VISSCO JOHARI

ULTRASOUND

JUS1

Instruction Manual

Rx Only

ULTRASOUND
JUS1

INSTRUCTION MANUAL

R_x ONLY

PRESCRIPTION USE STATEMENT

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/she practices to use or order the use of the device.

PREFACE

This manual is intended as a guide for the operators of the JUS1 Ultrasound. It contains precautionary instructions, general instructions for operation and maintenance recommendations. In order to facilitate the proper operation of JUS1 Ultrasound and to obtain maximum efficiency and life from this unit, READ AND UNDERSTAND THIS MANUAL THOROUGHLY.

Be thoroughly acquainted with the operating procedures, as well as the indications, contraindications, warnings, and precautions before administering any treatment to a patient. Other resources must be referred for additional information regarding the application of therapeutic ultrasound.

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GLOSSARY

SYMBOLS:

The precautionary instructions found in this section and throughout the manual are indicated by specific symbols. It is important to understand these symbols and their definitions before operating this equipment:

"CAUTION" indicator describes possible safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.

"WARNING" indicator describes possible safety infractions that could have the potential to cause serious injury and equipment damage.

"DANGER" indicator describes possible safety infractions that are imminently hazardous situations that would result in death or serious injury.

"HIGH VOLTAGE" indicator describes possible safety infractions that could potentially cause serious injury or death due to high voltage or electric shock.

"NON-IONIZING RADIATION" indicator describes possible safety infractions that could cause serious injury and related health hazards by exposing user to non-ionizing radiation.

"EXPLOSION HAZARD" indicator describes possible safety infractions that could cause serious injury or death by triggering an explosion.

"MANDATORY TO READ INSTRUCTIONS" indicator describes instructions that should essentially be read and followed by the user to avoid injury and/or damage to equipment.

"NOTE" may be found throughout this manual. Notes are helpful information to assist in the particular area or function being described.

COMMON TERMS :

APPLICATOR : The ultrasonic energy is delivered to the patient using a hand held assembly called the applicator. The applicator consists of the sound head, the transducer or crystal and related electronics.

BARIUM TITANATE : This is the piezoelectric crystal used in JUS1 to create the ultrasound beam of 1 MHz by vibrating 1,000,000 (1 MHz) times per second. When an electric current is applied to these crystals, they change shape rapidly. The rapid shape changes or vibrations of the crystal produce ultrasound waves.

BEAM NON -UNIFORMITY RATIO (BNR): The nature of an ultrasound beam is changeable and varies with distance from the centre of the transducer. The US beam closest to the centre of the sound head is called the near field or interference field. The behaviour of the US in this field is very irregular with areas of significant interference. BNR is a quality indicator for US applicators and give an indication of this near field interference. Numerically, BNR is a ratio of the highest intensity found in the beam field to the average intensity as indicated on the output display of the unit. For most applicators, BNR is thought to be between 4 and 5.

COLLIMATED BEAM (Coll) : The shape of the ultrasound beam is collimated, i.e., cylindrical. It is neither focused nor dispersed and resembles a column. The beam waves travel parallel to each other and therefore it spreads minimally as it propagates.

CONTINUOUS MODE: During this mode, the ultrasound is transmitted continuously to the tissue without any interruption. This mode provides the maximal energy and is used when a maximal effect is desired.

COUPLING MEDIA : The coupling medium is an agent used to facilitate transmission of the ultrasound energy from the sound head to the tissues. Given an ideal circumstance, this transmission would be maximally effective with NO absorption of the ultrasound energy, nor any distortion of its path etc. The coupling media used in this context is aqueous gel.

DUTY CYCLE: A duty cycle represents the percentage of the "On" time to "Total" time for which ultrasound energy was applied to tissues. This is used to describe the pulsed modes of ultrasound. The lower the percentage, the lower temporal average intensity. 100% duty cycle represents continuous mode of ultrasound.

from the transducer surface. This measurement is used to calculate the ultrasound intensity in W/cm^2.

PULSE DURATION: Pulse Duration is defined as the time during which the ultrasound is being delivered in the pulsed mode. It is determined by the product of number of cycles and period of each cycle.

PULSE FREQUENCY : The pulse frequency is the number of pulses per second and is expressed in hertz.

PULSED MODE: When the output of the ultrasound is interrupted during treatment, i.e., the ultrasound beam is turned "ON" and "OFF" at fixed intervals, it is called Pulsed mode. For example, in the 20% duty cycle mode, the ultrasound is delivered for 2 msec and off for 8 msec throughout the treatment period.

PULSE RATIO: The pulse ratio determines the concentration of ultrasound energy on a time basis. The pulse ratio determines the proportion of time that the machine is ON compared with the OFF time during a treatment period.

SOUND HEAD: The component of the applicator which makes contact with the patient's skin is called the sound head. The aluminium face of the sound head encloses a transducer (a vibrating crystal) that converts electrical energy to mechanical energy.

ULTRASOUND INTENSITY: Ultrasound power delivered to the patient expressed in total power as watts (W) or in terms of the sound head's effective radiating area, watts per centimetre squared (W/cm^2).

1.0 SAFETY PRECAUTIONS

PLEASE READ THIS INSTRUCTION MANUAL CAREFULLY before using Ultrasound JUS1 because it is UNSAFE to use this device before reading the whole manual.

The instructions on the following pages will show you how to use and care for your JUS1 in a general manner. READ, UNDERSTAND AND PRACTICE THE PRECAUTIONARY AND OPERATING INSTRUCTIONS . You should be particularly familiar with the indications and contraindications before proceeding.

After carefully reviewing this instruction manual, if you have difficulty operating this unit, please CONTACT CUSTOMER SERVICE at toll free number 1 -800-102-8684 for assistance.

