

PATIENT MANUAL

LATITUDE™ Communicator

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Zastaralá verze. Nepoužívat.
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This manual contains instructions for the use of Models 6288* and 6290 LATITUDE Communicators. These instructions are nearly identical for both models. Unless specified as applying to one model only, instructions (as well as technical information) apply to both models. The model number for your Communicator is located on its bottom label.

* Model 6288 may not be available in all geographies.

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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 emergency services.

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 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 several communication methods:

- Cellular data network (see page 18); or
- Internet (using the LATITUDE USB Ethernet Adapter (see page 8).

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 can be used in Saudi Arabia. For more information, see “Traveling with Your Communicator” on page 54.



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)

The following items are optional connection accessories, available separately:

- LATITUDE USB Cellular Adapter
- LATITUDE USB Ethernet Adapter
- LATITUDE USB Accessory Adapter

Optional Health Monitoring Equipment (Not available in all geographies)

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 LATITUDE USB Accessory Adapter is included with the weight scale and blood pressure monitor. The LATITUDE USB Accessory Adapter provides a wireless connection between these products and the Communicator. See “How to Set Up the Communicator to Use the Weight Scale and Blood Pressure Monitor (Not available in all geographies)” on page 57.

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 implanted 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.

LATITUDE Patient Support

Your implanted device and the LATITUDE Communicator are manufactured by Boston Scientific. In specific cases, your health care provider may instruct you to contact Boston Scientific for assistance with your Communicator. When instructed to contact Boston Scientific, dial 1 800.844.8246.

When to Use Your Communicator

The Communicator operates automatically on a schedule set by your health care provider. If the Communicator's Heart button flashes, you should press it to complete the requested action. See "Using the Heart Button" on page 26.

Note: 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.

Check the Communicator daily to see if any of the indicators are lit solid or flashing. Call your health care provider if the "Call Doctor" icon (refer to 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.

How the Communicator Works

The Communicator is designed to communicate with your implanted device wirelessly. There are three ways it may collect data from your implanted device.

1. Routine Device Checks

Depending on your implanted device, the Communicator may perform an automatic daily device check or a prompted weekly device check. The Communicator checks in with your implanted device and will collect and send data to your doctor when needed. This may happen automatically without your knowledge or the Communicator may prompt you to press the flashing Heart button.

2. Remote Scheduled Follow-ups

The Communicator performs remote scheduled follow-ups on a schedule set by your health care provider. The Communicator performs a full interrogation (collects and sends data from your implanted device). This may happen automatically without your knowledge or the Communicator may prompt you to press the flashing Heart button.

3. Manual Interrogations

The Heart button is designed to enable you to manually interrogate your implanted device.

This is a feature that must be enabled by your health care provider. Only press the Heart button if it is flashing or when instructed to do so by your health care provider. When the heart button is pressed, the Communicator checks to make sure the interrogation is permitted. See “Using the Heart Button” on page 26 for more information.

Caution:

- Normal use of the LATITUDE system has been accounted for in the projected battery life of your implanted device. Pressing 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 emergency services.

Cancelling an Interrogation

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.

Where to Place Your Communicator

Place your Communicator:

- Near an electrical outlet that is easily accessible.

- Close to where you sleep or near your bedside, within 3 meters (10 feet). If this is not possible, place your Communicator where you spend a considerable amount of time each day.
- Where you can sit comfortably and see the front of the Communicator.
- Depending on the communication method used:
 - **Cellular data network:** In a location where you get a good signal.
 - **Internet (using the LATITUDE USB Ethernet Adapter):** Near your internet modem/router.
- Where the Communicator and all its cables and accessories will be kept dry and not exposed to humidity or potential water contact.

