



PROGRAMMER MANUAL

Programmer Model 2740

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2797
2010

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

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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
	Serial number
	Temperature limitation

Symbol	Description
	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
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive 90/385/EEC.
	Conformité Européenne; compliance to EMC Directive and Low Voltage Directive of the European Union.
	European authorized representative

Symbol	Description
	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 B Applied part protection against electrical shock
	Output connector polarity
	Class II double insulated
	CEC Level V compliant
	UL recognized component mark
	IECEE CB compliant
	Indoor use only
	TUV/T-Mark for IEC/EN 60601-1 Compliance

Symbol	Description
IPX0	Degree of ingress protection per EN60529
IP65	Degree of ingress protection per EN60529
	The Inspire Programmer is MR unsafe
	The Technical Conformity mark signifies that this device complies with Japan Radio Law

How to Use this Guide

This guide presents information for users of the Inspire Programmer (Model 2740) for programming an Inspire Implantable Pulse 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, telemetry 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 at implant, device checks, 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 Implantable Pulse 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.

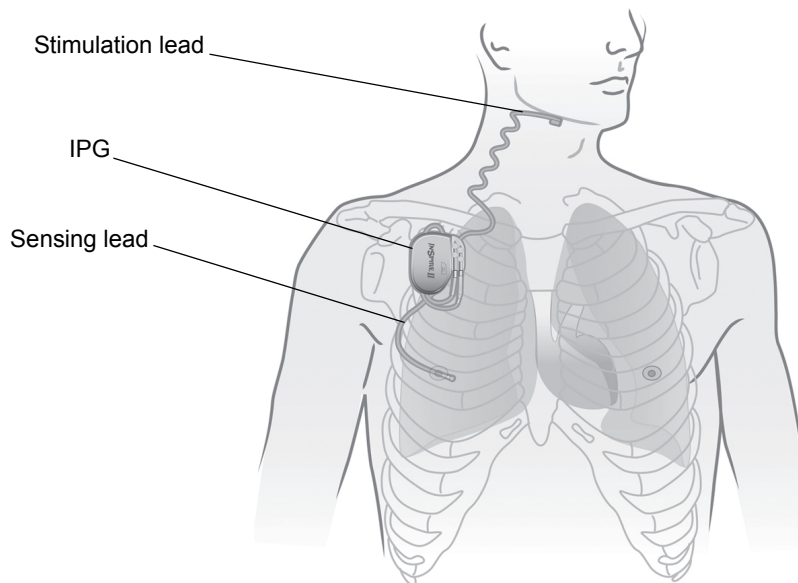


Figure 1-1. Inspire System Implanted Components

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 IPG, 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 parameters.

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 parameter 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 Parameters
- Sensing Parameters

Parameters that appear on the advanced screen views of the Record Thresholds screen (page 41), Adjust Stimulation screen (page 45), or Adjust Sensing screen (page 51), are labeled as advanced parameters 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 IPG parameters	The stimulation and sensing parameters currently used by the IPG. The combined stimulation and sensing parameters are also known as the therapy parameters.
Default parameters	Default therapy parameters determined by the IPG manufacturer.

Table 1-1. General Therapy Terms

Term	Definition
Functional threshold	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–IPG connection.
Initial session parameters	The therapy parameters at the start of the current programming session.
IPG	Inspire implantable pulse generator.
IPG battery status	The current state of the IPG battery. If the battery status is Low or Depleted, schedule an IPG replacement procedure.
Sensation threshold	The lowest amplitude at which a patient can feel stimulation.
Sensing	Defines how the IPG determines inhalation and exhalation in order to time the delivery of stimulation.
Sensing parameters	Therapy parameters that determine when the IPG delivers stimulation.
Session (programming session)	A series of interactions between the Inspire programmer and IPG during which the therapy parameters 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 parameters	Therapy parameters that determine how stimulation is delivered.
Telemetry	Short-range wireless communications with the IPG.
Therapy	When therapy is turned on, the IPG delivers stimulation based on the current sensing and stimulation parameters.
Usage	The total time the patient has used Inspire therapy since the last programming session.

Stimulation Parameter Terms

Table 1-2 defines terms related to stimulation parameters.

Table 1-2. Stimulation Parameter 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 parameter.
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 parameter.
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 parameter.
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.

Sensing Parameter Terms

Table 1-3 defines terms related to sensing parameters.

Table 1-3. Sensing Parameter Terms

Term	Definition
Exhalation	The end of inhalation as determined by the IPG. The IPG 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 IPG 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 parameter determines at what speed (slope) of decrease in the sensor signal the IPG will detect an exhalation. Increasing exhalation sensitivity configures the IPG to detect exhalations on more gradual decreases in the sensor signal; decreasing exhalation sensitivity configures the IPG to only detect exhalations on more rapid decreases in the sensor signal.
Exhalation threshold	<p>This parameter controls the height that the sensor signal must reach before the IPG will attempt to detect an exhalation. Increasing the exhalation threshold causes the IPG to look for exhalations more often; decreasing the exhalation threshold decreases how often the IPG looks for exhalations. This parameter allows for the management of signal artifacts that can cause the IPG to detect extraneous exhalations.</p> <p>Note: This is an advanced parameter.</p>
Inhalation	The start of inhalation as determined by the IPG. The IPG 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 IPG 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	<p>Inhalation sensitivity determines at what speed (slope) of increase in the sensor signal the IPG will detect an inhalation. Increasing inhalation sensitivity configures the IPG to detect inhalations on more gradual increases in the sensor signal; decreasing inhalation sensitivity configures the IPG to only detect inhalations on more rapid increases in the sensor signal.</p> <p>Note: This is an advanced parameter.</p>

Table 1-3. Sensing Parameter Terms

Term	Definition
Inhalation threshold	<p>This parameter controls the height that the sensor signal must reach before the IPG will attempt to detect an inhalation. Increasing the inhalation threshold causes the IPG to look for inhalations more often; decreasing the inhalation threshold decreases how often the IPG looks for inhalations.</p> <p>Note: This is an advanced parameter.</p>
Invert signal	<p>A feature that switches the polarity of the sensor signal before the IPG processes it for inhalations and exhalations.</p> <p>This feature could be used to correct a situation in which stimulation is being delivered during exhalation instead of inhalation.</p>
Maximum stimulation time	<p>The maximum time that stimulation is delivered during one respiratory cycle. This parameter also controls the length of the stimulation burst used for test stimulation.</p> <p>Note: This is an advanced parameter.</p>
Off period (Hard)	<p>A percentage of the respiratory period during which stimulation will not be delivered. The hard off period follows immediately after the IPG detects an exhalation.</p>
Off period (Soft)	<p>A percentage of the respiratory period during which the IPG 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.</p> <p>Note: This is an advanced parameter.</p>
Respiratory period	<p>The IPG measures the respiratory period from exhalation to exhalation. The respiratory period is used for the calculation of the off period.</p>






Therapy Icons

Electrode Configuration

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 IPG 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 Configuration” on page 46 for more information.

Table 1-4. Electrode Configuration Icons

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

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

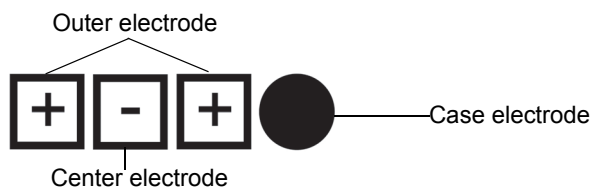


Figure 1-2. Default Electrode Configuration

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.

Telemetry

A telemetry icon (Figure 1-3) is used on certain programming buttons to indicate when telemetry is required to execute an action, such as:

- Connect to IPG
- Configure IPG
- Test Telemetry
- Turn On/Off Therapy
- Test Stimulation
- Start Waveform



Figure 1-3. Telemetry Icon

When the programmer communicates with the IPG, a large telemetry icon displays (Figure 1-4). The color of this icon corresponds to the telemetry status: green indicates telemetry success and orange indicates telemetry failure.



Figure 1-4. Telemetry 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 implantable pulse generator.

- Tablet
 - Handheld computer
 - Inspire programmer software
 - Medical-grade power supply and three-prong power cord
- Telemetry cable
 - Telemetry head
 - Bluetooth wireless communications interface
 - Medical-grade power supply and two-prong 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.

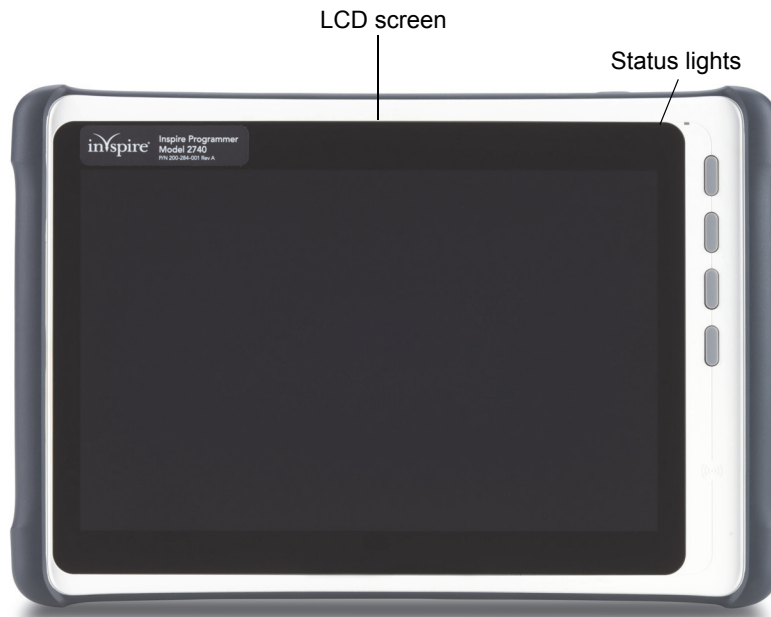


Figure 2-1. Tablet Front

Table 2-1. Tablet Front

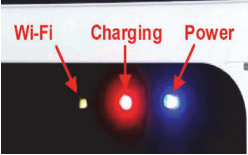

Icon/Item	Description	Function
	Status lights	WiFi Charging Power
	Docking connector	Interface connector for use with docking station (not included)

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 15.

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 three-prong 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.

Telemetry Cable

The telemetry cable is the communications interface between the IPG and the tablet. The telemetry cable includes a telemetry head, a wireless communication module, and a medical-grade power supply with power cord (Figure 2-5). The telemetry cable has two operating ranges, one for very short range communications with the IPG (up to 5 cm or 2 in) and another for short range communication with the tablet (up to 5 m or 16 ft).

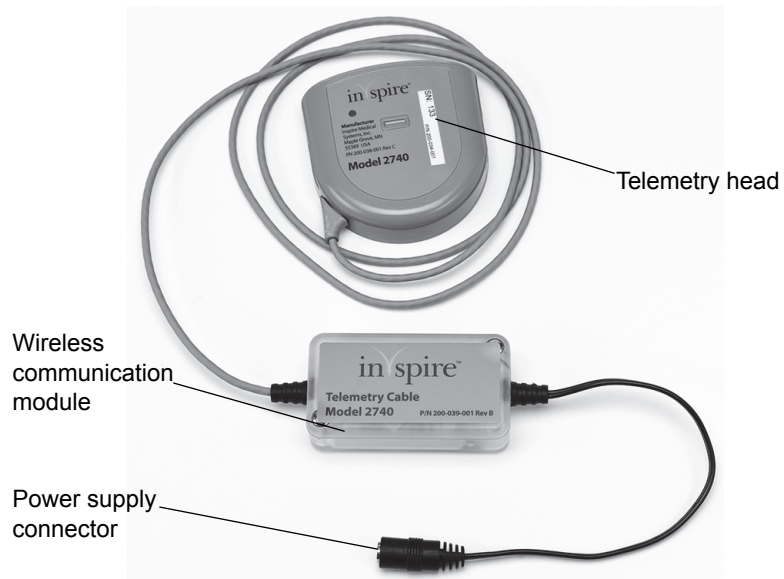


Figure 2-5. Telemetry Cable

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 three-prong 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 Telemetry Cable to Power

The telemetry cable must be plugged into an electrical outlet to operate. Complete the following instructions to connect the telemetry cable to power (Figure 3-3).

