage to the TIR-1.

Note: Ensure that sensor end is clean and free of debris. See Maintenance and Cleaning of this manual for proper cleaning instructions.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

CAUTION: Comply with local laws in the disposal of the instrument and/or its accessories, including batteries.

Note: When using The TIR-1 with a device with wireless features, consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

Note: In accordance with international telecommunication requirements, the frequency band of 2.4 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

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

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular

installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2: 2007, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

Note: This Class B digital apparatus complies with Canadian ICES-003.

Note: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

About Body Temperature and Fever

Body temperature can vary from one person to the next and also varies by location on the body and time of day. Temperatures measured from different sites, even at the same time, should not be directly compared.

Fever indicates that body temperature is higher than normal. This may be caused by a number of conditions including infection, overexertion, overdressing or immunization. Some people may not experience fever even when they are ill. These include, but are not limited to, infants younger than 3 months old, persons with compromised immune systems, persons taking antibiotics, steroids or antipyretics (aspirin, ibuprofen, acetaminophen), or persons with certain chronic illnesses. Please consult your physician when you feel ill even if you do not have fever.

Chapter 2: Description

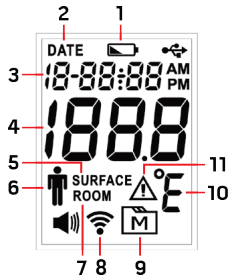
General System Description

The TIR-1™ Thermometer includes:

- The TIR-1 device
- Two (2) AA alkaline batteries
- Infrared sensor cover

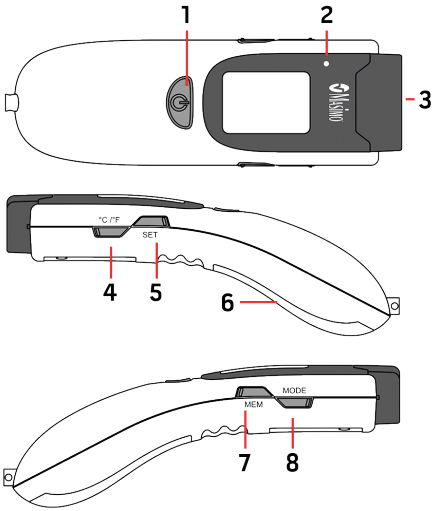
Features

Display



1. Low battery indicator
2. Date Indicator
3. Date/Time
4. Temperature Reading
5. Object Surface Temperature Indicator
6. Body Temperature Indicator
7. Room Temperature Indicator
8. Bluetooth indicator
9. Memory Mode
10. Unit of Measurement °F/°C
11. Error Warning

Controls



1. **Power/Start Measurement**
2. **Bluetooth LED**
3. **Infrared Sensor**
4. **Change Scale °C/°F**
5. **SET: Set Date/Time**
6. **Battery Compartment**
7. **MEM: Recall Stored temperature**
8. **MODE: Body, Surface, or Room**

Bluetooth Function

Temperature may be transmitted from TIR-1 to a Masimo device using a Bluetooth connection. Pairing must be completed before data will be received. To pair TIR-1 to a Masimo device, see ***Pairing TIR-1 to a Masimo Device*** on page 20.

Bluetooth Indicator and LED

The Bluetooth indicator on the display remains solid and does not indicate connection status. The Bluetooth LED indicates connection status.

Bluetooth LED	Status
Flashing	Bluetooth function ON and waiting for connection
Solid	Bluetooth connection is established

Chapter 3: Basic Setup and Use

The following information provides instructions to setup TIR-1 and begin taking patient temperatures, as well as pair to a Masimo device.

1. Install batteries into TIR-1.
2. Take a patient's temperature using TIR-1.
3. Pair TIR-1 to a Masimo device to display patient's temperature measurements on the Masimo device screen.

Installing Batteries

1. To remove Battery Cover, press down at the arrow mark and also on the center of the cover; SLIDE it in the direction of the arrow as shown in *Figure 1*.
2. Install (2) AA alkaline batteries with polarity as shown in the battery compartment. All LCD display segments will briefly illuminate during self-test, and you will hear a "beep".
3. Close the battery cover by pressing down both the arrow mark and the bottom of the cover, SLIDING the cover in the opposite direction of the arrow as shown in *Figure 2*.