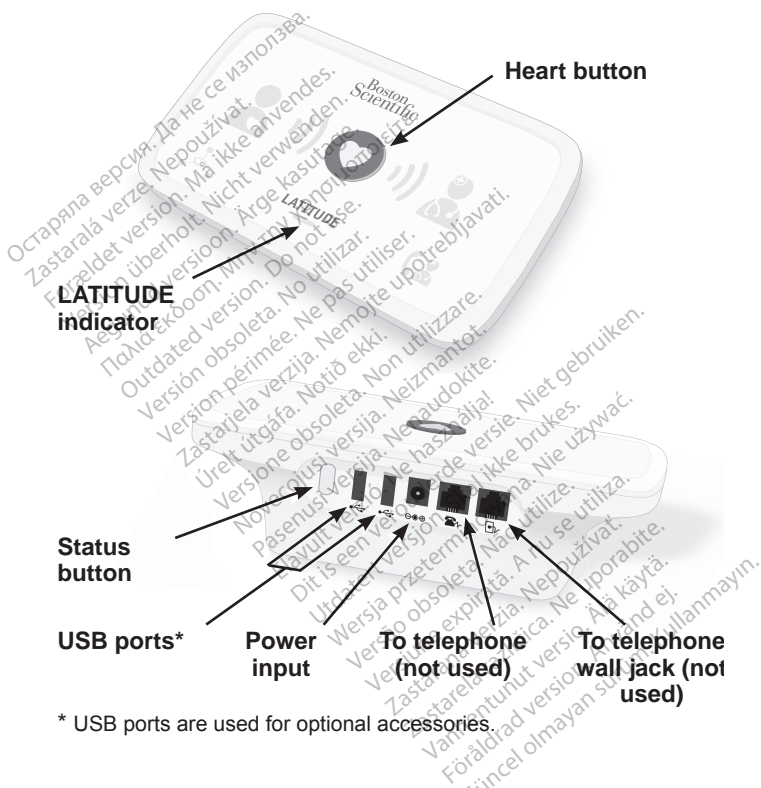
Important Notes

- **It is very important that the Communicator remains plugged into the electrical outlet.**
- **Your Communicator should remain connected to the internet service unless you are subscribed to the cellular data network plan.**
- When setting up your Communicator, use only **one** type of connection. Set up a cellular data network, or an internet connection using the LATITUDE USB Ethernet Adapter. Choose one connection method 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 1 meter (3 feet) away from televisions, videocassette recorders (VCRs), digital video disc (DVD) players, personal computers, and other electronic equipment.
- Patients with S-ICD implanted devices supported on LATITUDE: The wireless communication between the Communicator and an S-ICD is orientation and distance sensitive. In some positions, the Communicator may need to be closer to the S-ICD to complete an interrogation. If you need assistance, contact your health care provider.
- 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.

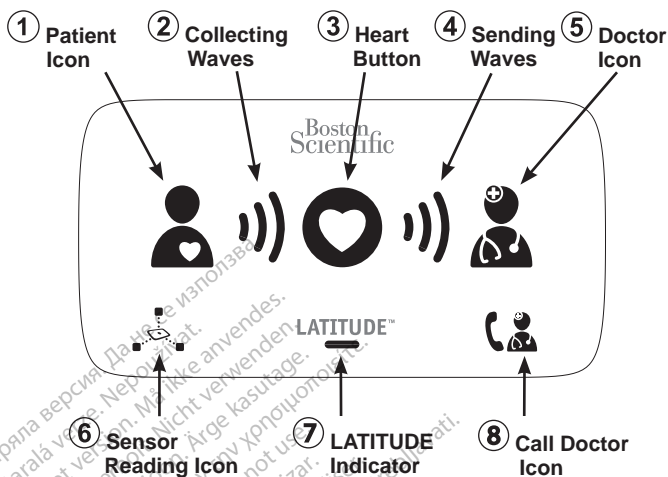
Buttons, Connectors, and Indicators

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 28 and “Status Button” on page 33 for more information.



* USB ports are used for optional accessories.

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 a software upgrade.
8. **Call Doctor Icon:** Call your doctor when lit any color.

Figure 2. Indicators

For more information about indicators, see “Indicator Descriptions” on page 28.

Installing Your Communicator

Confirming Switch Settings

- The white switches on the bottom of the Communicator must match the 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.

