

OmniSWD[®]

Shortwave Diathermy System User Manual

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OmniSWD[®]

ACP manufactures a premier line of rehabilitation technologies to assist health care professionals with improved outcomes and quality-of-life for Patients. The ACP product line includes Pain Control Systems, Muscle Stimulators, Interferential Therapy, Therapeutic Ultrasound, Pulsed Shortwave Diathermy devices, and advanced Therapeutic Exercise Systems. Our OMNISWD[®], MEGAPULSE[®], OMNIVERSA[®], NEUROPROBE, OMNISTIM[®], OMNISOUND[®], OMNICYCLE[®], OMNISTAND[®], OMNIVR[®], and SYNCHRONY DYSPHAGIA SOLUTIONS by ACP[®] represent the most recent worldwide advances available for therapeutic application of electromedical devices and other rehabilitation technology.

ACP is internationally recognized for its contribution to research in the development of medical applications for therapeutic rehabilitation. The Company sponsors and conducts research at leading health care institutions and major universities throughout the world.

SYMBOLS ON THE PRODUCT

Symbol	Used for	Symbol	Used for
SN	Serial number	Ϊ	Type BF medical device per: IEC 60601
	Date of manufacture		Manufacturer
\triangle	Caution, consult accompanying documents	Ŕ	Caution, electrical precautions
IP2X	Classification against water intrusion	CE ₀₁₂₀	CE mark of confidence compliant to MDD (93/42/EEC)
	Proper disposal required. Do not dispose of with regular household waste. Follow state and/or local regulations.	\sim	Alternating current device.
	Observe the user manual	Ĩ	Consult instructions for use
Ť	Protect the product from humidity		ON / OFF push button
(((,,)))	RF Emitting Device	\mathbf{R}_{only}	Rx Only
Consult INSTRUCTIONS Consult tuning instructions before adjustment	Consult Tuning Instructions		

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CTIVE EQUIPMENT
CTIVE EQUIPMENT

DIATHERMY INDICATIONS & CONTRAINDICATIONS

CAUTION: Federal law restricts this device for sale or use by, or on the order of, a Practitioner licensed by the laws of the state in which he/she practices to use or order the use of the device.

Please notice that Accelerated Care Plus cannot provide medical advice. If you have specific medical questions, please contact your healthcare professional.

Indications

Diathermy is used therapeutically to increase the temperature of tissues. It is generally accepted that heat produces the following desirable therapeutic effects:

- Relieves pain
- Increases the extensibility of collagen tissues
- Decreases joint stiffness
- Relieves muscle spasm
- Increases local blood flow

OmniSWD Shortwave Diathermy system is indicated for use in the following conditions or applications:

- Disorders of the musculoskeletal system
 - o Muscle spasm
 - o Joint stiffness
 - Joint contractures
- Chronic inflammatory or infective conditions
 - o Tenosynovitis
 - o Bursitis
 - o Synovitis
 - o Chronic inflammatory pelvic diseases

Contraindications

- Do not apply shortwave diathermy if the patient does not understand the potential risks.
- Do not apply shortwave diathermy if the patient is not able to cooperate with the operator in maintaining the proper position and in reporting the presence of a heating sensation which is the only indication of an adequate or excessive dose.
- Do not apply shortwave diathermy on pregnant patients.
- Do not apply thermal shortwave diathermy if there are open wounds, hemorrhage, ischemic tissue, tuberculous joints, or acute infections within the treatment area.
- Do not apply shortwave diathermy on patients who do not possess normal pain and thermal sensation in the area to be treated.
- Do not apply over or in close proximity to active cancer (except in terminal / palliative / hospice care), as therapy may increase blood flow to the tumor.
- Do not apply shortwave diathermy on patients, or within 10 feet of a person, with Cardiac Pacemakers or implanted defibrillators.
- Do not apply shortwave diathermy on patients, or within 10 feet of patients, who have <u>ANY</u> implanted systems with RF programming, or metallic lead, or any implanted system that may or may not contain a lead. Both the thermal and sub-thermal modes of operation pose a risk of tissue destruction.
 - If you are a physician who implants or monitors patients with leads or implanted systems with or without leads, explain to the patient what diathermy is, and stress that they should NOT receive shortwave or microwave diathermy therapy.
 - o If you are a health care professional who uses diathermy (shortwave) in your practice:
 - Be sure to ask the patient about possible implants before deciding to administer shortwave or microwave diathermy therapy. If the patient has an implanted lead or an implant with or without a lead, diathermy should not be used even if the implant has been turned off. Examples of implanted systems that may or may not contain a lead include cardiac pacemakers and defibrillators, cochlear implants, bone growth stimulators, deep brain stimulators, spinal cord stimulators, other nerve stimulators, and infusion pumps.
 - Do not administer shortwave diathermy therapy to a patient who has had an implant in the past unless you are absolutely certain that the implant and all leads in their entirety have been removed.

NOTE: Leads are often left implanted after the implant is removed.

NOTE: If there is a scar in or near the treatment area, check with the patient and/or the patient's chart to determine if there is metal under the scar.

DIATHERMY WARNINGS & PRECAUTIONS

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Warnings

- Do not operate this device until the User Manual, including all Indications for Use, Contraindications, Warnings and Precautions, have been carefully read and understood.
- Operation of this device or placement of lead wires, probes, pads and electrodes in close proximity (less than 5 feet) to an operating shortwave or microwave diathermy unit may produce instability in the device output or burns at the treatment site.
- Treatment should not be applied over the carotid sinus nerves, (located in the anterior neck triangle), including, stellate ganglion, vagus nerve, or laryngeal or pharyngeal muscle. Particular care should be taken for patients with a known sensitivity to the carotid sinus reflex, as carotid sinus stimulation may alter blood pressure and cardiac contractility.
- Do not apply treatment over testes, heart or eyes. Electromagnetic effects may affect organ function.
- Treatment should not be applied when high fever is present, over swollen, severe infection, (osteomyelitis, sepsis, tuberculosis, etc.), or inflamed areas or skin eruptions, (e.g., phlebitis, thrombophlebitis, varicose veins, etc.).
- Do not apply over the lumbar or abdominal region, or over the uterus during menstruation as therapy may temporarily increase menstrual flow.
- Do not apply treatment over exposed spinal cord (i.e. following laminectomy, spinal fusion, etc.).
- Do not apply directly over the cranial region, as little is known about the electromagnetic effects on the cerebrum to determine if it represents a serious hazard when shortwave diathermy is applied to the head.
- Do not apply directly over the epiphysis of growing bones in children and adolescents because shortwave diathermy may enhance or inhibit bone growth.

NOTE: The mean age for skeletal maturity in females is 15.5 years; in males, 17.5 years.

