Intelect® MOBILE

User Manual

Ref 2776
Intelect® Mobile
Ultrasound

chattanooga™

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FOREWORD

This manual has been written for the operators of the Intelect® Mobile Ultrasound. It contains general instructions for operation, precautionary instructions, and maintenance recommendations. In order to obtain maximum life and efficiency from your Intelect Mobile Ultrasound, and to assist in the proper operation of the unit, read and understand this manual thoroughly.

The specifications put forth in this manual were in effect at the time of publication. However, owing to DJO, LLC's policy of continuous improvement, changes to these specifications may be made at any time without obligation on the part of DJO, LLC.

Before administering any treatment to a patient, you should become acquainted with the operating procedures, as well as the indications, contraindications, warnings, and precautions. Consult other resources for additional information regarding the application of therapeutic ultrasound.

Product Description

The Intelect Mobile Ultrasound, designed and manufactured by DJO, LLC, offers a new dimension in portable ultrasound therapy made possible by advanced software design and digital signal processing. The result is a unit with extraordinary versatility based on simplicity of operation.

The Intelect Mobile Ultrasound allows you to select a frequency of 1 or 3 MHz (excluding the 1 cm^2 applicator) without changing applicators. Sound heads are available in 1 cm^2, 2 cm^2, 5 cm^2 and 10 cm^2 and include the patent pending Electronic Signature™ feature. Duty cycle may be set at 10%, 20%, 50% or Continuous.

NOTE: The unit was calibrated during the manufacturing process. The unit is ready to be placed into service upon delivery.

The following features are available on the Intelect Mobile Ultrasound:

- **Clinical Portable Battery Powered Option**
  The Intelect Mobile Ultrasound is a truly portable ultrasound unit that does not confine you to a wall socket to operate. Dual frequency application in the clinic or on the road.
- **Clinical Indications™**
  An efficient approach for setting up a treatment using preset parameters.
- **Electronic Signature™**
  Automatically calibrate the system to any size Intelect Mobile Ultrasound sound head.
- **Ergonomic Applicators**
  A new ergonomic design that offers a 20 degree contour in the applicator hand grip. This ergonomic extra will help deliver uniform ultrasound with greater clinician comfort.
- **Head Warming**
  A feature traditionally available in more expensive brands of ultrasound. This will help curb the anxiety of patients during the first moments of treatment.
- **Clear LCD display**
  Guide the operator through the setup process providing continuous feedback about treatment settings. Gives you optimal visibility during attended procedures.
- **User Protocols**
  User protocols allow you to set, save, and change the parameters of each program (protocol) in order to tailor it to meet your patients' specific needs. Ten storage slots are available for user protocols.

PRECAUTIONARY INSTRUCTIONS

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

⚠ CAUTION

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

⚠ WARNING

Text with a **"WARNING"** indicator will explain possible Safety infractions that will potentially cause serious injury and equipment damage.

⚠ DANGER

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

EXPLOSION HAZARD

Text with an "Explosion Hazard" indicator will explain possible safety infractions if this equipment is used in the presence of flammable anesthetics.

NOTE: Throughout this manual "NOTE" may be found. These notes are helpful information to aid in the particular area or function being described.

⚠ CAUTION

- Read, understand and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any ultrasound device. Observe the precautionary and operational decals placed on the unit.
- Do not operate this unit when connected to any unit other than DJO devices. Do not operate the unit in an environment of shortwave diathermy use.
- The ultrasound generator should be routinely checked before each use to determine that all controls function normally; especially that the intensity control properly adjusts the intensity of the ultrasonic power output in a stable manner. Also, determine that the treatment time control actually terminates ultrasonic power output when the timer reaches zero.
- 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.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.
- Handle the applicator with care. Inappropriate handling of the applicator may adversely affect its characteristics.
- Before each use inspect applicator for cracks, which may allow the ingress of conductive fluid.
- Inspect treatment head cables and associated connectors before each use.
- The Intelect battery pack is designed for use only with Chattanooga Intelect Mobile Stim, Combo, Laser, and Ultrasound systems.
- This unit should be operated in temperatures between 15 to 40 °C (59 to 85 °F), and transported and stored in temperatures between -7 to 43 °C (20 to 110 °F), with relative humidity ranging from 30% - 60%.
- Where the integrity of the external protective earth conductor arrangement is in doubt, equipment shall be operated from its internal electrical power source.
- The battery pack should be removed when storing the unit for extended periods of time.

⚠ CAUTION

- DO NOT disassemble, modify, or remodel the unit or accessories. This may cause unit damage, malfunction, electrical shock, fire, or personal injury.
- Failure to use and maintain the Intelect Mobile Ultrasound and its accessories in accordance with the instructions outlined in this manual will invalidate your warranty.
- DO NOT remove the cover. This may cause unit damage, malfunction, electrical shock, fire, or personal injury. There are no user-serviceable parts inside the unit. If a malfunction occurs, discontinue use immediately and consult the dealer for repair service.
- DO NOT permit any foreign materials or liquids to enter the unit. Take care to prevent any foreign materials including, but not limited to, inflammables, water, and metallic objects from entering the unit. These may cause unit damage, malfunction, electrical shock, fire, or personal injury.
- If you have difficulty operating the unit after carefully reviewing this operator's guide, contact your DJO dealer for assistance.
- This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off, try to correct the interference using one or more of the following: Reorient or relocate the receiving device, increase the separation between the equipment, connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected and/or consult the factory field service technician for help.
- Use of parts or materials other than DJO's can degrade minimum safety.

⚠ CAUTION

- Do not operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Remove battery pack if unit is not to be used for an extended period.