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

Note: A flashing LED status light displays on the telemetry wireless interface until the tablet establishes a connection.

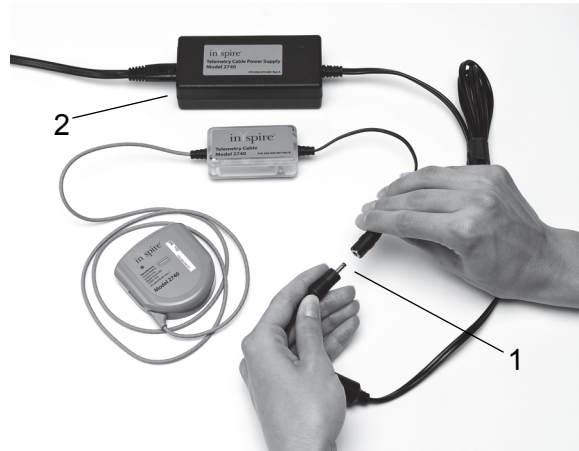


Figure 3-3. Telemetry Cable Power Supply Connections

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 IPG	<ul style="list-style-type: none"> Starts a programming session with an IPG. Accesses the Home screen and all session activities. <p>Note: Button is disabled until the tablet has established a connection to the telemetry cable.</p>
Test Telemetry	<ul style="list-style-type: none"> Evaluates telemetry strength before connecting to the IPG and is used to determine best position for telemetry cable and head. <p>Note: Button is disabled until the tablet has established a connection to the telemetry cable.</p>
Reports	<ul style="list-style-type: none"> Accesses reports for previous programming sessions. Reports can be reviewed and exported.
Settings	<ul style="list-style-type: none"> Accesses the Programmer Settings screen; allows access to data management controls and adjustments to date and time, language, and number format.
Demo	<ul style="list-style-type: none"> Starts a practice programming session. Makes it possible to practice using the programmer with a simulated IPG when no patient is present.
Shut Down	<ul style="list-style-type: none"> Powers off the tablet.

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

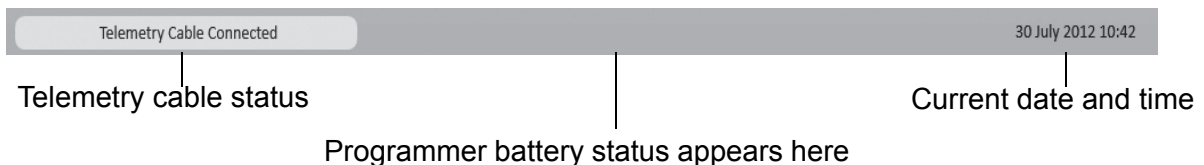


Figure 3-5. Start Screen Footer Information

Telemetry Cable Status

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

- **Telemetry Cable Connected** — Wireless link between tablet and telemetry cable is established. Status background color is gray. Wireless communication module LED is solid. Telemetry buttons are enabled.
- **Searching for Telemetry Cable** — Wireless link between tablet and telemetry cable is not established. Status background color is blue. Wireless communication module LED is flashing. Telemetry buttons are disabled.
- **Demo Mode** — Wireless link between tablet and telemetry 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 an IPG 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.

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** drop-down menu and choose one of the languages that displays below.
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 Telemetry Head and Connecting to IPG

The telemetry head must be properly positioned over the IPG to establish the signal strength required to connect to the IPG.

Confirming Telemetry Connection

The telemetry cable status line in the lower-left corner of the screen will indicate that a communication link between the tablet and the telemetry cable is established. See “Telemetry Cable Status” on page 20 for more information.

A solid LED status light displays on the telemetry wireless communications module when the tablet and telemetry cable establish a connection (see Figure 2-5).

Note: This light flashes when telemetry communications are occurring between the tablet and IPG but a connection has not been established yet.

Testing Telemetry Strength

Complete the following steps to evaluate telemetry head positioning before connecting to the IPG.

1. Ensure that the tablet and telemetry cable are on.
2. Confirm that a wireless link between the tablet and the telemetry cable has been established by checking the telemetry cable status line in the screen footer.
3. Position the telemetry head directly over the IPG (Figure 3-7).
4. Select the **Test Telemetry** button on the Start screen, Record Thresholds screen, Adjust Stimulation screen, or Adjust Sensing screen.
5. The screen will display one of the following strength ratings.
 - Good
 - Moderate
 - Low
 - Electrical Interference
6. If signal strength is not good, follow the on-screen instructions: remove the source of interference or reposition the telemetry head directly over the IPG for a stronger signal.
7. Select the **Done** button when the telemetry head is positioned properly and the telemetry strength is Good.



Figure 3-7. Correct Positioning of Telemetry Head over IPG

Telemetry Head Status Light

A status light is located on the top of the telemetry head (Figure 3-7) so that it can be observed when the telemetry head is positioned over the IPG. The colors of the status light correspond to the strength of the telemetry signal and are described in Table 3-2.

Note: The telemetry head status light will illuminate whenever telemetry is being used, not just when testing telemetry.

Table 3-2. Telemetry Head Status Light Color Descriptions

Status Light Color	This Means	To Do This
Off	No telemetry occurring.	No action required.
Green	Telemetry successful.	No further positioning of the telemetry head is required.
Amber	Telemetry is unsuccessful.	Position telemetry head directly over the IPG.
Alternating green and amber	Telemetry cable has not established a wireless connection to the tablet. Electrical interference is interrupting telemetry.	Confirm that the tablet is on. Remove source of electrical interference.

Connecting to IPG

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

Table 3-3. Telemetry Communication Screens

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

A large telemetry icon displays on all Telemetry Communication screens (Figure 3-8). The color of this icon corresponds to the color of the telemetry head status light to indicate telemetry success (green) or telemetry failure (amber).



Figure 3-8. Telemetry Communication Screen

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

Table 3-4. Telemetry Troubleshooting

Problem	Action
No Connection Between Tablet and Telemetry Cable	Ensure that the tablet is within wireless range. Move tablet closer to telemetry cable if necessary. Ensure telemetry cable is powered on. Check for loose cord connections and restore power to the telemetry cable.
Telemetry Buttons Disabled	Connect telemetry cable to power. Ensure tablet is within wireless range to establish connection and enable all telemetry buttons.
IPG Not Found	Reposition telemetry head directly over IPG.
Electromagnetic Interference	Remove cause of interference and reposition telemetry head directly over IPG. 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 IPG. The telemetry 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 telemetry cable status line located in the lower-left corner of the tablet screen.

Exiting a Session and Turning Off the Programmer

Allow all telemetry communications to complete before a patient leaves. If a patient is allowed to leave during a test or impedance measurement, the IPG may not be restored to therapy settings. Verify that all parameter 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 telemetry 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

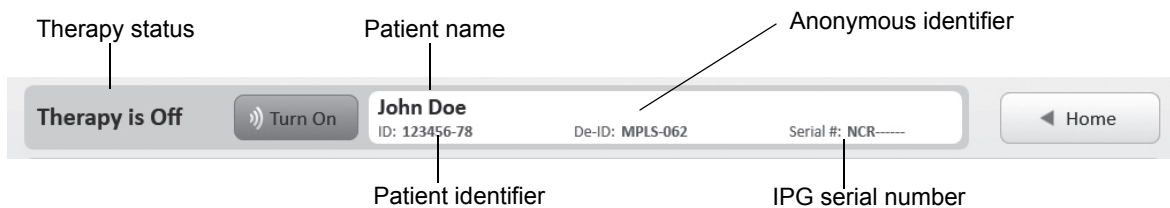


Figure 4-1. Common Information Screen Header

- **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 IPG.
- **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** — IPG serial number.
- **Home/Back Button** — Select button to access the Home screen or the previous screen visited.

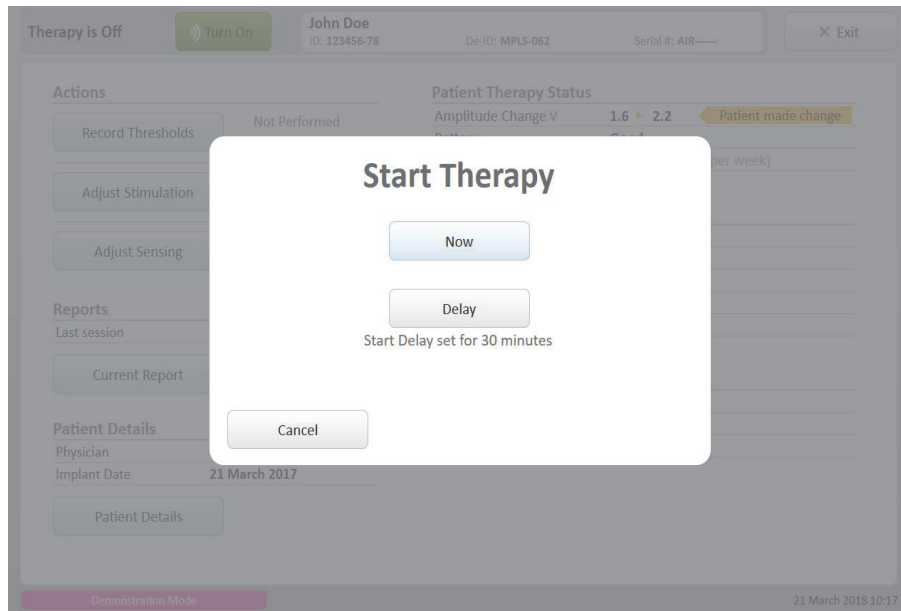


Figure 4-2. Start Therapy Screen

Screen Footer Information

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

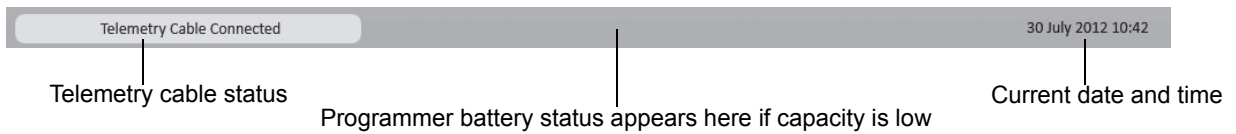


Figure 4-3. Common Information in Screen Footer

Telemetry Cable Status

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

- Telemetry Cable Connected — Wireless link between tablet and telemetry cable is established. Status background color is gray. Wireless communication module LED is solid. Telemetry buttons are enabled.
- Searching for Telemetry Cable — Wireless link between tablet and telemetry cable is not established. Status background color is blue. Wireless communication module LED is flashing. Telemetry buttons are disabled.
- Demo Mode — Wireless link between tablet and telemetry 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 at 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 on 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 IPG	<ul style="list-style-type: none"> Starts a programming session with an IPG. Accesses the Home screen and all session activities. Note: Button is disabled until the tablet has established a connection to the telemetry cable.
Test Telemetry	<ul style="list-style-type: none"> Evaluates telemetry strength before connecting to the IPG and is used to determine best position for telemetry cable and head. Note: Button is disabled until the tablet has established a connection to the telemetry cable.
Reports	<ul style="list-style-type: none"> Accesses reports for previous programming sessions. Reports can be reviewed and exported.
Settings	<ul style="list-style-type: none"> Accesses the Programmer Settings screen. Allows access to data management controls and adjustments to date and time, language, and number format.

Table 4-1. Start Screen Button Descriptions

Demo	<ul style="list-style-type: none">• Starts a practice programming session.• Makes it possible to practice using the programmer with a simulated IPG when a patient is not present.
Shut Down	<ul style="list-style-type: none">• Powers off the tablet.

