



PATIENT MANUAL

# LATITUDE<sup>®</sup> Communicator

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## **LATITUDE Patient Management**

LATITUDE Patient Management 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 intended to assist with medical 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 device data to the LATITUDE system through a standard telephone line or over a cellular data network using the LATITUDE Cellular Data Plan (see page 41). 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.

Your Communicator is designed to be used only in the United States, Canada, and Puerto Rico.

The telephone (land line) 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 IP (VoIP), if those systems provide an analog interface for connecting the Communicator.



Read the instructions in this manual thoroughly before using the Communicator. Keep all of your LATITUDE 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
- AC adapter (GlobTek® Model GTM41060-1505)
- Communicator installation guide
- Communicator patient manual (this book)
- Accessories:
  - Communicator telephone cord

## **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 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.

An accessory for the Communicator is a USB adapter that is included with the scale and blood pressure monitor.

## **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 regular schedule that is set by your health care provider. Other functions require 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 or flashing.

Use the Communicator only as instructed by your health care provider. The Communicator's Heart button (Figure 1 on page 9) may flash if it needs you to manually complete a scheduled interrogation of your implanted device. 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 10) is lit.

## **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 pulse generator 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 a telephone wall jack (not required if you are subscribed to the LATITUDE Cellular Data Plan).
- Near an electrical outlet that is easily accessible.
- Where you can sit comfortably and see the front of the Communicator.
- 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.

## Important Notes

- **It is very important that the Communicator remain plugged into the electrical outlet.**
- **Your Communicator should remain connected to a telephone line unless you are subscribed to the LATITUDE Cellular Data Plan.**
- 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, VCRs, 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.
- Boston Scientific personnel may contact the clinic or patient if an implanted device uses too much RF telemetry to perform remote interrogations.

## Identifying 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 19 for a description of each indicator.

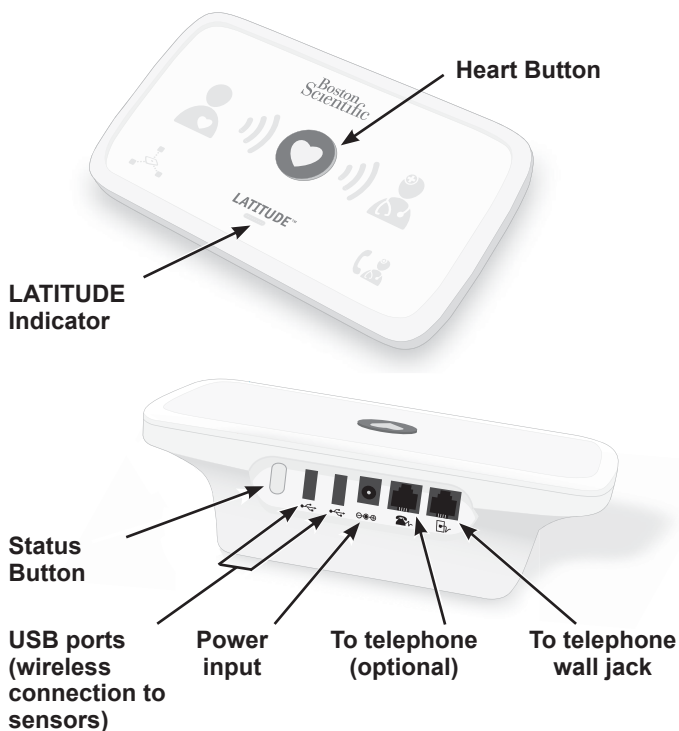
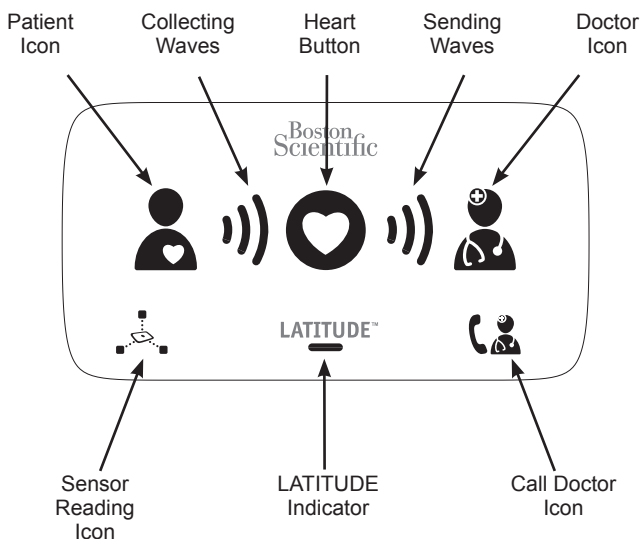


