Charging the Charger

The Charger should be charged at least once a week. The Charger Status light will be yellow when the battery is low.

- Do not try to charge your Implant while the Charger is plugged into a power outlet. When the Charger is plugged into a power outlet, the Charger buttons are disabled.
- Only use the AC power adapter provided with the Charger.
- Be careful not to touch the metal prongs of the AC adapter when you plug the adapter into a power outlet.

1 Plug the provided AC adapter into a power wall socket where you can easily unplug it again after charging.

2 Connect the other end of the cord to the USB port of the Charger.

3 The Charger Status light slowly flashes White while it is charging.

After the Charger is fully charged, the Charger Status light changes to solid White.

4 Unplug the Charger.

Caution: Be careful when removing the power adapter for your Patient Remote or Charger from a power outlet. Use only the certified AC Adapter provided with your Patient Remote and Charger. These adapters have double-reinforced insulation between the input and output circuits and using other AC adapters may result in electrical or thermal injury.

Note As a safety measure, the buttons on the Charger are disabled when the Charger is plugged into a power outlet.

Understanding the Lights and Sounds of the Charger

The Charger is designed to alert you as it performs different tasks. Use the chart below as a handy guide.

Activity and Light[1]		This means:	Sounds	Vibrations
No Activity				
No lights		Charger is in stand-by mode.		
Yellow		Charger battery is low.		
Charging the Charger Battery				
White		Charger is plugged in a power outlet and the battery is charged.		
White Slow Flashing		Charger is plugged in and Charger battery is charging.		

[1] This column refers to the Charger Status light (in the center of the Charger), unless indicated as the Power Button or Stop Therapy button.

[2] Stop charging your Implant when your Patient Remote shows the Implant battery level is High. It is recommended that you do **not** wait until the Charger Status light changes from Blue to White. For more information, see "Charging Your Implant", on page 35.

[3] When your Implant battery reaches Full charge, the Charger may vibrate and make a pulsing sound every 6 seconds while it remains over your Implant.

1

Activity and Light[1]		This means:	Sounds	Vibrations
Charging Your Implant Battery				
Blue		Power button pressed to start charging.		1 Click
		Charger is searching for your Implant.	Long, low tone repeated	Vibration repeated
		Charger is connected and charging your Implant.	Quick 2-tone sound	1 vibration
		If the Charger moves away from your Implant and begins searching again.	Long, low tone repeated	Vibration repeated
White		Your Implant is charged to Full.[2]	[3]	[3]
Stopping Therapy				
Pink		Stop Therapy button is pressed. The button starts flashing after you hold the button for 10 seconds.	1 click when pressed.	1 Vibration
Pink Fast Flashing		Charger is searching for your Implant.	Long, low tone repeated	Vibration repeated
Stop Therapy Button		The Stop Therapy button turns White when Therapy is turned OFF.		
Registering a New Patient Remote				
Blue		Press Power button and hold for at least 10 seconds.		1 Click

[1] This column refers to the Charger Status light (in the center of the Charger), unless indicated as the Power Button or Stop Therapy button.

[2] Stop charging your Implant when your Patient Remote shows the Implant battery level is High. It is recommended that you do not wait until the Charger Status light changes from Blue to White. For more information, see "Charging Your Implant", on page 35.

[3] When your Implant battery reaches Full charge, the Charger may vibrate and make a pulsing sound every 6 seconds while it remains over your Implant.

Activity and Light[1]		This means:	Sounds	Vibrations
Blue Fast Flashing		After holding Power button for 10 seconds the Charger starts searching for your Implant.		
White		Patient Remote is registered.	Quick 2-tone sound	1 Vibration
Power button Blue		When Patient Remote is registered, Power button changes to Blue.		

[1] This column refers to the Charger Status light (in the center of the Charger), unless indicated as the Power Button or Stop Therapy button.

[2] Stop charging your Implant when your Patient Remote shows the Implant battery level is High. It is recommended that you do not wait until the Charger Status light changes from Blue to White. For more information, see "Charging Your Implant", on page 35.

[3] When your Implant battery reaches Full charge, the Charger may vibrate and make a pulsing sound every 6 seconds while it remains over your Implant.

