CAUTION:
Federal (USA) law restricts this device to distribution and use by or on the lawful order of a physician.
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INTRODUCTION

The LATITUDE Consult™ System provides clinicians a convenient and secure way to review data from a Boston Scientific Corporation (BSC) implanted device.

Intended Use

The LATITUDE Consult System is intended to read data from a compatible Boston Scientific implanted device and transfer it to a central server. The LATITUDE Consult System can provide implanted device data that may be used as part of the clinical evaluation of the patient.

This literature is intended for use by health care providers of the LATITUDE Consult Communicator System.

How the System Works

The LATITUDE Consult Communicator is used to read data from a patient's implanted device via a telemetry wand placed over the patient's device. Once the data is read, the clinician uses the Communicator to send the data to the secure LATITUDE Consult server. Depending on the configuration of the LATITUDE Consult System, reports can be automatically sent to the clinician or the clinician can contact Boston Scientific to request a review of the data and/or obtain reports. This data will also be made available and can be viewed within the LATITUDE NXT system by any clinic that has enrolled the patient.

Contraindications

The LATITUDE Consult Communicator is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE Consult System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being read.

Warnings

The Communicator is MR (Magnetic Resonance) Unsafe. The Communicator is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Under no circumstances should the Communicator be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.


LATITUDE Consult is a trademark of Boston Scientific Corporation or its affiliates.

Clinician User Manual - 3
Precautions

In order to ensure a review by Boston Scientific of the patient’s implanted device data, the clinician must call Boston Scientific at 1-800-CARDIAC (227-3422) after sending the data and request a LATITUDE Consult review.

At all times your institution (clinic) is responsible for the clinical and technical interpretation of LATITUDE Consult reports. The institution acknowledges that if a technical consultation on the data is desired, an institution employee may call 1-800-CARDIAC to request a technical review by Boston Scientific. Your local Boston Scientific representative may also be notified to assist with technical support of the device. If your institution requests reports to be sent automatically and does not receive a report within 15 minutes of a LATITUDE Consult transmission to BSC, your institution should call 1-800-CARDIAC to receive LATITUDE Consult System status; it is your institution’s responsibility, and not BSC’s, to ensure that the report is received by your institution.

Adverse Effects

None known.

System Limitations

This system is intended for use by health care providers in a health care facility. As appropriate, clinical care needs to be provided to the patient, separate from the use of the Communicator.

The LATITUDE Consult System can only read data from an implanted device and cannot reprogram, command lead tests, or change any functions of the implanted device. Therefore, LATITUDE Consult Communicator interrogations are not intended to be used in place of in-office follow ups that involve programming of the implanted device (e.g., changing device settings) or commanding lead tests (e.g., pacing threshold test). The implanted device can only be programmed with a Boston Scientific Programming System.

There are many internal and external factors that can hinder, delay, or prevent reading and sending implanted device information. These factors include:

- Health Care environment
  - Delays in contacting clinicians may occur for a variety of reasons including fax and computer equipment that may be down or offline, and the unavailability of health care staff.
  - To read or send implanted device data, the LATITUDE Consult Communicator must be plugged into an electrical outlet.
• The LATITUDE Consult Communicator needs an analog telephone line or an Internet connection to send (transmit) data to the remote, secure server. See “LATITUDE Consult Communicator” on page 6.

• Analog telephone connection. Variations in infrastructure compatibility among telephone service providers as well as variations in the quality of the telephone line from the health care facility to the telephone company equipment and switching stations can affect sending the LATITUDE Consult Communicator implanted device data.

• Internet connection. Work with your System Administrator to ensure the LATITUDE Consult Communicator system is approved for use in your network environment.
  • If the LATITUDE Consult Communicator is using an Internet connection, the Communicator should be located within 100 feet (30 meters) of the LATITUDE Wireless Internet Adapter.
  • If a server call fails, ensure that TCP port 443 is not blocked by your network and is not forwarded through a web proxy. A web proxy exception may be needed for LATITUDE Consult information flowing to www.pocrptr.bostonscientific.com:443. LATITUDE Consult uses the DNS address(es) provided by DHCP. As such, those DNS servers must be able to resolve the name www.pocrptr.bostonscientific.com to 204.155.22.179. See “IT/Security Information” on page 6.

• Equipment. Reading or sending implanted data can be prevented due to:
  • The implanted device cannot establish and complete a telemetry (reading implanted device data) session
  • The Communicator is damaged or malfunctions

• Data processing. Sending implanted device data can be delayed or prevented due to:
  • Temporary, scheduled, and unscheduled downtime of computer servers
  • Variations in server loads and processing times
  • Other data processing issues

NOTES:
• The system does not provide continuous real-time monitoring.
• The LATITUDE Consult Communicator is non-sterile equipment. DO NOT STERILIZE. The wand must be contained in a sterile barrier to be used in the sterile field.
• The Communicator is designed for use only in the United States. Use of the Communicator in other countries is restricted.

