SensiumVitals Wireless Monitoring System

User Manual

Part Number: TZ202000-IFU

SensiumVitals Wireless Monitoring System Directions for Use

Changes in equipment, software, or procedures occur periodically; information describing these changes will be included in future editions of the guide.

The information in this document is subject to change and does not represent a commitment on the part of Toumaz to provide additional services or enhancements.

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About This Guide

This guide describes the Toumaz SensiumVitals Wireless Monitoring System and provides instructions for wireless monitoring of patients.

The SensiumVitals Wireless Monitoring System is used to monitor a patient's vital signs, including heart rate, respiratory rate, and axillary temperature.

Symbols

This document uses the following symbols:

Warnings indicate potentially hazardous situations which, if not avoided, could result in injury or death.

Caution indicates conditions that could damage equipment or other property.

Notes contain supplementary information or emphasize a point or procedure.

Chapter 1
General Information

Intended Use

The SensiumVitals Wireless Monitoring System is intended for use by health care professionals for routine surveillance of patient physiological parameters in a healthcare setting. Data is transmitted wirelessly to a central location. Alerts can be set on an individual patient basis to inform healthcare professionals when vital sign readings are measured outside of preset limits.

The device is not intended to be used in the ICU or CCU and is intended to supplement vital signs monitoring by healthcare professionals, not to replace it. The device is intended for use on general care patients and on patients who are 18 years of age or older.

Heart rate monitoring

- Uses ECG to detect the heart rate (HR) only;

- Cannot be used to detect the absence of a heart rate;

- Provides intermittent HR readings in a range of 30–200 beats per minute (BPM) when conditions are appropriate;

- Cannot be used to detect any forms of arrhythmia or any other conditions usually detected through an ECG.

Respiratory rate monitoring

- Uses impedance pneumography to detect respiratory rate (RR);

- Provides intermittent RR readings in a range of 5–60 breaths per minute (BrPM);

- Due to the nature of impedance pneumography, it is possible that RR readings often appear as not available. This situation is more likely to happen when the patient is moving.

Axillary temperature monitoring

• Measures the axillary temperature using a probe underneath the axilla;

• Provides intermittent axillary temperature readings in a range of 89.6 to 111.2°F;

• Due to the dependence on the patient's proper arm position, it is possible that axillary temperature sometimes appears as unavailable;

• Cannot be used to detect rapid drops of core body temperature.

Monitoring symbols

The following symbols may appear in the Wireless Monitoring Application.

♥/MIN	Heart Rate (in beats per minute)
🫁/MIN	Respiratory Rate (in breaths per minute)
🌡°F	Axillary Temperature (in degrees Fahrenheit or Celsius, depending on your configuration)
➕👤	Add Patient to Wireless Monitoring
➖👤	Remove patient from Wireless Monitoring
🔄	System is processing information. Please wait.
(Blinking)	Notification
📍	Replace Patch
(Blinking)	Replace Patch Now
📶	Patch Out of Range
📶 (Blinking)	Signal Lost (patch out of range for longer than specified time)
??	Invalid Data
--	Data Unavailable

General warnings and cautions

General warnings

⚠	**WARNING—Do not use the SensiumVitals Wireless Monitoring system on critical care patients.**
⚠	**WARNING—Remove patch before defibrillating the patient.**
⚠	**WARNING—The system is not designed for use with pacemakers, implantable defibrillators, or neurostimulators.**
⚠	**WARNING—The system is not designed for use near magnetic resonance imaging (MRI) equipment. Patch must be removed from any patient about to undergo an MRI.**
⚠	**WARNING—The patch is not designed for use on patients under the age of 18.**
⚠	**WARNING—Do not apply the patch on breached or compromised skin surfaces or on mucosal membranes.**
⚠	**WARNING—The patch is a single-use device. After the patch is removed from a patient, do not reuse the patch, whether on the same patient or on a different patient.**

General Cautions

⚠	**CAUTION—The patch is a radio frequency (RF) emission device and should not be used in RF sensitive areas.**
⚠	**CAUTION—The system is not designed for direct X-ray exposure. Patch must be removed from any patient about to undergo an upper torso X-ray.**
⚠	**CAUTION—The system is not designed for use near X-ray computed tomography (CT) equipment. Patch must be removed from any patient about to undergo a CT scan.**
⚠	**CAUTION—The patch is designed to be shower-proof, but vital sign readings may be temporarily unavailable during a shower depending on the condition of the ECG electrodes used.** **It is not designed to be immersed in water or any other liquid.**

Safety and compliance information

This device has been designed for compliance with applicable Safety and Electromagnetic Compatibility (IEC & FCC) regulations. See *FCC compliance statement (United States)* on page *33*.

System information

This section describes the system components, patch components, and the main screens of the Wireless Monitoring Application.

System components

System components and descriptions are provided in the following graphic and table.
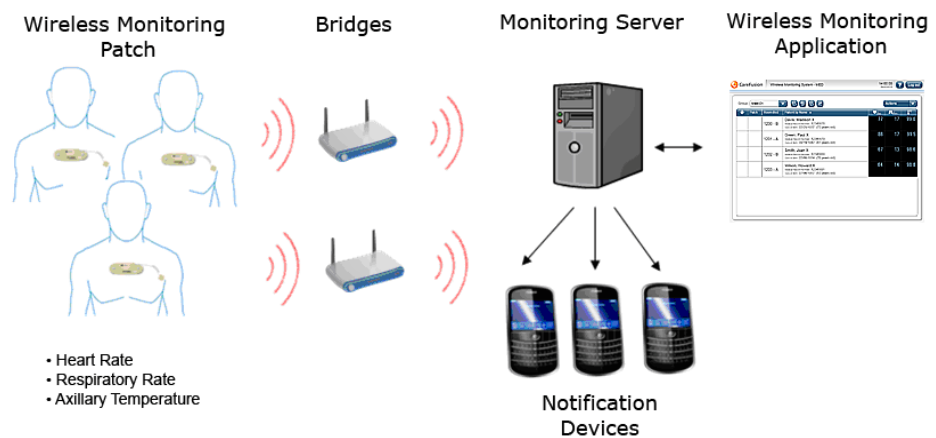
System component descriptions

