Inspire®

SleepSync™ Programming System Manual for Clinicians

For use with:

- # 2740S SleepSync Programmer Application
- # 2740C Inspire Programmer Cable

Rx ONLY

Inspire, the cloud design and Inspire SleepSync are trademarks of Inspire Medical Systems, Inc. The ® symbol indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries. All other names and marks mentioned are the trade names, trademarks, or service marks of their respective owners. © 2024 Inspire Medical. All rights reserved.

This product and/or the use of this product in a method may be covered by one or more patents or patent applications, available at www.inspiresleep.com/patents.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Inspire Medical Systems is under license. Other trademarks and trade names are those of their respective owners.

Table of Contents

This page is intentionally blank.

How to Use this Guide

This guide presents information regarding the Inspire SleepSync Programming System. The chapters are organized as follows:

Therapy Overview	This chapter is a brief overview of Inspire therapy and its indications along with programmer terminology and icons.
Programmer Components	This chapter describes the SleepSync Programming System which includes the SleepSync Programmer Application, programmer cable, and accessories.
Installation and Setup	This chapter describes how to install and set up the SleepSync Programmer Application.
Getting Started	This chapter provides instructions on how to program the patient's generator and manage patient data.
Screen Descriptions	This chapter provides detailed descriptions of the SleepSync Programmer Application screens.
Clinical Programming Sessions	This chapter provides instructions for programming procedures (workflows) at implant, initial activation, sleep study and follow up visits.
Troubleshooting	This chapter contains solutions to problems that may be encountered during programmer use.
Warnings and Precautions	This chapter provides programmer warnings and precautions.
Supplemental Information	This chapter provides general reference information, such as device specifications and proper procedures for cleaning, servicing, and maintaining the programmer. This chapter also includes HIPPA and regulatory information.
Limited Warranty	This chapter describes the device limited warranty. This warranty applies only in the United States. Areas outside the United States should contact an Inspire Medical Systems representative for exact warranty terms.

This page is intentionally blank.

Explanation of Symbols

Symbols on Package Labeling and Device

Refer to the package label and device labels to see which symbols apply.

Symbol	Title	Description	Standard Reference
	Caution, consult accompanying documents	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1; ISO 7000-0434A
	Consult electronic instructions for use (eIFU)	Indicates the need for the user to consult the instructions for use	ISO 15223-1; ISO 7000-1641
	Consult instructions for use or consult electronic instructions for use	To signify that the instruction manual/booklet must be read	IEC 60601-1; ISO 7010-M002
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1; ISO 7000-2498
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1; ISO 7000-2493
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1
	Medical device	Indicates the item is a medical device	ISO 15223-1
	Model number	Indicates the model number or type number of a product	ISO 15223-1; IEC 60417-6050
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1; ISO 7000-3082
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1; ISO 7000-2497

Symbol	Title	Description	Standard Reference
	Collect separately	Do not dispose of electronic products in the general waste stream	BS EN 50419
	Non-ionizing electromagnetic radiation	Indicates generally elevated, potentially hazardously levels of non-ionizing radiation	IEC 60417; ISO 7000-5140
	Type BF Applied part protection against electrical shock	To identify a type BF applied part complying with IEC 60601-1	IEC 60601-1; ISO 7000-5333
	MR unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment	ASTM F2503-13
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1; ISO 7000-2606
	Fragile	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 15223-1; ISO 7000-0621
	Keep dry	Indicates a medical device that needs to be protected from moisture	ISO 15223-1; ISO 7000-0626
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1; ISO 7000-0533
	Relative humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1; ISO 7000-2620
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223-1; ISO 7000-2621
Rx ONLY	Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	CFR Title 21

Symbol	Title	Description	Standard Reference
	Federal Communications Commission (FCC) compliance mark (USA)	Complies with United States Regulations for Radio Frequency Devices	CFR Title 47
	Class II double insulated	Class II equipment	IEC 61140; ISO 7000-5172
	For indoor use only	To identify electrical equipment designed primarily for indoor use	IEC 60417; ISO 7000-5957
IP22	Degree of ingress protection per EN60529	Protected against objects larger than 12.5 mm. Protected against dripping water at a 15 degree angle	IEC 60601-1; IEC 60529
IP65	Degree of ingress protection per EN60529	Dust tight. Protected against powerful water jets.	IEC 60601-1; IEC 60529
	Output connector polarity	---	---

This page is intentionally blank.

Chapter 1: Therapy Overview

This chapter is a brief overview of the Inspire system technology and icons.

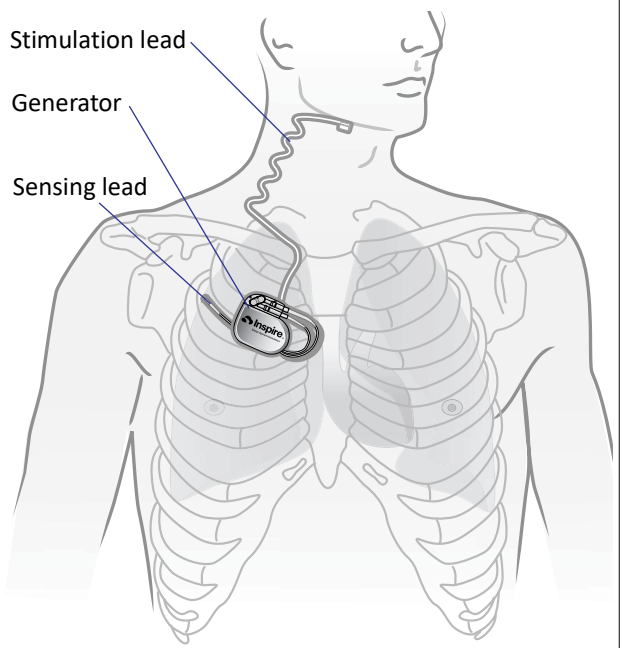
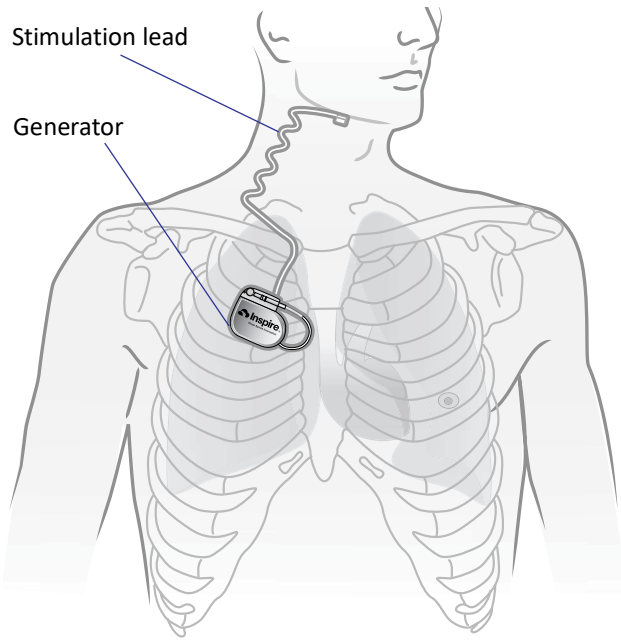
Introduction

The Inspire® Upper Airway Stimulation (UAS) system stimulates the hypoglossal nerve, synchronous with respiration, to elicit a neuromuscular response at the base of the tongue and to maintain airway patency in patients with moderate to severe obstructive sleep apnea (OSA).

Table 1-1 illustrates the implanted components necessary for the Inspire systems. Models 3024 and 3028 utilize an Inspire Generator, an Inspire Stimulation Lead, and an Inspire Respiration Sensing Lead. Model 3150 uses an Inspire Generator and the Inspire Stimulation Lead. Model 3150 doesn't need a sensing lead as the generator monitors the respirations.

The implanted system is programmed using the Inspire SleepSync Programmer Application and the Programmer Cable. The patient uses an Inspire Sleep Remote to turn therapy on and off and to temporarily pause stimulation. Patients may also be allowed the option of adjusting the strength of stimulation within a selected range.

Table 1-1. Inspire System Implanted Components

Models 3024 and 3028	**Model 3150**
	

Intended Use

Inspire Upper Airway Stimulation therapy is intended to treat OSA patients meeting specific criteria. Please refer to the *Inspire System Implant Manual* for a detailed list of the indications for use and contraindications, clinical warnings/precautions, and clinical summary. The SleepSync Programmer reads data from the generator, writes data to the generator, and facilitates the testing of the implanted system.

Therapy Phases

Inspire therapy takes place in four phases: (1) heal, (2) tune, (3) fine tune, and (4) living with Inspire.

Heal

The Inspire SleepSync Programmer is used to test the implanted system during the implant surgery. Afterward, patients will rest, heal, and follow up with their surgeons to check their healing progress.

Tune

Once the body has healed, therapy acclimation will start, typically lasting 1-3 months. During this phase, the generator is turned on, and, patients learn how to use the Sleep Remote to increase the stimulation level to get comfortable, restful sleep.

Fine Tune

During this phase, patients undergo a polysomnogram (PSG) or sleep study, during which the physician determines the optimal stimulation settings.

Living With Inspire

On an annual or semi-annual basis, patients return for an office visit to monitor therapy use and efficacy. Sleep studies are performed as needed.

Terminology

This section introduces and defines common terms used throughout this guide for determining the setting values, reading on-screen information, and evaluating patient responses. More information about these terms will be presented in later chapters.

The definitions are divided into the following three categories.

- General Therapy Terms
- Stimulation Settings
- Sensing Settings

Settings on the advanced screen views are labeled as advanced settings in the following definitions.

General Therapy Terms

Table 1-2 defines general therapy terms related to Inspire therapy.

Table 1-2. General Therapy Terms

Term	Definition
Current generator settings	The stimulation and sensing settings currently used by the generator. The combined stimulation and sensing settings are also known as the therapy settings.
Default settings	Default therapy settings determined by the generator manufacturer.
Functional level	Lowest amplitude at which a significant tongue motion is observed, such as the tongue protruding past the lower teeth.
Impedance	The resistance to the flow of stimulation energy. Impedance measurements can be used to assess the integrity of leads, lead electrodes, and the lead-generator connection.
Initial session settings	The therapy settings at the start of the current programming session.
Generator	Inspire generator.
Generator battery status	The current state of the generator battery. If the battery status is Low or Depleted, schedule a generator replacement procedure.
Sensation level	The lowest amplitude at which a patient can feel stimulation.
Sensing	Defines how the generator determines inhalation and exhalation in order to time the delivery of stimulation.
Sensing settings	Therapy settings that determine when the generator delivers stimulation.
Session (programming session)	A series of interactions between the Inspire SleepSync Programmer and generator during which the therapy settings are reviewed and/or modified.
Start impulse	An initial stimulation to let a patient know that therapy is on and working.
Step size	The amount of voltage that the generator will increment or decrement in response to a Sleep Remote button press.
Stimulation (Stim)	Mild electrical signals delivered to the hypoglossal nerve to elicit a neuromuscular response at the base of the tongue and to maintain airway patency.
Stimulation settings	Therapy settings that determine how stimulation is delivered.
Therapy	When therapy is turned on, the generator delivers stimulation based on the current sensing and stimulation settings.
Usage	The total time the patient has used Inspire therapy since the last programming session.

Stimulation Setting Terms

Table 1-3 defines terms related to stimulation settings.

Table 1-3. Stimulation Setting Terms

Term	Definition
Amplitude	The stimulation level measured in volts. Increasing amplitude will increase stimulation strength; decreasing amplitude will decrease stimulation strength.
Electrode configuration	The electrodes and polarities used to deliver the stimulation. **Note:** This is an advanced setting.
Patient amplitude control	This feature allows the patient to use the Sleep Remote to adjust the stimulation amplitude within predefined limits set by the physician.
Pause time	The length of time that the patient is allowed to suspend therapy if needed during the night.
Pulse width	The stimulation pulse duration. Increasing pulse width will increase stimulation strength; decreasing pulse width will decrease stimulation strength. **Note:** This is an advanced setting.
Ramp	A duration of therapy in which the stimulation strength gradually increases until it reaches the full stimulation strength set by the clinician. Ramp duration allows the patient to ease into therapy for comfort.
Rate	Number of stimulating pulses delivered per second. Increasing rate will increase stimulation strength; decreasing rate will decrease stimulation strength. **Note:** This is an advanced setting.
Start delay	The period between the time the patient activates the therapy for the night and the time stimulation begins. This interval allows the patient to fall asleep before therapy starts.
Therapy duration	The length of time that therapy is delivered once it is turned on. This should correspond to the amount of time the patient will spend asleep.
Timing	A term referring to the start delay, pause time, and therapy duration settings.

Sensing Setting Terms

Table 1-4 defines terms related to sensing settings.

Table 1-4. Sensing Setting Terms

Term	Definition
Exhalation	The end of inhalation as determined by the generator. The generator detects that exhalation has occurred when a decrease in the sensor signal meets the exhalation sensitivity and threshold criteria. When therapy is turned on, the generator starts to deliver stimulation when it determines that inhalation has occurred, and it stops stimulation when it determines that exhalation has occurred or when the maximum stimulation time expires.
Exhalation sensitivity	This setting determines how sensitive the generator is to changes in the sensor signal that indicate exhalation. Increasing exhalation sensitivity configures the generator to detect exhalations earlier with respect to the sensor signal; decreasing exhalation sensitivity configures the generator to detect exhalations later.
Exhalation threshold	This setting controls the properties the sensor signal must meet before the generator will attempt to detect an exhalation. Increasing the exhalation threshold causes the generator to look for exhalations more often; decreasing the exhalation threshold causes the generator to look for exhalations less often. This setting allows for the management of signal artifacts that can cause the generator to detect extraneous exhalations. **Note:** This is an advanced setting.
Inhalation	The start of inhalation as determined by the generator. The generator detects that inhalation has occurred when an increase in the sensor signal meets the inhalation sensitivity and threshold criteria. When therapy is turned on, the generator starts to deliver stimulation when it determines that inhalation has occurred, and it stops stimulation when it determines that exhalation has occurred or when the maximum stimulation time expires.
Inhalation sensitivity	Inhalation sensitivity determines how sensitive the generator is to changes in the sensor signal that indicate inhalation. Increasing inhalation sensitivity configures the generator to detect inhalations sooner with respect to the sensor signal; decreasing inhalation sensitivity configures the generator to detect inhalations later. **Note:** This is an advanced setting.
Inhalation threshold	This setting controls the properties that the sensor signal must meet before the generator will attempt to detect an inhalation. Increasing the inhalation threshold causes the generator to look for inhalations more often; decreasing the inhalation threshold causes the generator to look for inhalations less often. **Note:** This is an advanced setting.
Invert signal	A feature that switches the polarity of the sensor signal before the generator processes it for inhalations and exhalations. This feature could be used to correct a situation in which stimulation is being delivered during exhalation instead of inhalation.

Table 1-4. Sensing Setting Terms (Continued)

Term	Definition
Maximum stimulation time	The maximum time that stimulation is delivered during one stimulation burst. This setting also controls the length of the stimulation burst used for test stimulation. **Note:** This is an advanced setting.
Off period (Hard)	A percentage of the respiratory period during which stimulation will not be delivered. The hard off period follows immediately after the generator detects an exhalation.
Off period (Soft)	A percentage of the respiratory period during which the generator may detect an inhalation if the sensitivity and threshold criteria are met. When the soft off period expires, inhalation is more likely to be detected. The soft off period occurs during the final portion of the hard off period. **Note:** This is an advanced setting.
Respiratory period	The generator measures the respiratory period from exhalation to exhalation. The respiratory period is used for the calculation of the off period.

Therapy Icons

Electrodes

Electrodes are used to deliver stimulation to the patient. There are three electrodes in the Inspire system, two on the lead (the two outer lead electrodes work together as one) and one that is integrated into the generator case. The two lead electrodes are designed so that one center electrode is placed between the outer electrode.

Table 1-5 describes the icons used to represent electrodes on the programming screens. See “Electrode” on page 57 for more information.

Table 1-5. Electrode Icons

Icon	Description	Icon	Description
	Negative lead electrode		Positive generator case electrode
	Positive lead electrode		Unused (off) generator case electrode
	Unused (off) lead electrode		

These icons are used to indicate the polarity of all system electrodes. For example, the default electrode is shown in Figure 1-1.

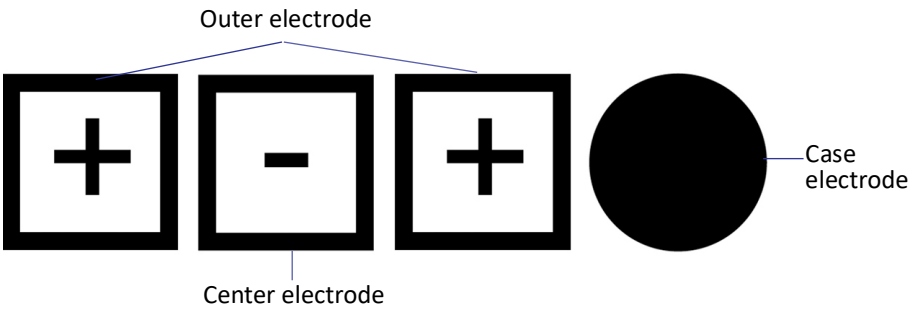


Figure 1-1. Default Electrode

In this configuration, the three square lead electrode icons indicate that the outer electrode is positive and the center electrode is negative. The round, filled-in case electrode indicates that the electrode is off and not used in this configuration.

Generator Communication

A communication icon (Figure 1-2) is used on certain programming buttons to indicate when communication with the generator is required to execute an action, such as:

- Connect to Generator
- Configure Generator
- Test Connection
- Turn On/Off therapy
- Test Stimulation
- Start Waveform

Figure 1-2. Communication Icon

When the programmer communicates with the generator, a large communication icon displays (Figure 1-3). The color of this icon corresponds to the connection status: blue indicates different levels of communication success and orange indicates communication failure.

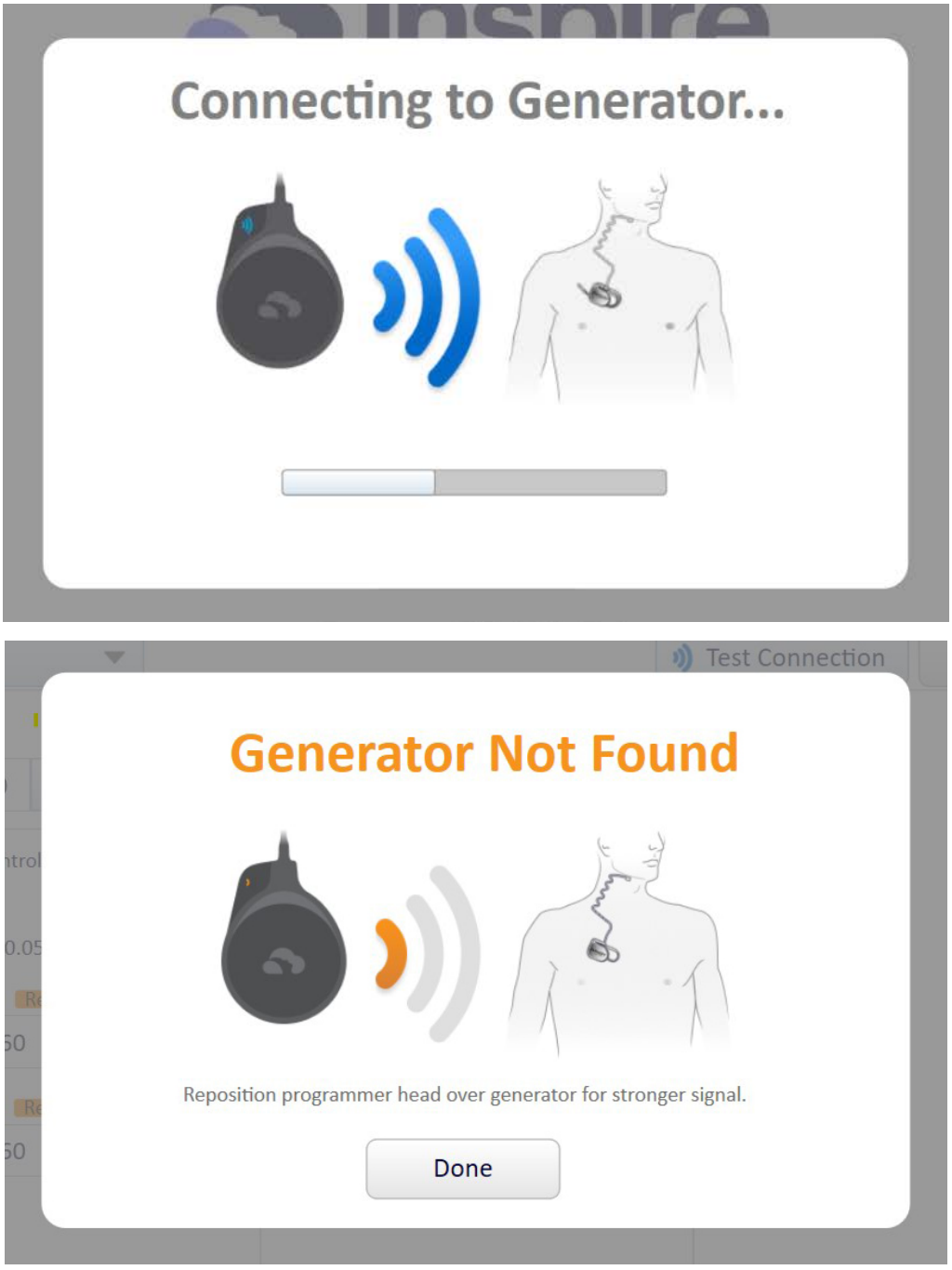


Figure 1-3. Communication Screen

This page is intentionally blank.

Chapter 2: Programmer Components

This chapter describes the Inspire SleepSync Programming System components and accessories.

Package Contents

In addition to the packaged components listed below, the SleepSync Programmer Application must be installed on your computer.

- **Programmer Cable–2740C**
- Medical-grade power supply and power cord
- Inspire portability kit
- IT Quick Guide which directs users to the downloadable **SleepSync Programmer Application–2740S**
- Manual Reference Card

Programmer Cable

The programmer cable is the communications interface between the generator and the SleepSync Programmer Application running on your computer. The programmer cable includes the programmer head, the controller, and a medical-grade power supply with power cord (Figure 2-1). The programmer cable has two operating ranges, one for very short-range communications with the generator (up to 5 centimeters or 2 inches) and another for short-range communication with the SleepSync Programmer Application (approximately 5 to 10 meters or 16 to 33 feet).

Figure 2-1. Programmer Cable

Portability Kit

The portability kit provides a convenient way to safely transport your Inspire SleepSync Programmer Application components (Figure 2-2), which also includes a luggage tag.

Figure 2-2. Portability Kit

Chapter 3: Application Installation and Setup

This chapter describes how to install and set up the Inspire SleepSync Programmer Application on your computer.

Application Installation

System Requirements

- Windows 10 Pro, release 2004 or newer
- Bluetooth® 4.0 or later
- 1 GHz (or faster) processor
- 1 GB RAM for 32-bit OS, or 2 GB RAM for 64-bit OS
- TPM 2.0 (Trusted Platform Module)
- BitLocker encryption to maintain the privacy of protected health information (PHI). For more information, see “Security” on page 133.

Enable Data Sharing (Recommended)

By default, patient programmer data (i.e. session reports) will not be shared between Windows accounts on the same computer. Data sharing is unnecessary if only a single Windows account will be used for programming or if users with different Windows accounts do not need to view the same data.

Data sharing should be enabled if different Windows users on the computer will want to view the same data. To enable data sharing, complete the following steps:

1. Log into an administrator account on the programmer computer.

   Note: If the programmer computer will be on your organization’s domain, you must be connected to your organization’s network to enable sharing of data. A VPN can be used to connect to the network if needed.

2. Open the group policy editor. The group policy editor can be found by typing “Edit group policy” in Windows search.
3. In the left-hand navigation menu, open Local Computer Policy → Computer Configuration → Administrative Templates → Windows Components → App Package Deployment.
4. Find the “Allow a Windows app to share application data between users” setting and double-click to change the value.
5. In the resulting popup window, choose the Enabled option, then select **Apply.**
6. Select **OK** and then close the group policy editor.

If the data-sharing setting changes after using the programmer, previous data may become temporarily inaccessible. Reverting to the previous setting will make the previous data visible again. Before changing this setting, it is recommended to upload the data (refer to “Uploading Patient Data” on page 31) or save the data to PDF (refer to “Save session reports to PDF” on page 66).

Installation

1. Download the installation file with the link provided in the IT Quick Guide.
2. Install the application.
   a. To install for one Windows account at a time, log into the desired account and double-click the installer. Proceed with the installation.
   b. To install for all Windows accounts on the computer at the same time, complete the following steps:
      i. Type “powershell” into Windows search.
      ii. Right click on the application and select **“Run as administrator”.**
      iii. Enter administrator credentials (if necessary).
      iv. In the PowerShell window, run the following command (replacing the bold text with the actual file path to the installer):

      ```
      Add-AppProvisionedPackage –online -skiplicense –packagepath
      "<path to installer>"
      ```

      Notes:
      - This command must be exactly correct or it will not work.
      - The path to the installer must include the installer file itself (ending in `.msixbundle`).

For more information on installation, visit
https://professionals.inspiresleep.com/programmer.

First-time Setup

Setup Steps

If a single Windows account will be used for programming or if “Enable Data Sharing (Recommended)” has been enabled, these steps will only need to be completed once. If multiple accounts are being used and data is *not* being shared, these steps will need to be completed for each individual account.

1. **Log in to SleepSync**
   a. Open the Windows Start menu and begin typing “Inspire SleepSync.” The application should appear in the Start window.
   b. Select the **SleepSync Programmer Application** to launch it.
   c. After you launch the application, the Setup Wizard screen displays (Figure 3-1). Select the **Log in to SleepSync** button.

Figure 3-1. Setup Wizard Screen

   d. On the next screen (Figure 3-2), select the **Pair a programmer cable and manage patient data** option, and then select **Continue**.

Notes:

- This option provides access to all functions in the application. It is recommended that you select this option.
- Select the **Manage patient data only** option if you do not want to enable programming and pair a programmer cable. For more information, see “Manage Patient Data Only” on page 31.

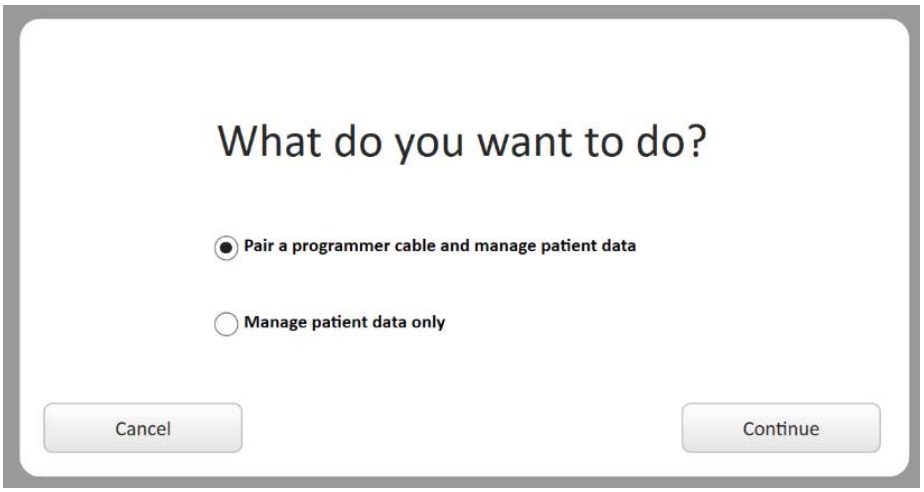


Figure 3-2. Program Patients and Use Inspire SleepSync Option

e. Log in with your Inspire SleepSync user ID, which is an email address, and password. Then select **Sign in**.

f. SleepSync utilizes multi-factor authentication. Follow the instructions on-screen. Select either **Send Code** or **Call Me**. When prompted, enter the code.

   Note: The phone number associated with the account will be used to text or call. You will see the last four digits listed on the pop-up screen.

g. If you belong to more than one practice, select the desired practice from the dropdown menu (Figure 3-3), (there is no practice selector if you belong to a single practice), and then select **Continue**.

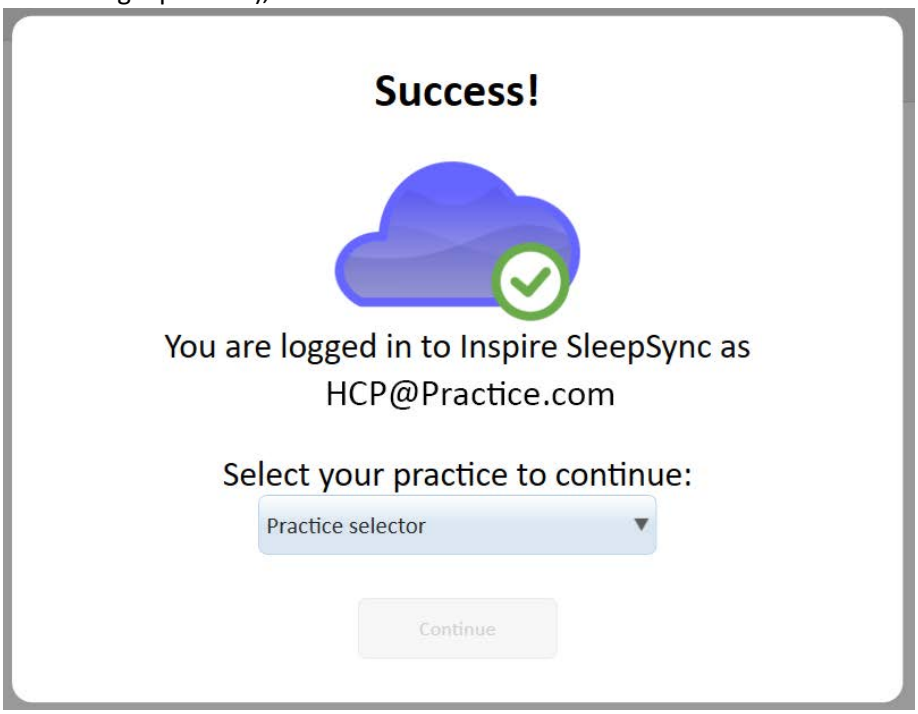


Figure 3-3. Select a Practice Screen

2. **Enable Programming**
   a. The Enable Programming button becomes active (Figure 3-4) after logging in. Select **Enable Programming** to continue.

Figure 3-4. Enable Programming

   b. After a self-check and when programming is enabled successfully, the following screen displays (Figure 3-5). Select **OK** to continue.

Figure 3-5. Programming Enabled Successfully Screen

3. **Pair the Programmer Cable**

Notes:

- Only 2740 Programmer Cables that have a dark gray controller are compatible with the 2740S. See Figure 2-1 on page 11.
- If another user on the computer has already paired to the programmer cable, this step is not required and the Setup Wizard will exit.

a. The **Pair Programmer Cable** button becomes active (Figure 3-6) after programming is enabled. Select the **Pair Programmer Cable** button to continue. See “Connecting the Programmer Cable to Power” on page 26.

Note: Bluetooth must be enabled on your computer.

Figure 3-6. Setup Wizard Pair Programmer Cable Button

b. On the Pair a Programmer Cable screen (Figure 3-7), select **Continue**.

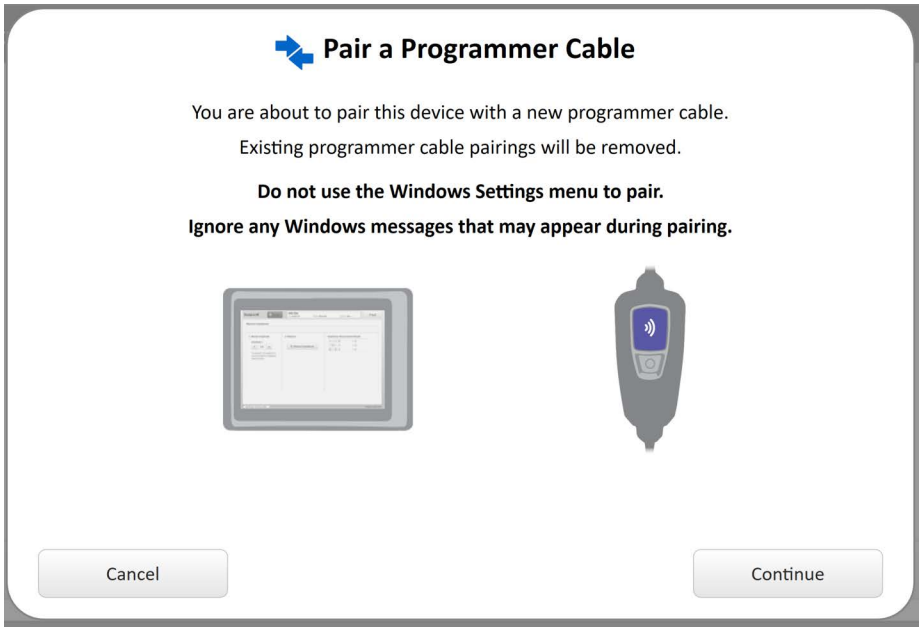


Figure 3-7. Pair a Programmer Cable Screen

c. Follow the on-screen instructions (Figure 3-8) to prepare the programmer cable, and then select **Continue**.

Note: Make sure your computer is within 6 feet of the programmer cable.

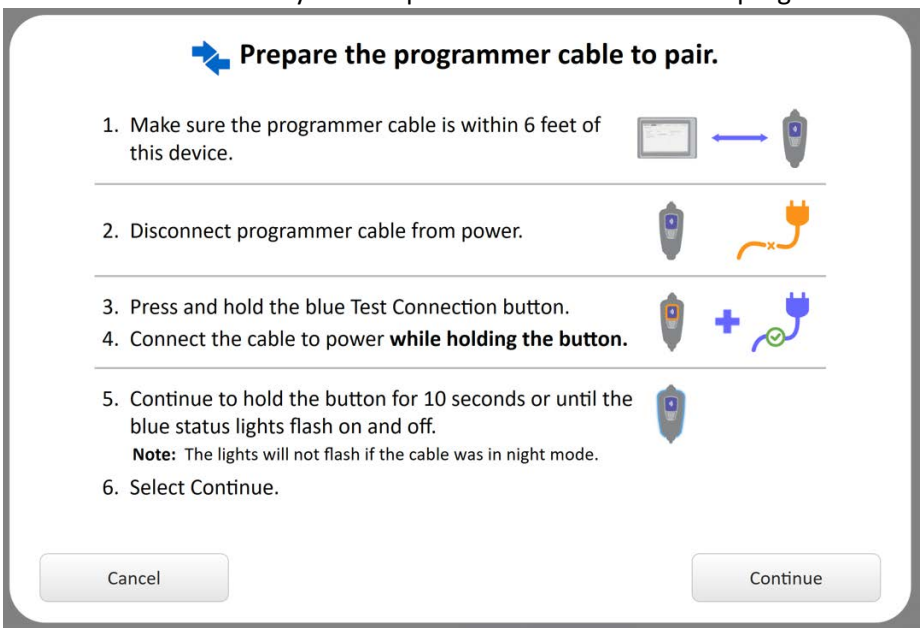


Figure 3-8. Pair a Programmer Cable Instructions

d. The system begins searching for the programmer cable. When the programmer cable is located, the following screen displays (Figure 3-9).

Note: You can cancel the pairing process by pressing the **Therapy Off** button on the programmer cable.

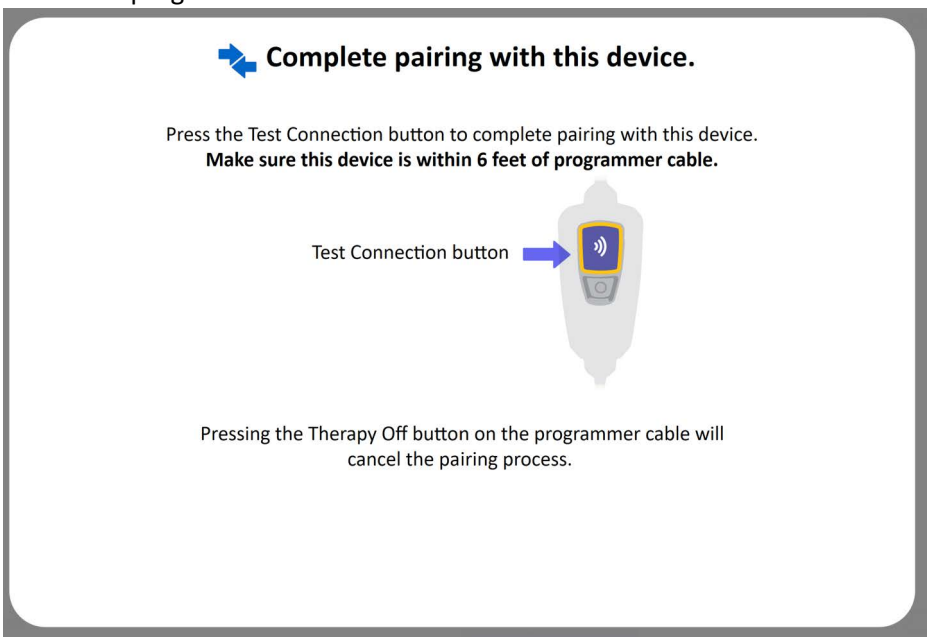


Figure 3-9. Pair a Programmer Cable Test Connection Screen

e. Press the **Test Connection** button as instructed.

f. When pairing has completed successfully (Figure 3-10), select **Continue**.

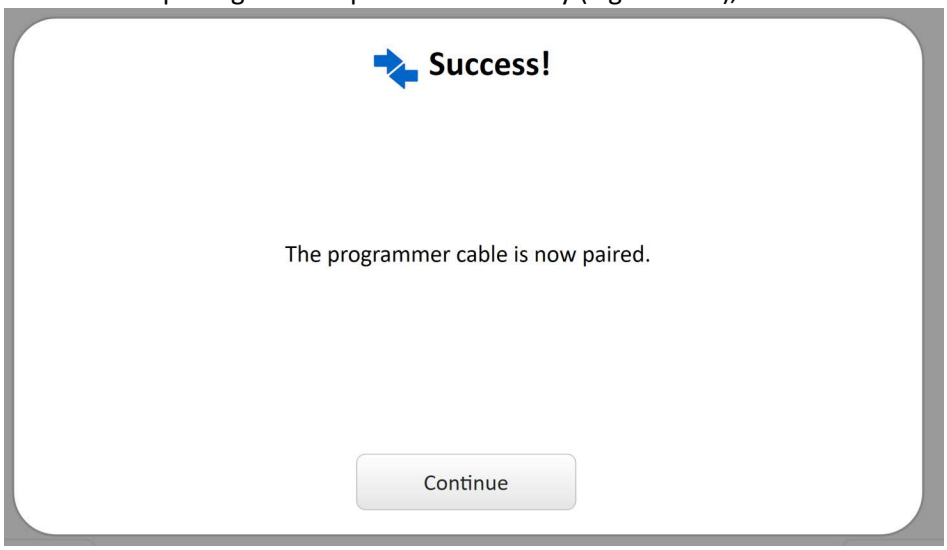


Figure 3-10. Programmer Cable Paired Successfully

4. **Update the Programmer Cable Firmware**

Notes:

- If the programmer cable has already been paired with the SleepSync Programmer Application, its firmware will be up to date and this step can be skipped.
- If the update fails, ensure a reliable Internet connection and try again.

a. After pairing the programmer cable, the SleepSync Programmer Application will alert you that a firmware update is due. Select the **Start** button shown in Figure 3-11.

Figure 3-11. Firmware Update Screen

Note: If you choose to delay the firmware update, full programming functionality will not be available.

b. If prompted, log in to SleepSync.

c. Wait for the update to download (Figure 3-12).

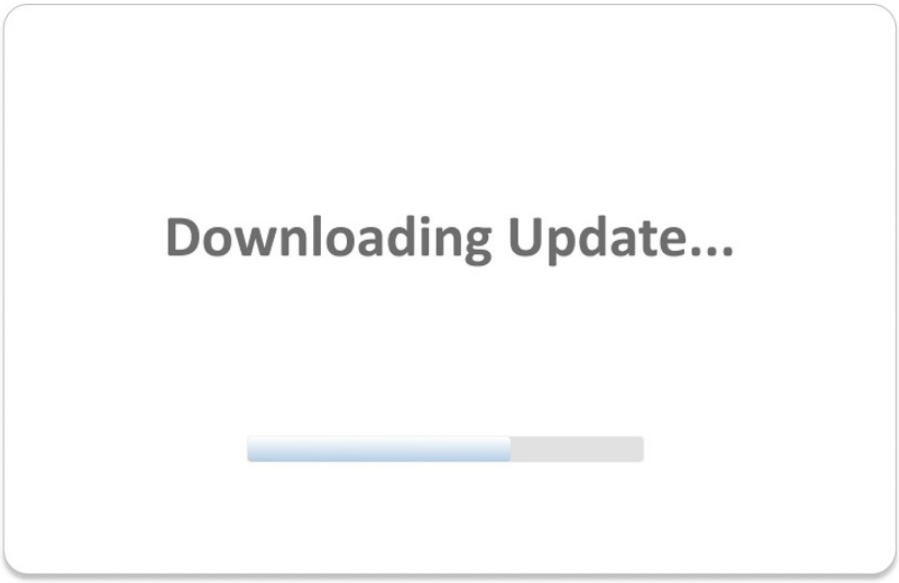


Figure 3-12. Downloading Update

d. Wait for the cable to be updated (Figure 3-13).

