Boston Scientific

SUMMARY

Boston Scientific's LATITUDE® NXT Patient Management System enables a clinician to periodically monitor patient and device information remotely via a LATITUDE NXT Wave™ Communicator in the patient's home. The clinician can review this information on the LATITUDE NXT website to supplement in-clinic visits.

This article describes how to properly configure the Communicator to match the patient's phone dialing protocol and country location. It also describes the proper configuration for use with other connection methods.

Products Referenced

LATITUDE NXT Patient Management System
LATITUDE NXT Wave Communicator
Models 6498, 6280, 6288, 6290

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Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

For comprehensive information on device operation, reference the full instructions for use found at: **www.bostonscientific-elabeling.com**.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator

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How to Set Configuration Switches for LATITUDE® NXT Wave™ Communicators

A LATITUDE NXT Wave™ Communicator is an in-home monitor that uses wireless technology to transfer data from a patient's implanted device to a secure internet website*. Data travels to the website through one of three connection methods: cellular, internet or standard telephone line.

Configuring LATITUDE NXT Wave Communicators

If applicable (i.e., connecting over a phone line) Wave™ Wireless Communicators (Models 6498, 6280, 6288, and 6290) must be configured to match the dialing protocol of the patient's phone line and country location. The Communicator may be configured to meet local conditions by adjusting eight (8) small slide switches located on the bottom of the Communicator (Figure 1).
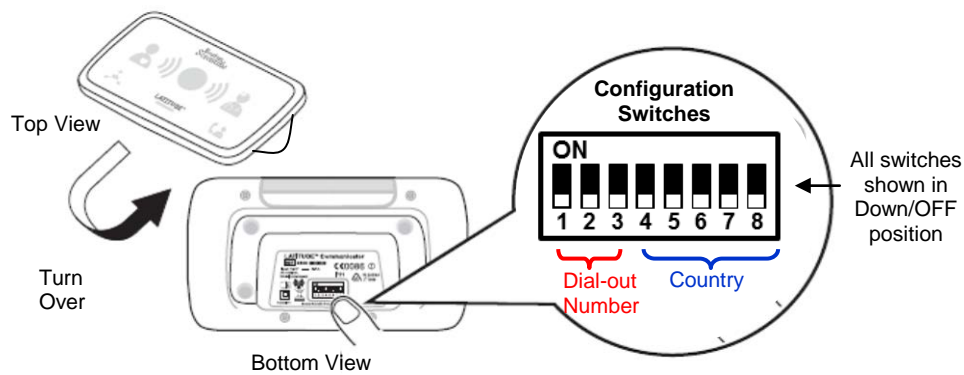
Figure 1. Configuration switches on bottom of NXT Wave Communicator.

Switches 1 through 3 (Figure 1) are used to configure the dial-out number. Switches 4 through 8 (Figure 1) are used to configure the country location. These small switches can be toggled manually by sliding the switch to an ON (Up) position or OFF (Down) position. **Tip!:** A pen can be used to slide the switches up or down.

LATITUDE NXT Wave Communicator switches are preset to match the dial-out number and the country most often used for that particular geography.

- The preset switch positions may match the dial-out number and country for the patient's home location. If this is the case, the Communicator can be used immediately without altering the position of the configuration switches.

- If extra dialing is required to obtain an outside phone line, or if the preset country switch positions do not match the patient's home country, the Communicator switches may be adjusted using the procedure described below.

Please Note: Boston Scientific Wave™ Communicators are supported by the LATITUDE® NXT system. Not all models are approved and/or market-released in all geographies.

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*The LATITUDE NXT system is not intended to assist with medical emergencies. Patients who are not feeling well should call their physician or emergency services number as they deem necessary.

Setting the Switch Configuration

Switches 1 through 3 are used to configure the dial-out number. These switches are only used when the connection is made via a landline or a digital phone line (i.e., cellular or internet). Switches 4 through 8 are used to configure the country location. These switches are used for all connection types. For countries with no landline connections available (i.e., Saudi Arabia), all 8 switches must be set correctly. This is discussed in the section on exceptions.

STEP 1. Set switches 1-3 (dial-out number) if connecting over a telephone line (analog or digital).

Using a Phone Line
For some landlines, a special "dial-out" number may be needed in order to obtain a dial tone to call out. For example, many businesses (hotels, medical/managed care facilities, etc.), require a "prefix" to route your call to an outside line. If this is the case, switches 1 through 3 on the bottom of the Communicator must be set to match the dial-out number. For example, if your building dial-out number is "9", you must set the first three switches as follows: Switch 1 = ON (Up). Switch 2 = OFF (Down), Switch 3 = ON (Up). Switch settings for various dial-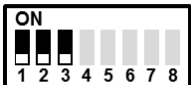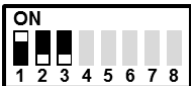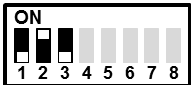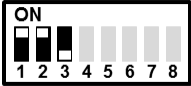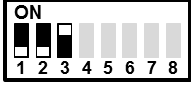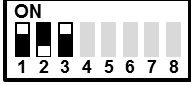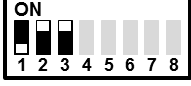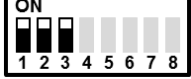out options are shown in **Table 1**. **Please note, most homes require no special dial-out number. In this case, switches 1 through 3 should remain in the OFF (Down) position.**