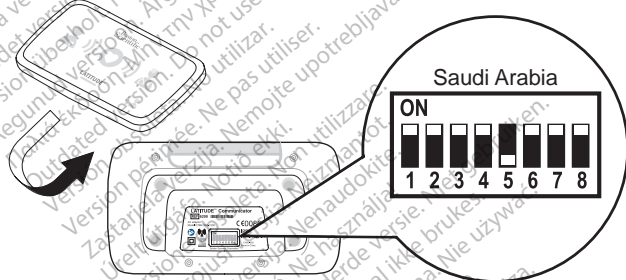


Figure 3. Switch Settings

Connect Your Communicator to the LATITUDE System

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

- **Cellular data network:** Follow the steps in “Using the Cellular Data Network” on page 18.
- **Internet (using the LATITUDE USB Ethernet Adapter):** Follow the steps in “Using a USB Ethernet Adapter Connection” on page 21.

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

Using the Cellular Data Network

If you have signed up for the cellular data network, no Ethernet cables need to be attached.

- *Model 6288* has built-in capability that enables cellular communication between your Communicator and the LATITUDE system. *Model 6288* requires no additional equipment for connection.
- *Model 6290* uses a USB Cellular Adapter to enable cellular communication between your Communicator and the LATITUDE system and must be connected to the Communicator. The following instructions call out “*Model 6290 only*” where applicable.

Refer to “Cellular Data Network” on page 51 for more information.

Where to Place Your USB Cellular Adapter

Important: Maintain a distance of at least 15 centimeters (6 inches) 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 following steps to set up the Communicator for a cellular data network connection.

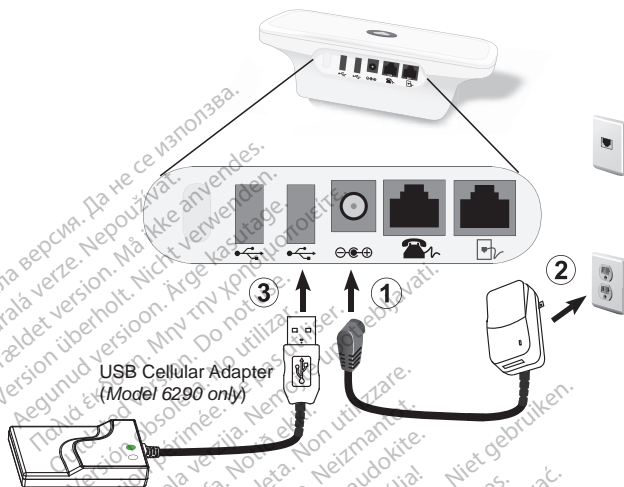





Figure 5. Using the Cellular Data Network

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. *Model 6290 only.* Insert the USB connector of the Cellular Adapter into one of the USB ports labeled . Refer to “Figure 5. Using the Cellular Data Network” on page 19.

- The power indicator  on the top of the Cellular Adapter is lit if properly connected. 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 “Using the Heart Button” on page 26.
- 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 24.
- If the wave lights are not lit a solid green, refer

to “Troubleshooting” on page 35.

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

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Internet (using the LATITUDE USB Ethernet Adapter)

Contact your health care provider to obtain a new or replacement LATITUDE USB Ethernet Adapter.

Complete the steps below to set up the Communicator for an Internet (LATITUDE USB Ethernet Adapter) connection.

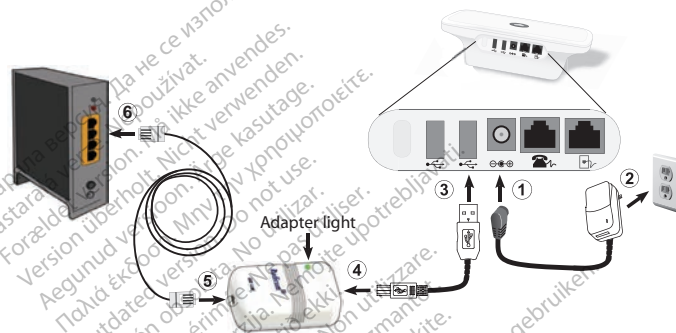



Figure 6. Using a USB Ethernet Adapter Connection

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.