Figure 3-13. Updating Cable

e. Proceed with re-pairing the updated cable. Select **Continue** from Figure 3-14 and repeat steps 3c-3f to complete the pairing process.

Figure 3-14. Re-Pairing

f. After pairing has successfully completed, wait while the update is confirmed (Figure 3-15).

Figure 3-15. Please Wait

g. Once you see the Success! window (Figure 3-16) select **OK**.

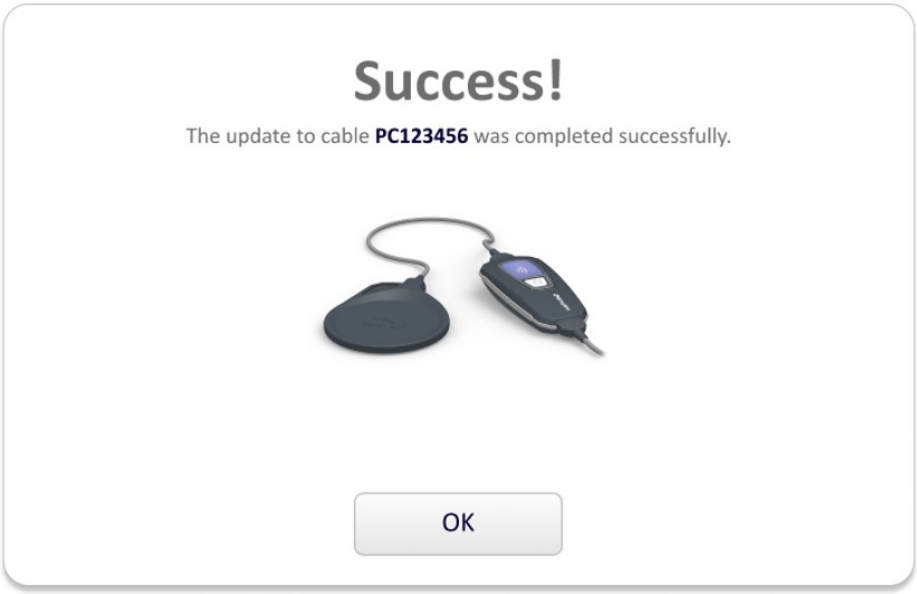


Figure 3-16. Success

Congratulations on completing installation and setup!

For more information on setup, visit https://professionals.inspiresleep.com/programmer.

Chapter 4: Getting Started

This chapter describes how to program the patient's generator and manage patient data.

Begin Programming

Launching the SleepSync Programmer Application

To start the SleepSync Programmer Application, open the Windows Start menu and begin typing "Inspire SleepSync." The application should appear in the Start window. Select the application to launch it.

Note: For future access, it is recommended to right-click on the application and select either **"Pin to Start"** or **"Pin to taskbar."**

Navigating the Start Screen

When you launch the SleepSync Programmer Application, the Start screen displays (Figure 4-1). Refer to "Start Screen" on page 36.

Note: If you have yet to complete the full setup process, a different Start screen displays and you will not be able to start a programming session. See Figure 4-5.

Figure 4-1. Start Screen

Adjusting the Programmer Settings

Before starting a session, it is recommended to review the programmer settings to ensure the desired data control settings are selected.

Note: Settings adjustments can be made without a generator present.

Select the **Settings** button from the Start screen to adjust the following:

Data Controls

- Allow patient data in PDFs
  Select this check box to allow patient data to be included when you save reports to PDFs.
- Enable editing of patient details
  Select this check box to allow editing of the data in the patient data fields.
- Delete data after SleepSync upload
  Select this check box to have patient data deleted after it has been uploaded to SleepSync.

  Note: This selection will also delete data stored before making this selection.

App Size

- Select the **App Size** control to choose the desired screen size of the application window.

Select the **Save** button to save the new settings.

Connecting the Programmer Cable to Power

The programmer cable must be plugged into an electrical outlet to operate. Complete the following instructions to connect the programmer cable to power (Figure 4-2).

1. Connect the programmer cable power supply to the programmer cable.
2. Connect the power cord to the programmer cable power supply.
3. Connect the power cord to an electrical outlet (100–240 VAC).

Figure 4-2. Programmer Cable Power Supply Connections

Positioning the Programmer Head

The programmer head must be properly positioned over the generator to establish the signal strength required to connect to the generator. See Table 4-1.

Confirming Connection
The cable connection status line in the lower-left corner of the screen will indicate that a communication link between the computer and the programmer cable is established. See “Cable Status Screen” on page 42 for more information.

A fully lit status light displays on the programmer cable controller when your computer and programmer cable establish a connection.

Testing Connection Strength
Complete the following steps to evaluate programmer head positioning before connecting to the generator. Start the process from either the programmer cable or the SleepSync Programmer Application.

Starting the process from the programmer cable:

1. Ensure the programmer cable is connected to power.
2. Position the programmer head directly over the generator (Figure 4-3).
3. Press the **Test Connection** button on the controller.
4. The strength gauge will display one of the following ratings in Table 4-1.
5. If signal strength is not good, reposition the programmer head directly over the generator for a stronger signal or remove the source of interference.
6. Wait 30 seconds for the process to end or press the **Test Connection** button again to cancel.

Starting the process from the SleepSync Programmer Application:

1. Ensure that the application is running and that the programmer cable is on.
2. Confirm that a wireless link between the your computer and programmer cable has been established by checking the cable connection status line in the screen footer.
3. Position the programmer head directly over the generator (Figure 4-3).
4. Select the **Test Connection** button on the Start screen or on a screen within a programming session.
5. The screen will display one of the following strength ratings shown in Table 4-1.
6. If signal strength is not good, follow the on-screen instructions:
   – reposition the programmer head directly over the generator for a stronger signal, or
   – remove the source of interference.
7. Select the **Done** button when the programmer head is positioned properly and the communication strength has reached a rating of good, shown in Table 4-1.

Table 4-1. Signal Strength Indicators

				
Good	Moderate	Low	Generator Not Found	Electrical Interference

Figure 4-3. Correct Positioning of Programmer Head over Generator

Programmer Head Strength Gauge
A strength gauge is located on the top of the programmer head (Figure 4-3) so that it can be observed when the programmer head is positioned over the generator. The strength ratings are described in Table 4-1.

Note: The programmer head strength gauge will illuminate whenever communication is active, not just when testing the connection.

Connecting to the Generator

After testing the connection, maintain good programmer head position and select the **Connect to Generator** button on the Start screen. As the programmer connects to the generator, one or more of the following Communication Screens described in Table 4-2 displays. If necessary, take the recommended actions.

Table 4-2. Communication Screens

Message	Event	Action
Connecting to generator	Displays when the **Connect to Generator** button has been selected.	Wait for connection to be established.
Configuring generator	Displays when the generator is being updated for the start of a session.	Wait for connection to be established.
Generator Not Found or Electrical Interference	Displays when the programmer head is not correctly positioned over the generator.	Reposition the programmer head over the generator or remove source of interference. After 30 seconds of communication failure, the **Exit Session** button is available to end the current session.

A large communication icon displays on all Communication Screens (Figure 4-4). The icon corresponds to the programmer head status light to indicate communication success or failure.

Note: You may notice a delay between the strength rating on the head and the rating on-screen regarding the connection status.

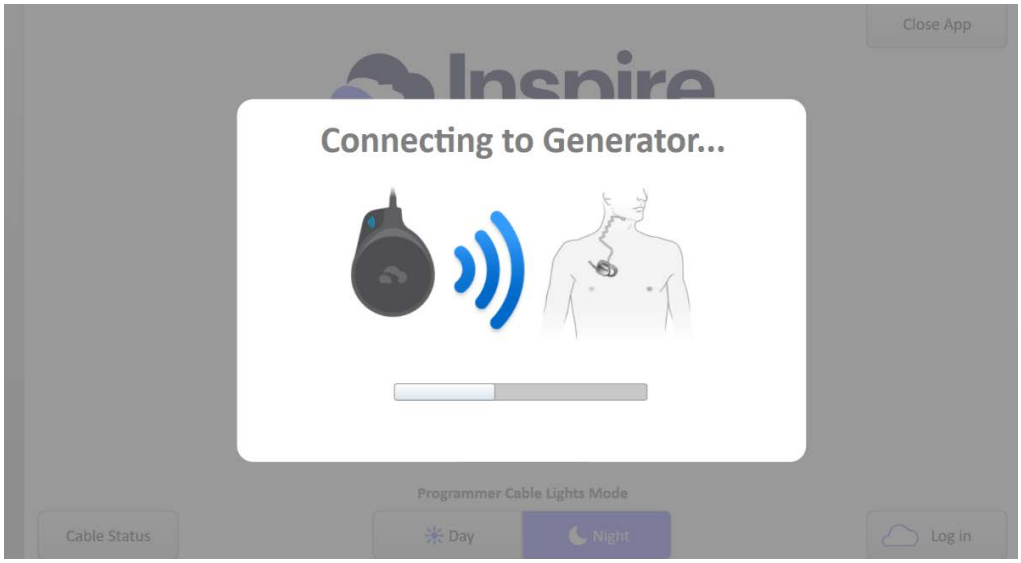


Figure 4-4. Communication Screen

Table 4-3 describes common connection problems and their solutions.

Table 4-3. Communications Troubleshooting

Problem	Action
No Connection Between Your Computer and the Programmer Cable	Ensure that your computer is within wireless range and that Bluetooth connectivity is turned on. Move your computer closer to the programmer cable if necessary. Disconnect the programmer cable from power and reconnect it. Ensure that the programmer cable is powered on. Check for loose cord connections and restore power to the programmer cable.
Communication Buttons Disabled	To establish connection and enable all communication buttons, ensure that your computer is within wireless range and that Bluetooth connectivity is turned on. Disconnect the programmer cable from power and reconnect it.
Generator Not Found	Reposition the programmer head directly over generator.
Electrical Interference	Remove the cause of interference and reposition the programmer head directly over the generator. Electrical equipment, such as inductive plethysmography, CRT monitors, and electrical power supplies are possible causes of interference.

Program the Patient's Generator

Refer to "Clinical Programming Sessions" on page 79 for instructions on programming.

Ending the Programming Session

Allow all communications to complete before a patient leaves. If a patient is allowed to leave during a test stimulation or impedance measurement, the generator may not be restored to therapy settings. Verify that all setting changes have been made on the Home screen before exiting a session.

Always end sessions properly, according to the following instructions:

1. From any screen, select the **Home** button to access the Home screen.
2. Select the **Exit** button to end the session and display the Start screen.

Note: If the patient is not in Inspire SleepSync, you will have the option of uploading the patient's data. Follow the on-screen instructions to log in (if you are not logged in) and upload the patient's data.

Using Demonstration Mode

Use Demonstration Mode to practice using the programmer with a simulated generator. Demonstration Mode is displayed near the bottom of the Start screen, see Figure 4-1 on page 25. The programmer cable is not needed for Demo Mode.

1. Ensure that the SleepSync Programmer Application is running.
2. Select the **Demo** button from the Start screen.
3. After selecting **Demo**, another window will display. Choose which demo experience you want: Model 3028 and prior or Model 3150.

Manage Patient Data

Logging in to Inspire SleepSync

Inspire SleepSync is a cloud-based system for managing Inspire patients. Patient data can be stored both in Inspire SleepSync and on your computer.

You must log in to Inspire SleepSync when:

- You want to access details for a patient whose data is in Inspire SleepSync.
- You want to view Therapy Reports (Figure 5-24).
- You want patient data to be uploaded to Inspire SleepSync.

Note: To log in, you must have a user ID and password. If you need login credentials, send an email request to sleepsync@inspiresleep.com.

To log in, select the **Log in** button on the Start screen (Figure 4-1). When the Login screen displays, log in with your Inspire SleepSync user ID and password, and then select **Sign in**. SleepSync utilizes multi-factor authentication. Follow the instructions on-screen. Select either Send Code or Call Me. When prompted, enter the code.

Notes:

- The phone number associated with the account will be used to text or call. You will see the last four digits listed on the pop-up screen.
- You will be logged out automatically after 15 minutes of inactivity.

Uploading Patient Data

After logging in, patient data can be uploaded to Inspire SleepSync. If a patient has already been uploaded to the selected practice, new data from that patient will upload automatically (sync) in the future when logged in.

To upload patient data from the Inspire SleepSync Programmer Application (Model 2740S), refer to “Upload Tab” on page 67 for instructions. If an Internet connection is not available from your current device, a separate device can be used to upload the data as follows:

1. Save the desired reports to a portable USB drive. Refer to Table 5-6 on page 68 for instructions.

   Notes:
   - Do not save the reports more than five folders deep on the USB drive.
   - To move the data to another computer, select the “Technical Support Logs” checkbox under the “Additional Options” dropdown on the Save PDF screen before selecting Save PDF. See Figure 5-26 on page 74.
2. Transfer the USB drive to another device with the Inspire SleepSync Programmer Application installed and an Internet connection.
3. After connecting the USB drive, the application will detect the session reports and begin the upload, as described in Table 5-6 on page 68.

Patient data can also be uploaded to Inspire SleepSync from a patient’s Model 2500 Sleep Remote or from a USB drive containing Model 2740 Inspire Programmer reports. Refer to Table 5-6 on page 68 for additional information.

Viewing Therapy Reports

After logging in to Inspire SleepSync, patient therapy reports can be viewed. Refer to Figure 5-24 on page 70 for additional information.

Manage Patient Data Only

If you did not complete the full setup process (enabling programming and pairing a programmer cable), you will not be able to start a programming session or connect to a generator. However, you can still upload and manage patient data from legacy products such as a Model 2500 Sleep Remote or Model 2740 Inspire Programmer.

After selecting **Log in to SleepSync** from the Setup Wizard Screen (Figure 3-1), choose **Manage patient data only** option (Figure 4-5).

Note: This option is for managing patient data only. If you want to program patients at a later time, the programming setup will still be available.

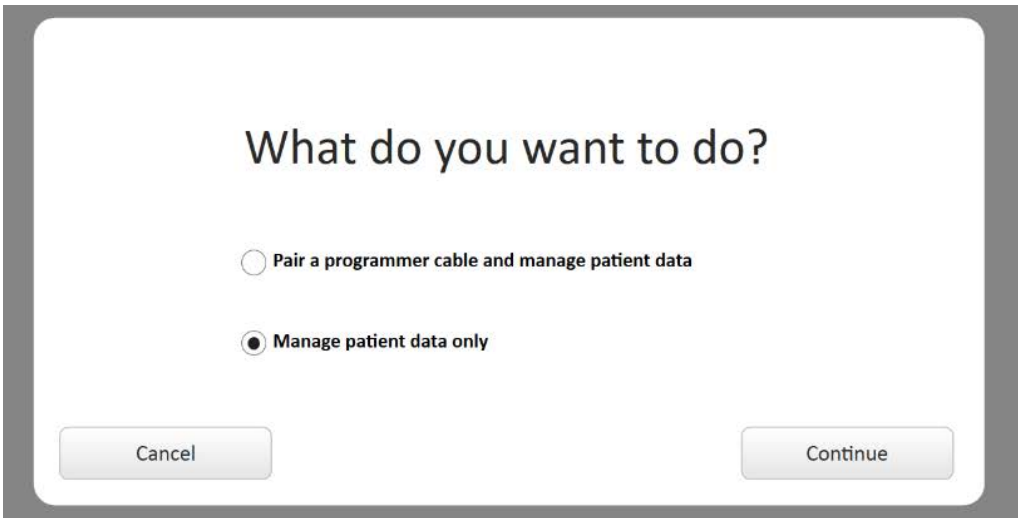


Figure 4-5. Manage Patient Data Only Option

After selecting **Continue,** complete the login process. Upon successful login, the following screen displays (Figure 4-6).

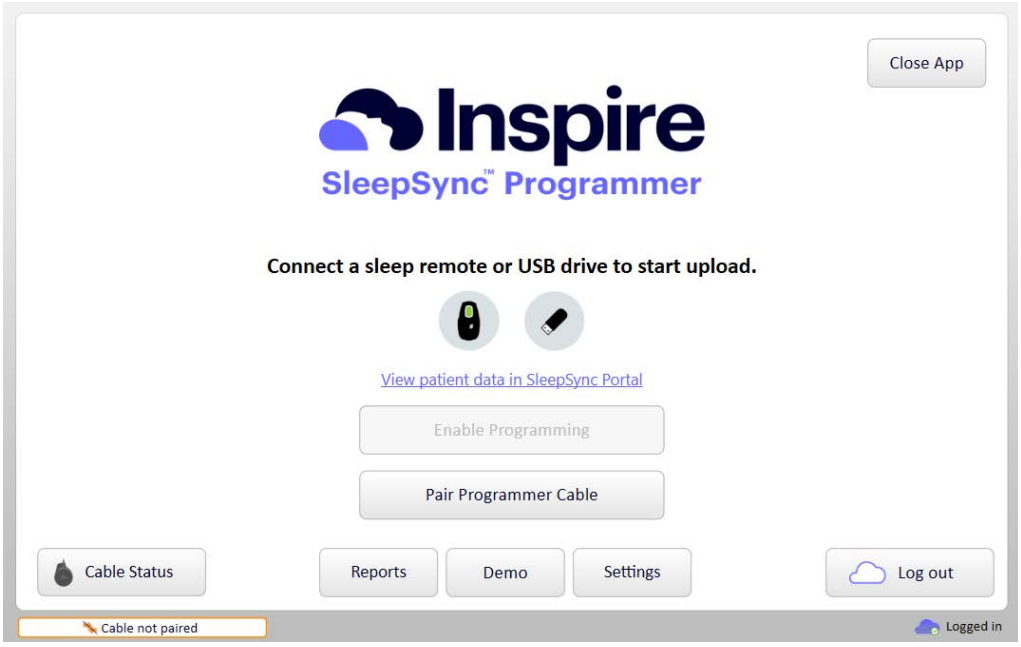


Figure 4-6. Connect a Device for Patient Upload Screen

Connect a Model 2500 Sleep Remote or a USB drive containing exported data from a 2740 programmer to your computer to start uploading patient data.

If the patient's data is not in Inspire SleepSync already, the Upload Patient Data screen displays (Figure 5-23). Otherwise, if the patient is a current patient, an upload progress screen displays.

Moving the Application Window

If you desire to move the application window, refer to “Programmer Settings Screen” on page 40 for instructions on selecting a window size that is smaller than full screen.

To drag the application to a different location, click the gray border at the top of the screen and drag (Figure 4-7).

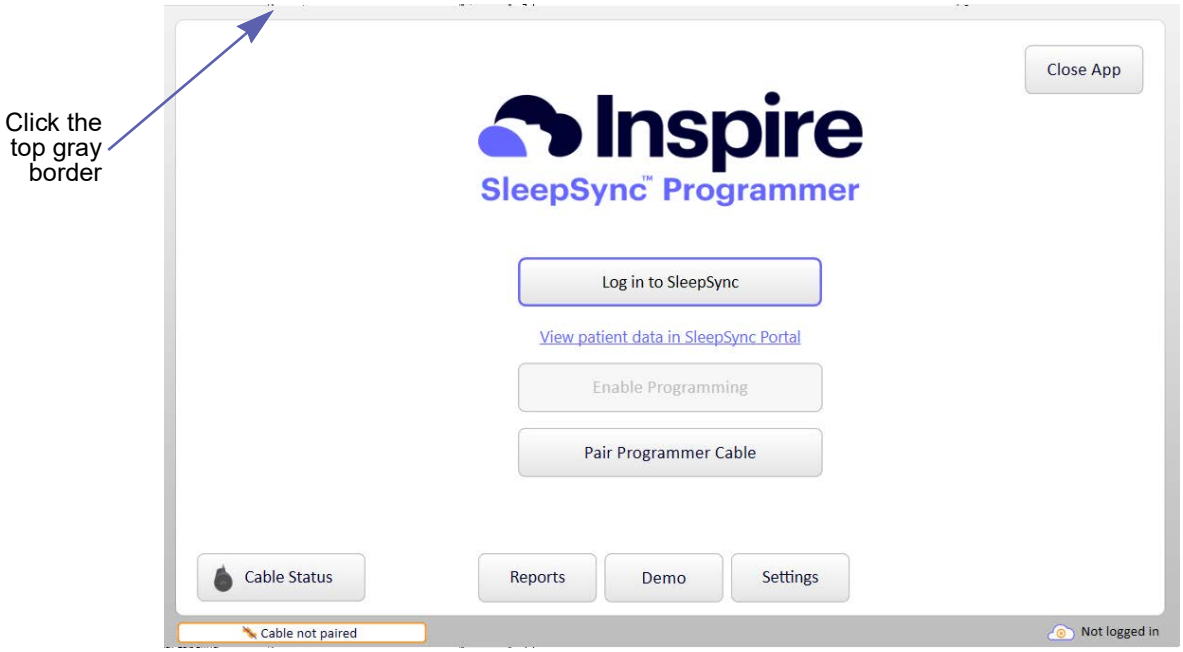


Figure 4-7. Moving the Application Window

Ending Programmer Use

When all programming and patient data management is completed, end programmer use properly by following these instructions:

1. Navigate to the application Start screen and select **Close App** to close the Inspire SleepSync Programmer Application.
2. Log out of the programming computer.
3. Disconnect the programmer cable from its power supply and then unplug the power cord from the electrical outlet.
4. Store the programmer cable, medical-grade power supply, and power cord in the Inspire potability kit. Store the portability kit and its contents in a secure location.

Note: The Inspire SleepSync Programming System is not designed for continual use over extended periods of time (>24 hours).

This page is intentionally blank.

Chapter 5: Screen Descriptions

This chapter provides descriptions of the Inspire SleepSync Programmer Application screens.

Common Screen Elements

All SleepSync Programmer Application screens, with the exception of the Start screen, Programmer Settings screen, and Patient List screen, display common information in the screen header (Figure 5-1).

Screen Header Information

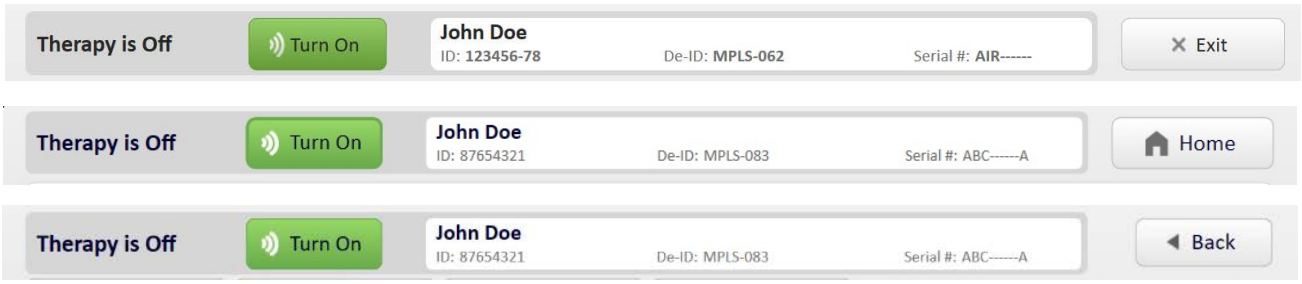
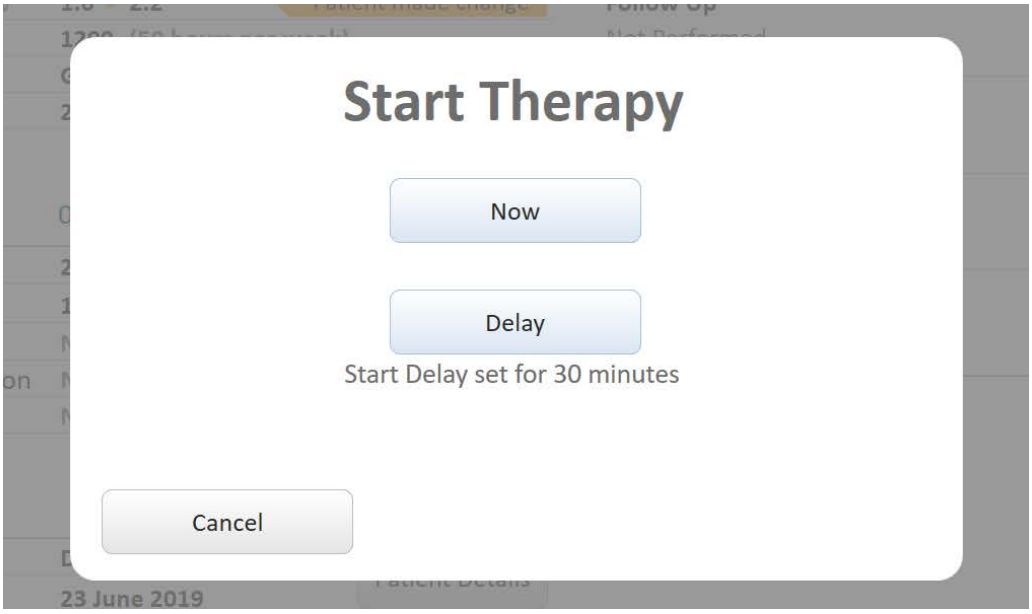


Figure 5-1. Common Information Screen Headers

- Therapy Status — When the therapy is on, the therapy status displays Therapy is On. This means that therapy is being delivered or will be delivered once the start delay or pause time has expired.
- When the therapy is off, the therapy status display's Therapy is Off. This means therapy is not being delivered and will not be delivered until a therapy on command is received by the generator.
- Turn On/Turn Off Therapy Button — Select button to turn stimulation on or off. Turning stimulation on accesses the Start Therapy Screen (Figure 5-2), where you may choose to start therapy immediately or postpone until the start delay expires.
- Patient Name — As entered on the Patient Details screen.
- Patient ID — As entered on the Patient Details screen.
- De-ID — De-identified ID, an anonymous identifier assigned to the patient for use when confidentiality is required, as entered on the Patient Details screen.
- Serial Number — Generator serial number.
- Home/Back Button — Select button to access the Home screen or the previous screen visited.
- Exit Button – Select this button to return to the Start screen.

Models 3024 and 3028



Model 3150

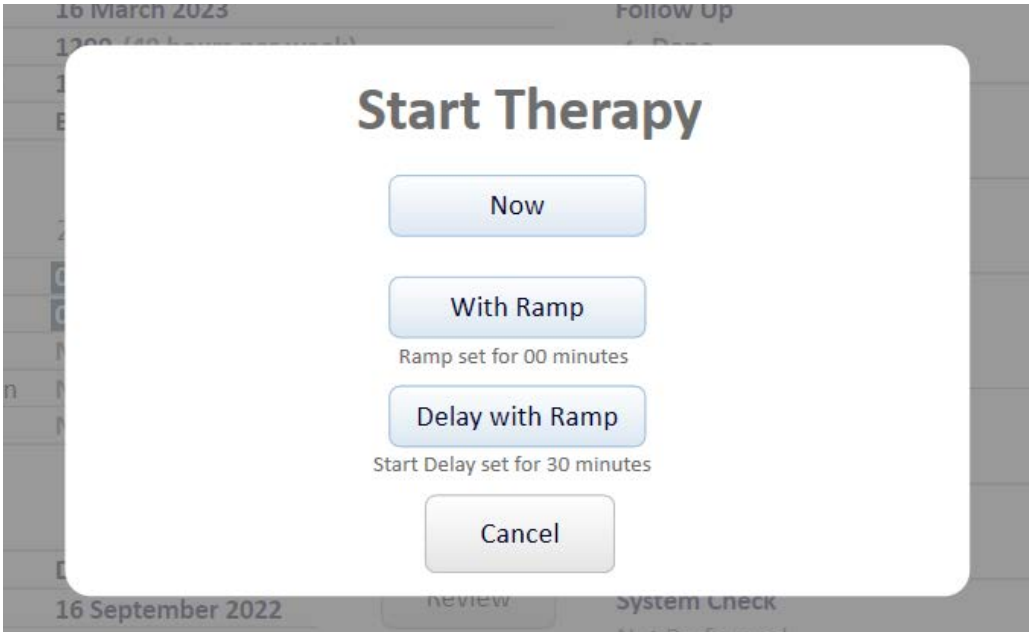


Figure 5-2. Start Therapy Screen

Screen Footer Information

All programmer screens also display common information in the screen footer (Figure 5-3):

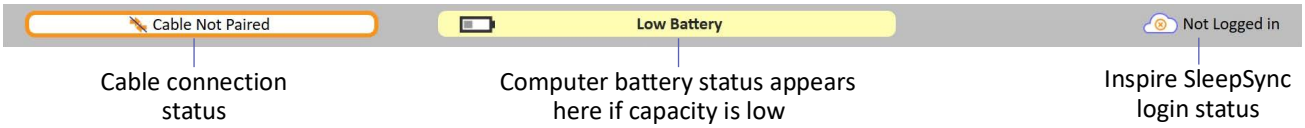


Figure 5-3. Start Screen Footer Information

Cable Connection Status

The cable connection status displays one of the following messages in the lower-left corner of all programming screens (see Figure 5-3).

- Connected to Cable — Wireless link between your computer and programmer cable is established. Status background color is white with a blue border. Programmer cable controller status light is fully lit. Connection buttons are enabled.
- Searching for Cable — Wireless link between your computer and programmer cable is not established. Status background color is white with a gray border. Programmer cable controller status light is partially lit. Communication buttons are disabled.
- Cable Not Paired — A cable is not paired. Status background is white with an orange border.
- Demo Mode — Wireless link between your computer and programmer cable is not active, but the SleepSync Programmer Application may be used for demonstration. Status background color is pink.

Computer Battery Status

The SleepSync Programmer Application displays one of the following messages in the bottom-center of all screens if your computer battery is low or depleted.

- Battery Low — Your computer's battery is nearing depletion and should be connected to power supply soon.
- Recharge Battery — Your computer must be attached to a power supply to prevent a shutdown.

SleepSync Programmer Application Login Status

The user's SleepSync Programmer Application login status displays in the lower-right corner of all programming screens as follows:

- Logged in
- Not logged in

Start Screen

Figure 5-4. Start Screen

The buttons on the Start Screen (Figure 5-4) are described in Table 5-1.

Table 5-1. Start Screen Button Descriptions

Button	Description
Connect to Generator	• Starts a programming session with a generator. • Accesses the Home screen and all session activities. **Note:** Button is disabled until a connection with the programmer cable has been established.
Test Connection	Evaluates communication strength before connecting to the generator and is used to determine best position for programmer cable and head. **Note:** Button is disabled until a connection with the programmer cable has been established.
Reports	• Accesses reports for previous programming sessions. • Reports can be reviewed and saved as PDFs.
Settings	• Accesses the Programmer Settings screen (Figure 5-5). • Allows adjustments to data controls, app size, and number format. • Provides access to system diagnostic tools. • Provides system status information such as serial numbers and software version. • Provides an online link to Inspire manuals.
Demo	• Starts a practice programming session. • Makes it possible to practice using the SleepSync Programmer Application with a simulated generator when no patient is present.
Close App	Closes the SleepSync Programmer Application.
Programmer Cable Lights Mode	Day mode uses full lighting. Night mode turns visible lights off and activates infrared lighting.
Log out Log in	Button label changes depending on user's login/logout status of Inspire SleepSync and enables the user to login or logout.
Cable Connection Status	• Displays the Cable Status Screen (Figure 5-6), which provides status information on pairing and the Bluetooth connection with the programmer cable. • Allows pairing of a new programmer cable.

Programmer Settings Screen

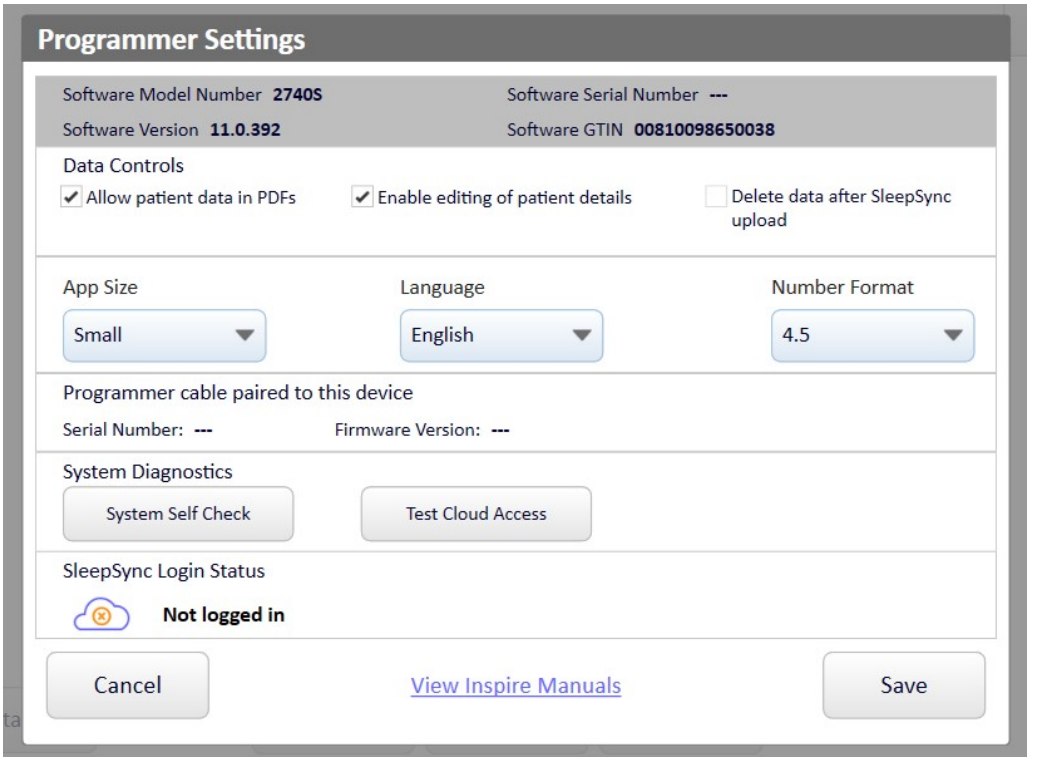


Figure 5-5. Programmer Settings Screen

The Programmer Settings screen (Figure 5-5) allows you to view the programmer information, modify App Size and Number Format, and includes a link for viewing Inspire User Manuals (see “Adjusting the Programmer Settings” on page 26 for more information):

- System Information
  - Software Model Number
  - Software Version
  - Software Serial Number
  - Software GTIN
- Data Controls
  - Allow patient data in PDFs
  - Enable editing of patient details
  - Delete data after SleepSync upload
- App Size
  - Select Full Screen, Medium, or Small
- Language (currently only available in English)
- Number Format
- Programmer Cable Paired to This Device
  - Serial Number
  - Firmware Version
- System Diagnostics
  - System Self Check
  - Test SleepSync Access
- SleepSync Login Status (User ID of the logged-in user)
- View Inspire Manuals hyperlink

Cable Status Screen

The Cable Status screen communicates whether a programmer cable is paired to the SleepSync Programmer Application and whether an active Bluetooth connection exists with that cable. The Cable Status screen also allows for the pairing of a new programmer cable. Only pair if you do not want to use the currently paired programmer cable any more.

Note: The cable serial number is printed on the back of the controller.

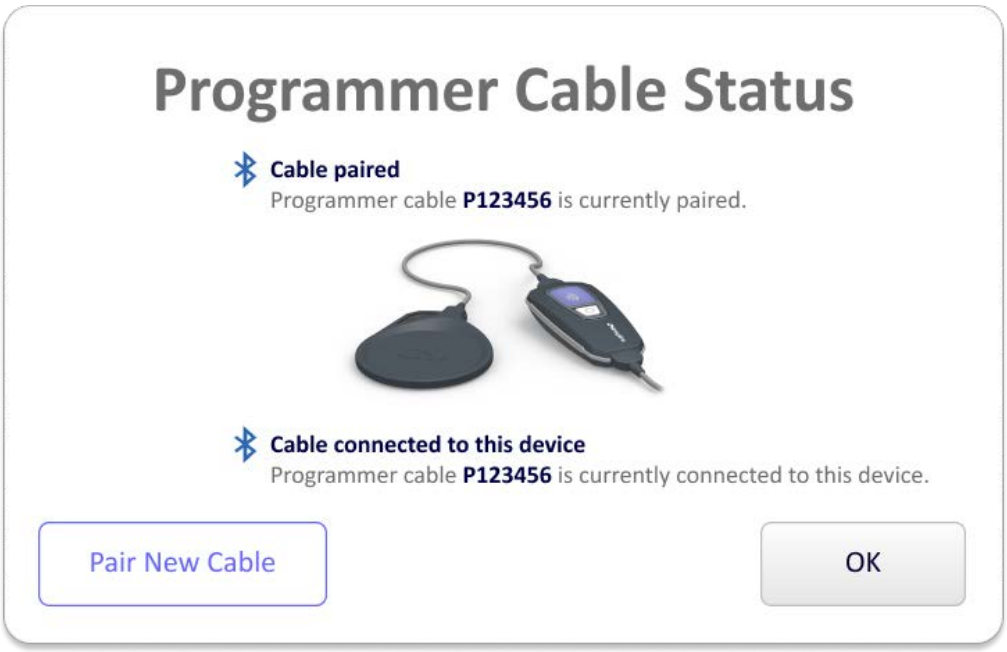
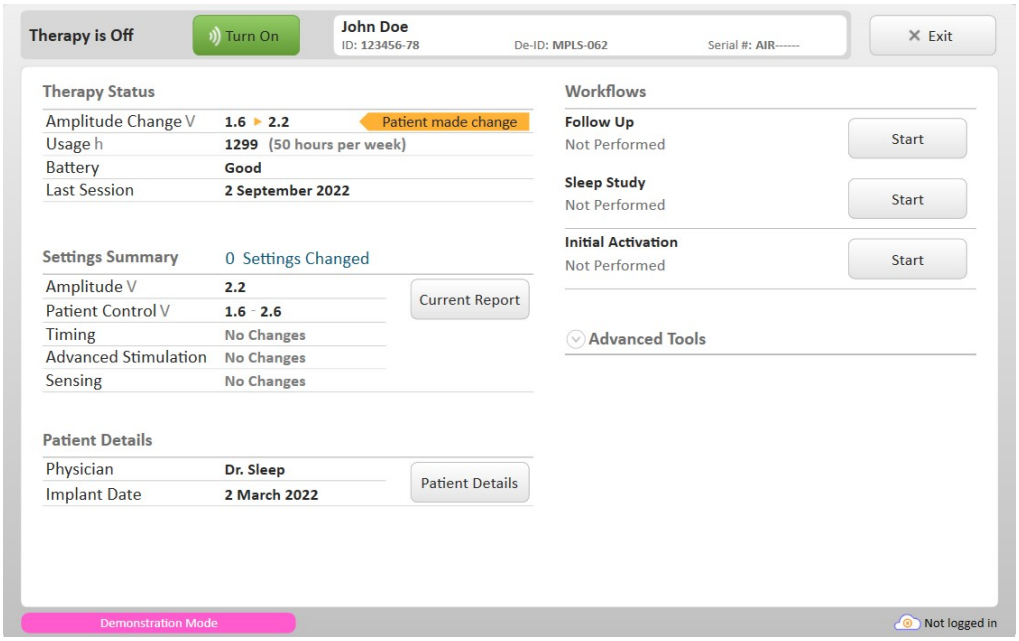


Figure 5-6. Cable Status Screen

Note: The cable will occasionally require firmware updates. When prompted, follow the directions to update the firmware on the cable. It is recommended to perform firmware updates immediately as programming may not be possible without updated cable firmware.