Using Cellular or Internet Connection Methods
Connections over a cellular data network or an internet adapter do not require a dial-out number. **Switches 1 through 3 should remain in the OFF (Down) position.**

Table 1. Position of Switches 1 through 3 to Accommodate Dial-out Numbers
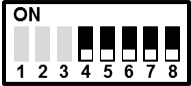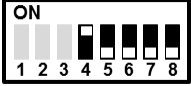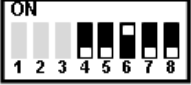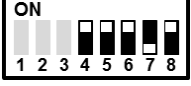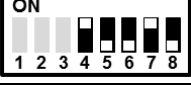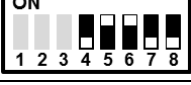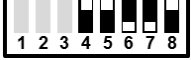
Dial-Out Number	Switch 1	Switch 2	Switch 3	Summary
None	Down/OFF	Down/OFF	Down/OFF	
0	Up/ON	Down/OFF	Down/OFF	
1	Down/OFF	Up/ON	Down/OFF	
7	Up/ON	Up/ON	Down/OFF	
8	Down/OFF	Down/OFF	Up/ON	
9	Up/ON	Down/OFF	Up/ON	
*99	Down/OFF	Up/ON	Up/ON	
Pulse Dialing (Japan Only)	Up/ON	Up/ON	Up/ON	

STEP 2. Set the country location (switches 4 through 8) for all connection methods.

Switches 4 through 8 on the bottom of the Communicator must be set to your home country (Table 2).
If you will be traveling with your Communicator, please refer to the section below.

Table 2. Position of Switches 4 through 8 for Use in Different Countries

Country	Switch 4	Switch 5	Switch 6	Switch 7	Switch 8	Summary
USA	Down/OFF	Down/OFF	Down/OFF	Down/OFF	Down/OFF	
Australia	Up/ON	Down/OFF	Down/OFF	Down/OFF	Down/OFF	
Austria	Down/OFF	Down/OFF	Up/ON	Down/OFF	Down/OFF	
Belgium	Up/ON	Up/ON	Up/ON	Down/OFF	Up/ON	
Canada	Up/ON	Up/ON	Down/OFF	Down/OFF	Down/OFF	
Czech Republic	Up/ON	Down/OFF	Down/OFF	Up/ON	Down/OFF	
Denmark	Down/OFF	Up/ON	Up/ON	Down/OFF	Down/OFF	
Finland	Up/ON	Up/ON	Up/ON	Down/OFF	Down/OFF	
France	Down/OFF	Down/OFF	Down/OFF	Up/ON	Down/OFF	
Germany	Up/ON	Up/ON	Up/ON	Up/ON	Up/ON	
Greece	Up/ON	Up/ON	Down/OFF	Up/ON	Down/OFF	
Hong Kong	Down/OFF	Up/ON	Down/OFF	Down/OFF	Up/ON	
Hungary	Up/ON	Down/OFF	Down/OFF	Up/ON	Up/ON	
Ireland	Down/OFF	Down/OFF	Down/OFF	Up/ON	Up/ON	
Israel	Up/ON	Down/OFF	Up/ON	Up/ON	Down/OFF	
Italy	Up/ON	Up/ON	Down/OFF	Up/ON	Up/ON	
Japan	Up/ON	Up/ON	Down/OFF	Down/OFF	Up/ON	

Country	Switch 4	Switch 5	Switch 6	Switch 7	Switch 8	Summary
Mexico	Up/ON	Down/OFF	Up/ON	Down/OFF	Up/ON	
Netherlands	Down/OFF	Down/OFF	Up/ON	Up/ON	Down/OFF	
New Zealand	Down/OFF	Up/ON	Down/OFF	Down/OFF	Down/OFF	
Norway	Down/OFF	Up/ON	Up/ON	Up/ON	Up/ON	
Poland	Down/OFF	Up/ON	Down/OFF	Up/ON	Down/OFF	
Portugal	Down/OFF	Up/ON	Up/ON	Up/ON	Down/OFF	
Slovakia	Up/ON	Down/OFF	Up/ON	Down/OFF	Down/OFF	
Spain	Up/ON	Up/ON	Up/ON	Up/ON	Down/OFF	
Sweden	Down/OFF	Down/OFF	Down/OFF	Down/OFF	Up/ON	
Switzerland	Up/ON	Down/OFF	Down/OFF	Down/OFF	Up/ON	
United Kingdom	Down/OFF	Down/OFF	Up/ON	Up/ON	Up/ON	

Exception: Geographies with No Phone Line Support (currently Saudi Arabia)
For some geographies, connections over a phone line (landline) are not supported. In this scenario, all eight switches must be set correctly for connections over an internet connection to be successful. Switches 1 through 8 must be set to the home country (Table 3). If you will be traveling with your Communicator, please refer to the Section "Traveling with the Communicator."