Item	Description
SensiumVitals Wireless Monitoring Patch	Collects and transmits vital sign data from patients to the system.
Bridges	Sends the vital sign data from each patch to the Monitoring Server.
Monitoring Server	Provides a link between the bridges and the Wireless Monitoring Application. Manages vital sign data and notifications.
Wireless Monitoring Application	Displays vital sign data and notifications. Caregivers can use it to access system features.
Notification devices	Pager, PDA, or other device—used to receive and display notifications.

Patch components

The disposable patch, when applied to the patient and activated, collects and transmits patient vital sign data: heart rate, respiratory rate, and axillary temperature. The vital sign data are then displayed on the Wireless Monitoring Application.
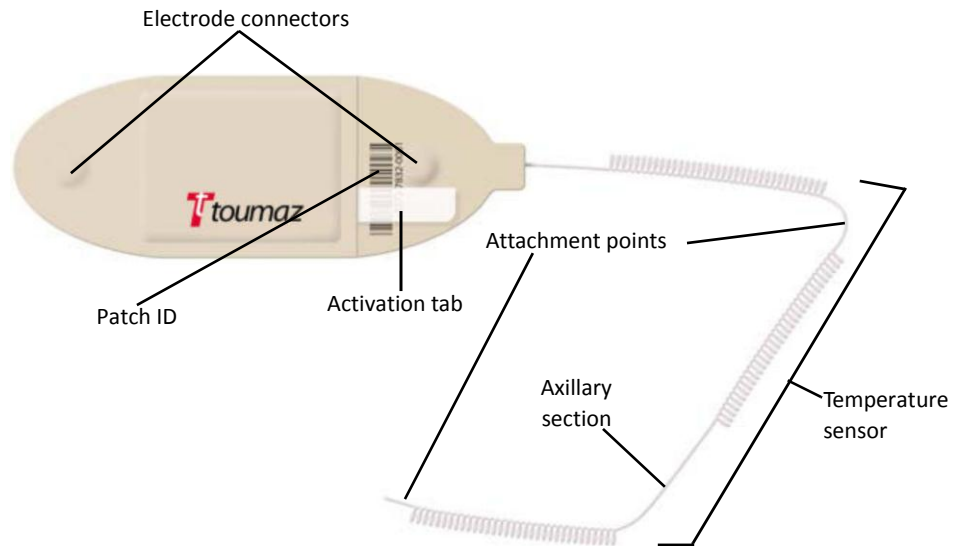
Patch component descriptions

Item	Description
Electrode connectors	Connectors on the underside of the patch where monitoring electrodes are attached.
Patch ID	Barcode and number which uniquely identify the patch.
Activation tab	Removing this tab activates the patch.
Temperature sensor	Used to read the patient's axillary temperature.
Attachment points	Used to secure the temperature sensor in the proper location.
Axillary section	The part of the temperature sensor which is placed beneath the patient's axilla.

Wireless Monitoring Application screens

The Wireless Monitoring Application is a web-based application accessed using Internet Explorer on a standard hospital PC computer.

Main screen

Main screen components

Identifier	Component	Description
A	Unit name	Displays the unit for which the data is being displayed.
B	System time and date	Displays the current system time and date.
C	**About** button	Displays SensiumVitals Wireless Monitoring System information and provides a link to online help.
D	**Log out** button	Logs you out of the system.
E	**Group** drop-down list	Allows you to display a particular group in a unit or display all patients in the unit.
F	**Add Patient** button	Allows you to add a patient to wireless monitoring.
G	**Replace Patch** button	Allows you to replace a patch on a patient being monitored.
H	**Remove Patient** button	Allows you to remove a patient from wireless monitoring.
I	**Patient History** button	Allows you to view patient vital sign history and access patient settings.
J	**Actions** drop-down list	Allows you to assign beds (depending on access rights) and run a Clinical Data Report.

Main screen components (continued)

Identifier	Component	Description
K	Notification column	Displays a notification icon (see *Monitoring symbols* on page *2*) if there is a notification for that patient. Click the icon to see notification details. Click the column heading to sort the patients with open notifications at the top of the list.
L	Patch Status column	Displays icons relating to patch status (see *Monitoring symbols* on page *2*). If no icon is displayed, the patch is okay. Click the column heading to sort the patients by patch status. Those patients whose patches require attention appear at the top of the list.
M	Room-Bed column	Indicates the patient's room and bed number. Click the column heading to sort patients in room-bed number order.
N	Patient by *X* column	Displays a list of patients currently being monitored. By default, this list is sorted by *Name*. Click the column heading to sort patients by *Vital Sign Status*, with red and yellow vital sign alerts at the top of the list. When the list displays all patients in a unit, this column displays only the patients' names. However, when a group is selected using the **Group** drop-down list, this column displays the patient name, ID, and date of birth.
O	Vital signs columns	These columns display the latest vital signs—heart rate, respiratory rate, and axillary temperature—for each patient in the list. • Vital signs that are within normal limits are displayed in blue on a black background. • Vital signs that exceed yellow preset limits are displayed in black on a yellow background. • Vital signs that exceed red preset limits are displayed in white on a red background. • If the system receives invalid data, question marks are displayed. • If the system has not received vital sign data for a period of time, dashes are displayed. • Dashes are also displayed while a patch is being activated.

