Inspire
Sleep Apnea Innovation

PROGRAMMER MANUAL

Programmer Model 2740

!USA Rx Only

Table of Contents

Explanation of Symbols on Package Labeling and Device

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

⚠	Caution, consult accompanying documents
📖	Consult instructions for use
NON STERILE	Nonsterile
	Fragile
	Keep dry
SN	Serial number
	Temperature limitation
	Atmospheric pressure limitation
%	Relative humidity limitation
FC	Federal Communications Commission notice (USA)
!USA	For US audiences only
	Manufacturer
	Product complies with 2002/96/EC
(((•)))	Non-ionizing electromagnetic radiation

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Explanation of Symbols

Wireless radio-frequency communications

Radio-frequency communications interface module (Bluetooth)

Canada ICES-003, Class/Classe B | Canada interference-causing equipment standard #3 Class B device

$C\,E$
2797
2010

Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive 90/385/EEC.

$C\,E$

Conformité Européne; compliance to EMC Directive and Low Voltage Directive of the European Union
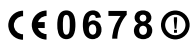
$C\,E\,0678$! | Compliance with R&TTE Directive 1999/5/EC for radio-frequency devices

EU | REP | European authorized representative

Compliance with Australia and New Zealand Telecommunications (A-Tick symbol)2

Compliance with Underwriters Laboratories for general product safety in accordance with UL 60950-1 (ITE) and CAN/CSA C22.2 No. 60950-1 (ITE)

MET Laboratories certified in compliance with UL 60950-1 and CSA C22.2 No. 60950-1

Compliance with TUV for general product safety in accordance with IEC/EN 60950-1 (ITE)

RoHS
COMPLIANT
2002/95/EC

Compliance with the restrictions of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2006 (RoHS)

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☑ RoHS	Compliance with the restrictions of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2006 (RoHS)
✔	Compliance with the restrictions of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2006 (RoHS)
🔋	Battery status
⏻	Power button
◯	Function button (unused)
▣	Dashboard button (unused)
Ⓐ	Custom action "A" bottom (unused)
Ⓑ	Custom action "B" button (unused)
⚷	Security button (unused)
RFID ((●))	RFID antenna area (unused)
📷	Camera button (unused)
RFID	RFID code scanner button (unused)

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4 | Explanation of Symbols

Symbol	Description
	Bar code scanner button (unused)
	Type B Applied part protection against electrical shock
	Windows® button (unused)
	Volume increase button (unused)
	Volume decrease button (unused)
	Dangerous voltage
	Output connector polarity
	Class II double insulated
	Canadian Electric Code (CEC) Level IV compliant
	UL recognized component mark
	Indoor use only
	TUV/T-Mark for IEC/EN 60601-1 Compliance
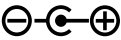
(Hg)   Lamps contain mercury

IPXO   Degree of ingress protection per EN60529

(MR)   The Inspire therapy system is MR unsafe

Explanation of Symbols

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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.

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Therapy Overview 1

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

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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.
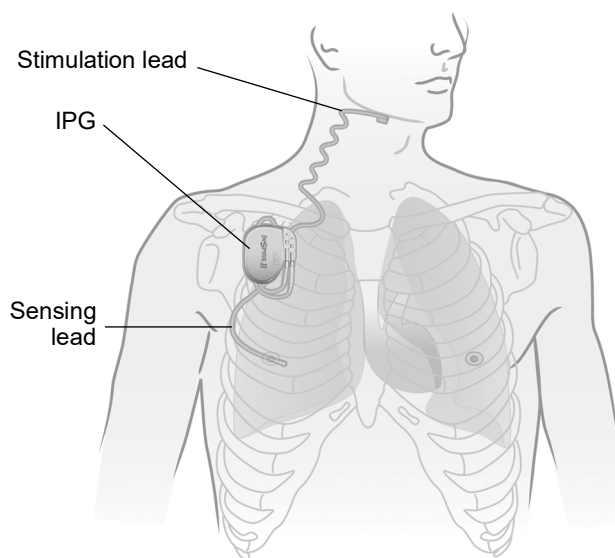
Figure 1-1. Inspire System Implanted Components

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 65), Adjust Stimulation screen (page 68), or Adjust Sensing screen (page 77), 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.
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.

Table 1-1. General Therapy Terms

Term	Definition
IPG	Inspire implantable pulse generator.
IPG battery status	The current state of the IPG battery. If the battery status is Low, schedule an IPG replacement procedure. If the battery status is Depleted, the therapy delivered by the IPG may not be within specification.
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.
Sub-discomfort threshold	The highest stimulation amplitude that is comfortable for the patient while awake.
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 inspiration 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	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. **Note:** This is an advanced parameter.

Table 1-3. Sensing Parameter Terms

Term	Definition
Inhalation	The start of inspiration 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	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. **Note:** This is an advanced parameter.
Inhalation threshold	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. **Note:** This is an advanced parameter.
Invert signal	A feature that switches the polarity of the sensor signal before the IPG processes it for inhalations and exhalations. This feature could be used to correct a situation in which stimulation is being delivered during exhalation instead of inhalation.
Maximum stimulation time	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. **Note:** This is an advanced parameter.

Table 1-3. Sensing Parameter Terms

Term	Definition
Off period (Hard)	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.
Off period (Soft)	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. **Note:** This is an advanced parameter.
Respiratory period	The IPG measures the respiratory period from exhalation to exhalation. The respiratory period is used for the calculation of the off period.

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 74 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.
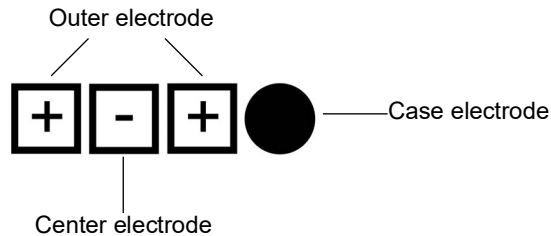
Figure 1-2. Default Electrode Configuration

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

Programmer Components

2

This chapter describes the programmer components and accessories.

Package Contents   22

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Package Contents

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

- Tablet
  - Handheld computer
  - Stylus for screen input
  - Inspire programmer software
  - Medical-grade power supply, three-prong power cord, and power supply storage bag
- Telemetry cable
  - Telemetry head
  - Bluetooth wireless communications interface
  - Medical-grade power supply, two-prong power cord, power supply storage bag, and telemetry cable storage bag
- Data backup kit

  Note: Based on programmer configuration, the contents of the data backup kit can vary.

  - Inspire universal serial bus (USB) flash drive
  - Tablet USB connection module (not included in all configurations)
  - Wireless printer adapter (USB module) (not included in all configurations)
  - Data backup kit storage bag
- Portability kit
  - Inspire roller bag
  - Luggage tag

Tablet

The tablet screen is controlled by the user with the attached stylus. 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. A dock for USB connection module (not included in all configurations) is located on the bottom of the tablet. The status lights and docking connector are described in Table 2-1 and Table 2-2. Unused controls are listed in Chapter 8.
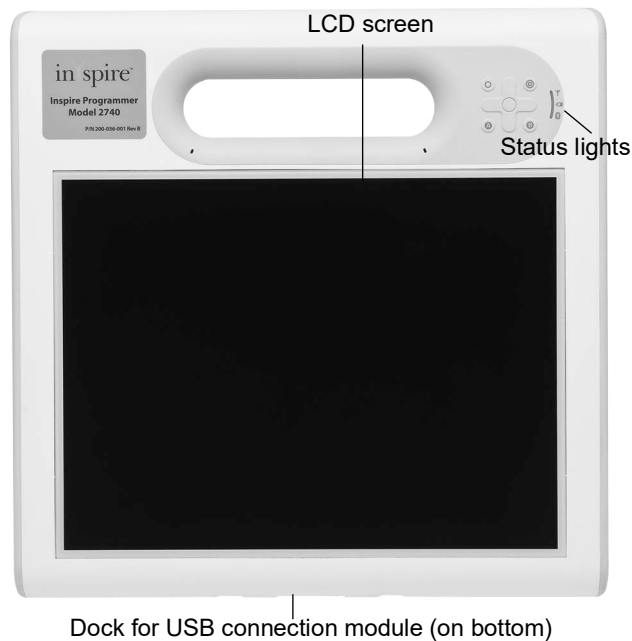
Figure 2-1. Tablet Front and Bottom

Table 2-1. Tablet Front
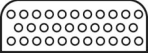
Icon/Item	Description	Function
	Status lights	WIFI (unused), not included on all tablets Programmer battery Wireless telemetry, not included on all tablets
	Docking connector (front bottom, not shown)	Interface connector for use with USB connection module

Table 2-2. Tablet Status Lights

Light	Status	Description
Programmer battery	Steady amber	Battery is charging
	Steady green	Battery is fully charged
	Flashing amber	< 10% battery charge remains
Wireless communication (not included on all tablets)	Steady green	Wireless communications between tablet and telemetry cable are enabled

Tablet Right Side

The right side of the tablet (Figure 2-2) contains the power adapter port and power button (described in Table 2-3). Unused controls are listed in Chapter 8.