⚠ WARNING

- Always keep the sound head in constant motion.
- Always keep the sound head in full contact with the patient's skin or submerged under water when setting intensity.
- Use ample conductive gel to ensure good coupling throughout the treatment. If needed, apply when setting intensity.
- Be sure to read all instructions for operation before treating a patient.
- 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. All of these conditions are likely to damage the sound head crystal. Damage resulting from these conditions is not covered under the warranty.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

⚠ WARNING

- Make certain that the unit is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.
- This device should be kept out of the reach of children.
- This device should be used only under the continued supervision of a licensed practitioner.
- The Intelect Mobile Ultrasound should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the Intelect Mobile Ultrasound should be observed to verify normal operation in the configuration in which it will be used.
- Federal law restricts this device to sale by, or on the order of, a physician or licensed practitioner.
- Dispose of all products in accordance with local and national regulations and codes.
- For continued protection against fire hazard, charge the battery pack only while installed on the Intelect Mobile Ultrasound.
- This equipment is not designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction of internal components of the system and therefore create a risk of injury to the patient.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous conditions causing damage to the battery pack or cells, the unit, or the applicator.
- To prevent electrical shock, disconnect the battery pack from the system before attempting any maintenance procedures.

⚠ WARNING

- Use only accessories that are specially designed for this device. Do not use accessories manufactured by other companies on this device. DJO is not responsible for any consequence resulting from using products manufactured by other companies. The use of other accessories or cables may result in increased emissions or decreased immunity of this device.
- If unit is not in use, power off unit or remove applicator.
- Equipment not in use should be protected against unqualified use.
- Use of other accessories other than those specified may result in increased emissions and decreased immunity.

DANGER

- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, with oxygen or nitrous oxide.
- The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the unit is used.
- DO NOT connect the unit to an electrical supply without first verifying that the power supply is the correct voltage. Incorrect voltage may cause unit damage, malfunction, electrical shock, fire, or personal injury. Your unit was constructed to operate only on the electrical voltage specified on the Voltage Rating and Serial Number Plate. Contact your DJO dealer if the unit is not properly rated.
- NiMH Batteries contain Class E Corrosive materials. In the event of battery cell rupture or leakage, handle battery pack wearing neoprene or natural rubber gloves. Contents of a ruptured or leaking battery can cause respiratory irritation. Hypersensitivity to nickel can cause allergic pulmonary asthma. Contents of cell coming in contact with skin can cause skin irritation and/or chemical burns.
- Never, under any circumstances, open the battery pack housing or cells. Should an individual battery from a battery pack become disassembled, spontaneous combustion of the negative electrode is possible. There can be a delay between exposure to air and spontaneous combustion.
- Charge the battery pack according to the instructions found in this manual. Never attempt to charge the battery pack on any other charging mechanism.

DANGER

- Use the battery pack only with the Intelect Mobile Series units.
- Do not reverse the polarity of the battery pack. Doing so can increase the individual cell temperature and cause cell rupture or leakage.
- Never dispose of the battery pack in fire. Never short circuit the battery pack. The battery pack may explode, ignite, leak or get hot causing serious personal injury.
- Dispose of NiMH batteries according to national, state and local codes and regulations.

OVERVIEW OF ULTRASOUND THERAPY

Utilizing ultrasound waves through muscle, nerve, and connective tissue has been well documented as effective in reducing pain, muscle spasms, and joint contractures.

There are several items that affect the penetration of ultrasound on the target tissues. Please refer to the documentation as a reference on the appropriate frequency for your clinical needs.

There are four sound heads available with the Intelect Mobile Ultrasound System: 1 cm^2, 2 cm^2, 5 cm^2, and 10 cm^2.

Select either 1 or 3 MHz frequencies for each applicator (only 3.3 MHz is available with the 1 cm^2 sound head). Frequency may be selected either before or during therapy.

Common Terms

Applicator - The hand held assembly used to deliver ultrasonic energy. The applicator includes the sound head, transducer, and related electronics.

Beam Non-Uniformity Ratio (BNR) – By nature, an ultrasound beam is not homogeneous. The 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. This measure may not exceed 5.0:1. Because of the areas of increased intensity, the sound head is moved continuously during the treatment.

Collimating (Coll)- The shape of the ultrasound beam. While neither focused nor dispersed, this ultrasound beam resembles a column when applied from the unit through the sound head.

Continuous Mode – The output of the ultrasound is not interrupted during the treatment time. This mode imparts the most energy to the tissues and is used when a maximal effect is desired. (See Duty Cycle).

Coupling Media – An agent used to insure that the ultrasound is transmitted from the sound head to the tissue to be treated. Gels or lotions labeled for therapeutic ultrasound use are recommended.

OVERVIEW OF ULTRASOUND THERAPY - COMMON TERMS (CONTINUED)

Duty Cycle – This is the ratio of the "On" time to "Total" time of the cycle, expressed as a percentage. The duty cycle describes the pulsed modes of ultrasound. The lower the percentage, the lower temporal average intensity. 100% is continuous ultrasound.

Effective Radiating Area (ERA) – A measure of the ultrasound beam made underwater, 5 mm from the radiating surface of the sound head. The ERA is always smaller than the geometric area of the sound head, but should be as close as possible. This measurement is used to calculate the ultrasound intensity in W/cm^2.

Frequency (Freq) – Selectable to 1 or 3 MHz with the 1 cm^2, 2 cm^2, 5 cm^2, or 10 cm^2 sound head (only 3.3 MHz is available with the 1 cm^2 sound head). The lower the frequency, the longer the wavelength, the deeper the penetration of ultrasound.