Cleaning, Handling, and Storing the Charger

The Charger is an important part of your Galvani System. The Charger is the only way you are able to charge your Implant battery so it is important to keep it safe.

Cleaning the Charger: Clean the Charger with a soft lint-free cloth. Avoid getting moisture into any openings and do not use aerosol sprays, solvents, or abrasives.

The Charger contains no patient serviceable parts: Do not attempt to open or disassemble the Charger to change the battery, the battery is not designed to be removed. Only use the provided power adapter (and optional international converter if applicable) to recharge the battery.

Storing the Charger: Do not expose the Charger to extreme temperatures, for example do not leave it in your car where the temperatures could be either be too high or too low. See "Device Specifications for the Charger", on page 61 for the recommended temperature range for the Charger. Keep the Charger away from children and pets. Avoid storing the Charger where it could be exposed to lint, dust, pests, or direct sunlight.

Note For more important information about caring for the Charger, review the Cautions on page 6.

Chapter 6 Your Follow-Up Visits

Your doctor or Study Coordinator will set up periodic clinic visits to check on you and your therapy.

What Happens

The doctor will use a Clinician Programmer to connect to your Implant. Some of the things that may happen:

- Your doctor can review the history logs saved by your Implant.
- Your doctor may adjust your therapy settings
- Your doctor may change your therapy schedule.

You and your doctor can discuss how the therapy is going and confirm that you are comfortable using your Patient Remote and Charger.

What to Bring

Remember to bring your Patient Remote to your follow-up visits and any notes and questions that you might have.

My Notes

Use the space below to write any notes you find helpful or for questions to ask your Study Coordinator.

Chapter 7 Troubleshooting and Support

Troubleshooting Your Wireless Connections

If you experience issues with the wireless communication between your Patient Remote and your Implant, try the following:

- Decrease the distance between your Implant and your Patient Remote.
- Remove any objects that are between your Implant and your Patient Remote. Because your Implant is located just below your ribs on your left side, keeping the Patient Remote in front of you rather than behind (held by a caregiver) will provide the best direct connection.
- Move away from other devices that may be causing wireless interference, i.e. other devices that are using wireless communication.
- Wait a few minutes and try connecting again.
- Do not operate other wireless devices (i.e., laptop, tablet, mobile phone, or cordless phone) at the same time.

  Note Wireless communications equipment, such as wireless home network devices, mobile and cordless telephones, and tablets, can affect the device operation.

General Troubleshooting Tips

What you see on your Patient Remote	Tips to try
“Could not connect. A connection could not be established with the implant. If you continue to experience issues, contact your treating physician.” or **"Could not connect, The Charger was not aligned over the implant within 60 seconds."**	• Make sure the your Patient Remote is close to your Implant when trying to connect to your Implant. An example might be if someone else is holding your Patient Remote while trying to connect and they are not close enough to your implant. • Make sure that there are no objects between your Patient Remote and your Implant. Contact your Study Coordinator or healthcare professional if you see this message when trying to connect to your Implant.
“The session with the implant has ended. Not Connected.”	If this message appears, your Implant and your Patient Remote need to be closer to each other. If someone else is using your Patient Remote for you, make sure that they are within 3 feet (1 meter) and there are no objects between your Implant and your Patient Remote.
"Connect to an implant to view its details here."	You will see this message on the Device Information screen when your Patient Remote is not connected to your Implant. Once your Implant is connected, the Device Information screen displays information about your Implant.

What you see on your Patient Remote	Tips to try
"**The remote has not connected to the implant for 1-week.**"	This message appears when you have not connected your Patient Remote to your Implant for one week. You should connect to your Implant and check the battery. Then, if needed, charge your Implant.
"**Your implant has not connected to a Clinician Programmer in more than ... Visit your clinician to re-enable your therapy**"	This message appears if you have not had a follow-up visit within the time limit set by your Study Coordinator or healthcare professional. Contact your Study Coordinator or healthcare professional to schedule a follow-up visit. Your therapy will remain disabled until your follow-up visit.
No Implants are listed after selecting **NEARBY IMPLANTS** from your Patient Remote	Your Implant battery is too low to connect to your Patient Remote. Charge your Implant and try to connect again after charging.

