Inspire

Sleep Apnea Innovation

PROGRAMMER MANUAL

Programmer Model 2740

℞ ONLY

The following is a trademark of Inspire Medical Systems, Inc.: Inspire®

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

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.

Symbol	Description
	Caution, consult accompanying documents
	Consult electronic instructions for use (eIFU)
	Consult instructions for use
	Nonsterile
	Fragile
	Keep dry
SN	Serial number

Symbol	Description
	Temperature limitation
	Atmospheric pressure limitation
	Relative humidity limitation
	Federal Communications Commission notice (USA)
	For US audiences only
	Manufacturer
	Product complies with 2002/96/EC
	Non-ionizing electromagnetic radiation

Symbol	Description
CE 2797 2010	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive 90/385/EEC.
CE	Conformité Européenne; compliance to EMC Directive and Low Voltage Directive of the European Union.
EC REP	European authorized representative
CLASSIFIED c UL us	Compliance with Underwriters Laboratories for general product safety in accordance with UL 60950-1 (ITE) and CAN/CSA C22.2 No. 60950-1 (ITE)
	Power button
	Type BF Applied part protection against electrical shock
	Output connector polarity
	Class II double insulated

Symbol	Description
	CEC Level V compliant
	UL recognized component mark
CB	IECEE CB compliant
	Indoor use only
	TUV/T-Mark for IEC/EN 60601-1 Compliance
IP22	Degree of ingress protection per EN60529
IP65	Degree of ingress protection per EN60529
	The Inspire Programmer is MR unsafe

Symbol	Description
	The Technical Conformity mark signifies that this device complies with Japan Radio Law
	The Regulatory Compliance Mark (RCM) signifies that this device complies with Australian Communications and Media Authority requirements

How to Use this Guide

This guide presents information for users of the Inspire Programmer (Model 2740) for programming an Inspire Generator. 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 programmer tablet, programmer cable, and accessories.
- **Getting Started**

  This chapter provides instructions on how to set up and start the programmer and how to start and end a programming session.
- **Screen Descriptions**

  This chapter provides detailed descriptions of the programmer screens.
- **Clinical Programming Sessions**

  This chapter provides instructions for programming procedures (workflows) at implant, initial activation, follow up, and sleep studies.
- **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 programmer. The patient uses a patient 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.

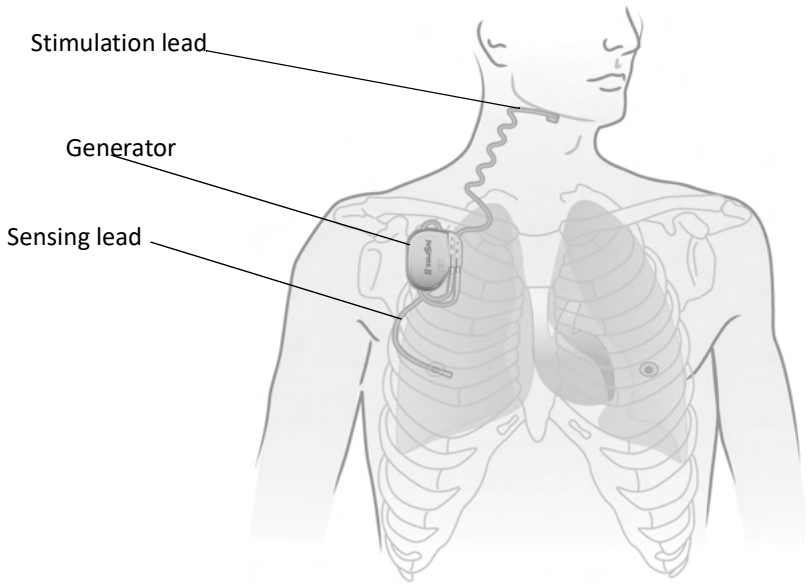


Figure 1-1. Inspire System Implanted Components

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) implant procedure, (2) therapy acclimation, (3) titration, and (4) therapy maintenance.

Implant Procedure

During this procedure, the generator, stimulation lead, and sensing lead are surgically implanted. The Inspire programmer is used to test the implanted system during surgery.

Therapy Acclimation

Therapy acclimation typically lasts for 1–3 months following implantation. During this phase, the device is activated and patients learn how to use the patient remote to increase the amplitude to a therapeutic level.

Titration

During this phase, patients undergo 1–2 polysomnograms (PSGs) or sleep studies, during which the physician determines the optimal stimulation and sensing settings.

Therapy Maintenance

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

Terminology

This section introduces and defines common terms used throughout this programming guide for setting 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 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 patient 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

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 47 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.

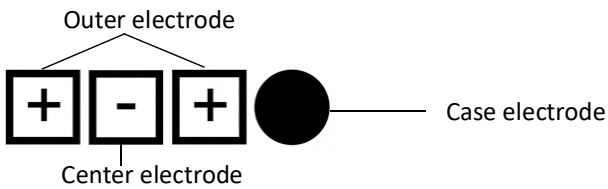


Figure 1-2. Default Electrode

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.

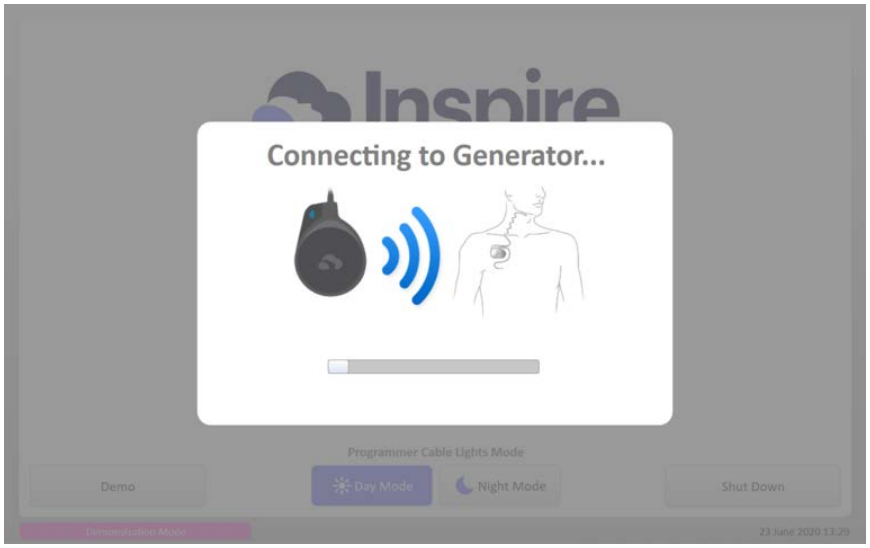


Figure 1-4. Communication Screen

Chapter 2: Programmer Components

This chapter describes the programmer components and accessories.

Package Contents

The programmer comes packaged with all components needed to work with an Inspire generator.

- Tablet
  - Handheld computer
  - Inspire programmer software
  - Medical-grade power supply and power cord
- Programmer cable
  - Programmer head
  - Bluetooth wireless communications interface
  - Medical-grade power supply and power cord
- Inspire universal serial bus (USB) flash drive
- Portability kit
  - Inspire computer bag
  - Luggage tag

Tablet

The tablet screen is controlled by the user with the touchscreen. The Inspire system uses the buttons and controls that are specified in this programming guide. Some of the buttons and controls on the tablet are not used when programming the Inspire system.

Tablet Front and Bottom

The front of the tablet (Figure 2-1) contains an LCD screen and status lights. The status lights and docking connector are described in Table 2-1 and Table 2-2. Unused controls are listed in Chapter 8.

Figure 2-1. Tablet Front

Table 2-1. Tablet Front

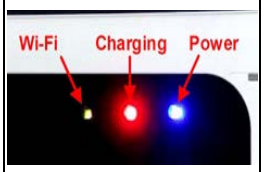
Icon/Item	Description	Function
	Status lights	WiFi Charging Power
	Docking connector	Interface connector for use with docking station (not included)

Table 2-2. Tablet Status Lights

Light	Status	Description
WiFi	Green	N/A - WiFi not used
Charging	Red (solid)	Charging
	Off	Fully charged
	Red (flashing)	Abnormal charging condition
Power	Blue	System ON
	Yellow	Standby (unused)

Tablet Right Side

The right side of the tablet (Figure 2-2) contains the USB port. Unused controls are listed in Chapter 8.

Figure 2-2. Tablet Right Side

Tablet Left Side

The left side of the tablet (Figure 2-3) contains the power adapter port. Unused controls are listed in Chapter 8.

Figure 2-3. Tablet Left Side

Tablet Back

The back of the tablet (Figure 2-4) has a hand strap to assist in holding the tablet.

Figure 2-4. Tablet Back

Tablet Battery

The tablet has a high-capacity lithium-ion battery. When fully charged, the tablet can run on battery power for more than three hours.

For information about battery status indicators and charging the battery, see “Charging Status” and “Charging Battery” on page 17.

Warning: To avoid personal injury, handle the battery with care. Do not puncture, short, or expose it to fire or water.

Tablet Power Supply

A medical-grade tablet power supply provides power to the tablet and charges the battery. A power cord is included.

Warning: Use only the tablet power supply provided with the tablet. Do not use the tablet power supply to power any other electronic devices.

Programmer Cable

The programmer cable is the communications interface between the generator and the tablet. The programmer cable includes the programmer head, the controller, and a medical-grade power supply with power cord (Figure 2-5). 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 tablet (approximately 5 to 10 m or 16 to 33 ft).

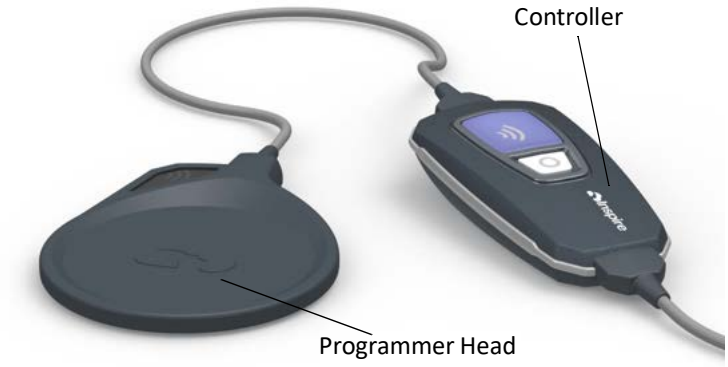


Figure 2-5. Programmer Cable

Data Backup Kit

The included USB flash drive allows the user to download and back up session reports.

Figure 2-6. Data Backup Kit

Portability Kit

The portability kit provides a convenient way to safely transport the programmer. The portability kit consists of a computer bag and a luggage tag for your contact information (Figure 2-7).

Figure 2-7. Portability Kit

Chapter 3: Getting Started

This chapter describes how to start and end a programming session.

Turning On the Programmer

This section describes how to turn on the programmer. The tablet can be operated either on battery power or plugged into an electrical outlet. The battery should be fully charged prior to operating the programmer on battery power.

Charging Status

The battery status light that is located on the front, upper-right corner of the tablet (see Figure 2-1) indicates the charging status of the battery.

- Steady red — The battery is charging.
- Off — The battery is fully charged.

Note: In storage, the battery slowly self-discharges. If the tablet is not used regularly, plug it into an electrical outlet for 2 hours every 4 weeks to maintain the battery charge.

Charging Battery

The battery automatically charges to full capacity while the tablet is powered by an electrical outlet. The tablet does not need to be on to charge the battery. The battery should be fully charged prior to storing the programmer.

Only charge the battery when its temperature is between 0°C and 40°C. If the battery has been subjected to extreme temperatures, wait until it cools to room temperature before recharging.

Connecting Tablet to Power

To connect the tablet to an electrical outlet (Figure 3-1):

1. Open the cover on the tablet power adaptor port and insert the single-prong end of the tablet power supply cable into the tablet.
2. Insert the power cord into the tablet power supply.
3. Insert the end of the power cord into the electrical outlet (100–240 VAC).

Figure 3-1. Tablet Power Supply Connections

Powering On Tablet

Press and hold the power button on the top of the tablet (Figure 3-2) until the power light is illuminated. Once the tablet powers on and the software loads, the Start screen displays.

Figure 3-2. Tablet Power Button

Connecting 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 3-3).

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 3-3. Programmer Cable Power Supply Connections

Starting a Session

Navigating the Start Screen

Once the programmer is powered on, the Start screen displays (Figure 3-4).

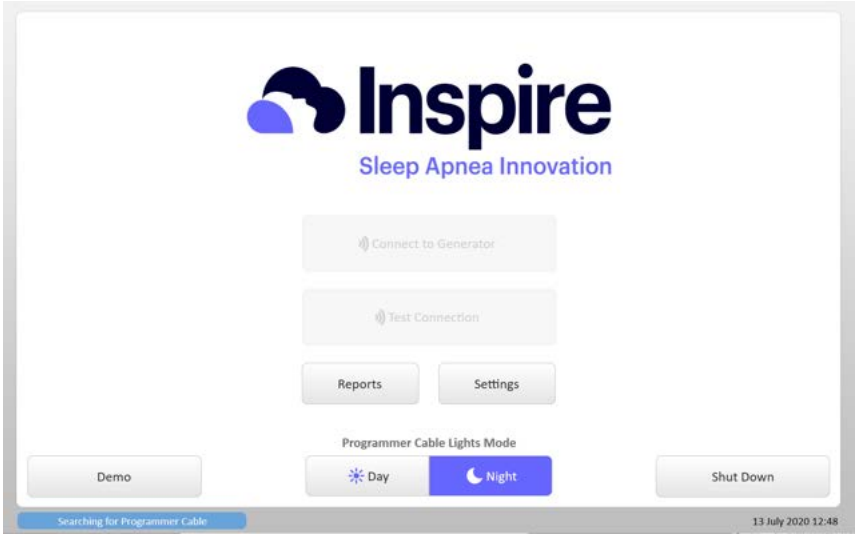


Figure 3-4. Start Screen

The buttons on the Start screen are described in Table 3-1.

Table 3-1. 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 the tablet has established a connection to the programmer cable.
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 the tablet has established a connection to the programmer cable.
Reports	• Accesses reports for previous programming sessions. • Reports can be reviewed and exported.
Settings	• Accesses the Programmer Settings screen; allows access to data management controls and adjustments to date and time, language, number format, and programmer cable mode.
Demo	• Starts a practice programming session. • Makes it possible to practice using the programmer with a simulated generator when no patient is present.
Shut Down	• Powers off the tablet.
Programmer Cable Lights Mode	• Day mode uses full lighting. • Night mode turns visible lights off and activates infrared lighting.

Important status notifications appear at the bottom of the Start screen along with the current date and time (Figure 3-5).

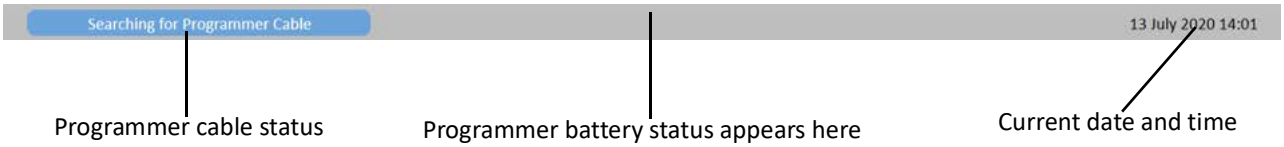


Figure 3-5. Start Screen Footer Information

Programmer Cable Status

The programmer cable connection status displays one of the following messages in the lower-left corner of all programming screens.