Important: For the following steps, make sure you use the Ethernet cable provided with the USB

Ethernet Adapter provided with the Communicator.

3. Insert the standard (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.
 - The USB Ethernet Adapter is properly connected if the green light in 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 "Using the Heart Button" on page 26
 - 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 24.
- If the wave lights are not lit a solid green, refer to “Troubleshooting” on page 35.

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



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When operating normally, only the LATITUDE indicator will light green. None of the other Communicator indicators will light during a daily device check or automatic interrogation. They will light when you use the Heart button as described on page 10.

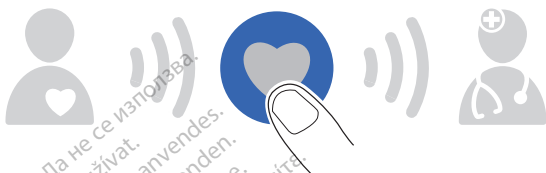
Note: When color is used in this manual to explain operation of the Communicator, an indicator shown as gray means that it is not lit. An indicator shown as any other color, including white, means that it is lit.

(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.

Using the Heart Button

Press the Heart button any time it is flashing, or when instructed to do so by your health care provider. Stay next to the Communicator until data is sent.



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” on page 35.



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

Shows the Communicator is collecting data from your implanted device.

- Flashes green in sequence and repeats, showing the Communicator is interrogating your implanted device.
- Lights 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 page 10 before using this button.



Sending Waves

Shows the Communicator is connecting to the LATITUDE system.

- Flashes green in sequence and repeats, showing a connection to the LATITUDE system is in progress.
- Lights 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” on page 35.

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.

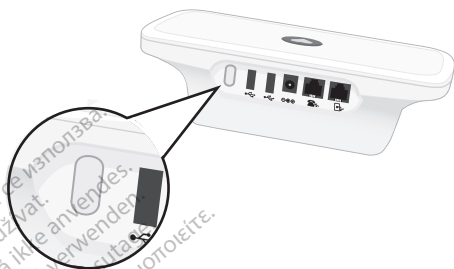


Figure 7. Status Button

The Status button performs one 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



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You can press the Status button on the back of the Communicator 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

Troubleshooting Icon and LATITUDE Indicators

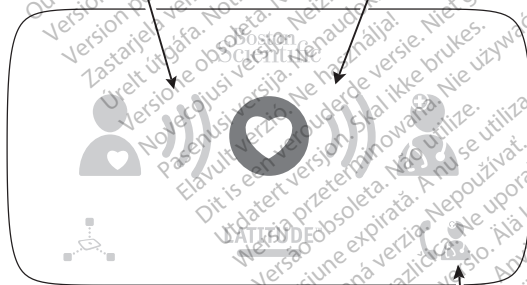
One or more of the indicators on the front of the Communicator may light or flash to indicate some type of Communicator, communication, or LATITUDE system issue. A general description of the types of indicators are shown in Figure 8. A description of each indicator is provided in this section, along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

Yellow Collecting Waves

Indicate errors collecting information from your implanted device

Yellow Sending Waves

Indicate errors sending information to the LATITUDE system



Call Doctor Icon

Call your doctor when lit any color

Figure 8. Types of Indicators

Heart Button is Flashing LATITUDE Indicator is Green



Description: You need to complete a previously scheduled interrogation or perform a manual device check.

- 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.

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

This process typically lasts only one minute but may take longer.

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 longer.

Action: No action is required.

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



LATITUDE™



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 is Not Lit



LATITUDE™



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 11.
- Face the Communicator. Sit directly in front of the Communicator. Make sure you are within 1 meter (3 feet) of the Communicator.
- Move any wireless electronic products (such as cordless or cellular phones or baby monitors) that are within 1 meter (3 feet) 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 11.
- Face the Communicator. Sit directly in front of the Communicator. Make sure you are within 1 meter (3 feet) 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 1 meter (3 feet) 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 cellular providers were detected when attempting to connect using the cellular data network.
- No internet connection was detected when attempting to connect using the LATITUDE USB Ethernet Adapter.

