TALISMANN™

neuromodulation system

User's Guide

bioventus®

Innovations For Active Healing

Environmental Policy

Service personnel are advised that when changing any part of the TalisMann system, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. When the life cycle of a TalisMann component has been completed, the product should be discarded according to the laws and regulations of the local authority. For more information regarding these recommended procedures, please contact Bioventus. Bioventus is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

bioventus®

Bioventus LLC
4721 Emperor Blvd Suite 100
Durham, NC 27703 USA
Telephone: 888-453-2136
Website: TalisMann.com

List of Symbols

	Caution
	Warning
	Class II Equipment (Double Insulated)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must Not Be Disposed of with Other Household Waste
	Refer to Instruction Manual/Booklet
	Consult Instructions for Use
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
	Single Patient Multiple Use
	MR Conditional
	Storage Temperature
	Humidity Limitation
	Atmospheric Pressure Limitation
IP68	Protection Against Ingress of Water
	Keep Dry
	Use By
	Quantity
Rx Only	Prescription Only
MD	Medical Device

Table of Contents

1

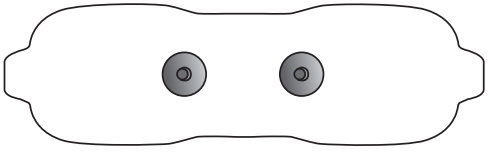
Introduction

The TalisMann Neuromodulation System is intended to be operated by patients to help manage their pain. The TalisMann Pulse Generator and Receiver works by providing electrical impulses from an implanted neurostimulator to a target area in the body. These impulses are intended to interrupt or change the pain signals, inducing the feeling of tingling or numbness (paresthesia), and possibly reducing or replacing the feeling of pain. The TalisMann system is made up of implanted components from the TalisMann Pulse Generator and Receiver and Implant Kit (TM-1000) and external components from the User Kit (PNS-5000). The TalisMann System includes:

- An implanted lead
- A TalisMann Pulse Generator and Receiver
- An External Electric Field Conductor (E-EFC)
- A Gel Electrode
- A downloaded Mobile Application (MAPP)

Lead

Pulse Generator/Receiver



Gel Electrode

E-EFC

This guide includes important safety information about your TalisMann system, describes the external components of your TalisMann system that are used to activate the implanted lead, and reviews how to set up and use your system. Be sure to read this guide before

using your TalisMann system. Ask your doctor to explain and demonstrate any procedures you do not understand.

Note: Your User Kit contains a Medical Device Identification (ID) Card. Complete your card as soon as possible and carry it with you at all times. Your Medical Device ID Card identifies you as a person with an implanted medical device.

You may need this card to bypass security screening devices, which are common at airports, grocery stores, libraries, etc. You may also need this card if you require medical treatment. This card includes the website address for TalisMann. A copy of the TalisMann User's Guide is posted on the TalisMann.com.

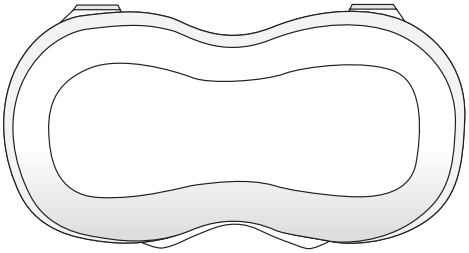
2

User Kit

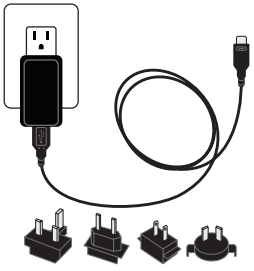
Your User Kit includes the following:

- External Electric Field Conductor (E-EFC)
- System Charger Set
- Gel Electrode Carrying Case
- User's Guide
- User's Reference Card
- Medical Device Identification Card
- Mesh Tote Bag

External Electric Field Conductor (E-EFC)



Gel Electrode Carrying Case



System Charger Set

3

Warnings and Cautions

Be sure to follow your doctor's guidance. Use your TalisMann system only as instructed in the User's Guide.

Indications for Use

The TalisMann Neuromodulation System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The TalisMann Neuromodulation System is not intended to treat pain in the craniofacial region.

Device Use and Suitability

The TalisMann Neuromodulation System is designed to reduce pain in patients with chronic pain of peripheral nerve origin. Components of the TalisMann Pulse Generator and Receiver and Implant Kit and Clinician Kit are for use by trained clinicians, and components of the User Kit are for use by individual patients. Additional information, including clinical safety and performance, can be found at www.TalisMann.com.

The TalisMann Neuromodulation System may not be suitable for treatment of acute pain, for pain that is not of peripheral nerve origin, or for patients whose required stimulation parameters cannot be met by the TalisMann Neuromodulation System. The TalisMann Neuromodulation System implant procedure may be performed in any sterile surgical setting.

Device Materials

Materials in the User Kit that may contact the patient during device use include:

- Hydrogel
- Plastic

Both materials have been tested to verify biocompatbility.

Essential Performance

The TalisMann System does not have Essential Performance as there is no performance necessary (as defined by IEC 60601) to avoid unacceptable risks, in that all sources of identified risk have been mitigated (through application of appropriate risk control measures) to the greatest extent possible and to an acceptable degree. There are no sources of residual risk which outweigh the benefits accrued from the use of the device and which would thus be deemed unacceptable.

Contraindications

The TalisMann System is contraindicated for:

- Patients who are unable to operate the TalisMann system.
- Patients who are poor surgical candidates.
- Patients who have a cancerous lesion present near the target stimulation point or near to where the Gel Electrode will adhere.
- Patients with bleeding disorders or active anticoagulation that cannot be stopped for a few days close to the time of the surgical procedure.
- Patients who are unable to remove the E-EFC.
- Patients who are unable to communicate a device malfunction from device use.

⚠ Warnings

- The TalisMann System may interfere with other implanted devices such as cardiac pacemakers, defibrillators, and other implanted stimulators. The effect of other implanted devices, including but not limited to implanted drug pumps and other stimulation devices on the TalisMann System is unknown.

A risk/benefit determination should be performed before using the TalisMann System for:

- Patients exposed to diathermy. Shortwave, microwave and/ or therapeutic ultrasound diathermy should not be used on patients who have a TalisMann System. The energy generated by diathermy can be transferred through the TalisMann system components, causing tissue damage at the lead site and potentially resulting in severe injury. Diathermy may also damage the TalisMann system components, resulting in loss of therapy. Injury or damage can occur during diathermy treatment whether neurostimulation is turned on or off. All

patients are advised to inform their health-care professionals that they should not be exposed to diathermy.

- Patients exposed to therapeutic ultrasound.

Magnetic Resonance Imaging (MRI) Safety Information

The TalisMann System is MR Conditional. A person implanted with this device can be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe injury or device malfunction. Full MRI safety information is available in the MRI Guidelines Manual, which can be obtained at www.TalisMann.com or by calling 888-453-2136. An MRI examination of a patient with a TalisMann System should not be conducted until the information in the Clinician's Guide and MRI Guidelines is read and understood.

All external components of the TalisMann system, including the Gel Electrode, External Electric Field Conductor (E-EFC), Clinician's Programmer, Clinician's Programmer Charger, and Tester are MR Unsafe and are contraindicated for the MR environment. Do not bring them into the MR system room.

Pregnancy

The effects of electrical stimulation on pregnancy are not known. Do not use electrical stimulation during pregnancy.

Programming

Only a trained clinician should program the TalisMann system.

Flammable Fuel, Chemicals or Environment

The TalisMann is not intended to be used in oxygen-rich environments.

Turn off stimulation when you are near a refueling station, flammable fuel, fumes or chemicals. If your system is on, it could ignite the chemicals or fumes, causing severe burns, injury or death.

Driving and Operating Machinery

Turn off stimulation while driving or operating machinery.

Electromagnetic Compatibility Warnings

Medical Devices/Therapies

Operation of the TalisMann system in close proximity (e.g., 1 meter or 3 feet) to shortwave or microwave therapy equipment may produce instability in the E-EFC output.

The following medical therapies or procedures may turn stimulation off. They may also permanently damage the TalisMann external components and may cause injury, particularly if used close to the system components.

- Lithotripsy
- Electrocautery
- External defibrillation
- Ultrasonic scanning
- High-output ultrasound

Electromagnetic interference (EMI) from the following medical procedures is unlikely to affect the TalisMann system:

- Computerized Axial Tomography (CT or CAT) scans
- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy

Note: Turn off stimulation and remove the Gel Electrode before undergoing a medical procedure.

Electrosurgery Devices

If you require electrosurgery, tell your doctor you have an implanted TalisMann System. Electrosurgery devices should not be used close to an implanted TalisMann System. Contact between an active electrode of the electrosurgery device and the TalisMann System can stimulate the receiver and cause severe injury.