- Programmer Cable Connected — Wireless link between tablet and programmer cable is established. Status background color is blue. Programmer cable controller status light is fully lit (see Figure 3-5). Connection buttons are enabled.
- Searching for Programmer Cable — Wireless link between tablet and programmer cable is not established. Status background color is white with pulsing border. Controller status light is partially lit (see Figure 3-5). Communication buttons are disabled.
- Demo Mode — Wireless link between tablet and programmer cable is not active, but programmer may be used for demonstration. Status background color is pink.

Programmer Battery Status

The programmer battery status displays one of the following messages in the bottom-center of all screens if the battery is low or depleted.

- Battery Low — The programmer battery is nearing depletion and should be connected to power supply soon.
- Recharge Battery — The programmer must be attached to the power supply to prevent an automatic shutdown.

Current Date and Time

The current date and time display in the lower-right corner of all programming screens as follows.

- Current date — Displays on all screens in a DD Month YYYY format.
- Current time — Displays on all screens in a 24-hour format.

Using the Touchscreen

To select a programming button, gently touch the displayed button on the tablet screen (Figure 3-6).

Figure 3-6. Select Programming Buttons on Touchscreen

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.

To adjust the programmer settings:

1. Select the **Settings** button from the Start screen.
2. Set data control options.
3. Set the correct date and time.
4. Set the language to your native language.
5. Set the appropriate number format for your region.
6. Set the programmer cable lighting mode. Day mode will enable all lights on the programmer cable and night mode will disable lights for nighttime use.

After modifying programmer settings select the **Save** button.

Setting Data Controls

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

- USB Export — Select this check box to enable or disable the option to transfer session reports to the Inspire USB flash drive.
- Patient Information Storage — Select this check box to enable or disable the storage/editing of patient name and ID.
- Patient Information Export — Select this check box to enable or disable the exporting of patient details.

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

Setting Language

1. Select the **Settings** button from the Start screen.
2. Select the **Language** menu and choose one of the languages.
3. Select the **Save** button to save the new language.

Setting Number Format

1. Select the **Settings** button from the Start screen.
2. Select the **Number Format** drop-down menu and choose one of the formats that displays below.
3. Select the **Save** button to save the new number format.

Setting Date and Time

1. Select the **Settings** button from the Start screen.
2. Select the arrow buttons to adjust the day, month and year.
3. Select the arrow buttons to adjust the 24-hour clock.
4. Select the **Save** button to save the new date and time.

Note: The programmer does not automatically adjust for daylight savings time. Manually update the date and time when local time changes occur.

Positioning Programmer Head and Connecting to Generator

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

Confirming Connection

The programmer cable status line in the lower-left corner of the screen will indicate that a communication link between the tablet and the programmer cable is established. See “Programmer Cable Status” on page 22“ for more information.

A fully lit status light displays on the programmer cable controller when the tablet 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 tablet.

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 3-7).
3. Press the Test Connection button on the controller.
4. The strength gauge will display one of the following ratings in Table 3-2.
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 tablet:

1. Ensure that the tablet and programmer cable are on.
2. Confirm that a wireless link between the tablet and programmer cable has been established by checking the programmer cable status line in the screen footer.
3. Position the programmer head directly over the generator (Figure 3-7).
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 3-2.
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 3-2.

Table 3-2. Communication Strength Ratings

Good	
Moderate	
Low	

Table 3-2. Communication Strength Ratings

Generator not found	
Electrical Interference	

Figure 3-7. Correct Positioning of Programmer Head over Generator

Programmer Head Strength Gauge

A strength gauge is located on the top of the programmer head (Figure 3-7) so that it can be observed when the programmer head is positioned over the generator. The strength ratings are described in Table 3-2.

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 the good programmer head position and select the **Connect to Generator** button on the Start screen. As the programmer connects to the generator, the tablet displays one or more of the following Communication Screens described in Table 3-3. If necessary, take the recommended actions.

Table 3-3. 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 programmer head over 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 3-8). The icon corresponds to the programmer head status light to indicate communication success or failure.

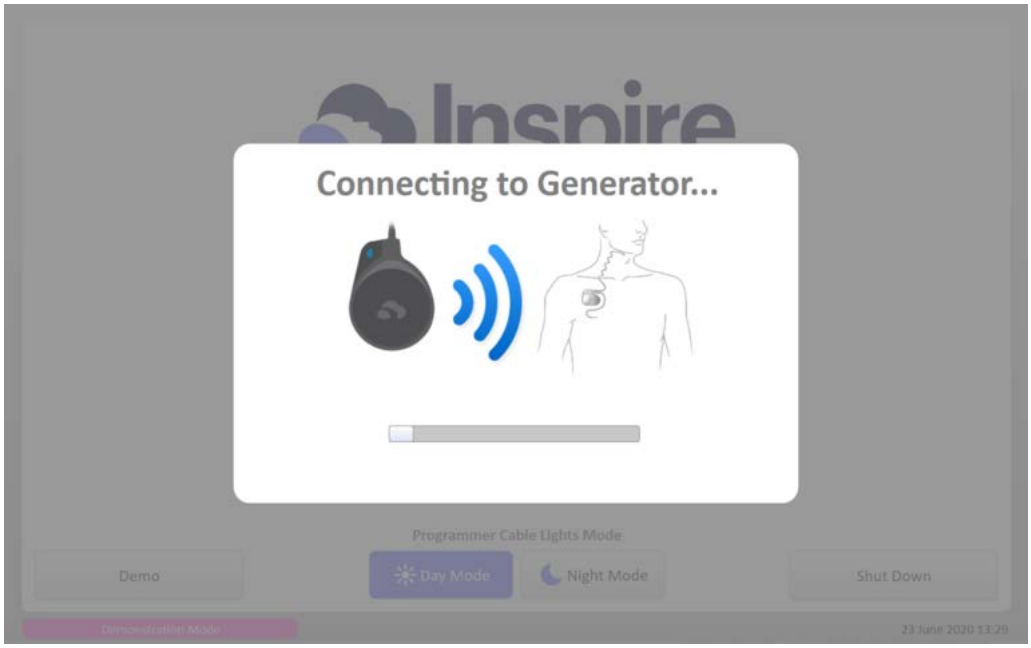


Figure 3-8. Communication Screen

Table 3-4 describes common problems associated with establishing a wireless connection between the tablet, programmer cable, and generator along with their solutions.

Table 3-4. Communications Troubleshooting

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

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 tablet is on.
2. Select the **Demo** button from the Start screen.

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

Exiting a Session and Turning Off the Programmer

Allow all communications to complete before a patient leaves. If a patient is allowed to leave during a test 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.
3. Select the **Shut Down** button to power off the tablet.

   Note: The tablet will continue to charge when powered off and should be fully charged before storing. The charging light will turn off when the tablet is fully charged.
4. To power off the programmer cable and disconnect it from mains power, unplug the power cord from the electrical outlet.
5. To disconnect the tablet power supply from mains power, unplug the power cord from the electrical outlet.

Note: The programmer is not designed for use over extended periods of time (>24 hours) without restarting.

Chapter 4: Screen Descriptions

This chapter provides descriptions of the programmer screens.

Common Screen Elements

All programmer screens, with the exception of the Start screen, Programmer Settings screen and Select a Patient screen, display common information in the screen header (Figure 4-1).

Screen Header Information

Figure 4-1. 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 4-2), 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 — Deidentified 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.

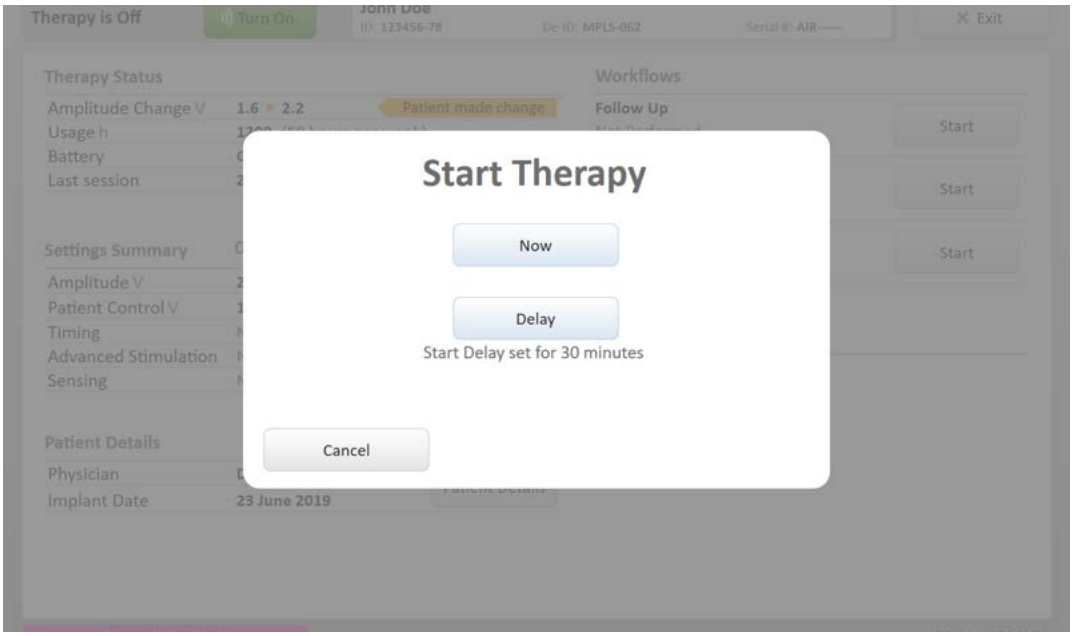


Figure 4-2. Start Therapy Screen

Screen Footer Information

All programmer screens also display common information in the screen footer. (Figure 4-3):

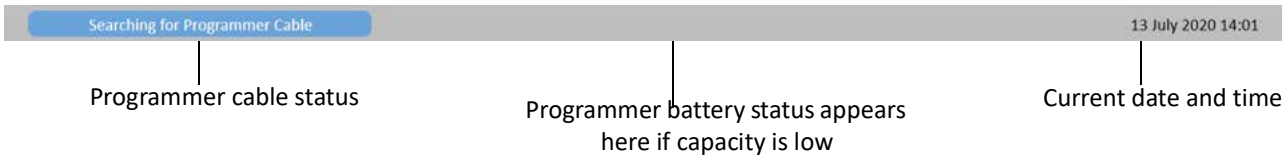


Figure 4-3. Common Information in Screen Footer

Programmer Cable Status

The programmer cable connection status displays one of the following messages in the lower-left corner of all programming screens.

- Programmer Cable Connected — Wireless link between tablet and programmer cable is established. Status background color is blue. Programmer cable controller status light is fully lit (see Figure 3-5). Connection buttons are enabled.
- Searching for Programmer Cable — Wireless link between tablet and programmer cable is not established. Status background color is white with pulsing border. Controller status light is partially lit (see Figure 3-5). Communication buttons are disabled.
- Demo Mode — Wireless link between tablet and programmer cable is not active, but programmer may be used for demonstration. Status background color is pink.

Programmer Battery Status

The programmer battery status displays one of the following messages in the bottom-center of all screens if the battery is low or depleted.

- Battery Low — The programmer battery is nearing depletion and should be connected to power supply soon.
- Recharge Battery — The programmer must be attached to the power supply to prevent an automatic shutdown.

Current Date and Time

The current date and time display in the lower-right corner of all programming screens as follows.

- Current date — Displays on all screens in a DD Month YYYY format.
- Current time — Displays on all screens in a 24-hour format.

Start Screen

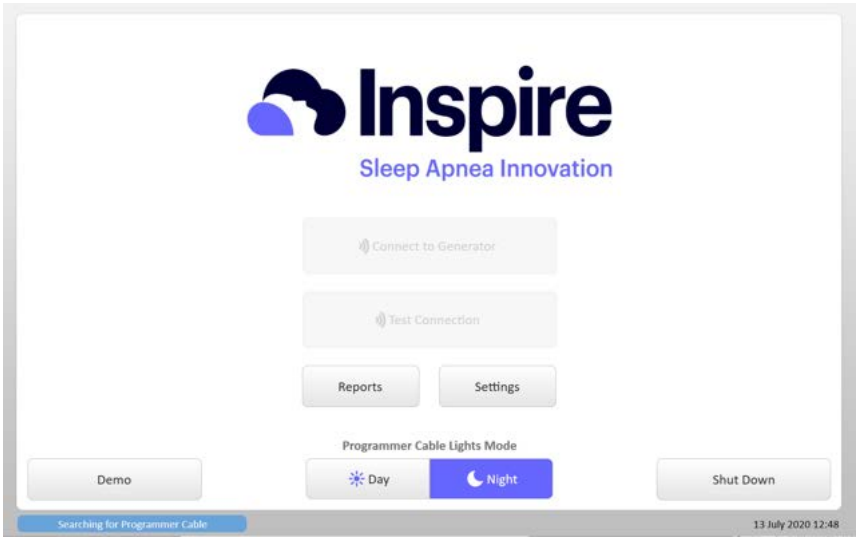


Figure 4-4. Start Screen

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

Table 4-1. 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 the tablet has established a connection to the programmer cable.
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 the tablet has established a connection to the programmer cable.
Reports	• Accesses reports for previous programming sessions. • Reports can be reviewed and exported.
Settings	• Accesses the Programmer Settings screen. • Allows access to data management controls and adjustments to date and time, language, and number format.
Demo	• Starts a practice programming session. • Makes it possible to practice using the programmer with a simulated generator when a patient is not present.

Table 4-1. Start Screen Button Descriptions

Shut Down	• Powers off the tablet.
Day Mode	• Sets the programmer cable to Day Mode.
Night Mode	• Sets the programmer cable to Night Mode.

Programmer Settings Screen

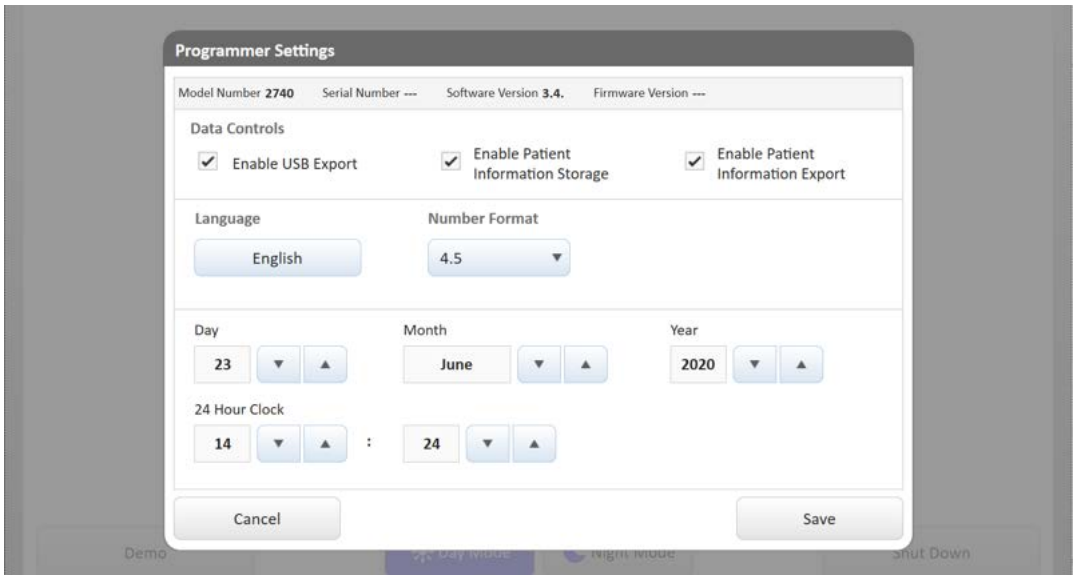


Figure 4-5. Programmer Settings Screen

The Programmer Settings screen (Figure 4-5) allows the modification of general programmer settings, including:

- Patient data management
- Date and time
- Language
- Number format

See “Adjusting Programmer Settings” on page 23 for more information.