Power adaptor port, USB port (not included in all configurations), and cover

Power button

Figure 2-2. Tablet Right Side

Table 2-3. Tablet Right Side

Icon/Item	Description	Function
	Power adapter port, USB port (not included in all configurations), and cover	Connects the tablet power supply and connects to USB flash drive for tablets supporting the USB port
	Power button	Turns the system on **Note:** Use the on-screen controls rather than this button to turn the programmer off

Tablet Back

The back of the tablet (Figure 2-3) has storage for the stylus and provides access to the battery. The functions of the controls on the back of the tablet are described in Table 2-4.
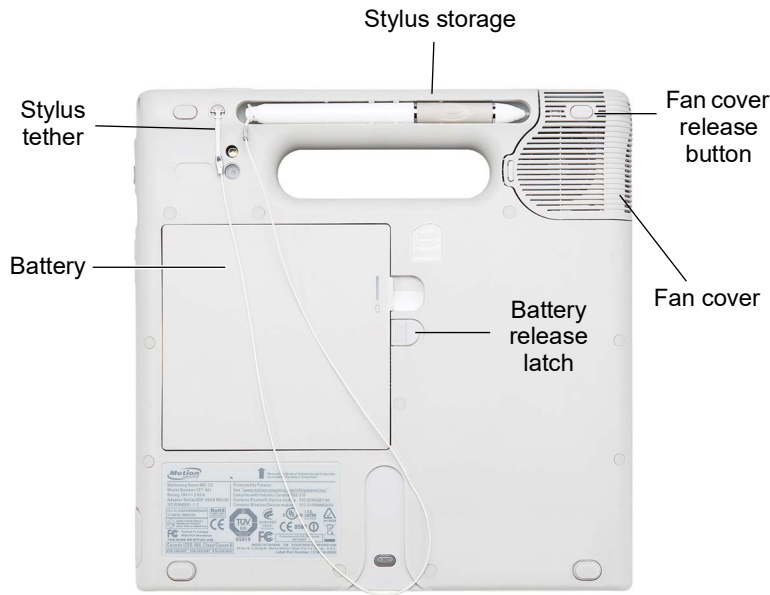
Figure 2-3. Tablet Back

Table 2-4. Tablet Back

Description	Function
Stylus tether	Attaches the stylus to the tablet
Stylus storage	Stores the stylus when not in use
Fan cover	Protects the fan assembly
Battery	Powers the system when it is not plugged in

See "Using the Stylus" on page 41 and the stylus
troubleshooting guide on page 121 for more information about
operating the stylus.

Tablet Battery

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

For information about battery status indicators and charging the battery, see "Checking Battery Status" and "Charging Battery" on page 34.

> **Warning:** To avoid personal injury, handle the battery with care. Do not open, puncture, short, or expose it to fire or water. Keep the battery in an environment with ambient temperature between -20°C and 60°C (4°F and 140°F). For example, do not leave the battery in a closed car in hot weather for an extended period of time.

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 2-4).

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).

Telemetry head

Wireless communication module

Power supply connector
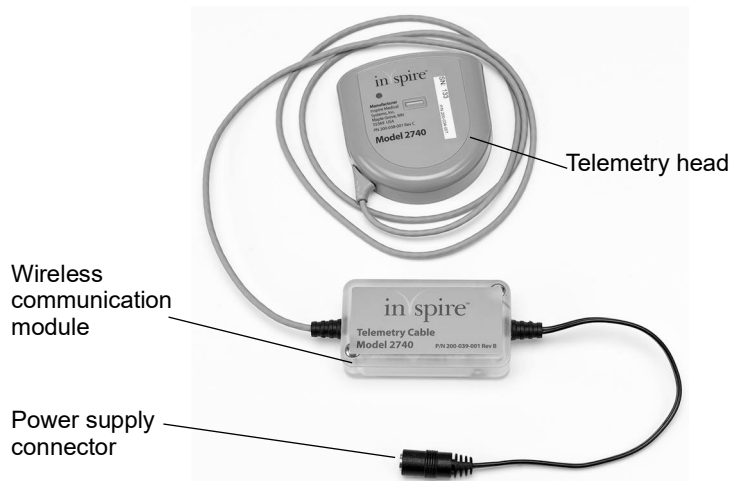
Figure 2-4. Telemetry Cable

Data Backup Kit

The data backup kit allows the user to download and back up session reports. The backup system consists of an Inspire system branded universal serial bus (USB) flash drive, and may also include a printer adapter and USB connection module (Figure 2-5).

USB connection module (not included in all configurations)

USB flash drive

Printer adapter (not included in all configurations)

Figure 2-5. Data Backup Kit

Portability Kit

The portability kit provides a convenient way to safely transport the programmer. The portability kit consists of a roller bag and a luggage tag for your contact information (Figure 2-6).

Figure 2-6. Portability Kit

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Getting Started

<div style="text-align: right">**3**</div>

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

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Turning On the Programmer

This section describes how to turn on the programer. 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.

Checking Battery Status

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

- Steady amber — The battery is charging
- Steady green — The battery is fully charged
- Flashing amber — < 10% battery charge remaining

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.

To avoid injury, keep the battery within the recommended temperature range. Never expose the battery to temperatures above 60°C (140°F) when charging. 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 three-prong end of 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).
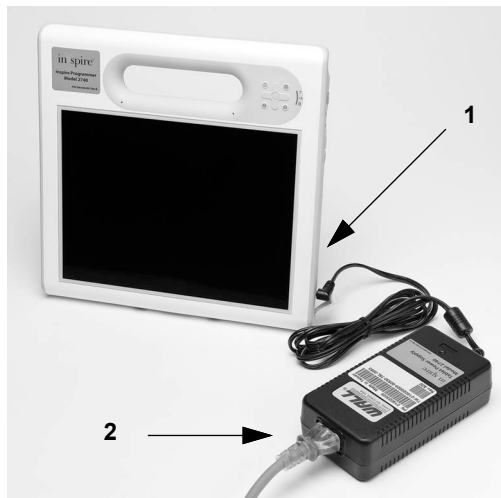
Figure 3-1. Tablet Power Supply Connections

Powering On Tablet

Press and hold the power button on the side of the tablet (Figure 3-2) until the power button is illuminated. Once the tablet powers on and the software loads, the Start screen displays.
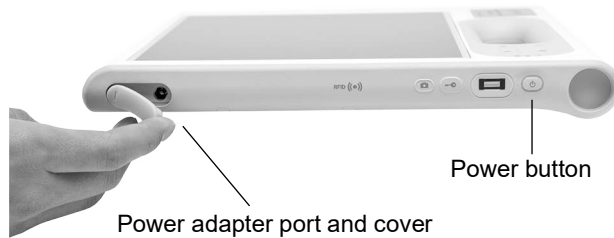
Figure 3-2. Tablet Power Button and Power Adapter Port

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.
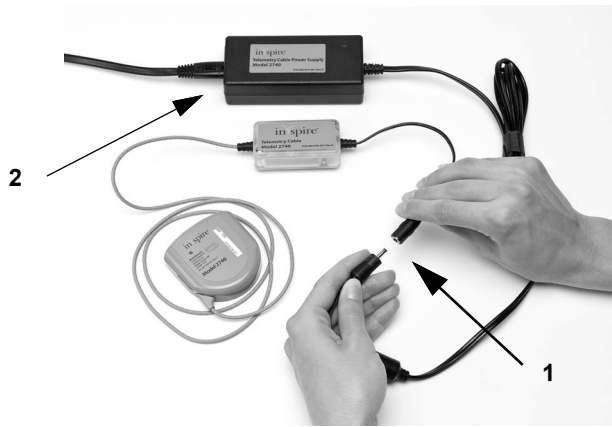
Figure 3-3. Telemetry Cable Power Supply Connections

Starting a Session

Navigating the Start Screen

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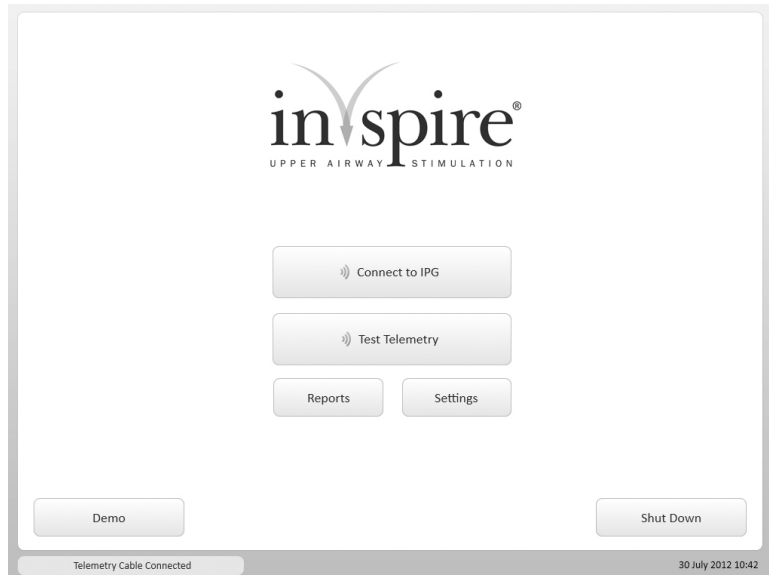
Figure 3-4. Start Screen

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

Table 3-1. Start Screen Button Descriptions

Button	Description
Connect to IPG	- 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	- 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	- Accesses reports for previous programming sessions - Reports can be reviewed and exported
Settings	- Accesses the Programmer Settings screen; allows access to data management controls and adjustments to date and time, language, and number format
Demo	- Starts a practice programming session - Makes it possible to practice using the programmer with a simulated IPG when no patient is present
Shut Down	- 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).

Telemetry cable status   Current date and time

Programmer battery
status appears here
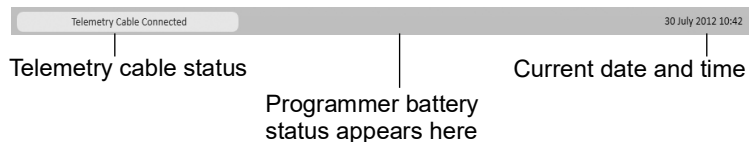
Figure 3-5. Start Screen Footer Information

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.
- Battery Disconnected — The programmer battery has been removed, and the programmer is being powered by an electrical outlet via the power supply cord.

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 Stylus

Remove the stylus from its storage bay on the back of the tablet (see Figure 2-3 for location of stylus).

To select a programming button, gently touch the displayed buttons on the tablet screen with the tip of the stylus (Figure 3-6). The cursor moves with the stylus, and the buttons are highlighted when the stylus hovers over or selects a button.

