# **LATITUDE® Patient Management**

Communicator Patient Manua

Look inside the back cover for a Communicator setup video DVD.

#### Restricted Device:

Federal law (USA) restricts this device to sale, distribution, and use by, or on the lawful order of a physician trained or experienced in device implant and follow-up procedures.

Scientific

# **A Message to Patients**

Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

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# **LATITUDE** Patient Management

LATITUDE Patient Management is a remote monitoring system that provides implanted device data to both clinicians and cardiac device patients. This remote monitoring system is designed to improve patient care while providing convenience to you. LATITUDE Patient Management provides clinicians access to your implanted device data via the Internet.

A key component of the system is the LATITUDE Communicator, an easy-to-use in-home monitoring device for patients. The Communicator uses wireless communication technology to automatically gather data from your implanted device at times scheduled by your physician. This data is sent to the LATITUDE database through a standard telephone line. The LATITUDE Patient Management system uses advanced security methods to protect your personal medical information.

The LATITUDE Patient Management system is not intended to assist with medical emergencies. If you are not feeling well, call your physician or 911.

#### **Patient Website**

Patients can view information about their implanted device from a personalized patient website by using an Internet-connected personal computer. The patient website also provides access to a wide range of cardiac related health information. Patients must have approval by their clinic to gain access to the passwordprotected patient website. If your clinic approves, you should receive a user name and password a few days after receiving your Communicator. Contact your clinic or physician to get approval to access the patient website.

Use of the website is not required and has no effect on the operation of your Communicator. After being received by the Communicator, information from your implanted device may take a reasonable amount of time to appear on the patient website. The patient website is located at: www.latitude.bostonscientific.com

**CAUTION:** Information provided on the patient website is not intended to replace professional medical care. If you are feeling poorly or are in need of immediate care, call your physician or 911.

#### **Clinician Website**

The clinician website provides doctors and clinicians a convenient and secure way to obtain and analyze the data and health-related information that they scheduled the Communicator to collect from your implanted device. After being received by the Communicator, information from your implanted device may take a reasonable amount of time to appear on the clinician website.

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

#### The LATITUDE Communicator

The LATITUDE Communicator is an in-home monitoring system that communicates with your implanted device. The Communicator provides an easy-to-use system that you can use from the comfort of your home, saving you a trip to your physician's office. While use of the Communicator does not eliminate the need for in-office visits that may be scheduled by your physician, it can minimize the number of them.

The Communicator automatically reads implanted device information at times scheduled by your physician. The Communicator does not reprogram or change any functions of your implanted device. Only your clinician can do this during an office visit.

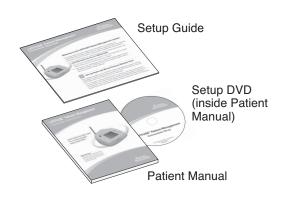
The Communicator can also collect information from an optional LATITUDE weight scale or blood pressure monitor (if your physician prescribed the LATITUDE Heart Failure Management System). These specially designed products provide additional information to monitor your health. Refer to the LATITUDE Weight Scale and Blood Pressure Monitor Patient Manual that is included with these products.



Read the instructions in this manual thoroughly before using the Communicator.

# Please keep this manual for future reference.

Keep all of your LATITUDE information, including this manual (with setup DVD) and the setup guide, in a convenient location for easy access in the future.



# **Items You Should Receive**

The following items are included with the Communicator:

- · Communicator unit with attached antenna
- · Communicator telephone cord
- Power supply (Globtek Model GTM21089-1305-W2)
- · Communicator Setup Guide
- Communicator Patient Manual
- Communicator Setup Video DVD (inside the back cover of this manual)

# When to Use Your Communicator

The Communicator performs many functions automatically on a regular schedule that is set by your physician. Other functions require you to respond to messages, follow instructions and answer questions displayed on the touch screen.

Use the Communicator only as instructed by your physician or clinician. The Communicator's Action button (see "Identifying Parts" on page 9) will light or flash whenever there are messages or instructions you need to follow. Check the Action button every day. If it is lit or flashing, press it and then follow the instructions on the Communicator screen.

