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VISSCO JOHARI

Stimulator

For Joint Stimulation

Instruction Manual

Before using the JointStim Stimulator all instructions and warning must be read carefully

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which he or she practices to use or order the use of the device. A precscription must be obtained and is required to use this product. This product is permitted to be used in the home or clinic for all patients in which it is prescribed for.

This instruction manual will help you achieve maximum results using the **JointStim** stimulation device.

The **JointStim** stimulator is to be used by the prescribed patient only. This device is not to be shared with family members and when not in use it is to be stored away from the reach of children.

Intended use of JointStim stimulator

The JointStim stimulator external, non-invasive, non-narcotic, electrotherapy system is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee.

The JointStim stimulator is also indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the hand.

User Manual **JointStim**

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User Manual JointStim

1.0 RECOMMENDED USAGE

1.1 PROVEN RESULTS OVER TIME

After detailed research it has been proven that this unit has best results if utilized 5-9 hours daily. This unique form of electrical therapy is meant to be applied sub-threshold, where the current is set to the patients comfort level. The JointStim stimulator is also recommended to be used while you are sleeping. The body heals the most while at rest; we have found the best joint relief is attained throughout your sleeping period. For optimal results it is recommended that you use this device for a minimum of90 days. Some patients may see results almost immediately, although other patients may be required to continue treatment from 6 months to 1 year.

2.0 COMPONENTS OF THE JOINTSTIM S TIMULATOR

2.1 JOINTSTIM STIMULATORUNIT

JointStim stimulator device is a small hand held unit; battery powered, and is very user friendly. The unit connects to your electrode garments through lead wires allowing the electrical therapy to occur. The device has rechargeable batteries and includes a patient compliance meter to record treatment. We developed a dual channel unit in case there is bilateral therapy, where both hands and both knees can assimulate therapy.

2.2 HAND AND WRIST WRAP

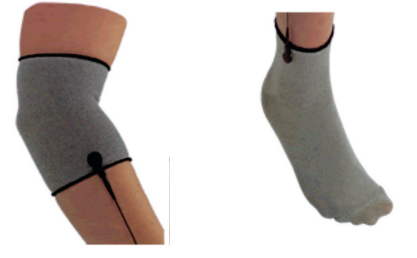
The hand and wrist wrap is an innovative product that utilizes conductive fabric technology which fits easily on the patient. This is a one size fits all garment, it will stretch to fit any patient. Make sure you remove all jewelry before applying the garment. Place the glove on the injured hand/wrist and wear the elbow sleeve on your elbow, on the same arm as your injured hand. Common question, "why should I use two garments when my hand or wrist is the injured body part not the elbow." (Electricity exists as two distinct poles, a positive pole and a negative pole. Just as your car battery has two terminals. Electrical stimulation of the body needs two opposite poles to

enable the flow of electrons and wave forms from one pole to the other. If you connect only one conductive garment to the patient all by itself, nothing will happen because you have not completed the circuit. Two connections to the patient are necessary for the JointStim STIMULATOR to complete the circuit between the extremities.)

The lead wires on the garment electrode connect into the wires of the JointStim stimulator allowing for the device to begin therapy.

The red (positive) lead wire is where the therapy will take place, so connect this wire to the hand and the black (negative) wire to the sleeve.

2.3 KNEE WRAP



The knee wrap is a conductive garment equally distributing the current throughout the sleeve, providing the most effective amount of therapy equally to the affected area. Make sure you remove all jewelry before applying the garment. Place the sleeve on your injured knee and the conductive sock on the same leg of the injured body part.

Common question, "why should I use two garments when my knee is the injured body part." (Electricity exists as two distinct poles, a positive pole and a negative pole. Just as your car battery has two terminals. Electrical stimulation of the body needs two opposite poles to enable the flow of electrons and wave forms from one pole to the other. If you connect only one conductive garment to the patient all by itself, nothing will happen because you have not completed the circuit. Two connections to the patient are necessary for the JointStim STIMULATOR to complete the circuit between the extremities.) Connect the lead wires to the knee sleeve and the conductive sock. This allows the current to flow and begin proper therapy. The lead wires on the garment electrode connect into the wires of the JointStim stimulator. The red (positive) lead wire is where the therapy will take place, so connect this wire to the hand and the black (negative) wire to the sleeve.

