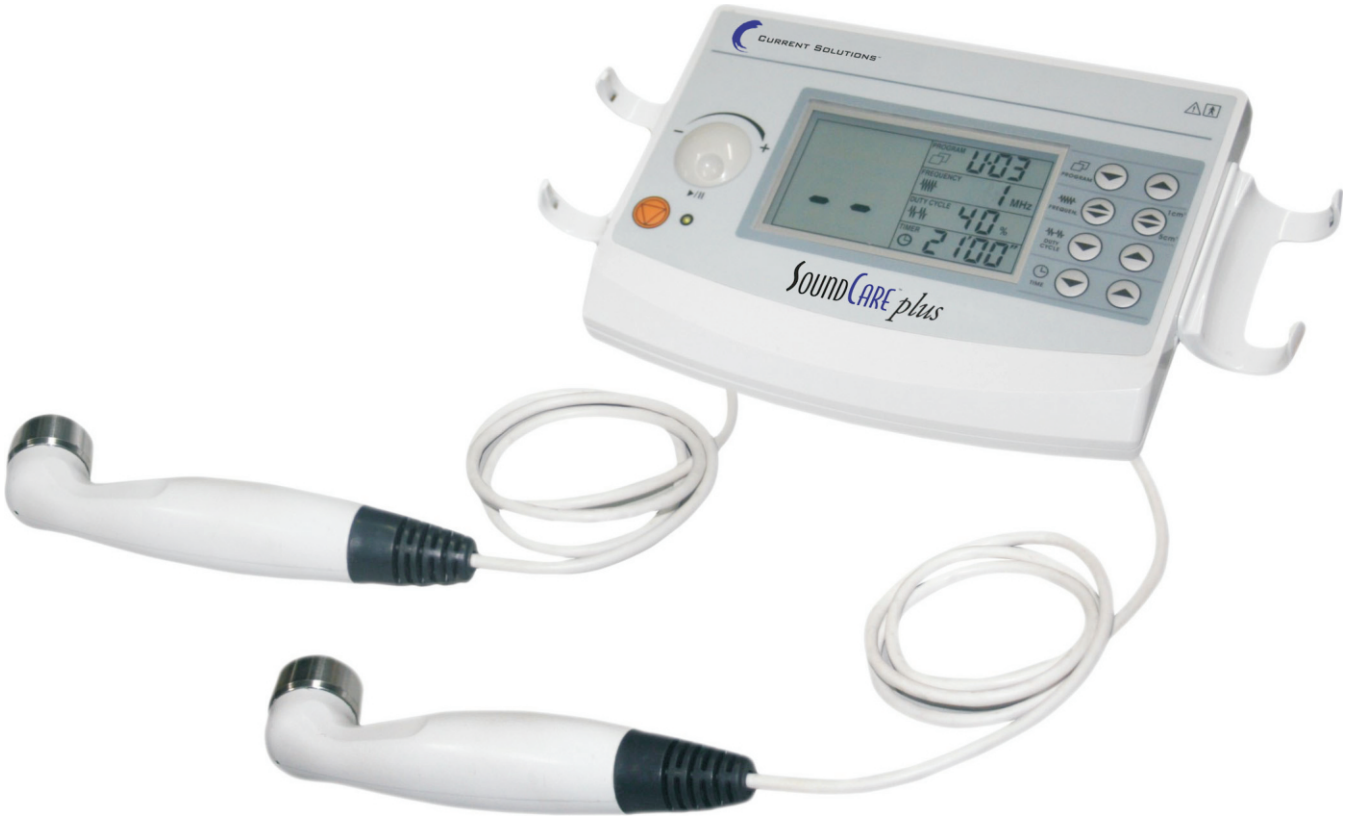
SoundCare™ plus

INSTRUCTION MANUAL

SoundCare™ Plus Pain Relief Device
Operating instructions
Medical device for pain treatment
based on ultrasound



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Contents

1. FOREWORD

1.1 General

This manual has been written for the users of the ultrasound therapy SoundCare™ Plus. It contains general information on the operation, precautionary practices, and maintenance information. In order to maximize use, efficiency, and the life of the system, please read this manual thoroughly and become familiar with the controls, as well as the accessories before operating the system.

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Current Solutions™, LLC . does not guarantee its contents and reserves the right to improve and amend it at any time without prior notice .Amendments will however be published in a new edition of this manual .

1.2 Therapy possibilities

The ultrasound therapy SoundCare™ Plus is an apparatus featuring an ultrasound therapy unit. Pain affects the quality and enjoyment of life, especially for those who suffer chronic pain. SoundCare™ Plus is ultrasound therapy device for the treatment of chronic and acute muscular pain.