Figure 1. Buttons and connectors



**Figure 2. Indicators**

## How to Connect Your Communicator

Complete the following steps to connect and install the Communicator. There are two different procedures depending on whether you use a standard telephone line or the LATITUDE Cellular Data Plan:

- Connections When Using a Telephone (page 11)
- Connections for the LATITUDE Cellular Data Plan (page 14)

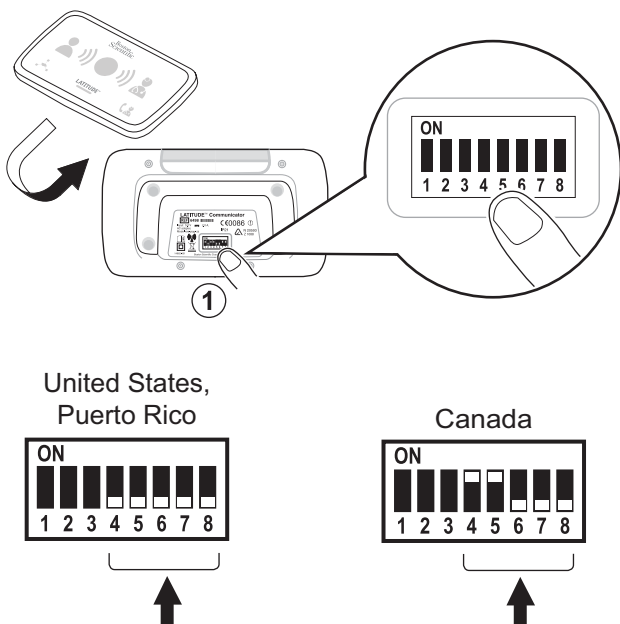
These instructions also appear in the Communicator installation guide.

**NOTE:** If you have DSL Internet service, you may need to use a DSL filter between the wall phone jack and the Communicator. Refer to “DSL Internet Service” on page 48.

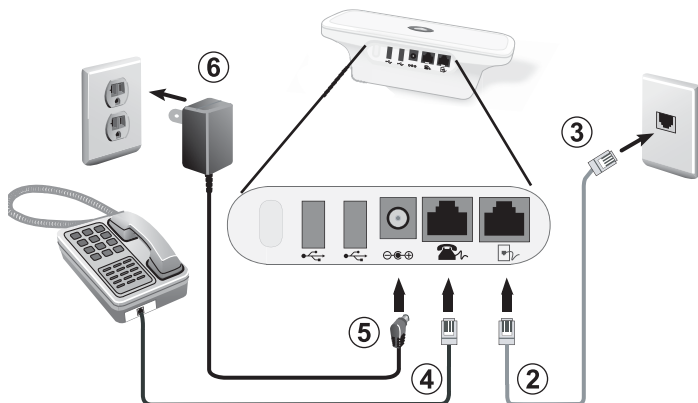
## Connections When Using a Telephone

Complete the following steps to setup the Communicator.

1. Set switches 4 through 8 on the bottom of the Communicator to match your country as shown in Figure 3. If you are in a location that requires you to enter a dial-out number or prefix to place an external telephone call, set switches 1, 2, and 3. Refer to “Setting Switches for PBX or Dial-out Numbers” on page 52.




**Figure 3. Switch settings**





*Connecting a telephone is optional*

#### **Figure 4. Connecting to a telephone wall jack**

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

2. Plug one end of the Communicator telephone cord (included) into the jack labeled  .
3. 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 48.

4. If you also want to use a telephone with this wall jack, you may plug your telephone into the jack labeled  .
5. Insert the AC adapter into the jack labeled  .
6. Plug the AC adapter into an electrical outlet that is easily accessible.
7. Make sure the LATITUDE Indicator on the front of the Communicator is lit. The LATITUDE Indicator flashes for up to one minute while the Communicator starts up.

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 on.

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

8. When electrical power is supplied, the Communicator begins a startup process. The Communicator lights all the indicators for approximately one second to indicate all indicators are working.
9. During the initial startup process, the Heart button will flash with a white light. Press the flashing Heart button, then wait until the Sending Waves light.

