INSTRUCTIONS FOR USE

ActaStim-S Spine Fusion Stimulator

ActaStim·S

Theragen

Dear ActaStim-S patient,

Your doctor has prescribed Theragen's ActaStim-S Bone Growth Stimulator System as an important part of your spine fusion surgery recovery plan. Here at Theragen, we want you to know that we are here to help you on your path to recovery.

As a spine fusion patient myself, I had many of the same questions and concerns that you have right now. How soon will I recover from surgery? When will I start feeling normal again? Is what I'm feeling right now "normal"? How much activity is enough and how much is too much?

Your doctor is the best person to answer those questions, but ActaStim-S will help by giving your Doctor a very special insight into your day-to-day recovery through the proprietary ActaStim Sync app that you will be using in conjunction with your ActaStim-S device.

The ActaStim-S device is designed to be portable, convenient and comfortable. Like a medication that you take every day, you won't feel the stimulation working but the healing therapeutic signal has been shown to benefit patients with daily use according to your doctor's directions.

In an important Level I clinical trial, described in Section 8, a device having the signal that ActaStim-S delivers was shown to increase spine fusion success significantly compared to placebo when used as directed (ActaStim-S is designed to be used 24 hours a day). Our ultimate goal is to help as many patients as possible return to activities of daily living. ActaStim-S will be effective when used as indicated.

The ActaStim Sync app is your daily companion. You are able to track your pain levels, make a note of specific achievements, and sync activity and usage data from your ActaStim-S device. You will be able to produce a report that you can share with your Doctor before, at and between your appointments to help them fully understand how you are progressing day-to-day. This extra insight will place them in a better position to answer any questions that you have.

On behalf of the Theragen team, I would like to wish you the very best for your recovery journey. We're here to support you. Please let us know how we can help.

Yours in health,

J. Chris McAuliffe

CEO, Theragen Inc.

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1. SYSTEM COMPONENTS

1a Generator Cable (long, 48")

1b Generator Cable (short, 12")

2 Electrodes (Type 1: Quantity 10, Type 2: Quantity 2)

3 Generator (silver) w/Belt Clip

4 Battery

5 Charging Cable

6 Power Supply Block

7 Battery Charger (white) w/Extra Battery

8 Battery Charger Dock

9 Electrode Shower Covers (Quantity 20, disconnect electrode lead wires from Generator Cable before showering)

10 Travel Case

11 Quick Start Guide (not shown)

12 Instructions For Use (not shown)

2. SAFETY INFORMATION

Read all of these instructions before using

- Use the product only for its intended use.
- Do not use unapproved components. Only use system components provided with the system or obtained from the company as supplies or replacements.
- In the case of a malfunction, **contact Customer Support at 1-800-901-5667.**
- **WARNING:** Do not attempt to repair or modify the device.
- Do not use system components with any other devices.
- Do not submerge or expose the device to liquids.
- Disconnect the generator while bathing, showering or swimming.
- Do not connect the battery charger to the wall outlet if wet.
- If the battery charger has fallen into water, unplug from the wall outlet before retrieving.
- Do not operate the battery charger if it has a damaged power cord or has been dropped or immersed into water.
- Do not short circuit, crush, penetrate or otherwise damage the battery or connect conductive materials across the battery terminals. These and other abuses can lead to serious injury or burns.
- If the generator is not being used, remove the battery. This will avoid indicators (visual, sound and vibration) from activating.
- Do not expose the system to prolonged heat, sunlight or cold. Normal operating temperature is 5 to 40°C (41 to 104°F) and normal storage and transport temperature is -25 to 70°C (-13 to 158°F).
- There are 2 generator lead wire lengths. If there is a situation where there is a risk of the longer lead wire causing strangulation, use the shorter length.
- There is a USB connector available when the generator lead wire is removed from the generator. This is for downloading device data by a physician or Theragen and is NOT TO BE USED FOR CHARGING THE DEVICE.
- If anything happens that is unexpected or different to what is contained in these instructions, **contact Customer Support at 1-800-901-5667.**

3. PRESCRIBING INFORMATION

Description

ActaStim-S passes a specific current between the electrodes in order to promote healing by inducing a therapeutic, low level electrical current at the fusion site. Federal law restricts this device to sale by or on the order of a physician, prescription (Rx) only. This device is not intended for re-sale.