Home Screen

Models 3024 and 3028



Model 3150

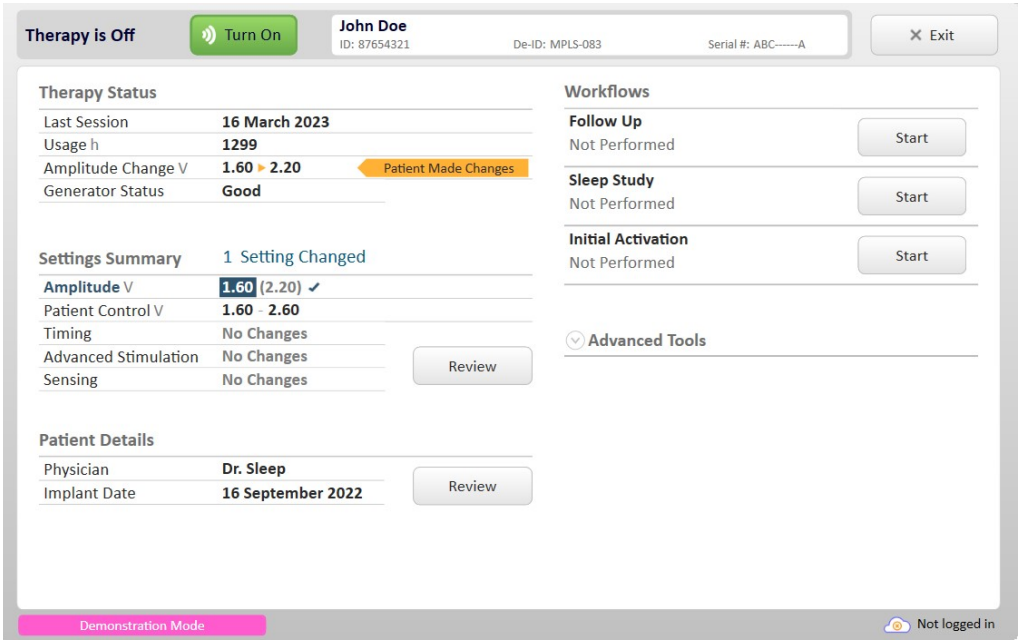


Figure 5-7. Home Screen

The Home screen (Figure 5-7) is divided into five sections:

- Therapy Status
- Workflows
- Settings Summary
- Patient Details
- Advanced Tools

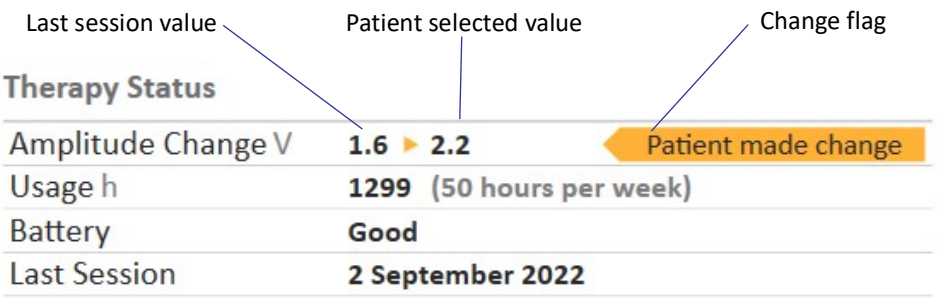
Therapy Status

It is important to review this information at the start of each session.

- Amplitude Change — Displays No Patient Change when the patient has not changed the therapy amplitude set during the last session.

  If the patient has changed the therapy amplitude since the last session, both the last session value and the new patient-selected value display along with a orange change flag as shown in Figure 5-8.
- Usage — The number of hours Inspire therapy has been used since the last programming session. The average usage per week also displays in parentheses.
- Battery — 3024 and 3028 only. The generator battery has three status values: Good, Low, and Depleted. If the battery status displays Low or Depleted, the physician should plan to replace the patient's generator.
- Generator Status— 3150 only. This can display a variety of values: Battery Good, Battery Low, Battery Depleted or Fail. If the battery status displays Low or Depleted, the physician should plan to replace the patient's generator. If the generator check has failed, you would have seen the Generator Check Screen, see Figure 6-2 on page 82.
- Last Session — The date of the most recent programming session.

Models 3024 and 3028



Model 3150

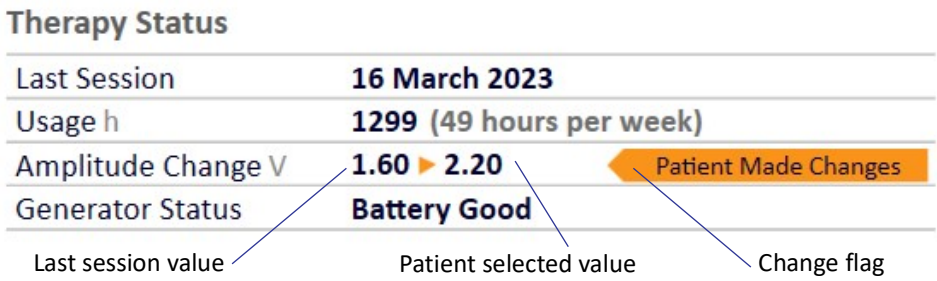


Figure 5-8. Patient Therapy Status

Workflows

This section provides access to guided clinical activities that may be performed during a session and displays the status of those activities for the current session.

The workflow activities performed are determined by the clinician. The activities do not need to be performed in any specific order, and the programmer has no requirements for how many activities are performed in a session.

Follow up

- Button accesses the Follow Up screen which guides the user through adjusting settings to improve comfort or efficacy. See “Follow Up” on page 96 for more information.
- Status Indicators:
  - Not Performed indicates activity has not been started (Figure 5-9).
  - Started indicates the Follow Up workflow has been started but not fully completed.
  - Done with a check mark indicates activity has been completed.

Sleep Study

- Button accesses the Sleep Study workflow which guides the user through relevant activities and records any setting changes made. See “Sleep Study” on page 108 for more information.
- Status Indicators:
  - Not Performed indicates activity has not been started.
  - Started indicates the Sleep Study workflow has been started but not fully completed (Figure 5-9).
  - Done with a check mark indicates activity has been completed.

Initial Activation

- Button accesses the Initial Activation workflow which guides the user through activities to be performed when a patient’s therapy is first activated after implant. See “Initial Activation” on page 90 for more information.
- Status Indicators:
  - Not Performed indicates activity has not been started.
  - Started indicates the Initial Activation workflow has been started but not fully completed.
  - Done with a check mark indicates activity has been completed (Figure 5-9).

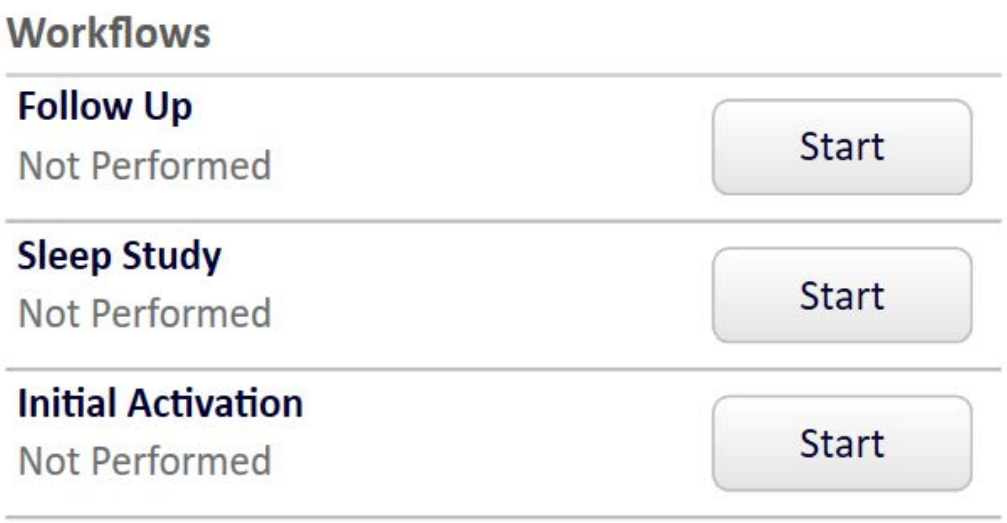


Figure 5-9. Action Status Indicators

Settings Summary

A summary of the settings, that are configured to the generator, display in this section of the Home screen. The following items are displayed here.

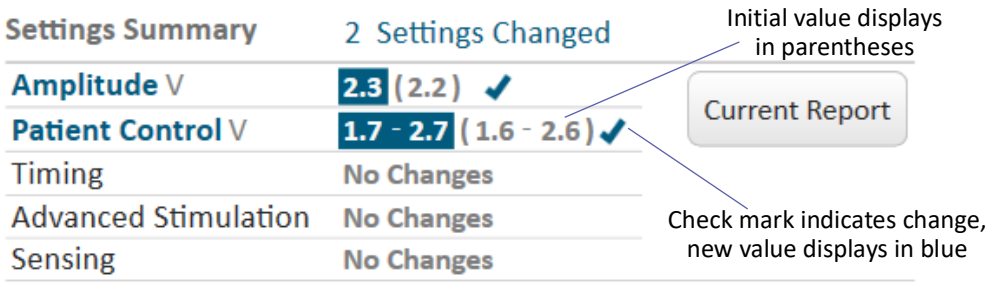
- Amplitude
- Patient Control
- Timing — The number of timing settings that have been changed during the session.
- Advanced Stimulation — The number of advanced stimulation settings that have been changed during the session.
- Sensing — The number of sensing settings that have been changed during the session.

(See Table 1-2 on page 3 and Table 1-3 on page 4 for an explanation of these terms.)

When settings change during a session, the values on the Home screen update and a blue setting value and check mark indicates the setting has changed (Figure 5-10). Initial values from the start of the session are displayed in gray and in parentheses.

Data from the current session can be viewed at any time by selecting the **Current Report** button for Model 3024 and 3028 generators and the **Review** button for Model 3150 generators which accesses the Reports screen (see Figure 5-25).

Models 3028 and 3024



Model 3150

Figure 5-10. Status Indicators for Settings Summary

Patient Details

The physician's name and implant date display in this section of the Home screen if that information has been entered on the Patient Details screen.

Patient information can be updated at any time by selecting the **Patient Details** button for Models 3024 and 3028 and the **Review** button for Model 3150. These buttons access the Patient Details screen (see the following section).

Advanced Tools

This option is hidden by default. When the dropdown arrow is selected, three additional activities are available to the user if desired.

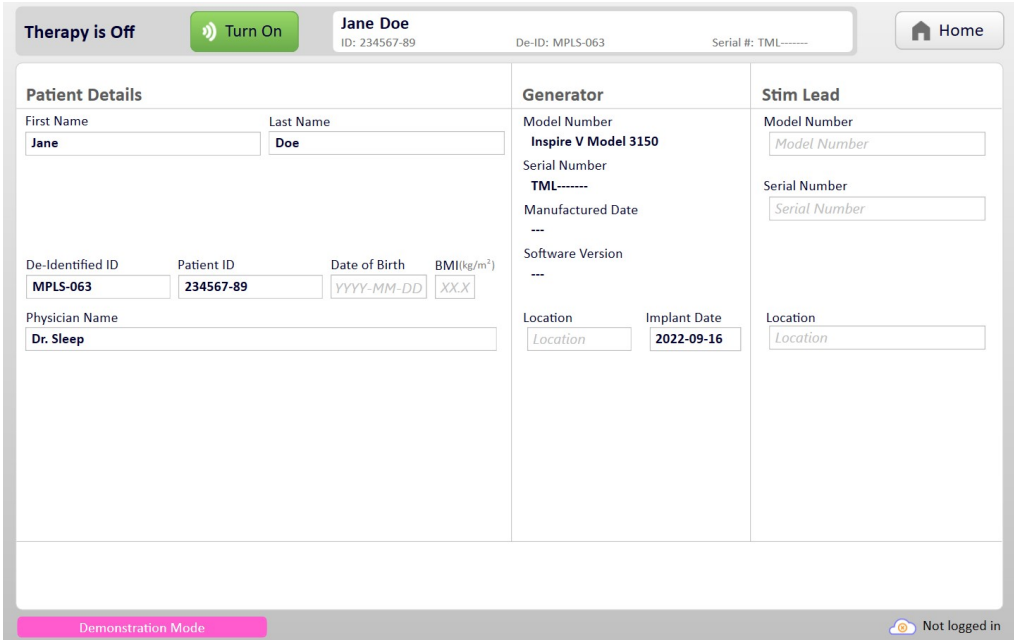
Adjust Stimulation
See "Adjust Stimulation Screen" on page 51.

Adjust Sensing
See "Adjust Sensing Screen" on page 59.

System Check
- Button accesses the System Check workflow, which guides the user through troubleshooting activities. See "Start System Check (Advanced Tools) Workflow" on page 81 for more information.
- Status Indicators:
  - Not Performed indicates activity has not been started.
  - Started indicates the System Check workflow has been started but not fully completed.
  - Done with a check mark indicates activity has been completed.

Patient Details Screen

Models 3024 and 3028



Model 3150

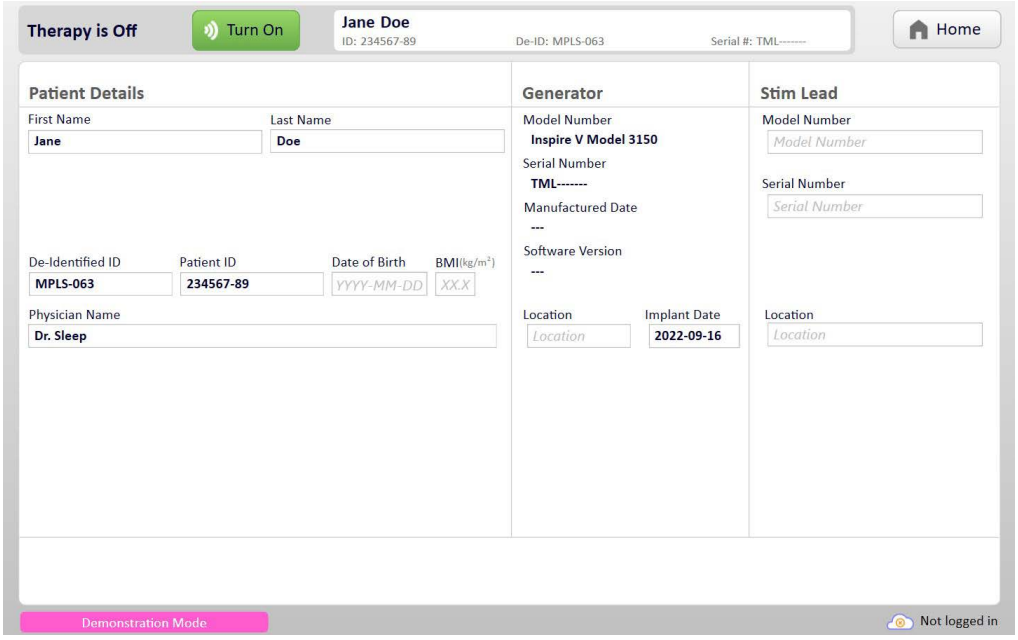


Figure 5-11. Patient Details Screen

Access the Patient Details screen (Figure 5-11) from the Home screen.

- Select any field to enter or edit patient information.
- Select the **Save** button to save updated patient information and return to the Home screen for Models 3024 and 3028.
- Select the **Cancel** button to reject changes made to patient information and return to the Home screen without saving for Models 3024 and 3028.
- Select the **Home** button to return to the Home screen.

Notes:

- Any changes made on this screen will be made active when returning to the Home screen.
- The information entered on this screen is not stored in the generator. Uploading the patient to Inspire SleepSync will allow this information to be present on multiple programmers. Otherwise, patient information will need to be entered on each programmer.
- The ability to edit the First Name, Last Name, Patient ID, and Date of Birth fields is controlled from the Programmer Settings screen (**Enable editing of patient details**).

On-Screen Keyboard

For touchscreen devices only, the standard Windows on-screen keyboard is enabled when you select an editable field.

Patient Details Information Fields

- First Name — Enter the patient's first name.
- Last Name — Enter the patient's last name.
- Date of Birth — Select the patient's date of birth.
- De-Identified ID — Enter the anonymous identifier. This will be the only patient information included on de-identified reports.
- Patient ID — Enter a patient identifier, such as a medical record number.
- Physician Name — Enter the name of the physician responsible for the patient.
- Implant Date — Enter the date that the patient's generator was implanted.
- Location — Enter the location of the generator in the body.
- Stim Lead Model Number — Enter the model number of the stimulation lead.
- Stim Lead Serial Number — Enter the serial number of the stimulation lead.
- Stim Lead Location — Enter the location of the stimulation lead electrodes in the body.

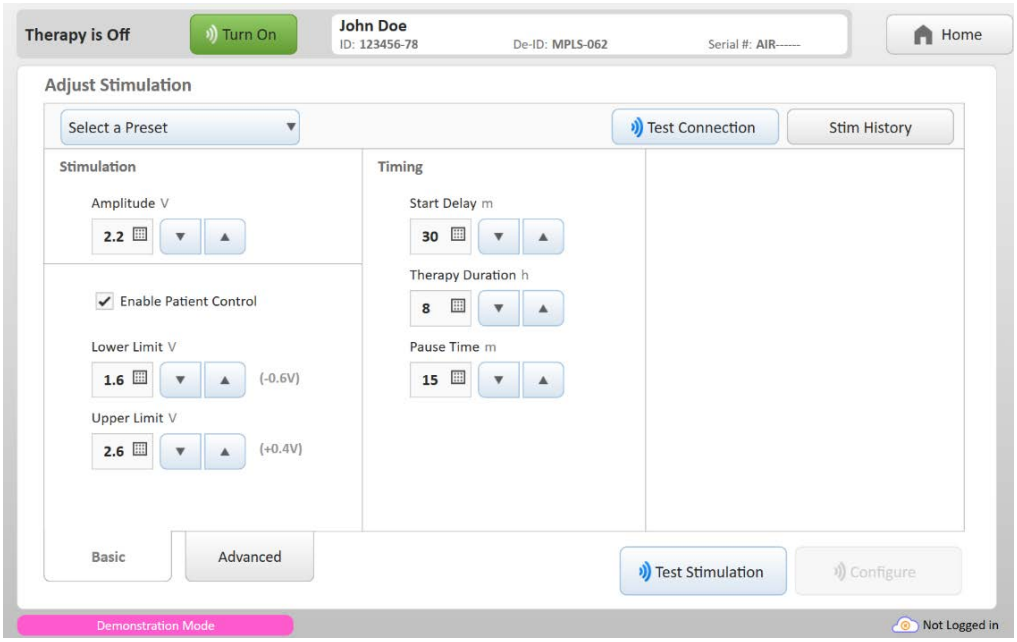
Sense Lead information—only applicable for Models 3024 and 3028

- Sense Lead Model Number — Enter the model number of the sensing lead.
- Sense Lead Serial Number — Enter the serial number of the sensing lead.
- Sense Lead Location — Enter the location of the sensor in the body.

Adjust Stimulation Screen

The Adjust Stimulation screen is used to modify and test stimulation settings (Figure 5-12). The setting values initially displayed on the screen are the values currently in use by the generator. When setting values are changed and differ from the current generator settings, the fields are highlighted in blue (Figure 5-13). Selecting the **Configure** button will configure the generator with the highlighted values and clear the highlighting.

Models 3024 and 3028



Model 3150

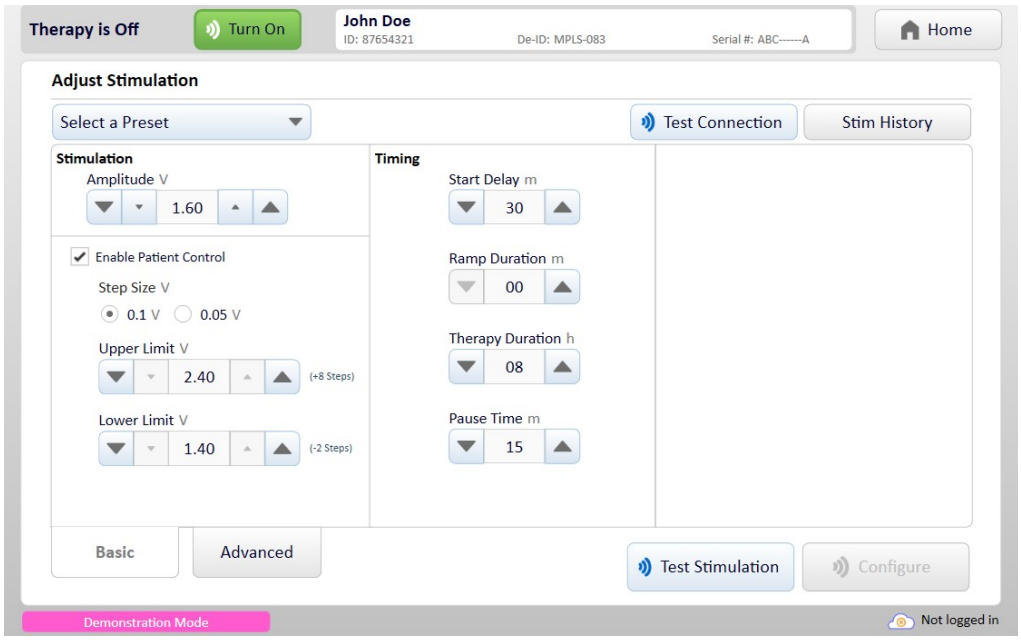


Figure 5-12. Adjust Stimulation Screen, Basic View

Basic Screen View

The basic screen view divides the settings into two sections: stimulation and timing.

Stimulation

- Use the arrow buttons to increase or decrease amplitude values.

  Note: Model 3150 enables the clinician to increase or decrease values by 0.025 V, 0.05 V or 0.1 V depending on the chosen electrode options. Use the smaller arrows to adjust by smaller increments.

  Patient Control Settings

  – Select the Enable Patient Control box to allow (check) or disallow (uncheck) patients to adjust amplitude within a predetermined range.

  – Use the arrow buttons to set the upper and lower limits of this range. To visualize prospective new settings, click the upper or lower limit numbers. This will show all possible values with the configured stimulation value shown in yellow. See Table 5-2.

  – When Patient Control is enabled, changing the amplitude value will cause the upper and lower limit values to change as well, tracking the amplitude value.

  – The values displayed in parentheses next to the upper and lower limits indicate the relative value, or difference, between the amplitude value and the limit value.

  – Review flags indicate that the patient has changed the amplitude value, and thus the amplitude values should be reviewed.

  Notes:

  - The current amplitude range is shown underneath the heading in Table 5-2. The new amplitude range won't take effect until the generator is configured.
  - The number of levels in the Patient Control range affects the behavior of the Patient Sleep Remote amplitude gauge as shown in Table 5-2. If the range is less than the 11 bars shown on the remote, the upper limit symbol will light up before all bars are used. If the range is greater than the 11 bars shown on the remote, the control range will be scaled across all 11 bars.

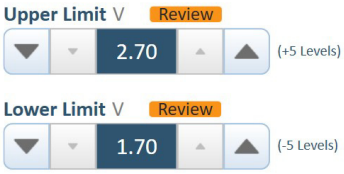
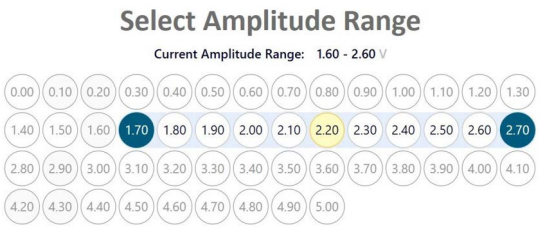
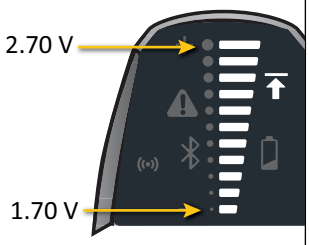
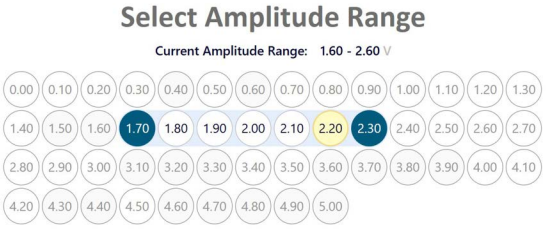
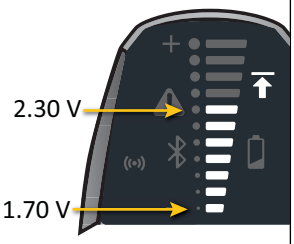
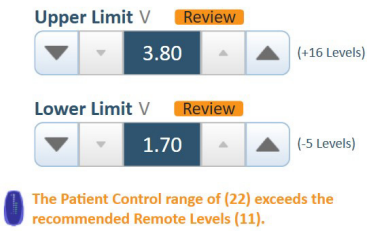
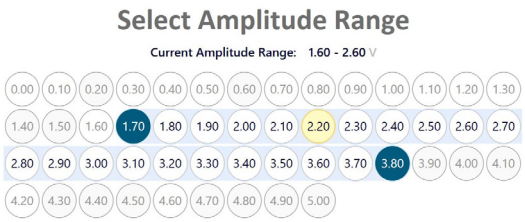
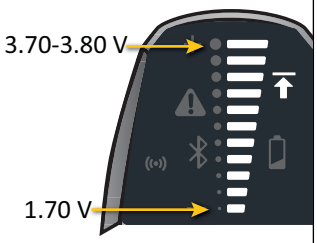
Timing

Use the arrow buttons to increase or decrease the following timing settings.

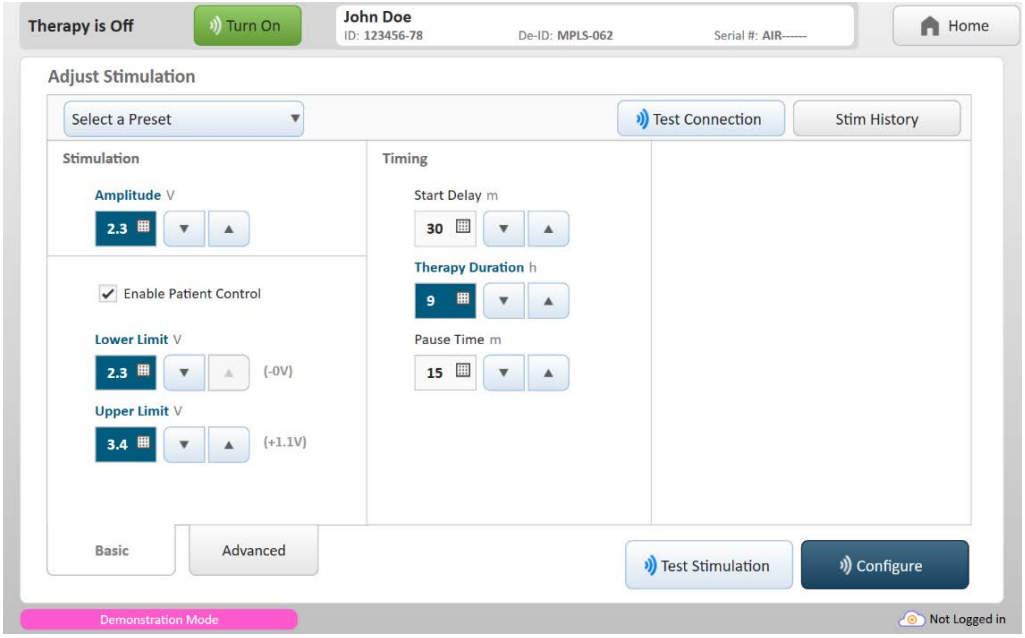
- Start Delay
- Ramp Duration (3150 only)
- Therapy Duration
- Pause Time

See Table 1-2 on page 3 for definitions of these terms.

Table 5-2. Visualization of Patient Control Range and Effects on Remote

	Programmer View	Range	Remote
11 Levels			
	The Sleep Remote will use all 11 bars to display 1.70 at the lowest bar and 2.70 at the highest		
<11 Levels			
	The Sleep Remote will use only 7 bars to display 1.70 at the lowest bar and 2.30 at the highest. The remaining bars will not be utilized.		
>11 Levels			
	The Sleep Remote will use all 11 bars to display 1.70 at the lowest bar and 3.8 at the highest. The Sleep Remote cannot display all possible amplitude values. Instead, the Patient Control Range will be scaled across all 11 bars.		

Models 3024 and 3028



Model 3150

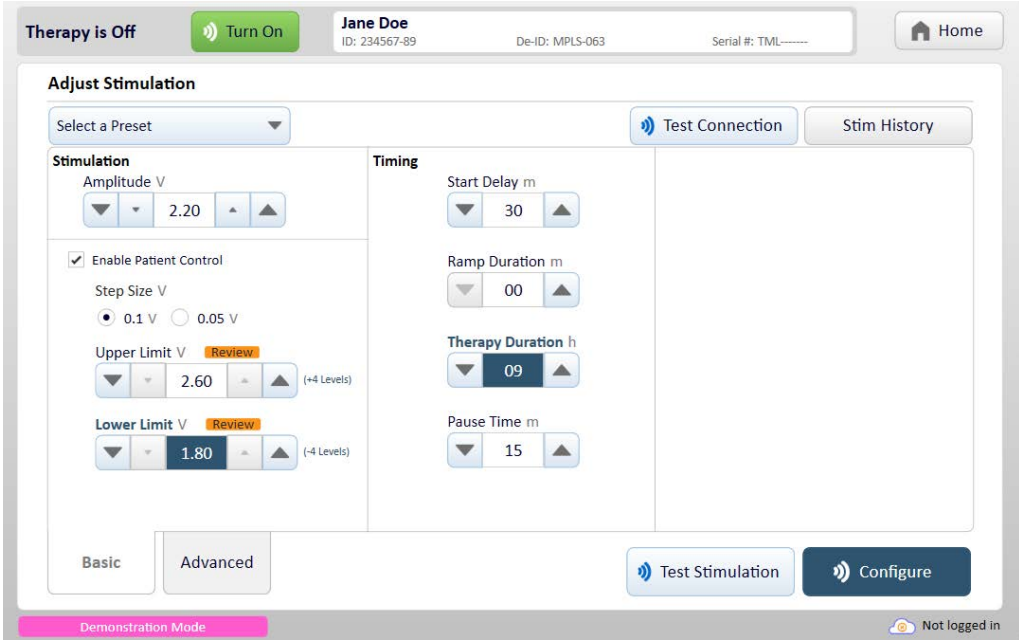


Figure 5-13. Changed Settings on Adjust Stimulation Screen

Programming Buttons

Test Stimulation

- The **Test Stimulation** button requires that the programmer cable is connected. Confirm connection by checking the cable connection status in the screen footer (Figure 5-3).
- Select the **Test Stimulation** button to test the displayed settings, which may differ from those currently configured in the generator. Testing stimulation will not change the current generator settings.
- During test stimulation, the generator delivers stimulation for the duration of the maximum stimulation time.
- It is recommended to test stimulation with the therapy off.

The Test Stimulation button is disabled until a connection to the programmer cable is established.

Configure

Select the **Configure** button to configure the generator with all displayed settings that differ from the current generator settings.

It is important to note that if the **Configure** button is not pressed before leaving this screen, the setting changes will not be saved to the generator.

Notes:

- The Configure button requires that the programmer cable is connected. Confirm connection by checking the cable connection status in the screen footer (Figure 5-3)
- The Configure button is enabled when changes are made to the settings currently in use by the generator.
- After selecting the **Configure** button, the highlighting is cleared because the displayed values now match the newly configured generator settings.
- When therapy is turned on or setting changes are made with the therapy on, the generator needs approximately 1–3 minutes to resynchronize with respiration. For this reason, it is recommended to make changes only after observing therapy performance for 3–5 minutes.

The Configure button is disabled until a connection to the programmer cable is established.

Select a Preset

Use the **Select a Preset** button to change stimulation settings to one of the following:

- Initial Session Settings — Selects the generator stimulation settings from the start of the current programming session.
- Current Generator Settings — Selects the stimulation settings currently in use by the generator.

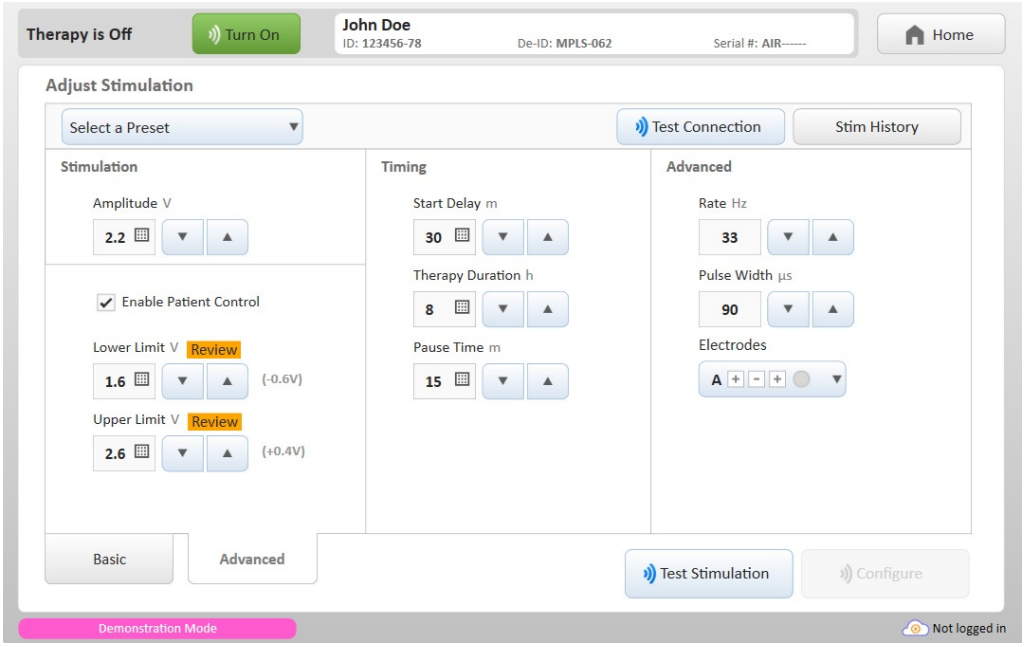
  Note: Selecting the Current Generator Settings preset clears all highlighting.
- Default Settings — Selects the default stimulation settings. See “Default Settings” on page 132 for more information.

Stim History

Select the **Stim History** button to access stimulation levels and settings stored in the programmer from earlier in the session or from previous sessions.

Advanced Screen View

Models 3024 and 3028



Model 3150

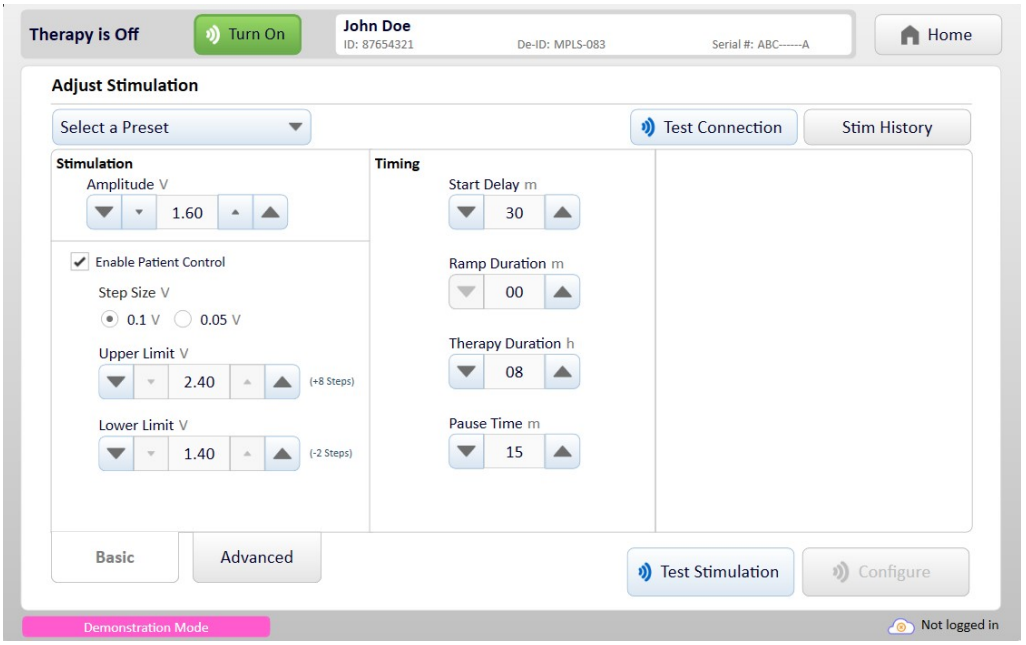


Figure 5-14. Adjust Stimulation Screen, Advanced View

To modify advanced stimulation settings, select the **Advanced** tab at the bottom of the screen.

- Use the arrow buttons to increase or decrease the following settings.
  - Start Impulse % (3150 only)
  - Rate
  - Pulse Width
  - Electrode

See Table 1-2 on page 3 for definitions of these terms.

- Select the **Test Stimulation** button to test the settings displayed on the screen.
- Select the **Configure** button to configure the generator with all displayed settings that differ from the current generator settings.

Electrode
Select the **Electrode** button to change the location at which stimulation is delivered.

Electrodes are used to deliver stimulation to the patient. There are three electrodes in the Inspire system: two on the lead and one integrated into the generator case. (The two outer lead electrodes work together as one.)

The two lead electrodes are designed so that one center electrode is placed between the outer electrode (Figure 5-15).

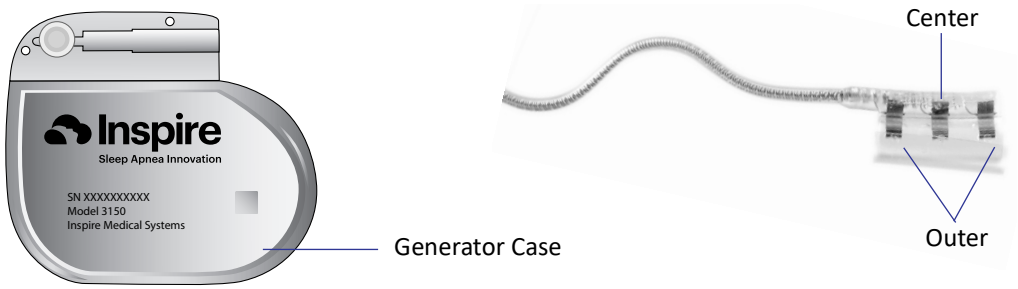


Figure 5-15. Inspire System Electrodes

Icons are used on the **Electrode** button to indicate the polarity of all system electrodes. For example, the default electrode is shown in Figure 5-16.

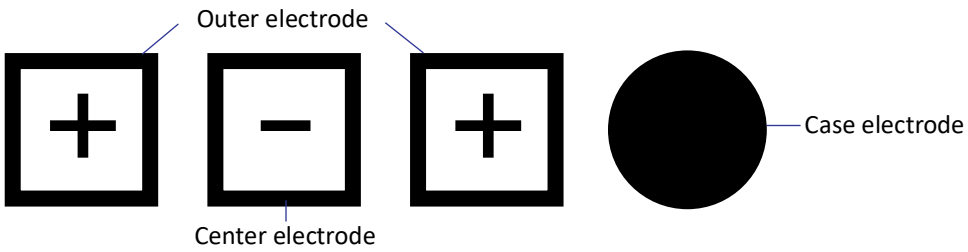


Figure 5-16. Default Electrode Configuration

In this configuration, the three square lead electrode icons indicate that the outer electrode is positive and the center electrode is negative. The round, filled-in case electrode indicates that the electrode is off and not used in this configuration.

See Table 1-4 on page 5 for more information about these icons.

There are five electrode options to choose from, starting with A (default) and moving to E (least used). See Table 5-3.

Table 5-3. Electrode Options

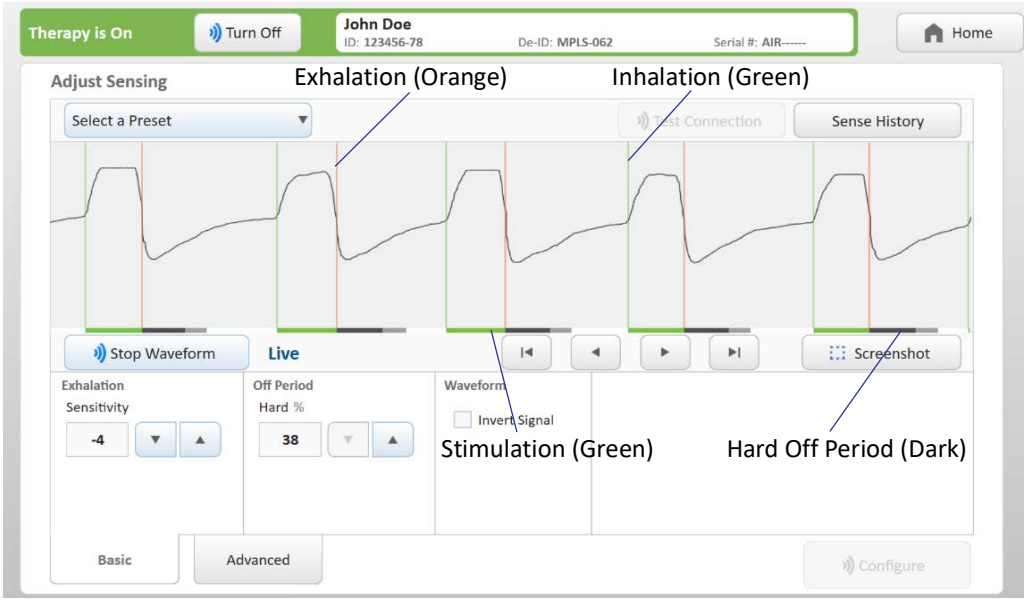
A	 **Default electrode**
B	
C	
D	
E	

Adjust Sensing Screen

The Adjust Sensing Screen (Figure 5-17) allows for real-time evaluation of the respiratory sensor waveform and adjustment of sensing settings. Adjustments to sensing settings can modify when stimulation is delivered during the respiratory cycle.

The setting values initially displayed on the screen are the values currently in use by the generator. When setting values are changed and differ from the current generator settings, the fields are highlighted in blue. Selecting the **Configure** button will configure the generator with the highlighted values and clear the highlighting.

