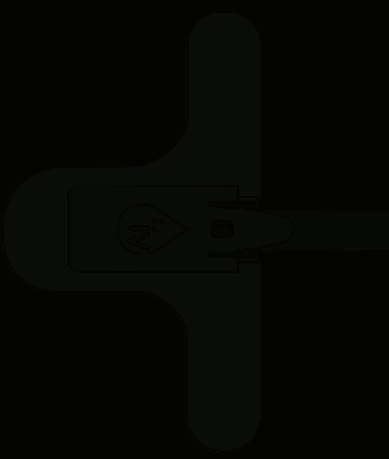
User Manual

Model 400 Patient Monitoring System

RX only



Early IV Infiltration Detection

Disclaimer

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For firmware version 5.1.1 and higher

To request a manual for a previous firmware version, contact ivWatch Technical Support at 855-489-2824, Option 2 or email at TechnicalSupport@ivWatch.com.

Patents

ivWatch, LLC is the owner of the following patents and other patents pending in the United States of America and other jurisdictions elsewhere in the world:

Australian Patent No. 2013257212
Australian Patent No. 2013257212
Australian Patent No. 2018211312
Canadian Patent No. 2867135
Japanese Patent Registration No. 6306572
Japanese Patent Registration No. 6555762
European Patent No. 2830488
Belgium Patent No. EP2830488
Switzerland Patent No. EP02830488
Germany Patent No. 602013042197.8
France Patent No. EP2830488
United Kingdom Patent No. EP2830488
Netherlands Patent No. EP2830488
Japanese Patent Registration No. 6301961
Japanese Patent Registration No. 6659645
United States Patent No. 9326686
Australian Patent No. 2013316021
Australian Patent No. 2017245353
European Patent No. 2830487
Belgium Patent No. EP2830487
Switzerland Patent No. EP02830487
Germany Patent No. 602013057210.0
France Patent No. EP2830487
United Kingdom Patent No. EP2830487
Italy Patent No. 502019000074894
Netherlands Patent No. EP2830487
Japanese Patent Registration No. 6386643
Japanese Patent Registration No. 6396904
Japanese Patent Registration No. 6599948
Japanese Patent Registration No. 6599949
Japanese Patent Registration No. 6673884
United States Patent No. 7826890
Australia Patent No. 2017245349
Australia Patent No. 2019202806
Belgium Patent No. EP2844316
Belgium Patent No. EP3545827
Belgium Patent No. EP3563758
Canada Patent No. 2867138
Europe Patent No. 2844316
Europe Patent No. 3545827
Europe Patent No. 3563758
France Patent No. EP2844316
France Patent No. EP3545827
France Patent No. EP3563758
Germany Patent No. 602013074826.8
Germany Patent No. 602013075564.7
Germany Patent No. 602013077345.9
Israel Certificate of Patent No. 234598
Israel Certificate of Patent No. 234599
Italy Patent No. 502021000061568
Italy Patent No. 502021000020207
Italy Patent No. 502021000032063
Japan Patent Registration No. 6760908
Japan Patent Registration No. 6761005
Japan Patent Registration No. 6761082
Japan Patent Registration No. 6791826
Netherlands Patent No. EP2844316
Netherlands Patent No. EP3545827
Netherlands Patent No. EP3563758
Switzerland Patent No. EP03545827
Switzerland Patent No. EP03563758
Switzerland Patent No. EP02844316
United Kingdom Patent No. EP2844316
United Kingdom Patent No. EP3545827
United Kingdom Patent No. EP3563758

CE Symbol	Applicable ivWatch Devices
CE 0123	ivWatch Patient Monitor and Extension Module
CE	Fiber Optic Sensor Cable, SmartTouch Sensor, Patient Cable, and Sensor Receptacle
EC REP EMERGO EUROPE Westervoortsedijk 60, 6827 AT Arnhem The Netherlands	Indicates the authorized representative in the European Community

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01

DEVICE DESCRIPTION

Device Description

The ivWatch Model 400 Patient Monitoring System provides continuous monitoring of peripheral intravenous (IV) sites to aid in the detection of conditions that may indicate an IV infiltration event. The monitoring system is an adjunct to the healthcare 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.

HOW MONITORING AND DETECTION WORK

The ivWatch Patient Monitoring System uses visible and near-infrared (IR) light to measure changes in the optical properties of tissue near the IV insertion site. A sensor placed adjacent to the patient's IV site takes measurements of tissue fluid volume changes. The monitoring system provides notifications (audible and visual) when it detects changes consistent with IV fluid leaking and pooling in the tissue adjacent to the IV.

IVWATCH SYSTEM COMPONENTS

1. ivWatch Patient Monitor
2. Extension Module
3. Fiber Optic Sensor Cable
4. Sensor Receptacle
5. Patient Cable
6. SmartTouch Sensor
7. Data Cable
8. Adapter and Power Cord

SAFETY INFORMATION

The following indications, warnings, and precautions are presented by topic and should be reviewed in their entirety prior to using the ivWatch Model 400 Patient Monitoring System.

Indications for use

The ivWatch Model 400 is indicated for the detection of subcutaneous infiltrations and extravasations of 10 cc or less of optically clear and iron sucrose infusates, as an adjunctive device to the clinical evaluation in the healthcare setting of adults and pediatrics with peripherally-inserted catheters (PIVs). 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 Model 400 is intended for use by healthcare practitioners who have been trained in the use of the device.

Intended use

The ivWatch Model 400 is intended to aid in the detection of infiltrations and extravasations during peripheral IV infusion therapy in pediatric and adult patients. The user profile is healthcare 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. The ivWatch Model 400 may have reduced sensitivity if used with dark, colored, or cloudy fluids.

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

This device is not for use in an explosive environment.

Oxygen-rich environments

Do not use the ivWatch Patient Monitor in an oxygen enriched environment, i.e. oxygen tents, hyperbaric chambers. Oxygen enriched environment does not refer to patients on breathing tubes.

Immersion in liquid

Do not immerse any of the ivWatch Model 400 components in liquid. The ivWatch Patient Monitor must be disconnected and the sensor removed from the patient prior to patient bathing to prevent electrical shock. Other than for bathing and MRI, the monitoring run should be stopped only when the IV is removed.

Indoor use

The ivWatch Patient Monitoring System is designed for indoor use and should not be exposed to extreme temperatures, humidity, or moisture. See “Specifications” section for additional information.

Magnetic resonance imaging (MRI)

The ivWatch Patient Monitor, Extension Module, Patient Cable, and SmartTouch Sensor pose a safety hazard if brought into the MRI environment. The Sensor Receptacle contains no ferromagnetic materials. Non-clinical testing has demonstrated that the Fiber Optic Sensor Cable is MR Conditional.

Please see the “MRI Safety Information” section of this manual for more information.

Use on intact skin only

The ivWatch Sensor Receptacle, Fiber Optic Sensor Cable, Patient Cable, and SmartTouch Sensor 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.

Defibrillation

The ivWatch Patient Monitoring System does not have a defibrillation-proof rating. Disconnect the device prior to defibrillation.

PRECAUTIONS

IV infusions of dark, colored, or cloudy fluids

The device has not been tested for monitoring infusions of dark, colored, or cloudy fluids. Dark, colored, or cloudy fluids block light and may reduce the system’s sensitivity.

Cable positioning

Route all cables and power cords to reduce the possibility of equipment or patient entanglement. Position excess cable length so that it does not pose a hazard.

Cleaning

Do not immerse any components of the ivWatch Model 400 Patient Monitoring System in liquid. Always disconnect the ivWatch Patient Monitor from the power supply prior to cleaning. Clean the system components as directed in “Cleaning the System for Reuse” section.

Compatibility

Use only components that are manufactured by ivWatch, LLC. Monitors, cables, 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 ivWatch Model 400 Patient Monitoring System (e.g., 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

Detection of infiltration events depends on the transmission of light through the patient’s skin; as such, the use of the ivWatch Patient Monitoring System is preferable in normal to low-light conditions. Ambient light is measured continuously by the device, and if above a specified threshold, the system will issue an ‘Excessive Light’ notification.

Light-blocking barriers

Do not place an opaque dressing under the Sensor Receptacle or SmartTouch Sensor. Light-blocking barriers (e.g., a 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 cables. Kinking or compressing the cables could damage the sensor, activating a notification on the ivWatch Patient Monitor to test the Fiber Optic Sensor Cable. Kinking or compressing the Fiber Optic Sensor 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.

Sterilization

Do not sterilize any components of the ivWatch Model 400 Patient Monitoring System. Sterilization may damage or reduce the system's sensitivity.

Tattooed, scarred, or bruised tissue

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

Trained healthcare practitioner

Do not rely solely on the ivWatch Patient Monitoring System for IV monitoring. All monitoring runs should be managed by a trained healthcare practitioner who is experienced in IV administration and management. The ivWatch Patient Monitoring System is not intended to replace IV monitoring by a trained healthcare practitioner.

Stacking the ivWatch Model 400 Monitor with other equipment

If the ivWatch Model 400 is adjacent or stacked with other equipment, monitor all the equipment to verify they are operating normally.

CLINICAL DEVICE SENSITIVITY

In controlled clinical studies, the ivWatch Model 400 Patient Monitoring System demonstrated a detection sensitivity of 99% of 10 cc or less of fluid in adults and adolescents 18 years of age and older. In a clinical study in a pediatric healthcare setting, the ivWatch Model 400 Patient Monitoring System detected 80% of infiltrations before detection by a trained clinician.

CLINICAL BENEFIT

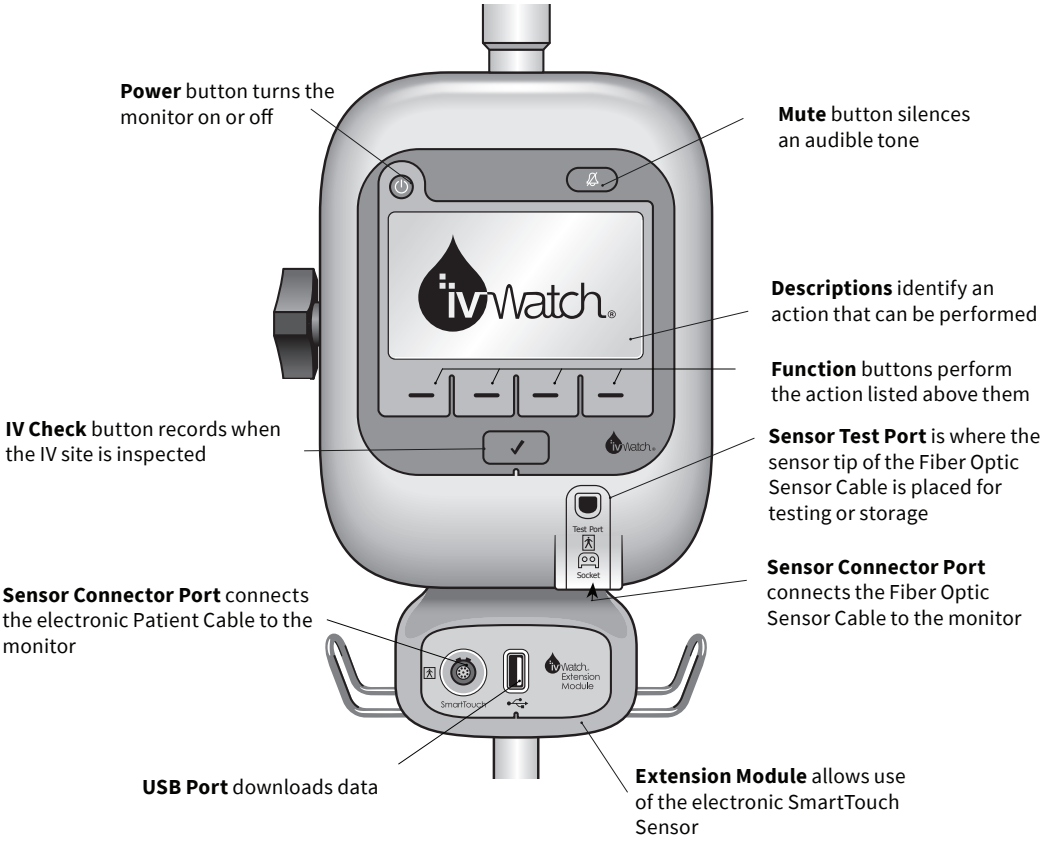
The clinical benefit of using the ivWatch Model 400 is early detection of infiltration and extravasation events.