Indications for Use

The ActaStim-S Spine Fusion Stimulator is a noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. The device is Rx only, and intended for single patient use in adult patients only.

Contraindications

There are no known contraindications.

Warnings

Cardiac pacemakers or cardioverters may be adversely affected by ActaStim-S. The concomitant use of ActaStim-S and a pacemaker or cardioverter must be assessed on an individual basis, such as with an electrocardiogram, prior to use. The patient should be referred to a cardiologist for monitoring of pacemaker function while wearing the active stimulator device. If there are any observable adverse changes in the pacemaker rhythm or output, ActaStim-S should not be used.

The safety and effectiveness of ActaStim-S in pregnant women have not been studied, and the effects of ActaStim-S on the mother or the developing fetus are unknown. A patient who is either pregnant or is intending to become pregnant should be referred to her doctor prior to treatment with ActaStim-S.

Precautions

The safety and effectiveness of ActaStim-S in individuals with the following conditions have not been studied, and therefore the safety and effectiveness of ActaStim-S in these individuals are unknown:

- spondylitis, infection, Paget's disease
- cancer, diabetes mellitus, renal disease
- trauma of the lumbar spine
- osteoporosis

Apply the electrodes after the skin has been cleaned and dried. If erythema develops at the electrode sites, the electrodes should be relocated adjacent to the original sites. If the reaction does not resolve after 48 hours after relocating the electrodes, the patient should be instructed to consult with the physician.

Do not submerge or expose ActaStim-S to water. The patient must be instructed to remove ActaStim-S during bathing, showering or swimming.

Compliance with the treatment schedule, daily battery pack changes, and replacing the electrodes (1 to 7 days) as needed are essential for proper device function. This system should only be used with components and replacement parts supplied by Theragen. Other components, parts and accessories may not be compatible, and may damage ActaStim-S. If any component does not function properly, contact **Customer Support at 1-800-901-5667**. No attempt should be made to modify or repair ActaStim-S.

Patients should be able to use ActaStim-S in accordance with the instructions for use. **If a patient cannot comply with these instructions for any reason, use of ActaStim-S is not recommended.**

Adverse Events

During a multi-center clinical study of 349 patients treated with a device delivering the same output parameters as ActaStim-S for the indication listed above, skin irritation was the most common adverse effect associated with the use of the device. It occurred in 9 patients (2.6% of the trial population): 4 patients treated with the active device and 5 patients treated with the placebo device.

Recommended Usage

ActaStim-S is designed to deliver 270 days of continuous therapeutic treatment for 24 hours per day. The recommended daily therapeutic treatment is continuous for 24 hours.

4. DIRECTIONS FOR USE

General

The stimulator and all of the following instructions have been specifically designed for safe, comfortable and easy use by a patient. They include the required assembly, operation, troubleshooting and maintenance (battery charging and cleaning) activities.

Begin using the stimulator immediately after reading the instructions for use and having received instructions from the prescribing physician.

The device is intended for use 24 hours per day until treatment is determined to be complete by the prescribing physician. Compliance with the instructions provided by the prescribing physician are critical to achieving effective treatment. Proper care of ActaStim-S is also required for the proper function of ActaStim-S.

The system has been designed to give 24 hours of treatment from a fully charged battery and routine charging and swapping of the 2 batteries every 24 hours will help ensure no inadvertent gaps in treatment. Indicators are provided to demonstrate the latest point at which a fully discharged battery will need recharging if treatment is to avoid being interrupted.