> **Note:** Both ends of the stylus will operate the tablet screen.

Figure 3-6. Select Programming Buttons on Screen with Stylus

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.

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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 40 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 2-4).

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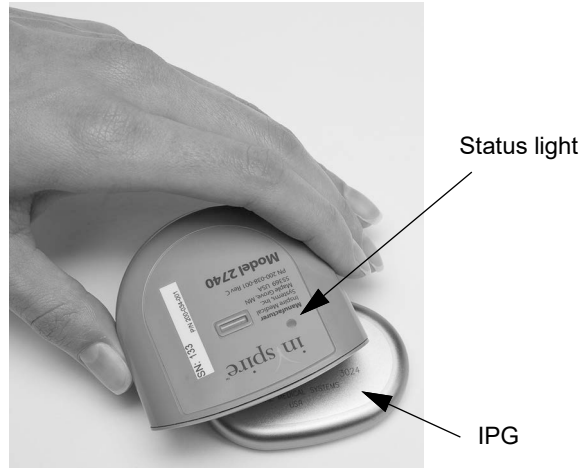
Figure 3-7. Correct Positioning of Telemetry Head over IPG

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	Confirm that the tablet is on
	Electrical interference is interrupting telemetry	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 recommend 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. A green status light indicates that the battery 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.

Screen Descriptions

4

This chapter provides descriptions of the programmer screens.

Programmer Model 2740

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
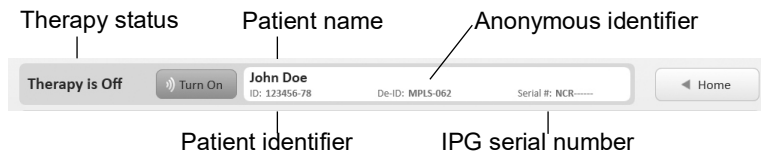
Figure 4-1. Common Information in Screen Header

- 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 that 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):
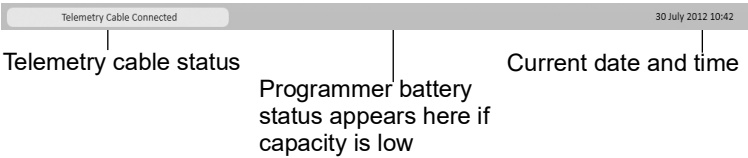
Figure 4-3. Common Information in Screen Footer

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.
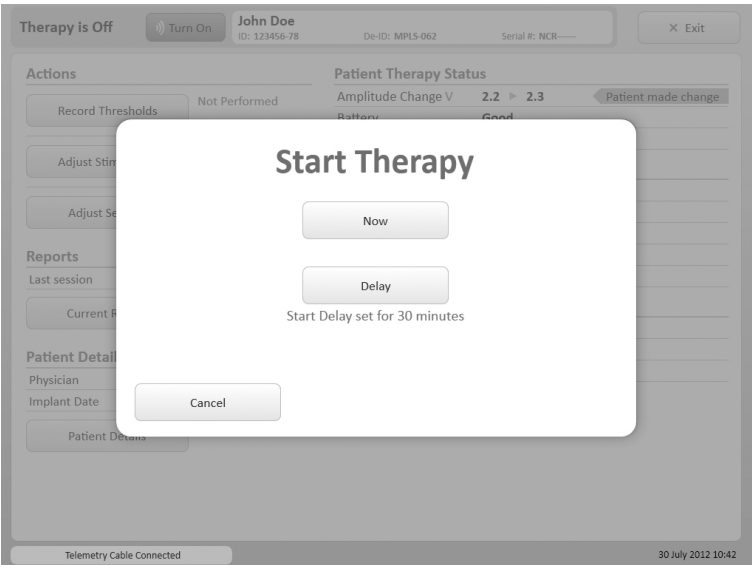- Searching for Telemetry Cable — Wireless link between tablet and telemetry cable is not established. Status background color is blue. Wireless communication module LED is flashing. Telemetry buttons are disabled.
- Demo Mode — Wireless link between tablet and telemetry cable is not active, but programmer 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.
- Battery Disconnected — The programmer battery has been removed, and the programmer is being powered by an electrical outlet via the power supply cord.

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.
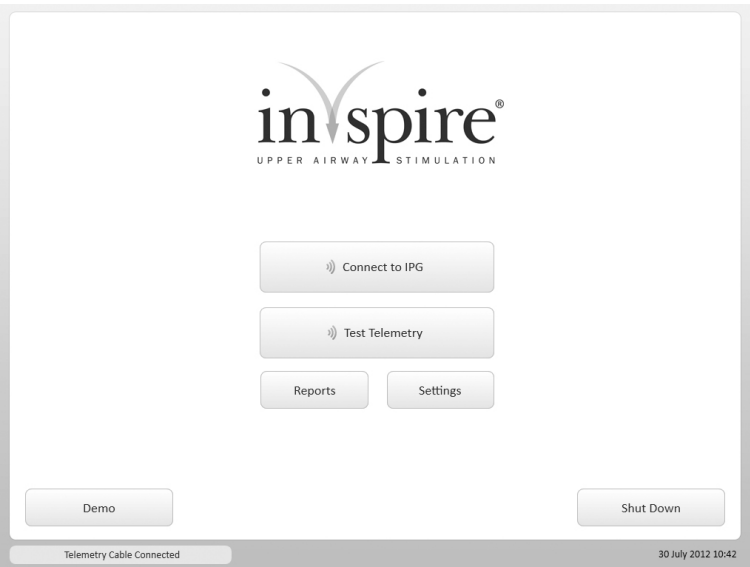
Start Screen

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	- 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	- 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	- Accesses reports for previous programming sessions - Reports can be reviewed and exported
Settings	- Accesses the Programmer Settings screen. - Allows access to data management controls and adjustments to date and time, language, and number format
Demo	- Starts a practice programming session - Makes it possible to practice using the programmer with a simulated IPG when a patient is not present
Shut Down	- Powers off the tablet

Programmer Settings Screen
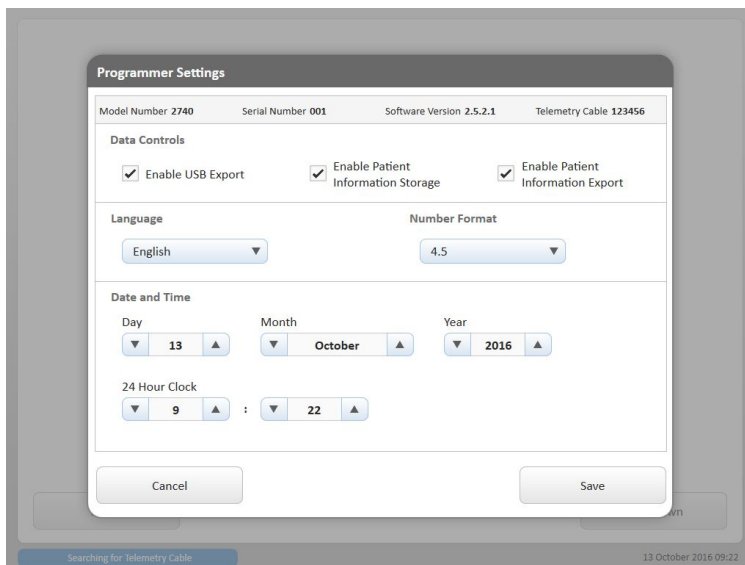
Figure 4-5. Programmer Settings Screen

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 41 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.

Last session value   Patient-selected value   Change flag

Patient Therapy Status		
Amplitude Change V	**2.2** ▶ **2.3**	Patient made change
Battery	**Good**	
Usage h	**948** (36 hours per week)	
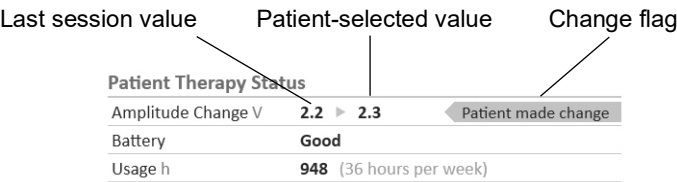
Figure 4-7. Patient Therapy Status

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 65 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 68 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 77 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. Actions 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 14 and Table 1-3 on page 15 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

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 86).

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

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

Three 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.
- Sub-discomfort — The highest amplitude that is comfortable for the patient while awake.