Home Screen

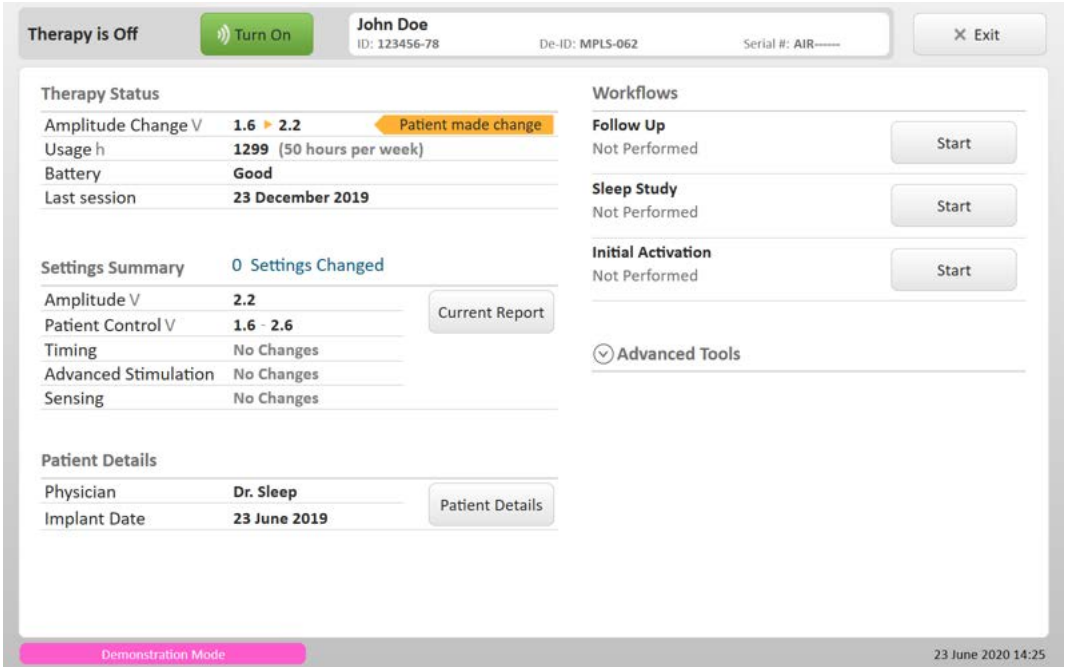


Figure 4-6. Home Screen

The Home screen (Figure 4-6) is divided into five sections:

- Therapy Status
- Workflows
- Setting 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 gold change flag as shown in Figure 4-7.
- 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.

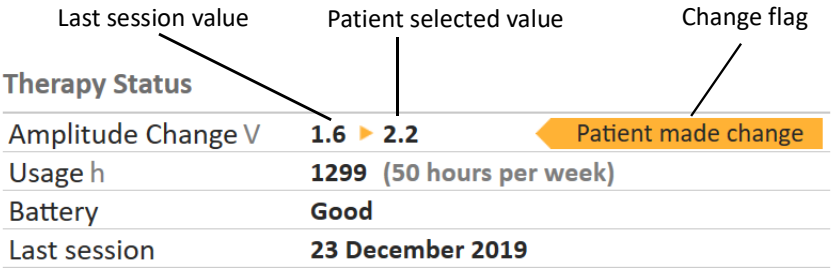


Figure 4-7. Patient Therapy Status

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 70 for more information.
- Status Indicators:
  - Not Performed indicates activity has not been started (Figure 4-8).
  - 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 76 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 4-8).
  - 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 67 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 4-8).

Figure 4-8. 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 4-9). 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 4-21).

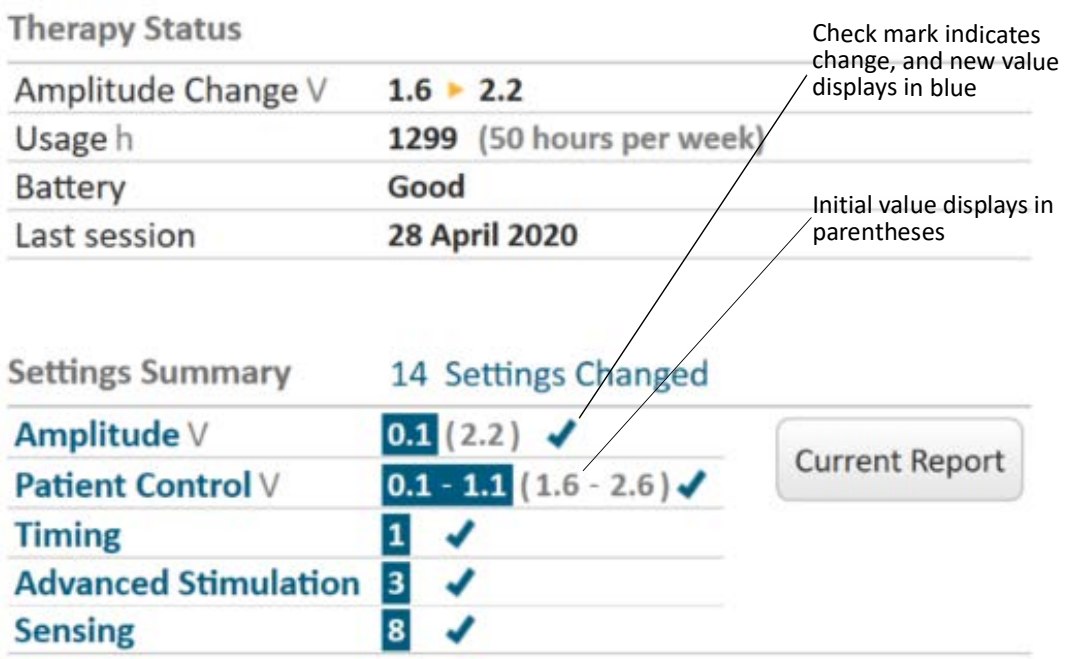


Figure 4-9. Status Indicators for Setting Summary

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 dropdown arrow is selected, three additional activities are available to the user if desired.

System Check

- Button accesses the System Check workflow which guides the user through troubleshooting activities. See “Start System Check Workflow” on page 63 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

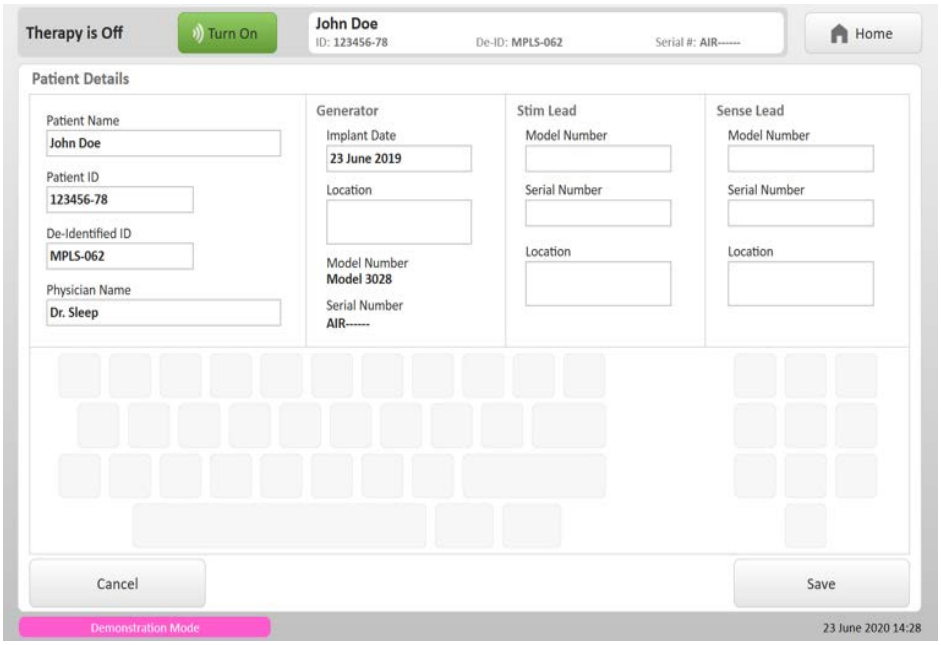


Figure 4-10. Patient Details Screen

Access the Patient Details screen (Figure 4-10) from the Home screen.

- Select any field to enable the on-screen keyboard.
- Use the on-screen keyboard 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 stored in the programmer, not the generator. If a different programmer is used to communicate with the patient's generator, this information will need to be entered into that programmer as well.

Note: The ability to edit the Patient Name and Patient ID fields is controlled from the Programmer Settings screen (Patient Information Storage).

On-Screen Keyboard

The keyboard is only enabled when an editable field has been selected. Capital letters display by default on the keyboard. Table 4-2 describes the keyboard buttons and their functions.

Table 4-2. On-Screen Keyboard Buttons

Button	Description
	Change letter case
	Backspace
	Access special characters
	Move cursor within a field

Patient Details Information Fields

- Patient Name — Enter the patient's name.
- Patient ID — Enter a patient identifier, such as a medical record number.
- De-Identified ID — Enter the anonymous identifier. This will be the only patient information included on de-identified reports.
- 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 4-11). 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 4-12). Selecting the **Configure** button will configure the generator with the highlighted values and clear the highlighting.

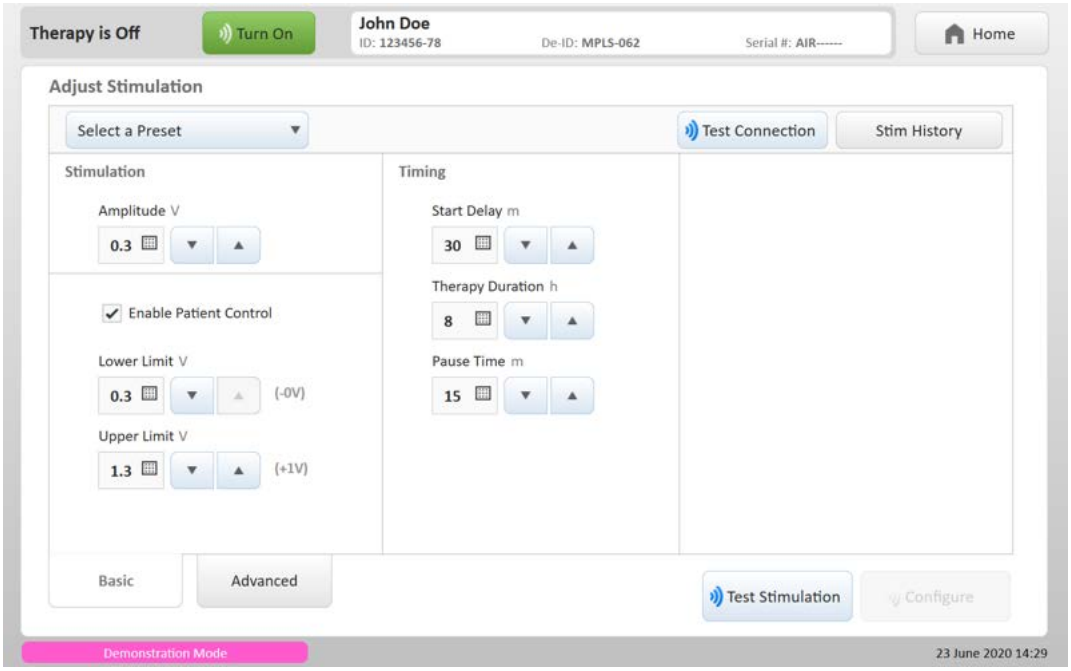


Figure 4-11. Adjust Stimulation Screen, Basic View

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 for definitions of these terms.

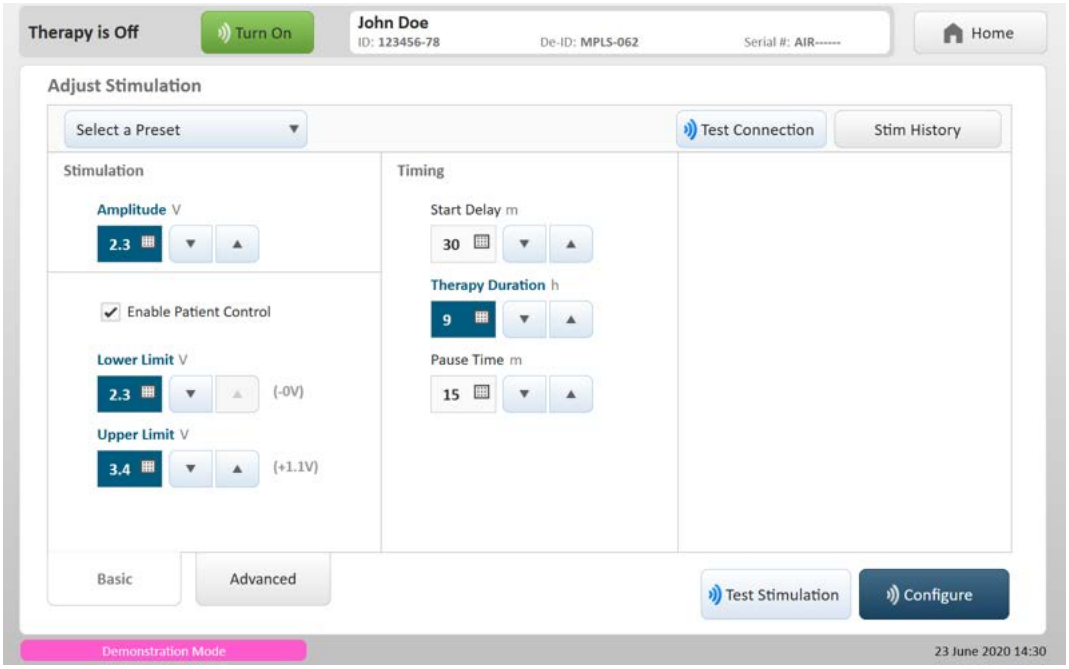


Figure 4-12. Changed Settings on Adjust Stimulation Screen

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 programmer cable status in the screen footer (Figure 4-3).
- 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 programmer cable status in the screen footer (Figure 4-3)
- 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 96 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

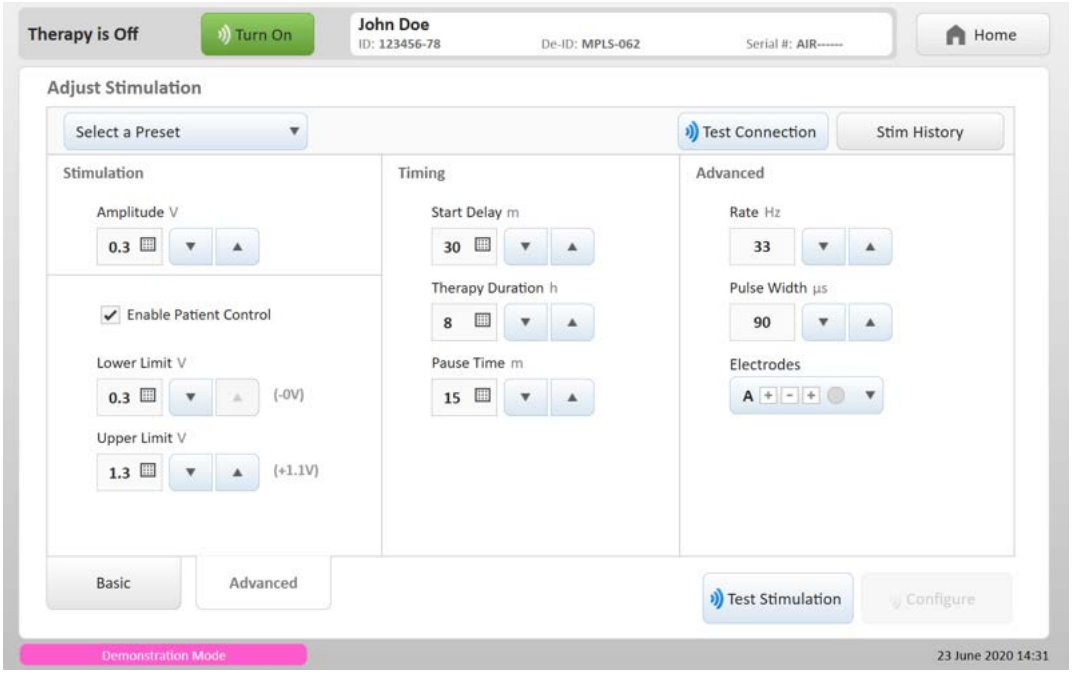


Figure 4-13. Adjust Stimulation Screen, Advanced View

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 4-14).