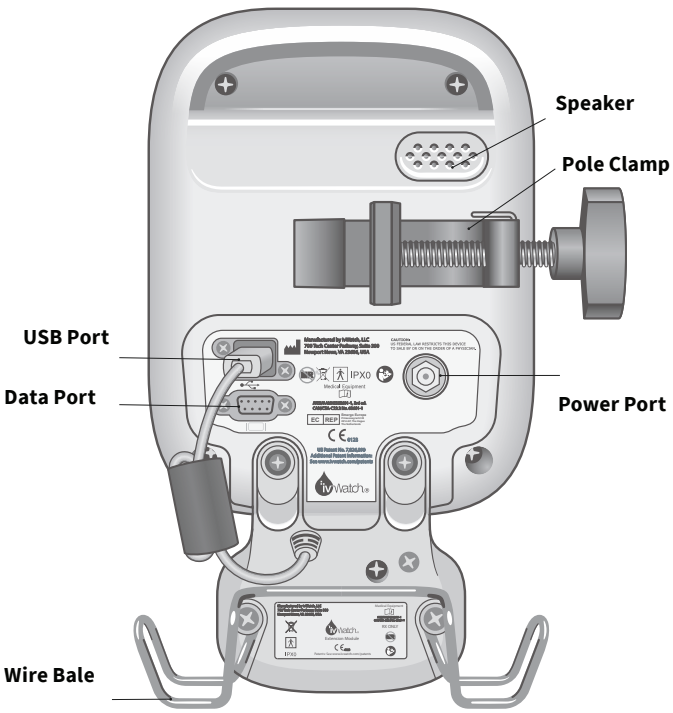
02

INSTRUCTIONS FOR USE

Instructions for Use

The ivWatch Patient Monitor and Extension Module shown below contain the software and user interface for the system. The components should be inspected for visible damage prior to use.





USING THE IVWATCH PATIENT MONITOR

The ivWatch Patient Monitor attaches to an IV pole and may be placed on the pole at a height of up to 5.5 feet. A grounded wall outlet is required to recharge the monitor battery.

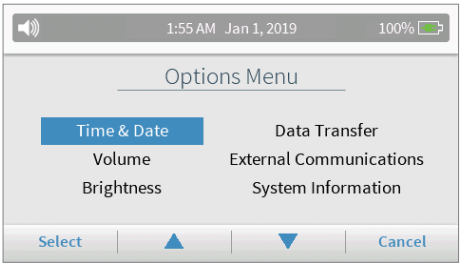
The ivWatch Patient Monitor can be used on battery power for limited periods of time, but during normal use, the monitor should be powered by the medical-grade AC power supply. The ivWatch Patient Monitor should be fully charged prior to its first use. Inspect the components for visible damage prior to use. See “Patient Monitoring Using Battery Power” section for more information.

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

Note:
The Power Port, Data Port, and USB Port are on the back of the ivWatch Patient Monitor. See “Specifications” section for additional information about the monitor ports and connectivity.

Options Menu

Use the “up” and “down” arrow buttons to highlight the desired option to change. Press the “Select” button to go to the highlighted option screen. Press the “Cancel” button to return to the previous screen.

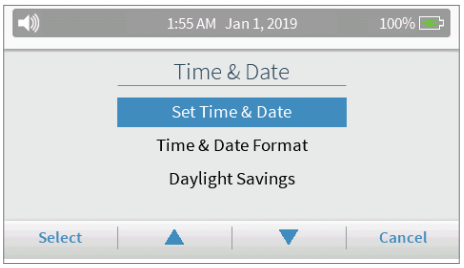


Options Menu screen

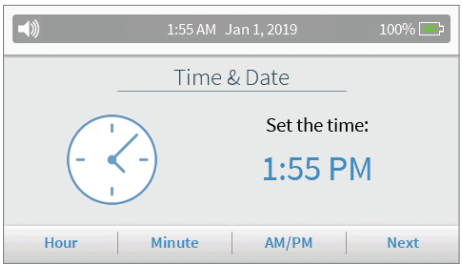
Modifying the Time & Date

To modify the Time & Date, select “Time & Date” in the Options Menu. Press the “Select” button when “Set Time & Date” is highlighted.

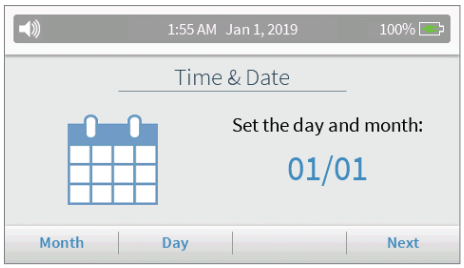
The time cannot be changed after a monitoring run has started. “Hour” and “Minute” buttons are upward-adjustable only.



Time & Date Menu screen

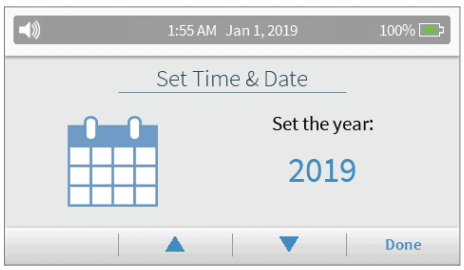


Press the “Next” button to accept the displayed time and view the Month/Day screen. “Month” and “Day” buttons are upward-adjustable only.



Press the “Next” button to accept the displayed month and day and to view the Year screen.

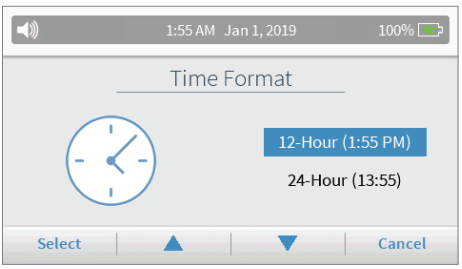
Use the “up” and “down” arrow buttons to select the year. Press the “Done” button to accept the displayed year and to return to the Time & Date Menu screen and then press the “Cancel” button to return to the Options Menu screen.

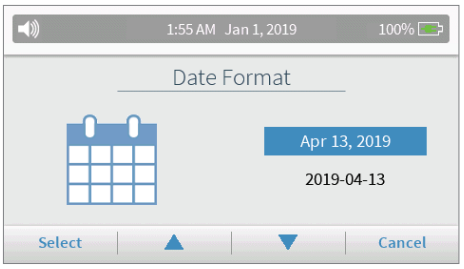


Changing the Time & Date Format

From the Time & Date Menu, select “Time & Date Format” to choose the desired time format (12-hour or 24-hour) and date format. Use the “up” and “down” arrow buttons to select the desired time format.

Press the “Select” button to accept the change and proceed to the Date Format screen or the “Cancel” button to return to the Options screen without changing the time format.





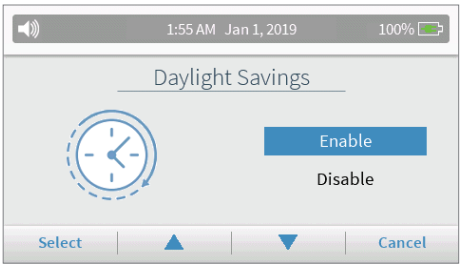
Use the “up” and “down” arrow buttons to select the desired date format.

Press the “Select” button to accept the change and proceed to the Time & Date Menu screen or the “Cancel” button to return to the Time & Date Menu screen without changing the date format.

Auto-Adjustment for Daylight Savings

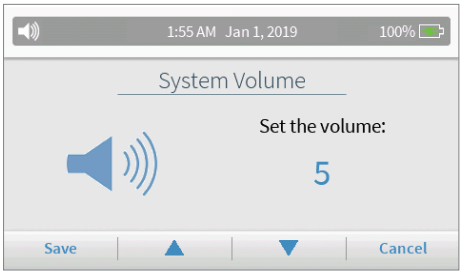
Press the “up” and “down” arrow buttons to highlight the desired option to enable or disable automatic daylight savings time adjustment (US Only).

Press “Select” to return to the Time & Date Menu screen and then “Cancel” to return to the Options Menu screen.



Changing the Volume Setting

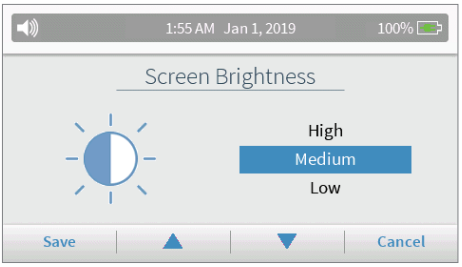
To modify the Volume, select “Volume” in the Options Menu.Use the “up” and “down” arrows buttons to select the volume level. Volume is demonstrated when highlighted. There are five volume levels. Press the “Save” button to accept the change or the “Cancel” button to return to the Options screen without changing the volume level.



Changing the Screen Brightness

To modify the Brightness, select “Brightness” in the Options Menu. Use the “up” and “down” arrow buttons to select the brightness level. Brightness is demonstrated when highlighted.

Press the “Save” button to accept the change or the “Cancel” button to return to the Options screen without changing the screen brightness.

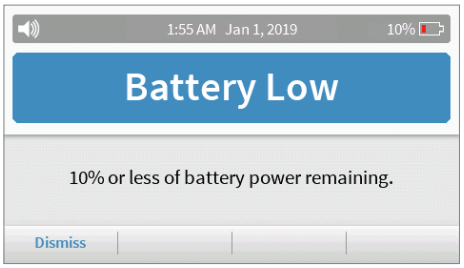


Patient Monitoring Using Battery Power

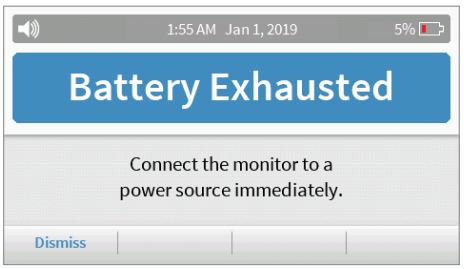
The ivWatch Patient Monitor can be used on battery power for at least 5 hours when fully charged. During normal operation, the monitor should be powered by the medical-grade AC power supply included in the package.

