MODEL 400

TO AID IN INTRAVENOUS INFILTRATION DETECTION

User Manual
Rx Only

Part No. ML-0000866 REV.06

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***NOTE** : For the most current release of this manual, refer to the on line version on the ivWatch website at www.ivwatch.com/manuals.*

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

01

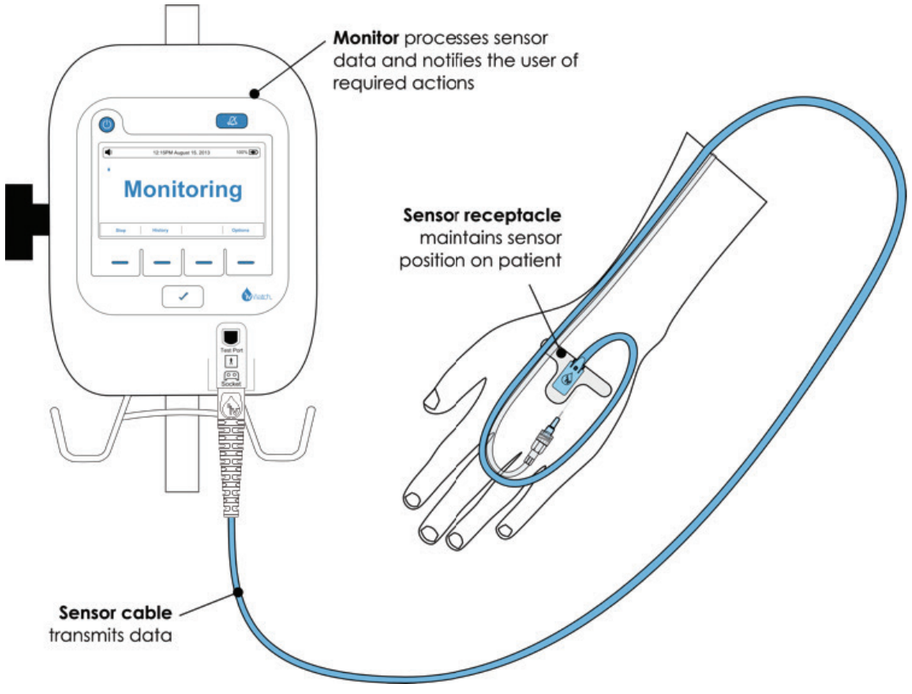
DEVICE DESCRIPTION

The ivWatch® Model 400 provides continuous monitoring of peripheral IVs to aid in the detection of conditions that may indicate an intravenous (IV) infiltration event. The monitoring system is an adjunct to the health care practitioner and is in no way intended to replace regular assessment of the IV site or any other standardized practice for IV administration and management.

The complete system includes the monitor, a reusable sensor cable, an AC adapter, and a disposable adhesive sensor receptacle used to position and secure the sensor on the patient.

HOW MONITORING AND DETECTION WORK

The monitoring system uses visible and near-infrared (IR) light to measure slight changes in the optical properties of tissue near the IV insertion site. A sensor placed adjacent to the IV insertion site on the patient's hand or forearm takes measurements. The monitor provides notification (audible and visual) when it detects changes consistent with IV fluid leaking and pooling in the tissue adjacent to the IV.



SYSTEM COMPONENTS

1. Patient Monitor
2. Adapter and Power Cord
3. Sensor Cable and Receptacle
4. Reference Card (not shown)

SAFETY INFORMATION

The following indications, warnings, and precautions are presented by topic and should be reviewed in their entirety prior to using this monitor.

INDICATIONS

The ivWatch Model 400 is indicated for the detection of subcutaneous infiltrations and extravasations of 10cc or less of optically clear, uncolored infusates, as an adjunctive device to the clinical evaluation in the hospital setting of patients 18 years old or greater with peripherally-inserted IVs (PIVs) on the forearm or dorsal aspect of the hand.

The device is indicated to assess patients for subcutaneous infiltrations and extravasations but should not serve as a substitute for regular clinician assessment of the PIV site. The ivWatch 400 is indicated for use by physicians, or under the direction of a physician, who have been trained in the use of the ivWatch Model 400.

INTENDED USE

The ivWatch Model 400 is intended for use in monitoring IV infusion of optically clear, uncolored fluids at sites on the forearm or the dorsal aspect of the hand in adult patients. The user profile is health care practitioners who are experienced in IV administration and management and located at hospitals and similar medical care facilities.

CONTRAINDICATIONS

The ivWatch Model 400 is not intended for use with power injectors or for monitoring peripheral IV infusions of colored, dark or cloudy fluids (for example, TPN, rifampin, and multi-vitamin “banana bags”). The system is not validated for use in pediatrics.
The ivWatch sensor should not be placed over tattooed, scarred, or bruised tissue. Neither the ivWatch Patient Monitor or Sensor Cable should not be taken into an MR environment.

WARNINGS

USE OF THE DEVICE AS AN AID TO DETECTION OF SUBCUTANEOUS IV INFILTRATION

The ivWatch Model 400 must only be used as an adjunct to regular assessments of IV placement by clinicians.
The device cannot serve as a substitute for regular clinician assessment, and should not be used in the absence of standard clinical supervision and procedures that are typically utilized (i.e. when the device is not used) for detection of subcutaneous infiltrations and extravasations.

EXPLOSIVE ENVIRONMENTS

Do not plug in or use the monitor in an environment that contains concentrations of flammable gas (eg, anesthesia), vapors, or dust.

OXYGEN-RICH ENVIRONMENTS

Do not use the monitor in oxygen-rich environments. Note that this statement applies to oxygen enriched environments, such as oxygen tents. It is not meant to apply to patients on breathing tubes.

IMMERSION IN LIQUID

Do not immerse the monitor or sensor cable in liquid. The monitor must be disconnected and the sensor removed from the patient prior to patient bathing to prevent electrical shock. Other than for bathing, the monitoring run should be stopped only when the IV is removed.

INDOOR USE

The monitoring system is designed for indoor use and should not be exposed to extreme temperatures, humidity, or moisture. See “Specifications” on page 46 for additional information.

IV INSERTION SITE

This monitoring system was designed for peripheral IV insertion site infiltration monitoring on the forearm or the dorsal aspect of the hand. Monitoring has not been tested for other IV placement locations.

MAGNETIC RESONANCE IMAGING (MRI)

The monitor and sensor cable pose a safety hazard if brought into the MRI environment. The receptacle contains no ferromagnetic materials. Disconnect the sensor cable and monitor prior to taking the sensor receptacle into the MR environment. See “MRI Safety Information” on page 56 for more information.

PEDIATRIC USE

The ivWatch Model 400 has not been cleared by the FDA for use in pediatric populations.

USE OF INTACT SKIN ONLY

The ivWatch sensor receptacle and sensor cable should only make contact with intact skin.

CHANGES OR MODIFICATIONS TO PRODUCT

Changes or modifications to the ivWatch Model 400 not expressly approved by ivWatch could void the user's authority to operate the equipment.

PRECAUTIONS

IV INFUSIONS OF OPTICALLY CLEAR, UNCOLORED FLUIDS

Use this monitoring system only for monitoring infusions of optically clear, uncolored fluids; examples of these include saline and saline-based solutions, sugar solutions (D5W), Lactated Ringer's solution, and colorless crystalloid solutions. The device has not been tested for monitoring infusions of dark, colored or cloudy fluids (for example, TPN, rifampin, and multi-vitamin "banana bags"). Dark, colored or cloudy fluids block light and may reduce the system's sensitivity.

CABLE POSITIONING

Route the sensor cable and power cord to reduce the possibility of equipment or patient entanglement. Place excess cable length so that it does not pose a hazard.

CLEANING

Do not immerse the monitor or the sensor in liquid. Always disconnect the monitor from the power supply prior to cleaning. Clean the system components as directed in "Preparing the System for Reuse" on page 44.

COMPATIBILITY

Use only components that are manufactured by ivWatch, LLC. Monitors, sensors, and receptacles made by other manufacturers have not been tested and may reduce the system's sensitivity.

DISPOSAL

Dispose of the packaging and material components according to local regulations.

EQUIPMENT MODIFICATION

Do not modify components of the monitoring system (eg, remove the ground pin on the electrical plug). Modifications could result in increased electrical hazard, unknown changes in product performance, and potential risk to the user and patient.

EXCESSIVE LIGHT

Use the monitoring system in normal to low-light conditions. Detection of infiltration events depends on the transmission of light through the patient's skin; as such, excessive ambient light over the sensor area may activate a notification on the monitor to change the lighting conditions. Failure to change the lighting conditions may degrade the system's performance.

LIGHT-BLOCKING BARRIERS

Do not place a dressing under the sensor receptacle. Light-blocking barriers (eg, bandage) between the patient's skin and the sensor may reduce the system's sensitivity.

PATIENT MOVEMENT

Minimize patient movement during a monitoring run to reduce the possibility of sensor displacement.

PRESCRIPTION ONLY

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

REUSE

Do not reuse any of the components originally provided as a sterile product.

SENSOR CABLE DAMAGE

Do not kink or compress the sensor cable. Kinking or compressing the cable could damage the sensor, activating a notification on the monitor to test the sensor cable. Kinking or compressing the cable could also result in the exposure of glass fibers which can pose a safety risk.

SENSOR INTERFERENCE

Sensor placement should not be on the same arm as a blood pressure cuff or arterial blood pressure measurement device.

STERILIZATION

Do not sterilize any components of the monitoring system. Sterilization may damage or reduce the system's sensitivity.

