Inspire
Sleep Apnea Innovation

Inspire SleepSync™ Programmer Manual

The Inspire SleepSync Programmer
Inspire SleepSync Programmer Application–Model 2740S
Inspire® Programmer Cable–Model 2740C

Rx ONLY

Table of Contents

Explanation of Symbols

Explanation of Symbols on Package Labeling and Device

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

Note:

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	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
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1; ISO 7000-2609
	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

Symbol	Title	Description	Standard Reference
	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
	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

Symbol	Title	Description	Standard Reference
	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
EC REP	Authorized representative in the European Community	Indicates the item is a medical device	ISO 15223-1; ISO 20417
CH REP	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland	ISO 15223-1; ISO 20417
	Importer of record	Indicates the entity importing the medical device into the locale	ISO 15223; ISO 7000-3725
Rx ONLY	Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	CFR Title 21
	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	---	---

How to Use this Guide

This guide presents information regarding the Inspire SleepSync Programmer. 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 Inspire SleepSync Programmer which includes the SleepSync application, programmer cable, and accessories.
- **SleepSync Application Installation and Setup**
  This chapter describes how to install and set up the SleepSync 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 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.

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 (Figure 1-1) 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).

The implanted components of the Inspire system consist of an Inspire Generator, the Inspire Stimulation Lead, and the Inspire Respiration Sensing Lead.

The implanted system is programmed using the Inspire SleepSync Programmer. The patient uses a 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.

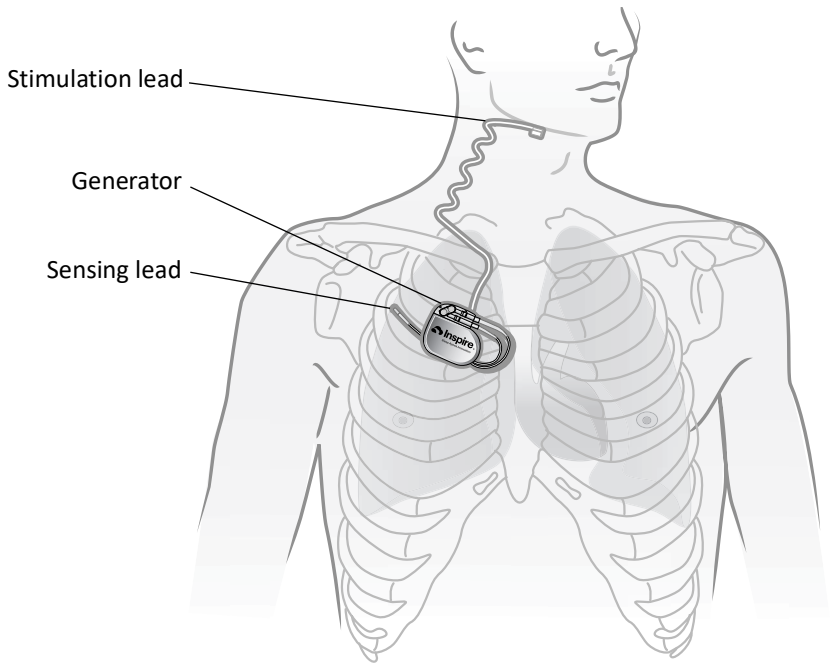


Figure 1-1. Inspire System Implanted Components

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.

Therapy Phases

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

Heal

During this procedure, the generator, stimulation lead, and sensing lead are surgically implanted. The Inspire SleepSync Programmer is used to test the implanted system during surgery. Afterward, patients will rest, heal, and follow up with their surgeons to check their healing progress.

Tune

Therapy acclimation typically lasts for 1–3 months following implantation. 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 programming 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 that appear on the advanced screen views are labeled as advanced settings in the definitions that follow.

General Therapy Terms

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

Table 1-1. 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.
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 1-2 defines terms related to stimulation settings.

Table 1-2. 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.
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 1-3 defines terms related to sensing settings.

Table 1-3. 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 at what speed (slope) of decrease in the sensor signal the generator will detect an exhalation. Increasing exhalation sensitivity configures the generator to detect exhalations on more gradual decreases in the sensor signal; decreasing exhalation sensitivity configures the generator to only detect exhalations on more rapid decreases in the sensor signal.
Exhalation threshold	This setting controls the height that the sensor signal must reach 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 decreases how often the generator looks for exhalations. 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 at what speed (slope) of increase in the sensor signal the generator will detect an inhalation. Increasing inhalation sensitivity configures the generator to detect inhalations on more gradual increases in the sensor signal; decreasing inhalation sensitivity configures the generator to only detect inhalations on more rapid increases in the sensor signal. **Note:** This is an advanced setting.
Inhalation threshold	This setting controls the height that the sensor signal must reach 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 decreases how often the generator looks for inhalations. **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 1-3. Sensing Setting Terms (continued)

Term	Definition
Maximum stimulation time	The maximum time that stimulation is delivered during one respiratory cycle. 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, only inhalation sensitivity criteria is used to detect inhalation. 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 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 1-4 describes the icons used to represent electrodes on the programming screens. See “Electrode” on page 46 for more information.

Table 1-4. Electrode Icons

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

These icons are used to indicate the polarity of all system electrodes. For example, the default electrode is shown in Figure 1-2.

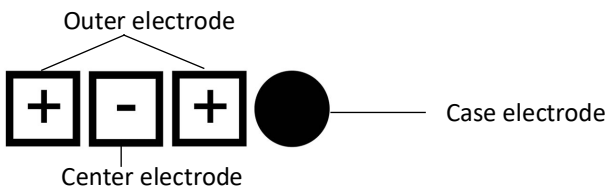


Figure 1-2. Default Electrode

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 1-3) 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 1-3. Communication Icon

When the programmer communicates with the generator, a large communication icon displays (Figure 1-4). The color of this icon corresponds to the connection status: blue indicates different levels of communication success and orange indicates communication failure.

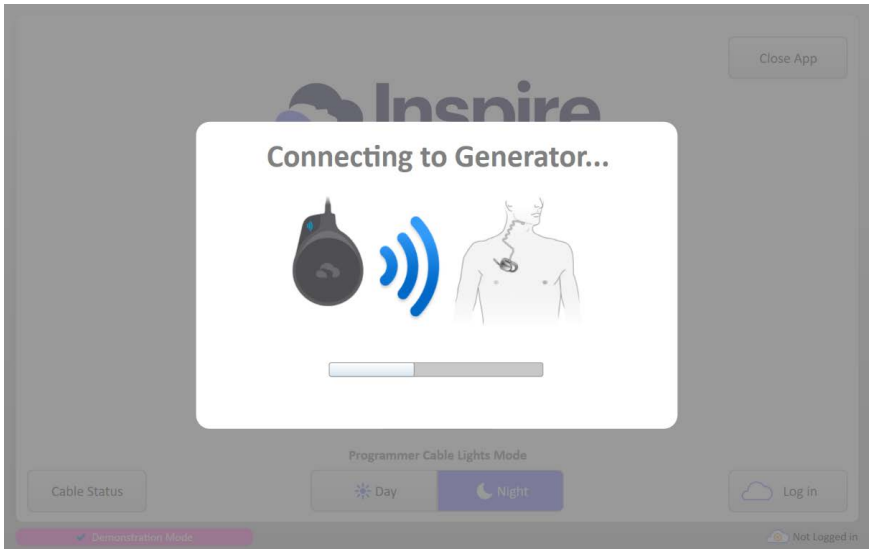


Figure 1-4. Communication Screen

Chapter 2: Programmer Components

This chapter describes the Inspire SleepSync Programmer components and accessories.

Package Contents

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

- Programmer cable–2740C
- Medical-grade power supply and power cord
- Portability kit
  - Inspire computer bag
  - Luggage tag
- IT Quick Guide which directs users to the downloadable SleepSync application–2740S
- Manual Reference Card

Programmer Cable

The programmer cable is the communications interface between the generator and the SleepSync 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 cm or 2 in) and another for short range communication with the SleepSync application (approximately 5 to 10 m or 16 to 33 ft).

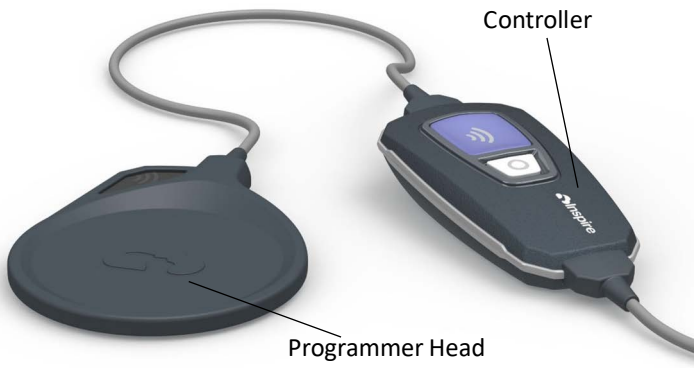


Figure 2-1. Programmer Cable

Portability Kit

The portability kit provides a convenient way to safely transport the Inspire SleepSync Programmer (Figure 2-2).

Figure 2-2. Portability Kit

Chapter 3: Application Installation and Setup

This chapter describes how to install and set up the SleepSync 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 95.

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>"
            ```

            Note: This command must be exactly correct or it will not work.

            Note: 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

Enable Data Sharing (Recommended)

By default, patient programmer data (i.e. session reports) will not be shared between Windows accounts. This sharing of data is not needed if:

1. Only a single Windows account on the computer will be used for programming
2. 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 is changed 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 25) or save the data to PDF (refer to "Save session reports to PDF" on page 53).

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

Note: Bluetooth connectivity must be enabled on your computer.

a. Navigate to the SleepSync application once it is installed on your computer by selecting the windows icon in the lower left portion of your screen.
b. Scroll down to the SleepSync application.
c. Open the SleepSync application by selecting it.

d. After you launch the application, the Setup Wizard screen displays (Figure 3-1). Select the **Log in to SleepSync** button.

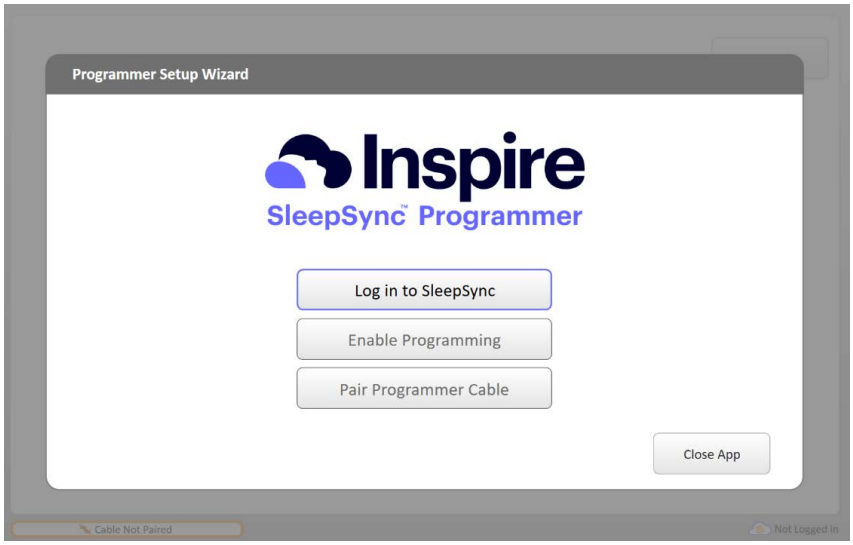


Figure 3-1. Setup Screen

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

Note: This option provides access to all functions in the application. It is recommended that you select this option.

Note: Select the **Manage patient data only** option if you do not want to enable programming and pair a programmer cable. For more information, see “Uploading Patient Data” on page 25.

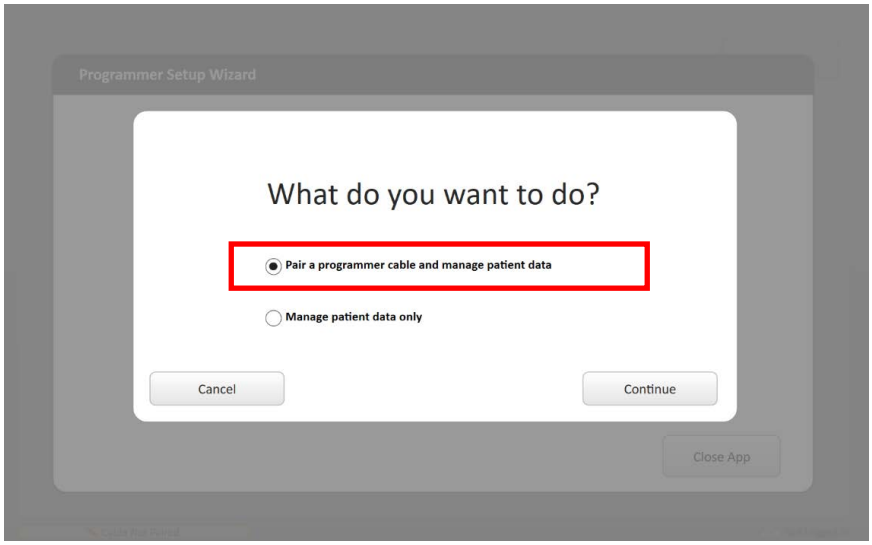


Figure 3-2. Program Patients and Use Inspire SleepSync Option

f. Log in with your Inspire SleepSync user ID, which is an email address, and password (Figure 3-3). Then select **Sign in**.

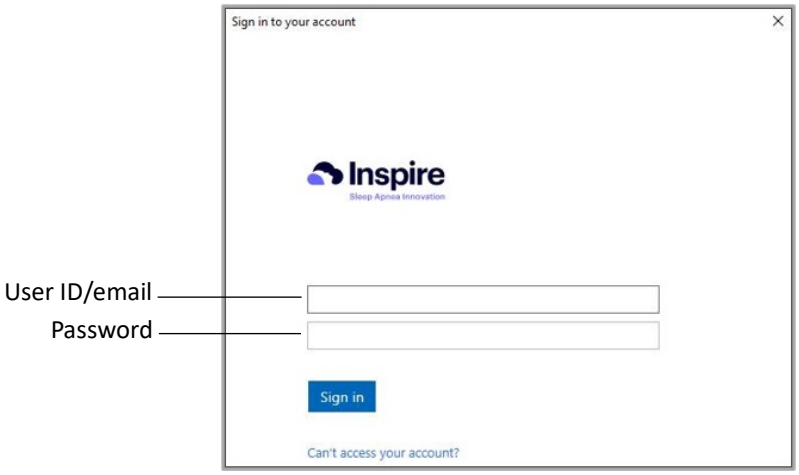


Figure 3-3. Inspire SleepSync User Login Screen

g. If you belong to more than one practice, select the desired practice from the drop-down menu (Figure 3-4)(there is no practice selector if you belong to a single practice), and then select **Continue**.

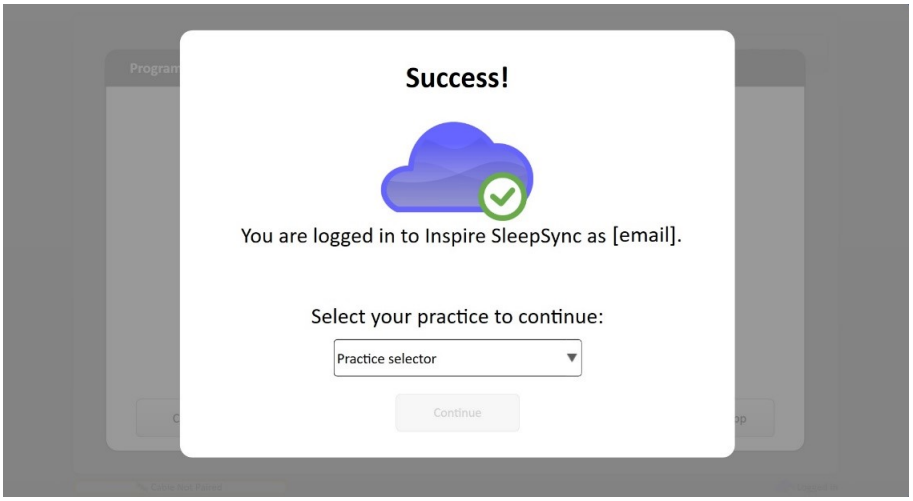


Figure 3-4. Select a Practice Screen

2. Enable Programming

a. The Enable Programming button becomes active (Figure 3-5). Select **Enable Programming** to continue.

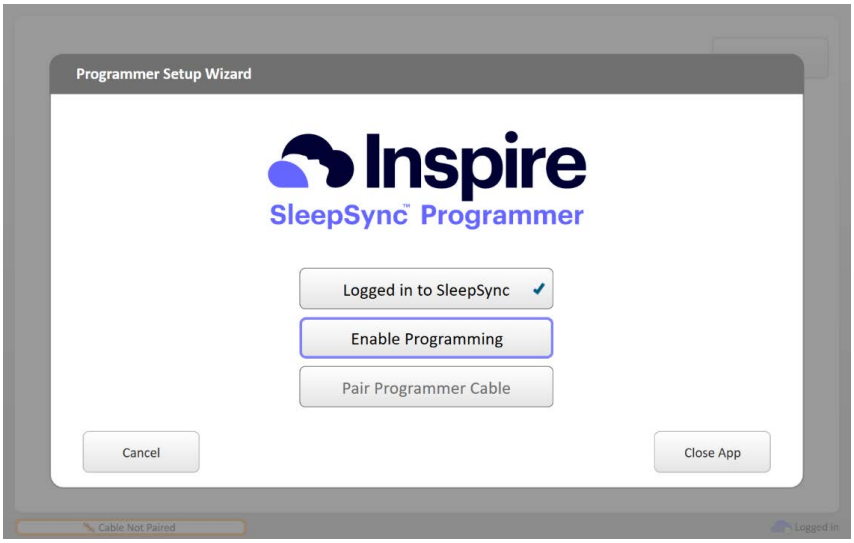


Figure 3-5. Enable Programming

b. After a self-check and when programming is enabled successfully, the following screen displays (Figure 3-6). Select **OK** to continue.

Figure 3-6. Programming Enabled Successfully Screen

3. Pair Programmer Cable

a. The **Pair Programmer Cable** button becomes active (Figure 3-7). Select the **Pair Programmer Cable** button to continue.

Note: Bluetooth connectivity must be enabled on your computer.