Figure 4-14. 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 4-15.

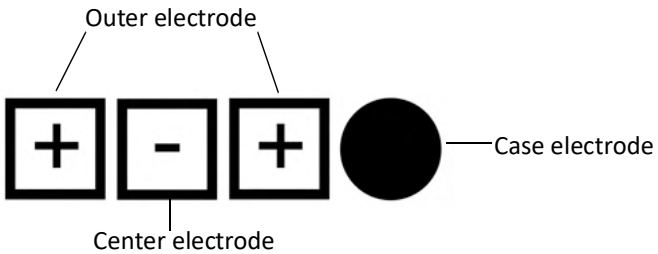


Figure 4-15. Default Electrode Configuration

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 4-3 on page 48.

Table 4-3. Electrode Options

A	 Default electrode
B	
C	
D	
E	

Adjust Sensing Screen

The Adjust Sensing screen (Figure 4-16) 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 4-16. 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 4-17).

- 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.

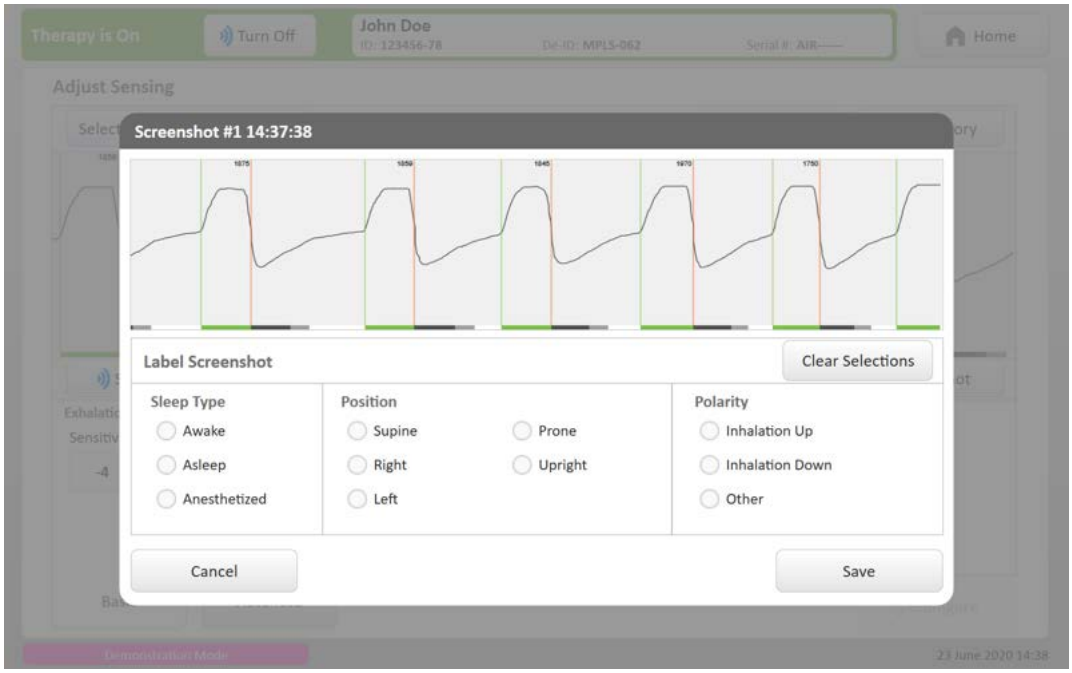


Figure 4-17. Screenshot Screen

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 programmer cable status in the screen footer (Figure 4-3).
- 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 96 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 4-18. Adjust Sensing Screen, Advanced View

To modify advanced sensing settings, select the Advanced tab at the bottom of the screen (Figure 4-18).

- 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.

Select a Patient Screen

The **Reports** button on the Start screen accesses the Select a Patient screen (Figure 4-19). All patients with whom the programmer has communicated are listed here.

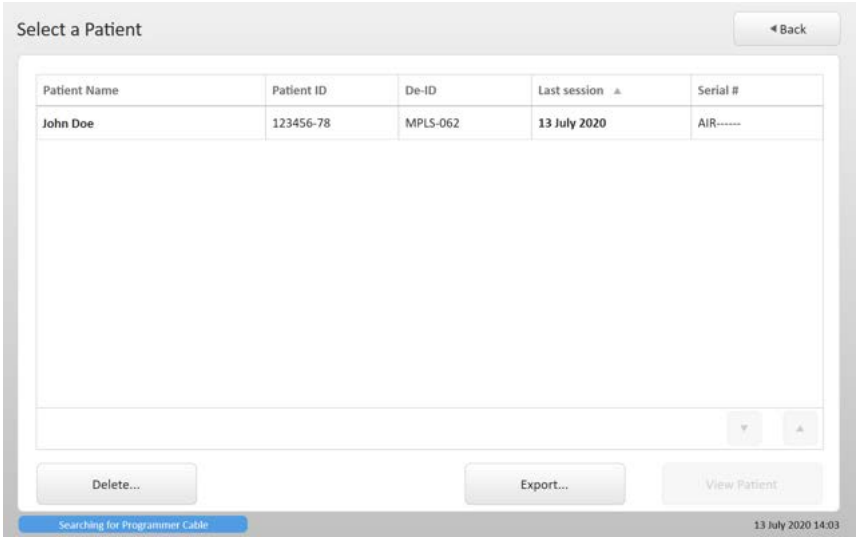


Figure 4-19. Select a Patient Screen

Patient name, ID, deidentified-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.

Refer to Table 4-4 for information about the functions of the buttons on the Select a Patient screen.

Table 4-4. Select a Patient Screen Buttons

To:	Do This:
View patient	Highlight patient name and select **View Patient** button to access Reports screen. **Note:** View Patient Button is disabled unless a patient name is highlighted.
View next or previous group of patients	Select the up or down arrow buttons at the bottom of the screen. **Note:** If arrow buttons are disabled, there are no additional patients to view.
Delete a patient	Highlight patient name and select **Delete** button to display the Delete Reports screen (Figure 4-20). • 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.
Export patient reports to external USB flash drive	Attach the Inspire USB flash drive to the tablet. • Highlight patient name and select the **Export** button to display Export Report screen (Figure 4-22). If **Export** button is disabled, go to Programmer Settings screen to enable USB export. • Specify a date using the arrow buttons to export all reports since that date. • Select the information to be included in the export by checking one or more of the following boxes: patient information, device information, waveform screenshots, and advanced settings. • Select **Export** button to complete export. **Note:** If a patient name is not highlighted before selecting the **Export** button, reports for all patients will be exported.

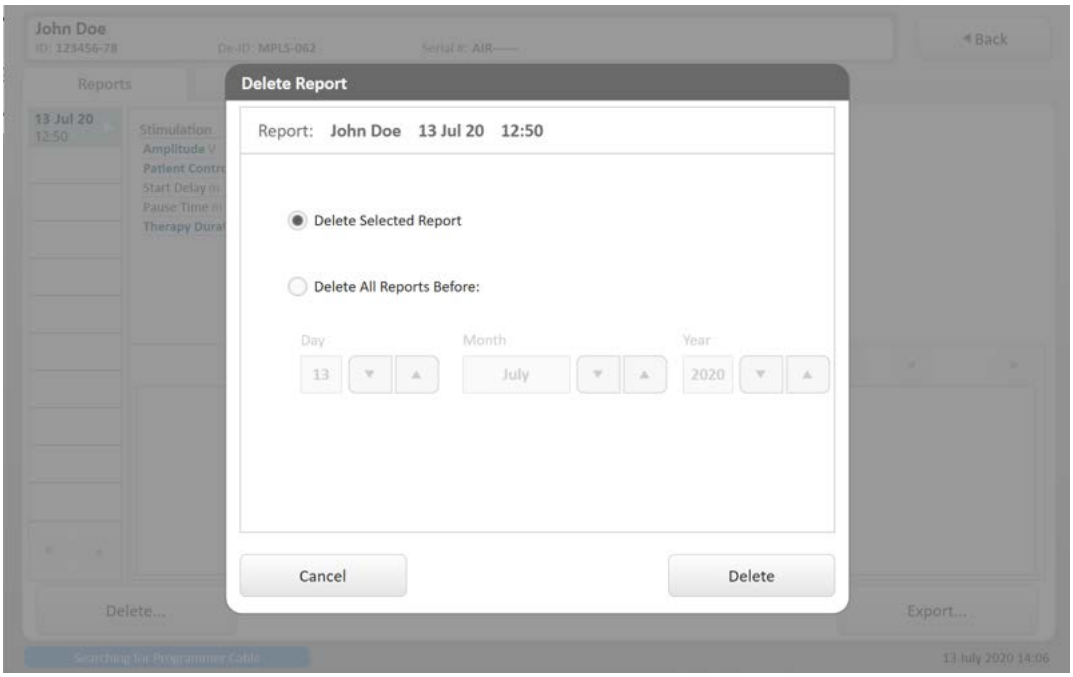


Figure 4-20. Delete Report Screen

Reports Screen

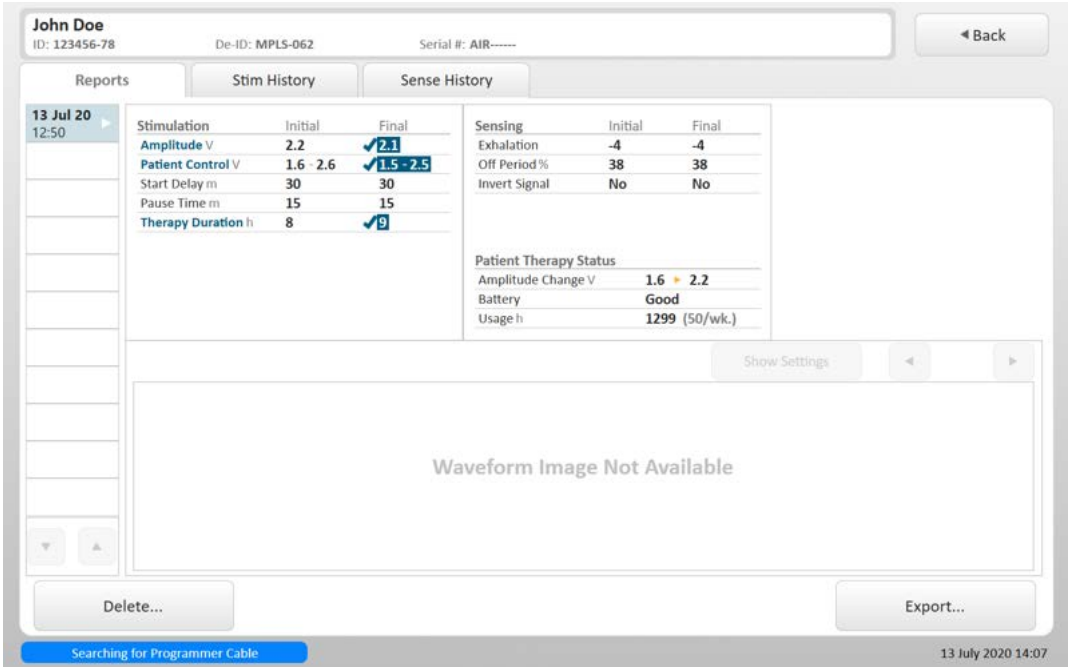


Figure 4-21. Reports Screen

The **Current Report** button on the Home screen accesses the Reports screen (Figure 4-21), 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 Select a Patient 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 4-5 for information about the functions of the buttons on the Reports screen.

Table 4-5. 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.
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.

Table 4-5. Reports Screen Buttons

Delete a session report	Highlight report and select the **Delete** button to display the Delete Report screen (Figure 4-20). • 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).
Export session report to external USB flash drive	Attach the Inspire USB flash drive to the tablet. • Highlight report and select the **Export** button to display Export Report screen (Figure 4-22). If **Export** button is disabled, go to Programmer Settings screen to enable USB export. • Select **Export Selected Report** button to export current report, or • Select **Export Combined Visit Report** button to export a report that combines programming sessions from the same visit, or **Note:** The option to export combined reports will only be available if multiple reports are detected within a +/-24-hour period. • Select **Export All Reports Since** button and specify the date using the arrow buttons to export multiple reports for the current patient. • Select the information to be included in the export by checking one or more of the following boxes: patient information, device information, waveform screenshots, and advanced settings. **Note:** Session reports will be exported as PDF (portable document format) files. The programming log contains a CSV (comma separated value) file of all generator setting changes for the session and a CSV file of the raw waveform data. • Select **Cancel** button to return to Reports screen. • Select **Export** button to complete export.