High-Frequency Surgical Equipment

Remove the Gel Electrode before medical treatment. If you are connected to the TalisMann system and high-frequency surgical equipment, you may experience a skin burn where the Gel Electrodes adhere. The TalisMann E-EFC may also become damaged.

Body-Worn Devices

Although unlikely, body-worn medical devices may interfere with the RF communication used in the TalisMann system. Stimulation control may be delayed. Examples of a body-worn device are a pain pump or an insulin pump and a monitoring device. To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the TalisMann system and all other electronic devices. See the “Troubleshooting” section for help. See the “Appendix” for more information.

The TalisMann system’s wireless technology may cause EMI to other body-worn medical devices. Refer to the instructions for use for those devices for information on recommended minimum separation distances.

Security Screening Devices

Certain types of security devices may affect stimulation. Examples include those used at the entrances and exits of public buildings such as libraries, airports and retail stores. Ask for help to bypass the device. Show your Medical Device Identification Card if you must pass through the device:

- Turn off your TalisMann system.
- Pass through the security screening device quickly.
- Stay as far from the emitter as possible. Walk, for example, in the center of a pass-through security gate.

Cell Phones

There is potential for interference between electronic devices, including cell phones. Stimulation control may be delayed. If interference is suspected or anticipated, distance yourself from the source of interference. To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the TalisMann system and all other electronic devices.

Precautions

Post-Operative Care

After the implant procedure, check the incision site for infection, possible device rejection or other possible adverse effects.

Contact your physician immediately if you have:

- Excessive redness or discharge around the incision site.
- Prolonged pain at the incision site.
- Warmth and swelling of the incision site.
- Fever
- Dizziness
- Bleeding

Known or Suspected Heart Problems

Consult your doctor if you have or suspect you have a heart condition. Doctors should use caution when treating patients with suspected or diagnosed heart problems.

Implant Failure

Implanted receivers may fail at any time. If a TalisMann fails or breaks, then the TalisMann system may need to be removed or replaced. It is possible that small fragments of the lead could remain at the implantation site after removal, which will indefinitely prevent you from being eligible for certain procedures, such as diathermy, therapeutic ultrasound, or MRI in the affected area. Immediately contact your doctor if implant failure is suspected.

Postural Changes

Changes in posture or abrupt movements may change the stimulation you feel. Turn off stimulation before stretching or exercising.

For Single Patient Use Only

Do not adhere the Gel Electrode to any other person or any other part of your body.

Keep Out of Reach of Children

Keep all TalisMann components out of the reach of children.

Skin Abnormalities

Do not adhere the Gel Electrode to skin that is swollen, infected or inflamed or to skin that is broken. Do not adhere the Gel Electrode over veins that are swollen or inflamed.

Skin Irritation

It is normal for the skin under the Gel Electrode to become red. The redness should disappear about one hour after you remove the Gel Electrode.

Some people may be allergic or hypersensitive to the electrical stimulation or the gel on the Gel Electrode. Persistent redness, lesions or blisters are signs of irritation. Stop using the TalisMann system until the irritation is gone. To avoid irritation, remove the Gel Electrode every three to four hours for 15 minutes. Talk to your doctor if irritation persists.

Sensations Caused by Stimulation

As with other nerve stimulation devices, the TalisMann System achieves pain relief by causing different sensations to be felt in the area of treatment. These sensations (also referred to as “paresthesia”) include tingling and numbness. While these sensations are normal during TalisMann use, stimulation should not proceed to the point of being painful.

Gel Electrode Expiration Date

Do not use a Gel Electrode with a “Use by” date that has expired.

Gel Electrode Placement and Stimulation

- Only use Gel Electrodes supplied by Bioventus.
- Only your doctor should decide where to place the Gel Electrode.
- Only your doctor should program your TalisMann system.
- Turn off stimulation before adhering, removing or handling the Gel Electrode.
- Do not adhere the Gel Electrode across your chest or near your heart. Electrical stimulation of the heart may disturb heart rhythm.
- Apply Gel Electrode only to the areas recommended by your doctor. Avoid

placing the Gel Electrode across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus).

- Do not adhere the Gel Electrode over anything other than skin. Do not adhere it over an adhesive bandage, for example. The Gel Electrode must be in full contact with the skin or the stimulation could cause serious injury.
- Do not place the Gel Electrode over skin folds, scarred tissue, irritated skin, uneven skin surfaces or broken skin.
- Always check the Gel Electrode gel pads before use. Do not use the Gel Electrode if the gel appears dry, worn, dirty or irregular.
- Remove the clear protective cover from the Gel Electrode before using.
- Do not handle the Gel Electrode with both hands while stimulation is on. Serious injury can occur if electrical current passes through your heart.
- Do not apply the Gel Electrode to anyone else or any other part of the body than that determined by your doctor.

Adverse Effects

In the unlikely event that any of the following occurs, stop using your TalisMann system, remove the Gel Electrode and immediately contact your doctor.

Risks Related to the Implant Procedure

If the lead is not placed properly, it may need to be removed or your therapy may need to be adjusted. Nerve injury is possible, although unlikely. Possible surgical complications include infection and device rejection. Contact your physician immediately if you experience fever, swelling, bleeding or prolonged pain at the implant site.

Risks Related to Stimulation

- Stimulation of skin and muscles surrounding the lead may cause increased pain.
- You may have undesirable movements during stimulation. If this occurs please contact your physician.

If you experience any discomfort during stimulation, or notice any skin abnormalities:

- Stop stimulation immediately.
- Remove the Gel Electrode.
- Notify your physician.

Additional Risks Related to the TalisMann System

- If the lead moves, it may change the stimulation effectiveness.
- While very unlikely, the tissue around the lead may react to the implanted materials.
- External electromagnetic interference (EMI) may cause the TalisMann components to malfunction. EMI may also affect stimulation.
- You may have persistent pain at the implant site.
- Although rare, the skin overlying the lead may erode.
- Portable and mobile radio frequency communications equipment can affect medical electrical equipment.
- The TalisMann external components could overheat if the components fail. Overheating could cause burning.

Temperature

The TalisMann E-EFC can heat up to 43°C during operation in extremely hot areas/rooms. If this occurs turn off stimulation, remove E-EFC, and set aside until temperature is within operational conditions.

4

Environmental Conditions that Affect Use

Storage and Handling

Keep all TalisMann components dry and protect them from extreme changes in temperature and humidity. Do not use or store your components where they could come in contact with water, such as by sinks, bathtubs and shower stalls. Do not expose them to weather conditions such as rain or snow. Do not store your TalisMann components in a car where they can be exposed to extreme hot or cold temperatures.

Place your TalisMann components in an air-tight plastic bag before moving them from hot to cold temperatures. Let them adjust slowly (for at least two hours) to the new temperature before use.

Changes to the TalisMann system not approved by Bioventus could void your authority to operate the equipment.

Gel Electrode Storage Temperature Range: 5°C to 27°C (41.0°F to 80.6°F)

External Electric Field Conductor (E-EFC) Storage Temperature Range: -20°C to +60°C (-4°F to +140°F)

Radio Communication Information

Several components of the TalisMann system use radio communication. They have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 (Radio Frequency Devices) of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential environment. This equipment generates, uses and can radiate radio frequency energy. If not used as instructed, this equipment may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur. 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 of the following measures:

- Move or adjust the receiving antenna.
- Move the equipment farther from the receiver.
- Contact the dealer or an experienced radio/television technician for assistance.

The antenna for each transmitter must not be near to or operating with any other antenna or transmitter.

Electromagnetic Emissions

The TalisMann system is medical electrical equipment and was tested for electromagnetic compatibility (EMC) in accordance with International Electrotechnical Committee (IEC) 60601-1-2. The TalisMann system should be configured and used in accordance with the instructions provided in this manual.

End-Of-Life Waste Management

WEEE Regulations place an obligation on distributors to offer consumers a take-back system where WEEE items can be disposed of free of charge.

5

Device Description

⚠ **CAUTION:** Do not attempt to repair any of the components in your User Kit. If a component does not work, contact Customer Service or your local distributor. Unauthorized repair can void your warranty. Use only TalisMann components with your TalisMann system.

This section describes the StimRouter Lead, TalisMann E-EFC, Gel Electrode, and Electrode Carrying Case, System Charger Set, and TalisMann Mobile Application (MAPP).

StimRouter Lead with TalisMann Pulse Generator and Receiver

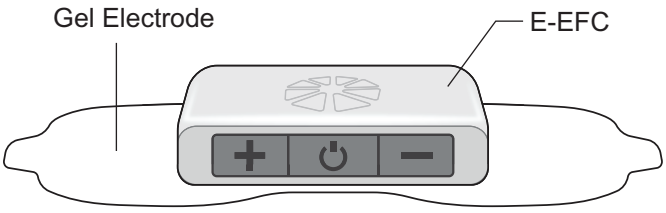
The StimRouter Lead is flexible and approximately 15 cm (6 in.) in length. The lead has a stimulation end and a receiver end. The lead implantation places the stimulation end near or at the targeted peripheral nerve. The TalisMann Neuromodulation Pulse Generator/Receiver is attached to the proximal end of the StimRouter lead and is placed under the skin into a surgically created pocket. The TalisMann Neuromodulation Pulse Generator/ Receiver receives the signal from the E-EFC and then generates the stimulation pulse through the lead to the stimulation end. See Figure 5-1.