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:



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



Press the “Dismiss” button to clear these notification messages.

Note:

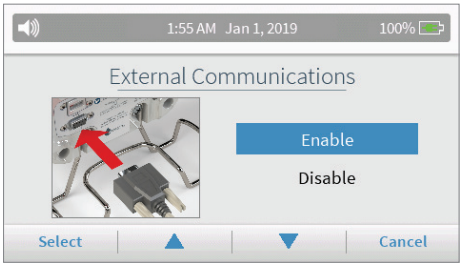
Low-battery messages are accompanied by audible tones; pressing the “Dismiss” button removes the notification message and mutes the audible tone.

Setting Up External Communications

External Communications can be setup with third-party systems to sync real-time monitoring historical event data, which can then be incorporated into central monitoring and documentation solutions.

Procedure:

1. Connect the ivWatch Data Cable to the Data Port in the back of the ivWatch Patient Monitor.
2. See partner system user manual for additional information regarding connection settings and equipment. If necessary, connect any additional cables or adapters to the ivWatch Data Cable.
3. On the ivWatch Patient Monitor, select “External Communications” in the Options Menu and use the “up” and “down” arrow buttons to highlight and select “Enable.”



4. On the next screen, use the “up” and “down” arrows to highlight and select the appropriate partner communications protocol from the table on the next page.

5. Verify that the sync icon located at the top left of the screen, is visible and not blinking.

Note:

Patient identification data is not entered into the ivWatch Patient Monitor and therefore no patient specific data is stored.

Partner System	Communications Protocol Selection	Supplementary Information	Firmware Version
Philips IntelliBridge EC10	ivWatch Custom Protocol	Use IntelliBridge EC5 cable to connect the ivWatch Data Cable to the Philips IntelliBridge system.	4.2.0 or higher

* If your communications partner is not listed above, please refer to the most current release of the user manual at www.ivWatch.com.

Turning Off the ivWatch Patient Monitor

To shut the monitor off, complete the following steps:

1. Press and hold the “Power” button. The Shutdown screen appears.
2. Press the “Yes” button to turn off the ivWatch Patient Monitor (and end a monitoring run in progress).

Shutdown screen

3. Unplug the electrical plug from the grounded wall outlet, coil the power cord, and place it on the wire bale.
4. If monitoring for this patient is finished, see “Cleaning the System for Reuse” section.

For temporary storage in patient rooms and hospital work areas:

1. Do not disconnect any cables or power plug from the ivWatch Patient Monitor.
2. Carefully coil the Fiber Optic Sensor Cable or Patient Cable loosely around the wire bale.

For long-term storage:

1. Disconnect any cables or power plugs from the ivWatch Patient Monitor.
2. Carefully coil the Fiber Optic Sensor Cable or Patient Cable loosely around the wire bale.
3. Store the components in a dry environment.

Note:

The monitoring history is stored and can be seen on the “History” screen. See “Historical Event Data” section for information about reviewing and saving data.

MONITORING IVS WITH IVWATCH SENSORS

There are two sensor options when monitoring an IV with the ivWatch system. One option is the Fiber Optic Sensor Cable, which is a reusable 10-foot fiber optic cable. A single-use Sensor Receptacle is used to attach the Fiber Optic Sensor Cable to the patient. Another sensor option is the SmartTouch Sensor, which is a single-use sensor that connects to a 12-foot reusable Patient Cable.

Monitoring with the Fiber Optic Sensor Cable

Setting up a monitoring run

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

To set up a monitoring run, complete the following steps:

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

Start-up Screen

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.

The volume and display brightness settings are demonstrated when the ivWatch Patient Monitor is turned on.

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

Note:
Allow the ivWatch Patient Monitor to run in monitoring mode for at least 1 minute before starting the infusion. This allows the monitor to take critical baseline measurements.

⚠ Caution:

Dark, colored, or cloudy fluids may reduce the system's sensitivity.

Do not place an opaque dressing under the Sensor Receptacle. Light-blocking barriers (e.g., 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.

Note:

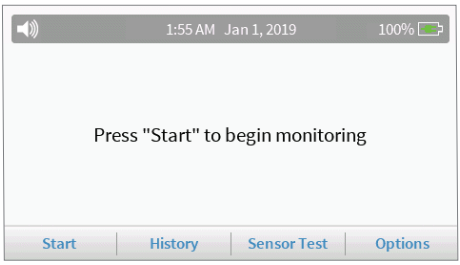
During normal operation, the monitor should be plugged into a power source, but for ambulatory activities, a fully charged monitor can be used on battery power for limited periods of time. See "Patient Monitoring Using Battery Power" section.

Note:

Volume, brightness, date, and time settings can be changed on the Options screen. Follow the instructions on the display or see "Options Menu" section.

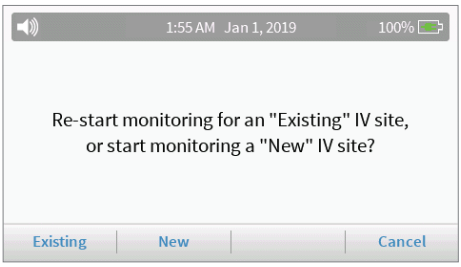
6. Connect a Fiber Optic Sensor Cable to the ivWatch Patient Monitor (as shown).

7. Press the “Start” button to begin the monitoring run.

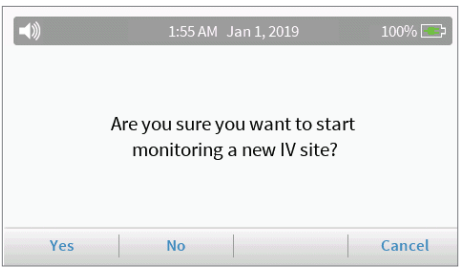


8. To start monitoring a new IV site:

a. Press the “New” button to start a monitoring run with a new IV site.



b. Confirm that the IV site is new by pressing the “Yes” button.



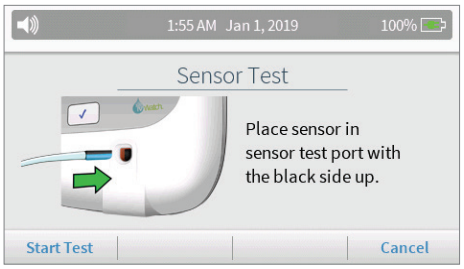
Note:

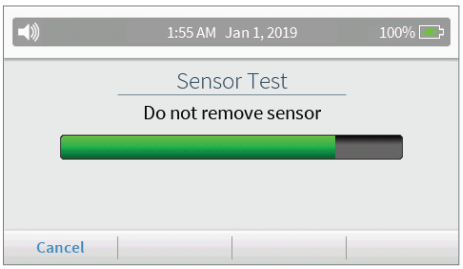
The date and time should be verified prior to beginning a monitoring run. The time cannot be changed after a monitoring run has started. The Time & Date options are not available during a monitoring run to prevent errors in data collection.

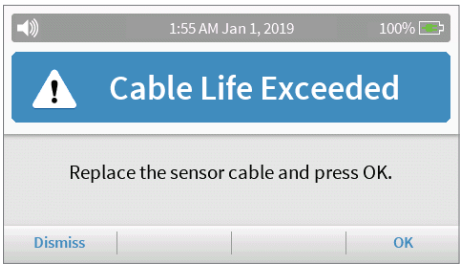
⚠ Caution:

If you are using a new Fiber Optic Sensor Cable (one that was just removed from the packaging), be sure to remove any dust covers which are attached to the optical interface of the fibers (on the proximal end) prior to inserting that end of the Fiber Optic Sensor Cable into the sensor port on the ivWatch Patient Monitor.

c. Follow the on-screen prompts by placing the sensor in the sensor test port and pressing the “Start Test” button.

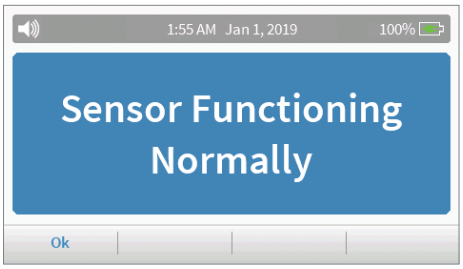






If a Cable Life Exceeded screen is issued, replace the Fiber Optic Sensor Cable and perform the Sensor Test again. Cable Life Exceeded only applicable to software versions 5.1.5 and lower.

d. Press “OK” to proceed to sensor placement. If the Fiber Optic Sensor Cable passes the sensor test, the Sensor Functioning Normally screen will be issued.



9. To re-start monitoring of existing IV site, for example, when monitoring was stopped for a patient to receive an MRI and monitoring is needed again on the same IV site: Press the “Existing” button to start a monitoring run with an existing IV site and proceed to sensor placement.

Note:
A sensor test will be conducted to verify the integrity of the Fiber Optic Sensor Cable. This can also be done on the Home screen by selecting “Sensor Test” (For additional information, see “Testing the Fiber Optic Sensor Cable” section). During a sensor test, if the cable has been damaged, a “Sensor Not Functioning” error message will appear (For more information see “Error Message Table” section).

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

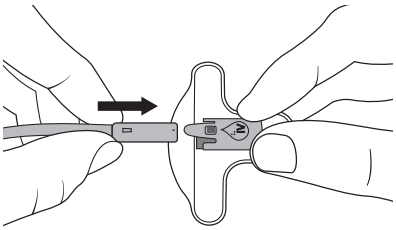
Note:
If the Fiber Optic Sensor Cable has been damaged (or if damage is suspected), press “Cancel” to return to the Home screen. From the Home screen, press “Sensor Test” to test the integrity of the Fiber Optic Sensor Cable. Follow the on-screen instructions or see the “Troubleshooting” section for testing the Fiber Optic Sensor Cable. Resume set up with a working Fiber Optic Sensor Cable.

10. Insertion of the sensor into the Sensor Receptacle:

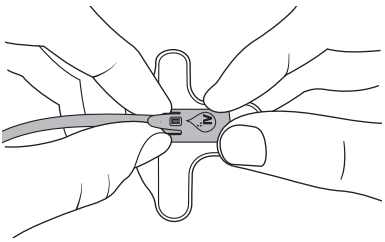
a. Ensure that the sensor is clean prior to use. If necessary, wipe the sensor head with isopropyl alcohol and allow it to dry.

b. Remove the Sensor Receptacle from the package.

c. Hold the Fiber Optic Sensor Cable by the sheath to prevent damage to the cable during insertion.



d. Fully insert the sensor head into the Sensor Receptacle until there is a “click” sound.



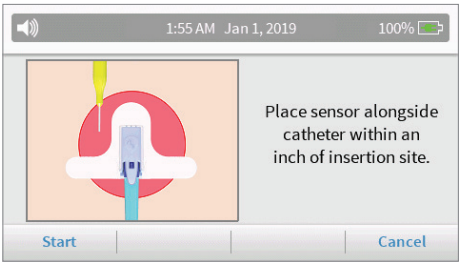
Note:

Ensure that the tab on the sensor snaps into the slot of the Sensor Receptacle.

11. Placing the sensor:

a. Properly route the Fiber Optic Sensor Cable from the ivWatch Patient Monitor to the patient.

b. Position the sensor adjacent to the catheter between the insertion site and the catheter tip. The sensor should be placed within an inch of the insertion site as shown on the monitor display. Do not stretch the Sensor Receptacle during application.