TATTOOED, SCARRED, OR BRUISED TISSUE

Do not place the sensor receptacle over tattooed, scarred, or bruised tissue as these conditions may reduce the system's sensitivity.

TRAINED HEALTH CARE PRACTITIONER

Do not rely solely on the monitoring system for IV monitoring. All monitoring runs should be managed by a trained health care practitioner who is experienced in IV administration and management. The monitoring system is not intended to replace IV monitoring by a trained health care practitioner.

STACKING THE IVWATCH MODEL 400 MONITOR WITH OTHER EQUIPMENT

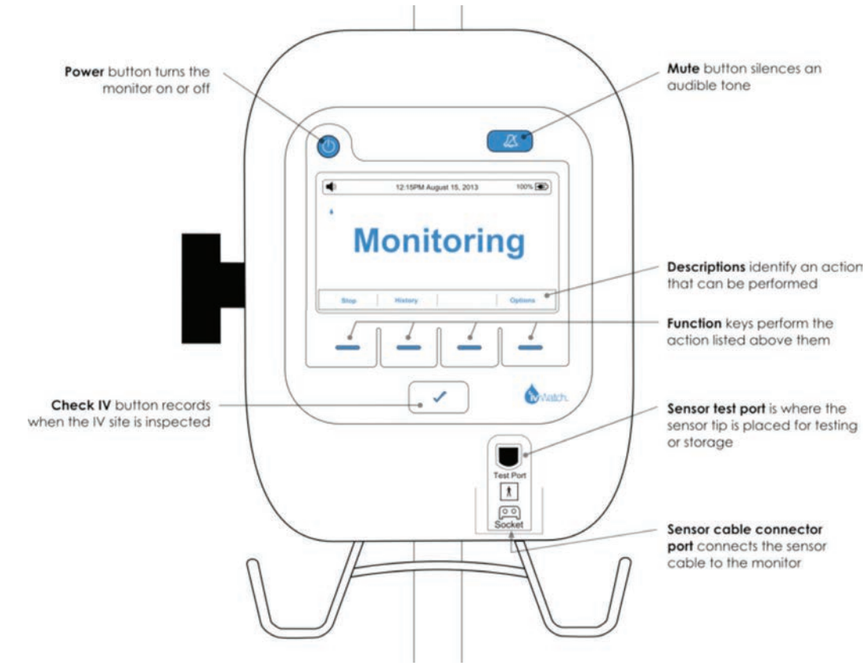
Do not use the ivWatch Model 400 adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe the ivWatch Model 400 to verify normal operation in the configuration in which it will be used.

02

INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

The monitor should be fully charged prior to its first use. Inspect the components for visible damage prior to use. If desired, test the sensor cable (see “Testing the Sensor” on page 33) to see if the sensor is damaged.



USING THE MONITOR

The monitor attaches to a standard IV pole; the monitor may be placed on the pole at a height of up to 7 feet. A grounded wall outlet is required to recharge the monitor battery.

***NOTE** : The power port and USB port are on the back of the monitor. See “Specifications” on page 45 for additional information about the monitor ports and connectivity.*

The monitor can be used remotely on battery power for limited periods of time, but during normal use, the monitor should be powered by the medical-grade AC power supply. See “Patient Monitoring Using Battery Power” on page 23 for more information.

SETTING UP A MONITORING RUN

Begin a monitoring run after the IV catheter has been placed in accordance with facility protocols for IV administration and management.

IMPORTANT NOTE : *Allow the patient monitor to run in monitoring mode for at least 1 minite before starting the infusion. This allows the monitor to take critical baseline readings.*

TO SET UP A MONITORING RUN, COMPLETE THE FOLLOWING STEPS:

1. Use the clamp to securely mount the monitor on the IV pole.
2. Position the monitor so that the display is easily viewed.
3. Press Power on the front of the monitor. The Start-up screen appears briefly.

Start-up Screen

⚠ CAUTION :

- Use this monitoring system only with optically clear fluids, uncolored fluids. Refer to the Precautions section of this manual for examples of colored, dark or cloudy fluids that should not be used with the monitoring system as they may reduce the system's sensitivity.
- Do not place a dressing under the sensor receptacle. Light-blocking barriers (eg, bandages and occlusive dressings) between the patient's skin and the sensor may reduce the system's sensitivity.
- Do not place the sensor over tattooed, bruised, or scarred tissue as these conditions may reduce the system's sensitivity.

4. If the monitor does not turn on, insert the power plug into the power port on the back of the monitor and connect the electrical plug to a grounded wall outlet. Verify that the battery symbol shows that the monitor is charging.

NOTE : *During normal operation, the monitor should be plugged into a power source, but for ambulatory activities, a fully charged monitor can be used on battery power for extended periods of time. See "Patient Monitoring Using Battery Power" on page 23.*

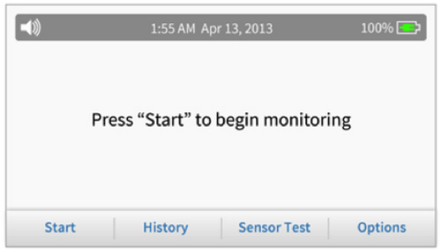
The volume and display brightness settings are demonstrated when the monitor is turned on.

NOTE : *These and other settings can be changed on the Options screen. (Follow the instructions on the display, or see "Options" on page 41).*

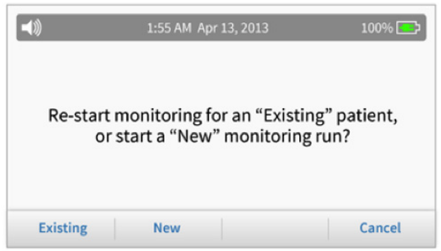
5. Check the time, date, and battery status as displayed on the top of the Home screen.

NOTE : *The date and time should be verified prior to beginning a monitoring run. The time cannot be changed after a monitoring run has started. The **Time & Date** option is not available during a monitoring run to prevent errors in data collection.*

6. Press the Start key to begin the monitoring run.



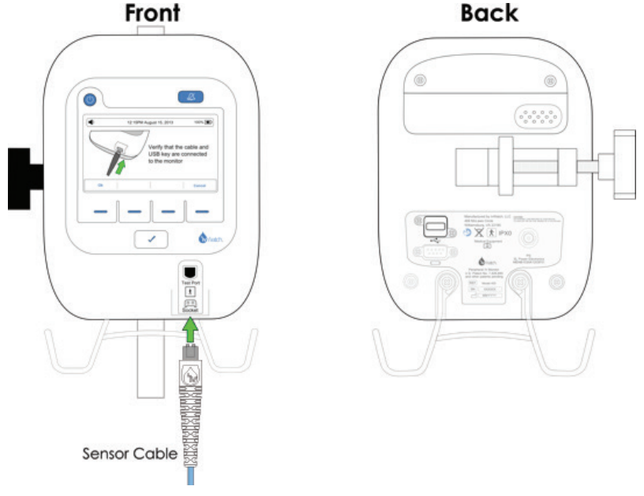
7. Press the New key to start a new monitoring run.



NOTE : *See "Continuing a Monitoring Run with an Existing Patient" on page 25 if the monitoring run is for an existing patient.*

8. Confirm that the patient is new by pressing the Yes key.

9. Connect a sensor cable to the monitor (as shown on the display).



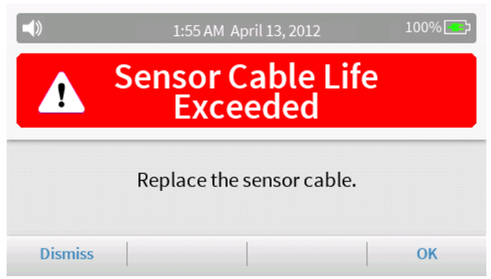
⚠ **CAUTION :** If you are using a new sensor cable (one that was just removed from the packaging), be sure to remove any clear plastic caps covering the optical interface of the fibers prior to inserting that end of the sensor cable into the sensor port on the monitor.

a. If the cable has been damaged (or if damage is suspected), press Cancel to return to the Home screen.

b. From the Home screen, press Sensor Test to test the integrity of the sensor. (Follow the instructions on the display, or see "Testing the Sensor" on page 33.)

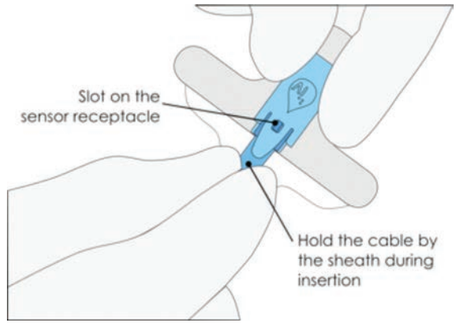
c. Resume the monitoring run setup at step 9 with a working sensor cable.

NOTE : *In order to maximize the sensitivity of the ivWatch system, each sensor cable is limited to 10 catheter line days (or 240 hours) of monitoring. The system tracks the amount of time that a sensor cable has been used for monitoring. Whenever a monitoring run is started, the system performs a check to see if the cable has exceeded its usage limit. When the system detects that a sensor cable has exceeded its usage limit, a Sensor Cable Life Exceeded error will be displayed. Replace the sensor cable if prompted by this error.*



10. Press OK to confirm sensor cable connection.

⚠ **CAUTION :** Route the sensor cable to reduce the possibility of equipment or patient entanglement. Place excess cable length so that it does not pose a hazard.