IT/Security Information

The LATITUDE Wireless Internet Adapter needs an Ethernet connection that connects to the public Internet. The following information may be helpful for firewall configuration.

If DHCP IP address reservations based on MAC address are required, you can locate the Communicator's MAC address on the About screen. To access the About screen, from the LATITUDE Consult Communicator Home screen, click the Gear icon, then click the About icon to display the Communicator's MAC address.

See "Internet connection" on page 5 for DNS server information.

LATITUDE CONSULT COMMUNICATOR

A key component of the LATITUDE Consult System is the LATITUDE Consult Communicator. The Communicator is able to read data from an implanted Boston Scientific device, and then send that data to the LATITUDE Consult server through an analog telephone line (supports pulse or tone analog dialing modes) or equivalent.

The Communicator is a portable device which can be used provided there is an accessible AC power outlet available. When the Communicator has completed collecting data from the implantable system, it can be unplugged without losing data. If necessary, you can reconnect the system in another location with an AC power outlet, and utilize either: 1) an accessible analog telephone line or 2) an Internet connection using the LATITUDE Wireless Internet Adapter.

The Communicator is designed to communicate with the secure server using an analog connection, for example:

1. An analog telephone line, such as those used by many fax machines. The Communicator may work on other telephone systems, such as Digital Subscriber Line (DSL) and Voice Over IP (VoIP). If those systems provide an analog interface for connecting the Communicator. 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 Consult Communicator.

OR
2. An Internet connection. The LATITUDE Wireless Internet Adapter is available separately for this type of connection. Work with your System Administrator to ensure the LATITUDE Consult Communicator system and equipment is approved for use in your network environment.

Due to the size and portability of the Communicator, it is recommended that it be placed in an area that is secure.

Figure 1 and Table 1 identify the main parts of the Communicator.

![Figure 1. Communicator (front and rear views)](image)

**Table 1. Communicator components**

<table>
<thead>
<tr>
<th>Callout</th>
<th>Description</th>
</tr>
</thead>
</table>
| A | Start Action button (round, blue)  
- Can be pressed to – start reading data from a patient's implanted device, send implanted device data to the server, or illuminate the LCD touch screen when it is dim (black). |
| B | Touch Screen  
- Gently touching the screen surface with a finger operates the touch screen. Respond to on-screen instructions or questions by touching the screen with a fingertip. Do not use tools or sharp objects as they can damage the touch screen. If the Communicator touch screen is dim* (black), simply touch any part of the screen to illuminate the screen.  
* After a period of non-use, the Communicator enters a power-saving mode and the LCD screen dims. |
SETUP

The following items are included with the LATITUDE Consult Communicator:

- Communicator with attached telemetry wand
- Communicator telephone cord
- Power supply
- Clinician User Manual

Table 1. Communicator components (continued)

<table>
<thead>
<tr>
<th>Callout</th>
<th>Description</th>
</tr>
</thead>
</table>
| Indicator Light (oval) | Press to illuminate the LCD touch screen when it is dim (black). The Indicator Light is lit or flashes when there are messages or instructions to follow:  
  - White Light Blinking - Notification that clinician action is required:  
    - Implanted device is out of range: While reading implanted device data, the indicator will blink if communication with the implanted device has been lost. If this occurs, move the wand closer to the implanted device, the flashing should stop, and reading should resume.  
    - Reading of implanted device data is complete and ready to send.  
    - No dial tone or other issue with analog telephone line when attempting to connect to the server.  
  - Waiting for confirmation to erase implanted device data.  
  - Solid White - Implanted device data has been successfully sent. Call Boston Scientific at 1-800-227-3422 to request a LATITUDE Consult review of the implanted device data.  
  - Yellow Light - Notification that an error has occurred that requires clinician attention:  
    - Blinking Yellow - Reading of implanted device data was unsuccessful.  
    - Sending of implanted device data was unsuccessful.  
    - Solid Yellow - Communicator error, call Boston Scientific at 1-800-227-3422. |
| Power Light (round, green) | Indicates the Communicator is connected to power. |
| Wand Cradle | Place the telemetry wand in the cradle when not in use. |
| Telemetry Wand | The telemetry wand is used to read the data from the patient's implanted device. The telemetry wand should remain in the cradle when not in use. |
| Power Input jack | Connection for the Communicator’s power supply. |
| Connection to a telephone or a fax machine (optional) | The Communicator and a telephone/fax machine can share the same telephone wall jack. To do this, connect the telephone or fax machine to this jack on the back of the Communicator. |
| Connection to telephone wall jack (if using analog telephone line) | Connect one end of the telephone cord to this jack and the other end to a telephone wall jack that supports an analog telephone line. |
A 110 VAC outlet is needed to provide power to the Communicator.

