

# ManaSport+™



## INSTRUCTIONS FOR USE

### Noninvasive Ultrasound Device

### Customer Service

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### Manufactured For:

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**MANAMED®**

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Instructions for Use





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## PURPOSE OF DEVICE

The ManaSport+ is a portable and rechargeable prescriptive device.

It is intended to be used for adults only, under the direction of a medical professional. The ManaSport+ is intended for Home Use.

## INDICATIONS FOR USE

Apply stationary use of ultrasound to:

Generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation.

Apply continuous movement of ultrasound for:

1. Pain.
2. Pain relief, muscle spasms, and joint contractures.
3. Relief of pain, muscle spasms, and joint contractures that may be associated with:
  - Adhesive capsulitis,
  - Bursitis with slight calcification,
  - Myositis,
  - Soft tissue injuries, and
  - Shortened tendons due to past injuries and scar tissues.
4. Relief of pain, muscle spasms, and joint contractures resulting from:
  - Capsular tightness, and
  - Capsular scarring.
5. Localized increase in blood flow.
6. Increased range of motion of contracted joint using heat and stretch techniques.

## CONTRAINDICATIONS

Do not use this device on persons whose pain syndromes are undiagnosed. Contraindications for the use of ultrasound include:

- Over an area of the body where a malignancy is known to be present
- Over the eyes
- Over or near growth centers until bone growth is complete
- Over the reproductive organs
- Over the pregnant uterus
- Over a healing bone fracture
- Over an active implanted medical device such as an implanted deep brain stimulation device
- On the brain, spinal cord, or large subcutaneous peripheral nerves
- Ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result
- Ultrasound therapy should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed
- Application over parenchymatous organs – liver, spleen, lungs, endocrine glands, gonads
- Bone protuberances just under the skin - vertebral spinous processes, ankles, epicondyles
- Peripheral nerves close under the skin surface
- Allergies to the applied ultrasound gels
- Near brain, cervical ganglia, spine, laminectomy sites (can cause spinal-cord heating)
- Total hip arthroplasties with methylmethacrylate or high-density polyethylene. These have a high coefficient of absorption, more than soft tissue, and the prosthesis could loosen due to unstable cavitation in the cement
- Arthroplasties—the effect on bony ingrowth arthroplasties is not well defined; for this reason the most prudent course is avoiding ultrasonic therapy over these areas
- In an area of the body where infectious disease is present
- Blood vessels in poor condition should not be treated as the vessel walls could rupture as a result of the treatment
- Patients suffering from cardiac disease should not receive treatment over the cervical ganglia, the stellate ganglion, the thorax in the region of the heart, or the vagus nerve, as a reflex coronary vasospasm might result. Only low intensities and short treatment times should be used if these patients are treated in other areas because the stimulation of practically any afferent autonomic nerve (especially the vagus nerve) in the body could cause a change in cardiac rate
- Patients with thrombophlebitis or other potentially thromboembolic diseases should not be treated because a partially disintegrated clot could result in an obstruction of the arterial supply to the brain, heart or lungs
- Over areas of recent bleeding or hemorrhage
- Over areas of active tuberculosis

## WARNINGS

- If the treatment is reported as painful or too hot at any point during treatment, turn off device and remove the device from the skin.
- Instruct the patient to inform the practitioner if the patient feels any pain or burning during treatment.
- Instruct the patient how to turn off the Device and remove the Applicator if the patient feels any pain or burning during treatment.
- The Device should be kept out of the reach of children.
- The device and accessories are not sterile. DO NOT apply this device and accessories over an open wound or inflamed skin.
- DO NOT apply directly over a bone that is near the skin surface.

(continued next page)



## WARNINGS (continued)

- Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous. To reduce the risk of burns, electric shock, and fire, this device must be used in accordance with the instructions.
- Do not crush the device and its accessories.
- Carefully examine the device and its accessories, and do not use if they show any sign of deterioration.
- Do not tamper with this device and its accessories in any way. There are no user serviceable parts. If for any reason they do not function satisfactorily, return to the authorized service center at address given.
- Do not use at the same time as other topical analgesics.
- Handle ultrasound applicator with care. Inappropriate handling of the ultrasound applicator may adversely affect its characteristics.
- An appropriate coupling medium should be used in order to ensure energy transmission to the tissue.

## Precautions

Precaution should be taken when using the device:

- Over an area of the spinal cord following a laminectomy, i.e. when major covering tissues have been removed
- On patients with hemorrhagic diatheses
- Over areas where metal prosthesis or other metallic implants are embedded in tissue which may form a reflective surface to the ultrasound energy causing unintended irradiation of tissue and excessive heating.
- Over an acute infection or sepsis
- On patients with peripheral artery disease
- Over a deep vein thrombosis
- Over an anesthetized area or in conjunction with a condition that causes impairment of sensation, such as caused by chemotherapy.
- Caution should be used for persons with suspected or diagnosed heart problems.
- Caution should be used for persons with suspected or diagnosed epilepsy.
- Caution should be used if you have any of the following:
  - if you have a tendency to bleed internally following an injury;
  - if you recently had surgery, or have ever had surgery on your back;
  - if areas of skin lack normal sensations, such as skin that is numb.
- Consult with your physician before use over the menstrual uterus.
- Do not use this device while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
- Keep this device and its accessories out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.
- Do not use this device in high humidity areas such as a bathroom.
- Stop using this device at once if you feel discomfort, dizziness or nausea, and consult your physician.
- Do not attempt to move the ultrasound head while the device is operating.
- For ultrasound treatment, only use the ultrasound applicator sold with this device.
- When applying ultrasound by means of any applicator, ultrasound gel shall be used for correct passage of the ultrasound waves. It is recommended to use an FDA cleared water-based conductive gel, specifically SONOMED TECHNOLOGY, INC. Gel #K883917. The applicators have not been tested for use with other gels or oils and can be damaged.
- On patients with hemorrhagic diatheses
- Over areas where there is sensory impairment or sensory loss
- Over acute skin conditions such as eczema, dermatitis, etc
- Over the anterior aspect of the neck
- On patients who are febrile