- Do not apply treatment on a patient connected to patient monitoring devices, or within 5 feet of any active patient monitoring devices.
- Thermal Shortwave Diathermy should not be performed when metal is present in tissues in the treatment field. This includes Total Knee Arthroplasty, Total Hip Arthroplasty, other joint replacements, screws, wires, shrapnel, some stents, etc. Shunts may contain a valve rather than a pump. Good clinical practice with either sub thermal or thermal Short Wave Diathermy (SWD) is to remove all external metal from the treatment field such as buttons, snaps, under-wire bra, belt buckle, metal zippers on clothing or pillowcase covers, intra-uterine device, shrapnel, body piercing, jewelry.
- Do not apply directly over or in close proximity to Deep Vein Thrombosis (DVT). Thermal agents should be avoided in early phases of a DVT. Therapists should follow the guidelines provided by the referring physician on recommended activity level and modality use.
- Do not apply shortwave diathermy through synthetic blend clothing. Certain plastics and synthetics (e.g., nylon, polyvinyl chloride, and polyethylene terephthalate), which are usually regarded as good insulators, can also be

heated significantly by shortwave diathermy units. Some fabric blends that contain synthetics can also be heated. Additionally, synthetics can trap moisture near the body, which can rapidly heat and burn a patient.

- Always keep cables spaced apart. Route cables as designed for the unit, using all spacing insulators and cable supports provided. Do not put anything else between the cables and never cross cables.
- Keep cables at least several inches away from any objects or material, especially metal or grounded objects.
- Do not lean on or hold the cables while the generator is activated. In addition to the strong heating effect, a deteriorated cable could break down and expose the user to high voltages.
- Keep all line cords away from the diathermy unit cables. Do not store or coil line cords where they can come close to the cables on an operating diathermy unit.
- Before increasing generator output in response to a report of inadequate patient heating, verify that cables are properly routed, evenly spaced, and away from any metal or grounded objects. The heating effect may be "stolen" from the patient at a spot where the cables are close to a metal object or each other. Increasing the generator output under these circumstances will cause increased heating at that spot.
- Use a nonconductive treatment table and a mattress or couch without metal parts (e.g., decorative buttons, springs) near the patient, applicators, or cables. Do not use conductive mattresses or mattress covers.
- During application of shortwave diathermy, the operator and any other patients should stand at least 2 feet from the device.
- Do not apply shortwave diathermy over areas with excess adipose tissue.
- All equipment and accessories should be kept out of the reach of children or unqualified persons.
- Do not apply over areas of hemorrhage or active bleeding.
- Avoid applying to the body if wet. Dry the area thoroughly, as water in the treatment field may lead to uneven heating.
- All hearing aids should be removed during shortwave diathermy treatment.
- Do not turn on the output of the OmniSWD[®] until the head (Drum) is properly placed above/over the treatment area.
- Caution should be used when applying thermal shortwave over areas of body which lack normal sensation. Absent or diminished sensation should be avoided or, if unavoidable, treated with caution. Establishment of acceptable intensity levels for desensitized areas may be related to the intensity levels tolerated on normal skin in opposite or related body parts.

Precautions

- Application site and settings should be based on the guidance of the prescribing practitioner.
- Do not connect this device to any wall outlet that has not been properly grounded, or to any electrically nonisolated medical device.
- Use only ACP specified accessories and/or supplies with ACP devices. Do not use any power cords, or power supplies, other than the ones provided or specified for this device. Use of any other power supply could seriously damage the device and will void the warranty.
- When cleaning the device, never immerse them or wash them with water. See the infection control section in this manual for cleaning instructions. Devices should not be submerged in water or other liquids.
- Failure to follow the manufacturer's prescribed maintenance for this device may lead to device failure and transient or unreliable performance. State and federal survey and JCAHO (Joint Commission on Accreditation of Healthcare Organizations) require all equipment to be maintained and calibrated according to the manufacturer recommended schedules.
- A potential electric shock hazard exists once the device outer casing has been in part, or fully, removed. Only qualified service personnel should perform service and repairs. Warranty will be voided if the outer casing has been removed or tampered with.
- Inspect and cleanse the skin prior to application. Following treatment, check the skin for evidence of irritation or burns, and if present, treat as appropriate. If the patient has, or complains of, skin irritation following treatment; shorten the treatment time on the next treatment session or use an alternative type of therapy or drum inductive applicator placement.
- The treatment area should be checked from time to time, and if there is evidence of, or if the patient complains of, pain or overheating during treatment, adjust the output downward until it is tolerated by the patient. If the patient continues to complain of pain or overheating, discontinue the treatment and shorten the treatment time on the next treatment session, or use an alternative type of therapy or drum inductive applicator placement.
- Do not apply treatment directly over/under hot or cold packs due to possible activation of chemical packs with diathermy treatment. Caution is recommended when treatment follows the application of hot or cold therapy, which may alter the patient's sensation. Application of thermal agents over areas of impaired circulation should be performed with caution as the circulation may be insufficient to heat or cool the tissue, altering the patient's perception of warmth and pain. Burns or tissue necrosis may result from subsequent treatment.
- Treatment should not follow the application of medicated patches, salves, or creams. The presence of RF energy may be altered by the presence of these materials on the patient's skin. Some medications can alter the patient's sensation. Heat can also increase the absorption of medication and may be contraindicated. If there is a medical necessity to perform such treatments, these patients should be monitored diligently during application.
- Caution should be used in the presence of recent surgical procedures, fractures or healing bone and soft tissue when therapy may disrupt the healing process. Thermal shortwave diathermy should be applied with caution over bone where minimal or no soft tissue is present.
- Caution should be taken with patient exhibiting psychological or physical hypersensitivity to the therapeutic treatment. Several attempts should be made to place them at ease so that their confidence and cooperation can be gained during the treatment.
- If the device operator is pregnant, she should remain at least 5 meters away from the applicator when the unit is turned on.

THE OmniSWD[®]

Delivery of the OmniSWD®

Upon receipt of the unit check for any damage which may have occurred in transit. If any signs of damage are found then retain all packing material and inform the carrier and the Company or its agent from whom the unit was purchased.

Check that the AC voltage and frequency stamped on the rear panel of the unit are as required. If the AC supply is not within the range specified on the rear panel; DO NOT CONNECT THE UNIT TO YOUR AC SUPPLY.

The AC supply must be capable of providing .75A (220-240V 50/60Hz) or 1.5A (100-120V 50/60Hz). Connect the AC plug to a suitable socket. The OmniSWD[®] is now ready for use.

Introduction

In 1890, Darsenval first applied high frequency currents therapeutically. In the early 1920's investigators began experimenting with shortwave therapy devices of various configurations for a variety of purposes. After World War II, microwave therapy was introduced following the development of radar. Both shortwave and microwave therapy are now in use on a routine basis in physical medicine.

Although, the specific mechanisms behind the use of high frequency currents are not altogether understood, it is well established that this energy causes vibration of ions and molecules within the cells and tissues. Depending on the intensity of the high frequency energy applied, this vibrating effect causes more or less tissue heating. Significant stimulatory effects may occur in the tissue at thermal and sub thermal levels of high frequency energy exposure. When the frequency used is high, e.g.: 27,000,000 Hz (27 MHz) as applied in shortwave equipment, the energy may be directed to the body without direct electrical contact of the electrodes.