Programmer Settings Screen

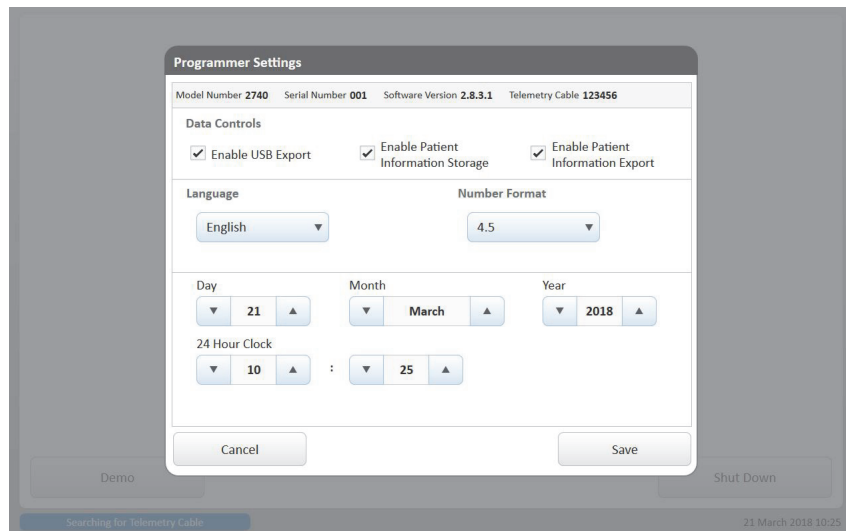


Figure 4-5. Programmer Settings Screen

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 21 for more information.

Home Screen

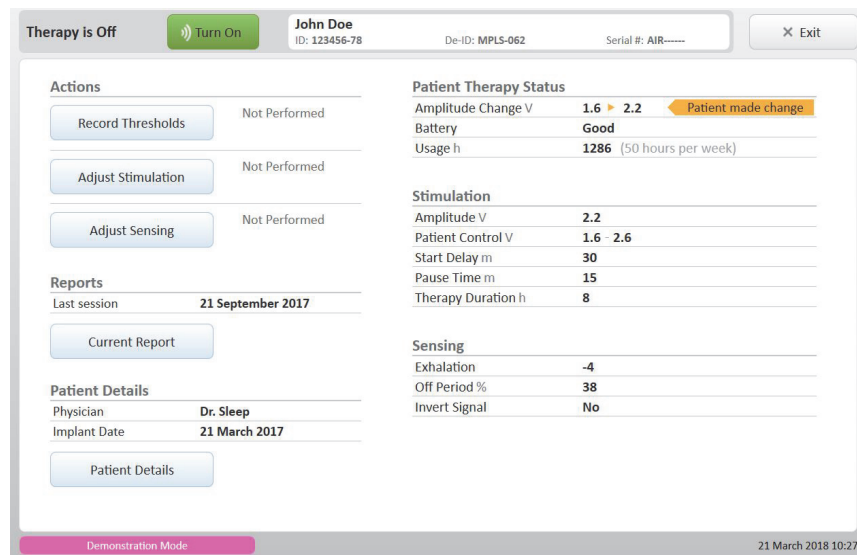


Figure 4-6. Home Screen

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

- Patient Therapy Status
- Actions
- Stimulation and Sensing Parameters
- Reports
- Patient Details

Patient 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.
- **Battery** — The IPG 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 IPG.
- **Usage** — The number of hours Inspire therapy has been used since the last programming session. The average usage per week also displays in parentheses. The last session date for the IPG displays in the reports section of the Home screen.

Patient Therapy Status	
Amplitude Change V	2.2 ▶ 2.3 Patient made change
Battery	Good
Usage h	948 (36 hours per week)

Figure 4-7. Patient Therapy Status

Actions

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

The session 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.

Record Thresholds

- Button accesses the Record Thresholds screen where patients' functional and sensory responses to stimulation are evaluated. See "Record Thresholds Screen" on page 39 for more information.
- **Status Indicators:**
 - Not Performed indicates activity has not been completed.
 - The number of stimulation threshold parameter sets recorded displays when thresholds have been saved on Record Thresholds screen (Figure 4-8).

Adjust Stimulation

- Button accesses the Adjust Stimulation screen where stimulation parameters are modified and tested. See “Adjust Stimulation Screen” on page 42 for more information.
- Status Indicators:
 - Not Performed indicates activity has not been completed.
 - A blank status indicator line displays when the Adjust Stimulation screen has been accessed but no parameters were changed.
 - Changes Made with a blue check mark indicates stimulation parameters were changed (Figure 4-8).

Adjust Sensing

- Button accesses the Adjust Sensing screen where sensing parameters are modified and tested and real-time sensor waveforms are evaluated. See “Adjust Sensing Screen” on page 48 for more information.
- Status Indicators:
 - Not Performed indicates activity has not been completed (Figure 4-8).
 - A blank status indicator line displays when the Adjust Sensing screen has been accessed but no parameters were changed and no waveform screenshots were saved.
 - Changes Made with a blue check mark indicates sensing parameters were changed.
 - The number of waveforms recorded displays when sensor waveform screenshots have been saved on Adjust Sensing screen.

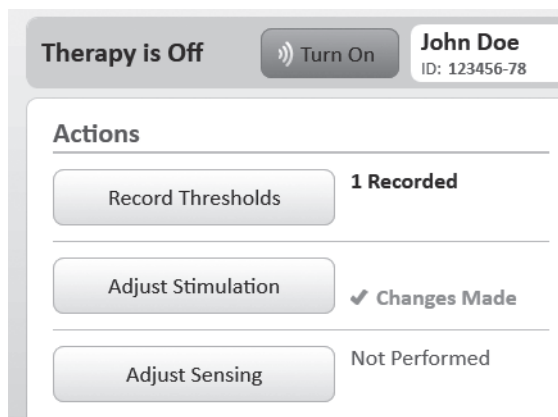


Figure 4-8. Action Status Indicators

Stimulation and Sensing Parameters

A summary of the stimulation and sensing parameters that are configured to the IPG display in this section of the Home screen. The following basic therapy parameters and values always display here.

- Amplitude
- Patient Control
- Start Delay
- Pause Time
- Therapy Duration
- Exhalation (Sensitivity)
- Off Period (Hard)
- Invert Signal

(See Table 1-2 on page 4 and Table 1-3 on page 5 for an explanation of these terms.)

When stimulation and sensing parameters change during a session, the values on the Home screen update, and the following status indicators display (Figure 4-9).

- Blue parameter value and check mark — indicates parameter has changed and highlights the new value.
- Gray value in parentheses — displays the initial parameter value from the start of the session.

Advanced parameters display in this section of the Home screen only when the current or initial session values are not default values. Advanced parameters are indicated by the following (Figure 4-9).

- Shaded gray background — indicates a non-default, advanced parameter.
- Vertical bar — separates the parameter values of the following combined parameters.
 - Exhalation sensitivity | Exhalation threshold
 - Hard off period | Soft off period
 - Inhalation sensitivity | Inhalation threshold

The value displayed after the vertical bar is always an advanced parameter.

Patient Therapy Status	
Amplitude Change V	2.2 ► 2.3
Battery	Good
Usage h	948 (36 hours per week)
Stimulation	
Amplitude V	2.3
Patient Control V	2.0 2.7
Start Delay m	✓ 40 (30)
Pause Time m	15
Therapy Duration h	8
Sensing	
Exhalation	✓ +2 +1 (0 0)
Off Period %	50
Invert Signal	No

Check mark indicates change, and new value displays in blue

Initial value displays in parentheses

Gray background indicates advanced parameter

Initial values for combined parameter

Vertical bar separates new

Advanced parameter

Figure 4-9. Status Indicators for Stimulation and Sensing Parameters

Reports

This section of the Home screen displays the date of the most recent session report stored on the programmer.

Data from the current session can be viewed at any time by selecting the **Current Report** button, which accesses the Reports screen (see page 54).

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).

Patient Details Screen

The screenshot shows the 'Patient Details' screen. At the top, there is a status bar with 'Therapy is Off', a 'Turn On' button, and patient information: 'John Doe', 'ID: 123456-78', 'De-ID: MPLS-062', and 'Serial #: AIR-----'. A 'Home' button is on the right. The main form is divided into four columns: 'Patient Name' (John Doe), 'Patient ID' (123456-78), 'De-Identified ID' (MPLS-062), and 'Physician Name' (Dr. Sleep). The 'IPG' column contains 'Implant Date' (21 March 2017) and 'Location'. The 'Stim Lead' column contains 'Model Number', 'Serial Number', and 'Location'. The 'Sense Lead' column contains 'Model Number', 'Serial Number', and 'Location'. Below the form is a virtual keyboard. At the bottom, there are 'Cancel' and 'Save' buttons. A pink bar at the very bottom indicates 'Demonstration Mode' and the date/time '21 March 2018 10:28'.

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 IPG. If a different programmer is used to communicate with the patient's IPG, 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 — Enter the name of the physician responsible for the patient.
- Implant Date — Enter the date that the patient's IPG was implanted.
- IPG Location — Enter the location of the IPG 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.

Record Thresholds Screen

The Record Thresholds screen is used to evaluate and record the patient's response to stimulation (Figure 4-11).

Basic Screen View

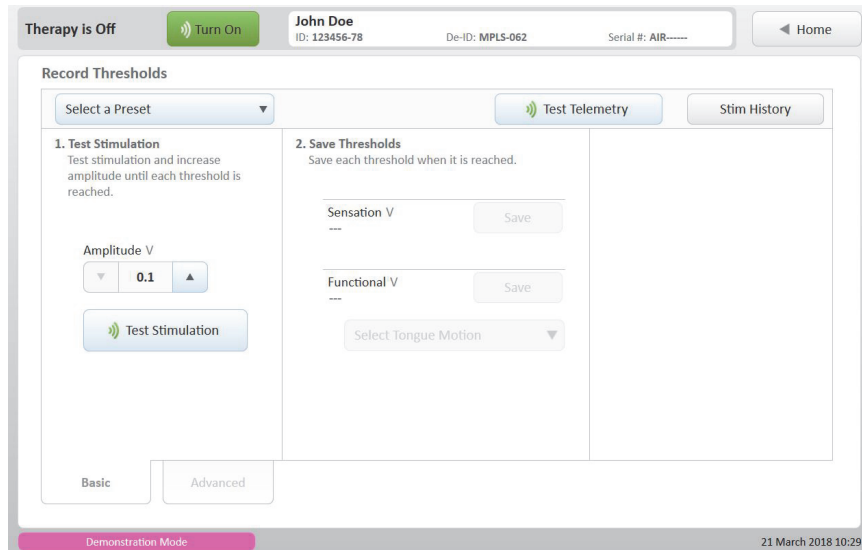


Figure 4-11. Record Thresholds Screen, Basic View

Two stimulation thresholds are typically evaluated during this process:

- Sensation — The lowest amplitude at which the patient can feel stimulation.
- Functional — The lowest amplitude at which the tongue protrudes past the lower teeth.

The Record Thresholds screen uses temporary settings to perform test stimulations. Changing amplitude or stimulation parameters on this screen will not change the current IPG parameters.

Complete the numbered steps on-screen to adjust amplitude and save stimulation thresholds:

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.
 - The **Test Stimulation** button requires that the telemetry cable is connected. Confirm connection by checking the telemetry cable status in the screen footer (Figure 4-3). The button is disabled until a connection is established.
 - It is recommended to test stimulation with the therapy off.
 - During test stimulation, the IPG delivers stimulation for the duration of the maximum stimulation time.
3. Repeat steps 1 and 2 until each threshold is reached.
4. Select the **Save** buttons to record the amplitude when each threshold is reached. Thresholds may be saved for each unique set of parameters.
Note: **Save** buttons are disabled until a test stimulation has been performed at the displayed amplitude.
5. Select a description of the patient's tongue motion at the saved threshold amplitude. This step may only be performed after a threshold has been saved.
Note: The option to select a tongue motion is not available at the sensation threshold.

The default stimulation parameters used in the basic screen view are the current IPG parameters. Use the **Select a Preset** button to change test stimulation parameters to one of the following:

- Initial Session Parameters — Selects the IPG stimulation parameters from the start of the current programming session.
- Current IPG Parameters — Selects the stimulation parameters currently in use by the IPG.
- Default Parameters — Selects the default stimulation parameters (see “Default Parameters” on page 84 for more information).