Models 3024 and 3028



Model 3150

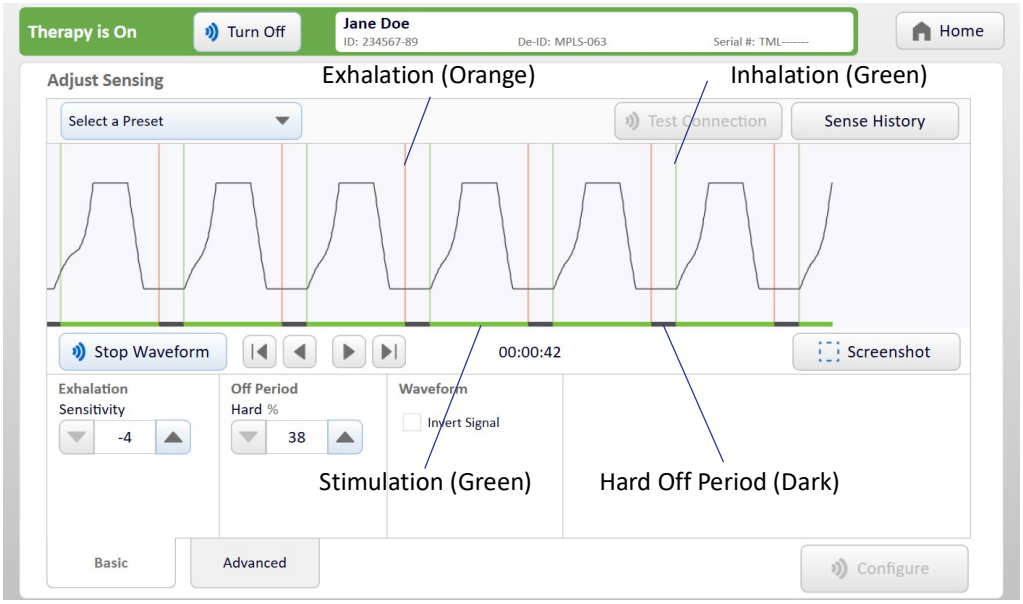


Figure 5-17. Adjust Sensing Screen, Basic View

Basic Screen View

Use the arrow buttons to increase or decrease the following sensing settings.

- Exhalation Sensitivity
- Hard Off Period

Select the Invert Signal box to invert the sensor signal before it is processed.

See Table 1-3 on page 4 for more information about the terminology and settings used on this screen.

Programming Buttons

The programming buttons on the Adjust Sensing screen are disabled until a connection to the programmer cable is established.

Start Waveform

- Select this button to start the generator waveform mode, during which the generator sends real-time data that is graphed on the programmer.

  Notes:

  - Starting the waveform will turn therapy on at the current generator settings. Models 3024 and 3028 will automatically change the amplitude to 0.1 V if the amplitude is 0 V. Model 3150 will turn on and generate a waveform even if the amplitude is 0 V.
  - If the generator is in start delay, ramp, or pause, the programmer will automatically start therapy at the configured amplitude.
  - When therapy is turned on or setting changes are made with the therapy on, the generator needs approximately 1–3 minutes to resynchronize with respiration. For this reason, it is recommended to make changes only after observing therapy performance for 3–5 minutes.

- The **Stop Waveform** button stops the waveform. If therapy was on when the waveform started, therapy will remain on. If therapy was off when the waveform was started, therapy will turn off.
- Select the left and right arrow buttons to scroll through the waveform. Select the left and right arrow buttons with a solid bar to jump to the beginning or end of the waveform.

Screenshot

Select this button to save an image of the displayed waveform in the session report and to access the Screenshot Screen (Figure 5-18).

- Choose one or more of the following optional labels to include with the waveform screenshot: sleep type, position, and polarity.
- Select the **Clear Selections** button to remove label selections.
- Select **Cancel** button to return to Adjust Sensing screen without saving the waveform.
- Select **Save** button to add an image of the waveform and any selected labels to the session report.

Note: The **Screenshot** button is disabled until the **Start Waveform** button has been selected.

Models 3024 and 3028

Model 3150

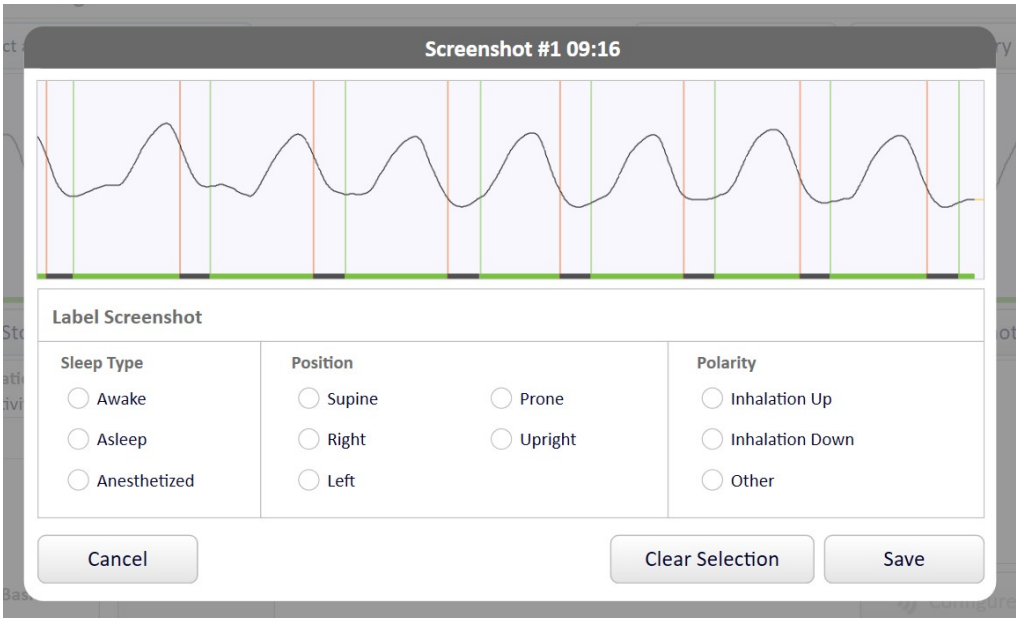


Figure 5-18. Screenshot Screen

Configure
Select the **Configure** button to configure the generator with all displayed settings that differ from the current generator settings.

It is important to note that if the **Configure** button is not pressed before leaving this screen, the setting changes will not be saved to the generator.

Notes:
- The Configure button requires that the programmer cable is connected. Confirm connection by checking the cable connection status in the screen footer (Figure 5-3).
- The Configure button is enabled when changes are made to the settings currently in use by the generator.
- After selecting the **Configure** button, the highlighting is cleared because the displayed values now match the newly configured generator settings.
- When therapy is turned on or setting changes are made with the therapy on, the generator needs approximately 3 minutes to resynchronize with respiration. For this reason, it is recommended to make changes only after observing therapy performance for 3–5 minutes.

Select a Preset
Use the **Select a Preset** button to change sensing settings to one of the following:

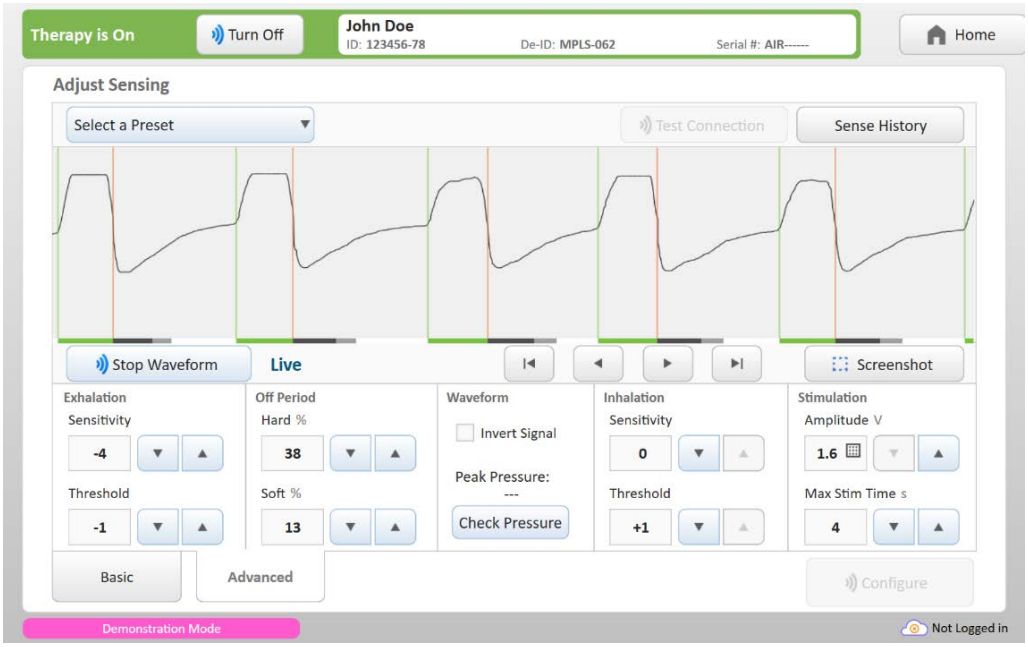
- Initial Session Settings — Selects the generator sensing settings from the start of the current programming session.
- Current Generator Settings — Selects the sensing settings currently in use by the generator.

  Note: Selecting the Current Generator Settings preset clears all highlighting.
- Default Settings — Selects the default sensing settings (see “Default Settings” on page 132 for more information).

Sense History
Select the **Sense History** button to access sensing settings stored in the programmer from earlier in the session or from previous sessions.

Advanced Screen View

Models 3024 and 3028



Model 3150

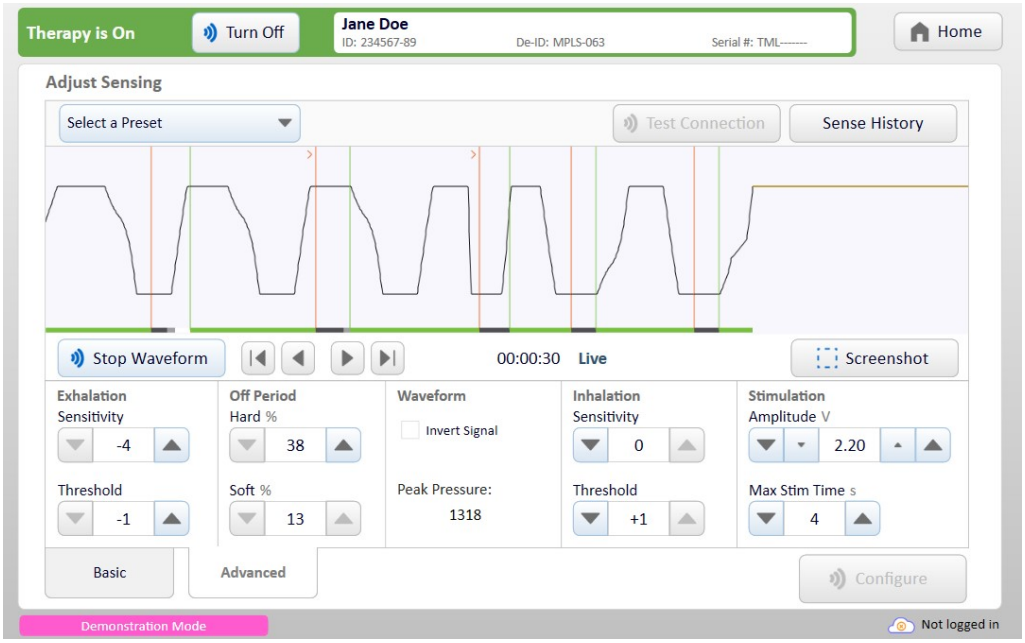


Figure 5-19. Adjust Sensing Screen, Advanced View

To modify advanced sensing settings, select the **Advanced** tab at the bottom of the screen (Figure 5-19).

- Use the arrow buttons to increase or decrease the following settings.
  - Exhalation, Sensitivity and Threshold
  - Off Period, Hard and Soft
  - Inhalation, Sensitivity and Threshold
  - Stimulation Amplitude
  - Max Stim Time
- If the patient has a Model 3024 or 3028 generator, select the **Check Pressure** button to measure the current peak-to-peak sensor pressure. Measurement results are most accurate when the sensing has been allowed to synchronize with the patient's respiration for several minutes.

  Note: This button is enabled only when therapy is on.
- If the patient has a Model 3150 generator, the Peak Signal Level displays automatically.

Patient List Screen

You can access the Patient List screen by selecting the **Reports** button on the Start Screen (Figure 5-4).

You must be logged in to SleepSync to see a complete list of patient data in the Patients tab. If you do not log in to SleepSync, you will only see locally stored patients on your device. Manage uploading patient data to SleepSync from the Upload tab.

The screen is divided into two tabs: Patients and Upload.

Patients Tab

At the top of the tab is a search bar, which you can use to search for a particular patient with their name, ID, De-ID or generator serial number. Results are displayed as you type.

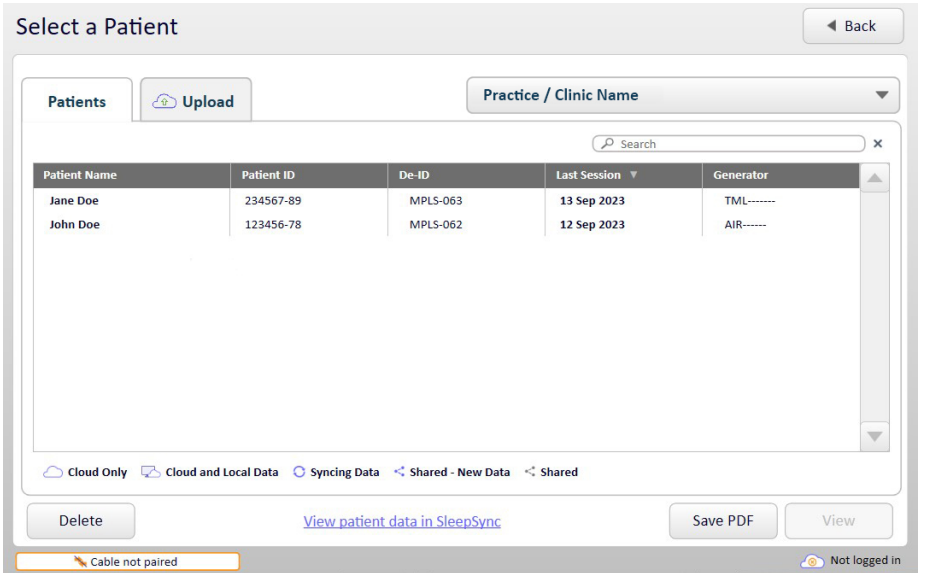


Figure 5-20. Patient List Screen, Patients Tab

Patient name, ID, de-identified ID, date of last session, and generator serial number display for each patient. By default, patients are organized by last session date with the most recent session appearing at the top.

- To reverse the order in which reports display, select the last session column header.
- To sort by another identifier, select a different column header.

Note: Sample patients named John Doe or Jane Doe may appear on this screen and is associated with all demonstration mode reports.

Refer to Table 5-4 for information about the meanings of the icons in the Patient Name column on the Patient List screen.

Note: Icons are only visible if you are logged into SleepSync.

Table 5-4. Patient List Screen, Icons

Icon	Meaning	Icon	Meaning
No icon	The patient information is stored only on your computer.		The patient data is syncing with Inspire SleepSync.
	The patient information is stored only in Inspire SleepSync.		New data from another practice is available.
	The patient information is stored on both your computer and in Inspire SleepSync.		Data is shared with another practice.

Refer to Table 5-5 for information about the functions of the buttons on the Patient List screen.

Table 5-5. Patient List Screen Buttons, Patients Tab

To:	Do This:
View patient	Highlight patient name and select the **View** button to access the Reports screen. **Note:** The **View** button is disabled unless a patient name is highlighted.
Delete locally stored patient report(s)	Highlight patient name and select **Delete** button to display the Delete Report Screen (Figure 5-21). • Specify a date using the arrow buttons to remove all reports saved prior to that date. • Select **Delete** button to confirm that you wish to permanently remove all locally stored reports older than the specified date for that patient. **Notes:** ▸ If a patient name is not highlighted before selecting the **Delete** button, reports for all patients will be deleted. ▸ Data will not be deleted from Inspire SleepSync.

Table 5-5. Patient List Screen Buttons, Patients Tab

Save session reports to PDF	• Highlight patient name and select the **Save PDF** button to display the Save PDF screen (Figure 5-26). • Specify a date using the arrow buttons to save all reports since that date. • Select the information to be included in the PDF by checking one or more of the following boxes: patient information, device information, waveform screenshots, and technical support logs. The Technical Support Logs option is hidden under the Additional Options dropdown menu. • Select **Save PDF** button to save. **Note:** If a patient name is not highlighted before you select the **Save PDF** button, reports for all patients will be saved as PDFs.
View patient data from a different practice	If you belong to more than one practice, select the desired practice from the dropdown menu. Patient data from the new practice will now display.
View patient data in Inspire SleepSync	Select this link to be directed to the Inspire SleepSync web portal. Once you log in, you can search for your patient.

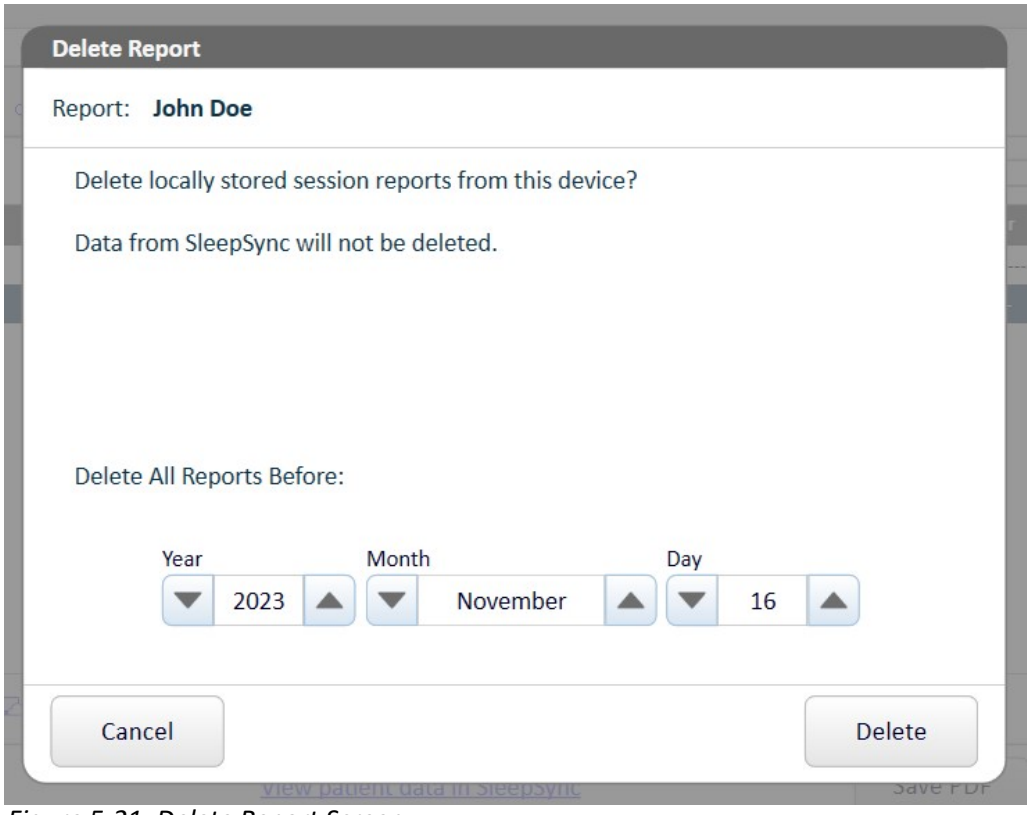


Figure 5-21. Delete Report Screen

Upload Tab

Data available for uploading to Inspire SleepSync will appear in the Upload tab when you are logged into Inspire SleepSync. If there is no data available for uploading, the table will be blank.

Patients will only show up on this list if they do not yet belong to the currently selected practice. There might be data that needs to be uploaded for patients that already belong, but that data will sync in the background.

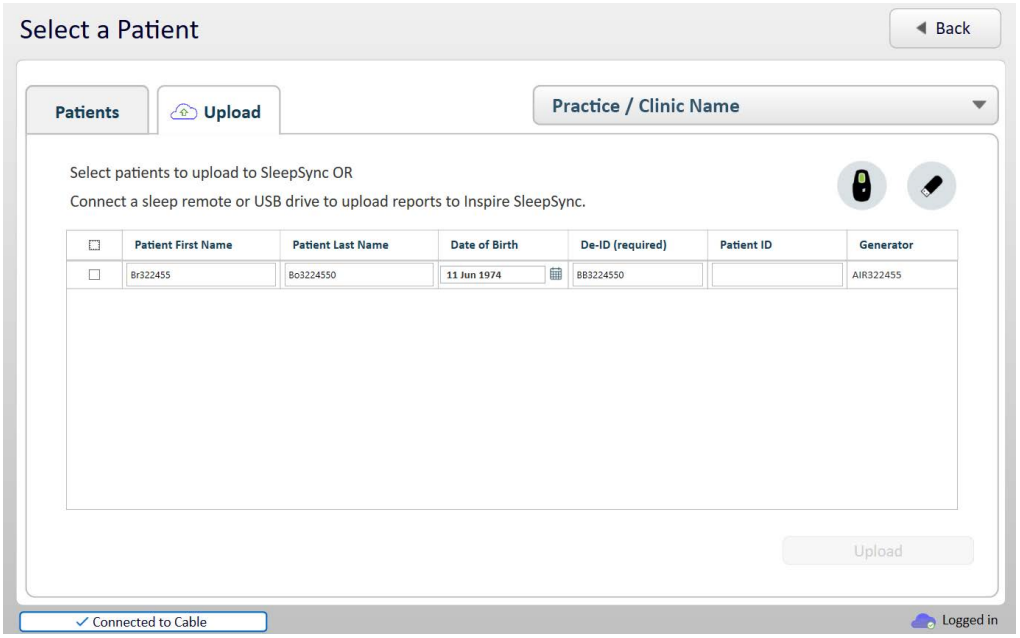


Figure 5-22. Patient List Screen, Upload Tab

Table 5-6. Patient List Screen Buttons, Upload Tab

To:	Do This:
Upload patient data to Inspire SleepSync	• Check the box next to the desired patient, and verify that the De-ID field is filled in. **Note:** De-ID is required. For new patients, you must provide a De-ID. • If desired, edit the patient fields. • Select the **Upload** button. • When the upload is successful, a confirmation message displays. Select **OK** to close the dialog. The first patient data upload must be done manually. After that, the patient's data is uploaded automatically when you are logged into Inspire SleepSync. When a programming session is complete and you are not logged into Inspire SleepSync, you will be asked if you want to upload the patient's data to Inspire SleepSync. • If you are not logged in, you will be prompted to log in first. • Select **Yes** to upload the patient's data to Inspire SleepSync, or select **No** to end the session without uploading the patient's data to Inspire SleepSync.
Upload data to Inspire SleepSync using a patient's Sleep Remote	• Connect the patient's Model 2500 Sleep Remote to your computer with a USB cable. • If the patient has already had data uploaded to the selected practice in Inspire SleepSync, the patient's data will be uploaded automatically. • For patients who have not had data uploaded to the selected practice in Inspire SleepSync, the Upload Patient Data Screen (Figure 5-23) displays. • If desired, edit the patient fields. **Notes:** ▸ De-ID is required. For new patients, you must provide a De-ID. ▸ If you are in a programming session, the Sleep Remote and USB drives will be ignored.
Upload programmer reports to Inspire SleepSync from a USB drive	Data that has been exported from a Model 2740 programmer or saved from the SleepSync Programmer Application onto a USB drive can be uploaded to Inspire SleepSync. • Connect the USB drive to your computer. • If the patient has already had data uploaded to the selected practice in Inspire SleepSync, the patient's data will be uploaded automatically. • For patients who have not had data uploaded to the selected practice in Inspire SleepSync, the Upload Patient Data Screen (Figure 5-23) displays. • If desired, edit the patient fields. **Notes:** ▸ De-ID is required. For new patients, you must provide a De-ID. ▸ If you are in a programming session, the USB connection will be ignored.
Upload patient data to a different practice	If you belong to more than one practice, select the desired practice from the dropdown menu. Patient data will be uploaded to the selected practice.

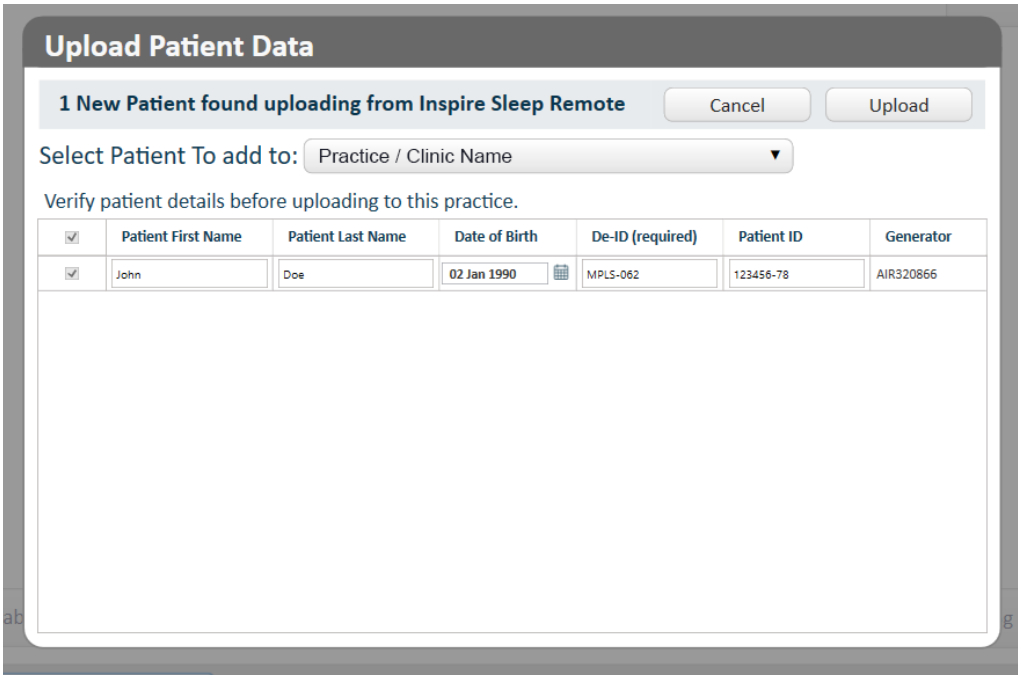


Figure 5-23. Upload Patient Data Screen

If a patient's data is already in the USB reports, the fields will be filled in. Otherwise, the fields will be empty, except the De-ID field, which will be pre-populated but can be edited to fit your practice needs.

Note: The value in the Generator field is added automatically and cannot be changed.

Therapy Report Screen

The Therapy Report Screen (Figure 5-24) shows patient data for patients in Inspire SleepSync only.

- From the Patient List screen, select a patient.
- Select the **View** button.

Notes:

- You must be logged in to Inspire SleepSync to view therapy reports.
- You can scroll down, as shown in Figure 5-24, to view more information.
- Healthcare professionals can also access patient data through the SleepSync Web Portal.

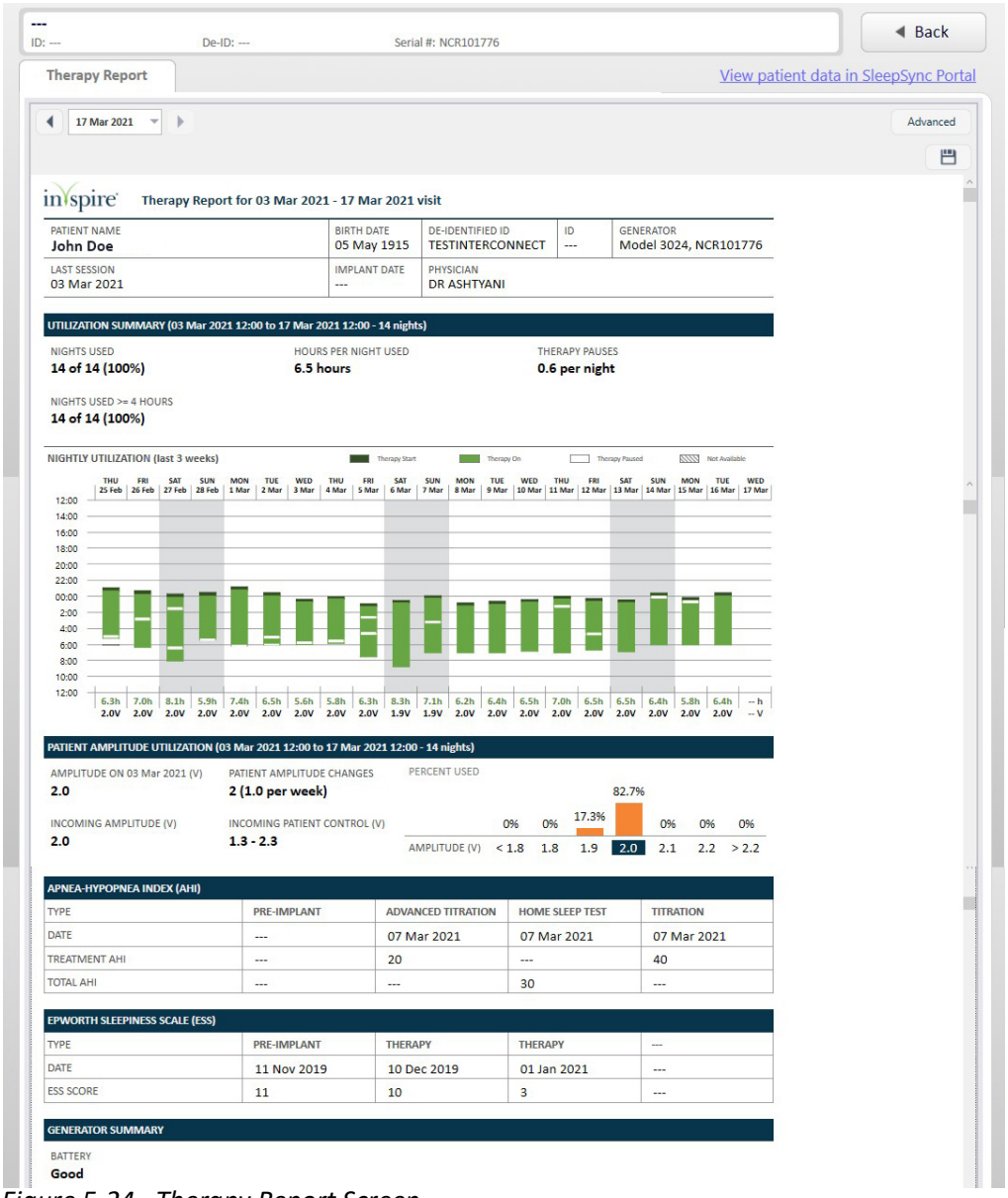


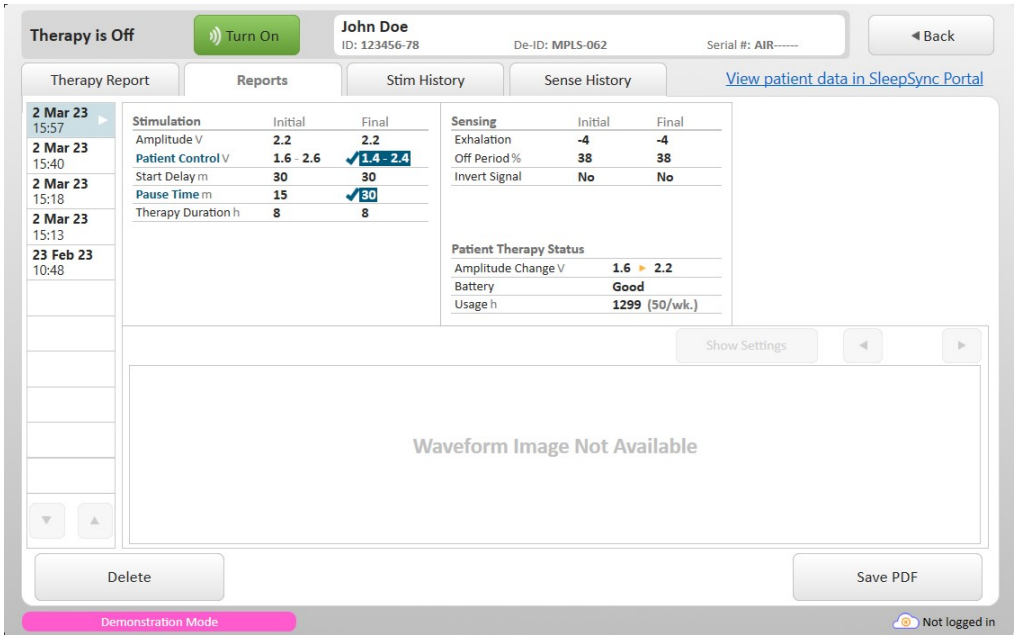
Figure 5-24. Therapy Report Screen

Reports Screen

The Reports screen displays patient data that is on your computer.

Note: If a patient's data is in Inspire SleepSync only, the data does not appear on this screen.

Models 3024 and 3028



Model 3150

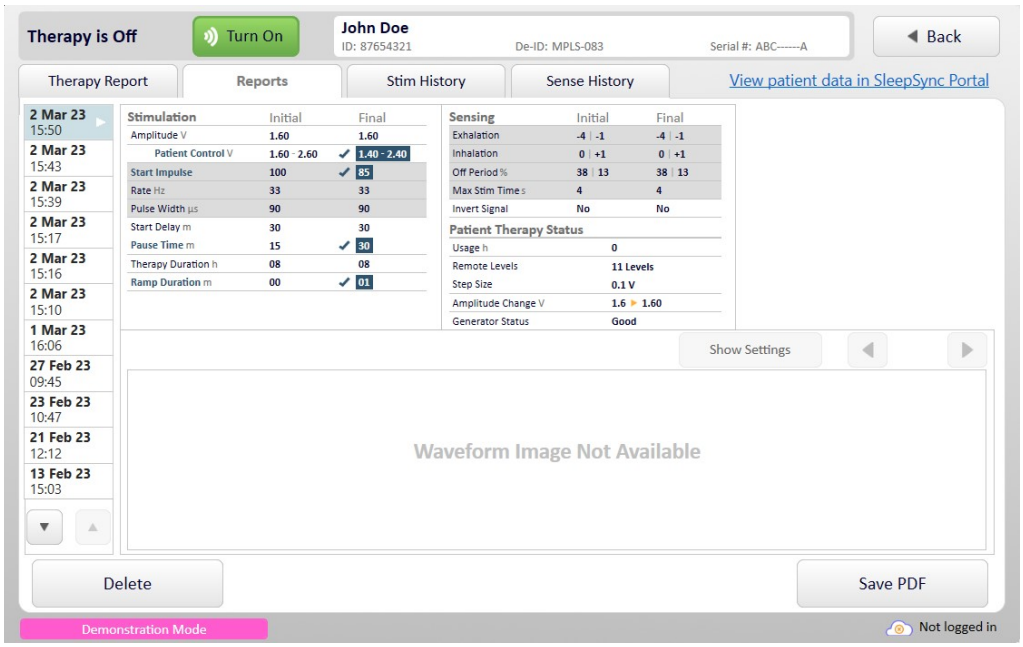


Figure 5-25. Reports Screen

You can access the Reports screen from the Home screen. If the patient has a Model 3024 or 3028 generator, select the **Current Reports** button. If the patient has a Model 3150 generator, select the **Review** button in the Settings Summary section. See Figure 5-10 on page 47. The Reports screen (Figure 5-25), contains all session reports for the current generator which are organized by date and time. You can also access the Reports screen by selecting the **View Patient** button on the Patient List screen.

Each report summarizes the patient therapy status, recorded levels, and stimulation and sensing settings for a given session. Blue highlighted information with a check mark indicates changes made during the session. Advanced settings display only if the initial or final value differs from the default value. Saved waveforms also display.

Note: Waveforms appear in the report once the screenshot is saved.

From this screen, session reports for the current patient can be deleted or retained for records.

Refer to Table 5-7 for information about the functions of the buttons on the Reports screen.

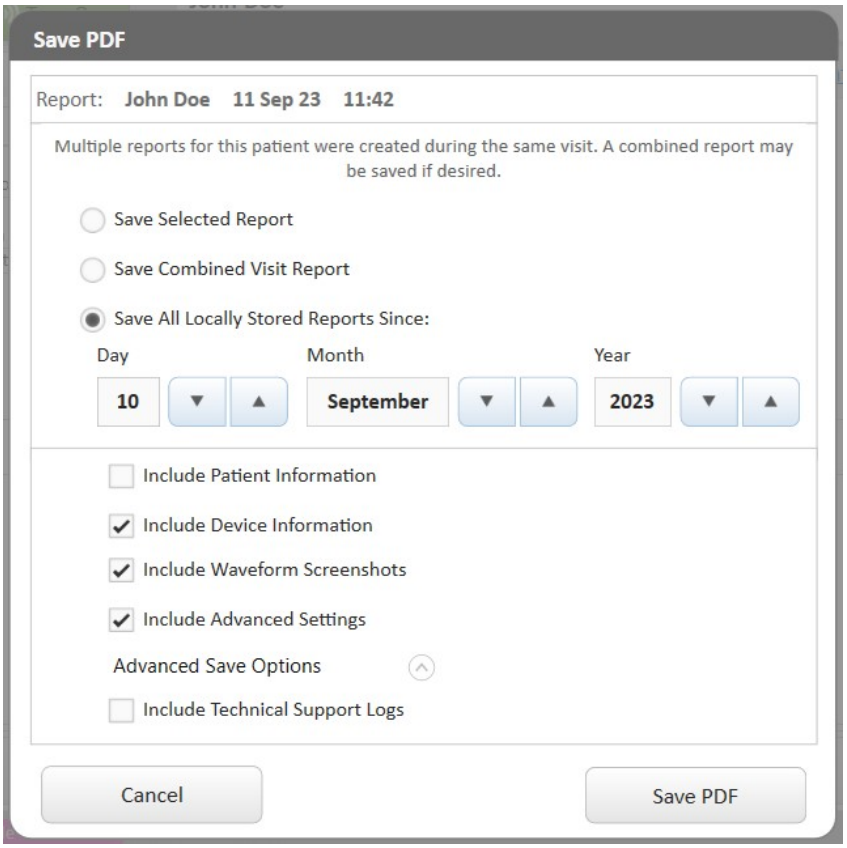
Table 5-7. Reports Screen Buttons

To:	Do This:
View selected report	Select the date and time of the desired report in the left column of the screen.
View additional reports	Select the up or down arrow buttons below the list of reports in the left column of the screen. **Note:** If the arrow buttons are disabled, there are no additional reports to view.
View additional sets of recorded levels	Select the right or left arrow buttons above the levels information. **Note:** If the arrow buttons are disabled, there are no additional levels to view.
Show or hide settings for the displayed waveform	Select the **Show Settings** or the **Hide Settings** button.
View additional waveform screenshots	Select the right or left arrow buttons above the waveform image. **Note:** If the arrow buttons are disabled, there are no additional screenshots to view.
Delete a session report	Highlight a report and select the Delete button to display the Delete Report screen (Figure 5-21). • Select the **Delete Selected Report** option to remove current report, or • Select the **Delete All Reports Before** option and specify the date using the arrow buttons to remove multiple reports for the current patient. • Select the **Cancel** button to return to Reports screen. • Select the **Delete** button to confirm that you wish to permanently remove the selected report(s).

Table 5-7. Reports Screen Buttons

Save a session report to PDF	Highlight a report and select the **Save PDF** button to display the Save PDF screen (Figure 5-26). • Select the **Selected Report** button to save current report, or • Select the **Combined Visit Report** button to save a report that combines programming sessions from the same visit, or **Note:** The option to save combined reports will only be available if multiple reports are detected within a +/-24-hour period. • Select the **All Locally Stored Reports Since** button and specify the date using the arrow buttons to save multiple reports for the current patient. • Select the information to be included in the save operation by checking one or more of the following boxes: patient information, device information, waveform screenshots, and technical support logs. The Technical Support Logs option is hidden under the Additional Options dropdown menu. • Select the **Cancel** button to return to the Reports screen. • Select the **Save as PDF** button to save.