If the Patient list is long, vital sign warnings might appear below the "bottom" of the Main Screen. To avoid this, use the **Group** drop-down list to limit the number of patients shown.

Patient History screen

To display the Patient History screen, do one of the following:

- Select a patient and click the **Patient History** 🔲 button

- Click one of a patient's vital signs on the main screen

Always verify in the Patient History screen that the correct patient's information is displayed (item A). If it is not, click **Main Screen** (item E) and select the correct patient.
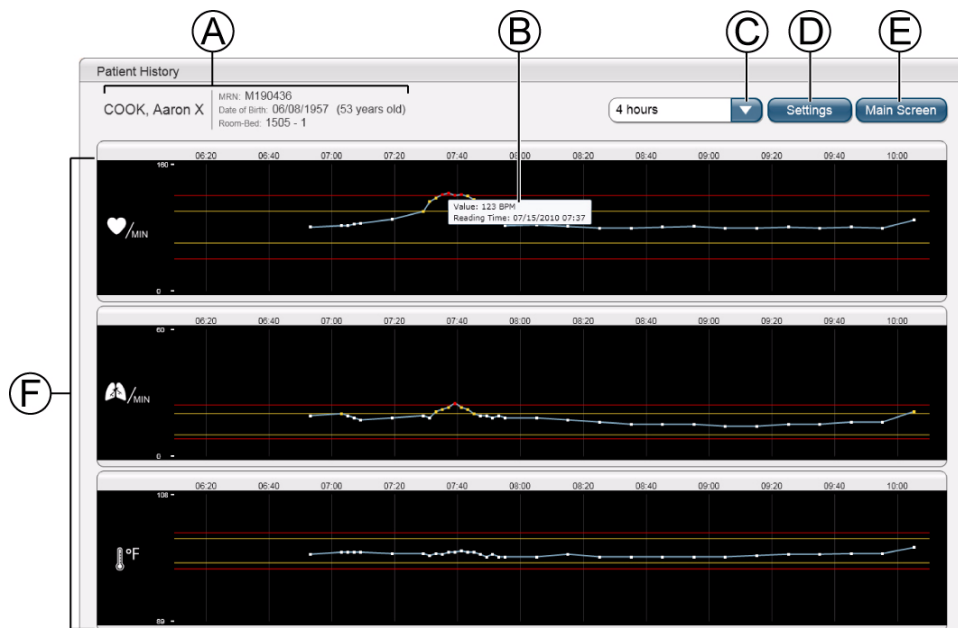
Patient history screen components

Identifier	Component	Description
A	Patient demographic data	Displays patient's name, ID, date of birth, age, and room/bed number.
B	Value and reading time of a vital sign data point	Move the mouse over a data point on the chart to display.
C	**Display Period** drop-down list	Allows you to choose the period of time to display vital sign data; for example, for the last four hours.
D	**Settings** button	Displays and allows you to modify (depending on privileges) vital sign limits and the documentation interval.
E	**Main Screen** button	Returns you to the main screen.
F	Vital sign history	Displays the heart rate, respiratory rate, and axillary temperature data over the selected time period. Depending on the display period, data points are displayed as dots or as line segments. Data points within the set limits are displayed in blue. Data points outside the yellow limits are displayed in yellow. Data points outside the red limits are displayed in red.

Chapter 2
Using the SensiumVitals Wireless Monitoring System

Logging in and out

The Wireless Monitoring Application is a web-based application accessed using Internet Explorer on a standard hospital PC computer. Only authorized personnel can log in to the Wireless Monitoring Application.

To log in

1. Enter your user ID and appropriate password at the Log in screen.

| User ID: | |
| Password: | |

| Log in |

2. Click **Log in**.

   The main screen appears.

To log out

- Click **Log out** in the upper right corner of the main screen.

After a period of inactivity, the application automatically logs out.

Starting patient monitoring

Required equipment

⚠ **CAUTION—Use of 3M Red Dot 2560 Monitoring Electrodes is recommended.**

- Patch
- 3M™ Red Dot™ 2560 Monitoring Electrodes (2)
- Skin cleaning solution
  - ◦ Isopropyl alcohol or a special skin preparation solution can be used.
- Clipper
- Water-resistant plastic or paper medical tape such as 3M Transpore™ or 3M Transpore™ White

Applying the patch

⚠ **WARNING—Do not use the SensiumVitals Wireless Monitoring system on critical care patients.**

⚠ **WARNING—Do not apply the patch on breached or compromised skin surfaces or on mucosal membranes.**

1. Open the patch packaging and inspect the patch to ensure that it is intact and that the expiration date printed on the packaging has not been reached.
2. Connect each electrode to the patch as shown.
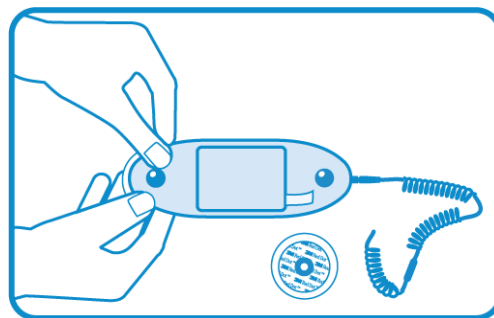
3. Without attaching the patch, but using the patch as a guide, locate the two areas on the patient's upper torso where the electrodes will be applied.

   • Center the patch horizontally on the upper torso, with the center of the electrodes on the second intercostal space.
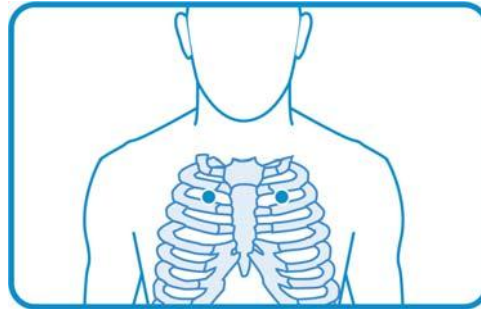
4. Clip hair from the electrode sites and thoroughly clean the skin with an approved skin cleansing solution; allow to dry.