Appendix A Registering a New Patient Remote

Your Study Coordinator or healthcare professional may have already registered your Patient Remote. If not, or if you have a replacement Patient Remote, it will need to be registered with your Implant.

Notes:

- Make sure your Implant battery is not low. If the battery is low, you should charge it before registering (see "Chapter 5 Using the Charger", on page 34).
- You will need the Charger to register a new Patient Remote. Before starting, prepare the Charger with either the adhesive patch or with the charging belt to hold it over your Implant. For details, see "Using the Adhesive Patch When Charging", on page 36 and "Using the Charging Belt When Charging", on page 39.

1 Log into your Patient Remote.

2 Select the large button in the center of the screen **NEARBY IMPLANTS**.

On the next screen you may see a list of all implants within close range.

3 Select your specific implant from the list using the serial number your Study Coordinator or healthcare professional gave you. (There may only be one implant listed if you are at home.)

4 On the Charger, press and hold the Power button for 10 seconds. You can do this with or without turning the charger ON first.

When you press and hold the button, the Charger Status light changes to solid Blue.

5 After 10 seconds the Blue Charger Status light starts flashing and you can stop pressing the Power button.

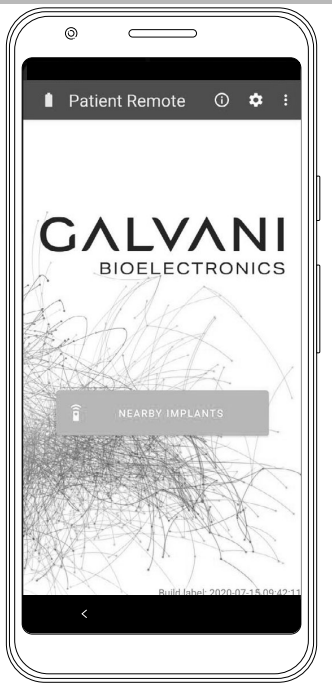

Figure 48 Nearby Implants

Note For next steps, you will need to keep the Patient Remote near your body with the registration screen active.

6 Place the Charger over your Implant (using either an adhesive patch or the charging belt).

When the Charger locates the Implant, you will feel 1 vibration and hear 2 pings.

If the Charger cannot find your Implant within 60 seconds, the Charger Status light will turn OFF and you will need to start the process again with Step 4.

7 The Charger Status light turns solid White and Power button turns solid Blue to show that your Patient Remote has been registered properly. You will also see a confirmation on your Patient Remote.

You can continue to use the charger to recharge your Implant battery or you can turn the Charger OFF with the Power button. For instructions, see "Chapter 5 Using the Charger", on page 34.

Appendix B Quick Reference Information

Connect to Your Implant	Using your Patient Remote:	**Select NEARBY IMPLANTS from the main screen.**	**See "Chapter 3 View and Monitor Your Implant", on page 24.**
Stop Therapy	Using your Patient Remote:	**Select DISABLE THERAPY from the main screen.**	**See "Using Your Patient Remote to Stop Therapy", on page 31.**
		OR	
	Using the Charger:	**Press and Hold the Stop Therapy button for 10 seconds.** **When you hear the tone, place the Charger over your Implant.** • **You will feel 1 vibration and 2 pings.** • **The Charger Status light stops flashing and changes to solid White.** • **The Stop Therapy button changes to solid White** **Your therapy is now OFF**	**See "Using The Charger to Stop Therapy", on page 32.**

Delay Therapy	Using your Patient Remote:	**Select DELAY NEXT THERAPY from the main screen.** **Select the amount of time to delay therapy.** **Select CONFIRM.**	**See "Delaying Therapy", on page 30.**
Check Implant Battery	Using your Patient Remote:	**View the BATTERY section on the main screen.**	**See "View Implant Battery Status", on page 28.**
Charge Implant	From your Patient Remote:	**Select HOW TO CHARGE from the Battery section of the main screen.**	**See "Chapter 5 Using the Charger", on page 34.**