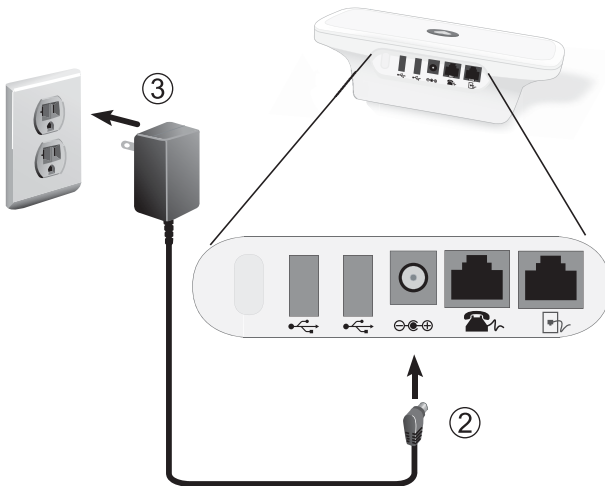
This is done to check if the Communicator can interrogate your implanted device and send your data to the LATITUDE system. Refer to the

“Indicator Sequence When Using the Heart Button” on page 17 section for more information.

## Connections for the LATITUDE Cellular Data Plan


If you have signed up for the LATITUDE Cellular Data Plan, no telephone cords need to be attached. Refer to “LATITUDE Cellular Data Plan” on page 41 for more information.

1. Set switches 4 through 8 on the bottom of the Communicator to match your country as shown in Figure 3 on page 11.



**Figure 5. Connections when using the LATITUDE® Cellular Data Plan**



2. Insert the AC adapter into the jack labeled .
3. Plug the AC adapter into an electrical outlet that is easily accessible.
4. Make sure the LATITUDE Indicator on the front of the Communicator is lit. The LATITUDE Indicator flashes for up to one minute while the Communicator starts up.

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 on.

**Important:** Your Communicator should remain connected to the electrical outlet.

5. When electrical power is supplied, the Communicator begins a startup process. The Communicator lights all the indicators for approximately one second to indicate all indicators are working.
6. During the initial startup process, the Heart button will flash with a white light. Press the flashing Heart button, then wait until the Sending Waves light.

This is done to check if the Communicator can interrogate your implanted device and send your data to the LATITUDE system. Refer to “Indicator Sequence When Using the Heart Button” on page 17 for more information.

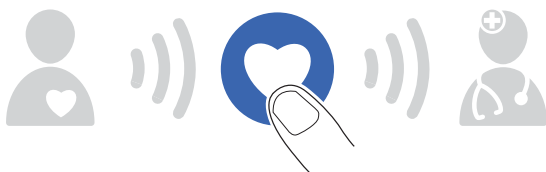
## Normal Operation of the Communicator



During normal operation, only the LATITUDE indicator will be lit (green). The Communicator automatically interrogates your implanted device on a regular schedule that is set by your health care provider. Daily device checks are also performed automatically. 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 “Indicator Sequence When Using the Heart Button” on page 17.

## 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 detailed information describing the colors and purpose of all the indicators is provided later in the manual.



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



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



All three Collecting Waves will light green. The Heart button lights white indicating the interrogation was successful.



The Sending Waves light 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 indicating the Communicator successfully sent your data to the LATITUDE system. All the indicators shown stay lit for two minutes to indicate the entire process was successful.

## Indicator Descriptions

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

- Manually interrogating your implanted device
- Connecting and sending your 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 27.



### Patient Icon

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

- Lights blue when the Heart button is pressed and an interrogation has started. The Patient icon stays lit for 2 minutes after a successful interrogation.



### Collecting Waves

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Indicates the Communicator is collecting data from your implanted device or an error occurred while collecting data.

- These waves light green in sequence and repeat, indicating the Communicator is interrogating your implanted device.
- All three waves light green for 2 minutes to indicate the interrogation was successful.



## Heart Button

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The Heart button flashes with a white light if you need to complete a previously scheduled interrogation. The Heart button lights a solid white to indicate the interrogation is complete.

The Heart button can also be used to manually initiate an interrogation of your implanted device. Refer to “Interrogating Your Implanted Device” on page 43 before using this button.



## Sending Waves

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Indicates the Communicator is connecting to the LATITUDE system.