2.4 CONDUCTIVE SPRAY

Apply the conductive spray to the body parts where the gloves and the sleeves are being worn. Spray 3 times evenly covering the areas of treatment.

2.5 PATIENT LEAD WIRES

3.0 INSTRUCTION FOR THE JOINTSTIM STIMULATOR

1. Be sure that you have located all the components of the JointStim stimulator. Once you have located all the items read all the information and familiarize yourself with the device and its components.
2. Your treatment area must be removed of any clothing or jewelry, so the stim unit can completely cover the affected area. If a pre-existing rash is present, please consult with your physician before beginning your therapy.
3. The treatment area should be clean and dry, so the conductive patches can be most effectively applied.
4. The JointStim stimulator's conductive wrap will be assembled for you to begin therapy.

A. Makes sure you remove all jewelry before applying the garment. The conductive knee wrap should be positioned just

over your knee and the conductive sock must be placed on the same leg. Connect the lead wires to the knee sleeve and the conductive sock. This allows the current to flow and begin

proper therapy. The lead wires on the garment electrode connect into the wires of the JointStim stimulator. The red (positive) lead wire is where the therapy will take place, so

connect this wire to the hand and the black (negative) wire to the sleeve.

B. Makes sure you remove all jewelry before applying the garment. Place the glove on the effective hand/wrist and the sleeve on your elbow the same arm as your hand.

The lead wires on the garment electrode connect into the wires of the JointStim stimulator allowing for the device to begin therapy.

The red (positive) lead wire is where the therapy will take place, so connect this wire to the hand and the black (negative) wire to the sleeve.

4.0 SPECIFICATIONS

4.1 Accessories

- Electrical Stimulator device 1 piece
- Electrode Leads 2 pieces
- Electrodes Self Adhesive Square 2” 4 pieces
- AAA Battery 4 pieces
- AC Adapter 110V/220VAC,5.5V DC/1.5A 1 pieces
- User Manual 1 piece
- Carry Bag 1 piece

4.2 Technical Information

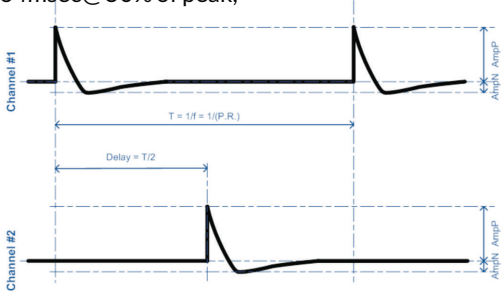
Channel:	Dual
Power supply:	5.5 V DC.
Operating conditions:	5°C to 40°C (41 °F to 104°F) with a relative humidity of 30% - 75%, atmospheric pressure from 700 to 1060Hpa.
Storage conditions:	-10°C to 50°C (14°F to 122°F) with a relative humidity of 10% - 90%, atmospheric pressure from 700 to 1060 Hpa. -10°C to S0°C with a relative humidity of 10% - 90%, atmospheric pressure from 700 to 1060Hpa.
Dimensions:	5 X 2. 7 X 1.2 inches (L *W*H)
Weight:	0.30 lbs (with battery)
Tolerance:	There may be a ±5 % tolerance of all setting and ±10% tolerance of output of intensity.

4.3 NORMALMODE

Waveform:

Monophasic spike-shaped pulse. Positive spike is defined by following pattern:

- 1.8msec@ 10% of peak;
- 0.64msec@ 50% of peak;



Pulse Amplitude:

Adjustable, from O to 16V peak at 500 ohms load each channel

Pulse Rate:

Specification in time domain is defined by following patter:

- Cycle#I-Freq=85Hzfor25min;
- Cycle#2-Freq=80Hzfor55min;
- Cycle#3-Freq=75Hzfor25min;

Repeated 4 times per 7 hours of treatment

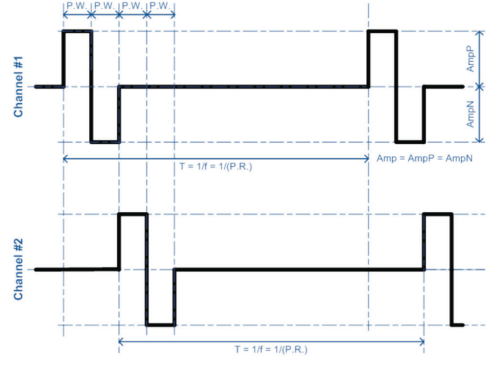
Treatment Time:

Predefined: 1:45 hours, 3:30 hours, 5:15 hours or 7:00 hours.