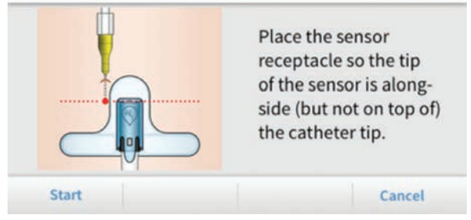


NOTE : *Ensure that the tab on the sensor snaps into the slot of the sensor receptacle.*

12. Placing the sensor:

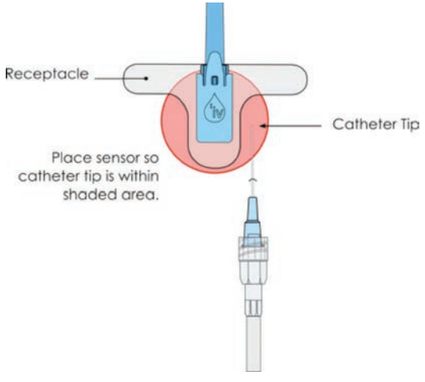
a. Properly route the sensor cable from the monitor to the patient.

b. Position the sensor receptacle adjacent to the catheter tip (as shown on the display). Do not stretch the receptacle during application.

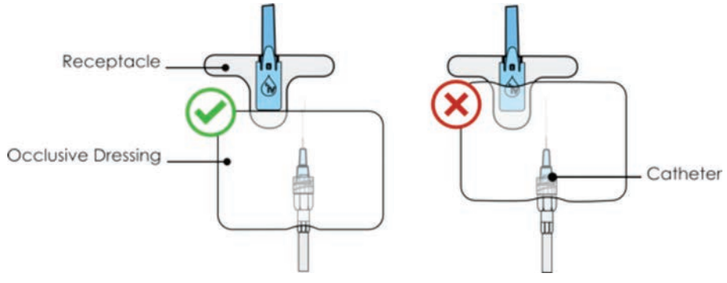


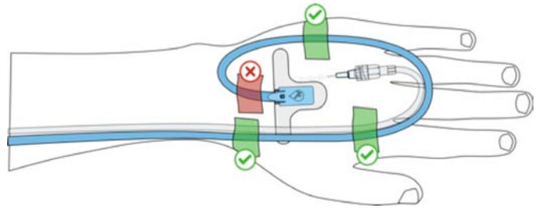
c. Position the sensor receptacle so that the tip of the catheter is located in the shaded area shown in the figure to the right.

NOTES : *Avoid placement of the sensor directly over a large vein for best performance. The sensor receptacle should not be removed and replaced. If it must be removed, use a new sensor receptacle for that patient.*

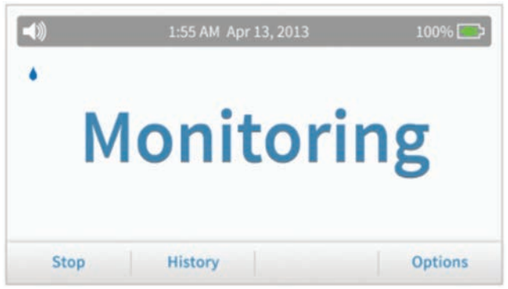


13. Cover the injection site with an occlusive dressing according to facility protocols. The occlusive dressing should not be placed over the blue portion of the ivWatch receptacle.





14. Secure the sensor cable, ensuring that the cable is not kinked or compressed. Recommended locations to secure the cable are indicated by green check marks. Use facility protocols for securing the IV line to the patient.



Monitoring screen

15. Press the Start key to begin the monitoring run.
The Monitoring screen appears.

NOTES :

- *The droplet animation in the upper corner of the display shows that monitoring is active.*
- *The elapsed monitoring time is displayed instead of the time and date at 3-second intervals, starting after the first minute that monitoring is active.*

⚠ **CAUTION :** Route the sensor cable and power cord to reduce the possibility of equipment or patient entanglement. Place excess cable length so that it does not pose a hazard.

16. Setup is complete, and the monitoring run is in progress. Proceed to "Monitoring a Patient."

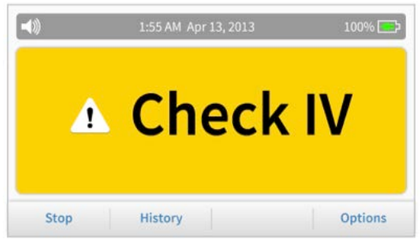
MONITORING A PATIENT

Always check the IV insertion site in accordance with facility protocols for IV administration and management. Monitoring run status is clearly displayed by the screen color.

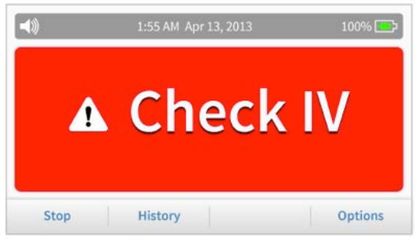
The blue *Normal* screens show that a monitoring run is active, with no notifications or error conditions.

> ***NOTE :*** *The elapsed monitoring time is displayed instead of the time and date at 3-second intervals, starting after the first minute that monitoring is active. The droplet animation in the upper corner of the display shows that monitoring is active.*

The yellow infiltration *Watch* status screens show that conditions may indicate a possible infiltration event, but the system allows the monitoring run to continue.



The red *Warning* status screens show that either a probable infiltration event or a system error has occurred that must be corrected (eg, a sensor error) prior to continuing the monitoring run.



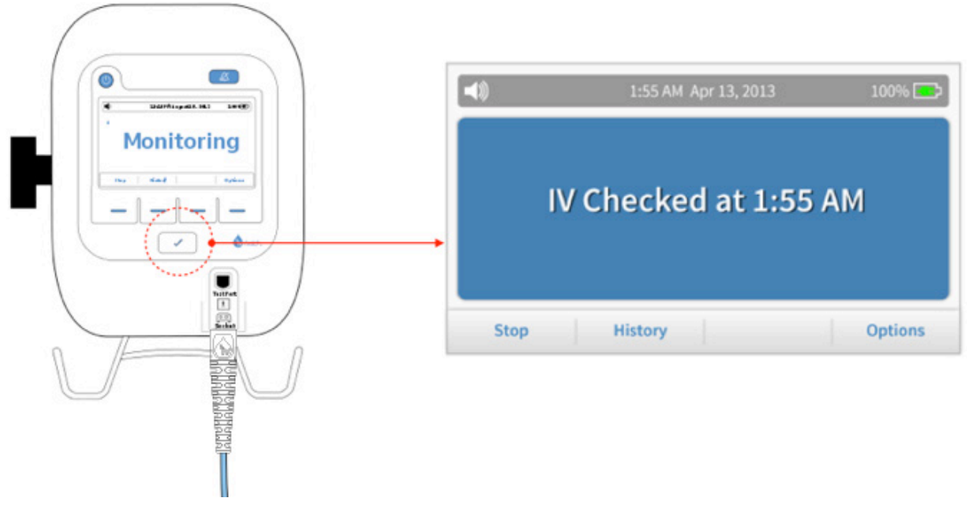
IV MONITORING: WATCHES AND WARNINGS

The Monitoring screen continues to be displayed until there is indication of an infiltration event (eg, Check IV), a battery event occurs (eg, low battery), or an error is detected in the system (eg, Sensor monitoring error).

NOTE *: Monitoring sensitivity for an individual patient may vary according to medical status, skin condition, age, and the duration of the monitoring run.*

> ⚠ **CAUTION :** Do not rely solely on the monitoring system for IV monitoring. All monitoring runs should be managed by a trained health care practitioner who is experienced in IV administration and management. The monitoring system is not intended to replace IV monitoring by a trained health care practitioner.

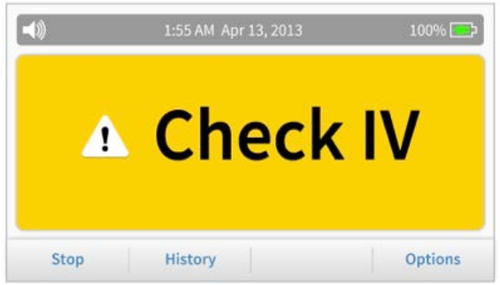
1. Press ✓ on the front of the monitor (the IV Check button) whenever the IV insertion site is inspected to record the action in the time record on the History screen. The monitor will display an IV Checked confirmation screen showing the time at which the IV Check button was pressed.



2. If conditions indicate a possible infiltration, the yellow Check IV watch screen appears, accompanied by an audible tone.

   NOTES : *The notification tone can be muted by pressing the Mute button. Audible tones are silenced for 2 minutes after Mute has been pressed.*

3. Check the IV insertion site per facility protocols for IV administration and management.



Check IV watch screen

4. Press the IV Check button to indicate that the IV insertion site has been inspected.

   NOTE : *Do not use the IV Check button to silence a notification without checking the IV and sensor.*

   During an infiltration watch, the system allows the monitoring run to continue, but the screen remains in watch status. If conditions change and there is no further detection of an infiltration event, monitoring returns to normal status.

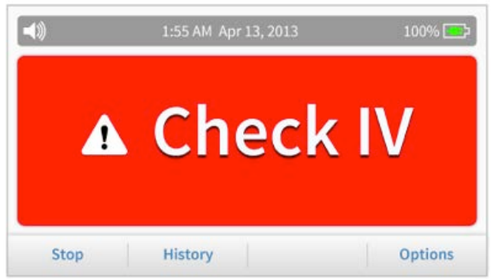
Monitoring screen during an infiltration watch

5. If a probable infiltration event is detected, the Red Check IV warning screen appears, accompanied by an audible tone.