Figure 5-1: The StimRouter Lead and the TalisMann Pulse Generator and Receiver.

External Electric Field Conductor (E-EFC)

The E-EFC generates the trancutaneous signal and transmits the signal via the Gel Electrode/ skin interface to the TalisMann Neuromodulation Pulse Generator/ Receiver. The E-EFC snaps onto the Gel Electrode (See Figure 5-2) and responds to wireless commands from the MAPP. The E-EFC has three buttons: power, plus, and minus.

Figure 5-2: The E-EFC attached to the Gel Electrode.

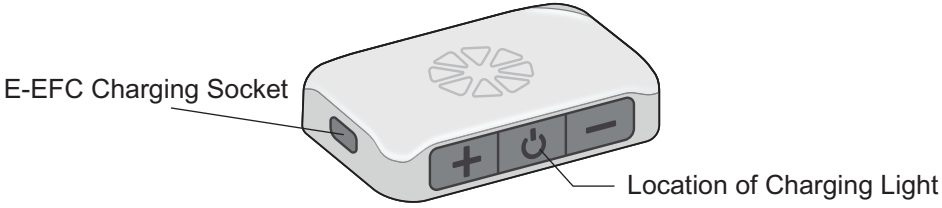


Charging Socket

The E-EFC charging socket is located on the front panel of the E-EFC. When the E-EFC is charging a green charging light will appear on the side panel of the E-EFC. See Figure 5-3.

Figure 5-3: The E-EFC charging socket and charging light location.

Light



The E-EFC light illuminates the Power button on the E-EFC. Light colors indicate the status of the E-EFC:

- WHITE –
  Solid: E-EFC is off and is fully charged – Connected to USB
  Blinking: E-EFC is off and is currently charging – Connected to USB
- GREEN –
  Solid: E-EFC is in standby mode and is fully charged – Connected to USB
  Blinking: E-EFC is in Standby mode.
  Fast Blinking – E-EFC is in stimulation mode
- AMBER –
  Blinking: Battery is Low
- PINK –
  Blinking: Information signal that action is required.
  Solid Pink: E-EFC encountered a non-recoverable error.

- BLUE –
  Blinking: E-EFC is in pairing mode, ready to make Bluetooth connection with MAPP or CPS

Gel Electrode

Gel Electrode features: (See Figure 5-4)

- Two gel pads that adhere the Gel Electrode to the skin. The gel pads also transmit the stimulation signal from the E-EFC to the TalisMann Neuromodulation Pulse Generator/Receiver.
- Two snaps for E-EFC placement.
- Two tabs for removing the Gel Electrode from the skin.
- A liner to protect the gel pads on the back of the Gel Electrode.

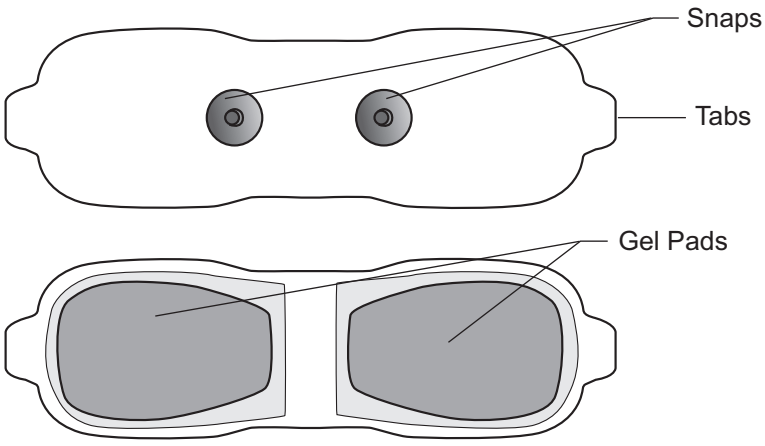


Figure 5-4: Gel Electrode (top and bottom views).

The Gel Electrode is disposable and can be reused while the gel pads are intact. The Gel Electrode is designed to fully adhere to the skin or for a maximum of four days.

The typical lifespan of the Gel Electrode is two to four days, depending on:

- The number of hours of use.
- The number of times the Gel Electrode is adhered to and removed from the skin.
- Hygiene and skin care in the area of Gel Electrode placement.

Gel Electrode Liner

Every Gel Electrode is supplied with an electrode liner. See Figure 5-5. The liner is used to keep the gel pads on the Gel Electrode from drying out.

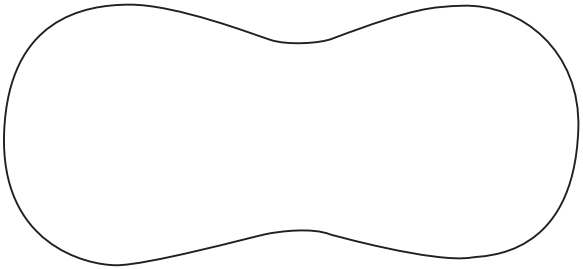


Figure 5-5: Gel Electrode liner.

Always store the Gel Electrode with the liner attached. Store the liner in the Electrode Carrying Case between uses, to keep the liner clean and protected.

A liner can be reused for as long as it can stick to the entire surface of the gel pads on the back of the Gel Electrode.

Electrode Carrying Case

The Electrode Carrying Case is used to store the E-EFC, Gel Electrode, and the Gel Electrode liner. See Figure 5-6.

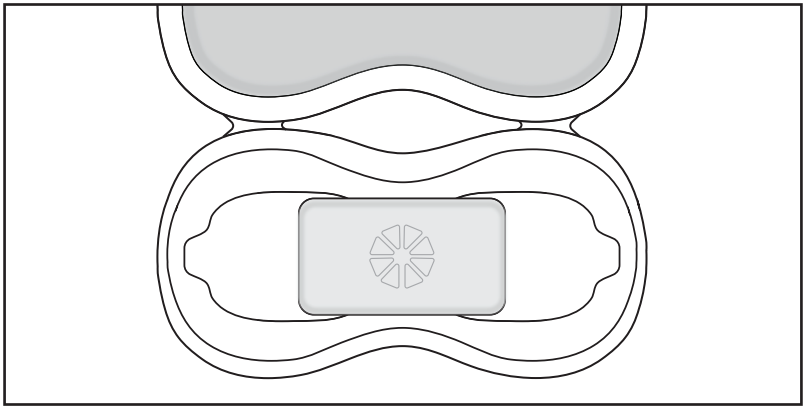


Figure 5-6. Inside of the Gel Electrode Carrying Case.

System Charger Set

The system charger set is a plug-in AC/DC adapter that connects to a main power supply and includes a USB C cable, a charger, and interchangeable blades for U.S. and international outlets. The system charger set is used to charge E-EFC battery. See Figure 5-7.

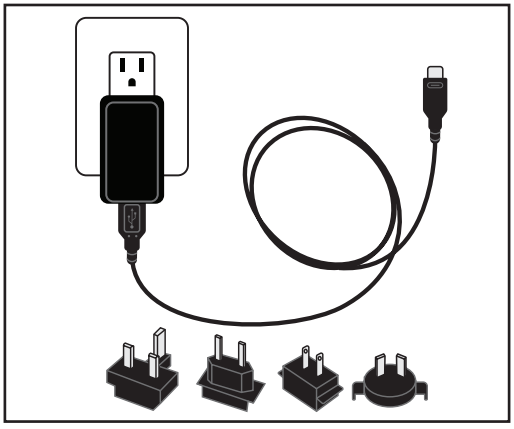


Figure 5-7: System charger set.

⚠ **CAUTION:** Use only the charger included in your User Kit. Using other chargers could damage the system.

⚠ **CAUTION:** The AC/DC adapter portion of the system charger set must be disconnected from the main power supply to completely disconnect the power input.

Mobile Application (MAPP)

The TalisMann system has an optional mobile application that can be used to control the Talismann system. Please download the MAPP from your device's application store by searching for "Stimrouter Plus". The app logo is:

The StimRouter Plus MAPP communicates wirelessly to the E-EFC. The StimRouter Plus MAPP is used to:

- Turn Stimulation on and off.
- Adjust stimulation intensity
- Select a stimulation program

Please ensure that the StimRouter Plus MAPP has been downloaded on your mobile device.

6

Set-Up Instructions

Charging the E-EFC

The E-EFC comes with a rechargeable Lithium Polymer battery installed. Charge the E-EFC daily, or when the E-EFC battery is low. Low battery is indicated by the MAPP or by amber or pink lights on the E-EFC.

Note: Charge the E-EFC for at least two hours immediately before a programming session.