Appendix C Device Specifications

Device Specifications for the Patient Remote

Table 1. Model 31101 Patient Remote Device Specifications	
Power	~ 18 Watts (5 Volts DC, 3 Amp)
AC/DC inputs	100-240 VAC 50/60 Hz
AC/DC Model	AC/DC Voltage Adapter Model G1000-US USB to USB-C Cable Model G016C B91K
AC cable length	~ 1m, detachable
Connector type	USB-C at device
Operating conditions	Temperature range of 0 to 35°C, Relative humidity range of 15 % to 90 %, non-condensing, atmospheric pressure range of 70 kPa to 106 kPa
Storage and transport conditions	0°C to 35°C, 0 to 90% humidity
Weight	Maximum weight of 150 g.
Dimensions	Maximum dimensions of 151.3 mm x 70.1 mm x 8.2 mm

Model 31101 Patient Remote Device Specifications -Continued-	
IP rating	IP22 (see explanation of Symbols)
Compliance	Radio Equipment Directive 2014/53/EU
Battery	Non-replaceable, rechargeable, Lithium Ion Polymer
Battery capacity	3000 mAHr
Idle	7 Days
Use	4 Hours (nominal use)
Device service life	36 months

Device Specifications for the Charger

Table 2. Model 31102 IPG Charger Device Specifications	
AC/DC inputs	100-240 VAC 50/60 Hz
AC cable length	~ 1m, detachable
Connector type	USB-C at device
Operating conditions	Temperature range of +5 °C to +40 °C, Relative humidity range of 15 % to 90 %, non-condensing, atmospheric pressure range of 70 kPa to 106 kPa

Model 31102 IPG Charger Device Specifications -Continued-	
Storage and transport conditions	10-40 C, 30 - 75 % humidity
Weight	Maximum weight of 200 g.
Dimensions	Maximum dimensions of 80 mm x 80 mm x 25 mm
IP rating	IP22 (see explanation of Symbols)
Compliance	FCC, ETSI, IEC 60601-1  The Model 31102 IPG Charger is an Applied Part in conformance with IEC 60601-1 requirements for applied parts.
Battery	Non-replaceable, rechargeable, Lithium Ion Polymer
Battery capacity	1100 mAHr
Idle	6 Days
Use	2 Hours
Device service life	36 months

Device Specifications for the IPG

Table 3. Model 21101 Implantable Pulse Generator (IPG)	
Mechanical Specifications	
Size (main body) Anchoring and handling tabs	5.4 cc 41.4 x 19.8 x 7.8 mm 2 each 2.3 x 10.7 mm
Weight	10.7 g
Independent programmable channels	1
Header configuration	1 x 4
Connector ports for lead	1
Lead compatibility	Galvani GB-1 Connector
Enclosure can material	Titanium
Header material	Epoxy (Med-301)
Anchoring and Handling Tabs material	Titanium
Operating conditions	+20° C to +40° C
Storage conditions	+10° C to +40° C Relative humidity 30% to 75% noncondensing Atmospheric pressure 70 kPa to 106 kPa

Model 21101 Implantable Pulse Generator (IPG) -Continued-	
Stimulation Specifications	
Number of programs	1
Electrode configuration	1 channel programmable as bipolar, alternating bipolar or alternating monopolar
Therapy schedule	Automatic
Pulse control	Current regulated
Stimulation waveform	Symmetric Biphasic
Stimulation current	0 - 20 mA
Pulse frequency	1 - 30 pps
Pulse width	10 - 2000 µs
Compliance voltage	18 V

The IPG contains a radio-opaque marker to allow the identification of the implant using radiography. The marker is a capitol “G” placed over the battery inside the enclosure can.