If using the cellular data network:

- Make sure the USB Cellular Adapter is plugged into the Communicator.
- Move the Communicator to another location that may have better cellular reception.

If using the Internet (LATITUDE 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 USB port on the back of 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 on the back of the Communicator 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, cellular data network, or internet.

Action: If using the cellular data network:

- Move the Communicator to another location that may provide a stronger cellular signal.

If using the Internet (LATITUDE 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 on the back of the Communicator 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. Refer to “Confirming Switch Settings” on page 16.

If using the Internet (LATITUDE 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 on the back of the Communicator 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.

Cellular Data Network

The cellular data network is an optional connection method to send implanted device data to the LATITUDE system. Contact your health care provider to set up this connection method.

Model 6288 requires no additional equipment for connection between your Communicator and the LATITUDE system.

Model 6290: You need a LATITUDE USB Cellular Adapter that enables cellular communication between your Communicator and the LATITUDE system. If a replacement adapter is ever needed or require a different connection method, contact your health care provider.

The cellular data network only sends data. It does not send voice signals and it cannot be used with your cellular phone service.

Note: Your Communicator is designed to use an internet connection, if available. If connected, your Communicator may send your implanted device data over the internet even if you are subscribed to the cellular data network.

Troubleshooting and Support

Using the cellular data network 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.

You can verify the cellular data network connection by following the instructions in “Checking the Communicator Can Connect to the LATITUDE System” on page 52 If you travel to another location

with your Communicator, check the connection from that location.

The Sending Waves may light yellow if your Communicator cannot connect through an activated cellular data network. If this happens, refer to the Sending Waves sections of this manual, page 46 through 58. If the Communicator is still unable to connect, contact your health care provider for assistance.

Discontinuing Your Cellular Data Network Plan

Contact your health care provider to discontinue use of the cellular data network. For information on returning, replacing, or disposing of your USB Cellular Adapter, see page 56.

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 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 connection method.

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 42 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.

The LATITUDE Communicator has been designed to work in Saudi Arabia. If using the cellular data network or Ethernet adapter, the Communicator is allowed to be used in other countries. When traveling to a country outside of Saudi Arabia, the data transmitted from the Communicator will be subject to laws of that country. The laws of that country may provide less privacy protection for your data than the laws of your home country. Please contact your health care provider for specific information about data privacy.

Model 6288 only: Use of this Communicator outside the Saudi Arabia may be restricted due to RF laws.

If you take your Communicator with you, check that the Communicator can connect to the LATITUDE system. Refer to “Checking the Communicator Can Connect to the LATITUDE System” on page 52.

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 or Accessories

If you need to replace your Communicator or any accessories because of damage or malfunction, 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, or any accessories, contact your health care provider to learn how to return them.


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

How to Set Up the Communicator to Use the Weight Scale and Blood Pressure Monitor (Not available in all geographies)

The LATITUDE USB Accessory Adapter is included with a LATITUDE weight scale and blood pressure monitor. The LATITUDE USB Accessory Adapter provides a wireless connection between these products and the Communicator.



Figure 10. LATITUDE USB Accessory Adapter Connection

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

Leave the USB Accessory Adapter plugged into the Communicator so it can receive data when you use your weight scale or blood pressure monitor.

Hotspot Feature (Not available in all geographies)

The hotspot feature on your mobile device may be used for a wireless connection.

To use hotspot, you must have the USB Accessory Adapter plugged into your Communicator. The pairing PIN number is “123456”. Enable hotspot and *Bluetooth*® on your mobile device while near your Communicator for at least 1 hour each day and for manual device interrogations. This allows enough time for the Communicator to contact the LATITUDE system. You may incur charges from your mobile phone network provider. For assistance, contact your mobile device service provider.