Lead Zirconate Titanate – A synthetic crystal used to create the ultrasound beam by vibrating 1,000,000 (1 MHz) or 3,000,000 (3 MHz) times per second. This type of crystal is both durable and efficient in its functions.

Power – A measure of the intensity of the ultrasound delivered to the patient. Unit of measure is watts (W).

Pulse Duration – Refers to the amount of time the ultrasound is being delivered in the pulsed mode. For example, in the 20% duty cycle mode, the ultrasound is delivered for 2 msec and off for 8 msec (at 100 Hz) throughout the treatment period.

Pulse Frequency – The pulse frequency is the number of pulses per second and is expressed in hertz. The available pulse frequencies on the Intelect Mobile Ultrasound are 16, 48, and 100 Hz.

Pulsed Mode – The output of the ultrasound is automatically interrupted during the treatment time. This limits the amount of energy delivered to the tissues.

Sound Head – The aluminum face of the applicator that contacts the patient's skin. It covers a transducer mechanism that converts electrical energy to mechanical energy in the form of a vibrating crystal.

OVERVIEW OF ULTRASOUND THERAPY - COMMON TERMS (CONTINUED)

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 centimeter squared (W/cm^2).

Description of Ultrasonic Field

The spatial distribution of the radiated field is essentially a collimated beam of the ultrasonic energy having a cross-sectional area of 8.5 cm^2 for the 10 cm^2 sound head when measured at a point 5 mm from the transducer face.

The energy distribution within the radiated field is 3.0 W/cm^2 maximum and it takes a generally conic shape, having decreasing intensity at progressively increasing distance from the face of the transducer. This field distribution applies for the radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30 °C and with the line voltage variations in the range of 10% of the rated line voltage.

INDICATIONS

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:

- Relief of pain, muscle spasms and joint contractures
- Relief of pain, muscle spasms and joint contractures that may be associated with:
  - Adhesive capsulitis
  - Bursitis with slight calcification
  - Myositis
  - Soft tissue injuries
  - Shortened tendons due to past injuries and scar tissues
- Relief of sub-chronic and chronic pain and joint contractures resulting from:
  - Capsular tightness
  - Capsular scarring

CONTRAINDICATIONS

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

ADDITIONAL PRECAUTIONS

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

- Over an area of the spinal cord following a laminectomy, i.e., when major covering tissues have been removed.
- Over anesthetic areas.
- On patients with hemorrhagic diatheses.

DANGER

Patients with an implanted neurostimulation device must not be treated with or be in close proximity to any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy or laser diathermy anywhere on their body. Energy from diathermy (shortwave, microwave, ultrasound and laser) can be transferred through the implanted neurostimulation system, can cause tissue damage and can result in severe injury or death. Injury, damage or death can occur during diathermy therapy even if the implanted neurostimulation system is turned "off."

Potential for Burns

It is possible for ultrasound therapy to cause burns if the therapy is not performed properly. Skin burns can result from one or more of the following:

- If the intensity (power) is too high.
- If you are using too low a frequency.
- Using a stationary technique (holding the sound head in one place).
- Moving the sound head too slowly.
- Treating an area with sensory nerve damage (or the loss of normal skin sensations).
- Desensitized areas can be overheated or burned without the patient's knowledge. Use extreme caution with these patients (e.g., diabetes, neural damage, etc.).
- Bony prominences are especially vulnerable: they reflect sound waves and increase intensity to the periosteum.

Preventing Overheating of the Sound Heads

To prevent the sound head from becoming overheated, do the following:

- Check to be sure proper contact is being made throughout the treatment.
- When treating in water, make sure that the sound head is completely under water.
- 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.

Preventing Adverse Effects

Perform the following procedures to avoid the negative effects of ultrasound therapy.

Sound Head Movement

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, or if the sound head does not maintain good contact with the skin, the therapeutic effect of the sound waves will be reduced and the sound head may overheat.

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.

Output Power

Choose a lower watt setting to reduce output or select a pulsed duty cycle. Higher output levels have a greater potential for patient discomfort.

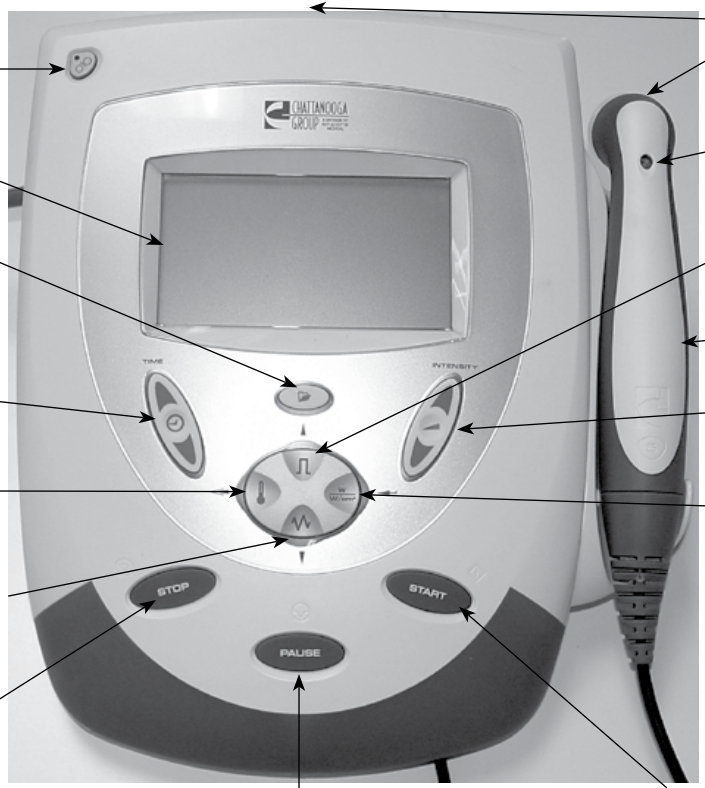
Coupling

Coupling is described as contact between the sound head and the treatment site and may be accomplished through the use of a coupling agent, such as gel, lotion or water (underwater treatments only). Anything used as a coupling agent must be highly conductive. Air is a very poor conductor of ultrasonic waves.