Radio Frequency: This unit generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. Harmful interference to other devices can be determined by turning this unit off and on. Try to correct the interference using one or more of the following: reorient or relocate the receiving device, increase the separation between the equipment, connect the unit to an outlet on a different circuit from that which the other device(s) are connected, and consult ManaMed for help. If the unit is used close to radio frequency sources (e.g., electromagnetic security systems, cellular telephones, RFID or other in-band transmitters), it may cause abnormal Bluetooth connection.

## Be aware of the following:

- Consult with your physician before using this device;
- This device is not effective for pain associated with Central Pain Syndromes, such as headaches;
- This device is not a substitute for pain medications and other pain management therapies;
- This device is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
- Stop using the device and consult with your physician if the device does not provide pain relief;
- Use this device only with the accessories recommended for use by the manufacturer.

The accessories may be packaged together with the device or packaged separately as the replacement.

Store the device away from high-temperature and direct-sunlight. Storage outside of stated storage temperature may result in measurement error or device malfunction.

Do not share the use of the device and its accessories with others; they are intended for single person use.

This device contains batteries. If overheating of the device occurred, stop the operation immediately and contact customer support.

Dispose of this battery-containing device according to the local, state, or federal laws.

Skin burns may occur, and check the skin of the treatment area periodically.

## Adverse Reactions

You should stop using the product and should consult with your physician if you experience adverse reactions from the device.



# QUICK START GUIDE



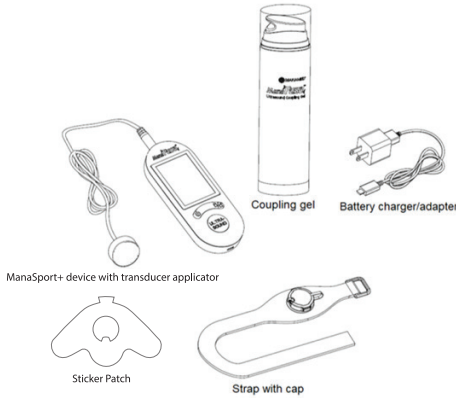
See accompanying documents / User's Manual.



CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

**CONTENTS: ManaSport+ Device, Applicator, Gel, Adapter, Cap, Strap, Manual**

The ManaSport+ provides non-invasive therapy of low-intensity pulsed ultrasound for the treatment of selected medical conditions such as soft tissue injuries, shortened tendons due to past injuries and scar tissues, relief of pain, muscle spasms and joint contractures. ManaSport+ transmits a low-intensity ultrasound signal to the patient's treatment site through ultrasound gel. The patient will experience little or no sensation while in ultrasound mode.

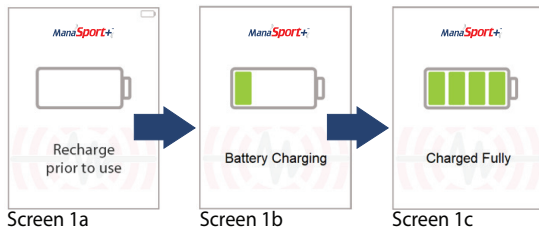


The ManaSport+ system in a carrying case consists of one ManaSport+ device and the following biocompatible components/accessories.

- 1) Transducer applicator connected to the ManaSport+ device to generate a low-intensity ultrasound or stimulation signal at the treatment site.
- 2) Coupling gel applied to the transducer applicator to transmit the ultrasound signal to the depth of the treatment site.
- 3) Strap with a cap to hold the transducer applicator down on the treatment site.
- 4) Battery charger/adapter to charge the subject device.
- 5) Sticker Patch to hold the transducer applicator down on the treatment site.

If you suspect you may be missing an item, please contact Customer Service at 888-508-0712.

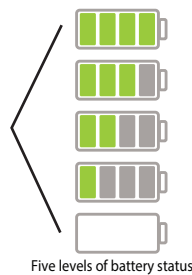
## Charge the battery before use



When the remaining battery of the device cannot last for 20 min, its display will switch to reminding you of recharge prior to use (Screen 1a). Plug the power supply adapter to the wall socket as well as ManaSport+ using the charging port located at its bottom end. The BATTERY icon on the device's display keeps flashing or steady, depending on the state of the charge. When the battery is charging, the BATTERY icon will keep flashing (Screen 1b). Once the battery is fully charged, the BATTERY icon will become solid (Screen 1c). Note: The device cannot be used when it is being charged.