1.3 Treatment head

The ultrasound treatment heads for the SoundCare™ Plus are so-called multi-frequency heads. This treatment head can now supply both 1 and 3MHz ultrasound. The head has excellent beam characteristics, fully meeting the requirements of the existing standards. The excellent beam characteristics, ergonomic design and effective contact control of the multi-frequency treatment heads make an optimal treatment possible. Standard accessories include a ultrasound head with $5cm^2$ Aer that can work at 1MHz and 3MHz. User can also choose to purchase ultrasound head with $1cm_2$ Aer that can also work at 1MHz and 3MHz.

1.4 Finally

You have made a wise choice in selecting the SoundCare™ Plus. We are confident that your unit will continue to give satisfaction over many years of use. Nevertheless, if you have any queries or suggestions, please contact your authorized distributor.

2. SAFETY PRECAUTIONS

2.1 PRECAUTION-ARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definition of these symbols is as follows.

Caution: Text with a "CAUTION" indicator will explain possible safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.

Warning: Text with a "WARNING" indicator will explain possible safety infractions that will potentially cause serious injury and equipment damage.

Danger: Text with a "DANGER" indicator will explain possible safety infractions that are imminently hazardous situations that would result in death or serious injury.

2.2 CAUTION

Caution:

- Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any ultrasound device. Observe the precautionary and operational decals placed on the unit.
- Keep yourself informed of the contraindications.
- Never leave the patient unattended during treatment.
- Do not operate the device when connected to any other medical devices.
- Do not operate this unit in an environment where other devices are used that intentionally radiates electromagnetic energy in an unshielded manner.
- Ultrasound should be routinely checked before each use to determine that all controls function normally, especially that the intensity control does properly adjust the intensity of the ultrasonic power output in stable manner. Also, determine that the treatment time control does actually terminate ultrasonic power output when the timer reaches zero.
- Do not use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.
- Before each use, inspect Ultrasound Applicator for cracks, which may allow the ingress of conductive fluid.
- Inspect Applicator cables and associated connectors before each use. The ultrasound therapy controls unit is not designed to prevent the ingress of water or liquids. Ingress of water of liquids could cause malfunction of internal components of system and therefore create risk of injury to the patient.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Refer to recent surgical procedures when muscle contraction may disrupt the healing process.
- Do not use over the menstruating or pregnant uterus, and over areas of the skin which lack normal sensation.

- SoundCare™ Plus should not be used on driving, operating machinery, or during any activity in which in voluntary muscle contractions may put the user at under risk of injury.

2.3 WARNING

Warning

- Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
- The apparatus may not be used in close proximity (i. e. less than 2 meters) to short-wave equipment.
- The apparatus may not be used in so - called " wet rooms " (hydrotherapy rooms)
- The user must keep the device out of the reach of children.
- Only use the device for the recommended applications. The device should be used medical supervison.
- Use of controls or adjustments or performance of procedures other than those specified here in may result in hazardous exposure to ultrasonic energy.
- Before administering any treatment to a patient you should become acquainted with the operating procedures for each mode of treatment available, as well as the indications, contraindications, warnings,and precautions. Consult other resources for additional information regarding the application of Ultrasound.
- Do not use solvents to clean the device.
- A damaged device must no longer be used.
- The device must only be serviced, repaired and opened by authorized sales centre.
- Dispose of the device in accordance with local regulations. Keep the operating instructions with the device.
- Pregnant and nursing women use the device cautiously.
- The group of immaturity bone uses the device cautiously.
- Continuous and effect treatment time is not over than 30min every day.
- Don't use cell phone during using the device.
- The use of sensitive coupling glue cautiously.
- Always keep the sound head in constant motion.

2.4 Danger

Danger

Patients with an implanted neuro–stimulation device must not be treated with or be in close proximity to any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy, or laser diathermy anywhere on their body. Energy from diathermy (shortwave, microwave, ultrasound, and laser) can be transferred through the implanted neurostimulation

system, can cause tissue damage, and can result in severe injury or death. Injury, damage, or death can occur during diathermy therapy even if the implanted neurostimulation system is turned "off."

3. Indications and Contraindications

3.1 Indications

1) Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:
- Relief of pain, muscle spasms and joint contractures
- Relief of pain, muscle spasms and joint contractures that may be associated with:
- Adhesive capsulitis
- Bursitis with slight calcification
- Myositis
- Soft tissue injuries
- Shortened tendons due to past injuries and scar tissues

2) Relief of sub-chronic and chronic pain and joint contractures resulting from:
- Capsular tightness
- Capsular scarring