Head Max. Temp. Disclaimer

Head Max. Temp. is for the protection of the equipment, not for the protection of the patient.

NOMENCLATURE



Power On/Off

LCD

Clinical Resources

Time

Head Warming (Back)

Frequency (Down Arrow)

Stop

Pause

Start

Intensity Display (Enter)

Intensity

Applicator

Duty Cycle/Pulse Frequency (Up Arrow)

LED Indicator (Output Power)

Sound Head

LCD Intensity/ Contrast Dial

Sound Head

The aluminum face of the applicator that contacts the patient's skin. It covers a transducer mechanism that converts electrical energy to mechanical energy in the form of a vibrating crystal.

Power On/Off

The Power On/Off button controls the flow of electricity to the unit.

LCD

The LCD (Liquid Crystal Display) allows the user to view and monitor the information displayed during ultrasound therapy. The following information is displayed on the LCD:

- Frequency
- Duty Cycle
- Power
- Treatment Time
- Clinical Indications

Clinical Resources

Select this button to access the following functions:

- Clinical Indications
- Utilities
- Retrieve User Protocols
- Save User Protocols

Use the Up and Down arrow buttons to navigate through the available options.

Time

Press the Up or Down arrow buttons to set total treatment time of therapy.

Head Warming

Select this button to warm the sound head prior to treatment. The sound head is warmed to slightly above body temperature to increase patient comfort. A small icon of a thermometer will appear, and a fan will turn on indicating that head warming is on.

NOTE: The Head Warming function is only possible prior to touching the Start button initiating a treatment, and while the intensity is at 0. When the Start button is pressed, Head Warming is turned off. Also note that when the Head Warming feature is used, a small amount of ultrasound energy is being emitted.

Frequency

Select this button to change to a frequency of 1 MHz or 3 MHz. The Frequency of ultrasound determines the depth of penetration. One megahertz penetrates approximately 3 to 5 centimeters, and 3 megahertz penetrates less than, or equal to 2 centimeters. Both 1 and 3 MHz frequencies are available and can be changed throughout the course of treatment by pressing the Frequency button.

Start

Select Start to begin a treatment session or to accept a protocol.

Pause

Use this button to pause the treatment session. When pressed, the  icon displays. To restart therapy, press the PAUSE button.

Stop

Select this button to stop a treatment session.

NOMENCLATURE

Intensity Display

Select this button to change display from W/cm^2 (Intensity) to Watts (Power).

Intensity

Use the Up or Down arrow to increase or decrease output power intensity.

Applicator

The hand held assembly used to deliver ultrasonic energy. The applicator includes the sound head, transducer, and related electronics.

Duty Cycle

Select this button to change to a duty cycle of 10%, 20%, 50%, or Continuous.

Pulse Frequency

Press and hold the Duty Cycle (down arrow) button to change the pulse frequency in all duty cycles except Continuous. The available pulse frequencies are 16, 48, and 100 Hz.

Battery Indicator

When displayed on the LCD, this symbol indicates the battery pack option is present on the Intelect Mobile Ultrasound. This symbol also displays the charge status of the battery.

LCD Intensity/Contrast Dial

If the intensity of the LCD display diminishes, turn the dial until the display contrast is optimal.

Charge Indicator

This symbol displays when the unit is connected to mains power and the battery pack is charging.

NOTE: During battery operation, if the unit is left on, but not active, for more than five minutes, it will power off to conserve battery power. To restore power, press the Power On/Off button.

Applicator Symbols


This symbol indicates that although the applicator is plugged in, no ultrasound energy (other than the ultrasound energy required to warm the sound head) is being emitted from the applicator.


This symbol indicates that therapy has been started, but the sound head has become uncoupled with the patient's skin.


This symbol indicates that therapy is in progress, the sound head is adequately coupled with the patient's skin, output is being distributed to the patient, and the applicator is functioning normally.

This symbol indicates that the Pause button has been pressed, and no output is being emitted from the applicator.


This symbol indicates that the applicator has been unplugged from the unit.

UNIT SPECIFICATIONS

DIMENSIONS

Height (with base).....16.3 cm (6.4 in)
Width (with applicator).....28.8 cm (11.3 in)
Width (without applicator).....23.9 cm (9.4 in)
Depth (front to rear).....32.8 cm (12.9 in)

WEIGHT

Standard Weight (with applicator and base).....2.3 kg (5.07 lb)
Battery Pack.....0.85 kg (1.87 lb)

POWER

Input.....100 - 240 V - 1.0 A, 50/60 Hz 75 W Max

Electrical Class ..... CLASS I

Degree of Protection Against Electrical Shock .....TYPE B

Degree of Protection Against Ingress of Water .....IPXO

Battery Type..... Nickel Metal Hydride (NiMH)
..... (1.2V x 20 size AA)

ULTRASOUND TECHNICAL SPECIFICATIONS

Sound Heads ..... 1 cm^2, 2 cm^2, 5 cm^2, 10 cm^2

Duty Cycles

Pulsed ..... 10%, 20%, and 50%

Continuous 100%

Pulse Frequency ..... 16, 48, and 100 Hz

Pulse Duration ..... 1 msec, +/-20% (10% Duty Cycle Pulsed Mode)
..... 2 msec, +/-20% (20% Duty Cycle Pulsed Mode)
..... 5 msec, +/-20% (50% Duty Cycle Pulsed Mode)

Output accuracy ..... +/- 20% above 10% of maximum

Amplitude ..... 0 to 2.5 W/cm^2 in Continuous mode, 0-3 W/cm^2 in pulsed modes

Temporal Peak to Average Ratios:

2:1, +/- 20%, for 50% Duty Cycle
5:1, +/- 20%, for 20% Duty Cycle
9:1, +/- 20%, for 10% Duty Cycle

Maximum Treatment Time ..... 30 Minutes

Output

Pulsed ..... 1 MHz signal, modulated 100% by the 100 Hz rectangular wave with the selected Duty Cycle.