### When Not to Use Your Communicator

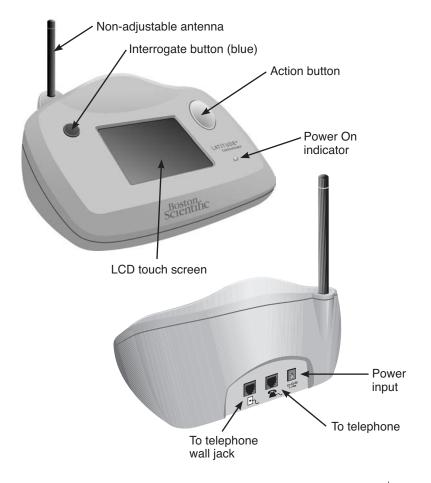
The Communicator is designed to work only with the implanted device of the patient for whom it was prescribed. It will not work with other patients' implanted devices and should be used only as authorized by the prescribing physician. The Communicator is contraindicated for use with any pulse generator other than a Guidant or Boston Scientific device.

Ask your physician 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.

# **Important Safety Notes**

- The Communicator interrogates your implanted device, as scheduled by your physician, and sends this information to the LATITUDE Patient Management secure database, which provides access to your information by your authorized physician(s). Therefore, it is very important that the Communicator remain plugged into the power outlet and telephone line.
- Electrical safety advisory notice: It is recommended that
  the customer install a surge arrestor in the electrical outlet
  to which the Communicator is connected. This is to avoid
  damage to the Communicator caused by local lightning
  strikes and other electrical surges.
- The Communicator is designed to operate on standard, analog telephone lines like those found in most homes.
   The Communicator may work on other telephone systems, such as Digital Subscriber Line (DSL) and Voice Over IP (VoIP) Internet systems, 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 where telephones are typically provided by the facility.
- Your Communicator is designed to be used in the continental United States, Alaska, Hawaii, and Puerto Rico.

# **Identifying Parts**



# **Buttons and Indicator Lights**

Button/Light	Color	Meaning
Action Button	White light	Interrogate your device or answer health questions. Refer to "Interrogating Your Implanted Device" on page 26 and "Answering Health-related Questions" on page 24.
	Yellow light	Respond to Communicator alert. Indicates some type of Communicator problem. Respond to the information displayed on the touch screen.
	Red light	Your immediate response is required. Indicates that the Communicator identified a potential change in your implanted device that your physician asked to be alerted to. Write down any telephone numbers and/or codes that appear in alert messages. Call the LATITUDE Patient Services number on the screen and report any codes. Then press the menu button next to the OK text.
Interrogation Button	Blue	Used to initiate an interrogation of your implanted device. Refer to "Interrogating Your Implanted Device" on page 26 before using this button.
Power On	Green light	Indicates the Communicator is connected to power.

# **Touch Screen Display**

The Communicator has a touch screen display that is sensitive to the touch of a finger. Gently touching the screen surface with your finger operates the touch screen. Respond to onscreen instructions or questions by touching the desired button with your fingertip. Do not use tools or sharp objects as they can damage the touch screen. If you need to use the Communicator and the touch screen is dim (black), simply touch any part of the screen or press the Action button to turn on the screen.

# Non-adjustable Antenna

The antenna on the Communicator is used to communicate with your implanted device using radio frequency signals.

**CAUTION:** The antenna does not pivot or extend. Do not attempt to bend or adjust the antenna. Do not pick the Communicator up by the antenna or handle it in a manner that could damage the antenna.

### Where to Place Your Communicator

Place your Communicator:

- close to where you sleep—for optimum performance, the Communicator should be no more than 8 feet from where you sleep;
- where you can comfortably see the touch screen;

- · near an electrical outlet;
- · and near a telephone wall jack.

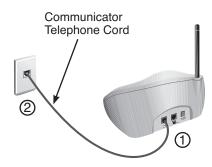
The Communicator may typically be placed on a nightstand in your bedroom.

**CAUTION:** If you do not plug a telephone into the back of the Communicator, make sure there are no objects behind the Communicator that could come in contact with the open telephone jack as it is a live jack.

#### **How to Connect Your Communicator**

Complete the following steps to connect and install the Communicator. These instructions also appear in the *LATITUDE Patient Management Communicator Setup Guide*.

- Find the Communicator telephone cord that came with the Communicator and plug one end into the jack labeled on the back of your Communicator.
- 2. Plug the other end of the cord into the telephone jack on the wall of your room.