US Federal law restricts this device to sale by, or on order of, a physician or practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device. This device should be used only under the CONTINUED SUPERVISION of a physician or a licensed practitioner.

DO NOT use this equipment in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide. Failure to comply with this precaution may cause the risk of an explosion.

Patients with an implanted neuro-stimulation device MUST NOT BE TREATED WITH OR BE IN CLOSE PROXIMITY to any diathermy device. Ultrasound energy can be transferred through the implanted neuro-stimulation 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 neuro-stimulation system is turned "OFF."

DO NOT operate this unit in an environment where other devices are being used that intentionally radiates electromagnetic energy in an unshielded manner.

This system is not designed to prevent the ingress of water or liquids. DO NOT allow water or liquids to enter the internal components of the device as water could cause their malfunction and create a risk of fire or damage to device and injury to patient.

DO NOT operate this device, perform procedures or make adjustments other than those specified in this manual to avoid hazardous exposure to ultrasonic energy.

DO NOT operate this device during lightning, thunderstorms or a condition that could have an adverse effect on continuity of power flow. Use a commercially available surge suppressor if power problems are encountered.

1.3.1 CAUTIONS

- DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel as damage may result.
- DO NOT disassemble, modify, or remodel this unit or accessories. This may cause unit damage, malfunction, electrical shock, fire, or personal injury.
- There are no user-serviceable parts inside this unit. If a malfunction occurs, DISCONTINUE USE immediately and contact the dealer or customer service (toll free number 1-800-102-8684) for repair.
- This device MUST be operated in temperatures between 50°F to 104°F (10°C to 40°C), and transported and stored in temperatures between 40 to 114°F (5 to 45°C), with relative humidity ranging from 30% to 60%.
- DO NOT permit any foreign materials including, but not limited to, inflammables, water, and metallic objects to enter this device. These may cause damage to device, malfunction of internal components of the system, electrical shock or fire and therefore create a risk of injury to the patient.
- DO NOT operate this unit in an environment of short-wave diathermy use.
- DO NOT operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile radio-frequency communications equipment can adversely affect functioning of Medical Electrical Equipment.
- HANDLE the applicator WITH CARE. Inappropriate handling of the applicator may adversely affect its characteristics and functioning.
- Failure to use and maintain this unit and its accessories in accordance with the instructions outlined in this manual will INVALIDATE YOUR WARRANTY.

1.3.2 WARNINGS

- KEEP THIS DEVICE OUT OF REACH OF CHILDREN.
- Always keep the sound head in CONSTANT MOTION.
- Always keep the sound head in FULL CONTACT with the patient's skin.
- Use ample conductive gel to ensure GOOD COUPLING throughout the treatment. If needed, apply when setting intensity.
- DO NOT drop the applicator on hard surfaces.

- DO NOT cool an overheated sound head with ice water or ice packs.
- DO NOT allow the sound head to reach maximum temperatures repeatedly.
- DO NOT use the controls or adjustments or procedures in a way other than those specified herein. This may result in hazardous exposure to ultrasonic energy.
- Make certain that the DEVICE IS ELECTRICALLY GROUNDED by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.

All of the above conditions are likely to damage the sound head transducer/ crystal. Damage resulting fro m these conditions is not covered under the warranty.

1.3.3 ADDITIONAL PRECAUTIONS

Additional precaution should be used when the ultrasound is used with the following conditions:

- LAMINECTOMY: Over an area of the spinal cord following a laminectomy, i.e., when major covering tissues have been removed.

- LOCAL ANAESTHESIA: Over anaesthetic or desensitized areas.

- HAEMORRHAGE : On patients with haemorrhagic diatheses.

- EPIPHYSES: Over or near epiphyses, i.e., growth centers of long bones in children until bone growth is complete.

- SUBCUTANEOUS BONY PROMINENCES: On areas having small treatment parts and bony prominences with little soft tissue coverage.

1.3.4 POTENTIAL FOR BURNS

It is possible for ultrasound therapy to cause burns if the therapy is not administered properly. Burns can occur in following conditions:

- HIGH INTENSITY: Using very high Intensity (power).

- VERY LOW FREQUENCY: Using very low frequency.

- STATIONARY: Holding the sound head in one place.

- SLOW -MOVEMENT : Moving sound head very slowly.

- DESENSITIZED AREA: Treating an area with sensory nerve damage or an area with loss of normal skin sensations. Desensitized areas can overheat or burn without patient's knowledge. Extreme caution should be exercised with patients having diabetic neuropathy or any other form of neural damage.

- BONY PROMINENCES: Treating an area with small joints and bony prominences with little soft tissue coverage. Periosteum of bones reflect ultrasound waves leading to standing waves and causing burning sensation in the bony area.

- METALLIC IMPLANTS: Treating an area having a metal implant. Due to the tendency of metal to have higher heat conductivity than human tissue, metal implants heat up quickly increasing the risk of burns. Hence ultrasound therapy should never be used directly over metal implants.

- IMPLANTED NEURO -STIMULATION DEVICE: Patients with an implanted neuro-stimulation device MUST NOT BE TREATED WITH OR BE IN CLOSE PROXIMITY to any therapeutic ultrasound anywhere on their body. Ultrasound energy can be transferred through the implanted neuro-stimulation system, can cause tissue damage and can result in severe injury or death. Injury, damage or death can occur during ultrasound therapy even if the implanted neuro-stimulation system is turned "OFF."

1.3.5 PREVENTING ADVERSE EFFECTS

- PATIENT SUSCEPTIBILITY : Some patients are more sensitive to ultrasound output and may experience a reaction similar to a heat rash. Be sure to inspect the treatment area during and following treatment, and discontinue if an adverse reaction does occur.