⚠ Caution:

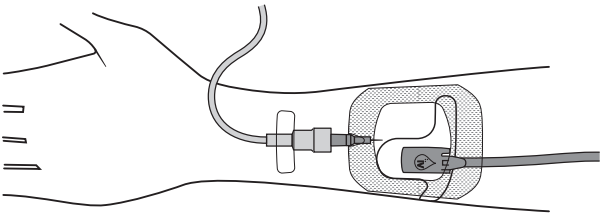
Route the Fiber Optic Sensor Cable to reduce the possibility of equipment or patient entanglement. Position excess cable length so that it does not pose a hazard.

Note:

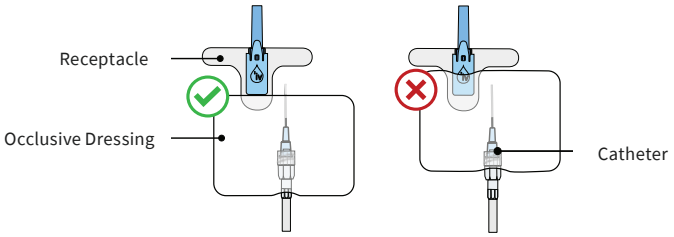
Avoid placement of the sensor directly over a large vein.

The Sensor Receptacle should not be removed and placed again. If it must be removed, use a new Sensor Receptacle for that patient.

The Sensor Receptacle has been sterilized. If the packaging is damaged or unintentionally opened before use, please discard and use a new Sensor Receptacle.



12. If it's preferred for the Sensor Receptacle to be under an occlusive dressing, cover the IV site and Sensor Receptacle with an occlusive dressing according to facility protocols. The occlusive dressing should not be placed over the blue portion of the Sensor Receptacle.



13. Secure the Fiber Optic Sensor Cable, ensuring that the cable is not kinked or compressed. Use facility protocols for securing the IV line to the patient.

14. Press the "Start" button to begin the monitoring run.

Monitoring screen

15. Setup is complete, and the monitoring run is in progress. Proceed to "IV Monitoring" section.

Note:

The droplet animation in the upper corner of the display shows that monitoring is active.

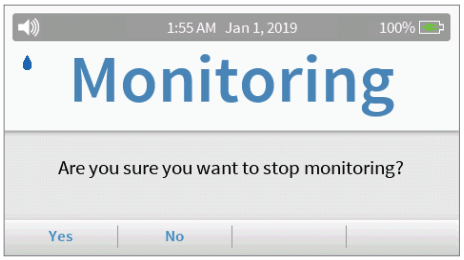
The elapsed monitoring time is displayed instead of the time and date at 3-second intervals, starting after the first minute that monitoring is active.

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” button.
2. Press the “Yes” button to confirm ending the monitoring run.

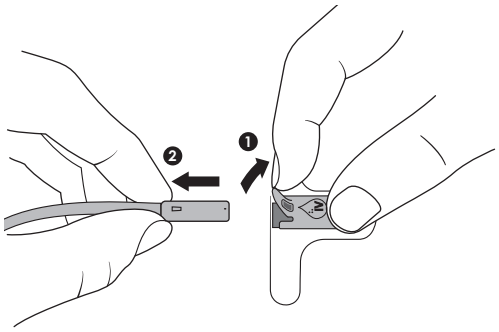


Monitoring screen

Note:

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

3. Carefully remove the Sensor Receptacle from the patient with the sensor still inserted in the Sensor 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.
6. Clean the sensor head and place it in the sensor test port to protect it from damage (see “Cleaning the System for Reuse” section).
7. Coil the Fiber Optic Sensor Cable and place it on the wire bale below the ivWatch Patient Monitor. If the monitoring run is going to resume with the same patient, proceed to “Setting up a Monitoring Run” section.
8. If the monitoring run is finished, proceed to “Turning Off the ivWatch Patient Monitor” section.

Note:

Do not reuse the Sensor Receptacle.

Note:

The monitoring history is stored and can be seen on the “History” screen. See “Historical Event Data” section for information about reviewing and saving data.

Monitoring with the SmartTouch™ Sensor

Setting up a monitoring run

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

To set up a monitoring run, complete the following steps:

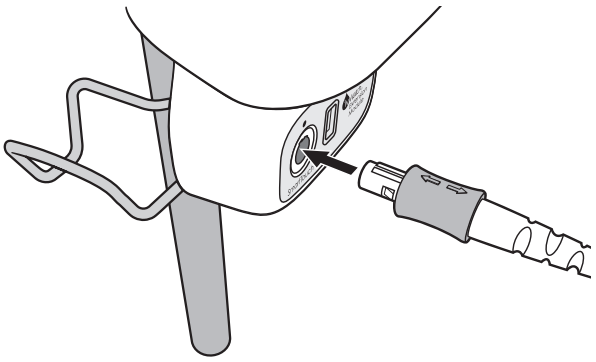
1. Use the clamp to securely mount the ivWatch Patient Monitor on the IV pole. Ensure the Extension Module is secured to the ivWatch Patient Monitor and connected via the USB cable.
2. Position the monitor so that the display is easily viewed.
3. Press "Power" on the front of the monitor. The Start-up screen appears briefly.

Start-up Screen

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.

The volume and display brightness settings are demonstrated when the ivWatch Patient Monitor is turned on.

5. Check the time, date, and battery status as displayed on the top of the Home screen.
6. Connect the Patient Cable to the Extension Module.



7. Remove the SmartTouch Sensor from its packaging.

Note:

Allow the ivWatch Patient Monitor to run in monitoring mode for at least 1 minute before starting the infusion. This allows the monitor to take critical baseline measurements.

⚠ Caution:

Dark, colored, or cloudy fluids may reduce the system's sensitivity.

Do not place an opaque dressing under the SmartTouch Sensor. Light-blocking barriers (e.g., 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.

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 limited periods of time. See "Patient Monitoring Using Battery Power" section.

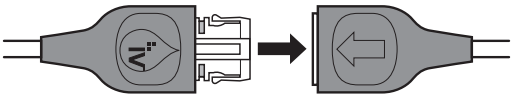
Note:

Volume, brightness, date, and time settings can be changed on the Options screen. (Follow the instructions on the display or see "Options Menu" section).

Note:

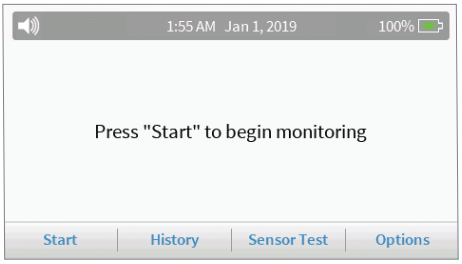
The date and time should be verified prior to beginning a monitoring run. The time cannot be changed after a monitoring run has started. The Time & Date options are not available during a monitoring run to prevent errors in data collection.

8. Connect the SmartTouch Sensor to the Patient Cable by connecting both ends of the blue connector.



> **⚠ Caution:**
>
> Route the SmartTouch Sensor and Patient Cable to reduce the possibility of equipment or patient entanglement. Position excess cable length so that it does not pose a hazard.

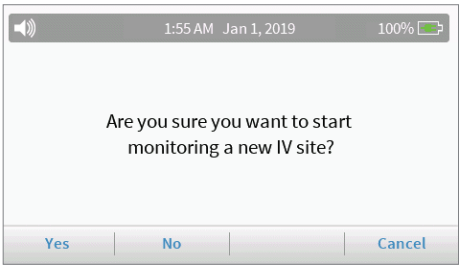
9. Press the “Start” button to begin the monitoring run.



10. To start monitoring a new IV site:

a. Press the “New” button to start a monitoring run with a new IV site.

b. Confirm that the IV site is new by pressing the “Yes” button.

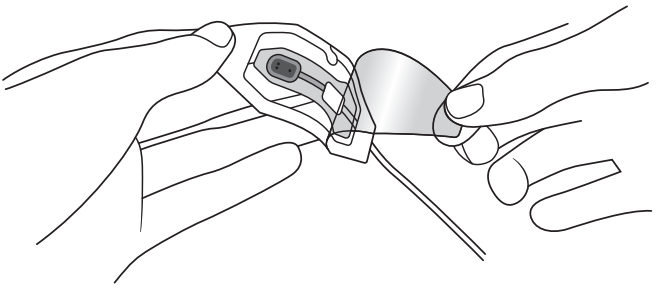


11. To re-start monitoring of existing IV site, for example, when monitoring was stopped for a patient to receive an MRI and monitoring is needed again on the same IV site: Press the “Existing” button to start a monitoring run with an existing IV site and proceed to sensor placement.

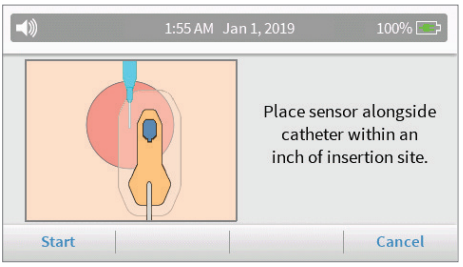
> **Note:**
>
> Do not change the time before re-starting a monitoring run; otherwise, timeline data errors will be displayed. The Time & Date option is not available during a monitoring run.

12. Placing the sensor:

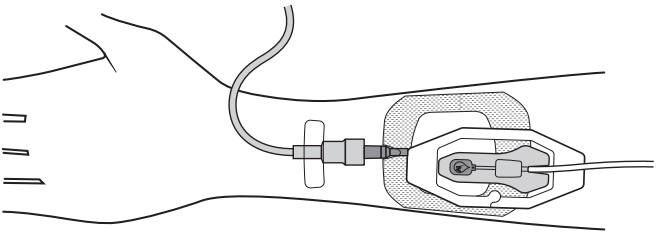
a. Remove the clear liner from the bottom of the SmartTouch Sensor.



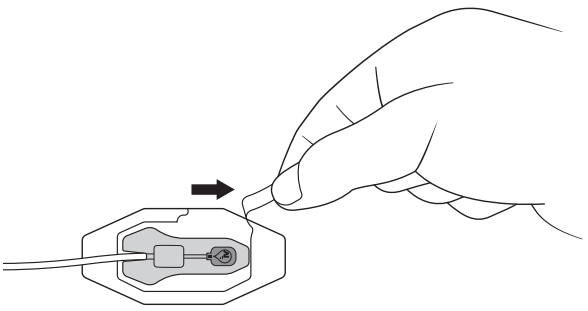
b. Position the SmartTouch Sensor adjacent to the catheter between the insertion site and the catheter tip. The sensor should be placed within an inch of the insertion site as shown on the monitor display. Do not stretch the sensor during application.



SmartTouch Sensor placement screen



c. Remove the top white border from along the edges of the sensor's polyurethane layer.



⚠ Caution:

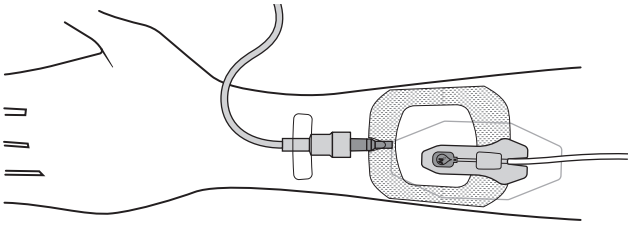
If you are using a new SmartTouch Sensor (one that was just removed from the packaging), be sure to remove the bottom clear liner, which may obstruct the optical interface of the sensor prior to placing the sensor near the IV site.

