

PATIENT MANUAL
MANUAL DEL PACIENTE

LATITUDE® Communicator
Comunicador LATITUDE®

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ENGLISH

LATITUDE® Communicator



This manual contains instructions for the use of Models 6280 and 6290 LATITUDE Communicators. These instructions are identical for both models. Technical differences, however, do exist between the models and are identified where appropriate. The model number for your Communicator is located on its bottom label.

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LATITUDE Patient Management System

The LATITUDE Patient Management System (referred to as “LATITUDE system” throughout this manual) is a remote monitoring system that gives your health care provider access to your implanted device data between scheduled office visits. The LATITUDE system is designed to improve patient care while providing convenience to you.

The LATITUDE system uses advanced security methods to protect your personal medical information. Only authorized health care providers have access to your information through the secure clinician website.

The LATITUDE system is not meant to assist with health emergencies. If you are not feeling well, call your health care provider or dial 911.

The LATITUDE Communicator

The LATITUDE Communicator is an in-home monitoring system that uses a wireless communication system to communicate with your implanted device. The Communicator does not provide continuous monitoring. It automatically reads implanted device information at times scheduled by your health care provider.

At scheduled intervals, the Communicator sends your implanted device data to the LATITUDE system using one of three communication methods:

- Standard telephone line (see page 18); or
- Cellular data network (see page 21); or
- Ethernet (Internet) (see page 25).

The Communicator receives periodic schedule updates made by your health care provider when it connects to the LATITUDE system.

The Communicator does not reprogram or change any functions of your implanted device. Only your health care provider can do this during an office visit.

Model 6280 only: Your Communicator is designed to be used only in the United States, Canada, Puerto Rico, and Mexico. For more information, see “Traveling with Your Communicator” on page 60.

The telephone (landline) feature of the Communicator is designed to operate on standard telephone lines like those found in most homes. The Communicator supports tone dialing over an analog line. The Communicator may work on other telephone systems, such as digital subscriber line (DSL) and voice over Internet Protocol (VoIP), if those systems provide an analog interface for connecting the Communicator.



Follow the instructions in this manual when using the Communicator. Keep all of your Communicator information in a convenient location for easy access in the future.

Items You Should Receive

The following items are included with the Communicator:

- Communicator unit
- Alternating current (AC) adapter
- Communicator Quick Start Guide
- Communicator Patient Manual (this book)
- Communicator telephone cord

The following items are optional connection accessories, available separately:

- LATITUDE NXT USB Cellular Adapter
- USB Ethernet Adapter

Optional Health Monitoring Equipment

If prescribed by your health care provider, your Communicator can also collect information from an optional LATITUDE heart failure management system. This system includes a LATITUDE weight scale and LATITUDE blood pressure monitor.

These specially designed products provide additional information to monitor your health. Refer to the handbook that is included with the weight scale and blood pressure monitor products.

A universal serial bus (USB) sensor adapter is included with the weight scale and blood pressure monitor. The USB sensor adapter provides a wireless connection between these products and the Communicator. See “Connecting the USB Sensor Adapter” on page 67.

Clinician Website

The clinician website provides authorized health care providers a convenient and secure way to obtain and analyze information from a patient's implanted device.

The LATITUDE system normally displays your device information on the clinician website within 15 minutes. However, it may take longer for your information to appear due to many external factors.

The website provides advanced analysis and trending tools designed at improving patient care. Only your physician and medical personnel authorized by your physician can access your medical data on the password-protected clinician website.

When to Use Your Communicator

The Communicator performs many functions automatically on a schedule set by your health care provider. Other functions need you to respond when the indicators on the front of the Communicator light or flash. Check the Communicator daily to see if any of the indicators are lit solid or flashing.

Use the Communicator only as instructed by your health care provider. The Communicator's Heart button (Figure 1 on page 14) will flash if it needs you to manually complete an interrogation of your implanted device as scheduled by your health care provider. If the Heart button is flashing, press it and then watch the indicators on the Communicator. Call your health care provider if the Call Doctor icon (Figure 2 on page 15) is lit any color.

When Not to Use Your Communicator

The Communicator is designed to work only with your implanted device. It will not work with another patient's implanted device. The Communicator should be used only as authorized by the prescribing physician. The Communicator is not for use with any implanted device other than a Boston Scientific device.

Ask your health care provider if you have questions about any risks with using the Communicator or your implanted device. There is also valuable information about risks and reliability in the patient handbook for your implanted device.

Where to Place Your Communicator

Place your Communicator:

- Near an electrical outlet that is easily accessible.
- Where you can sit comfortably and see the front of the Communicator.
- Depending on the communication method used:
 - **Standard telephone line:** Near a telephone wall jack.
 - **Cellular data network:** In a location where you get a good signal.
 - **Ethernet (Internet):** Near an Internet connection.
- Close to where you sleep or near your bedside. If this is not possible, place your Communicator where you spend a considerable amount of time each day.
- Where the Communicator and all its cables and accessories will be kept dry and not exposed to humidity or potential water contact.

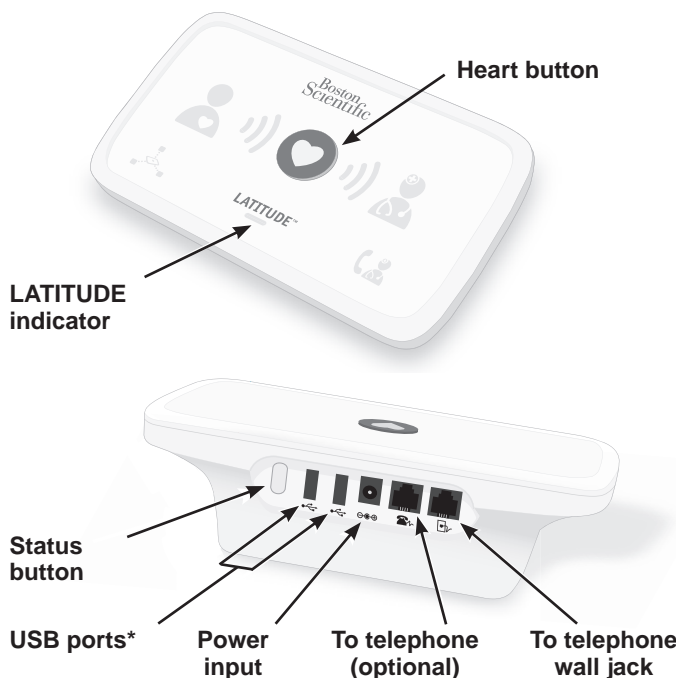
Important Notes

- **It is very important that the Communicator remains plugged into the electrical outlet.**
- **Your Communicator should remain connected to telephone or Internet service unless you are subscribed to the LATITUDE Cellular Data Plan.**
- When setting up your Communicator, use only **one** type of connection (standard telephone line, cellular data network, or Ethernet) even though you may have cables or adapters for more than one.

- This equipment needs to be installed and put into service in accordance with the information in the provided documentation. Call your health care provider if you need assistance setting up or using your Communicator.
- Some household appliances and other sources of electromagnetic energy could interfere with wireless communication between the Communicator and your implanted device. When you are using the Communicator, you should be at least 3 ft (1 m) away from televisions, videocassette recorders (VCRs), digital video disc (DVD) players, personal computers, and other electronic equipment.
- Electrical safety: It is recommended that the customer install a surge protector between the electrical wall outlet and the Communicator. This is to avoid damage to the Communicator caused by local lightning strikes and other electrical surges. Electrical cable wall plugs and other accessories must be in good condition before use.
- Boston Scientific personnel may contact the clinic or patient to advise on the best Communicator placement if an implanted device uses too much radio-frequency (RF) telemetry.

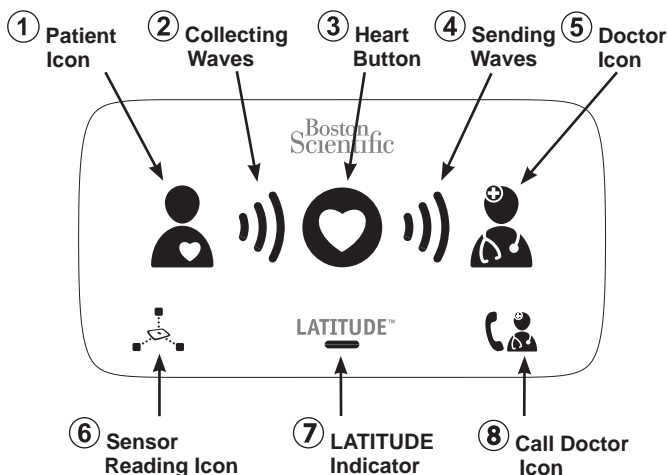
Buttons, Connectors, and Indicators

Figure 1 and Figure 2 show the buttons, indicators, and connectors on the front and back of the Communicator. Refer to “Indicator Descriptions” on page 31 for a description of each indicator.