Specifications

Model:	6288 and 6290 (Unless specified, values apply to both models.)
Dimensions:	Length: 20.3 cm (8.00 in) Width: 11.4 cm (4.50 in) Height: 6.9 cm (2.71 in)
Weight:	0.38 kg (0.83 lbs)
Power Source:	5.0 VDC, 3.0 A, continuous service Class II AC adapter: <i>Model 6288:</i> GlobTek™ GTM41060-1505 (included) Boston Scientific 353258-001 <i>Model 6290:</i> GlobTek™ GTM41061-1512-7.0 (included) Boston Scientific 353169-001
Power Supply:	Input: 100-240 VAC, 0.6 A, 50-60 Hz Maximum Output: 15 W
Supply Mains Isolation:	AC adapter plug
Protection against electric shock:	Class II
Minimum Operational Loop Current:	20 mA
Expected Service Life:	Up to 15 years
Safety Classification of Ports:	RJ-11 ports: TNV-3 circuit USB ports: SELV circuit

Model 6288 only:

Short Range Device (SRD) Receiver: Category 2

Analog Dialing Mode: Tone

Operating Temperature: 5° C to 40° C (41° F to 104° F)

Storage and Transport Temperature*: -25° C to 70° C (-13° F to 158° F)

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)

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

Communicator Implanted Device Radio (*Model 6288*):

Receive Bandwidth: ±150 kHz

Frequency Band: 869.85 MHz

Modulation Transmit Type: ASK (Amplitude-Shift keying)

Effective Radiated Power: <2.0 dBm (1.6 mW)

Antenna Type: Monopole

Antenna Gain: 2.1 dBi at 869.85 MHz

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)
Antenna Type: Monopole
Antenna Gain: 0.0 dBi at 403.5 MHz

USB Accessory 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: 0° C to 70° C
(32° F to 158° F)
Storage and Transport Temperature: -20° C to 85° C
(-4° F to 185° F)
Operating Humidity: 10% to 85% noncondensing
Storage and Transport Humidity: 10% to 85% noncondensing
Antenna Type: Monopole
Antenna Gain: 2.6 dBi at 2442 MHz

DSL Filter (if supplied):

Digital Subscriber Line (DSL) in-line filter

Excelsus™ Technologies, Inc. - Model Z-200SM

Boston Scientific - Model 6421

DC Loop Current: 20-100 mA DC

Model 6288 Cellular Radio:

EGSM-900:

TX 880–915 MHz

RX 925–960 MHz

Effective Radiated Power:
29.0 dBm

Antenna Type: Monopole

Antenna Gain: 1.0 dBi at
897.4 MHz

DCS-1800:

TX 1710–1785 MHz

RX 1805–1880 MHz

Effective Radiated Power:
26.0 dBm

Antenna Type: Monopole

Antenna Gain: 4.0 dBi at
1747.4 MHz

LATITUDE NXT USB Cellular Adapter (Model 6296):

EGSM-900:

TX 880–915 MHz

RX 925–960 MHz

Effective Radiated Power:
28.7 dBm

Antenna Type: Monopole

Antenna Gain: 1.7 dBi at
897.4 MHz

DCS-1800:

TX 1710–1785 MHz
RX 1805–1880 MHz
Effective Radiated Power:
26.7 dBm
Antenna Type: Monopole
Antenna Gain: 2.2 dBi at
1747.4 MHz

W-CDMA 900:

TX 880–915 MHz
RX 925–960 MHz
Effective Radiated Power:
18.0 dBm
Antenna Type: Monopole
Antenna Gain: 1.7 dBi at
897.4 MHz

W-CDMA 2100:

TX 1920–1980 MHz
RX 2110–2170 MHz
Effective Radiated Power:
18.4 dBm
Antenna Type: Monopole
Antenna Gain: 1.8 dBi at
1949.9 MHz

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 in the presence of flammable gas mixtures, including anesthetics, oxygen, or nitrous oxide.
- The user is cautioned to maintain a 20 cm spacing from the product to ensure compliance with European Norm (EN) requirements.
- *Model 6288 only:* 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 3.3 m (11 ft) away from the Communicator.