WARNING: Use only the medical-grade charger included in the User Kit. Use of any other charger could result in serious injury.

WARNING: The E-EFC battery is not replaceable. Do not attempt to remove or replace the E-EFC battery.

To charge the E-EFC:

1. Open and assemble the System Charger Set. The System Charger set comes with interchangeable blades for U.S. and international outlets. Select the appropriate blade that fits the chosen power outlet and slide the blade onto the end of the charger. Then connect the USB C cable to the charger cable.
2. Connect the USB C cable to the E-EFC. See Figure 6-1.
3. Plug the charger into a power outlet.

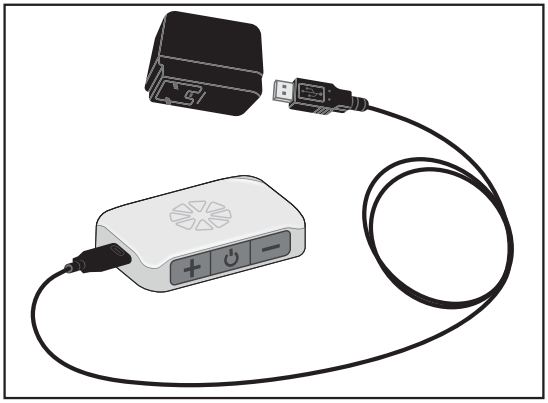


Figure 6-1: Charging set-up.

4. The E-EFC should fully charge within 8 hours.

Note: The E-EFC will not allow stimulation to start while the E-EFC is charging and connected to the USB C cable. Please remove the E-EFC from the charger before beginning stimulation.

Preparing the Skin

The skin below the Gel Electrode should be clean, dry, and free from irritation, infection or injury. It is important to develop a good skin care daily routine and to follow the steps listed in this section. Always check your skin before using the TalisMann system. If you have any concerns, contact your doctor.

Note: There may be a raised area on the skin where the TalisMann Pulse Generator and Receiver has been placed.

⚠ **CAUTION:** Skin inflammation in the region of the Gel Electrode may be aggravated by pressure from the electrode. If the skin is inflamed or swollen, do not use your TalisMann system until the inflammation is gone. If the skin has a cut or scrape, do not adhere the Gel Electrode.

To prepare the skin:

1. Clean the skin where the Gel Electrode will adhere with a wet washcloth.
   If any lotions or oils are on the skin, then clean with soap and water. Rinse well and dry.

2. Do not shave with a razor in the area where the Gel Electrode will be placed because it can increase the risk of skin irritation. If necessary, remove excess body hair from the skin area using scissors or electrical trimmers.
3. Always check the skin for redness or a rash.

Connecting the Gel Electrode and E-EFC

To connect the Gel Electrode and E-EFC:

1. Obtain a new Gel Electrode or one with gel pads that can still fully adhere to the skin.
2. Check the “Use by” date on the Gel Electrode box.
3. Do not remove the liner at this time.
4. Set the Gel Electrode on a flat surface with the gel pads facing down.
5. Snap the E-EFC onto the Gel Electrode. See Figure 6-2.

Note: To ensure proper stimulation, the E-EFC must be connected to the Gel Electrode properly.

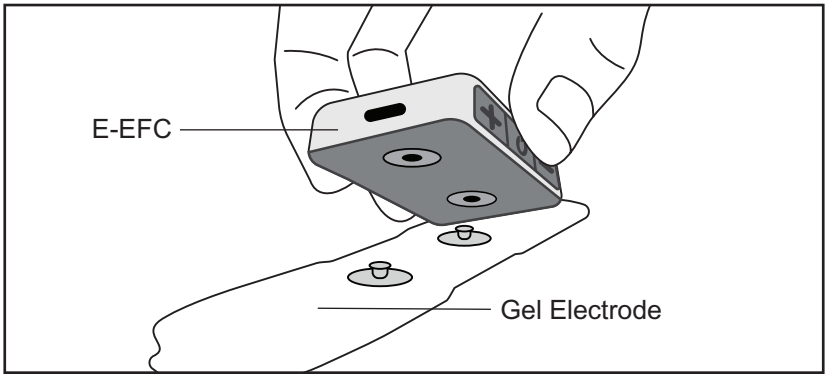


Figure 6-2: TalisMann E-EFC connecting to Gel Electrode.

Adhering the Gel Electrode

A Gel Electrode can be reused as long as the gel pads are intact and can fully adhere to the skin or for a maximum of four days of use.

WARNINGS:

- Do not touch the gel pads of the Gel Electrode with both hands while stimulation is on. Serious injury can occur if electrical current passes through your heart.
- Turn stimulation off before adhering, removing or handling the Gel Electrode.
- Do not pinch or stretch the skin while adhering the Gel Electrode.
- If the gel pads start to peel off at the edges or detach from the Gel Electrode, immediately dispose of and get a new Gel Electrode.

To adhere the Gel Electrode:

1. Remove the liner and store it in the Electrode Carrying Case. See Figure 6-3. Do not bend the liner. Keep the liner clean and protected so it can be reused when the Gel Electrode is removed from the skin.
2. Visually inspect the gel pads on the back of the Gel Electrode. Make sure the gel is smooth and the gel pads are not dry, worn or dirty.
3. Using the index finger and thumb, grasp the edges of the E-EFC attached to the Gel Electrode so the gel pads face downward. See Figure 6-4.

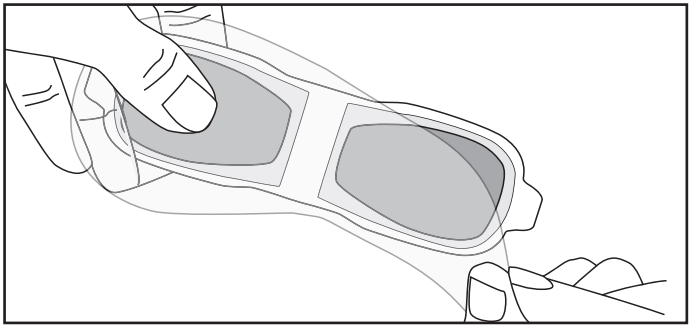


Figure 6-3: Remove the Gel Electrode liner.

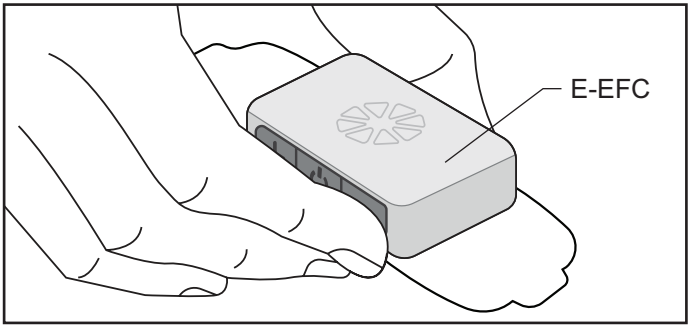


Figure 6-4: Grasp the edges of the E-EFC attached to the Gel Electrode.

4. There are two gel pads underneath the plus and minus buttons of the stimulator. The gel pad underneath the minus button should be placed on the skin above the TalisMann Pulse Generator and Receiver. See Figure 6-5.

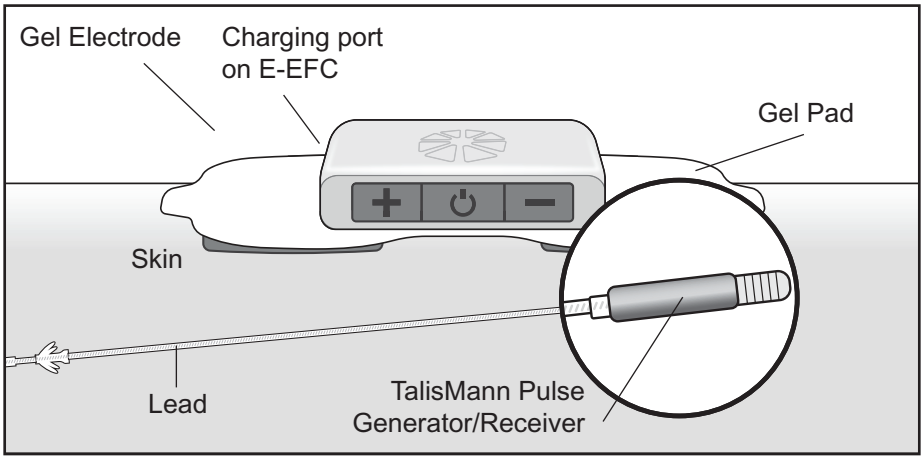


Figure 6-5: Correct stimulation position. (Illustration not to scale.)

Note: The effectiveness of the stimulation is sensitive to the alignment and rotation of the Gel Electrode in relation to the TalisMann Pulse Generator and Receiver. If the alignment or rotation of the Gel Electrode changes, the stimulation intensity may need to be adjusted.