   • To avoid allergic reactions to the electrodes, refer to the electrode manufacturer's directions.

⚠ **WARNING—Be sure to place the patch exactly as shown in these instructions. An improperly-placed patch can return false data.**

5. Apply the patch to the patient as follows:
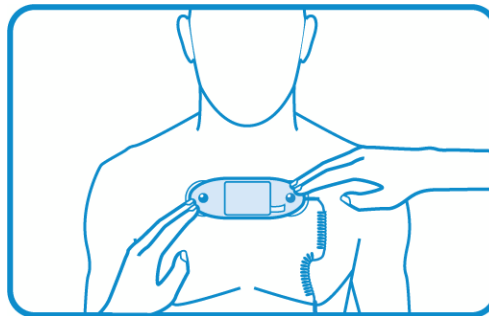
   a. Orient the patch so that the temperature sensor points toward the patient's non-dominant arm.

   b. Peel off the backing from the electrodes and inspect the electrode gel to make sure that it is intact and not dried out.

   c. Apply the patch, making sure it is well centered on the torso with the center of the electrodes on the second intercostal space, and pressing lightly.

6. Apply the temperature sensor as follows:

    a. Raise the patient's arm to 90 degrees and center the axillary section underneath the axilla.

    b. Gently lift the two attachment points of the temperature sensor and position them on either side of patient's shoulder as shown in the following figure.

    c. Secure the temperature sensor to each attachment point location using medical tape.
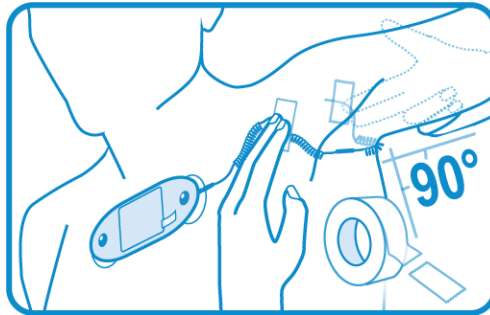
 To avoid patient discomfort or skin irritation, do not create unnecessary tension in the coils.

When installed correctly, the coils are only slightly extended and the two attachment points are at approximately the same level as shown.
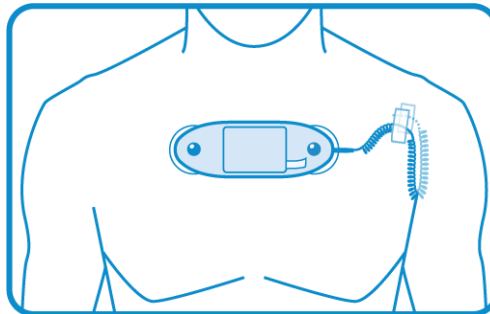
7. Pull out the activation tab.

⚠ **CAUTION—Make sure the activation tab opening is perfectly sealed after the patch has been activated.**
Doing this helps avoid patch malfunctions due to moisture.

8. Press down on the activation tab opening to seal it shut.
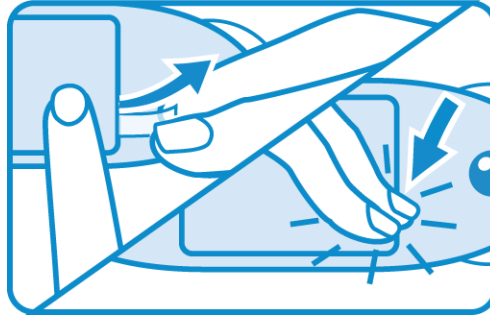
⚠ **WARNING—Patient interference with the patch can cause false data to be sent.**

9. Advise patient to not remove, pull on, adjust, or otherwise interfere with the patch.

Adding patient to wireless monitoring

1. On the main screen of the Wireless Monitoring Application, click **Add Patient**
    to open the patient list.

⚠️ **WARNING—Always verify that the patient's information is correct.**

2. Do one of the following to open the Add Patient to Wireless Monitoring screen:

    • Scan the patient's wristband.

    • Select the appropriate patient from the list, as shown.

You can do either of the following to help you find the patient in the patient list:

• Enter the **MRN** (or patient ID) in the text box to locate the patient.

• Click any column heading to sort by that column.

If the correct patient's information is not displayed in the Add Patient to Wireless Monitoring screen, click **Cancel** and select the correct patient.

If the correct patient is not listed, it is possible that the patient was transferred to another unit, or was recently transferred into your unit and the Hospital Information System has not yet been updated. Verify the status of the patient in the HIS.

3. On the Add Patient to Wireless Monitoring screen, do the following:

a. Enter the new patch ID number using one of the following methods:

   • Enter the ID number in the **Patch ID** text box.

   • Scan the barcode on the patch.

     The barcode appears on both the patch and the packaging. If you are unable to scan the patch at the patient's bedside, you can use the patch ID on the packaging instead.

b. Set a documentation interval for transferring the data into the patient's electronic medical record:

   i. Click the **Documentation Interval** drop-down list.

   ii. Select the new time interval.

The Documentation Interval controls how often the system copies data into the patient's electronic medical record.

Standard yellow and red vital sign limits (yellow and red limits) are defined and set by the hospital for all patients who are being monitored with the SensiumVitals Wireless Monitoring System. Vital sign limits can be modified for a specific patient.

WARNING—Make sure that yellow and red vital sign limits are appropriate to the patient's condition.

    c.   Set vital sign limits as follows:

        i.   Click the text box that displays the vital sign limit you wish to change.

       ii.   Enter different upper and/or lower limits as needed.