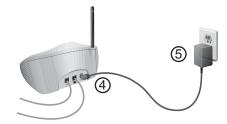


If you also want to use a telephone with this wall jack, you may plug your telephone into the jack labeled on the back of your Communicator.

CAUTION: Once you connect the Communicator to a telephone wall jack, the second telephone jack becomes a live jack. Do not touch the inside of this telephone jack.

- 5. Plug the power supply into an electrical outlet.





6. Make sure the power light on the Communicator is on.

The green light indicates the Communicator is connected to power. (If the green light is not on, check that both ends of the adapter cord are plugged in firmly.)



7. The installation of the Communicator is now complete. Instructions should appear on the touch screen.

**Important:** Your Communicator should remain connected to the power outlet and telephone line.

8. Complete the instructions shown on the Communicator touch screen as described in "Using the Communicator for the First Time" on page 17.

#### **How to Use Your Communicator**

The Communicator provides step-by-step instructions that are displayed on the touch screen. The information in this section describes use of the buttons, lights, and touch screen in addition to instructions for performing menu items and options that are displayed on the touch screen.

#### **CAUTIONS:**

- The Communicator may not communicate with your implanted device if you are too close to some household appliances. You should be at least 36 inches (3 ft.) away from televisions, VCRs, and personal computers when you are using the Communicator.
- The Communicator uses a wireless (radio frequency) communication system to communicate with your implanted device and optional weight scale and blood pressure monitor. This communication can be disrupted by electromagnetic interference. Avoid placing your Communicator next to or in the immediate vicinity of other wireless products and sources of electromagnetic energy. Call LATITUDE Patient Services at 1-866-484-3268 if you need help finding a suitable location for your Communicator or have questions about possible sources of interference.

#### **Responding to Action Button Alert Lights**

Action button alert lights serve to notify you that some sort of action needs to be taken. The colors and meanings of each light are described in the table on page 10.

If the Communicator touch screen is dim when one of the colored lights turns on, the light will flash to attract your attention. Press the Action button to brighten the touch screen and view the alert message. The light will stop flashing, but will remain lit.

Respond to the alert message and touch the appropriate button on the touch screen, such as **OK** or **Continue**. The light will then turn off. Please respond to alert messages as soon as possible.

**Important:** You should write down any telephone numbers and/or codes that appear in alert messages before touching the **OK** or **Continue** button, as doing so causes the Communicator to display a different screen and the alert message will no longer appear.

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

The Communicator has internal memory that stores your interrogation and setup information in case the electric power is interrupted or the power supply is unplugged.

A message appears when power is restored to the Communicator asking if you want to check the setup. If the Communicator has been moved, touch the **Yes** button and follow the check setup instructions. You can touch the **No** button if the Communicator wasn't moved.

#### What to Do if the Touch Screen is Black

The Communicator touch screen will dim (go black) after the Communicator has not been used for 10 minutes. To turn the touch screen on, press the Action button or touch the screen. Then check for a message or instruction on the top of the screen. The Action button light may also flash when the Communicator is not being used and the touch screen is black. Refer to "Responding to Action Button Alert Lights" on page 15 for additional information.

# **Using the Communicator for the First Time**

The Communicator is programmed to display a series of instructions to step you through a personalized setup process. This process needs to be performed after the Communicator or optional weight scale and blood pressure devices are installed. This is done to make sure the Communicator is connected correctly and that it can communicate with your implanted device, make a telephone call to the LATITUDE database, and receive signals from the weight scale and blood pressure devices.

The setup process may also need to be performed if the Communicator was moved, to make sure everything is functioning properly.

A. When you first connect and install the Communicator, you should see a message similar to the one shown in Figure 1.

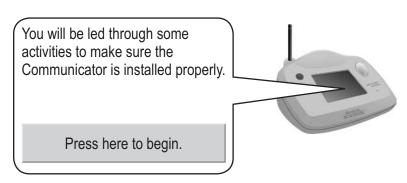


Figure 1. Starting the setup process.

B. Touch the **Press here to begin** button and follow the remaining instructions on the touch screen. The Communicator will continue to display all the remaining setup instructions, including placing a telephone call to the LATITUDE database and interrogating your implanted device.