* USB ports are used to connect the USB sensor adapter and/or the LATITUDE NXT USB Cellular Adapter or USB Ethernet Adapter.

Figure 1. Buttons and Connectors



1. **Patient Icon:** Stay close to the Communicator when lit any color.
2. **Collecting Waves:**
Green = successfully collecting data.
Yellow = error collecting data.
3. **Heart Button:** Press when flashing or press to send data.
4. **Sending Waves:**
Green = successfully sending data.
Yellow = error sending data.
5. **Doctor Icon:** Data successfully sent when lit blue.
6. **Sensor Reading Icon:** Sensor reading received when lit.
7. **LATITUDE Indicator:**
Green = Communicator is active and ready to use.
Yellow = Flashes yellow during start-up process or to indicate an error.
8. **Call Doctor Icon:** Call your doctor when lit any color.

Figure 2. Indicators

For more information about indicators, see “Indicator Descriptions” on page 31.

Installing Your Communicator

Confirming Switch Settings

- Confirm that the white switches numbered 4-8 on the bottom of the Communicator match the country switch settings as shown in Figure 3.
- If the white switches on the bottom of your Communicator do not match the switch settings shown below, slide them up or down to set them as shown.
- Landline telephone connection only: Switches numbered 1-3 may differ from those shown if a dial-out number or prefix is needed to place an outside telephone call. Refer to “Setting Switches for PBX or Dial-out Numbers” on page 66 for those switch settings.

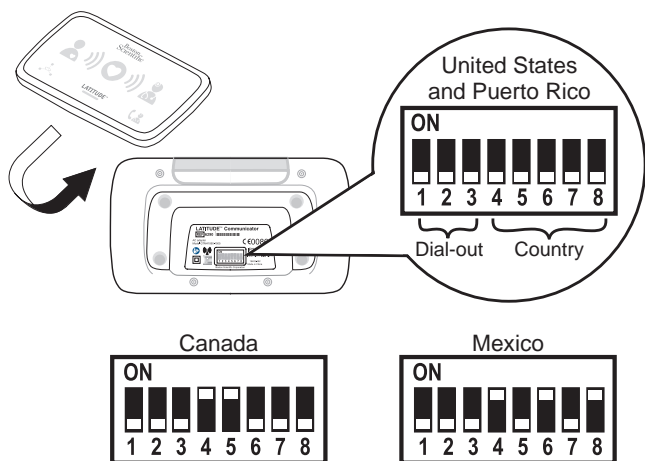


Figure 3. Switch Settings

Connect Your Communicator to the LATITUDE System

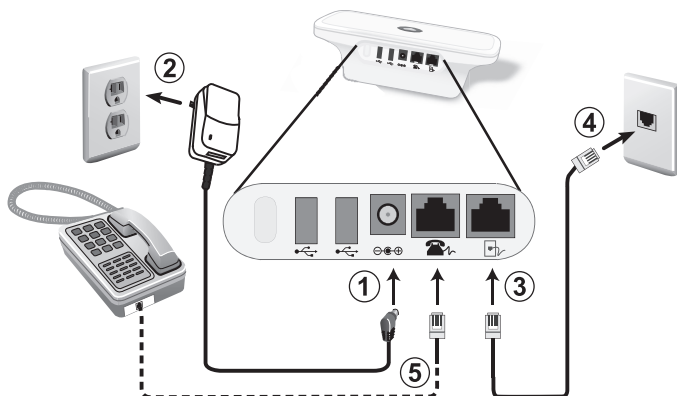
Follow one of the three connection methods listed below to connect to the LATITUDE system:

- **Standard landline telephone:** Follow the steps in “Using a Landline Telephone Jack Connection” on page 18.
- **Cellular data network:** Follow the steps in “Using the LATITUDE Cellular Data Plan” on page 21.
- **Ethernet (Internet):** Follow the steps in “Using a USB Ethernet Adapter Connection” on page 25.

Note: Stay close to the Communicator during the entire installation process to ensure the best connection between your implanted device and the Communicator.

Using a Landline Telephone Jack Connection


Complete the steps below to set up the Communicator for a landline telephone connection.




5. Connecting a telephone is optional.

Figure 4. Using a Landline Telephone Jack Connection

1. Insert the AC adapter (included) into the jack labeled $\ominus \oplus$.
2. Plug the AC adapter into an electrical outlet that is easily accessible.
 - The LATITUDE indicator will flash yellow for up to one minute.
 - All the Communicator indicators will light for approximately one second.
 - If the LATITUDE indicator is not lit, check that both ends of the AC adapter are plugged in firmly. Check if the light on the AC adapter is lit.

3. Plug one end of the Communicator telephone cord (included) into the jack labeled .
4. Plug the other end of the cord into the telephone jack on the wall.

Note: If you have DSL Internet service, you may need to use a DSL filter between the telephone wall jack and the Communicator. Refer to “DSL Internet Service” on page 63.

5. Optional: To use a telephone with this wall jack, you may plug your telephone into the jack labeled .

Note: Your Communicator and a telephone can share the same telephone wall jack. However, they cannot be used at the same time.

6. When the Heart button flashes, press it.
 - Your Communicator’s wave lights will flash green in sequence and repeat for several minutes as shown in “Indicator Sequence When Using the Heart Button” on page 29.
 - If you have previously completed initial setup, the Heart button will not flash at this point.

7. Your Communicator has successfully connected to the LATITUDE system if the wave lights are lit a solid green as shown below.



Setup is complete, and no further action is needed at this time. Leave your Communicator plugged in.

- If this process takes longer than several minutes, software download and installation may be occurring. Refer to “Software Download and Installation” on page 27.
- If the wave lights are not lit a solid green, refer to “Troubleshooting Errors” on page 38.

Important: Your Communicator should remain connected to the electrical outlet and telephone wall jack.

Using the LATITUDE Cellular Data Plan

If you have signed up for the LATITUDE Cellular Data Plan, no telephone or Ethernet cables need to be attached. Instead, a USB Cellular Adapter provided upon subscription to the Data Plan must be connected to the Communicator. Refer to “LATITUDE Cellular Data Plan” on page 55 for more information.

Where to Place Your USB Cellular Adapter

Important: Maintain a distance of at least 6 inches (15 cm) between the USB Cellular Adapter and your implanted device.

Place your USB Cellular Adapter:

- Away from other electronic products or metal surfaces.
- Alongside the Communicator and not under or on top of it.

How to Set Up Your USB Cellular Adapter

Complete the steps below to set up the Communicator for a cellular data network connection.

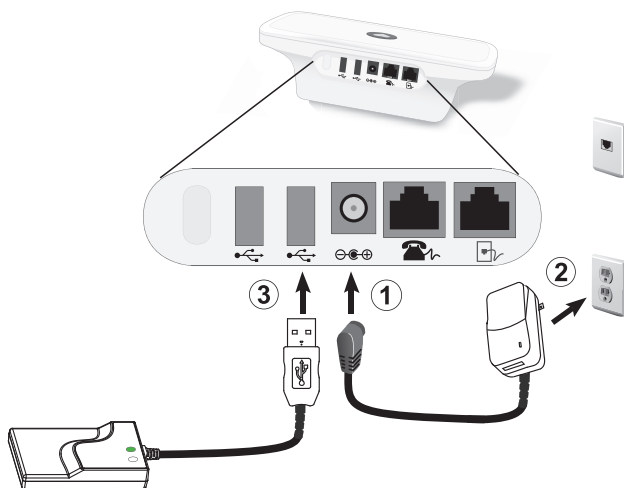





Figure 5. Using the LATITUDE Cellular Data Plan

1. Insert the AC adapter (included) into the jack labeled $\ominus \bullet \oplus$.
2. Plug the AC adapter into an electrical outlet that is easily accessible.
 - The LATITUDE indicator will flash yellow for up to one minute.
 - All the Communicator indicators will light for approximately one second.
 - If the LATITUDE indicator is not lit, check that both ends of the AC adapter are plugged in firmly. Check if the light on the AC adapter is lit.