Figure 1

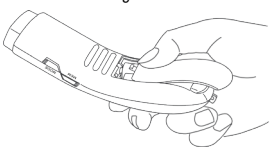


Figure 2

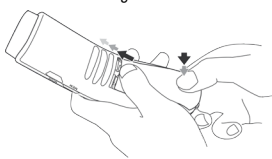


Figure 3



DO NOT press the battery cover to force it closed. If the battery cover does not close tight as shown in *Figure 3*, remove the battery cover by SLIDING as described in Step 1. Repeat Step 3 to close the battery cover tight.

CAUTION: Closing the battery cover by force may damage the battery cover latch and result in battery damage. Always follow the instructions and close the battery cover by SLIDING only.

- Set Date and Time as described in ***Setting Date/Time*** on page 23.
- TIR-1 defaults to °F temperature scale and BODY mode.

Note: If TIR-1 will be stored for a long period, remove the batteries.

Body Temperature Measurement

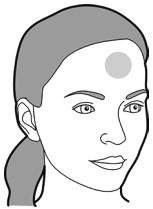


Figure 1

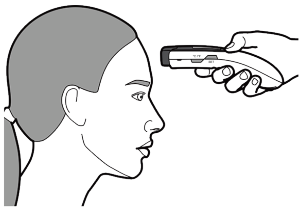


Figure 2

1. Remove the protective cap (if installed) and inspect the sensor. Remove any debris and clean the sensor as necessary.
2. Remove hair and perspiration from center forehead area as shown in *Figure 1*.
   - If the patient was lying face down or was wearing a hat or garment covering the skin, allow the forehead to be exposed to the air in the room for 5 minutes prior to taking reading.
   - Relocate patient if in drafty environment.
3. Aim at center forehead area 1/2" to 2" (1.2 to 5 cm) away from skin surface. Be sure thermometer is perpendicular to skin surface (at right angle) as shown in *Figure 2*.
4. Press and release the Power/Start Measurement button. See ***Features*** on page 13. Hold thermometer in place until a double beep is heard and the temperature is displayed on the LCD. Ensure the Body temperature icon is displayed. See ***Display*** on page 13.
5. If properly paired to a Masimo device, the TIR-1 reading also displays in the *Temperature* window on the *Main Screen*. See ***Temperature Window*** on page 27.

For additional information on TIR-1 operation such as changing temperature scale and modes, see ***Chapter 4: Operation*** on page 23.

Note: If temperature is suspected to be incorrect or display reads *LO* or *HI*, see ***TIR-1 Messages*** on page 39.

Pairing TIR-1 to a Masimo Device

Note: Verify compatibility between the TIR-1 and the Masimo device before attempting to pair.

Note: If pairing TIR-1 to a Root with noninvasive blood pressure and temperature, the temperature probe must be disabled. See ***Active Channels*** on page 31.

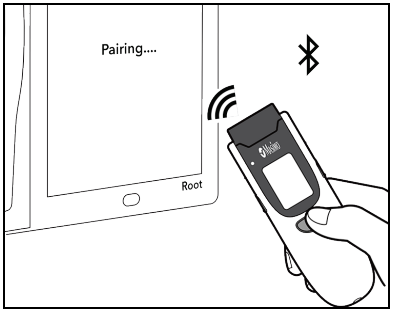
To pair TIR-1 with a Masimo device:

1. On the Masimo device, at the bottom right corner of the touchscreen, press the **Main Menu** icon .
2. Select the **Device Settings** menu icon.
3. Select the **Bluetooth** menu icon.
4. On the **Bluetooth** screen, ensure Bluetooth is turned On.
5. Select the Thermometer *Pair* button.
6. To place TIR-1 into paring mode, take a measurement. See ***Body Temperature Measurement*** on page 19. The Bluetooth indicator appears on the display and the Bluetooth LED blinks. See ***Bluetooth Indicator and LED*** on page 15.

   Note: TIR-1 remains in pairing mode until it powers down (Sleep Mode) after 30 seconds of non-use.

   Note: To exit pairing mode, press the MODE, SET, MEM or C/F buttons.

7. After the measurement is taken and the LED is blinking (within the 30 seconds after being placed in pairing mode), hold the TIR-1 close to the Masimo device (Root shown in the example).