## Display Symbols and Descriptions

Symbol	Name	Description
	<b>Low Battery</b>	The battery runs low and needs to be charged prior to use.
	<b>Battery Status</b>	Shows how much charge is left in the battery.
	<b>Calendar Broken Star</b>	A 20-minute treatment was not completed on this calendar day.
	<b>Calendar Starmark</b>	A 20-minute treatment was completed on this calendar day.
	<b>Calendar Double Starmark*</b>	Two 20 minute treatments were completed on this calendar day.
	<b>Calendar Double Checkmark Plus*</b>	Three or more 20-minute treatments were completed on this calendar day.
	<b>Ultrasound Symbol</b>	Flashes during use to show you are having your treatment.
	<b>Countdown Timer</b>	Counts down from 20 minutes to show treatment time remaining.
	<b>Treatment Complete</b>	Automatically displays when countdown timer reaches zero to show that treatment is complete.
	<b>Lock Symbol</b>	Locks the buttons to prevent unintended operation.
	<b>Unlock Symbol</b>	Unlock the buttons to operate the device.



The strap can provide you with a hand-free treatment. However, if you prefer to continuously move the transducer applicator throughout your treatment area, you can skip operations 2a to 4c, and only refer to Operation 4a at the bottom of this page.

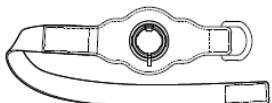
Specifically, please refer to the detailed instructions below for continuously moving the applicator..

- a. Apply the ultrasound gel. The entire treatment area should be covered with the ultrasound gel, and the transducer applicator should also always be covered with the ultrasound gel.
- b. Position the transducer applicator flat against the skin and keep transducer applicator constantly moving, slowly and with constant pressure, during treatment.
- c. The treatment area should not exceed 2 to 3 times the size of the transducer applicator.

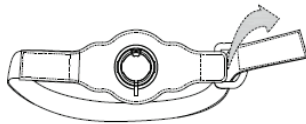
## How to install the strap with a cap:

The strap is suitable for a treatment site of extremities. Position the strap with the cap facing up, as shown in the following Operation 2a;

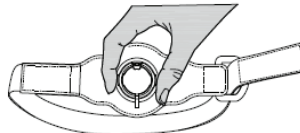
- Pull the long end of the strap through the plastic loop, as shown in the following Operation 2b;
- Use 2 fingers of yours to squeeze the cap tabs together to open the cap cover, as shown in the following Operation 2c;
- Slide the strap and place the port of the cap over the treatment site marked with an 'X' by your physician/doctor, as shown in the following Operation 2d (Contact your physician/doctor if you are not sure where to locate your treatment site);
- Tighten the strap by pulling on the long end and fasten the strap in place, as shown in the following Operation 2e (Note: Do not make the strap too tight);



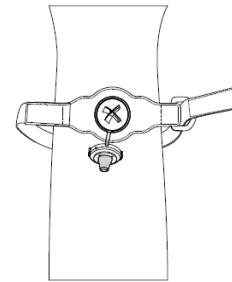
Operation 2a



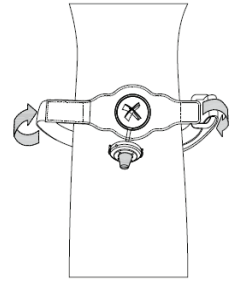
Operation 2b



Operation 2c



Operation 2d

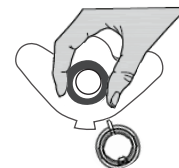


Operation 2e

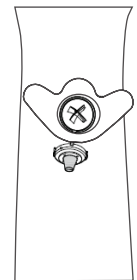
## How to install the Sticker Patch with a cap:

The Sticker Patch is suitable for a treatment site of hard-to-reach areas or for convenience.

- Remove the cap from the strap and insert it into the Sticker Patch; The sticky side of the patch will be on the opposite side of the top of the cap;
- Once mounted, use 2 of your fingers to squeeze the cap tabs together to open the cap cover, as shown in the image Operation 3a;
- Place the port of the cap over the treatment site marked with an 'X' by your physician/doctor, as shown in the following



Operation 3a



Operation 3b

## Preparation before use:

- Remove the cap from the gel bottle, and hold the transducer applicator, so the cable is down and the smooth side of the applicator is up. Press down the gel bottle nozzle to pump gel onto the smooth side of the applicator, as shown in the following Operation 4a. You only need on full pump of gel on the applicator (Note: For the first time, you may need to press the gel bottle nozzle a couple of times to start the gel flowing);
- Place the transducer applicator with the gel side down into the port of the cap, and the gel will touch the skin over your treatment site, as shown in the following Operation 4b;
- Align the lead wire coming out of the transducer applicator with the notch of the cap cover, and close the cap cover, as shown in the following Operation 4c (Note: The other end of the lead wire of the transducer applicator is connected to the top port of the device);

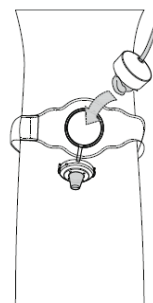
## IMPORTANT:

Patients should ensure the entire applicator surface is covered with the ultrasound gel.

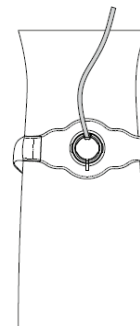
Patient should also ensure complete skin contact with the treatment applicator before beginning therapy.