# **Menu Screens**

When using the Communicator, there are two primary menu screens from which most operations begin:

- · Main Menu screen
- Options Menu screen

# Main Menu Screen

The Main Menu screen and the types of information and menu choices that are displayed on the top and bottom portions of the screen are shown in Figure 2. The Main Menu screen serves as the starting point for most operations that you may perform.

A **Set Up** button is displayed only when this function needs to be performed. A **Health Questions** button appears only on the scheduled date for patients who are prescribed this feature. See "Answering Health-related Questions" on page 24. A **Check Phone Line** button is displayed if the Communicator cannot detect a telephone dial tone.

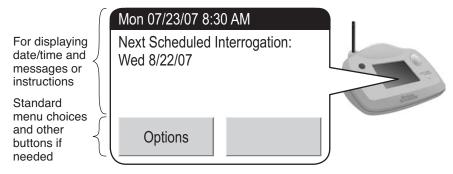


Figure 2. Main Menu screen.

# **Options Menu Screens**

The Options Menu screens are shown in Figure 3. (The Options Menu screens are displayed by touching the **Options** button from the Main Menu screen as shown in Figure 2.) Touch the **More options** button to advance through the multiple Options Menu screens. Refer to the following sections for instructions on using each option. Touching the **Exit options** button returns you to the Main Menu screen.

#### **View Schedule**

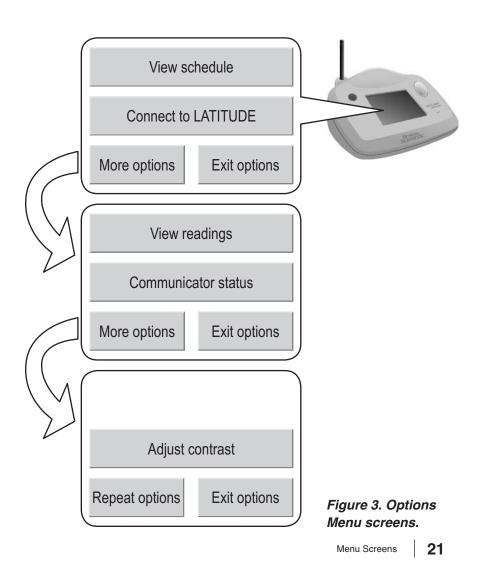
The View Schedule screen displays the dates of your last interrogation and next scheduled interrogation. Touching the **OK** button at the bottom of the screen returns you to the Main Menu screen.

#### **Connect to LATITUDE**

Touching the **Connect to LATITUDE** button makes the Communicator attempt a call to the LATITUDE system. You do not need to use this option during normal operation of the Communicator. You should only use this option if instructed to do so by LATITUDE Patient Services or your doctor.

#### **View Readings**

The View Readings screen displays the date and measured values of your latest weight and blood pressure readings, if you



use these products. The View Readings screen will be displayed only if you use the scale and blood pressure monitor.

You can display this screen by touching the **View readings** button from the Options Menu screen as shown in Figure 3. Touching the **OK** button at the bottom of the screen returns you to the Main Menu screen.

#### **Communicator Status**

The Communicator Status screen displays the current status of the Communicator. Normally, the status will be "OK." However, if any error code numbers or messages appear, write them down and call LATITUDE Patient Services at 1-866-484-3268. Touching the **OK** button will return you to the Main Menu screen.

#### **Adjust Contrast**

The contrast on the Communicator touch screen can be changed.

#### How to change the touch screen contrast:

1. From the Options Menu screen (see Figure 3 on page 21), touch the **Adjust contrast** button to display the screen shown in Figure 4.

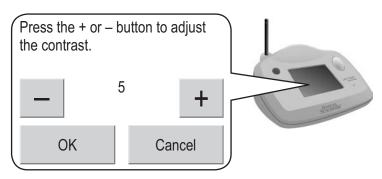


Figure 4. Adjust Contrast screen.

- 2. Touch the + or buttons to increase or decrease the contrast to your preference. The contrast can have a value from 1 to 10, with 1 having the least contrast.
- When you have finished adjusting the contrast, touch the OK button to save your new contrast setting and return to the Main Menu screen. Touch the Cancel button to return to the Main Menu screen without making any changes to the contrast.