5. Firmly adhere the Gel Electrode to the skin. Make sure the Gel Electrode is in full contact with the skin. If the Gel Electrode is not firmly adhered to the skin and moves, stimulation may become uncomfortable or ineffective.

7

Operating Instructions

⚠ **CAUTION:** Use only the Bioventus components designed and manufactured for the TalisMann System. The use of non-Bioventus components may damage your system and cause injury.

This section includes instructions on how to operate your TalisMann System, including instructions for:

- Using the Mobile Application.
- Selecting a Stimulation Program.
- Turning stimulation On.
- Adjusting Stimulation Intensity.
- Turning stimulation Off.
- Tracking TalisMann Usage.
- Updating TalisMann Firmware.
- Removing the Gel Electrode.
- Removing the E-EFC from the Gel Electrode

Before you operate your TalisMann system, be sure to read the previous sections of this guide. Important safety information and features of your TalisMann components are described. If you have any questions, problems, or experience any new symptoms or painful areas, contact your doctor for appropriate diagnosis and treatment. Your doctor is familiar with your specific situation and the best source of additional guidance.

Using the SitmRouter Plus MAPP

Click the icon on your mobile device to open the SitmRouter Plus MAPP. The SitmRouter Plus MAPP has four main screens: E-EFC Setup, Controls, Activity and More.

E-EFC Setup

Users can connect new E-EFCs and modify connected E-EFCs from the E-EFC Setup screen.

Connect a New E-EFC

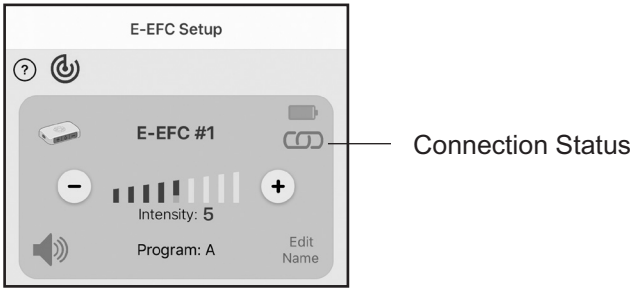
Simultaneously, press and hold the plus (+) and minus (-) buttons on the E-EFC until the blue light flashes. Click the “Connect New E-EFC” button from the “Setup” tab of the MAPP. If you experience any issues when connecting the E-EFC to the MAPP, please contact Bioventus.

Re-connection to Same E-EFC

Restarting the MAPP application will automatically re-connect to the E-EFC that has been previously connected via “Connect a New E-EFC” button.

Modify Connected E-EFC(s)

Click the box of a connected E-EFC. The box will expand and allow the user to:



- Verify the E-EFC connection Status.

Figure 7-1: Verify E-EFC Connection Status.

- Change stimulation intensity of the currently selected therapy program by pressing the plus or minus buttons

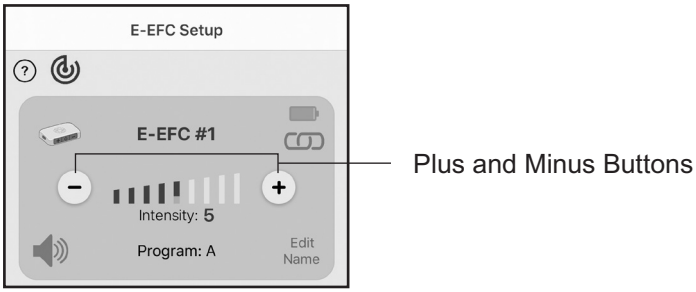


Figure 7-2: Stimulation Intensity Adjustment.

- Turn E-EFC audio cues on or off by pressing the audio icon

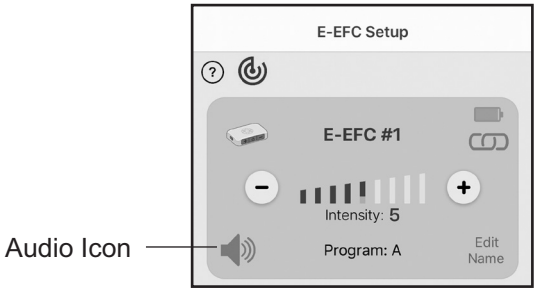


Figure 7-3: Audio Cues On/Off.

- Change the name of the selected E-EFC by pressing “Edit Name”.

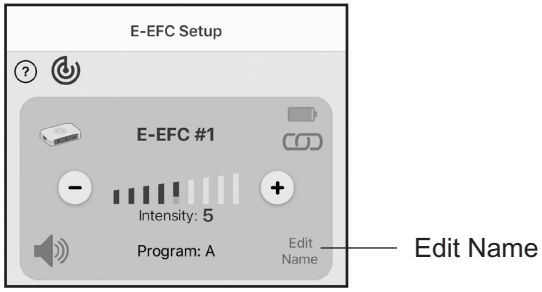
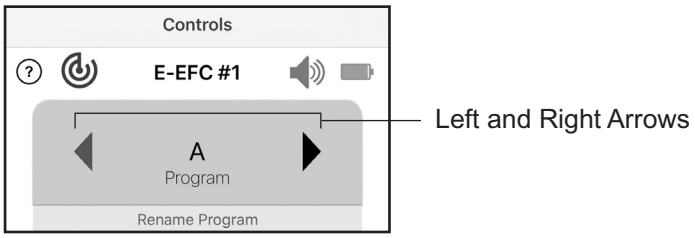


Figure 7-4: Edit E-EFC Name.

Controls

Users can modify settings of a selected E-EFC, enter and exit stimulation mode, and view program parameters from the Controls screen.

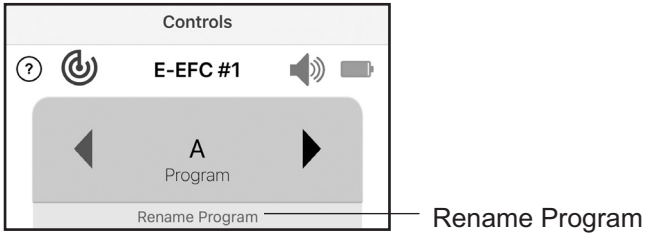
- Change the selected therapy program by pressing the left and right arrows. A therapy program will not be active unless started from the StimRouter Plus MAPP.
- Starting stimulation directly from the E-EFC will begin the last run therapy



program and will not change the active program.

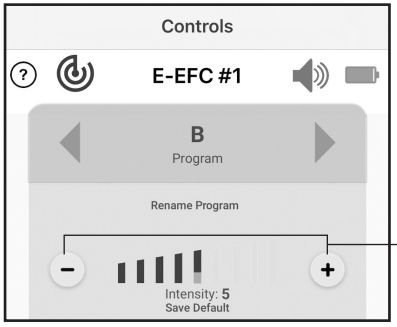
Figure 7-5: Select a Therapy Program.

Note: Stimulation Programs may not be selected from the E-EFC. Stimulation Programs may only be selected from the MAPP.



- Rename a therapy program by pressing “Rename Program”.

Figure 7-6: Rename a Program.

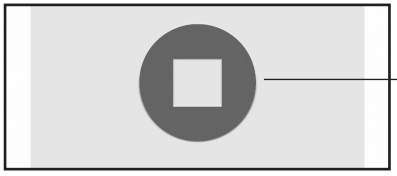


- Change stimulation intensity of the currently selected therapy program by pressing the plus or minus buttons.

Figure 7-7: Change Stimulation Intensity.

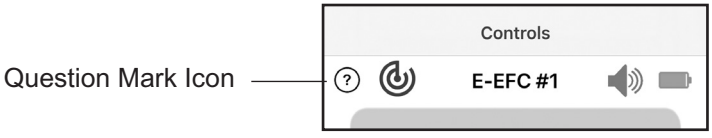
- Start stimulation by double tapping the green “start” icon. The selected E-EFC will enter stimulation mode.

Figure 7-8: Start Button.



- Stop stimulation by double tapping the red “stop” icon. The selected E-EFC will leave stimulation mode and return to standby mode.

Figure 7-9: Stop Button.

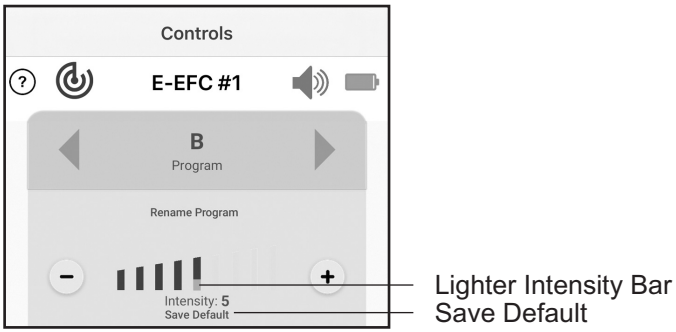


- Open the MAPP User’s Guide by pressing the question mark icon.

Figure 7-10: Question Mark Icon.