4.4 INTENSIVE MODE

Waveform:

Symmetrical biphasic square wave;



Pulse Amplitude:

Adjustable, from O to 40Vpp at 500 ohms load each channel;

Pulse Width : 50to250µsec

Pulse Rate : 80 to 95Hz;

Treatment Time:

Predefined: Continuous, 0:30 hours or 1:00 hours.

4.5 Sub-modes

Intensive Mode/ Pl Intensive/ Normal Mode

Pulse Width: Adjustable in range 50 to 250µsec;

Pulse Rate: Specification in time domain is defined by following patter:

- Cycle #1- Freq= 95Hz for 30min;
- Cycle #2 - Freq= BO Hz for 30min;

Intensive Mode/ P2 Intensive/ Burst Mode

Pulse Width:

Adjustable in range 50 to 250µsec;

Pulse Rate:

BOHz (fixed);

Description:

The period is defined with series of 9 pulses in contraction phase and with the relax time in duration of 9 periods on the same frequency (Freq);

Intensive Mode/ P3 Intensive/ Pulse Width Modulation

Pulse Width:

50 to 250µsec controlled by modulation process;

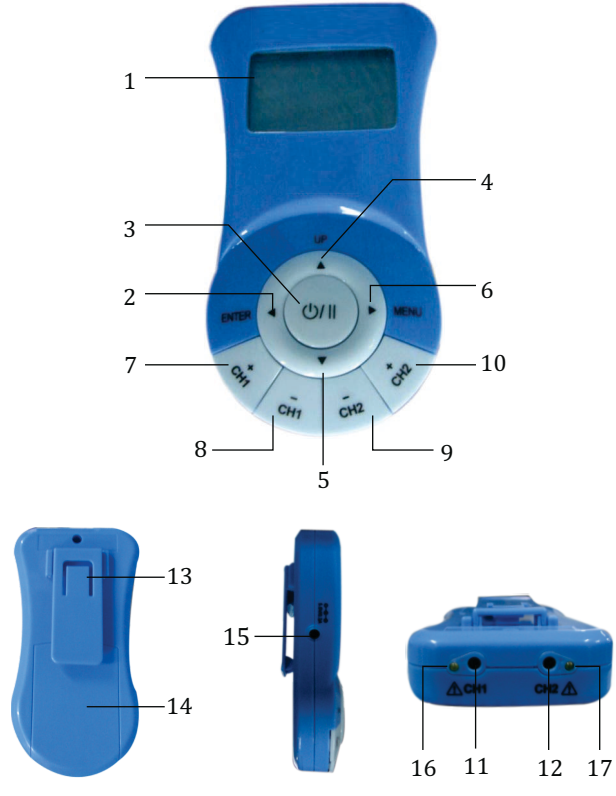
Pulse Rate:

Freq= BO Hz (fixed);

- Cycle Time: 5sec/5sec / The period of increasing the pulse width from 50µsec to 250µsec is 5sec; The period of decreasing the pulse width from 250µsecto 50µsec is 5sec;