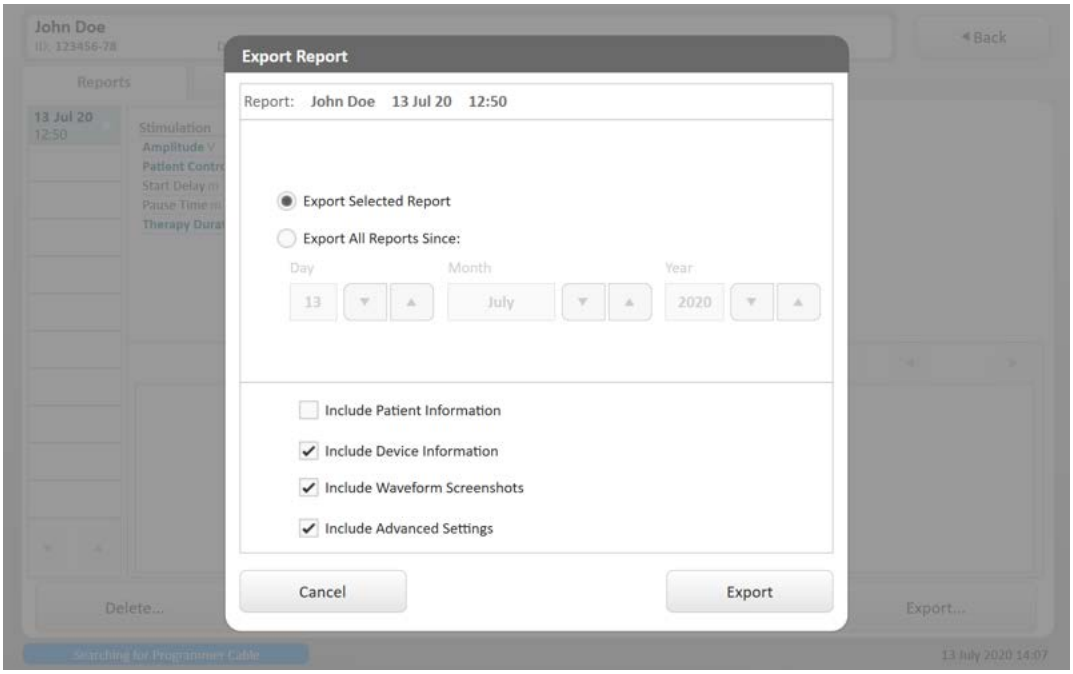


Figure 4-22. Export Report Screen

Stimulation History Screen

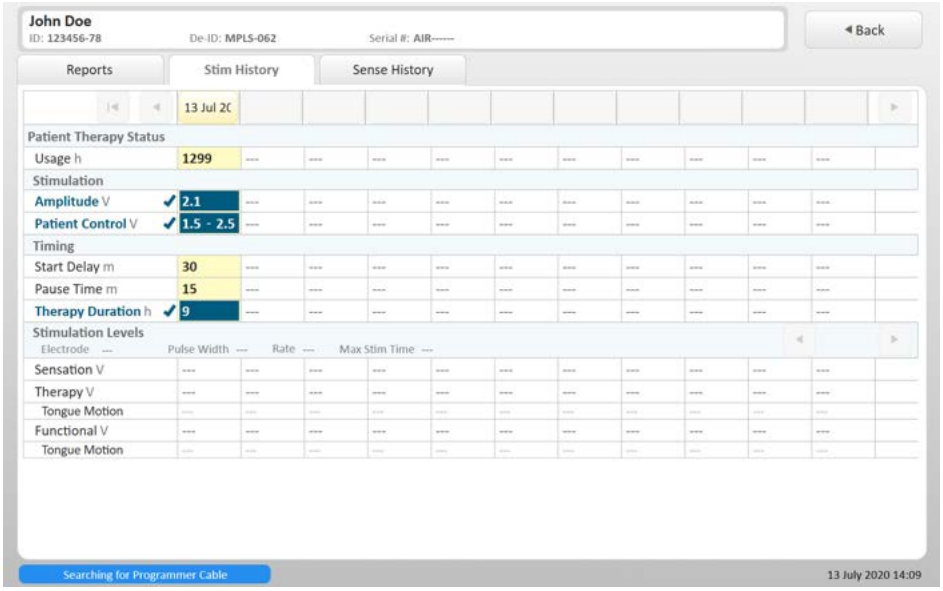


Figure 4-23. Stimulation History Screen

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 4-23). This screen displays a summary of usage, stimulation levels, and final stimulation settings for a particular date.

Refer to Table 4-6 for information about the functions of the buttons on the Stimulation History screen.

Table 4-6. 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

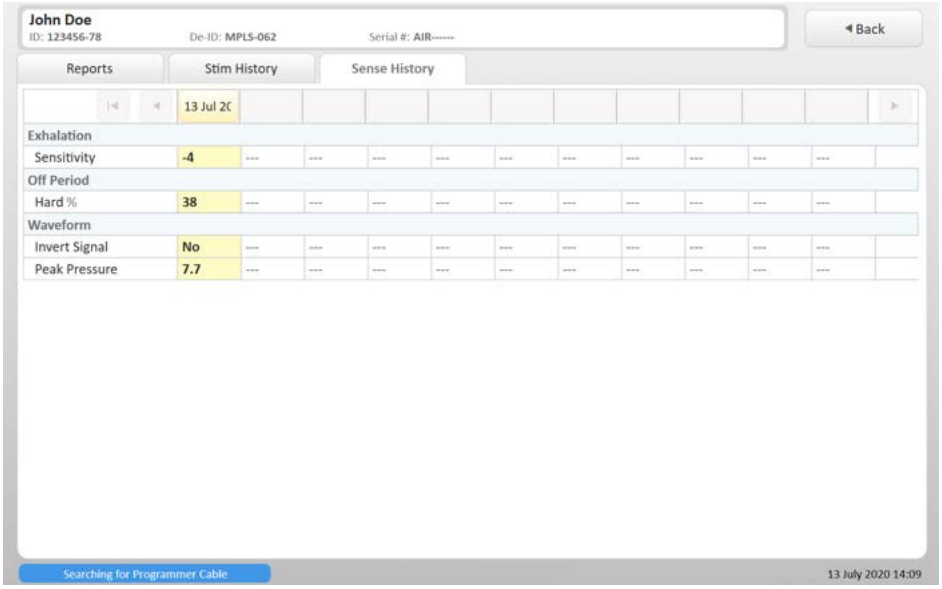


Figure 4-24. Sensing History Screen

The **Sense History** button on the Adjust Sensing screen and the Sense History tab on the Reports screen access the Sensing History screen (Figure 4-24). This screen displays a summary of the final sensing settings for a particular date.

Refer to Table 4-7 for information about the functions of the buttons on the Sensing History screen.

Table 4-7. 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 5: Clinical Programming Sessions

This chapter describes implant, device check, and sleep study sessions.

Introduction

The programmer is used during implant, device checks, and sleep studies to select stimulation and sensing settings that maintain airway patency.

When To Use Workflows

The tablet software 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 "Turning On the Programmer" on page 17 and "Starting a Session" on page 20.

Enter Patient Details

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

- Select any field to enable the on-screen keyboard.
- Use the on-screen keyboard 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 ability to edit the Patient Name and Patient ID 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.

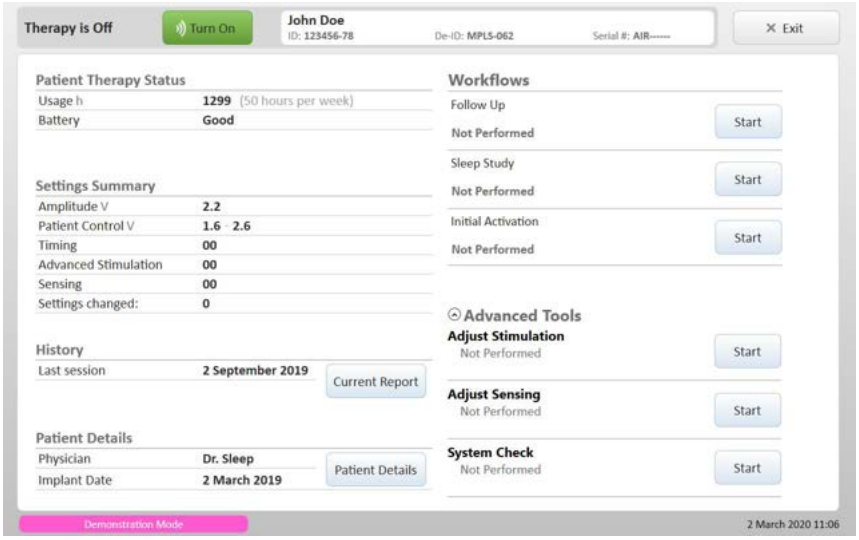


Figure 5-1. Session Home Screen

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.

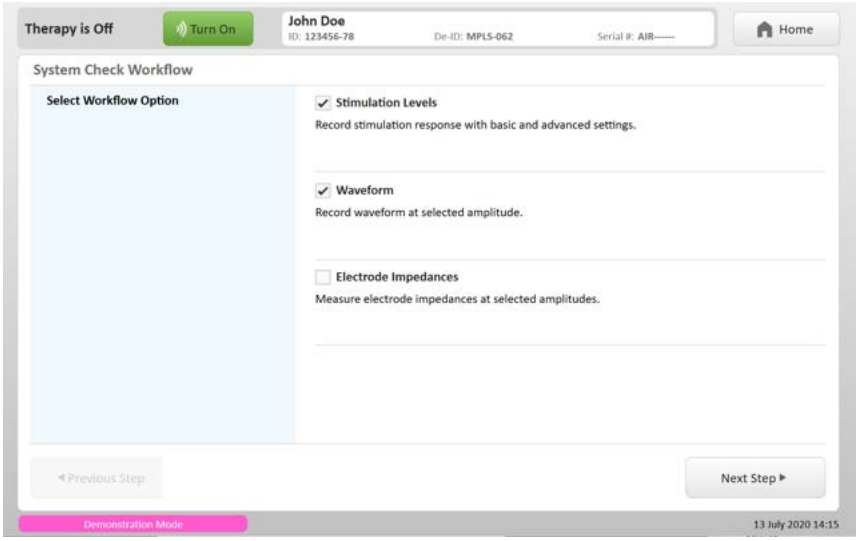


Figure 5-2. Check Workflow Screen

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**.

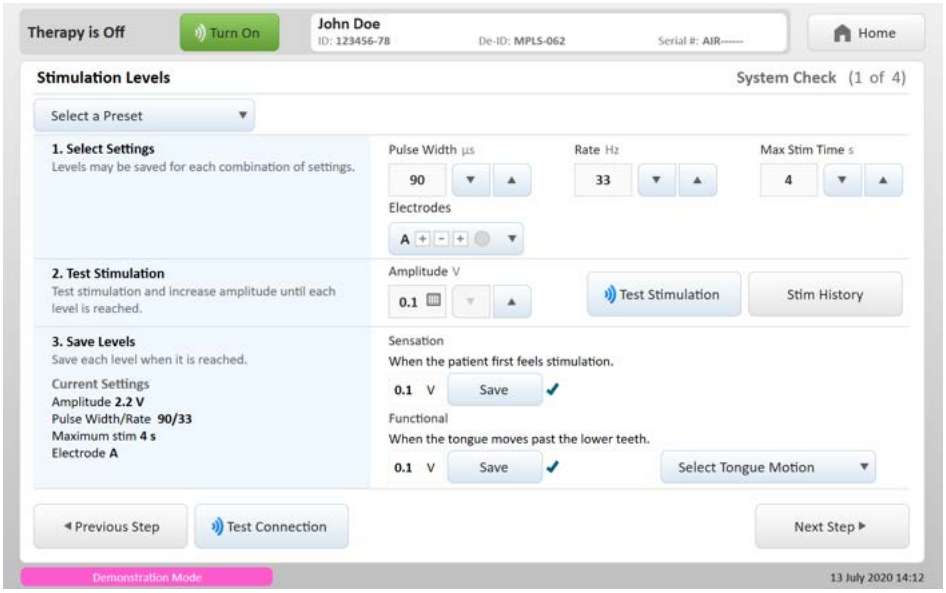


Figure 5-3. System Check - Stimulation Levels Screen

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 5-4. 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.

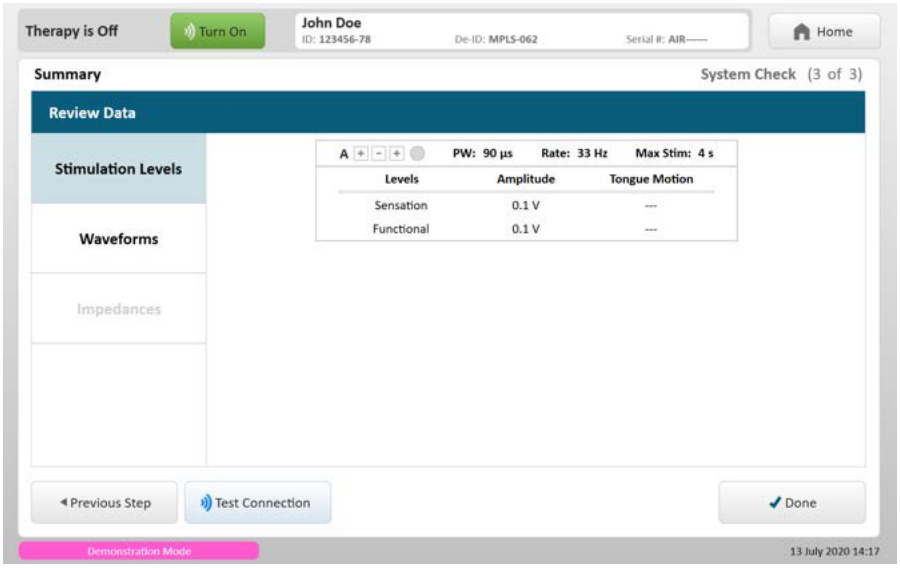


Figure 5-5. System Check - Summary Screen

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.

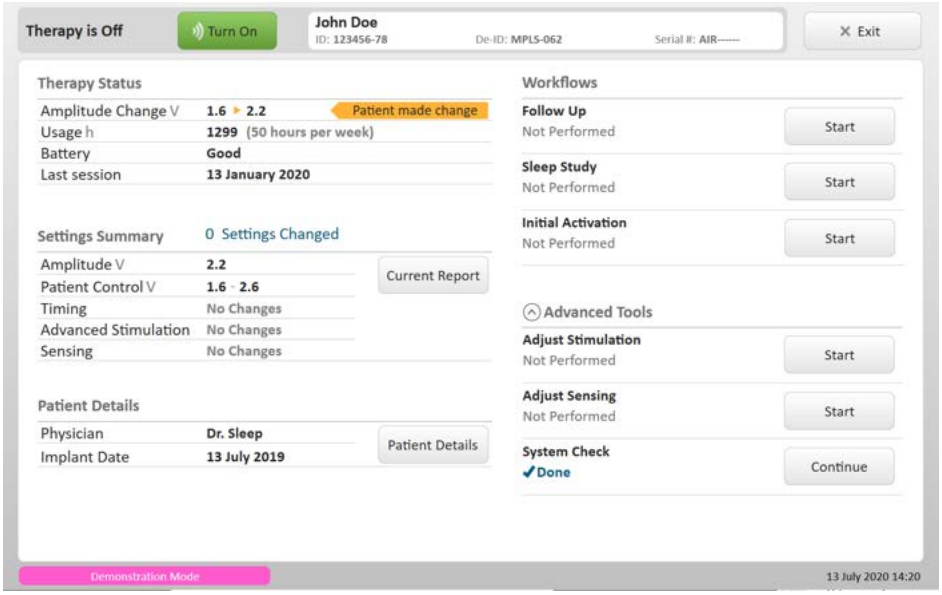


Figure 5-6. End Implant Session - Home Screen

Retain Records

Export a session report if desired.