Examine the skin for signs of irritation when replacing the electrodes. If irritation is present, relocate the electrodes to a place adjacent to that site but still within the guidance. Disconnect the ActaStim-S generator during bathing, showering or swimming, and reconnect as soon as practical following these activities. Either remove the electrodes or cover the electrodes with the electrode covers during showering.

Placement of Electrodes

There are 2 types of electrodes provided. Both types are designed to work effectively. One or other type may be preferred based on how well they stick to the skin and how easily they can be removed.

Clean and dry the skin where the electrodes are to be placed. Trimming (not shaving) body hair from the electrode application area is often helpful. Choose one of the 2 electrode types provided with the system.

Remove the electrode from the pouch and remove the plastic backing material from the electrode. **Place one electrode on the back, two to three inches to the left of the area of the spinal fusion and the second electrode two to three inches to the right of the area of the spinal fusion so that the electrodes are on the back, four to six inches apart.**

Depending on the ability to move after surgery, it may be helpful to ask another person to assist in placing these electrodes. The patient should consult their prescribing physician if they have any questions or concerns regarding proper electrode placement.

If the skin becomes abnormally red at the electrode sites, the electrodes should be moved adjacent to the original sites. If the redness does not go away after 48 hours with the electrodes removed, the patient should contact their prescribing physician.

If there are issues with the electrodes remaining in place, try the alternative electrode type and/or consider applying an electrode cover over the top of the electrode.

Assembly of System

Choose the generator lead wire length that is most convenient for use. This will depend on the location chosen to place or carry the generator. Please ensure that the spare length of wire is not so long as to present a strangulation hazard.

Connect the end of generator lead wire that has the small block to the 2 pins of the electrode lead wires.
Note: This may be done before connecting the electrodes to the back if that is easier to manage.

Connect the other end of the generator lead wire (largest block) to the generator.

If it is desired to attach the generator to a belt, waistband or pocket, locate the belt clip and slide the flat side of the clip into the generator until the retainer slides into the hole in the generator.

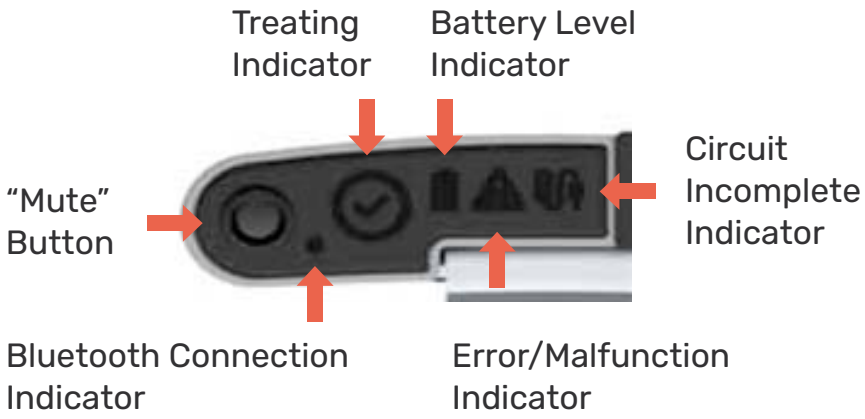
To remove the belt clip, pull the bottom of the curved end approximately ¼" away from the generator so that the clip can be pushed upwards until clear of the generator

Insert a battery. The battery can only be properly inserted in one orientation and incorrect insertion will be obvious, leaving a gap between the bottom of the battery pack and the generator. Check that there is enough charge to start treatment (green or solid orange battery status – see page 14 for description of battery indicators). If not, try the other battery provided and charge the original.

ActaStim-S will go through a self-check routine and will immediately start delivery of treatment. There is no on/off button. **Please do not insert the battery until you are ready to start treatment.**

To stop treatment, remove the battery.

Indicators and Troubleshooting Actions



The Battery Level, Error/Malfunction and Circuit Incomplete indicators also have an accompanying vibration and audible buzzer in case the icons are not visible.