Models 3024 and 3028, when the Reports are accessed in a programming session



Models 3024, 3028, 3150 when the Reports are accessed from the Start Screen

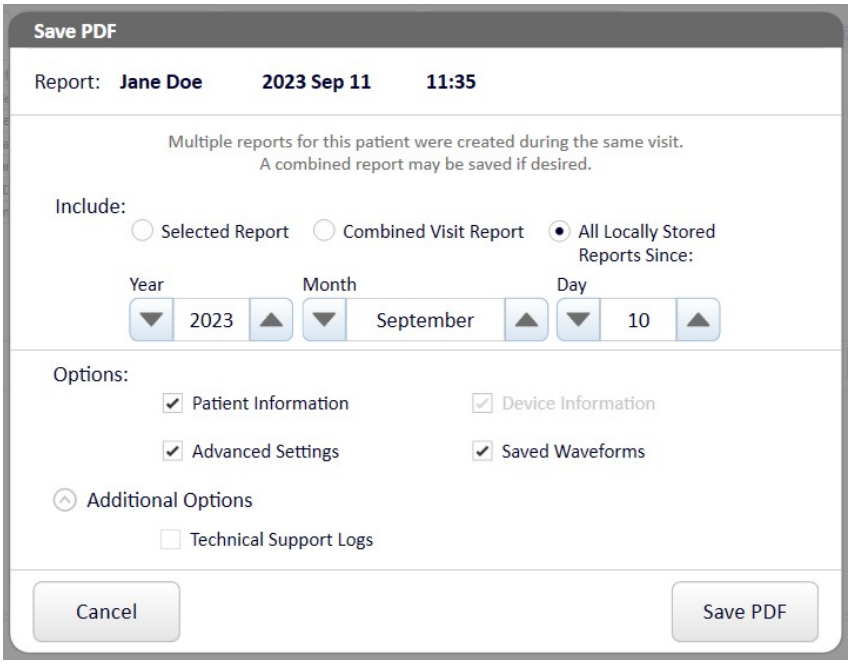
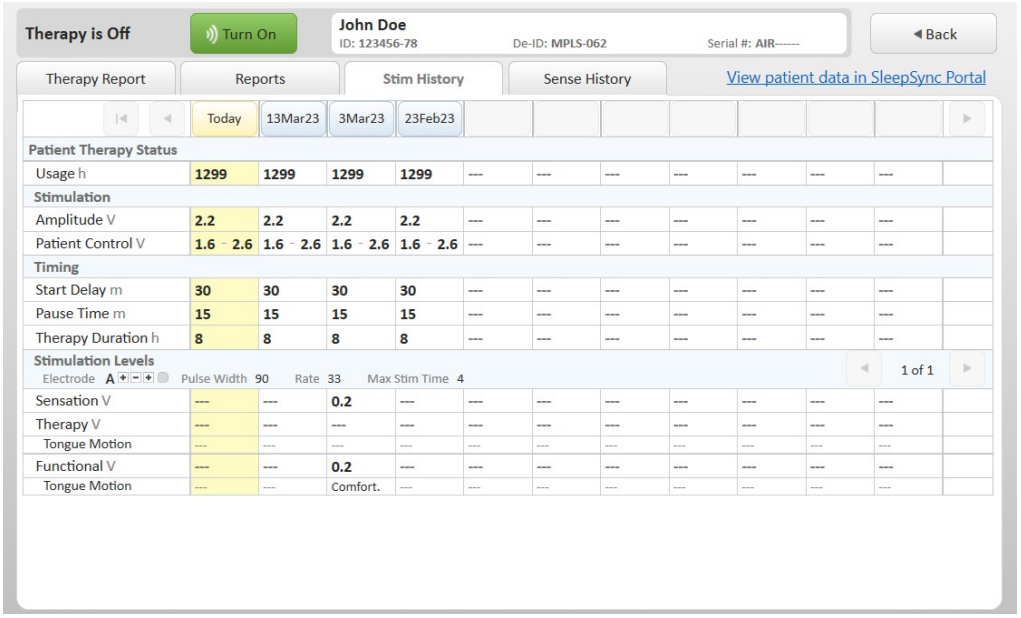


Figure 5-26. Save PDF Screen

Stimulation History Screen

Stimulation History shows patient information that exists on your computer.

Models 3024 and 3028



Model 3150

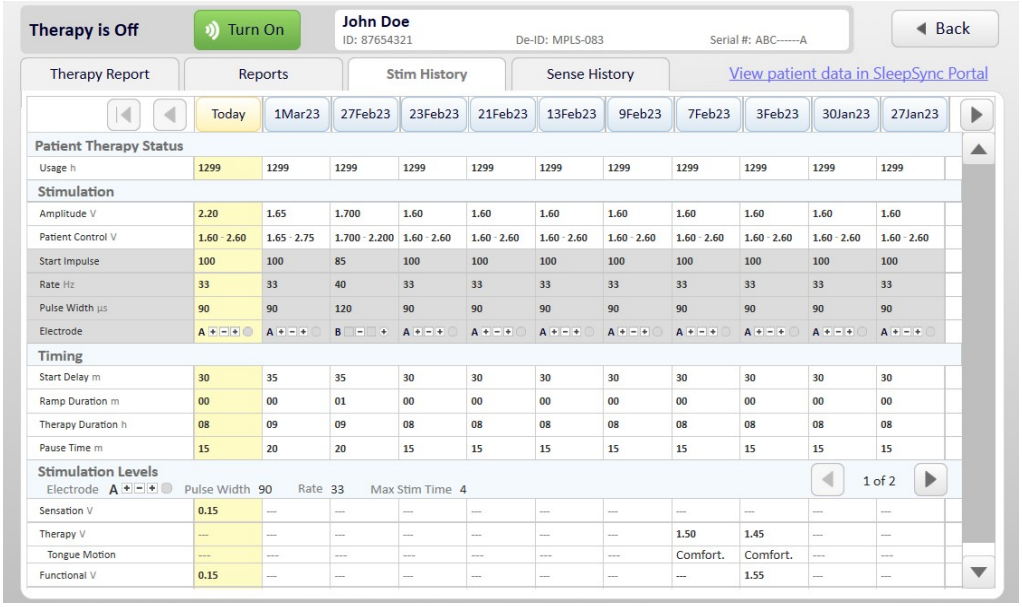


Figure 5-27. Stimulation History Screen

The **Stim History** button, located on various screens, accesses the Stimulation History Screen (Figure 5-27). This screen displays a summary of usage, stimulation levels, and final stimulation settings for a particular date.

Refer to Table 5-8 for information about the functions of the buttons on the Stimulation History screen.

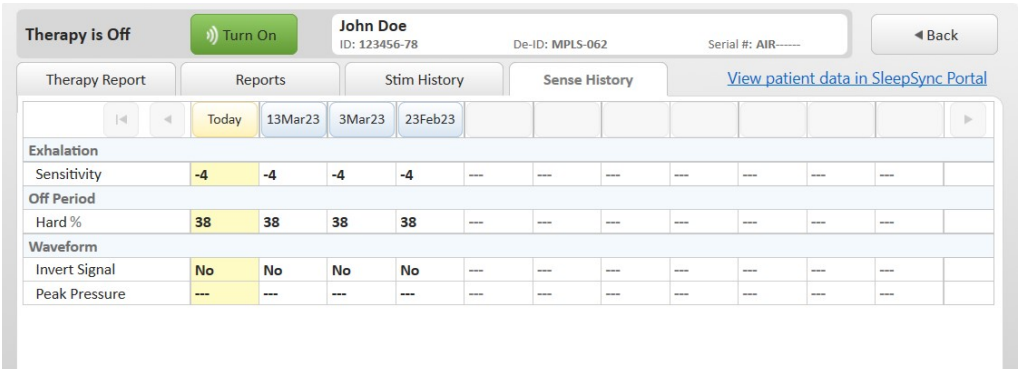
Table 5-8. Stimulation History Screen Buttons

To:	Do This:
View more detailed information about the sessions for a given date	Select that date in the header row to review the relevant session reports on the Reports screen.
View the next or previous set of dates	Select the left and right arrow buttons at the top of the screen. **Note:** If the arrow buttons are disabled, there are no additional dates to view.
View additional sets of recorded stimulation levels	Select the right or left arrow buttons in the levels section of the screen. **Note:** If the arrow buttons are disabled, there are no additional levels to view.

Sensing History Screen

Sensing History shows patient information stored only on your computer.

Models 3024 and 3028



Model 3150

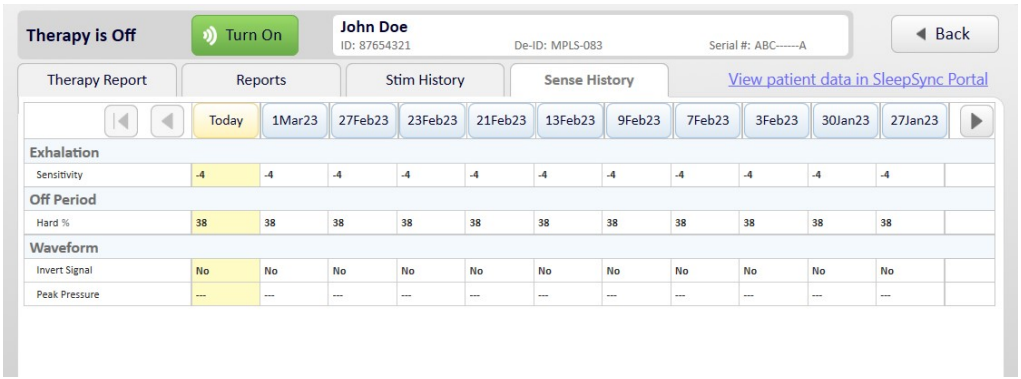


Figure 5-28. Sensing History Screen

The **Sense History** button on the Adjust Sensing screen and the Sense History tab on the Reports screen accesses the Sensing History screen (Figure 5-28). This screen displays a summary of the final sensing settings for a particular date.

Refer to Table 5-9 for information about the functions of the buttons on the Sensing History screen.

Table 5-9. Sensing History Screen Buttons

To:	Do This:
View more detailed information about the sessions for a given date	Select that date in the header row to review the relevant session reports on the Reports screen.
View the next or previous set of dates	Select the left and right arrow buttons at the top of the screen. **Note:** If the arrow buttons are disabled, there are no additional dates to view.

This page is intentionally blank.

Chapter 6: Clinical Programming Sessions

This chapter describes implant, initial activation, sleep study, and follow up sessions.

Introduction

The programmer is used during implant, initial activation, sleep study, and follow up visits to select stimulation and sensing settings that maintain airway patency.

Workflows

When to use Workflows

The SleepSync Programmer Application includes workflows intended to guide the user through common clinical scenarios.

- Follow Up - Use this workflow to make basic and advanced adjustments to the patient's stimulation settings. This can be done to improve patient comfort or therapy effectiveness.
- Sleep Study - Use this workflow when the patient is undergoing an overnight sleep study.
- Initial Activation - Use this workflow when first turning on a patient's therapy after the implant procedure.

When to use the Advance Tools workflows

The following sections contain additional detail on the activities performed during clinical programming sessions.

- Adjust Stimulation
- Adjust Sensing
- System Check - Use this workflow to assess the integrity of the implanted system by checking stimulation levels, observing waveforms, or measuring impedances. This is commonly done during surgical implant or advanced troubleshooting.

Generator Implant

Implant programming occurs during the surgical implant procedure. The programming goals of this session are to verify stimulation function, sensor performance, and proper lead connections to the generator.

Implant Session Overview

- Start Session
- Enter Patient Details
- Check Generator Status
- Record Functional Level
- Assess Sensor Performance
- End Session
- Retain Records

Start Session

With the generator still in its sterile box, follow the steps for “Begin Programming” on page 25 and “Connecting the Programmer Cable to Power” on page 26.

Enter the Patient Details

The first time you connect to a generator, the SleepSync Programmer Application displays the Patient Details screen before the Home screen.

Select any field to enter or edit patient information.

For the Model 3024 and 3028 generators:

- Select the **Save** or the **Home** button to save updated patient information and return to the Home screen.
- Select the **Cancel** button to reject changes made to patient information and return to the Home screen without saving.

For the Model 3150 generator:

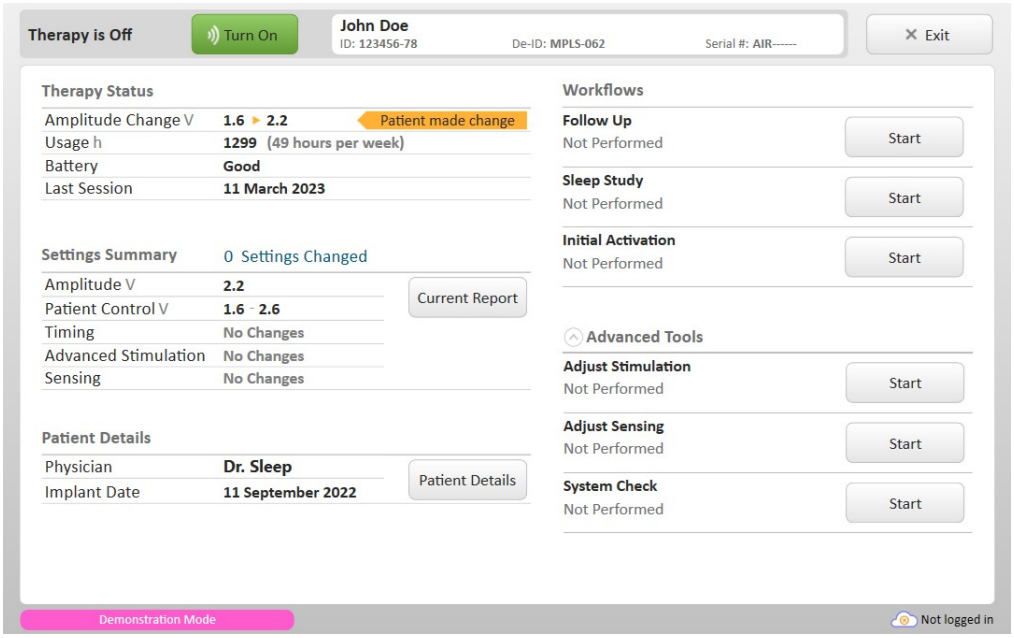
- Select the **Home** button to save updated patient information and return to the Home screen.

Note: The ability to edit the Patient First Name, Last Name, Patient ID, and Date of Birth fields is controlled from the Programmer Settings Screen (Data Controls).

Start System Check (Advanced Tools) Workflow

1. Select the dropdown arrow next to Advanced Tools on the Session Home Screen.
2. Select the **Start** button, next to System Check, to start the System Check.

Models 3024 and 3028



Model 3150

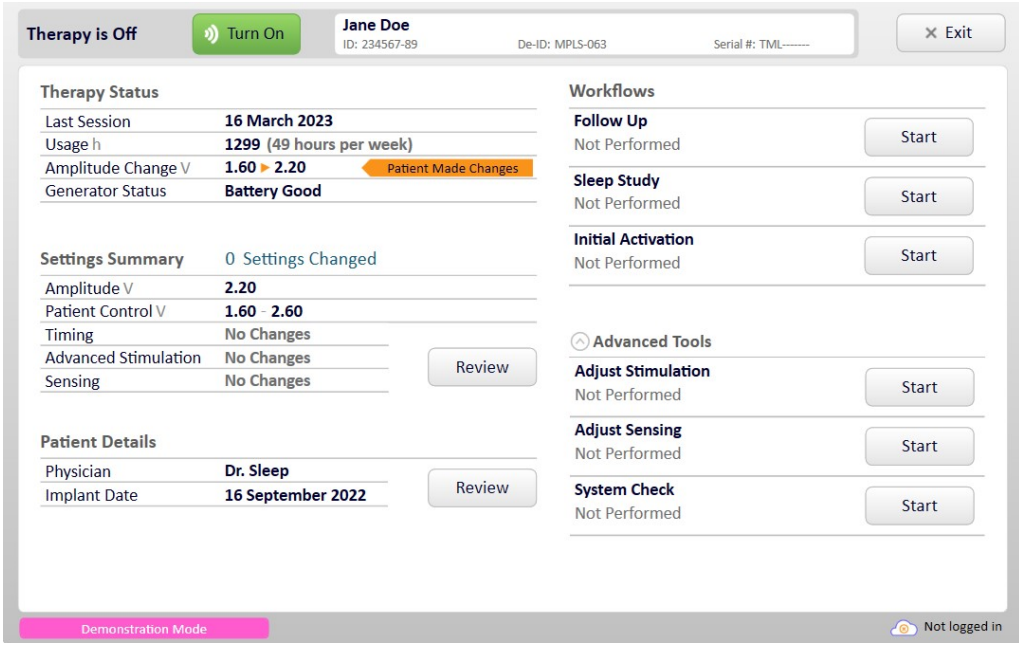


Figure 6-1. Session Home Screen

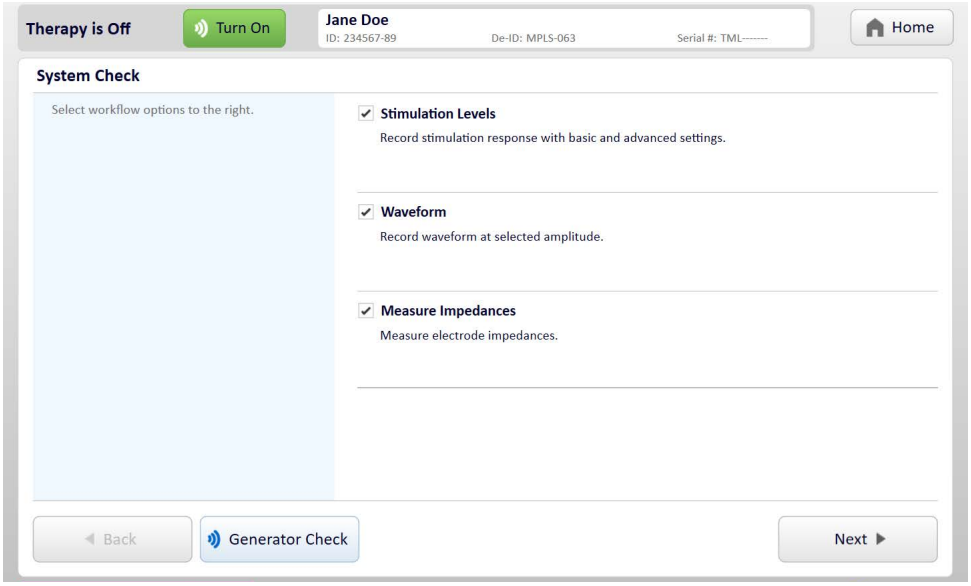
Check Generator Status

For all models, verify that the generator battery status is good by looking at the Therapy Status section on the Home screen.

The SleepSync Programmer Application runs a Model 3150 generator check automatically upon each new session within 24 hours and will alert you if there is an issue.

To check the Model 3150 generator manually, select **Generator Check** from the System Check screen (Figure 6-2, top). Once the check is complete, you can copy the information to the clipboard by selecting the **Copy to Clipboard** button. Select the **Back** button to return to the System Check screen.

Model 3150 System Check



Model 3150 Generator Check Summary

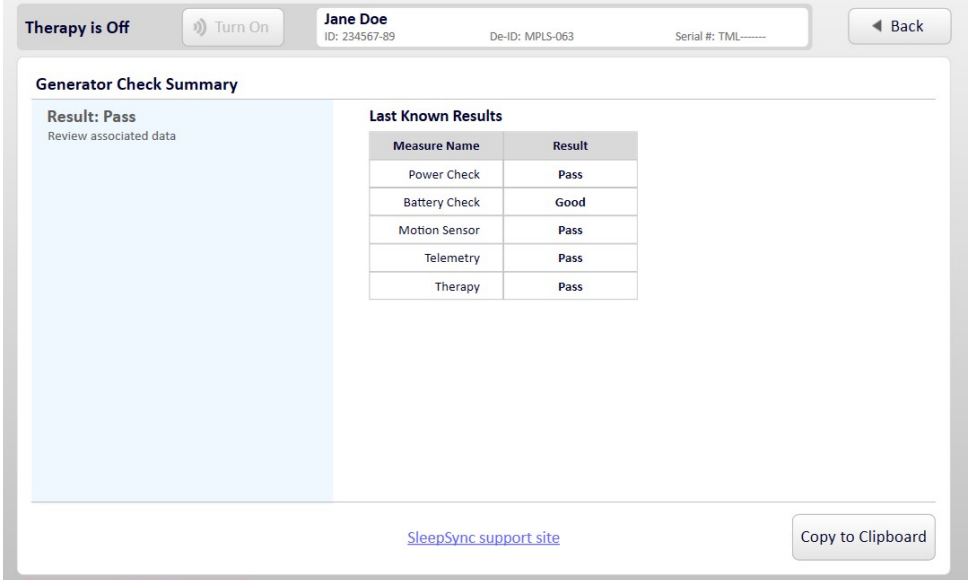
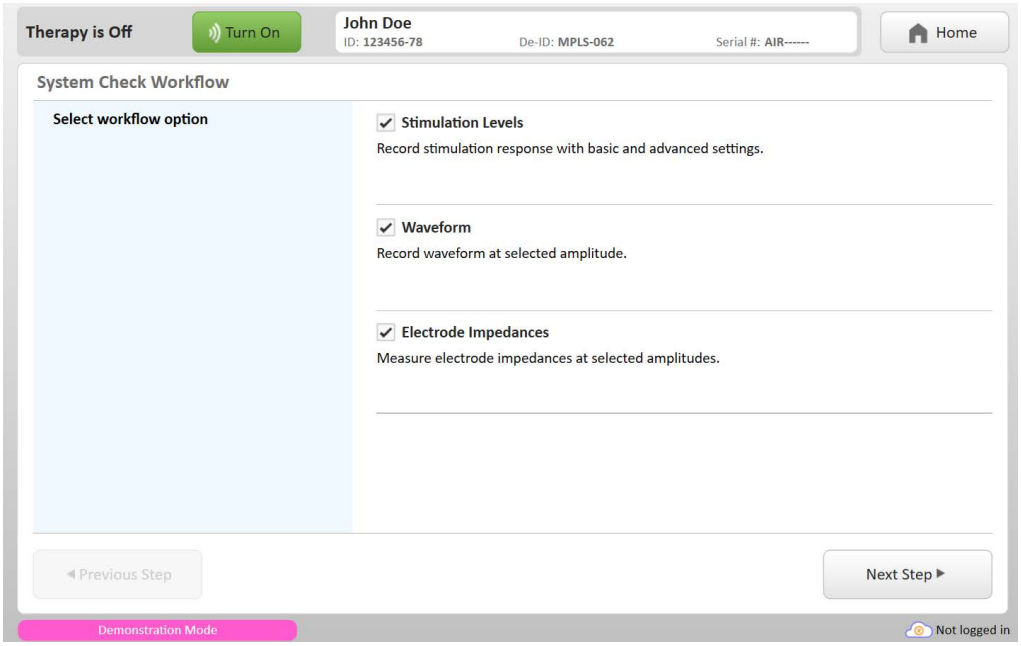


Figure 6-2. System Check and Generator Check Summary for Inspire 3150 Generator

3. Ensure Stimulation Levels and Waveform are selected, then select the **Next Step** button from the System Check Screen.

   Note: The **Impedances** option can be selected if desired.

Models 3024 and 3028



Model 3150

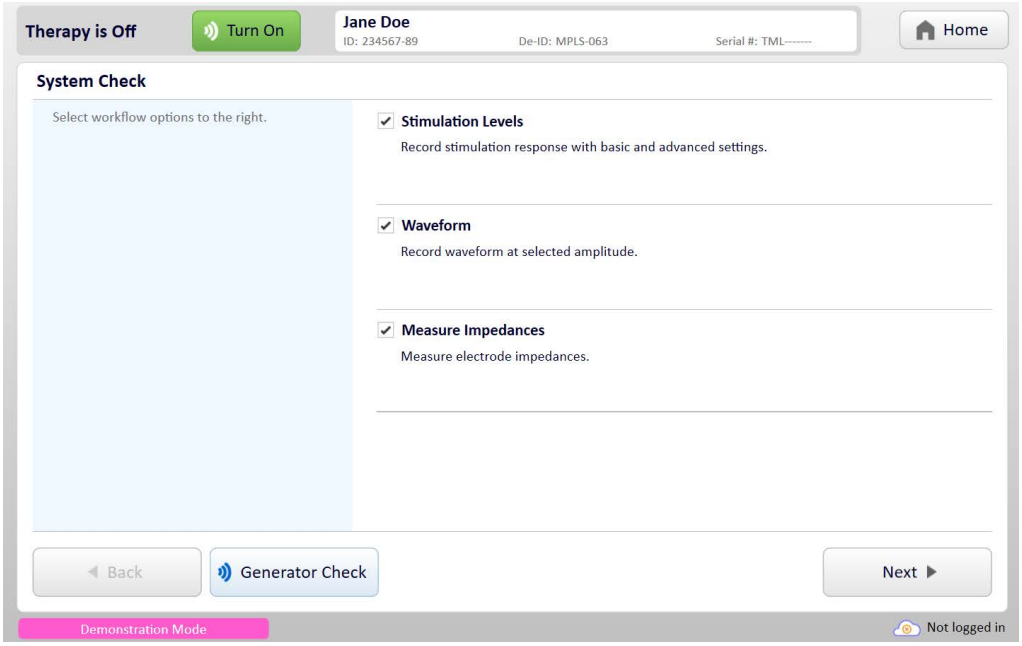


Figure 6-3. System Check Screen

Save Functional Level

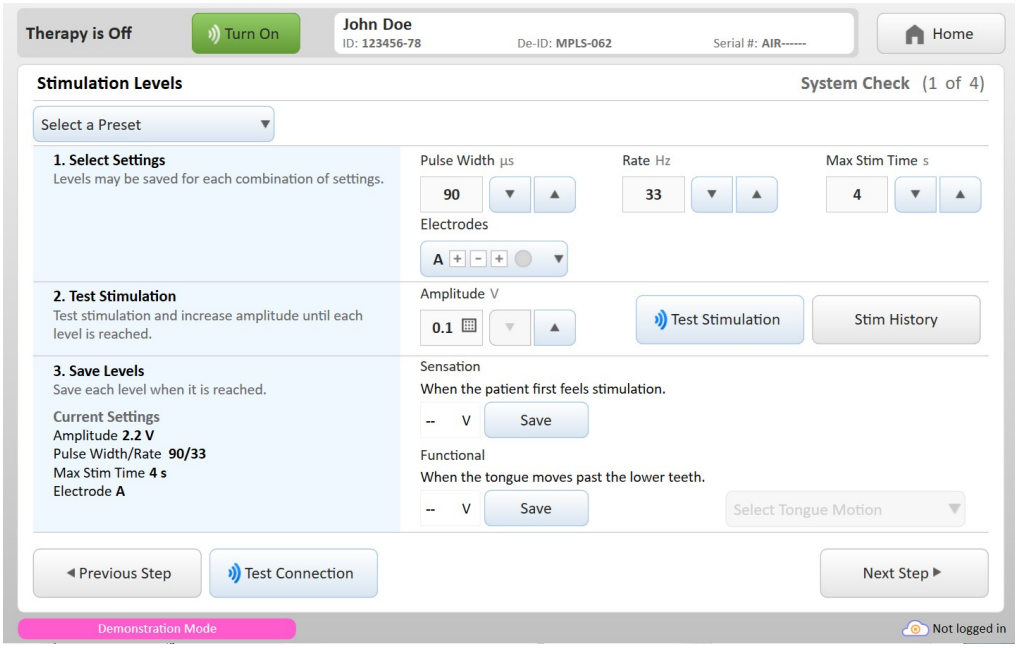
After the stimulation lead is connected to the generator, complete the following steps to confirm correct electrode placement and correct lead-generator connection:

1. Use the arrow buttons to select the test stimulation amplitude value.
2. Select the **Test Stimulation** button to deliver one burst of stimulation at the selected amplitude; observe the patient's tongue response.
3. Repeat Steps 1 and 2 until the functional level is reached. If the electrode is correctly placed, the tongue will move distinctly forward when stimulated at the functional level. If a tongue response cannot be obtained at any amplitude, the stimulation lead may not be properly connected to the generator or nerve.

   Note: If no tongue response is observed, alternate stimulation settings may be attempted. In addition, the Impedances portion of the System Check may be utilized for troubleshooting.
4. Select the **Save** button next to the functional level to save the stimulation level.

   Note: The sensation level is not recorded during implant.
5. Select **Next Step.**

Models 3024 and 3028



Model 3150

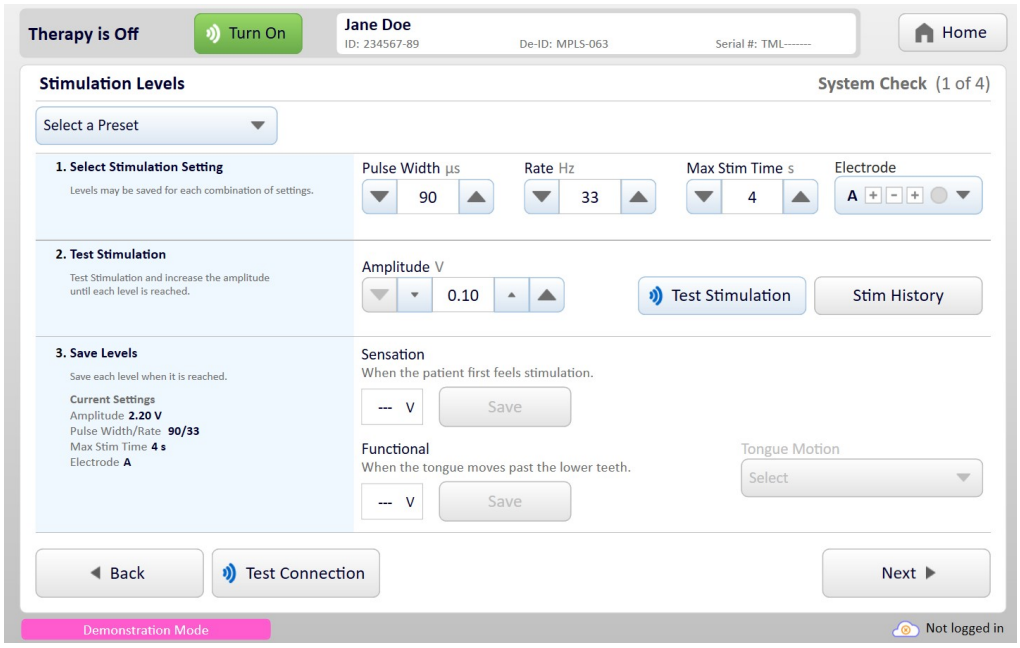


Figure 6-4. System Check - Stimulation Levels Screen

Assess the Sensor Performance

Models 3024 and 3028: Once the sensing lead is connected to the generator, complete the steps below to confirm the sensor performance and the correct lead-generator connection.

1. On the Waveforms screen, change the amplitude to 1.5 V and select the **Set Amplitude** button.
2. Select the **Start Waveform** button to start the real-time waveform.
3. Review the waveform and verify that the waveform moves up or down with inhalation and exhalation.
4. Select the **Screenshot** button to access the Screenshot screen and document the sensor performance.
   a. Select Anesthetized under the Sleep Type labels. Additional labels may be selected if desired.
   b. Select the **Save** button to save the displayed waveform in the session report.
5. Select the **Next Step** button. Stimulation and the real-time waveform will stop.

Notes:

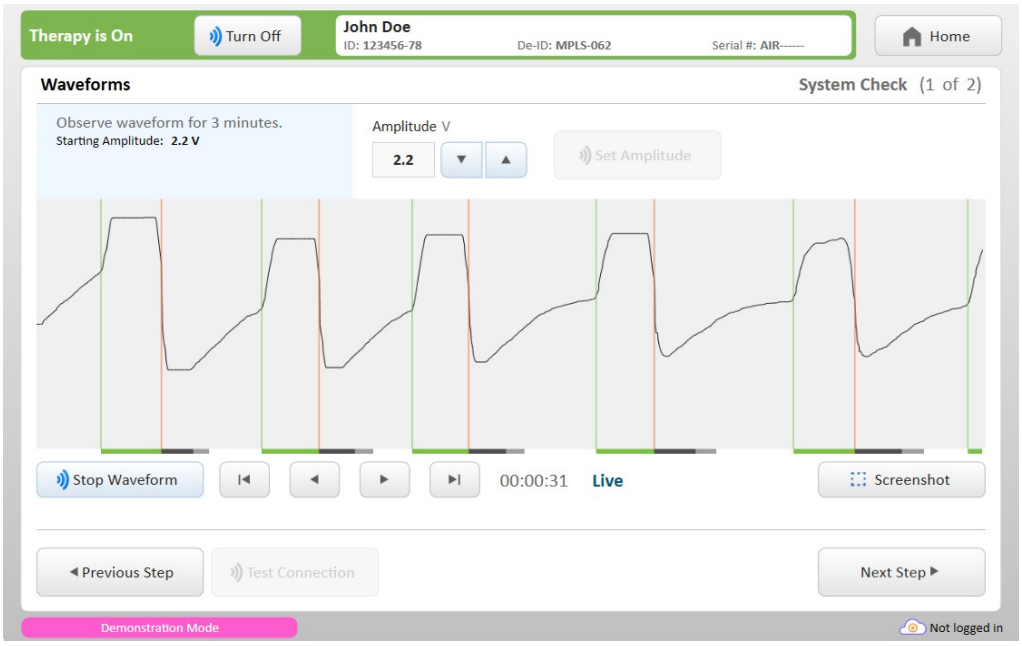
- The amplitude will automatically return to its initial value when the workflow was started (for Implant, this should be 0 V).
- During surgery, the patient's respiratory rate is controlled by the ventilator. Sensor signal quality typically improves after surgical wounds heal.

Model 3150: Because the 3150 does not have a sensing lead, assessment of the waveform is optional. The primary method of testing the motion sensor functionality is the generator check, see "Check Generator Status" on page 82. If waveform is run, verify that the waveform moves up or down with inhalation and exhalation.

The SleepSync Programmer Application runs a Model 3150 generator check automatically upon the first session within a 24 hour window and will alert you if there is an issue.

To check the Model 3150 motion sensor manually, select **Generator Check** from the System Check workflow under Advanced Tools. Once the check is complete, select the **Back** button to return to the System Check screen. Confirm that the Motion Sensor measurement has a result of Pass.

Models 3024 and 3028



Model 3150

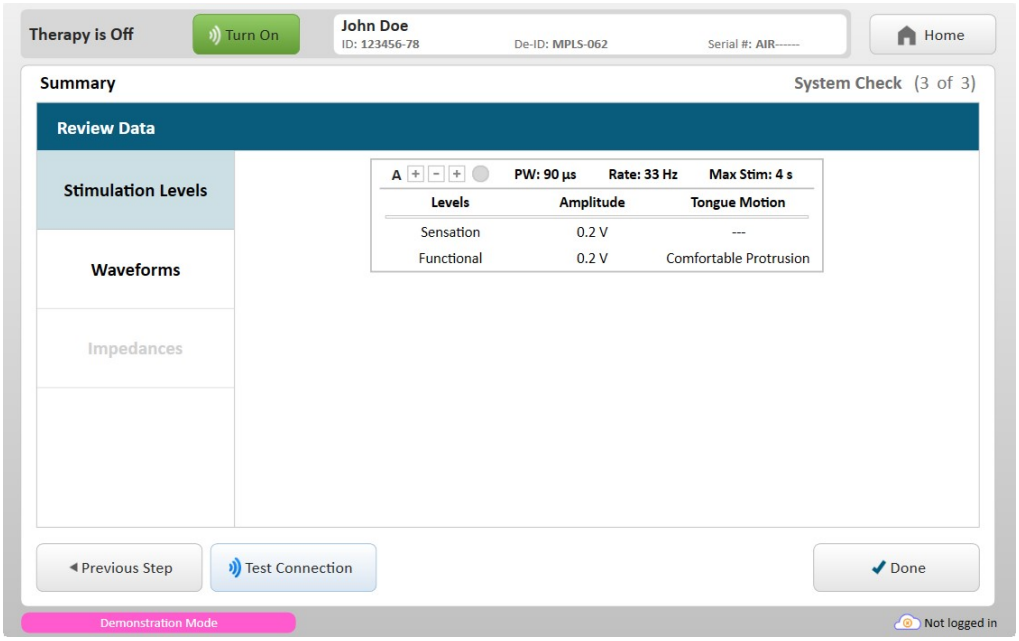
Figure 6-5. System Check - Waveforms Screen

Review Data

The Summary screen will allow for the review of data that was collected during the workflow.

1. Review the Stimulation Levels data.
2. Review the Waveforms data.
3. Select the **Done** button to complete the workflow.

Models 3024 and 3028



Model 3150

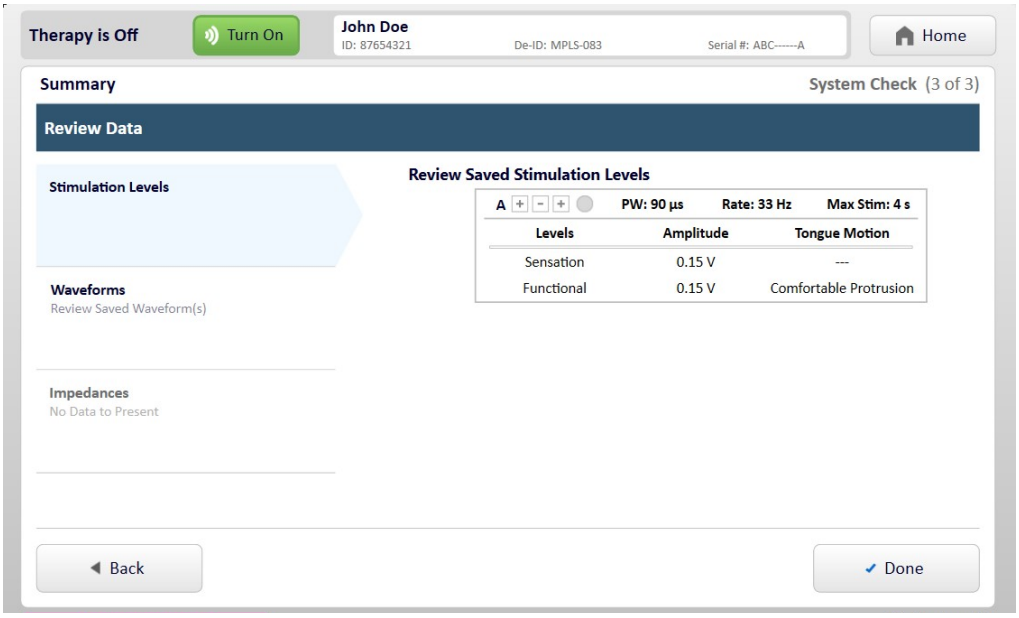


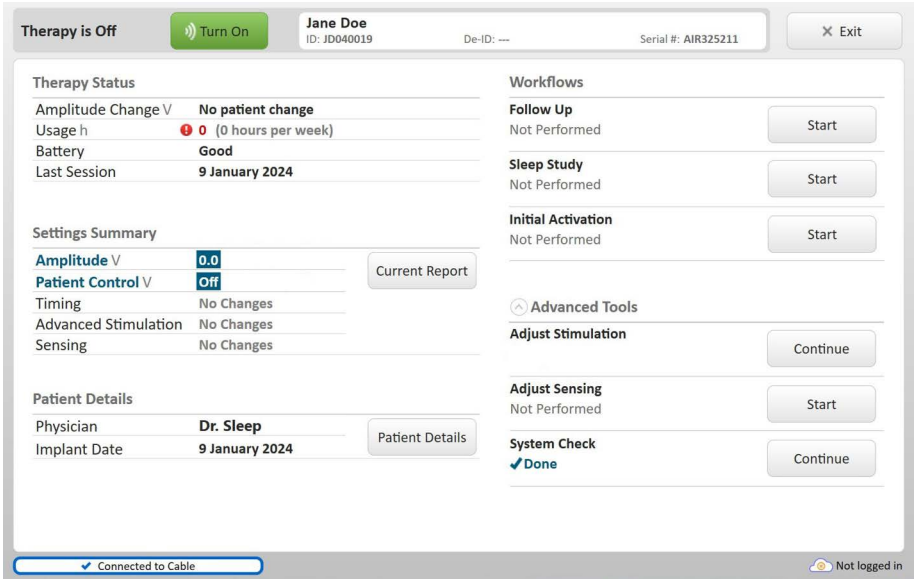
Figure 6-6. System Check - Summary Screen

End Session

Before ending the implant session:

1. Confirm that therapy is turned off.
2. Confirm that the amplitude is programmed to 0 V.
3. Confirm that the System Check has been completed.
4. Select the **Exit** button on the Home screen.

Models 3024 and 3028



Model 3150

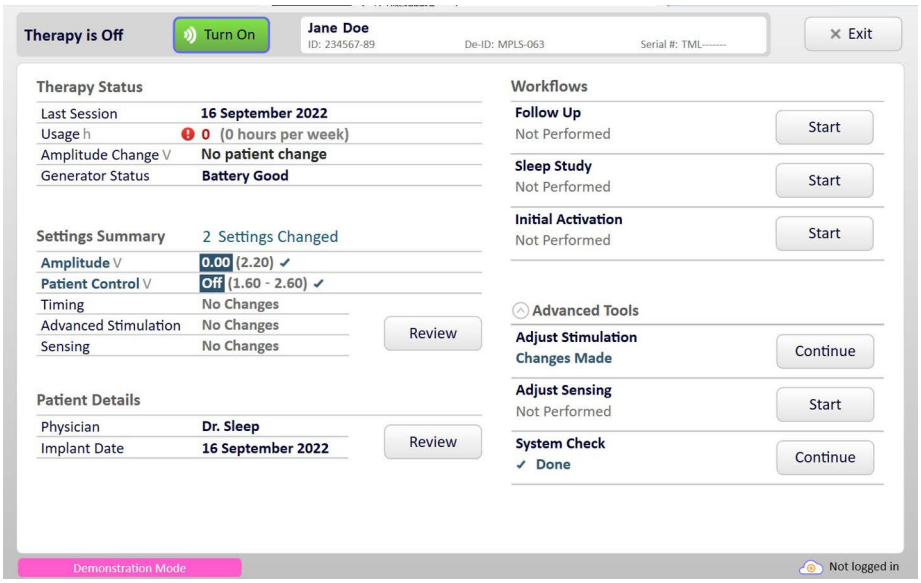


Figure 6-7. End Implant Session - Home Screen

Retain Records

Save a session report if desired. See “Saving Session Report as PDF” on page 116 for instructions.