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.

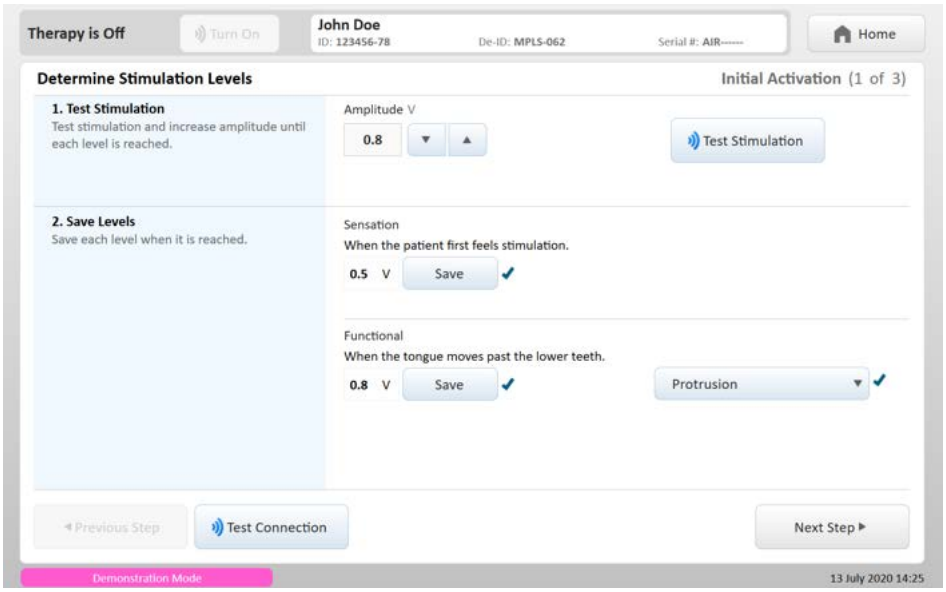


Figure 5-7. Initial Activation - Determine Stimulation Levels Screen

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 5-8. 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.

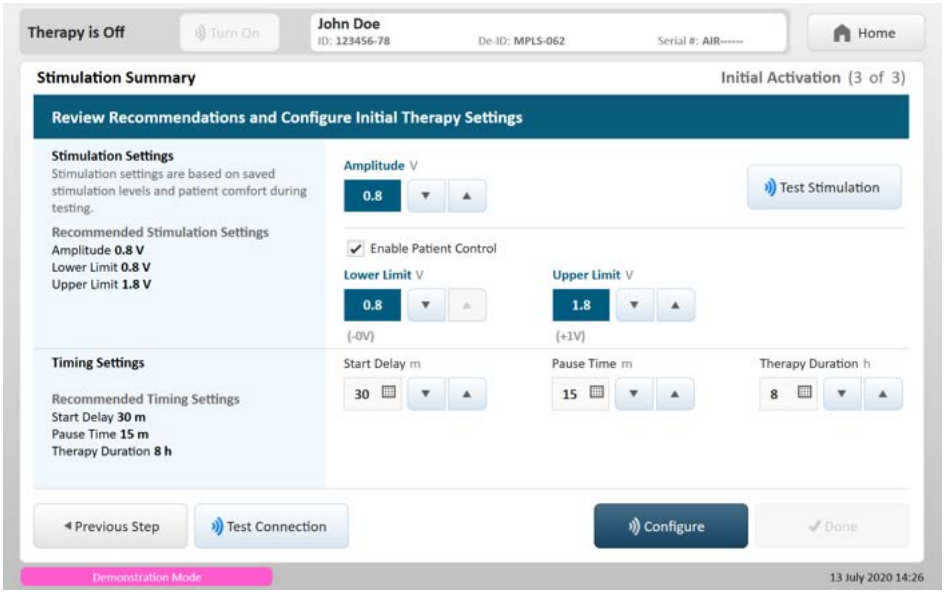


Figure 5-9. Initial Activation - Stimulation Summary Screen

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.

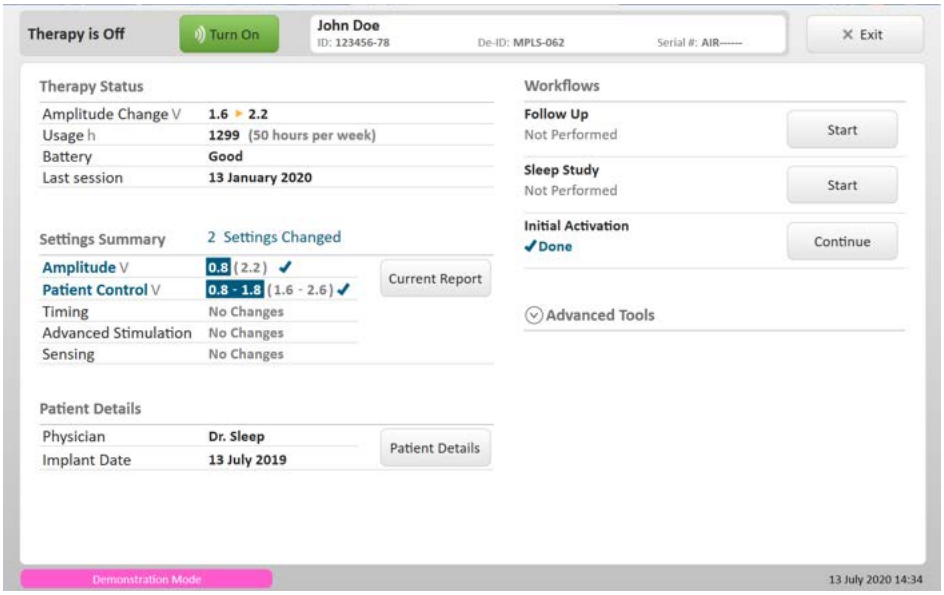


Figure 5-10. End Initial Activation - Home Screen

Retain Records

Export a session report if desired. See “Exporting a Report” on page 81 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 gold 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.

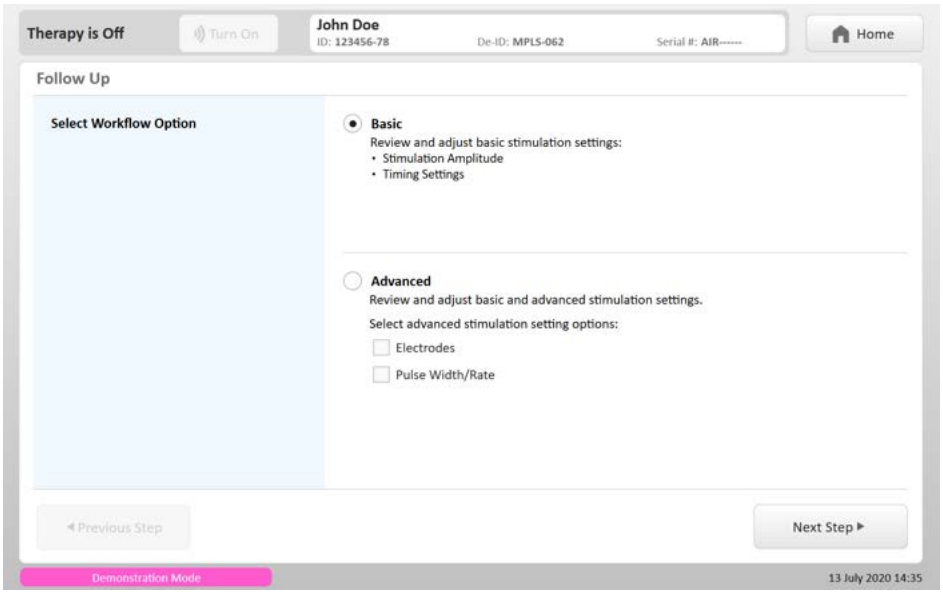


Figure 5-11. Follow Up Screen

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.

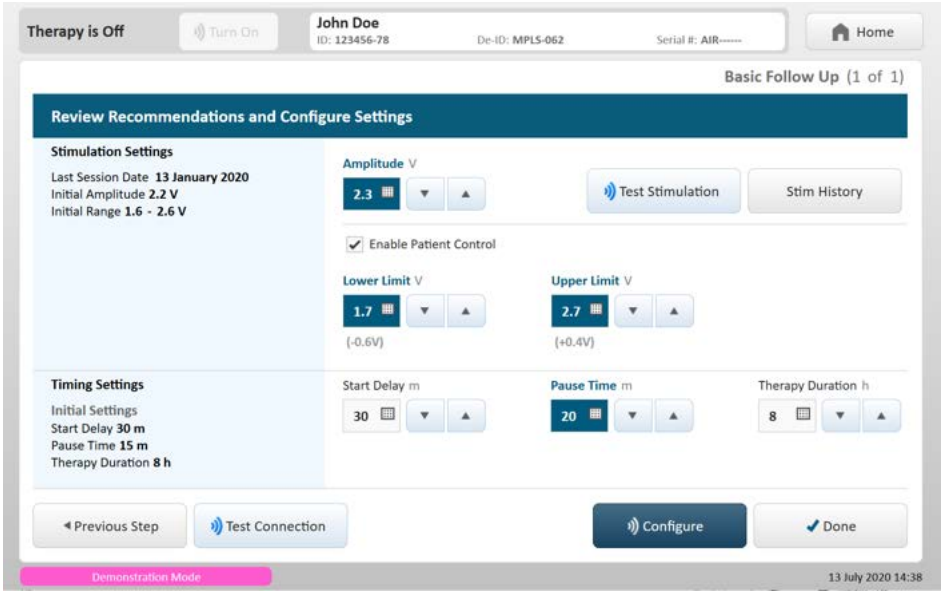


Figure 5-12. Basic Follow-up Screen

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.

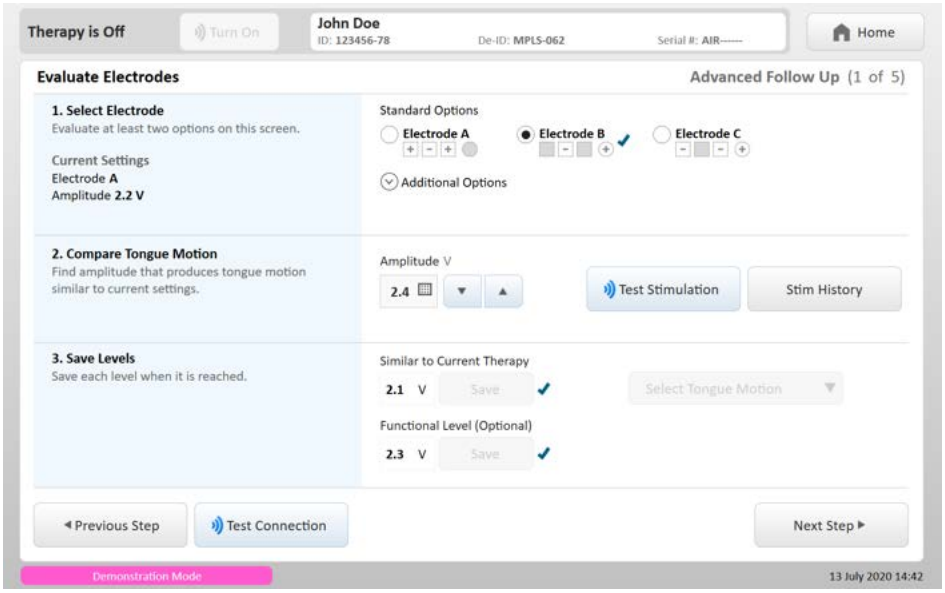


Figure 5-13. Advanced Follow Up - Evaluate Electrodes Screen

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 **Configure** to program the new electrode and amplitude.
5. Select the **Next Step** button.

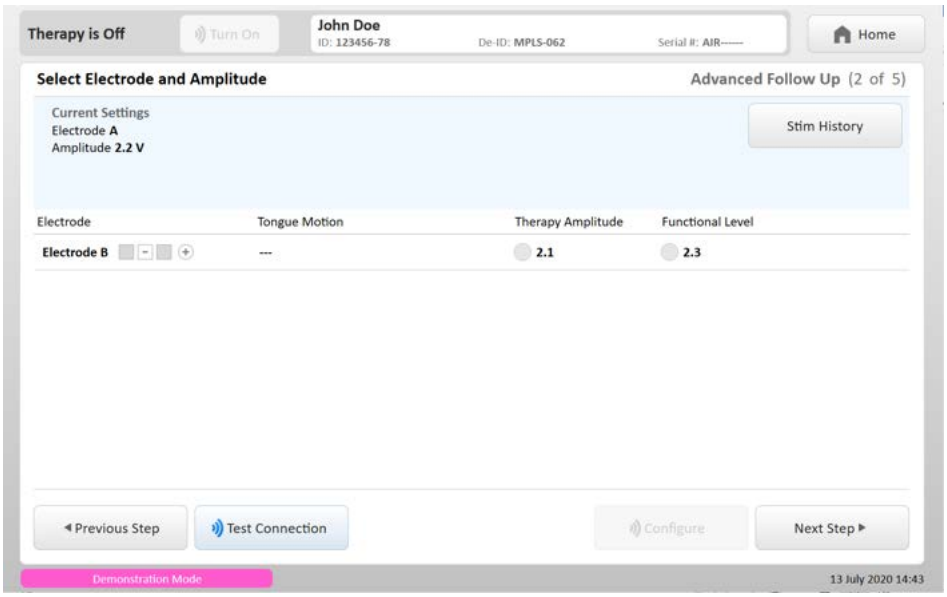


Figure 5-14. Advanced Follow Up - Select Electrode and Amplitude Screen

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.

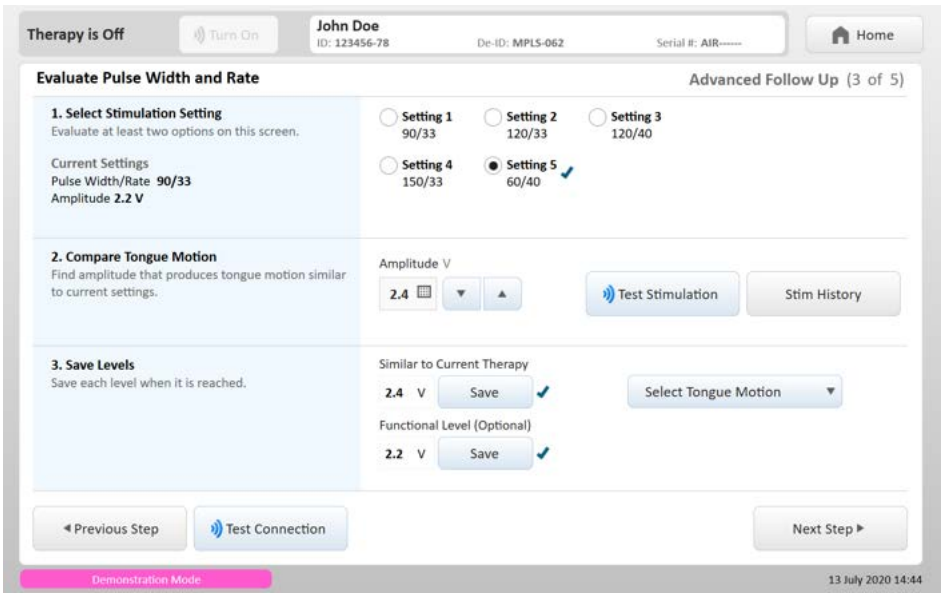


Figure 5-15. Advanced Follow Up - Evaluate Pulse Width and Rate Screen

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 **Configure** to program the new pulse width / rate and amplitude if the desired settings are new.
5. Select the **Next Step** button.