If using an analog telephone line, the Communicator can share the same wall jack with a telephone or a fax machine. To continue to use the telephone or fax machine, plug its telephone cord into the jack with the telephone icon located on the back of the Communicator.

**NOTE:** The LATITUDE Wireless Internet Adapter is required to set up an Internet connection. See “Configuring the Communicator using an Internet connection” on page 11. If the Communicator is connected through the Internet, an analog telephone line is not necessary.

---

**Figure 2. Connecting the Communicator**

**Powering up the Communicator**

1. Insert the power supply cord into the jack labeled as shown below.

![Power Supply Connector](image)

2. Plug the power supply into an electrical outlet that is easily accessible.

3. Make sure the green power light on the Communicator is On (see Figure 1 on page 7).
   - If the power light is not On, check that both ends of the power supply are plugged in firmly (steps 1 and 2).
INITIAL CONFIGURATION

The default configuration for the LATITUDE Consult Communicator is the Point of Care (POC) configuration and the 72-hour Episode Collection configuration.

The POC configuration is designed for use in locations such as the Emergency Room (ER) or Operating Room (OR), where an analog telephone line or Internet connection for sending device data to the Boston Scientific server may not be close to the patient. With a POC configuration, after reading patient data, the Consult Communicator can be moved to a different location to transmit that data.

An additional configuration is Heart Failure (HF). HF configuration is designed for use in locations such as a Heart Failure clinic, where the LATITUDE Consult Communicator is always connected to an analog telephone line or Internet connection and patient data is automatically transmitted to the Boston Scientific server. An HF configuration can be requested by contacting Boston Scientific at 1-800-CARDIAC (227-3422).

In addition to the POC and HF configurations, the Communicator can also be configured to collect the most recent stored episodes from the last 72 hours or from the last 6 months. The Episode Collection configuration can be changed by contacting Boston Scientific at 1-800-CARDIAC (227-3422).

Configuring the Communicator using an analog telephone line

NOTE: This needs to be performed only once, unless the Communicator is connected to an analog telephone line with a different PBX\(^2\) prefix or dialing method.

1. From the Home screen, press the gear icon to display the Settings screen.

2. Press the phone icon to display the two phone line choices.

3. Press the Pulse (rotary dial) or Tone (dialing icon to correspond to the dialing service of the analog telephone line that will be used for sending implanted device data.

4. Press OK to confirm and continue.

PBX - private branch exchange; a private telephone network used within an enterprise.
5. If the analog telephone line has a PBX prefix (the number to dial to get an outside line), press the ◀️ or ▶️ icons on the screen to display the desired prefix number. Press OK to confirm the selection.

*NOTE:* If there is no PBX prefix, just press OK when the default selection for No PBX displays.

6. Press the Home icon 🏡 to return to the Home screen. The settings are saved in the Communicator. The Communicator is now configured and ready for use.

**Configuring the Communicator using an Internet connection**

*NOTE:* The LATITUDE Wireless Internet Adapter (WIA) is required to set up an Internet connection.

*NOTE:* The LATITUDE Consult Communicator requires software version 1.20.00 or higher to use the Wireless Internet Adapter.
Figure 3. Connecting the Communicator

1. Confirm that the LATITUDE Consult Communicator is using software version 1.20.00 or higher.
   
   a. From the LATITUDE Consult Communicator Home screen, click the Gear icon, then click the About icon to display the software version.

   b. If not version 1.20.00 or higher, the software must be upgraded to use an Internet connection. See "Software Upgrades" on page 19.

2. Insert the micro end of the USB power cable (included with the Wireless Internet Adapter) into the port on the back labeled "USB."

3. Insert the standard end of the USB power cable into the USB power adapter (included with the Wireless Internet Adapter).

4. Plug the USB power adapter into an electrical outlet.
• The power light on the front of the Wireless Internet Adapter will light solid green.

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

5. Insert the Ethernet cable (included with the Wireless Internet Adapter) into the port on the back of the Wireless Internet Adapter labeled “ETHERNET.”

6. Plug the other end of the Ethernet cable into the Ethernet port of a modem, router, or an Ethernet wall jack.

7. Position the Communicator within 100 Feet (30 meters) of the Wireless Internet Adapter. Avoid physical obstructions between the Communicator and Wireless Internet Adapter whenever possible.

8. To begin pairing, press the button on the back of the Wireless Internet Adapter for at least one second. The indicator on front will flash green indicating pairing mode is active.