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 145 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 14 for definitions of these terms, and see "Electrode Configuration" on page 74 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 on page 14 for definitions of these terms.
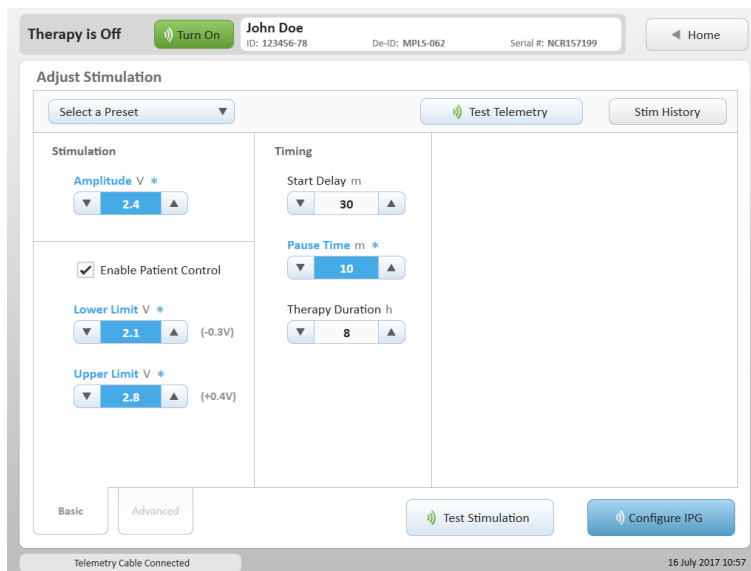
Figure 4-14. Changed Parameters on Adjust Stimulation Screen

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 145 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
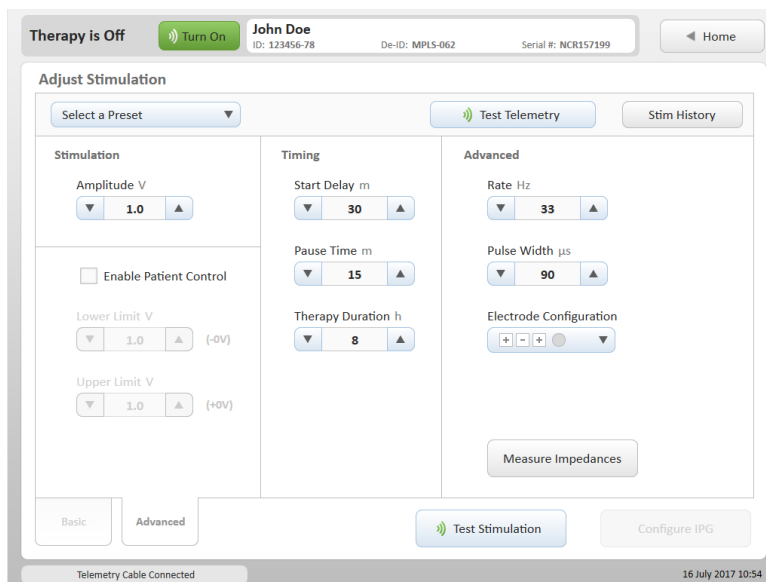
Figure 4-15. Adjust Stimulation Screen, Advanced View

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 14 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).
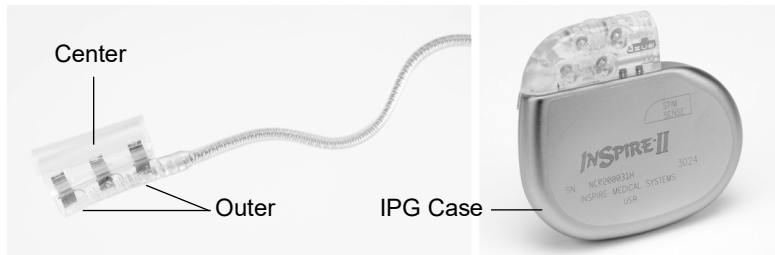
Figure 4-16. Inspire System Electrodes

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.
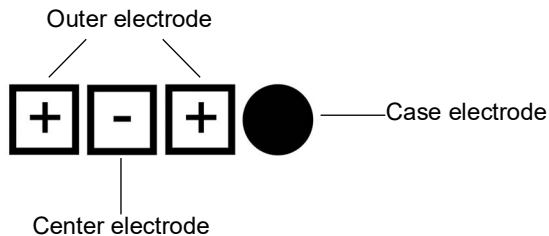
Figure 4-17. Default Electrode Configuration

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 18 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.
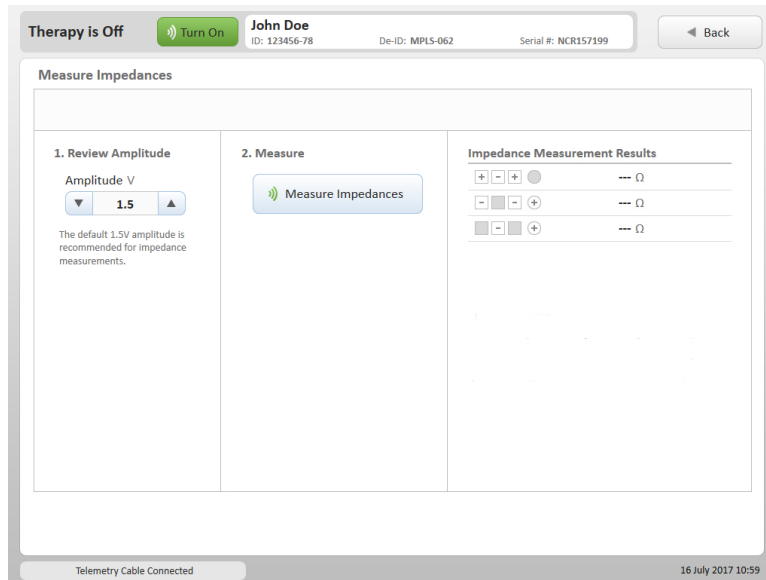
Figure 4-18. Measure Impedances Screen

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 outside the range of 200–7000 ohms may indicate a problem:

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

– A measured impedance > 7000 ohms may indicate an open circuit, 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 greater than 2000 ohms are outside the IPG measurement range and 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.
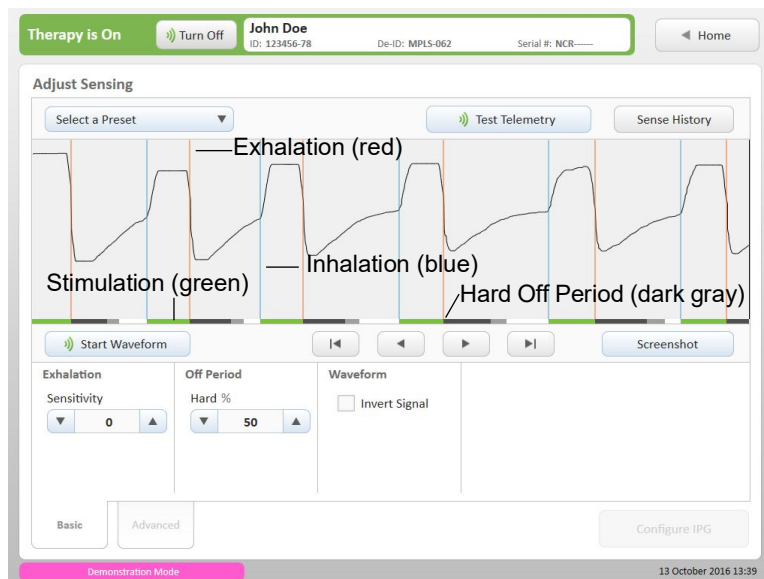
Figure 4-19. Adjust Sensing Screen, Basic View

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 15 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.
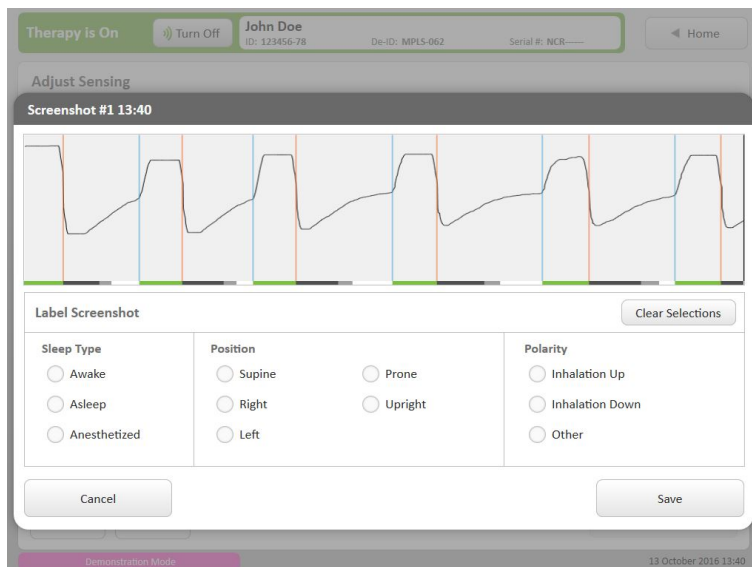
Figure 4-20. Screenshot Screen

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 145 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.

Patient Name	Patient ID	De-ID	Last session ▲	Serial #
Mohandas Gandhi	531	PRB-069	25 December 2014	NCR200012
George Washington	642	VIR-021	25 November 2014	NCR200011
Leonardo Pisano Bigollo	12358	13-21-34	25 October 2014	NCR200010
William Shakespeare	321	LON-016	25 September 2014	NCR200009
Blaise Pascal	654	PAR-012	25 August 2014	NCR200008
Ludwig van Beethoven	987	BON-001	25 July 2014	NCR200007
Alfred Nobel	248	STK-001	25 June 2014	NCR200006
Miguel de Cervantes	135	ADH-001	25 May 2014	NCR200005
Isaac Newton	246	LNC-001	25 April 2014	NCR200004
Leonardo da Vinci	789	VNC-001	25 March 2014	NCR200003
Rene Descartes	456	IEL-001	25 February 2014	NCR200002
Albert Einstein	123	Wurt-001	25 January 2014	NCR200001
Socrates	469399	XYZ789	30 July 2012	NCR200019
Julia Child	19122004	97531	30 July 2012	NCR200017
Erwin Schrodinger	1935	123ABC	30 July 2012	NCR200013