# **Setting the Time Zone**

The Communicator originally receives the date and time as part of the setup process. You only need to set the time zone. The time on the Communicator automatically adjusts for daylight-saving time (DST) if you indicate that your area observes DST.

You should only need to reset the time zone if the Communicator is moved to a new location or taken on an extended vacation. If this occurs, the Communicator will prompt you for the time zone.

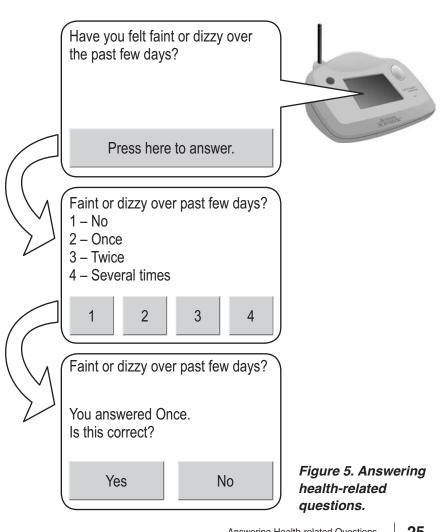
# **Answering Health-related Questions**

The Communicator may prompt some patients to answer a set of personal health questions. Patients who are prescribed this service typically answer these questions on a regular basis, such as once a week.

The Communicator sends responses to these questions, along with information read from the patient's implanted device, to the LATITUDE database over the telephone line.

The Action button will illuminate with a white light when these questions need to be answered. If this white light is on or is flashing, press the Action button and messages on the Communicator will lead you through the health questions.

For each question, the Communicator will display a series of screens such as the example in Figure 5. First, the Communicator will display the question. Touch the **Press here to answer** button to see the possible answers. Next, touch the button that corresponds to the answer that best describes how you feel. The Communicator will repeat your answer and ask you to confirm that it is the correct choice.



Once you have answered all questions, the Communicator will display a message indicating that you are finished. Touch the **OK** button to return to the Main Menu screen.

# **Interrogating Your Implanted Device**

The Communicator automatically interrogates your implanted device on a regular schedule that is set by your physician. This may happen without your awareness and should not require any action on your part.

However, if the Communicator is unable to automatically interrogate your device after repeated attempts, it may prompt you to interrogate your implanted device. This could occur if you are too far away from the Communicator when it attempts to communicate with your implanted device. In this situation, the white Action button lights or flashes and a message appears on the Communicator that instructs you how to begin and complete the interrogation using the blue Interrogate button.

The blue Interrogate button is designed to enable you to manually interrogate your implanted device, at unscheduled times, as prescribed by your physician.

You should only use the blue Interrogate button when instructed to do so by your physician or when prompted by the Communicator. When using the Interrogate button, you should stay close to the Communicator during the entire interrogation

process to ensure optimum communication between your implanted device and the Communicator.

When you press the Interrogate button, the Communicator checks to make sure that the interrogation is permitted, because some physicians will choose to turn this feature off. If the interrogation is permitted, messages appear on the Communicator that instruct you how to begin and complete the interrogation.

If the interrogation is not permitted, either because the limit has been reached or because the feature has been disabled, the Communicator automatically calls the LATITUDE database. This is done to check for a change in the number of patient initiated 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 blue Interrogate button more than as prompted by your Communicator or as instructed by your physician may lead to a decrease in the battery life of your implanted device.
- If you feel poorly or are in need of immediate care, call your physician or 911.

# **Traveling with Your Communicator**

You can use your Communicator away from home if you will be gone for an extended period. However, whenever you travel for an extended period of time, with or without your Communicator, you should consult your physician before planning to do so. Settings to some of the scheduled events programmed into the Communicator may need to be temporarily changed to use your Communicator away from home.

**NOTE:** Your Communicator is designed to be used in the continental United States, Alaska, Hawaii, and Puerto Rico.

# Communicator Use of the Telephone System

The Communicator periodically makes toll-free telephone calls when there is a need to send data to the LATITUDE Patient Management secure database. These calls usually last for approximately five minutes.