8. TIR-1 should appear under the *Devices Found* list on the Masimo device screen. Select the TIR-1 thermometer under the *Devices Found* list.

   Note: The MAC Address for TIR-1 may also be displayed next to the name to assist in identifying the correct thermometer to pair.

9. Select the *Pair* button. TIR-1 will pair with the Masimo device.

10. After successfully pairing, each measurement taken using TIR-1 is displayed in the *Temperature* window on the *Main Screen* of the Masimo device. See ***Temperature Window*** on page 27.

    Note: TIR-1 can be paired to multiple Masimo devices, however, TIR-1 will only send measurements to the last device it communicated with.

Chapter 4: Operation

The following information describes TIR-1 operation and settings on Root when properly paired using the Bluetooth connection and is to be used with the information in the ***Operator's Manual for Root*** and ***Operator's Manual for Root with noninvasive blood pressure and temperature***.

TIR-1 Stand-Alone

The following information provides instructions for settings and temperature memory recall on TIR-1.

Power ON/OFF

TIR-1 is powered on by pressing the Power/Start Measurement button. See ***Features*** on page 13. TIR-1 automatically powers down (Sleep Mode) after 30 seconds of non-use.

Setting Date/Time

The time and date displayed on TIR-1 are both set using the following procedure. This setting is necessary at initial setup and when the batteries are changed.

CAUTION: When TIR-1 is paired to a Masimo device, the time and date of the Masimo device is used as the time stamp. To synchronize the date/time of the TIR-1 to the Masimo device, adjust the date/time settings on the TIR-1 to match the Masimo device.

1. Press the Power/Start Measurement button to turn TIR-1 ON.
2. Press and hold the SET button until the currently set date displays. The "months" digits flash. See ***Display*** on page 13.
3. Press the MODE button to increase (+) the month or press the °C/°F button to decrease (-) the month.
4. Press the SET button to save the month and change the day. The "day" digits flash.
5. Press the MODE button to increase (+) the day or press the °C/°F button to decrease (-) the day.

6. Press the SET button to save the day and change the year. The "year" digits flash.
7. Press the MODE button to increase (+) the year or press the °C/°F button to decrease (-) the year.
8. Press the SET button to save the year and change the hour and AM/PM. The "hour" digits flashes and "AM" or "PM" displays.
9. Press the MODE button to increase (+) the hour or press the °C/°F button to decrease (-) the hour. The AM or PM setting is determined by the hour setting.
10. Press the SET button to save the hour and change the minutes. The "minutes" digits flash.
11. Press the MODE button to increase (+) the minutes or press the °C/°F button to decrease (-) the minutes.
12. Press the SET button to save the date and time settings. TIR-1 automatically turns OFF.

Changing Temperature Scale

The temperature scale may be changed to Celsius or Fahrenheit using the following procedure. When properly paired, the temperature scale setting on TIR-1 determines the displayed temperature scale on the Masimo device. The Masimo device temperature scale settings cannot change the temperature scale settings on TIR-1.

1. Press the Power/Start Measurement button to turn TIR-1 ON.
2. Press and hold the °C/°F button until a single beep is heard. The current scale is displayed. See ***Display*** on page 13.
3. Press the °C/°F button again to change scale.
4. When the desired scale is displayed, press the Power/Start Measurement button to save the scale setting and exit this function.

Operation Modes

Body Temperature Mode



In *Body* temperature mode, the icon at the left is shown on the display and temperature is adjusted to an oral (sublingual) temperature approximation. See ***Display*** on page 13. Normal oral temperature is typically 95.0°F to 100.7°F (35.0°C to 38.2°C) but varies by age, gender and time of day [1]. Body is the default mode of operation.

[1] Sund-Levander, M., Forsberg, C. & Wahren, L. (2002). Normal oral, rectal and axillary body temperature in adult men and women; a systematic review. Scandinavian Journal of Caring Science, 16(2), 122-128.

Surface and Room Temperature Modes

Surface temperature mode measures the surface temperature of an object placed within the Field Of View (FOV) of the thermometer. At 2" (5cm) away, the FOV is a 0.84" (2.1cm) circle (±8° cone angle FOV). Accuracy varies with the type of object being measured and the temperature of the surrounding environment.

Room temperature mode measures the temperature of the room in which the thermometer is located. Allow 20 minutes for the thermometer to adjust to abrupt changes in room temperature.