Operation 4a



Operation 4b



Operation 4c



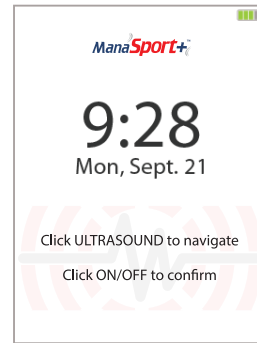
## Use of Ultrasound function:

Your physician/doctor may have marked your treatment site with an 'X'. This is the spot to place the transducer applicator to treat your symptom by using ultrasound. Contact your physician/doctor if you are not sure where to treat your symptom.

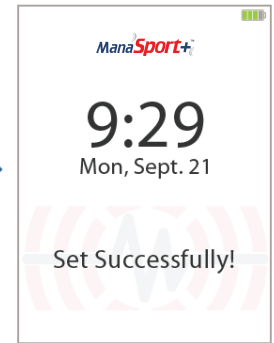
After the above steps are done, you can click the ON/OFF button on the device to turn it on: After showing the following display screen (Screen 5a) for 2 seconds, the device will then go to the next screen (Screen 5b) of Date and Time automatically. Follow the instruction of the screen to conform or change the time and date, and you will see the 'Set Successfully' screen of Date and Time (Screen 5c). Note: The display screen of Date and Time will only appear for the first time of power on, or by pressing the ON/OFF and ULTRASOUND buttons simultaneously.



Screen 5a



Screen 5b

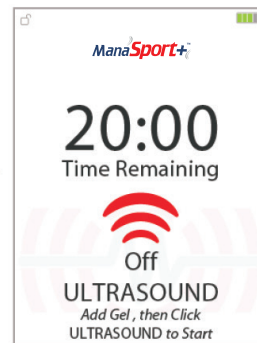


Screen 5c

After the "Set Successfully" screen of Date and Time, the device will automatically proceed to the next screen of Ultrasound calendar/summary (Screen 5d) and last for 5 seconds. Clicking the + or - button on the right side of the device can show different-month screens of Ultrasound calendar/Summary. Note: The screen of Ultrasound calendar/summary will appear each time when the device is turned on, or by clicking ON/OFF after the device is on.



Screen 5d



Screen 5e



Screen 5f

After the screen of calendar/summary (Screen 5d), the device will automatically proceed to the next screen of Ultrasound standby (Screen 5e). Follow the instruction on this screen to add more ultrasound gel on the transducer applicator if needed, and click the ULTRASOUND button to start the Ultrasound function (Screen 5f). Relax and enjoy the 20 minute treatment of ultrasound provided.

To avoid the unintended operation, the device will automatically be locked after 60 seconds of no operation, or you could click the Lock/Unlock button to lock the device (Screen 5g). After the 20-minute timer counts down to zero, you can see a "Treatment Completed" screen (Screen 5h). It means a 20-minute treatment of Ultrasound is complete. After showing the "Treatment Completed" screen for 20 seconds, the device will turn off automatically (alternatively, you could press and hold the ON/OFF button to turn off the device). Please be aware that you still can press and hold the ON/OFF button to turn off the device, even though the device is locked.

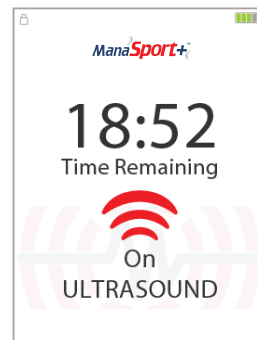
## ManaSport+ Quantity of Treatment and Frequency of Use

ManaSport+ should be used for 20 minutes per day or as prescribed by your doctor. The ultrasound will be automatically stopped after the maximum timer of 20 minutes runs out. It is very important to follow your physician/doctor's protocol to get the full medical benefit of the treatment. If you have concerns about your treatment, please contact your doctor directly. The device is a single patient reusable device. This device is prescription only and may not be used without a physician's order.

**Note: To ensure the patient safety, we implement the maximum temperature protection of 43° C. When the transducer applicator senses the surface temperature reaching 43° C., the output of the ultrasound will stop and automatically resume when it cools down. "Temperature protection" will display below "ULTRASOUND" (Screen 5k).**

## Data Record

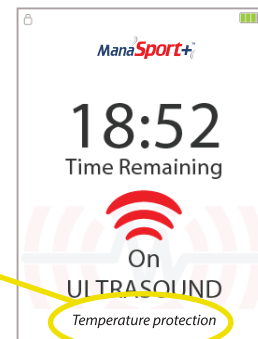
Your daily use time of Ultrasound is recorded, as shown on Screen 7a. When a 20-minute treatment is completed, a red star mark will show on the calendar date. When two 20-minute treatments are completed, two red star marks will show on the calendar date. When three or more 20-minute treatments are completed, two red star marks and one plus will show on the calendar date. When a 20-minute treatment is not completed, a grey broken star mark will show on the calendar date. Please refer to the above section of "Use of Ultrasound function" for how to view the data recorded. After the "Set Successfully" screen of Date and Time, the device will automatically proceed to the next screen of Ultrasound calendar/summary (Screen 7a) and last for 5 seconds. Clicking the + or - button on the right side of the device can show different-month screens of Ultrasound calendar/Summary. It is worth noting that no patient information (such as age and history) is recorded and stored, so there is no issue of privacy or security.