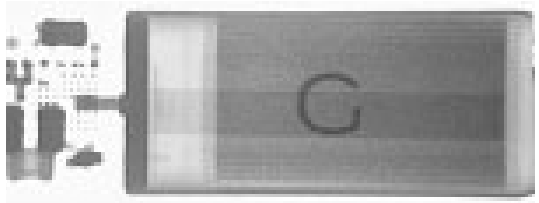

Figure 49 IPG Radiography Marker

Device Specifications for the IPG Lead

Table 4. Implantable Lead Models 11302, 11305	
Mechanical Specifications	
Lead Length	65 cm
Cuff Size, Model 11303 Cuff Size, Model 11305	6.6 mm 7.7 mm
Lead Body Diameter	Distal portion: 1.5 mm Proximal portion: 1.35 mm proximal
Electrode Array	Pt/Ir (90/10)
Electrode Interconnect	MP35N
Cuff	Silicone (Nusil MED-4870)
Deployment Tab	Silicone (Elastosil LR3003/20 w. 12.5% BaSO4)
Deployment Tab Suture	5-0 braided polyester
Lead Body Conductors	ETFE coated MP35N LT/DFT 28Ag
Distal lead Body Tubing	Silicone (Nusil MED-4719)
Distal lead body segment length	30 cm
Proximal lead Body Tubing	Polyurethane (Pellethane 2363-55D)
Proximal lead body segment length	31 cm

Implantable Lead Models 11302, 11305 Continued-	
Transition Sleeve	Silicone (Nusil MED-4750)
Transition sleeve length	4 cm
Anchor	10 mm x 10 mm Dacron enforced silicone (Nusil MED-6605)
Anchor to Cuff Distance	20 cm
Connector Contact Rings	MP35N
Connector Retention Sleeve	MP35N
Connector Body	Polyurethane (Pellethane 2363-75D)
Connector Backfill	Acrylic adhesive (Loctite 3936)
Operating conditions	+20° C to +40° C
Storage conditions	+10° C to +40° C Relative humidity 30% to 75% noncondensing Atmospheric pressure 70 kPa to 106 kPa

Battery Information[1]

Table 5. Battery Information

Patient Charger (Model 31102)	
Specification	Non-replaceable, rechargeable, Lithium Ion Polymer
Capacity	1100 mAh
Idle time	6 Days (BOS*)
Charing run time	2 hours (BOS*)
Service life	36 months

Patient Remote (Model 31101)	
Specification	Non-replaceable, rechargeable, Lithium Ion Polymer
Capacity	3000 mAh
Idle time	7 days
Use time	4 days (nominal use)

Implantable Pulse Generator (Model 21101)	
Specification	Non-replaceable, rechargeable, Lithium Ion
Capacity	50 mAh nominal (BOS*)
Idle time	24 months (BOS*)
Charing run time	2 – 7 weeks, therapy dependent (BOS*)
Service life	120 months

* Beginning of service (BOS)

1 The system contains no user-serviceable components.

Appendix D Wireless Network Coverage

Table 6. Network Coverage Outside the United States and United Kingdom

Albania	Cyprus	Hong Kong	Liechtenstein	Norway	Spain
Australia	Czech Republic	Hungary	Lithuania	Poland	Sweden
Austria	Denmark	Iceland	Luxembourg	Portugal	Switzerland
Belarus	Estonia	Ireland	Macedonia	Romania	Taiwan
Belgium	Finland	Israel	Malta	Russia	Turkey
Bosnia and Herzegovina	France	Italy	Mexico	Reunion	Ukraine
Bulgaria	Germany	Japan	Moldova	Serbia	Jersey
Canada	Gibraltar	South Korea	Montenegro	Singapore	Guernsey
China	Greece	Kosovo	Netherlands	Slovenia	Isle Of Man
Croatia	Guadeloupe	Latvia	New Zealand	South Africa	

Appendix E Regulatory Information

Regulatory Information: United States

FCC Regulatory Compliance (US)

The Implantable Pulse Generator Model 21101 and IPG Charger Model 31102 were tested and found to comply with the applicable limits pursuant to the FCC rules in Part 15 and 18 Subpart C (15.247). Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The Clinician Programmer Model 41101 and Patient Remote Model 31101 comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment OFF and ON, the user is encouraged to try to correct the interference by one or more of the measures described in "Troubleshooting Your Wireless Connections", on page 53.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format:

Table 7. Registration Identification Information

Module	Registration Identifier
IPG	FCC ID: 2AVN4-21101
IPG Charger	FCC ID: 2AVN4-31102

Notes:

- For the Clinician Programmer - Model 41101 (FCC ID: A3LSMT837V) refer to http://www.samsung.com/ (model: T837V)
- For the Patient Remote - Model 31101 (FCC ID: A4RG020G) refer to support.google.com/ (model: Pixel 3a & Pixel 3a XL 2019)

Radio Frequency Exposure

The Galvani System consisting of the IPG, IPG Charger, Clinician Programmer and Patient Remote meets the U.S. Federal Communications Commission's (FCC) requirements for exposure to radio waves and is designed and manufactured not to exceed the FCC's emission limits for exposure to radio frequency (RF) energy.