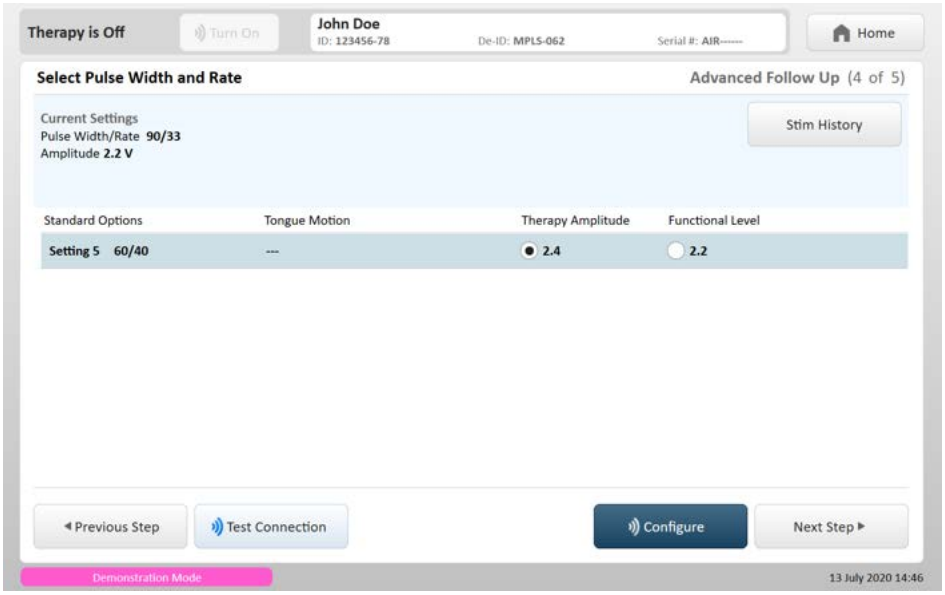


Figure 5-16. Advanced Follow Up - Select Pulse Width and Rate Screen

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.

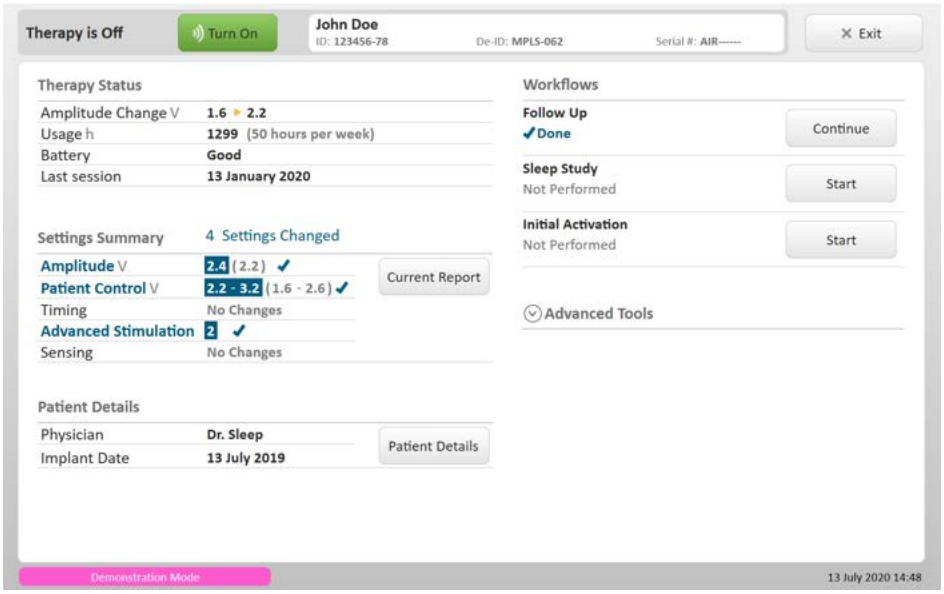


Figure 5-17. End Follow-Up - Home Screen

Retain Records

Export a session report if desired. See “Exporting a Report” on page 81 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 tablet 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 tablet screen or programmer head.

Table 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 gold 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 canula 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.

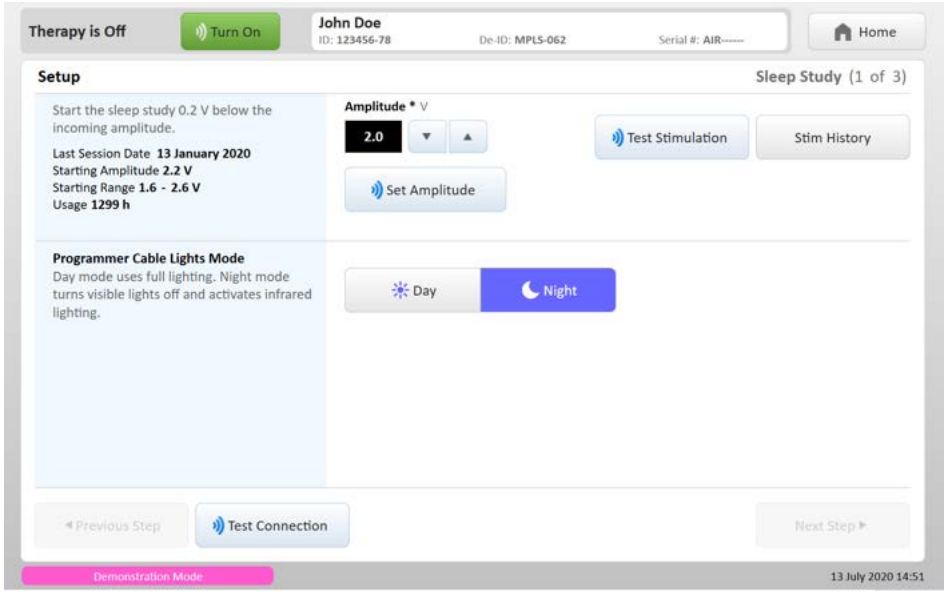


Figure 5-18. Sleep Study - Setup Screen

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.

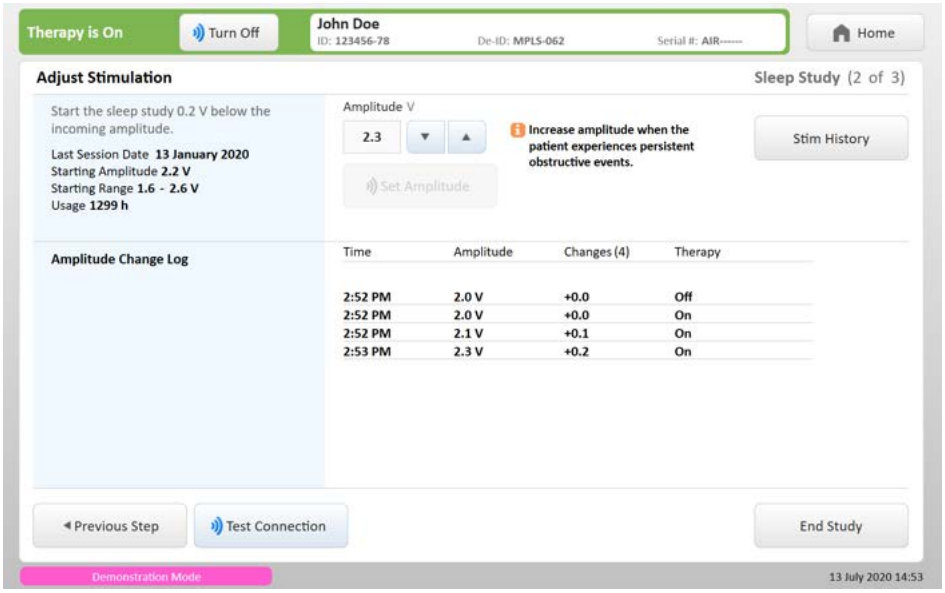


Figure 5-19. Sleep Study - Adjust Stimulation Screen

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.

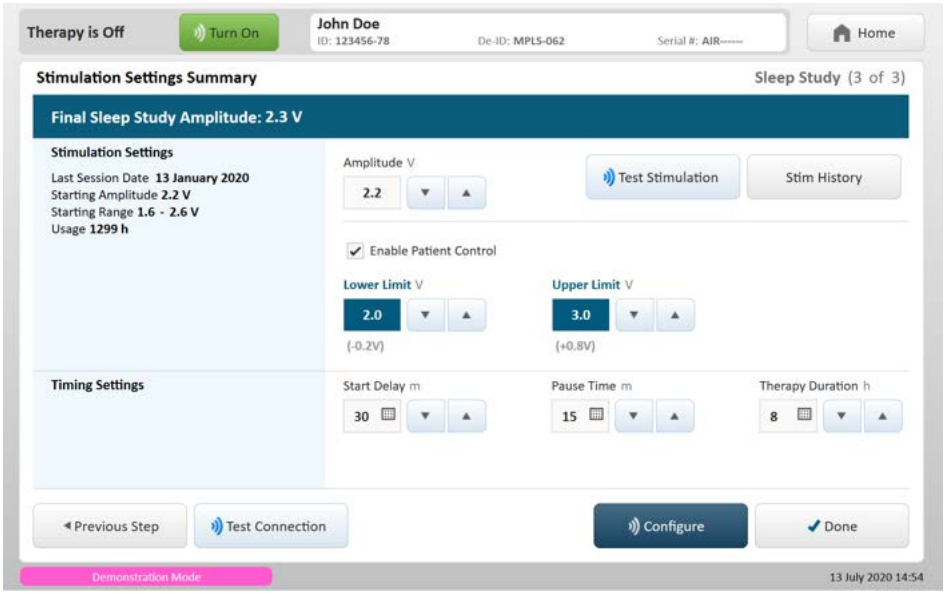


Figure 5-20. Sleep Study - Stimulation Settings Summary Screen

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.

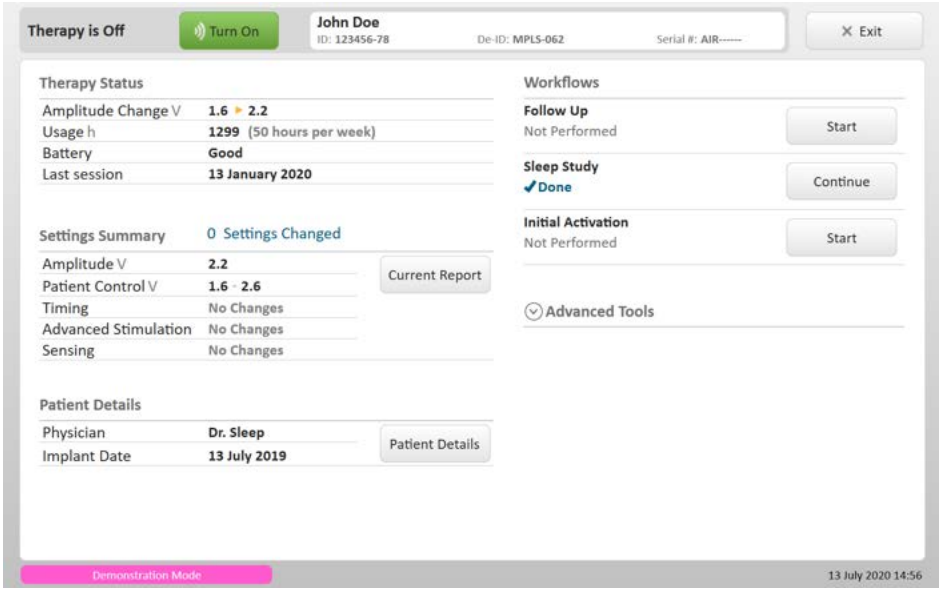


Figure 5-21. Ending the Sleep Study Session - Home Screen

Retain Records

Export a session report if desired. See “Exporting a Report” on page 81 for instructions.

Exporting a Report

1. Attach the Inspire USB flash drive to the tablet.
2. Select the **Reports** button on the Start screen.
3. Highlight the patient's name and select the **View Patient** button.
4. Confirm that the correct session report is displayed and select the **Export** button.

   Note: If **Export** button is disabled, go to Programmer Settings screen to enable USB export. Select **Export Selected Report** button to export the current report only.

5. Select **Export Combined Visit Report** button to export a report that combines programming sessions from the same visit.

   Note: The option to export combined reports will only be available if multiple reports are detected within a +/-24-hour period.

6. Select the information to be included in the export by checking one or more of the following boxes: patient information, waveform screenshots, and advanced settings.
7. Select **Export** button to complete the export.

Note: Session reports will be exported as PDF (portable document format) files. The programming log contains a CSV (comma separated value) file of all generator setting changes for the session and a CSV file of the raw waveform data.

Chapter 6: 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 25. 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 6-1) is displayed on the programmer head and on the tablet screen. When this error is encountered, remove any possible sources of interference and reposition the programmer head over the generator.

Figure 6-1. 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 tablet is within range of the programmer cable.
2. Wait 60 seconds for the connection process to continue.
3. Tap the touchscreen. If this allows connection to proceed, continue tapping and restart the tablet at the earliest convenience.

Programmer Cannot Find Generator

Refer to the steps described in "**Testing Connection Strength**" on page 25. If those measures do not resolve the problem, the generator battery may be depleted. Try the following:

1. Use the patient's remote to turn off the generator therapy. Try this several times if not immediately successful.
2. If the patient's remote is able to turn off the generator, retry communication using the programmer.
3. If the patient's remote cannot communicate with the generator either, wait 24 hours and try using the patient's 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 programmer cable status line in the screen footer always displays “searching for programmer cable”:

1. Navigate to the Start screen.
2. Ensure that the programmer cable is powered on.
3. Move tablet to within 1 m (3 ft) of the programmer cable.
4. If this does not resolve the problem, navigate to the Home screen and select the **Exit** button to end the session and display the Start screen.
5. Select the **Shut Down** button to power off the tablet and wait for the software to complete the shutdown process.
6. Disconnect the programmer cable.
7. Reconnect the programmer cable and press and hold the tablet power button until the power light is illuminated.
8. Repeat steps 1–3.
9. If these steps do not resolve the problem, confirm that the programmer serial number (e.g., 101) displays on the Programmer Settings screen.
10. If the programmer serial number does not display, use a different programmer and call Inspire Medical Systems.

Tablet

Tablet Will Not Power On

If the tablet will not power on, the battery may be fully discharged.

1. Connect the tablet to an electrical outlet.
2. Press and hold the power button on the side of the tablet until the power light is illuminated.

If this does not resolve the problem, contact Inspire Medical Systems.