   NOTES : *The notification tone can be muted by pressing the Mute button. Audible tones are silenced for 2 minutes after Mute has been pressed.*

6. Check the IV insertion site per facility protocols for IV administration and management.

7. Press IV Check to indicate that the IV insertion site has been inspected.



Check IV warning screen

Note : *Stop a monitoring run after a probable infiltration event. The monitoring run can be continued without loss of the patient history. See "Continuing a Monitoring Run with an Existing Patient" on page 25.*

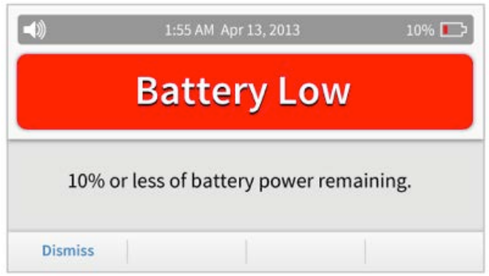
8. Proceed to "Ending a Monitoring Run" on page 24.

PATIENT MONITORING USING BATTERY POWER

The monitor can be used remotely on battery power for at least 5 hours when fully charged. During normal operation, the monitor should be powered by the medical-grade AC power supply included in the package.

While the monitoring run is on battery power, note the remaining charge on the battery to ensure that power loss does not interrupt the monitoring run:

The following message appears when there is approximately 10% of battery charge remaining:



NOTE : *Low-battery messages are accompanied by audible tones; pressing the Dismiss key removes the notification message and mutes the audible tone.*

When approximately 5% of battery charge remains, the following message appears:

Press the Dismiss key to remove these notfication messages

ENDING A MONITORING RUN

If an infiltration event has been verified, stop monitoring and remove the IV.

To end a monitoring run, complete the following steps:

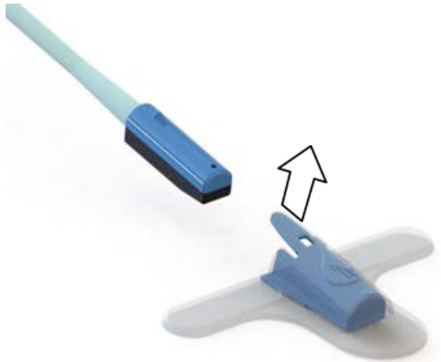
1. Press the Stop key.

NOTES :

- *Monitoring runs can be stopped from any screen that shows a Stop key*
- *A monitoring run in progress ends when the monitor is turned off.*

2. Press the Yes key to confirm ending the monitoring run.

3. Carefully remove the sensor receptacle from the patient (with the sensor still inserted in the receptacle).



4. To remove the sensor from the receptacle, lift the receptacle tab, and then gently slide the sensor head out of the receptacle.

5. Dispose of the sensor receptacle.

NOTE : *Do not replace or reuse the sensor receptacle.*

6. Clean the sensor tip and place it in the sensor test port to protect it from damage.

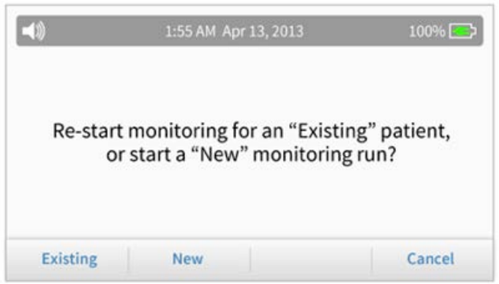
7. Coil the sensor cable, and place it on the wire bale below the monitor. If the monitoring run is going to resume with the same patient, proceed to "Continuing a Monitoring Run with an Existing Patient" on page 25.

NOTE *: The monitoring history for the existing patient will not be displayed if a monitoring run is continued after turning off the monitor, but the history will be stored. See "History and Event Data" on page 31 for information about reviewing and saving data.*

8. If the monitoring run is finished, proceed to "Turning Off the Monitor."

CONTINUING A MONITORING RUN WITH AN EXISTING PATIENT

If the IV insertion site has changed or the monitoring run was stopped (e.g., for a bath or an MRI scan), a monitoring run can be continued. Doing so ensures that the history data and related IV check information for up to 72 hours can be reviewed.



To continue a monitoring run, complete the following steps:

NOTE : *Do not change the time before continuing a monitoring run; otherwise, timeline data errors will be displayed. The Time & Date option is not available during a monitoring run.*

1. Press the Start key to begin the monitoring run.

2. Press the key for Existing.

NOTE : *See "Setting Up a Monitoring Run" on page 14 if the monitoring run is for a new patient.*

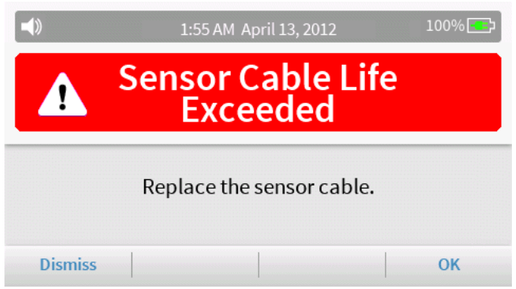
3. Connect a sensor cable to the monitor (as shown on the display).

a. If the cable has been damaged (or if damage is suspected), press Cancel to return to the Home screen.

b. From the Home screen, press Sensor Test to test the integrity of the sensor. (Follow the instructions on the display, or see "Testing the Sensor" on page 33.)

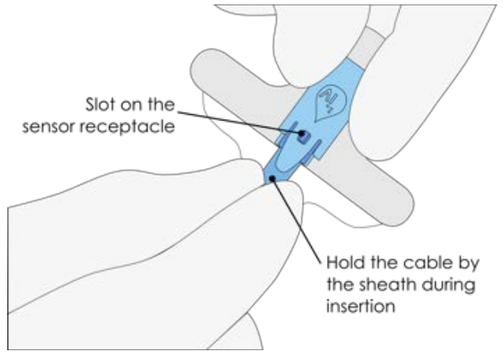
c. Resume the monitoring run setup at step 4 with a working sensor cable.

⚠ **CAUTION :** If you are using a new sensor cable (one that was just removed from the packaging), be sure to remove any clear plastic caps covering the optical interface of the fibers (on the proximal end of the sensor cable) prior to inserting that end of the sensor cable into the sensor port on the monitor.



NOTE : *In order to maximize the sensitivity of the ivWatch system, each sensor cable is limited to 10 catheter line days (or 240 hours) of monitoring. The system tracks the amount of time that a sensor cable has been used for monitoring. Whenever a monitoring run is started, the system performs a check to see if the cable has exceeded its usage limit. When the system detects that a sensor cable has exceeded its usage limit, a Sensor Cable Life Exceeded error will be displayed. Replace the sensor cable if prompted by this error.*

4. Press the OK key to confirm sensor cable is connected to the monitor.



5. Insertion of the sensor into the sensor receptacle:

   a. Ensure that the sensor is clean prior to use. If necessary, wipe the sensor head with isopropyl alcohol and allow it to dry.

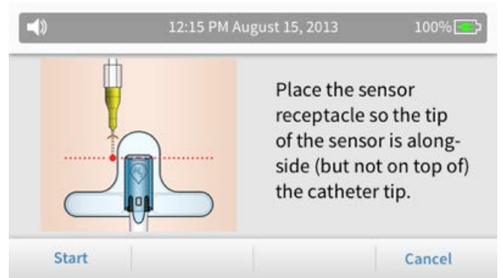
   b. Open a new sterile ivWatch sensor receptacle kit.

   c. Remove the sensor receptacle from the package.

   d. Hold the sensor cable by the sheath to prevent damage to the cable during insertion.

   e. Fully insert the sensor tip into the sensor receptacle.

NOTE : *Ensure that the tab on the sensor snaps into the slot of the sensor receptacle.*



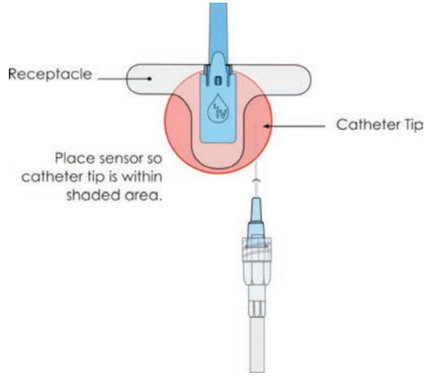
6. Placing the sensor:

   a. Properly route the sensor cable from the monitor to the patient.

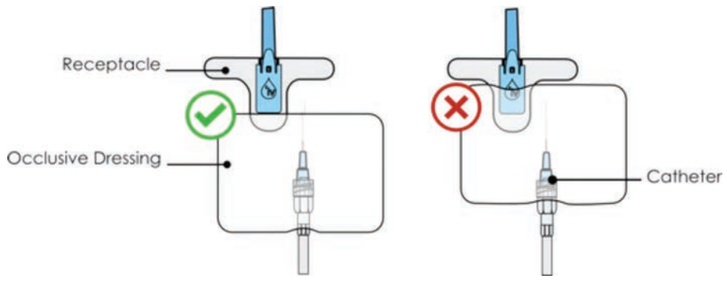
   b. Position the sensor receptacle adjacent to the catheter tip (as shown on the display). Do not stretch the receptacle during application.

c. Position the sensor receptacle so that the tip of the catheter is located in the shaded area shown in the figure below.