3. Insert the USB connector of the Cellular Adapter into one of the USB ports labeled . Refer to “Figure 5. Using the LATITUDE Cellular Data Plan” on page 22.

- Confirm that the USB Cellular Adapter is properly connected by verifying that the power indicator  on the top of the Cellular Adapter is lit. It will remain lit except during a LATITUDE system reboot.

Note: The wireless indicator  on the top of the USB Cellular Adapter will flash at various times and at various sequences. This indicator is of no concern during normal operation.

4. When the Heart button flashes, press it.
 - Your Communicator’s wave lights will flash green in sequence and repeat for several minutes as shown in “Indicator Sequence When Using the Heart Button” on page 29.
 - If you have previously completed initial setup, the Heart button will not flash at this point.

5. Your Communicator has successfully connected to the LATITUDE system if the wave lights are lit a solid green as shown below.



Setup is complete, and no further action is needed at this time. Leave your Communicator plugged in.

- If this process takes longer than several minutes, software download and installation may be occurring. Refer to “Software Download and Installation” on page 27.
- If the wave lights are not lit a solid green, refer to “Troubleshooting Errors” on page 38.

Important: Your Communicator should remain connected to the electrical outlet and to the USB Cellular Adapter.

Using a USB Ethernet Adapter Connection

Contact LATITUDE Patient Services at 1-866-484-3268 to obtain a USB Ethernet Adapter. There is a cost for the adapter unless your clinic has made other arrangements. If a replacement adapter is ever needed, contact LATITUDE Patient Services.

Complete the steps below to set up the Communicator for an Ethernet connection.

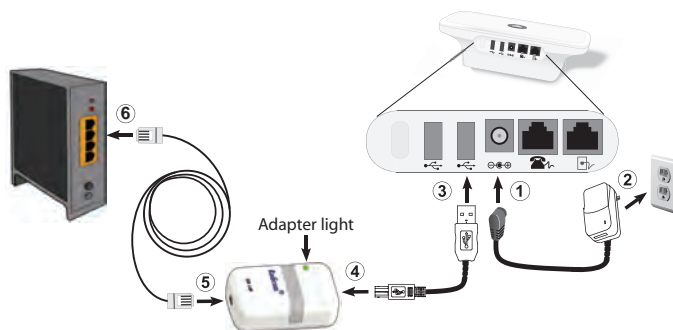



Figure 6. Using a USB Ethernet Adapter Connection

1. Insert the AC adapter (included) into the jack labeled $\ominus \text{C} \oplus$.
2. Plug the AC adapter into an electrical outlet that is easily accessible.
 - The LATITUDE indicator will flash yellow for up to one minute.
 - All the Communicator indicators will light for approximately one second.
 - If the LATITUDE indicator is not lit, check that both ends of the AC adapter are plugged in firmly. Check if the light on the AC adapter is lit.

Important: For the following steps, make sure you use the Ethernet cable provided with the USB Ethernet Adapter and not the telephone cord provided with the Communicator.

3. Insert the narrow end of the USB cable (included with the USB Ethernet Adapter) into one of the USB ports on the Communicator labeled .
4. Insert the square end of the USB cable into the end of the USB Ethernet Adapter nearest the adapter light.
5. Insert the Ethernet cable (included with the USB Ethernet Adapter) into the opposite end of the adapter.
6. Plug the Ethernet cable into an Ethernet port for your Internet service, such as a modem, router, or Ethernet wall jack.
 - Confirm that the USB Ethernet Adapter is properly connected by verifying the green light on its front is lit (solid or flashing).
7. When the Heart button flashes, press it.
 - Your Communicator's wave lights will flash green in sequence and repeat for several minutes as shown in "Indicator Sequence When Using the Heart Button" on page 29.
 - If you have previously completed initial setup, the Heart button will not flash at this point.

8. Your Communicator has successfully connected to the LATITUDE system if the wave lights are lit a solid green as shown below.



Setup is complete, and no further action is needed at this time. Leave your Communicator plugged in.

- If this process takes longer than several minutes, software download and installation may be occurring. Refer to “Software Download and Installation” on page 27.
- If the wave lights are not lit a solid green, refer to “Troubleshooting Errors” on page 38.

Important: Your Communicator should remain connected to the electrical outlet and your Internet service.

Software Download and Installation

Updated software may occasionally be pushed to your Communicator for download and installation.

During initial Communicator setup: If a software update is waiting, pressing the Heart button will trigger the download and installation process, which could take an additional several minutes. Wait for the Heart button to flash again, then press it. Follow the remaining setup steps for the connection method you are using.

During normal use, with Communicator already set up: Software download and installation may happen without your knowledge.

Normal Operation of the Communicator



Your Communicator performs device checks every day, and when operating normally, only the LATITUDE indicator will be lit green. Also, the Communicator automatically interrogates your implanted device on a regular schedule set by your health care provider. None of the Communicator indicators will light during a scheduled interrogation or daily device check. They will light when you use the Heart button as described in “Interrogating Your Implanted Device” on page 57 or when using the Status button as described in “Checking that the Communicator Can Connect to the LATITUDE System” on page 59.

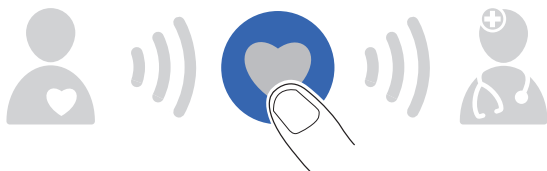
Note: When color is used in this manual to explain operation of the Communicator, an indicator shown as gray means that it is not lit. An indicator shown as any other color, including white, means that it is lit.

(A gray heart shown inside the blue circle means that it is not lit. A white heart shown inside the blue circle means that it is lit.)

To summarize, if the LATITUDE indicator is lit green, your Communicator is operating normally.

Indicator Sequence When Using the Heart Button

This section describes how the indicators will light after you press the Heart button. The Communicator interrogates your implanted device and then sends your data to the LATITUDE system. More details about the colors and purpose of the indicators appear later in this manual.



The Communicator begins interrogating your implanted device after the Heart button is pressed.



The Patient icon lights blue. The Collecting Waves flash green in sequence and repeat while the Communicator interrogates your device.



All three Collecting Waves will light green. The Heart button lights solid white, showing the interrogation was a success.



The Sending Waves flash green in sequence and repeat while the Communicator places a call and starts sending your data to the LATITUDE system.



The Doctor icon lights blue showing the Communicator successfully sent your data to the LATITUDE system. All the indicators shown stay lit as shown for 2 minutes to show the entire process was a success.

Indicator Descriptions

The indicators will light to indicate the Communicator's progress when:

- Manually interrogating your implanted device
- Manually connecting and sending your implanted device information to the LATITUDE system
- Collecting a measurement from a prescribed weight scale or blood pressure monitor

One or more indicators may light or flash a different color to indicate some type of action may need to be taken. Refer to “Troubleshooting Errors” on page 38.



Patient Icon

Shows the Communicator is interrogating (collecting data from) your implanted device.

- Lights solid blue when the Heart button is pressed and an interrogation has started.
- Lights solid blue for 2 minutes after a successful interrogation.



Collecting Waves

Show the Communicator is collecting data from your implanted device.

- Flash green in sequence and repeat, showing the Communicator is interrogating your implanted device.
- Light green for 2 minutes to indicate the interrogation was a success.



Heart Button

- A flashing white light means you need to complete a previously scheduled interrogation. Press Heart button to complete.
- A solid white light for 2 minutes means the interrogation is complete. Note that solid white light may appear dim.
- May also be used to manually initiate an interrogation of your implanted device. Refer to “Interrogating Your Implanted Device” on page 57 before using this button.



Sending Waves

Show the Communicator is connecting to the LATITUDE system.

- Flash green in sequence and repeat, showing a connection to the LATITUDE system is in progress.
- Light green for 2 minutes to indicate the connection to the LATITUDE system was a success and any collected device data was sent.



Doctor Icon

Lights blue for 2 minutes to indicate the Communicator has successfully connected to the LATITUDE system. The Communicator sends any data it has collected from your implanted device, weight scale, or blood pressure monitor.



Sensor Reading Icon

Shows the Communicator has successfully communicated with a prescribed weight scale or blood pressure monitor.