Screen 5g



Screen 5h



Screen 5k



Screen 7a



## Use of Ultrasound function: Connecting to a Smart Device via Bluetooth (optional)

Note: Bluetooth LE is an optional feature available on specific versions of ManaSport+ for use with compatible smart devices. For a full list of compatible smart devices, see herein or on our website at [www.manamed.com](http://www.manamed.com)

The ManaSport+ provides a Bluetooth LE wireless option to allow connection to a compatible smart device. The Bluetooth communication is only available to smart devices using the Manasport+ App. When a Bluetooth connection is established, the Bluetooth connected icon will appear. ManaSport+ can only communicate to a single device at one time to minimize the risk of unauthorized access. The user interface can also be controlled by a smart phone or tablet. ManaSport+ (app) that must be downloaded from an app store and installed to your personal smart device to operate the ManaSport+ device from a smart phone. Follow the instructions below to use your ManaSport+ with your personal smart device.

### Step 1: Download the ManaSport+ app



To download the app: go to the App Store (Apple) or Google Play (Android) for your device and search for "ManaSport+."

Select download/install.

Notes: All updates will be pushed to the App Store or Google Play. To update the app, login to the App Store or Google Play, find the app, and then click update.

### Step 2: Pair the ManaSport+ to your smart device.

You must pair your ManaSport+ controller with your smart device (smart phone or tablet) before starting a treatment. See App compatibility section herein for compatible mobile devices. Bluetooth must be enabled on your smart device in order to connect to the controller. For Android devices, Location Services must also be enabled for pairing.

Open the ManaSport+ app and fill out the initial sign in screen. This allows you to create a login for the ManaSport+ application. You must enter your first name, last name, email, and create a password. If you ever need to reset your password, you can open the app and click "forgot password". Reset instructions will go to your email.

Once your profile has been completed, the smartphone will be ready to pair with the ManaSport+ device, click connect on the app to pair the device. Once successfully paired, the device is ready to assist in operating the ManaSport+ device.

### Notes:

- Once paired, your ManaSport+ and smart device should connect automatically every time they are both switched on with Bluetooth enabled.
- If the pairing fails, your smart device will advise you of this and prompt you to retry the process.

Once the controller and the app on your smart device are successfully paired you may start using your ManaSport+ via the app versus the buttons the ManaSport+.





## Use of Ultrasound function via Personal Smart Device: (continued)

Step 3: Power on the ManaSport+ device:

Power on the device via the power button on the ManaSport+ device. Open the ManaSport+ app on your phone. When the app is paired with the device, a solid Bluetooth symbol will show in the top left corner of the ManaSport+ device. If it is solid, the device is ready for use via the app. Your mobile phone is ready to control the ManaSport+.

If the Bluetooth symbol is blinking, the app is not connecting to the device. Follow step 2 again.

## App Home Screen Overview

Now that you have paired your ManaSport+ app on your smart device, you are ready to use the ManaSport+ system.

The app home screen allows you to power off the device, unlock the device, and start the ultrasound stimulation.

When in the home screen, you can press the ultrasound button to begin your twenty minute treatment. The timer will countdown from 20 minutes. Once completed, the device will record your usage and turn off.

### Note

- If no gel is detected, the app will alert you to add gel. To clear the alarm, click confirm and then press ultrasound again to begin treatment.



## App Menu Options

If you push the three lines in the top left corner of your device, you can access the menu portion of the app. In this section, you can enter other screens of the app. Here is where the app serves as an educational tool and a usage tool for patients.

This menu includes

- ManaSport+ device usage viewable via the application.
- ManaSport+ Instructions for Use
- Warnings and Precautions
- Patient Educational videos
- ManaMed Contact Information.



## Use of Ultrasound function via Personal Smart Device: (continued)

### ManaSport+ (Personal Smart Device App) Troubleshooting

#### ManaSport+ (Personal Smart Device App) Error Messages:

Bluetooth connection is interrupted	If during a stimulation treatment the Bluetooth connection signal is disrupted, the stimulation will continue. To stop the stimulation, grab the device and press the Ultrasound button. Stimulation will be paused and reset back to 20 minutes. In an emergency situation, you may hold the power button the ManaSport+ device for three seconds for an emergency shut off.
Smartphone Device Battery Low	Should your smartphone device issue a battery low alert, the ManaSport+ will continue to function. It would be recommended to plug in your smartphone device while you finish your treatment.
Cybersecurity Compliance	BLE connection can adopt pairing encryption connection and AES-128 algorithm for encryption. During the pairing process, the master and slave keep multiple keys: STK, LTK, IRK and CSRK; STK / LTK is mainly used for data encryption during transmission; Irk is mainly used for device authentication; CSRK is mainly used for message signature and verification; The use of multiple keys and CRC verification ensure the encryption and accuracy of BLE data transmission. For more information on the cybersecurity visit our website at <a href="http://www.ManaMed.com">www.ManaMed.com</a> .

### ManaSport+ App Apple™ Compatibility



Compatible with Apple products (iOS 11 or higher)

- iPhone 13 Pro Max
- iPhone 13 Mini
- iPhone 12 Pro Max
- iPhone 12 Mini
- iPhone SE (The Second Generation)
- iPhone 11 Pro Max
- iPhone 11
- iPhone XR
- iPhone 8 Plus
- iPhone 7

### ManaSport+ App Android™ Compatibility



Compatible with Android™

- Samsung Galaxy S21
- Samsung Galaxy Note 20
- Google Pixel 5
- Google Pixel 4a
- OnePlus 9 Pro
- OnePlus 8T
- Motorola Edge Plus
- Motorola Moto G Power (2021)
- LG V60 ThinQ 5G
- 1TCL 10 Pro

## USER MAINTENANCE

Contains no serviceable parts.  
Contact ManaMed Customer Service at 888-508-0712.