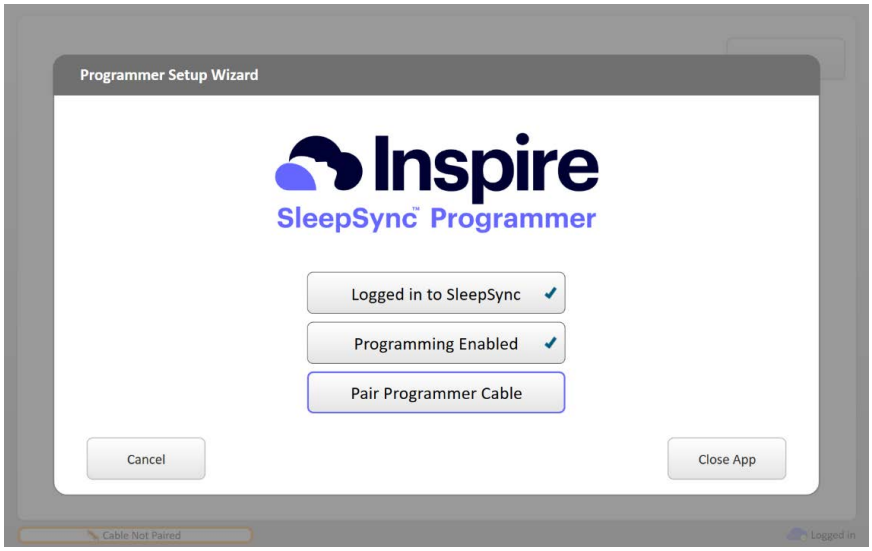


Figure 3-7. Setup Wizard Pair Programmer Cable Button

b. On the Pair a Programmer Cable screen (Figure 3-8), select **Continue**.

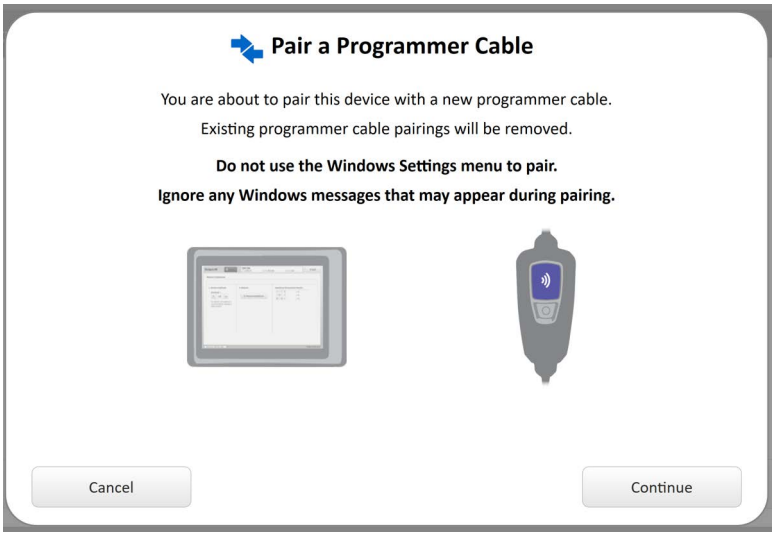


Figure 3-8. Pair a Programmer Cable Screen

c. Follow the on-screen instructions (Figure 3-9) to prepare the programmer cable, and then select **Continue**.

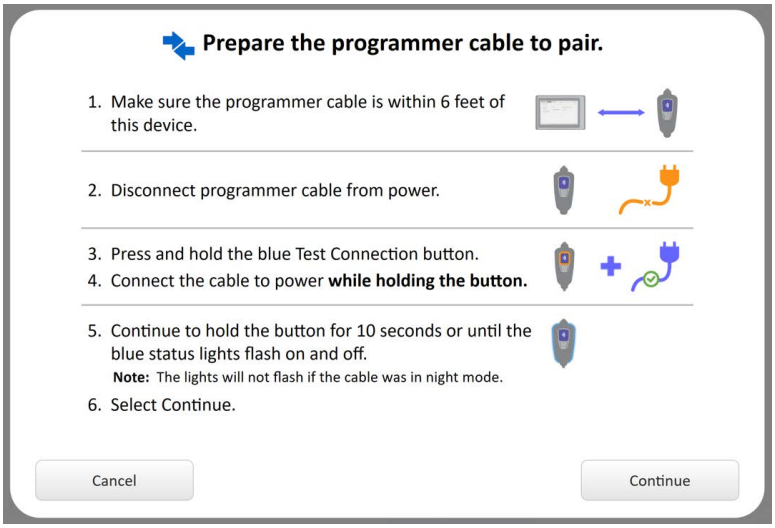


Figure 3-9. Pair a Programmer Cable Instructions

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

d. The system begins searching for the programmer cable. When the programmer cable is located, the following screen displays (Figure 3-10).

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

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

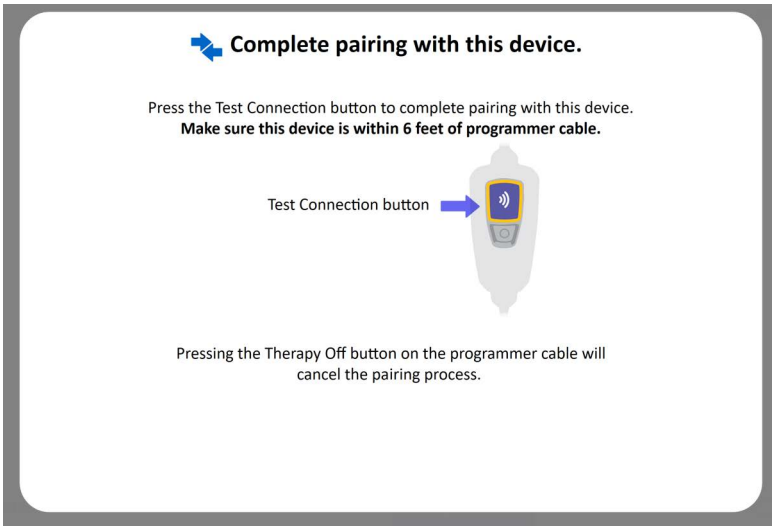


Figure 3-10. Pair a Programmer Cable Test Connection Screen

e. When pairing has completed successfully (Figure 3-11), select **Continue**.

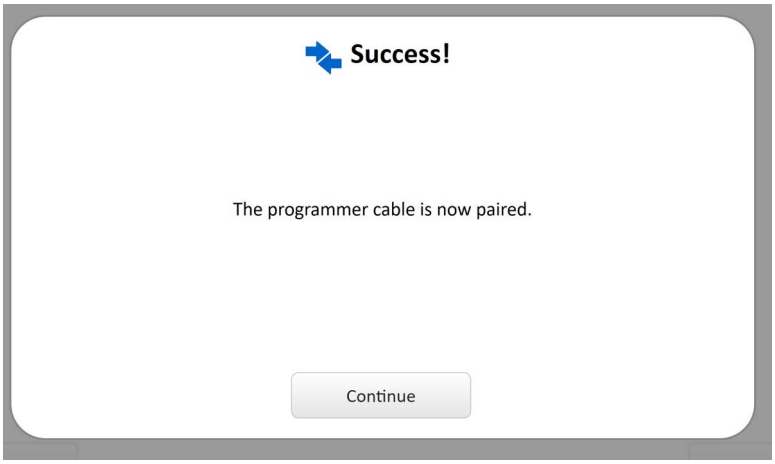


Figure 3-11. Programmer Cable Paired Successfully

Congratulations on completing installation and setup!

Note: After successful pairing, the application will alert you that the cable needs a firmware update. Follow the prompts to execute the firmware update. Pair the cable again; then the cable setup will be complete.

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 Application

To start the SleepSync 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 application, the Start screen displays (Figure 4-1). Refer to "Start Screen" on page 31.

Note: If you have not completed the full setup process, a different Start screen displays and you will not be able to start a programming session. See Figure 4-7.

Figure 4-1. Start Screen

Adjusting Programmer Settings

Before starting a session, it is important to adjust the programmer settings to ensure the accuracy of the data collected.

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.
- Select the **Save** button to save the new data control settings.

App Size

- Select the **Settings** button from the Start screen.
- Select the **Screen Size** control and choose the desired screen size.
- Select the **Save** button to save the new screen size.

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 Programmer Head

The programmer head must be properly positioned over the generator to establish the signal strength required to connect to the generator.

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 34 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 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 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 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.

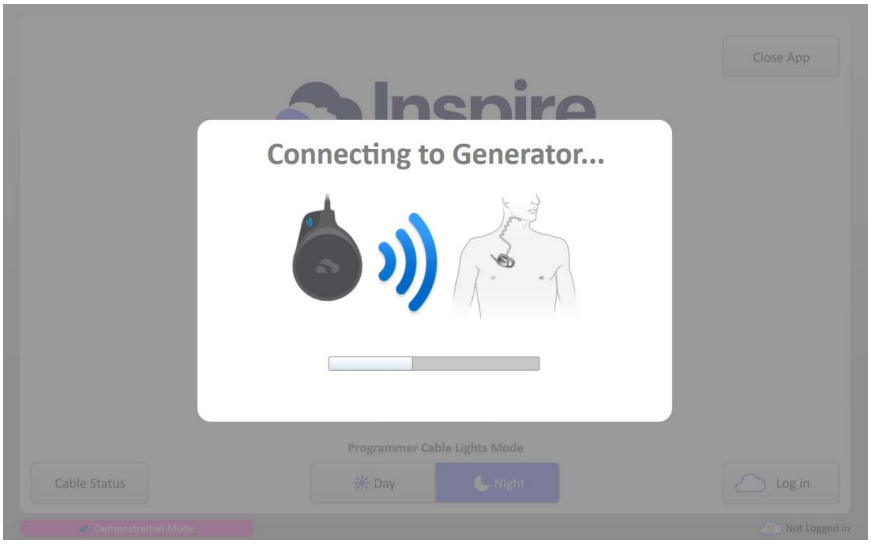


Figure 4-4. Communication Screen

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 63 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. The programmer cable is not needed for Demo Mode.

1. Ensure that the SleepSync application is running.
2. Select the **Demo** button from the Start screen.

   Note: Demonstration Mode is displayed in the cable connection status line located in the lower-left corner of the screen.

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 (Figure 4-5), log in with your Inspire SleepSync user ID and password, and then select **Sign in**.

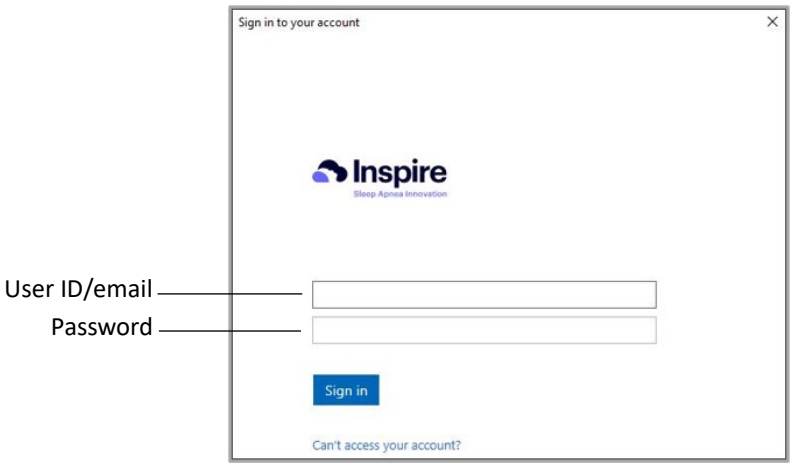


Figure 4-5. Inspire SleepSync User Login Screen

Note: 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.

To upload patient data from the Inspire SleepSync Programmer Application (Model 2740S), refer to “Upload Tab” on page 54 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 5-3 for instructions.

   Note: Do not save the reports more than five folders deep on the USB drive.

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 5-4.

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 5-4 for additional information.

Viewing Therapy Reports

After logging in to Inspire SleepSync, patient therapy reports can be viewed. Refer to Figure 5-24 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 the **Manage patient data only** option (Figure 4-6).

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.

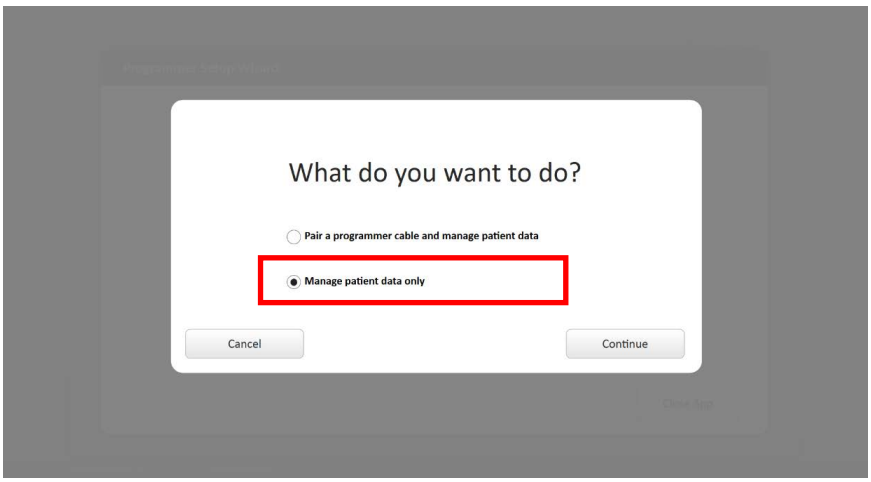


Figure 4-6. Manage Patient Data Only Option

After selecting **Continue**, complete the login process. Upon successful login, the following screen displays (Figure 4-7).

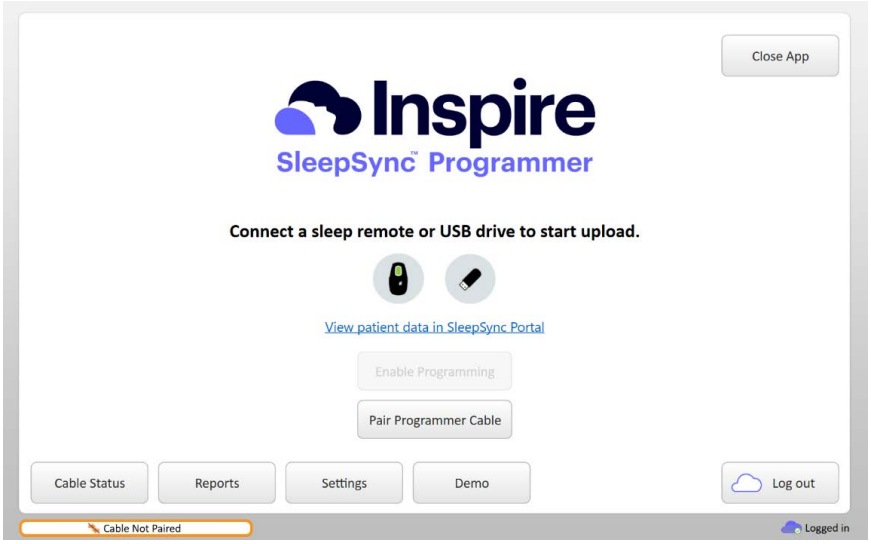


Figure 4-7. Connect a Device for Patient Upload Screen

Connect a 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 33 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 4-8).

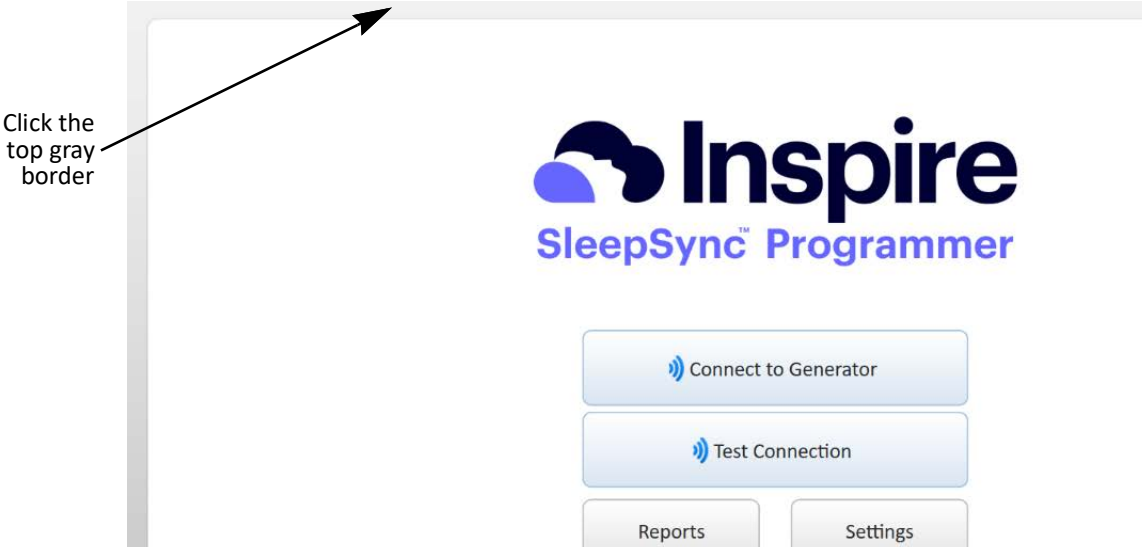


Figure 4-8. Moving the Application Window

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 computer bag. Store the computer bag and its contents in a secure location.

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

Chapter 5: Screen Descriptions

This chapter provides descriptions of the SleepSync application screens.

Common Screen Elements

All SleepSync 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 Header

- 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 displays 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.
- Serial Number — Generator serial number.
- Home/Back Button — Select button to access the Home screen or the previous screen visited.

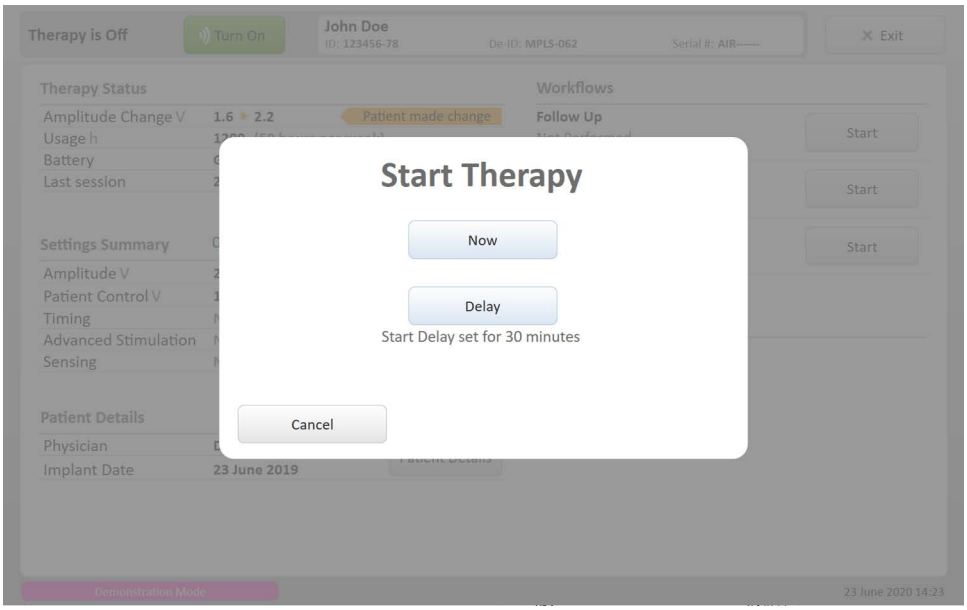


Figure 5-2. Start Therapy Screen

Screen Footer Information

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

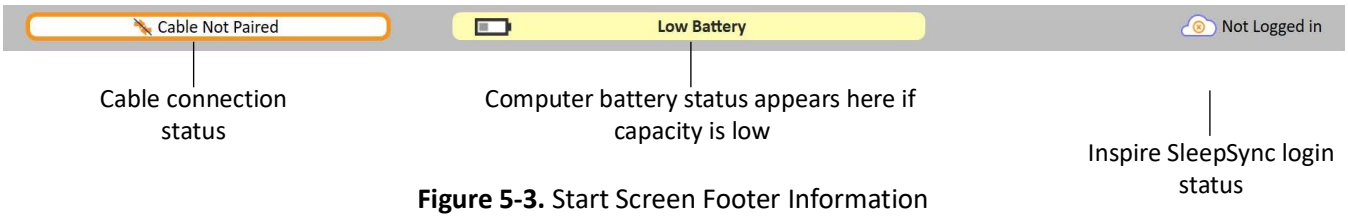


Figure 5-3. Start Screen Footer Information

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 application may be used for demonstration. Status background color is pink.