- SOUND HEAD : If movement of the sound head is too slow, the patient may feel periosteal pain characterized by a deep ache or pain. If motion is too fast, the therapeutic effect of sound waves will be reduced and sound head may overheat.

COUPLING : Coupling is described as contact between the sound head and treatment site and may be accomplished through the use of a coupling agent, such as gel or lotion. For direct coupling, you may need to apply more conductive gel or lotion during the treatment to achieve better coupling. You can also reduce the power or duty cycle during the treatment if you are treating an area where it is difficult to obtain good coupling.

2.0 INTRODUCTION TO ULTRASOUND THERAPY

2.1 PRODUCT DESCRIPTION

JUS1 is a second generation microcomputer controlled desktop device which delivers continuous and pulsed Ultrasound Therapy of 1 MHz through a unique ultrasound applicator for professional use. This ABS constructed device can be easily carried around the clinic and has a special stand to fix the applicator when not in use. The membrane key panel, LED display and indicators on the device allow easy touch control of treatment and give the device an attractive appearance. The embedded software cannot be altered except by a trained engineer and no attempt should be made to do so.

2.2 INTENDED USE

JUS1 Ultrasound device is intended to be used for applying therapeutic deep heat within body tissues for:

- Relief of pain
- Muscle spasms
- Joint contractures

2.3 WHAT IS THERAPEUTIC ULTRASOUND

Therapeutic Ultrasound is a treatment modality utilizing sound waves to treat pain, inflammation, muscle spasm and joint contractures. Ultrasound therapy has been used by physical therapists since the mid-19th century.

Therapeutic ultrasound is a unique form of penetrative energy. Ultrasound energy is not electrical, although electricity is used in its generation; it is not chemical energy, although it will accelerate chemical reactions; it is not radiation energy like x-ray or ultraviolet, for it will not penetrate a vacuum; and it is not thermal energy, although absorption of ultrasound in tissue produces heating.

Ultrasound is a mechanical energy. It is a form of sound with a frequency beyond the maximum that can be detected by the human ear, i.e., above 20 kHz. These waves are not different from "normal" sound in their physical properties, except that they have higher frequencies. The frequencies used in therapy are typically between 1.0 MHz and 3.0 MHz (1MHz = 1 million cycles per second).

2.4 HOW THERAPEUTIC ULTRASOUND WORKS

Ultrasound waves are transmitted through soft tissues like nerve, muscle and connective tissues with the help of a sound head or applicator crystal. This sound head must be constantly kept in motion to avoid undesirable effects. Therapeutically, ultrasound has the following effects:

1. DEEP THERMAL EFFECTS : It is most prominently seen in dense collagenous tissues and requires relatively high intensity waves in continuous mode to achieve this effect. Thermal effects cause increased blood flow to the localised area, increased tissue extensibility and helps to reduce local swelling and chronic inflammation. Increased blood flow delivers the necessary oxygen and nutrients and removes cell wastes.

2. NON-THERMAL EFFECTS (CAVI TATION & ACOUSTIC STREAMING): Ultrasound introduces energy into the body. This energy causes microscopic gas bubbles around the tissues to expand and contract rapidly, a process called cavitation. It is theorized that the expansion and contraction of these bubbles help speed cellular processes and improves healing of injured tissues.

   Introducing ultrasound energy also causes acoustic streaming, which is described as small scale eddying of fluids near cell membranes and surface of stable cavitation gas bubbles. This phenomenon is known to affect diffusion rates and membrane permeability. Sodium ion permeability is altered resulting in changes in the cell membrane potential. Calcium ion transport is modified which in turn leads to an alteration in the enzyme control mechanisms of various metabolic processes, especially concerning protein synthesis & cellular secretions.

   The result of the combined effects of stable cavitation and acoustic streaming is that the cell membrane becomes 'excited' (up-regulates), thus increasing the activity levels of the whole cell. The ultrasound waves act as a trigger for this process, but it is the increased cellular activity which is in effect responsible for the therapeutic benefits of the modality.

2.5 INDICATIONS OF USE

Application of therapeutic deep heat for the following:

1. RELIEF OF PAIN, SWELLING, MUSCLE SPASMS AND JOINT CONTRACTURES that may be associated with but not limited to the following conditions:
   - Inflammatory Conditions like:
     - Capsulitis
     - Bursitis
     - Myositis
     - Myofascitis
     - Tendinitis
     - Osteoarthritis
     - Periarthritis
     - Fibrositis
     - Sciatic Neuralgia
     - Brachial Neuralgia
   - Oedema
   - Adhesion and Scar formation
   - Sprains, strains and Herniation
   - Compression neuropathies
   - Painful neuromas of the stump after amputation

2. HEALING OF WOUNDS associated with but not restricted to following types of lesions:
   - Venous leg ulcers
   - Vascular ulcers
   - Neuropathic ulcers
   - Burns
   - Surgical wounds

2.6 CONTRAINDICATIONS OF USE

1. UNDIAGNOSED PAIN: This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
2. NEOPLASTIC GROW TH: This device should not be used when cancerous lesions are present in the treatment area.
3. SKIN LESIONS: This device should not be used when open wounds or skin lesions are present in the treatment area.
4. INFECTIONS: 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.
5. EPIPHYSES : This device should not be used over or near epiphyseal plates, i.e., bone growth centers in children until bone growth is complete.
6. FRACTURE: This device should not be used over a healing fracture.
7. HEART: This device should not be used over the thoracic area, especially if the patient is using a cardiac pacemaker.
8. EYE: This device should not be used over or applied to the eye since ultrasound waves may cause damage to the retina or lens.
9. PREGNANCY: This device should not be used over a pregnant uterus as effect of therapeutic ultrasound on a developing human foetus has not been fully explored.
10. ISCHAEMIA: 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.
11. BLEEDING DISORDERS: This device should not be used in individuals with bleeding disorders.
12. DESENSITIZED AREA : This device should not be used in areas with decreased temperature sensation. If your injury prevents you from feeling normal hot and cold temperatures, ultrasound should not be used since you would not be able to report any discomfort or burning sensations to your physical therapist.
13. REPRODUCTIVE ORGANS: This devices should not be used over or near reproductive organs as there effect on these organs is unknown.
14. JOINT REPLACEMENT: This device should not be used over body parts with total joint replacements. Many total joint replacements use special cement to hold the new joint in place, and ultrasound may rapidly heat this cement and damage surrounding body parts.