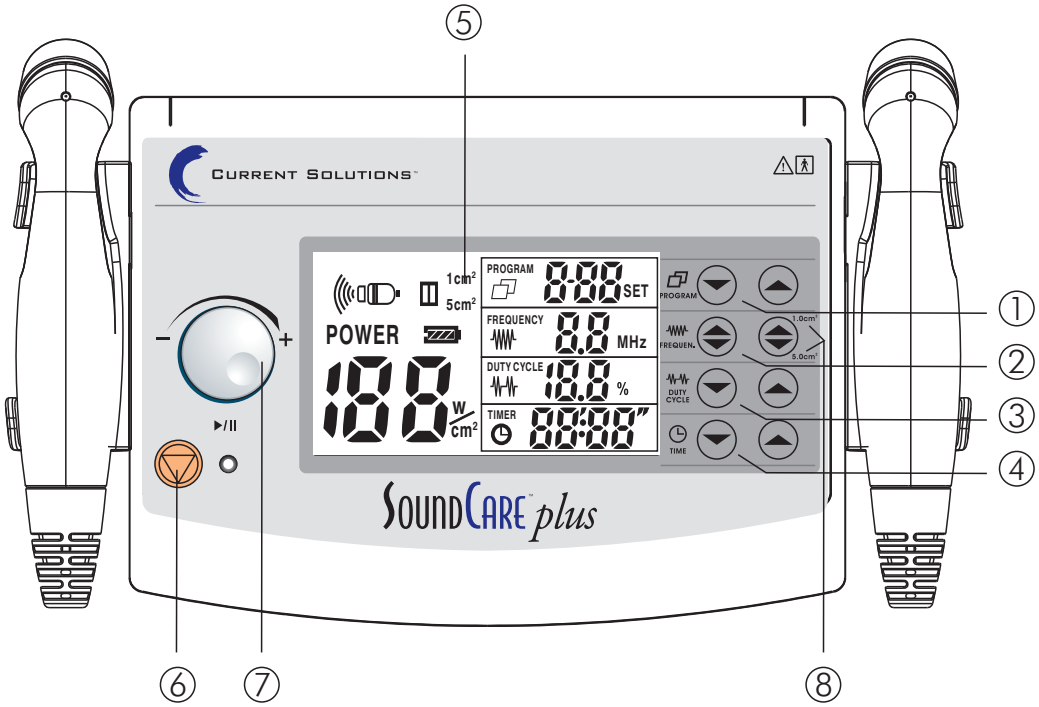
3) This device should be used in the hospital and home.
4) This device should be operated only by the experienced physician.

3.2 Contraindications

- This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- This device should not be used when cancerous lesions are present in the treatment area.
- This device should not be used when open wounds are present in the treatment area.
- This device should not be used on patients suspected of carrying serious infectious disease and or disease where it is advisable, for general medical purposes, to suppress heat or fevers.
- This device should not be used over or near bone growth centers until bone growth is complete.
- This device should not be used over the thoracic area if the patient is using a cardiac pacemaker.
- This device should not be used over a healing fracture.
- This device should not be used over or applied to the eye.
- This device should not be used over a pregnant uterus.
- This device should not be used on 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.
- This device should not be used over a tumours.

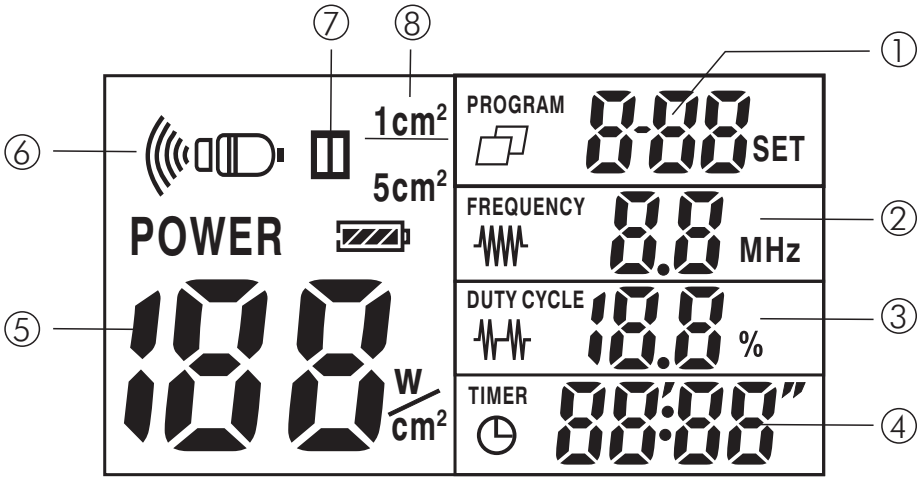
4. PRESENTATION

4.1 Presentation of the device



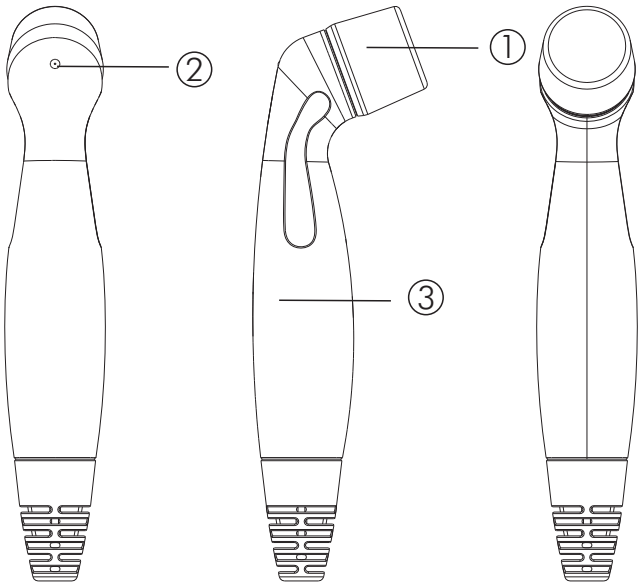
1) Program adjustment button
2) 1MHz and 3MHz adjustment button
3) Duty cycle adjustment button
4) Timer adjustment button
5) Liquid crystal display
6) Stop button
7) Output intensity adjustment knob
8) Treatment head select button