Select a Patient · Back

Delete... · Export... · View Patient

Telemetry Cable Connected · 30 July 2012 15:42

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). - 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 data backup kit to the tablet. - 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, advanced parameters, and programming log. - 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.
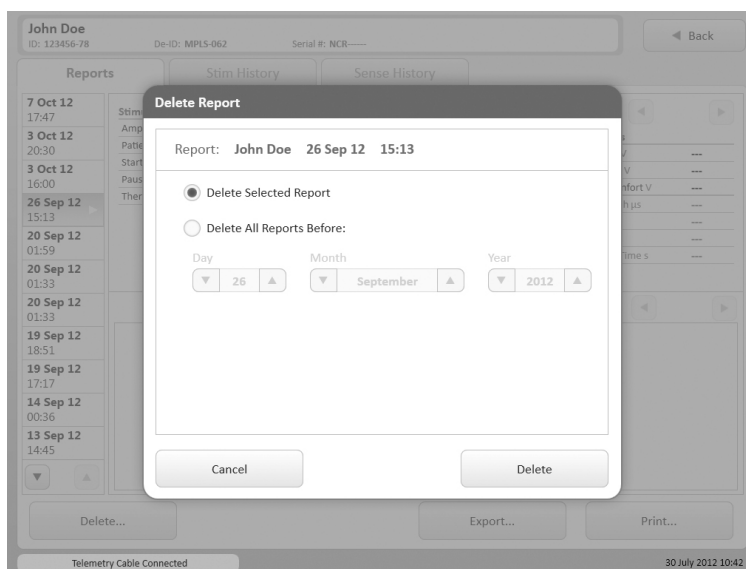
Figure 4-23. Delete Report Screen
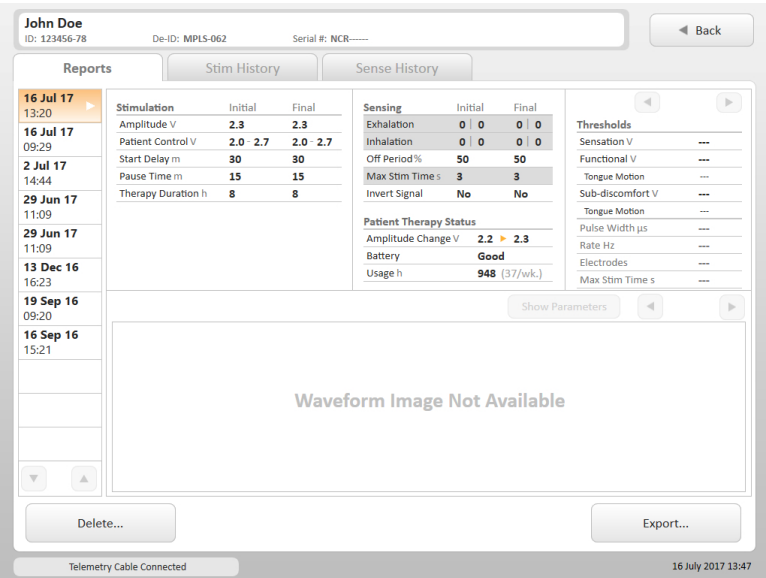
Reports Screen

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

To:	Do This:
Delete a session report	Highlight report and select the **Delete** button to display the Delete Report screen (Figure 4-23). ▫ 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).

Table 4-4. Reports Screen Buttons

To:	Do This:
Export session report to external USB flash drive	Attach the data backup kit to the tablet.
	◦ 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, advanced parameters, and programming log.
	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.
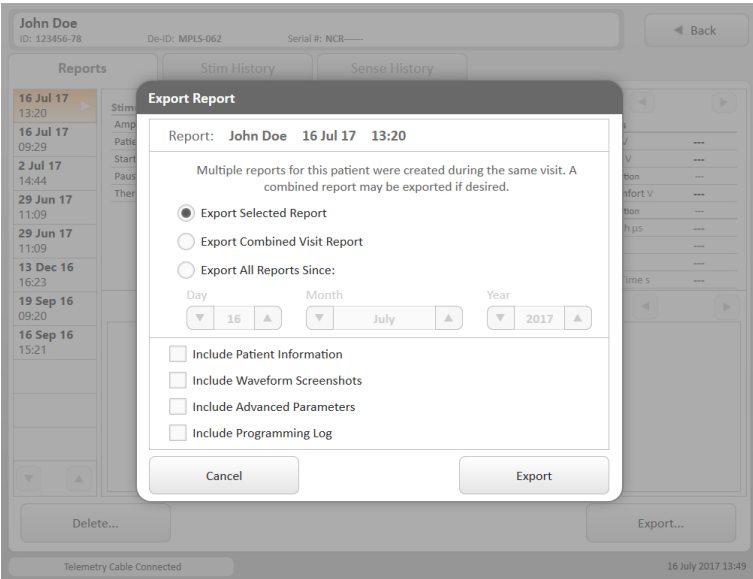
Figure 4-25. Export Report Screen

Stimulation History Screen
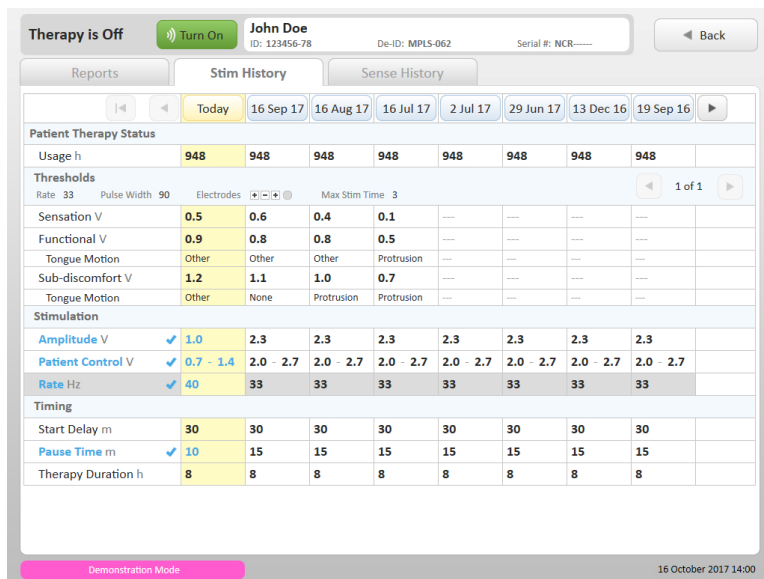
Figure 4-26. Stimulation History Screen

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.

Note: If viewing stim history for reports that were created with a version of the software prior to 2.5, the usage data will not display. Refer to the Reports screen for usage data.

Sensing History Screen

John Doe								
ID: 123456-78		De-ID: MPLS-062		Serial #: NCR------				◀ Back

		2 Mar 13	12 Aug 12	10 Feb 12	5 Aug 11	17 Jan 11	19 Jul 10		
Exhalation									
Sensitivity		0	+1	0	+1	0	+1	---	---
Threshold		0	0	0	+1	0	0	---	---
Off Period									
Hard %		50	63	50	50	50	50	---	---
Soft %		13	25	25	13	13	13	---	---
Waveform									
Invert Signal		No	No	No	No	No	No	---	---
Peak Pressure		---	---	---	---	---	---	---	---
Stimulation									
Max Stim Time s	✔	4	4	3	4	3	3	---	---

Searching for Telemetry Cable	2 March 2013 10:40

Figure 4-27. Sensing History Screen

The **Sense History** button on the Adjust Sensing screen and the Stim 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 Stimulation 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.

Note: If viewing sense history for reports that were created with a version of the software prior to 2.5, the pressure data will not display. Refer to exported reports for pressure data.

Clinical Programming Sessions

5

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

Programmer Model 2740

Sleep Study   106

Exporting Reports   113

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 34 and "Starting a Session" on page 38.

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 62 for more information.

Check IPG Status

Verify that the IPG battery status is good. See "Checking Battery Status" on page 34 for more information.

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:

- Sensation and sub-discomfort thresholds are not recorded during implant
- See "Record Thresholds Screen" on page 65 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 inspiration and expiration. 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 77 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 113 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 34 and "Starting a Session" on page 38.

Recommended Settings for Therapy Activation

When activating therapy for the first time, modify the sensing settings to match the following:

- Exhalation Sensitivity: -4
- Exhalation Threshold: -1
- Hard Off Period: 38
- Inhalation Threshold: +1

1. Select the **Adjust Sensing** button on the Home screen.
2. Select the Advanced tab at the bottom of the screen.
3. Decrease the Exhalation Sensitivity value to -4 and Exhalation Threshold value to -1.
4. Decrease the Hard Off Period value to 38.
5. Increase the Inhalation Threshold value to +1.

6. Select the **Configure IPG** button to update the IPG settings.

7. Return to the Home screen.

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 58). 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 (sensation, functional, and sub-discomfort (optional)):

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 65 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 68 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 inspiration. If the patient's chest moves out when the signal moves up, then inspiration 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 77 for more information.

Review Session Data

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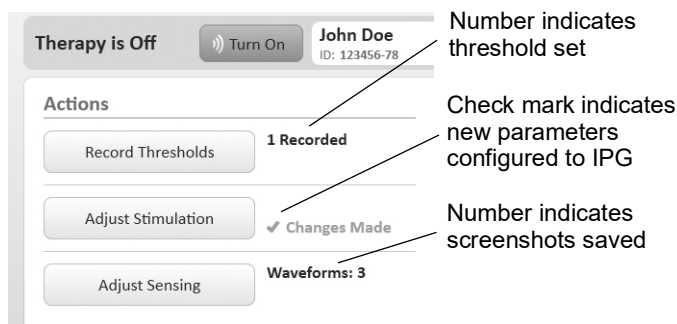
Figure 5-1. Completed Action Indicators

End Session

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

Retain Records

See "Exporting Reports" on page 113 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 Inspiration and Expiration on PSG
- Activate Therapy
- Adjust Stimulation
- Adjust Sensing
- Review Final Parameters
- End Session
- Retain Records

Perform Device Check

See "Device Check" on page 101 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 43 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 inspiration on the PSG flow sensors. It is recommended to have both a nasal pressure cannula and a nasal/oral thermistor to reliably determine inspiration from expiration 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.
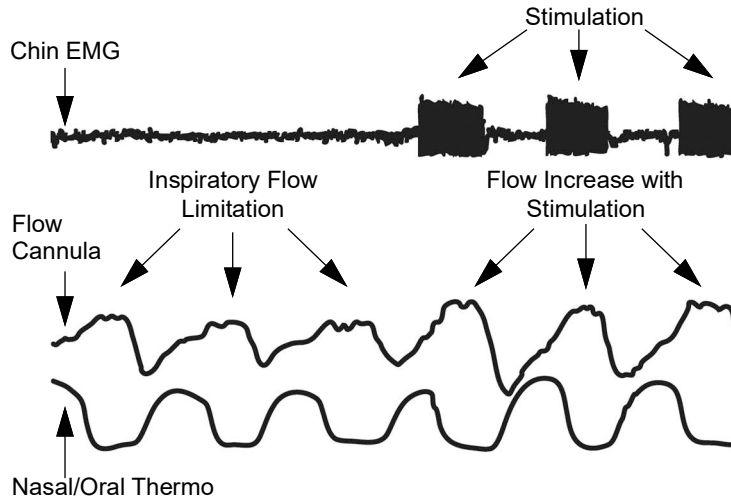
Figure 5-3. Airflow Responses to Stimulation