Additional user privileges may be required to change some or all vital sign limits.

    d.   After completing the required changes, click **Add**.

A message appears to confirm that the patient was added to monitoring.

4.   Click **OK** to return to the main screen.

When a patient is added to monitoring, allow up to 15 minutes before the data is available on the main screen.

Monitoring is intermittent. Vital sign data is usually updated once every 2 minutes, but can vary depending on the configuration of your unit.
.

Monitoring patients

Editing patient settings and vital sign limits

1. On the Patient History screen, click **Settings**.

   The Patient Settings screen appears.

2. To set a different documentation interval, do the following:

   a. Click the **Documentation Interval** drop-down

   list. b. Select a different documentation interval.

   > The Documentation Interval controls how often the system copies data into the patient's electronic medical record.

3. To change a vital sign limit, do the following:

   a. Click the text box that displays the vital sign limit you wish to change.

   b. Enter different upper and/or lower limits as needed.

   > Additional user privileges may be required to change some or all vital sign limits.

4. When you have made the required changes, click **Save**.

   A message confirms that the changes have been saved.

5. Click **OK** to return to the Patient History screen.

Notifications

⚠️ **WARNING—Always address received notifications, even if they are not for a patient under your care.**

Physiological and system notifications are sent from the Monitoring Server to the Wireless Monitoring Application and, if set up to do so, a handheld notification device.

Receiving notifications

Notification types and descriptions

Type	Description
Physiological	
Axillary Temperature	Outside of yellow or red preset limits
Heart Rate	Outside of yellow or red preset limits
Respiratory Rate	Outside of yellow or red preset limits
System	
Replace Patch	Two hours of use remaining
Replace Patch Now	Patch is no longer functional
Signal Lost	Patch is outside of coverage area beyond a specified length of time. Caregiver is advised to check on the patient if it is unknown why the patient is no longer being monitored. This notification may also appear if the patch was improperly activated.
Reading Problem	The system was unable to interpret vital sign data for several attempts in a row. This notification may also appear if the patch was incorrectly attached.

Acknowledging Notifications

When a notification is received, it must be acknowledged in the Wireless Monitoring Application.

Depending on your system configuration, vital sign notifications may not be sent until two or more consecutive yellow or red vital sign statuses are recorded.

Depending on your system configuration, some notifications may not require acknowledgement.

To acknowledge a notification from the Wireless Monitoring Application

1. At the main screen, click the notification symbol associated with the appropriate patient.

    The Acknowledge Notifications window displays both the physiological and system notifications for that patient.

2. Click **Acknowledge**.

    A message confirms that notifications have been acknowledged.

3. Click **OK** to return to the main screen.

Reminder notifications

When a notification is not acknowledged within a specified period of time, a reminder notification may be sent. Reminder notifications contain the same information as the original notifications that they refer to.

Escalation notifications

When a notification is not acknowledged within a specified period of time, an escalation notification may be sent to another caregiver handheld device. Escalation notifications contain the same information as the original notifications that they refer to.

Replacing a Patch

1. Remove the patch, electrodes, and temperature sensor from the patient.

2. Dispose of the patch in accordance with the hospital waste procedure.

⚠ **WARNING—The patch is a single-use device. After the patch is removed from a patient, do not reuse the patch, whether on the same patient or on a different patient.**

3. Apply a new patch to the patient as described in *Applying the patch* on page *10*.

Updating patch information in the Wireless Monitoring Application

1. On the main screen, select the patient whose patch was replaced and click **Replace Patch** 🔲 .

> **Replace Patch**
>
> 🔲 Replace patch for:
>
> | COOK, Aaron X | MRN: M190436
Date of Birth: 06/08/1957 (53 years old)
Room-Bed: 1505 - 1 |
> |---|---|
>
> New Patch ID: [   ] - [   ] - [   ]
>
> [Cancel] [Replace]

2. Do one of the following to enter the new patch ID number:

    •   Enter the new ID number in the **New Patch ID** text box.

    •   Scan the barcode on the patch.

        The barcode appears on both the patch and the packaging. If you are unable to scan the patch at the patient's bedside, you can use the patch ID on the packaging instead.

3. Click **Replace**.

    A message confirms that the patch has been replaced.

4. Click **OK** to return to the main screen.

Removing a patient from wireless monitoring

1. Remove the patch, electrodes, and temperature sensor from the patient.

2. Dispose of the patch in accordance with the hospital waste procedure.

⚠️ **WARNING—The patch is a single-use device. After the patch is removed from a patient, do not reuse the patch, whether on the same patient or on a different patient.**

3. On the main screen of the Wireless Monitoring Application, select the patient to be removed from wireless monitoring and click **Remove Patient** 👤.

   The Remove Patient from Wireless Monitoring screen appears.

4. Click **Remove**.

   A message confirms that the patient was removed from monitoring.

5. Click **OK**.

   The main screen appears.

Running a Clinical Data Report

1. From the **Actions** drop-down list on the main screen, select **Clinical Data Report**.

The Clinical Data Report dialog box appears.

2. In the **From** and **To** boxes, enter the date range for the report.

   Alternatively, click the calendar icons to select the date range from calendars.

3. Select the unit for the report from the **Unit** drop-down list.

4. Select a patient, or select **All patients**, from the **Patient** drop-down list.

   • Select **Discharged Patients Only** to include only discharged patients in the report.

5. Click **View Report**.

   The report can take several minutes to generate and be displayed.

   You can print a clinical data report by clicking the print icon in the Adobe Acrobat Reader menu bar.

Assigning beds to groups

Beds can be assigned to groups within a unit. A group can then be selected on the main screen using the **Groups** drop-down list, and only patients in beds assigned to that group will appear on the list. Notifications for patients in that group are sent to the corresponding notification devices, as configured by IT for the group.