Normal Operation

When first connected ActaStim-S goes through a self-check routine which illuminates several of the indicators before reaching a settled state.

If everything is operating correctly the “treating” check mark will be illuminated green and the “battery level” indicator will be either green (full) or orange (charge spare battery).

These indicators will turn off after 30 seconds leaving a blank set of icons. Pressing the mute button will re-illuminate the relevant icons. If ActaStim-S senses a change in state in the interim, the relevant icons, audio and vibrate will automatically activate.

Connection Issue

If the “circuit incomplete” indicator is illuminated (orange) then the circuit is not complete and treatment is not being provided (treating check mark will not be illuminated). This could have 2 causes:

- There is a disconnect between the electrodes and the back and/or the electrode leads and the generator lead wire connection block and/or the generator lead wire block and the generator. Check all connections to ensure they are complete.
- If all connections are complete then the circuit will be detecting that the resistance provided by the electrode gel and/or patient’s body is outside of ActaStim-S operating range. It is most likely that this could result from:
  - The electrodes being too dry. Moisten them by applying a small amount of water onto the skin facing surface and gently rubbing it into the surface.
  - The electrodes reaching the end of their useful life (approximately 1 to 7 days). Use fresh electrodes.
  - The skin not being clean and dry. Clean and dry the skin before re-applying the electrodes
  - Dehydrated skin. Skin resistance changes throughout the day as a body’s hydration level changes. Remove ActaStim-S and hydrate well by drinking water before re-applying ActaStim-S after around 30 minutes.

If none of the above eliminates the “circuit incomplete” icon, contact **Customer Support at 1-800-901-5667.**

Charge Spare Battery

When the battery level indicator is solid (not flashing) orange this indicates that the 2nd battery should start to be charged if it hasn't already done so. There is enough time left to charge a fully depleted battery.

Replace Battery

When the battery level indicator is flashing orange, the battery needs to be replaced with a more fully charged one. Ideally, the battery being replaced should be re-charged at that time to avoid any chance of disruption to treatment, but at the least should be recharged once the orange battery level indicator first comes on.

Error

If the error/malfunction icon illuminates (orange) remove the battery and replace it. If the problem persists, contact **Customer Support at 1-800-901-5667.**

End of Life

After 270 days of use ActaStim-S will stop operating and this will be indicated by the battery level, error/malfunction and circuit incomplete icons all flashing orange. Remove the battery and refer to disposal instructions.

Smart Phone Connection

This icon indicates that the generator is available for smart phone connection via Bluetooth.

Mute button

If audible/vibration (A/V) notification is happening, a short press will mute the A/V for 8 hours if treatment is being provided or for 15 minutes if treatment is not being provided. If ActaStim-S has automatically turned off the indicator lights, a short press will restore the indicator lights for 30 seconds to check status.

Battery Charging

Decide whether the battery charger is to be laid down or to be used with the dock. If it is to be used laid down, then connect the charging cable to the bottom of the charger and to the power supply block.

If the dock is to be used, insert the charger into the dock ensuring it is fully inserted and connect the charging cable to the dock socket and wall socket plug. Plug in the wall socket plug.

Charge the battery at room temperature (24°C (75°F)). Charging may require up to 3 hours. Charging time may vary in warmer or colder temperatures.

Remove the battery to be charged from the generator or if it has already been removed, locate it.

Insert it into the battery charger. The indicator on the front, plus the light around the top will glow orange for charging or green for fully charged.

These light around the top can be “muted” by pressing the button on the front of the charger.

Compliance and Activity Monitoring

Pressing the Mute button for 2 seconds or more will turn on the Bluetooth Low Energy (BLE) feature and allow a Smart Product (Phone, Tablet, PC) to connect and recover device history. This availability is confirmed by the Bluetooth connection icon illuminating (blue) after blinking blue whilst trying to connect.
Refer to the Quick Start Guide and follow the prompts within the ActaStim Sync app to complete connecting and extract compliance and activity data.