3.0 PACKAGE COMPONENTS

Remove the equipment and all accessories from shipping carton. Visually check if any parts or accessories are missing or if there is any damage to any parts. For any complaints, please contact the dealer or customer service (1-800-102-8684).

All package components must be unpacked cautiously. The package contains sophisticated medical equipment which should be handled carefully. All packaging should be retained to be used in case you need to return the equipment/equipment parts for repair or replacement.

3.1 STANDARD ACCESSORIES

The equipment contains the following standard accessories:

SR. NO.	NAME OF COMPONENT	QTY
1	JUS1 Ultrasound Generator	1
2	Ultrasound Applicator with Sound Head of 5 cm^2	1
3	Adapter with AC Cord	1
4	Seaweed Natural Conductive Gel - 100 ml bottle	1
5	Instruction Manual	1
6	UltraSound Applicator Stand	1

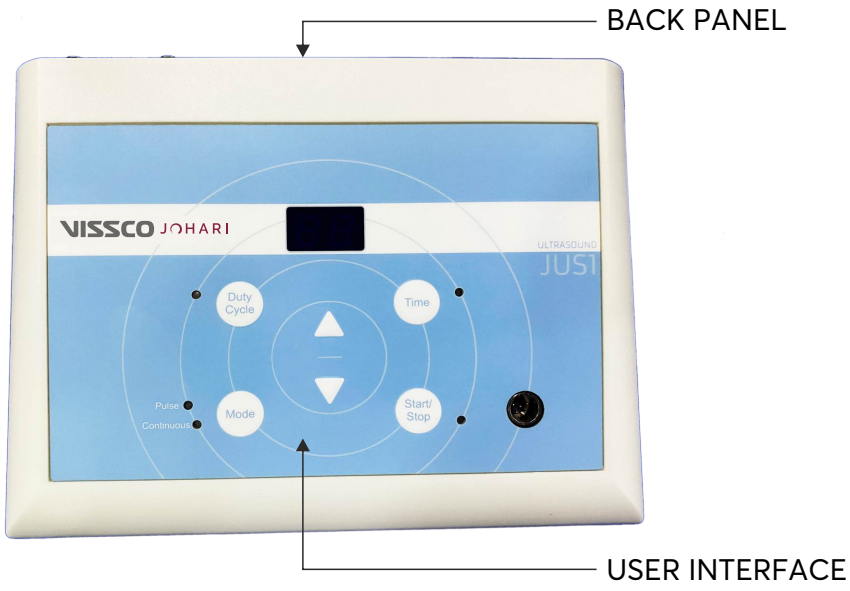
3.2 OPTIONAL ACCESSORIES

The following optional accessories can be purchased as per requirement at additional cost from the manufacturer. The user must use accessories that are manufactured by Johari Digital Healthcare Ltd (JDHL). Damage to device or accessories resulting from using products not manufactured by JDHL voids the warranty.

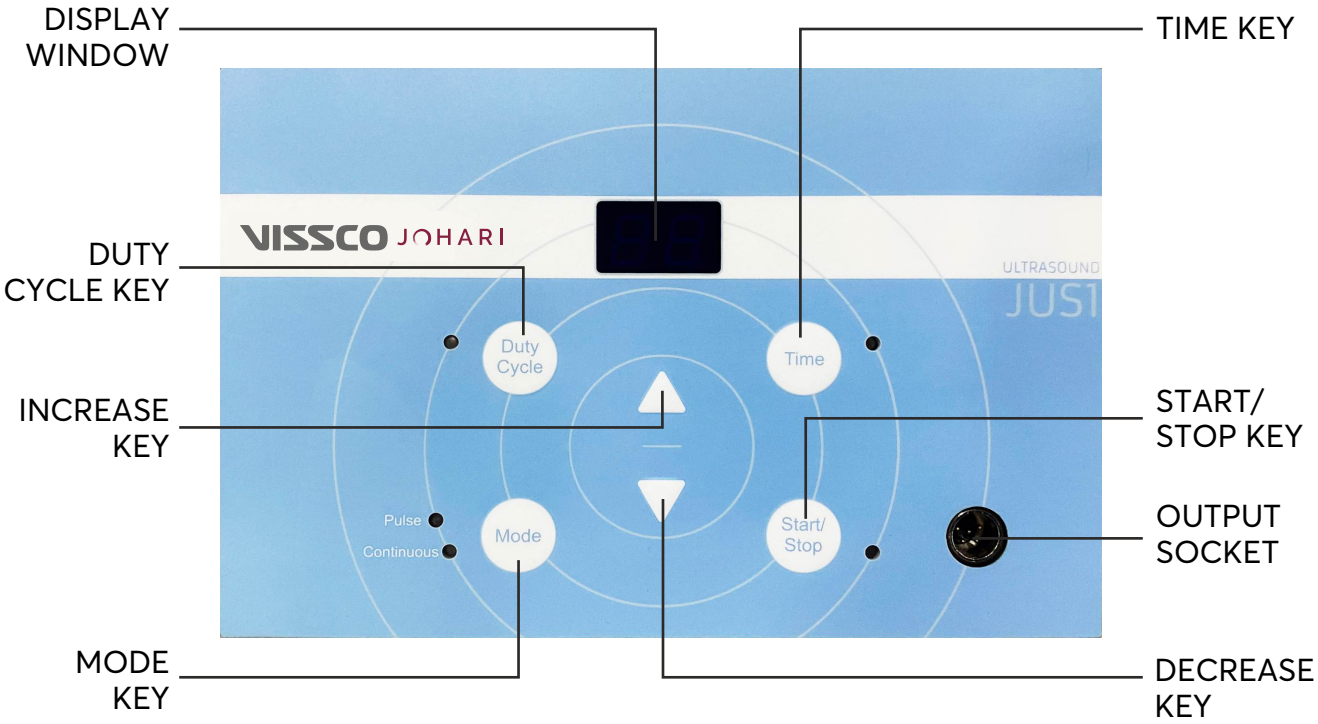
SR. NO.	NAME OF COMPONENT	QTY
1	JUS1 Ultrasound Carrying Bag	1
2	Seaweed Natural conductive gel - 100 ml bottle	1