- Change settings for default stimulation while stimulation is active by adjusting

stimulation to the desired level using the + and - buttons. When the desired level is reached, press “Save Default”. The saved default stimulation will be noted by a lighter colored intensity bar. Stimulation will begin at the default level whenever



stimulation is started for the selected program.

Figure 7-11: Change Default Stimulation Intensity.

Activity

Users can view the usage history of the currently connected E-EFC, filtered by program duration and intensity.

More

Users can obtain information about their TalisMann system from the More tab.

User Instructions

Users can open a copy of TalisMann User’s Guide.

Device Details

Details about the currently selected E-EFC.

About

Details about the SitmRouter Plus MAPP software.

Contact

Contact details for reaching the TalisMann team.

Utilities

Reload Activity Logs and Upgrade E-EFC Firmware.

Turning Stimulation On

To turn stimulation on from the MAPP:

Stimulation can be turned on from either the MAPP or E-EFC.

From the Controls tab of your MAPP, double tap the green “start” icon button. The E-EFC will blink green, indicating stimulation is ON.

To turn stimulation on from the E-EFC:

Press the power button of E-EFC for half a second. The E-EFC will give an audio cue and the light will flash green, indicating stimulation is ON.

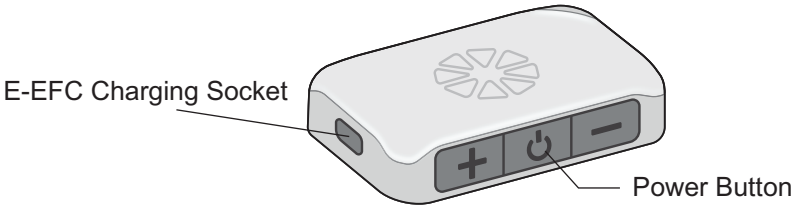


Figure 7-12: E-EFC Power Button.

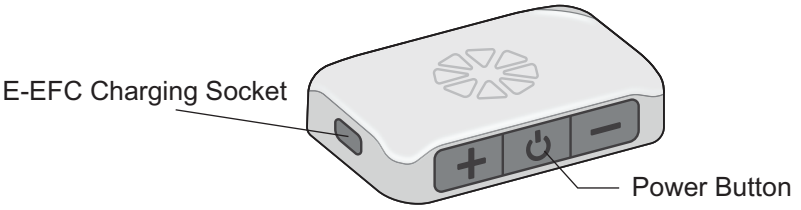
Note: The E-EFC will enter silence mode (LED turned off) after 20 seconds with no interaction. Pressing any button on the E-EFC while the E-EFC is in silence mode will remove E-EFC from silence mode and will not lead to any action by the E-EFC.

Adjusting Stimulation Intensity

The default stimulation intensity level of “5” is equivalent to the amplitude set by your clinician. To adjust stimulation intensity, press the plus or minus button on the E-EFC or MAPP. A level of “0” equals no stimulation.

To adjust stimulation intensity:

1. Stimulation intensity can be changed from the MAPP or directly from the E-EFC



only while stimulation is active. Press the plus or minus button once for each level of change. Users can use plus or minus buttons directly on the E-EFC or in the E-EFC Setup and Controls tabs of the MAPP. The new intensity level will show in the MAPP.

Figure 7-13: E-EFC Plus and Minus Buttons.

Note: Stimulation intensity should be increased until you feel a tingling sensation, numbness, skin crawling, itching or a feeling of “pins and needles” (paresthesia) in the treatment area. Be careful not to increase the stimulation intensity level beyond your doctor’s recommendation or to a painful level. Allow the system to demonstrate a change in setting before making another change.

Note: You will not be able to increase stimulation intensity if the default stimulation set by your clinician is equal to the maximum stimulation allowed by the TalisMann system.

Note: The stimulation intensity level resets to the saved default level when stimulation is stopped.

Turning Stimulation Off

Once you turn stimulation on, your E-EFC will continue to stimulate whether the MAPP is within range or not.

To turn stimulation off use one of the following methods:

- Press and hold the Power button on the E-EFC for half a second. The TalisMann System will return to standby mode.
- Turn the E-EFC off. Press and hold the power button on the E-EFC. The E-EFC can be turned off at all times.

- Double tap the red Stop icon on the Controls screen of the MAPP. The TalisMann system will return to standby mode and the green light will blink every half second.
- If you cannot turn stimulation off using the E-EFC or MAPP, then carefully grasp the tab on the Gel Electrode. Quickly pull the Gel Electrode away from the skin.
- Do not touch the gel pads on the back of the electrode with both hands while stimulation is turned on. See the “Removing the Gel Electrode” section in this guide.

Tracking TalisMann Usage

The MAPP allows users to view the usage history of the currently connected E-EFC from the Activity tab.

Select a Stimulation Program

Select a stimulation program to view, or select “All” to view usage data for all stimulation programs.

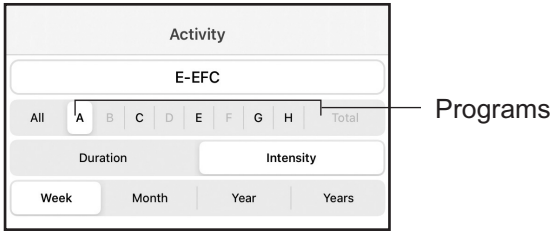


Figure 7-14: Select a stimulation program to view.

Duration

Select Duration to see how long the selected program was used during the selected time period.

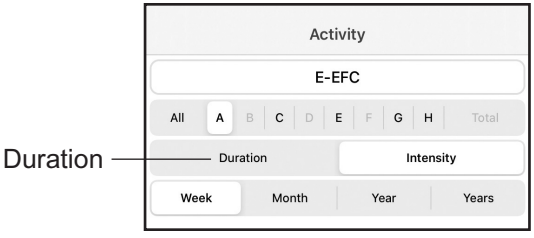


Figure 7-15: Select Duration.

Intensity

Select Intensity to view the last used intensity for the selected program.

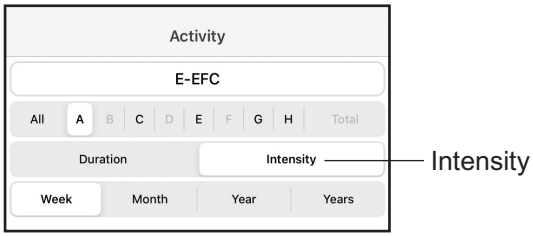


Figure 7-16: Select Intensity.

Time Period

Select a time period to view by choosing Week, Month, Year, or Years.

Note: When “All” programs are selected, users will also have the option of choosing Day.

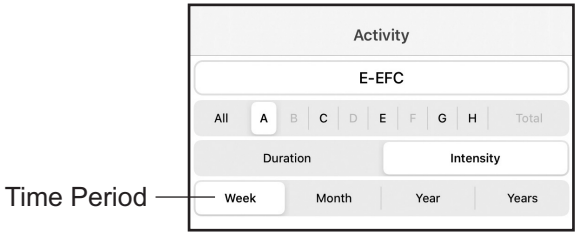


Figure 7-17: Select Time Period.

Changing Date Ranges

Swipe left or right, or use the arrows at the bottom of the Activity screen to change date ranges according to the selected time period. Swipe to change the date range by one period. Use arrows to change the date range by 5 periods, or to go directly to the first or last usage record.

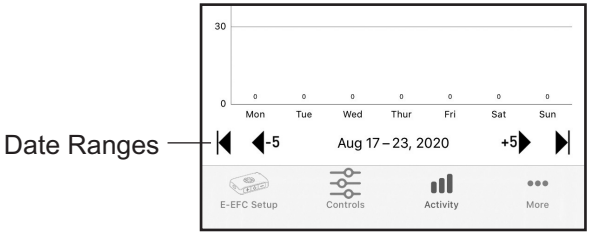


Figure 7-18: Change Date Ranges.

Update E-EFC Firmware

The E-EFC firmware may be updated periodically to introduce additional functions or correct unforeseen software issues. You can check any time to see if your firmware has an available update by selecting “Utilities” from the “More” tab of the MAPP and clicking “Check E-EFC Firmware.” The current firmware version will be displayed along with whether or not an upgrade is available for the currently selected E-EFC. See figure 7-19. If an upgrade is available, click on the E-EFC and follow the prompts to upgrade to the latest firmware version. If you experience any issues when updating firmware, please contact Bioventus.

Figure 7-19: Check availability of E-EFC firmware update.

Removing the Gel Electrode

Remove the Gel Electrode from the skin every three to four hours for 15 minutes to allow the skin under the electrode to breathe. The skin may become irritated from prolonged contact with the gel pads on the Gel Electrode.

WARNING: Do not handle the Gel Electrode with both hands while stimulation is on. Serious injury can result if electrical current passes through your heart. Turn stimulation off before adhering, removing or handling the Gel Electrode.

To remove the Gel Electrode:

1. Stop stimulation.
2. Grasp the tab on the Gel Electrode and gently pull the electrode away from the skin. See Figure 7-20.