Computer Battery Status

The SleepSync 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 Application Login Status

The user's SleepSync 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.

Table 5-1. Start Screen Button Descriptions (continued)

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 application with a simulated generator when no patient is present.
Close App	Closes the SleepSync 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

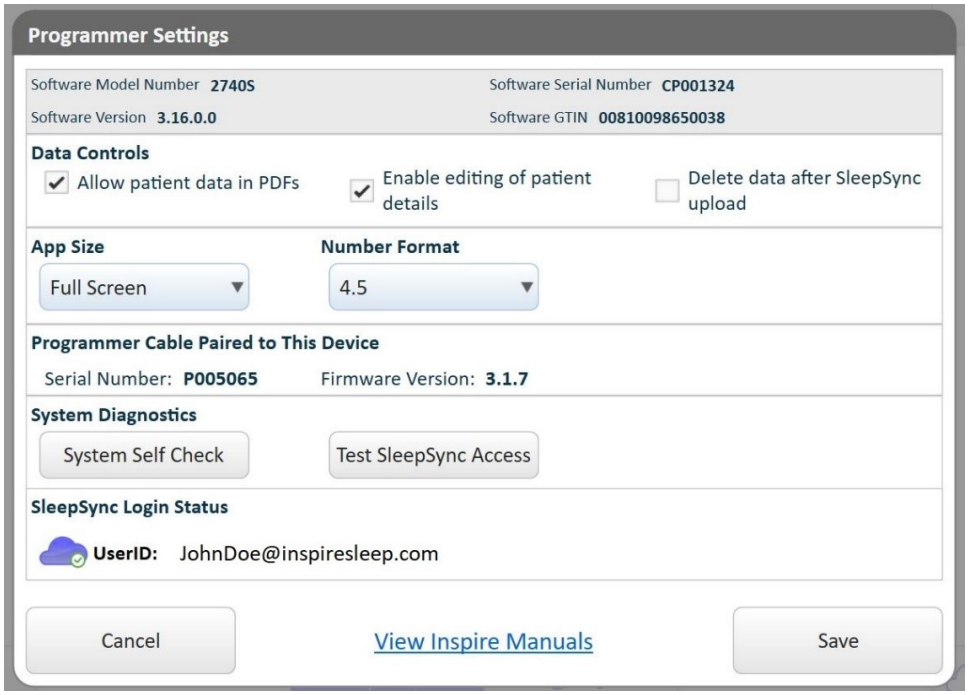


Figure 5-5. Programmer Settings Screen

The Programmer Settings screen (Figure 5-5) allows you to view the programmer information, modify App Size and Number Format, and a link for viewing Inspire User Manuals (see “Adjusting Programmer Settings” on page 19 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 one of: Full Screen, Medium, Small
- 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 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.

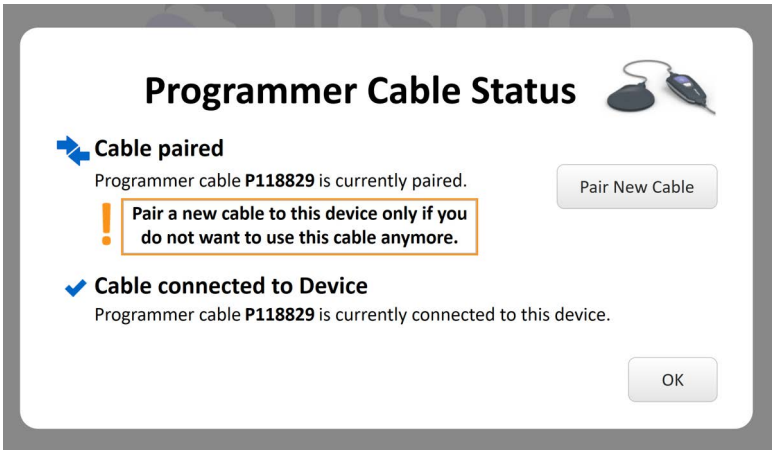


Figure 5-6. Cable Connection Status Screen

Home Screen

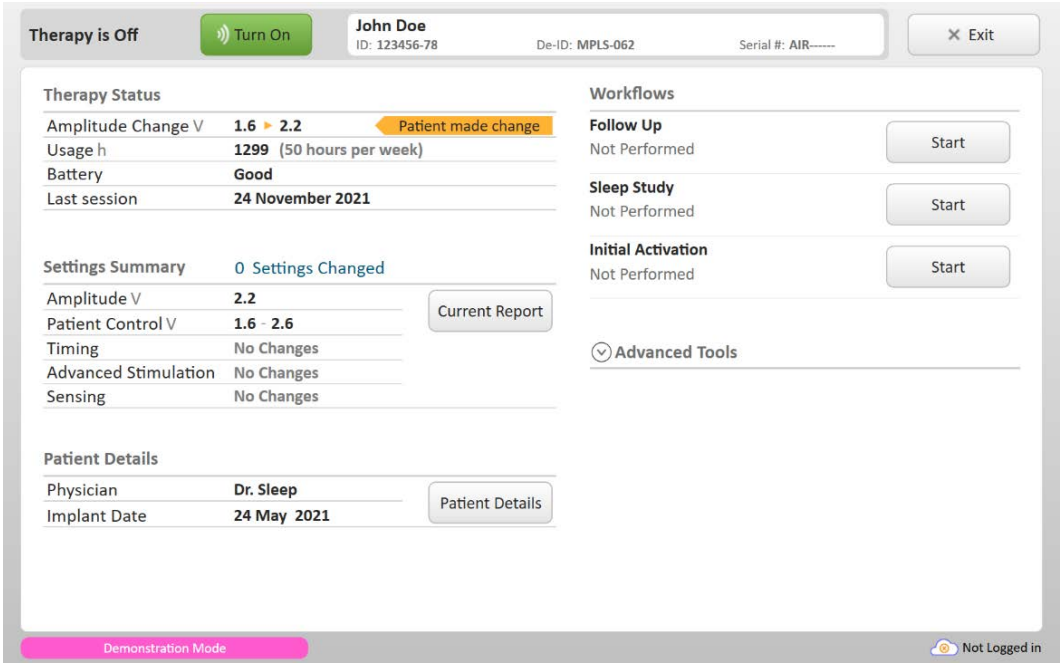


Figure 5-7. Home Screen

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 — 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.
- Last Session — The date of the most recent programming session.

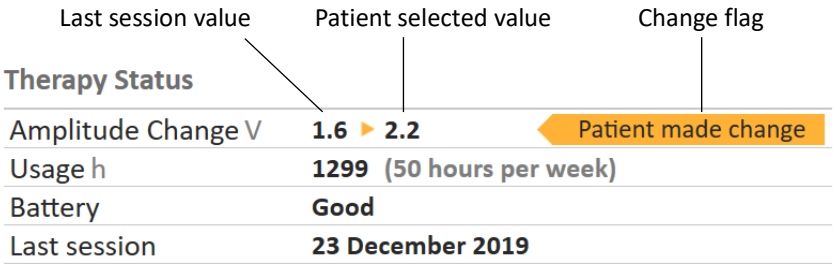


Figure 5-8. Patient Therapy Status

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 72 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 79 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 69 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 4 and Table 1-3 on page 5 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 which accesses the Reports screen (see Figure 5-25).

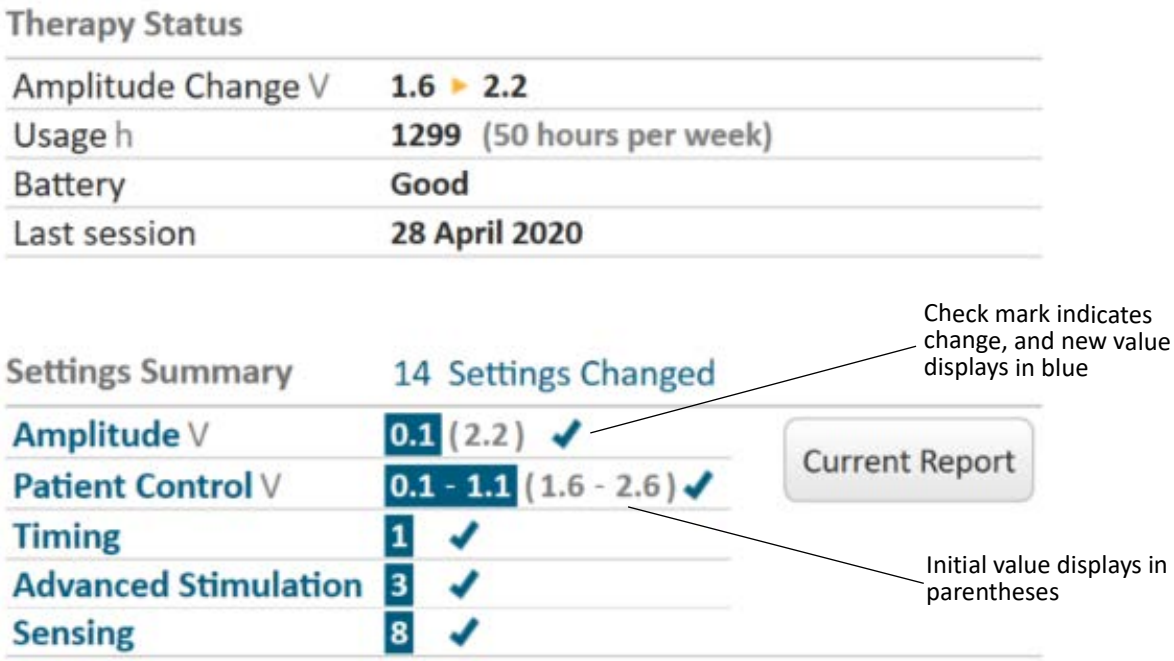


Figure 5-10. Status Indicators for Settings Summary

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, which accesses the Patient Details screen (see the following section).

Advanced Tools

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

Adjust Stimulation

See "Adjust Stimulation Screen" on page 42.

Adjust Sensing

See "Adjust Sensing Screen" on page 48.

System Check

- Button accesses the System Check workflow, which guides the user through troubleshooting activities. See "Start System Check Workflow" on page 64 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

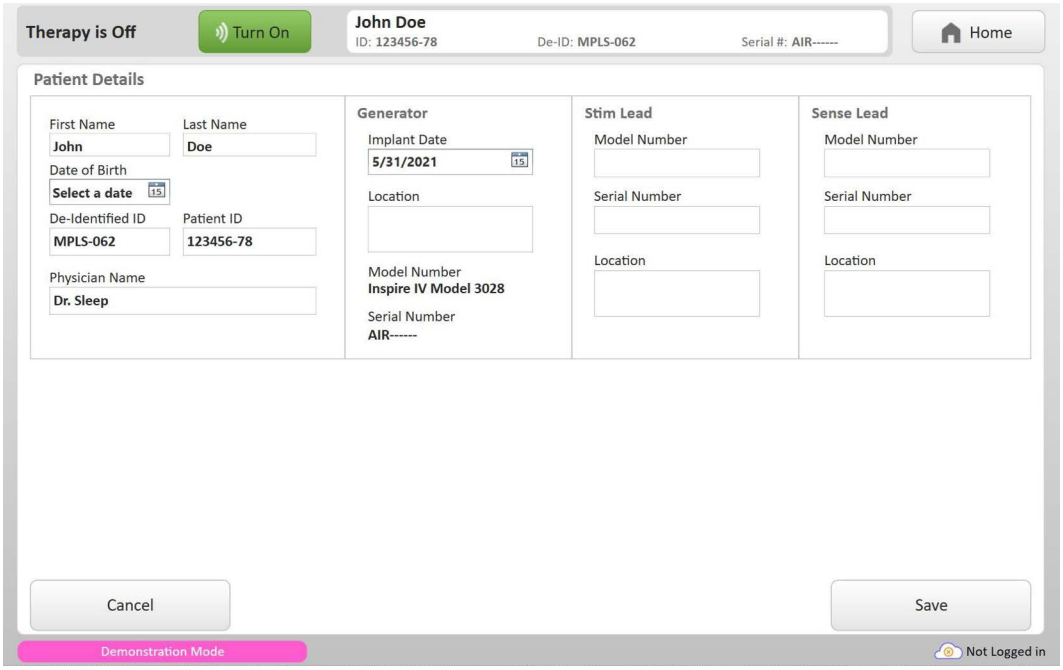


Figure 5-11. Patient Details Screen

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

Note: 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.

Note: 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 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.

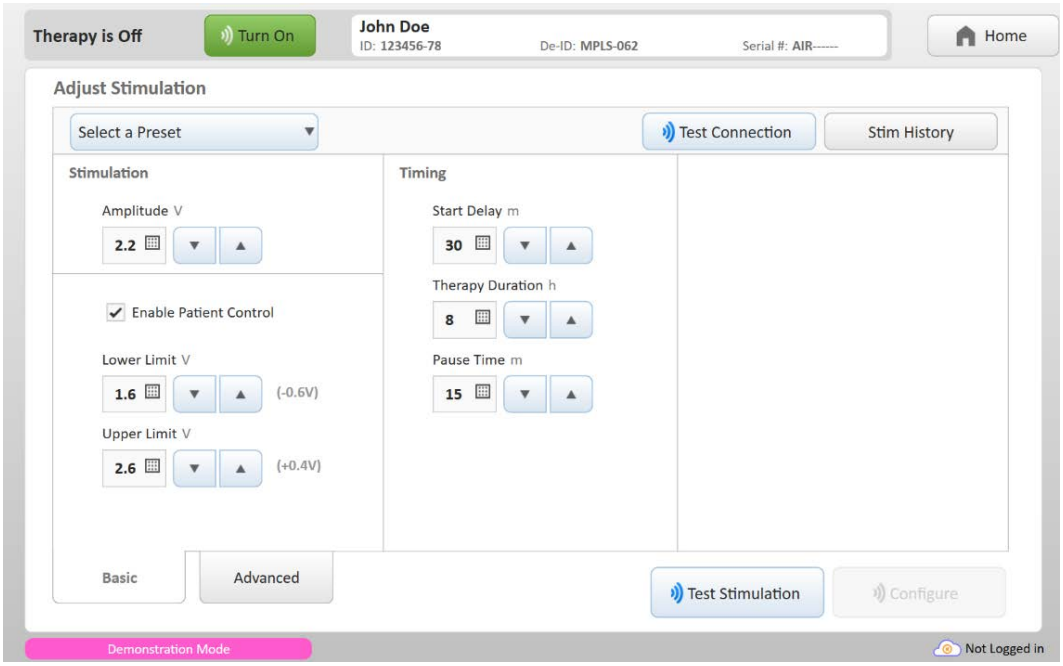


Figure 5-12. Adjust Stimulation Screen, Basic View

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.
- 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.
  - 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. The difference will remain constant as the limit values track changes in the amplitude.
- Review flags indicate that the patient has changed the amplitude value, and thus the amplitude values should be reviewed.

Timing

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

- Start Delay
- Therapy Duration
- Pause Time

See Table 1-2 on page 4 for definitions of these terms.

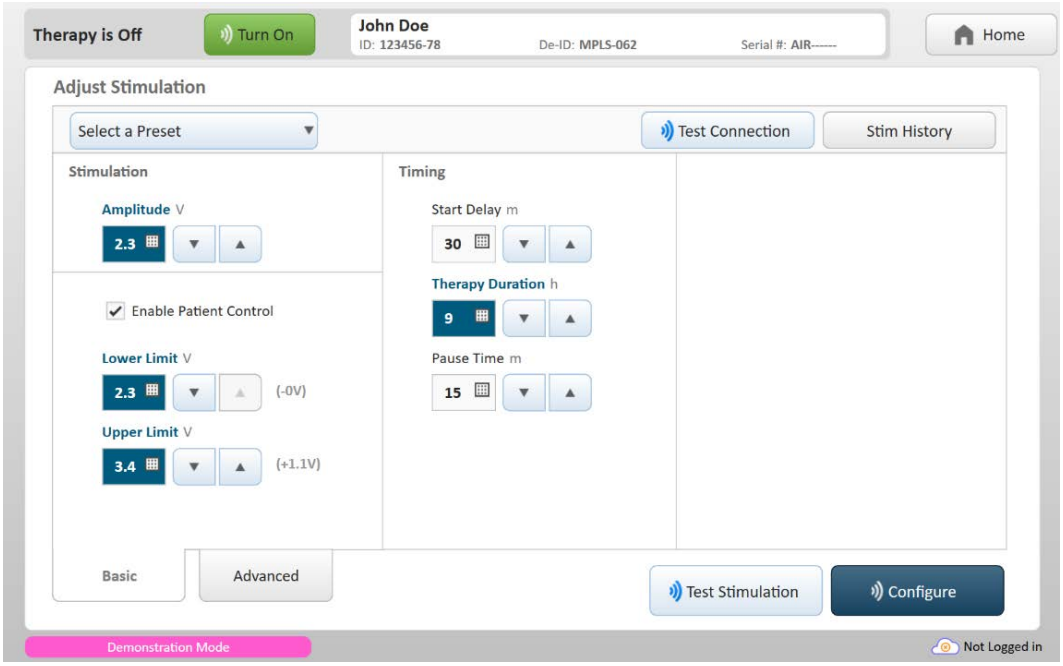


Figure 5-13. Changed Settings on Adjust Stimulation Screen

Programming Buttons

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

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.

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.

