ManaSport™

INSTRUCTIONS FOR YOUR NEW MANASPORT

Noninvasive
Ultrasound Stimulator

Customer Service

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Manufactured For:

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ManaSport™

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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 not 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)

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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 buns, 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

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.

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QUICK START GUIDE

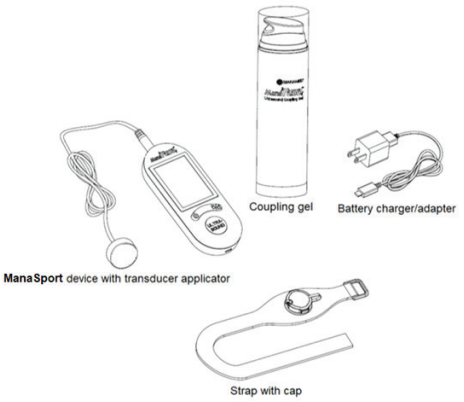
ManaSport™

See accompanying documents / User's Manual.

℞ only 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 sub-chronic and chronic 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.

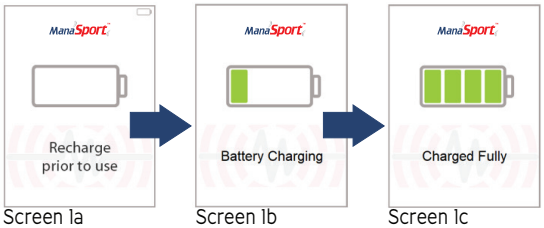


If you suspect you may be missing an item, please contact Customer Service at 888-508-0712.

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.

Charge the battery before use

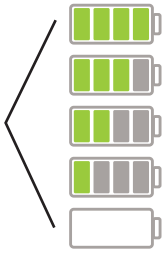


Screen 1a Screen 1b Screen 1c

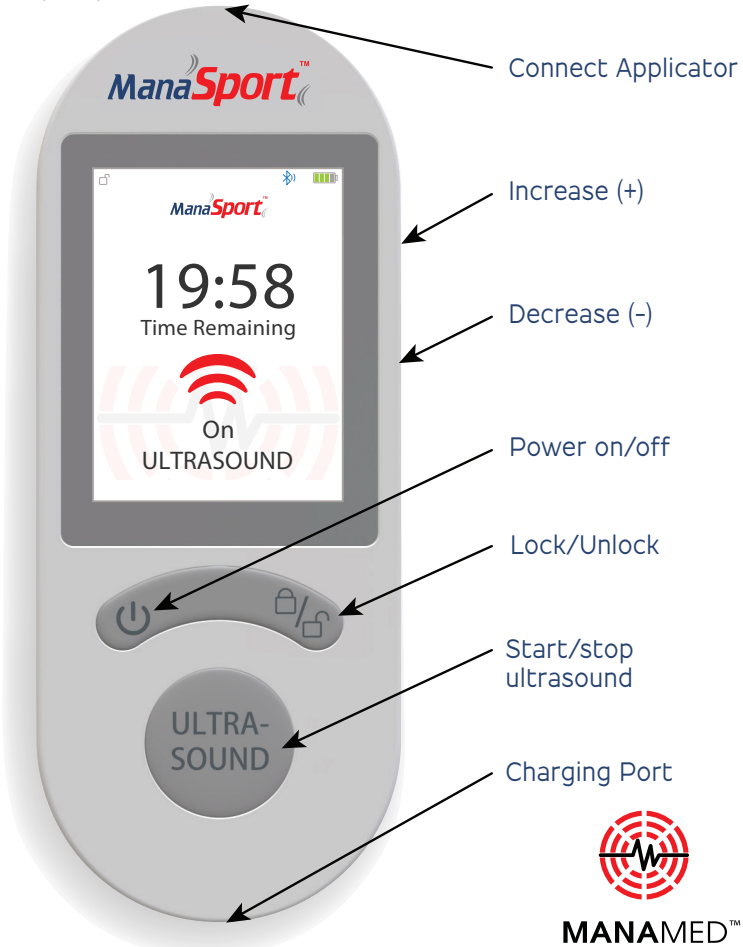
When the remaining battery of the device cannot last for 20 min, its display will switch to reminding you of recharge prior to use (Screen 1a). Plug the power supply adapter to the wall socket as well as ManaSport using the charging port located at its bottom end. The BATTERY icon on the device's display 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
	Low Battery	The battery runs low and needs to be charged prior to use.
	Battery Status	Shows how much charge is left in the battery.
	Calendar Broken Star	A 20-minute treatment was not completed on this calendar day.
	Calendar Starmark	A 20-minute treatment was completed on this calendar day.
	Calendar Double Starmark*	Two-20 minute treatments were completed on this calendar day.
	Calendar Double Checkmark Plus*	Three or more 20-minute treatments were completed on this calendar day.
	Ultrasound Symbol	Flashes during use to show you are having your treatment.
20:00	Countdown Timer	Counts down from 20 minutes to show treatment time remaining.
	Treatment Complete	Automatically displays when count-down timer reaches zero to show that treatment is complete.
	Lock Symbol	Locks the buttons to prevent unintended operation.
	Unlock Symbol	Unlock the buttons to operate the device.



Five levels of battery status



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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.