9. From the Home screen of the Communicator, press the gear icon to display the Settings screen.

10. Press the upgrade icon on the Communicator to pair with the wireless Internet adapter.

11. If pairing is successful, the Communicator screen will display “Software is up-to-date.” Then the Wireless Internet Adapter and LATITUDE Consult Communicator are successfully paired.

12. Press the Done icon to confirm and continue.

13. Press the Home icon to return to the Home screen. The settings are saved in the Communicator. The Internet connection is now configured and ready for use.

---

3. WIA pairing mode will end automatically after 60 minutes or manually by pressing the button on the back of the Wireless Internet Adapter for 5 seconds.
READING DATA FROM THE PATIENT’S IMPLANTED DEVICE

**NOTE:** Should it be necessary to stop reading the patient’s implanted device for any reason, simply move the wand away from the device. Then cancel the operation on the Communicator screen.

1. Ensure the Communicator is powered On. See “Powering up the Communicator” on page 9 for details.
2. Have the patient sit or lie down in a comfortable position where the wand can reach and the Communicator screen can be viewed.
3. Place the telemetry wand over the patient’s implanted device and keep it in place until the reading is complete.
4. Press the patient icon on the Home screen to begin reading data from the patient’s implanted device.
   **NOTE:** If the wand moves away from the implanted device during the reading process, the Communicator displays a message to reposition the wand. Once communication is restored, reading of the implanted device data automatically continues.
5. When the Communicator finishes reading the implanted device data, depending on the configuration, it will either automatically begin sending the data or will display the Continue button, which will allow you to manually send the data.

<table>
<thead>
<tr>
<th>Automatically Sending</th>
<th>Continue</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Sending data icon" /></td>
<td><img src="image" alt="Continue icon" /></td>
</tr>
</tbody>
</table>

- If the Continue button displays, the Communicator may be powered off, moved to another location, connected to an analog telephone line or Internet connection, and powered back On in order to send the patient data.
6. Place the wand back in the cradle and see the next section for Sending data.
NOTES:

- If the reading of the implanted device data is unsuccessful and a retry is not successful, call Boston Scientific at 1-800-CARDIAC (227-3422).
- The Communicator can be unplugged and moved without loss of data.
- A patient’s implanted device data remains on the Communicator until it is sent or erased. It must be either sent or erased before another patient’s implanted device data can be read.
- To erase the implanted device data from the Communicator, press the Erase Data icon \( \text{ icon}\) from the Home screen. Once it is erased, this data will not be recoverable from the Communicator.

SENDING (TRANSMITTING) THE PATIENT’S IMPLANTED DEVICE DATA

NOTE: This section does not apply to Communicators with the HF configuration as the data is automatically sent once it has been read from the patient’s implanted device.

1. Ensure the Communicator is powered On. See Figure 2 on page 9.
2. If using an analog telephone line:
   - Plug one end of the Communicator telephone cord into the jack labeled \( \text{ jack}\) on the back of the Communicator.
   - Plug the other end of the Communicator telephone cord into the analog wall jack such as those used by many fax machines.
3. If using an Internet connection:
   - Ensure the Communicator is within 100 feet (30 meters) of the LATITUDE Wireless Internet Adapter.
4. If the Communicator was unplugged after reading the implanted device data, it can be moved to a different location, connected to an analog phone line or Internet connection, and then powered back On. Then, press the send icon \( \text{ icon}\) on the Home screen to begin sending the data and continue with step 6.
5. If the data has been read from the patient’s implanted device and the Continue button \( \text{Continue}\) is displayed, press the Continue button to begin sending.
NOTE: During the sending process, do not disconnect the power cord, or disrupt the connection (analog telephone connection or Internet connection) until the data has been sent. If the Communicator is disconnected, simply reconnect it and retry sending the data. Implanted device data will not be lost.

6. When the implanted device data has been sent, press the Done icon

NOTES:

• If the sending of the implanted device data is unsuccessful and a retry is not successful, call Boston Scientific at 1-800-CARDIAC (227-3422).
• As soon as the patient’s implanted device data has been successfully sent, that data is erased from the Communicator.
• If using an analog telephone line, the Communicator can share the same wall jack with a telephone or a fax machine. See “Setup” on page 8. The Communicator is designed to relinquish the line when a connected fax/telephone is used. If the Communicator does not relinquish the line (e.g. restore dial tone), unplug the Communicator from electrical power. The Communicator can be plugged back in after the line has been used.
• Occasionally, a software upgrade might be available for the Communicator, in which case the touch screen will display that a software upgrade is in progress. Do not disconnect the power cord, or disrupt the connection (analog telephone line connection or Internet connection) until the upgrade is complete. If the Communicator is disconnected, simply reconnect it and retry the upgrade.