Patients admitted in a unit but without room/bed information can still be monitored and are considered part of the **Default Bed Group**. See Step 3, below.

Additional user privileges are required to use the Assign Beds feature.

Assigning beds to groups

1. From the **Actions** drop-down list, select **Assign Beds**.
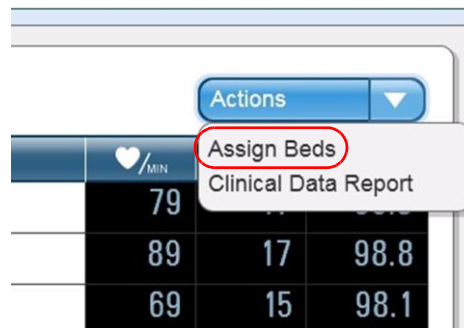
The Assign Beds screen appears.
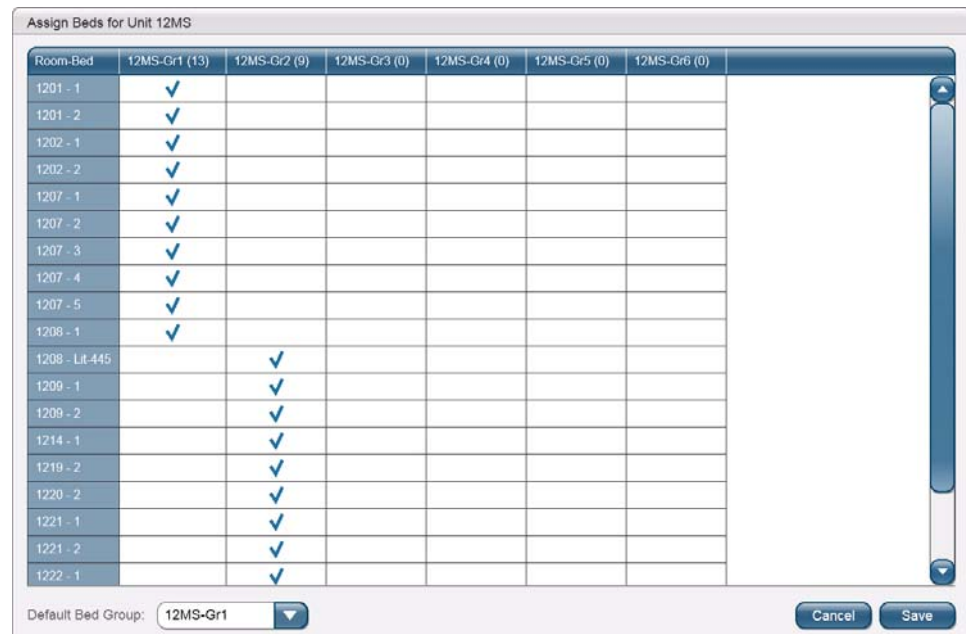
2. Click a cell in the group column to assign a bed to a group.

   A blue check mark indicates the assigned group for a bed. A bed can be reassigned as often as needed.

3. To set the group to which patients are admitted without room/bed information assigned, click the **Default Bed Group** drop-down list and select a group.

4. Click **Save**.

   A message confirms that your selections have been saved.

5. Click **OK** to return to the main screen.

Chapter 3
Troubleshooting

Logging in and out

I am entering the correct user name and password, but the system is not logging me in

- Your computer's CAPS LOCK may be on. If so, turn it off and try again.

- If that doesn't work, double-check your user name and password.

- If your user name and password are correct and the system still won't log you in, contact your facility's IT department for assistance.

Adding a patient

Scanning the patient's or patch's bar code doesn't work

Sometimes bar codes don't print properly, and scanners have a hard time reading them. If you attempt to scan a bar code and it doesn't work, enter the code manually.

If the problem persists with different bar codes, then you may have a faulty scanner. Contact your facility's IT department for assistance.

I need to add a patient to wireless monitoring, but the patient's name isn't in the list

There are several reasons why a patient's name may not be in the Add patient to wireless monitoring list:

- The patient may have already been added to wireless monitoring. Check the main screen, then follow the procedures under *The patient's name is not displayed on the main screen* on page *26* to see if the patient is already being monitored.

- The patient may have recently been admitted or transferred to your unit, and the system hasn't been updated yet.

If neither of the above applies, check with your facility's IT department for assistance.

I am unable to access the Assign Bed feature

Additional user privileges are required to assign beds. Ask someone who has these privileges for assistance.

If you know that you should have access to this feature, but you do not, contact your facility's IT department for assistance.

I can't change the vital sign limits

Additional user privileges may be required to change some or all vital sign limits. Ask someone who has these privileges for assistance.

If you know that you should have the ability to change vital sign limits, but you do not, contact your facility's IT department for assistance.

The patient's demographic information is incorrect

The SensiumVitals Wireless Monitoring System's patient information is taken from the Hospital Information System (HIS). Check with the HIS administrator to make sure that all information is correct and up to date.

Monitoring a patient

The patient's name is not displayed on the main screen

If the patient's name is not visible on the main screen, check the following:

- Check the **Group** drop-down list to make sure that the proper group is being shown, or select **All** to display all patients being monitored.

- If there is a scroll bar to the right of the patient list, the list is too long to be displayed on one screen. Scroll down to see if the patient is farther down the list.

- It is possible that the patient was not added to wireless monitoring, even if a patch was applied and activated. Follow steps 1 and 2 of the procedure *Adding patient to wireless monitoring* on page *14*. If the patient's name is on the Patient List screen, follow the rest of the procedure to add the patient to wireless monitoring.

- It is also possible that the patient was transferred to another unit, or was recently transferred into your unit and the Hospital Information System has not yet been updated. Verify the status of the patient in the HIS.

If, after doing all of the previous steps, the patient's name still is not displayed on the main screen, contact your facility's IT department for assistance.