Inspect the unit and all components for any damage that may have occurred during shipping or general handling prior to each use (for example, frayed or cut charging cord, cracked plastic housings, etc).

Refer to image of ManaSport+ for description of all components.  
Do not attempt to connect the wall supply if any damage is noticed.  
Avoid subjecting the unit to shocks, such as dropping the device.  
Battery is not replaceable; replacement units are available through customer service.  
Contact ManaMed to receive replacements instructions for any damaged items.

## STORAGE

For optimal battery performance, store in a cool, dry, well-ventilated place.

Store away from sources of heat and direct sunlight.

## DISPOSAL

This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.

This unit contains rechargeable batteries. Do not discard the unit in regular waste. Bring the unit to your local recycle center or contact ManaMed.



The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the ManaSport+ as replacement parts, may result in increased emissions or decreased immunity of the ManaSport+.



Designates Class II medical electrical equipment.



This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.



This symbol designates the degree of protection against electrical shock from the wrap as being a type B applied part.



Consult instructions for use.



CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

**WARNING:** This device is not protected against water. Equipment is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide. The rechargeable batteries supplied in this unit are not field replaceable. If you have any issues please contact 888-508-0712. for a replacement unit.

## USING THE AC ADAPTER / BATTERY CHARGER

**IMPORTANT:** Charge device before first use.

**WARNING:** Use only the charger provided by ManaMed™. The use of the wrong charger can cause excessive heat, damage to the circuit and shorten the life of the battery.

**CHARGING:** Plug in the power supply adapter to the wall socket using the plug located at the bottom end of the device. The BATTERY icon on the device will keep flashing or steady, depending on the state of the charge. When the battery is charging, the BATTERY icon will keep flashing. Once the battery is fully charged, the BATTERY icon will become solid.

**Note:** The device cannot be used when it is being charged.

## CLEAN AFTER TREATMENT

- Use your two fingers to squeeze the cap tabs together to open the cap cover, and take out the ultrasound head; Wipe and clean the ultrasound gel on the ultrasound head with a blue cloth or paper towel;
- Wipe and clean the ultrasound gel in the cap with a blue cloth or paper towel.

## CLEANING AND MAINTENANCE

**UNIT DEVICE:** To clean the device, please wipe it with a soft cloth. You can use wipe of water, alcohol, and mild detergent for cleaning first, and then use the dry cloth to wipe it again.

**TRANSDUCER APPLICATOR:** After the treatment is completed, wipe the transducer applicator with a soft cloth or paper towel to remove the ultrasound gel. You can use wipe of water, alcohol, and mild detergent for cleaning first, and then use the dry cloth to wipe it again.

Unit must be completely dry prior to use. To ensure that, leave the device in the OFF position and disconnected from the wall outlet for at least 30 minutes (and as long as necessary for the unit to dry completely) after cleaning or disinfecting.

- Do not use hair dryer to accelerate drying.
- Do not place the device on top of or in front of portable or stationary radiators to accelerate drying.
- Do not use abrasive cleaners.



# ULTRASOUND GEL

Ultrasound gel is provided for use with ManaSport+. Patients are instructed to place gel on the transducer applicator every time you use ManaSport+. This gel allows the ultrasound signal to reach the depths of the treatment site through your skin. If the transducer applicator is not properly applied, the patient will receive an alert from the device. For the best result, only use the gel supplied. If you need more gel, please email ManaMed at Support@ManaMed.com or contact your DME supplier. The gel is sourced from Hony Medical Co., Ltd. (Reference Gel #K221999).

Caution: Some patients may experience mild skin irritation to the gel. If you feel your skin is sensitive to the gel, please contact your physician or use a different FDA-cleared ultrasound gel.

## ManaSport+ Expected Service Life

The expected service life of ManaSport+ and its accessories is 365 days from the initial treatment. Once ManaSport+ reaches 365 days, it will provide no further treatment.

## ManaSport+ Expected Shelf Life

The shelf life of ManaSport+ is not applicable because of low likelihood of time-dependent product degradation. Among all the accessories marketed with ManaSport+, the ultrasound gel may have a certain shelf life, and you can find the corresponding shelf life or expiration date on the bottle of ultrasound gel.

## Limited Warranty

ManaMed ("Seller") warrants that the original purchaser ("Purchaser") of its ManaSport+ purchased by the Purchaser directly from Seller ("Device") that the Device confirms to Seller's manufacturing specifications. The warranty will be one year for the date of purchase. In the event of a breach of this warranty, with a 30-day written notice, Seller will, at its sole option, either repair or replace the Device or issue a refund at the original purchase price. This warranty is null and void if the Device is resold or a transfer of the Device by Purchaser to any other person or entity. Seller expressly disclaims any and all other warranties, either expressed or implied, relating to the system or its performance, including, without limitation, any implied warranty of merchantability and any implied warranty of fitness for a particular purpose. This limited warranty does not cover damages due to eternal causes, including, without limitation, accident, usage not in accordance with product instructions, misuse, neglect, alteration, or repair.