Continuous ..... 1 MHz, nominal signal that is activated as long as the timer is operating.

Timer Accuracy ..... +/-0.2 minute

ULTRASOUND TECHNICAL SPECIFICATIONS (CONTINUED)

1 cm² Sound Head

Frequency ..... 3.3 MHz (all +/- 5%)
Power ..... 0 watt to 2 watts
Effective Radiating Area ..... 0.7 cm² – 1 cm²
Maximum beam non-uniformity ratio 5.0:1
Beam Type ..... Collimating
Degree of Protection Against Ingress of Water IPX7
*Coupling ..... 1-2 watts

2 cm² Sound Head

Frequency ..... 1 MHz (all +/- 5%)
Power ..... 0 watt to 4 watts
Effective Radiating Area ..... 1.4 cm² – 2 cm²
Maximum beam non-uniformity ratio 5.0:1
Beam Type ..... Collimating
Degree of Protection Against Ingress of Water IPX7
*Coupling ..... 1-4 watts

5 cm² Sound Head

Frequency ..... 1 MHz (all +/- 5%)
Power ..... 0 watt to 10 watts
Effective Radiating Area ..... 3.5 cm² – 5 cm²
Maximum beam non-uniformity ratio 5.0:1
Beam Type ..... Collimating
Degree of Protection Against Ingress of Water IPX7
*Coupling ..... 2-8 watts

10 cm² Sound Head

Frequency ..... 1 MHz (all +/- 5%)
Power ..... 1 MHz: 0 watt to 20 watts
..... 3 MHz: 0 watt to 10 watts
Effective Radiating Area ..... 6.8 cm² – 10 cm²
Maximum beam non-uniformity ratio 5.0:1
Beam Type ..... Collimating
Degree of Protection Against Ingress of Water IPX7
*Coupling ..... 1 MHz: 2-18 watts
..... 3 MHz: 2-8 watts

*Output range at which Coupling Control, when enabled, is operational. Outside this range, the unit will always indicate coupled.

DESCRIPTION OF DEVICE MARKINGS

The markings on the unit are assurance of its conformity to the highest applicable standards of medical equipment safety and electromagnetic compatibility. One or more of the following markings may appear on the device:

Listed by Intertek Testing Services NA Inc.
UL/IEC/EN 60601-1
IEC/EN 60601-1-2
IEC 60601-2-10

Refer to ACCOMPANYING DOCUMENTS

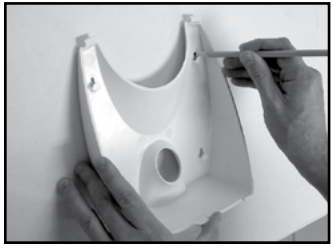
Degree of Protection Against Electrical Shock Type B

EU Directive on Waste Electrical and Electronic Equipment (WEEE), ensures that product is appropriately disposed of or recycled at the end of its life.

MOUNTING THE UNIT ON THE WALL

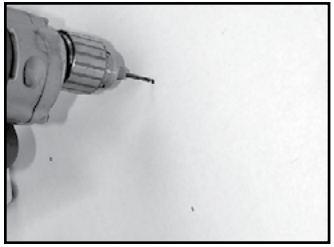
The Intelect Mobile Ultrasound can be operated while the unit is resting on a flat surface, or mounted on a wall. To mount the unit on a wall, do the following:

1. Remove the mounting bracket from the back of the unit.

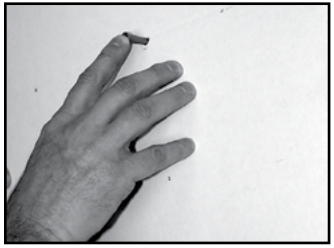


2. Using the bracket as a guide, mark the 4 wall holes with a pencil or pen.

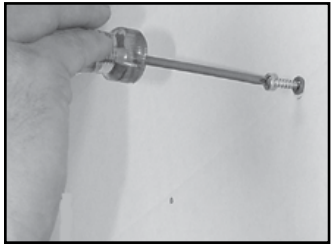
MOUNTING THE UNIT ON THE WALL (CONTINUED)



3. Using a 9/64 (3.6 mm or 0.357 cm) drill bit, drill four holes you marked in the previous step.



4. Press 4 appropriately sized sheetrock anchors into the wall so that the sheetrock anchor is flush with the wall.



5. Screw four #8 flathead wood screws (2.54 cm or 1 inch) into the wall anchors. Make sure you leave 0.635 cm (1/4 of an inch) between the wall and the head of the screw.

MOUNTING THE UNIT ON THE WALL (CONTINUED)

6. Replace the mounting bracket on the back of the unit.

7. Line up the screw heads with the holes on the mounting brackets, and slide the unit down slightly until the screw heads are securely fastened to the mounting bracket.