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 94 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

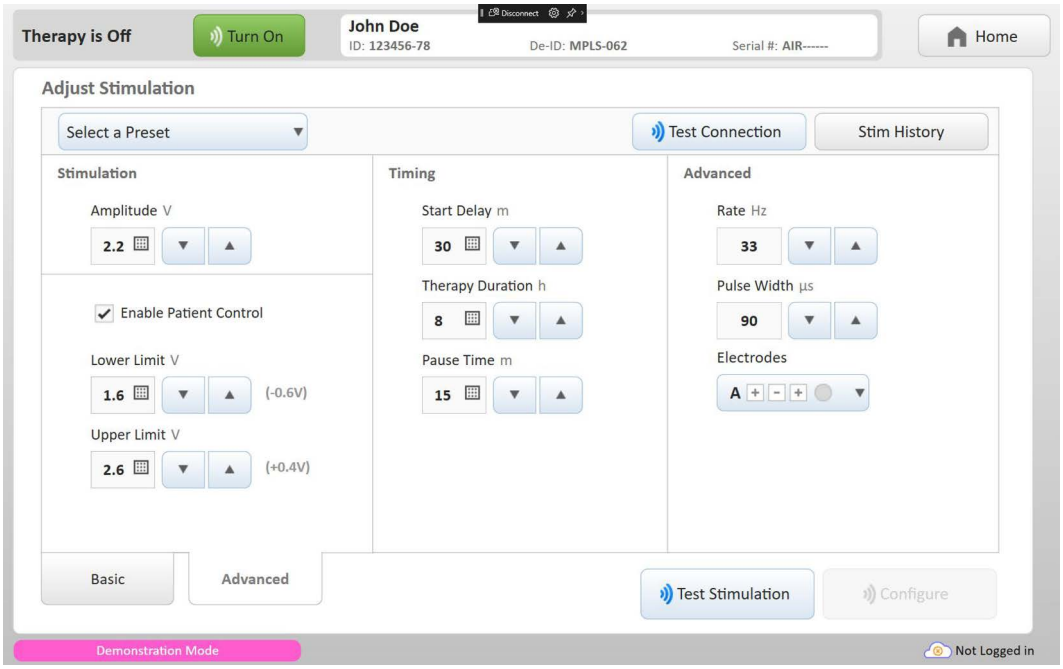


Figure 5-14. Adjust Stimulation Screen, Advanced View

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.
  - Rate
  - Pulse Width
  - Electrode

  See Table 1-2 on page 4 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 that is integrated into the generator case.

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.

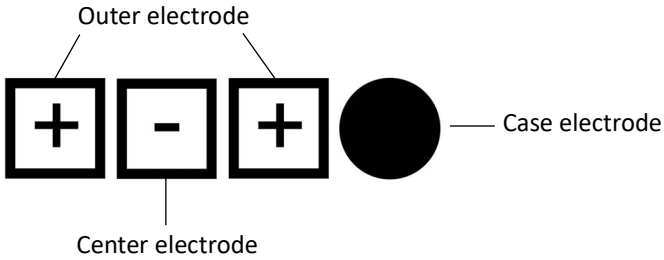


Figure 5-16. Default Electrode Configuration

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 7 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 5-2.

Table 5-2. 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.

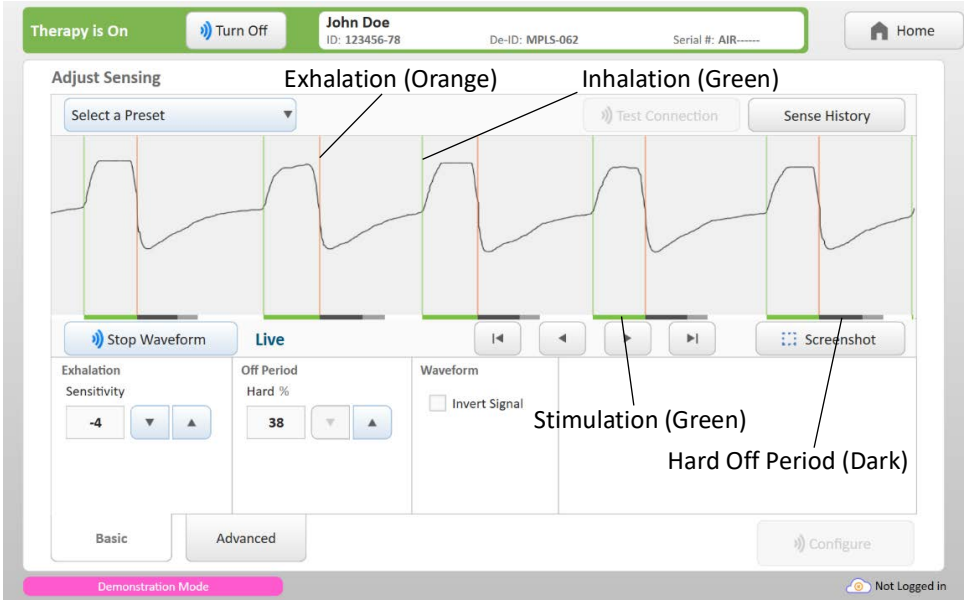


Figure 5-17. Adjust Sensing Screen, Basic View

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 5 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. If the generator amplitude is 0V, the programmer will automatically change the amplitude to 0.1V.

  – 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.

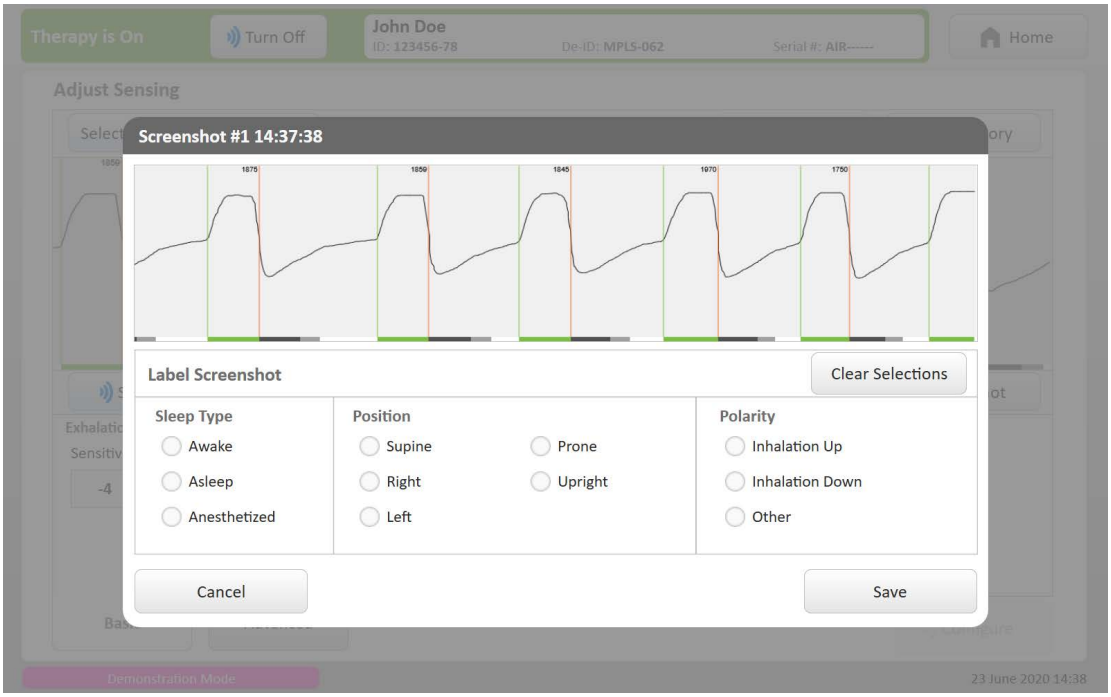


Figure 5-18. Screenshot Screen

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 94 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

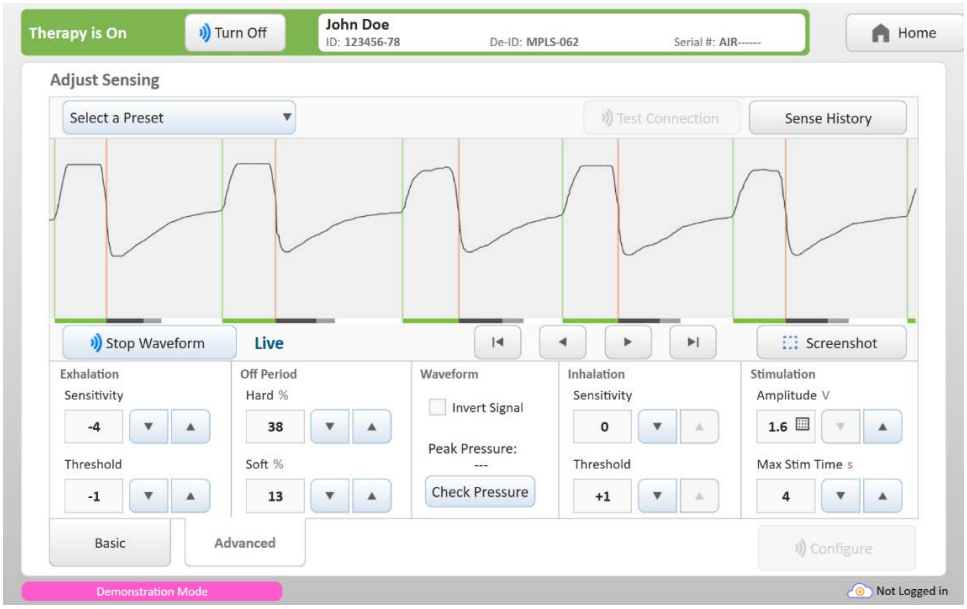


Figure 5-19. Adjust Sensing Screen, Advanced View

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 Threshold
  - Soft Off Period
  - Inhalation Sensitivity
  - Inhalation Threshold
  - Amplitude
  - Max Stim Time
- Select **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.

Patient List Screen

The **Reports** button on the Start screen accesses the Patient List screen (Figure 5-20).

If you are not logged in to Inspire SleepSync, you will see data for local patients only. To see all patients, both local and in Inspire SleepSync, you must be logged in. See the Start screen (Figure 4-1).

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

Patients Tab

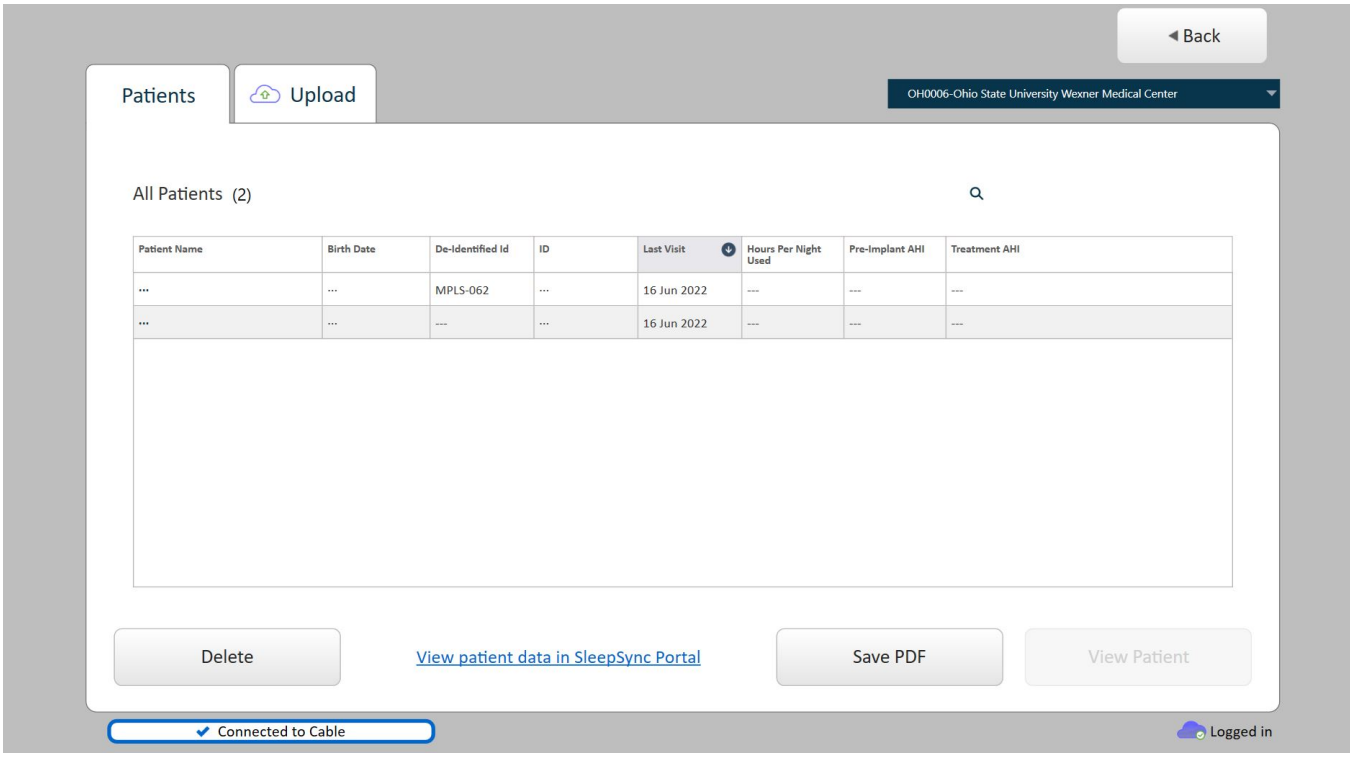


Figure 5-20. Patient List Screen, Patients Tab

At the top of the tab is a search bar, which you can use to search for a particular patient. Results are displayed as you type.

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: A sample patient named John Doe may appear on this screen and is associated with all demonstration mode reports.

Status icons in the Patient Name column indicate the following if you are logged into Inspire SleepSync:

- The patient information is stored only on your computer (no icon).
- The patient information is stored only in Inspire SleepSync.
- The patient information is stored on both your computer and in Inspire SleepSync.

Refer to Table 5-3 for information about the functions of the buttons on the Patient List screen.

Table 5-3. Patient List Screen Buttons, Patients Tab

To:	Do This:
View patient	Highlight patient name and select **View Patient** button to access the Reports screen. **Note: View Patient** button is disabled unless a patient name is highlighted.
Delete a patient	Highlight patient name and select **Delete** button to display the Delete Reports 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 reports older than the specified date for that patient. **Note:** If a patient name is not highlighted before selecting the **Delete** button, reports for all patients will be deleted.
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. • 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 drop-down menu. Patient data from the new practice will now display.

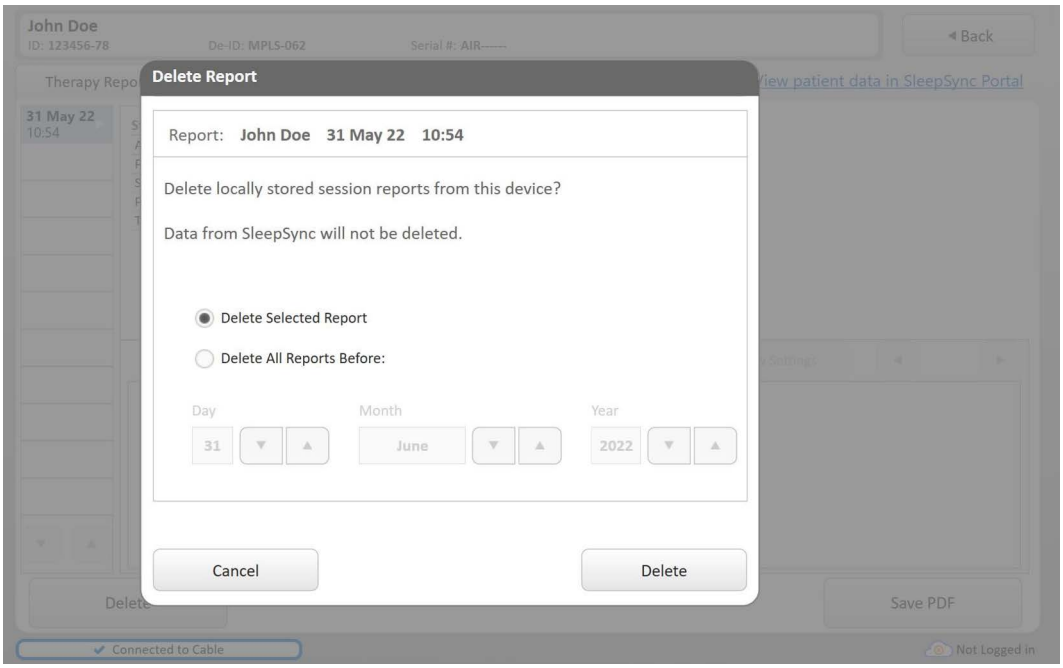


Figure 5-21. Delete Report Screen

Upload Tab

Note: 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.

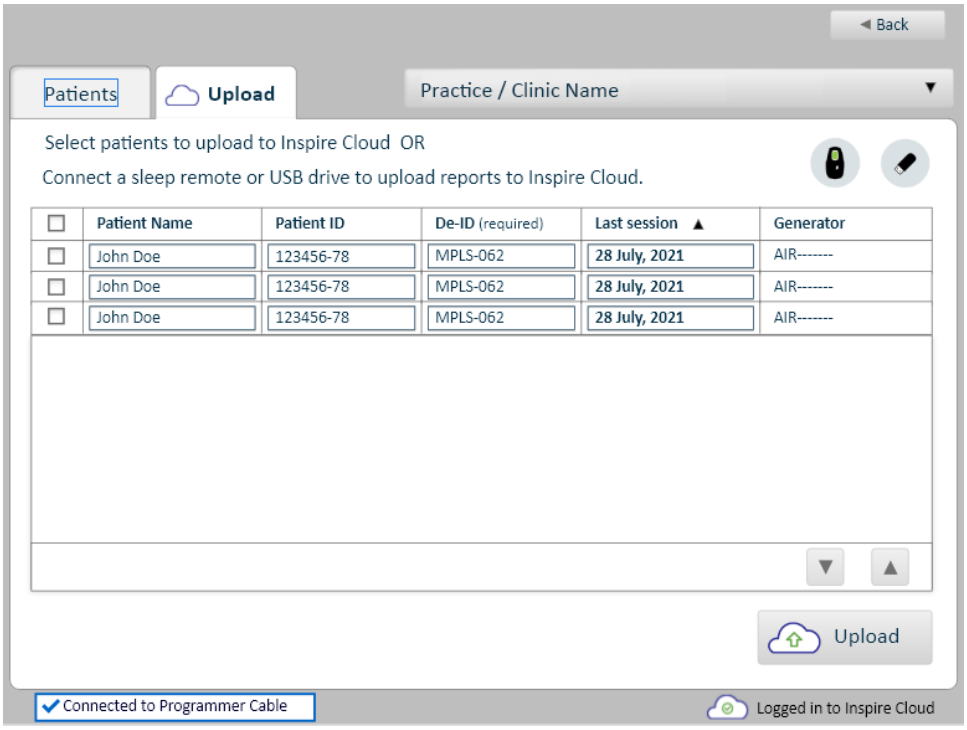


Figure 5-22. Patient List Screen, Upload Tab

Table 5-4. 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. • 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 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. **Note:** De-ID is required. For new patients, you must provide a De-ID. **Note:** 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. **Note:** De-ID is required. For new patients, you must provide a De-ID. **Note:** 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 drop-down menu. Patient data will be uploaded to the selected practice.