4.2 Liquid crystal display



1) Program indicator
2) Frequency indicator
3) Duty cycle indicator
4) Timer indicator
5) Output intensity/power
6) Ultrasound output indicator
7) Pause indicator
8) Treatment head type

4.3 Treatment head



1) Sound head
The component of the Applicator which makes contact with the patient during the Ultrasound therapy treatment of the time.
2) Applicator LED
The component of the Applicator which indicates if the Sound head is working or Nonworking on the treatment area.
3) Applicator
The assembly that connects to the System and incorporates the Sound Head.

4.4 Symbol definitions

Below are the definitions for all of the symbols used in the Ultrasound therapy device . Study and learn these symbols before any operation of the system.

ON/OFF SWITCH

STOP TREATMENT

START / PAUSE BUTTON

ULTRASOUND INTENSITY

ULTRASOUND APPLICATOR STATE

POLARITY OF POWER SUPPLY

THE CONNECTION SOCKET OF TREAMENT HEAD

⏸	PAUSE
W	ULTRASOUND OUTPUT POWER
W/cm²	ULTRASOUND OUTPUT INTENSITY
◷	TREATMENT TIME

4.5 Key Function

ON/OFF Switch
- With this button the SoundCare™ Plus is turned on or off.

Pause Knob
- Pause/Restore treatment working

Intensity Knob
- Rotating the intensity control Knob to start treatment
- Set intensity by rotating the intensity control Knob to the prescribed level
- Clockwise-Increase Intensity
  Counterclockwise-Decreases Intensity

Escape button
- Stop treatment

UP and DOWN Arrows
- Controls used in various modality parameter screens to navigate or change a value up or down within the parameter.

5.0 INSTALLATION

5.1 Reception of equipment and accessories

Remove the Therapy System and all accessories from shipping cartons. Visually inspect for damage. Report any damage to the carrier.
Your ultrasound therapy is supplied with case containing:

Part	Quantity
Ultrasound therapy unit	1
Ultrasound head with 5cm² AER	1
Ultrasound head with 1cm₂ AER	1
Adapter 1.35A to 100～240V	1
Lead for adapter	1

5.2 Connection

Mains supply connections must comply with the national requirements regarding medical rooms. The equipment has a safety earth (ground) connection, and must be connected to an earthed (grounded) wall socket.

Prior to connection of this devices to the mains supply, check that the voltage and frequency stated on the type plate correspond with the available mains supply.

The mains adapter is a part of the supply circuit on which the device's safety partl y depends. We recommend that you use the MPU50-160 type with of medical power. If you can not find the same type of medical power, please choose the same specifications (Output:DC15V/1.35A) medical power.

Connect the supplied mains adapter to the connector.

Connect the mains adapter to a wall socket.

Caution: For your health, if you change the AC/DC adaptor, it must conform to the requirement of the standard medical electrical equipment.

5.3 Connect the treatment head

Plug the applicator's connection plug into the corresponding socket connection on SoundCare™ Plus in accordance with the direction that marked at the applicator connector.

If connect correctly, LCD will show the picture in Figure 1, if connect error, LCD will show the picture in Figure 2.

Figure 1

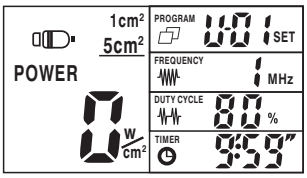
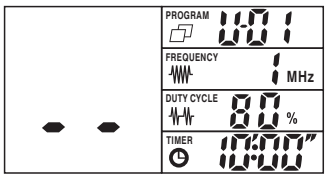


Figure 2



Caution: SoundCare™ Plus can only use the applicator that attached with main unit by the manufacturer. Please do not use other type of applicator.

5.4 Switching on and self-test

Switch on the device, using the ON/OFF switch

Immediately after switching on, the apparatus carries out a self-test.

At the end of the self-test a beep is heard. When an error is found an error code will appear on the display. See section 8 for details.