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

Advanced Screen View

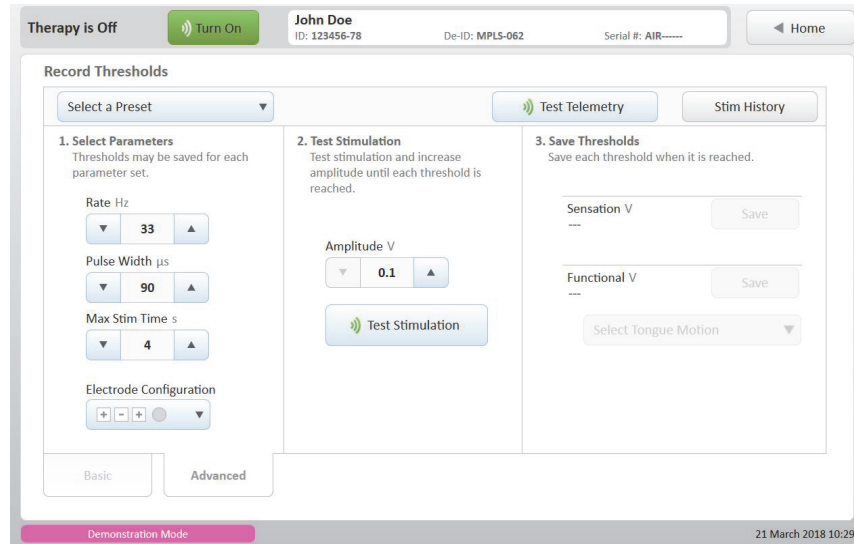


Figure 4-12. Record Thresholds Screen, Advanced View

To record thresholds using stimulation settings other than the current IPG settings, select the Advanced tab at the bottom of the screen (Figure 4-12). Changing amplitude or stimulation parameters on this screen will not change the current IPG settings.

Complete the numbered steps on-screen.

1. **Select Parameters** — Use the arrow buttons to increase or decrease the following parameters: rate, pulse width, max stim time, and electrode configuration (see Table 1-2 on page 4 for definitions of these terms, and see “Electrode Configuration” on page 46 for more information)
Note: Increasing these parameters will increase the strength of stimulation. Changing electrode configuration will change the location at which stimulation is delivered.
2. Alternately select the **Test Stimulation** button and increase the amplitude using the arrow buttons until each threshold is reached.
3. Select the **Save** buttons to record the amplitude when each threshold is reached. Thresholds may be saved for each unique set of parameters.
4. Select a description of the patient’s tongue motion at the saved threshold amplitude. This step may only be performed after a threshold has been saved.
Note: The option to select a tongue motion is not available at the sensation threshold.

Adjust Stimulation Screen

The Adjust Stimulation screen is used to modify and test simulation parameters (Figure 4-13). The parameter values initially displayed on the screen are the values currently in use by the IPG. When parameter values are changed and differ from the current IPG parameters, the fields are highlighted in blue (Figure 4-14). Selecting the **Configure IPG** button will configure the IPG with the highlighted values and clear the highlighting.

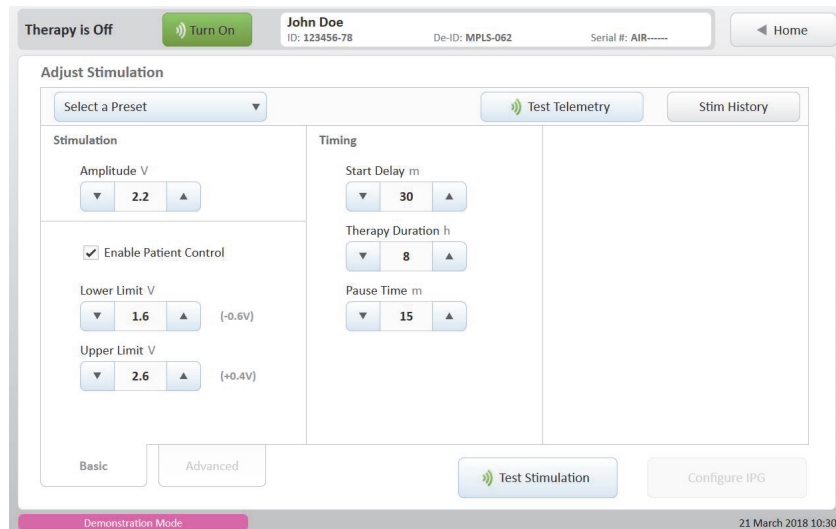


Figure 4-13. Adjust Stimulation Screen, Basic View

Basic Screen View

The basic screen view divides the parameters 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 parameters.

- Start Delay
- Pause Time
- Therapy Duration

See Table 1-2 for definitions of these terms.

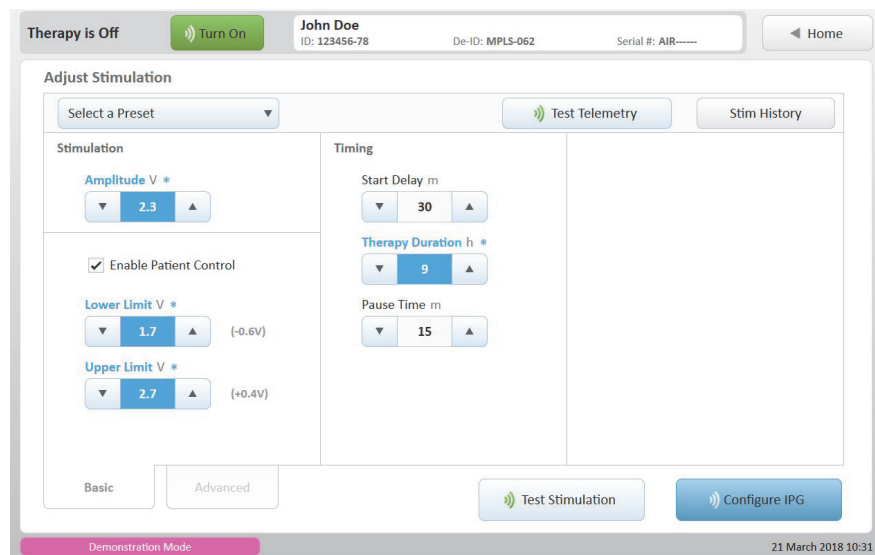


Figure 4-14. Changed Parameters on Adjust Stimulation Screen

Programming Buttons

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

Test Stimulation

- The **Test Stimulation** button requires that the telemetry cable is connected. Confirm connection by checking the telemetry cable status in the screen footer (Figure 4-3).
- Select the **Test Stimulation** button to test the displayed parameters, which may differ from those currently configured in the IPG. Testing stimulation will not change the current IPG parameters.
- During test stimulation, the IPG delivers stimulation for the duration of the maximum stimulation time.
- It is recommended to test stimulation with the therapy off.

Configure IPG

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

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

Notes:

- The **Configure IPG** button requires that the telemetry cable is connected. Confirm connection by checking the telemetry cable status in the screen footer (Figure 4-3)
- The **Configure IPG** button is enabled when changes are made to the parameters currently in use by the IPG.
- After selecting the **Configure IPG** button, the highlighting is cleared because the displayed values now match the newly configured IPG settings.
- When therapy is turned on or parameter changes are made with the therapy on, the IPG 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 parameters to one of the following:

- Initial Session Parameters — Selects the IPG stimulation parameters from the start of the current programming session.
- Current IPG Parameters — Selects the stimulation parameters currently in use by the IPG.
Note: Selecting the Current IPG Parameters preset clears all highlighting.
- Default Parameters — Selects the default stimulation parameters. See “Default Parameters” on page 84 for more information.

Stim History

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

Advanced Screen View

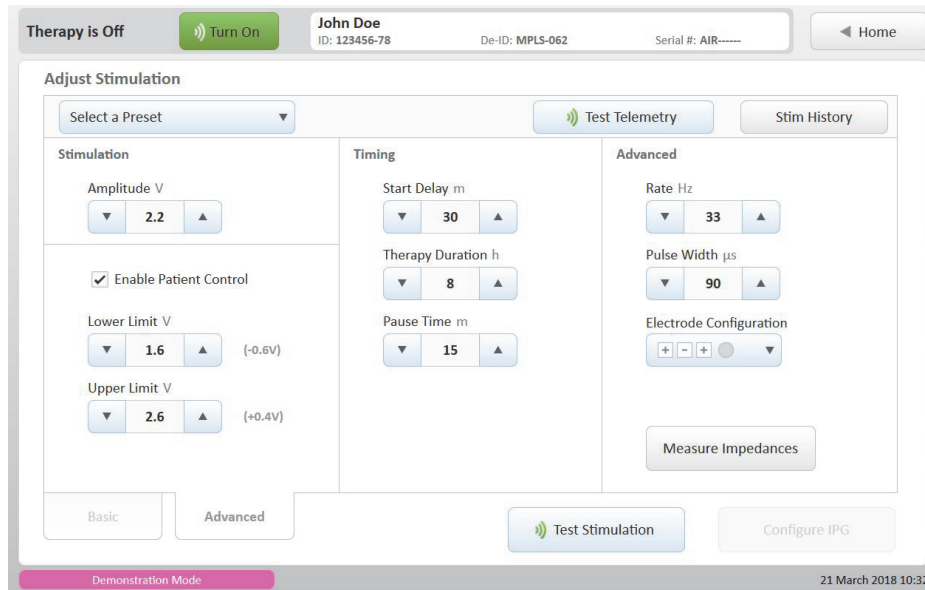


Figure 4-15. Adjust Stimulation Screen, Advanced View

To modify advanced stimulation parameters or measure electrode impedances, select the Advanced tab at the bottom of the screen.

- Use the arrow buttons to increase or decrease the following parameters.
 - Rate
 - Pulse Width
 - Electrode Configuration

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

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

Electrode Configuration

Select the **Electrode Configuration** 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 IPG case.

The two lead electrodes are designed so that one center electrode is placed between the outer electrode (Figure 4-16).



Figure 4-16. Inspire System Electrodes

Icons are used on the **Electrode Configuration** button to indicate the polarity of all system electrodes. For example, the default electrode configuration is shown in Figure 4-17.

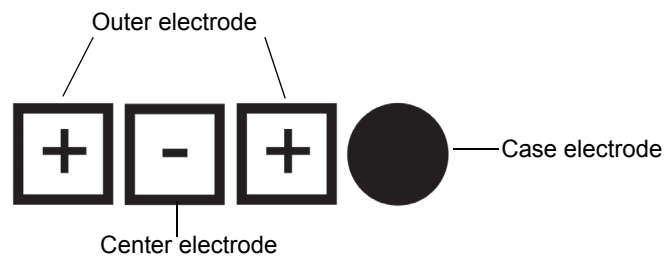


Figure 4-17. Default Electrode Configuration

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.

Measure Impedances

The **Measure Impedances** button accesses the Measure Impedances screen (Figure 4-18), which is used to assess the integrity of leads, lead electrodes, and the lead–IPG connection.

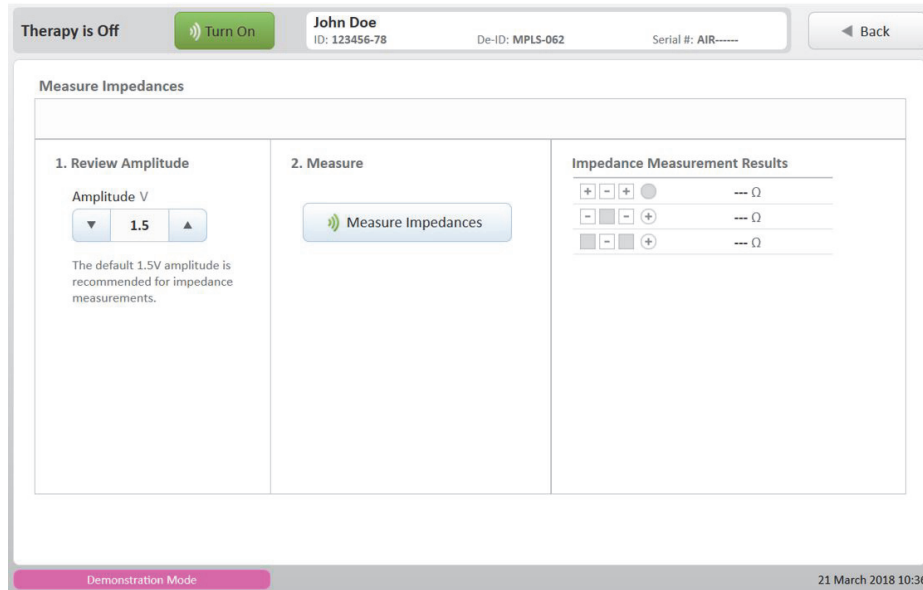


Figure 4-18. Measure Impedances Screen

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.