Setting Mode of Operation

TIR-1 remains in the set Mode with each press of the Power/Start Measurement button. If TIR-1 is allowed to power OFF (as opposed to pressing the Power/Start Measurement button and taking a new measurement), the Mode changes back to Body.

1. Press the Power/Start Measurement button to turn TIR-1 ON.
2. Press and hold the MODE button until a beep is heard and the currently set mode (Body, Surface or Room) flashes. See ***Display*** on page 13.
3. Press the MODE button until the desired mode displays.
4. Press the Power/Start Measurement button to save the mode setting and exit this function.

Temperature Recall

Up to 30 temperature measurements are stored on TIR-1 memory and can be viewed at a later time. Once 30 are reached, the oldest is deleted with each new measurement thereafter. If only 10 temperature readings are stored, only 10 stored temperatures can be recalled and displayed.

Note: The stored temperature measurements on TIR-1 cannot be recalled on the Masimo device. The Masimo device records temperature measurements separately. See ***Temperature Window*** on page 27.

1. Press the Power/Start Measurement button to turn TIR-1 ON.
2. Press and hold the MEM button. The date and a number from 1 to 30 display indicating the stored temperature number. See ***Display*** on page 13. ***Example:*** DATE 03/12/2018; 01 (01 is the most recent temperature measurement and 30 is the oldest).
3. Release the MEM button. The time, temperature reading and mode displays. ***Example:*** 12:26AM; 98.6 °F; SURFACE.
4. Press and release the MEM button to cycle through the stored temperatures.
5. Press the Power/Start Measurement button to exit this function.

TIR-1 when Paired to a Masimo Device

The following information describes TIR-1 operation and settings on a Masimo Device when properly paired using the Bluetooth connection and is to be used with the information in the Operator's Manual for the Masimo Device.

Temperature Window

The *Temperature Window* displays on the Main Screen when TIR-1 is paired to the Masimo device.



Ref.	Feature	Description
1	Numeric Value	Indicates current reading of the measurement. Touch to access settings.
2	Trend Graph	Displays measurements taken over a period of time. Touch to display measurement. See ***Temperature Trends*** on page 33.
3	Alarm Limits and Unit of Measure	Indicates high and low alarm limits and the selected unit of measurement. Touch to access settings. See ***Temperature Alarms*** on page 32 and ***Temperature Alarms*** on page 32.

After successfully pairing TIR-1 with the Masimo device, the temperature and scale data is transmitted with each measurement taken. The reading is displayed in the *Temperature* window on the *Main Screen* of the Masimo device, and the TIR-1 name is displayed at the top of the window.

Selecting the *Temperature Window* on the screen opens the *Temperature Settings*. See ***Temperature Settings*** on page 31. If TIR-1 is disconnected (un-paired) from the Masimo device, the *Temperature Window* no longer displays on the *Main Screen*.

Note: If pairing TIR-1 to a Root with noninvasive blood pressure and temperature, the temperature probe must first be disabled before the reading can be displayed. See ***Active Channels*** on page 31.

Accessing Main Menu Options

To access the Main Menu options

At the bottom right corner of the touchscreen, press the **Main Menu** icon.



With TIR-1 connected, the following *Main Menu* option content changes.



Layout*

See ***Layout*** on page 28.



Device Settings

See ***Device Settings*** on page 34.



Temperature

See ***Temperature Settings*** on page 31.



About

See ***About*** on page 36.

* When paired with Root devices only.

Layout



The **Layout** menu allows the user to view and customize settings for the Main Screen Layout through the following options:



Available layouts

See ***Available Layouts*** on page 29.



Active Channels*

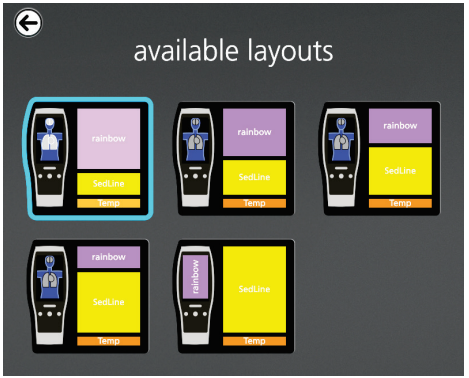
See ***Active Channels*** on page 31.