5.5 Therapy system set up

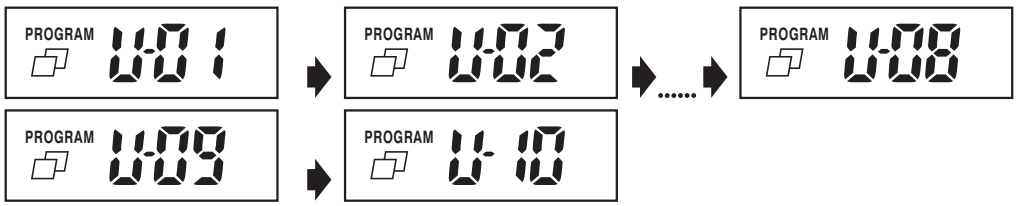
SoundCare™ Plus has 10 kinds of treatment procedures model. Users can program their own operating parameters of the treatment process:

1. Ultrasonic frequency;
2. The treatment duty cycle;
3. Treatment time.

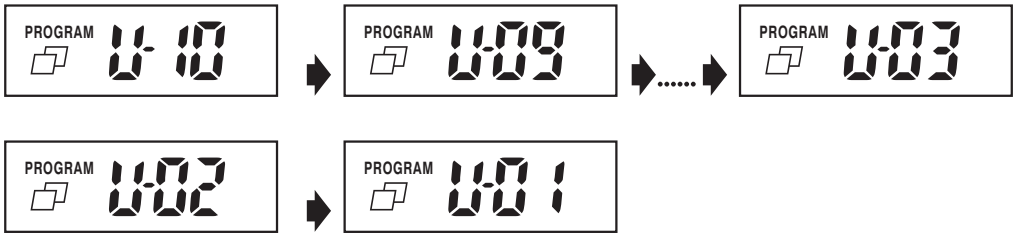
Operating parameters will be stored automatically; power-down or shutdown will not be lost.

5.5.1 Choice/ Select therapy mode: U01-U10

- Mode up key: Press this button to choice the program

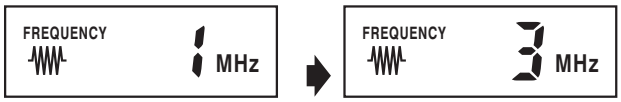


- Mode Down key: Press this button to choice program

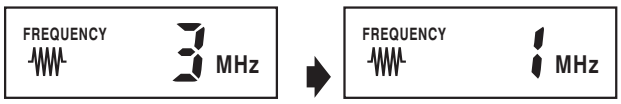


5.5.2 Choice/ Select the Ultrasound Frequency: 1MHz or 3MHz

- Freq up key: Press this button to choice the Ultrasound Frequency

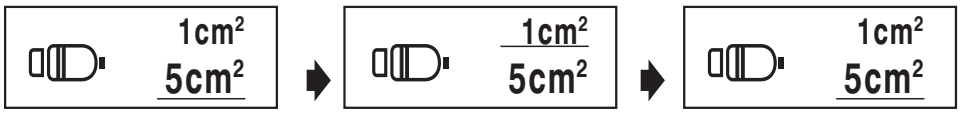


- Freq Down key: Press this button to choice the Ultrasound Frequency



5.5.3 Choice/ Select the treatment head 1cm^2 or 5cm^2

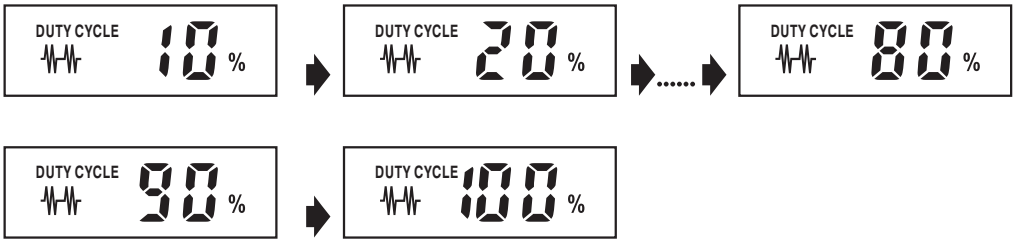
- Select the treatment head 1.0cm^2 or 5.0cm^2 by treatment head select button.



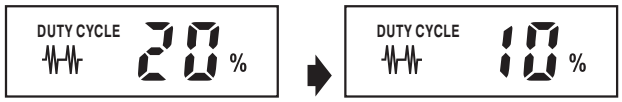
CAUTION: The user can select the treatment head 1.0cm^2 or 5.0cm^2 by treatment head select button when the two types of treatment head have been connected with the device. The device can default to select the treatment head automatically when only one treatment head is connected with the device.