## Technical Specifications

Ultrasound frequency: 1.5 +/- 20% MHz  
Ultrasound Duty cycle: 100%  
Ultrasound effective radiating area (ERA): 3.9 +/- 20% square cm (cm<sup>2</sup>)  
Ultrasound power: 0.60 +/- 20% watts (W)  
Ultrasound spatial average temporal avg. (SATA): 0.16 +/- 20% W/cm<sup>2</sup>  
Ultrasound beam non-uniformity ratio (BNR): 4.0 maximum  
Ultrasound beam type: Collimated  
Battery: 3.7 VDC Lithium battery  
Input Voltage (USB) of battery charger: 5.0 VDC

## TECHNICAL DATA

### Specifications:

Dimensions: 14cm x 5.6cm x 2.4cm  
Weight: Approx. 0.13 kg

### SYSTEM OPERATING ENVIRONMENT:

Temperature: +10°C (50°F) to +40°C (104°F)  
Humidity: 30%-75%. Keep dry.

Source of Power: DC 5 V or Inner Battery (3.7 volt Li-ion battery)

**CAUTION:** Charge batteries using only the power source provided by ManaMed.

### POWER SUPPLY:

**Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 5 V @ 1 Amp)**

Use only UL/60601-1 approved power supplies from ManaMed for use in hospital settings.  
Maximum cable length for the power cable: 1 meter

### TOLERANCES:

Output +/-20%.

### BATTERY CHARGE:

Takes approximately 4 hours (from depleted state)..



### BATTERY RUN TIME:

10 hours



## Troubleshooting

ManaSport+ will alert you by displaying an alert screen, if something is not working properly. See the following table for common alerts and problems as well as what to do if you get an alert or problem. If you get any other problem, do not try to fix ManaSport+ by yourself and contact customer service at 888-508-0712.

Alert / Problem	What does this mean?	What should I do?
 Contact Manufacturer	Contact customer service: ManaSport+ will display the yellow "Contact manufacturer" screen when detecting that it is not working properly.	Call customer service at 888-508-0712. Do not try to fix ManaSport+ by yourself.
 Recharge prior to use	Low battery: ManaSport+ will display the "Low Battery" screen, when the battery level is very low. You are not able to start treatment or view history.	You must charge ManaSport+. Plug ManaSport+ into a power source with the provided charger.
Blank screen, and ManaSport+ does not turn on.	The battery may be completely discharged or the ManaSport+ device has malfunctioned.	Plug ManaSport+ into a power source with the provided charger and fully charge its battery. If ManaSport+ still does not respond, contact customer service at 888-508-0712.
The battery area on ManaSport+ or the battery charger gets excessively warm.	The battery or charger may be malfunctioning.	Stop charging ManaSport+ and contact customer service at 888-508-0712.

### Instructions for reporting adverse events:

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics. If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report. However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself. You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

#### Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

Report Online at [www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home](http://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at [www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf](http://www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf). Call FDA at 1-800-FDA-1088 to report by telephone.

Reporting Form FDA 3500 commonly used by health professionals. The form is available at [www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf](http://www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf).

## Summary of ManaSport+ Wireless Functions

The MSPORT02 can be operated manually through the buttons on the device. An optional wireless control unit can be controlled via a Bluetooth App. This allows the user an alternative way to operate the device wirelessly. Also, the App can access the data and usage of the device. Currently the optional App is not available. If the optional APP or its update is available, the user may only obtain it from the trusted source instructed by ManaMed. At any time, you can switch to manually operate the subject device by pressing its buttons to deal with any risks and problems that may arise.

## Summary of ManaSport+ Wireless Security Methods

The BLE function of Non-invasive ultrasound device is classified as a device with negligible Cybersecurity Risk. In the process of BLE encrypted data transmission, STK or LTK is used as the key, AED128 algorithm is used to encrypt the transmitted data, and then 32bit message integrity verification and 24bit CRC verification are included. The receiver uses the same key for verification and decryption to ensure the integrity and accuracy of the data. Non-invasive ultrasound device also complies with the BLE 4.2 protocol, and its data integrity is validated during transmission.

## Radio Frequency Wireless Information

Radio Frequency Wireless technology is used in the ManaSport+ for communication between an optional phone app and the ultrasound device.