3. Analyze Impedance Measurement Results. Measurement results lower than 200 ohms may indicate a problem.

- A measured impedance < 200 ohms may indicate a short between lead conductors, preventing stimulation from reaching the patient.

Use the test stimulation feature on the Adjust Stimulation screen to confirm high or low impedance measurement results. Impedance values should be considered for information only.

Adjust Sensing Screen

The Adjust Sensing screen (Figure 4-19) allows for real-time evaluation of the respiratory sensor waveform and adjustment of sensing parameters. Adjustments to sensing parameters can modify when stimulation is delivered during the respiratory cycle.

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



Figure 4-19. Adjust Sensing Screen, Basic View

Basic Screen View

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

- 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 parameters used on this screen.

Programming Buttons

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

Start Waveform

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

Notes:

- Starting the waveform will turn therapy on at the current IPG settings. If the IPG amplitude is 0V, the programmer will automatically change the amplitude to 0.1V.
 - When therapy is turned on or parameter changes are made with the therapy on, the IPG 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 but does not stop the therapy.
 - Select the **Turn Off** therapy button to stop the therapy and waveform mode.
 - 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 4-20).

- 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.

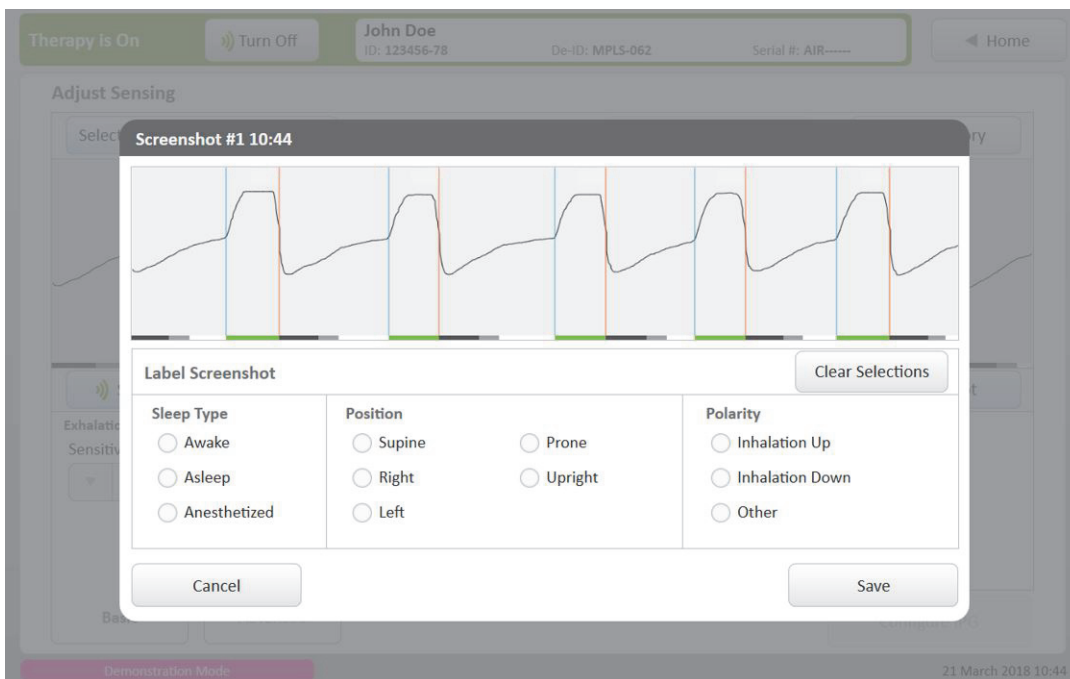


Figure 4-20. Screenshot Screen

Configure IPG

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

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

Notes:

- The **Configure IPG** button requires that the telemetry cable is connected. Confirm connection by checking the telemetry cable status in the screen footer (Figure 4-3).
- The **Configure IPG** button is enabled when changes are made to the parameters currently in use by the IPG.
- After selecting the **Configure IPG** button, the highlighting is cleared because the displayed values now match the newly configured IPG settings.
- When therapy is turned on or parameter changes are made with the therapy on, the IPG 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 parameters to one of the following:

- Initial Session Parameters — Selects the IPG sensing parameters from the start of the current programming session.
- Current IPG Parameters — Selects the sensing parameters currently in use by the IPG.
Note: Selecting the Current IPG Parameters preset clears all highlighting.
- Default Parameters — Selects the default sensing parameters (see “Default Parameters” on page 84 for more information).

Sense History

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

Advanced Screen View

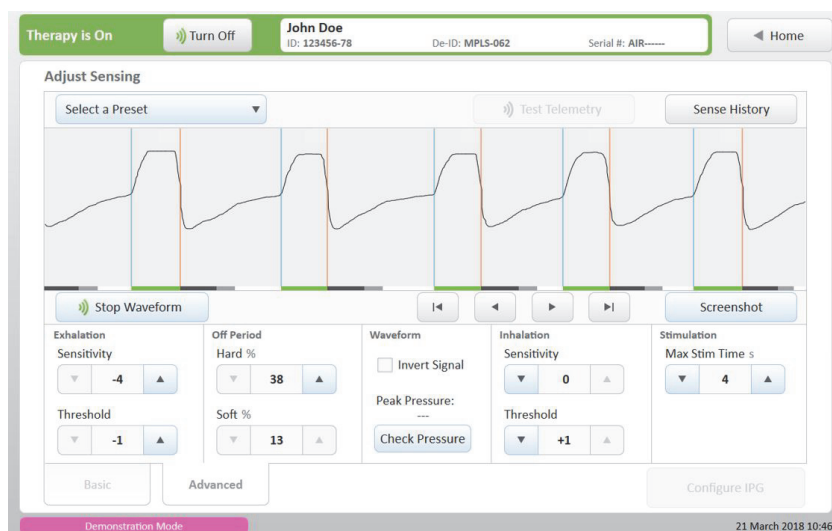


Figure 4-21. Adjust Sensing Screen, Advanced View

To modify advanced sensing parameters, select the Advanced tab at the bottom of the screen (Figure 4-21).

- Use the arrow buttons to increase or decrease the following parameters.
 - Exhalation Threshold
 - Soft Off Period
 - Inhalation Sensitivity
 - Inhalation Threshold
 - 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 4-22). All patients with whom the programmer has communicated are listed here.

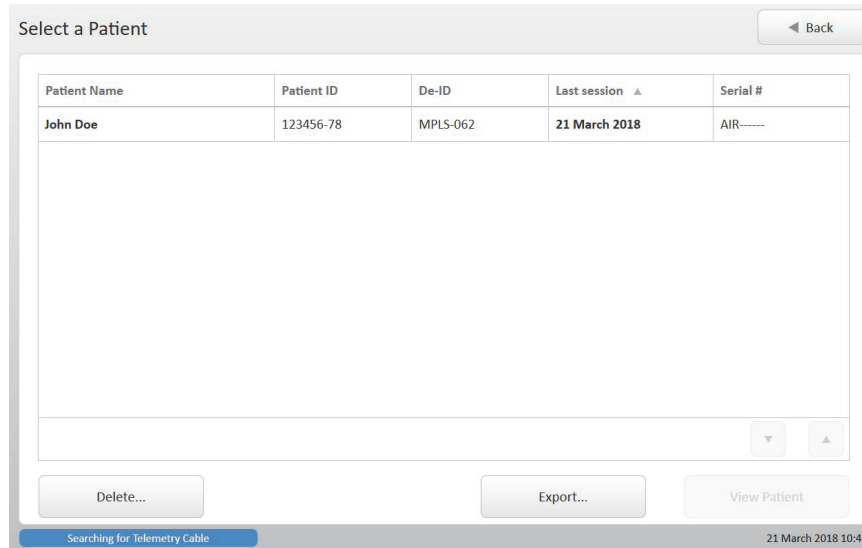


Figure 4-22. Select a Patient Screen

Patient name, ID, deidentified-ID, date of last session, and IPG 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 4-3 for information about the functions of the buttons on the Select a Patient screen.

Table 4-3. 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 4-23). <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • Highlight patient name and select the Export button to display Export Report screen (Figure 4-25). 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, waveform screenshots, and advanced parameters. • 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.

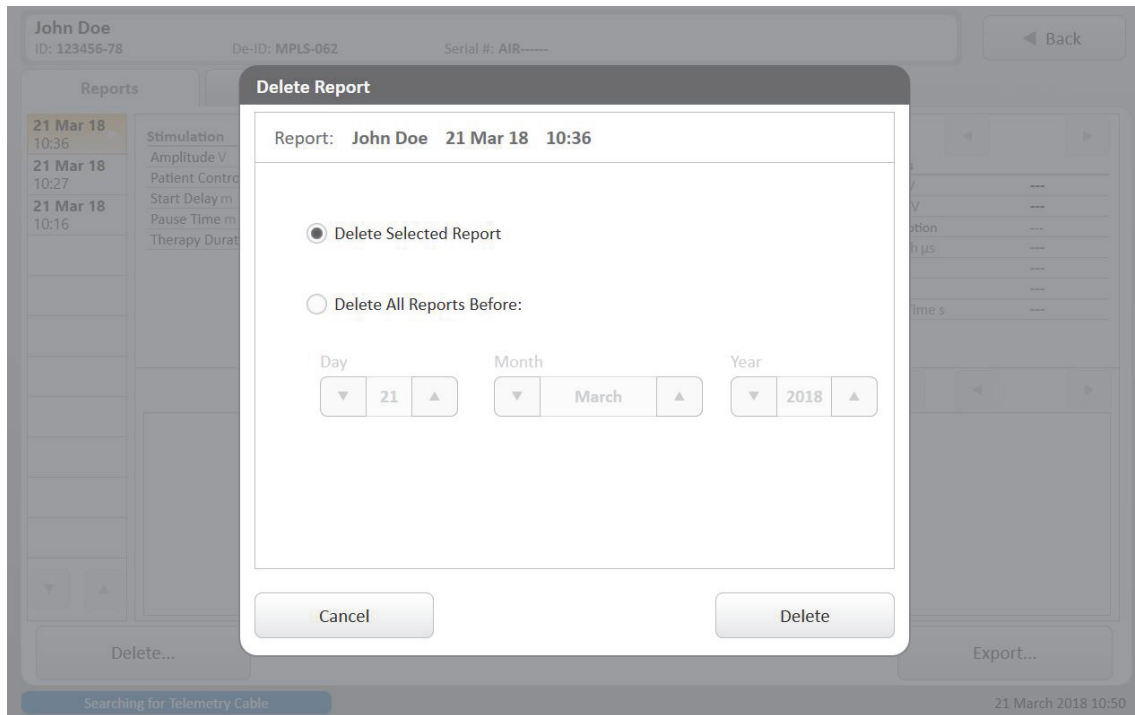


Figure 4-23. Delete Report Screen

Reports Screen

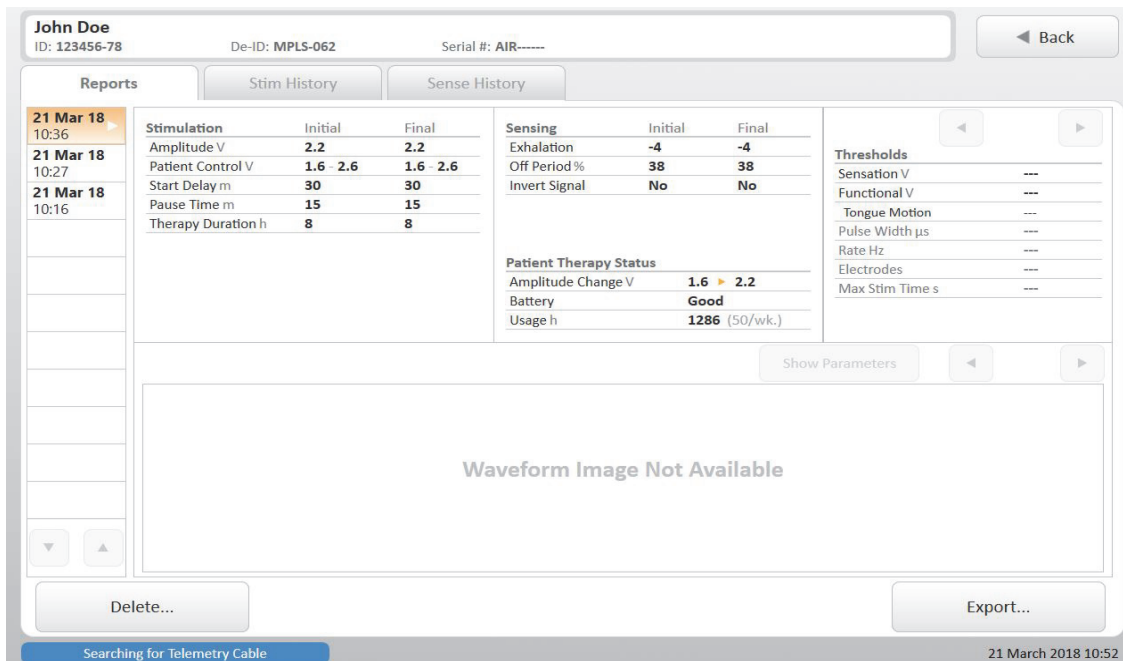


Figure 4-24. Reports Screen

The **Current Report** button on the Home screen accesses the Reports screen (Figure 4-24), where all session reports for the current IPG 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 thresholds, and stimulation and sensing parameters for a given session. Blue highlighted information with a check mark indicates changes made during the session. Advanced parameters 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 4-4 for information about the functions of the buttons on the Reports screen.