- Flashes green five times and lights solid green for 5 minutes to indicate the Communicator successfully received a weight or blood pressure measurement.



LATITUDE Indicator

Shows the Communicator is connected to electrical power. It also shows if the Communicator startup process is being performed or if the Communicator is ready to use.

- Lights green to indicate the Communicator is connected to electrical power and is ready to use.
- Flashes yellow during the startup process.
- May flash yellow for a long time. This means that new software is being installed on the Communicator.



Call Doctor Icon

Lights yellow or red (flashing or solid) to signal a problem that you should report to your health care provider. Refer to the error in “Troubleshooting Errors” on page 38.

A red light ranks higher than a yellow light. If an error for each color occurs at the same time, only the red light is displayed.

- Flashes yellow briefly after the Communicator is plugged into AC power.
- The light turns off after the Communicator completes the startup process.
- If the startup process does not complete, it lights solid yellow.

Status Button

The Status button is located on the back of the Communicator as shown in Figure 7.



Figure 7. Status Button

The Status button performs one of the following actions depending on how long the button is pressed:

- **Press for less than 3 seconds:** The Communicator indicators will light to show:
 - The status of the last interrogation.
 - The status of the last connection to the LATITUDE system.

The indicators will light for 2 minutes. If the Call Doctor icon was flashing, it will stop flashing and light solid.

- **Press and hold for more than 3 seconds:** The Sending Waves flash green in sequence and repeat while the Communicator connects to the LATITUDE system.

Note: If you pressed the Heart button, the Status button will not function until the resulting interrogation is completed or is cancelled.

Confirming Successful Operation



You can use the Status button to check if the Communicator has been operating normally. The above image shows that all the Collecting and Sending Waves are lit green, confirming that the last interrogation and the last connection to the LATITUDE system were a success. When all the waves are green, no action is needed.

Troubleshooting Errors

Troubleshooting Icon and LATITUDE Indicator Errors

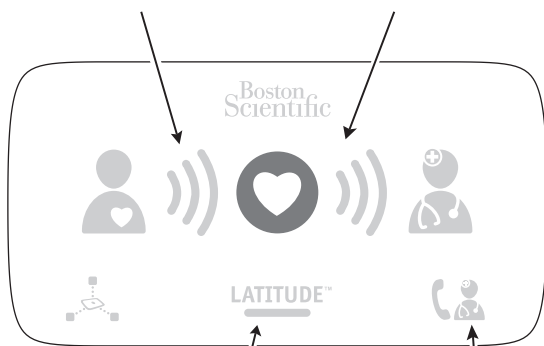
One or more of the indicators on the front of the Communicator may light or flash to indicate some type of Communicator, communication, or LATITUDE system error. A general description of the types of errors are shown in Figure 8. A description of each error is provided in this section, along with suggested actions to resolve each error.

Yellow Collecting Waves

Indicate errors collecting information from your implanted device

Yellow Sending Waves

Indicate errors sending information to the LATITUDE system



LATITUDE Indicator

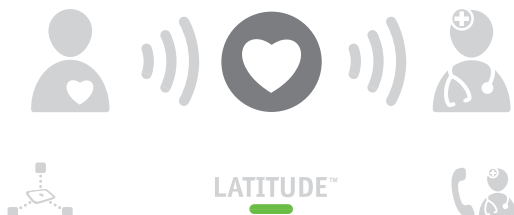
Yellow light indicates an error

Call Doctor Icon

Call your doctor when lit any color

Figure 8. Types of Errors

Heart Button is Flashing LATITUDE Indicator is Green



Description: You need to complete a previously scheduled interrogation.

- Action:**
- Press the Heart button to complete the interrogation.
 - If the Heart button is lit a solid white, the interrogation has been a success. No further action is required.

No Indicators are Lit



Description: No indicators are lit.

The Communicator is not connected to electric power or it is not functioning.

- Action:**
- If the LATITUDE indicator is not lit, check that both ends of the AC adapter are plugged in firmly.
 - Check if the light on the AC adapter is lit.
 - If the Communicator is plugged into electric power and the light on the AC adapter is lit, contact your health care provider.

LATITUDE Indicator is Flashing Yellow No Other Indicators are Lit



Description: The LATITUDE indicator is flashing yellow.

The Communicator is starting up or may be downloading and installing software.

This process typically lasts only one minute but may take up to 10 minutes.

Action:

- No action is required unless the LATITUDE indicator flashes for longer than 10 minutes. In that case, contact LATITUDE Patient Services at 1-866-484-3268.

Call Doctor Icon is Red LATITUDE Indicator is Yellow



Description: The Call Doctor icon is red (flashing or solid), and the LATITUDE indicator is yellow.

A potential problem with your implanted device was detected, but the Communicator cannot send any information collected from your implanted device to the LATITUDE system.

The Call Doctor icon and LATITUDE indicator will light solid as shown until the problem is resolved.

Action: Your immediate response is required. Call your health care provider.

Call Doctor Icon is Yellow LATITUDE Indicator is Yellow



Description: The Call Doctor icon is yellow (flashing or solid), and the LATITUDE indicator is yellow.

Indicates one of the following errors:

- Your Communicator is currently unable to monitor your implanted device.
- Monitoring of your implanted device was suspended through the LATITUDE system.

The Call Doctor icon and LATITUDE indicator will light solid yellow until the problem is resolved.

Action: Call your health care provider.

Call Doctor Icon is Yellow LATITUDE Indicator Not Lit



Description: The Call Doctor icon is lit a solid yellow, and the LATITUDE indicator is not lit. This indicates your Communicator may not be working properly.

Action: You may need a replacement Communicator. Contact your health care provider.

Troubleshooting Yellow Wave Indicator Errors

One or more of the Wave indicators will light yellow to indicate some type of error as described in the following Wave sections. Wave indicators light yellow for 60 minutes unless the error is resolved sooner. After 60 minutes, all Wave lights are turned off and the LATITUDE indicator is lit green, even if the problem was not resolved.

If the error fails to resolve after trying the action steps in the following section, call your health care provider.

Note: In addition to the Wave indicators lighting yellow to indicate an error, the LATITUDE indicator lights yellow at the same time.

One Yellow Collecting Wave



Description: The Communicator was unable to start an interrogation of your implanted device, or your implanted device was out of range at the time of the attempted interrogation.

- Action:**
- Ensure the Communicator is optimally placed as described in “Where to Place Your Communicator” on page 12.
 - Face the Communicator. Sit directly in front of the Communicator. Make sure you are within 10 ft (3 m) of the Communicator.
 - Move any wireless electronic products (such as cordless or cellular phones or baby monitors) that are within 3 ft (1 m) of the Communicator.

To verify that troubleshooting was a success:

- Press the Heart button to start another interrogation. If the interrogation was a success, all three Collecting Waves will light green for 2 minutes.

Two Yellow Collecting Waves



Description: The Communicator started but was not able to complete the interrogation within the time allowed.

- Action:**
- Ensure the Communicator is optimally placed as described in “Where to Place Your Communicator” on page 12.
 - Face the Communicator. Sit directly in front of the Communicator. Make sure you are within 10 ft (3 m) of the Communicator.
 - Remain still until the interrogation is complete. Do not move away from the Communicator.
 - Move any wireless electronic products (such as cordless or cellular phones or baby monitors) that are within 3 ft (1 m) of the Communicator.

To verify that troubleshooting was a success:

- Press the Heart button to start another interrogation. If the interrogation was a success, all three Collecting Waves will light green for 2 minutes.

Three Yellow Collecting Waves



Description: Any of the following reasons could cause this error:

- You may have exceeded your weekly interrogation limit, or you may not be allowed to use the Heart button.
- The Communicator was unable to establish wireless communication with your implanted device due to interference from another person's implanted device.

Action:

- If you are planning to interrogate your device, wait 10 minutes. Then try pressing the Heart button again to initiate the interrogation.
- Do not press the Heart button while the interrogation is in progress unless you intend to stop the interrogation.
- If you see three yellow waves after pressing the Heart button, contact your health care provider.

One Yellow Sending Wave



Description: The Communicator was not able to make a connection to the LATITUDE system for one of the following reasons:

- No dial tone was detected when attempting to use the telephone line.
- No cellular providers were detected when attempting to connect using the LATITUDE Cellular Data Plan.
- No Ethernet connection was detected when attempting to connect using the USB Ethernet Adapter.