The Communicator can only make outgoing calls; it cannot receive any calls. The Communicator is designed to operate on standard, analog telephone lines like those found in most homes. The Communicator may work on other telephone systems, such as Digital Subscriber Line (DSL) and Voice Over IP (VoIP) Internet systems, 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 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. However, 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't be used at the same time. Your telephone has priority use of the telephone line.

# What to Do If You Need to Use the Phone 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 and wait for two or more seconds. The Communicator will disconnect and dial tone will be restored. 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 lines, 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 most DSL service providers to connect telephones, an answering machine, or a fax machine to your telephone line.

If you use DSF filters for these devices, you will need to install a DSL filter to use the LATITUDE Communicator. For assistance, contact your DSL service provider or LATITUDE 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.

If your Communicator becomes damaged, or it malfunctions, contact LATITUDE Patient Services at 1-866-484-3268.

# **Cleaning the Communicator**

When necessary, clean the Communicator housing and touch screen with a soft, clean, lint-free cloth moistened in water or mild detergent. If necessary, you may use isopropyl alcohol or window cleaner. 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.

**CAUTION:** Do not use other cleaning fluids. They may damage the Communicator touch screen. Never spray any cleaning fluid directly on the Communicator touch screen. Do not allow moisture to accumulate on or around the buttons.

# **Returning the Communicator**

Do not dispose of the Communicator. If return or replacement is necessary, contact LATITUDE Patient Services at 1-866-484-3268 to make arrangements for returning the Communicator. LATITUDE Patient Services will replace your Communicator if it becomes defective and provide a postage-paid return label, packaging and instructions for returning your Communicator.

# **Specifications**

Model: 6476

LCD Display: Monochrome, 240 x 320 pixel, with touch

screen control

Power Source: 5.0 VDC, 2.0 A, AC adapter, GlobTek

model GTM21089-1305-W2 (included)

Power Supply Input: 100-240 VAC, 0.5 A, 50-60 Hz

Dimensions: Length: 7.75 in (19.7 cm)

Width: 5.75 in (14.6 cm) Height: 7.00 in (17.8 cm)

Weight: 1.25 lbs

Operating Temperature: 50° F to 104° F (10° C to 40° C)
Storage Temperature: -22° F to 158° F (-30° C to 70° C)

Operating Humidity: 25% to 75% noncondensing Storage Humidity: 25% to 95% noncondensing

Storage Pressure: 50 to 106 kPa

Radio Frequency Transmitters

Transmitters

Frequency: 916.5 MHz +403/-408 KHz

Sensor Radio

Frequency: 2402.0 to 2480.0 MHz

**Protection Against Ingress** 

Pulse Generator Radio

of Water: IXP0 Ordinary equipment

# Safety, EMC and FCC Compliance Standards

- This equipment has been tested and found to comply with applicable safety portions of the UL 60601-1:2003 standard.
- This equipment has been tested and found to comply with the following EMC standards: EN 60601-1-2:2001.
- This device complies with Title 47, Part 15 of the FCC Rules.
   Operation is subject to the following two conditions: (1) This
   device may not cause harmful interference, and (2) this device
   must accept any interference received, including interference
   that may cause undesired operation of the device.
- Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate this equipment.
- This equipment complies with Part 68 of the FCC rules and the requirements adopted by the ACTA. On the bottom of this equipment is a label that contains, among other information, a product identifier in the format US: AAAEQ##TXXX. If requested, this number must be provided to the telephone company. The Ringer Equivalence Number (REN) for this product is part of the product identifier. The digits represented by ## are the REN.
- The REN is used to determine the number of devices that may legally connect to a telephone line. In most, but not all areas, the sum of RENs should not exceed five (5.0). You should contact your telephone company to determine the maximum REN for your calling area.
- This equipment uses the following USOC jacks: RJ11C.

- An FCC compliant telephone cord and modular plug are provided with this equipment, which is designed to connect to the telephone network or premises wiring using a Part 68 compliant compatible jack. See installation instructions for details.
- If the Communicator causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice isn't practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it is necessary.
- 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.
- Connection to party line service is subject to state tariffs. Contact the state public utility commission, public service commission or corporation commission for information.
- 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.
- For information about the electromagnetic environment in which the Communicator is intended to be used, please contact LATITUDE Patient Services at 1-866-484-3268.