Table 4-4. 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 thresholds	Select the right or left arrow buttons above the threshold information. Note: If arrow buttons are disabled, there are no additional thresholds to view.
Show or hide parameters for the displayed waveform	Select the Show Parameters or Hide Parameters 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 4-4. Reports Screen Buttons

Delete a session report	<p>Highlight report and select the Delete button to display the Delete Report screen (Figure 4-23).</p> <ul style="list-style-type: none">• 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	<p>Attach the Inspire USB flash drive to the tablet.</p> <ul style="list-style-type: none">• Highlight report and select the Export button to display Export Report screen (Figure 4-25). 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, waveform screenshots, and advanced parameters. Note: Session reports will be exported as PDF (portable document format) files. The programming log contains a CSV (comma separated value) file of all IPG parameter 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.

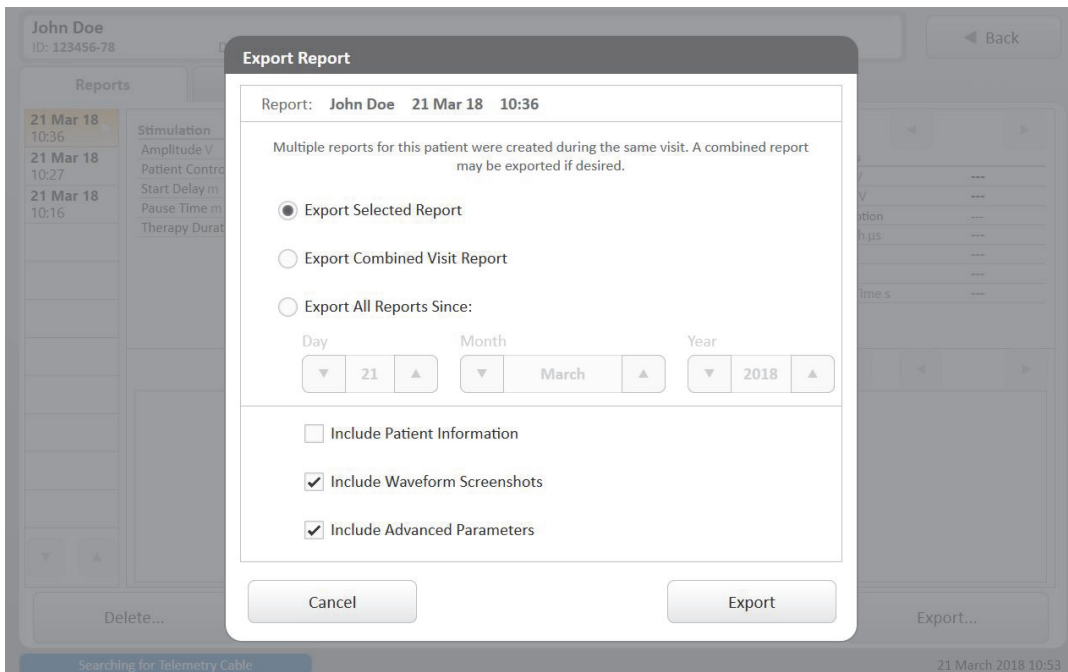


Figure 4-25. Export Report Screen

Stimulation History Screen

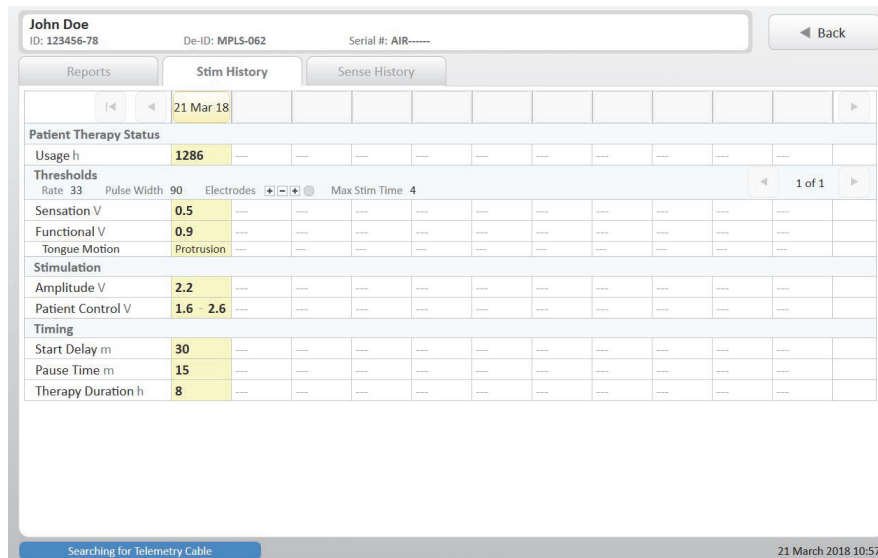


Figure 4-26. Stimulation History Screen

The **Stim History** button on the Record Thresholds and Adjust Stimulation screens as well as the Stim History tab on the Reports screen access the Stimulation History screen (Figure 4-26). This screen displays a summary of usage, stimulation thresholds, and final stimulation parameters for a particular date.

Refer to Table 4-5 for information about the functions of the buttons on the Stimulation History screen.

Table 4-5. 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 thresholds	Select the right or left arrow buttons in the thresholds section of the screen. Note: If arrow buttons are disabled, there are no additional thresholds to view.

Sensing History Screen

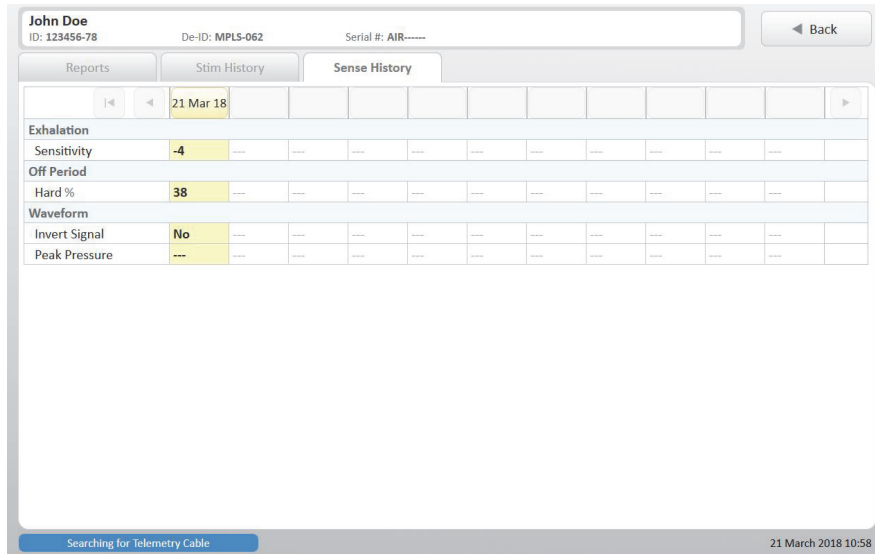


Figure 4-27. Sensing History Screen

The **Sense History** button on the Adjust Sensing screen and the Sense History tab on the Reports screen access the Sensing History screen (Figure 4-27). This screen displays a summary of the final sensing parameters for a particular date.

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

Table 4-6. 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 parameters that maintain airway patency.

IPG 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 IPG.

Implant Session Overview

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

Start Session

With the IPG still in its sterile box, follow the steps for “Turning On the Programmer” on page 15 and “Starting a Session” on page 18.

Enter Patient Details

The first time you connect to an IPG, the programmer displays the Patient Details screen before the Home screen. Use the on-screen keyboard to enter the patient information. See “Patient Details Screen” on page 37 for more information.

Check IPG Status

Verify that the IPG battery status is good. See Figure 4-7.

Record Functional Threshold

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

1. Select the **Record Thresholds** button on the Home screen.
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; observe the patient's tongue response. If a tongue response cannot be obtained at any amplitude, the stimulation lead may not be properly connected to the IPG or nerve.
4. Repeat steps 2 and 3 until the functional threshold is reached. If the electrode is correctly placed, the tongue will move distinctly forward when stimulated at the functional threshold.
5. Select the **Save** button next to the functional threshold to save the threshold amplitude value.
6. Select a description of the patient's tongue motion at the saved threshold amplitude.

Notes:

- The sensation threshold is not recorded during implant.
- See “Record Thresholds Screen” on page 39 for more information.

Assess Sensor Performance

After the sensing lead is connected to the IPG, complete the following steps to confirm sensor performance and correct lead–IPG connection:

1. Select the **Adjust Sensing** button on the Home screen.
2. Select the **Start Waveform** button to start the real-time waveform.
Note: If the IPG stimulation amplitude is 0 V, the programmer will automatically change the amplitude to 0.1 V.
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 IPG.
4. Select the **Screenshot** button to access the Screenshot screen and document the sensor performance.
 - a. Select “Anesthetized” under the Sleep Type labels. You may select any additional labels to apply to the screenshot.
 - b. Select the **Save** button to save the displayed waveform in the session report.
5. Select the **Turn Off** therapy button to stop stimulation and the real-time waveform.

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

See “Adjust Sensing Screen” on page 48 for more information.

End Session

Before ending the implant session:

1. Select the **Adjust Stimulation** button on the Home screen.
2. Change the amplitude value to 0V and select the **Configure IPG** button.
3. Confirm that therapy is turned off.
4. Select the **Exit** button on the Home screen.

Retain Records

Export a session report if desired. See “Exporting Reports” on page 70 for instructions.

Device Check

Device check goals are to review therapy status and to update stimulation parameters if necessary.

Device Check Overview

- Start Session
- Review Patient Therapy Status
- Record Thresholds
- Adjust Stimulation
- Check Waveform
- Review Session Data
- End Session
- Retain Records

Start Session

Follow the steps for “Turning On the Programmer” on page 15 and “Starting a Session” on page 18.

Recommended Settings for Therapy Activation

When activating therapy for the first time, ensure that the sensing settings are set to default parameters.

1. Select the **Adjust Sensing** button on the Home screen.
2. Use the **Select a Preset** button to select Default Parameters.
3. If the **Configure IPG** button turns blue, select the button to update the IPG settings.

Review Patient Therapy Status

Review the information displayed in the Patient 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 (see Figure 4-7 on page 33). Talk to the patient to assess how effectively the patient is using the therapy.

Record Thresholds

Before recording thresholds, confirm that the therapy is turned off. Complete the following steps once for each stimulation threshold:

1. Select the **Record Thresholds** button on the Home screen.
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; observe the patient's tongue response.
Note: Select the **Stim History** button to review previous session thresholds.
4. Repeat steps 2 and 3 until the threshold is reached.
5. Select the **Save** button next to the threshold to record the amplitude value.
6. Select a description of the patient's tongue motion at the saved threshold amplitude.
Note: The option to select a tongue motion is not available at the sensation threshold.