5.5.4 Choice/ Select the duty cycle: 10%-100%, stepping 10%

- Duty up key: Press this button to increase the duty cycle

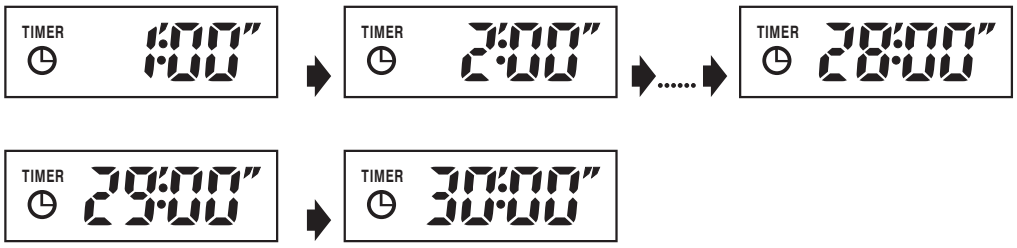


- Duty Down key: Press this button to decrease the duty cycle

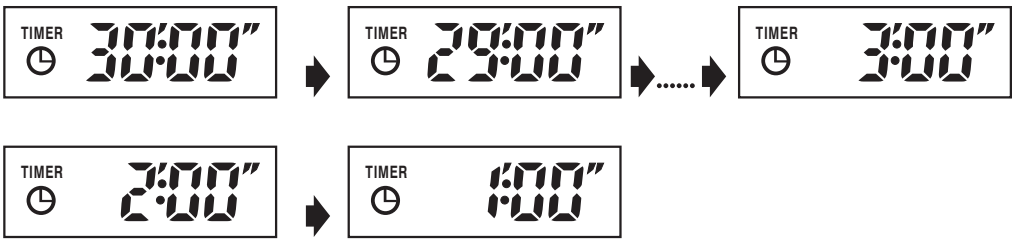


5.5.5 Setting the treatment time:1 min-30min, stepping 1 min

- Time up key: Press this button to increase the treatment time



- Time up key: Press this button to decrease the treatment time



5.6 Disconnecting from the mains

Switch off the SoundCare™ Plus, using the mains switch.
Pull out the mains plug of the mains adapter from the wall socket.

6. OPERATION

6.1 Measures with regard to treatments

6.1.1 Before the treatment

- Put the patient in a comfortable position. The area to be treated should be properly supported and exposed and perfectly relaxed.
- Inform the patient on the purpose of the treatment and the sensation he will perceive in the course of the therapy.
- Ensure there are no contraindications to treatment
- Inspect the patient's skin accurately for any abrasions, inflammation, surface veins etc.
- Clean the area to be treated with a 70% alcohol or soap.
- It is advisable to shave areas of excessive hair-growth.

6.1.2 During the treatment

- The treatment-head has to be moved constantly in a slow tempo, also in case of the semi-statically method.
- Ask the patient regularly about his/her experiences. If necessary, the treatment can be adjusted. By using knob [6], the intensity can be reduced.
- In case of indications of pour transmission of ultrasound energy, it is advised to add the contact-gel or reposition the ultrasound-head.
- During the treatment, if the ultrasonic applicator connected well, the applicator LED will light; if the ultrasonic applicator doesn't contact well, the applicator LED will blink slowly,the system will be think this is no-load in the applicator. When treatment was pause, the applicator LED light will be extinguished. And the countdown will also be suspended.

Caution

The massage performed with the head should be applied with a regular movement, not too slow to avoid inducing heat, nor too fast to prevent a bad contact which would reduce the effectiveness of the treatment.

Warning

If you want to replace treatment head, you need to turn the power switch OFF, so that the device is in shutdown state in order to the replacement of treatment head.

6.1.3 After the treatment

- Clean the skin of the area treated as well as the treatment-head by using a towel or a tissue.
- The treatment-head should be cleaned up with a 70% alcohol solution
- Check if there are any signs of improvement (e.g. pain, circulation and mobility).
- When entering the next treatment-session, the patient is instructed to report any possible reaction.

6.2 Operating the apparatus

6.2.1 Switch on the apparatus

Turn the apparatus on with switch. The apparatus executes a self-test; checking all important functions and presents itself with the start up settings. The start up settings is adjustable at memory location. To personalize the start up settings, refer to chapter 5.5, Therapy system set up.

6.2.2 Adjusting parameters

Press the buttons [1], [2], [3], [4] to select a parameter.

6.2.3 Ultrasound intensity

The ultrasound intensity is adjusted with intensity control knob. The ultrasound intensity can only be adjusted during the treatment. The ultrasound intensity can be displayed in W or W/cm^2. (Press the buttons [1], [2], [3], [4] can change the displayed W or W/cm^2)

6.2.4 Pause

Press the knob [6] to pause the treatment. Press again the knob [6] to restore the treatment.

6.2.5 Emergency stop

Pressing button [5] simultaneously will terminate all active treatments.

6.3 The treatment head

A treatment head is a precision instrument. Great care is taken in the development and production in order to obtain the best possible beam characteristics. Rough treatment (jarring or dropping) can adversely affect these characteristics, and must therefore be avoided.

6.4 The contact medium

In order to ensure efficient transfer of energy, a contact medium is required between the treatment head and the body. Air causes virtually total reflection of the ultrasound energy. The best medium for the transfer of ultrasound energy is a gel. But the ultrasound gel is expected by the user to buy their own.