Initial Activation

The goal during Initial Activation is to program the patient with stimulation and timing settings that will promote effective and comfortable use of Inspire therapy.

Initial Activation Overview

- Start Session
- Start Initial Activation Workflow
- End Session
- Retain Records

Start Session

Turn on the programmer and start a programming session by connecting to the generator.

Start Initial Activation Workflow

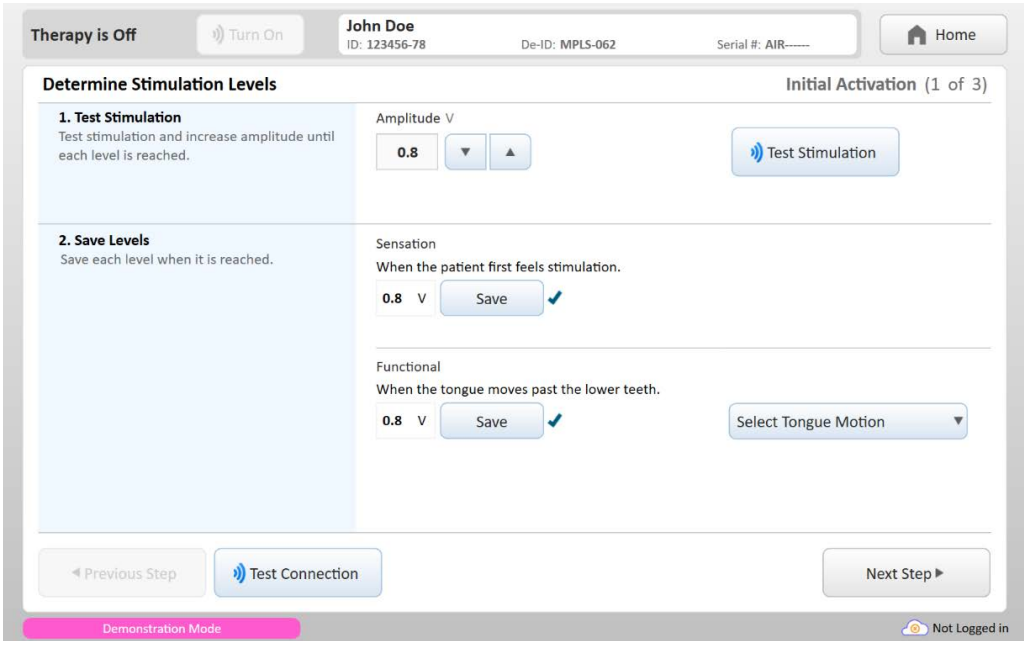
From the Home screen select **Start** for the Initial Activation workflow.

Determine Stimulation Levels

Therapy must be turned off prior to starting the Initial Activation workflow.

1. Use the arrow buttons to select the test stimulation amplitude value.
2. Select the **Test Stimulation** button to deliver one burst of stimulation at the selected amplitude; observe the patient's tongue response.
3. Repeat steps 1 and 2 until the patient can feel stimulation.
4. Select the **Save** button for the Sensation level to record the amplitude value.
5. Repeat steps 1 and 2 until a functional tongue motion is observed.
6. Select the **Save** button for the Functional level to record the amplitude value.
7. Select a description of the patient's tongue motion at the Functional level.
8. Select the **Next Step** button

Models 3024 and 3028



Model 3150

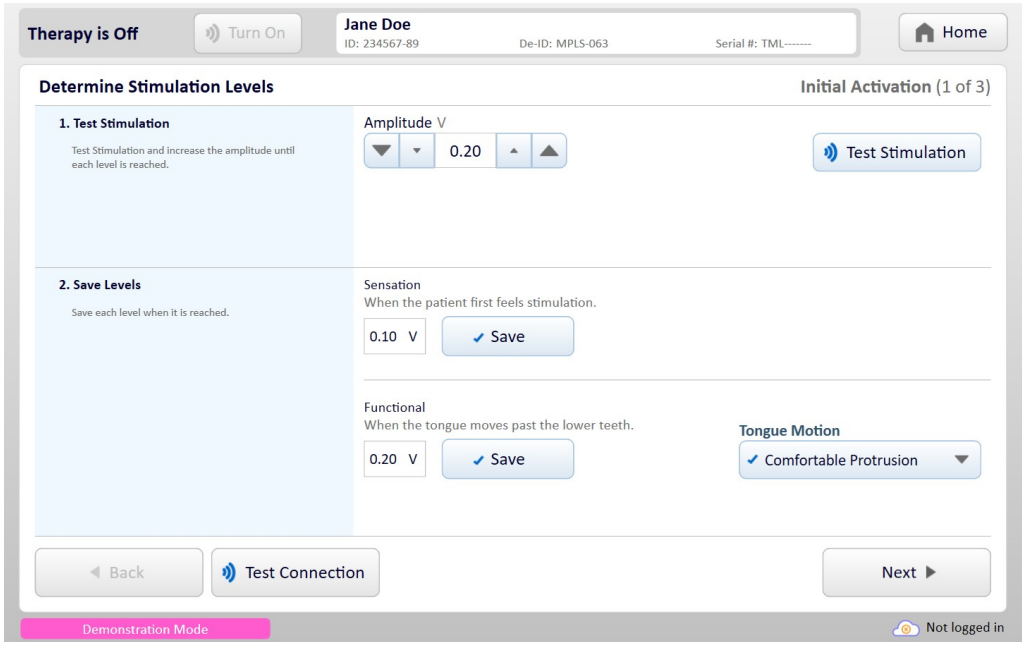


Figure 6-8. Initial Activation - Determine Stimulation Levels Screen

Observe Waveform

1. It is recommended to start with the functional level. Select the **Set Amplitude** button.
2. Select the **Start Waveform** button and observe the waveform for 3 minutes.

   Note: This will turn on therapy and deliver stimulation based on the current generator settings.
3. If stimulation is uncomfortable for the patient, decrease the amplitude and select the **Set Amplitude** button.
4. If necessary, repeat step 3 until a comfortable amplitude is achieved.
5. Select the **Screenshot** button to annotate and save the displayed waveform in the session report.
6. Select the **Next Step** button.

   Note: This will stop stimulation and the real-time waveform.

Models 3024 and 3028

Model 3150

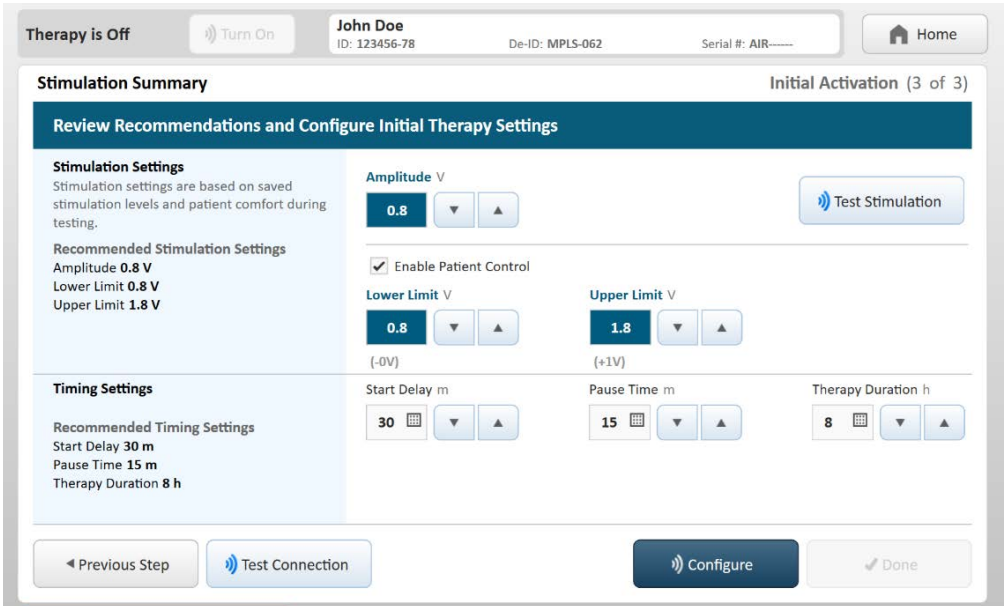
Figure 6-9. Initial Activation - Observe Waveform Screen

Stimulation Summary

1. Review the Stimulation and Timing settings.
2. If desired, make any final changes.

   Note: The software will default the amplitude lower limit to the functional level and the upper limit to a value 1 V above the functional level.
3. Select the **Configure** button.
4. Select the **Done** button.

Models 3024 and 3028



Model 3150

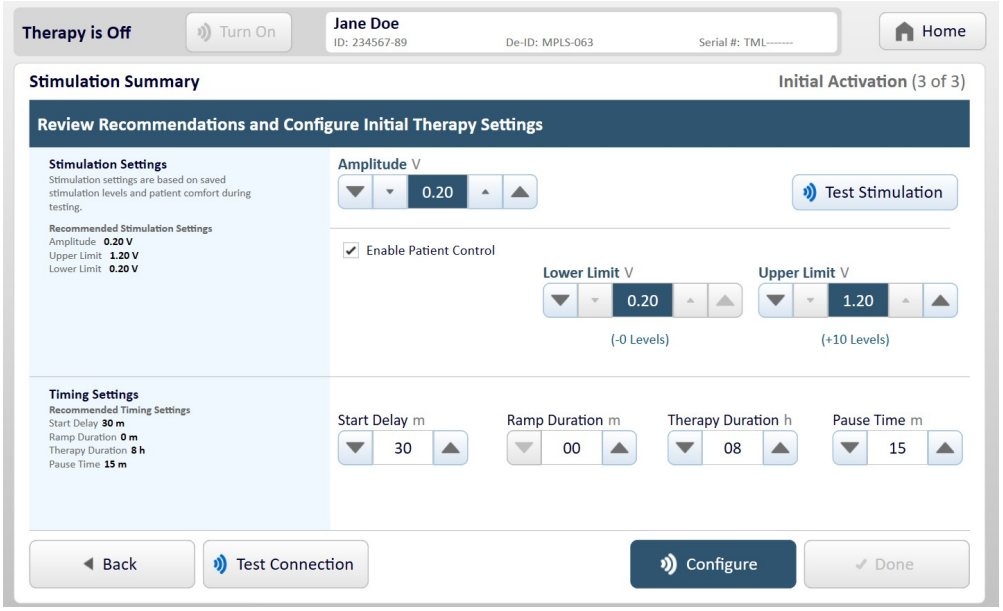


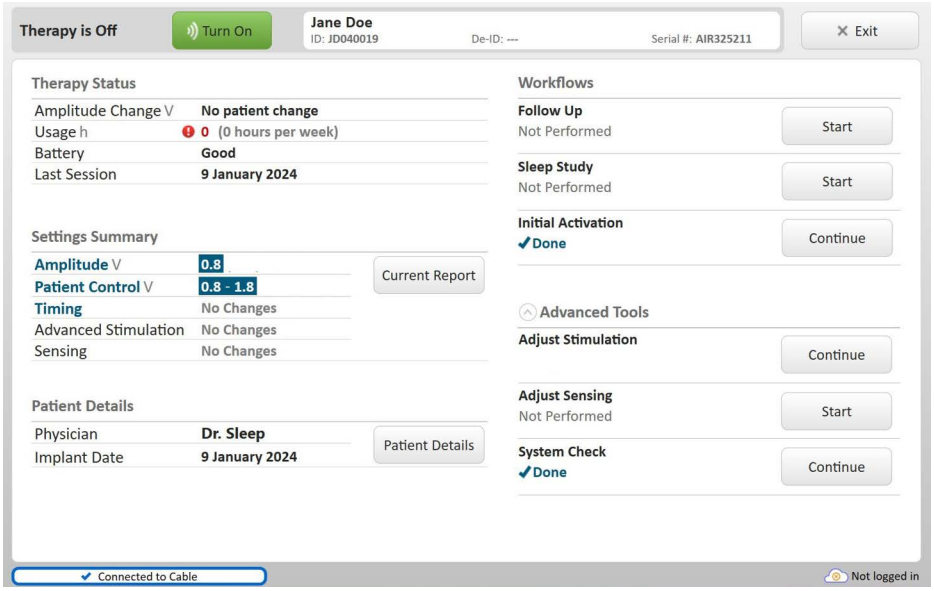
Figure 6-10. Initial Activation - Stimulation Summary Screen

End Session

Before ending the Initial Activation session:

1. Confirm that therapy is turned off.
2. Confirm the patient has the desired amplitude and control range.
3. Confirm that the Initial Activation Workflow has been completed.
4. Select the **Exit** button on the Home screen.

Models 3024 and 3028



Model 3150

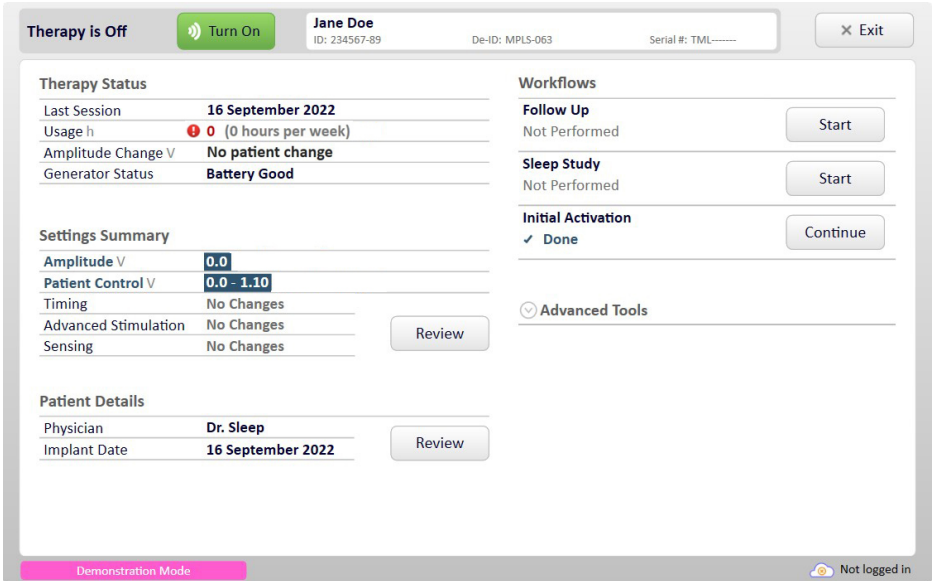


Figure 6-11. End Initial Activation - Home Screen

Retain Records

Save a session report if desired. See “Saving Session Report as PDF” on page 116 for instructions.

Follow Up

The goal during Follow Up is to review and adjust stimulation settings to promote effective and comfortable use of Inspire therapy.

Follow Up Overview

- Start Session
- Review Therapy Status
- Start Follow Up Workflow
- Basic Follow Up
- Advanced Follow Up
- End Session
- Retain Records

Start Session

Turn on the programmer and start a session by connecting to the generator.

Review Therapy Status

Review the information displayed in the Therapy Status section of the Home screen. Note usage hours and any amplitude changes that the patient has made since the last visit, which are indicated by orange change flags. Talk to the patient to assess how effectively the patient is using the therapy.

Start Follow Up Workflow

From the Home screen, select **Start** for the Follow Up workflow.

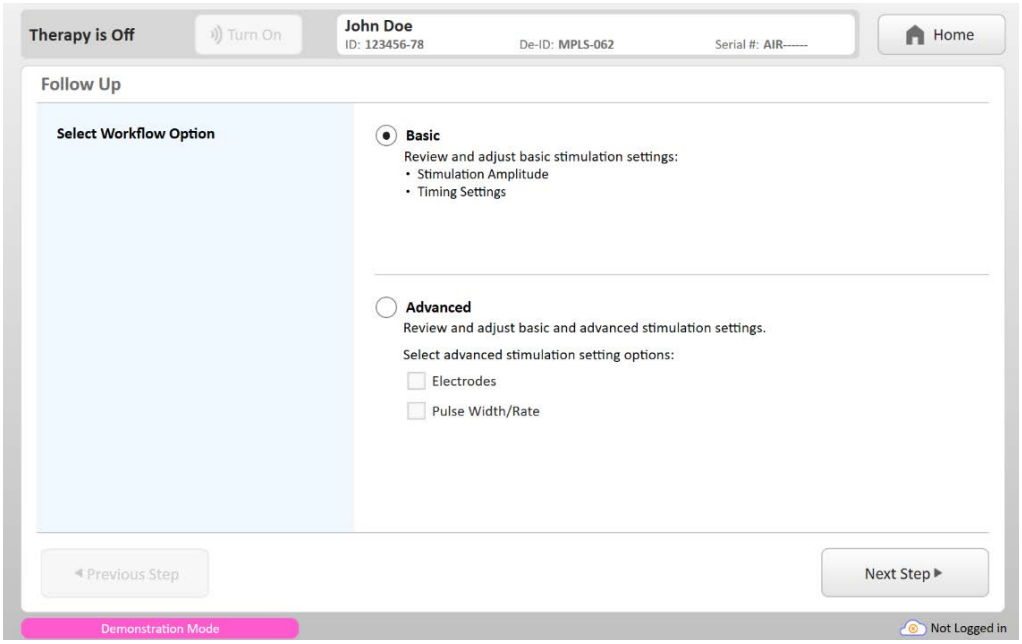
If minor amplitude and timing adjustments are desired, select the following Workflow option:

1. Select the **Basic** option.
2. Select the **Next Step** button.

If advanced programming and improvements in therapy effectiveness are desired, select the following Workflow option:

1. Select the **Advanced** option.
2. Select the stimulation settings to be evaluated. One or both options can be chosen.
3. Select the **Next Step** button.

Models 3024 and 3028



Model 3150

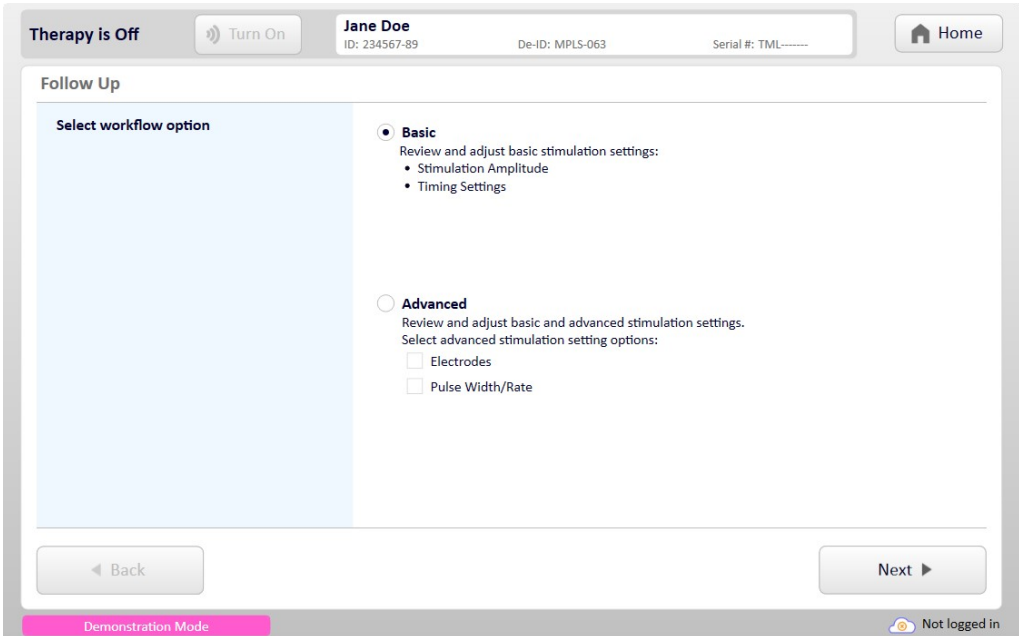


Figure 6-12. Follow Up Screen

Basic Follow Up

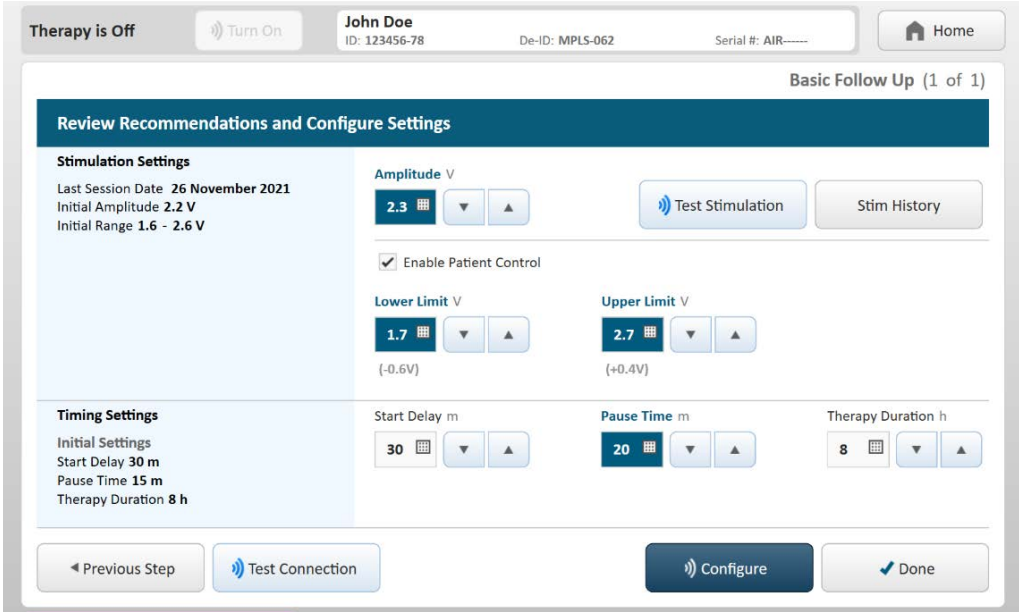
The following steps apply only to the Basic Follow Up.

1. Review the Stimulation and Timing settings.

   Note: Pay attention to any Review flags that may appear.

2. Make desired changes using the arrows.
3. If there are any new settings to program in the generator, select the **Configure** button.
4. Select the **Done** button.

Models 3024 and 3028



Model 3150

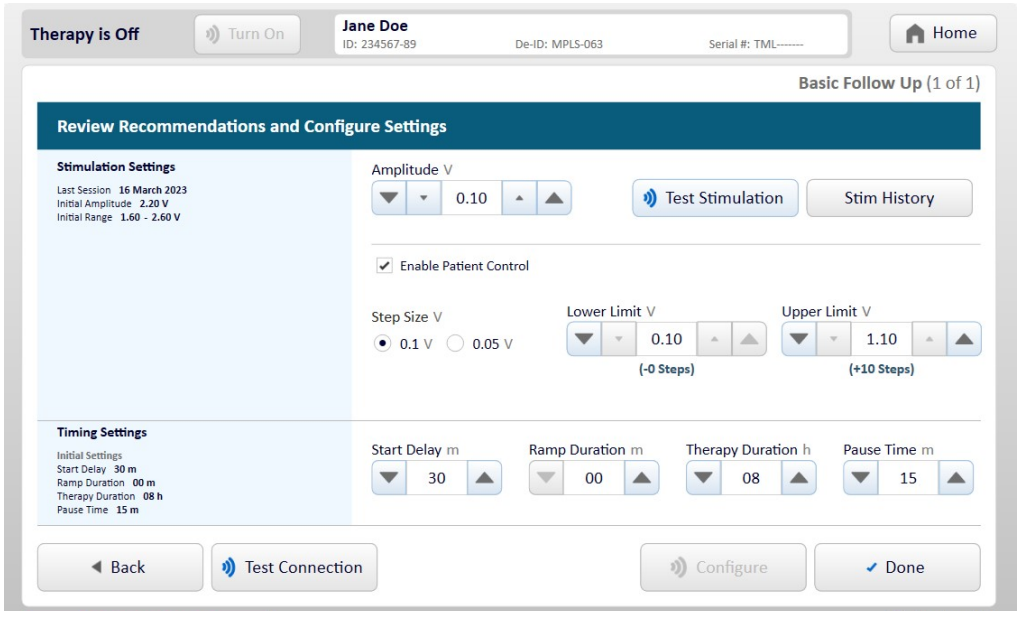


Figure 6-13. Basic Follow-up Screen

Advanced Follow Up

The following steps apply only to the Advanced Follow Up.

Electrodes
Complete these steps if the Electrodes option was selected.

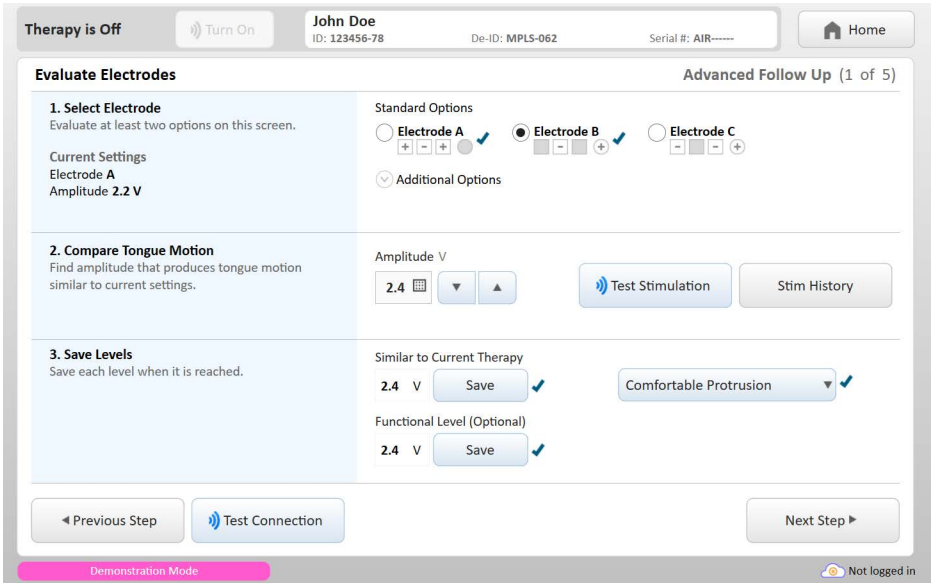
Evaluate Electrodes

1. Select an electrode option for evaluation.
2. Use the arrow buttons to select the test stimulation amplitude value.
3. Select the **Test Stimulation** button to deliver one burst of stimulation at the selected electrode and amplitude; observe the patient's tongue response.
4. Repeat steps 2 and 3 until the patient experiences a tongue motion similar to current therapy.
5. Select the **Save** button for the Similar to Current Therapy level to record the amplitude value.
6. Select a description of the patient's tongue motion at the Similar to Current Therapy level.
7. If desired, repeat steps 2 and 3 until a functional tongue motion is observed. Select the **Save** button for the Functional level and select a description of the patient's tongue motion.

   Note: Saving a Functional level is optional.
8. Select a different electrode option for evaluation.

   Notes:
   - It is recommended to evaluate at least two electrode options.
   - Each electrode option must have its own saved stimulation levels. Selecting a different electrode option will reset the stimulation levels. The saved levels for any previous electrode option can be viewed again on the next screen.
9. Repeat steps 2-7 for the new electrode selection.
10. If desired, select additional electrodes for evaluation and repeat steps 2-7 for each selection.
11. Select the **Next Step** button.

Models 3024 and 3028



Model 3150

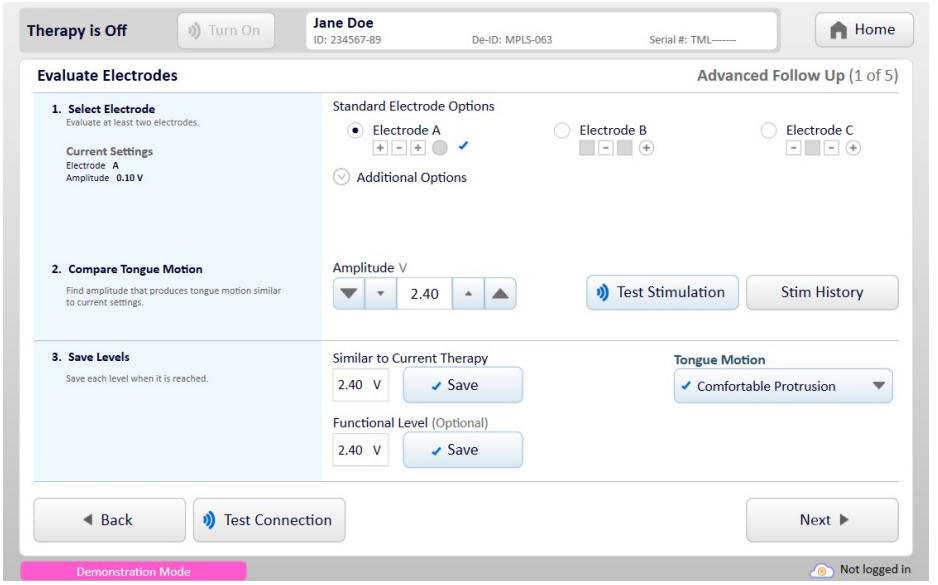


Figure 6-14. Advanced Follow Up - Evaluate Electrodes Screen

Select Electrode and Amplitude

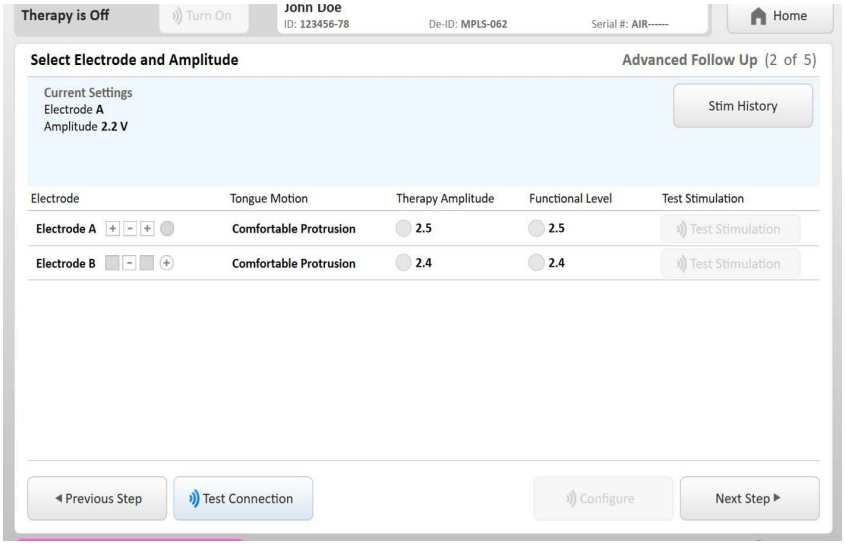
Data that was saved from the previous screen will show here.

Note: Therapy Amplitude is equivalent to the "Similar to Current Therapy" level from the previous screen.

1. Review the level and tongue motion data that was saved on the previous screen.

   Note: If more than one configuration displays, you may select each option individually and then select **Test Stimulation** to determine which is most comfortable to the patient.
2. Once the desired electrode and stimulation level has been determined, select that option.
3. Select **Configure** to program the new electrode and amplitude.
4. Select the **Next Step** button.

Models 3024 and 3028



Model 3150

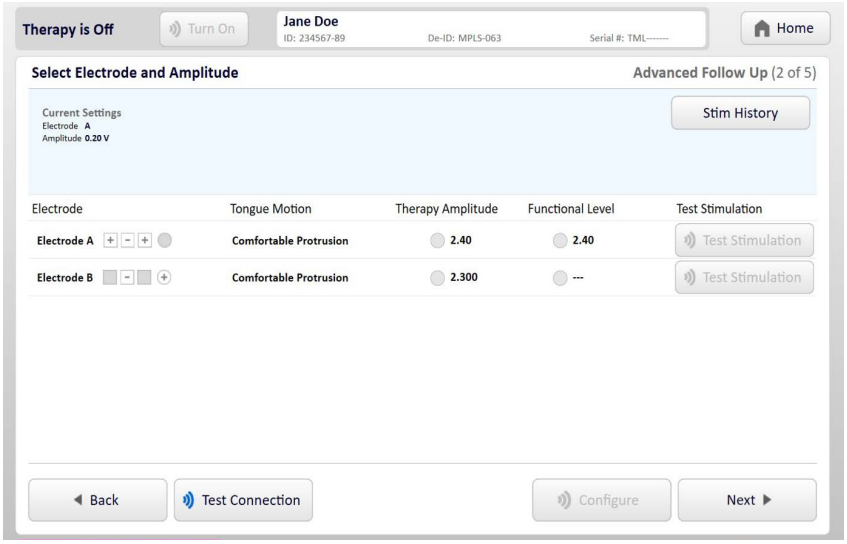


Figure 6-15. Advanced Follow Up - Select Electrode and Amplitude Screen

Pulse Width and Rate
Complete these steps if the **Pulse Width and Rate** option was selected.

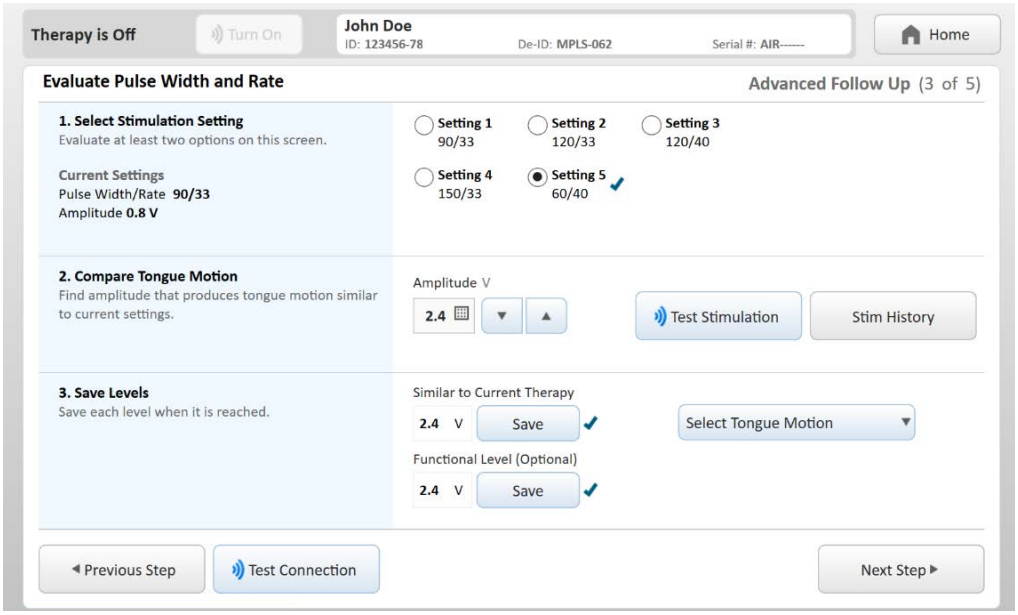
Evaluate Pulse Width and Rate

1. Select a pulse width/rate option for evaluation.
2. Use the arrow buttons to select the test stimulation amplitude value.
3. Select the **Test Stimulation** button to deliver one burst of stimulation at the selected amplitude and pulse width/rate combination; observe the patient's tongue response.
4. Repeat steps 2 and 3 until the patient experiences a tongue motion similar to current therapy.
5. Select the **Save** button for the Similar to Current Therapy level to record the amplitude value.
6. Select a description of the patient's tongue motion at the Similar to Current Therapy level.
7. If desired, repeat steps 2 and 3 until a functional tongue motion is observed. Select the **Save** button for the Functional level and select a description of the patient's tongue motion.

   Note: Saving a Functional level is optional.
8. Select a different pulse width/rate option for evaluation. These levels can be viewed again if the previous pulse width/rate option is selected.

   Note: It is recommended to evaluate at least two pulse width/rate options.
9. Repeat steps 2-7 for the new pulse width/rate selection.
10. If desired, select additional pulse width/rate options for evaluation and repeat steps 2-7 for each selection.
11. Select the **Next Step** button.

Models 3024 and 3028



Model 3150

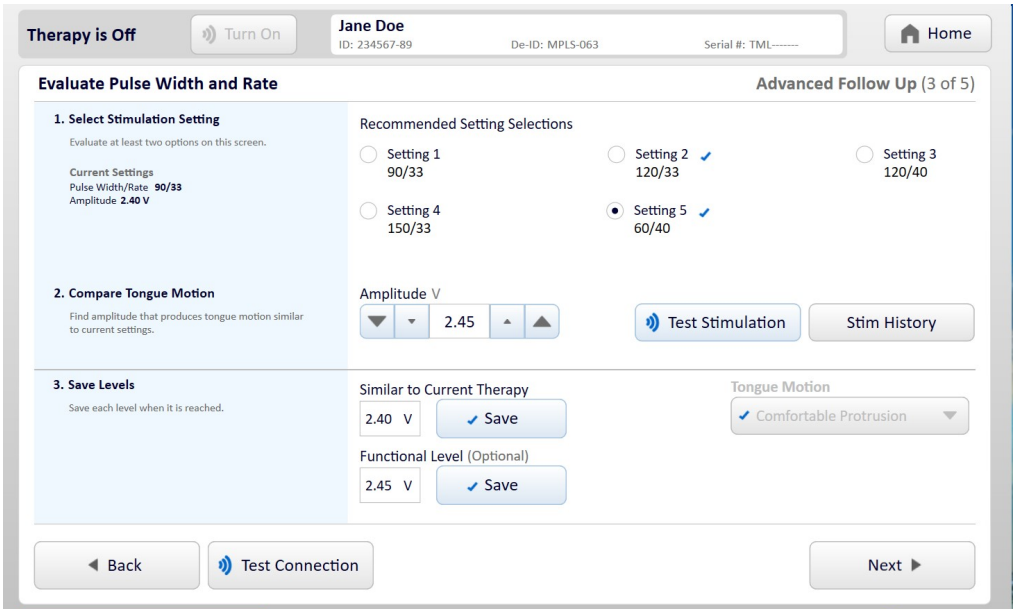


Figure 6-16. Advanced Follow Up - Evaluate Pulse Width and Rate Screen

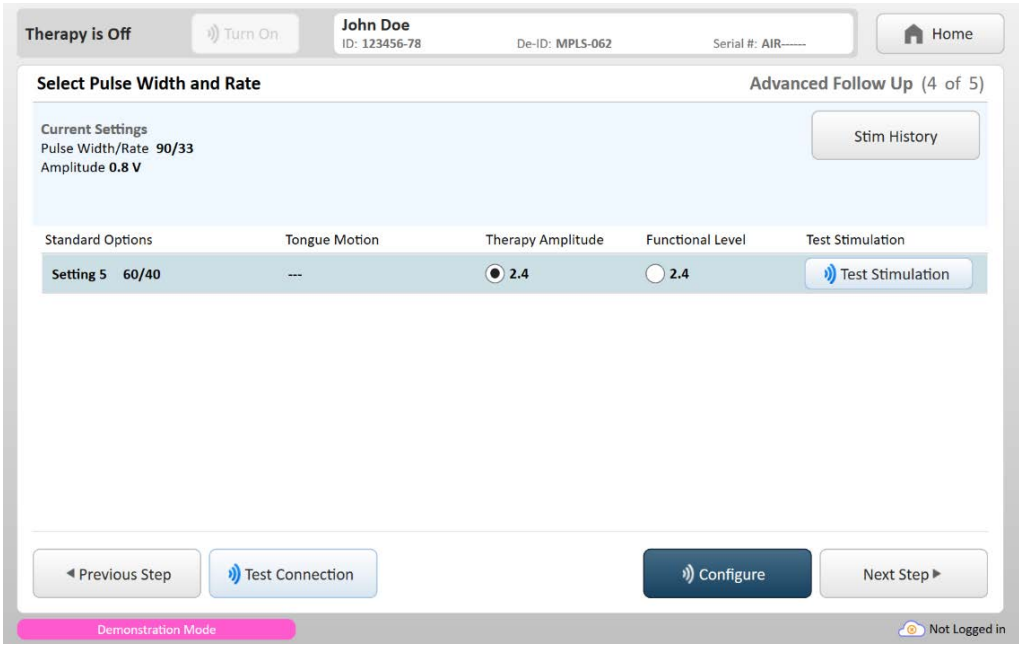
Select Pulse Width and Rate

1. Review the level and tongue motion data that was saved on the previous screen.
2. Select the desired setting.

   Notes:

   - If more than one setting displays, you may select **Test Stimulation** to determine which is most comfortable to the patient.
   - Therapy Amplitude is equivalent to the “Similar to Current Therapy” level from the previous screen.
3. Select **Configure** to program the new pulse width/rate and amplitude if the desired settings are new.
4. Select the **Next Step** button.

