

Patient's Manual

Draft - 11/11/04

LATITUDE™ Communicator

Restricted Device:
Federal law (USA)
restricts the device to
sale, distribution, and
use by or on the
lawful order of a
physician.

GUIDANT

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LATITUDE Patient Management

LATITUDE™ Patient Management is a remote monitoring system that provides implant device data to both clinicians and cardiac device patients that formerly required an office visit. LATITUDE Patient Management provides clinicians anytime, anywhere access to the status of your implanted device data.

A key component of the system is the LATITUDE Communicator, an easy-to-use in-home monitoring device for patients. The Communicator uses advanced medical monitoring technology to automatically gather and send implanted device data to the LATITUDE secure database through a standard telephone line.

The LATITUDE Patient Management system employs multiple levels of security and encryption methods to protect patients' personal medical information.

Patient Website

Patients can view information about their implanted device and condition 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 register and have approval by their clinic to gain access to the password-protected patient website. The patient website is located at: www.latitude.guidant.com.

CAUTION: Personal information provided on the patient website is not intended to replace professional medical care. If you are not feeling well, call your physician.

Clinician Website

The clinician website uses the power of the internet to provide doctors and clinicians with a convenient and secure way to obtain and analyze a patient's implanted device and health-related information. The website provides advanced analysis and trending tools aimed 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 Guidant 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 routine follow-up visits.

The Communicator automatically reads implanted device information at times specified by the patient's physician. The Communicator does not reprogram or change any functions of the patient's implanted device. Only the patient's 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 prescribed by your physician). These specially designed devices may be prescribed by your physician to provide additional information in monitoring the health of the patient. Refer to the *LATITUDE Weight Scale and Blood Pressure Monitor Patient's Manual* that is included with these devices.



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

Please keep this manual for future reference.

You can store this manual, along with your other LATITUDE Patient Management documents, in the documentation box that was shipped with your Communicator.



Items You Should Receive

The following items are included with the Communicator:

- Communicator unit with attached antenna
- Communicator telephone cord
- AC power adapter
- Documentation box
- *Communicator Setup Guide*
- *Communicator Patient's Manual*
- Communicator Setup Video (DVD and VHS formats)

When to Use Your Communicator

The Communicator performs many functions automatically on a regular schedule. Other functions require you to respond to messages, follow instructions, and answer questions displayed on the screen and announced over the speaker.

Use the Communicator as instructed by your physician or clinician. The Communicator's Action button will light or flash whenever there are messages or instructions you need to follow. Check daily to see if the Action button is lit or flashing.

When Not to Use Your Communicator

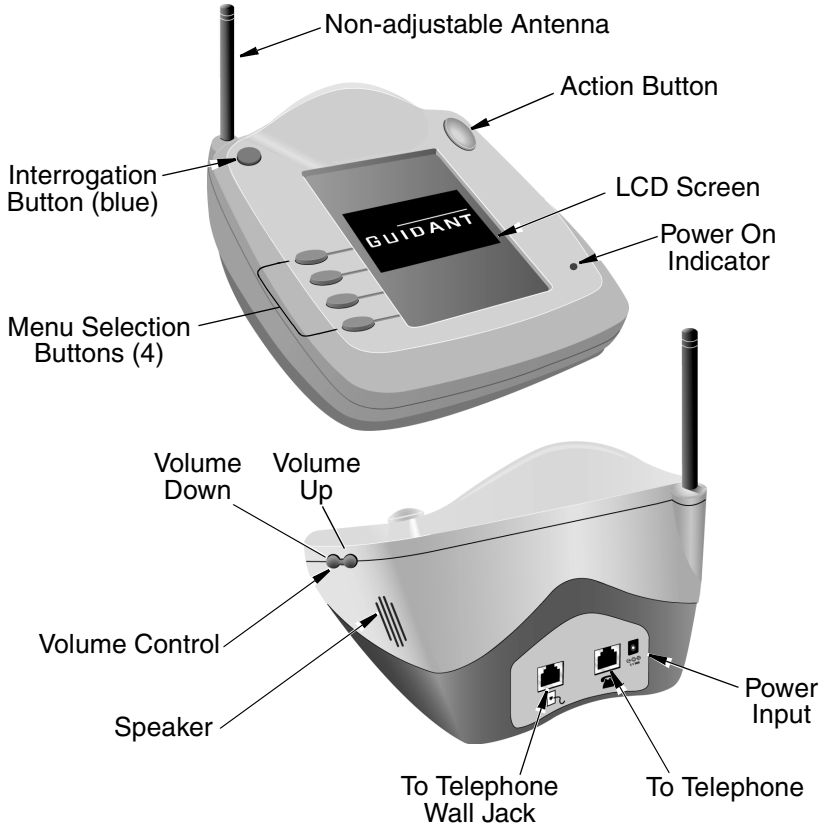
The Communicator is designed to work only with the implanted device of the patient for whom it was prescribed. It will not work with other patients' implanted devices and should be used only as authorized by the prescribing physician.