Electrode Care and Replacement

If removing the electrode temporarily for any reason, replace the plastic backing material to protect them. Before replacing them on the back, check to see that the surface is still clean and tacky. If not, apply a few drops of water to the skin facing surface and gently rub into the gel to help rehydrate. If this does not improve the surface properties, use a new pack of electrodes as supplied. Typically, a new set of electrodes may be required after a few days of use (1-7).

When supplies of electrodes are running low, contact **Customer Support at 1-800-901-5667** for additional supplies.

Cleaning Instructions

Use a damp cloth to clean the system (excluding the electrode skin facing surfaces). Do not use detergents or other cleaning products.

5. PATIENT COUNSELING INFORMATION

Compliance - Compliance with device use and care is critical to assure the proper function of ActaStim-S and to ensure effective treatment.

Battery - Change the battery approximately every 24 hours or as indicated by ActaStim-S. Charge the spare battery immediately on removal or at least when indicated by ActaStim-S (orange light).

Electrodes - Replace the electrodes when needed and clean the electrode application sites thoroughly with soap and water, and dry the site before applying the electrodes.

Skin Irritation - Examine the skin for irritation when replacing the electrodes. If irritation is present, relocate the electrodes adjacent to the original sites. The patient should be evaluated periodically to assess the skin for sensitivity.

Bathing - Disconnect ActaStim-S during bathing, showering or swimming. It should be reconnected as soon as practical following these activities. Either remove the electrodes, or cover the electrodes with the protective retainer patches, during showering.

6. STORAGE AND HANDLING

The system should be stored in a dry place at temperatures no lower than -25°C (-13°F) and no higher than 70°C (158°F).

7. DISPOSAL INSTRUCTIONS

When the prescribing physician determines that treatment is complete ActaStim-S should be disposed of according to local statutes and regulations or returned to Theragen for proper disposal. The battery is a lithium ion rechargeable battery.

8. CLINICAL INFORMATION

Evidence from a randomized, prospective cilnical study of a device that delivers the same signal as this device (SpinalPak, P850022/S009), was used to support FDA approval of this device.

In that study, 349 subjects who had lumbar fusion were enrolled and split into two groups. One group received treatment with the SpinalPak (active), and the other was given an inactive device (placebo). After 12 months, 87 subjects (79%) in the active treatment group achieved lumbar fusion, compared to 64 subjects (61%) in the placebo group.

Of the 349 subjects enrolled in the clinical study and who used the device at least once, nine experienced skin irritation and cited this as a reason to withdraw from the study (2.6%). Of these nine subjects, four were in the active group and five were in the placebo group. Three other subjects withdrew from the study because of adverse events: one placebo had a wound infection (non-device related); one placebo had back spasms; and, one active was "not progressing".

Eight subjects who completed the study experienced adverse events:

(1) leg pain (placebo);
(2) recurrent pain due to over-activity (placebo);
(3) post-surgical wound seroma (active);
(4) superficial wound disruption from a staple reaction (placebo);
(5) pedicle fracture - screw removed (placebo);
(6) a pedical screw placement (active);
(7) an aneurysm clipping (placebo); and
(8) a cluneal nerve neuroma at the graft site (active).

These eight subjects continued in the study, and were included in the effectiveness analyses.

9. TECHNICAL INFORMATION

Equipment Classification

Classification: Charger - Class II, Generator – Internally Powered
Type Applied Parts: Type BF (Electrodes, Generator Cable)
IP Rating of the System (Generator, battery, generator lead, electrodes): IP22 where:
The first characteristic numeral of 2 means both:

- Protected against access to hazardous parts with a finger
- Protected against solid foreign objects of 12,5 mm ⌀ and greater

The second characteristic numeral of 2 means:

- Protected against vertically falling water drops when enclosure tilted up to 15°

Mode of operation: Continuous

Output Waveform

60 KHz (plus or minus 10%) sinusoidal
5 to 10 mA (r.m.s.) at impedances between 100 and 450 Ohms
Greater than 3mA (r.m.s.) at impedances between 450 Ohms and 750 Ohms