Models 3024 and 3028



Model 3150

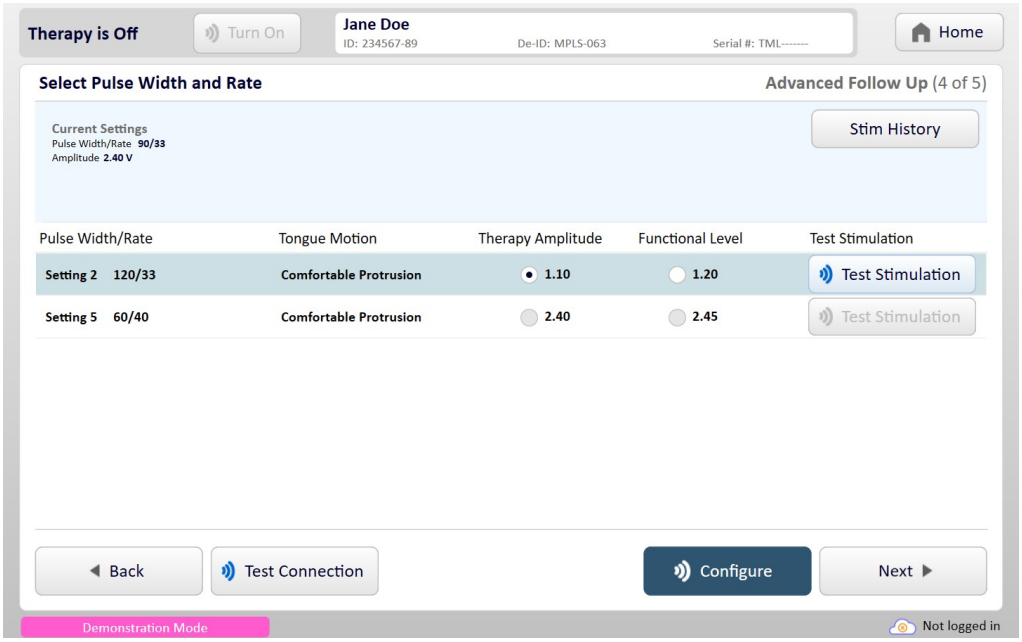
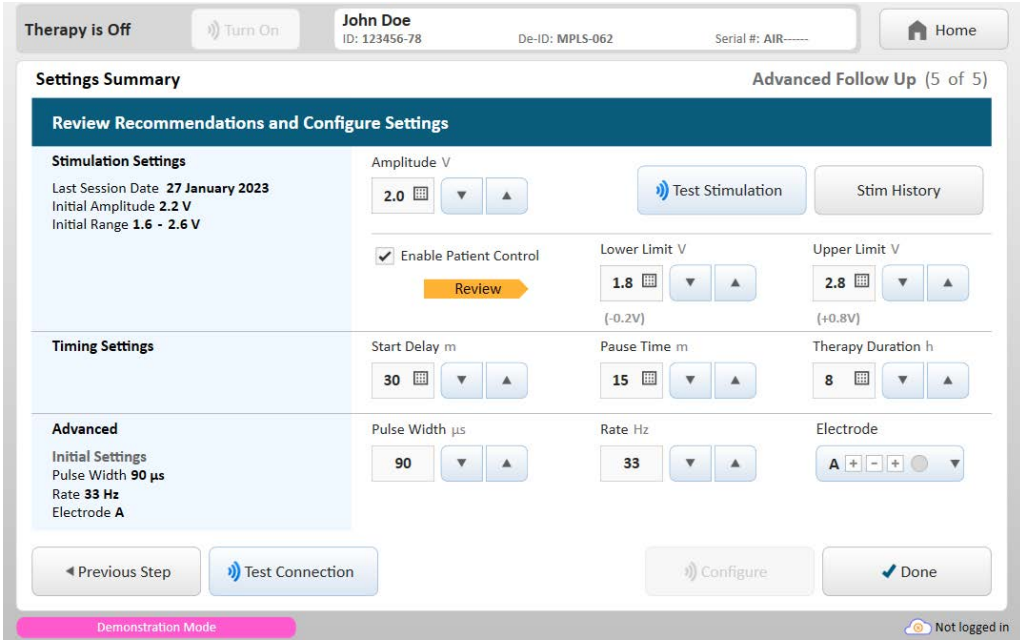


Figure 6-17. Advanced Follow Up - Select Pulse Width and Rate Screen

Settings Summary

1. Review the recommended settings.
2. If desired, make additional changes using the arrows and select the **Test Stimulation** button to evaluate.
3. If there are new settings to program in the generator, select the **Configure** button.
4. Select the **Done** button.

Models 3024 and 3028



Model 3150

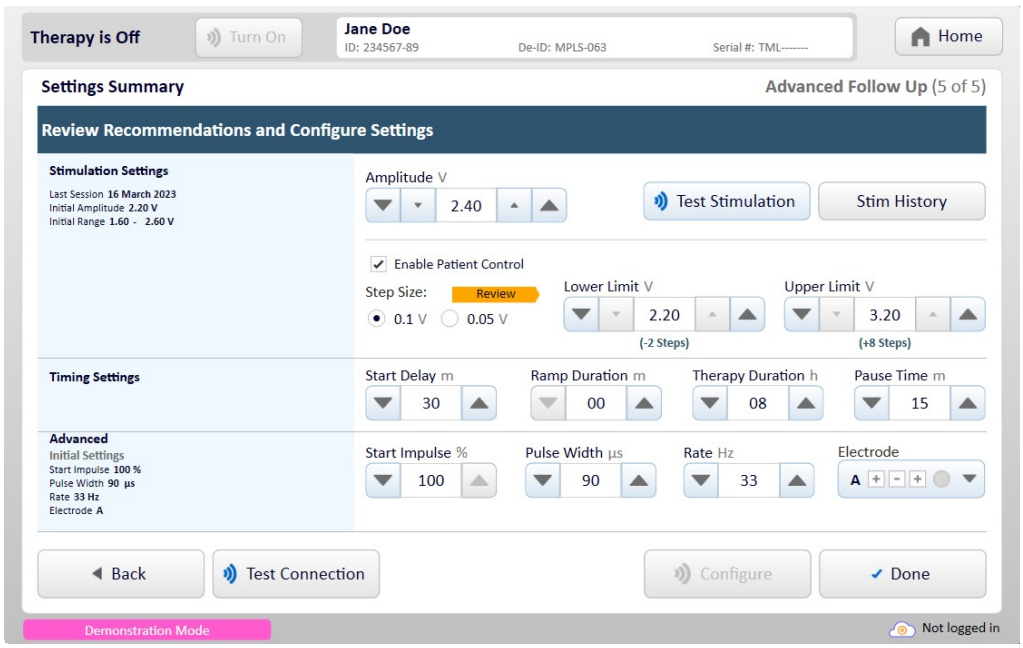


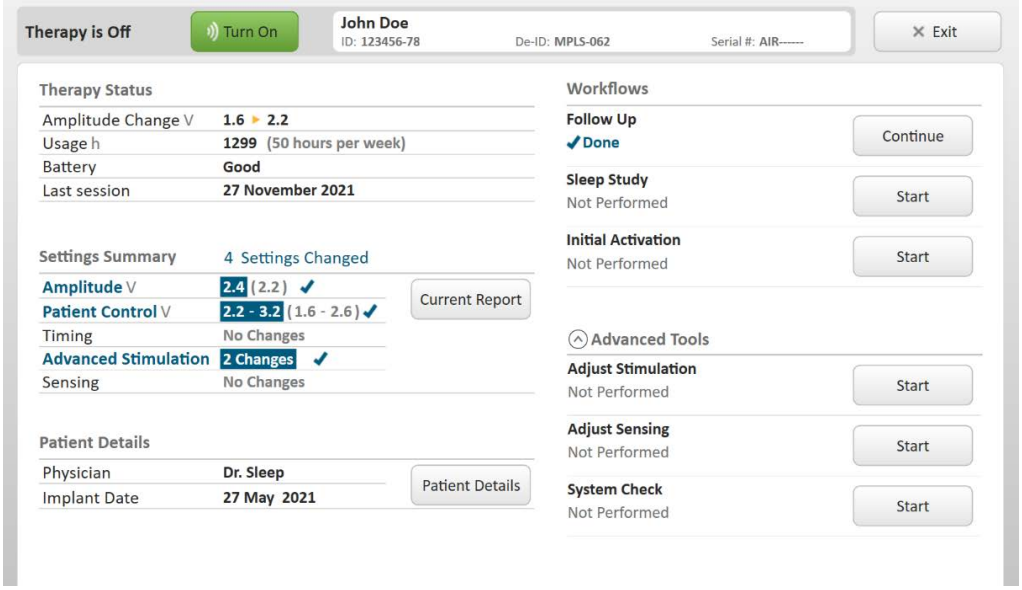
Figure 6-18. Settings Summary Screen

End Session

Before ending the Follow Up session:

1. Confirm that therapy is turned off.
2. Review the Settings Summary and confirm desired changes.
3. Confirm that the Follow Up Workflow has been completed.
4. Select the **Exit** button on the Home screen.

Models 3024 and 3028



Model 3150

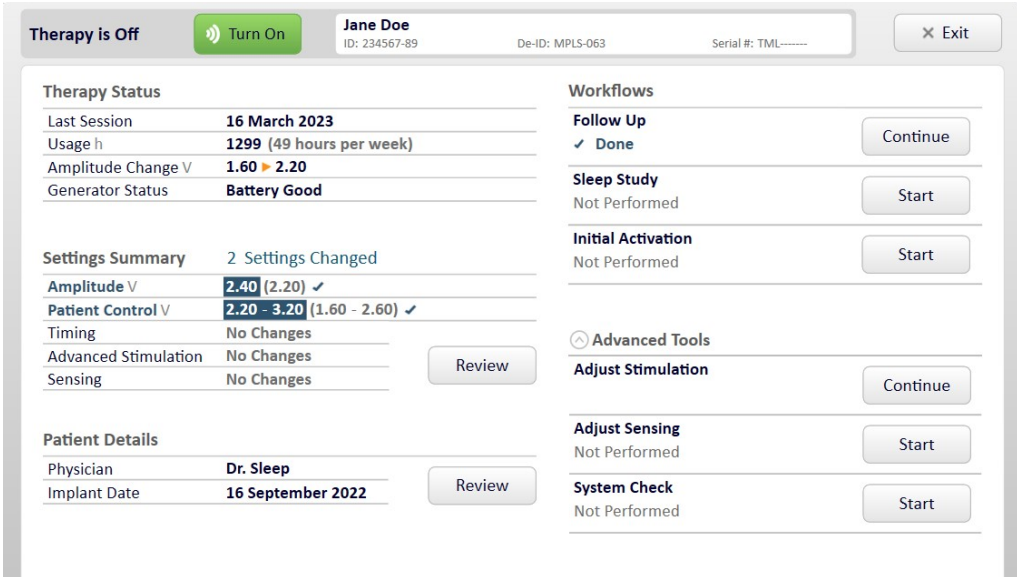


Figure 6-19. End Follow Up - Home Screen

Retain Records

Save a session report if desired. See “Saving Session Report as PDF” on page 116 for instructions.

Sleep Study

The goal of a Sleep Study is to evaluate the patient's response to therapy. A polysomnogram (PSG) is used to evaluate sleep quality.

Sleep Study Overview

- Attach Programmer Head
- Place Programmer Cable in Night mode (Optional)
- Start Session
- Review Therapy Status
- Start Sleep Study Workflow
- End Session
- Retain Records

Attach Programmer Head

After the sleep technician wires the patient for the PSG, complete the following steps to attach the programmer head:

1. Route programmer cable over the patient's shoulder.
2. Select the **Test Connection** button from the SleepSync Programmer Application or the programmer cable.
3. Move programmer head around implanted generator to find best location for a good signal strength considering all sleep positions. Monitor the strength gauge on the SleepSync Programmer Application screen or programmer head.

Table 6-1. Signal Strength Indicators

				
Good	**Moderate**	**Low**	**Generator Not Found**	**Electrical Interference**

4. Affix programmer head in optimal (good) position.
5. Confirm communications signal strength in all sleep positions.

Place Programmer Cable in Night Mode (Optional)

Full programmer cable lighting may disrupt a patient's sleep. To disable and dim programmer cable lighting:

1. Turn on the programmer.
2. Select **Night** mode from the Start screen.

Start Session

Start a session by connecting to the generator.

Review Therapy Status

Review the information displayed in the Therapy Status section of the Home screen. Note usage hours and any amplitude changes that the patient has made since the last visit, which are indicated by orange change flags. Talk to the patient to assess how effectively the patient is using the therapy.

Start Sleep Study Workflow

From the Home screen select **Start** for the Sleep Study Workflow.

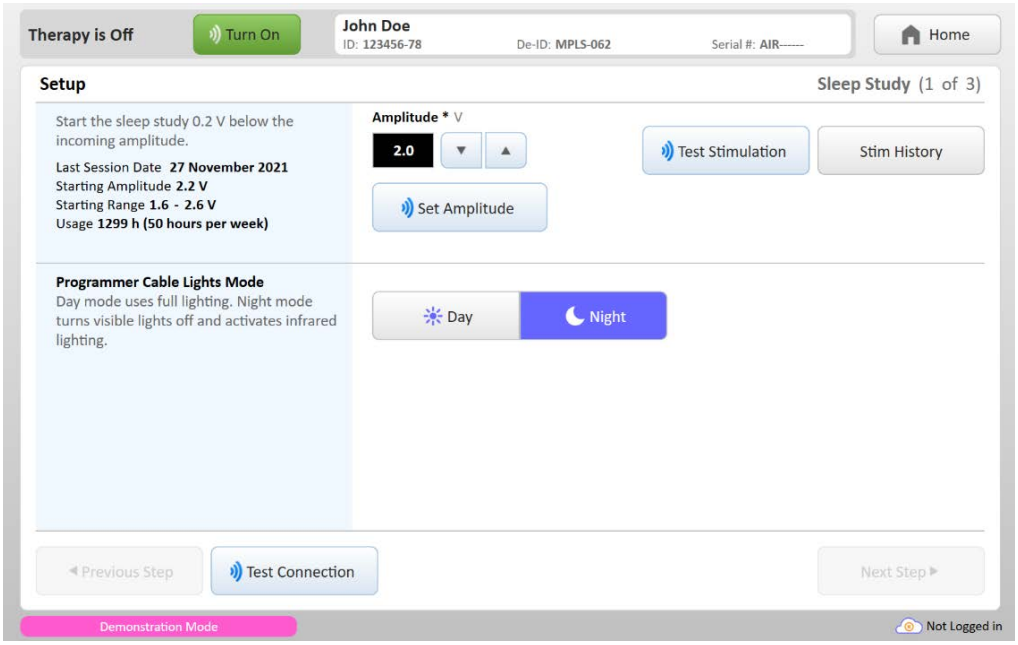
Setup

1. Once the PSG recording has started, use the arrow buttons to select the test stimulation amplitude value. It is recommended to start the sleep study two steps below the incoming amplitude.
2. Select the **Test Stimulation** button to deliver one burst of stimulation at the selected amplitude. Confirm that the stimulation is visible on the chin or submental EMG signal.
3. Determine inhalation and exhalation on PSG. During bio-calibrations, identify the direction of inhalation on the PSG flow sensors.

   Note: It is recommended to have both a nasal pressure cannula and a nasal/oral thermistor to reliably determine inhalation from exhalation during the sleep study.
4. Select **Set Amplitude** to program the amplitude.

   Note: Set Amplitude is different from Configure; to set an amplitude is to make a temporary change. The amplitude will return to its starting value when the sleep study is ended or when the workflow is exited.
5. If desired, change the programmer cable lights mode.
6. Select the **Next Step** button.

Models 3024 and 3028



Model 3150

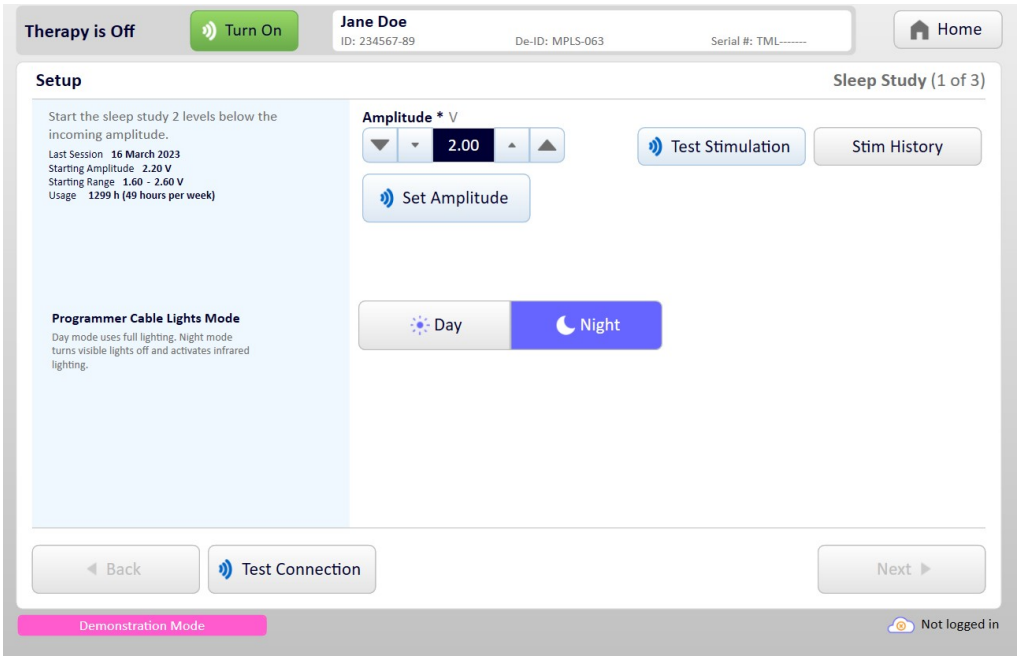


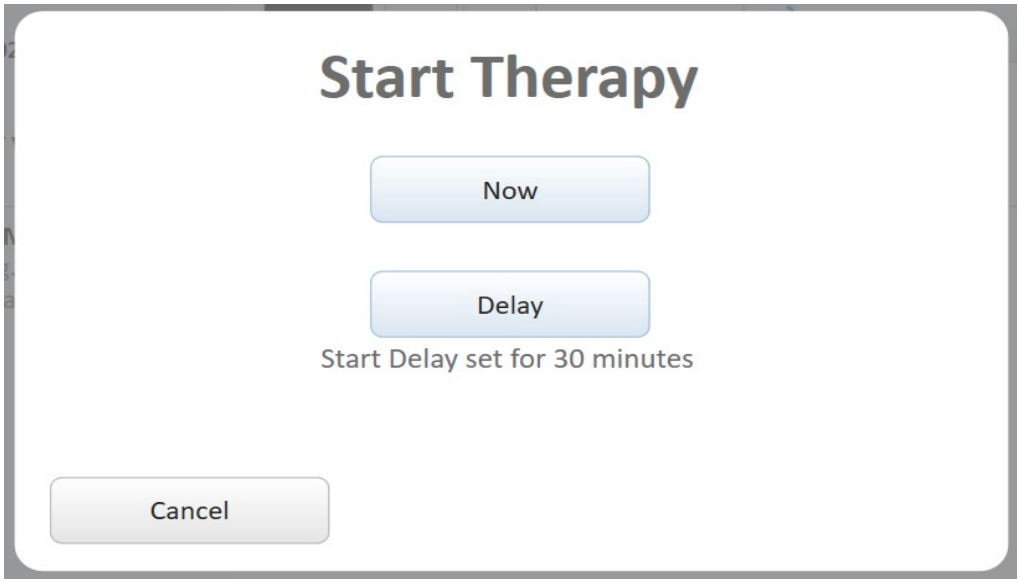
Figure 6-20. Sleep Study - Setup Screen

Adjust Stimulation

1. After the patient has fallen asleep, select the **Turn On** therapy button.
   – For patients with Models 3024 or 3028, select **Now** or **Delay** button from the Start Therapy screen.
   – For patients with Model 3150, select **Now, With Ramp** or **Delay with Ramp** button from the Start Therapy screen (Figure 6-21).

   Note: While waiting for the patient to fall asleep, review the patient's sleep history to determine which sleep positions and stages contribute most to overall AHI. Target these sleep positions and stages to provide the maximum therapeutic benefit to the patient.

Models 3024 and 3028



Model 3150

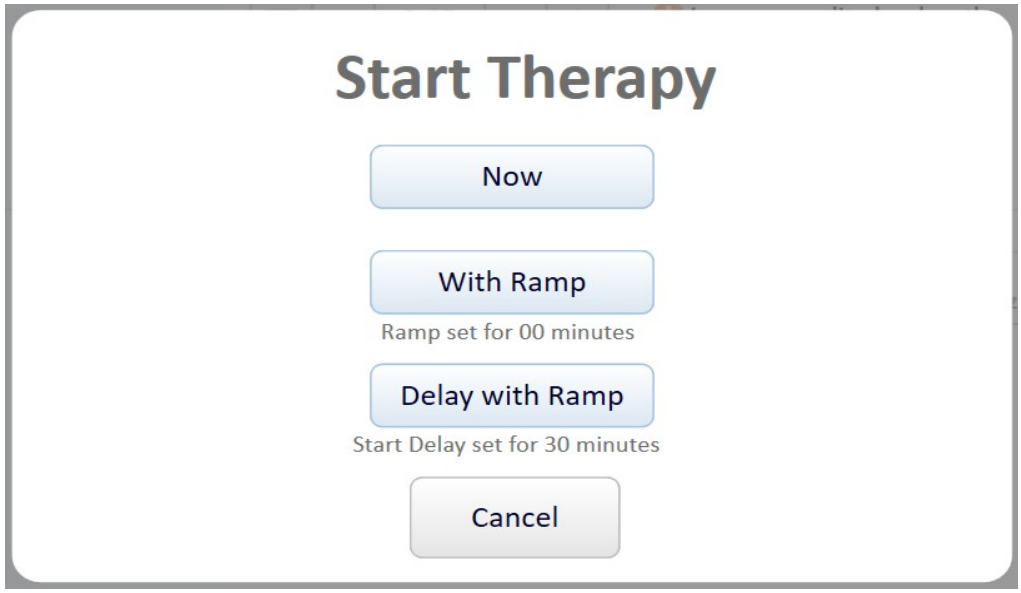
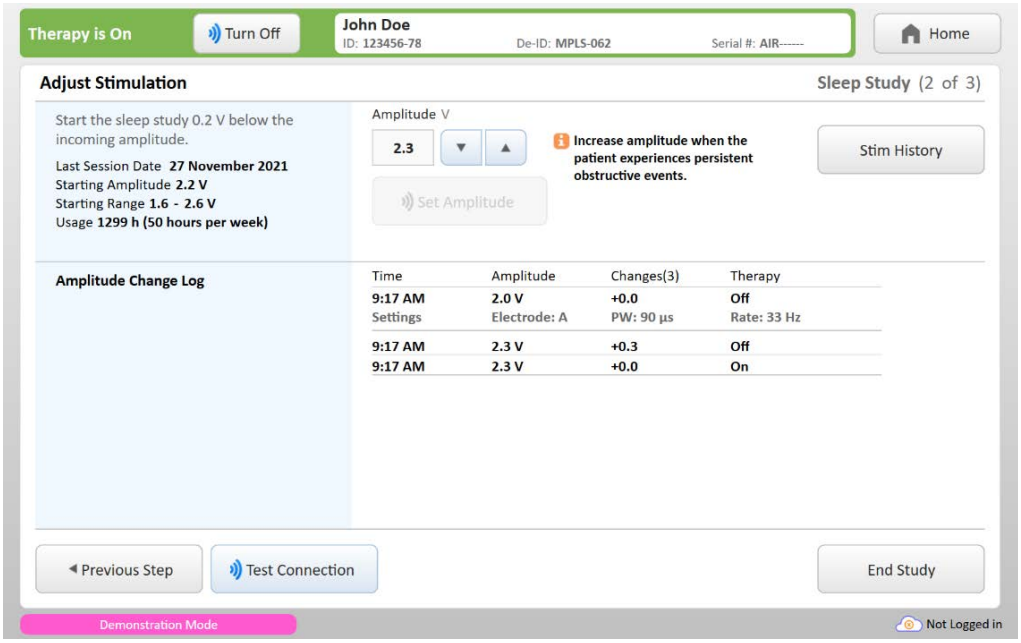


Figure 6-21. Turn On Therapy Screen

2. Monitor the patient's response to therapy and if necessary, make adjustments throughout the study as follows:
   a. If persistent obstructive events occur, increase the amplitude and select **Set Amplitude**. Observe the airflow response for at least 10 minutes and reevaluate the effectiveness of the amplitude setting.
   b. If the programmed amplitude wakes the patient, turn therapy off, reduce the amplitude, select **Set Amplitude**, and wait for the patient to fall back asleep.

      Note: Changes to the amplitude, therapy on/off state, and advanced stimulation settings will be logged and can be reviewed during the study.
3. Once the sleep study is completed, select the **End Study** button.

Models 3024 and 3028



Model 3150

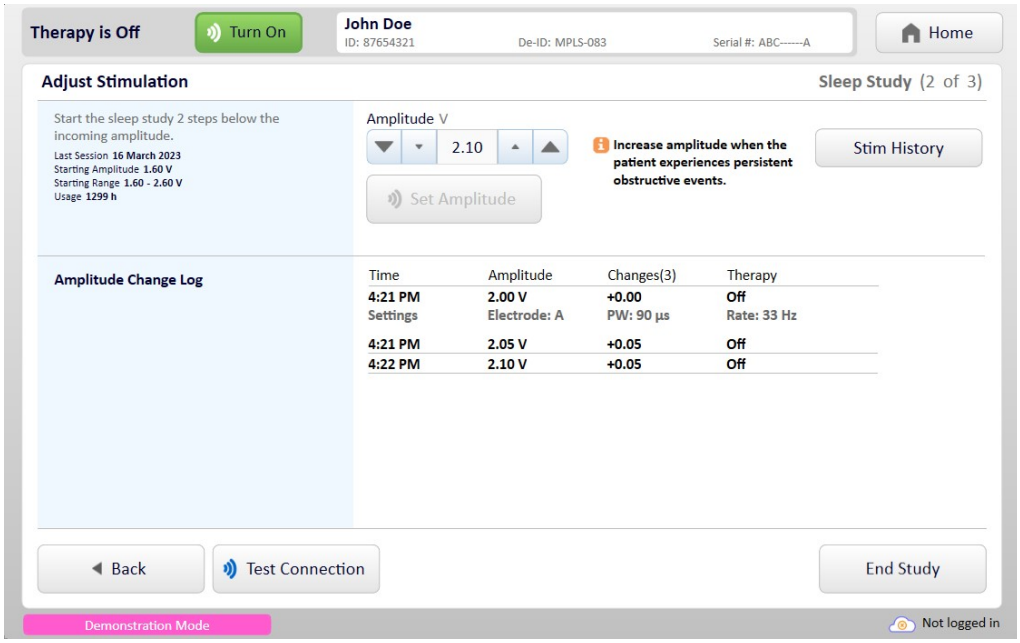


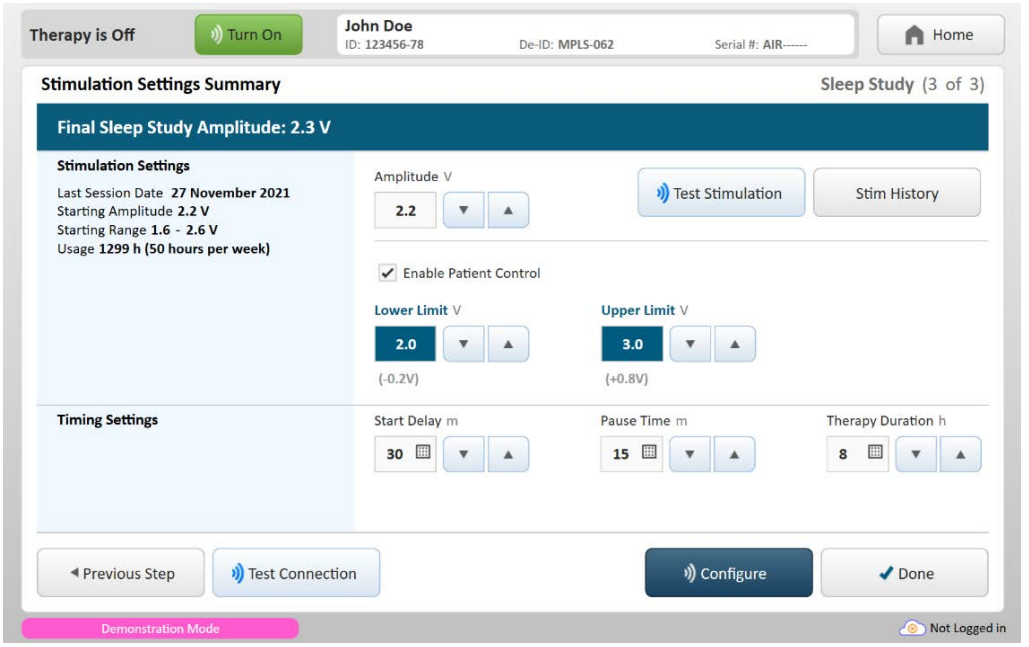
Figure 6-22. Sleep Study - Adjust Stimulation Screen

Stimulation Settings Summary

1. Review the final sleep study amplitude and current settings.
2. New control limits may be recommended. Select **Configure** to program any changes.

   Note: Consult the managing physician if a change to the amplitude is desired.
3. Select the **Done** button.

Models 3024 and 3028



Model 3150

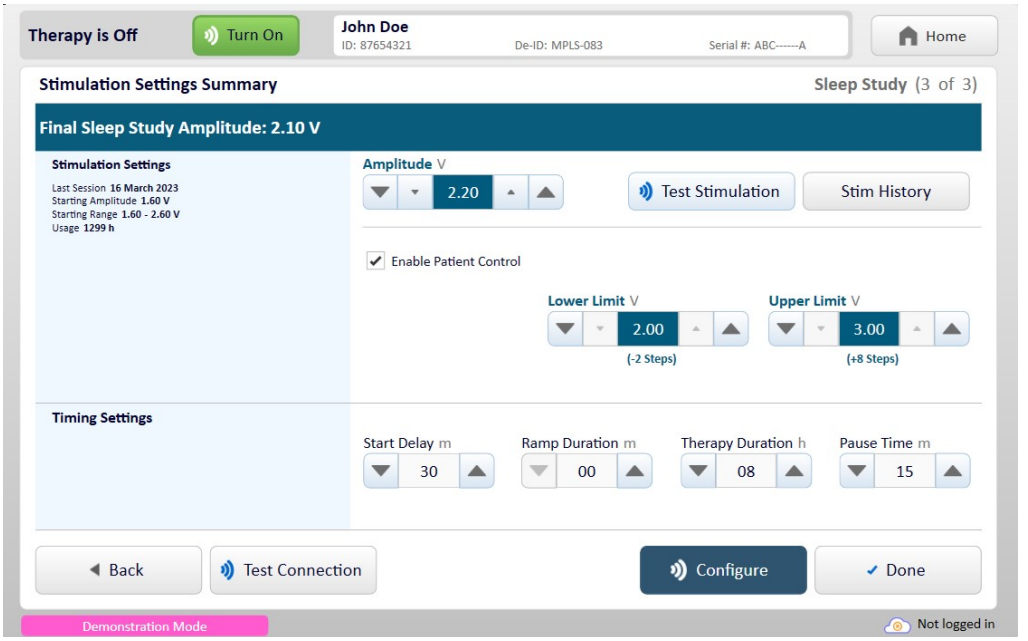


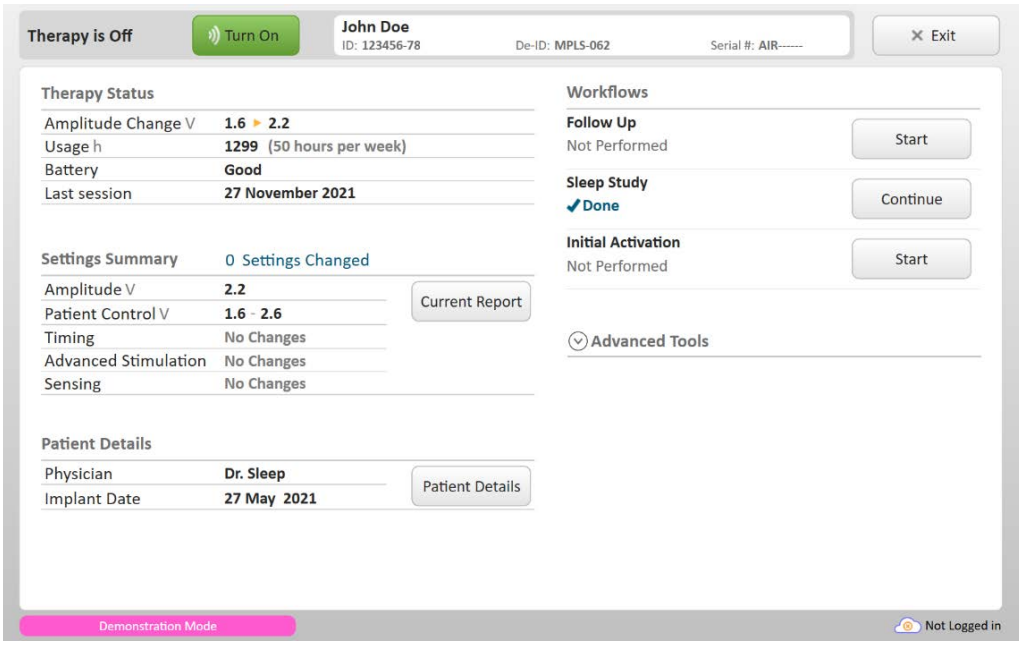
Figure 6-23. Sleep Study - Stimulation Settings Summary Screen

End Session

Before ending the Sleep Study Session:

1. Confirm that the Sleep Study workflow has been completed.
2. Select the **Exit** button on the Home screen.

Models 3024 and 3028



Model 3150

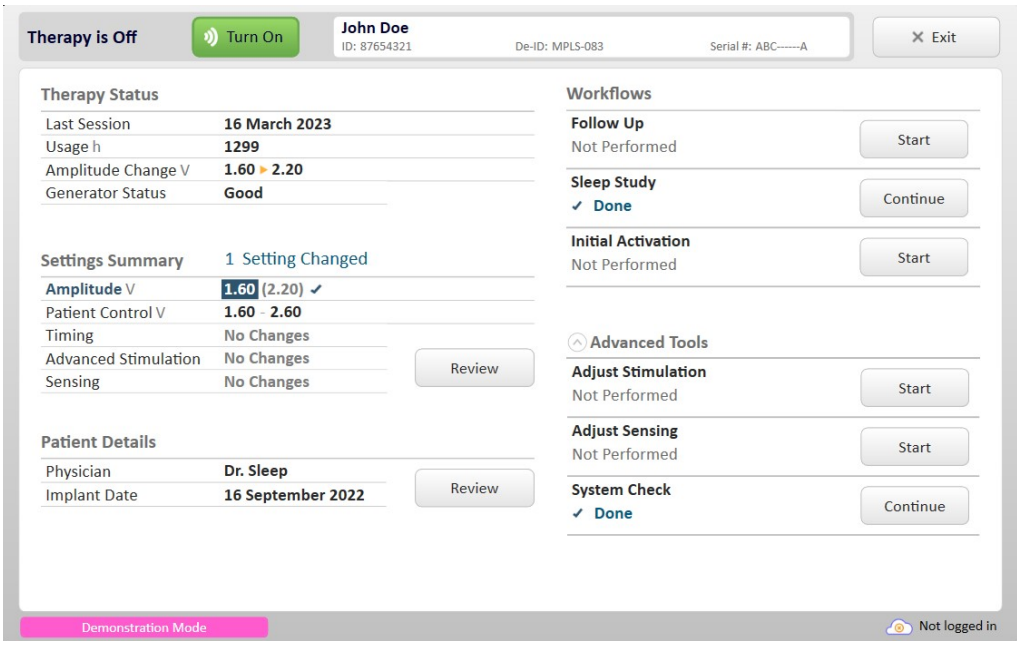


Figure 6-24. Ending the Sleep Study Session - Home Screen

Retain Records

Save a session report if desired. See “Saving Session Report as PDF” on page 116 for instructions.

Saving Session Report as PDF

1. Select the **Reports** button on the Start screen.
2. On the Patient List screen, highlight the patient's name and select the **View** button.
3. Confirm that the correct session report is displayed and select the **Save PDF** button.
4. Select the **Selected Report** button to save the current report only.
5. Select the **Combined Visit Report** button to save a report that combines programming sessions from the same visit.

   Note: The option to save combined reports will only be available if multiple reports are detected within a +/-24-hour period.
6. Select the information to be included by checking one or more of the following boxes: patient information, device information, waveform screenshots, and technical support logs. The Technical Support Logs option is hidden under the Additional Options dropdown menu.
7. Select the **Save PDF** button to save the report.

Chapter 7: Troubleshooting

This chapter contains solutions to problems that may be encountered during programmer use.

Communications

For problems commonly associated with communications, see "**Testing Connection Strength**" on page 27. If those steps do not resolve the problem, review the following solutions.

Note: In some cases, the SleepSync Programmer Application may take up to 10 seconds to reflect a change in signal conditions. It is recommended to observe each solution for at least 10 seconds before moving on to the next.

Electrical Interference

The presence of electrical equipment near the programmer cable or generator may interfere with communications. When electrical interference is detected, the symbol below (Figure 7-1) is displayed on the programmer head and on the screen. When this error is encountered, the following steps are recommended.

1. Keep the programmer cable three feet away from electronic devices and power supplies, including the power supplies used near the tablet or computer running the SleepSync Programmer Application.
2. If interference is encountered, unplug any unnecessary electrical equipment in the environment.
3. If interference is encountered, move the tablet or computer and programmer cable to different locations to assess whether the interference can be resolved.

Figure 7-1. Electrical Interference Symbol

Loss of Power to Programmer Cable

If power is disconnected from the programmer cable, reconnect to power. Normal operation resumes after power is restored. Review generator settings by accessing the Home screen.

1. Make sure your computer is within range of the programmer cable.
2. Wait 60 seconds for the connection process to continue.
3. Restart the SleepSync Programmer Application at the earliest convenience.

Programmer Cannot Find Generator

Refer to the steps described in "**Testing Connection Strength**" on page 27. If those measures do not resolve the problem, the generator battery may be depleted. Try the following:

1. Use the patient's Sleep Remote to turn off the generator therapy. Try this several times if not immediately successful.
2. If the patient's Sleep Remote is able to turn off the generator, retry communication using the programmer.
3. If the patient's Sleep Remote cannot communicate with the generator either, wait 24 hours and try using the patient's Sleep Remote again to turn off therapy.
4. If still unsuccessful, the generator may need to be replaced. Contact Inspire Medical Systems.

Cannot Establish Connection to Programmer Cable

If the cable connection status line in the screen footer always displays "searching for programmer cable":

1. Move your computer to within 1 m (3 ft) of the programmer cable.
2. Disconnect the programmer cable from power and reconnect it.
3. If there is still no connection, close the SleepSync Programmer Application by navigating to the Start Screen (Figure 4-1) and selecting the **Close App** button.
4. Disconnect the programmer cable from power and reconnect it.
5. Open the SleepSync Programmer Application and repeat steps 1–2.
6. If there is still no connection, navigate to the Cable Status Screen (Figure 5-6). If a cable is paired but not connected, confirm that the serial number of the cable (the serial number is located on the back of the programmer cable controller) matches the serial number on the Cable Status screen.

If no cable is paired or if you desire to use a new cable, you can pair a new cable from the Cable Status screen.

If these steps do not resolve the problem, select the Technical Support link.

Pairing

Do not use the Windows Settings menu to attempt pairing. Only pair using the SleepSync Programmer Application.

If pairing is not successful, try the following:

1. Attempt to pair again.
   a. It is recommended that you retry at least 2-3 times.
2. Ensure that your setup is correct.
   a. Navigate to the Programmer Settings Screen (Figure 5-5) and select the **System Self Check** button. Ensure that the self check is successful.
   b. Ensure that the programmer cable is within six feet of your computer.
3. Close any other applications on the computer that may be using Bluetooth.

   Note: It is recommended to quit Microsoft Teams if you are having problems with pairing. Right-click on the Teams icon in the taskbar and select **Quit**. Simply *closing* the Teams window by right-clicking the taskbar icon or using the X in the upper

right corner won't have the desired result. Teams can be opened again once pairing is complete.

4. Ensure that you are successfully entering pairing mode when on the Pair a Programmer Cable Instructions (Figure 3-8).
   a. Be sure to start pressing the **Test Connection** button ***before*** connecting the cable to power.
   b. Continue holding the button for 10 seconds or until all the lights flash on and off.

Notes:

- The on/off light pattern for pairing mode is different from the normal rotating pattern that occurs after connecting the programmer cable to power.
- If you hold the button for 10 seconds and don't see any lights on the programmer cable, the device may be in Night mode (see "Start Screen" on page 38). Pairing will still work and you can continue with the pairing process.