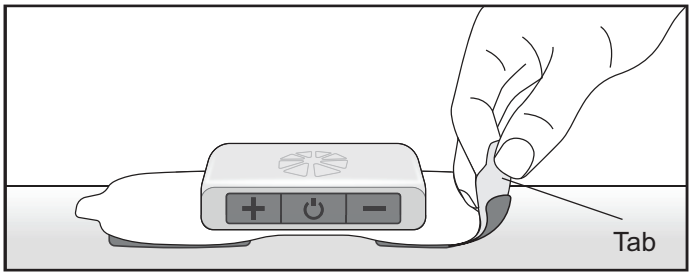


Figure 7-20: Grasp the tab on the Gel Electrode to remove.

WARNING: Do not grasp the gel pads on the back of the electrode. See Figure 7-20. If stimulation is not turned off and the gel pads are touched, electrical shock could occur.

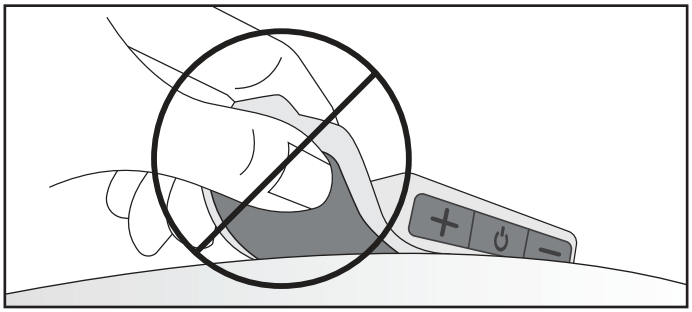


Figure 7-21: Do not grasp the gel electrodes.

3. Attach the Gel Electrode liner to the gel pads. Without the liner attached, the gel pads on the back of the Gel Electrode will lose their adhesiveness.

4. Store the Gel Electrode and E-EFC in the Electrode Carrying Case

Removing the E-EFC from the Gel Electrode

Remove the E-EFC from the Gel Electrode when the gel pads can no longer adhere to the skin or after a maximum of four days of use.

To remove the E-EFC:

1. Make sure the Gel Electrode liner is on.
2. Hold the E-EFC with your thumb and index finger and gently pull the Gel Electrode away from the E-EFC to unsnap it. See Figure 7-22

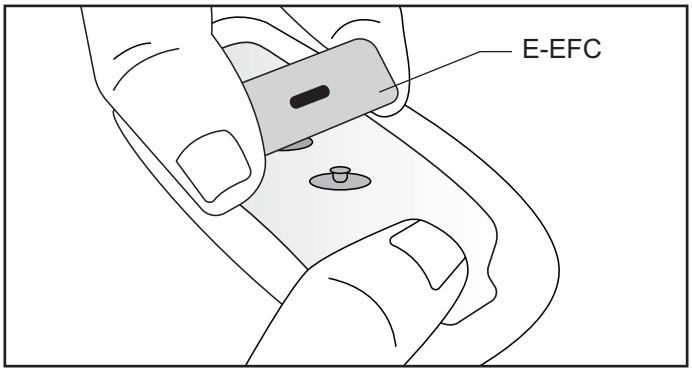


Figure 7-22: Removing the E-EFC from the Gel Electrode.

3. Store the E-EFC in the User Kit or the Electrode Carrying Case or attach it to a new Gel Electrode.

Note: Do not discard the E-EFC.

Replacing the Gel Electrode

The typical lifespan of the Gel Electrode is two to four days, depending on:

- The number of hours of use.
- The number of times the electrode is adhered to and removed from the skin.
- Hygiene and skin care in the area of Gel Electrode placement.

To ensure maximum Gel Electrode lifespan and performance always attach the electrode liner to the gel pads when storing the Gel Electrode.

Dispose of the Gel Electrode when any of the following occurs:

- The gel pads start to peel off at the edges or detach from the Gel Electrode.
- The gel pads appear worn or dirty.
- The gel pads lose their adhesiveness.
- After a maximum of four days of use.

Note: Do not discard the E-EFC.

If you have questions about Gel Electrode performance, contact Customer Service or your local distributor.

System Errors

If an error occurs with your TalisMann system, the E-EFC will give an audio cue and the light on the E-EFC will turn red. A pop-up window will appear in your MAPP describing the error. For more information on error indicators, please refer to the “Troubleshooting” chapter in this guide.

Selecting a Stimulation Program

Your physician can store up to eight programs on your E-EFC. Please refer to the “Using the MAPP” earlier in this chapter for instructions on changing programs through the MAPP.

Registering a New Component

The E-EFC and MAPP must be electronically registered to each other to communicate.

You will need to re-register the components if:

- You purchase a replacement E-EFC.

To register the E-EFC and MAPP:

1. If necessary, charge the E-EFC.
2. Turn on the E-EFC. The on/off button should not be FLASHING GREEN and the stimulation must be turned off.
3. Place the mobile device with the MAPP and E-EFC close together on a table. They should be no more than a few inches apart and should not be touching.
4. Make certain that any other E-EFC is at least 10 feet away from the components to be registered.
5. To start the registration process, simultaneously press and hold the Plus (+) and Minus (-) buttons on the E-EFC. The E-EFC light will flash blue. Open the E-EFC setup tab of the MAPP and press “Connect New E-EFC.” An audio alert indicates that the registration process has begun.
6. The E-EFC will appear on the MAPP’s E-EFC Setup tab.

Note: If the E-EFC does not appear on the list of E-EFCs on the E-EFC Setup tab of the

MAPP, an error has occurred. Repeat the procedure. If the problem persists, reconnect the E-EFC to the system charger and completely charge the E-EFC before beginning the pairing process again.

You will need to re-register the components if:

* You purchase a replacement E-EFC.

Registering a Replacement E-EFC:

1. Ensure the E-EFC is charged
2. Ensure that the E-EFC is on and stimulation is not active
3. Place the mobile device with the MAPP and the E-EFC close together on a table
4. Ensure the E-EFC to be registered is at least 10 feet away from any other E-EFCs.
5. Simultaneously press and hold the Plus (+) and Minus (-) buttons on the E-EFC. The E-EFC light will flash blue. Open the E-EFC setup tab of the MAPP and press “Connect New E-EFC.” An audio alert indicates that the registration process has begun.
6. The MAPP will give you the option to duplicate or replace a previously paired E-EFC (if any exist). Selecting either option will transmit all configuration parameters to the new E-EFC. Selecting “duplicate” will create a new entry in the connected E-EFC list, allowing the user to have two separate E-EFCs with identical parameters. Selecting “replace” will replace the previously paired E-EFC with the new unit.

8

Cleaning

Cleaning

All User Kit components may be cleaned as needed with water by carefully wiping them with a damp cloth. Do not use detergents or other cleaning agents, unless otherwise specified below. Do not clean the Gel Electrode.

Note: TalisMann electronic components are not waterproof. Do not immerse them in water.

Gel Electrode Liner

The Gel Electrode liner may be cleaned using a damp cloth and lukewarm water.

Electrode Carrying Case

The Electrode Carrying Case is made of polypropylene and is not dishwasher safe. It may be cleaned by wiping with a damp cloth using mild detergent.

Disinfecting

Electronic Components

All User Kit electronic components may be wiped as needed using CaviWipes™ or equivalent (if available), or wipes or cloths saturated (but not dripping) with 70% isopropyl alcohol. (IPA)

Note: Do not attempt to disinfect the Gel Electrode. If infection is a concern, discard the Gel Electrode and use a new electrode.

9

Troubleshooting

Should a technical problem occur that is not covered in this section or cannot be resolved by the suggested solutions in this section, please contact Bioventus. Do not attempt to modify, disassemble or repair the E-EFC. There are no user serviceable parts inside the E-EFC.

Mobile Application troubleshooting can be found in the Mobile Application internal guide, accessible through the Controls screen in the Mobile Application.

E-EFC and Stimulation	Solutions
Stimulation Not As Effective As Usual	• Check the orientation of the Gel Electrode. Align the end of the Gel Electrode with the E-EFC charging port cover directly over the receiver end of the lead. • Make sure the Gel Electrode is securely adhered to the skin. • Visually inspect the Gel Electrode to make sure the gel pads are smooth and not dry. • Review the skin care instructions. Clean the skin with a damp cloth. • Change the Gel Electrode, if the skin is dry. • Trim hair from the Gel Electrode site. • Contact Customer Service or your local distributor.
Undesirable Motor Response	• Decrease the stimulation intensity level. • Check the placement of the Gel Electrode.