INSTALLING THE BATTERY PACK

The Intelect Mobile Ultrasound accommodates both AC mains power and an optional battery pack. The pack contains 20 Nickel Metal Hydride (NiMH) drycell batteries. The unit can operate with the rechargeable power supply for approximately five hours of continuous use.
To install the battery pack in the Intelect Mobile Ultrasound, do the following:

1. Locate the battery access door at the bottom of the unit and loosen the screw with a regular screwdriver.

2. Remove the battery access door and retain this cover.

INSTALLING THE BATTERY PACK (CONTINUED)

3. Connect the battery pack cable to the unit's battery connector in the bottom of the battery recess.

4. Put the battery pack into the unit, making sure to orient it as shown.

5. Replace the battery access door and re-tighten the screw using the screwdriver.
6. Reverse the steps in this section in order to remove the battery pack.

CHARGING & USING THE BATTERY PACK

CHARGING THE BATTERY PACK

The battery pack is automatically charged by the unit whenever there is mains power connected. Charging may be interrupted during operation of the unit by the control circuitry to limit total power consumption. A fully charged battery will provide 2-5 hours of treatment depending on the power, duty cycle, and frequency used.

NOTE: Even when the battery pack is connected, the unit will default to mains power.

USING THE BATTERY PACK

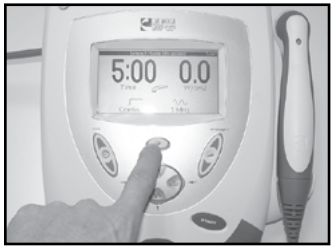
To save battery power, the Intelect Mobile Ultrasound is equipped with a "power off" function. This function is activated when the unit is powered on and has been left idle for approximately 5 minutes, at which time the unit powers off. To restore power, press the Power On/Off button.

USING CLINICAL INDICATIONS

The indications contained in this section are to be used only as guidelines.

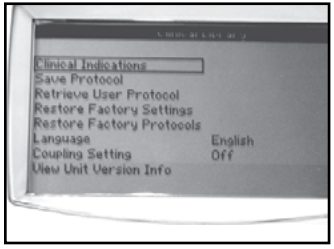
Each patient should be individually assessed to determine the appropriateness of the parameter setting prior to use.

To select an indication for a patient, do the following:



1. Press the Clinical Resources button.

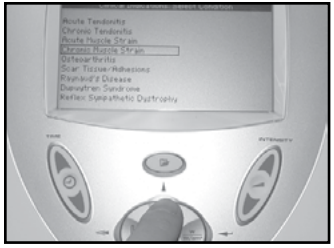
   The Clinical Resources menu displays.



2. Using the Duty Cycle (up arrow) and Frequency (down arrow) buttons, highlight Clinical Indications and press the DISPLAY (enter) button.

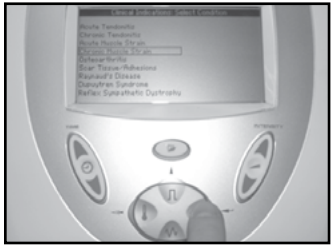
   The Clinical Indications menu displays.

USING CLINICAL INDICATIONS (CONTINUED)



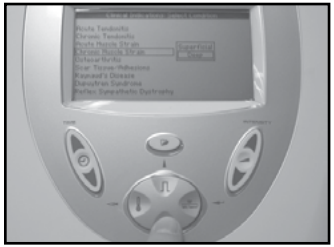
3. Using the DUTY CYCLE (up arrow) and FREQUENCY (down arrow) buttons, highlight the appropriate indication. The following indications are available:

- Acute Tendonitis (Superficial or Deep available)
- Chronic Tendonitis (Superficial or Deep available)
- Acute Muscle Strain (Superficial or Deep available)
- Chronic Muscle Strain (Superficial or Deep available)
- Osteoarthritis (Superficial or Deep available)
- Scar Tissue/Adhesions (Superficial or Deep available)
- Raynaud's Disease
- Dupuytren Syndrome
- Reflex Sympathetic Dystrophy

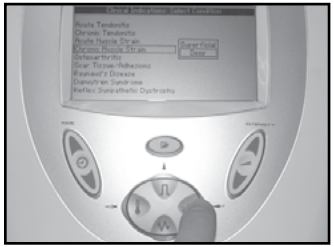


4. Press the DISPLAY (enter) button to accept the highlighted selection.

USING CLINICAL INDICATIONS (CONTINUED)



5. If available, highlight the appropriate ultrasound tissue depth (Superficial or Deep) with the indication you selected using the DUTY CYCLE (up arrow) and FREQUENCY (down arrow) buttons.



6. Press the DISPLAY (enter) button to accept the highlighted selection.

   You are returned to the main screen with the settings from the indication you selected displayed.

7. Review the final protocol settings for the ultrasound treatment. Make any necessary modifications or corrections.

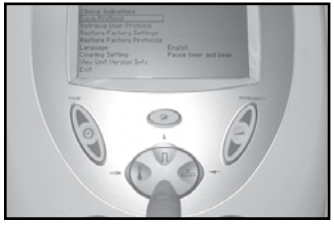
USING CLINICAL INDICATIONS (CONTINUED)

8. Press the Intensity button (either the up or down arrow) to adjust the output to the prescribed intensity.
9. To begin therapy, continue with the instructions outlined in the section entitled "Preparing the Patient's Skin for Ultrasound Therapy" on **page 40**. Then, proceed to **step 7** on **page 43**.