4.0 IDENTIFICATION AND DESCRIPTION OF PARTS

4.1 ULTRASOUND GENERATOR



4.1.1 CONTROLS AND FUNCTIONS



OUTPUT SOCKET: This socket is used to attach the ultrasound applicator to the JUS1 Device.

START/STOP KEY: This key is used to start or stop the device.

TIME KEY: This key is used to select the desired treatment time (selectable from 1 to 60 minutes).

DISPLAY WINDOW : This window displays either the treatment time, % Duty Cycle or power intensity.

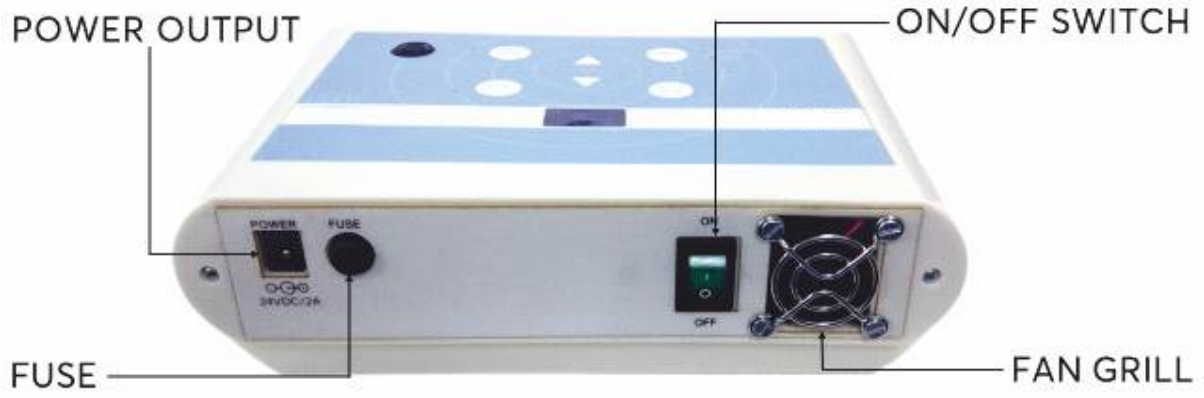
DUTY CYCLE KEY: This key is used during Pulsed Mode to select the desired duty cycle. The available options are 10%, 20% and 50%.

INCREASE KEY: (▲) To increase the value of the parameter which is selected, i.e., either the Mode, Time or Power Intensity.

DECREASE KEY: (▼) To decrease the value of the parameter which is selected, i.e., either the Mode, Time or Power Intensity.

MODE KEY: This key is used to select either "Continuous Mode" or "Pulsed Mode."

4.1.2 BACK PANEL



POWER OUTPUT : This output is used to attach the AC cord to the JUS1 generator.

"ON/OFF" SWITCH: This switch is used to turn the power supply "ON" or "OFF".

FUSE: This is a safety device with a fuse rating of 4A - Slow Blow. It breaks the electric circuit if the current in the device exceeds 4A.

FAN GRILL: It provides an outlet to air circulated through a fan inside the JUS1 generator.

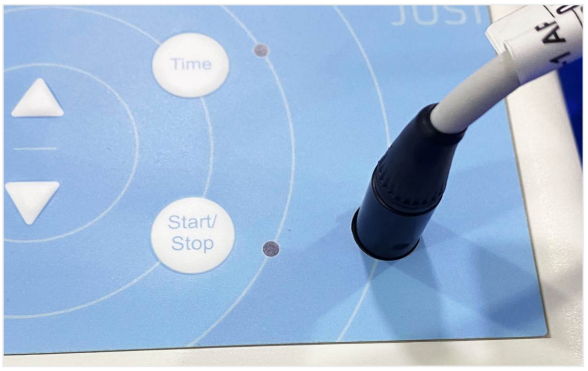
4.2 ULTRASOUND APPLICATOR WITH STAND

SOUND HEAD: This is the component which makes contact with the patient's skin. The aluminium face of the sound head encloses a transducer (a piezoelectric crystal) that converts electrical energy to mechanical energy.

APPLICATOR: This is the assembly which incorporates the sound head and connects to the JUS1 device.

4.2.1 HOW TO ASSEMBLE APPLICATOR BEFORE USE

Connect applicator output socket as shown in picture.