Ask your physician if you have questions about any risks. Refer to your handbook for your implanted device for more information.

Important Safety Notes

- The Communicator monitors your implanted device 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.
- Your Communicator is designed to be used in the continental United States, Alaska, and Hawaii.

Identifying Parts



Buttons and Indicator Lights

Button/Light	Color	Meaning
Action Button	White light	Answer health questions. Indicates that you need to answer a set of personal health questions. Refer to “Answering Health Related Questions” on page 22.
	Yellow light	Respond to system alert. Indicates some type of system problem. Respond to the information displayed on the screen.
	Red light	Respond to urgent alert. Indicates the Communicator read a fault error from your implanted device. Call the Guidant Patient Services number on the screen as soon as possible and report the error code on the screen. Then press the menu button next to the OK text.
Interrogation Button	Blue	Used by patient to initiate an interrogation of their implanted device. Refer to “Interrogating Your Implanted Device” on page 25 before using this button.
Menu Selection Buttons (4)	Gray	Used to submit appropriate responses to messages appearing on the display.
Power On	Green light	Indicates the Communicator has power connected.

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.

Voice Messages

The Communicator uses voice messages to reinforce screen messages and assist patients with visual impairments. Each voice message corresponds to the text message or instruction on the screen. The volume of these messages can be controlled as described in “Changing the Volume of Voice Messages” on page 16.

Where to Place for Your Communicator


Where to place your Communicator:

- within 8 ft. of where you sleep
- where you can sit and see the screen comfortably
- near an AC electrical outlet
- near a telephone wall jack

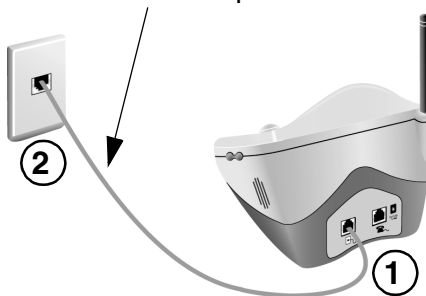
The Communicator may typically be placed on a night stand or dresser top in the patient’s bedroom.

How to Connect Your Communicator

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


1. Find the Communicator telephone cord that came with the Communicator and plug one end into the jack labeled  on the back of the Communicator.

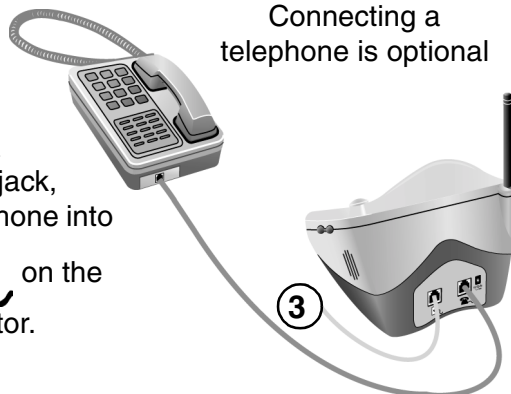
Communicator Telephone Cord

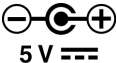


2. Plug the other end of the cord into the telephone jack on the wall of your room.

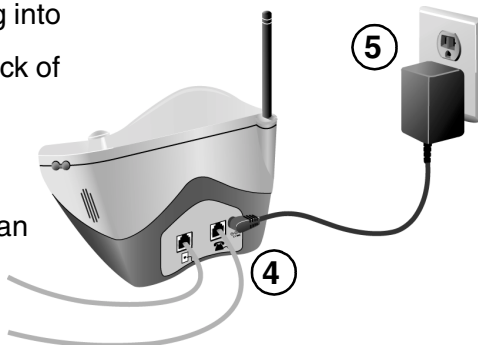
Connecting a telephone is optional

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



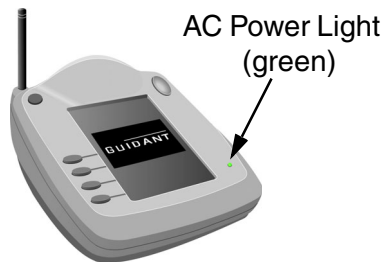
- Insert the power supply plug into the  jack on the back of the Communicator.

- Plug the power supply into an electrical outlet.



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

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



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

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

8. Complete the instructions shown on the Communicator screen as described in “Using the Communicator for the First Time” on page 18.