High frequency energy used in therapy when absorbed by the body produces thermal effects by inducing a current into the tissue which increases tissue kinetic energy through resistive heating. Temperature increases occur when energy is expended in the tissue faster than it can be removed by the circulatory system or by conduction into adjacent tissues. Temperature is therefore a yardstick of net energy absorption in the tissue.

Energy absorption in tissue is the underlying factor which must control dosage. Shortwave should not be used merely to maximally increase temperature in the tissue undergoing treatment. Dosage needs to be applied based on the nature and location of injury and whether acute or chronic in nature. It is well recognized that lower dose applications are generally used in acute conditions and higher dose applications are used in more chronic conditions.

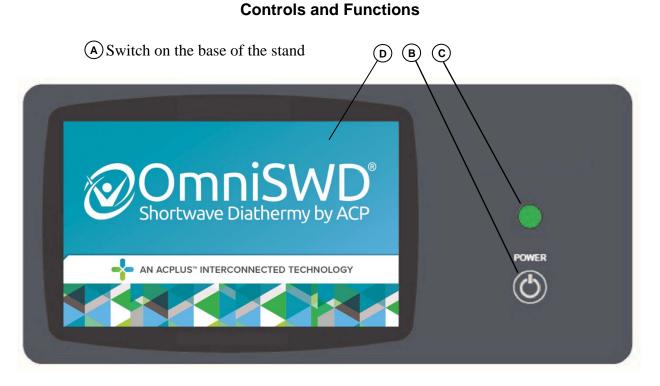


FIGURE 1 - OmniSWD[®] - Front Panel

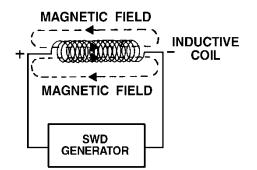
The letter associated with each control or indicator in this section corresponds to the labeling in FIGURE 1.

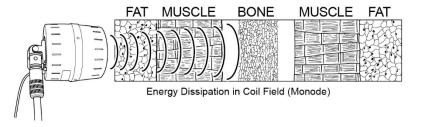
- A. Mains AC Power ON/OFF switch (A) . This is a two position rocker switch, up for ON, down for OFF. The switch is located on the bottom back portion of the device base.
- B. Membrane push button ON/OFF switch (B) This is a membrane switch to control the display.
- C. The mode LED (C) will illuminate when the display screen is activated.
- D. All other controls will be via the touchscreen (\mathbf{D})

TREATMENT GUIDELINES

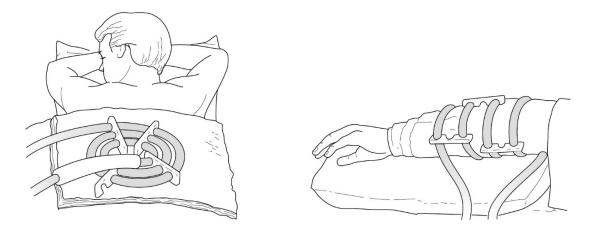
Inductive Shortwave

A coiled conductor is placed in the drum inductive applicator which is usually in the shape of a drum. The current flowing through the coils produces a magnetic field at right angles to the alignment of the coils. The magnetic field induces more current into the muscle and less in the subcutaneous fat than the capacitive technique. Today the drum monode electrode is the most commonly used pulsed shortwave electrode. Drum inductive applicators are generally referred to as monodes. Drum inductive applicators are operated in the pulsed mode to avoid overheating of the coils.





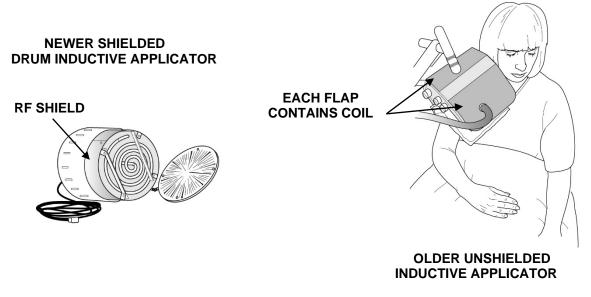
Historically, inductive electrodes were manually coiled or circumferentially wound around the area of the body to be treated.



PANCAKE COIL

CIRCUMFERENTIAL COIL

Modern drum inductive applicators are heavily shielded to prevent unwanted emissions and their corresponding interference with the operation of computers, telephones and other electrotherapy equipment used in the clinic. The new systems also provide adequate RF shielding to protect the operator and other medical equipment from stray radiation fields.



Depth of Penetration

Pulsed shortwave with magnetic field monode drum inductive applicators should be used to treat deeper tissue. Penetration depth for fat at 27 MHz is approximately 62.6 inches (159cm) whereas depth for muscle is 5.5 inches (14cm). This is somewhat modified by the SAR (Specific Absorption Rate) of the applicator and the method of application.

For inductive field applicators, if the drum inductive applicator is in direct contact with the skin (with a towel layer in between), the primary effects will be in a field formed from the surface to a depth of 2 inches (5cm).

Thermal and Subthermal Dosage

Pulsed shortwave diathermy provides outputs capable of producing thermal or subthermal effects. Average power output in watts is controlled by the peak power and the duty factor. The duty factor is controlled by the pulse duration and the pulse rate. The higher the average output, the greater the thermal effects in the tissue.

AVERAGE POWER (WATTS) = PEAK POWER (WATTS) x DUTY FACTOR

DUTY FACTOR = PULSE RATE (PPS) x PULSE DURATION (µsec)

64W = 200 W x 800 PPS x 400 μsec

PULSE DURATION	-	AVERAGE POWER IN WATTS (W)				EFFECT	
400 μSec	4.0W	8.0W	16.0W	32.0W	48.0W	64.0W	4°C
200 μSec	2.0W	4.0W	8.0W	16.0W	24.0W	32.0W	2°C
100 μSec	1.0W	2.0W	4.0W	8.0W	12.0W	16.0W	1°C
65 μSec	.65W	1.3W	2.6W	5.2W	7.8W	10.4W	SUBTHERMAL
40 μSec	.40W	.8W	1.6W	3.2W	4.8W	6.4W	(Barely Perceptible
20 μSec	.20W	.40W	.80W	1.6W	2.4W	3.2W	Warmth)
PULSE RATE	50 PPS	100PPS	200PPS	400PPS	600PPS	800PPS	

PSWD DOSE WITH OmniSWD® CHART FOR A 15 MINUTE TREATMENT:

Calculated values in watts

INFECTION CONTROL EQUIPMENT AND PRINCIPLES OF USE

Definitions

- **Barrier Film** One-time use, disposable plastic film for use over touch/operator surfaces of equipment to reduce risks of cross-contamination and need for high level disinfection of equipment between patients.
- **Germicidal Disposable Wipe** Low level and/or intermediate level disinfectant germicidal disposable wipe for use on electrotherapeutic devices and accessories.
- **Plastic Wire Sleeve** Barrier to be used on applicator wire, covering the junction of the drum inductive applicator and generator unit.
- Drum Inductive Applicator Cover Barrier to be used between the drum inductive applicator and skin.