5.0 PRODUCT SPECIFICATIONS

5.1 DEVICE SPECIFICATIONS

5.1.1 DIMENSIONS OF ULTRASOUND GENERATOR

Length (Left to right)	20 cm
Width (front to back):	15.55 cm
Height (front): H1:	4.1 cm
Height (back): H2:	6.2 cm

5.1.2 DIMENSIONS OF APPLICATOR

Length of Applicator:	21 mm
Applicator Head Area:	5 cm^2

5.1.3 WEIGHT

Standard Weight of Generator :	460 g
Standard Weight of Applicator :	160 g

5.2 TEC HNICAL SPECIFICATIONS

5.2.1 POWER SPECIFICATIONS

Power In put:	100 - 240 VAC ~, 50/60 Hz 1.3A Max
Power Output:	24 V, 2.5 A
AC/DC Power Adapter :	24V DC/2.5A
Electrical Class:	CLASS II
Electrical Type:	TYPE B

5.2.2 ULTRASOUND GENERATOR SPECIFICATIONS

Treatment Time:	Selectable: 1-60 Minutes in steps of 1 min
Frequency:	1 MHz ± 10%
Modes:	Continuous
	Pulsed: 10%, 20% and %50% Duty Cycles
Modulation:	100%
Modulation Waveform:	Rectangular
Modulation Frequency:	48 Hz ± 5%
Temporal Peak/Average Intensity Ratio:	10:1, 5:1, 2:1 ± 5%
Maximum Output Power:	Continuous: 12.5W with 5cm^2 applicator
	Pulsed: 15W with 5cm^2 applicator
Maximum Intensity:	2.5 W/cm^2
Amplitude:	Continuous: 0 to 2.5 W/cm^2
	Pulsed: 0 to 3 W/cm^2
Contact Indication :	Yes

5.2.2 ULTRASOUND APPLICA TOR HEAD SPECIFICATION

Piezoelectric Crystal:	Barium Titanate disc with a specially coated face
Frequency:	1 MHz
Maximum Effective Ratio:	2:1
Beam Type:	Collimated (Cylindrical)

6.0 SETUP AND OPERATION

6.1 PATIENT PREPARATION

It is important to properly prepare the patient's skin for ultrasound therapy to ensure that most of the ultrasound energy reaches the targeted areas and the risk of skin irritation is reduced. Since every person's tolerance to heat is different, the ultrasound intensity should be adjusted accordingly.

The following steps must be followed to prepare the patient's skin for ultrasound therapy:

1. The treatment area of the skin where the applicator sound head needs to be placed must be washed with mild soap and water.

2. After washing, the skin must be dried thoroughly.

3. Generous amount of conductive ultrasound gel must be applied to treatment area on the patient as well as on the applicator sound head.

The patient should not feel any heat during treatment. If the patient reports that the transducer feels hot on the skin surface, it is likely that the coupling medium is inadequate.

If the patient reports a deep aching sensation during the treatment, stop immediately. Periosteal burns may feel like a deep ache while the ultrasound is still on, and only later in the day will feel intensely painful.

6.2 OPERATING STEPS

The User Interface on JUS1 Ultrasound Generator consists of a Membrane Keyboard, LED Display and LED indicators. The operator is able to view parameter options on the display and make selections and adjustments by pressing the membrane keys on the user interface. The Display window will provide continuous information during the treatments concerning power and elapsed time.

The following steps sh ould be followed for giving ultrasound therapy:

1. CONNECT THE POWER SUPPLY AND APPLICATOR: Connect the power adapter to the output socket on the back panel of the device. Connect the power adapter to a wall socket. Connect the applicator pin to the output socket on the front of the device.

2. SWITCH "ON" DEVICE: Switch "ON" the device, using ON/OFF switch on the back panel of the device. The unit will go through self-diagnostics and start showing "---" on the Display window. LED of continuous mode will glow and a single tone audible sound will be heard when any keys are pressed.

1. SELECT THE MODE OF TREATMENT: Press Mode Key to select the mode.

A. If Pulsed Mode is selected, choose the Duty Cycle by following the steps as below:

i. Press DUTY CYCLE key. Time LED will start flashing and display will show "10"

ii. Use "▲" or "▼" key to select desired % duty cycle (selectable from 10%, 20% and %50%).

iii. Press "DUTY CYCLE" key again to confirm. Now DUTY CYCLE LED will go off and display will show "----"

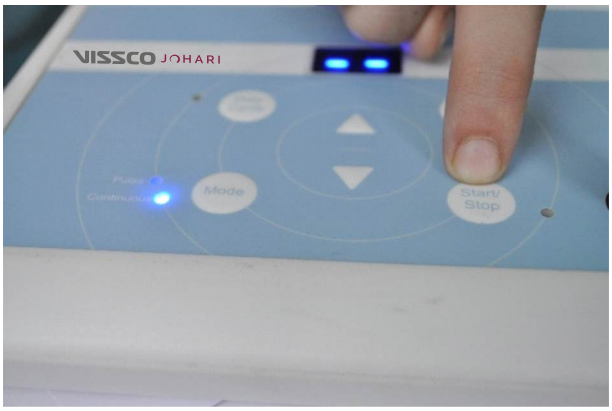
B. If CONTINUOUS MODE is selected, skip the points of step 3 and go directly to step 4.

4. SELECT THE TIME/ DURATION OF TREATMENT:

i. Press TIME key.
Time LED will start flashing and display will show "10"

ii. Use "▲" or "▼" key to select desired treatment time.

iii. Press "TIME" key again to confirm. Time LED will go off and display will show "----"



5. START THE TREATMENT
Press "START/STOP" key. Time LED will go off and display will show "0.0"

4. INCREASE OR DECREASE POWER INTENSITY:

After starting the treatment, use "▲" or "▼" key to increase or decrease power intensity (selectable from 0.1 to 2.5 W/cm^2 in Pulsed Mode)

5. SWITCHING OFF AND DISCONNECT POWER ADAPTER: Switch off the device by switching "OFF" the ON/OFF switch. Pull out the power adapter from the wall socket. Pull out the power adapter from device.