- These waves light green in sequence and repeat, indicating a connection to LATITUDE is in progress.

- All three waves light green for 2 minutes to indicate the connection to the LATITUDE system was successful and any collected device data was sent.



## **Doctor Icon**

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Lights blue to indicate the Communicator has successfully connected to the LATITUDE system. The Communicator sends any data from your implanted device, scale, or blood pressure monitor that is stored in the Communicator's memory.



## Sensor Reading Icon

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

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

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## LATITUDE Indicator

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Indicates the Communicator is connected to electrical power. It also indicates 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.

The LATITUDE indicator could flash yellow for an extended period. This indicates that new software was downloaded from LATITUDE and is being installed on the Communicator.



- If an error exists, the LATITUDE Indicator stays yellow for 60 minutes or until the error is resolved.



## **Call Doctor Icon**

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The Call Doctor icon lights yellow or red to indicate a problem was detected that should be communicated to your health care provider. Refer to the error description in “Troubleshooting Errors” on page 27.

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

The Call Doctor icon flashes yellow briefly after the Communicator is plugged into electrical power. The light turns off after the Communicator successfully 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 6.



Figure 6. 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 display:
  - 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 blinking, it will stop blinking and stay lit.

- Press and hold for more than 3 seconds: The Sending Waves light 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 Normal Operation



You can use the Status button to check if the Communicator is operating normally. The above image shows that all the Collecting and Sending Waves are lit green, indicating that the last interrogation and the last connection to LATITUDE system were successful. When the waves are lit like this, you don't need to take any action.



## Troubleshooting Errors

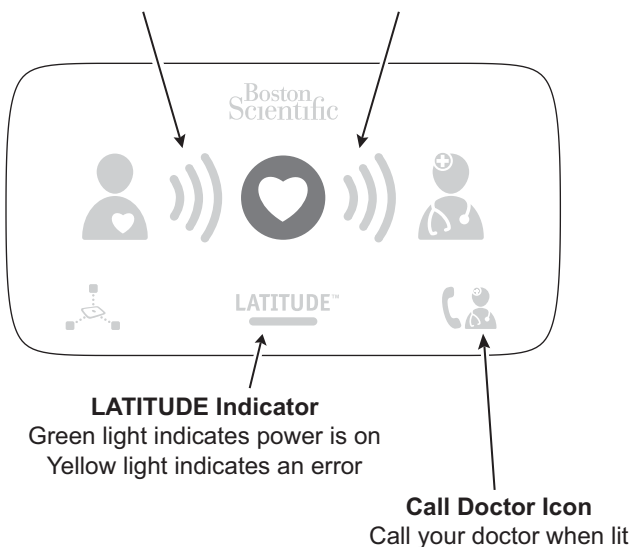
One or more of the indicators on the front of the Communicator may light or flash to indicate some type of Communicator, phone communication, or LATITUDE system error. A general description of the types of errors are shown in Figure 7. A description of each error is provided on the following pages along 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



**Figure 7. Types of errors**

## No Indicators are Lit



**Description:** 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 on.
  - If the Communicator is plugged into electric power and the light on the AC adapter is on, contact your health care provider.

## Call Doctor Icon is Red and LATITUDE Icon is Yellow



**Description:** The Call Doctor icon is red and the LATITUDE icon is yellow.

The Call Doctor icon will stay lit until the problem is resolved.

If the Call Doctor icon is flashing, it will light solid after the error is acknowledged (by pressing the Status button).

A potential problem with your implanted device was detected.

The Communicator is monitoring your device but it cannot send any information collected from your implanted device to the LATITUDE system.

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

## Call Doctor Icon is Yellow and LATITUDE Icon is Yellow



**Description:** The Call Doctor icon is yellow and the LATITUDE icon is yellow.

The Call Doctor icon will stay lit until the problem is resolved.

If the Call Doctor icon is flashing, it will light solid after the error is acknowledged (by pressing the Status button).

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.

**Action:** Call your health care provider.



## Call Doctor Icon Lit



**Description:** Only the Call Doctor icon is lit yellow (the LATITUDE Indicator is not lit). This indicates your Communicator may not be working properly.

**Action:** Press the Status button and check that the Call Doctor icon lights a solid yellow and does not flash. Also check that the LATITUDE icon still does not light. If only the Call Doctor icon lights a solid yellow, you may need to get a replacement Communicator. Call your health care provider.