* Applies to Root with noninvasive blood pressure and temperature only.

Available Layouts

When a Radical-7 or Radius-7 is docked to Root and/or multiple MOC-9 modules and TIR-1 are connected, the user will have the option to select from several pre-configured layouts. Image below shows layout options available with Radical-7 docked in Root with SedLine connected through MOC-9, and TIR-1 is connected through Bluetooth.

Note: On Root with noninvasive blood pressure and temperature, the layouts are the same, as only the device measuring temperature changes.



Active Channels

When attempting to pair TIR-1 to a Root with noninvasive blood pressure and temperature, the temperature channel must be disabled in order to use TIR-1 with Root (if not, *Unable to handle Temperature channel on bluetooth* message displays).

Note: On Root (without noninvasive blood pressure and temperature) *Active Channel*, menu changes are not necessary for TIR-1 operation.

On Root with noninvasive blood pressure and temperature, from the **Layouts** screen, touch **Active Channels**, and then change any of the following options:

Options	Description	Factory Default Settings	Configurable Options*
Temperature	Enables or disables the Root with noninvasive blood pressure and temperature, built-in temperature probe.	Enabled	Enabled or Disabled

* If the Masimo device is currently monitoring a patient, or there is an active alarm, the alarm must be cleared or acknowledged, or the ability to disable the temperature probe is locked out.

Temperature Settings



Note: The *Temperature Settings* display only when TIR-1 is paired to a Masimo Device.

From the *Temperature Settings* screen, access any of the following options:

Temperature Alarms on page 32.

Additional Settings on page 33.

Temperature Trends on page 33.

Information about the parameter

Temperature Alarms



From the *Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	80.2 °F to 109.9 °F (26.9 °C to 43.2 °C), in increments of 0.1, or Off When set to Off, alarms are disabled.

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	80.1 °F to 109.8 °F (26.8 °C to 43.1 °C) in increments of 0.1, or Off When set to Off, alarms are disabled.

Additional Settings

From the *Additional Settings* screen, change the following option:

Options	Description	Factory Default Settings	User Configurable Settings
Unit of Measure	The unit of measure for temperature.	°F	°F, °C
Measurement Timeout	Length of time a Spot Check temperature will remain displayed on-screen after a measurement is taken.	5 minutes	5, 10, 15, 30, 60 and 90 minutes

Temperature Trends



From the *Trends* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Y-axis Min	The lower limit a measurement will be shown.	80.0°F (26.7°C)	80.0°F to 109.9°F (26.7°C to 43.2°C) in steps of 0.1
Y-axis Max	The upper limit a measurement will be shown.	110.0°F (43.3°C)	80.1°F to 110.0°F (26.8°C to 43.3°C) in steps of 0.1

Device Settings



The **Device Settings** menu allows the user to view and customize settings for the Masimo device.

The **Device Settings** options are:



Bluetooth

See ***Bluetooth*** on page 35.

Bluetooth

Use the Bluetooth screen to enable or disable Bluetooth connectivity, connect devices to the Masimo device using a Bluetooth connection or view connected device information. For complete information on the Masimo device Bluetooth menu, see the Operator's Manual for the Masimo device.

Option	Description	Factory Default Setting	Configurable Settings
Bluetooth	Enables or disables Bluetooth connectivity.	Off	On or Off
Thermometer*	Pairs the TIR-1 thermometer to Root.	NA	Pair

* After paring, the TIR-1 MAC address is displayed. The Pair button is also replaced with the Info button to access the Info Screen. See the ***Accessing the Thermometer Info Screen*** on page 36.

About



Listed under *Temperature*, use the *About* screen to view the serial number as well as software version and MAC address information for TIR-1. These details may be helpful during troubleshooting.

Option*	Description
Serial Number	Displays the serial number for the device.
SW Version	Displays software version number.
MAC address**	Displays the TIR-1 Bluetooth MAC address.

* These fields are read-only and cannot be configured by the user.

** The MAC address is also located on the TIR-1 label.

Accessing the Thermometer Info Screen

The following information is for viewing the TIR-1 Thermometer Info screen. Bluetooth information as well as disconnecting (un-pairing) from the Masimo device is available on this screen.