Switch Settings for Countries with no landline option
Table 3 indicates correct switch settings for using the Communicator in your home. If you will be traveling with your Communicator, please refer to the section "Traveling with the Communicator".

Table 3. Position of Switches 1 through 8 for Exception Countries

Country	Switch 1-2	Switch 3	Switch 4	Switch 5	Switch 6-8	Summary
Saudi Arabia	Up/On	Up/On	Up/On	Down/OFF	Up/On	

Traveling with the Communicator

Depending on the Communicator model number and method of connection, the LATITUDE Communicator may or may not be able to be used in other countries.

- **Model 6280**, **6288**, and **6498** Communicators use either the ISM (US, Australia and Canada) or the SRD (Europe and Saudi Arabia) frequency band to communicate with the pulse generator. Use of these Communicators outside of the patient's home country may be restricted by local regulations.
- **Model 6290** Communicators use the MICS frequency band to communicate with the pulse generator. This allows traveling patients to use the Model 6290 in any region that permits the MICS band (including US, Europe, Japan, Australia and Canada).
  - **Exception:** US patients with an S-ICD supported on LATITUDE may be restricted from using their Communicator in other countries due to radio-frequency (RF) laws.
- **If using a landline connection while traveling** outside of the country where the Communicator was initially set up, switches should be set to match the dialing code and the country location of the travel country (Table 2). **Due to changes made to the phone line access number in some countries, additional traveling restrictions may apply.**
- **If using a cellular or internet connection while traveling** outside of the country where the Communicator was initially set up, switches should remain set for the home country (Table 2 or 3).

Please contact Boston Scientific LATITUDE Patient Services or Customer Support for additional information.

LATITUDE® NXT Patient Management System from Boston Scientific CRM

Intended Use
The LATITUDE™ NXT Patient Management System is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database. The LATITUDE NXT System provides patient data that can be used as part of the clinical evaluation of the patient.

Contraindications
The LATITUDE NXT Patient Management System 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 NXT System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.

Precautions
Alerts may appear on the LATITUDE NXT website on a daily basis. Primary notification of alert conditions is through the View Patient List page on the LATITUDE NXT website. The clinician needs to log onto the LATITUDE NXT website in order to receive alerts. Although secondary notification through email and SMS text messages is available, these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the website. Implanted device data and alerts are typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to two weeks may elapse before the LATITUDE NXT server detects these conditions and informs the clinic user that monitoring is not occurring. If both of these conditions occur at the same time, this notification could take up to 28 days. Implanted device data and alert notification may be delayed or not occur at all under various conditions, which include but are not limited to the following: System limitations; the Communicator is unplugged; the Communicator is not able to connect to the LATITUDE NXT server through the configured phone system; the implanted device and the Communicator cannot establish and complete a telemetry session; the Communicator is damaged or malfunctions; the patient is not compliant with prescribed use or is not using the LATITUDE NXT System as described in the patient manual; if subscribed to the LATITUDE Cellular Data Plan, missing two or more payments discontinues the subscription; the clinic user can identify any patients that are not being monitored as described above by using the Not Monitored filter on the View Patient List.

Adverse Effects:
None known.

System Limitations:
The LATITUDE NXT System does not provide continuous real-time monitoring. As a remote monitoring system, the LATITUDE NXT System provides periodic patient monitoring based on clinician configured settings. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of implanted device, sensor, and patient information as intended by the clinician. These factors include: implanted device clock; patient environment; cellular data service; telephone system; communicator memory capacity; clinic environment; schedule/configuration changes; or data processing.

Refer to the product labeling for specific instructions for use. Rx only. (Rev. C)

LATITUDE™ (NXT) Patient Management System

Important Safety Information
LATITUDE™ NXT Patient Management is a remote monitoring system that gives your health care provider access to your implanted device data. The LATITUDE Patient Management system is not intended to assist with medical emergencies. If you are not feeling well, call your physician or 911. The Communicator does not provide continuous monitoring.

The Communicator is designed to operate on standard 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 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 not for use with any pulse generator other than a Boston Scientific device. Ask your physician if you have questions about any risks with using the Communicator or your implanted device.

It is very important that the Communicator remain plugged into the power outlet. Your communicator should remain connected to a telephone line, ethernet adaptor or cellular adaptor. Some household appliances and other sources of electromagnetic energy could interfere with the communication between your Communicator and your implanted device. You should be at least 36 inches (3 ft.) away from televisions, VCRs, DVD players, personal computers, and other electronic equipment, when you are using the Communicator.

It is recommended that the customer install a surge arrestor in the electrical outlet to which the Communicator is connected.

Rx only (Rev.D)