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 minimum expiration, minimum off period, and maximum inspiration 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 expiration (Figure 5-4).
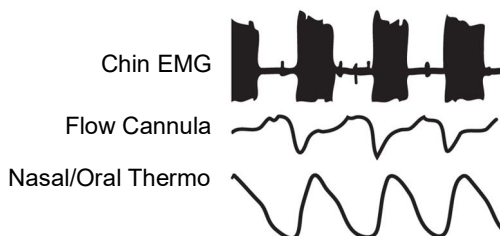
Figure 5-4. Inversion

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).
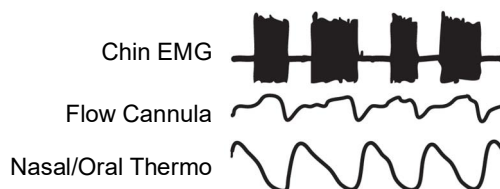
Figure 5-5. Good Stimulation Timing
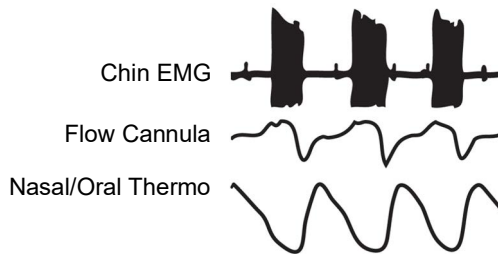
Figure 5-6. Stimulation Starting Late

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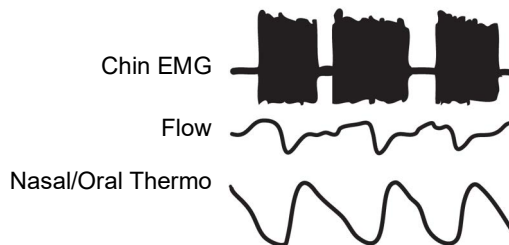
Figure 5-7. Missed Exhalation

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 data backup kit 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.

5. Select **Export Selected Report** button to export the current report only. 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, advanced parameters, and programming log.
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.

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Troubleshooting

6

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

Programmer Model 2740

Telemetry

For problems commonly associated with telemetry connections, see "Telemetry Troubleshooting" on page 47. 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 the stylus:

1. See stylus troubleshooting tips on page 121.

2. If those steps do not resolve the problem and the programmer remains frozen (no on-screen motion at all) for more than 2 minutes:

   – Press and hold the power button until the tablet shuts off.

   – Disconnect and reconnect the telemetry cable from power.

   – 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 tablet screen with the stylus. 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 47. If those measures do not resolve the problem, the IPG battery may be depleted. Try the following:

1. Use the patient's programmer to turn off the IPG therapy. Try this several times if not immediately successful.
2. If the patient's programmer is able to turn off the IPG, retry communication using the programmer.
3. If the patient's programmer cannot communicate with the IPG either, wait 24 hours and try using the patient's programmer 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 button 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 button is illuminated.

If the tablet still will not turn on, try the following:

1. Disconnect the tablet from the power supply.
2. Remove the battery. See "Changing the Battery" on page 140 for instructions.
3. Determine the model of the tablet by looking at the "Marketing Name" on the label that is located on the back of the tablet in the lower left corner.
4. Complete the steps for the correct tablet model.

   – MC-C5: Hold the power button for two minutes.
   – MC-C5te: Simultaneously hold the dashboard button, security button, and camera button for 10 seconds.

   – MC-C5m: Simultaneously hold the dashboard button, security button, and Windows® button for 10 seconds. Wait for 5 minutes.

5. Reconnect the tablet power supply only.
6. Press and hold the power button until it is illuminated.
7. Insert the battery. See "Changing the Battery" on page 140 for instructions.

If none of these solutions resolve the problem, contact Inspire Medical Systems.

Programmer Model 2740

Blank Screen Displays after Power On

If the tablet is powered on and the light on the power button is illuminated but the Start screen does not display, follow this procedure to reset the tablet:

1. Remove the battery. See "Changing the Battery" on page 140 for instructions.
2. Disconnect the tablet from the power supply.
3. Press and hold the tablet power button until the light turns off.
4. Wait 2 minutes to allow the power to completely drain from the tablet.
5. Reconnect the tablet to the power supply.
6. Press and hold the power button on the tablet until the light is illuminated.
7. Insert the battery. See "Changing the Battery" on page 140 for instructions.

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 87.
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.

System Initialization Error

A system error that reads "System initialization has failed!" displays after the tablet is powered on if the battery that maintains the programmer date and time settings is depleted.

1. Select Continue on the error screen.
2. Check that the correct date and time is displayed in the lower right-hand corner of the Start screen.
3. If date is incorrect, select the **Settings** button on the Start screen to access the Programmer Settings screen.
4. Select the correct date and time and then select the **Save** button.

To avoid future system errors at start up, always store the tablet with the battery attached and fully charged. If the tablet is not used regularly, plug it into an electrical outlet for 2 hours every 4 weeks to maintain the battery charge.

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.

Stylus

If the stylus tip is inoperable, flip the stylus over and gently use the back end of the stylus.

If the stylus tip is damaged, follow the instructions for "Replacing Stylus Tip" on page 142.

Contact Inspire Medical Systems if replacing the stylus tip does not resolve the problem.

Migrating IPG from Earlier Version of Programmer Software

The following settings have been eliminated in this version of the programmer software.

*   Amplitude ramp

If these settings are currently used by a patient's IPG, the new software will update the IPG with valid parameters the first time it communicates with the IPG.

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.

Start Screen   **Programmer Settings Screen**

Settings Button   Language Menu   Save Button
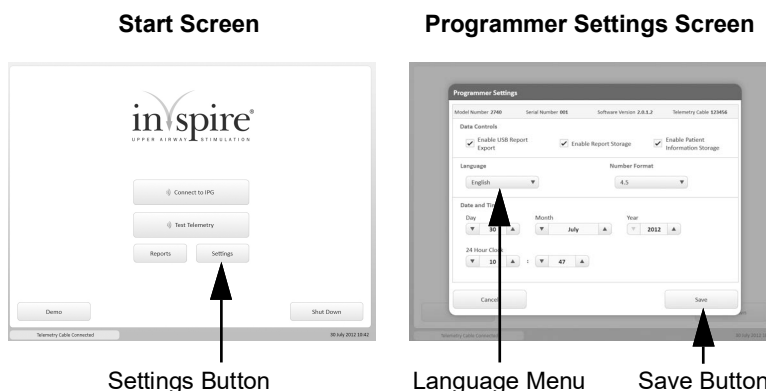
Figure 6-1. Change Language Buttons

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.

   Note: The IPG will reset to default parameters.
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.

Invalid Setting

It is possible for telemetry errors to cause a generator to have an invalid setting. To protect against invalid settings, a failsafe behavior was established. This failsafe, upon detecting invalid settings, will reset the generator to valid values. When this occurs, the programmer will inform the user that an invalid setting was detected and all settings should be reviewed to ensure they are correct for the patient.   While the failsafe resets the generator to valid settings, it does not reset the generator to the previously intended therapy and sensing settings or patient activation defaults. Therefore, after the reset, all therapy settings, including the advanced sense settings, should be reviewed before ending a programming session to ensure the settings are at the intended values.

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 all components of the data backup kit from each other and from the tablet.
2. Reconnect the data backup kit 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 30 for 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 000 001. See "IPG Reset" on page 124 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 120 for more information.

Out-of-Range Impedances

Impedance measurement results outside the range of 200–7000 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 48 for more information.)
- Never let a patient leave after a forced programmer shutdown until you reconnect to the IPG and confirm the IPG settings.

See "Migrating IPG from Earlier Version of Programmer Software" on page 122 for more information.

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 43 for instructions.)

Warnings and Precautions 7

This chapter contains the programmer warnings and precautions.

Programmer Model 2740

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.
- To avoid personal injury, handle the battery with care. Do not open, puncture, short, or expose it to fire or water. Keep the battery in an environment with ambient temperature between -20°C and 60°C (4°F and 140°F). For example, do not leave the battery in a closed car in hot weather for an extended period of time.
- 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 anaesthetic 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 37°C (41°F to 99°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 or the stylus tip. 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.

• Change stylus pen tips regularly, especially if you work in an environment that contains particles or debris. Dropping the stylus onto a rough surface may damage the stylus tip or embed particles in it that can damage the tablet display.

• 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.

• Store the stylus in the stylus bay on the back of the tablet (see Figure 2-3). Carrying it in a pocket, toolbox, or similar receptacle that contains particles or debris may damage the stylus tip or embed particles in it that can damage the tablet display.

• 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 lithium-ion battery packs 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 batteries 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. Replace the internal battery pack only with an Inspire Medical Systems battery or an Inspire-recommended equivalent to avoid the risk of fire or explosion resulting in personal injury.

• 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.

• If you use an external battery pack to power your tablet, be sure you use only an Inspire Medical Systems recommended product. Using an external battery that was not recommended may cause the tablet to overheat, emit smoke, burst and/or ignite and cause personal injury or damage to the unit.