For satisfying FCC RF exposure compliance requirements, body-worn operations are restricted to belt clips, charging belt, adhesive patches or similar accessories according to the Instructions for Use (IFU).

Specific Absorption Rate (SAR) Information

The Galvani System meets the requirements for exposure to radio waves established by the Federal Communications Commission (USA).

The RF exposure limit set by the FCC for wireless devices employs a unit of measurement known as the Specific Absorption Rate (SAR). The SAR is a measure of the rate of absorption of RF energy by the human body expressed in units of watts per kilogram (W/kg). The SAR limit adopted by the U.S is 1.6 W/kg averaged over one gram of tissue. The highest SAR value of the Galvani System components complies with this limit when devices are used as intended, and according to the instructions for use, with device accessories as provided. It is recommended to keep items which have metal components away from the devices while they are being used.

Regulatory Information: Europe

EU Compliance Notice

The IPG Model 21101 and IPG Charger Model 31102 are in compliance with the essential requirements of the Radio Equipment Directive (RED) 2014/53/EU by application of:

- IPG Model 21101
  - ETSI EN 301 489-1 V2.2.3 (2019-11) standard harmonized under Article 3.1b (EMC), and
  - ETSI EN 300 328 V2.2.2 (2019-07) standard harmonized under Article 3.2 (Spectrum)
- IPG Charger Model 31102
  - ETSI EN 301 489-1 V2.2.3 (2019-11) standard harmonized under Article 3.1b (EMC), and
  - ETSI EN 300 328 V2.2.2 (2019-07) and ETSI EN 300 330 V2.1.1 (2017-02) standards harmonized under Article 3.2 (Spectrum)and the Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment by application of EN 50581:2012.

The Clinician Programmer Model 41101: complies with the essential requirements of the Radio Equipment Directive (2014/53/EU), the Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment by application of EN 50581:2012, and the Eco-Design Directive (2009/125/EC) implemented by Regulation (EC) No 1275/2008 for standby and OFF mode, and networked standby, electric power consumption using test methods from EN 50564:2011. For additional Regulatory information, certification, and compliance marks specific to this product refer to www.samsung.com - (model: T837V)

The Patient Remote Model 31101: complies with Directive 2014/53/EU (Radio Equipment Directive), Directive 2011/65/EU on restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), the Eco-Design Directive (2009/125/EC) implemented by Regulation (EC) No 1275/2008 for standby and OFF mode, and networked standby, electric power consumption using test methods from EN 50564:2011, and REACH (Registration, Evaluation, Authorization and Restriction of Chemicals, EC No 1907/2006). For additional Regulatory information, certification, and compliance marks specific to this product refer to: support.google.com/ (model: Pixel 3a & Pixel 3a XL 2019)

Disposal Guidelines for Battery-Powered Devices

The Clinician Programmer Model 41101 and Patient Remote Model 31101 components contain batteries and labels affixed to each device in accordance with European Council directives Eco-Design Directive (2009/125/EC). This directive calls for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return all Galvani System devices including IPG Charger Model 31102, Clinician Programmer Model 41101, and Patient Remote Model 31101 to Galvani Bioelectronics at the end of its operating life.

Specific Absorption Rate (SAR) Information - EU

The Galvani System meets the requirements for exposure to radio waves established by the European Telecommunications Standards Institute (ETSI).

The SAR limit adopted by the EU in 1999/519/EC is 2 W/kg averaged over 10 grams of tissue. The highest SAR value of the Galvani System components complies with this limit when devices are used as intended, and according to the instructions for use, with device accessories as provided. It is recommended to keep items which have metal components away from the devices while they are being used.

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® low energy (BLE) technology as it is implemented in the devices.