# Radio Frequency Wireless Description

## Wireless Protocol Characteristics

Operation Frequency	2.4 GHz ISM
Protocol Type	Frequency Hopping
Bluetooth Version:	V4.2
Frequency modulation	GFSK
Frequency deviation	± -320 kHz
EIRP	Measured max -6.2 dBm (0 dBm configured as maximum output power)
Effective emission power	4.4 [dBm]
Data rate	2 Mbps
Number of Channel:	40
Channel width	2 MHz
Antenna Type:	PCB Antenna
Antenna Gain	0dBi
Hardware Version:	V1.0
Software Version:	V1.1
Wireless QoS:	Transfer Rate > 0.5kbps, Packet Error Rate < 10%, Transfer Completion < 1S
Communication:	Wireless 2.4GHz(BLE mode)
Transmission Range:	Up to 10 meters
Data Storage:	Transferred data is received and temporarily saved in the connected mobile terminal.
Waterproof Rating	IPX2
Quality of service requirement	2 meter range between app on phone and stimulation modules
<b>Wireless Security Method</b>	
Device identification	32 bits, shared only with other ManaSport+ devices
Data integrity checks	Each data frame protected by a 24 [b] length CRC
Acknowledgement	Each point-to-point communication is acknowledged
<b>Coexistence with other ManaSport+ Devices</b>	
<b>Each Smartphone App control and module is assigned a unique ID.</b>	
Designed for coexistence with wireless products in the same RF band.	- Bluetooth (IEEE 802.15.1) - Wi-Fi (IEEE 802.11)
Utilizes established coexistence principles to minimize cross-talk with other wireless devices.	- FDMA (Frequency Division Multiple Access) - TDMA (Time Division Multiple Access)
Out of range behavior	The MSPORT02 can still be operated independently if the control on the smartphone is suddenly interrupted, without any impact on the MSPORT02 functions.
Interference from other devices	<ul style="list-style-type: none"> <li>• Bluetooth LE wireless technology includes adaptive frequency hopping and will automatically reattempt a connection if the connection fails.</li> <li>• Interference from other RF wireless and mobile communication devices is possible. Refer to EMC Tables for recommended distances between ManaSport+ and other RF devices.</li> <li>• When used in a residential environment (for which CISPR 11 class B is normally required) this product might not offer adequate protection for radio-frequency communication services. The user might need to take mitigation measures, such as moving the product to another location or remove possible sources of interference.</li> </ul>
List the effects of delayed/failed communication of each wireless function.	The smartphone is only auxiliary control MSPORT02 and synchronous view of MSPORT02 usage data, these functions can be completed independently by MSPORT02. The MSPORT02 can still be operated independently if the control on the smartphone is suddenly interrupted, without any impact on the MSPORT02's work. Moreover, all the usage data is stored in the MSPORT02 body instead of the mobile APP, and the App needs to synchronize the usage data from MSPORT02 every time it connects.
In the event of a wireless function failure, how is the device designed to fail safely?	In the unlikely event of wireless function failure, the user is aware of the interrupted connection via the App interface, and the user has the option of attempting to reconnect to the receiver (e.g., smart phone or tablet), if needed. If Bluetooth is unavailable for any reason or excessively delayed, no harm will come as the collected data can be reacquired if needed.
A brief description of the wireless QoS needed for a safe and effective operation of the device.	Based on the intended use of MSPORT02, the App should command MSPORT02 correctly and can synchronize to the correct usage data. The QoS PASS/FAIL criteria was defined as follows: Transfer Rate > 0.5kbps, Packet Error Rate < 10%, Transfer Completion < 1S



# ELECTROMAGNETIC COMPATIBILITY (EMC)

## TABLES - RF EMISSIONS CLASS B

The ManaSport+ is a portable and rechargeable prescriptive device.

Warning: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

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, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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

Technical description:

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.
2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

### GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The ManaSport+ is intended for use in the electromagnetic environment specified below.

The customer or the user of the ManaSport+ should assure that it is used in such an environment.

Emissions Tests	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR11	Group 1	ManaSport+ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR11	Class B	ManaSport+ is 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 IEC 61000-3-3	Complies	

### GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The ManaSport+ is intended for use in the electromagnetic environment specified below.

The customer or the user of the ManaSport+ 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	±8kV contact ±15kV air	±8kV contact ±15kV 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 IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	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 IEC61000-4-11	<5%U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40%U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70%U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5%U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 seconds	<5%U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40%U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70%U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5%U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ManaSport+ requires continued operation during power mains interruptions, it is recommended that the ManaSport+ be powered from an uninterrupted power supply or a battery.
Power Frequency (50/60Hz) Magnetic Fields IEC61000-4-8	30 A/m at 50 or 60 Hz	30 A/m at 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.



# ELECTROMAGNETIC COMPATIBILITY (EMC)

## TABLES - RF EMISSIONS CLASS B (continued)

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The ManaSport+ is intended for use in the electromagnetic environment specified below. The customer or the user of the ManaSport+ should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC61000-4-6	3Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ManaSport+, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ 150 KHz to 80 MHz $d = .35 \sqrt{P}$ 80 MHz to 800 MHz $d = .70 \sqrt{P}$ 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 <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> . Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	
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.			
<sup>a</sup> 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 the fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ManaSport+ is used exceeds the applicable RF compliance level above, the ManaSport+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ManaSport+.			
<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE MANASPORT+			
The ManaSport+ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ManaSport+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ManaSport+ as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = .35 \sqrt{P}$	800 MHz to 2.5 GHz $d = .70 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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.





## Standards

The ManaSport+ complies with current medical standards.

The ManaSport+ also complies with the IEC 60601-1 standard on general safety requirements for electro-medical devices, the IEC 60601-1-2 standard on electromagnetic compatibility, the IEC 60601-2-5 standard on basic safety and essential performance of ultrasonic physiotherapy equipment, IEC 61689 field specifications and methods of measurement in the frequency range 0.5 MHz to 5 MHz, IEC 60601-1-6 General requirements for basic safety and essential performance - Collateral standard: Usability, and the IEC 60601-1-11 standard for use in the home environment.

The ManaSport+ also complies with the ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity, ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization.

The ManaSport+ also complies with AAMI TIR69:2017, ANSI C63.27-2017, AAMI TIR 18-2010.

## FCC Statement

This device 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.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- a) Reorient or relocate the receiving antenna
- b) Increase the separation between the equipment and receiver
- c) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- d) Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.