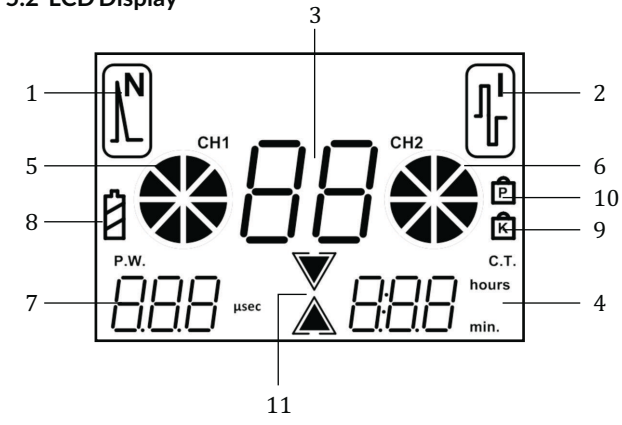
5.0 PRESENTATION

5.1 Front and Rear Panel



1) LCD display: Shows the operating state of the device.
2) Parameter Selection (ENTER): press the button to enter setting state.
3) ON/OFF/ START/STOP/PAUSE button: Press the button to turn on the device, keep button for approx 3 seconds to turn off the device.
4) Up button
5) DOWN button
6) Therapeutic mode selection (MENU). Return to the previous sub menu - back command. Exit setting mode to the user interface.
7) Increasing the output intensity of channel 1 (CHl +)
8) Decreasing the output intensity of channel 1(CH1-). To unlock the current treatment program.
9) Decreasing the output intensity of channel 2(CH2-). To unlock the current treatment program.
10) Increasing the output intensity of channel 2 (Ch2+)
11) Output socket: electrical signal output after connection of the cable with adhesive electrodes channel 1.
12) Output socket: electric signal output after connection of the cable with adhesive electrodes channel 2.
13) Belt Clip
14) The battery compartment cover for opening,
15) Adapter Receptacle
16) Indicator of treatment: Indicator of treatment is lit when the stimulus is present on the channel 1 or flashes when there is no-load condition on the same channel;
17) Indicator of treatment: Indicator of treatment is lit when the stimulus is present on the channel 2 or flashes when there is no-load condition on the same channel.

5.2 LCD Display



1) Indicator of Normal mode (N);
2) Indicator of Intensive mode (I);
3) Indicator of program in Intensive mode.
4) Timer and CT/ CN counter;
5) Channel 1 intensity indicator and intensity bar;
6) Channel 2 intensity indicator and intensity bar;
7) Waveform pulse width parameter indicator [in Intensity mode);
8) Low-batteryindicator.
9) The keyboard is locked indicator.
10) Indicator of program lock/unlock.
11) Indicator of RUN state;

6.0 INSTRUCTIONS FOR USE:

6.1Battery

6.1.1 Check/ Replace the Battery

Over time, in order to ensure the functional safety of device, changing the battery is necessary.

1) Slide the battery compartment cover and open.
2) Insert the 1.SV batteries into the battery compartment.
3) Make sure you are installing batteries properly. Be sure to match the positive and negative ends of the battery to the markings in the battery compartment of the device.
4) Close the battery compartment by battery compartment cover.

6.1.2 Disposal of Battery

Spent batteries do not belong in the household waste. Dispose of the battery to the current federal, state and local regulations. As a consumer, you are obligated by law to return spent battery.

Caution:

1) Battery may be fatal if swallowed. Therefore, keep the battery and the product out of the range of children, if a battery was swallowed, consult a physician immediately.
2) If a battery has leaked, avoid contact with skin, eyes and mucus membranes, Rinse the affected spots with lots of clear water immediately and contact a physician immediately.
3) Battery may not be charged, dismantled, thrown into fire or short circuited.

4) Protect battery from excess heat. Take the battery out of the product if they are spent or in case you no longer use the article. This prevents damage caused by leaking battery.
5) Always replace the same type battery.

6.1.3 Recommended battery

High quality Alkaline battery 1.SV AAA must be used.

6.2 Connect electrodes to lead wires:

Insert the lead wire connector into electrodes connector (standard 0.08 inch female connection). Make sure no bare metal of the pins is exposed.

Caution: Always use the electrodes with the requirements of the IEC/EN60601-1, ISO10993-1/-5/-10, and IEC/EN60601-1-2, such as with CE mark, or which are legally marketed in the US under 5IO(k) procedure.

6.3 Connect Lead wires to device:

1) Before proceeding to this step, be sure the device completely turns OFF.
2) The wires provided with the system insert into the jack sockets located on the top of the device.
3) Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.

4) This device has two output receptacles controlled by Channel 1 and Channel 2 at the top of the unit. You may choose to use one channel with one pair of lead wires or both channels with two pairs of lead wires. Using both channels gives the user the advantage of stimulating two different areas at the same time.

Caution: Do not insert the plug of the patient lead wire into any AC power supply socket.

6.4 TurnOn:

Before using the device for first time, you are strongly advised to take careful note of the counter indications and safety measures detailed at the beginning of this manual (Safety Information).

In order to turn on the device, keep the ⏻/M button pressed down until the operation page appears on the screen.

6.5 Select the Mode

There are 2 modes available Normal and Intensive. The mode can be selected by pressing the (MENU) button.

6.6 Steps to Set Program and Setup Parameters

6.6.1 Normal Mode

Step # 1 Mode Selection

Press the (MENU) button to set the stimulation mode according to the need of therapeutics which was recommended by your therapist. When the indicator for Normal Mode is glowing, press (ENTER) button to accept selected mode Normal Mode.