To access the Thermometer Info screen:

1. On the Masimo device, go to the Bluetooth device settings.
2. Next to the *Thermometer* (and MAC address for the paired TIR-1), touch the information icon  to display the Thermometer Info screen.

TIR-1 Info

The Thermometer Info screen displays the following information for TIR-1:

Option*	Description
Serial Number	Displays the serial number for the device.
FW Version	Displays firmware version number.
MAC address**	Displays the TIR-1 Bluetooth MAC address.

* These fields are read-only and cannot be configured by the user.

** The MAC address is displayed on the Bluetooth screen as well as on the TIR-1 label on the device.

Disconnecting TIR-1 from the Masimo Device

While viewing the Thermometer Info screen:

1. Touch the **Forget** button.
2. On the *Forget Device* pop-up window, select the **Forget** button to confirm.
   Note: Select the **Cancel** button to leave TIR-1 paired to the Masimo device.

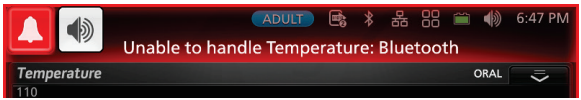
Chapter 5: Alarms and Messages

The following information is to be used with the ***Operator's Manual for Root*** and ***Operator's Manual for Root with noninvasive blood pressure and temperature.***

Alarms

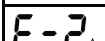
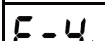
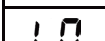
When TIR-1 is paired to a Root with noninvasive blood pressure and temperature with the temperature channel enabled, *Unable to handle Temperature: Bluetooth* message displays and a High priority alarm sounds.

This alarm and message indicates that the temperature probe on Root with noninvasive blood pressure and temperature cannot be used simultaneously with TIR-1 to measure a patient's temperature. In order to use TIR-1 on Root with noninvasive blood pressure and temperature, the temperature probe function must be disabled. See ***Active Channels*** on page 31.



TIR-1 Messages

The following information is displayed on the TIR-1 display.

Message	Explanation	Next Step
	Low Battery	Replace batteries as soon as practical.
	Very Low Battery	Replace batteries prior to further use.
	Ambient temperature too LOW	Allow TIR-1 to warm to temperature above 50°F (10°).
	Ambient temperature too HIGH	Allow TIR-1 to cool to temperature below 104°F (40°C).
	Sensor error or ambient temperature unstable	• Allow TIR-1 to equilibrate to the current room temperature for 20 minutes. • Contact Masimo Support if this error persists.
	Body Mode temperature is below 94°F (34.4°C)	Remove Sensor Lens cap. Allow patient to warm up in ambient room temperature above 50°F (10°C).
	Body Mode temperature is above 108°F (42.2°C)	• Repeat the temperature. • If this condition persists, the ambient temperature of the thermometer may be outside the acceptable limits. Allow to cool for 20 minutes.
--	Displayed temperatures appear to be too low	• Remove sensor lens cap. Allow thermometer and patient to adjust to room temperature for 20 minutes. • Remove perspiration, oil and makeup from forehead.

Root Messages

Message	Explanation	Alarm Priority	Next Step
Unable to handle Temperature: Bluetooth	A TIR-1 is paired, with the temperature channel enabled, to a Root with noninvasive blood pressure and temperature.	High	On Root with noninvasive blood pressure and temperature, disable the temperature channel before pairing TIR-1. See ***Active Channels*** on page 31.
Unable to handle Temperature: Internal	The temperature channel is enabled, with a TIR-1 paired, to a Root with noninvasive blood pressure and temperature.	High	On Root with noninvasive blood pressure and temperature, unpair TIR-1 before enabling the temperature channel. See ***Active Channels*** on page 31.

Chapter 6: Troubleshooting

For information on troubleshooting Root, refer to the ***Operator's Manual for Root*** and ***Operator's Manual for Root with noninvasive blood pressure and temperature.***

Symptom	Possible Cause	Correction
TIR-1 does not take a measurement when the Power/Start Measurement button is pressed.	• The batteries in TIR-1 may be depleted. • Internal failure.	• Replace the batteries in TIR-1. • TIR-1 requires service. See ***Service and Return Procedure*** on page 57.
Cannot pair TIR-1 to Root.	• The paired device Bluetooth may be off. • TIR-1 may be out of Bluetooth range with Root. • Internal failure.	• Ensure Bluetooth on the paired device is turned on. • Ensure TIR-1 is within range of the paired device when pairing. • TIR-1 requires service. See ***Service and Return Procedure*** on page 57.