Universal Precautions - Body Substance Isolation

Universal Precautions (UP) must be implemented in the care of all patients to protect employees from occupational exposure to blood borne pathogens. Personal protective equipment (gloves, masks, gowns) should be available and worn by staff when occupational exposure to blood, body fluids containing blood, semen and vaginal secretions is likely to occur. Health care workers with exudating lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves. Equipment must be cleaned/disinfected and protective barriers used when appropriate.

Cleaning / Disinfecting of the OmniSWD®

Modality equipment shall be cleaned / disinfected per facility infection control policy. ACP recommends the following guidelines:

Proper cleaning procedures at the end of each treatment and/or at the end of each day are recommended.

Before cleaning the OmniSWD[®], make certain that the machine is OFF and that the plug has been removed from the wall socket. Periodically clean the outer case, drum inductive applicator and cables with ACP approved infection control products. Use of other cleaning solutions or disinfectants may damage the finish of the outer case. Care must be taken to avoid getting excess moisture into the unit. NEVER IMMERSE THE OmniSWD[®] IN ANY LIQUID OR CLEANING SOLUTION.

The drum inductive applicator cables and connectors should be inspected periodically for signs of damage, especially cable insulation.

Cleaning and Low Level Disinfection

This is a recommended daily housekeeping practice to keep the equipment clean and free of contaminants which could contribute to transmission of infection. The following practices are recommended for use when treating intact skin without the presence of physiologic fluids such as blood and urine.

- Clean equipment daily with ACP germicidal wipes. At the end of the day, wipe common contact surfaces, such as control panel and diathermy arm and head, with germicidal disposable wipe and allow to air dry. This technique will inactivate *M. tuberculosis* as well as most bacteria and viruses. This will also facilitate removal of organic material contaminants from equipment.
- Clean diathermy head with ACP germicidal wipes after each patient use.

Intermediate Level Disinfection

This method is recommended to keep the equipment clean and free of contaminants when used between patients for treatment of non-intact skin or incontinence management, where there is an increased risk of patient cross-contamination.

- After each use, clean common contact surfaces, such as control panel and diathermy arm and head, with ACP germicidal wipes.
- With a second ACP germicidal cloth, wipe again leaving surfaces wet for at least 5 minutes. Allow the surface to air dry before patient use.
- Barriers should also be used on the equipment for treatment of non-intact skin or incontinence management. This technique will inactivate *M. tuberculosis* as well as most bacteria and viruses.

Use of Barriers

The use of an all-purpose barrier film that provides surface protection from cross-contamination from a variety of applications should be used whenever dealing with non-intact skin or the chance of coming in contact with bodily fluids. Barrier film is designed to cover any surface that may be touched during a patient treatment to help prevent cross-contamination. Barrier film is for single-use only. The film is discarded after each patient treatment. The procedure for use is as follows:

- 1. Wash hands.
- 2. Apply intermediate level disinfection prior to barrier application.
- 3. Select, tear and place barrier film over the operatory surfaces of the OmniSWD[®] unit.
- 4. Select, tear and place barrier film over adjustment points of the drum inductive applicator arm, such that if the position of drum inductive applicator needs to be adjusted during treatment parts of the drum inductive applicator arm that may be touched are covered.
- 5. Apply plastic cover over drum inductive applicator.
- 6. Prepare any items which may come in contact with the therapist during treatment, such as pens, assessment tools, cart handles, etc.
- 7. Don gloves.
- 8. Perform shortwave treatment.
- 9. After treatment, wash hands, don new gloves and remove plastic barrier film from OmniSWD[®] unit and discard.
- 10. Carefully remove plastic drum inductive applicator cover in an inside-out manner, ensuring the outside of the plastic cover does not come in contact with the drum inductive applicator. Discard.
- 11. Use intermediate level disinfection prior to the treatment of the next patient.





MODES OF OPERATION

Thermal Effect Variables

I. Tissue Energy Dissipation

The extent of the thermal effect in tissue is based on the tissue energy dissipation. **Specific Absorption Rate (SAR)** is a measure of the rate at which energy is absorbed by the human body when exposed to a radio frequency (RF) electromagnetic field. It is defined as the power absorbed per mass of tissue and has units of watts per kilogram (W/kg).

ACP has performed testing on human subjects in the triceps Surae (Gastrocnemius) muscle group using to determine the rate of heating and establish dosage for raising the tissue temperature by 1, 2, or 4 degrees C. This also allowed the calculation of the SAR as follows:

In a human tissue load consisting mainly of muscle the temperature of muscle at 2.5cm depth changes by 4 degrees C over 15 minutes. This represents 900 seconds or a rate of .00444 degrees C per second.

Specific Heat of Water and Muscle

The specific heat of water is 4.181 Joules/gram (at 20°C), i.e. if 4.181 Joules are applied to 1 gram of water the temperature will increase by 1 degree C. Muscle tissue specific heat is very similar to water and thus the specific heat of water is used for the calculation of the SAR.

Estimate of in-vivo tissue volume heated under the shortwave field:

The area of the treatment area is estimated at 200 cm2 (based on the applicator coil diameter and field calculations) for a depth of 2.5 cm (measured in prior research by BYU researchers $_{9,10}$) for a total volume of 500 cm³ or 0.5 Kg of tissue.

Total Energy required to heat to 4°C in-vivo:

To raise tissue volume of 500 cm³ by 4 degrees C would require a total of 500g x 4.181 x 4 = 8,362J (using the same specific heat as water)

Power = Joules/ Time = 8362/900 = 9.29W for 500g

SAR = 18.58 W/Kg in-vivo

II. Drum Inductive Applicator Design

The SAR is also controlled by the shape of the magnetic field, the drum inductive applicator design and the positioning on the patient. Typical values for the OmniSWD[®] drum inductive applicator is 18.58 SAR in muscle tissue and 4.57 in a saline water phantom. The higher the SAR value, the greater the thermal effect in the tissue.

III. Treatment Time

In general treatment times for pulsed shortwave is 15 minutes. The dosage charts have been computed based on a 15 minute application time. The sensation of mild, moderate or vigorous warmth by the patient should be the final indicator of obtaining the desired temperature in tissue. Start with the lowest dose capable of providing the desired sensation of temperature to the patient. Increase the pulse rate and pulse duration to increase the dose as clinically

appropriate (assuming the patient has normal sensation). Preprogrammed doses may be selected on the front panel for ease of operator selection.

IV. Safety

Due to the design of the drum inductive applicator, a strong magnetic field is produced with only a small incidental amount of electrical field. As the distance away from the drum inductive applicator increases, the amount of energy in the magnetic field drops rapidly and becomes equal to the energy in the electrical field. The nominal distance where this occurs is called the boundary between near and far fields. This distance has been measured to be approximately 5 feet. However, both the magnetic and electrical field intensities are well below all applicable RF exposure standards at a distance of 2 feet from the drum inductive applicator.