REVIEWING TRANSMITTED DEVICE DATA

Upon successful transmission of the implanted device data to the LATITUDE Consult server, data can be reviewed by:

• Calling Boston Scientific at 1-800-CARDIAC (227-3422) and requesting a LATITUDE Consult review of the implanted data and optionally request reports be sent to an email address or fax number.
• Automatically sending reports to the configured set of email addresses and/or fax numbers of a clinician and/or BSC Representative for review of the implanted device data.

NOTE: To configure automatic sending of reports, call Boston Scientific at 1-800-CARDIAC (227-3422).
The following is a list of the available optional reports:

- Transmission Report
- Quick Notes Report
- Combined Follow-up Report
- Presenting EGM Report
- Heart Failure Management Report
- Arrhythmia Logbook Report
- Event Detail / Episodes Report
- Device Settings Report

The implanted device data in each report is current as of the time the device was read, which can include up to 12 months of device/lead trend data and the most recent 72 hours or 6 months of stored episodes, depending on the Episode Collection configuration. See "Initial Configuration" on page 10.

The LATITUDE Consult System collects data that are protected health information. Designated Boston Scientific personnel have access to this data. In certain circumstances, Boston Scientific may contact clinician(s) regarding data received and/or Communicator status.

CARE AND MAINTENANCE

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

Prior to each use, perform a visual inspection and verify the following:

- Mechanical and functional integrity of the Communicator, cables, and power supply.
- Legibility and adherence of the Communicator labels.
- Appearance of Home screen after power is supplied to the Communicator. (The normal power-up process verifies that the Communicator has passed its internal checks and is ready for use.)

4. Adobe Acrobat Reader® program or compatible PDF viewer is required to view reports that are created in Portable Document Format (PDF).

5. Heart Failure Management Report is available for all configurations. For the HF configuration, the HF Management report is faxed, or if email is used, then the email provides a link directly to the HF report (and another link to all reports).
CAUTIONS:

• Do not drop or mishandle the Communicator in a manner that would cause damage.

• Avoid getting liquid on the Communicator other than cleaning it as recommended. Do not use abrasive cloth or solvents to clean the Communicator.

• Do not submerge the Communicator in liquid.

• Do not attempt to open the Communicator. The Communicator contains no user-accessible fuses or batteries.

• Use the Communicator as described in this clinician manual. Use only authorized parts and accessories. Do not attempt to modify or alter the Communicator or its accessories. If the Communicator becomes damaged or malfunctions, contact Boston Scientific at 1-800-CARDIAC (227-3422).

• The Communicator is not waterproof or explosion-proof and cannot be sterilized. Do not use it in the presence of flammable gas mixtures including anesthetic mixture with air, oxygen, or nitrous oxide.

Cleaning the Communicator

When necessary, clean the Communicator housing and touch screen with a soft, clean, lint-free cloth moistened in water, isopropyl alcohol, 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 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.

• Avoid using any cleaning fluid near the electrical or phone jacks on the back of the Communicator.

Returning, Replacing, or Disposing of the Communicator

Do not dispose of the Communicator in the trash. If return or replacement is necessary, contact Boston Scientific at 1-800-CARDIAC (227-3422) for return and replacement instructions. The Communicator may contain encrypted personal health information.
Software Version, Upgrades, and Setup/Connection Testing

Software Version

From the Home screen, select the Gear icon , then the About icon to display the current software version.

NOTE: In order to use an Internet connection, the Communicator must have software version 1.20.00 or higher installed. If the Communicator does not have software version 1.20.00 or higher, then it must be upgraded over an analog telephone line connection first. (See “Configuring the Communicator using an Internet connection” on page 11.)

Software Upgrades

If a software upgrade is available, it will be automatically installed on the Communicator immediately after sending implanted device data.

• If there is implanted device data on the Communicator from a previously un-sent transmission, the data will be sent automatically before the upgrade is installed.

• If this data is not to be sent, it must be erased before checking for upgrades by pressing the Erase data icon  from the Home screen and following the prompts.

Setup/Connection Testing

To manually check for software upgrades, test the setup and connection, or pair with the Wireless Internet Adapter (see “Configuring the Communicator using an Internet connection” on page 11), perform the following:

1. Ensure that the Communicator is powered On. See Figure 2 on page 9.

2. If using an analog telephone line

   • Plug one end of the Communicator telephone cord into the jack labeled  on the back of the Communicator.

   • Plug the other end of the Communicator telephone cord into the analog wall jack such as those used by many fax machines.

3. If using an Internet connection

   • Ensure the Communicator is within 100 feet (30 meters) of the LATITUDE Wireless Internet Adapter.
4. From the Home screen, press the gear icon 🛠️ to display the Settings screen.