Tablet is Slow to Respond or Freezes

If the programmer is not responsive to touchscreen input for more than 2 minutes:

1. Press and hold the power button until the tablet shuts off.
2. Disconnect and reconnect the programmer cable from power.
3. Power on the tablet and proceed from where you left off.

   Note: Never let a patient leave after a forced programmer shut-off until you reconnect to the generator and confirm the generator settings.

If the tablet is slow or appears to freeze during connection (progress bar stops for 30 seconds on the communication screen, the light on the programmer head is not flashing, and you have waited for 30 seconds), take these steps:

Storage Full Notification

A storage full notification displays when the tablet’s memory has reached full capacity. Session reports must be deleted to free up space.

1. Select the **Reports** button from the Start screen.
2. Identify reports that may be deleted.
3. Select the **Shut Down** button on the Start screen and restart the programmer before the next programming session, otherwise the next session report will not be stored.

Battery Life

If the length of the battery life is poor (e.g., lasts for less than 45 minutes) even when the battery is fully charged, contact Inspire Medical Systems.

Abnormal Charging Condition

A blinking power status light indicates an abnormal charging condition. Check that the tablet power cord is properly inserted into the tablet and that the device is not charging in high temperature conditions.

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 6-2). Disconnect and reconnect power to the programmer cable, and if the error is not resolved, contact Inspire Medical Systems.

Figure 6-2. Error Mode Indicator

Settings

Daylight Savings Time

The programmer does not automatically adjust for daylight savings time. Use the Programmer Settings screen to manually update the date and time when local time changes occur.

Wrong Language or Number Format

If programmer screens do not display your native language:

1. Select the **Settings** button on the Start Screen.
2. Choose the correct language from the drop-down menu.
3. Select the **Save** button.

Refer to Figure 6-3 to locate these buttons if you cannot read the programmer screens.

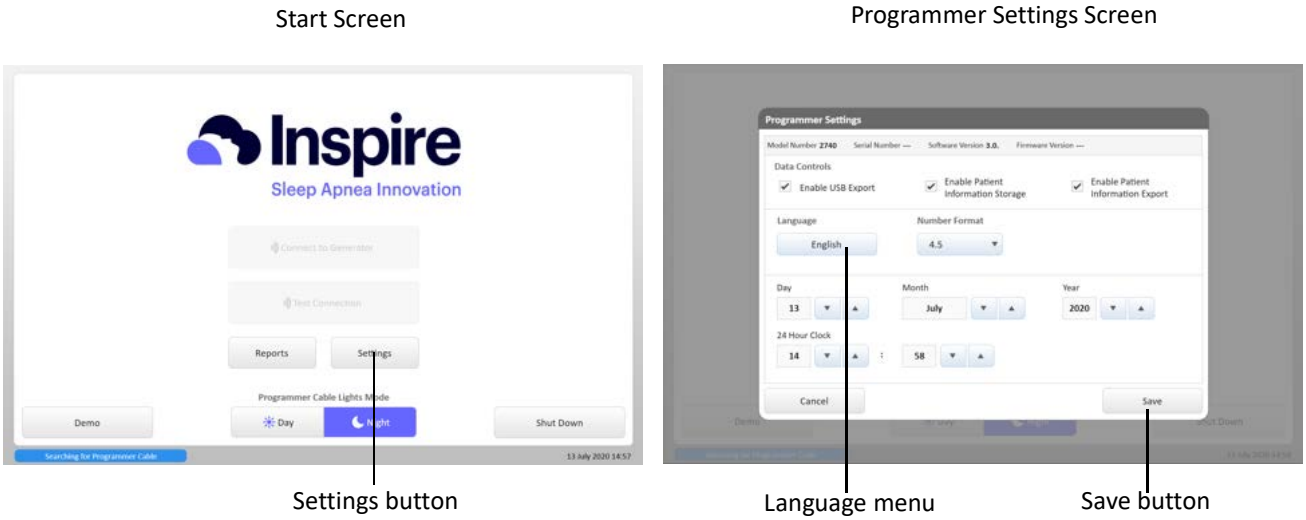


Figure 6-3. Change Language Buttons

If programmer screens do not display the correct number format, use the Programmer Settings screen to change the number format.

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. Push the **Configure** button. If you leave a screen before pushing 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 programmer software, 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. (See "Exiting a Session and Turning Off the Programmer" on page 29 for more information.)
- 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 connection interrupting stimulation. To reduce the likelihood of halting stimulation:

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

Measure Impedances

The Measure Impedances screen (Figure 6-4) 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.

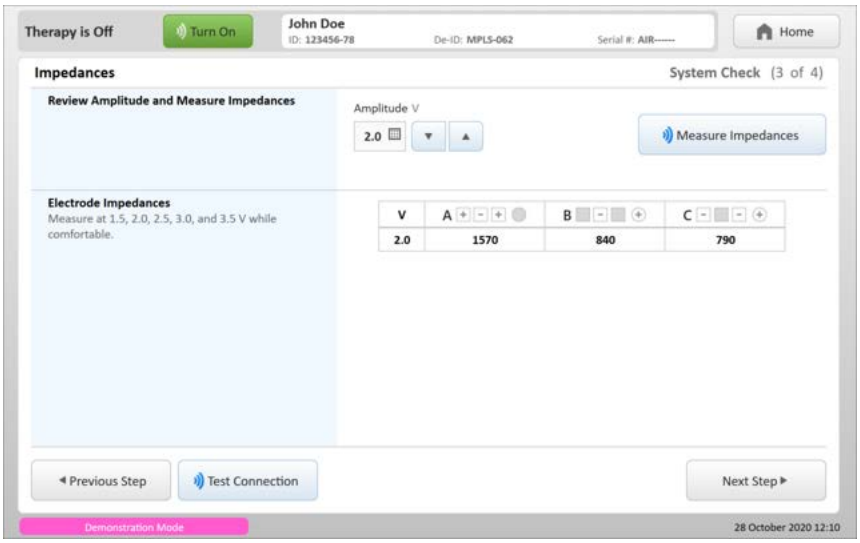


Figure 6-4. Measure Impedances Screen

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.

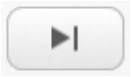


Figure 6-5. Arrow Button to Navigate to Live Waveform Image

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 generataor 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 check box for Enable Patient Information Storage.

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, the programmer may have run out of storage space. See "Storage Full Notification" on page 84 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 parameters.
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.

Exporting

Cannot Export Report

If the **Export** button is disabled, select the Enable USB Report Export check box on the Programmer Settings screen.

Export Failure Screen

If an export failure screen displays, follow these steps:

1. Disconnect the Inspire USB flash drive from the tablet.
2. Reconnect the Inspire USB flash drive to the tablet.
3. Wait 30 seconds and retry export.
4. If these measures do not resolve the problem, use a different USB drive with FAT32 formatting.

Missing Information

If an exported report is missing patient information, screenshots, or advanced settings such as electrode configuration or level measurement settings, select the check box that corresponds to the desired information on the Export Report screen and repeat the export.

Note: The option to include patient information, screenshots, and advanced settings in an exported 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 7: 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 programmer. 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.
- Only charge the battery when its temperature is between 0°C and 40°C.
- Use only the tablet power supply provided with the tablet. Do not use the tablet power supply to power any other electronic devices.
- 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 tablet components or otherwise cause malfunctions.
- Do not place the system components in an unsteady location. If the tablet is placed in an unsteady location, such as on an unstable stand or incline, the tablet may fall or tip over and cause injury.
- 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 Model 2740 power supplies for other equipment. This can generate heat or fire. In addition, do not use other power supplies with the system.
- When using the tablet 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).
- Certain environments may contain particles or debris that can adhere to the tablet LCD screen. To avoid damaging the display, clean it frequently by diluting a household, water-based glass cleaner to a 50/50 ratio with water, and spray a small amount on a clean, soft cloth and gently wipe the screen. Always shut down and unplug the programmer before cleaning. Do not spray cleaner directly on the tablet.
- 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.
- Restrict access to the Model 2740 to authorized users as the tablet does not provide user authentication. Tablet Wi-Fi and general-purpose Bluetooth functionality are disabled, therefore network security controls such as firewalls are not required. Tablet operation system (Microsoft Windows) is protected using write filtering, therefore, anti-virus software is not required nor supported. 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.
- Dispose of the tablet (containing a lithium-ion battery pack) only at approved disposal sites. To locate an appropriate site, contact the solid waste disposal officials where you live, or look for a rechargeable battery recycling Web site that lists disposal locations.
- Do not dispose of tablets (containing a lithium-ion battery pack) in a fire. They may explode. Dispose of used batteries according to the manufacturer's instructions. The label on the battery lists the manufacturer's name.

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.

Tablet Battery Pack

- The tablet contains an internal lithium-ion (Li-ion) battery pack. Do not attempt to remove or replace the battery pack.
- Always store the programmer with the battery charged and attached to the tablet.
- If the programmer is stored for more than 4 weeks without use, connect it to power until it is fully charged. The tablet does not need to be turned on to charge.
- Do not use or leave the tablet and its battery pack near a heat source. Heat can melt the insulation and damage other safety features, possibly causing it to leak, overheat, emit smoke, burst and/or ignite.

Chapter 8: Supplemental Information

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

Programmer Maintenance

Tablet Cleaning and Disinfecting

When necessary, clean the tablet according to the following guidelines.

- Always shut down and unplug the programmer before cleaning.
- Keep liquid, including the cleaning fluid, out of any openings.
- Test cleaning products on a small portion of the programmer before use.
- Do not spray cleaner directly on the tablet.
- Clean the exterior case of the programmer with a soft cloth lightly dampened with water.
- To clean the LCD screen, dilute a household, water-based glass cleaner to a 50/50 ratio with water and spray a small amount on a clean, soft cloth and gently wipe the screen.
- Periodically disinfect the tablet, stylus, and programmer cable according to your institutional polices for surface and equipment safety and cleanliness.

Storing the Programmer

Always store the programmer with the battery fully charged.

If the programmer is stored for more than 4 weeks without use, connect it to power until the battery is fully charged. The tablet does not need to be turned on to charge.

Servicing Programmer

The system 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 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 for shipment.

Please write the programmer serial number on all correspondence. The programmer serial number is located on the programmer head and on the back of the tablet.

Contact Inspire Medical Systems for replacement parts.

Default Settings

Table 8-1 lists the default values for all basic and advanced settings.

Table 8-1. 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.

Tablet

Table 8-2. Tablet Specifications[a]

Description	Specifications
Temperature with power on	Temperature: 5°C–30°C (41°F–86°F) Humidity: 20–80% Air pressure: 700–1013 hPa (10.2–14.7 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: 700–1013 hPa (10.2–14.7 psi)
Tablet power supply Sinpro M/N: HPU3*-105 (UL agency approval under UL 60601-1)	Input: 100–240 VAC, 47–63 Hz, 0.6-0.4A. Output: 12V, 2.5A.
Ingress protection	IP65
Mode of operation (continuous or non-continuous)	Continuous

[a] All measurements are approximate

Programmer Cable

Table 8-3. Programmer Cable for Model 2740[a]

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
Bluetooth	2.4 GHz ISM band
Ingress protection	IP22
Mode of operation (continuous or non-continuous)	Continuous

[a] All measurements are approximate

Protected Health Information

Introduction

The following information is intended to assist customers in safeguarding electronic protected health information (ePHI) and complying with the requirements of the USA Health Insurance Portability and Accountability Act (HIPAA) Security Rule, 45 C.F.R. 165.514 and European privacy laws.

This information is not intended as a comprehensive or exhaustive list of issues and recommendations. Your 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.

Inspire Programmer (Model 2740)

The Inspire Programmer (Model 2740) retains in memory all patient identifiers and data entered during a programming session. The option not to store PHI is available on the Programmer Settings screen. Disable (uncheck) the Patient Information Storage feature if you do not want PHI to be stored. Also, the option not to allow the export of PHI is available on the Programmer Settings screen. Disable (uncheck) the Patient Information Export feature if you do not PHI to be exported. In general, we recommend treating the programmer as if it contains PHI.

It is also recommended that reports retained from the device 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.

Essential Performance

Essential performance of the Model 2740 Inspire 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 Inspire Programmer (Model 2740) tablet, 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.

This device 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 various Radio Frequency (RF) wireless communication devices. It may contain one or more radio-type devices that operate in the 450–1550 KHz band, 13.56 MHz, as well as devices that operate in the 2.4 or 5.4 GHz band. All radio-type devices embedded in your tablet have met all the qualifications for use under FCC regulations and guidelines.

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 yourself. Such action may void the warranty on the tablet. Contact Inspire Medical Systems for information about servicing your wireless communication device.

Cables

Only Inspire Medical Systems provided cables should be used with the Inspire system. Use of other cables may result in unacceptable interference with other devices or the programmer 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 Programmer (Model 2740) utilizes RF communications between the tablet 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 programmer tablet or programmer cable, the programmer's Bluetooth suffered no decrease in performance.

Table 8-4. Electromagnetic Emissions

The Inspire Programmer (Model 2740) is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
Radio frequency (RF) emissions CISPR 11	Group 1	The programmer uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The programmer is suitable for use in professional healthcare facility environments. **Note:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. **Warning:** This system is intended for use by health care professionals only.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN 61000-3-3	Complies	

Table 8-5. Electromagnetic Immunity

The Inspire Programmer (Model 2740) is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer 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.
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 8-5. Electromagnetic Immunity (continued)

The Inspire Programmer (Model 2740) is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer 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 tablet contains an integrated battery that must be charged for use without mains power. 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 8-6. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

<table>
<tr><td colspan="4">The Inspire Programmer (Model 2740) is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer 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, 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/IEC 610000-4-8</td><td>30 A/m</td><td>30 A/m</td></tr>
</table>

Table 8-6. Guidance and Manufacturer's Declaration – Electromagnetic Immunity (continued)

The Inspire Programmer (Model 2740) is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer 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 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

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

Table 8-7. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Model 2740 Inspire Programmer

The Model 2740 Inspire Programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the programmer 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

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.

Unused Tablet Features

The tablet has several controls, indicators, and other features that are not used by the programmer software. These features are not operational and do not affect the operation of the programmer.

This section provides a brief overview of the unused features.

Tablet Front

The unused features on the front of the tablet (Figure 8-1) are described in Table 8-8.

Figure 8-1. Unused Tablet Features, Front

Table 8-8. Unused Tablet Features, Front

Item	Function
Function button	None
WiFi Light	Indicates WiFi connection (unused)

Tablet Right Side

The unused features on the right side of the tablet (Figure 8-2) are described in Table 8-9.

Figure 8-2. Unused Tablet Features, Right Side

Table 8-9. Unused Tablet Features, Right Side

Item	Function
HDMI port	None
SIM port	None
SD port	None

Tablet Left Side

The unused features on the left side of the tablet (Figure 8-3) are described in Table 8-10.

Figure 8-3. Unused Tablet Features, Left Side

Table 8-10. Unused Tablet Features, Left Side

Item	Function
Audio port	None

Tablet Back

The unused features on the back of the tablet (Figure 8-4) are described in Table 8-11.

Figure 8-4. Unused Tablet Features, Back

Table 8-11. Unused Tablet Features, Back

Item	Function
Camera	None
Speaker	None

Disposing of Programmer

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

Chapter 9: 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. Ask your doctor if you have any questions. 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

200-349-101 Rev A