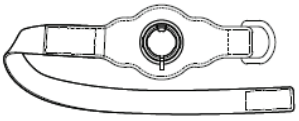
b. Position the transducer applicator flat against the skin and keep transducer applicator constantly moving, slowly and with constant pressure, during treatment.

c. The treatment area should not exceed 2 to 3 times the size of the transducer applicator.

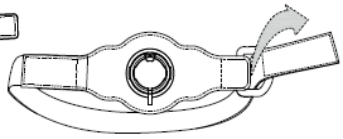
How to install the strap with a cap:

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;

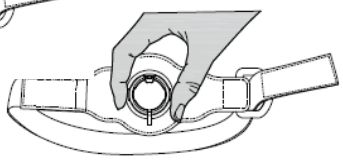
- Pull the long end of the strap through the plastic loop, as shown in the following Operation 2b;
- Use 2 fingers of yours to squeeze the cap tabs together to open the cap cover, as shown in the following Operation 2c;
- Slide the strap and place the port of the cap over the treatment site marked with 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);



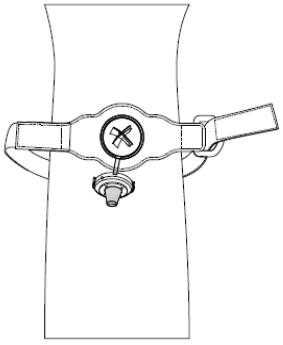
Operation 2a



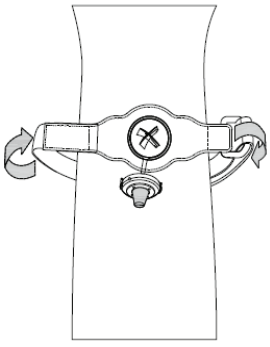
Operation 2b



Operation 2c



Operation 2d



Operation 2e

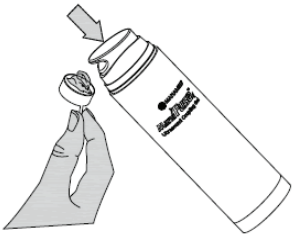
Preparation before use:

- 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);

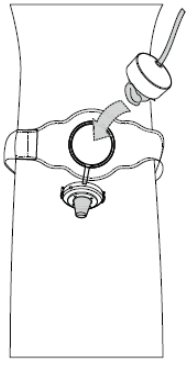
IMPORTANT:

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

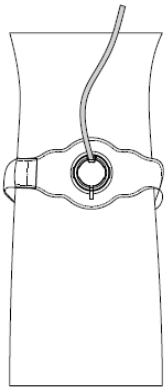
Patient should also ensure complete skin contact with the treatment applicator before beginning therapy.



Operation 4a



Operation 4b



Operation 4c

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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.

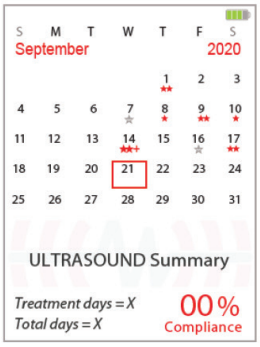
Screen 5a

Screen 5b

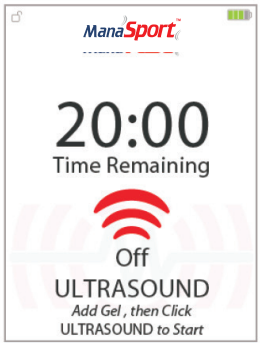
Screen 5c

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.

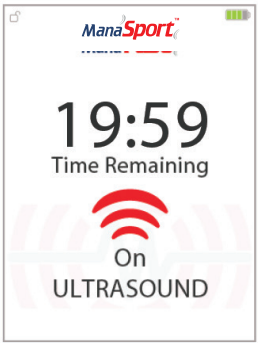
After the screen of calendar/summary (Screen 5d), the device will automatically proceed to the next screen of Ultrasound standby (Screen 5e). Follow the instruction on this screen to add more ultrasound gel on the transducer applicator if needed, and click the ULTRASOUND button to start the Ultrasound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



Screen 5d



Screen 5e



Screen 5f

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.

Screen 5g

Screen 5h

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.

Data Record

Your daily use time of Ultrasound is recorded, as shown on Screen 7a. When a 20-minute treatment is completed, a red starmark will show on the calendar date. When two 20-minute treatments are completed, two red starmarks will show on the calendar date. When three or more 20-minute treatments are completed, two red starmarks and one plus will show on the calendar date. When a 20-minute treatment is not completed, a grey broken starmark 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 7a

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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

Store in a dry location between +10°C (50°F) and +40°C (104°F).

Do not expose to heat exceeding 50°C (122°F) for extended periods of time.

Do not store items in 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.

TRANDUCER 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.

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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 contact SONOMED TECHNOLOGY, INC., P.O. BOX 10489, State College, PA 16805, or by calling 908-722-4549, Reference Gel #K883917.

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 (cm2)
Ultrasound power: 0.60 +/- 20% watts (W)
Ultrasound spatial average temporal avg. (SATA): 0.16 +/- 20% W/cm2
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

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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 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.
	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.
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. 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.

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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 excepted 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_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 in U_T) for 25 cycles <5%U_T (>95% dip in U_T) for 5 seconds	<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 in U_T) for 25 cycles <5%U_T (>95% dip in U_T) 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_T is the a.c mains voltage prior to application of the test level.

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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 ManaFuse, 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[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:
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.

[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 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 ManaFuse.

[b] 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.

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