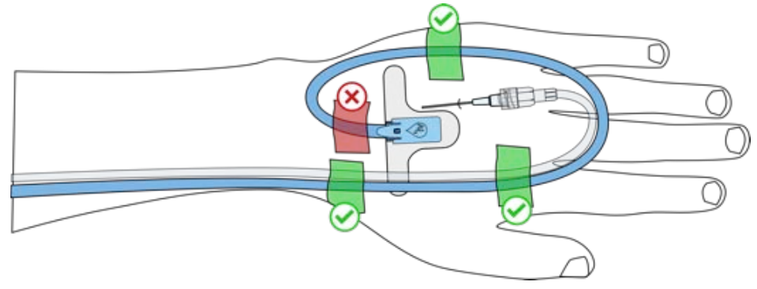
NOTE : *Avoid placement of the sensor directly over a large vein for best performance.*



7. Cover the injection site with an occlusive dressing according to facility protocols. The occlusive dressing should not be placed over the blue portion of the ivWatch receptacle.



8. Secure the sensor cable, ensuring that the cable is not kinked or compressed. Recommended locations to secure the cable are indicated by green check marks. Use facility protocols for securing the IV line to the patient.



Monitoring screen

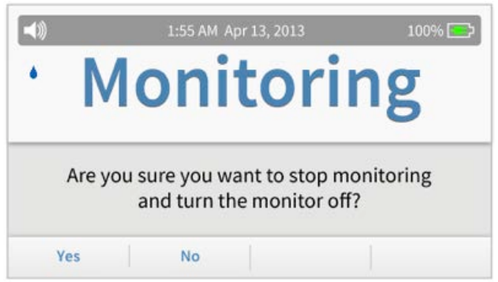
9. Press the Start key to begin the monitoring run. The Monitoring screen appears.

NOTES :

- *The droplet animation in the upper corner of the display shows that monitoring is active.*
- *The elapsed monitoring time is displayed instead of the time and date at 3-second intervals, starting after the first minute that monitoring is active.*

TURNING OFF THE MONITOR

To shut the monitor off, complete the following steps:



Shutdown screen

1. Press and hold the Power button. The Shutdown screen appears.

2. Press the Yes key to turn off the monitor (and end a monitoring run in progress).

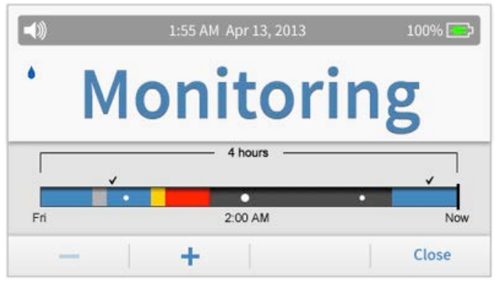
   NOTE : *The monitoring history for the existing patient will not be displayed if a monitoring run is continued after turning off the monitor, but the history will be stored. See "History and Event Data" on page 31 for information about reviewing and saving data.*

3. Unplug the electrical plug from the grounded wall outlet, coil the power cord, and place it on the wire bale below the monitor.

4. If monitoring for this patient is finished, see "Preparing the System for Reuse" on page 45.

HISTORY AND EVENT DATA

The History screen shows a time-line of a monitoring run, including IV checks, watches, and warnings.



History screen

The colors indicate the following monitoring states:

- Normal = *Blue*
- ✓ IV Check *button pressed*
- Watch status = *Yellow*
- Warning status = *Red*
- Monitoring error = *Gray*
- No monitoring = *Black*

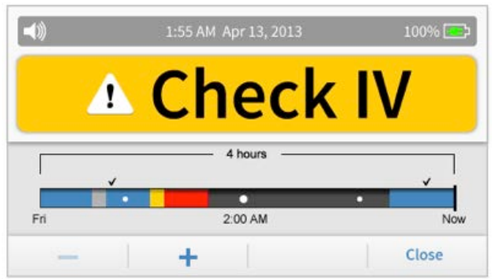
To review history and event data, complete the following steps:

1. Press the History key.

2. Press the plus (+) key to expand the timeline range (eg, from 4 hours to 8 hours) or the minus (–) key to collapse the timeline range (eg, from 24 hours to 8 hours).

3. Press the Close key to return to the previous screen.

   NOTE : *If the History screen is not closed, the monitor returns to the prior screen after 30 seconds.*

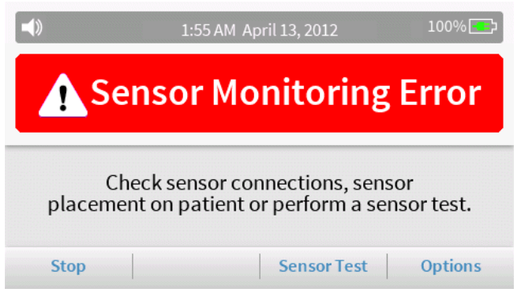


03

TROUBLESHOOTING

TROUBLESHOOTING

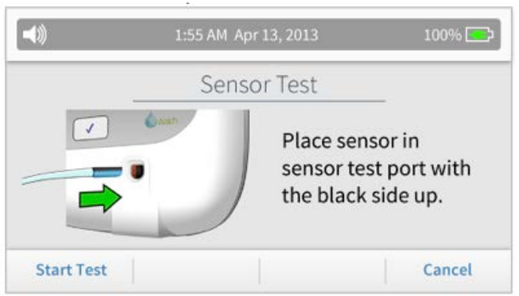
The monitoring system does not require periodic calibration and has no serviceable parts. If it does not appear to be functioning and troubleshooting does not resolve the issue, contact Technical Support at (855) 489-2824.



Sensor Monitoring Error screen

TESTING THE SENSOR

A sensor test cannot be performed during a monitoring run unless sensor performance degrades. The system detects the change, and a notification appears on the display.

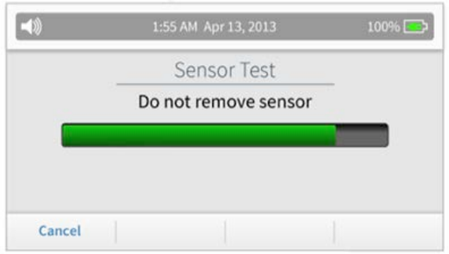


NOTE : *Do not remove the sensor during testing.*

To test the sensor cable, complete the following steps:

1. Ensure that the monitor is on and the sensor cable is connected to the monitor.
2. From the Home screen (or the Sensor Monitoring Error screen), press the Sensor Test key.
3. Insert the sensor into the sensor test port (as shown on the display).
4. To begin the sensor test, press the Start Test key. Press the Cancel key to end the test and return to the previous screen.

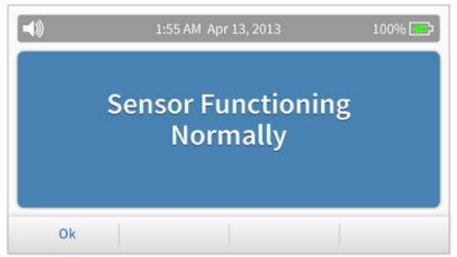
A message appears during the test.



5. To interrupt testing, press the Cancel key.

6. Review the sensor test results:

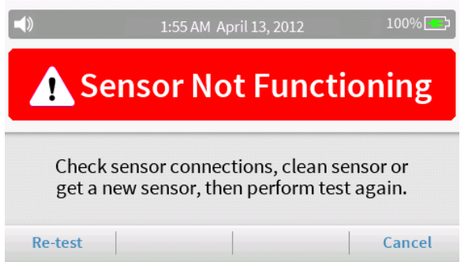
a. If the sensor test passed, a message appears stating that the sensor is functioning normally. Press the OK key to return to the previous screen.



b. If the sensor is not functioning, an error message appears.

c. Follow the instructions on the display prior to retesting the sensor.

d. Press the Re-test key to perform the test again, or press Cancel to return to either the Sensor Monitoring Error screen or the Home screen.



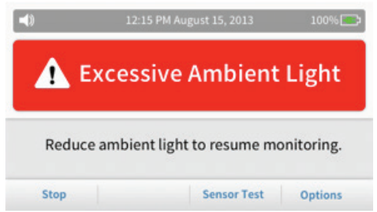
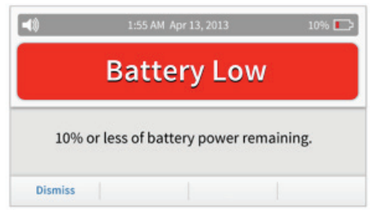
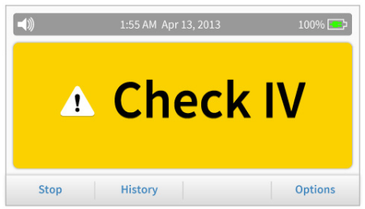
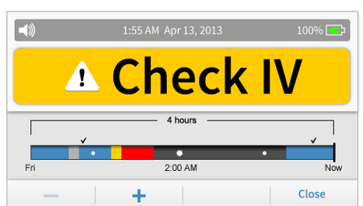
TROUBLESHOOTING TABLE

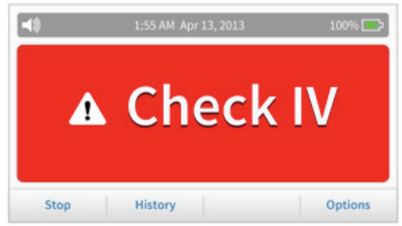
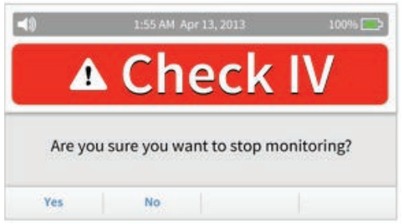
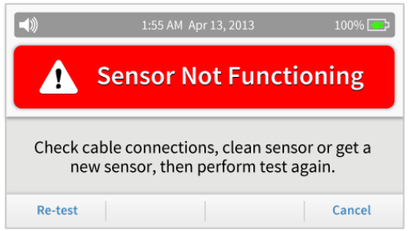
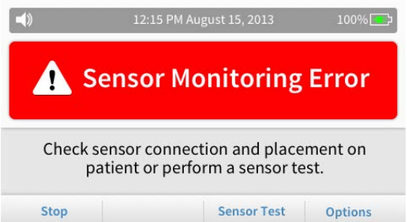
The Troubleshooting Table describes possible device issues and how to resolve them.