Table 8. BLE Radio Specifications

BLE Attribute	Specification	
	IPG Model 21101	IPG Charger Model 31102
Frequency (range)	2402 to 2480 MHz	
Type of Transmission	Digital Transmission System (DTS)	
Rated RF output power	-2.8 dBm	
Antenna Peak Gain	-11.5 dBi	1.1 dBi
Type of Modulation	GFSK	
Data rate	1Mb/s	
Number of channels	40	
Protocol	Bluetooth® LE (BLE)	

Note The radio receiver in the BLE devices use the same frequency and bandwidth as the transmitter. Antenna cables are not used during normal use of the devices or while programming devices.

The table below summarizes the technical details of the wireless powering technology:

Table 9. Wireless Power Transfer (WPT) Specifications

WPT Attribute	Specification	
	IPG Model 21101	IPG Charger Model 31102
Frequency (ISM band)	6.78 MHz	
Type of Transmission	CW	
Peak electric field strength	-	2.2 V/m rms
Peak magnetic field strength	-	0.225 A/m rms
Antenna Type	Coil antenna embedded in header	Internal coil antenna

Quality of Service for Wireless Technology

Bluetooth® low energy (BLE) wireless technology enables communication between the IPG device, and the Clinician Programmer or Patient Remote. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, home, or other commercial establishment environment).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The IPG encrypts its wireless communication.
- Only one patient controller or clinician programmer may communicate with the generator at the same time.
- A unique key for each unit that is checked during each transmission.
- Built-in pairing that specifies valid and legitimate pairing among units.
- Proprietary authentication in addition to the pairing procedure specified in Bluetooth® low energy, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the generator.

Troubleshooting for Wireless and Coexistence Issues

If you experience issues with the wireless communication between the implantable pulse generator and the clinician programmer or Patient Remote, try the following:

- Decrease the distance between the devices
- Move the devices so they share line of sight
- Move the devices away from other devices that may be causing interference
- Wait a few minutes and try connecting again
- Do not operate other wireless devices (i.e., laptop, tablet, mobile phone, or cordless phone) at the same time

  Note Wireless communications equipment, such as wireless home network devices, mobile and cordless telephones, and tablets, can affect the device operation.

Appendix F Safety and Compatibility Standards Conformity

The following statements refer to these Galvani products:

- IPG Charger Model 31102
- Patient Programmer Model 31101
- Clinician Programmer Model 41101 (only used by and relating to Clinical staff)

These products comply with the following standards:

- IEC 60601-1, Medical Electrical Equipment Safety
- IEC 60601-1-2, Electromagnetic Compatibility
- EN 45502-1, Safety, Marking and Information of Medical Devices

Electromagnetic Compatibility Notes and Cautions

The IPG Charger, Patient Remote, and Clinician Programmer gave been tested and meet US and European regulatory limits for Electromagnetic Compatibility (EMC). EMC evaluation confirms the ability of electronic devices, including computers, to function properly together in the electronic environment. However, depending on the specific circumstances, the IPG Charger, Patient Remote (i.e. PR), or Clinician Programmer (i.e. CP) may still interfere with other electronics which are susceptible. Should this interference occur with other devices it is suggested to try to correct the interference by doing one or more of the following:

- Determine the Galvani product is the cause by turning the equipment OFF and ON.
- Relocate or reorient Galvani product devices away from the device being affected, if possible.
- Plug the Galvani product devices into a different electrical outlet circuit if the AC adapters are being used while being recharged.
- Depending on specific circumstances, the IPG Charger, Patient Remote, or Clinician Programmer essential performance may be negatively effected by close proximity to MRI or other High Energy surgical equipment (diathermy, ultrasound, electrocautery, ablation).
- The IPG Charger and Patient Remote use the identical power supply cables and AC adapter. The power cable maximum length is ~ 1m (40 in). The Clinician Programmer maximum cable length is ~ 1m (40 in). The identical cables and AC adapters were included in the system testing to demonstrate compliance with the requirements of IEC 60601-1-2 2007.
- Use of accessories and cables other than those specifically listed may result in increased emissions or decreased immunity of the IPG Charger, Patient Remote, or Clinician Programmer.

The IPG Charger, Patient Remote, or Clinician Programmer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, these devices should be observed to verify normal operation in the configuration in which it will be used.

Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the IPG Charger, Patient Remote, or Clinician Programmer including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Compatibility Declaration Tables

This section lists EMC Declaration tables. Galvani devices are intended for use in the electromagnetic energy environment as specified below. The customer or user of these devices should assure that they are used in such an environment. The IPG Charger, Patient Remote, and Clinician Programmer contain RF transmission and receiving capabilities; consequently, it is possible that other portable and mobile RF communications equipment may interfere with them.

Table 10. Guidance and Manufacturer Declaration – Electromagnetic Emissions

The IPG Charger, Patient Remote, and Clinician Programmer products are intended for use in the electromagnetic energy environment specified below. The customer/user of these devices should assure that they are used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The IPG Charger, Patient Remote, and Clinician Programmer products use RF energy only for its internal function. The IPG Charger emits RF energy while recharging the IPG or if used to disable stimulation from the IPG. The Patient Remote and Clinician Programmer use RF energy primarily for communication between devices. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Emissions during recharging of the IPG are at a higher level than for basic device to device communication yet comply with standards. Interference issues, although unlikely, may occur during recharging.

Table 10. Guidance and Manufacturer Declaration – Electromagnetic Emissions

The IPG Charger, Patient Remote, and Clinician Programmer products are intended for use in the electromagnetic energy environment specified below. The customer/user of these devices should assure that they are used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Class B	The IPG Charger, Patient Remote, and Clinician Programmer are suitable for use in all environments and locations, domestic and international, which utilize standard power supply networks found in homes, clinics, office buildings, and other establishments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 11. Guidance and Manufacturer Declaration – Electromagnetic Immunity

The IPG Charger, Patient Remote, and Clinician Programmer are intended for use in the electromagnetic environment specified below. The customer/user should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical home, commercial, clinic, or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home, commercial, clinic, or hospital environment.

Table 11. Guidance and Manufacturer Declaration – Electromagnetic Immunity			
The IPG Charger, Patient Remote, and Clinician Programmer are intended for use in the electromagnetic environment specified below. The customer/user should assure that they are used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods. At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical home, commercial, clinic, or hospital environment. If the user of the IPG Charger, Patient Remote, and Clinician Programmer requires continuous operation during power mains interruptions, it is recommended that these devices be powered from an uninterruptible power source.
	Voltage Dips > 95% reduction, 0.5 period. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial, or hospital environment.
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance

Table 11. Guidance and Manufacturer Declaration – Electromagnetic Immunity

The IPG Charger, Patient Remote, and Clinician Programmer are intended for use in the electromagnetic environment specified below. The customer/user should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the IPG Charger and Patient Remote, and Clinician Programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range.[b]

Table 11. Guidance and Manufacturer Declaration – Electromagnetic Immunity

The IPG Charger, Patient Remote, and Clinician Programmer are intended for use in the electromagnetic environment specified below. The customer/user should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance

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 IPG Charger, Patient Remote, and Clinician Programmer are used exceeds the applicable RF compliance level above, the IPG Charger, Patient Remote, and Clinician Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IPG Charger, Patient Remote, and Clinician Programmer.

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

Table 12. Recommended separation distances between portable and mobile RF communications equipment and the IPG Charger, Patient Remote, and Clinician Programmer.

The IPG Charger, Patient Remote, and Clinician Programmer are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/user of these devices may help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IPG Charger, Patient Remote, and Clinician Programmer as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter W	**150 kHz to 80 MHz** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 12. Recommended separation distances between portable and mobile RF communications equipment and the IPG Charger, Patient Remote, and Clinician Programmer.

The IPG Charger, Patient Remote, and Clinician Programmer are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/user of these devices may help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IPG Charger, Patient Remote, and Clinician Programmer as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter W	**150 kHz to 80 MHz** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$

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

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.

Table 13. Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band[a] (MHz)**	**Service[a]**	**Modulation[b]**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380 –390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						

Table 13. Immunity to RF Wireless Communications Equipment

Test Frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
Test Frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
2450	2 400 – 2 570	Bluetooth®, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Caution: Investigational Device.

Limited Federal Law (US) to investigational use. Exclusively for Clinical Investigations (UK).

Galvani Bioelectronics
Gunnels Wood Road
Stevenage, Hertfordshire,
United Kingdom

Website: www.galvani.bio

UK freephone: +44 (0)80 036 88514
USA toll free: +1 (877) 613-9001

℞ Only