Note:

Avoid placement of the sensor directly over a vein.

The SmartTouch Sensor has been sterilized. If the packaging is damaged or unintentionally opened before use, please discard and use a new SmartTouch Sensor.

The SmartTouch Sensor is not waterproof. Avoid contact with water or other fluids (wiping, washing, immersion, etc.).



13. Press the “Start” button to begin the monitoring run. The Monitoring screen appears.

Monitoring screen

14. Setup is complete, and the monitoring run is in progress. Proceed to “IV Monitoring” section.

Note:

The droplet animation in the upper corner of the display shows that monitoring is active.

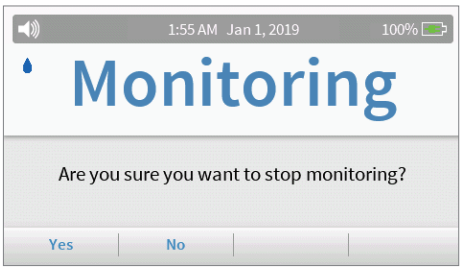
The elapsed monitoring time is displayed instead of the time and date at 3-second intervals, starting after the first minute that monitoring is active.

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” button.
2. Press the “Yes” button to confirm ending the monitoring run.



Monitoring screen

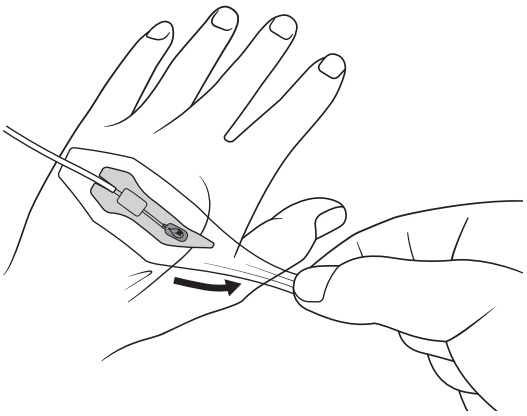
3. Disconnect the Patient Cable from the SmartTouch Sensor by pulling the two ends of the blue connectors away from each other.

Note:

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

4. Carefully remove the SmartTouch Sensor from the patient.

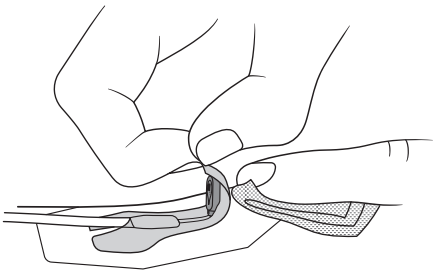
a. Parallel stretch method: Gently stretch the clear dressing layer (bottom-most layer) of the sensor parallel to the patient's skin. Work your way around the sensor, gently stretching the clear dressing layer parallel to the skin until the sensor releases from the patient.



Note:

Do not reuse the SmartTouch Sensor.

b. Electronics-only method: If the patient's IV site will continue to be used and removing the clear dressing layer of the SmartTouch will disrupt the IV site, use adhesive remover to lift up on the front tab of the tan layer of the sensor. Work the adhesive remover underneath the tan cloth layer to carefully pull away the electronics and tan cloth portion of the sensor from the IV site. Only the clear dressing layer will stay on the patient.



5. Dispose of the SmartTouch Sensor.
6. Clean the Patient Cable (see "Cleaning the System for Reuse" section).
7. Coil the Patient Cable and place it on the wire bale below the Extension Module. If the monitoring run is going to resume with the same patient, on the same IV site, proceed to "Setting Up a Monitoring Run" section.
8. If the monitoring run is finished, proceed to "Turning Off the ivWatch Patient Monitor" section.

Note:

The monitoring history is stored and can be seen on the "History" screen. See "Historical Event Data" section for information about reviewing and saving data.

IV MONITORING

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

The Blue Monitoring screen shows that a monitoring run is active, with no notifications or error conditions.

Note:

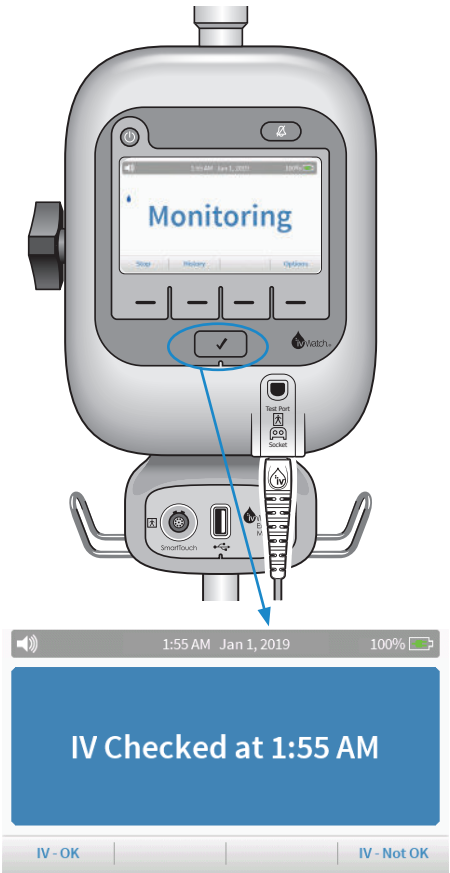
The elapsed monitoring time is displayed instead of the time and date at 3-second intervals, starting after the first minute that monitoring is active. The droplet animation in the upper corner of the display shows that monitoring is active.

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

Note:

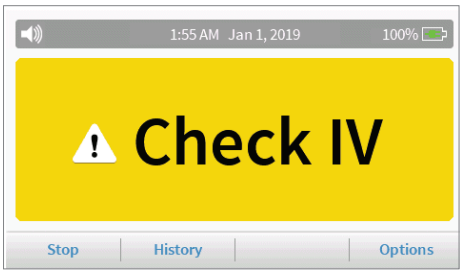
Monitoring sensitivity for an individual patient may vary according to medical status, skin condition, age, and the duration of the monitoring run.

Press " ✓ " on the front of the monitor (the IV Check button) whenever the IV insertion site is inspected to record the action on the History screen. The ivWatch Patient Monitor will display an IV Checked confirmation screen showing the time at which the IV Check button was pressed. Next, select the option that best describes the status of the inspected IV insertion site per facility protocols ("IV-OK" or "IV-Not OK"). If no option is selected in 15 seconds, the screen will return to the monitoring screen.



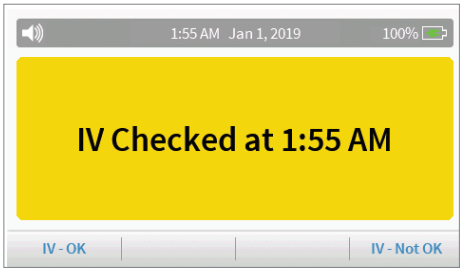
Yellow Notifications

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



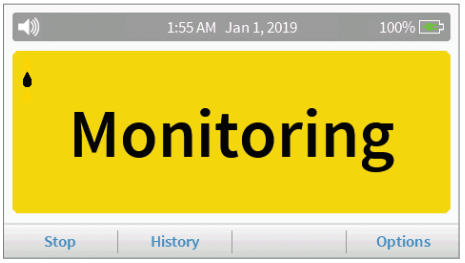
Yellow Check IV

1. Check the IV insertion site per facility protocols for IV administration and management.
2. Press the "IV Check" button to indicate that the IV site was inspected. Select the option that best describes the status of the inspected IV site per facility protocols ("IV-OK" or "IV-Not OK"). If no option is selected within 15 seconds, the screen will return to a yellow monitoring screen.



Yellow IV Checked

3. During a Yellow Check IV notification state, the system allows the monitoring run to continue, but the screen remains in the yellow status. If conditions change and there is no further detection of an infiltration event, monitoring returns to normal (blue) status.



Yellow Monitoring

⚠ Caution:

Do not rely solely on the ivWatch Patient Monitoring System for IV monitoring. All monitoring runs should be managed by a trained healthcare practitioner who is experienced in IV administration and management. The ivWatch Patient Monitoring System is not intended to replace IV monitoring by a trained healthcare practitioner.

Note:

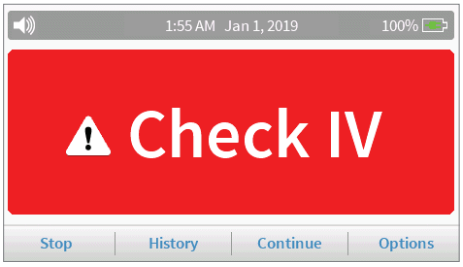
The notification tone can be muted by pressing the Mute button. Audible tones are silenced for 2 minutes after Mute has been pressed.

Note:

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

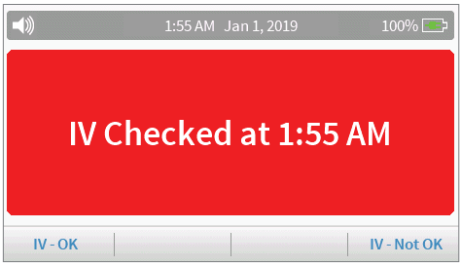
Red Notifications

If conditions indicate a probable infiltration, the Red Check IV screen appears, accompanied by an audible tone.



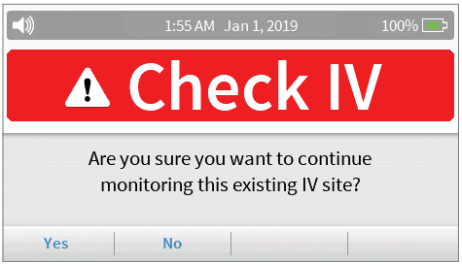
Red Check IV

1. Check the IV insertion site per facility protocols for IV administration and management.
2. Press the “IV Check” button to indicate that the IV site was inspected. Select the option that best describes the status of the inspected IV site per facility protocols (“IV-OK” or “IV-Not OK”). If no option is selected within 15 seconds, the screen will return to a Red Check IV screen.



Red IV Checked

3. During a Red Check IV notification state, the monitoring run can be continued. Press the “Continue” button and press “Yes” to confirm the monitoring run should be continued. This will return the monitor display to a blue monitoring state with a red bar at the top of the screen showing the date and time of the last Red Check IV event. If the monitoring run is stopped and re-started with an “Existing” IV site, the red bar indicating the time and date of the last Red Check IV event will still be displayed.



Note:

Stop a monitoring run after a probable infiltration event (see “Ending a Monitoring Run” section for the type of sensor in use) or press the “Continue” button to continue the monitoring run. The monitoring run can be continued without loss of the patient history through either of these workflows.

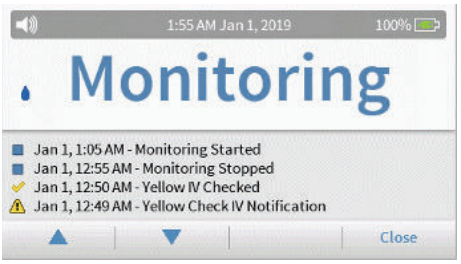
Note:

The red bar will not be displayed if the monitoring run is stopped and re-started with a “New” IV site. Also, if the patient monitor is turned off, the red bar will not be displayed during the next monitoring run.