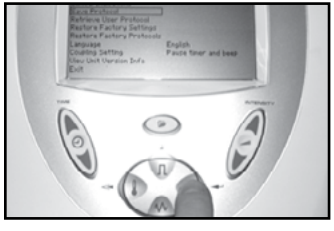
CREATING A USER PROTOCOL

This is a library you create. You may store up to 10 protocols in the User Protocol Library. To create User Protocols, do the following:

1. Make the desired parameter changes.
2. Press the Clinical Resources button.
   The Clinical Resources menu displays.



3. Press the FREQUENCY (down arrow) or DUTY CYCLE (up arrow) buttons to highlight the Save Protocol option.

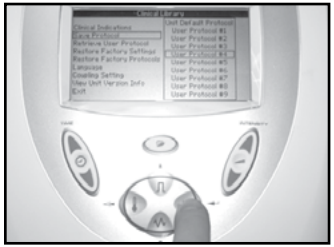


4. Press the DISPLAY (enter) button to accept the Save Protocol selection.
   The Save Protocol menu displays.

CREATING A USER PROTOCOL (CONTINUED)

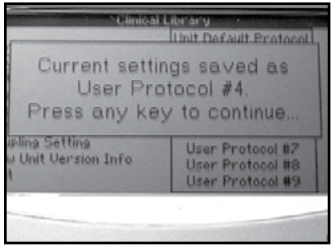
5. Use the DUTY CYCLE (up arrow) and FREQUENCY (down arrow) buttons to highlight any unused user protocol.

   If you select Unit Default Protocol, this will become the protocol displayed when the unit powers up.



6. Press the DISPLAY (enter) button to accept the highlighted selection and save your custom protocol.

   The User Protocol Confirmation window displays to indicate that the protocol is now saved as the number you specified.



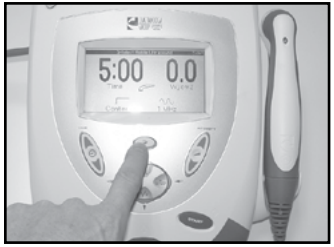
7. Press any button on the Operator Interface.

   The Clinical Resources menu displays and your new user-defined protocol is now saved.

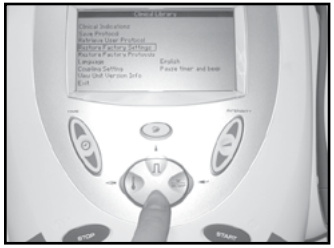
RESTORING FACTORY SETTINGS

Certain default utility settings on the unit may be changed to suit your requirements. These settings consist of the unit's language, coupling settings, and head warming activation. However, you may want to return the unit to its original settings.

To restore the original power up default settings on the unit, do the following:

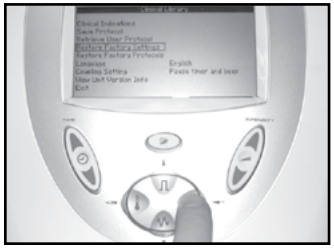


1. Press the Clinical Resources button.
   The Clinical Resources menu displays.

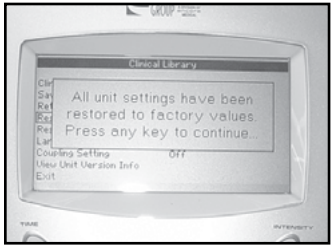


2. Press the DUTY CYCLE (up arrow) or FREQUENCY (down arrow) buttons to highlight the Restore Factory Settings option.

RESTORING FACTORY SETTINGS (CONTINUED)



3. Press the DISPLAY (enter) button to accept the highlighted selection.
   The Restore Factory Settings Confirmation window displays.



4. Press any button to confirm that you have restored the factory settings on your unit.
   The default power up settings are restored and you are returned to the Clinical Resources menu.

RESTORING FACTORY PROTOCOLS

If necessary, you can choose to restore the user-defined protocols to the unit's original parameters when it was shipped to you. To do this, do the following:

1. Press the Clinical Resources button.
   The Clinical Resources menu displays.

2. Press the DUTY CYCLE (up arrow) or FREQUENCY (down arrow) buttons to highlight the Restore Factory Protocols option.

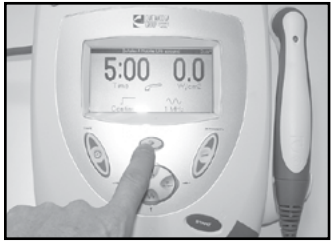
RESTORING FACTORY PROTOCOLS (CONTINUED)

3. Press the DISPLAY (enter) button to accept the highlighted selection.
   The Restore Factory Protocols Confirmation window displays.

4. Press any button to confirm that you have restored the factory protocols on your unit.
   The user-defined protocols are erased and restored to the original parameters. You are returned to the Clinical Resources menu.

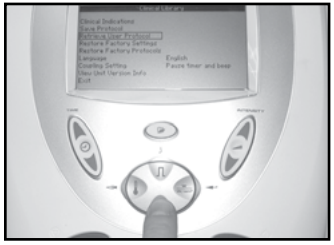
SELECTING A USER-DEFINED PROTOCOL

To select a predefined ultrasound therapy program, do the following:



1. Press the Clinical Resources button.

   The Clinical Resources menu displays.

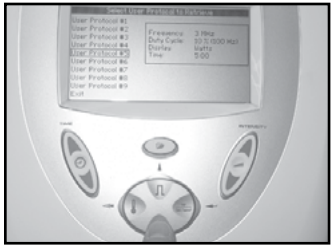


2. Use the DUTY CYCLE (up arrow) or FREQUENCY (down arrow) buttons to highlight the Retrieve User Protocol option.

3. Press the Display (Enter) button to accept the highlighted selection.

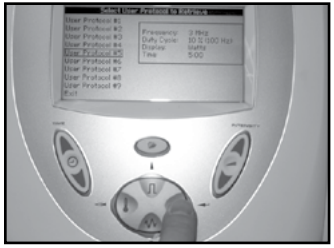
   A list of user-defined protocols displays.