The patient's vital sign data are not appearing on the main screen

If a patient's vital sign data aren't being read by the system, the vital sign data columns show dashes (--). If this is the case, check the following:

• Check the Patch column to see if the "Patch Activating" icon (⚙) is displayed. If so, wait a few minutes for it to disappear.

> NOTE: The patch can take up to 15 minutes in the worst case to activate and display data on the main screen.

• Check the Patch column to see if the Out of Range/Signal Lost icon (📶) is displayed. If so, see *The Patch status column displays the Out of Range/ Signal Lost icon* on page *28*.

• Check the Patch column to see if the "Replace Patch" icon (🔄) is displayed. If so, replace the patch following the instructions under *Replacing a Patch* on page *20*.

• Make sure that the activation tab has been removed.

• If you have checked all of these items, properly applied and activated the patch, and the patient is not out of range, the patch may be faulty. Wait a few minutes for the next reading. If dashes (--) are still displayed, replace the patch following the instructions under *Replacing a Patch* on page *20*.

If, after doing all of the previous steps, the vital sign data columns still display dashes (--), contact your facility's IT department for assistance.

There are question marks (??) in the patient's heart rate column

This is normal, but should not happen often. It can be due to temporary electrical interference, the patient moving in certain ways, or something striking the patch. However, if the question marks persist, check the following:

• Make sure that the patch is properly placed on the patient.

• Make sure that the electrodes are firmly attached to the patch and to the patient.

• Replace the monitoring electrodes with fresh electrodes.

• If the problem persists for longer than a specified period of time, the system will send a notification to replace the patch. If this is the case, replace the patch following the instructions under *Replacing a Patch* on page *20*.

If, after doing all of the previous steps, the heart rate column still displays question marks (??), contact your facility's IT department for assistance.

There are question marks (??) in the patient's respiratory rate column

Due to the nature of impedance pneumography, it is possible that respiratory rate readings are often not available, especially when the patient is moving. It can take several minutes after the patient has stopped moving for respiratory rate data to be

displayed. However, if the patient is not moving and question marks persist, do the following:

- Make sure that the patch is properly placed on the patient.

- Make sure that the electrodes are firmly attached to the patch and to the patient.

- Replace the monitoring electrodes with fresh electrodes.

- If the problem persists for longer than a specified period of time, the system will send a notification to replace the patch. If this is the case, replace the patch following the instructions under *Replacing a Patch* on page *20*.

If, after doing all of the previous steps, the respiratory rate column still displays question marks (??), contact your facility's IT department for assistance.

There are question marks (??) in the patient's temperature column

Temperature readings might become unavailable if the patient is moving or if the patient's arm is not covering the temperature sensor completely. It can take several minutes after the patient's arm has returned to the proper position for temperature data to be displayed. Question marks can also be displayed if the patient experiences a rapid drop in core body temperature.

If question marks persist, check the following:

- Make sure that the temperature sensor is properly placed on the patient.

- If the problem persists for longer than a specified period of time, the system will send a notification to replace the patch. If this is the case, replace the patch following the instructions under *Replacing a Patch* on page *20*.

If, after doing all of the previous steps, the temperature column still displays question marks (??), contact your facility's IT department for assistance.

The Patch status column displays the Out of Range/Signal Lost icon

If the Out of Range/Signal Lost icon ( ) is displayed in the Patch column, check the following:

- The signal loss may be temporary. Wait a few minutes for the next patch reading. If the icon goes away, the signal has been restored.

- If the Out of Range/Signal Loss icon remains, verify the location of the patient. The patient may have been temporarily moved to an area where there is no coverage.

- If the Out of Range/Signal Loss icon is still displayed, and the patient is in the assigned room, the patch may be faulty. Replace the patch following the instructions under *Replacing a Patch* on page *20*.

If, after doing the previous steps, the Patch column still displays the Out of Range/Signal Lost icon, contact your facility's IT department for assistance.

A patient appears in my group list, but isn't under my care

Check to make sure that bed assignments are up to date. A bed that another caregiver is responsible for may have been inadvertently assigned to you.

Also, your group could be the "default group" to which patients without room/bed information are assigned. The patient will be removed from your group when the room/bed information has been updated.

It may also be that the patient was recently transferred into your group in the system, but has not yet been physically moved.

Patient History

Some data points in the Patient History screen are 10 minutes apart and others are 2 minutes apart

This is normal and not a cause for worry. Vital sign data is usually updated once every 10 minutes, but can vary depending on the configuration of your unit. Frequency automatically increases to as much as once every two minutes when the vital sign data are outside of preset limits.

Some data points in the Patient History screen are yellow or red when they're within the vital sign limits

This is normal and not a cause for worry. A data point is marked yellow or red if it falls outside of the yellow or red vital sign limits at the time it was recorded. If the vital sign limits are later changed, yellow and red dots may fall within the new limits.

Some data points in the Patient History screen are blue when they're outside the vital sign limits

This is normal and not a cause for worry. A data point is marked blue if it falls within the yellow vital sign limits at the time it was recorded. If the vital sign limits are later changed, blue dots may fall outside the new limits.

Removing patients from Wireless Monitoring

A patient has been discharged, but the patient's name is still on the wireless monitoring list

Even if a patient is discharged from a facility, the patient must be manually removed from wireless monitioring using the procedures under *Removing a patient from wireless monitoring* on page *21*.

General application questions

Online help doesn't work

Contact your facility's IT department.

Clinical reporting doesn't work

Contact your facility's IT department.

Notification questions

There is a notification on the main screen, but the notification was never sent to my pager

Check to make sure that bed assignments are up to date. The bed you believe you are responsible for may have been inadvertently assigned to another caregiver.

If you are not receiving pages for *any* patients, contact your facility's IT department to have your pager serviced or replaced.