Application Startup

If the application will not open, try the following steps:

1. Open Task Manager.
2. Select the **Inspire SleepSync Programmer** in the list of processes.
3. Select **End task**.
4. Open the SleepSync Programmer Application.

The SleepSync Programmer Application will not be operational when running as administrator.

1. Close the application and open it again without running as administrator.
2. If you are not attempting to run as administrator, ensure that Administrator Approval Mode is turned on for your Windows computer. Updating this setting requires a group policy change.

Programmer Cable - Error Mode

If the programmer cable detects an error, it will enter a error mode and will display orange lights as shown below (Figure 7-2). Disconnect and reconnect power to the programmer cable, and if the error is not resolved, contact Inspire Medical Systems.

Figure 7-2. Error Mode Indicator

Therapy

Setting Changes Not in Generator

If setting changes made during a session do not appear on the Home screen, in a session report, or in the generator:

1. Return to the appropriate programming screen and repeat the desired setting changes.
2. Select the **Configure** button. If you leave a screen before selecting this button, the changes will not be saved to the generator.
3. Review settings on the Home screen before ending the session.
4. Always allow all communications to complete before a patient leaves. If a patient is allowed to leave during a test stimulation or impedance measurement, the generator may not be restored to therapy settings.

Usage

The therapy usage status displays red on the Home screen when therapy has been on for less than 4 hours per night since the last programming session. Reference the last session date on the Home screen.

Therapy Is On But Stimulation Is Not Active

If you have selected the **Therapy On** button but therapy appears to be inactive, the generator may be in start delay or pause time.

Patient Amplitude Change Is Incorrect

If the previous programming session was not ended properly or was conducted with an earlier version of the application, the patient amplitude change information that displays on the Home screen may be incorrect.

To ensure that patient amplitude change information is correct follow these guidelines:

- Always review therapy settings and properly end the programming session before the patient leaves.
- Never let a patient leave after a forced programmer shutdown until you reconnect to the generator and confirm the generator settings.

Jerky or Halting Stimulation

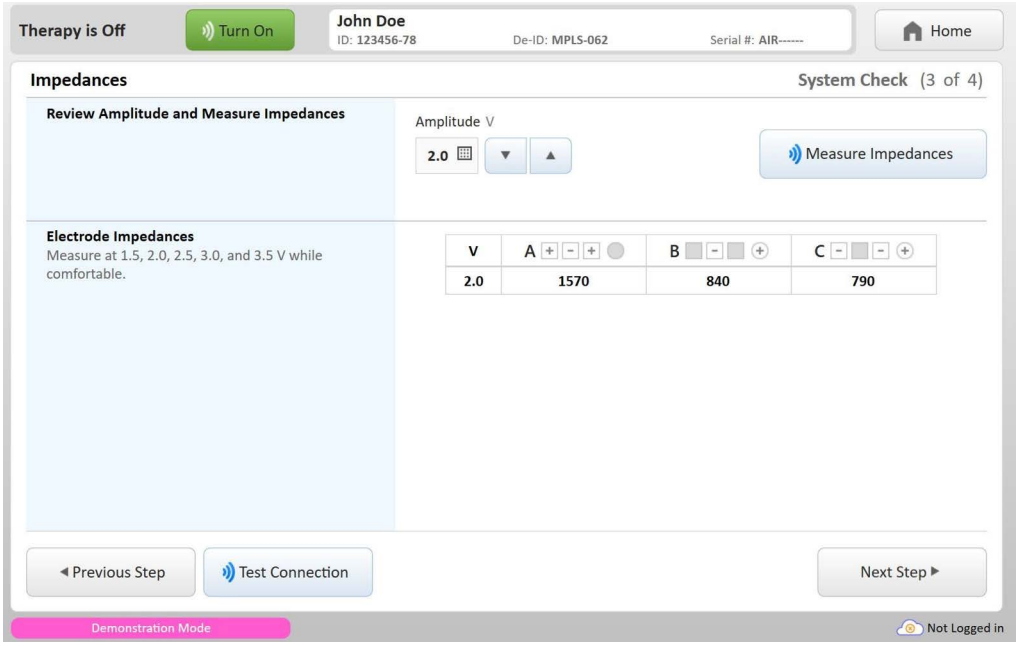
Jerky or halting stimulation can occur as a result of wireless communications interrupting stimulation. To reduce the likelihood of halting stimulation:

1. Turn off therapy before testing stimulation or changing generator settings.
2. Reposition programmer head to achieve stronger signal strength.

Measure Impedances

The Measure Impedances screen (Figure 7-3) can be accessed from the System Check (Advanced Tools) workflow. This screen is used to assess the integrity of leads, lead electrodes, and the lead-generator connection.

Models 3024 and 3028



Model 3150

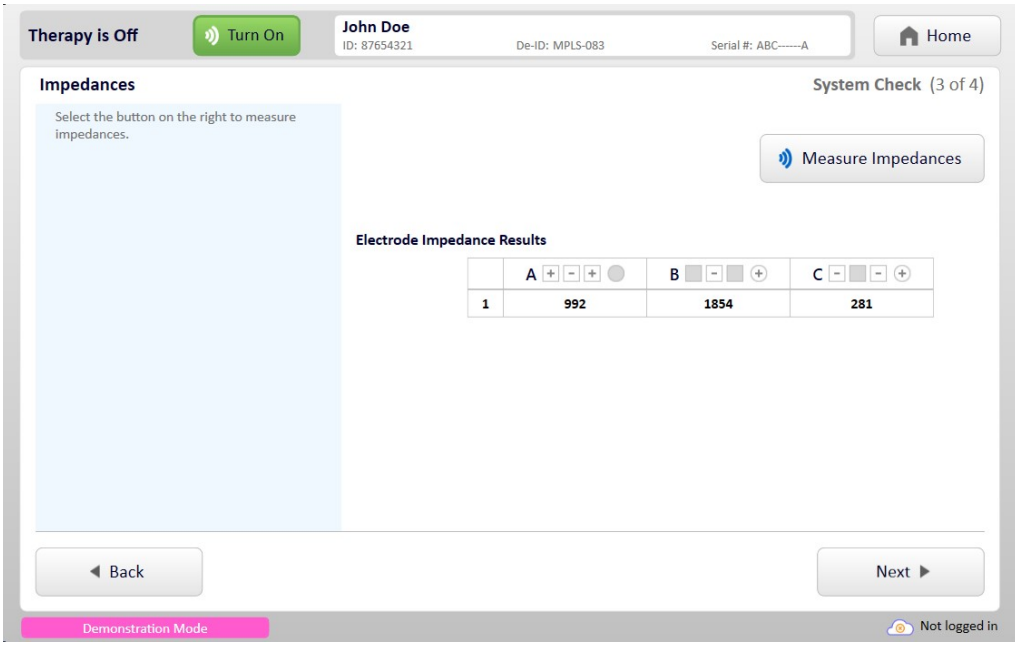


Figure 7-3. Measure Impedances Screen

Follow the numbered steps on screen to measure impedances for Models 3024 and 3028:

1. Review Amplitude.
   - Use the arrow buttons to increase or decrease amplitude.
   - The default amplitude setting is 1.5 V. Higher amplitudes increase measurement accuracy, but may be uncomfortable for the patient.
2. Select the **Measure Impedances** button.
   - It is recommended to measure impedances at 1.5, 2.0, 2.5, 3.0, and 3.5 V while the patient remains comfortable.
   - Analyze impedance measurement results.
   - A measured impedance < 200 ohms may indicate a short between lead conductors preventing stimulation from reaching the patient.
   - Additionally, certain combinations of impedance results may indicate a problem. These will be flagged as abnormal if they occur.

For Model 3150, select the **Measure Impedances** button.

Impedance values should be considered for information only.

Waveforms

Waveform Is Not Moving

First, confirm that waveform mode is turned on. Then press the arrow button pictured below to return to the live waveform image.

Table 7-1. Arrow Button to Navigate to Live Waveform Image

3024 and 3028	3150
	

Waveform Is Flat or Orange

If the waveform is flat:

1. Wait for 30 seconds.
2. Select the **Stop Waveform** button and then select the **Start Waveform** button to restart waveform. Wait for 30 seconds after the waveform displays.

If the waveform is orange:

1. Select the **Turn Off** therapy button.
2. Ensure the programmer cable is within connection range.
3. Ensure the programmer head is positioned directly over the generator and the connection strength gauge is showing at least one blue bar.
4. Select the **Start Waveform** button to restart therapy in waveform mode.

   Note: The programmer head may shift when the patient changes sleep positions. Assess connection performance in all sleep positions.

Managing Patient Data and Reports

Report Data Display as "---"

When data such as levels or peak pressure display as "---", it means that a value was not collected during the programming session.

If settings such as amplitude display as "---", the report may be corrupted. The data may be available in a previous or later report.

Reports Do Not Contain Patient Information

Review the data controls on the Programmer Settings screen. Select the **Allow patient data in PDFs** check box. See "Adjusting the Programmer Settings" on page 26.

Cannot Find a Report

If you cannot locate a particular report and the generator underwent a reset, then the report may be stored under the serial number 000001 or 300000.

If you cannot locate a particular report and a generator reset did not occur, your computer may have run out of storage space.

If a patient's data appears to be missing from the Reports screen, the programmer may be configured to delete patient data from the computer after the data has been uploaded to SleepSync. See "Adjusting the Programmer Settings" on page 26. To view this patient data, log into SleepSync and the patient will appear on the Reports screen.

Note: To prevent future patient reports from being deleted, work with your IT personnel to determine if deselecting the "Delete data after SleepSync upload" option in the programmer settings makes sense for your organization.

Patient Details Changed Automatically

Each time you start a programming session while logged into SleepSync, the programmer synchronizes with SleepSync to ensure the patient information is current. If newer patient information is available from SleepSync, the programmer will automatically update the patient information accordingly.

Uploads

Programmer Doesn't Upload Data From the USB Drive

If the programmer does not automatically detect a USB drive, review the following solutions.

1. If you connected the USB drive to the computer while a programming session was in progress, the programmer will not detect the USB drive. After the session is completed, unplug the USB drive and then reconnect the USB drive to the computer.
2. The programmer may not be able to detect the data on the USB drive. See "Uploading Patient Data" on page 31.
   a. Ensure the desired files are saved no more than five folders deep on the USB drive.
   b. When saving the files to the USB drive, ensure the "Technical Support Logs" checkbox is selected under the "Additional Options" dropdown menu on the Save PDF screen. See Figure 5-26 on page 74.

Data Missing From USB Drive After an Upload

After successfully uploading data to SleepSync from the USB drive, the programmer will create a new folder on the USB drive called "Uploaded" and move the uploaded files there. Use the file explorer on the computer to navigate to the "Uploaded" folder on the USB drive to access the files.

Programmer Doesn't Upload Data From a Model 2500 Sleep Remote

If the programmer does not automatically detect a Model 2500 Sleep Remote, review the following solutions.

1. If you connected the Sleep Remote to the computer while a programming session was in progress, the programmer will not detect the Sleep Remote. After the session is completed, unplug the Sleep Remote and then reconnect the Sleep Remote to the computer.
2. The Sleep Remote may have no stored data available for upload.

Sleep Remote Doesn't Have a USB Connector

If the Sleep Remote does not have a USB connector, it is a Model 2580 Sleep Remote. The programmer only supports uploads from the Model 2500 Sleep Remote. To upload Model 2580 data to SleepSync, use the Inspire Sleep mobile application.

Uploaded Patient to Incorrect Practice

If you accidentally upload a patient to an incorrect practice, contact Inspire Medical Systems.

Abnormal Impedances

Impedance measurement results less than 200 ohms may indicate a lead–generator connection problem. Test stimulation to confirm a good lead–generator connection.

Impedance values greater than 2000 ohms are outside the generator measurement range and should be considered for information only.

Certain combinations of impedance results may be flagged as abnormal. Repeat the measurement and if the flagged results persist, contact Inspire Medical Systems.

Generator

Generator Reset

A generator reset can occur in response to a low generator battery or electromagnetic disturbance.

Models 3024 and 3028: The generator serial number is cleared by the reset and must be re-entered during the next programming session. When prompted by the generator reset screen,

1. Enter the numeric portion of the serial number which can be found in the patient's medical records.
2. Select the **Check** button.
   a. If the patient information displayed is correct, select the **Configure** button to configure the generator with the entered serial number.
   b. If the patient information is incorrect, enter the correct serial number and select the **Check** button. Confirm that patient information is correct and select the **Configure** button.

   Note: The generator will reset to default settings.
3. If the serial number is unavailable, select the **Cancel** button. When prompted, select the generator model and select the **Configure** button. The generator will be configured with a temporary serial number and the session report will be stored under the temporary serial number without a patient name or ID.

Model 3150: No action is required.

Generator Check Failure

If a Generator Check failure occurs with a Model 3150, a "Reset Generator" button will appear in the lower-left corner of the screen. Select this button and confirm the generator reset on the following window. This will end the current programming session. The generator settings will be preserved through the generator reset.

After the generator reset has finished, start a new programming session. If the Generator Check failure occurs again, contact Inspire Medical Systems with the error code shown on the screen.

Invalid Setting

It is possible for the generator to have an invalid setting. If an invalid setting is detected at the start of a programming session, that setting is reprogrammed to a valid value. When this occurs, all settings should be reviewed to ensure they are correct for the patient.

Saving

Save PDF Failure Screen

If a Save PDF failure screen displays, select a different location to save the PDF and retry.

Missing Information

If a saved report is missing patient information, device information, waveform screenshots, or advanced settings (such as electrode configuration or level measurement settings), or technical support logs, select the check box that corresponds to the desired information on the Save PDF screen and repeat the save.

To include technical support logs, select the Advanced Save Options dropdown and then select Include Technical Support Logs.

The option to include patient information, screenshots, and advanced settings in a saved report always displays regardless of whether the content is available for a particular report. Review the report on screen to determine if the content is available.

Additional Troubleshooting Information

For additional troubleshooting information, please visit https://professionals.inspiresleep.com/programmer/

This page is intentionally blank.

Chapter 8: Warnings and Precautions

This chapter contains the programmer warnings and precautions.

Warnings

- Do not modify this equipment without authorization of the manufacturer.
- Battery capacity — The generator battery capacity can be measured using the SleepSync Programmer Application. Patients should schedule an appointment with their physician when the generator battery status displays Low or Depleted. Depending on generator battery settings and usage, the generator may last for days or weeks after the battery status displays Low.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the programmer and other equipment should be observed to verify normal operation.

Precautions

Defibrillation

When a patient is in ventricular or atrial fibrillation, the first consideration is patient survival. Use of external defibrillation or cardioversion while the programmer head is in contact with the patient may induce potentially damaging electrical currents into the programmer. It is recommended to remove the programmer head from the patient prior to the use of defibrillation.

Setup

- When moving the system between environments with very different humidity and/or temperature ranges, allow sufficient time to adjust to the new humidity or temperature.
- Do not drop the system components or subject them to other mechanical shocks.
- Do not apply heavy pressure to the system components or subject them to strong impact. Excessive pressure or impact can cause damage to the components or otherwise cause malfunctions.
- Do not place the system components in an unsteady location. Do not place the system components in direct sunlight or next to equipment that generates heat. This can damage the programmer and may generate heat or fire.
- Do not use the programmer cable power supply for other equipment. This can generate heat or fire. In addition, do not use other power supplies with the programmer cable.
- When viewing the screen for long periods of time, rest your eyes for approximately 10–15 minutes every hour. Failing to rest your eyes can cause eye strain and other deterioration of eye health.

- The programmer can be susceptible to electromagnetic interference and must be used according to the electromagnetic compatibility (EMC) guidelines found in this manual.

Operating Environment

- To avoid possible electric shock, do not allow the patient to touch the programmer or use the programmer in the patient environment (within 1.5 meters/5 feet).
- The programmer is not certified for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.
- Operate the system at the recommended temperature range of 5 °C to 30 °C (41 °F to 86 °F). Store it at a temperature of -20 °C to 60 °C (-4 °F to 140 °F).
- Electromagnetic disturbances from the programmer may interfere with other equipment or the programmer could be interfered with by other equipment, including portable and mobile Radio Frequency (RF) communications equipment. If interference occurs, relocate the equipment.
- Do not bring the programmer into Zone 4 (magnet room), as defined by the American College of Radiology. The programmer is MR Unsafe.
- Electromagnetic interference could be caused by unseen sources such as radio frequency identification (RFID) devices or wireless charging (Qi). If interference is suspected, relocate the equipment and use the Test Connection feature to evaluate connection performance.
- Do not open or attempt to service this product. Opening or servicing the system components can result in electric shock.
- Return system components to Inspire Medical Systems for secure decommissioning. Notify Inspire Medical Systems of any suspected security event.

Disposal

Do not dispose of the system components if they are no longer being used or if they become inoperable. They must be returned to Inspire Medical Systems.

Power Cord and Other Cables

- Do not touch mains connected parts (power cords) and the patient simultaneously because of a risk of electrical shock to the patient and user.
- Power cord sets used in other countries must meet the requirements of that country. Use the appropriate power cord for your locale. For information about power cord set requirements, contact Inspire Medical Systems.
- Do not plug the power cord into an extension cord or multiple portable socket outlet (MPSO). The device has not been tested for safety or electromagnetic emissions in this configuration, and proper performance cannot be guaranteed. Plug the power cord directly into an electrical outlet.
- When using the power cord, make sure to position it around objects so it will not be cut or punctured.
- Make sure the connection where the power cord connects to the mains power is easily accessible and can be easily disconnected by the user.

Chapter 9: Supplemental Information

This chapter describes how to maintain, clean, and service the programmer. It also includes default settings, device specifications, protected health information safeguards, and regulatory information.

Programmer Maintenance

Programmer Cable Cleaning Recommendations

Follow these recommendations when performing general cleaning for the programmer cable:

- Always unplug the programmer cable before cleaning.
- Keep liquid, including the cleaning fluid, out of any openings.
- Test cleaning products on a small portion of the programmer cable before use.
- Use a drop of dish soap and a damp cloth for regular cleaning. Do not submerge the device in water.
- Periodically disinfect the programmer cable according to your institutional policies for surface and equipment safety and cleanliness.
- Contact Inspire Medical Systems for further details on specific cleaning and disinfectant products.

Programmer Head Cleaning

Follow these recommendations when removing adhesives or other difficult residue from the programmer head portion of the device:

1. Use 96% or higher isopropyl (IPA) wipes.
2. The repeated use of adhesive removers such as Goo Gone® Adhesive Remover is not recommended for the programmer head.

Sleep Study Recommendations

These recommendations can help keep Programmer Heads clean during sleep studies.

1. Do not apply tape directly to the Programmer Head. Alternative methods include:
   a. Wrap the head in Coban™ tape before applying tape.
   b. Place a Post-It® note, gauze or other material between the tape and the Programmer Head.
2. Use 3M™ Transpore™ tape. Residue from this tape is easier to clean than Micropore™ tape or Cover-Roll® tape.
3. Clean the Programmer Head after each sleep study.

Portability Kit

Clean the case with a soft cloth lightly dampened with water.

Servicing the Programmer Cable

The programmer cable has been carefully engineered, manufactured, and tested to provide trouble-free service. Contact Inspire Medical Systems if service or repair is required. Contact information is printed on the back cover of this programming guide.

If possible, please ship the programmer cable back to Inspire Medical Systems in its original shipping container. If the original container is not available, contact Inspire Medical Systems regarding packaging the programmer cable for shipment.

Please write the programmer cable serial number on all correspondence. The programmer cable serial number is located on the back of the controller of the programmer cable.

Contact Inspire Medical Systems for replacement parts.

Default Settings

Table 9-1 lists the default values for all basic and advanced settings.

Table 9-1. Default Setting Values

Setting	Value
Amplitude	0.0 V
Electrode configuration	 Configuration A
Exhalation sensitivity	-4
Exhalation threshold	-1
Hard off period	38%
Inhalation sensitivity	0
Inhalation threshold	+1
Invert signal	Off
Maximum stimulation time	4 s
Patient control	Off
Pause time	15 m
Pulse width	90 µs
Ramp (Model 3150 only)	0 m
Rate	33 Hz
Soft off period	13%
Start delay	30 m
Start Impulse (Model 3150 only)	100%
Therapy duration	8 h

Device Specifications

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the third edition of IEC 60601-1, respectively).

Anyone connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems.

Local laws take priority over the requirements mentioned above. Contact Inspire Medical Systems with any questions.

Programmer Cable

Table 9-2. Model 2740C Programmer Cable

Description	Specifications
Temperature with power on	Temperature: 5 °C–37 °C (41 °F–99 °F) Humidity: 20–80% Air pressure: 697–1060 hPa (10–15.4 psi)
Temperature with power off for storage or transportation	Temperature: -20 °C–60 °C (-4 °F–140 °F) Humidity: RH 10–90% RH Air pressure: 187–1060 hPa (2.7–15.4 psi)
Programmer cable power supply (Class I) Globtek P/N: TR9CE1500CCP-IMR6B (Type BF applied part, Class I system) (UL agency approval under UL 60601-1)	Input: 100–240 VAC, 50-60 Hz, 0.6 A Output: 12 VDC, 1.5A, 18W
Telemetry	175 kHz Short-range inductive link (<15 dBμA/m at 10 m)
Bluetooth connectivity	2.4 GHz ISM band (<10 mW)
Ingress protection	IP22
Mode of operation (continuous or non-continuous)	Continuous

Security

Overview

The Inspire SleepSync Programmer Application (Model 2740S) is designed with features to ensure the security of the Inspire system and associated patient data. To provide safe and secure operation of the application, it is recommended that customers adopt the best practices described in this section along with the security policies and best practices recommended by their respective organizations.

This information is not intended as a comprehensive or exhaustive list of issues and recommendations. The following information is also intended to assist customers in

safeguarding electronic protected health information (ePHI) and complying with the requirements of the United States Health Insurance Portability and Accountability Act (HIPAA) Security Rule, 45 C.F.R. 165.514 and European privacy laws.

An organization's particular needs and security requirements may call for additional actions and controls. Each organization must reach its own decisions on how to implement appropriate safeguards.

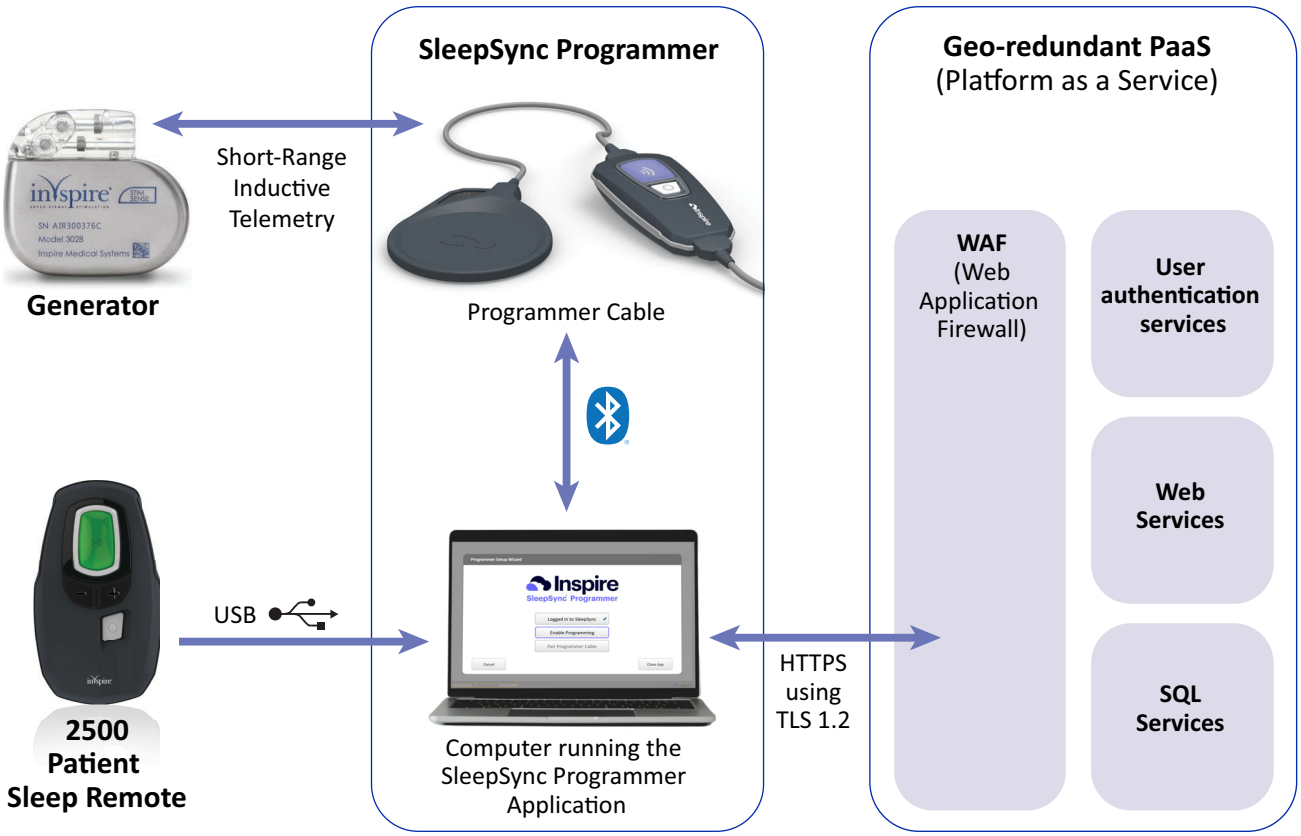
Communications Security

HTTPS using TLS 1.2 or newer is required for all communications to SleepSync servers. Users uploading or downloading data from the SleepSync servers are required to authenticate using credentials issued by Inspire. Multi-factor authentication is required.

The SleepSync Programmer's Bluetooth communications are encrypted using a dedicated certificate. Unique certificates are assigned to each Programmer Cable and each installation of the application also downloads a unique certificate for use by the application when programming is enabled.

Each upload from the Programmer is cryptographically signed.

The application requires that TPM 2.0 be enabled on the computer where the software is installed. The TPM feature is used to secure stored keys used for communications with other Inspire devices.



Internet Access

The SleepSync Programmer Application (Model 2740S) requires a network connection during installation to provision and register the software. After these steps are complete, a network connection is not required for any programming functionality. To enable the optional function of uploading session reports to the SleepSync Web Portal, a network connection is required.

To support provisioning and upload, the SleepSync Programmer Application requires network egress to the following sites via HTTPS protocol (tcp/443):

- access.inspiresleep.net
- cloud.inspiresleep.net
- portal.inspiresleep.net

Access control

For programming operations and local data access control, the SleepSync Programmer Application (Model 2740S) relies on the customer's computer access credentials. Inspire recommends that only users who have authorization to access patient data should be permitted to log in to the computer running the application.

The application saves all patient identifiers and data entered during a programming session on your local computer. The option to prevent entry and editing of PHI is available on the Programmer Settings screen. Disable (uncheck) the **Enable editing of patient details** feature if you do not want PHI entered or updated on the computer. Also, the option not to allow PHI in saved reports is available on the Programmer Settings screen. Disable (uncheck) the **Allow patient data in PDFs** feature if you do not want PHI to be included. Finally, the option to have session reports automatically deleted from your computer after a successful upload to SleepSync is available on the Programmer Settings screen. Enable (check) the **Delete data after SleepSync upload** feature if you want locally stored data to be deleted. In general, it is recommended to treat the programmer computer as if it contains PHI.

It is also recommended that reports retained from the programmer be treated in the same manner as any other medical record, particularly if any patient identifier (such as a patient name or record label) has been included in the report.

Data Access Model

The SleepSync Programmer Application (Model 2740S) supports two data access models:

- **Shared Access**. All users of the application share read/write/delete access to the patient data stored on the computer.
- **Segregated access**. Each user of the application has a separate storage location for patient data which cannot be read/written/deleted by other users.

Refer to "First-time Setup" on page 15 for details on how to set up the computer to support each access model.

Data Confidentiality

Inspire Medical Systems recommends that patient data only be saved to secure network fileservers or encrypted USB drives. If it is necessary to save data to other locations, the data should be de-identified. This can be done by disabling the **Allow patient data in PDFs** control from the Programmer Settings screen.

Data Encryption	The SleepSync Programmer Application (Model 2740S) requires that BitLocker be enabled on the computer where the software is installed so that all data saved on the computer, including patient data, is encrypted.
Infrastructure	The Inspire SleepSync Programmer accesses usage data that is hosted on two regional data centers, both located in the United States. The centers are connected through a dedicated 10Gb optical fiber for continuous replication. Both primary and backup centers have dedicated external networks with failover, guaranteeing a high level of availability.
Logs	The SleepSync Programmer Application (Model 2740S) generates log information as part of its normal operation which may be useful in case of a security event. Logs created by the application are stored in text format. For more information about the logs, contact Inspire Medical Systems.
Malware Protection	Install anti-malware software on the computer where the SleepSync Programmer Application (Model 2740S) is installed and ensure signatures are up to date.
Security Patching	Keep the computer up to date with vendor-supplied security patches.
Network Security	Connect the computers and servers running the SleepSync Programmer Application (Model 2740S) to known and secure networks.
Network Firewall and Segmentation	The computer running the SleepSync Programmer Application (Model 2740S) should be on a network segment protected from access from the Internet by a firewall. Consider implementing network segmentation to protect the computer from threats coming from other systems on the organization's network.
Software Firewall	Windows Defender firewall should be enabled on the computer running the SleepSync Programmer Application (Model 2740S) to protect against threats which could occur on the local network.
Physical Security	Keep the computer running the SleepSync Programmer Application (Model 2740S) and the Programmer Cable (Model 2740C) in a secure location and environment to reduce the probability of unauthorized access and unauthorized modifications to the system. Enable automatic screen locking when the computer sits idle.
Secure Data Backup	Use backup software which encrypts data written to archives. In addition, patient data can be uploaded to SleepSync as a means of data backup.

Secure Decommissioning

Although uninstalling the Model 2740S software will erase its data from the system, it is recommended that when a computer used for running the SleepSync Programmer Application (Model 2740S) is decommissioned that all data be securely erased per NIST 800-88 or equivalent media sanitization standard.

Security Monitoring

Regularly review system log files for evidence of security events. Regularly review access to the system and revoke access credentials promptly when a person's access to the computer is no longer required.

Programmer Application Updates

Inspire Medical Systems will contact you when SleepSync Programmer Application software updates are available.

Firmware Updates

If you are logged into Inspire SleepSync, the SleepSync Programmer Application will notify you if a firmware update is available. Inspire Medical Systems will also contact you when 2740C firmware updates are available.

Security Event

If you suspect a security event has occurred, stop using the SleepSync Programmer Application (if possible) and notify Inspire Medical Systems of the suspected security event.

Software Bill of Materials (SBOM)

The Software Bill of Materials is provided in the Model_2740S_SBOM.txt file in the user's AppData folder. The information in this file will be updated when the application is upgraded to ensure the list of software components and versions are current.

Essential Performance

Essential performance of the programmer has been determined to be uninterrupted performance or recovery from performance interruption with or without a restart of the programmer.

FCC Notice (USA)

Electromagnetic disturbances can potentially disrupt, degrade, or otherwise interfere with authorized electronic emissions, which may include television, AM/FM broadcasts, cellular services, radar, air traffic control, and pagers.

The Federal Communications Commission (FCC) Rules and Regulations have established Radio Frequency (RF) emission limits to provide an interference-free RF spectrum. Many electronic devices, including computers, generate RF energy incidental to their intended function and are, therefore, covered by these rules.

The programmer cable and all accessories meet the U.S. and European regulatory limits for Electromagnetic Compatibility (EMC). EMC is the ability of electronic devices, including computers, to function properly together in the electronic environment. However, there is no guarantee that in a specific installation it will not cause interference. Should this equipment cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, you are encouraged to try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna.
- Relocate the programmer.
- Separate the equipment and the programmer.
- Plug the equipment and the programmer into different electrical outlet circuits.

The programmer cable complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Class A Equipment

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules.

Embedded in the programmer are Radio Frequency (RF) wireless communication devices that operate in the 2.4 or 5.4 GHz band.

This equipment complies with FCC Radio Frequency Electromagnetic Signal (RF) exposure limits set forth for an uncontrolled environment of portable transmission. This product has been evaluated for RF exposure at a distance of 20 cm (8 inches). Operation at a separation distance less than 20 cm (8 inches) from the radiating element to nearby persons will not expose nearby persons to RF levels that exceed the FCC rules for RF exposure.

Warning: Do not attempt to service the wireless communication devices built into the programmer cable yourself. Contact Inspire Medical Systems for information about servicing your wireless communication device.

Cables

Only cables provided by Inspire Medical Systems should be used with the programmer cable. Use of other cables may result in unacceptable interference with other devices or the programmer cable itself might become more vulnerable to interference from other devices.

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits for radio frequency devices used in an uncontrolled environment. To satisfy the grant limitations of co-location and simultaneous operation, the device should not be operated within 20 cm of any other antenna or transmitter.

This equipment contains an internal antenna transmitter whose effective use may be affected if it is co-located or operating in conjunction with any other antenna or transmitter.

Electromagnetic Compatibility Declarations

The Inspire SleepSync Programming System utilizes RF communications between your computer and programmer cable. RF communications utilize the 2.4 to 2.485GHz ISM band and frequency shift keying modulation. Frequency-hopping spread spectrum is utilized to avoid interference with other devices. Effective radiated power from RF communications are less than 10mW.

Additional non-standardized testing was performed to demonstrate that the Bluetooth wireless communications of the programmer can coexist with potential interfering devices like a Wi-Fi router. With the source of interference located 1 meter (3 feet) from the computer or programmer cable, the programmer's Bluetooth connectivity suffered no decrease in performance.

Table 9-3. Electromagnetic Emissions

The programmer cable is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer cable should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
Radio frequency (RF) emissions: CISPR 11	Group 1	The programmer cable uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions: CISPR 11	Class A	The programmer cable is suitable for use in professional healthcare facility environments. **Note:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. **Warning:** This system is intended for use by health care professionals only.
Harmonic emissions: EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions: EN 61000-3-3	Complies	

Table 9-4. Electromagnetic Immunity

The programmer cable is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer cable should ensure that it is used in such an environment.		
Immunity Test	**Compliance**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD): EN/IEC 61000-4-2	Contact: ±4 kV, ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Electrostatic discharge may result in a temporary loss of function, requiring the user to restart the programmer cable.
Electrical fast transient/burst: EN/IEC 61000-4-4	±2kV AC Terminals 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment. Electrical fast transients or bursts in mains power may result in temporary loss of function.
Surge: EN/IEC 61000-4-5	±0.5 kV, ±1 kV line-to-line ±0.5 kV, ± 1kV, ±2 kV line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines: EN/IEC 61000-4-11	40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles Voltage Dips 0% UT; 0.5 cycle at 0, 45, 90, 135, 180, 225, 270, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° Voltage Interruptions 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. The programmer cable requires uninterrupted mains power to operate. Interruptions in mains power may result in temporary loss of function.
Note: UT is the A.C. mains voltage prior to application of the test level.		

Table 9-5. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The programmer cable is intended for use in the electromagnetic environment specified below. The customer or user of the programmer cable should ensure that it is used in such an environment.		
Immunity Test	**Compliance**	**Electromagnetic Environment Guidance**
Conducted RF: EN/IEC 61000-4-6	6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the programmer cable, including cables, than 30 cm (12 inches). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF: EN/IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	
Proximity Fields from RF Wireless Communications Equipment Immunity: EN/IEC 61000-4-3	380 to 390 MHz: 27 V/m 430 to 470 MHz: 28 V/m 704 to 787 MHz: 9 V/m 800 to 960 MHz: 28 V/m 1.7 to 1.99 GHz: 28 V/m 2.4 to 2.57 GHz: 28 V/m 5.1 to 5.8 GHz: 9 V/m	
Magnetic Field Immunity: EN/IEC 61000-4-8	50 Hz and 60 Hz: 30 A/m	
Magnetic Field Immunity – Proximity Fields: EN/IEC 61000-4-39	134.2 kHz: 65 A/m 13.56 MHz: 7.5 A/m	

[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 programmer is used exceeds the applicable RF compliance level above, the programmer cable should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the programmer cable.

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Inspire Programmer Cable

Portable and mobile radio-frequency (RF) communications equipment (for example, mobile or cellular phones and amateur radio equipment) can affect medical electrical equipment. Portable radio-frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Programmer Cable, including cables specified by Inspire. Otherwise, the Programmer Cable's performance could be degraded.

Disposing of Programmer Cable

Do not dispose of the programmer cable or its components if it is no longer being used or if it becomes inoperable. It must be returned to Inspire Medical Systems.

Chapter 10: Inspire Medical Systems, Inc. Limited Warranty

This chapter describes the limited warranty.

Summary

Inspire provides a limited warranty against defects. The warranty period for implanted products is 3 years. All other products have a warranty period of 2 years or less.

The warranty information below is intended for doctors (referred to as physicians in the warranty), but is included here for reference. Speak to your doctor if you have any questions and to find out if other terms may apply. The information below takes precedence over the information contained in this Summary.

Inspire Medical Systems' products consist of generators, tools to connect the generator to implantable leads, leads, Inspire Sleep Remotes, and physician programmers.

1. **EXCLUSION OF WARRANTIES, NO WARRANTIES FOR TOOLS.** The implied warranties of MERCHANTABILITY and fitness for a particular purpose and all other warranties, express or implied with regard to tools are EXCLUDED from any transaction and shall not apply. Inspire Medical Systems will not be liable for any damages, whether direct, consequential, or incidental caused by tool defects, failures, or malfunctions, whether such claims are based on warranty, contract, tort or otherwise. No person has any authority to bind Inspire Medical Systems to any representation or warranty with respect to tools. You may have other rights, which vary from state to state. If one or more of the provisions of this exclusion of warranties for tools shall be deemed void or unenforceable, the remaining provisions shall continue to have full force and effect.
2. **LIMITED WARRANTY FOR PRODUCTS OTHER THAN TOOLS.** This limited warranty is available if products other than tools fail to function within normal tolerances due to defects in materials or workmanship that manifest during the specified warranty period.

During the operational life of an generator, battery energy is consumed to monitor the patient's breathing and provide therapy. On the basis of individual patient physiology, certain patients may require more frequent therapy, thus requiring replacement of the generator in less than the warranty period shown below. This is considered normal for those patients and not a malfunction or defect in the generator.

If the purchaser complies with the Terms and Conditions, Inspire Medical Systems will issue a limited warranty toward the purchase of a new Inspire Medical Systems generator product. The limited warranty credit amount will be the full purchase price of either the original unit or the replacement unit, whichever is less.

- For patient products, for example, generator, lead, Inspire Sleep Remote, Inspire Medical Systems will issue a credit to the hospital conducting replacement surgery on behalf of the original patient. Any cost reductions extended as a result of this warranty shall be fully and accurately reflected on the patients' bill and reported to that applicable payor using the appropriate methodology.

- For physician products, for example, physician programmer, Inspire Medical Systems will issue a credit to the original purchaser of the product.

Terms and Conditions

1. The product labeling must indicate a limited warranty exists.
2. For implantable products, this limited warranty applies only for a product replacement in the original patient.
3. All registration materials must be completed and returned to Inspire Medical Systems within 30 days of first use.
4. The product must be replaced with an Inspire Medical Systems product.
5. If the product is implantable, it must be implanted before the product expires and implanted with other Inspire Medical Systems products.
6. The product must be returned to Inspire Medical Systems, 5500 Wayzata Blvd., Suite 1600, Golden Valley, MN 55416 within 30 days that the product first fails to function within normal tolerances. The product may be returned at no cost to you. Contact your Inspire Medical Systems representative for information on how to return the product.
7. Inspire Medical Systems will inspect the returned product and determine whether a limited warranty credit is due.
8. All products returned to Inspire Medical Systems become its property.

This limited warranty represents the entire obligation of Inspire Medical Systems for products other than tools and is made IN LIEU OF any other warranties, whether express or implied, including MERCHANTABILITY or fitness for a particular purpose.

Inspire Medical Systems will not be liable for any damages, whether direct, consequential, or incidental caused by product defects, failures, or malfunctions, whether such claims are based on warranty, contract, tort or otherwise.

No person has any authority to bind Inspire Medical Systems to any warranty or representation except those specifically contained herein.

This limited warranty gives specific legal rights, and you may also have other rights, which vary from state to state. If one or more of the provisions of this limited warranty shall be deemed void or unenforceable, the remaining provisions shall continue to have full force and effect.

Limited Warranty Period

The applicable limited warranty period for each product is listed and calculated as follows:

Within the United States:

1. Three (3) years from date a generator or lead is implanted in the patient.
2. One (1) year from the date a physician programmer or Inspire Sleep Remote is first used.

Outside the United States:

1. Three (3) years from date a generator or lead is implanted in the patient.
2. Two (2) years from the date a physician programmer or Inspire Sleep Remote is first used.

This page is intentionally blank.

Manufacturer
Inspire Medical Systems, Inc.
5500 Wayzata Blvd, Suite 1600
Golden Valley, MN 55416 USA
Tel: +1-844-672-4357
+1-763-205-7970
Fax: +1-763-537-4310
www.inspiresleep.com

200-483-001 REV E 2024-07