• Do not use the battery pack in combination with other types of battery packs (such as dry-cell battery packs) or battery packs with different capacities or brands. This can result in it being overdischarged during use or overcharged during recharging, possibly causing it to leak, overheat, emit smoke, burst and/or ignite.

• Do not use or leave the 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.

• Do not immerse the battery pack in water or allow it to get wet. Its protective features can be damaged, it can be charged with extremely high current and voltage, or abnormal chemical reactions may occur, possibly causing it to leak, overheat, emit smoke, burst and/or ignite.

• Do not disassemble or modify the battery pack. If disassembled, the battery pack could leak, overheat, emit smoke, burst and/or ignite.

• Do not connect the positive (+) and negative (-) terminals with a metal object such as wire. Short-circuiting may occur, causing the battery pack to leak, overheat, emit smoke, burst and/or ignite.

• Do not damage the battery pack with a sharp object. This action could damage or deform it, or internal short-circuiting can occur, possibly causing it to leak, overheat, emit smoke, burst and/or ignite.

• Do not use an apparently deformed or damaged battery pack, which may leak, overheat, emit smoke, burst and/or ignite.

• Do not directly solder the battery pack. Heat can melt the insulation and damage other safety features, possibly causing it to leak, overheat, emit smoke, burst and/or ignite.

• Store the battery pack in a location where children cannot reach it. Make sure children do not remove the battery pack from the tablet.

• If the battery pack leaks, gives off a bad odor, generates heat, becomes discolored or deformed, or in any way appears abnormal during use, recharging or storage, immediately remove it from the tablet, stop using it and contact Inspire Medical Systems.

• Do not transport the lithium-ion batteries used in your tablet in checked baggage. You may take up to two spare batteries in carry-on luggage in addition to the one in your tablet. Transporting batteries in checked baggage or transporting more than two spare batteries in carry-on baggage violates transportation law.

Supplemental Information   **8**

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 Model 2740

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 polices for surface and equipment safety and cleanliness.

Cleaning Fan Cover

If the fan cover becomes soiled, it can be removed and cleaned.

To clean the fan cover:

1. Select **Shut Down** button on the Start screen.
2. Unplug the tablet.
3. Turn the tablet over to the backside, and remove the battery from the battery compartment (Figure 8-1).
4. Press the fan cover release button (see Figure 2-3).
5. To remove, slide the fan cover away from the tablet.
6. Clean the fan cover using a damp cloth. Dry fan cover before replacing.
7. After the fan cover is clean and dry, slide it back onto the tablet until it snaps into place.

Battery

Changing the Battery

To remove the battery from the programmer:

1. Select the **Shut Down** button on the Start screen.
2. Unplug the tablet.
3. Turn the tablet over and place the display on a non-scratch surface.
4. Slide the battery compartment latch (Figure 8-1) to the right to release the battery.
5. Use the finger grip to gently lift the battery out of the battery compartment.

5. Lift to

4. Slide to
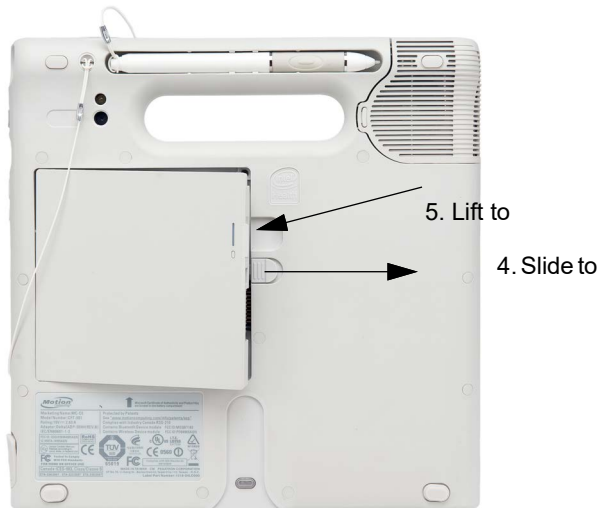
Figure 8-1. Removing the Battery

To insert the battery:

1. Select the **Shut Down** button on the Start screen.
2. Unplug the tablet.
3. Turn the tablet over and place the display on a non-scratch surface.
4. Match up the tabbed edge of the battery with the receiving slots in the battery compartment, and gently push the battery into the compartment (Figure 8-2) until it locks in place.
5. Plug the tablet into an electrical outlet and leave it plugged in until the battery is fully charged and the battery status light on the front of the tablet displays steady green.

Gently push battery into place

Figure 8-2. Inserting the Battery

Storing the Battery

Always store the programmer with the battery fully charged and attached to the tablet.

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. See "Charging Battery" on page 34 for more information.

Disposing of the Battery

A lithium-ion (Li-ion) battery must be disposed of in accordance with local, state, and federal regulations when it is no longer serviceable. Do not throw the battery into a waste container that would allow the battery to ultimately be deposited in a landfill. Return to Inspire Medical Systems.

Stylus

Store the stylus in the storage bay on the back of the tablet (Figure 8-1).

- Do not store the stylus vertically on the tip. Constant pressure on the tip can affect the stylus-to-screen interaction.
- Change the stylus tip regularly.
- Do not immerse the stylus in liquid. It contains electronic components that could be damaged.
- In certain environments, particles or debris can stick to the stylus tip or the display. To avoid damaging the display, clean it frequently with a soft, clean cloth.

Replacing Stylus Tip

Stylus tips eventually wear down or get damaged, so the stylus includes extra tips and a tool for replacing them.

Change the stylus tip every 90 days. If the stylus is used in a dirty environment, you should change the tip every 30 days. Particles can become embedded in the tip and scratch the display.

To replace the stylus tip (Figure 8-3),

1. Grasp the old tip with the replacement tool. Use the notch on the ring to grab the tip.
2. Pull the old tip out of the stylus.
3. Insert a new tip.
4. Apply slight pressure to push the tip into place.
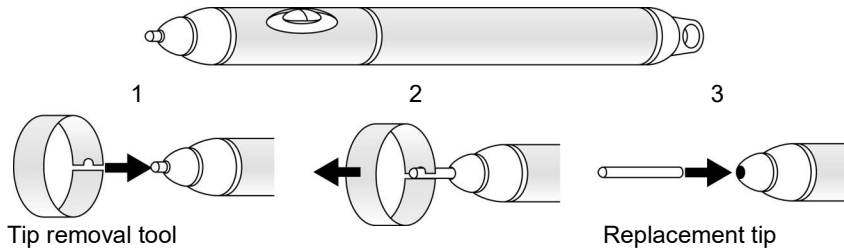
Figure 8-3. Replacing Stylus Tip

Tethering Stylus to Tablet

Complete the instructions outlined in Figure 8-4 to tether the stylus to the tablet.
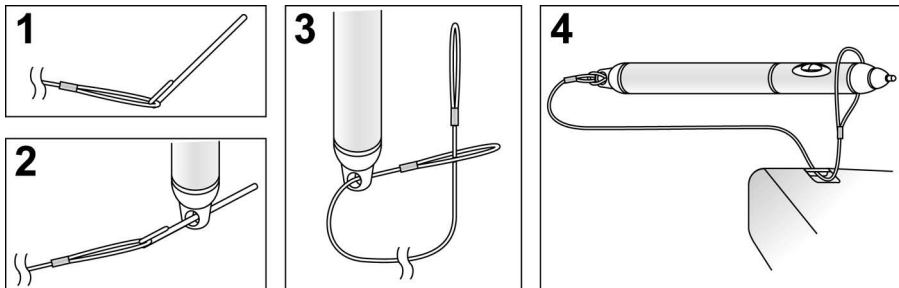
1. Loop end of tether onto a threading tool.
2. Pull threading tool through the tether hole of stylus.
3. Pull the opposite end of the tether through the loop.
4. Thread the remaining end of the tether under the metal anchor on the back of the tablet. Insert stylus tip through loop and pull completely through.

Figure 8-4. Tethering Stylus to Tablet

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 under the tablet battery.

Contact Inspire Medical Systems for replacement parts such as a stylus or stylus tips.

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 µs
Rate	33 Hz
Soft off period	13%
Start delay	30 m
Therapy duration	8 h

Device Specifications

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

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

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

Tablet

Table 8-2. Tablet Specifications[a]

Description	Specifications
Temperature with power on	Temperature: 5°C–37°C (41°F–99°F) Humidity: 20–80% Air pressure: 697–1060 hPa (10–15.4 psi)
Temperature with power off for storage or transportation	Temperature: -20°C–60°C (-4°F–140°F) Humidity: RH 10–90% RH Air pressure: 187–1060 hPa (2.7–15.4 psi)
Tablet power supply Sinpro M/N: MPU5*-107 (UL agency approval under UL 60601-1)	Input: 100–240 VAC, 47–63 Hz, 1.35A. Output: 16–21 V (19 V nominal), 2.63 A.
Ingress protection	IPX0
Mode of operation (continuous or non-continuous)	Continuous

[a] All 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 (ClassII) 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

[a] All measurements are approximate

Protected Health Information

Introduction

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

This information is not intended as a comprehensive or exhaustive list of issues and recommendations. Your organization's particular needs and security requirements may call for additional actions and controls. Each organization must reach its own decisions on how to implement appropriate safeguards.

Inspire Programmer (Model 2740)

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

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

Essential Performance

Essential performance of the Model 2740 Inspire programmer has been determined to be uninterrupted performance or recovery from performance interruption with or without a restart of the programmer.

FCC Notice (USA)

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

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

The Inspire Programmer (Model 2740) tablet, 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.

FCC Caution

This device was tested for Specific Absorption Rate (SAR) in a body-worn and portable configuration. The device was found to comply with the FCC requirements for RF exposure when held in the hand, or placed on the lap. Contact Inspire Medical Systems for additional information on the testing.

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 set forth for an uncontrolled environment.