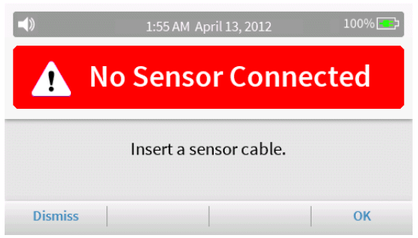
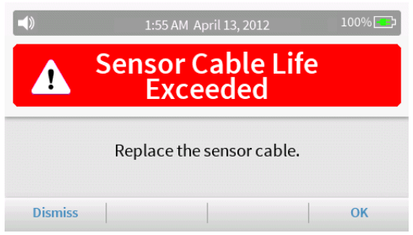
Problem	Possible Cause	Possible Solution
The monitor will not turn on. The monitor display remains blank.	▪ The power supply is not connected. ▪ The monitor may be turned off. ▪ The battery may be depleted. ▪ The display or the monitor is not functioning.	▪ Confirm that the monitor's electrical plug is in a grounded wall outlet. ▪ Press Power to confirm that the monitor is on. ▪ Replace the monitor.
The display is too bright or is difficult to see.	The screen brightness setting is too low or too high.	Select Options >> Brightness to adjust the display brightness.
The volume is too quiet or too loud.	The volume setting is too low or too high.	Select Options >> Volume to adjust the volume.
A Sensor Monitoring Error or a Sensor Not Functioning error message appears. (See the Error Message Table).	▪ The sensor is not properly connected to the monitor or to the sensor receptacle on the patient. ▪ The sensor is not functioning properly. ▪ The sensor receptacle is not properly attached. ▪ The patient is moving excessively. ▪ The sensor is fouled/dirty.	▪ Perform a sensor test. ▪ Check the cable. ▪ Verify that there are no kinks, bends, or breaks in the sensor cable and that the patient is not lying on the cable. ▪ Verify that the sensor is correctly inserted into the sensor receptacle. ▪ Verify that the sensor port and connector are clear of obstructions. ▪ Verify that the sensor receptacle is properly attached. ▪ Verify that the sensor is clean. ▪ Replace the sensor cable.
A Sensor Cable Life Exceeded error message appears (See the Error Message Table).	▪ The sensor cable has been used for monitoring in excess of 10 line days (or 240 hours).	▪ Replace the sensor cable.
Errors occur during data transfer.	▪ The USB drive is not inserted. ▪ The USB drive does not have enough space to save the data.	▪ Verify that the USB drive is properly connected and that there is sufficient free space on the drive.
Redness, itching, inflammation, or a similar reaction has occurred on the skin under or near the sensor receptacle.	The patient has had an allergic or irritant reaction to the adhesive used on the sensor receptacle.	▪ Remove the sensor receptacle and discontinue monitoring. ▪ Follow the facility protocol for allergic reactions.

ERROR MESSAGE TABLE

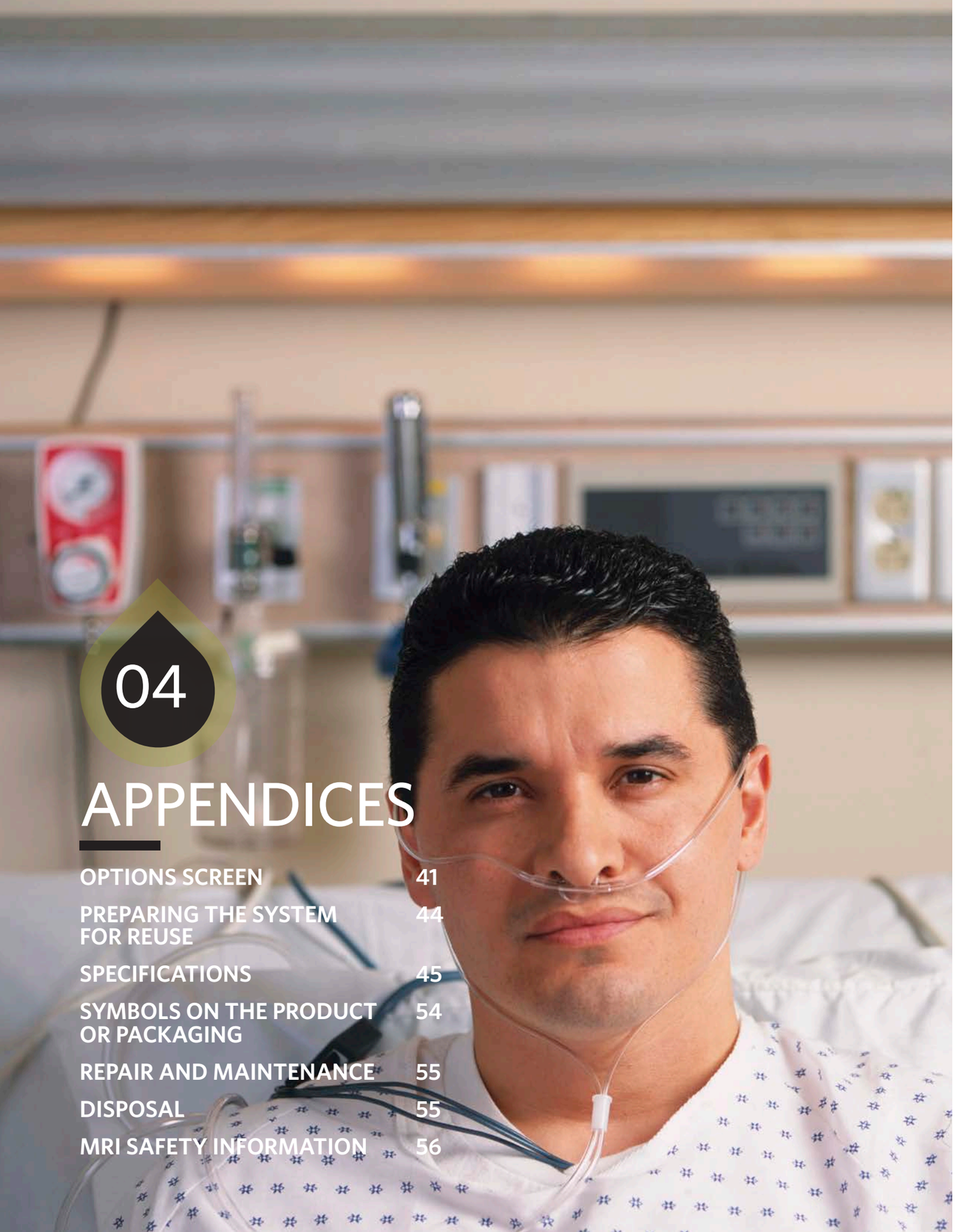
The Error Message Table shows common error screens and describes how to resolve them.

Error Message	Possible Solution
	Excessive Ambient Light Reduce the light, or cover the area around the sensor receptacle. Verify that no bright light sources are illuminating the IV insertion site.
	Battery Exhausted Plug the monitor into a power source or shut down the monitoring run within 15 minutes.
	Battery Low Plug the monitor into a power source or shut down the monitoring run within 30 minutes.
 	Check IV (Watch) Conditions corresponding to a possible infiltration event have been detected. ***NOTE :*** *The notification tone can be muted by pressing the Mute button.*

Error Message	Possible Solution
 	Check IV (Warning) A probable infiltration event has been detected. Perform an IV insertion site inspection. Begin a new monitoring run after the IV inspection. ***NOTE :*** *The notification tone can be muted by pressing the Mute button.*
	Sensor Not Functioning A sensor error was detected during a sensor test. Follow the instructions on the screen. Verify that there are no kinks, bends, or breaks in the sensor cable and that the patient is not lying on the cable. Verify that the proximal and distal ends of the sensor cable are clean. Replace the sensor cable. If the error persists with new cable, contact ivWatch customer support at (855) 489-2824.
	Sensor Monitoring Error A sensor error was detected during a monitoring run. Verify that there are no kinks, bends, or breaks in the sensor cable and that the patient is not lying on the cable. Verify that the sensor cable is connected to the patient monitor. Verify that sensor receptacle is securely attached to the patient's skin. Verify that the proximal and distal ends of the sensor cable are clean. Perform a sensor test. Replace the sensor cable. If the error persists with new cable, contact ivWatch customer support at (855) 489-2824.

Error Message	Possible Solution
	No Sensor Connected Insert a sensor cable.
	Sensor Cable Life Exceeded Sensor usage has exceeded 10 line days (or 240 hours). Replace the sensor cable.
	Invalid Factory Settings Error This message indicates that the monitor failed to verify the required factory settings during start up. Press and hold the power button for 20 seconds to power down the monitor, then press the power button to power the device on again. If the same error message is displayed, replace the monitor and/or contact ivWatch customer support at 855-489-2824.
	Missing Display Software Error This message indicates that the monitor could not locate the required display software during start up. Press and hold the power button for 20 seconds to power down the monitor, then press the power button to power the device on again. If the same error message is displayed, replace the monitor and/or contact ivWatch customer support at 855-489-2824.
	Invalid Display Software Version Error A message in this format indicates that the monitor detected a discrepancy between the version of the display software currently on the monitor and the version which was expected. Press and hold the power button for 20 seconds to power down the monitor, then press the power button to power the device on again. If the same error message is displayed, replace the monitor and/or contact ivWatch customer support at 855-489-2824.