5. Press the upgrade icon 🔄 to connect to the server and follow the prompts.

6. When the upgrade is complete, press the Done icon ✓.

**NOTE:** Do not disconnect the power cord, or disrupt the connection (analog telephone connection or Internet connection) until the upgrade is complete. If the Communicator is disconnected, simply reconnect it and retry the upgrade.
# APPENDIX A: COMMUNICATOR TECHNICAL SPECIFICATIONS

## Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>6299</td>
</tr>
<tr>
<td>LCD Display</td>
<td>Monochrome, 240 x 320 pixel, with touch screen control</td>
</tr>
<tr>
<td>Dimensions</td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>20.6 cm (8.1 in.)</td>
</tr>
<tr>
<td>Width</td>
<td>18.0 cm (7 in.)</td>
</tr>
<tr>
<td>Height</td>
<td>10.4 cm (4 in.)</td>
</tr>
<tr>
<td>Weight</td>
<td>0.78 kg (1.7 lb.)</td>
</tr>
<tr>
<td>Power Source</td>
<td>100-240 VAC, 47-63 Hz</td>
</tr>
<tr>
<td>Power Supply</td>
<td>15.0 VDC, 1.2 A, 18.0 W, AC adapter, Globtek model GTM41061-1818-3.0 (included)</td>
</tr>
<tr>
<td>Supply Mains Isolation</td>
<td>AC adapter plug</td>
</tr>
<tr>
<td>Protection against electrical shock</td>
<td>Class II</td>
</tr>
<tr>
<td>Minimum Operational Loop Current</td>
<td>20 mA</td>
</tr>
<tr>
<td>Expected Service Life</td>
<td>15 years</td>
</tr>
<tr>
<td>Duty Cycle</td>
<td>Continuous</td>
</tr>
<tr>
<td>Safety Classification of Ports</td>
<td>RJ11 ports: TNV-3 circuit</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>50° F to 95° F (10° C to 35° C)</td>
</tr>
<tr>
<td>Wand Temperature</td>
<td>34° F [1° C] (typical) to 48° F [9° C] (maximum) above operating temperature</td>
</tr>
<tr>
<td>Storage and Transport Temperature</td>
<td>-22° F to 158° F [-30° C to 70° C]</td>
</tr>
<tr>
<td>Operating Humidity</td>
<td>25% to 75%</td>
</tr>
<tr>
<td>Storage and Transport Humidity</td>
<td>25% to 95%</td>
</tr>
<tr>
<td>Storage and Transport Pressure</td>
<td>90 to 105 kPa</td>
</tr>
<tr>
<td>Altitude Rating</td>
<td>≤ 2,000 m</td>
</tr>
<tr>
<td>Protection Against Ingress of Water</td>
<td>IP00 Ordinary equipment</td>
</tr>
</tbody>
</table>
Radio Frequency Transmitters:

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4 gHz Radio</td>
<td></td>
</tr>
<tr>
<td>Operational Frequency</td>
<td>2402.0 to 2480.0 MHz</td>
</tr>
<tr>
<td>Modulation Type</td>
<td>Adaptive Frequency Hopping</td>
</tr>
<tr>
<td>Effective Radiated Power</td>
<td>13.82 dBm (24 mW)</td>
</tr>
<tr>
<td>Implant Device (PS) Radio</td>
<td></td>
</tr>
<tr>
<td>Receive Bandwidth</td>
<td>10 kHz to 110 kHz</td>
</tr>
<tr>
<td>Receive Frequencies</td>
<td>2.8 kHz, 56.9 kHz, 102.4 kHz</td>
</tr>
<tr>
<td>Transmit Frequency</td>
<td>57.0 kHz +/- 11.4 kHz</td>
</tr>
<tr>
<td>Modulation Transmit Type</td>
<td>OOK (On-Off keying)</td>
</tr>
<tr>
<td>Effective Radiated Power</td>
<td>≤ 5.32 μW (@ 300 m)</td>
</tr>
</tbody>
</table>

Phone Line: Analog line with Pulse or Tone dialing

Table 1. LATITUDE Consult™ Communicator Specifications (continued)

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, the complete Corresponding Source code may be obtained from us for a period of three years after our shipment of this product. The software is based in part of the work of the FreeType Team.
APPENDIX B: COMMUNICATOR STANDARDS INFORMATION

This appendix provides LATITUDE Consult™ Communicator (Model 6299) instructions for use information that is required by applicable standards and regulations.

Safety and Standards Compliance

- Changes or modifications not expressly approved by Boston Scientific could void the user’s authority to operate this equipment.

- The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the Communicator. Using accessories and cables supplied with the Communicator in other medical equipment and systems may result in increased emissions or decreased immunity of the other medical equipment or systems.

- Do not insert anything other than a telephone connector into the telephone jacks on the back of the Communicator. There can be voltage on the electrical contacts in the connector, and there is potential to receive a shock.