V. Dosage

Proper dosage is most important for effective application of therapy. Dosage levels on the OmniSWD[®] are established based on the pulse duration and pulse rate, i.e.: the greater the rate and duration, the more energy produced and the greater the thermal effect. The output peak power is fixed at 200 watts. Schliephake and Lehman developed the following dosage pattern:

Dose - Variable (VAR):	Barely detectable warmth (pulse duration [65 $\mu sec]$ and rate [100-400pps]) for pain and to increase local blood flow.
Dose 1 - 1∆T:	Mild warmth (pulse duration [100 $\mu sec]$ and rate [800pps]) for pain and to increase local blood flow.
Dose 2 - 2∆T:	Moderate warmth (pulse duration [200 μ sec] and rate [800pps]) for pain and to increase local blood flow, relieve muscle spasm and chronic inflammatory conditions, decrease joint stiffness and contractures, and increase the extensibility of collagen tissue in patients with reduced muscle mass and circulation.
Dose 4 - 4∆T:	Vigorous heating (pulse duration [400 μ sec] and rate [800pps]) for chronic inflammatory conditions and to decrease joint stiffness and contractures, and increase the extensibility of collagen tissue in patients with reduced muscle mass and circulation.

Treatment Time

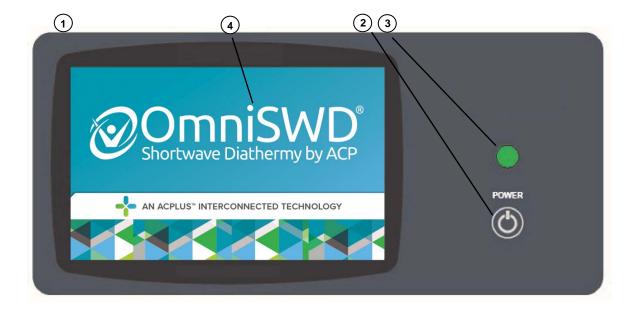
Generally treatment beyond 30 minutes is not recommended. General rule: Acute and inflammatory process 15-30 minutes, $1\Delta T$, $2\Delta T$, $4\Delta T$: 15 minutes treatment time. Always start with a low dose, and increase to a higher dose if needed, following patient response to treatment. Always start with a low dose and move to a higher dose if needed following the patient response and sensation (use sub-thermal treatment for patients with reduced or absent sensation).

Operating Instructions

Numbers in circles in the following operating instructions refer to the front panel drawing FIGURE below.

- 1. Connect the OmniSWD[®] to a suitable AC outlet, and energize the unit at the Mains AC Power switch. This is a two position rocker switch, up for ON, down for OFF. The switch is located on the bottom back portion of the device base.
- 2. Press the membrane switch on the control panel surface. This will power on the display.
- 3. The LED will illuminate with the display.
- 4. All other controls will utilize the touch screen controller built into the terminal display.

Select the desired protocol or output parameters. The connecting cables associated with the drum inductive applicators should be positioned in such a way that contact with a patient, conductive or energy absorbing object, is avoided.



User Interface

The OmniSWD® utilizes a touch screen to activate selections with the touch of a finger.



All screens and functions can be accessed from this 'Home' screen. The "Home" icon in the top left corner of all other

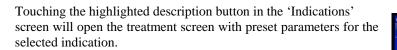
screens will always return to this screen.

Touching the 'Indications' button opens the Indications selection screen. Here you will find a listing of indications that can be scrolled through using the up and down arrows.

'Indications' buttons:
Relieves pain
Increases local blood flow
Relieves muscle spasm
Decreasing joint stiffness and contractures
Increasing the extensibility of collagen tissues
Chronic Inflammatory Conditions

Touching the information icon 'i' will open a set of screens that will contain detailed information about the selected indication including text and pictures describing parameters and electrode placement.

The up/down arrows enable the user to scroll through the various pages of applicable information on each topic. The back arrow will take you back to your starting point.



Once the applicator head has been positioned over the treatment area, the treatment can be started by touching the "start" button.

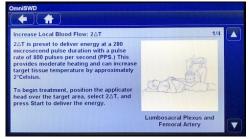
At any time, the treatment output can be stopped or paused by touching the "stop" button.

Any fields that are 'greyed-out' are not adjustable in this mode of operation.

Attempting to change any of the recommended ΔT controls will result in a warning message to communicate that you are attempting to increase the dosage beyond the recommended dose.



OmnISWD
Indications
Indications
Relieves Pain
Increase Local Blood Flow
Relieves Muscle Spasm
Decreasing Joint Stiffness and Contractures
Increasing the Extensibility of Collagen Tissue



Increase Local Blood Flow

0

15:00

Stop

2**Δ**T

Star

i

Chronic Inflammatory Conditions

Start

Stop

In the MANUAL MODE, programs can be saved and named into a favorite program list by pressing the 'save' icon button. If any parameters have been modified, the changes will be saved, and a program with the custom settings can be added to the system. To retrieve "Favorite" programs, start from the 'Home' screen, touching 'Favorites' will display the users saved programs by order of entry, with the newest programs listed at the bottom of the list. Press the "Edit" button to the right of the program name to further modify and/or edit the program name. Press the "Run" button to the right of the name to go to the run screen.

ACP Contact Information

On the Home Screen is an ACP contact information button that contains serial number, software version ACP Customer Support, ACP Clinical Question and Support phone number and email address, ACP website and physical mailing address.



Setup Procedure for Drum Inductive Applicator

- 1. Adjust the position of the drum inductive applicator by slackening the arm hand wheels. Position the drum inductive applicator over the treatment site with a terry cloth or cotton towel between the drum inductive applicator and the skin. As an alternative the drum inductive applicator may be placed 1/2" above the surface to be treated without direct contact.
- 2. When the drum inductive applicator has been placed in position, tighten the hand wheels on the arm to prevent movement.
- 3. Press the power button on the membrane control panel, and the green LED light will illuminate. Select INDICTIIONS or MANUAL MODE using the touchscreen controls.
- 4. INDICATIONS MODE: There are two to three protocols marked $1\Delta T$, $2\Delta T$, $4\Delta T$ or VAR under the desired indication. The protocol default settings cannot be changed in the Indications mode.
- 5. MAUAL MODE There are four (4) protocols marked 1ΔT, 2ΔT, 4ΔT or VAR. The VARIABE MODE (VAR) defaults setting are always 65usec pulse duration,400 PPS pulse rate 30 minutes. In MANUAL MODE, the PULSE DURATION and the PULSE RATE can be adjusted using the Up and Down Arrow switches. The desired selection will be displayed in the PULSE DURATION DISPLAY and the PULSE RATE DISPLAY. The Time setting can be changed for all protocols.
- 6. Touch the "start" button to begin treatment. The Device Output tuning bar will appear to indicate that output is active. If the Inductive Applicator cable is disconnected an Error Pop-up will appear to check the coaxial cable.
- 7. If the reflected power as shown on the display on the bottom left is high, it may be minimized by slowly adjusting the tuning know on the side of the drum applicator. The optimal setting is the highest forward power and the lowest reflected power. Tuning will ensure consistent dosage to the applicator head being transmitted to the treatment area.
- 8. If at any time during treatment the "stop" button is touched, the output will be paused, and the timer will stop counting down. To resume treatment touch the "start" button and the treatment will resume.
- 9. At the end of the treatment time, when the timer reaches 00:00, the buzzer will sound and the shortwave output will stop. The Average Power will be zero and Device Output bar will be blank on the touch screen display.