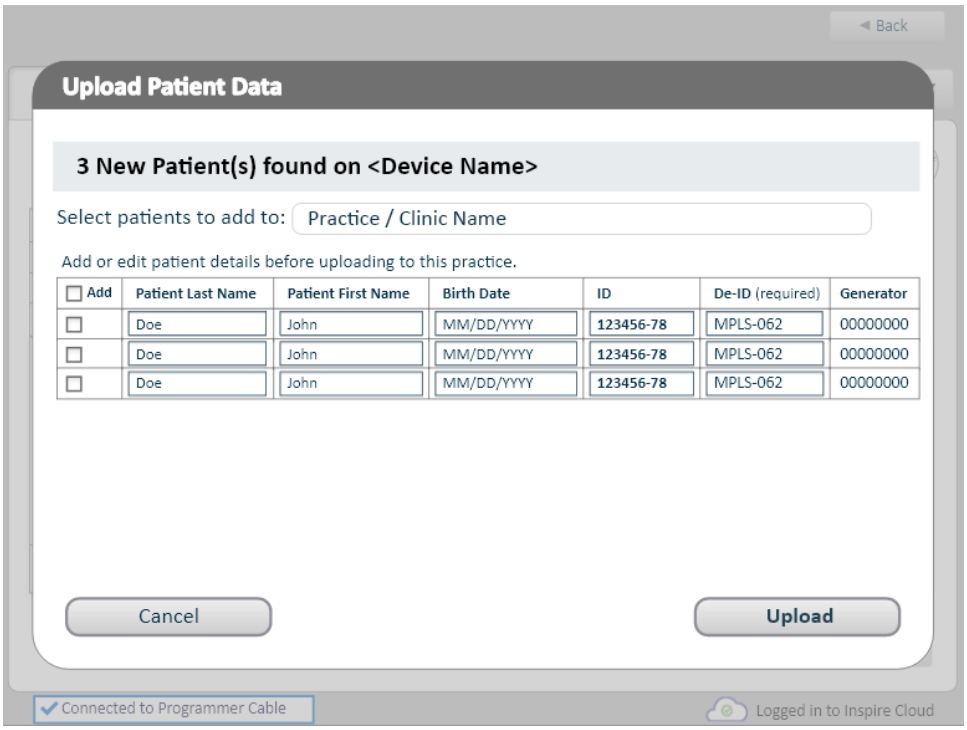


Figure 5-23. Upload Patient Data Screen

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.

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 Patient** button.

Note: You must be logged in to Inspire SleepSync to view therapy reports.

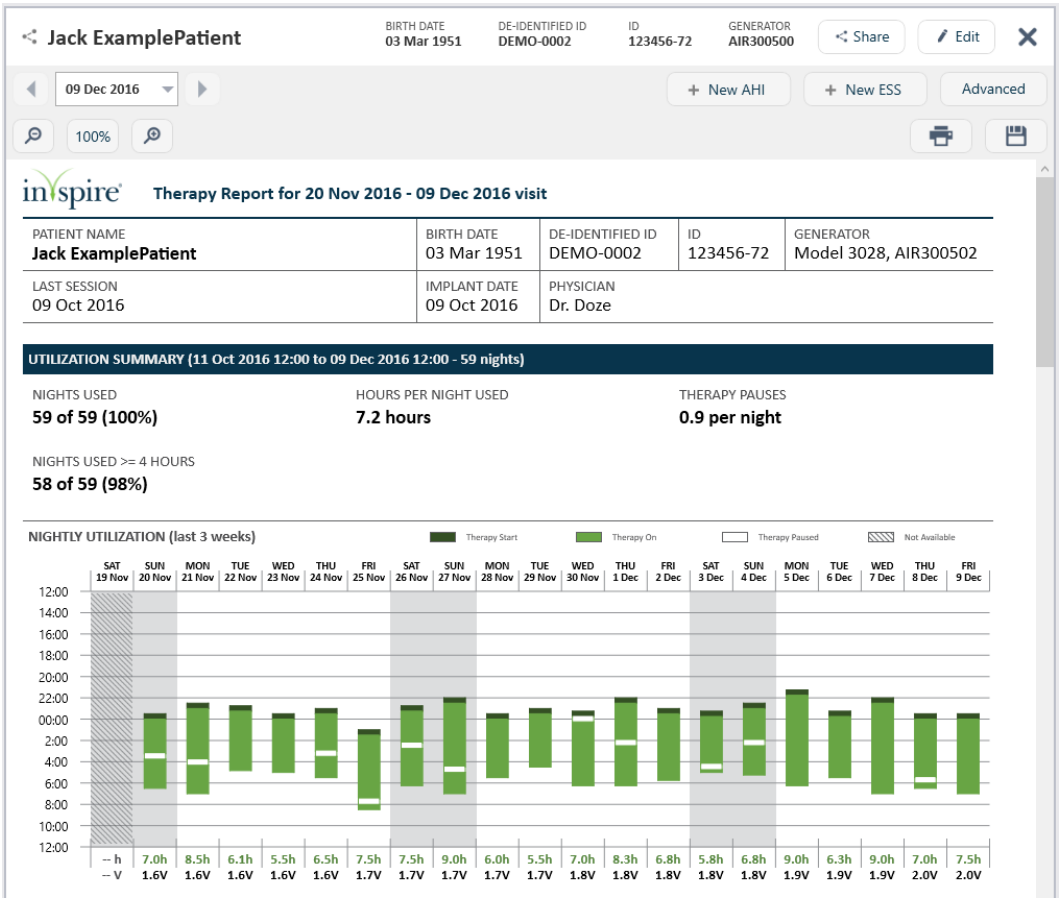


Figure 5-24. Therapy Report Screen

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.

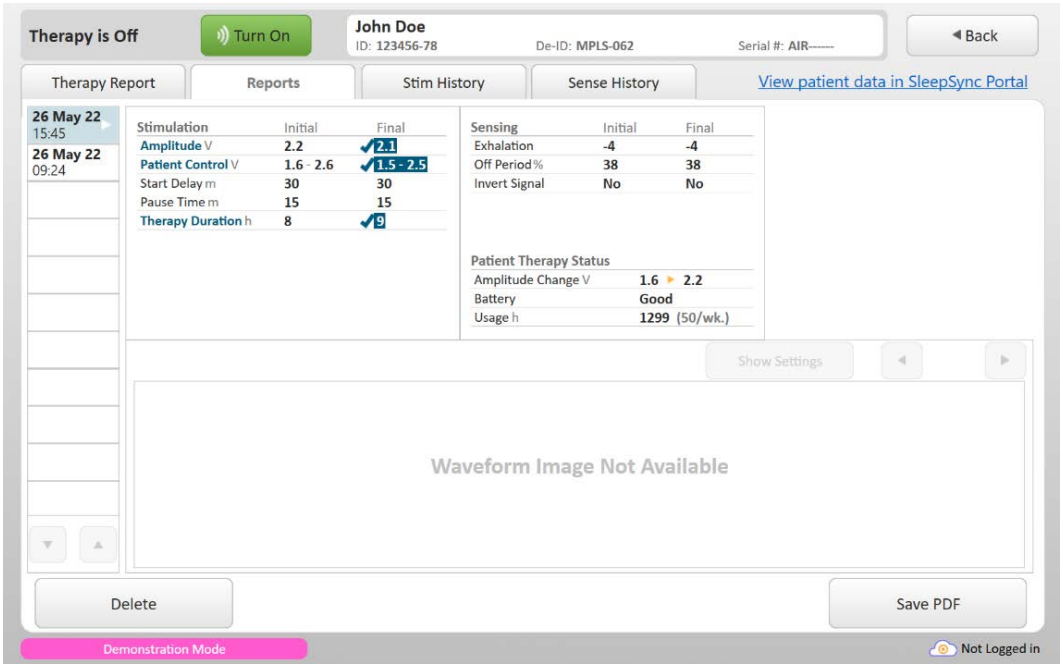


Figure 5-25. Reports Screen

The **Current Report** button on the Home screen accesses the Reports screen (Figure 5-25), where all session reports for the current generator are organized by date and time. The Reports screen can also be accessed 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.

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

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

Table 5-5. 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 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 arrow buttons are disabled, there are no additional levels to view.
Show or hide settings for the displayed waveform	Select the **Show Settings** or **Hide Settings** button.

Table 5-5. Reports Screen Buttons (continued)

View additional waveform screenshots	Select the right or left arrow buttons above the waveform image. **Note:** If arrow buttons are disabled, there are no additional screenshots to view.
Delete a session report	Highlight 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 **Cancel** button to return to Reports screen. • Select **Delete** button to confirm that you wish to permanently remove the selected report(s).
Save session report to PDF	Highlight report and select the **Save PDF** button to display the Save PDF screen (Figure 5-26). • Select **Save Selected Report** button to save current report, or • Select **Save 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 **Save All 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. • Select **Cancel** button to return to Reports screen. • Select **Save as PDF** button to save.

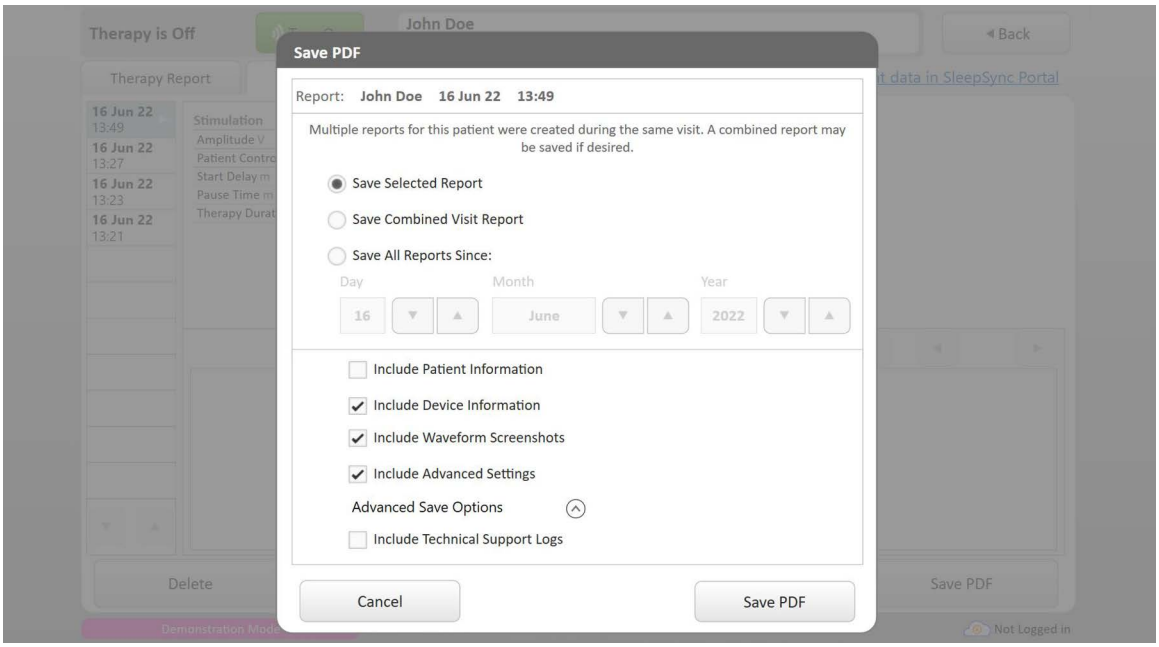


Figure 5-26. Save PDF Screen

Stimulation History Screen

Stimulation History shows patient information that exists on your computer.

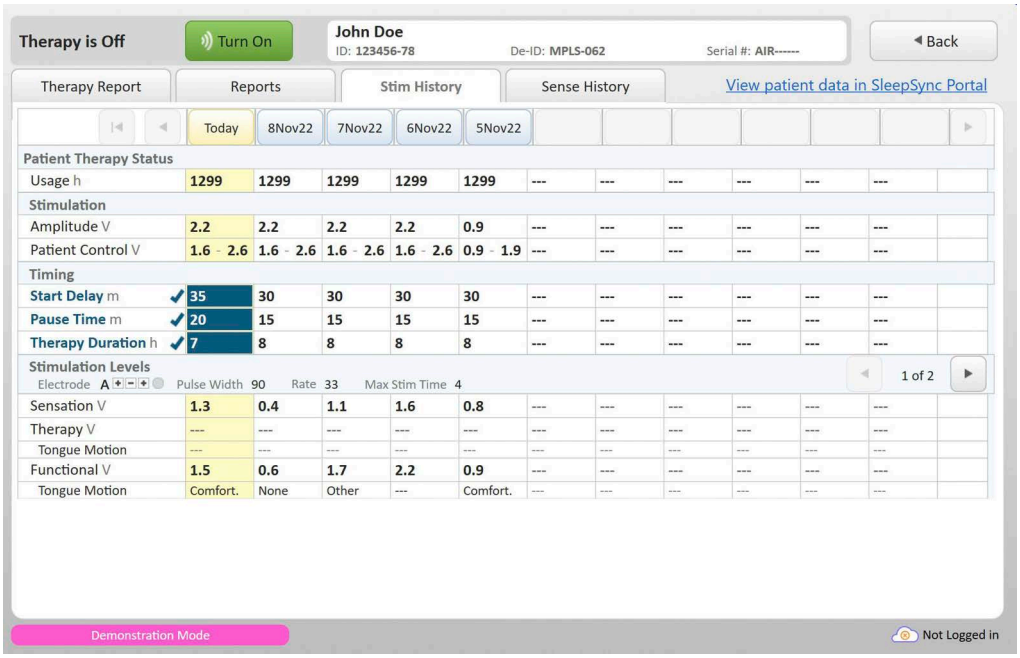


Figure 5-27. Stimulation History Screen

The **Stim History** button, located in various workflows on the Adjust Stimulation screen and on the Stim History tab of the Reports screen, 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 5-6 for information about the functions of the buttons on the Stimulation History screen.

Table 5-6. 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 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 arrow buttons are disabled, there are no additional levels to view.

Sensing History Screen

Sensing History shows patient information stored only on your computer.

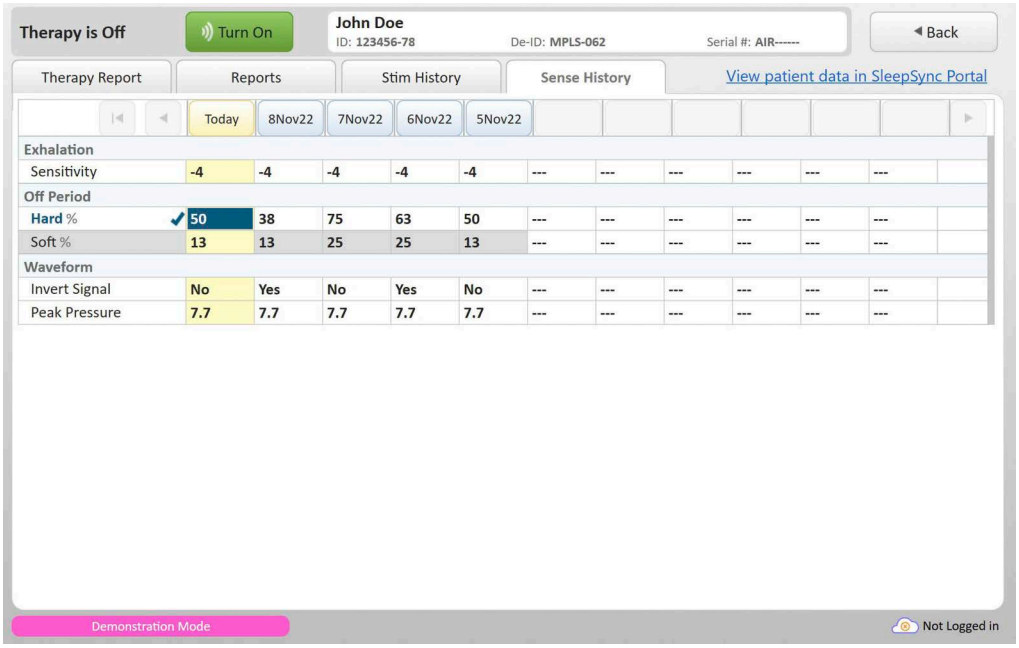


Figure 5-28. Sensing History Screen

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 5-7 for information about the functions of the buttons on the Sensing History screen.

Table 5-7. 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 arrow buttons are disabled, there are no additional dates to view.

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.

When To Use Workflows

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

- 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.
- Initial Activation - Use this workflow when first turning on a patient's therapy after the implant procedure.
- Sleep Study - Use this workflow when the patient is undergoing an overnight sleep study.
- 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.

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

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 19 and "Connecting The Programmer Cable to Power" on page 20.

Enter Patient Details

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

- Select any field to enter or edit patient information.
- Select the **Save** or **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.

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 (Patient Information Storage).

Check Generator Status

Verify that the generator battery status is good.

Start System Check Workflow

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

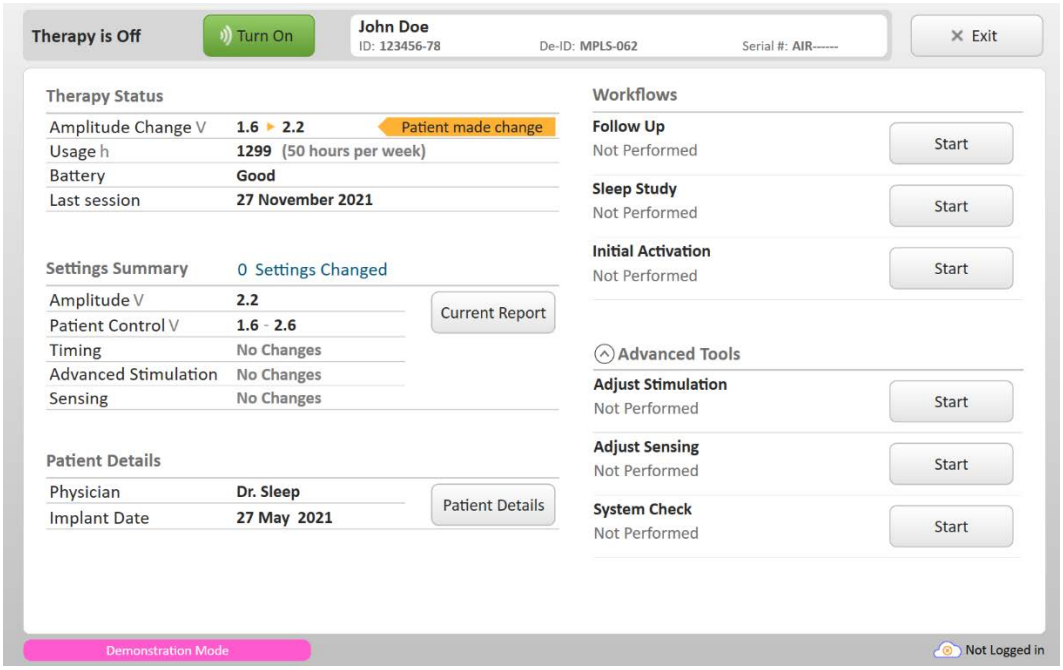


Figure 6-1. Session Home Screen

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

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

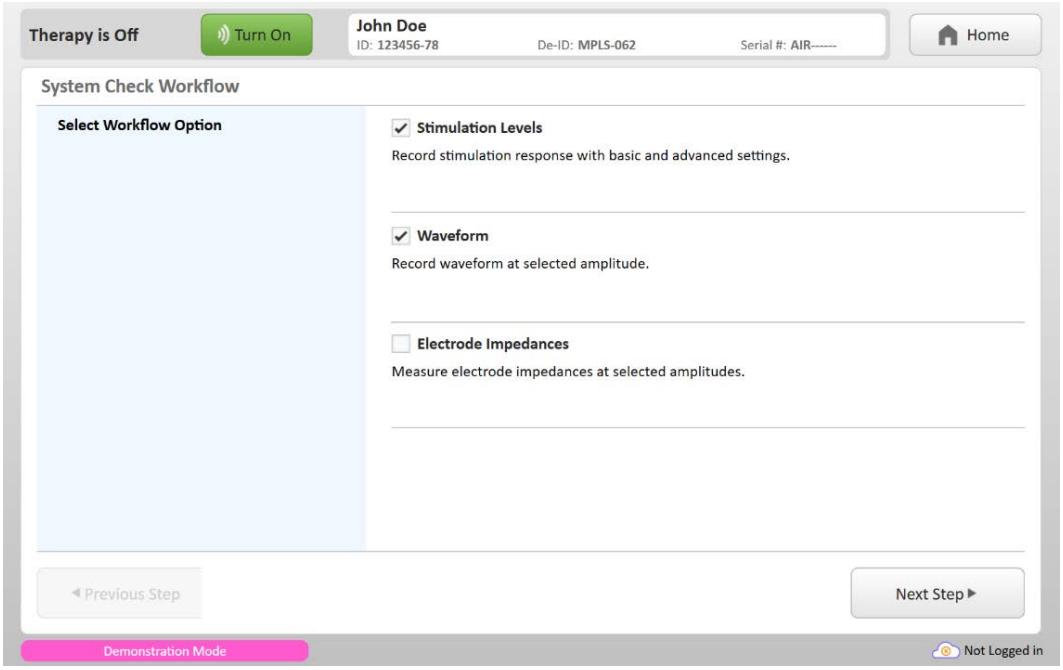


Figure 6-2. Check Workflow Screen

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 Workflow 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**.