This equipment also complies with FCC RF radiation exposure limits set forth for an uncontrolled environment, under 47 CFR 2.1093 paragraph (d)(2), which addresses RF exposure from radio frequency devices.

Operation is within 5.15 GHz–5.25 GHz frequency range. This frequency range may limit or restrict the effective use of this equipment to an indoor environment. This radiated output power is far below the FCC RF exposure limits.

Nevertheless, this device should be used in such a manner that the potential for human contact during normal operation is minimized.

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.

Note: Some programmer configurations were tested to different standard editions. The following information may contain multiple test and compliance levels.

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. **Note:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. **Warning:** This system is intended for use by health care professionals only.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN 61000-3-3	Complies	

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Table 8-5. Electromagnetic Immunity

The Inspire Programmer (Model 2740) is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD): EN/IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Electrostatic discharge may result in a temporary loss of function, requiring the user to restart the programmer.
	+/-8 kV contact +/-15 kV air	+/-8 kV contact +/-15 kV air	
Electrical fast transient/burst: EN/IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines +/-2kV for input AC power port +/-1 kV for signal I/O port 100 kHz repetition frequency	±2 kV for power supply lines (no input / output lines) +/-2kV for input AC power port +/-1 kV for signal I/O port 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment. Electrical fast transients or bursts in mains power may result in temporary loss of function.
Surge: EN/IEC 61000-4-5	±1 kV differential mode ±2 kV common mode +/-0.5 kV, +/-1 kV line-to-line +/-0.5 kV, +/-1 kV, +/-2 kV line-to-ground	±1 kV differential mode ±2 kV common mode +/-0.5 kV, +/-1 kV line-to-line +/-0.5 kV, +/-1 kV, +/-2 kV line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.

Table 8-5. Electromagnetic Immunity

The Inspire Programmer (Model 2740) is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines: EN/IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. The tablet contains an integrated battery that must be charged for use without mains power. The telemetry cable requires uninterrupted mains power to operate.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	Interruptions in mains power may result in temporary loss of function.
	<u>Voltage Dips</u> 0% UT; 0.5 cycle at 0, 45, 90, 135, 180, 225, 270, and 315^0	<u>Voltage Dips</u> 0% UT; 0.5 cycle at 0, 45, 90, 135, 180, 225, 270, and 315^0	
	0% UT; 1 cycle and 70% UT; 25/30 cycles	0% UT; 1 cycle and 70% UT; 25/30 cycles	
	Single phase: at 0^0	Single phase: at 0^0	
	<u>Voltage Interruptions</u> 0% UT; 250/300 cycle	<u>Voltage Interruptions</u> 0% UT; 250/300 cycle	

Note: U_T is the A.C. mains voltage prior to application of the test level.

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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**
			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
Conducted RF EN/IEC 61000-4-6	3 Vrms 150 kHz–80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
	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	
Radiated RF EN/IEC 61000-4-3	3 V/m 80 MHz–2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
	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	

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
Power frequency magnetic field: EN/IEC 610000-4-8	3 A/m	3A/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]
			Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the programmer is used exceeds the applicable RF compliance level above, the programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the programmer.

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

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

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Unused Tablet Features

The tablet has several controls, indicators, and other features that are not used by the programmer software. These features are not operational and do not affect the operation of the programmer. This section provides a brief overview of the unused features.

Tablet Front

The unused features on the front of the tablet (Figure 8-5) are described in Table 8-8.
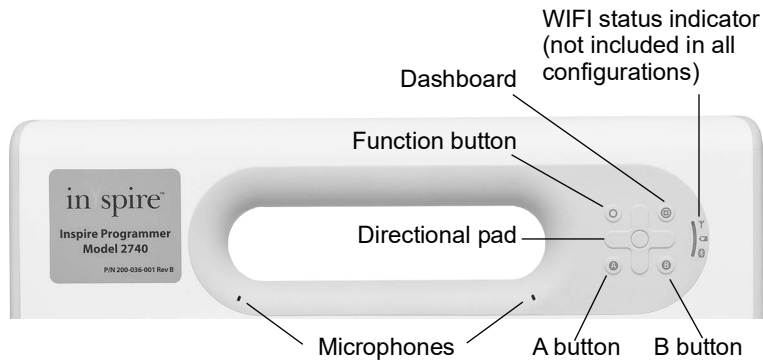

Figure 8-5. Unused Tablet Features, Front

Table 8-8. Tablet Unused Features, Front

Icon/Item	Description	Function
○	Function button	None
◉	Dashboard button	None
⊹	Directional pad	None
Ⓐ	A button	None
Ⓑ	B button	None
👣	Microphones	Records sounds and can be used for speech recognition
Ⴘ	WIFI	Wireless local area network (WIFI) status indicator (not included with all programmer configurations)

Tablet Right Side

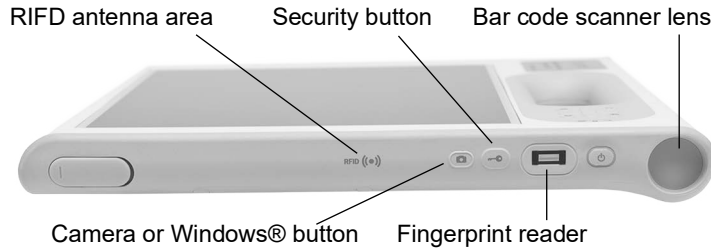The unused features on the right side of the tablet (Figure 8-6) are described in Table 8-9.

RIFD antenna area   Security button   Bar code scanner lens

Camera or Windows® button   Fingerprint reader

Figure 8-6. Unused Tablet Features, Right Side

Table 8-9. Unused Tablet Features, Right Side

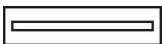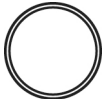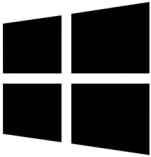| Icon/Item	Description	Function
RFID ((●))	Radio frequency identification (RFID) antenna area (not included in all configurations)	None
📷	Camera button (not included in all configurations)	None
⚷	Security button	None
▭	Fingerprint reader	None

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Table 8-9. Unused Tablet Features, Right Side

Icon/Item	Description	Function
(bar code scanner lens icon)	Bar code scanner lens	None
(Windows logo icon)	Windows® button (not included in all configurations)	None

Tablet Top

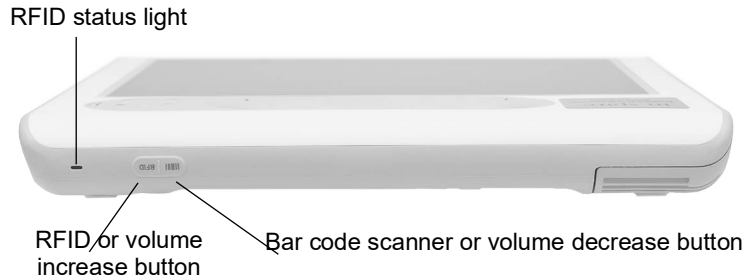The unused features on the top of the tablet (Figure 8-7) are described in Table 8-10.

RFID status light

RFID or volume increase button

Bar code scanner or volume decrease button

Figure 8-7. Unused Tablet Features, Top

Table 8-10. Unused Tablet Features, Top

Icon/Item	Description	Function
	RFID status light	None
(IIII RFID)	RFID button (not included in all configurations)	None
(IIII RFID)	Bar code scanner button (not included in all configurations)	None
🔊	Volume increase button (not included in all configurations)	None
🔈	Volume decrease button (not included in all configurations)	None

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Tablet Back

The unused features on the back of the tablet (Figure 8-8) are described in Table 8-11.
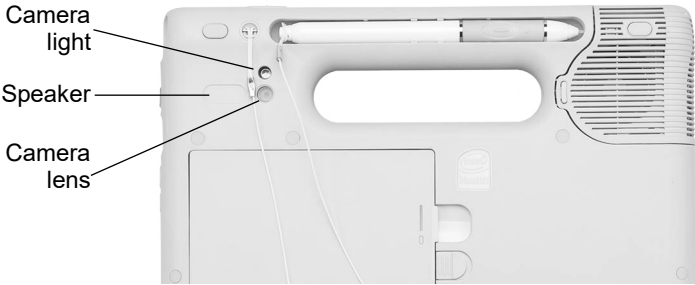
Figure 8-8. Unused Tablet Features, Back

Table 8-11. Unused Tablet Features, Back

Description	Function
Camera lens	None
Camera light	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 Systems.

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Inspire Medical Systems, Inc. Limited Warranty

9

This chapter describes the limited warranty.

Programmer Model 2740

Inspire Medical Systems, Inc. Limited Warranty

Inspire's Products consist of Implantable Pulse Generators (IPG), tools to connect the IPG to implantable leads, leads, patient 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 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 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 Purchaser complies with the Terms and Conditions, Inspire will issue a limited warranty credit toward the purchase of a new Inspire 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, e.g., IPG, lead, patient remote, Inspire 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 patient's bill and reported to the applicable payor using the appropriate methodology.

– For physician products, e.g., physician programmer, Inspire 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 within 30 days of first use.
4. The Product must be replaced with an Inspire Product.
5. If the Product is implantable, it must be implanted before the Product expires and be implanted with other Inspire Products.
6. The Product must be returned to Inspire Medical Systems, Inc., 5500 Wayzata Blvd, Suite 1600, Golden Valley, MN 55416 within 30 days of the date that the Product first fails to function within normal tolerances. The Product may be returned at no cost to Purchaser. Contact your Inspire representative for information on how to return the Product.
7. Inspire will inspect the returned Product and determine whether a limited warranty credit is due.
8. All Products returned to Inspire Medical Systems become Inspire's property.

This limited warranty represents the entire obligation of Inspire 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 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:

1. For an IPG or lead, three (3) years from date an IPG or lead is implanted in the patient.

2. For a programmer, one (1) year from the date the physician programmer or patient remote is first used.

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