Error Message	Possible Solution
	Invalid Display Software Version Error A message in this format indicates that the monitor detected a discrepancy between the version of the display software currently on the monitor and the version which was expected. Press and hold the power button for 20 seconds to power down the monitor, then press the power button to power the device on again. If the same error message is displayed, replace the monitor and/or contact ivWatch customer support at 855-489-2824.
	Device Firmware Error A message in this format (red text displayed on a grey screen) indicates that the monitor encountered a problem (on start up, or during normal operation). Press and hold the power button for 20 seconds to power down the monitor, then press the power button to power the device on again. If an error message in this format is displayed again after powering the device on, replace the monitor and/or contact ivWatch customer support at 855-489-2824.
	"Failed to load" Error This message indicates that the monitor failed to load the required display software during start up. Press and hold the power button for 20 seconds to power down the monitor, then press the power button to power the device on again. If the same error message is displayed, replace the monitor and/or contact ivWatch customer support at 855-489-2824.



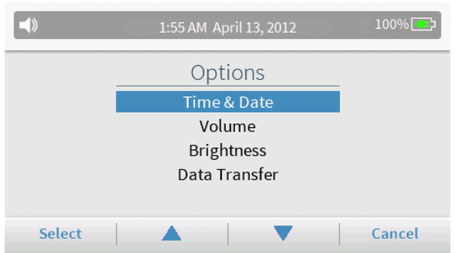
04

APPENDICES

OPTIONS SCREEN

The volume and display brightness settings can be changed on the Options screen. These settings are demonstrated when the monitor is turned on. The time and date can also be changed prior to a monitoring run. History and event data can be transferred to a USB drive.

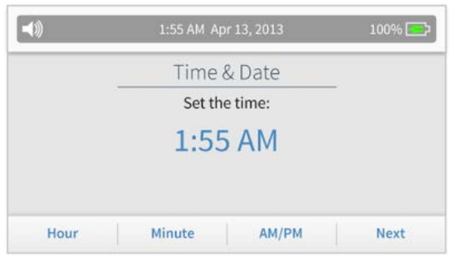
Use the up and down arrow keys to highlight the desired option to change. Press the Select key to go to the highlighted option screen. Press the Cancel key to return to the previous screen.



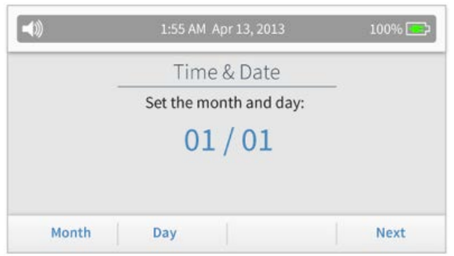
Options screen

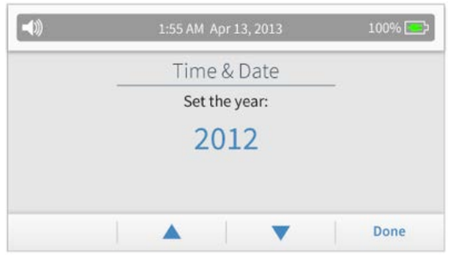
MODIFYING THE TIME AND DATE

The time cannot be changed after a monitoring run has started. Hour and Minute keys are upward-adjustable only.



Press the Next key to accept the displayed time and view the Month/Day screen. Month and Day keys are upward-adjustable only.





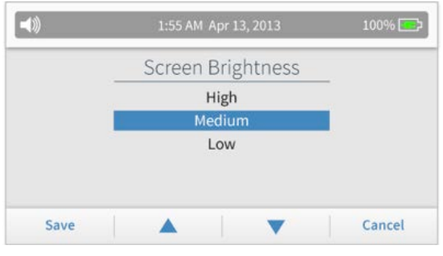
Press the Next key to accept the displayed month and day and to view the Year screen.

Use the up and down arrow keys to select the year. Press the Done key to accept the displayed year and to return to the Options screen.

CHANGING THE VOLUME SETTING

Use the up and down arrow keys to select the volume level. Volume is demonstrated when highlighted.

Press the Save key to accept the change or the Cancel key to return to the Options screen without changing the volume level.



CHANGING THE SCREEN BRIGHTNESS

Use the up and down arrow keys to select the brightness level. Brightness is demonstrated when highlighted.

Press the Save key to accept the change or the Cancel key to return to the Options screen without changing the screen brightness.

TRANSFERRING DATA TO A USB DRIVE

The history and event data stored on a monitor can be transferred to a SanDisk® Cruzer Fit™ or a SanDisk® Cruzer Glide™. General purpose USB drives may not be recognized by the ivWatch monitor, or may result in incomplete data transfers. The data size to be transferred is displayed. Insert the drive into the USB port on the back of the monitor. Note that patient identification data is not entered into the monitoring system and therefore no patient specific data is stored.

The monitor detects the drive and provides a message if it has inadequate free space for the selected files. Press the Transfer key to transfer the data or the Cancel key to return to the Options screen without transferring the data.

NOTE : *Only use a USB drive with a nonconducting case.*

PREPARING THE SYSTEM FOR REUSE

The monitor and sensor cable can be reused. The sensor receptacle is a sterile, single-use component. Dispose of used sensor receptacles.

To prepare the system for storage and reuse, complete the following steps:

1. As needed, remove any visible foreign material on the external surface of the monitor with disinfectant wipes. Allow the monitor to air dry.

2. Clean the sensor cable using PDI Super Sani-Cloth Germicidal Disposable wipes as follows:

   a. Use a PDI Super Sani-Cloth to wipe the sensor cable. Wipe the cable thoroughly and systematically, end to end, making sure that all surfaces are thoroughly wet with the disinfectant.

   b. Repeat (a) with a second PDI Sani-Cloth wipe.

   c. Place the sensor cable on a sterile surface and allow it to sit for a minimum of 2 minutes after thoroughly wiping with the disinfectant wipes.

3. Insert the sensor tip into the sensor test port when the monitor is not in use.

4. For temporary storage in patient rooms and hospital work areas:

   a. Do not disconnect the sensor cable or power plug from the monitor.

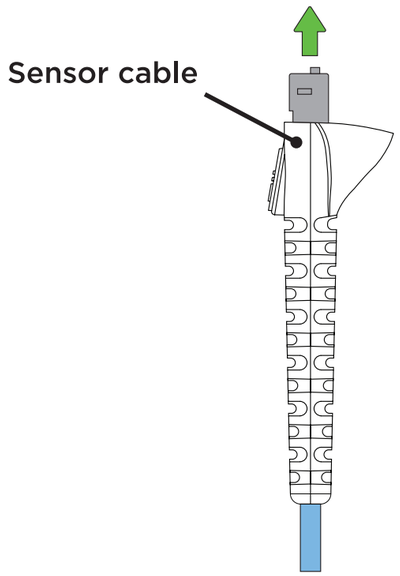
   b. Carefully coil the sensor cable loosely around the wire bale under the monitor.

5. For long-term storage:

   a. Do not disconnect the sensor cable or power plug from the monitor.

   b. Carefully coil the sensor cable loosely around the wire bale under the monitor.

   c. Store the components in a dry environment.



SPECIFICATIONS

Parameter	Description
Data Download/Transmission	USB port connector Sensor cable connector Supported USB drives: SanDisk® Cruzer Fit™ SanDisk® Cruzer Glide™
Data Storage	4 GB secure digital card FAT32-formatted memory stick Storage: Maximum 14 days of continuous run data (FIFO first in, first out)
Display	4.3-in LCD display Default brightness 400 nit Visual acuity of 1 30° viewing angle (cone) 4-meter viewing distance Shatter/splinter-resistant front lens Battery backup charging indicator (IEC 60601-1)
Input Power Ratings	100-240 V, 50-60 Hz, 1.0 A
Equipment Classification	Class I, Internally powered WARNING: To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.
Power Supply	SL Power, model MENB1030A1241F03
Internal Batteries	Lithium polymer battery pack provides a minimum of 5 hours of continuous monitoring when new
Wavelengths and Output Power	Wavelengths: 580–1000 nm Maximum emitted power: <2.0 mW This information of sensor wavelength range can be especially useful to clinicians, for example, those performing photodynamic therapy.
RFID (used to track sensor cable use hours)	Frequency range: 13.56 MHz +/- 7 kHz Effective radiated power: 84 uW

Parameter	Description
Monitor	V0 flame resistance, nonconducting
Compliance	**FCC ID 2AHPAM400.** 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. RFID - operation within the band 13.110-14.010 MHz (FCC 15.225:2016) Nontoxic materials (IEC 60601-1 clause 48) Cleaning (IEC 60601-1 subclause 44.7) Handling (IEC 60601-1 subclause 21.6)

***NOTE** : All measurements are approximate.*

COMPATIBLE SENSOR CABLE AND SENSOR RECEPTACLE

The ivWatch 400 patient monitor should only be used with the following ivWatch components:

Component	Part Number
ivWatch Sensor Cable	AC-1001000
ivWatch Sensor Receptacle	AM-1000001