- *Model 6290 only:* 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 0.5 meter (1.6 feet) 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 equipment has been tested and found to comply with applicable safety portions of the EN 60601-1:2006 standard.
- This equipment has been tested and found to comply with the following electromagnetic compatibility (EMC) standard: EN 60601-1-2:2007.
- Radio and Telecommunications Terminal Equipment (RTTE). Boston Scientific hereby declares that this device is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. To obtain a full text Declaration of Conformity, contact Boston Scientific using the information on the back cover.












- Accessory equipment connected to the analog and digital interfaces (signal inputs and signal outputs) must be certified according to the respective EN 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 EN 60601-1:2006. 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
	Follow instructions for use
IP21	Protection against ingress of solid foreign objects and water

Symbol	Meaning
	Ready for LATITUDE NXT 4.0
	CE mark of conformity (applies to USB Accessory Adapter)
	CE mark of conformity with the identification of the notified body authorizing use of the mark (applies to <i>Models 6290 and 6296</i>)
	CE mark of conformity with the identification of the notified body authorizing use of the mark and RTTE designation for radio equipment with a use restriction (applies to <i>Model 6288</i>)
	Authorized representative in the European Community
	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 compliance with Anatel Resolutions for telecommunication equipment (Brazil)
	Indicates this product complies with applicable Australian telecommunications and radiocommunications standards requirements and that this product can be connected to an Australian Telecommunications Network or facility (applies to <i>Models 6290 and 6296</i>)

Symbol	Meaning
	Indicates this product complies with applicable Australian telecommunications and radiocommunications standards requirements and that this product can be connected to an Australian Telecommunications Network or facility (applies to <i>Model 6288</i>)
	Indicates the product complies with applicable Australia radiocommunications standards (applies to USB Accessory Adapter)
	Representative sample of symbol that indicates that this device may lawfully be connected to the network in New Zealand
	Indicates this product complies with applicable Japanese telecommunications standards (applies to <i>Model 6296</i>)
	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.

What should I do if the Heart button is flashing?

Press the Heart button to complete a scheduled interrogation. A flashing Heart button does not indicate there is a problem with your implanted device.

Does the Communicator call emergency services 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 emergency services. See “LATITUDE Patient Management System” on page 6.

Where should I place my Communicator?

See “Where to Place Your Communicator” on page 11.

How do I set up my Communicator using the cellular data network and a USB Cellular Adapter?

See “Using the Cellular Data Network” on page 18.

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

See “Internet (using the LATITUDE USB Ethernet Adapter)” on page 22

How do I know the Communicator is working?

See “Normal Operation of the Communicator” on page 25.

What do these lights mean?

See “Indicator Descriptions” on page 28 or “Troubleshooting” on page 35.

How do I manually send my data?

See “Using the Heart Button” on page 26.

When do I use my Communicator?

See “When to Use Your Communicator” on page 9

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

See “Traveling with Your Communicator” on page 54.

How do I dispose of my Communicator and Accessories?

See “Returning, Replacing, or Disposing of the Communicator or Accessories” on page 56.

Where can I go for more help?

Contact your health care provider.