4. To stop the monitoring run, proceed to the corresponding "Ending a Monitoring Run" section for the type of sensor in use.

HISTORICAL EVENT DATA

The History screen shows historical events, including IV checks, yellow notifications and red notifications.



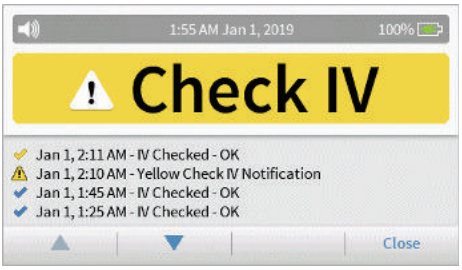
History Event Log

The icons indicate the following monitoring events:

- Start / Stop Monitoring
- IV Checked
- Yellow Check IV Event
- IV Checked - Yellow Check IV
- Red Check IV Event
- IV Checked - Red Check IV
- Other Error Event (i.e. Sensor Monitoring Error)

To review historical event data, complete the following steps:

1. Press the "History" button.
2. Press the "down" arrow button to see past events (e.g. when monitoring was started) or the "up" arrow button to see newer events.
3. Press the "Close" button to return to the previous screen.



Yellow Check IV with History Event Log

Note:

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

03

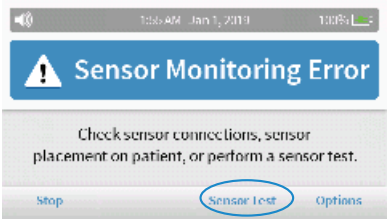
TROUBLESHOOTING

Troubleshooting

The ivWatch Model 400 Patient Monitoring System does not require periodic calibration. If it does not appear to be functioning and troubleshooting does not resolve the issue, contact Technical Support at 855-489-2824, Option 2 or email at TechnicalSupport@ivWatch.com.

Testing the Fiber Optic Sensor Cable

Fiber Optic Sensor Cable Test Steps



"Sensor Test" button location on monitor screen

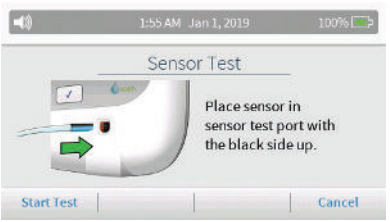
To test the Fiber Optic Sensor Cable, complete the following:

Ensure that the ivWatch Patient Monitor is on and the Fiber Optic Sensor Cable is connected to the monitor.

From the Home screen (or the Sensor Monitoring Error screen), press the "Sensor Test" button.

Note:

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

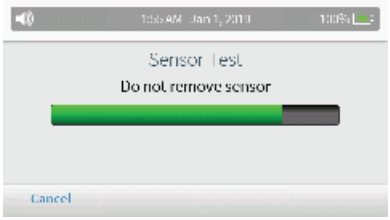


Note: Do not remove the sensor during testing.

Insert the sensor head into the sensor test port with the black side facing up as shown on the display that appears when the "Sensor Test" button is pressed.

To begin the sensor test, press the "Start Test" button.

a. Press the "Cancel" button to end the test and return to the previous screen.



Once the "Start Test" button is pressed, the sensor test begins. The display will change to show a progress bar that depicts the sensor test progress.

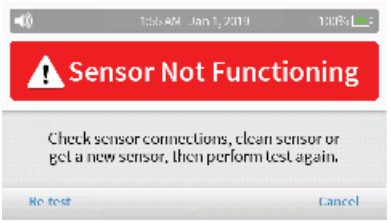
a. Press the "Cancel" button to interrupt the sensor test and return to the Home screen or Sensor Monitoring Error screen.

a. If the Fiber Optic Sensor Cable is functioning, the blue "Sensor Functioning Normally" message appears.

b. Press the "OK" button to return to the Home screen or Sensor Monitoring Error screen.

Note: If the sensor test was initiated from the Sensor Monitoring Error screen, pressing "Ok" will always return the monitor to that error screen along with the audible tone. The state will change to the normal "Monitoring" screen after a short time if the problem was resolved.

If the Sensor Monitoring Error screen continues, the error is likely due to another issue rather than the sensor cable. See the "Troubleshooting Table" section for additional solutions that may resolve the monitoring error.

Fiber Optic Sensor Cable Test Steps (continued)	
	a. If the Fiber Optic Sensor Cable is not functioning, the red "Sensor Not Functioning" error message appears. b. Follow the instructions on the display prior to re-testing the sensor. c. Press the "Re-test" button to perform the test again, or press "Cancel" to return to the Home screen or Sensor Monitoring Error screen. d. If performing a re-test of the sensor cable results in another "Sensor Not Functioning" error, replace the Fiber Optic Sensor Cable and perform another sensor test to ensure the new cable is functioning properly.

Troubleshooting Table

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

Problem	Possible Cause	Possible Solution
The ivWatch Patient Monitor will not turn on. The ivWatch Patient Monitor display remains blank.	The power supply is not connected. The ivWatch Patient Monitor may be turned off. The battery may be depleted. The display or the ivWatch Patient Monitor is not functioning.	Confirm that the ivWatch Patient Monitor's electrical plug is in a grounded wall outlet. Press "Power" to confirm that the ivWatch Patient Monitor is on. Replace the ivWatch Patient 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" section).	The Fiber Optic Sensor Cable is not properly connected to the ivWatch Patient Monitor, or to the Sensor Receptacle on the patient. The Patient Cable is not properly connected to the Extension Module, or to the SmartTouch Sensor on the patient. The sensor on the Fiber Optic Sensor Cable is not functioning properly.	Verify that there are no kinks, bends, or breaks in the Fiber Optic Sensor Cable, Patient Cable, or SmartTouch Sensor. Verify the patient is not lying on any of the cables. Verify that the Fiber Optic Sensor Cable is correctly inserted into the port in the ivWatch Patient Monitor, and the sensor into the Sensor Receptacle.

Troubleshooting Table (continued)

Problem	Possible Cause	Possible Solution
A Sensor Monitoring Error or a Sensor Not Functioning error message appears. (See the "Error Message Table" section)-continued.	The sensor on the SmartTouch Sensor is not functioning properly. The Sensor Receptacle is not properly attached. The SmartTouch Sensor is not properly attached. The sensor on the Fiber Optic Sensor Cable is fouled/dirty. The sensor on the SmartTouch Sensor is fouled/dirty. The patient is moving excessively.	Verify that the Patient Cable is correctly connected to the Extension Module, and to the SmartTouch Sensor. Verify that the sensors and connectors are clear of obstructions. Verify that the Sensor Receptacle or SmartTouch Sensor is properly attached. Verify that the sensors are clean. Perform a sensor test for the Fiber Optic Sensor Cable. Replace the Fiber Optic Sensor Cable, Patient Cable, or SmartTouch Sensor.
The monitor prompts to perform a Sensor Test when attempting to start a New monitoring run with a SmartTouch Sensor. *Applicable to software version 5.2.0.*	The SmartTouch Sensor, Patient Cable, or Extension Module is not properly attached. The SmartTouch Sensor, Patient Cable, Extension Module, or Patient Monitor is damaged.	Verify that the SmartTouch Sensor, Patient Cable, and Extension Module are correctly connected. Replace the SmartTouch Sensor. Replace the Patient Cable. If the monitor continues to prompt for a Sensor Test after replacing the SmartTouch Sensor and Patient Cable, the problem is likely a monitor hardware issue and will require troubleshooting by a trained technician.
A Sensor Cable Life Exceeded error message appears (See the "Error Message Table" section). *Applicable to software versions 5.1.5 and lower.*	The Fiber Optic Sensor Cable has been used for monitoring in excess of 10 line days (or 240 hours).	Replace the Fiber Optic 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. Restart the Patient Monitor.
External Communications Interrupted message appears and/or the sync icon is blinking with an "X" icon.	The ivWatch Data Cable is not connected or has become disconnected. The partner device has lost connection or has been turned off.	Verify that the cables are connected and the partner device is on.

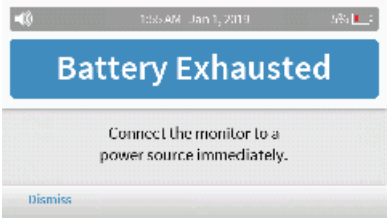
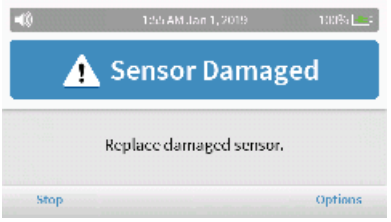
Problem	Possible Cause	Possible Solution
Redness, itching, inflammation, or a similar reaction has occurred on the skin under or near the Sensor Receptacle.	The patient has had an allergic or irritant reaction to the adhesive used on the Sensor Receptacle.	Remove the Sensor Receptacle and discontinue monitoring. Follow the facility protocol for allergic reactions.
Redness, itching, inflammation, or a similar reaction has occurred on the skin under or near the SmartTouch Sensor.	The patient has had an allergic or irritant reaction to the adhesive used on the SmartTouch Sensor.	Remove the SmartTouch Sensor and discontinue monitoring. Follow the facility protocol for allergic reactions.

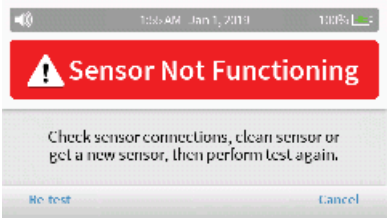
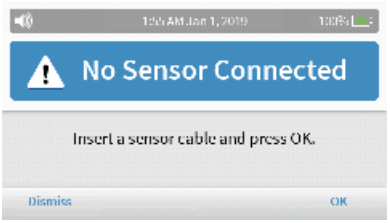
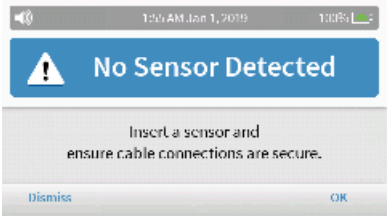
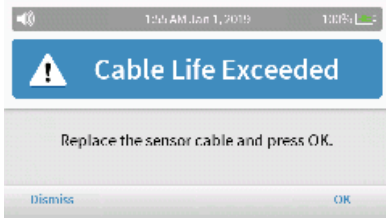
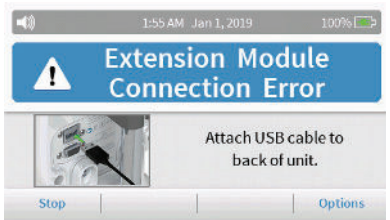
Error Message Table

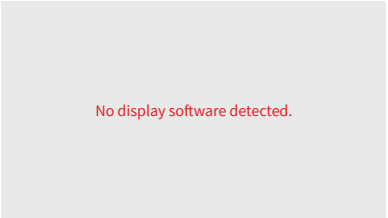
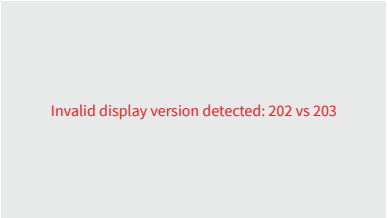
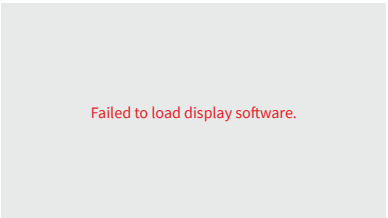
The Error Message Table shows common error screens and describes how to resolve them.