Action: If using a landline telephone connection:

- Check that the telephone cord provided with the Communicator is plugged in tightly to a telephone wall jack and the Communicator.
- Pick up the telephone and check for dial tone. If no dial tone, try a different telephone wall jack.

- If you have DSL Internet service, ensure you are using a DSL filter between the Communicator and the telephone wall jack.
- Check that the analog telephone service supports the tone dialing mode.

If using the LATITUDE Cellular Data Plan:

- If you have not activated the LATITUDE Cellular Data Plan, see page 55.
- Make sure the USB Cellular Adapter is plugged into the Communicator.
- Move the Communicator to another location that may have better cellular reception.
- If other locations do not work after trying another connection, try plugging the Communicator into an active telephone wall jack.

If using the USB Ethernet Adapter:

- Make sure the USB cable provided with the USB Ethernet Adapter is connected at one end to the USB Ethernet Adapter and at the other end to the Communicator.
- Make sure the Ethernet cable provided with the USB Ethernet Adapter is firmly connected at one end to the USB Ethernet Adapter and at the other end to the Ethernet port for your Internet service.
- If the green light on the front of the USB Ethernet Adapter is not on, make sure the Internet modem or router is powered on.

To verify that troubleshooting was a success:

- Press and hold the Status button until the Sending Waves flash green in sequence and repeat. If the connection is successful, all three Sending Waves will light green for 2 minutes.

Two Yellow Sending Waves



Description: An attempt to connect to the LATITUDE system failed due to connection issues relating to the landline telephone, cellular network, or Ethernet.

If using a landline telephone connection, another device (telephone, answering machine, or computer) may be using or attempting to use the telephone line.

Action: If using a landline telephone connection:

- Make sure your telephone is not being used at this time.
- Pick up the telephone and check for dial tone. If no dial tone, try a different telephone wall jack.
- Remove any splitters between the Communicator and the telephone wall jack.
- If you have DSL Internet service, ensure you are using a DSL filter between the Communicator and the telephone wall jack.

- Check that the switches on the bottom of the Communicator are set correctly for your country and whether you need to dial a number to get an outside line. Refer to “Confirming Switch Settings” on page 16.

If using the LATITUDE Cellular Data Plan:

- If you have not activated the LATITUDE Cellular Data Plan, see page 55.
- Move the Communicator to another location that may provide a stronger cellular signal.
- If other locations do not work after trying another connection, try plugging the Communicator into an active telephone wall jack.

If using the USB Ethernet Adapter:

- Make sure the Ethernet cable provided with the USB Ethernet Adapter is connected to the Ethernet port for your Internet service.

To verify that troubleshooting was a success:

- Press and hold the Status button until the Sending Waves flash green in sequence and repeat. If the connection is successful, all three Sending Waves will light green for 2 minutes.

Three Yellow Sending Waves



Description: The Communicator was able to establish a connection, but no information reached the LATITUDE system.

Action:

- Check that the switches on the bottom of the Communicator are set correctly for your country and whether you need to dial a number to get an outside line. Refer to “Confirming Switch Settings” on page 16.

If using the USB Ethernet Adapter:

- Make sure that other computers or devices connected to your Internet modem or router are able to access the Internet.

To verify that troubleshooting was a success:

- Press and hold the Status button until the Sending Waves light green and show progress.
- If you see three yellow waves after trying the above action, your Communicator may not be set up correctly in the LATITUDE system. Contact your health care provider.

LATITUDE Cellular Data Plan

The LATITUDE Cellular Data Plan uses a cellular data network rather than a standard landline telephone connection to send your implanted device data to the LATITUDE system. The LATITUDE Cellular Data Plan is an optional subscription service that must be activated before your Communicator can use this service. Upon subscription, you will receive a USB Cellular Adapter that enables cellular communication between your Communicator and the LATITUDE system.

The LATITUDE Cellular Data Plan uses a data-only network. It does not send voice signals and it cannot be used with your cellular phone service.

Note: Your Communicator is designed to use an Ethernet connection, if available, or a landline telephone connection if it is plugged into an active telephone jack. If connected, your Communicator will send your implanted device data over the Ethernet or landline telephone connection even if you are subscribed to the LATITUDE Cellular Data Plan.

Cellular Converter

You may already have a Multi-Tech Systems MultiConnect™ MT200A2W analog-to-wireless cellular converter from a previous Communicator. Your LATITUDE Communicator may use the Multi-Tech Systems MultiConnect™ MT200A2W analog-to-wireless cellular converter to access a cellular network. The MultiConnect Converter has been tested and found to be compatible with the LATITUDE Communicator. Use of the converter is optional.

Activating the LATITUDE Cellular Data Plan

Contact LATITUDE Patient Services at 1-866-484-3268 to subscribe to the LATITUDE Cellular Data Plan. There is a cost for this service unless your clinic has made other arrangements. An activated plan works only with your LATITUDE NXT USB Cellular Adapter. If a replacement adapter is ever needed, or if you need to update your subscription, contact LATITUDE Patient Services.

Once the LATITUDE Cellular Data Plan is activated, you can verify the connection by following the instructions in “Checking that the Communicator Can Connect to the LATITUDE System” on page 59. If you travel to another location with your Communicator, check the connection from that location.

Troubleshooting and Support

Subscription to the LATITUDE Cellular Data Plan does not guarantee coverage. Actual coverage may be affected by such things as terrain, weather, foliage, buildings and other construction, signal strength, customer equipment, and other factors.

The Sending Waves may light yellow if your Communicator cannot connect through an activated LATITUDE Cellular Data Plan. If this happens, refer to the Sending Waves sections of this manual, page 49 through page 54. If the Communicator is still unable to connect, contact LATITUDE Patient Services for assistance.

If your Communicator is not able to connect to the LATITUDE system using the LATITUDE Cellular Data Plan, try plugging the Communicator into an active telephone jack.

Discontinuing Your LATITUDE Cellular Data Plan

Contact LATITUDE Patient Services at 1-866-484-3268 to discontinue use of the LATITUDE Cellular Data Plan. You will need to discontinue your subscription if you stop using the LATITUDE system or if you want to return to using a landline telephone connection. Make sure your health care provider is aware of any changes in service.

For information on returning, replacing, or disposing of your USB Cellular Adapter, see page 65.

Interrogating Your Implanted Device

The Communicator automatically interrogates your implanted device on a regular schedule set by your health care provider. This may happen without your awareness and should not require any action on your part. Daily device checks are also performed automatically. None of the Communicator indicators will light during a scheduled interrogation or daily device check.

A scheduled interrogation will not be completed if you are out of range (10 ft/3 m) from the Communicator when it attempts to communicate with your implanted device. If the Communicator is unable to automatically interrogate your device after repeated attempts, the Heart button will flash to allow you to complete the interrogation manually. The Heart button also flashes the first time you use the Communicator.

The Heart button is designed to enable you to manually interrogate your implanted device. Manual interrogation is a feature that must be enabled by your health care provider. When you press the Heart

button, the Communicator checks to make sure that the interrogation is permitted. You should only use the Heart button if it is flashing or when instructed to do so by your health care provider.

If you press the Heart button by mistake (not intending to perform an interrogation), press and hold the Heart button again for at least 5 seconds to cancel the interrogation. The Collecting Waves may light yellow and show progress while the interrogation is being cancelled.

When using the Heart button, you should stay close to the Communicator during the entire interrogation process to ensure optimum communication between your implanted device and the Communicator.

If a manual interrogation is not permitted, either because the limit has been reached or because the feature is disabled, the Communicator automatically calls the LATITUDE system. This is done to check for a change in the number of manual interrogations allowed or to check if this feature has been re-enabled.

CAUTIONS:

- Normal use of the LATITUDE system has been accounted for in the projected battery life of your implanted device. Using the Heart button more often than when the Heart button flashes or more often than instructed by your health care provider may lead to a decrease in the battery life of your implanted device.
- If you feel unwell or are in need of urgent health care, call your health care provider or dial 911.

Interrupted Electrical Power

The Communicator has internal memory that stores your interrogation and other information in case the electrical power is interrupted or the AC adapter is unplugged. The LATITUDE indicator will transition back to green once power is restored to the Communicator.

Checking that the Communicator Can Connect to the LATITUDE System

Complete the following steps to check that the Communicator can connect to the LATITUDE system. You should do this if you have moved the Communicator or if there has been a change in your telephone service or LATITUDE Cellular Data Plan subscription.