  CAUTION: Once the Communicator is connected to an active telephone wall jack, the second telephone jack on the back of the Communicator becomes a live jack. Avoid contact inside this telephone jack if it is not being used.

- Accessory equipment connected to the Communicator must be certified according to the respective standards. Anyone connecting such accessories to the Communicator may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.

- A plug and jack used to connect this equipment to the premises wiring and telephone network must comply with the applicable FCC Part 68 rules and requirements adopted by the ACTA. A compliant telephone cord and modular plug is provided with this product. It is designed to be connected to a compatible modular jack that is also compliant. See installation instructions for details.

- 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.

- The telephone company may make changes in its facilities, equipment, operations or procedures that could affect the operation of the
If equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.

- If the facility has specially wired alarm equipment connected to the telephone line, ensure the installation of the Communicator does not disable the alarm equipment. If there are questions about what will disable alarm equipment, consult the telephone company or a qualified installer.

- Do not use the Communicator adjacent to or stacked with other equipment. If it is necessary to use the Communicator adjacent to or stacked with other equipment, please contact Boston Scientific at 1-800-227-3422 to verify normal operation.

- This device complies with Title 47, Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

- This equipment complies with Part 68 of the FCC rules and the requirements adopted by the ACTA. On the bottom of this equipment is a label that contains, among other information, a product identifier in the format US:AAAEQ##TXXXX. 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 be connected to a telephone line. Excessive RENs on a telephone line may result in the devices not ringing in response to an incoming call. In most but not all areas, the sum of RENs should not exceed five (5.0). To be certain of the number of devices that may be connected to a line, as determined by the total
RENs, contact the local telephone company. The REN for this product is 0.0.

- This equipment has been tested and found to comply with applicable safety portions of the AAMI ES 60601-1:2005, CAN/CSA-C22.2 NO. 60601-1:08 and IEC 60601-1:2005 standards.
- This equipment has been tested and found to comply with the following EMC standards: IEC 60601-1-2:2007.
- The LATITUDE Consult Communicator does not provide any performance which is essential to maintain freedom from unacceptable risk as defined by IEC 60601-1:2005.
- The LATITUDE Consult Communicator has the ability to:
  - Communicate with a Boston Scientific implanted device
  - Communicate implanted device data to the LATITUDE Consult System
  - Receive configuration updates from the LATITUDE Consult System

Electromagnetic Emissions and Immunity

Table 1. Guidance and manufacturer’s declaration—electromagnetic emissions

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The Model 6299 LATITUDE Consult Communicator is intended for use in the electromagnetic environment specified below. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>The Model 6299 LATITUDE Consult Communicator is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Model 6299 LATITUDE Consult™ Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 6299 LATITUDE Consult Communicator should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±5 kV contact ±8 kV air</td>
<td>±5 kV contact ±15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%</td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions, and voltage variations on power supply input lines</td>
<td>&lt;5% $U_T$ (&gt;95% dip in $U_T$) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$) for 5 cycles 70% $U_T$ (30% dip in $U_T$) for 25 cycles &lt;5% $U_T$ (&lt;95% dip in $U_T$) for 5 sec</td>
<td>&lt;5% $U_T$ (&gt;95% dip in $U_T$) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$) for 5 cycles 70% $U_T$ (30% dip in $U_T$) for 25 cycles &lt;5% $U_T$ (&lt;95% dip in $U_T$) for 5 sec</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the LATITUDE Consult Communicator requires continued operation during power mains interruptions, it is recommended that the LATITUDE Consult Communicator be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.
Table 3. Guidance and manufacturer’s declaration—electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 61000-4 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6 3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms 10 Vrms in ISM and amateur radio bands&lt;sup&gt;c&lt;/sup&gt; between 150 kHz and 80 MHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the LATITUDE Consult Communicator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances: d = 1.7 √P</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3 3 V/m 80 MHz to 2.5 GHz</td>
<td>10 V/m (80 MHz to 1000 MHz) d = 0.5 √P (80 MHz to 1000 MHz)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>17 V/m (380 MHz to 390 MHz) d = 0.29 √P (380 MHz to 390 MHz)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>14 V/m (430 MHz to 470 MHz) d = 0.36 √P (430 MHz to 470 MHz)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>24 V/m (600 MHz to 960 MHz) d = 0.21 √P (600 MHz to 960 MHz)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 V/m (1 GHz to 2.7 GHz) d = 1.7 √P (1 GHz to 2.7 GHz)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>24 V/m (1.7 GHz to 1.99 GHz) d = 0.21 √P (1.7 GHz to 1.99 GHz)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>24 V/m (2.4 GHz to 2.57 GHz) d = 0.21 √P (2.4 GHz to 2.57 GHz)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>8 V/m (5.1 GHz to 5.8 GHz) d = 0.63 √P (5.1 GHz to 5.8 GHz)</td>
<td></td>
</tr>
</tbody>
</table>
where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).