## Wave Indicator Colors

The Wave indicators will light yellow to indicate an error. Wave errors stay lit for 60 minutes, or until the cause of the error is resolved. Please respond to error indicators as soon as possible.

- Green. All three Collecting Waves will light green for 2 minutes to indicate a successful interrogation of your implanted device. All three Sending Waves will light green for 2 minutes to indicate the Communicator successfully sent your information to the LATITUDE system.
- Yellow. One or more of the Wave indicators will light yellow to indicate some type of error as described below. The Waves flash for 60 minutes unless the error is resolved sooner. After 60 minutes, all Wave lights are turned off and the LATITUDE icon is lit green, even if the problem was not resolved.

## One Yellow Collecting Wave



**Description:** The Communicator was unable to start an interrogation of your implanted device or your implanted device is now out of range.

- Action:**
- Ensure the Communicator is optimally placed as described in “Where to Place Your Communicator” on page 7.
  - 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 phones or baby monitors) that are within 11 ft (3.3 m) of the Communicator.

## Two Yellow Collecting Waves



**Description:** The Communicator was unable to establish wireless communication with your implanted device due to interference from other wireless electronic devices

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 7.
  - 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 phones or baby monitors) that are within 11 ft (3.3 m) of the Communicator.

## Three Yellow Collecting Waves



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

- You may have exceeded your weekly interrogation limit, so you are not able 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.
- 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.

**Action:**

- If the Communicator will use a telephone line, check that the telephone cord provided with the Communicator is plugged in tightly to a telephone wall jack and the Communicator.
- If a telephone is connected to the Communicator, pick the telephone up and check for dial tone.
- If the Communicator will use a telephone line, check that the analog telephone service supports the tone dialing mode.
- If you use the LATITUDE Cellular Data Plan, move the Communicator to another location that may have better cellular reception.

- After trying the above actions, initiate a connection to LATITUDE by pressing and holding the Status button until the Sending Waves light green in sequence and repeat. All three Sending Waves should light a constant green to indicate a successful connection was made to the LATITUDE system.
- Check if the Communicator can connect to the LATITUDE system. Refer to “Checking that the Communicator Can Connect to LATITUDE” on page 45.

## Two Yellow Sending Waves



**Description:** An attempt to connect to the LATITUDE system failed.

The Communicator established a connection using the LATITUDE Cellular Data Plan, but the connection was dropped or the signal was lost

**Action:** Check if the Communicator can connect to the LATITUDE system. Refer to “Checking that the Communicator Can Connect to LATITUDE” on page 45.

If using a telephone line:

- If you use a telephone, make sure your telephone is not being used at this time.
- Remove any splitters between the Communicator and the telephone wall jack.
- Ensure you are using a DSL filter between the Communicator and the telephone wall jack, if you have DSL internet service.



- Check that the switches on the bottom of the Communicator are set correctly for your country and if you need to dial a number to get an outside line. Refer to “Setting Switches for Your Country” on page 51 and “Setting Switches for PBX or Dial-out Numbers” on page 52.

If using the LATITUDE Cellular Data Plan:

- Move the Communicator to another location that may provide a stronger cellular signal.
- If other locations do not work after trying another connection (see below), try plugging the Communicator into an active telephone wall jack.

To verify troubleshooting was successful:

- Press and hold the Status button until the Sending Waves light 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.

A telephone, answering machine, computer or other device may be using or attempted to use the telephone line

- Action:**
- Check if the Communicator can connect to the LATITUDE system. Refer to “Checking that the Communicator Can Connect to LATITUDE” on page 45.
  - If you see three yellow waves after trying the above action, contact your health care provider.

## LATITUDE Cellular Data Plan

The LATITUDE Cellular Data Plan uses a cellular data network rather than a standard telephone line 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.

You need either a standard analog telephone line or the LATITUDE Cellular Data Plan to use the LATITUDE Patient Management 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 a telephone line if it is connected to an active telephone jack. If connected, your Communicator will send your device data over the telephone line even if you are subscribed to the LATITUDE Cellular Data Plan.

### Activating the LATITUDE Cellular Data Plan

Contact 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 only works with your Communicator. If a replacement Communicator is ever needed, contact Patient Services to update your subscription.

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 LATITUDE™ on page 45. 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, move the Communicator to another location and check the connection. If this does not work, contact Patient Services at 1-866-484-3268 for assistance.