1. Check that the Communicator is plugged in and the LATITUDE indicator is green.
2. Press and hold the Status button on the back of the Communicator for more than 3 seconds. The Sending Waves flash green in sequence and repeat while the Communicator attempts to connect to the LATITUDE system.

If both Collecting and Sending Waves light, you did not press the Status button long enough. Pressing the Status button for less than 3 seconds displays the status of the last interrogation and the status of the last attempt to connect to the LATITUDE system.

3. Watch the front of the Communicator. The Sending Waves should flash green in sequence and repeat, showing a connection to the LATITUDE system is in progress.
4. Wait several minutes for the connection to complete.
5. **If the connection was successful**, all three of the Sending Waves will light green for 2 minutes.
If the connection was unsuccessful, one or more of the Sending Waves will light yellow. Refer to the appropriate condition in the “Troubleshooting Yellow Wave Indicator Errors” section beginning on page 45 for actions to take.

Traveling with Your Communicator

You can use your Communicator away from home if you will be gone for an extended period. Consult your health care provider before planning to travel for an extended period, whether or not you take your Communicator. Your health care provider may need to temporarily change your interrogation schedule or, if you are traveling outside the country, give you information about connecting to the LATITUDE system.

Note (*Model 6280 only*): Your Communicator is designed to be used only in the United States, Canada, Puerto Rico, and Mexico. Use of the Communicator in other countries may be restricted due to radio-frequency (RF) laws. Please contact LATITUDE Patient Services at 1-866-484-3268 for specific information.

If you take your Communicator with you, check that the Communicator can connect to the LATITUDE system. Refer to “Checking that the Communicator Can Connect to the LATITUDE System” on page 59.

Communicator Use of the Telephone System (Landline Telephone Only)

The Communicator makes telephone calls when there is a need to send data to the LATITUDE system. These calls usually last for approximately 5 minutes.

The Communicator can only make outgoing calls. It cannot receive calls. The Communicator is designed to operate on standard landline telephone connections like those found in most homes and supports tone dialing over an analog line. The Communicator may work on other telephone systems, such as DSL and VoIP, if those systems provide an analog interface for connecting the Communicator. The Communicator should not be connected to a digital phone interface, such as those commonly used in some businesses, hotels, and managed care facilities (nursing homes, skilled care facilities, rehabilitation centers) where telephones are typically provided by the facility.

If you have other telephone equipment (including fax machine, answering system or computer modem) connected to the same phone line and the line is in use, the Communicator will wait and attempt to place a call later. If you have heavy phone line usage that delays or prevents the Communicator from placing or completing phone calls, it may be appropriate to install an additional telephone line.

Your Communicator and a telephone can share the same telephone wall jack; however, they cannot be used at the same time. The Communicator will relinquish control of the telephone line shortly after you pick up the phone, provided that the telephone line meets the specifications stated on page 68.

Using the Telephone While the Communicator is Making a Call

If you pick up the phone while the Communicator is using the telephone line, hang up the receiver, wait 3 or more seconds, and then pick up the telephone receiver again. The Communicator will disconnect and dial tone will be restored.

If the Communicator does not disconnect and restore dial tone, hang up the receiver. Then unplug the Communicator from electrical power. You can then use your phone. Plug the Communicator back in after you have finished using the phone.

The Communicator will attempt to reconnect later.

DSL Internet Service

This section applies only if you are using a landline telephone jack connection to the LATITUDE system.

If you have digital subscriber line (DSL) Internet service provided through your telephone line, you may need to install a DSL filter between the wall phone jack and the LATITUDE Communicator.

Most DSL filters are small rectangular devices with standard telephone jack connectors at each end. These filters are typically provided by DSL service providers to connect telephones, an answering machine, or a fax machine to your telephone line.

If you use DSL filters for such devices, you will need to install a DSL filter to use the Communicator. If you use a dual-port DSL filter, connect the Communicator to the port labeled PHONE or where you would typically connect a telephone. For assistance, contact your DSL service provider or LATITUDE Patient Services at 1-866-484-3268.

Care and Maintenance

Your Communicator does not require any regular service or maintenance.

Your Communicator does not require electrical safety testing after installation or during periodic maintenance.

To ensure optimum performance of your Communicator and accessories and protect them from damage, follow these directions:

CAUTIONS:

- Do not drop or mishandle the Communicator or its accessories in a manner that would cause damage.
- Avoid getting liquid on the unit other than cleaning it as recommended. Do not use abrasive cloth or solvents to clean the unit.
- Do not submerge the Communicator or its accessories in liquid.
- Do not attempt to open the Communicator or any of its accessories.
- Use this unit as described in this instruction manual. Use only authorized parts and accessories. Do not attempt to modify or alter this unit or accessories.

If your Communicator or accessories become damaged or malfunction, contact your health care provider.

Cleaning the Communicator and Accessories

When necessary, clean the Communicator and its accessories with a soft, clean, lint-free cloth moistened in water or mild detergent. Note that the finish on some types of furniture could be affected as a result of continuous contact with rubber material such as the type used on the base of the Communicator.

CAUTIONS:

- Do not use other cleaning fluids. They may damage the front lens of the Communicator. Never spray any cleaning fluid directly on the Communicator front lens. Do not allow moisture to accumulate on or around the lens or Heart button.
- Avoid using any cleaning fluid near the electrical plugs on the back of the Communicator.

Returning, Replacing, or Disposing of the Communicator, USB Cellular Adapter, or USB Ethernet Adapter

If you need to replace either your Communicator, USB Cellular Adapter, or USB Ethernet Adapter because it is damaged or no longer works, or if you need a different model, contact your health care provider to learn how to return and replace it.

If you no longer need to use either your Communicator, USB Cellular Adapter, or USB Ethernet Adapter:

- **United States:** Do not throw the Communicator or adapter in the trash. Dispose of it at a local recycling site that accepts electronics. Contact your local authorities to learn how to dispose of it.
- **Puerto Rico, Canada, or Mexico:** Do not dispose of the Communicator or adapter. Contact your health care provider to learn how to return it.

Your Communicator may contain encrypted health data. Dispose of it only as described above.

Setting Switches for PBX or Dial-out Numbers

(This section applies only to landline telephone connections.) You can use your Communicator with a private branch exchange (PBX) in a managed care facility, hotel, or other location that requires you to enter a dial-out number or prefix to place an outside call. The first three white switches (1, 2, and 3) on the bottom of the Communicator must be set to match your dial-out number. If using the USB Cellular Adapter or USB Ethernet Adapter, switches 1-3 do not matter.

Switch settings for different dial-out numbers are shown in Figure 9. Refer to “Confirming Switch Settings” on page 16 for information on switches 4-8.

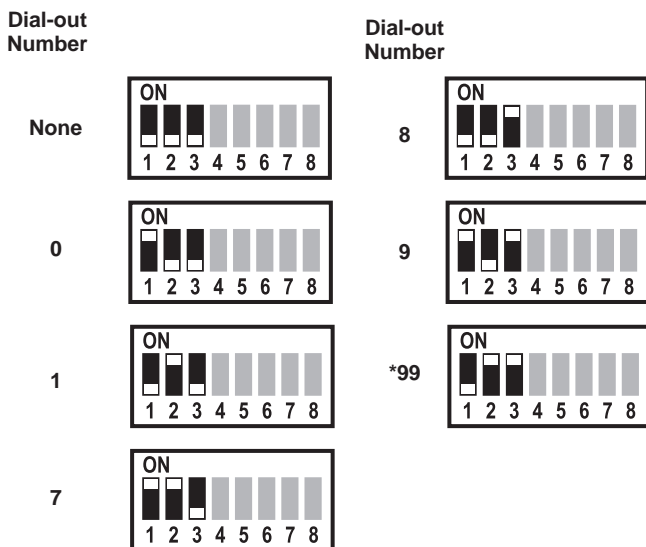


Figure 9. Dial-out Number Switch Settings

Connecting the USB Sensor Adapter

The USB sensor adapter is included with a LATITUDE weight scale and blood pressure monitor. The USB sensor adapter provides a wireless connection between these products and the Communicator. Refer to Figure 10.