Note: If errors persist after performing the listed possible solutions, contact Technical Support at 855-489-2824, Option 2 or email at TechnicalSupport@ivWatch.com.

Error Message	Possible Solution
	Sensor Monitoring Error - Fiber Optic Sensor A sensor error was detected during a Fiber Optic Sensor monitoring run. **Verify** that sensors are clean. **Verify** that there are no kinks, bends, or breaks in the Fiber Optic Sensor Cable and that the patient is not lying on any of the cables. **Verify** that the Fiber Optic Sensor Cable is connected to the ivWatch Patient Monitor, and the Sensor Cable into the Sensor Receptacle. **Verify** that Sensor Receptacle is securely attached to the patient's skin. **Perform** a sensor test. **Replace** the Fiber Optic Sensor Cable. **Note:** Applicable to software version 5.2.0: If this error occurs immediately after beginning a monitoring run with a SmartTouch Sensor connected, the monitor was not able to detect the SmartTouch. Stop the monitoring run and verify that the SmartTouch Sensor, Patient Cable, and Extension Module are properly connected and functioning.

Error Message	Possible Solution
	Sensor Monitoring Error - SmartTouch A sensor error was detected during a SmartTouch Sensor monitoring run. **Verify** that the Extension Module and Patient Cable are connected to the ivWatch Patient Monitor, and the SmartTouch Sensor is connected to the Patient Cable. **Verify** that SmartTouch Sensor is securely attached to the patient's skin. **Verify** that there are no kinks, bends, or breaks in the Patient Cable or SmartTouch Sensor and that the patient is not lying on any of the cables. **Replace** the SmartTouch Sensor and/or Patient Cable if needed.
	Excessive Ambient Light **Reduce** the light, or **cover** the area around the Sensor Receptacle or SmartTouch Sensor. **Verify** that no bright light sources are illuminating the IV insertion site.
	Battery Low **Plug** the ivWatch Patient Monitor into a power source or **stop** the monitoring run within 30 minutes.
	**Battery Exhausted** **Plug** the ivWatch Patient Monitor into a power source or **stop** the monitoring run within 15 minutes.
	**Sensor Damaged** SmartTouch Sensor was damaged during a monitoring run. **Replace** the SmartTouch Sensor.

Error Message	Possible Solution
	**Sensor Not Functioning** A sensor error was detected during a sensor test. **Verify** that there are no kinks, bends, or breaks in the Fiber Optic Sensor Cable and that the patient is not lying on the cable. **Verify** that the proximal and distal ends of the Fiber Optic Sensor Cable are clean. **Replace** the Fiber Optic Sensor Cable.
	**No Sensor Connected** **Insert** a Fiber Optic Sensor Cable. **Ensure** Patient Cable is connected to a SmartTouch Sensor. *Applicable to software versions 5.1.5 and lower.*
	**No Sensor Detected** A SmartTouch Sensor was not detected when attempting to start a monitoring run. **Verify** that the Extension Module and Patient Cable are connected to the ivWatch Patient Monitor, and the SmartTouch Sensor is connected to the Patient Cable. **Replace** the SmartTouch Sensor and/or Patient Cable if needed.
	External Communications Interruption External Communications have been interrupted and a signal has been lost. **Verify** that the ivWatch Data Cable is connected to the back of the ivWatch Patient Monitor, and that all steps have been taken in the “Setting Up External Communciations” section.
	**Fiber Optic Sensor Cable Life Exceeded** Sensor usage has exceeded 10 line days (or 240 hours). **Replace** the Fiber Optic Sensor Cable. *Applicable to software versions 5.1.5 and lower.*
	**Extension Module Disconnected** **Reconnect** USB cable on Extension Module to the back of the ivWatch Patient Monitor.

Error Message	Possible Solution
	Invalid Factory Settings Error This message indicates that the ivWatch Patient 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.
	**Missing Display Software Error** This message indicates that the ivWatch Patient 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.
	**Invalid Display Software Version Error** A message in this format indicates that the ivWatch Patient 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.
	Device Firmware Error A message in this format 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.
	**“Failed to Load” Error** This message indicates that the ivWatch Patient 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.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

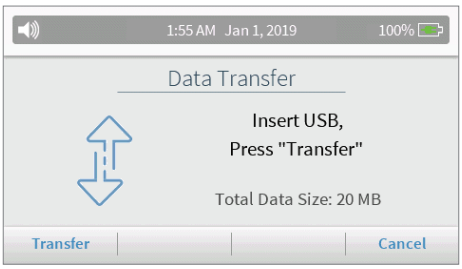
04

APPENDICES

Transferring Data to a USB Drive

The historical 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 Patient 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 ivWatch Patient Monitor or the USB part on the front of the Extension Module. Note that patient identification data is not entered into the ivWatch Model 400 and therefore no patient specific data is stored.

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

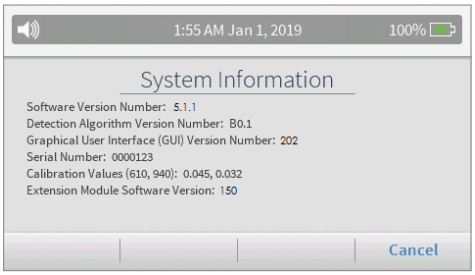


Note:

Only use a USB drive with a nonconducting case. A USB drive should not be inserted during a monitoring run. Ensure external communications are "disabled" prior to initiating a data transfer (see "Setting Up External Communications" section).

System Information

Various system information, versions, and serial numbers are located on the System Information screen, located from the Options Menu. Press the "Cancel" button to return to the Options Menu screen.



Note:

The System Information screen provided is only an example of the types of information available on this screen. The Extension Module Software Version will only be visible if an Extension Module is connected to the ivWatch Patient Monitor.

Cleaning the System for Reuse

Procedure:

1. Turn off the ivWatch Patient Monitor (refer to "Turning Off the ivWatch Patient Monitor" section).
2. Disconnect the ivWatch Patient Monitor from the electrical outlet, any third-party systems or equipment, and the Data Cable (if applicable).
3. Disconnect cables from the ivWatch Patient Monitor and Extension Module.

⚠ WARNING:

Power Source: To avoid electric shock, before cleaning, always disconnect the power source from the ivWatch Patient Monitor and turn the device off.

Cleaning and Disinfection of Reusable Components

Clean and disinfect the Patient Cable, Fiber Optic Sensor Cable, ivWatch Patient Monitor, and Extension Module:

1. Use two 70% isopropyl alcohol wipes to wipe the component. Visually inspect the component for soil.
2. If no soil is visible, repeat Step 1 with a second set of two 70% isopropyl alcohol wipes allowing the disinfectant to sit on the component for 2 minutes, or for the the manufacturer's minimum recommended amount of time.

⚠ Caution:

Never allow cleaning agents to pool on the equipment as prolonged contact could cause damage.

Not waterproof: The ivWatch Patient Monitor, Extension Module, power supply, Fiber Optic Sensor Cable, Patient Cable, and SmartTouch Sensor are not certified "waterproof". Never immerse components in water or other fluids.

Preventative Maintenance

ivWatch recommends the following tests be performed on the ivWatch Patient Monitoring System annually.

If any of the tests fail, contact Technical Support at 855-489-2824, Option 2 or email at TechnicalSupport@ivWatch.com.

- Inspect the ivWatch Patient Monitor, Extension Module, Fiber Optic Sensor Cable, Power Cable and Patient Cable for any mechanical damage.
- Inspect the ivWatch Patient Monitor and Extension Module for any breaks in the tamper-evident labels.
- Inspect all labels for legibility.

Functional Test Procedure:

1. **Charging:** While turned off, connect the ivWatch Patient Monitor to an AC outlet and fully charge the device.
2. **Power On Test:** Press the "Power" button on the top left of the ivWatch Patient Monitor. Ensure that the battery indicator on the top right of the LED screen displays the charging icon in green. If the battery icon is yellow, this means that the device is running off of the internal battery. If so, check the connections on the power cord and ensure that there is power in the AC outlet. If the connections are good, but the ivWatch Patient Monitor is running off of the battery, replace the power cord.
3. **Date and Time Check:** Ensure that the date and time displayed at the top middle of the LCD screen is accurate.
4. **Volume Test:** Press the "Options" button on the lower right of the LCD display. Scroll down using the arrow and press "Select" when the highlighted bar is over Volume. Using the scroll arrows, move the highlighted bar to each of the five volume level options in order to test each level.
5. **Brightness Test:** Press the "Options" button on the lower right of the LCD display. Scroll down using the arrow and press "Select" when the highlighted bar is over Brightness. Using the scroll arrows, move the highlighted bar to each of the three brightness levels in order to test each level.
6. **External Communications Test:** Press the "Options" button on the lower-right of the LCD display. Scroll down using the arrow and press "Select" when the highlighted bar is over Exter-

nal Communications. Using the scroll arrows, move the highlighed bar to Enable and press “Select”. On the next screen, use the scroll arrows to highlight and select the applicable partner communications standard. On the Options Menu, press “Cancel” to return to the current Monitoring screen and verify that the sync icon is shown in the upper left corner of the screen to the right of the volume icon.

7. **Fiber Optic Sensor Tests**

a. **Sensor Test Port Test:** Using a known working Fiber Optic Sensor Cable, perform a sensor test by placing the sensor into the test port of the ivWatch Patient Monitor with the black portion of the sensor facing up. Press the Sensor Test button and then the “Start Test” button. Verify that the display reads “Sensor Functioning Normally.”

b. **Monitoring and Check IV Test:** Using a known working Fiber Optic Sensor Cable, cover the black side of the sensor with your finger. Start a new monitoring run. While in monitoring mode, press the “Check IV” button. Ensure that the display reflects that the IV was checked. Stop the monitoring run.

c. **Sensor Cable Error and Silence Audible Notification Test:** Perform the procedure in b (Monitoring Test), only this time, remove the sensor from your finger while the monitoring run is active in order to cause a sensor monitoring error message on the display. Press the button on the top right of the ivWatch Patient Monitor that has the bell emblem to silence the audible notification. Ensure that the audible notification is silenced.

8. **SmartTouch Sensor Tests**

a. **Monitoring and Check IV Test:**
Using a known working SmartTouch Sensor, cover the bottom of the black side of the sensor with your finger. Start a new monitoring run. While in monitoring mode, press the “Check IV” button. Ensure that the display reflects that the IV was checked. Stop the monitoring run.

b. **SmartTouch Sensor Error and Silence Audible Notification Test:**
Perform the procedure in a (Monitoring Test), only this time, remove the sensor from your finger while the monitoring run is active in order to cause a sensor monitoring error message on the display. Press the button on the top right of the ivWatch Patient Monitor that has the bell emblem to silence the audible notification. Ensure that the audible notification is silenced.