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

## **Discontinuing Your LATITUDE Cellular Data Plan**

Contact Patient Services to discontinue use of the LATITUDE Cellular Data Plan. Your subscription will automatically be discontinued if you miss two or more payments. You will need to discontinue your subscription if you stop using the LATITUDE system or if you want to return to using a telephone line. Make sure your health care provider is aware of any changes in service.

## Interrogating Your Implanted Device

The Communicator automatically interrogates your implanted device on a regular schedule that is 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, without being set by a health care provider. 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 poorly or are in need of immediate medical care, call your health care provider or dial 911.

## **What to Do if the Electrical Power is Interrupted**

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 light green when power is restored to the Communicator.

## Checking that the Communicator Can Connect to LATITUDE

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 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 light 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 light in sequence and repeat indicating a connection to the LATITUDE system is in progress.
4. Wait approximately 5 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 “Wave Indicator Colors” section beginning on page 32 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 interrogation schedule may need to be temporarily changed to use your Communicator away from home.

**NOTE:** Your Communicator is designed to be used only in the United States, Canada, and Puerto Rico. Use of the Communicator in other countries is restricted due to radio frequency (RF) laws. Please contact 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 LATITUDE” on page 45.

## Communicator Use of the Telephone System

The Communicator makes toll-free 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 telephone lines like those found in most homes and supports tone dialing over an analog line. The Communicator may work on other telephone systems, such as Digital Subscriber Line (DSL) and Voice over IP (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 can not 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 54.

## **What to Do If You Need to Use 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. You can use your telephone to make or answer calls while you are interrogating your device.

## **DSL Internet Service**

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 Patient Services at 1-866-484-3268.

## Care and Maintenance

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

### CAUTIONS:

- Do not drop or mishandle the Communicator 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 in liquid.
- Do not attempt to open the Communicator.
- 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 becomes damaged or it malfunctions, contact your health care provider.

### Cleaning the Communicator

When necessary, clean the Communicator 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 or Replacing the Communicator

If your Communicator becomes damaged or it malfunctions, contact your health care provider for return and replacement instructions. Your Communicator may contain encrypted personal health information.

## Communicator Disposal

- United States. If your Communicator is not damaged, dispose of it properly at a local recycling site that accepts electrical and electronic equipment. Do not throw the Communicator in the trash. Many areas of the country have set up recycling sites to collect and recycle electrical and electronic waste. Contact your local authorities for further collection information.
- Canada. Do not dispose of the Communicator. If return or replacement is necessary, contact your health care provider.

## Setting Switches for Your Country

Switches 4 through 8 on the bottom of the Communicator must be set for the country where you are using the Communicator (Figure 8). Your Communicator is designed to be used only in the United States, Canada, and Puerto Rico.

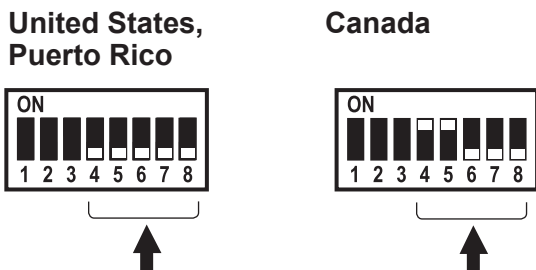


Figure 8. Country switch settings

## Setting Switches for PBX or Dial-out Numbers

You can use your Communicator in a managed care facility, hotel, or other location that requires you to enter a dial-out number or prefix to place an external call. The first three switches (1, 2, and 3) on the bottom of the Communicator must be set to match your dial-out number.

Switch settings for different dial-out numbers are shown in Figure 9. Switches 4 through 8 should be set to match the country you are in as shown in Figure 8.