Transport and Storage Conditions

-25°C to +5°C
+5°C to +35°C at a relative humidity up to 90%, non-condensing;
> 35°C to 70°C at a water vapor pressure up to 50 hPa

Operating Conditions

+5°C to +40°C
15 to 90% humidity
700 to 1060 hPa

Battery

Theragen p/n: 1101-0002
Voltage, nominal: 3.7 V
Capacity, nominal: 1,590 mAh

Power Supply

Manufacturer: CUI Inc
P/N: SWM6-5-NH-138
AC Input: 100-240 Vac, 0.6-3.0A, 50-60Hz
DC Output: 5V, 1.2A

10. ELECTROMAGNETIC COMPATIBILITY

ActaStim-S is intended for use in the Home Healthcare Environment (Restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (permanent or temporary), vehicles, stations, airports, museums and theaters.

In these environments there is no identified risk of loss in essential performance of the ActaStim-S device due to EM disturbances.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories and cables other than those specified or provided by Theragen of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Do not use unapproved components. Only use system components provided with the system or obtained from the company as supplies or replacements.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ActaStim-S system including cables specified by Theragen. Otherwise, degradation of the performance of this equipment could result.

Emissions Test	Standard	Compliance
RF Emissions	CISPR 11	Group 1, Class B
Harmonic Emissions	IEC 61000-3-2	Class A
Voltage Fluctuations / Flicker Emissions	IEC 61000-3-3	Yes

Immunity Test	Standard	Test Levels
Electrostatic Discharge (ESD)	IEC 61000-4-2	+/- 8 kV contact +/- 15kV air
Electrical Fast Transient / Burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surge	IEC 61000-4-5	± 2 kV
Voltage Dips and Interruptions	IEC 61000-4-11	Voltage dips: 1) 0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 2) 0 % UT; 1 cycle and 70 % UT; 25/30 Single phase: at 0° Voltage interruptions: 0 % UT; 250/300 cycle
Power Frequency H-Field	IEC 61000-4-8	30 A/m

Conducted RF	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF	IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz 27 V/m 385 MHz Pulse Modulation 18 Hz 28 V/m 450 MHz FM +/-5 kHz deviation 1 kHz sine 9 V/m 710/745/780 MHz Pulse Modulation 217 Hz 28 V/m 810/870/930 MHz Pulse Modulation 18 Hz

Radiated RF (cont.)		28 V/m 1,720/1,845/1,970 MHz Pulse Modulation 217 Hz 28 V/m 2,450 MHz Pulse Modulation 217 Hz 9 V/m 5,240/5,500/5,785 MHz Pulse Modulation 217 Hz

11. SYMBOL DESCRIPTIONS

Content quantity

Date of manufacture

Consult instructions for Use

Follow instructions for use

Manufacturer

Prescription only

Catalogue or part number

Serial number

Pressure range

Storage humidity range

Temperature limit

Type BF applied part

Recycle electronic equipment

Degree of ingress protection provided by ActaStim-S enclosure

12. WARRANTY AND CUSTOMER CARE INFORMATION

Theragen Inc. warrants that your ActaStim-S device will be free of defects for the maximum intended use period of 270 days. If your ActaStim-S device develops a fault within the specified period that cannot be resolved by our technical assistance team, Theragen will provide a replacement device free of charge providing that the device:

- Has been used for its intended purpose and in the manner described in this instruction manual.
- Has not been connected to an unsuitable power source.
- Has not been subjected to misuse or neglect; and
- Has not been modified or repaired by anyone other than an approved Theragen distributor or agent.

This warranty excludes the following consumable items that may need to be replaced after a period of time:

- Electrodes
- Battery
- Cables
- Power Supply (Excluding the Charger and Charger Dock).