Note:

The ivWatch Patient Monitoring System requires no additional periodic maintenance or calibration.

Specifications

Parameter	Description
Data Download/ Transmission	Supported USB drives: SanDisk® Cruzer Fit™ SanDisk® Cruzer Glide™
Data Storage	FAT 32 Formatted SD Card 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
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 SL Power, model ME30A1241F02
Internal Batteries	For standard monitoring, the 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 Fiber Optic Sensor Cable use hours) for software versions 5.1.5 and lower	Frequency range: 13.56 MHz +/- 7 kHz Effective radiated power: 84 uW
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 (Biocompatibility) - IEC 60601-1 Clause 11.7 Cleaning - IEC 60601-1 Clause 11.6.6 Handling -(Mechanical Strength) - IEC 60601-1 Clause 15.3 FCC Compliance only applicable to ivWatch Patient Monitors with software versions 5.1.5 and lower.

Note: All measurements are approximate.

Compatible ivWatch Components

The ivWatch Patient Monitor should only be used with the following ivWatch components:

Component	Reference Number
Fiber Optic Sensor Cable (Applied Part)	AC-1001000
Sensor Receptacle	AM-1000001 AM-1002074
Extension Module	AE-1001003
Patient Cable	AC-1001002
SmartTouch Sensor (Applied Part)	AC-1001003 AC-1002000
Data Cable	AC-1002004

Dimensions and Weight

Component	Length, in (cm)	Width, in (cm)	Depth, in (cm)	Weight, lb (kg)
ivWatch Patient 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 power supply
Fiber Optic Sensor	0.36 (0.9)	0.25 (0.6)	0.81 (2.1)	N/A
Fiber Optic Sensor Cable	118.1 (300)	N/A	N/A	0.10 (0.05)
Sensor Receptacle	2.25 (5.7)	1.31 (3.3)	0.42 (1.1)	0.003 (0.002)
Extension Module with Wire Bale	4.1 (10.4)	5.9 (15.0)	3.8 (9.7)	0.46 (0.21)

Note:

All measurements are approximate.

Dimensions and Weight - Continued

Component	Length, in (cm)	Width, in (cm)	Depth, in (cm)	Weight, lb (kg)
Patient Cable	144 (365.76)	N/A	N/A	0.21 (0.09)
SmartTouch Sensor	18 (45.7)	N/A	N/A	0.03 (0.01)
Data Cable	48 (121.92)	N/A	N/A	0.07 (0.15)
Power Supply / With Power Cord	72 (182.9) / 192 (487.7)	N/A	N/A	0.04 (0.19) / 1.15 (0.52)

Environmental

Component	Operation	Transport and Storage (Boxed)	Storage (Unboxed)
ivWatch Patient Monitor Extension Module Patient Cable Fiber Optic Sensor Cable	Temperature: 41 to 104°F (5 to 40°C) Relative Humidity: 15–75% Atmospheric pressure: 70-106 kPa	Temperature: -4 to 158°F (-20 to 70°C) Relative Humidity: 15–75% Atmospheric pressure: 50-106 kPa	Temperature: -4 to 158°F (-20 to 70°C) Relative Humidity: 15–75% Atmospheric pressure: 70-106 kPa
Sensor Receptacle	Temperature: 41 to 104°F (5 to 40°C) Relative Humidity: 15–75% Atmospheric pressure: 70-106 kPa	Temperature: 50 to 90°F (10 to 32°C) Relative Humidity: 30–70%	Temperature: 50 to 90°F (10 to 32°C) Relative Humidity: 30–70%
SmartTouch Sensor	Temperature: 41 to 104°F (5 to 40°C) Relative Humidity: 15–75% Atmospheric pressure: 70-106 kPa	Temperature: 50 to 80°F (10 to 27°C) Relative Humidity: 40–60%	Temperature: 50 to 80°F (10 to 27°C) Relative Humidity: 40–60%

Recommended environmental conditions based on IEC 60601-1-11 testing.

Note:

All measurements are approximate.

Electromagnetic Environment Guidance

The ivWatch Patient Monitoring System meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2: 4th Edition 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 Patient Monitoring System should ensure that the device is installed and used in accordance with the electromagnetic environment guidelines specified in this section.

For software versions 5.1.5 and lower, if RFID communication between the ivWatch Patient Monitor and the Fiber Optic Sensor Cable is delayed or fails, the ivWatch Patient Monitor may issue a Sensor Monitoring Error, a Sensor Not Functioning Error during a sensor test or a Sensor Not Connected Error.

The emissions characteristics of the ivWatch Model 400 Patient Monitoring System make it suitable for use in industrial areas and hospitals (CISPR 11, Class A). If it is used in a residential environment (for which CISPR 11, Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

⚠ WARNING:

Use of accessories, transducers, and cables other than those specified or provided by ivWatch could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the ivWatch Patient Monitor or Extension Module. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment: Guidance
Radiated and Conducted Emissions CISPR 11:2015+A1:2016 / EN 55011:2016 +A1:2017	Group 1 Class A	The ivWatch Model 400 Patient Monitoring System 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 IEC 61000-3-2:2018 / EN 61000-3-2:2019	Device power is less than 75 W, therefore testing is not required.	The ivWatch Model 400 Patient Monitoring System is suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes.
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3:2013	Device is not connected to a public mains network.	

Consistent with its intended use as an aid to the detection of IV infiltration, the ivWatch Model 400 Patient Monitoring System has no essential performance (as defined in IEC 60601-1).

Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF Immunity IEC 61000-4-6:2013/EN 61000-4-6:2014 4-3:2006+A1:2008+A2:2010 4-3:2006+A1:2008+A2:2010	3 V rms, 0.15 - 80 MHz 6 V rms, in the IMS radio band 0.15 - 80 MHz	Test at AC mains, 0.15 to 80 MHz 3 Vrms, AM: 80%, 1 kHz, 1.0-sec dwell	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the ivWatch Patient Monitor or Extension Module. Otherwise, degradation of the performance of this equipment could result.
Radiated Radio-frequency (RF) Immunity IEC 61000-4-3:2006+A1:2007+A2:2010 / EN 61000-4-3:2006+ A1:2008+A2:2010	3 V/m, 80 MHz - 2.7 GHz	3 V/m, AM:80%, 1kHz 3 sec dwell	

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 ivWatch Model 400 Patient Monitoring System is used exceeds the applicable RF compliance level above, the ivWatch Model 400 Patient Monitoring System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ivWatch Model 400 Patient Monitoring System.

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

Electrostatic Discharge (ESD) IEC 61000-4-2:2008 / EN 61000-4-2:2009	±8 kV contact ±2 kV, ±4 kV, 8 kV, ± 15 kV air	±8 kV contact ±2 kV, ±4 kV, 8 kV, ± 15 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 Transients IEC/EN 61000-4-4:2012	± 2 kV, 100 kHz for power supply lines ±1 kV, 100 kHz 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.
Voltage Surge IEC / EN 61000-4-5:2014+A1:2017	±0.5, ±1 kV line-to-line ±0.5, ±1 kV, ±2 kV line-to-ground	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.

Electromagnetic Immunity (continued)

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment : Guidance
Voltage Dips and Short Interruptions IEC / EN 61000-4-11:2004+A1:2017	0 % U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles at 0° 0 % U_T; 250/300 cycles	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 ivWatch Model 400 Patient Monitoring System requires continued operation during power mains interruptions, it is recommended that the ivWatch Model 400 Patient Monitoring System be powered from an interruptible power supply or a battery.
Power Frequency (50- and 60-Hz magnetic field) IEC 61000-4-8:2009 / EN 61000-4-8:2010	30 A/m	Test at AC mains for 120 VAC/60 Hz input voltage, 30 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.

Disposal

Dispose of the ivWatch Patient Monitor, Extension Module, Sensors, Cables, Batteries and packaging according to local disposal regulations and recycling requirements.

MRI Safety Information

⚠ **WARNING:**

The ivWatch Patient Monitor, Extension Module, Patient Cable, and SmartTouch Sensor are MR Unsafe and pose a safety hazard if brought into the MR environment. Do not bring these devices into the MRI scan room.

The Sensor Receptacle contains no ferromagnetic materials.

Non-clinical testing has demonstrated that the Fiber Optic Sensor Cable is MR Conditional.

A patient with this device can be safely scanned in an MR system with the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode).

Under the scan conditions defined above, the Fiber Optic Sensor Cable is expected to produce a maximum temperature rise of less than or equal to 2°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends radially up to 0.9cm and 1.6cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a gradient echo pulse sequence in a 3.0T MR system.

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

1. Discontinue the monitoring run (see "Ending a Monitoring Run" section for the cable being used).
2. If the conditions specified in the warning above related to the Fiber Optic Sensor Cable are met, disconnect the Fiber Optic Sensor Cable from the ivWatch Patient Monitor. If the conditions are not met, disconnect the Fiber Optic Sensor Cable from the Sensor Receptacle and do not take the Fiber Optic Sensor Cable into the MR environment.
3. Do not bring the ivWatch Patient Monitor, Extension Module, Patient Cable, or SmartTouch Sensor into the MR environment.
4. Inspect the IV insertion site after the MRI scan.
5. If the monitoring run is going to resume, proceed to the "Monitoring IVs with ivWatch Sensors" section for the sensor in use.

Note:

Do not bring any of the ivWatch Patient Monitoring System components into the MR environment if the IV catheter has been removed prior to the MRI scan.

Device Lifetime

Device	Lifetime
ivWatch Patient Monitor	At least 5 years; rated a minimum of 4,000 cycles of the transceiver.
Fiber Optic Sensor Cable	Sensor Cable may be used if the functional test passes which is tested before starting a monitoring run.
Sensor Receptacle	Expiration Date listed on device packaging.
Extension Module	At least 5 years; rated a minimum of 5,000 connector mating cycles.
Patient Cable	At least 3 years; rated a minimum of 5,000 connector mating cycles.
SmartTouch Sensor	Expiration Date listed on device packaging.

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
	Data 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.
MD	Medical Device
Rx ONLY	Federal law (US) restricts this device to sale by or on the order of a physician.
	Expiration date in YYYY-MM-DD format.

REF	Reference number
SN	Serial number
LOT	Lot number
	Manufacturing date
	Manufacturer
	Indicates that the component is MR Unsafe. Note that this symbol is intended to be the capital letters "MR" (in bold black letters) within a red circle and slash.
	Indicates that the component is MR Conditional. Note that this symbol is intended to be the capital letters "MR" (in bold black letters) with a yellow triangle.
	Indicates that the component has been sterilized using ethylene-oxide sterilization.
	Indicates that the component is a single-use component.
	Indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)
	Indicates the temperature limits to which the medical device can safety be exposed
	Indicates the range of humidity to which the medical device can safety be exposed
	Indicates the device does not contain the presence of natural rubber latex
	Indicates the authorized representative in the European Community
Manufactured by ivWatch, LLC 700 Tech Center Parkway, Suite 300 Newport News, VA 23606, USA	Manufacturer
Emergo Australia, Level 20 Tower II, Darling Park, 201 Sussex Street, Sydney, NSW 2000, Australia	Australian Sponsor

Note: Symbols on device packaging may be in black and white or color.

For the most current release of this manual, visit www.ivWatch.com.

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