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

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

NOTE 1: At 80MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3: The recommended separation distance is calculated using the formula $d = \left( \frac{5}{E_{10}} \right)^{1/2} P$.

### Table 3. Guidance and manufacturer’s declaration—electromagnetic immunity (continued)

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.</td>
</tr>
</tbody>
</table>

NOTE 1: At 80MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3: The recommended separation distance is calculated using the formula $d = \left( \frac{5}{E_{10}} \right)^{1/2} P$.  

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a. 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 6299 LATITUDE Consult Communicator is used exceeds the applicable RF compliance level above, the Model 6299 LATITUDE Consult 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 6299 LATITUDE Consult Communicator.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c. The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 50.5 MHz.

### Table 3. Guidance and manufacturer’s declaration—electromagnetic immunity (continued)

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment—guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The Model 6299 LATITUDE Consult™ Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 6299 LATITUDE Consult Communicator should assure that it is used in such an environment.
Table 4. Recommended separation distances between portable and mobile RF communications equipment and the LATITUDE Consult™ Communicator

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (meters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>d = 1.7√P</td>
</tr>
<tr>
<td>80 MHz to 1000 MHz</td>
<td>d = 0.5√P</td>
</tr>
<tr>
<td>380 MHz to 300 MHz</td>
<td>d = 0.29√P</td>
</tr>
<tr>
<td>430 MHz to 470 MHz</td>
<td>d = 0.36√P</td>
</tr>
<tr>
<td>800 - 960 MHz</td>
<td>1.7 - 1.99 GHz</td>
</tr>
<tr>
<td>2.4 - 2.57 GHz</td>
<td>2.1 - 2.17 GHz</td>
</tr>
<tr>
<td>5.1 GHz to 5.8 GHz</td>
<td>d = 0.63√P</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \(d\) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where \(P\) is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3: The recommended separation distance is calculated using the formula \(d = \frac{5}{E_1 \sqrt{P}}\).
APPENDIX C: SYMBOLS ON PACKAGING, DEVICE, AND ACCESSORIES

This appendix provides explanations of the symbols used on the LATITUDE Consult™ Communicator, its packaging, and its accessories.

Table 1. Symbols on Packaging, Device, and Accessories

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td><img src="image2" alt="Symbol" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>Follow instructions for use</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>MR Unsafe</td>
</tr>
<tr>
<td><img src="image6" alt="Symbol" /></td>
<td>Non-ionizing radiation</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>TÜV (Technischer Überwachungs-Verein) mark</td>
</tr>
<tr>
<td><img src="image8" alt="Symbol" /></td>
<td>Type B applied part (telemetry wand)</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>WEEE symbol (waste of electrical and electronic equipment) Do not throw in the trash</td>
</tr>
<tr>
<td><img src="image10" alt="Symbol" /></td>
<td>Analog line connection jack on Communicator</td>
</tr>
</tbody>
</table>
Table 1. Symbols on Packaging, Device, and Accessories (continued)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>📞</td>
<td>Telephone/fax connection jack on Communicator</td>
</tr>
<tr>
<td>⚡️</td>
<td>Power input jack on Communicator</td>
</tr>
<tr>
<td>🌋</td>
<td>Direct Current symbol on Communicator</td>
</tr>
</tbody>
</table>

Symbols on power supply:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>📚</td>
<td>Refer to Instructions</td>
</tr>
<tr>
<td>🇨🇳</td>
<td>Standard of the electronics industry of the People’s Republic of China</td>
</tr>
<tr>
<td>🏡</td>
<td>Indoor use only</td>
</tr>
<tr>
<td>🕺</td>
<td>EISA Energy Star tier 2</td>
</tr>
<tr>
<td>🇪🇺</td>
<td>Intertek S mark (Europe)</td>
</tr>
<tr>
<td>🇺🇸</td>
<td>Intertek ETL (North America)</td>
</tr>
<tr>
<td>🇨🇳</td>
<td>China Quality Certification (CQC) and Japan Product Safety Electric Appliance and Materials mark (PSE)</td>
</tr>
<tr>
<td>🗑️</td>
<td>Do not dispose of in trash</td>
</tr>
</tbody>
</table>

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Table 1. Symbols on Packaging, Device, and Accessories (continued)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol]</td>
<td>Keep dry</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Class II electrical device</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>CE mark of conformity</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Voluntary Control Council for Interference by Information Technology Equipment (Japan)</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>DC power jack</td>
</tr>
</tbody>
</table>

Symbols on shipping carton:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol]</td>
<td>Temperature symbol on outer shipping carton</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Humidity symbol on outer shipping carton</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Pressure symbol on outer shipping carton</td>
</tr>
</tbody>
</table>