#### **Electromagnetic Emissions and Immunity**

Table 1. Guidance and manufacturer's declaration—electromagnetic emissions—for all equipment and systems<sup>ab</sup>

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions (CISPR 11)	Group 1	The Model 6476 LATITUDE Communicator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class B	The Model 6476 LATITUDE Communicator is suitable for use
Harmonic emissions (IEC 61000-3-2)	Class A	in all establishments, including domestic establishements and those directly connected to the public low-voltage power supply
Voltage fluctuations/ flicker emissions (IEC 61000-3-3)	Complies	network that supplies buildings used for domestic purposes.

a The Model 6476 LATITUDE Communicator is intended for use in the electromagnetic environment specified above. The customer or the user of the Model 6476 LATITUDE Communicator should assure that it is used in such an environment.

b The Model 6476 LATITUDE Communicator is also compliant with IEC 60601-1-2:2007.

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment— guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 percent.
Electrical fast transient/ burst (IEC 61000-4-4)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment— guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines (IEC 61000-4-11)	$<5\% \ U_{\rm T}^{\rm b}$ $(>95\% \ {\rm dip}$ in $U_{\rm T}$ ) for 0.5 cycle $40\% \ U_{\rm T}$ $(60\% \ {\rm dip}$ in $U_{\rm T}$ ) for 5 cycles $70\% \ U_{\rm T}$ $(30\% \ {\rm dip}$ in $U_{\rm T}$ ) for 25 cycles $<5\% \ U_{\rm T}$ $(>95\% \ {\rm dip}$ in $U_{\rm T}$ ) for 5 sec	$<5\% \ U_{\rm T}$ $(>95\% \ {\rm dip}$ in $U_{\rm T}$ ) for 0.5 cycle $40\% \ U_{\rm T}$ $(60\% \ {\rm dip}$ in $U_{\rm T}$ ) for 5 cycles $70\% \ U_{\rm T}$ $(30\% \ {\rm dip}$ in $U_{\rm T}$ ) for 25 cycles $<5\% \ U_{\rm T}$ $(>95\% \ {\rm dip}$ in $U_{\rm T}$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 6476 LATITUDE Communicator requires continued operation during power mains interruptions, it is recommended that the Model 6476 LATITUDE Communicator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

a The Model 6476 LATITUDE Communicator is intended for use in the electromagnetic environment specified above. The customer or the user of the Model 6476 LATITUDE Communicator should assure that it is used in such an environment.

b  $U_{\rm T}$  is the AC main's voltage prior to application of the test level.

Table 3. Guidance and manufacturer's declaration—electromagnetic immunity—for equipment and systems that are not life-supporting  $^{\rm a\,b\,c}$ 

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 6476 LATITUDE Communicator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz	3 Vrms	<i>d</i> = (0.35) √ <i>P</i>
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = (3.17) \sqrt{P}$ (80 MHz to 800 MHz)
			$d = 6.34 \sqrt{P}$ (800 MHz to 2.5 GHz)
			where <i>P</i> is the maximum output power rating of

the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>d</sup> should be less than the compliance level in each frequency range.<sup>e</sup>

Interference may occur in the vicinity of equipment marked with the following symbol:



- a The Model 6476 LATITUDE Communicator is intended for use in the electromagnetic environment specified above. The customer or the user of the Model 6476 LATITUDE Communicator should assure that it is used in such an environment.
- b At 80 MHz and 800 MHz, the higher frequency range applies.
- c These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- d Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 6476 LATITUDE Communicator is used exceeds the applicable RF compliance level above, the Model 6476 LATITUDE Communicator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 6476 LATITUDE Communicator.

e Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

## **Explanation of Product and Label Symbols**

Symbol	Meaning
•7	Input from telephone jack
	Output to telephone (optional)
⊖- <b>⊕</b> -⊕ 5 V ===	AC/DC adapter power input
(((•)))	Non-ionizing electromagnetic radiation
i	See instruction manual
X	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)
TUV MRTL US	Mark for nationally recognized testing for safety standards

## **Explanation of Shipping Box Symbols**

Symbol	Meaning
<u>1</u> 1	This side up
早	Fragile, handle with care
*	Keep dry
₹ X	Do not use hooks
1	Temperature limitations
<b>%</b>	Humidity limitations
<b>\$••</b> \$	Atmospheric pressure limitations

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