Остаряла версия. Да не се използва.
 Zastaralá verze. Nepoužívat.
 Forældet version. Må ikke anvendes.
 Version überholt. Nicht verwenden.
 Aegunud versioon. Ärge kasutage.
 Πολύ έκδοση. Μην την χρησιμοποιείτε.
 Outdated version. Do not use.
 Versión périmée. Ne pas utiliser.
 Zastarjela verzija. Nemojte upotrebljavati.
 Úrejt útgaða. Notið ekki.
 Versione obsoleta. Non utilizzare.
 Zastarjela verzija. Nenaudokite.
 Útdatert versjón. Skal ikke brukas.
 Pasenusi versija. Neizmantot.
 Elavult verzió. Ne használd!
 Dit is een verouderde versie. Niet gebruiken.
 Utdatert versjon. Skal ikke brukas.
 Wersja przeterminowana. Nie używać.
 Versão obsoleta. Não utilize.
 Versiune expirată. A nu se utiliza.
 Zastarana verzija. Nepoužívať.
 Zastarela različica. Ne uporabite.
 Vanhentunut versio. Älä käyttää.
 Föråldrad version. Använd ej.
 Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
 Zastaralá verze. Nepoužívat.
 Forældet version. Må ikke anvendes.
 Version überholt. Nicht verwenden.
 Aegunud versioon. Ärge kasutage.
 Παλιά έκδοση. Μην την χρησιμοποιείτε.
 Outdated version. Do not use.
 Versión obsoleta. No utilizar.
 Version périmée. Ne pas utiliser.
 Zastarjela verzija. Nemojte upotrebljavati.
 Üreilt ütgäfa. Notið ekki.
 Versione obsoleta. Ne používajte.
 Novecojsi versija. Neizmantot.
 Pasenusi versija. Nenaudokite.
 Elavult verzió. Ne használja!
 Dit is een verouderde versie. Niet gebruiken.
 Utdatert versjon. Skal ikke brukes.
 Wersja przeterminowana. Nie używać.
 Versão obsoleta. Não utilize.
 Versiune expirată. A nu se utiliza.
 Zastarana verzija. Nepoužívať.
 Zastarela različica. Ne uporabite.
 Vanhentunut versio. Älä käyttää.
 Föråldrad version. Använd ej.
 Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
 Zastaralá verze. Nepoužívat.
 Forældet version. Må ikke anvendes.
 Version überholt. Nicht verwenden.
 Aegunud versioon. Ärge kasutage.
 Πολιά έκδοση. Μην την χρησιμοποιείτε.
 Outdated version. Do not use.
 Versión périmée. Ne pas utiliser.
 Zastarjela verzija. Nemojte upotrebljavati.
 Úrejt útgáfa. Notið ekki.
 Versione obsoleta. Non utilizzare.
 Zastarjela verzija. Nenaudokite.
 Útdatert versjon. Skal ikke brukes.
 Pasenusi versija. Neizmantot.
 Elavult verzió. Ne használja!
 Dit is een verouderde versie. Niet gebruiken.
 Utdatert versjon. Skal ikke brukes.
 Wersja przeterminowana. Nie używać.
 Versão obsoleta. Não utilize.
 Versiune expirată. A nu se utiliza.
 Zastarana verzija. Nepoužívať.
 Zastarela različica. Ne uporabite.
 Vanhentunut versio. Älä käyttää.
 Föråldrad version. Använd ej.
 Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
 Zastaralá verze. Nepoužívat.
 Forældet version. Må ikke anvendes.
 Version überholt. Nicht verwenden.
 Aegunud versioon. Ärge kasutage.
 Παλιά έκδοση. Μην την χρησιμοποιείτε.
 Outdated version. Do not use.
 Versión obsoleta. No utilizar.
 Version périmée. Ne pas utiliser.
 Zastarjela verzija. Nemojte upotrebljavati.
 Úrejt útɡáfa. Notið ekki.
 Versione obsoleta. Ne použivate.
 Novacijosi versija. Neizmantoti.
 Pasenusi verzija. Nenaudokite.
 Elavult verzió. Ne használja!
 Dit is een verouderde versie. Niet gebruiken.
 Utdatert versjon. Skal ikke brukes.
 Wersja przeterminowana. Nie używać.
 Versão obsoleta. Não utilize.
 Versiune expirată. A nu se utiliza.
 Zastarana verzija. Nepoužívať.
 Zastarela različica. Ne uporabite.
 Vanhentunut versio. Älä käyttää.
 Föråldrad version. Använd ej.
 Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
 Zastaralá verze. Nepoužívat.
 Forældet version. Må ikke anvendes.
 Version überholt. Nicht verwenden.
 Aegunud versioon. Ärge kasutage.
 Πολύ έκδοση. Μην την χρησιμοποιείτε.
 Outdated version. Do not use.
 Versión périmée. Ne pas utiliser.
 Zastarjela verzija. Nemojte upotrebljavati.
 Úrejt útgáfa. Notið ekki.
 Versione obsoleta. Non utilizzare.
 Zastarjela verzija. Nenaudokite.
 Útdatert versjón. Skal ikke brukas.
 Pasenusi versija. Neizmantot.
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