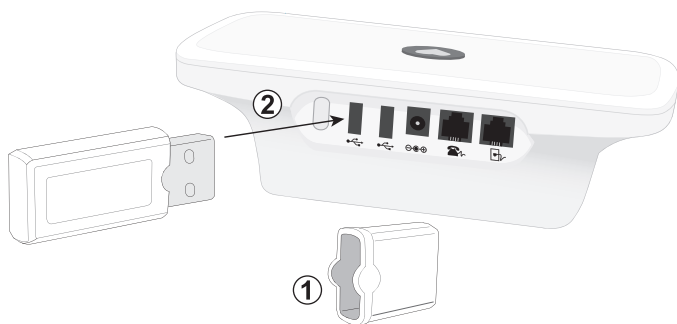



Figure 10. USB Sensor Adapter Connection

1. Remove the cap from the USB sensor adapter.
2. Plug the USB sensor adapter into either of the USB ports labeled  on the back of the Communicator.

Leave the USB sensor adapter plugged into the Communicator so the Communicator can receive measurements whenever you use your weight scale or blood pressure monitor.

Specifications

Models:	6280 and 6290 (Unless specified, values apply to both models.)
Dimensions:	Length: 8.00 in (20.3 cm) Width: 4.50 in (11.4 cm) Height: 2.71 in (6.9 cm)
Weight:	0.83 lbs (0.38 kg)
Power Source:	5.0 VDC, 3.0 A, continuous service Class II AC adapter, GlobTek® Model GTM41061-1512-7.0, part 350118-001 (included)
Power Supply:	
Input:	100-240 VAC, 0.6 A, 50-60 Hz
Maximum Output:	15 W
Supply Mains Isolation:	AC adapter plug
Minimum Operational Loop Current:	20 mA
Protection Against Electric Shock:	Class II
Expected Service Life:	Up to 15 years
Analog Dialing Mode:	Tone
Operating Temperature:	41° F to 104° F (5° C to 40° C)
Storage and Transport Temperature*:	-13° F to 158° F (-25° C to 70° C)
Operating Humidity:	15% to 93% noncondensing

Storage and Transport Humidity*:	Up to 93% noncondensing
Operating Pressure:	70 to 106 kPa
Storage and Transport Pressure*:	50 to 106 kPa
Protection Against Ingress of Solid Foreign Objects:	IP21 (≥ 12.5 mm diameter)
Protection Against Ingress of Water:	IP21 (light rain proof)

Communicator Implanted Device Radio (*Model 6280*):

Receive Bandwidth:	+190/-160 kHz
Frequency Band:	916.5 MHz
Modulation Transmit Type:	ASK (Amplitude-Shift keying)
Effective Radiated Power:	<-1.25 dBm (0.75 mW)

Communicator Implanted Device Radio (*Model 6290*):

Receive Bandwidth:	<300 kHz
MICS/MedRadio:	402-405 MHz
Modulation Transmit Type:	FSK (Frequency-Shift keying)
Effective Radiated Power:	<-16 dBm (25 μ W)

* Storage and transport specifications apply with or without Communicator protective packaging.

USB Sensor Adapter:

2.4 GHz wireless USB dongle

Delta Mobile Systems® Model DM210

Boston Scientific Model 6454

(included with LATITUDE weight scale and blood pressure monitor)

Operational Frequency: 2400.0 to 2480.0 MHz

Modulation Type: Adaptive Frequency Hopping

Effective Radiated Power: 14 dBm (25 mW)

Operating Temperature: 32° F to 158° F
(0° C to 70° C)

Storage and Transport Temperature: -4° F to 185° F
(-20° C to 85° C)

Operating Humidity: 10% to 85%
noncondensing

Storage and Transport Humidity: 10% to 85%
noncondensing

LATITUDE NXT USB Cellular Adapter (Model 6295):	
GSM-850:	TX 824-849 MHz RX 869-894 MHz Effective Radiated Power: 22.93 dBm
PCS-1900:	TX 1850-1910 MHz RX 1930-1990 MHz Effective Radiated Power: 26.42 dBm
W-CDMA 850:	TX 824-849 MHz RX 869-894 MHz Effective Radiated Power: 15.83 dBm
W-CDMA 1900:	TX 1850-1910 MHz RX 1930-1990 MHz Effective Radiated Power: 18.76 dBm

Safety and Standards Compliance

- Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate this equipment.
- Before each use, visually inspect your Communicator to make sure the housing has no cracks and the AC adapter and any other connecting items are intact.
- The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the LATITUDE Communicator.
- Keep your Communicator and all accessories out of the reach of small children and pets. Small parts may cause choking or serious injury if swallowed and attached cords may pose a strangulation hazard. Consult a health care professional immediately if this occurs.
- Do not insert any object other than a phone connector into the phone jacks on the back of the Communicator. There can be voltage on the electrical contacts in the jacks. There is potential to receive a shock.
- Do not use the Communicator adjacent to or stacked with other equipment. If it is necessary to use the Communicator adjacent to or stacked with other equipment, please contact LATITUDE Patient Services at 1-866-484-3268 to verify normal operation.

- Do not use the Communicator in the presence of flammable gas mixtures, including anesthetics, oxygen, or nitrous oxide.
- The user is cautioned to maintain an 8 in. (20 cm) spacing from the product to ensure compliance with Federal Communications Commission/Industry Canada (FCC/IC) requirements.
- To help prevent electromagnetic interference, it may be necessary to keep other wireless communications equipment such as cellular telephones and their base stations, mobile phones, and wireless home network devices at least 1.6 ft (0.5 m) away from the Communicator.
- Other wireless communication equipment could interfere with the Communicator even if the other equipment complies with CISPR (Special International Committee on Radio Interference) emission requirements.
- This device complies with Title 47, 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.

- This equipment complies with Part 68 of the FCC rules and the requirements adopted by the Administrative Council for Terminal Attachments (ACTA). On the bottom of this equipment is a label that contains, among other information, a product identifier in the format US: AAAEQ##TXXX. If requested, this number must be provided to the telephone company. The Ringer Equivalence Number (REN) for this product is part of the product identifier. The digits represented by ## are the REN.
- The REN is used to determine the number of devices that may legally connect to a telephone line. In most, but not all areas, the sum of RENs should not exceed five (5.0). You should contact your telephone company to determine the maximum REN for your calling area.
- This equipment uses the following Universal Service Order Codes (USOC) jacks: RJ11C.
- An FCC compliant telephone cord and modular plug are provided with this equipment, which is designed to connect to the telephone network or premises wiring using a Part 68 compliant compatible jack. See installation instructions for details.
- *Model 6290 only:* This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the

Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

- If your home has specially wired alarm equipment connected to the telephone line, ensure the installation of the Communicator does not disable your alarm equipment. If you have questions about what will disable alarm equipment, consult your telephone company or a qualified installer.
- The telephone company may make changes in its facilities, equipment, operations, or procedures that could affect the operation of the equipment. If this happens, the telephone company will provide advance notice in order for you to make necessary modifications to maintain uninterrupted service.

- If the Communicator causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice isn't practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it is necessary.
- Connection to party line service is subject to state tariffs. Contact the state public utility commission, public service commission or corporation commission for information.
- This equipment has been tested and found to comply with applicable safety portions of the AAMI ES 60601-1:2005, CAN/CSA-C22.2 NO. 60601-1:08 and IEC 60601-1:2005 standards.
- This equipment has been tested and found to comply with the following electromagnetic compatibility (EMC) standard: IEC 60601-1-2:2007.
- Accessory equipment connected to the analog and digital interfaces (signal inputs and signal outputs) must be certified according to the respective IEC standards. Anyone who connects additional equipment to the signal input parts or signal output parts may configure a medical system, and is therefore responsible that the system complies with the requirements of clause 16 of IEC 60601-1:2005. If in doubt, consult the technical service department or your local representative.

Essential Performance

The performance of the Communicator that is determined to be essential by Boston Scientific for electromagnetic compatibility (EMC) testing, as per IEC 60601-1-2, is the ability to:

- Communicate with your implanted device.
- Identify alert conditions in your implanted device.
- Receive measurements from optional health monitoring equipment.
- Communicate implanted device data and alert conditions to the LATITUDE system.
- Communicate measurements and alert conditions from optional health monitoring equipment to the LATITUDE system.
- Receive configuration updates from the LATITUDE system.