E-EFC and Stimulation	Solutions
E-EFC Charging Light Does Not Turn On	• Check the connection. • Check the charging cable (disconnect it and connect charger directly). • Contact Customer Service or your local distributor.
E-EFC is not responsive	• Perform a hard reset by pressing and holding the power button of the E-EFC for 8 seconds.
Repeating beep sequence, blinking pink LED	• Connect to the MAPP application to receive details on the specific fault and detailed troubleshooting steps.
3 beeps, blinking pink LED	
3 beeps, blinking amber LED	
LED solid pink, E-EFC unresponsive	• Hard reset the E-EFC by holding the power button down for greater than 10 seconds (or until the pink LED disappears), then turn the E-EFC back on. If the condition persists, contact Bioventus.

Table 9-1: Troubleshooting, E-EFC and Stimulation.

Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to Bioventus.

You may see a message in the MAPP of a Cyclic Redundancy Check (CRC) fault. These faults occur when a suspicious change or corruption of data is detected. CRC faults may be identified as a possible fault during troubleshooting. CRC faults should be reported to Bioventus. CRC faults could be an indication of a cybersecurity breach.

10

Technical Specifications

E-EFC Charger Specifications

Use medical Class II safety approved power supply provided/approved by Bioventus with the following ratings:

Manufacturer's Model No.	FRIWO FW7555M/05
Input	
Voltage	100-240 volts AC
Current	400mA
Frequency	50-60Hz
Output	
Voltage	5V ± 5%
Current	2400mA
Charging Cable	1 meter long USB A to USB C

E-EFC Specifications

Classification	Internally powered , or Class II Equipment when operated with a charger, continuous operation, type BF applied parts
Operating Voltage	Rechargeable Lithium Polymer 3.7 volt battery 310 mAh capacity
Dimensions	**Length** 57 mm (2.25 in.) **Width** 33 mm (1.3 in.) **Height** 11.5 mm (0.45 in.)
Weight	28 grams (0.704 oz.)
Environmental Ranges	**Operating Conditions** Temperature: 5°C to 40°C (41°F to 104°F) Relative Humidity: 25% to 85% (non-condensing) Atmospheric Pressure: 50kPa to 106kPa **Transport and Storage Conditions** Temperature: -25°C to 60°C (-13°F to 140°F) Relative Humidity: 10% to 90% Atmospheric Pressure: 50kPa to 106 kPa
Service Life	2 years

E-EFC Specifications (continued)

Ingress Protection Rating	IP68 per IEC529
FCC ID #	RYYEYSHSN
Burst Parameters	
Burst	Balanced biphasic
Burst Waveform	E-EFC - symmetric
Intensity*	0-130mA peak, 1mA resolution (positive phase)
Maximum Voltage	130V
Maximum Output	16.8mA (RMS)
Maximum Charge	32.5 microcoulombs per burst
Electrode Current Density	1.2mA RMS / cm^2
Burst Duration	100, 200, 300, 400, 500 µs
Typical Load	2700Ω in parallel to 22nF
Burst Repetition Rate**	1, 2, 5, 10, 12, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz
Timing Parameters	
On Time	1-60 seconds, 1 second resolution
Off Time	0-60 seconds, 1 second resolution (0 second = constant stimulation)
Ramp Up / Ramp Down	0-10 seconds, but not more than “On Time”/2 with 1 second resolution
Total Time	10 minutes - 12 hours
Conformity Certification	The TalisMann complies with Part 15 of the FCC rules. 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.

*Intensity: A measure of strength of the stimulation.
**Burst repetition rate: The number of times per second a burst is delivered.

Gel Electrode Specifications

Electrode Size	7.5cm^2
Dimensions	**Length** 119 mm (4.68 in.) **Width** 33.5 mm (1.31 in.) **Height** 2.3 mm (0.09 in.)
Weight	10 grams
Environmental Ranges	**Transport and Storage Temperature:** 5°C (41.0°F) to 27°C (80.6°F) **Operational Conditions Temperature:** 15°C (59°F) to 40°C (104°F) **Relative Humidity:** 25% to 85% **Atmospheric Pressure:** 50 kPa to 106 kPa
Service Life	2-4 days

System Characteristics

The TalisMann System communicates wirelessly between components.

Description	Industry-standard Bluetooth® Low Energy (BLE) 4.0 communication protocol
Operating Frequency Band	2.4 Ghz, ISM band (2402-2480 MHz)
Type of Modulation	FSK
Type of Modulating Signal	Binary data message
Data Rate [=Frequency of Modulating Signal]	250 Kbps
Effective Isotropic Radiated Power	4 dBm
Receiver Bandwidth	812 kHz around a selected frequency
EMC Testing	Complies with FCC 15.2473 (for U.S.) regulations Complies with IEC 60601-1-2 Complies with IEC 60601-2-10

- **Quality of Service (QOS):** The TalisMann System was designed and tested to have a response rate of 10-100ms latency.

System Characteristics (continued)

- **Wireless Interference:** The TalisMann System was designed and tested to not have interference from other RF devices (including other TalisMann Systems, WiFi networks, Cellular Devices, Microwaves and other Bluetooth® devices).

TalisMann System is not susceptible to the wide range of expected EMI emitters, such as Electronic Article Surveillance Systems (EAS), Radio Frequency Identification Systems (RFID), Tag Deactivators, and Metal Detectors. However, there is no guarantee that interference will not occur in a particular situation.

⚠ **Caution:** If performance of the TalisMann System is affected by other equipment, the user should turn the TalisMann System off, and move away from the interfering equipment.

Privacy of TalisMann Wireless Communication

The privacy of TalisMann wireless communication is ensured by the use of encrypted patient information and authenticated Bluetooth connections for security.

11

Appendix – EMI Tables

Electromagnetic Emissions

The TalisMann system is medical electrical equipment and was tested for electromagnetic compatibility (EMC) in accordance with International Electrotechnical Committee (IEC) 60601-1-2. The following tables provide information regarding the EMC testing and guidance for safe use of the system. The TalisMann system should be configured and used in accordance with the instructions provided in this manual.

There is potential for interference between electronic devices, including cell phones and other medical devices such as a body- worn insulin pump. Stimulation control may be delayed. Maintain a minimum safe separation distance of 15 cm (6 in.) between the TalisMann system and all other electronic devices. If interference is suspected or anticipated, distance yourself from the source of interference.

⚠ **Caution:** Using cables or accessories other than those supplied with the TalisMann system could result in increased emissions or decreased immunity.

Guidance and Manufacturer's Declaration Electromagnetic Emissions

The Talismann system is intended for home use in addition to use in the electromagnetic environment specified below. The customer or the user of the TalisMann system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The TalisMann system uses RF energy for short-range communications. Therefore, its RF emissions are very low, about 100 times lower than a commercially available cell phone. Though unlikely, portable and mobile RF communications equipment, such as the TalisMann E-EFC and clinician programmer, could affect medical electrical equipment.
RF emissions CISPR 11	Class B	The RF-enabled components of the TalisMann system are suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The TalisMann system is intended for home use in addition to use in the electromagnetic environment specified below. The user of the TalisMann system should assure that it is 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 Not applicable. No input/ output lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line (s) to line(s) ±2 kV to earth	±1 kV line to line Not applicable. No grounded interconnections.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. The TalisMann system continues operation during power mains interruptions, as it is normally powered by each component battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c.mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The TalisMann system is intended for home use in addition to use in the electromagnetic environment specified below. The customer or the user of the TalisMann system should assure that it is 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	3 Vrms 150 kHz to 80 MHz	Recommended separation distance (d) $d = 1.2\sqrt{P}$

WARNING: Portable and mobile RF communications equipment should be used no closer to any part of the TalisMann system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Otherwise, degradation of the performance of this equipment could result.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.5 GHz	10 V/m 26 MHz to 1 GHz 3 V/m 1 GHz to 2.5 GHz	$d = 0.4\sqrt{P}$ 80 MHz to 800 Mhz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration Electromagnetic Immunity

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 TalisMann system is used exceeds the applicable RF compliance level above, the TalisMann system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TalisMann system.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the TalisMann System

The TalisMann system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TalisMann system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TalisMann system 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**		
	150 kHz to 80 MHz ***d = 1.2√P***	**80 MHz to 800 MHz** ***d = 0.4√P***	**800 MHz to 2.5 GHz** ***d = 2.3√P***
0.01	4.7 in. (0.12 m)	1.6 in (0.04 m)	9.1 in. (0.23 m)
0.1	15 in. (0.38 m)	4.7 in. (0.12 m)	2 ft 5 in. (0.73 m)
1	3 ft 11 in. (1.2 m)	15.7 in. (0.4 m)	7 ft 7 in. (2.3 m)
10	12 ft 6 in. (3.8 m)	4 ft 2 in. (1.26 m)	24 ft 11 in. (7.3 m)
100	39 ft 4 in. (12 m)	13 ft 1 in. (4 m)	75 ft 6 in. (23 m)

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.

Bioventus LLC
4721 Emperor Blvd Suite 100
Durham, NC 27703 USA
Telephone: 888-453-2136
Website: TalisMann.com

Rx Only

LBL-000738 Rev. B
07/2025