Symptom	Possible Cause	Correction
When the Power/Start Measurement button is pressed, a measurement displays on TIR-1 but not on the paired device.	• TIR-1 may be out of Bluetooth range with the paired device. • TIR-1 is not paired to a device. • TIR-1 may be paired to multiple devices. • Paired device Bluetooth may be turned off. • Internal failure.	• Ensure TIR-1 is within range of the paired device. • Ensure TIR-1 is paired with a device. • Identify if TIR-1 is paired with multiple devices. Either forget (unpair), or turn Bluetooth off on the other device(s). • Ensure Bluetooth on the paired device is turned on. • TIR-1 requires service. See ***Service and Return Procedure*** on page 57.

Chapter 7: Specifications

The following specifications apply to TIR-1 unless otherwise noted. For Root, the following information is to be used with the content in the ***Operator's Manual, Root®*** or the ***Operator's Manual, Root® with noninvasive blood pressure and temperature.***

Display Range and Resolution

TIR-1

Measurement	Mode	Display Range
Temperature	Body	94˚F to 108˚F (34.4˚C to 42.2˚C)
	Surface	32˚F to 140˚F (0˚C to 60˚C)
	Room	50˚F to 104˚F (10˚C to 40˚C)

Accuracy not specified below 71.6˚F (22˚C) or above 108˚F (42.2˚C).

TIR-1 with Root

Measurement	Display Range	Resolution
Temperature	94˚F to 108˚F (34.4˚C to 42.2˚C)	0.1˚F (0.1˚C)

Accuracy

Accuracy [1], [2]	Mode	Specification	Range
Laboratory	Body	± 0.5°F (± 0.3°C)	71.6 to 96.7°F (22 to 35.9°C)
		± 0.4°F (± 0.2°C)	96.8 to 102.2°F (36 to 39°C)
		± 0.5°F (± 0.3°C)	102.3 to 108.0°F (39.1 to 42.2°C)
	Surface	± 2°F (±1°C)	32 to 140°F (0 to 60°C)
	Room	± 2°F (±1°C)	50 to 104°F (10 to 40°C)

Response Time

Response Time
Approx. 1 second

Electrical

Battery	
Power	Two 1.5V "AA" Alkaline Batteries
Battery Life	> 10,000 Temperatures (Typical)

Battery	
Batteries	3V ⎓ 2XAA

Environmental

Environmental Conditions	
Operating Temperature	10˚C to 40˚C (50˚F to 104˚F)
Storage Temperature	-20˚C to +60˚C (-4˚F to 140˚F)
Operating Humidity	15% - 85% Relative Humidity (non-condensing)
Storage Humidity	15% - 95% Relative Humidity
Storage Atmospheric Pressure	525 mmHg to 795 mmHg

Physical Characteristics

Physical Characteristics	
Dimensions	150 mm x 48.48 mm x 55.16 mm (5.90 in x 1.91 in x 2.17 in)

Compliance

EMC Compliance
IEC 60601-1-2 Class B

Safety Standards Compliance		
IEC 60601-1-6	ANSI/AAMI ES 60601-1	ISO 80601-2-56
IEC/EN 60601-1	CSA C22.2 No. 60601-1	ASTM E1965-98

Equipment Classification per IEC 60601-1	
Degree of Protection of Electrical Shock	This device has been tested and conforms to ASTM.
Mode of Operation	Continuous operation
Protection against harm from liquid ingress	IPX0, None
Environment	Not for use in the presence of flammable anesthetics.

Wireless Specifications

Communication (Bluetooth)	
Modulation Type	GFSK
Max Output Power	-3.64 dBm
Frequency Range	2402 to 2480 MHz

Radio Compliance	
Radio Modes	Bluetooth LE
USA	TM79030A01
	FCC Parts 15.207

Communication (Bluetooth)	
Antenna Peak Gain	5.16 dBi
Recommended Range	8 to 10 m
Quality of Service	5 to 10 seconds
Security	No

Radio Compliance	
	and 17.247
Canada	RSS-210
Europe	EN 300 328 EN 301 489-17

Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Suitable for use in all establishments, including domestic environments 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	NA	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	NA	