How to Use the Communicator

The Communicator provides step-by-step instructions that are displayed on the screen and announced over the speaker. The information in this section describes use of the buttons and lights in addition to instructions for performing menu items and options that are displayed on the 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.
- Cellular phones will not affect your Communicator.

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 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 screen and view the alert message. The light will stop flashing but will remain lit. Respond to the alert message and press a menu button next to the appropriate text, 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 or error codes that appear in alert messages before selecting OK or Continue, as doing so causes the Communicator to display a different screen and the alert message will no longer appear.

Changing the Volume of Voice Messages

You can change the volume of the voice messages by using the volume control (page 9) on the right-side of the Communicator. You can increase or decrease the volume of the voice messages or turn the volume off if you don't want to hear the messages.

When you press and hold the up or down volume control, you will hear the current message or an audible tone at the next volume level and each following level until the highest/lowest volume is reached.

To increase the volume: push the volume up control

To decrease the volume: push the volume down control

To turn messages off: press and hold the volume down control until you can no longer hear a tone or voice

What to Do if the Electrical Power is Interrupted

The Communicator has internal memory that stores all important setup information in case the electric power is interrupted or the AC power adapter is unplugged. This information is stored for up to seven days.

A message appears when power is restored to the Communicator asking if you want to check the installation. If the Communicator has been moved, select Yes and follow the check installation instructions. You can select No if the Communicator wasn't moved and the power was out for only a short time.

What to do if the Screen is Black

The Communicator screen will dim and go black after the Communicator has not been used for 10 minutes. If the screen is black, press the Action button to turn the screen on. Check for a message or instruction on the top of the screen.

One of the alert lights may also flash when the Communicator is not being used and the screen is black. Refer to “Responding to Action Button Alert Lights” on page 16 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 is installed to make sure the Communicator is connected correctly and that it can

communicate with your implanted device, make a telephone call to the LATITUDE secure database, and receive signals from the optional weight scale and blood pressure devices.

The setup process may also need to be performed if the Communicator was powered off (or 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 on following screen.

*You will be led through some activities to make sure the Communicator is installed properly. Please press the button next to the word **Begin**.*

Begin



- B. Press the button next to the **Begin** text and follow the remaining instructions on the screen.

The Communicator will continue to display and read all the remaining setup instructions, including placing a telephone call to the secure database and interrogating your implanted device.

Menu Screens

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

- Main menu screen
- Options menu screen

Main Menu Screen

The main menu screen and the types of information that is displayed on the top and bottom portions of the screen is shown below. The main screen serves as the starting point for most operations that you may perform.

The Set Up choice is displayed only when this function needs to be performed or after power has been interrupted. The Answer Questions Options choice appears only for patients who are prescribed this feature. See “Answering Health Related Questions” on page 22.

For displaying
date/time,
measurements,
messages, and
instructions

Thu 04/21/2005
03:40 PM

Menu choices

Set Up

Answer Questions

Options



Options Menu Screen

The options menu screen is shown below. Refer to the page numbers listed for instructions on using each option. Selecting the Cancel option returns you to the main menu screen.

page 23 —

View Latest Readings

page 23 —

Set Time Zone

page 24 —

Check Communicator

Return to
Main Menu —

Cancel



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 frequency, such as once a week.

The Communicator sends responses to these questions, along with information read from you implanted device to the LATITUDE Patient Management 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 the Communicator will display the first question. The white light remains on until you answer the first question.

For each question, press the menu button that corresponds to the answer that best describes how you feel. The Communicator will repeat your answer asking if it is the correct choice. You can select No if you need to change your answer. Answer all questions. Here is an example question with possible answers:

Have you felt faint or dizzy over the past few days?

- no
- once
- twice
- several times

Viewing Your Latest Readings

The latest readings screen displays the time and date when your implanted device was last interrogated and when you last answered the health related questions. The screen also displays the time, date, and measured values of the latest weight and blood pressure readings, if you use these devices.

Selecting the Cancel option at the bottom of the screen returns you to the options menu.

Setting the Time Zone

The Communicator originally receives the date and time when it makes a telephone call to the LATITUDE Patient Management secure database as part of the setup process. After that, the Communicator verifies its date and time setting whenever it makes a call to the database. You only need to set the time zone. The time on the Communicator automatically adjusts for daylight savings time (DST).

The Communicator stores the date, time, and time zone up to seven days if power is interrupted. Therefore, you should only need to reset the time zone if the Communicator is without power for an extended period, for example when moving to a new location or taking the Communicator on an extended vacation.

How to set the time zone

1. From the Options menu screen (page 21), select Set Time Zone.

2. The next screen will show the current time zone setting followed by a question asking if you would like to change this setting. To change the current setting, select Yes and follow the remaining instructions.