I am receiving notifications for patients not under my care

⚠ **WARNING—Always address received notifications, even if they are not for a patient under your care.**

Check to make sure that bed assignments are up to date. A bed that another caregiver is responsible for may now be assigned to you.

Also, your group could be the "default group" to which patients without room/bed information are assigned. You will stop receiving notifications when the patient's room/bed information has been properly entered.

A patient's vital sign data is yellow or red, but I didn't receive a notification

This is normal and not a cause for worry. Depending on your system configuration, vital sign notifications may not be sent until two or more consecutive yellow or red vital sign statuses are recorded.

It is also possible, depending on your system configuration, that notifications are turned off for your system. Check with your facility's IT department to verify this.

If you are not receiving pages for *any* patients, contact your facility's IT department to have your pager serviced or replaced.

Error message questions

The message "Internet Explorer cannot display the webpage" displays when I tried to open the main screen

Try again. If the problem persists, contact your facility's IT department for assistance.

Appendix A
Technical Specifications

Performance specifications

Item	Specification
Heart rate	30–200 beats per minute (bpm) ± 2 bpm
Respiratory rate	5–60 breaths per minute (BPM) ± 2 BPM
Temperature sensor	For axillary temperatures from 89.6°–111.2°F (32°–44°C) within 0.4°F (± 0.2°C)

Patch specifications

Item	Specification
Patch Weight	15 g
Duration of Use	Up to 5 days
Operating Temperature	50°–113°F (10°–45°C)
Storage Temperature	-4°–140°F (-20°–60°C)

Appendix B
Compliance and Safety Info

FCC compliance statement (United States)

Patch FCC ID: AEJ-TZ202055R1. Bridge FCC ID: AEJ-TZ202020R1.

These devices comply with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesired operation.

> ⚠ **CAUTION: Changes or modifications to these units not expressly approved by the party responsible for compliance could void the user's authority to operate these units.**

These units have been tested and found to comply with the limits for a Class A digital devices, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a non-residential installation. These units generate, use and can radiate radio frequency energy and, if not installed and used in accordance with the manufacturer's instructions, may cause interference harmful to radio communications.

📝 Please insure all warning and caution icons noted in this DFU are reviewed, understood and followed.

Safety

Patch—Safety

Regulations	Compliance Tests
IEC 60529 Degrees of protection provided by enclosure (IP Code)	IP64 Dust-tight and Splashing Proof
IEC 60601-1 Medical electrical equipment General Requirements for Safety	Patient leakage current < 10 µA Dielectric Strength @ 500 V
IEC 60601-2-27 Medical electrical equipment Particular requirements for the safety, including essential performance, of electrocardiographic monitoring	Heart rate: 30 to 200 +/- 2 bpm
IEC 60601-2-49 Medical electrical equipment Particular requirements for the safety of multifunction patient monitoring equipment	BF type applied part
ISO 10993 Biological Evaluation of Medical Devices Package	Cytotoxicity Irritation and delayed-type hypersensitivity
ASTM F2475 - 05 Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	Cytotoxicity Physicochemical
ISO 80601-2-56 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	Body temperature: 32°C to 44°C +/- 0.2°

Bridge—Safety

Regulations	Compliance Tests
IEC 60950-1 Information technology equipment Safety general requirements	Safety for interface with Telecommunication Network Equipment

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. The bridge should be installed and operated with minimum distance 20 cm between the radiator and your body.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. IEEE 802.11b or 802.11g operation of this product in the USA is firmware-limited to channels 1 through 11.

Electromagnetic compatibility

Patch—Electromagnetic Compatibility

Regulations	Compliance Tests	
IEC 60601-1-2 Medical electrical equipment Collateral standard: Electromagnetic Compatibility - Requirements and tests	**Emissions:**	30 to 230 MHz 40 dBµV/m
		230 to 1000 MHz 47 dBµV/m
	ESD:	+/- 8 kV Air discharges
		+/- 6 kV Contact discharges
	RF field:	3 V/m, 80 MHz to 2.5 GHz
	Magnetic field:	3 A/m
IEC 62311 Assessment of electronic and electrical equipment related to human exposure restrictions for	**Frequency:**	0 to 300 GHz
	Magnetic flux density:	100,000 to 0.1 µT
FCC, CFR 47, Part 15	**Intentional**	< 50mV/m @ 3
	Unintentional radiation @ 10m:	
	Frequencies (MHz)	**dBµV/m**
	30–88	90
	88–216	150
	216–960	210
	960+	300
FCC, CFR 47, Part 18	**Operating frequency:**	915 MHz +/-13.0 MHz
EN 300 220-01 Electromagnetic compatibility and Radio spectrum Matters (ERM) Short Range Devices (SRD)	**Output power class:**	7a, 5 mW

Bridge—Electromagnetic Compatibility

Regulations	Compliance Tests	
IEC 60601-1-2 Medical electrical equipment Collateral standard: Electromagnetic Compatibility - Requirements and tests	**Emissions:**	30 to 230 MHz 40 dBµV/m
		230 to 1000 MHz 47 dBµV/m
	ESD:	+/- 8 kV Air discharges
		+/- 6 kV Contact discharges
	RF field:	3 V/m, 80 MHz to 2.5 GHz
	Magnetic field:	3 A/m

Bridge—Electromagnetic Compatibility

Regulations	Compliance Tests	
FCC, CFR 47, Part 15	**Intentional**	< 50mV/m @ 3
	Unintentional radiation @ 10m:	
	Frequencies (MHz)	**dBµV/m**
	30–88	90
	88–216	150
	216–960	210
	960+	300
EN 300 220-01 Electromagnetic compatibility and Radio spectrum Matters (ERM) Short Range Devices (SRD)	**Output power class:**	7a, 5 mW