- Liberally apply transmission gel to the treatment area on the patient.
- Move the treatment head during therapy session in a circular motion. The area treated should be two times the diameter of the treatment head.
- If the body surface is very irregular, making it difficult to obtain good contact between the treatment head and the body, or if direct contact must be avoided (e.g. due to pain), the affected area may be treated under water (subaqual method). The water should be degassed (by previous boiling) in order to prevent air bubbles arising on the treatment head and the body.

Caution: Never apply the gel to the treatment head. The treatment head will register this as contact and may emit ultrasound energy, which could damage the treatment head.

Never apply the gel to the treatment head. The treatment head will register this as contact and may emit ultrasound energy, which could damage the treatment head.

Always use the gel with the requirements of the medical, such as with CE mark, or are legally marketed in the US.

7. MAINTENANCE

7.1 Cleaning of the apparatus

Switch off the apparatus and disconnect it from the mains supply.
The apparatus can be cleaned with a damp cloth. Use lukewarm water and a non-abrasive liquid household cleaner (no abrasive, no alcohol content solution). If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

Caution: Do not submerse the device in liquids. Should the device accidentally become submersed, contact the dealer or Authorized Service center immediately. Do not attempt to use a system that has been wet inside until inspected and tested by a Service Technician Certified by Authorized Service center. Do not allow liquids to enter the ventilation holes in the optional modules. This could permanently damage the modules.

7.2 Cleaning of the treatment heads

The treatment heads and cables should be regularly inspected for damage, e.g. hairline cracks, which could allow penetration by liquids. Clean the contact surface immediately after each treatment. Make sure that no ultrasound gel remains on the treatment head. We further recommend cleaning the head and cable daily, using lukewarm water. The treatment heads can be disinfected using a cloth moistened with 70% alcohol.

7.3 Maintenance

- Maintenance and all repairs should only be contact with the dealer agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- The service and or maintenance must be carried out conform the procedure described in the manual of the apparatus.
- Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

8. Diagnostics

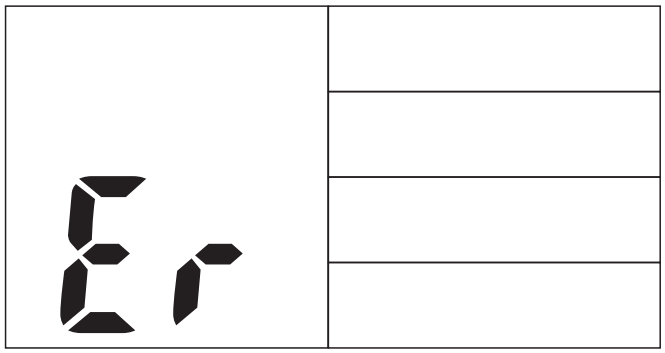
8.1 Displays fail to light up

Check if the mains adapter is connected to the device and mains supply.

8.2 Error

The device has discovered a fault during or after the self-test. The error displays the following figure 1. Remove any applicators or cables from the output sockets and switch the apparatus off and on again. If the code re-appears, contact your supplier. The device is probably defective.

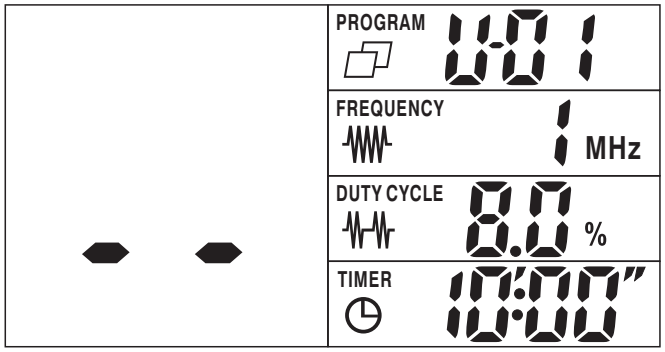
Figure 1



8.3 The contact control fails to operate

Check the connected plug of ultrasound applicator.

Figure 2



9. SPECIFICATIONS AND TECHNICAL DATA

9.1 Electrical date

Technical date of Treatment head

Acoustic Frequency:	1MHz±10%,3MHz±10%
Output Power:	0.5W-10.0W±20%,when duty factor≥80% for 5cm^2 0.5W-15.0W±20%,when duty factor≤70% for 5cm^2 0.1W-2.0W±20%, when duty factor≥80% for 1cm^2 0.1W-3.0W±20%, when duty factor≤70% for 1cm^2
Pluse repetition rate:	100Hz±10%
Duty factor :	10%-100%,Stepping 10%
Timer:	Max 30 minutes
Effective radiating area (A_{ER})	5.0cm^2±20%; 1.0cm^2±20%
Actual intensity:	3.0W/cm^2±20%(1.0MHz), 3.0W/cm^2±20%(3MHz)
R_{BN} (Max):	5.0
Beam type:	Collimated
Material of applicator:	Aluminium
Waterproof Grade	IPX7 Only for treatment head