See “Record Thresholds Screen” on page 39 for more information.

Adjust Stimulation

To avoid confusion, it is recommended to turn off therapy when assessing new stimulation parameters during a device check.

1. Select the **Adjust Stimulation** button on the Home screen.
2. Select the **Test Stimulation** button to evaluate the patient's physical and sensory response to stimulation with the current parameters.
Note: If a therapeutic amplitude has not been identified yet, start with the functional threshold value.
Note: If patient control is enabled for the first time, start with the lower limit at the functional threshold and the upper limit set 1.0 V above the functional threshold.
Note: When enabling patient control, it is important to thoroughly train the patient on the operation of the patient remote.
3. If desired, use the arrow buttons to select new stimulation parameters. Test and adjust stimulation parameters until the desired stimulation settings have been identified.
Note: The **Select a Preset** button can be used to select the initial session, current IPG, or default values.
4. Select the desired stimulation parameters so they are displayed.
5. Select the **Configure IPG** button to replace the current IPG settings with the new parameters. The changes are automatically saved in the session report.
Note: If the **Configure IPG** button is not pressed before leaving this screen, the parameter changes will not be saved to the IPG.

If appropriate, therapy may be turned on to assess the performance of the new IPG settings. See “Adjust Stimulation Screen” on page 42 for more information.

Check Waveform

1. Select the **Adjust Sensing** button on the Home screen.
2. Ask the patient to lie down, close his or her eyes, and relax.
3. Select the **Start Waveform** button to start the real-time waveform.
Note: This will turn on the therapy and deliver stimulation based on the current IPG settings.
4. Review the waveform and note the direction of inhalation. If the patient's chest moves out when the signal moves up, then inhalation is up on the waveform.
5. Select the **Screenshot** button to annotate and save the displayed waveform in the session report.
6. Repeat steps 3–5 for each sleep position if desired.
Note: Do not adjust sensing parameters. It is recommended to do this only when the patient is asleep.
7. Select the **Turn Off** therapy button to stop stimulation and the real-time waveform.

See “Adjust Sensing Screen” on page 48 for more information.

Review Session Data

Return to the Home screen and confirm that the appropriate session actions were completed (Figure 5-1).

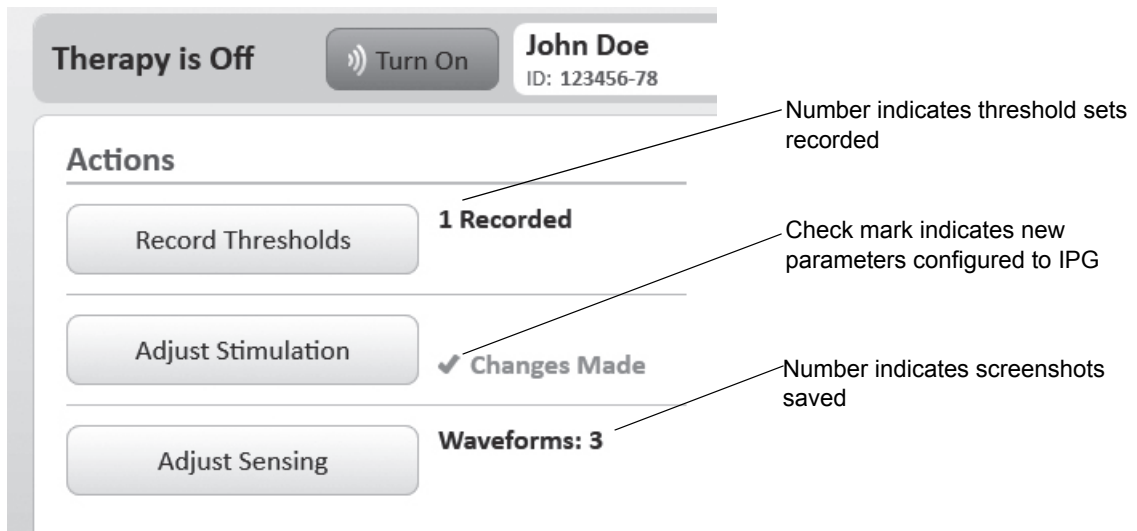


Figure 5-1. Completed Action Indicators

End Session

Select the **Exit** button on the Home screen.

Retain Records

See “Exporting Reports” on page 70 for instructions.

Sleep Study

The programming goals of a sleep study are to optimize stimulation and adjust sensing for a strong therapy response. A polysomnogram (PSG) is used to evaluate sleep quality.

Sleep Study Overview

- Perform Device Check
- Attach Telemetry Head
- Confirm Stimulation Artifact on Chin EMG
- Determine Inhalation and Exhalation on PSG
- Activate Therapy
- Adjust Stimulation
- Adjust Sensing
- Review Final Parameters
- End Session
- Retain Records

Perform Device Check

See “Device Check” on page 63 for instructions.

Attach Telemetry Head

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

1. Route telemetry cable over the patient's shoulder.
2. Select the **Test Telemetry** button from the Start screen.
3. Move telemetry head around IPG to locate best location for a good signal strength considering all sleep positions.
 - A green telemetry head status light indicates good signal strength.
 - An amber light indicates low signal strength.
 - Alternating green and amber lights indicate moderate or low signal strength.**Note:** See "Positioning Telemetry Head and Connecting to IPG" on page 22 for more information.
4. Affix telemetry head in optimal position.
5. Confirm telemetry signal strength in all sleep positions.

Confirm Stimulation Artifact on Chin EMG

Once PSG recording has started, deliver a test stimulation burst and confirm that the stimulation is visible on the chin or submental EMG signal (Figure 5-2).



Figure 5-2. Stimulation on Chin EMG

Determine Inhalation and Exhalation on PSG

During biocalibrations, identify the direction of inhalation on the PSG flow sensors. It is recommended to have both a nasal pressure cannula and a nasal/oral thermistor to reliably determine inhalation from exhalation during the sleep study.

Activate Therapy

Wait for the patient to fall asleep before activating therapy. Select the **Turn On** therapy button and then select the **Now** or **Delay** button from the Start Therapy screen (see Figure 4-2).

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.

Adjust Stimulation

Stimulation strength is adjusted to provide a patent airway without disturbing sleep. The ideal stimulation amplitude is typically above the functional threshold identified during the device check.

If therapeutic amplitudes have not been identified yet, start with an amplitude 0.2 V below the functional threshold.

The purpose of stimulation strength adjustment during a sleep study is to determine the therapeutic amplitude and range. The therapeutic range consists of the stimulation amplitudes that provide effective and comfortable therapy.

Use the following steps and Figure 5-3 to optimize airflow response to stimulation.

1. Select the **Adjust Stimulation** button on the Home screen.
2. If 5 or more obstructive events occur, increase the amplitude, observe the airflow response for at least 10 minutes, and reevaluate the effectiveness of the amplitude setting.
3. If the increased amplitude wakes the patient, turn therapy off, reduce the amplitude, and wait for the patient to fall back to sleep.

Note: Stimulation strength should not be increased to the point that it disturbs the patient's sleep.

4. Once the amplitude titration is complete, configure the final amplitude value that is both effective and comfortable. Update the patient amplitude control range to match the therapeutic amplitude range.

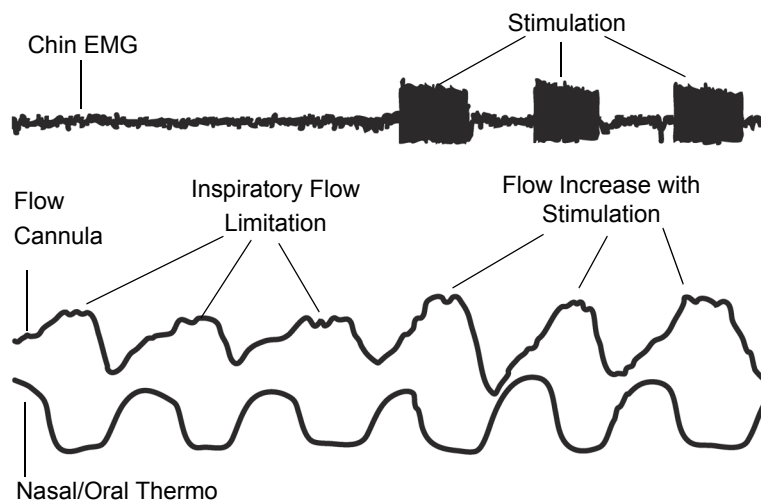


Figure 5-3. Airflow Responses to Stimulation

Adjust Sensing

Adjustments to sensing settings rarely are required when using the recommended settings. Contact your Inspire representative if sensing adjustments are required.

If therapeutic sensing parameters have not been identified, it is recommended to start with the default values.

Sensing is adjusted to deliver stimulation during the late expiratory and inspiratory portions of the respiratory cycle.

Adjust sensing parameters only when the patient is asleep, as the respiratory waveform is likely to be different when the patient is awake.

Do not adjust sensing immediately following patient position changes or changes to other therapy parameters. Wait for several minutes of steady sleep. If apneas or hypopneas are not occurring at a significant rate then adjustments typically do not need to be made. Avoid unnecessary adjustments and evaluate each change for a least 10 minutes before considering an additional change. Do not adjust sensing settings if stimulation adjustments may be effective.

1. Select the **Adjust Sensing** button on the Home screen.
2. The invert signal setting may be used if stimulation consistently occurs during exhalation (Figure 5-4).

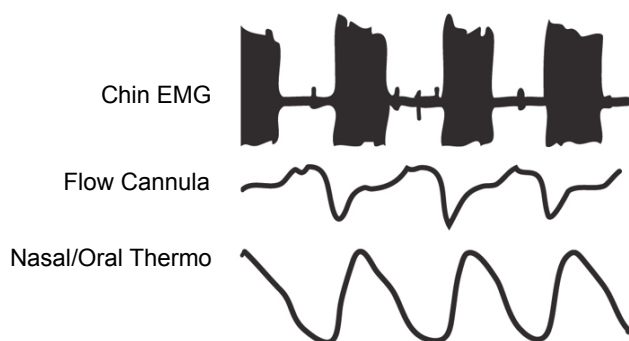


Figure 5-4. Inversion

3. The off period is used to control the time between stimulation bursts (Figure 5-5). Off period should be reduced if stimulation consistently starts late (Figure 5-6).

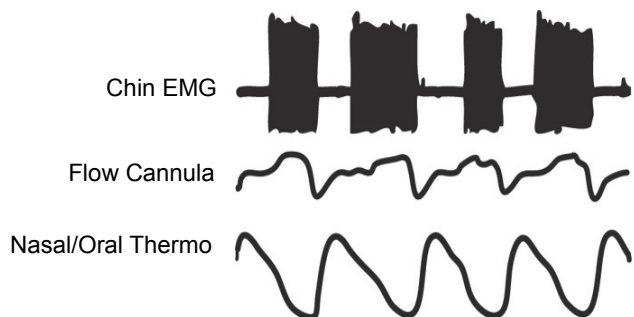


Figure 5-5. Good Stimulation Timing

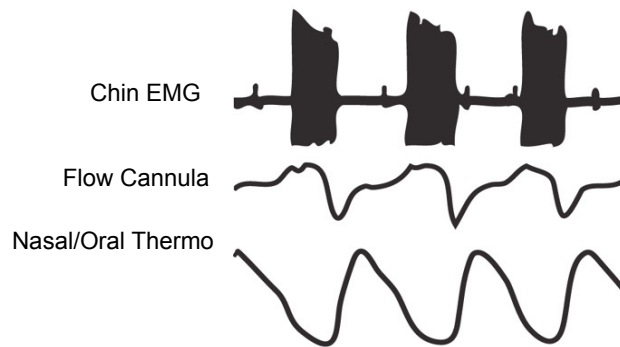


Figure 5-6. Stimulation Starting Late

4. Exhalation is used to adjust when stimulation is stopped. Exhalation sensitivity should be decreased if stimulation is stopping too often (Figure 5-7).