6.3 POST-TREATMENT PROCEDURES

- Immediately after treatment, the ultrasound head should be wiped off and returned to its stand.
- Next, the coupling medium should be wiped off the patient.
- The intensity level should be turned back to zero, so the intensity is not "ON" when the machine is turned "ON" for the next treatment.
- The patient should be questioned for any sensations they felt during or after the treatment and the response written in patient's file.

7.3 SYSTEM UTILITIES

7.3.1 AUDIBLE TONES

JUS1 device produces certain audible tones under certain conditions.

1. One short beep: Any button is pressed.
2. Two long beeps: On all warnings and info messages.
3. Three short beeps: To inform user that some request cannot be accepted.
4. Four long beeps: On all errors; whenever any error message is displayed.
5. One very long beep (approx. 4sec): At the end of treatment.

7.0 TROUBLESHOOTING

The JUS1 Ultrasound is equipped with internal diagnostics designed to facilitate troubleshooting. Hence the user must refer to this section for any issues associated with the device before contacting customer service.

7.1 NO DISPLAY

After turning "ON" Main Power, if no display is seen, check for the following:

1. AC cord securely connected to line supply.
2. AC cord securely connected to JUS1 Ultrasound.
3. Line fuses in power inlet module.
4. Main power supply.

If any of the above issues are detected, take corrective steps. If problem persists, contact JDHL customer service.

7.2 ERRORS, WARNINGS OR MESSAGES

The JUS1 Ultrasound system informs the user about all potential issues and/or detected issues by displaying Errors, Warnings or Messages.

- An Error indicates the problem in system which can be critical for patient safety or regular functionality of device.
- A Warning indicates some problems in system that are not critical for patient safety or regular functionality of device.
- Messages provide more information to user about the limits and behaviours of the device.

Refer the following table for details about error codes that may appear on the "Display Window" of the JUS1, their cause and the required action.

ERROR CODES	PROBLEM DESCRIPTION	ACTION
E1, E2, E3	Problem with power supply	Use power adapter manufactured by JDHL. If still problem persists, contact JDHL customer service.
E4	Problem with temperature control	Contact JDHL customer service.
E5	Problem with temperature control	Allow the device to cool for some time and restart the device. If problem persists, contact JDHL customer service.

E6, E7	Problem with Power supply unit or current	Contact JDHL customer service.
E8, E9	Undefined technical problem	Contact JDHL customer service.
EA	Error in communication with applicator	Ensure applicator is plugged in and restart. If problem persists, contact JDHL customer service.
EB	Applicator is not supported by this device	Use applicator that comes with the device.
EC	Applicator needs recalibration	Contact JDHL Customer service.
ED	Problem with applicator sound head crystal.	Contact JDHL Customer service.
EE	Faulty temperature sensor	Contact JDHL Customer service.
EF	Problem with temperature control	Contact JDHL Customer service.

8.0 MAINTENANCE AND SERVICE

8.1 USE AND CARE

8.1.1 USE AND CARE OF ULTRASOUND GENERATOR

1. SWITCH OFF THE JUS1 DEVICE, when not in use for several hours and especially at the end of the day, using the switch on the back panel.
2. DO NOT PULL THE AC CORD to unplug JUS1 adapter from socket. This will eventually damage the AC cord.

3. This device is NOT designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction of its internal components and create a risk of fire or damage and injury to patient.

8.1.2 USE AND CARE OF ULTRASOUND APPLICATOR

1. Inspect the applicator regularly for cracks, which could allow the ingress of conductive fluid.
2. Inspect the applicator regularly for a build-up of dried conductive fluid.
3. Clean the applicator after every use.
4. NEVER turn up the ultrasound intensity before the soundhead is coated with ultrasound gel that will conduct the soundwaves. When the intensity is turned up without applying the ultrasound gel, the soundwaves bounce back into the crystal, (ultrasound is not transmitted easily through air) heating the applicator head and adversely affecting its calibration. If the applicator operates when exposed only to air, the applicator will become hot. Under severe misuse conditions, the applicator can inflict burns.
5. ALWAYS unplug the applicator when not in use.
6. If the soundhead is dropped, the manufacturer or service provider should be contacted to determine if the crystal has been damaged, possibly changing its output and creating a risk of fire or damage to device and injury to patient.

8.2 CLEANING AND DISINFECTION

8.2.1 GENERAL CLEANING AND DISINFECTION

The JUS1 Ultrasound System MUST always be kept clean and free from dust or dirt. Presence of these can affect or damage the function of the device or its accessories. Collection of dust or dirt can cause growth of bacteria on surface and result in cross contamination.

CLEAN: Cleaning is the removal of foreign material from the surface of objects. It does not kill bacteria and other microbes present on surfaces. However, without thorough cleaning, disinfection and sterilization are ineffective.

DISINFECT: Disinfection is the destruction and elimination of most bacteria and other microbes from objects or substances to an extent where it is unlikely to contaminate intact skin or other materials. But, it does not kill all the microbes.

STERILIZE: Sterilization destroys all microorganisms from objects or substances with only one viable organism in every 100,000,000 ($1:10^{-8}$).

> It is not possible to sterilize JUS1 Ultrasound System without causing severe and irreversible damage to the unit. The ultrasound applicators are not required to be sterilized as they are intended for use on intact skin only. It is appropriate to periodically disinfect them.