Safety Features / Error Messages

The OmniSWD[®] is microprocessor controlled; it continually "self-checks" the operation of the system. If an error in the function of the microprocessor is detected the shortwave power will be immediately turned off and the word FAIL will be shown on the display. If the unit repeatedly fails after cycling the power, then qualified service personnel should be called. The unit incorporates a safety mechanism in case of overheating. If the unit overheats the treatment is automatically stopped, the buzzer sounds intermittently, and "HOT" is shown on the display.

Coaxial Cable - Applicator Head Error Warning

This pop-up window appears if a treatment is attempted without the applicator being plugged in (or if the cable/applicator is damaged). It will also appear if a fault occurs in the cable or applicator during a treatment.

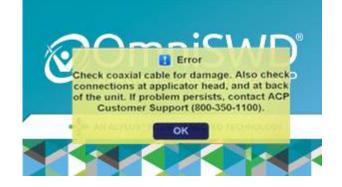
Treatment will be prevented from starting unless a functioning applicator/cable combination is plugged in.

If it persists, then contact ACP Customer Support at (1-800-350-1100).

System Fault Warning

This pop-up window appears if the machine detects a communications error between its two processors. This should be a very rare event if it happens at all, and may not recur if the mains power is switched off and on again. If it persists, then contact ACP Customer Support at (1-800-350-1100).





OmniSWD ACP i Service due Please refer to the user manual for more information OK Contraindications

Service Due Pop-Up

This is just a message that appear as a flag from the hours of use. The message is not an indication that something is wrong with your operating system or device. For service please contact ACP Customer Service at 1-800-350-1100 ext.3. Process to Reset the Service Due Timer:

- 1. Start the system
- 2. Go to settings
- 3. Go to maintenance
- 4. Insert the password: 12341924 and save
- 5. Go to service date
- 6. Press reset hours counter and confirm

Device Output Tuning Bar

A tuning bar feature exists on the device. However, the appearance of the tuning bar on the treatment run screen, is optional.

To turn off the tuning bar, enter the Systems Settings menu from the Home screen. Once in the Systems Settings menu press Device Output Tuning.

Press tuning bar ON and it will change to OFF. The tuning bar will no longer appear on the run screen.

	Device (Output Tuning
2. Press Start an under 10W on	the left side of the	e ceiling. ng bar. NOTE: Desired output is anything e tuning bar (represented by Yellow bar). nob on the applicator head (left/right) to
	Green bar and mini	imize the Yellow bar.
maximize the	Green bar and mini hen complete.	

Using Tuning Bar

Place the head in an upward facing position toward the ceiling.

Enter the systems settings menu from the Main Menu screen. Once in the Systems Settings menu press Device Output Tuning. To optimize the energy output:

Press the START button below. Gradually turn the Tuning Knob on the applicator head to display the most amount of green and the least amount of yellow on the bar below. Press DONE when complete.

Tuning POP-UPs

Output Tuning is Recommended (>10% variance)

If the Output tuning is greater than >10% variance, but less than < 20%, an

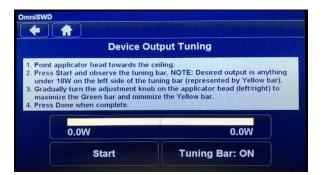
"Output tuning is recommended" caution will pop –up on the screen.

User has the option to select IGNORE to continue without tuning, or TUNE to be taken to the Device Output Tuning screen.

When IGNORE is selected, user is brought back to previous screen, and allowed to continue treatment.

If TUNE is selected, user is taken to Device Output Tuning screen. Press the START button below. Gradually turn the Tuning Knob on the applicator head to display the most amount of green and the least amount of yellow on the bar below. Adjust the tuning dial for minimum reflected power, while achieving forward power as close to 200 watts as possible. The goal for reflected power is less than or equal to 2 watts, but anything less than 10 watts is acceptable. Press DONE when complete.





Upon completion of tuning, user is prompted to select DONE. When DONE is pressed, User is returned to the previous screen viewed before Warning was generated. User is brought back to previous screen they were in before Caution pop-up warning was prompted.

Output Tuning is Required (>20% variance)

If the Output tuning is greater than >20%. An "Output tuning is required" will pop-up on the screen, It is required to tune the device to continue treatment.

Please select TUNE to be taken to the Device Output Tuning screen.

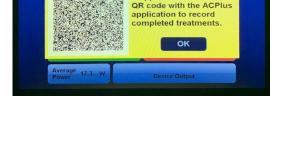
Press the Start button below. Gradually turn the Tuning Knob on the applicator head to display the most amount of green and the least amount of yellow on the bar below. Adjust the tuning dial for minimum reflected power, while achieving forward

power as close to 200 watts as possible. The goal for reflected power is less than or equal to 2 watts, but anything less than 10 watts is acceptable. Press DONE when complete.

Upon completion of tuning, user is prompted to select DONE. When DONE is pressed, User is returned to the previous screen viewed before Caution pop –up warning was generated.

End Of Treatment: QR Code

At the end of treatment a QR code Pop-can be scanned to record the treatment into the Electronic Medical Record via the ACPlus iOS application.

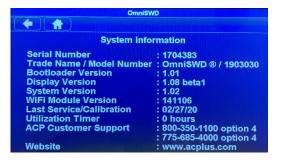


A treatment session has

stopped. Please scan the

Systems Information

A screen with the information will appear. The System information screen includes Serial Number, Trade Name / Model Number, Bootloader Version, Display version, Systems version, WiFi Module Version, Last calibration, utilization Tier, ACP Customer Support, and the ACP Website address.





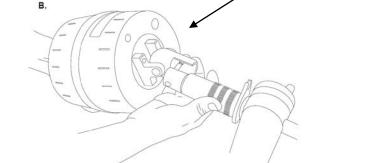
Drum Inductive Applicator Removal

It may be necessary to remove the Drum Applicator from the articulating arm to apply to a patient lying in a bed. To remove the Drum Applicator, first loosen the locking collar turning counter-clockwise until you can see the white nylon washer as shown.

Locked

Unlocked

Next, press gently on the drum applicator pin to dislodge the drum applicator from the articulating arm. The drum applicator can now be applied to a patient where the articulating arm might have obstructed the therapy.