Step #2 Treatment Time Setup

The treatment time is adjustable from 1:45, 3:30, 5:15 & 7:00

hours in Normal Mode. Press the **UP** or **DOWN** buttons to adjust treatment time setting. Press **(ENTER)** button to accept selected value of treatment time.

The device is ready for treatment in Normal Mode.

6.6.2 Intensive Mode

Step # 1 Mode Selection

Press the **(MENU)** button to set the stimulation mode according to the need of therapeutics which was recommended by your therapist. When the indicator for Intensive Mode is glowing, press **(ENTER)** button to accept selected mode Intensive Mode.

Step #2 Sub-mode selection

There are 3 sub-modes in the Intensive mode available Normal (P1), Burst (P2) and Pulse Width Modulation (P3). The therapeutic mode can be selected by pressing the **UP** and **DOWN** buttons. Press **ENTER** button to accept selected sub mode.

Step #3 Treatment Time Setup

The treatment time is adjustable from 0:30, 1:00 hours and continuous operation (0:00) in Intensive Mode. Press the UP or **DOWN** buttons to adjust treatment time setting. Press **(ENTER)** button to accept selected value of treatment time.

Step #4 Treatment Time Setup

Pulse width is adjustable from 50 µS to 250 µS. Press **UP** and **DOWN** buttons to adjust the setting. Press **(ENTER)** button to accept selected value of pulse width.

The device is ready for treatment in Intensive Mode.

6. 7 MENU /BACK Button Function During Setup

When user presses MENU /BACK button during setup, device will return to previous setup screen.

6.8 Adjust Channel Intensity

When all parameters are set and device is in ready for treatment state, press ⏻ button to start the stimulation. Press **Ch1 + / Ch1- or CH2-/CH2+** buttons to control the intensity outputs on channel #1 and #2. Slowly press the intensity buttons until you reach the setting recommended by your physician or therapist. Repeat for the other channel, if both channels are to be used.

6. 9 Lock the keyboard

In working state, if there is no operation in the panel for 30 seconds, the keyboard will be locked automatically. You should press CH1- button and keep it pressed more than 2sec to unlock the keyboard.

6.10 Stop the Treatrment

When you have activated the treatment timer, you can press the ⏻ Button to pause treatment. Press (ON/OFF /START) button to continue the treatment. The treatment could be cancelled by pressing (MODE) button.

6.11 Turn OFF

Keep ⏻ for approx. 2 seconds to Turn OFF the device.

Caution: If there is no operation in the panel for 3 minutes in the ready for treatment state, the device will be turned off automatically.

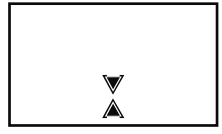
6.12 Reset to defaults

To reset the device to its default values, user must follow this

sequence:

- Turn off the device ifitis ON
- Press and hold **CH2**- (decrement) button
- Press and hold **ON/OFF** button until the device beeps to indicate it is ON, then release the **ON/OFF** button (please note that **CH2**- (decrement) button is still pressed). At this point, display should indicate that reset is about to happen with the following screen
- Hold **CH2**- (decrement) button until long beep is heard, then release the button.

Please note that reset will not be performed if **CH2**- (decrement) button is released before beep occurs. Once started, the reset procedure cannot be stopped except by powering off the device. This action will result with incomplete reset and undefined behavior of the device after next power up.



6.13 Patient Compliance Timer

When the system is in ready for treatment state, the user could check and reset C.T. value. To enter in C.T. View mode, press and hold **DOWN** button more than 2sec. The system will stay in C.T. view mode exact 5sec. After that, the system will return back in ready for treatment state.

When the system is in C.T. View state, the user could reset C.T. value. To reset C.T. value, press and hold **ENTER** button more than2sec.

6.14 Lock the protocol

To lock the protocol, user must follow this sequence:

- The device must be in ready for treatment state.
- Press and hold (CHl-) button
- Press and hold (CH2-) button
- Release(CHl-)button
- Release (CH2-) button
- The device will lock the current protocol and acknowledge the action with long buzzer beep.

6.15 Low Battery indicator

When the low battery indicator flashes, that indicates the device will turn off automatically soon, so the battery should be replaced with a new one as soon as possible. However, the unit may continue to operate for a few more hours depending on the setting and intensity level.