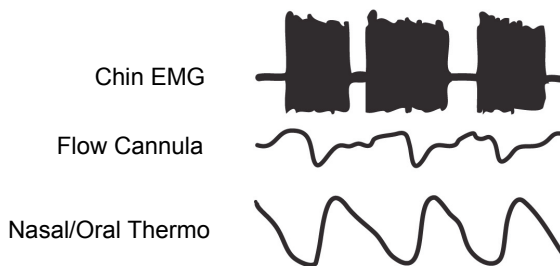


Figure 5-7. Missed Exhalation

5. Evaluate sensing settings in all relevant sleep positions.

Review Final Parameters

Return to the Home screen and confirm that the appropriate session actions were completed (see Figure 5-1). Review the session parameter changes to confirm the correct final values.

End Session

Select the **Exit** button on the Home screen.

Retain Records

See the following section for instructions.

Exporting Reports

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 parameters.
7. Select **Export** button to complete the export.

Notes:

- Session reports will be exported as PDF (portable document format) files.
- The programming log contains a CSV (comma separated value) file of all IPG parameter 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.

Telemetry

For problems commonly associated with telemetry connections, see “Telemetry Troubleshooting” on page 25. If those steps do not resolve the problem, review the following solutions.

Loss of Power to Telemetry Cable

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

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 telemetry 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 IPG and confirm the IPG settings.

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

1. Make sure tablet is within range of the telemetry cable.
2. Wait 60 seconds for the telemetry process to continue.
3. Tap the touchscreen. If this allows telemetry to proceed, continue tapping and restart the tablet at the earliest convenience.

Telemetry Cannot Find IPG

Refer to the steps described in “Telemetry Troubleshooting” on page 25. If those measures do not resolve the problem, the IPG battery may be depleted. Try the following:

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

Cannot Establish Connection to Telemetry Cable

If the telemetry cable status line in the screen footer always displays “searching for telemetry cable”:

1. Navigate to the Start screen.
2. Ensure that the telemetry cable is powered on.
3. Move tablet to within 1 m (3 ft) of the telemetry 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 telemetry cable.
7. Reconnect the telemetry 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.

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 and follow the instructions for deleting session reports in Table 4-4 on page 56.
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.

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 6-1 to locate these buttons if you cannot read the programmer screens.

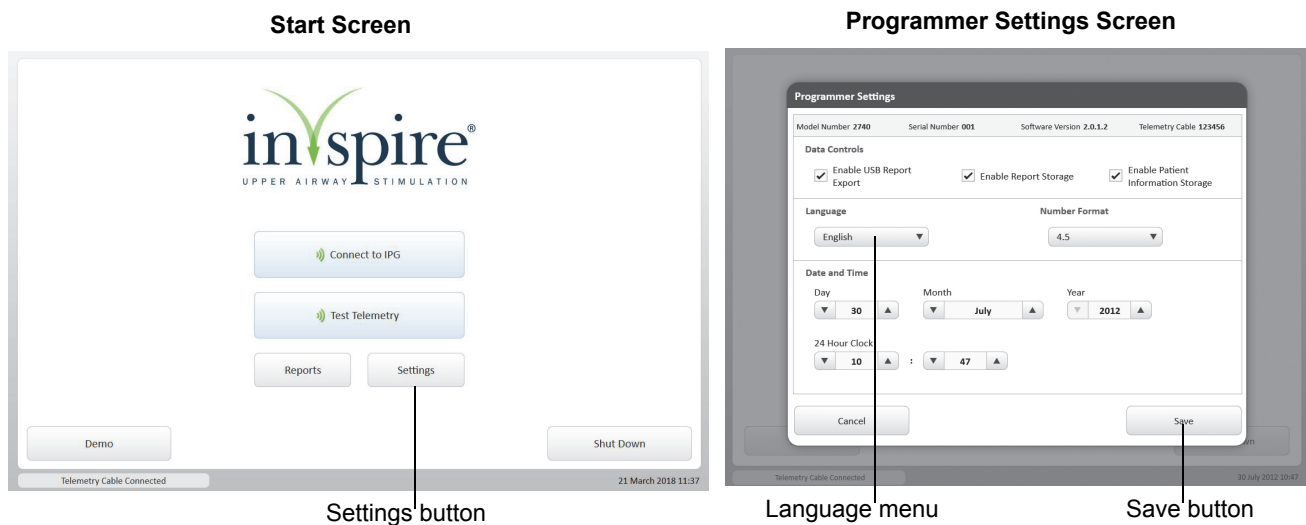


Figure 6-1. Change Language Buttons

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

IPG Reset

An IPG reset can occur in response to a low IPG battery or severe electromagnetic disturbance. The IPG serial number is cleared by the reset and must be reentered during the next programming session.

When prompted by the IPG reset screen,

1. Enter the numeric portion of the serial number, which can be found in the patient's medical records.
2. Select **Check** Serial Number.
 - a. If the patient information displayed is correct, select the **Configure IPG** button to configure the IPG with the entered serial number.
 - b. If the patient information is incorrect, enter the correct serial number, and select **Check** Serial Number. Confirm that patient information is correct and select the **Configure IPG** button.
3. If the serial number is unavailable, select **Cancel**. When prompted, select the IPG model and select the **Configure IPG** button. The IPG 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 parameters such as electrode configuration or threshold measurement parameters, select the check box that corresponds to the desired information on the Export Report screen (see Figure 4-25) and repeat the export.

Note: The option to include patient information, screenshots, and advanced parameters 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.

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 6-2. 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 IPG is in start delay or pause time, or the telemetry head is out of telemetry 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 telemetry head may not be properly positioned. Reposition the telemetry head directly over the IPG.

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

Reports

Report Data Display as “---”

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

If parameters 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 IPG underwent a reset, then the report may be stored under the serial number 000001 or 300000. See “IPG Reset” on page 74 for more information.

If you cannot locate a particular report and an IPG reset did not occur, the programmer may have run out of storage space. See “Storage Full Notification” on page 72 for more information.

Out-of-Range Impedances

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

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

Therapy

Parameter Changes Not in IPG

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

1. Return to the appropriate programming screen and repeat the desired parameter changes.
2. Push the **Configure IPG** button. If you leave a screen before pushing this button, the changes will not be saved to the IPG.
3. Review parameters on the Home screen before ending the session.
4. Always allow all telemetry communications to complete before a patient leaves. If a patient is allowed to leave during a test stimulation or impedance measurement, the IPG 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 IPG 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 parameters and properly end the programming session before the patient leaves. (See “Exiting a Session and Turning Off the Programmer” on page 26 for more information.)
- Never let a patient leave after a forced programmer shutdown until you reconnect to the IPG and confirm the IPG settings

Jerky or Halting Stimulation

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

1. Turn off therapy before testing stimulation or changing IPG parameters.
2. Reposition telemetry head to achieve stronger signal strength. (See “Positioning Telemetry Head and Connecting to IPG” on page 22 for instructions.)

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 IPG battery capacity can be measured using the programmer. Patients should schedule an appointment with their physician when the IPG battery status displays Low or Depleted. Depending on IPG battery settings and usage, the IPG 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.
- 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 telemetry head is in contact with the patient may induce currents into the device that may damage the device. It is recommended to remove the telemetry 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. If interference is suspected, use the Test Telemetry feature to evaluate telemetry performance.
- Do not open or attempt to service this product. Opening or servicing the system components can result in electric shock.

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 parameters, 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 telemetry cable according to your institutional policies 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 telemetry head and on the back of the tablet.

Contact Inspire Medical Systems for replacement parts.

Default Parameters

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

Table 8-1. Default Parameter Values

Parameter	Value
Amplitude	0.0 V
Electrode configuration	
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 μ s
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

^aAll measurements are approximate

Telemetry Cable

Table 8-3. Telemetry 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 (68°F–140°F) Humidity: RH 10–90% RH Air pressure: 187–1060 hPa (2.7–15.4 psi)
Telemetry cable power supply (Class II) Cincon M/N:TR30M090 (Type B applied part, Class II system) (UL agency approval under UL 60601-1)	Input: 100–240 VAC, 0.6–0.4 A, 47–63 Hz Output: 9 VDC, 3 A
Telemetry	175 kHz Short-range inductive link
Bluetooth	2.4 GHz ISM band
Ingress protection	IPX0
Mode of operation (continuous or non-continuous)	Continuous

^aAll 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 want 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, telemetry 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 telemetry cable. RF communications utilize the 2.4 to 2.485GHz ISM band and a combination of frequency and phase shift keying. Frequency-hopping spread spectrum is utilized to avoid interference with other devices. Effective radiated power from RF communications are less than 1mW.

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 telemetry 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.
Harmonic emissions EN 61000-3-2	Class A	<p>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.</p> <p>Warning: This system is intended for use by health care professionals only.</p>
Voltage fluctuations/flicker emissions EN 61000-3-3	Complies	

Table 8-5. Electromagnetic Immunity

<p>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.</p>			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
<p>Electrostatic discharge (ESD): EN/IEC 61000-4-2</p>	<p>+/-8 kV contact +/-15 kV air</p>	<p>+/-8 kV contact +/-15 kV air</p>	<p>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</p> <p>Electrostatic discharge may result in a temporary loss of function, requiring the user to restart the programmer.</p>
<p>Electrical fast transient/burst: EN/IEC 61000-4-4</p>	<p>±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</p>	<p>±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</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p> <p>Electrical fast transients or bursts in mains power may result in temporary loss of function.</p>
<p>Surge: EN/IEC 61000-4-5</p>	<p>+/-0.5 kV, +/-1 kV line-to-line +/-0.5 kV, +/-1 kV, +/-2 kV line-to-ground</p>	<p>+/-0.5 kV, +/-1 kV line-to-line +/-0.5 kV, +/-1 kV, +/-2 kV line-to-ground</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>

Table 8-5. Electromagnetic Immunity

<p>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.</p>			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
<p>Voltage dips, short interruptions and voltage variations on power supply input lines: EN/IEC 61000-4-11</p>	<p>40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <u>Voltage Dips</u> 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° <u>Voltage Interruptions</u> 0% UT; 250/300 cycle</p>	<p>40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <u>Voltage Dips</u> 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° <u>Voltage Interruptions</u> 0% UT; 250/300 cycle</p>	<p>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 telemetry cable requires uninterrupted mains power to operate.</p> <p>Interruptions in mains power may result in temporary loss of function.</p>
<p>Note: UT is the A.C. mains voltage prior to application of the test level.</p>			

Table 8-6. Guidance and Manufacturer's Declaration – 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
Conducted RF EN/IEC 61000-4-6	6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$
Radiated RF EN/IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz
Power frequency magnetic field: EN/IEC 61000-4-8	30 A/m	30 A/m	$d = 2,3\sqrt{P}$ 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 .

Table 8-6. Guidance and Manufacturer’s Declaration – Electromagnetic Immunity


<p>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.</p>			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>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.</p>			
<p>^aField 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.</p> <p>^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

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

<p>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.</p>			
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
<p>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.</p> <p>Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

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.

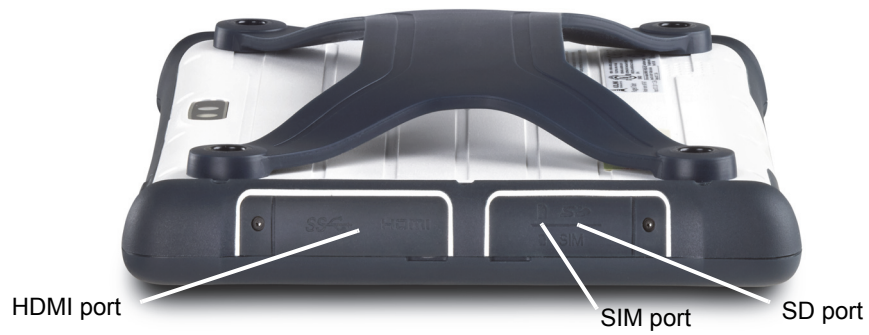


Figure 8-2. Unused Tablet Features, Right Side

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 Implantable Pulse Generators (IPG), tools to connect the IPG 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 IPG, 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 IPG in less than the warranty period shown below. This is considered normal for those patients and not a malfunction or defect in the IPG.

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 IPG 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, IPG, 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 an IPG 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 an IPG or lead is implanted in the patient.
2. Two (2) years from the date a physician programmer or Inspire Sleep Remote is first used.



Manufacturer

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