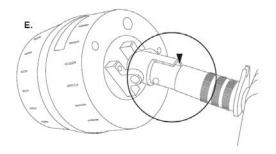


Drum Applicator Pin



Drum Inductive Applicator Reinstallation

To reinstall the drum applicator, reverse the above process. Be sure the pin is properly seated and the locking collar has been properly adjusted clockwise such that the white nylon washer is compressed and no longer visible at the notch indicated below. Verify that the drum applicator is secure prior to continued patient use.



TROUBLESHOOTING

The following table lists OmniSWD[®] problem symptoms and possible areas to check for the problem causes. If these suggested measures do not correct the machine malfunction, call your ACP Customer Support representative.

PROBLEM	CAUSE	REMEDY
Unit will not power on	 Main power switch turned off. Power Cord not plugged into the unit or AC outlet, main power switch turned off. 	 Verify the main power switch in back of the unit has the line symbol pressed down. Verify the power cord is connected and check that the cord is not frayed/damaged. Verify AC outlet is functional.
	 This condition may also occur if a software upload process has become corrupted 	Contact ACP Customer Support at (800)350-1100
System Fault Warning	 There is an internal failure in the unit 	Contact ACP Customer Support at (800) 350-1100
Coaxial Cable - Applicator Head Error Warning	 The unit detects a communications between its two processors error (e.g. drum not connected). 	 Verify that the drum inductive applicator connector is plugged into the back of the main unit. If the connector is plugged in properly, cycle power to see if the error resolves. If not, contact ACP Customer Support at (800) 350-1100
Tuning POP-UPs	The output power may be out of appropriate calibration range	 Adjust the tuning dial for minimum reflected power, it should be able to get down to 2 watts or under (though anything under 10 watts is acceptable). It should also be possible to adjust the tuning dial to get the forward power reading to be close to 200 watts with the reflected still reading around 2 watts
Treatment will not start	No program selected	Select desired treatment program and touch START button
Patient cannot detect output, when unit is ON and treatment is running	 Drum inductive applicator is not emitting output 	 Observe Device Output tuning bar. Retune the unit with the knob on the drum for maximum forward power. Use power meter to determine if unit has failed or is operating incorrectly. Retune the unit with the knob on the drum for maximum forward power. Contact ACP Customer Support at (800) 350-1100
	Patient has impaired sensation over treatment area	Discontinue treatment and test patient for impaired sensation over treatment area

Verify Calibration Accuracy

If clinicians are to give prescribed therapeutic doses of shortwave with reasonable accuracy, the machine used is required to meet the equipment performance standards (21 CFR 890.5290) instituted by the Food and Drug Administration. Periodic calibration of treatment parameters having a direct influence on the physiological effect of shortwave on tissue, i.e., power output, and time accuracy, is a significant part of this regulation. It is therefore suggested that the output be verified at the beginning of each treatment or as applicable to local facility protocols. The OmniSWD[®] has an integrated output meter built in for the purpose of verifying the output.

ACP Customer Support

For repair or service of ACP products and accessories, please call (800) 350-1100 and follow the prompts. Normal hours of operation are 6:00am to 5:00pm Pacific Standard Time. After hours, please leave a message and your call will be returned during the next scheduled workday.

Certificate of Conformance Inspection and Good Operating Practice

Certificate of Conformance Inspection is recommended to be performed at least biennially (every two years). This should include at minimum a safety inspection and to verify proper operation of your OmniSWDTM

- Always keep the system clean by disinfecting drum head and control panel.
- Routinely check for power cord fraying or any other damage to the power cord.

TECHNICAL SPECIFICATIONS

Technical Data - OmniSWD®

GENERAL:				
Power Supply:	120VAC 50/60Hz			
Power consumption:	250W max			
Fuses:	Externally Replaceable 2 x T 2A 5 x 20mm, 250V 2 ampere Interrupting Rating: 35A @ 250Vac Operating Speed: 0.06 seconds at 35A			
Size:	Approx. H: 870 mm (34.25 in) / D: 410 mm (16 in) / W: 410 mm (16 in)			
Weight:	39 kg (86 lbs.)			
FDA Classification:	Class II: Type BF			
Frequency:	27.12 MHz <u>+</u> 20 KHz			
Output Power:	200W Peak Power (±20%) into 50 Ohm load pulsed mode			
Output Modes:	Pulsed output waveforms are available as selected by the user interface. In pulsed mode the output is square wave modulated.			
Pulse modes presets:	Protocol 1AT - Timer is preset to 15 minutes, pulse rate is set $1 \triangle T$ to 800 PPS and pulse duration to 100 µSec. Protocol 2AT - Timer is preset to 15 minutes, pulse rate is set $2\triangle T$ to 800 PPS and pulse duration to 200 µSec. Protocol 4AT - Timer is preset to 15 minutes, pulse rate is set $4\triangle T$ to 800 PPS and pulse duration to 400 µSec. Protocol VAR - Timer is variable from 0 - 30 minutes, but Variable preset at 30 minutes, pulse rate is set to 400PPS, 65 µSec pulse duration. Pulse rate, timer and pulse duration are variable over their full range in this mode.			
Pulse Duration:	400, 200, 100, 65, 40, 20 µs available			
Pulse Repetition Rate:	50, 100, 200, 400, 600, 800 PPS available			
Timer:	The digital treatment timer indicates the set time in minutes and seconds prior to the start of treatment and treatment time remaining during treatment. The maximum setting of the timer is 30 minutes. The timer increments in 1 or 10 minute units.			
Timer accuracy:	+/- 1 second at all settings			
Electrode:	Manually Tunable Hi Q Drum Inductive Applicator			
Applicator Temperature	The applicator temperature may reach 54.3 degrees Celsius during normal operation			
Cooling:	Forced air by integrated fan			
ENVIRONMENTAL C	CONDITIONS:			
For Transport and Storage:	Temperature:-10 to 35°CRelative Humidity:5 to 95%Atmospheric Pressure:500 to 1060hPa			

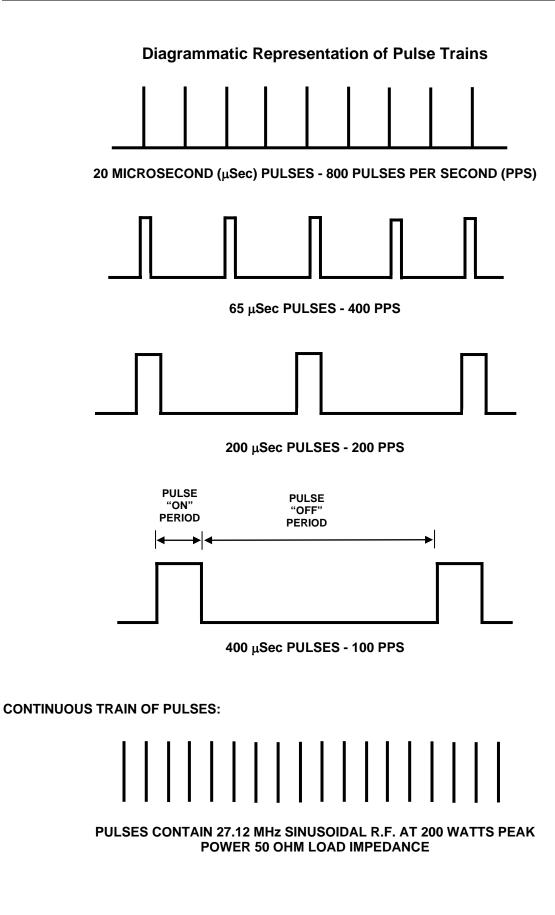
Each unit is supplied with a main power cable. Both the cable and the plug on the unit conform to international safety standards.