This warranty complements existing national guarantee obligations and does not affect your statutory rights as a consumer.
To claim service under this warranty, please contact us at:

1-800-901-5667 **help@actastim.com**

You will be asked to provide your ActaStim-S serial number located on the label on the back of your device next to the SN icon. Please have this available prior to calling us.

ActaStim·S

A product by Theragen™

Designed by & manufactured for:
Theragen Inc.
11220 Assett Loop, Ste 101, Manassas VA 20109, USA
Tel: 1-800-901-5667
ActaStim.com

Part: 2101-0000
Rev: 2
Issued: 10/20

QUICK START GUIDE

ActaStim-S Spine Fusion Stimulator

ActaStim·S

Theragen

Part #: 2101-0001
Rev: 2
Issued: 10/20

Assembly & Application

A Select appropriate Generator Cable length [long 1a or short 1b]. Connect Electrodes 2 to cable pins.

B Electrodes 2 will be placed on the lower back on either side of the site of spine fusion surgery area. Clean and dry the skin before attaching the electrodes.

C Connect Generator Cable 1a or 1b to Generator 3 .

D Insert Battery 4 into Generator 3 . This turns on device including display/audio/vibrate. Check back page for indicators.

E Generator 3 can be clipped on belt, carried in a pocket or bag, or placed on furniture.

Important Safety Information

Do not use Generator in the shower. (Disconnect Electrodes from Generator Cable)

Do not immerse in water

See patient manual for additional safety information.

Charger Operation

Connect Charging Cable 5 to Power Supply Block 6 .

Connect Charging Cable 5 to Battery Charger 7 or Battery Charger Dock 8 .

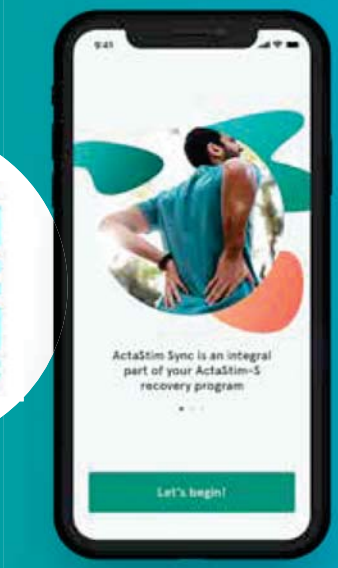
Battery Charging (Orange Icon)

Battery Charged (Green Icon)

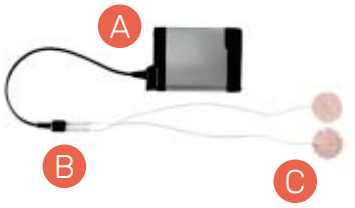
Theragen **Night Mode** (Dimmer Switch)

Get started with ActaStim Sync

- Scan QR code or search "**ActaStim Sync**" in the AppStore or Google Play
- Download ActaStim Sync app
- Open app and follow the prompts



Indicators & Troubleshooting

Indicator	Description	Action
	Button to Mute Audio/Vibrate and Turn Off Display	Press once, twice or three times to turn off audio and vibrate, or to toggle display on/off. 
	**Green Battery** = Charged **Green Check** = Treating	No action required.
	**Orange Electrodes** = Connection Issue *Battery may be green, orange or flashing*	1. Check connections Ⓐ and Ⓑ 2. Check that electrodes Ⓒ are in contact with the skin 3. Check manual 
	**Orange Battery** = Need to make sure that Spare Battery is charging as current battery is low **Green Check** = Treating	Check that Spare Battery is charging or start charging Spare Battery. 
	**Orange Flashing Battery** = Need to change Battery *No Green Check = Not Treating*	Remove battery from Generator and replace with charged Battery from Charger. 
	**Orange Triangle** = Product Fault *Battery may be green, orange or flashing* *No Green Check = Not Treating*	Call Customer Support 1-800-901-5667
	**Orange Flashing Battery, Triangle and Electrodes** = End of Product Life	270 days of treatment complete. Device will no longer provide treatment. Contact Physician.