7.0 CLEANING AND PREVENTATIVE MAINTENANCE

7.1 JointStim Stimulator Device

Keep the unit intact at all times, do not detach the unit for cleaning purposes. Do not use liquids or chemicals for cleaning; a decontamination formula can be used. Make sure when cleaning you are not using the unit for therapy and it is turned off. Remove the battery from the device every time you clean. Clean the device after use with a soft, slight moistened cloth. In case of more extreme soiling you can also moisten the cloth with mild soapy water. When finished with the treatment turn the device off and store in a safe place at room temperature and out of reach of children.

7.2 Wraps and Conductive Patches

The JointStim stimulator wraps or patches are not to be placed in a washing machine. Never use bleach, fabric softener or other detergents. Detach the conductive patches from the neoprene brace and hand washes both with warm water. Let both air dry before placing the conductive patches back on the neoprene wrap.

8.0 TROUBLESHOOTING

If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the device should be serviced.

Problem	Possible Cause	Solution
Display fail to light up	Battery contact failure	I. Try tresh baatteries 2. Ensure battaries are inserted correctly Check the following contacts • All contacts are in place. • All contacts are not broken
Stimulation weak	Electrodes 1. Dried out or Contaminated 2. Placement Lead wires 1. Old/worn/damaged	Replace and re-connect Replace
Stimulation is uncomfortable	Intensity is too high Electrodes are too close together Damaged or worn electrodes or lead wires Electrode active area size is too small	Decrease intensity Reposition the electrodes. Replace Replace electrodes with ones that have an active area no less than 16.0 cm^2 (4cm*4xm)
Intermittent output	Lead wires Program option in use	1. Verify connection is secure. 2. Turn down the intensity. Rotate lead wires in socket 90. If still intermittent, replace lead wire. 3. If still intermittent after replacing lead wire, a component may have failed. Call the repair department, Some programs will seem intermittent. This is expected. Refer to the Program Option Controls in the Operation section for a description of the program option
Stimulation is ineffective	Improper electrode and applicator placement Unknown	Reposition electrode and applicator Contact clinician

9.0 STORAGE

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

10.0 DISPOSAL

Used fully discharged batteries must be disposed in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose batteries correctly. Please dispose

11. WARRANTY:

This product warranty extends to the original consumer/ purchaser of the product.

11.1 Warranty duration

JointStim stimulator device is covered with 1 year warranty for all mechanical defects.

11.2 Warranty coverage

This product is warranted against defective materials or workmanship. This warranty ceases if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, commercial use, and repair by unauthorized personnel. This warranty does not extend to any units which are used in violation furnished by manufacturer, or to units which have been altered or modified, or to damage to products or parts there of which have the serial number removed, altered or defaced or rendered illegible. The warranty doesn't cover normal wear & tear or replacement of electrode cables, electrodes and other accessories.

11.3 Warranty disclaimers

This warranty is in lieu of all warranties expressed or implied and no representative or person is authorized to assume for manufacturer/ any other liable in connection with the sale of our products. There shall be no claims for defects or failure of performance or product failure/ any theory of tort, contract or commercial law including, but not limited in negligence, gross negligence, and strict liability, breach of warranty and breach of contract. Some states do not allow the exclusion or limitation of

implied warranties or consequential damages, so the above limitations may not apply to you. Manufacturer is not responsible or liable for indirect special or consequential damages arising out of or in connection with the use performance of the product or other damage with respect to loss of property or loss revenues or profit.

11.4 Legal remedies

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

11.5 Warranty performance

During the above warranty period, a product with a defect will be repaired or replaced with a reconditioned comparable unit at distributor's option when the product is returned to the distributor. The repaired or replacement product will be in warranty for the balance of the warranty period and an additional one-month period. No charge will be made for such repair or replacement.

11.6 Consumer service

For in warranty service for a product covered under the warranty period, no charge is made for service and return postage. Please return the product insured, packed with sufficient protection, postage insurance, prepaid to the address. Customer's duty/brokerage fee, if any; must be paid by the consumer.

11. 7 Out of warranty service

There will be charges rendered for repairs made to the product after the expiration of the aforesaid one (1) year warranty period, after purchaser is advised appropriately. The

distributor cannot assume responsibility for loss or damage during shipment. For your protection, carefully pack the product for shipment and insure it with the carrier. Ensure that you return the unit and accessories related to your problem and also that you indicate full return address. Also send a copy of sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.