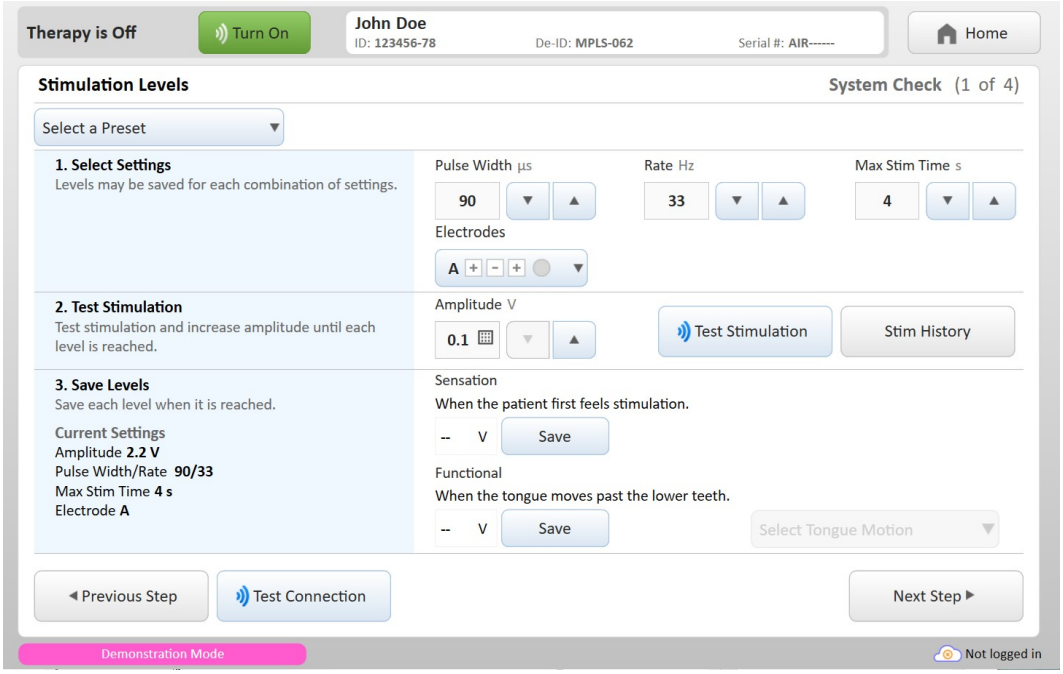


Figure 6-3. System Check - Stimulation Levels Screen

Assess Sensor Performance

After the sensing lead is connected to the generator, complete the following steps to confirm sensor performance and 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. If the waveform contains sharp high-frequency artifacts or a series of very short stimulation bursts, the sensor lead may not be properly connected to the generator.
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.

   Note: The amplitude will automatically return to its initial value when the workflow was started (for Implant, this should be 0 V).

Note: During surgery, the patient's respiratory rate is controlled by the ventilator. Sensor signal quality typically improves after surgical wounds heal.

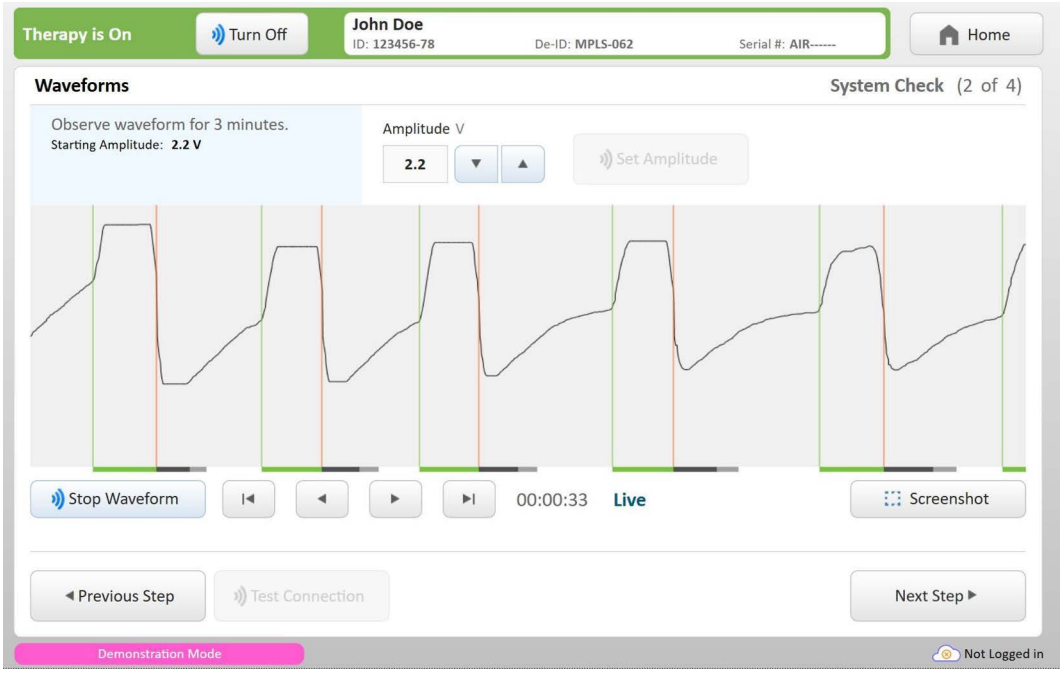


Figure 6-4. System Check - Waveforms Screen

Review Data

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

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

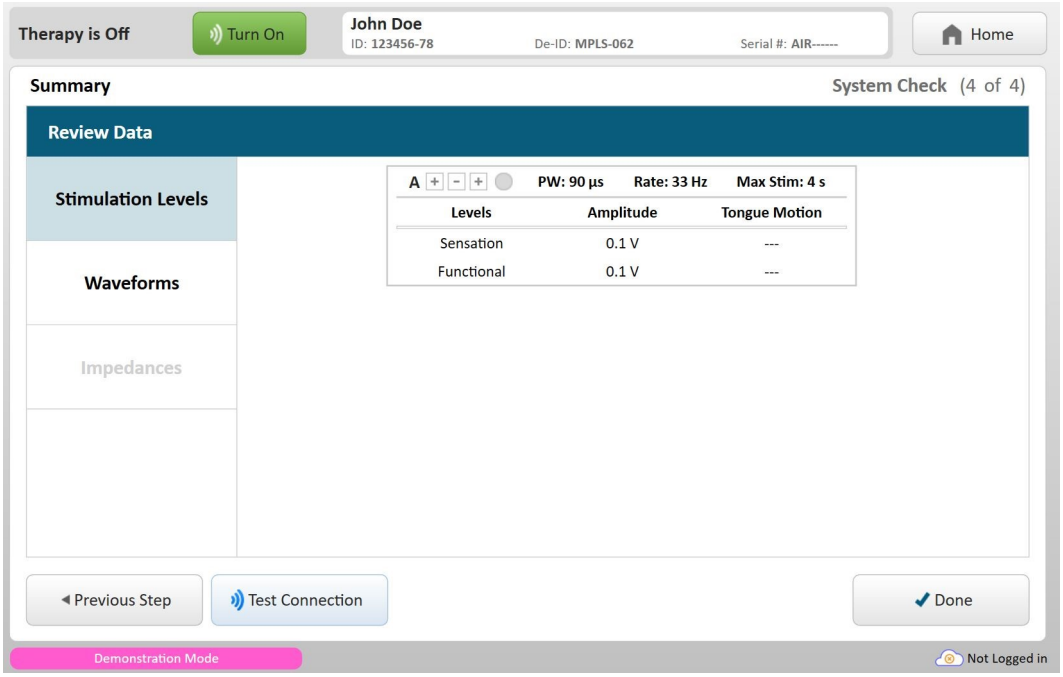


Figure 6-5. System Check - Summary Screen

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 Workflow has been completed.
4. Select the **Exit** button on the Home screen.

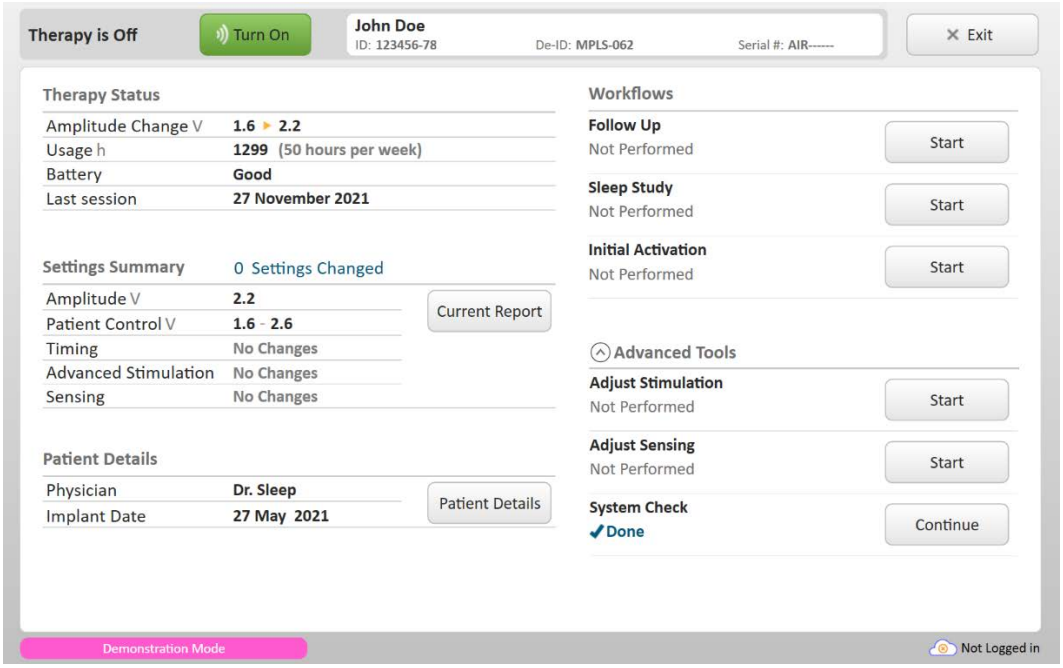


Figure 6-6. End Implant Session - Home Screen

Retain Records

Save a session report if desired. See “Saving Session Report as PDF” on page 84 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.

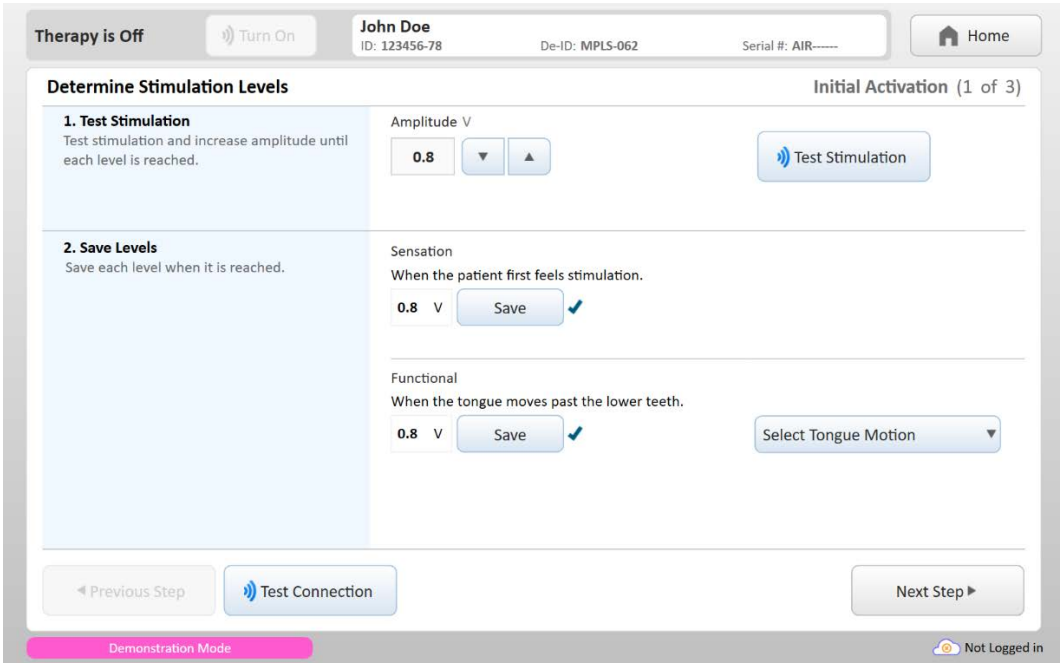


Figure 6-7. Initial Activation - Determine Stimulation Levels Screen

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.

Figure 6-8. Initial Activation - Observe Waveform Screen

Stimulation Summary

1. Review the Stimulation and Timing settings.
2. If desired, make any final changes.
3. Select the **Configure** button.
4. Select the **Done** button.

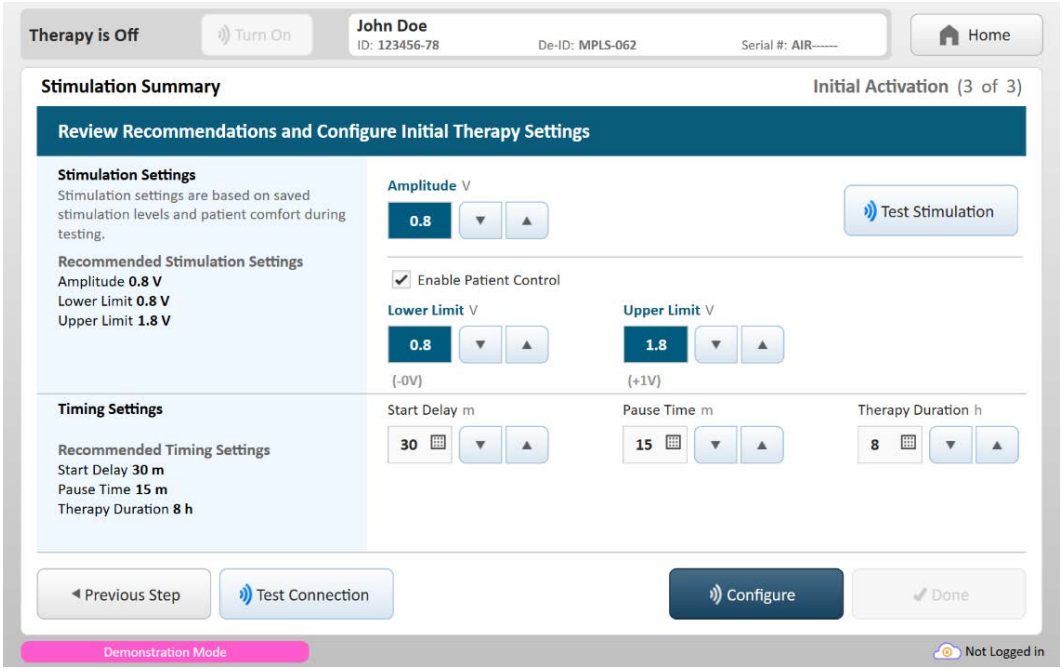


Figure 6-9. Initial Activation - Stimulation Summary Screen

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.

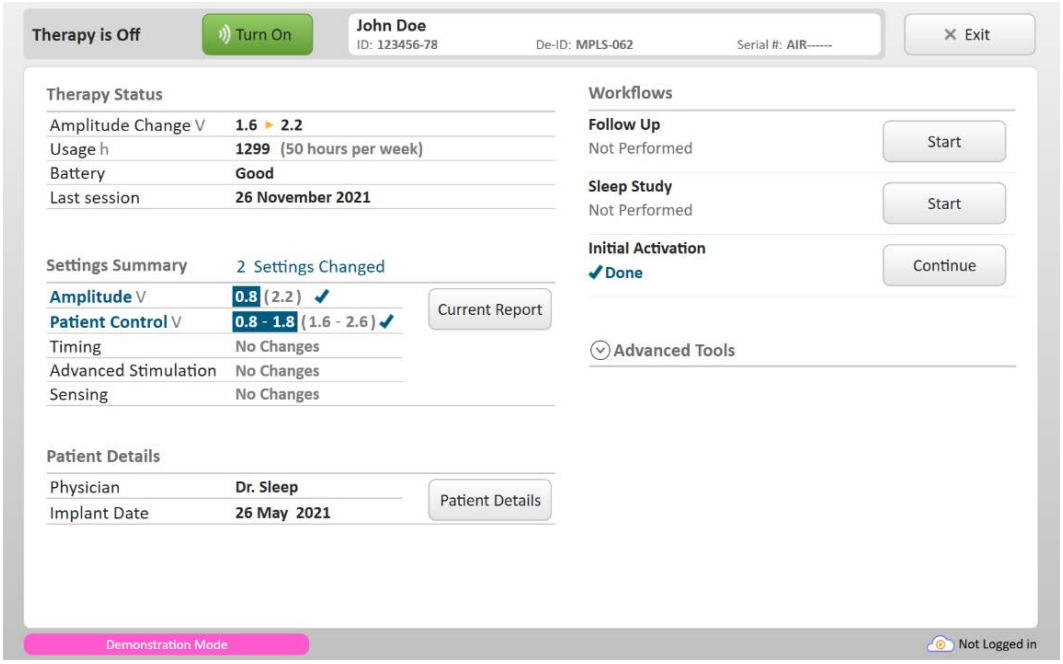


Figure 6-10. End Initial Activation - Home Screen

Retain Records

Save a session report if desired. See “Saving Session Report as PDF” on page 84 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.