8.2.2 STEPS FOR CLEANING AND DISINFECTION

The following steps must be followed while cleaning the JUS1 device and accessories:

1. Switch off the apparatus and unplug the power plug from the power outlet before cleaning it in order to prevent an electrical shock.
2. Clean the JUS1 generator and applicator by using a soft, clean cloth dampened with water and/or a mild cleaning solution. Avoid the use of abrasive wiping materials and acidic or corrosive cleaning solutions.
3. For DISINFECTING the device and accessories, use a soft cloth moistened with an antimicrobial cleaner.
4. Alcohol may be used to DISINFECT the aluminium surface, but avoid using alcohol over the plastic parts.
5. Wait until the unit is completely dry before operating it again.
6. DO NOT spray cleaning solutions near or over ventilation openings. Use a lint-free cloth and spray the cleaning fluid onto the cloth. Do not soak the cloth with liquid otherwise fluid may enter through ventilation openings or joints on the unit, e.g. the connecting sockets of the electrode cables, etc. This could permanently damage the device modules.

7. DO NOT submerge or wash the device in liquids. Should the device accidentally become submerged, contact the dealer or Authorized Service Centre or customer service (1-800-102-8684) 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 centre.

8.3 STORAGE

1. Keep the unit covered when not in use. This will help to keep out dust.
2. Store the equipment and its accessories in a clean and dry place, away from direct sunlight, source of heat like radiators, any form of moisture or humidity, excessive dust, vibrations and shocks.
3. KEEP THIS UNIT OUT OF REACH OF CHILDREN .

8.4 MAINTENANCE

8.4.1 ROUTINE MAINTENANCE

At least once a week or month, the following items should be checked by user to ensure proper operation of JUS1 Ultrasound device:

1. JUS1 GENERATOR: Check the JUS1 device for any dust, dirt or spills. In case of spills, wipe off the liquid immediately. Ingress of liquids into the device may cause damage, which are not covered under warranty.
2. SOUND HEAD SURFACE : Check for surface 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 sound head. We recommend cleaning the head and cable after every use or daily. The sound head can be periodically cleaned and disinfected using a clean cloth moistened with 70% alcohol.
3. POWER CORD AND APPLICATOR CABLE: Check to make sure the AC cord as well as the applicator cable does not have nicks, frays, kinks, cuts or abrasions to the insulation. If metallic wires are visible through the outer sheath, the AC cord or applicator cable has been compromised and requires replacement.
4. AIR VENT: Inspect air vent at the back of the device to ensure that it is not blocked.
5. POWER SUPPLY: Turn ON the device and switch it OFF to check if it cuts off the power.

8.4.2 ANNUAL MAINTENANCE

We recommend that annual maintenance checks should be performed to:

1. Check and examine the JUS1 device and its applicator.
2. Check applicator wire and connector.
3. Check output voltage and current.

If the equipment is out of calibration or any other fault is observed, the device and/or applicator should be returned to the factory.

8.5 SERVICE

8.5.1 USER

There are no user replaceable parts in the JUS1 device or accessories and the user must not attempt to repair or replace any parts. Opening and exposing the internal machinery of JUS1 device or any accessories voids all warranties.

8.5.2 MANUFACTURER

It is recommended that all Johari Digital Healthcare Ltd. (JDHL) products be returned to the factory or an Authorized Service Dealer for recalibration, repair or replacement. Should the JUS1 unit require service, contact JDHL Customer Service Department (1-800-102-8684) or the Authorized Dealer.

All units returned to the factory for service must include the following for warranty repair as well as out-of-warranty repair:

1. Written statement containing the following information:
   - Complaint Number - Obtain from Customer Service Department
   - Unit Model Number
   - Unit Serial Number
   - Contact person with Phone and Fax Numbers
   - Billing Address (for Out of Warranty Repair)
   - Shipping Address (Where to Ship Unit after Repair)
   - Detailed Description of Problem or Symptoms

2. Copy of original invoice issued during purchase of the unit.

3. Ship unit to Factory in the original container with all accessories and information as required in item one above to:

   JOHARI DIGITAL HEALTHCARE LTD.
   G-582-584, EPIP,
   BORANADA, JODHPUR 342001
   RAJASTHAN INDIA

Service to these units should be performed only by Service Technicians authorized by JDHL. The JUS1 Service Manual is available for use by certified technicians. The Service Manual contains safety precautions, nomenclature, specifications, troubleshooting, removal and replacement instructions, general maintenance, calibration instructions, parts lists, schematics, warranty and other information which would assist a certified service technician to repair the unit.

9.0 WARRANTY

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

WARRANTY PERIOD

The product is warranted to the original consumer for a period of one (1) year from the original date of purchase.

WARRANTY COVERAGE

This product is warranted to be free from defects in materials and workmanship for a period of one (1) year. This warranty ceases if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, repair by unauthorized personnel or any other cause not arising out of defect in materials or workmanship. This warranty does not extend to any units which are used in violation of the guidelines set forth in this manual, or to units which have been altered or modified, or to damage to products or parts which have had the serial number removed, altered, defaced or rendered illegible.

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.

LEGAL REMEDIES

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

WARRANTY PERFORMANCE

During the above one (1) year 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 replaced product will be in warranty for the balance of the one (1) year warranty period and an

additional one (1) month period. No charge will be made for such a repair or replacement.

CUSTOMER 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.

OUT OF WARRANTY SERVICE

There will be charges rendered for repairs made to the product after the expiration of the 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.

Model…… S. No……
Date……
Dealer's Name……
Address……
……
Customer's Name……
Address……
……

Dealer's Signature Customer's Signature

Please send above warranty information and in the case if replacement of any accessory is needed to following address:

JOHARI DIGITAL HEALTHCARE LTD.
G-582-584, EPIP, BORANADA, JODHPUR 342001 RAJ. INDIA
Tel: 1-800-102-8684 | Email: info@joharidigital.com | www.joharidigital.com

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