Electromagnetic Emissions and Immunity

**Table 1. Guidance and manufacturer's declaration—
electromagnetic emissions—for all equipment and systems^{a b}**

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions (CISPR 11)	Group 1	The LATITUDE Communicator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class B	The LATITUDE Communicator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	Complies	

- a. The LATITUDE Communicator is intended for use in the electromagnetic environment specified above. The customer or the user of the LATITUDE Communicator should assure that it is used in such an environment.
- b. The LATITUDE Communicator is also compliant with IEC 60601-1-2:2007.

**Table 2. Guidance and manufacturer's declaration—
electromagnetic immunity—for all equipment and systems^{a b}**


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 15 percent.
Electrical fast transient/burst (IEC 61000-4-4)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines (IEC 61000-4-11)	$<5\% U_T^b$ ($>95\%$ dip in U_T) for 0.5 cycle	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
	$40\% U_T$ (60% dip in U_T) for 5 cycles	$40\% U_T$ (60% dip in U_T) for 5 cycles	
	$70\% U_T$ (30% dip in U_T) for 25 cycles	$70\% U_T$ (30% dip in U_T) for 25 cycles	
	$<5\% U_T$ ($>95\%$ dip in U_T) for 5 sec	$<5\% U_T$ ($>95\%$ dip in U_T) for 5 sec	
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

- The LATITUDE Communicator is intended for use in the electromagnetic environment specified above. The customer or the user of the LATITUDE Communicator should assure that it is used in such an environment.
- U_T is the AC main's voltage prior to application of the test level.

**Table 3. Guidance and manufacturer's declaration—
electromagnetic immunity—for equipment and systems that are
not life supporting^{a b c d}**

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment— guidance
			<p>Portable and mobile RF communications equipment should be used no closer to any part of the LATITUDE Communicator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distances:</p>
Conducted RF (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz	3 Vrms 10 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz ^e	<p>$d = 1.7 \sqrt{P}$ (150 kHz to 80 MHz)</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^f should be less than the compliance level in each frequency range.^g</p>

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 1000 MHz ^h 3 V/m 1 GHz to 2.7 GHz ⁱ 8 V/m 5.1 GHz to 5.8 GHz	$d = 0.5 \sqrt{P}$ (80 MHz to 1000 MHz) $d = 0.29 \sqrt{P}$ (380 MHz to 390 MHz) $d = 0.36 \sqrt{P}$ (430 MHz to 470 MHz) $d = 0.21 \sqrt{P}$ (800 MHz to 960 MHz) $d = 1.7 \sqrt{P}$ (1 GHz to 2.7 GHz) $d = 0.21 \sqrt{P}$ (1.7 GHz to 1.99 GHz) $d = 0.21 \sqrt{P}$ (2.4 GHz to 2.57 GHz) $d = 0.63 \sqrt{P}$ (5.1 GHz to 5.8 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ⁱ should be less than the compliance level in each frequency range. ⁹
			Interference may occur in the vicinity of equipment marked with the following symbol:  Non-ionizing electromagnetic radiation

- The LATITUDE Communicator is intended for use in the electromagnetic environment specified above. The customer or the user of the LATITUDE Communicator should assure that it is used in such an environment.
- At 80 MHz and 1 GHz, the higher frequency range applies.

- c. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- d. The separation distances are calculated using the following equation adopted from the 4th edition draft of IEC 60601-1-2: $d = (5/E) \sqrt{P}$ where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer, d is the separation distance in meters (m), and E is the compliance level.
- e. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.
- f. 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 LATITUDE Communicator is used exceeds the applicable RF compliance level above, the LATITUDE Communicator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LATITUDE Communicator.
- g. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
- h. The compliance level used in the following sub-bands is higher than in the table: 380 – 390 MHz at 17 V/m, 430 – 470 MHz at 14 V/m, and 800 – 960 MHz at 24 V/m.
- i. The compliance level used in the following sub-bands is higher than in the table: 1700 – 1990 MHz at 24 V/m, and 2400 – 2570 MHz at 24 V/m.

Table 4. Recommended separation distances between portable and mobile RF communications equipment and the LATITUDE Communicator

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (meters)						
	150 kHz to 80 MHz $d = 1.7 \sqrt{P}$	80 MHz to 1000 MHz $d = 0.5 \sqrt{P}$	380 MHz to 390 MHz $d = 0.29 \sqrt{P}$	430 MHz to 470 MHz $d = 0.36 \sqrt{P}$	800-960 MHz 1.7-1.99 GHz 2.4-2.57 GHz $d = 0.21 \sqrt{P}$	1 GHz to 2.7 GHz $d = 1.7 \sqrt{P}$	5.1 GHz to 5.8 GHz $d = 0.63 \sqrt{P}$
0.01	0.17	0.050	0.029	0.036	0.021	0.17	0.063
0.1	0.54	0.16	0.092	0.11	0.066	0.54	0.20
1	1.7	0.50	0.29	0.36	0.21	1.7	0.63
10	5.4	1.6	0.92	1.1	0.66	5.4	2.0
100	17	5.0	2.9	3.6	2.1	17	6.3













- a. The LATITUDE Communicator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LATITUDE Communicator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LATITUDE Communicator as recommended in Table 4, according to the maximum output power of the communications equipment.













- b. For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.
- c. At 80 MHz and 1 GHz, the separation distance for the highest frequency range applies.
- d. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- e. The separation distances are calculated using the following equation adopted from the 4th edition draft of IEC 60601-1-2:
 $d = (5/E) \sqrt{P}$ where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer, d is the separation distance in meters (m), and E is the compliance level.

Software

The software included in this product contains copyrighted software that is licensed under the GNU General Public License (GPL). Under the terms of the GPL as published by the Free Software Foundation, you may obtain the complete corresponding source code from us for a period of three years after our shipment of this product.

Explanation of Product and Label Symbols

Symbol	Meaning
	Input from telephone jack
	Output to telephone (optional)
	AC/DC adapter power input
	Direct current (DC)
	Universal serial bus (USB) connector
P/N	Part number
	Serial number
	Reference number
	Non-ionizing electromagnetic radiation
	IEC 60601 Class II medical equipment, protection against electrical shock
	Manufacturer
	Date of manufacture
	Follow instructions for use
IP21	Protection against ingress of solid foreign objects and water

Symbol	Meaning
	Ready for LATITUDE NXT 3.0
	CE mark of conformity (applies to USB sensor adapter)
	Indicates the product complies with applicable Australia radiocommunications standards (applies to USB sensor adapter)
	Authorized representative in the European Community (applies to distribution box)
	Australian sponsor address (applies to distribution box)
	Power indicator (applies to USB Cellular Adapter)
	Wireless indicator (applies to USB Cellular Adapter)
	Waste, Electrical, and Electronic Equipment (WEEE) symbol. Indicates separate collection for electrical and electronic equipment (i.e., do not throw this device in the trash)
	Indicates this product has passed a comprehensive testing procedure and the production plant is regularly monitored as certified by a Nationally Recognized Testing Laboratory
	Temperature range limits
	Humidity range limits
	Atmospheric pressure range limits

Frequently Asked Questions

These FAQs are designed to point you to the right section in this manual for the answers.

Does the Communicator call 911 in an emergency?

No. The LATITUDE system is not meant to assist with health emergencies. If you are not feeling well, call your health care provider or dial 911. See “LATITUDE Patient Management System” on page 7.

Where should I place my Communicator?

See “Where to Place Your Communicator” on page 12.

How do I set up my Communicator using a landline telephone?

See “Using a Landline Telephone Jack Connection” on page 18.

How do I set up my Communicator using the LATITUDE Cellular Data Plan and a USB Cellular Adapter?

See “Using the LATITUDE Cellular Data Plan” on page 21.

How do I set up my Communicator using a USB Ethernet Adapter?

See “Using a USB Ethernet Adapter Connection” on page 25.

How do I know the Communicator is working?

See “Normal Operation of the Communicator” on page 28.

What do these lights mean?

See “Indicator Descriptions” on page 31 or “Troubleshooting Errors” on page 38.

How do I manually send my data?

See “Indicator Sequence When Using the Heart Button” on page 29.

When do I use my Communicator?

See “When to Use Your Communicator” on page 11 or “Interrogating Your Implanted Device” on page 57.

What do I need to do with my Communicator if I travel?

See “Traveling with Your Communicator” on page 60.

How do I dispose of my Communicator?

See “Returning, Replacing, or Disposing of the Communicator, USB Cellular Adapter, or USB Ethernet Adapter” on page 65.

Where can I go for more help?

Contact your health care provider or LATITUDE Patient Services at 1-866-484-3268.