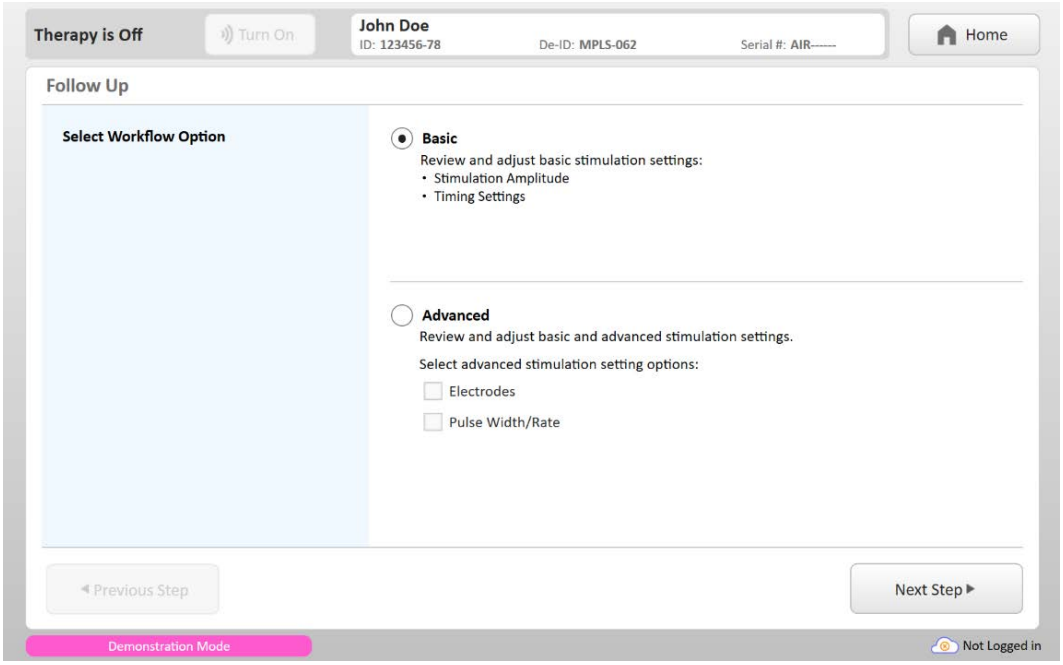


Figure 6-11. Follow Up Screen

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.

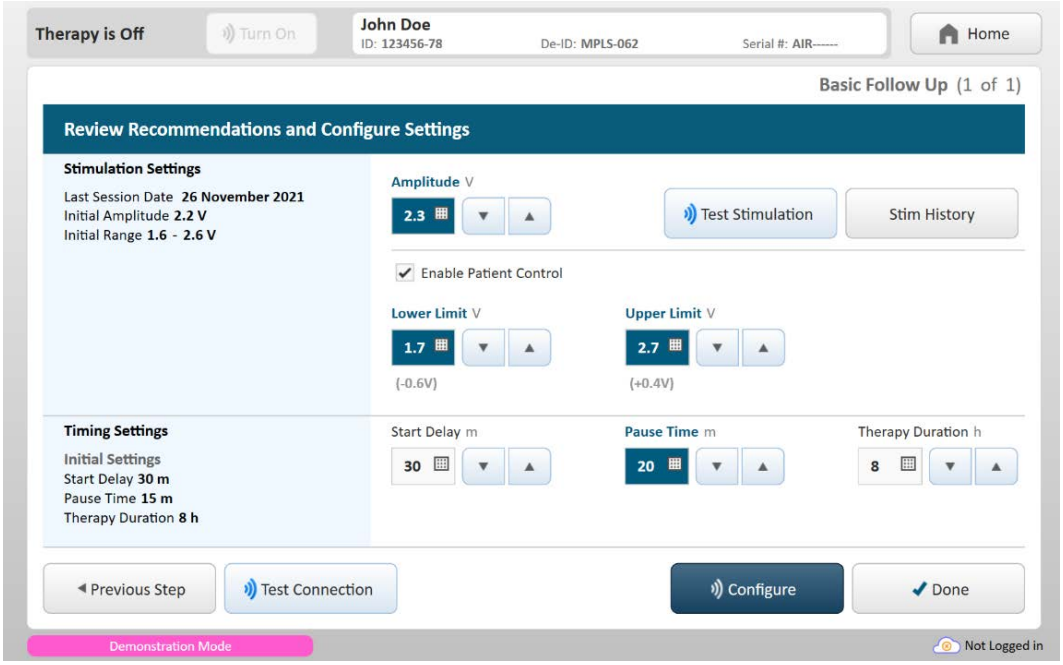


Figure 6-12. Basic Follow-up Screen

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.
   Note: It is recommended to evaluate at least two electrode options.

Note: Selecting a different electrode option will clear the saved stimulation levels. These levels can be viewed again if the previous electrode option is selected.

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.

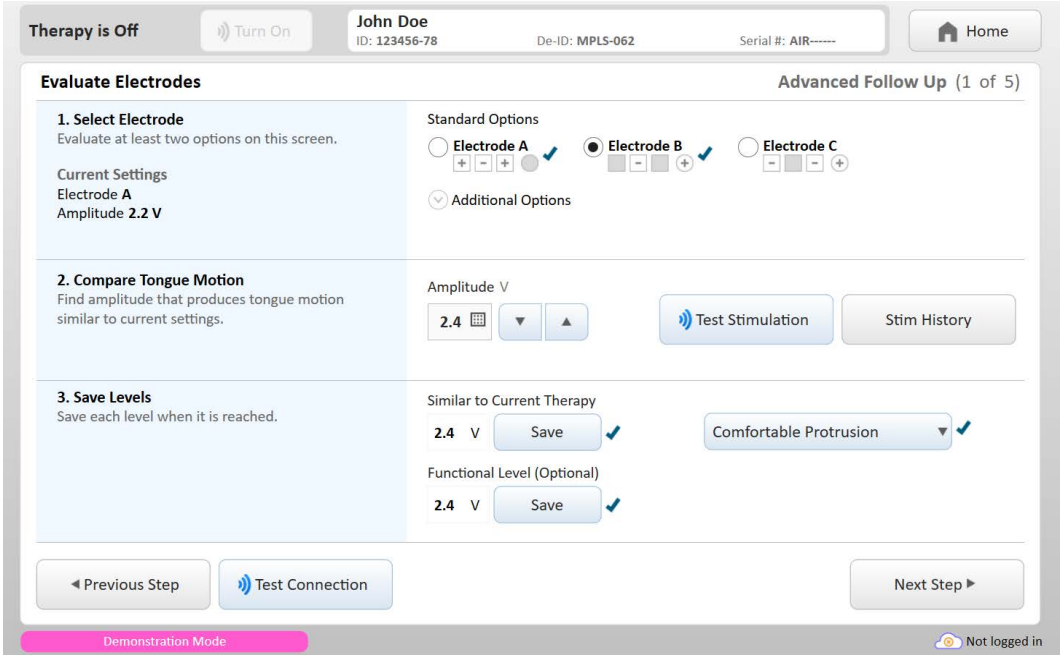


Figure 6-13. Advanced Follow Up - Evaluate Electrodes Screen

Select Electrode Amplitude

1. Review the level and tongue motion data that was saved on the previous screen.
2. Select the desired electrode.
3. Select the desired stimulation level if two levels are available.
   Note: Therapy Amplitude is equivalent to the “Similar to Current Therapy” level.
4. Select **Test Stimulation** if desired.
5. Select **Configure** to program the new electrode and amplitude.
6. Select the **Next Step** button.

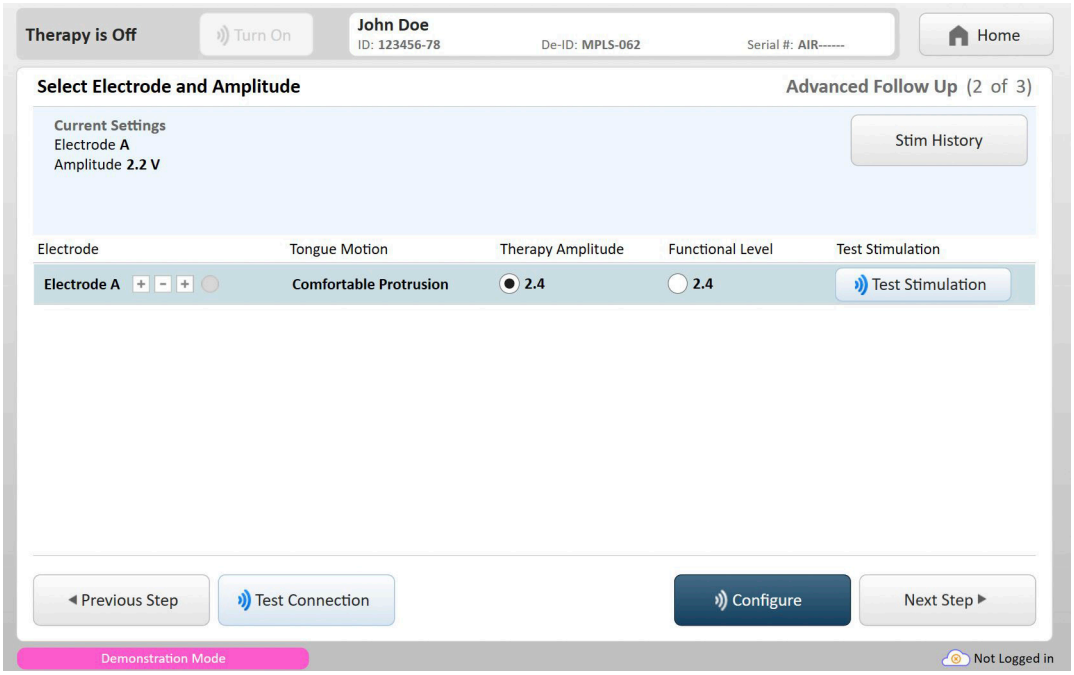


Figure 6-14. Advanced Follow Up - Select Electrode and Amplitude Screen

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.

   Note: Selecting a different pulse width/rate option will clear the saved stimulation levels.
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.

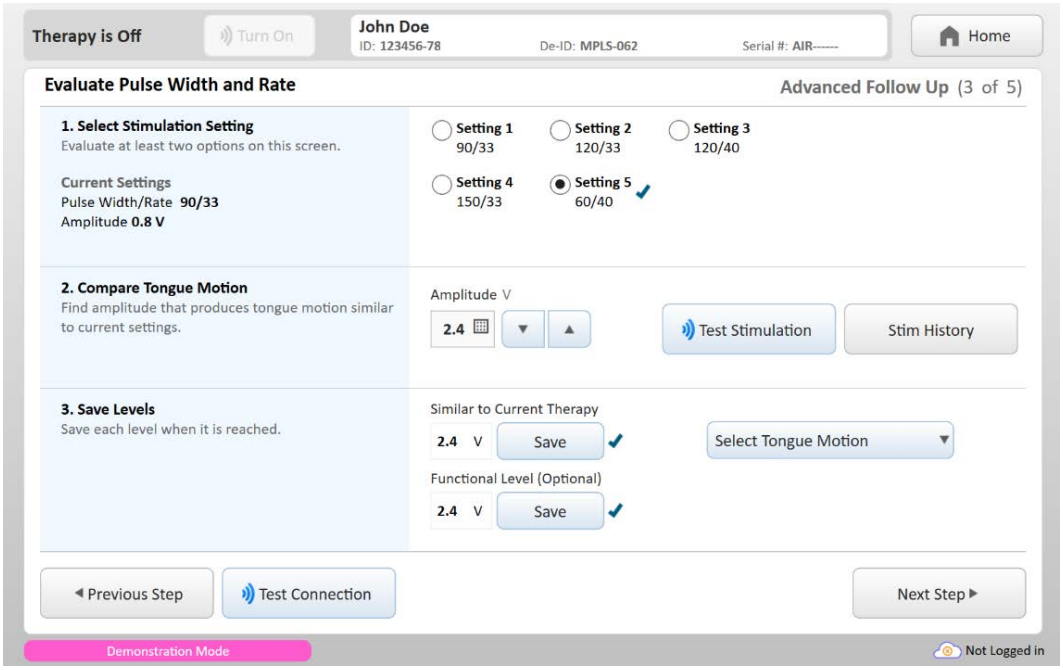


Figure 6-15. Advanced Follow Up - Evaluate Pulse Width and Rate Screen

Select Pulse Width/Rate and Amplitude

1. Review the level and tongue motion data that was saved on the previous screen.
2. Select the desired pulse width/rate option.
3. Select the desired stimulation level if two levels are available.
   Note: Therapy Amplitude is equivalent to the “Similar to Current Therapy” level.
4. Select **Test Stimulation** if desired.
5. Select **Configure** to program the new pulse width/rate and amplitude if the desired settings are new.
6. Select the **Next Step** button.

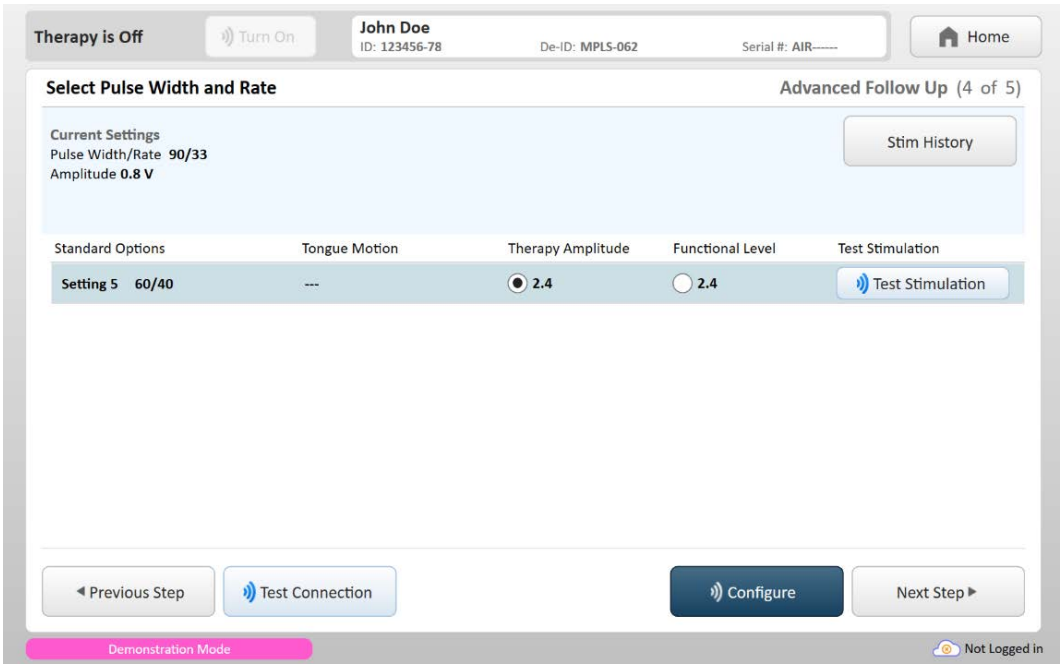


Figure 6-16. Advanced Follow Up - Select Pulse Width and Rate Screen

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.

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.

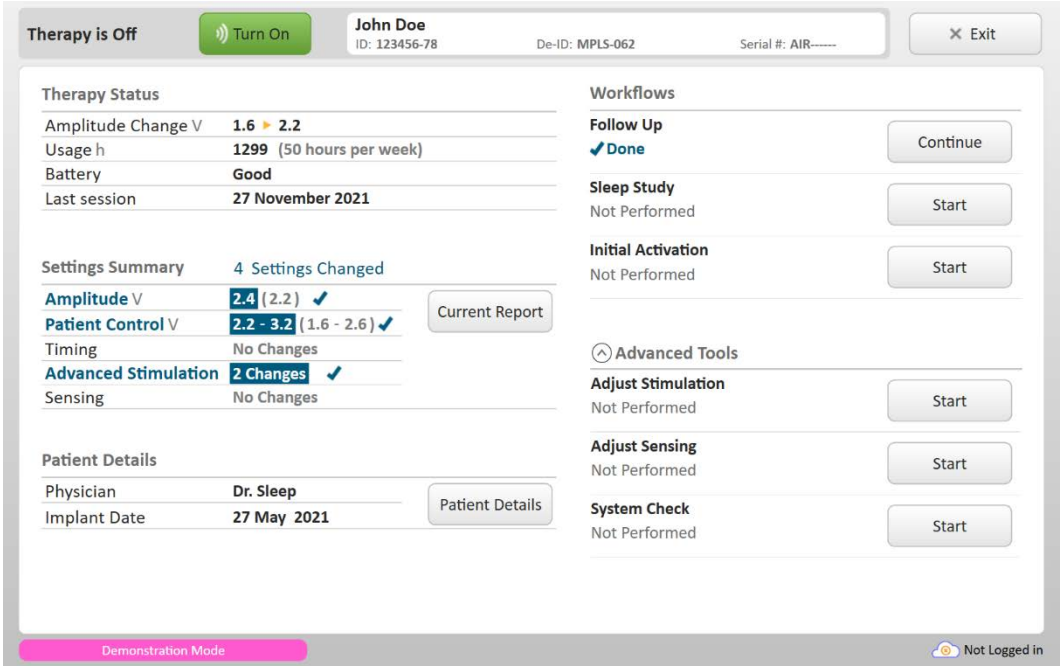


Figure 6-17. End Follow-Up - Home Screen

Retain Records

Save a session report if desired. See “Saving Session Report as PDF” on page 84 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 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 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 0.2 V 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: Amplitudes that are set are different from amplitudes that are configured. 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. Select the **Next Step** button.
6. If desired, change the programmer cable lights mode.