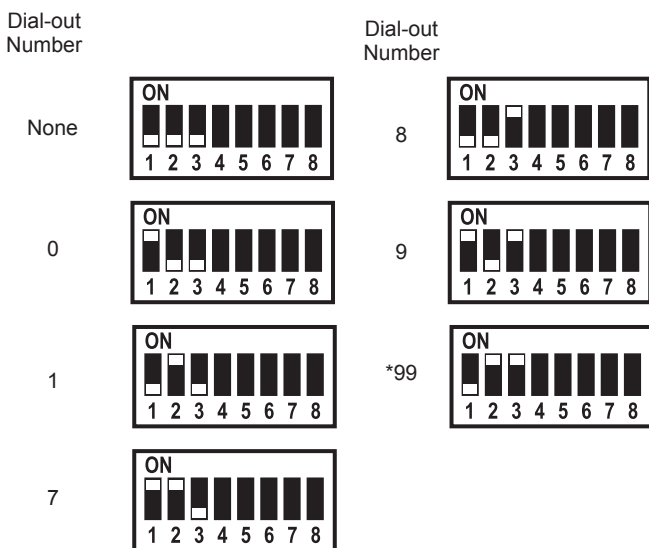



Figure 9. Dial-out number switch settings

## Connecting the USB Adapter

The USB adapter is included with a LATITUDE weight scale and blood pressure monitor. The USB adapter provides a wireless connection between these products and the Communicator. Plug the USB adapter into either of the USB ports labeled  on the back of the Communicator. Refer to Figure 10.

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

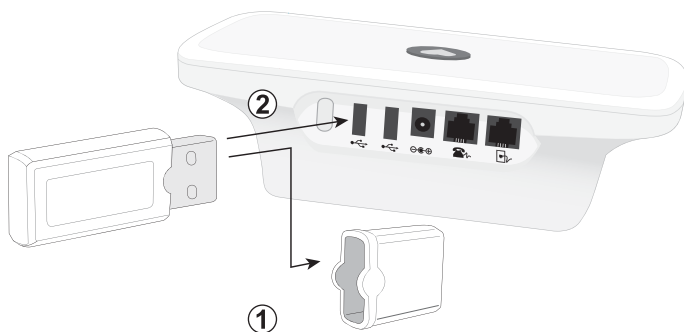


Figure 10. USB adapter connection

## Specifications

Model:	6498
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 GTM41060-1505, part 358462-001 (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
Expected Service Life:	Meets the useful life of the implanted device, from 5.6 to 12.6 years
Analog dialing mode:	Tone
Operating Temperature:	41° F to 104° F (5° C to 40° C)
Storage Temperature:	-13° F to 158° F (-25° C to 70° C)
Operating Humidity:	15% to 93% noncondensing
Storage Humidity:	15% to 93% noncondensing
Storage/Operating Pressure:	50 to 106 kPa
Protection Against Ingress of Water:	IP21 (light rain proof)



### Communicator Pulse Generator Radio:

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

### USB Adaptor:

2.4 GHz wireless USB dongle  
Delta Mobile Systems model DM210  
Boston Scientific model 6454 (included with LATITUDE  
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 Temperature: -4° F to 185° F (-20° C to 85° C)  
Relative Humidity: 10% to 85% noncondensing

### Cellular Radio:

GSM-850: TX 824–849 MHz, RX 869–894 MHz,  
Effective Radiated Power 30.0 dBm  
PCS-1900: TX 1850–1910 MHz, RX 1930–1990 MHz,  
Effective Radiated Power 26.5 dBm

## Safety and Standards Compliance

- Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate this equipment.
- The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the LATITUDE Communicator. Using accessories and cables supplied with the Communicator in other medical equipment and systems may result in increased emissions or decreased immunity of the other medical equipment or systems.
- 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. Consult a health care professional immediately if this occurs.
- Do not insert anything other than a telephone connector into the telephone jacks on the back of the Communicator. There can be voltage on the electrical contacts in the connector, and there is potential to receive a shock.
- The user is cautioned to maintain an 8 in (20 cm) spacing from the product to ensure compliance with FCC requirements.
- To help prevent electromagnetic interference, it may be necessary to keep other wireless communications equipment such as cordless telephones and their base stations, mobile phones and wireless home network devices at least 11 ft (3.3 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 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.
- 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 equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.
- This equipment has been tested and found to comply with applicable safety portions of the IEC 60601-1:2005 standard.
- This equipment has been tested and found to comply with the following EMC standards: 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.

## **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
	Consult instructions for use
<b>IP21</b>	Protection against ingress of water. Light rain proof.

Symbol	Meaning
	<p>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)</p>
	<p>Indicates this product has passed a comprehensive testing procedure and the production plant is regularly monitored as certified by a Nationally Recognized Testing Laboratory</p>
	<p>Temperature range limits</p>
	<p>Humidity range limits</p>
	<p>Atmospheric pressure range limits</p>



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