All information on supply voltages, model, serial number, and month/year of manufacture is located on the rear panel. The external fuse ratings and type information is located on the bottom of the unit.

Standards

The OmniSWD[®] has been designed to meet the requirements of IEC 60601-1:2005; "Safety of Medical Electrical Equipment, Part 1: General requirements."

Additionally, the OmniSWD[®] has been designed to meet the requirements of IEC 60601-2-3 "Specification for safety for shortwave therapy equipment," and the requirements of IEC 60601-1-2:2014 4th Edition "Collateral Standard: Electromagnetic Compatibility: General requirements."



PULSE DURATION		AVERAGE POWER IN WATTS (W)				EFFECT	
400 μSec	4.0W	8.0W	16.0W	32.0W	48.0W	64.0W	4°C
200 µSec	2.0W	4.0W	8.0W	16.0W	24.0W	32.0W	2°C
100 µSec	1.0W	2.0W	4.0W	8.0W	12.0W	16.0W	1°C
65 μSec	.65W	1.3W	2.6W	5.2W	7.8W	10.4W	SUBTHERMAL
40 μSec	.40W	.8W	1.6W	3.2W	4.8W	6.4W	(Barely Perceptible
20 μSec	.20W	.40W	.80W	1.6W	2.4W	3.2W	Warmth)
PULSE RATE	50 PPS	100PPS	200PPS	400PPS	600PPS	800PPS	

OmniSWD[®] Average Output Power

Calculated values in watts

OmniSWD® STANDARD AND OPTIONAL ACCESSORIES

ITEM	ITEM NO.	DESCRIPTION
	1903030	OmniSWD [®] Shortware Diathermy System 200 Watt peak power Shortwave Diathermy with Delta T control Shipping Weight: 101 lbs.

ITEM	ITEM NO.	DESCRIPTION
	89456	OmniSWD [®] Locking Power Cord, Hospital Grade, 10ft.
	57896	Cable, Applicator Head Coaxial, BNC to BNC
Contraction of the second	83454	OmniSWD [®] User Manual

Infection Control Supplies:

ITEM	ITEM NO.	DESCRIPTION
	55536	Super Sani-Cloth [®] Wipes, Single Use Packets (50 pk/bx)
	44425	Super Sani-Cloth® Wipes, Tub (160/Tub)
	96849	Sani-Cloth [®] Wipes w/ Bleach, Tub (75 wipes/tub)
	52479	Protective Film for Surfaces Infection Control – 4" x 6" (600 ft/roll)
	50593	Protective Film for Surfaces Infection Control – 12" x 14" (600 ft/roll)
	13296	OmniSWD [®] Drum Inductive Applicator Cover (100ea/box)

STANDARD LIMITED PRODUCT WARRANTY

The warranty information provided in this section is applicable only to products purchased from ACP, directly or through an authorized dealer. This section does <u>not</u> apply to leased products. The terms of maintenance and repair of any leased products are detailed in the separately executed agreement between the parties.

Warranty Coverage

This warranty provides coverage, for Equipment purchased, against manufacturer's defects in material and workmanship, and extends to the original owner of the product during the warranty period for that product. Only those items returned to the ACP Service Center within the warranty period, and also within thirty (30) days after notification to ACP of the defect, shall be eligible for repair under the Standard Limited Product Warranty. Buyer is responsible for shipping cost associated with sending the Equipment to the ACP Service Center. ACP shall ship Equipment to Buyer after repair at no cost to the Buyer provided repair is deemed to be under warranty. ACP may, at its discretion and only for valid warranty claim, repair or replace any part(s) that prove to be defective during the warranty period.

Warranty Exclusion

Any and all warranty coverage will be void if any of the following have occurred:

- 1. The product contains repairs or replacement parts not furnished by ACP.
- 2. The product is damaged resulting from misuse or negligence.
- 3. The product has been tampered with and/or altered, including serial number alteration.

Note: Use of the Equipment with accessories and/or supplies not approved by ACPL for use with the Equipment may void the warranty if such accessory or supply item caused damage to the Equipment.

Warranty Period

The following coverage is provided at no additional cost to the Buyer:

New Equipment / Product. Products purchased as new from ACP are warranted against manufacturer's defects in material and workmanship for a period of two (2) years from the date of purchase.

Refurbished Equipment / Product. Products purchased specifically as Refurbished Equipment are warranted against manufacturer's defects in material and workmanship for a period of one (1) year from the date of purchase.

Accessories. All accessories for ACP equipment / products are warranted against manufacturer's defects in material and workmanship for a period of three (3) months from the date of purchase.

Warranty Validation

The following information needs to be provided to the ACP Customer Support representative prior to the product being returned under warranty coverage:

- 1. Buyer name or account number as it appears under the "Bill TO" on the ACP or recognized ACP Dealer invoice.
- 2. Invoice Date and Number.
- 3. Model number, description, and serial number of equipment.
- 4. Detailed description of the problem.

Return of Defective Equipment

Any Equipment returned to the ACP Service Center under warranty coverage must have the Warranty coverage validated and must receive authorization from ACP Customer Support prior to being received at the Service Center.

Shipping charges, insurance, and any other costs incurred in sending product to ACP Service Center is the responsibility of the customer and will not be refunded. ACP shall cover the shipping charges and related costs to return the unit to the customer, provided repair is deemed to be under warranty.

ACP is not responsible for any loss or damage to the Equipment prior to receipt at the ACP Service Center. Equipment returned for warranty service must be shipped complete with all accessories (except for manuals), in its original packing or equivalent so as not to be damaged while in transit.

Note: Any Equipment sent to the ACP Service Center that is not covered by the ACP Limited Product Warranty is subject to a minimum service and handling fee.

IMPORTANT:

DO NOT SHIP THE EQUIPMENT TO ACP SERVICE CENTER WITHOUT FIRST SECURING AUTHORIZATION TO DO SO. EQUIPMENT SENT IN WITHOUT AUTHORIZATION FROM ACP CUSTOMER SUPPORT WILL NOT BE ACCEPTED.

Returned Materials Shipping Address:

Accelerated Care Plus Attn: ACP Service Center 4999 Aircenter Circle, Suite 103 Reno, NV 89502

Manufactured for ACP by:



EMS Physio Ltd Grove Technology Park A1 Downsview Road Wantage, Oxfordshire, OX12 9FE, UK Tel +44.0.1235.772272 Fax +44.0.1235.763518