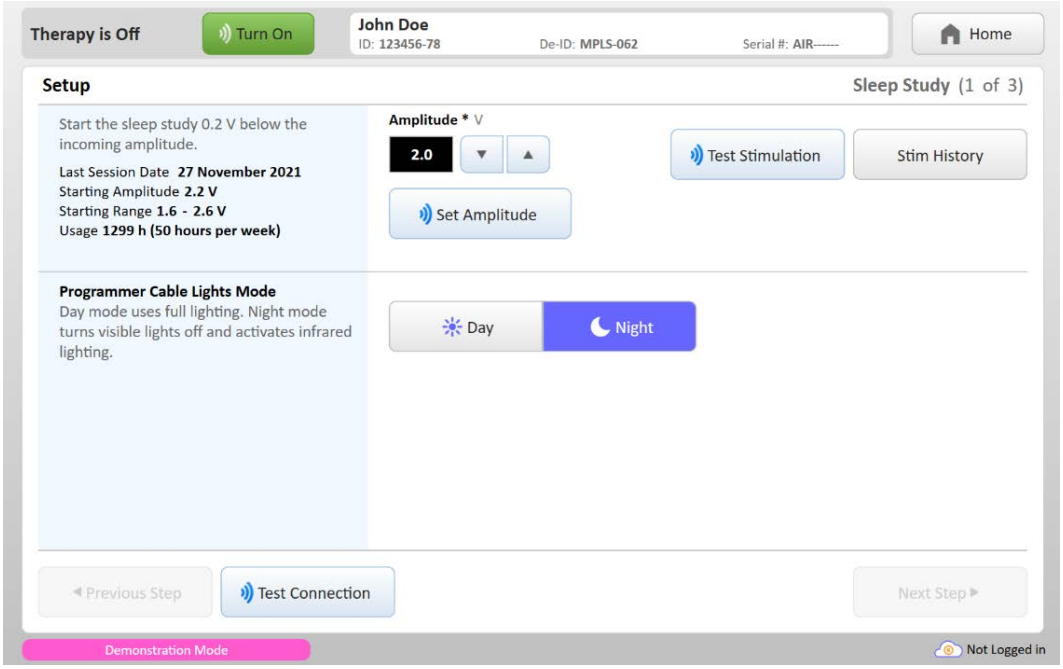


Figure 6-18. Sleep Study - Setup Screen

Adjust Stimulation

1. After the patient has fallen asleep, select the **Turn On** therapy button and then select the **Now** or **Delay** button from the Start Therapy screen.

   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.

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.

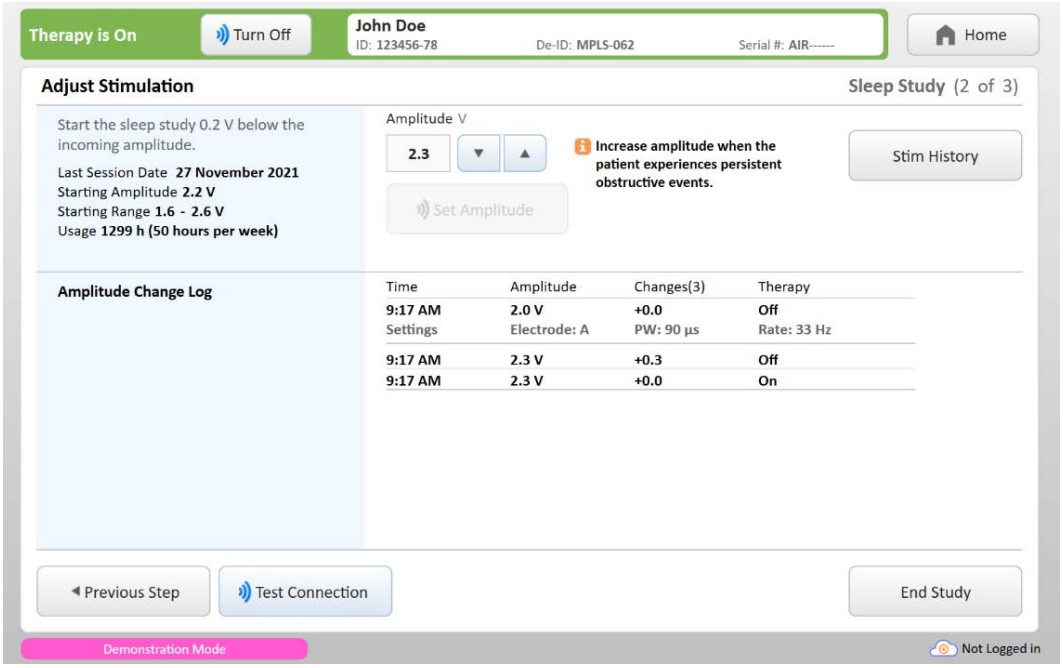


Figure 6-19. Sleep Study - Adjust Stimulation Screen

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.

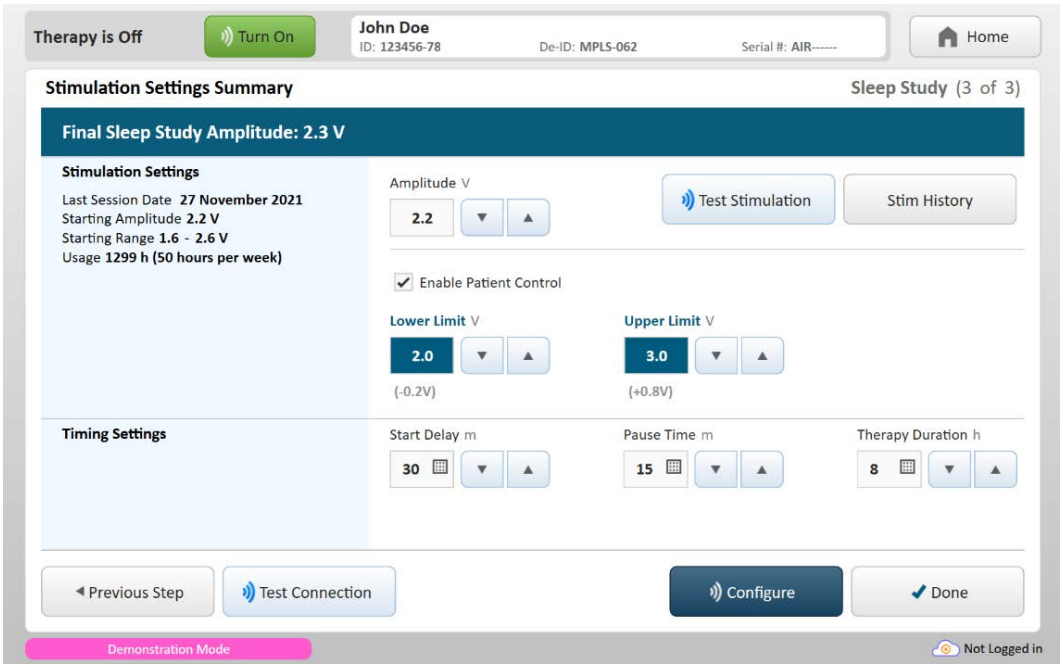


Figure 6-20. Sleep Study - Stimulation Settings Summary Screen

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.

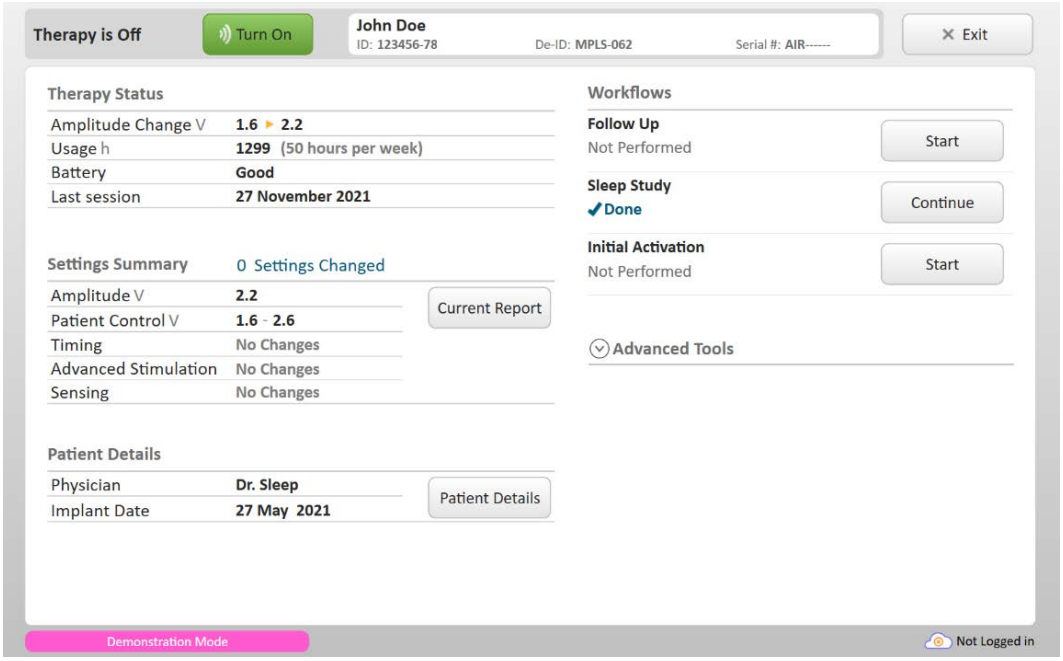


Figure 6-21. Ending the Sleep Study Session - Home Screen

Retain Records

Save a session report if desired. See “Saving Session Report as PDF” on page 84 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 Patient** button.
3. Confirm that the correct session report is displayed and select the **Save PDF** button.
4. Select the **Save Selected Report** button to save the current report only.
5. Select the **Save 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.
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 21. If those steps do not resolve the problem, review the following solutions.

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 by the SleepSync programmer.
2. If interference is encountered, unplug any unnecessary electrical equipment in the environment.
3. If interference is encountered, move the tablet 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 application at the earliest convenience.

Programmer Cannot Find Generator

Refer to the steps described in "**Testing Connection Strength**" on page 21. 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 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 application and repeat steps 1–2.
6. If there is still no connection, navigate to the Cable Connection Status screen (Figure 5-6). If a cable is paired but not connected, confirm that the serial number of the cable matches the serial number on the Cable Connection 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 Connection Status screen.

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

Pairing

Note: Do not use the Windows Settings menu to attempt pairing. Only pair using the SleepSync 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 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 Prepare the Programmer Cable to Pair instructions screen (Figure 3-10).
   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.

   Note: The on/off light pattern for pairing mode is different from the normal rotating pattern that occurs after connecting the programmer cable to power.

   Note: 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 31). Pairing will still work and you can continue with the pairing process.

Application Startup

The SleepSync application will not open 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 workflow. This screen is used to assess the integrity of leads, lead electrodes, and the lead-generator connection.

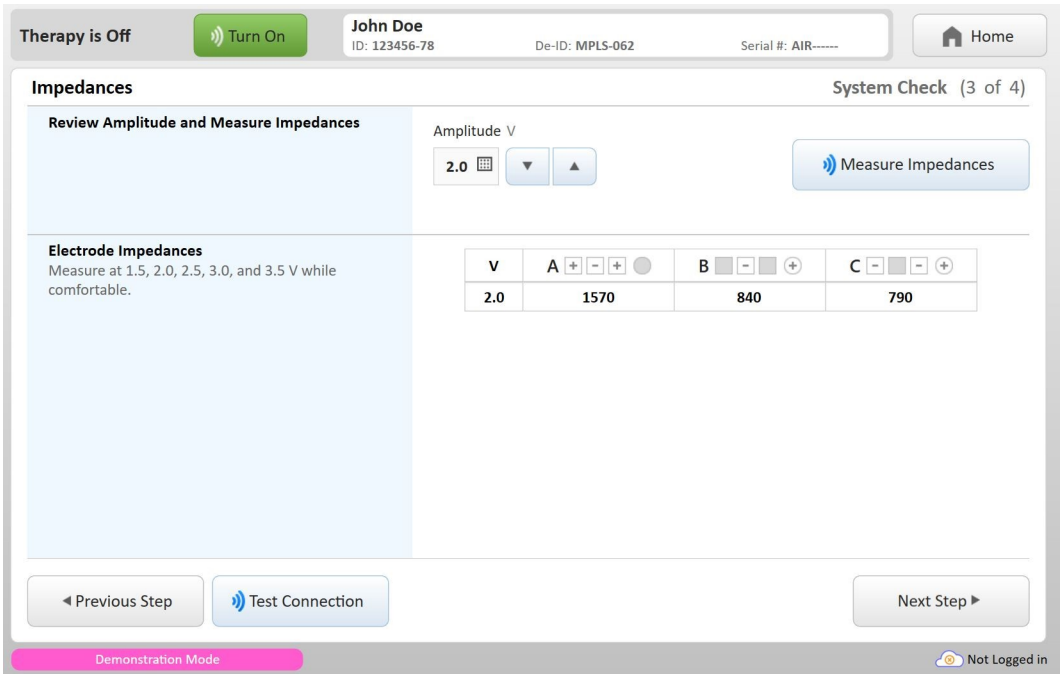


Figure 7-3. Measure Impedances Screen

Follow the numbered steps on screen to measure impedances:

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.
3. 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.

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.

Figure 7-4. Arrow Button to Navigate to Live Waveform Image

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, the generator is in start delay or pause time, or the programming head is out of connection range.

1. Select the **Turn Off** therapy button on the Adjust Sensing screen.
2. Select the **Start Waveform** button to restart therapy in waveform mode.
3. If that does not resolve the problem, the programmer head may not be properly positioned. Reposition the programmer head directly over the generator.

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

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 Programmer Settings" on page 19.

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. See "Programmer Cable - Error Mode" on page 87 for more information.

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 Reset

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

Invalid Setting

It is possible for the generator to be programmed with 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 drop-down 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.

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 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 currents into the device that may damage the device. 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 System 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 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
Rate	33 Hz
Soft off period	13%
Start delay	30 m
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, 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.

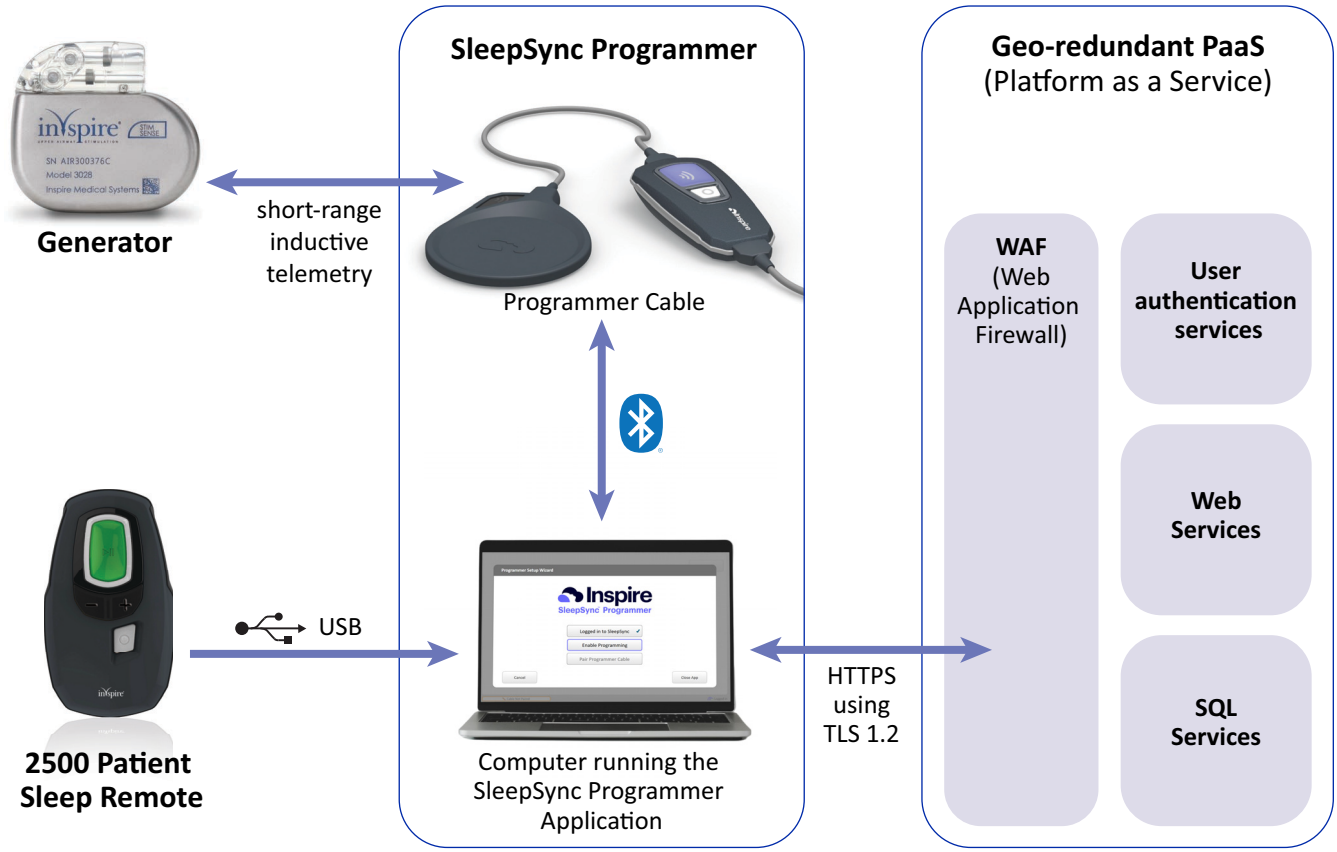
Communications Security

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 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 SleepSync, a network connection is required.

To support provisioning and upload, the SleepSync 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 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 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 12 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 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 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 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 application (Model 2740S) to known and secure networks.

Network Firewall and Segmentation

The computer running the SleepSync 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 application (Model 2740S) to protect against threats which could occur on the local network.

Physical Security

Keep the computer running the SleepSync 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 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 software updates are available.

Firmware Updates

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 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 user's AppData folder (C:\Users\<user name>\AppData\Local\Inspire Medical Systems, Inc\Inspire SleepSync Programmer\). 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 Programmer 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

<table>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment Guidance</th></tr>
<tr><td>Radio frequency (RF) emissions CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions EN 61000-3-3</td><td>Complies</td></tr>
</table>

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	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD): EN/IEC 61000-4-2	+/-8 kV contact +/-15 kV air	+/-8 kV contact +/-15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. 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	±2 kV for power supply lines ±1 kV for input/ output lines +/-2kV for input AC power port +/-1 kV for signal I/O port 100 kHz repetition frequency	±2 kV for power supply lines (no input/output lines) +/-2kV for input AC power port +/-1 kV for signal I/O port 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, +/-1 kV, +/-2 kV line-to-ground	+/-0.5 kV, +/-1kV 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.

Table 9-4. Electromagnetic Immunity (continued)

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	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
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	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

<table>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity Test</th><th>EN/IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment Guidance</th></tr>
<tr><td>Conducted RF EN/IEC 61000-4-6</td><td>6 Vrms in ISM bands between 0.15 MHz and 80 MHz
80% AM at 1 kHz</td><td>6 Vrms in ISM bands between 0.15 MHz and 80 MHz
80% AM at 1 kHz</td><td rowspan="3">Portable and mobile RF communications equipment should be used no closer to any part of the programmer cable, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$
80 MHz to 800 MHz
$d = 2.3\sqrt{P}$
800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].</td></tr>
<tr><td>Radiated RF EN/IEC 61000-4-3</td><td>3 V/m
80 MHz - 2.7 GHz
80% AM at 1 kHz</td><td>3 V/m
80 MHz - 2.7 GHz
80% AM at 1 kHz</td></tr>
<tr><td>Power frequency magnetic field: EN/IEC61000-4-8</td><td>30 A/m</td><td>30 A/m</td></tr>
</table>

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

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	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
			Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[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.

Table 9-6. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Model 2740C Programmer Cable

The programmer cable is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the programmer cable can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the programmer cable as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 9-6. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Model 2740C Programmer Cable

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.

Inspire Medical Systems, Inc. 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.

A. 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.

B. 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.

Inspire®
Sleep Apnea Innovation

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

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