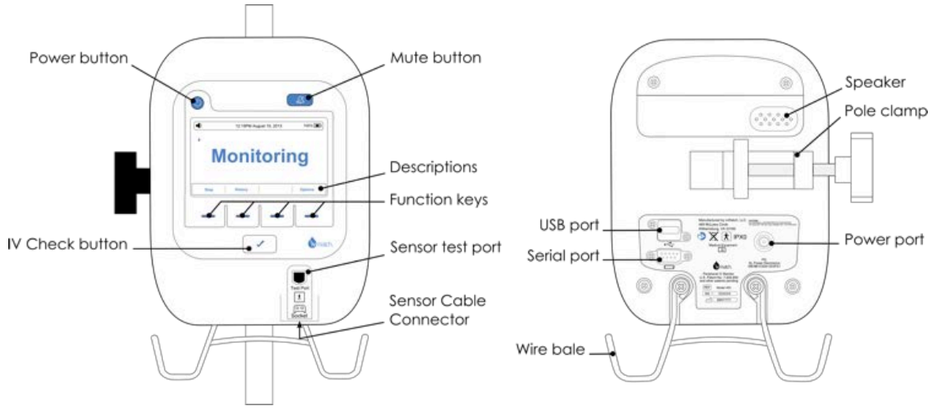
DIMENSIONS AND WEIGHT

Component	Length, in (cm)	Width, in (cm)	Depth, in (cm)	Weight, lb (kg)
Monitor (with pole clamp)	8.0 (20.3) 9.75 (24.8)	6.14 (15.6) 7.0 (17.8)	2.63 (6.7) 5.0 (12.7)	2.5 (1.1) 4.0 (1.8) including the power supply
Sensor	0.36 (0.9)	0.25 (0.6)	0.81 (2.1)	N/A
Sensor cable	118.1 (300)	N/A	N/A	N/A
Sensor receptacle	2.25 (5.7)	1.31 (3.3)	0.42 (1.1)	N/A

ENVIRONMENTAL

Parameter	Operation	Transport and Storage (Boxed)	Storage (Unboxed)
Ambient temperature	41 to 104°F (5 to 40°C)	-4 to 158°F (-20 to 70°C))	-4 to 158°F (-20 to 70°C)
Relative humidity, %	15–75 (noncondensing)	15-75 (noncondensing)	15-75 (noncondensing)
Atmospheric pressure, kPa	70-106	50-106	70-106

IVWATCH PATIENT MONITOR



ELECTROMAGNETIC ENVIRONMENT GUIDANCE

The ivWatch Model 400 meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2 (2001-09) standard for emissions and immunity.

Special precautions should be observed when installing and operating medical electrical equipment. The customer or user of the ivWatch Model 400 should ensure that the device is installed and used in accordance with the electromagnetic environment guidelines specified in this section.

Be Cautious Near RF Sources. It is good practice to keep the ivWatch Model 400 monitor separated away from other equipment, such as hand-held transmitters, cellular phones and electrosurgical equipment that may generate strong radio frequency interference (RFI). Refer to the Electromagnetic Immunity Section, Separation Distances, in this manual for recommended minimum distances.

ELECTROMAGNETIC EMISSIONS

The Model 400 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 400 Monitor should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions EN 55011:2009 + A1:2010 (CISPR 11:2009 + A1:2010) EN60601-1-2:2007/AC:2010 Emission Requirements	Group 1 Class A	The Model 400 Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
Harmonic emissions IEC61000-3-2:2006 + A1:2009 + A2:2009	Class A	The Model 400 Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	AC input	

Consistent with its intended use as an aid to the detection of IV infiltration, the ivWatch Model 400 has no essential performance (as defined in IEC60601-1 3rd Edition). Electromagnetic immunity testing of the ivWatch Model 400 was performed with a criterion of no change in performance.

ELECTROMAGNETIC IMMUNITY

The Model 400 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 400 Monitor should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted disturbances, induced by RF fields IEC61000-4-6:2009	0.15 to 80 MHz 3Vrms	Test at AC mains, 0.15 to 80 MHz 3 Vrms AM: 80%, 1 kHz, 1.0-sec dwell	Portable and mobile RF communications equipment should be used no closer to any part of the Model 400 Monitor, including cables, than the recommended separation distance shown in the "Electromagnetic Immunity – Separation Distances" table in this section. 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:
Radiated radio-frequency (RF) Electromagnetic Fields IEC61000-4-3:2006 + A1:2008 + A2:2010	80 to 2500 MHz 3 V/m	80 to 2500 MHz 3 V/m AM: 80%, 1 kHz, 1.0-sec dwell	

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 strength in the location in which the Model 400 Monitor is used exceeds the applicable RF compliance level above, the Model 400 Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 400 Monitor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

ELECTROMAGNETIC IMMUNITY

The Model 400 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 400 Monitor should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment : Guidance
Electrostatic discharge (ESD) IEC61000-4-2:2009	±6 kV contact ±8 kV air	Contact ±2kV, ±4kV, ±6kV Air ±2kV, ±4kV, ±8kV	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 transients/burst IEC61000-4-4:2004 + Corrigendum 2006	±2 kV for power supply lines ±1 kV for input/output lines	Test at AC mains (100 VAC/60 Hz and 240 VAC 50 Hz) input voltages	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2006	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Test at AC mains (100 VAC/60 Hz and 240 VAC 50 Hz) input voltages	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 61000-4-11:2004	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Test at AC Mains for (100 VAC/60 Hz and 240 VAC 50 Hz) input voltage	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 400 Monitor requires continued operation during power mains interruptions, it is recommended that the Model 400 Monitor be powered from an interruptible power supply or a battery.
Power frequency (50- and 60-Hz magnetic field) IEC61000-4-8:2010	3 A/m	Test at AC mains for 120 VAC/60 Hz input voltage, 3 A/m 60 sec each axis, 3 axis	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

***NOTE**: U_T is the AC mains voltage prior to application of the test level.*

ELECTROMAGNETIC IMMUNITY - CONDUCTED AND RADIATED

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Model 400 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 400 Monitor 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 Model 400 Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC61000-4-6	0.15 to 80 MHz 3Vrms	3 Vrms	$d=1.2\sqrt{P}$
Radiated RF IEC61000-4-3	80 to 2500 MHz 3 V/m	3 V/m	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 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 strength in the location in which the Model 400 Monitor is used exceeds the applicable RF compliance level above, the Model 400 Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 400 Monitor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

ELECTROMAGNETIC EMISSIONS

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE MODEL 400 MONITOR

The Model 400 Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 400 Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 400 Monitor 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		
	.16 MHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2500 MHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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 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.*

SYMBOLS ON THE PRODUCT OR PACKAGE

Refer to the appropriate product or package label for symbols that apply.

	Consult the instructions for use
	Read the instruction manual for more information. Note that this symbol is intended to be a figure depicting a person reading a book (shown in white) enclosed within a blue circular background.
	Power On/Off. Note that this symbol is intended to be the Power On/Off symbol (circle with short vertical line at 12 o'clock position) in white, within a blue circular background.
	Mute audible tone in progress. Note that this symbol is intended to be the muted audible tone symbol (bell with an overlaid slash) in white, within a blue circular background.
Socket	Sensor cable socket
	Type BF applied part
	Hazard
IPX0	Ingress protection rating: No special protection
	USB compatible port
	DB9 serial port
	Indicates compliance with the WEEE (Waste Electrical and Electronic Equipment) Directive.
RoHS	RoHS (Restriction of Hazardous Substances). Dispose of this product according to local regulation. Do not dispose of this product in an unsorted municipal waste stream.
CLASSIFIED c UL us	Underwriter Laboratories (UL) tested to (CAN/CSA-C22.2 No. 60601-1) and US (UL 60601-1) electrical safety requirements.
REF	Model number
SN	Serial number
	Manufacturing date
MR	Indicates that the component is MR Unsafe (applies to the ivWatch Model 400 Patient Monitor and sensor cable). Note that this symbol is intended to be the capital letters "MR" (in bold black letters) within a red circle and slash.
	Expiration date in YYYY-MM-DD format (applies to disposable sensor receptacle)
STERILE EO	Indicates that the component has been sterilized using ethylene-oxide sterilization (applies to disposable sensor receptacle)
	Indicates that the component is a single-use component (applies to disposable sensor receptacle)

REPAIR AND MAINTENANCE

It is recommended that the following checks be performed every 12 months:

- Inspect the Patient Monitor for any mechanical and/or functional damage
- Inspect the labels for legibility

The monitor has no serviceable parts and requires no additional periodic maintenance or calibration. If it does not appear to be functioning and troubleshooting does not resolve the issue, contact Technical Support at (855) 489-2824.

DISPOSAL

Dispose of the monitor, packaging, and batteries according to local disposal and recycling requirements and regulations.

MRI SAFETY INFORMATION

⚠ **WARNING :** The monitor and sensor cable are MR Unsafe and pose a safety hazard if brought into the MR environment. Do not bring the monitor or sensor cable into the MRI scan room. The receptacle is MR Safe. Disconnect the sensor cable and monitor prior to taking the sensor receptacle into the MR environment.

***NOTE** : Do not bring any monitoring system components into the MR environment if the IV catheter has been removed prior to the MRI scan.*

If the IV catheter is not removed for the MRI scan:

1. Discontinue the monitoring run (see “Ending a Monitoring Run” on page 24).

2. Disconnect the sensor cable from the sensor receptacle.

3. Do not bring the monitor or sensor cable into the MR environment.

4. Inspect the IV insertion site after the MRI scan.

5. If the monitoring run is going to resume, see “Continuing a Monitoring Run with an Existing Patient” on page 25.

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USER MANUAL /
04 APPENDICES

For the most current release of this manual,
visit the ivWatch website at www.ivwatch.com/manuals.

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