Using the Check Communicator Option

The Check Communicator screen provides two choices:

- Install/Set Up
- View Test Log
(This feature is not meant for general use by the patient.)

Install/Set Up

This option starts the same installation and setup instructions that are automatically displayed when you first install and setup the Communicator and optional weight scale and blood pressure monitor. This option provides a means to manually go through the setup process in situations where you may have moved the Communicator or scale and you want to run the setup process again to verify that these devices can still communicate with each other and that they are functioning properly.

View Test Log

The Communicator periodically runs tests to check all internal operations and places results in the test log file. This option is designed as a troubleshooting tool to help identify the source of a problem, should one occur with the Communicator. When talking to

Guidant Patient Services, you may be asked to view the test log screen and report any messages or codes that appear on the 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 requires no action on your part.

The blue Interrogate button is designed to enable a patient to manually interrogate their implanted device, as prescribed by their physician. This feature is normally disabled unless your physician desires the option that you can manually interrogate your device.

When you press the Interrogate button, the Communicator checks to make sure that the interrogation is permitted. If the interrogation is not permitted either because the limit has been reached or because the feature has been disabled, a message is displayed asking whether you want the Communicator to initiate a call to the LATITUDE database to check for a change in the status of this feature. If you respond yes, the Communicator automatically attempts the call. A response of the status of patient initiated interrogations will be displayed on the Communicator screen.

CAUTIONS:

- Use the manual interrogate device (blue) button as instructed by your physician. Excessive use can lead to a decrease in the battery life of your implanted device.

- If you feel poorly or are in need of immediate care, contact your physician.

Traveling with the Communicator

You can use your Communicator away from home if you will be gone for an extended period (within the U.S.). However, 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.

Communicator Use of the Telephone System

The Communicator periodically makes toll-free telephone calls to send data to the LATITUDE Patient Management secure database. These calls usually occur once a week at night and last for **10 to 30** minutes.

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.

The Communicator keeps trying to place the call for *up to a week*. 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.

When the Communicator is using the telephone line, it will detect if another device attempts to use the line. The Communicator will end its call and release the line, allowing the other device to use the 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 over use of the telephone line.

The Communicator can only make outgoing calls, it can not receive any calls. The Communicator functions with either pulse or tone dialing service.

Care and Maintenance

In order to insure 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 Guidant Patient Services at 1-866-GUIDANT (1-866-484-3268).

Cleaning the Communicator

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

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

Returning the Communicator

Do not dispose of the Communicator. Contact Guidant Patient Services to make arrangements for returning the Communicator. Guidant will replace your Communicator if it becomes defective and provide a postage-paid return label for returning your Communicator.

Specifications

Model:	6482
LCD Display:	Monochrome, 240 x 320 pixel
Power Source:	5 VDC 2.6 A, AC adapter, GlobTek model GTM21089-1305-W2 (included)
Dimensions:	Length: 8.00 in (20.3 cm) Width: 7.50 in (19.1 cm) Height: 7.25 in (18.4 cm)
Weight:	2.15 lb. (0.97 kg)
Operating Temperature:	50° F to 104° F (10° C to 40° C)
Storage Temperature:	- 40° F to 158° F (-40° C to 70° C)
Operating and Storage Humidity:	25% to 95% noncondensing
Atmospheric Pressure:	7.3 psi to 15.4 psi
Protection from Electric Shock (IEC 601-1):	Class II, Type BF
Protection Against Ingress of Water:	IXP0 Ordinary equipment
Mode of Operation:	Short time
Safety and Compatibility Standards	UL60601-1/EN60601-1-2. Medical electrical equipment; FCC CFR Title 47, Part 15. Radio frequency devices; FCC CFR Title 47, Part 68. Connection of terminal equipment to the telephone network.

Safety, EMC and FCC Compliance Standards

This equipment has been tested and found to comply with applicable safety portions of UL 60601-1:2003.



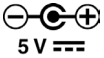




This equipment has been tested and found to comply with the following EMC standards: EN 60601-1-2:2001

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.








Changes or modifications not expressly approved by Guidant 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: ESCM500B6482. If requested, this number must be provided to the telephone company.

Explanation of Product and Label Symbols

Symbol	Meaning
	Input from telephone jack
	Output to telephone (optional)
	AC/DC adapter power input
	Non-ionizing electromagnetic radiation
	See instruction manual
	Class II medical equipment, protection against electrical shock
	Mark for nationally recognized testing for safety standards

Explanation of Shipping Box Symbols

Symbol	Meaning
	This side up
	Fragile, handle with care
	Keep dry
	Do not use hooks
	Temperature limitations
	Humidity limitations
	Atmospheric pressure limitations

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