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment 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 lines +/- 1 kV for input/ output lines	NA	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line(s) to line(s) +/- 2 kV line(s) to earth	NA	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
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 cycles 100% dip in mains voltage for 0.5 cycle 60% dip in mains voltage for 5 cycle 30% dip in mains voltage for 25 cycle	NA	Mains power quality should be that of a typical commercial or hospital environment.
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 typical location in a typical hospital environment.
Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms	NA	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 kHz to 80 MHz

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Radiated RF IEC 61000-4-3	3 V/m 80 MHZ to 2.5 GHz	3 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following 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) 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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment. **(b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Symbols

The following symbols may appear on the product or product labeling:

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
	Separate collection for electrical and electronic equipment (WEEE)	ETL CLASSIFIED C ETL US Intertek 5009094	ETL Intertek certification See ***Declarations on Page 1*** for certifications
CE 0123	Mark of conformity to European medical device directive 93/42/EEC	**Rx ONLY**	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician
	Type BF applied part	EC REP	Authorized representative in the European community

Symbol	Description	Symbol	Description
IC Model:	Industry Canada identification	FC	Federal Communications Commission (FCC) Licensing
	Keep dry		Non-ionizing electromagnetic radiation
	Manufacturer		Date of manufacture YYYY-MM-DD
	Caution	REF	Catalog number (model number)
	Not made with natural rubber latex		Product contains no PVC (polyvinyl chloride) material
	Storage temperature range		Storage humidity limitation
	Fragile, handle with care		Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note: eIFU is not available for CE mark countries.**

Citations

[1] Clinical Accuracy was validated per ISO 80601-2-56 on 160 subjects, adults and pediatrics, against a reference clinical thermometer for oral (adults) and rectal (peds) reference sites. Results found a clinical bias of -0.08°C (-0.14°F) with limits of agreement 0.50°C (0.90°F) and a clinical repeatability of 0.07°C (0.13°F).

[2] Clinical Accuracy was validated per ASTM E1956-98 on 295 subjects, adults and pediatrics, against a reference clinical thermometer for oral (adults) and rectal (peds) reference sites. Results found a clinical bias of -0.11°C with limits of agreement 0.54°C and a clinical repeatability of 0.09°C for 170 Oral (Adult) measurements and a clinical bias of 0.08°C with limits of agreement 0.44°C and a clinical repeatability of 0.08°C for 125 Rectal (Peds) measurements.

Chapter 8: Service and Maintenance

Maintenance and Cleaning

- TIR-1 has no user serviceable internal parts except battery replacement.
- Always replace Sensor Cap when not in use.
- Store in a dry location free of dust and away from direct sunlight.
- Use a soft dry cloth to clean the plastic housing or a cloth dampened with a solution of water and mild detergent. Occasionally, 70% isopropanol solution may be used. Use liquid sparingly and wipe off after cleaning.
- Never submerge in liquid.
- The sensor cavity at the front of the thermometer is recessed to help prevent debris from collecting in this area. If debris is noticed, clean with a dry, lint-free swab. Do not use liquid cleaners in the sensor cavity.

Service and Return Procedure

Contact Masimo for product support. If needed, an RMA will be provided for repair or replacement. Masimo can be reached at 800-326-4890. For customers outside the United States, local contact information can be found at http://service.masimo.com.

Clean contaminated/dirty equipment before returning per Maintenance and Cleaning instructions. Make sure the equipment is fully dry before packing. Package the device securely, in the original shipping box if possible, and enclose the following information and items:

- Include the RMA form provided, or a letter describing in detail any difficulties experienced with TIR-1. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included. Purchase Order number to cover repair if the device is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information. Person (name, telephone/Telex/fax number and country) to contact for any questions about the repairs.

- A certificate stating that the device has been decontaminated for bloodborne pathogens.
- Return the device to Masimo at the address listed in ***Contacting Masimo*** on page 58 below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product TIR-1 and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c)

supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and Masimo does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product. Additionally, Masimo will not be liable for any incidental, indirect, special, or consequential loss, damage, or expense arising from the use or loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Restrictions

1. Copyright Restrictions: The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C. §117.
2. Use Restrictions: Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other instrument. Purchaser may not disclose, publish, translate, release, distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.
3. Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.
4. U.S. Government Rights: If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.



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