Technical data of power supply

Supply voltage:	100V-240V
Frequency:	47Hz-63Hz
Power:	45W
Output voltage:	13-16V
Output current:	1.35A
Dimensions:	143mm(L)x73mm(W)x40mm(H)

Environmental conditions for use

Environment temperature:	10-40℃
Relative humidity:	30%-85%
Atmospheric pressure:	800-1060hPa

Environmental conditions for storage

Environment temperature:	-20℃-55℃
Relative humidity:	20%-90%
Atmospheric pressure:	700-1060hPa

9.2 Program List Table

Program	Frequency	Duty Cycle	Treatment Time	Suggest Intensity
U-01	1MHz	80%	10 minutes	1.0W/cm^2
U-02	1MHz	50%	10 minutes	1.0W/cm^2
U-03	1MHz	50%	20 minutes	1.5W/cm^2
U-04	1MHz	50%	15 minutes	1.0W/cm^2 1.5W/cm^2 2.0W/cm^2
U-05	3MHz	80%	15 minutes	1.0W/cm^2
U-06	1MHz	30%	15 minutes	1.5W/cm^2
U-07	1MHz	80%	15 minutes	1.0W/cm^2 1.5W/cm^2
U-08	1MHz	80%	8 minutes	1.5W/cm^2
U-09	1MHz	50%	12 minute	1.5W/cm^2
U-10	3MHz	80%	10 minutes	1.0W/cm^2

10. STORAGE

For a prolonged pause in treatment, store the device with the adapter in a dry room and protect it against heat, sunshine and moisture.
Store the machine in a cool, well-ventilated place.
Never place any heavy objects on the machine.

11. DISPOSAL

Please dispose of the device in accordance with the directive 2002/96/EC WEEE (Waste Electrical and Electronic Equipment). If you have any queries, please refer to the local authorities responsible for waste disposal.

12. STANDARDS AND REQUIREMENTS

Current Solutions™, LLC declares that the device complies with following normative documents: IEC/EN60601-1, IEC/EN60601-1-2, IEC/EN60601-2-5, IEC/EN61689, IEC60601-1-4,IEC62304,ISO10993-5, ISO10993-10, ISO10993-1,ISO14971.

13. GUIDANCE AND MAUFACTUER'S DECLARATION

13.1 Declaration-electro-magnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The SoundCare™ Plus device is intended for use in the electromagnetic environment specified below. The customer or the user of the SoundCare™ Plus should assures that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The SoundCare™ Plus device 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	The SoundCare™ Plus device is suitable for use in all establishments other than domestic 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	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

13.2 Declaration - electromagnetic immunity

Guidance and manufacturer's declaration-electromagnetic immunity			
The SoundCare™ Plus device is intended for use in the electromagnetic environment specified below. The customer or the user of the SoundCare™ Plus 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

13.3 Declaration- electromagnetic immunity

Guidance and- manufacturer's declaration. Electromagnetic immunity			
The SoundCare™ Plus device is intended for use in. the electromagnetic environment specified below. The customer or the user of the SoundCare™ Plus should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 Vrm	Portable and mobile RF communications equipment should be used no closer to any part of the SoundCare™ Plus device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 80MHz to 2.5MHz

			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. 

NOTE I At 80 MHz ends 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 du to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SoundCare™ Plus device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SoundCare™ Plus.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_i] V/m.

13.4 Recommended separation distances between portable and mobile

RF communications equipment and the SoundCare™ Plus device

Recommended separation distances between portable and mobile RF communications equipment and the SoundCare™ Plus device			
The SoundCare™ Plus device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SoundCare™ Plus device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SoundCare™ Plus 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 $d=1.2\sqrt{P}$	800 MHz to 2,5 GHz $d=2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer. NOTE I 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.			

14. WARRANTY

Please contact your dealer or the device centre in case of a claim under the warranty. If you have to send in the device, enclose a copy of your receipt and state what the defect is.

A. The following warranty terms apply:

- The warranty period for SoundCare™ Plus products is one years from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
- Defects in material or workmanship will be removed free of change with in the warranty period.
- Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.

B. The following is excluded under the warranty:

- All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
- All damage which is due to repairs or tampering by the customer or unauthorized third parities.
- Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
- Accessories which are subject to normal wear and tear.
- Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

15. NORMALZED SYMBOLS


Manufacturer's name and address


Date of manufacture


Type BF Applied Part

Serial Number of product

Batch code


Caution: Attention, see instructions for use


Disposal in accordance with Directive 2002/96/EC (WEEE)

IPX7 Only for treatment head: Protected against the effects of temporary immersion water

CE 0123 Complies with the European Medical Device Directive (93/42/EEC)
Notified body is TUV SUD(0123)

CB The electrical safety meet the CB system requirements


Indoor use only


Risk of electric shock

Complies with the safety requirements of Canada and U.S.
The certification body is UL, the cerificate number is E230351

Manufactured for:
Current Solutions™ LLC
3814 Woodbury Drive
Austin,TX 78704
Ph:(800)871-7858
www.currentsolutionsnow.com