SELECTING A USER-DEFINED PROTOCOL (CONTINUED)



4. Use the FREQUENCY (down arrow) button to highlight the appropriate protocol.

   As you highlight each protocol, a description of the protocol's parameters displays to the right.



5. Press the Display (Enter) button to select the highlighted protocol.

   The main screen displays with the parameters of the protocol you selected.

6. Verify the parameters of this program, and use the appropriate buttons on the Operator Interface to adjust any setting, if necessary. For example, to adjust the time, press the up and down arrows on the TIME button.

7. To begin therapy, perform all the procedures outlined in the section entitled "Preparing the Patient's Skin for Ultrasound Therapy" on **page 40**. Then continue with **step 7** of the section entitled "Starting, Stopping, and Interrupting Therapy" on **page 43**.

PREPARING THE PATIENT'S SKIN FOR THERAPY

Before applying the sound head to the patient, you must first prepare the patient's skin for ultrasound therapy. By properly preparing the patient's skin for ultrasound therapy, you will allow more ultrasound energy to reach the targeted areas and reduce the risk of skin irritation.

To prepare the patient's skin for ultrasound therapy, do the following:

1. Thoroughly wash the skin on which you intend to place the sound head with mild soap and water or alcohol wipe.
2. Dry the skin thoroughly.

3. Apply the ultrasound gel generously to the target area on the patient.

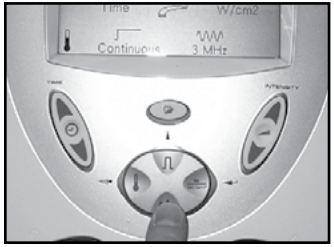
STARTING, STOPPING, AND INTERRUPTING THERAPY

The Operator Interface consists of buttons with a liquid crystal display (LCD). The operator is able to view parameter options on the display and make selections by pressing the buttons on the control panel. The LCD will provide continuous information during the treatments concerning power and elapsed time. Parameters are adjusted using control panel buttons on the front of the unit. The ultrasound output can be stopped by pressing the "PAUSE" or "STOP" buttons located on the control panel.

To apply ultrasound therapy, do the following:

1. Turn system power "ON" by pressing the Power On/Off Button.

   The unit will go through self diagnostics, and the home screen displays on the LCD.

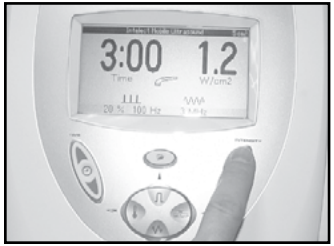


2. Press the Frequency button to select 1 or 3 MHz. When the button is pressed, the frequency will toggle from 1 to 3 MHz and back again as long as the button is being pressed.

   An audible tone will be heard when changes are made.

   NOTE: With 1 cm^2, 2 cm^2, and 5 cm^2 sound head, switching from 1 to 3 MHz results in no change in power (only 3.3 MHz is available with the 1 cm^2 sound head). When using a 10 cm^2 head with greater than 10 watts, changing from 1 to 3 MHz reduces power to 10 watts.

STARTING, STOPPING, AND INTERRUPTING THERAPY (CONTINUED)



3. Press the Duty Cycle (up arrow) button to select 10%, 20%, 50% or Continuous duty cycle. When the button is pressed, an audible tone will be heard as the duty cycle toggles through the options on the LCD.

4. Press and hold the Duty Cycle button to select a pulse frequency of 16, 48, or 100 Hz. You can not change pulse frequency when the Continuous duty cycle is displayed.

5. Press the Time button and raise or lower treatment time using the up and down arrows.

6. Press the Intensity button and raise or lower the unit's output using the up and down arrows.

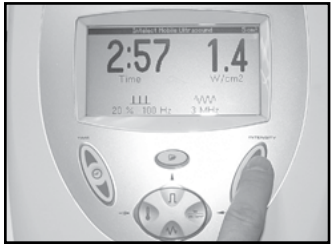
STARTING, STOPPING, AND INTERRUPTING THERAPY (CONTINUED)

7. Press the START button. The unit will beep 5 times and the ultrasound power will distribute the selected output.

   NOTE: When treatment time has expired a tone will sound three times.

8. The therapy can be interrupted at any time by pressing the STOP or PAUSE buttons. When the STOP button is pressed, the applicator stops emitting ultrasound energy, and the unit returns to the default settings. To resume therapy, press the Start button.

   When the PAUSE button is pressed, the  icon displays, the timer pauses, and the applicator stops emitting ultrasound energy. To resume therapy, press the PAUSE button again.



9. The parameters of the therapy can be changed at any time during the therapy session by pressing the appropriate button.

10. After therapy is complete, wipe excess ultrasound gel from the patient's skin and the sound head.

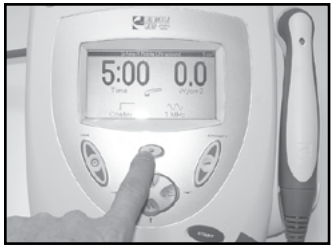
USING THE COUPLING FEATURE

The coupling feature of the Intelect Mobile Ultrasound is designed to indicate when the sound head is not making adequate contact with the patient's skin. "Good coupling" is achieved when the appropriate amount of gel is used, and the sound head is making satisfactory contact to the patient's skin. Good coupling results in the most efficient use of ultrasound therapy.

NOTE: The green light located on the back of the applicator flashes intermittently when the sound head breaks contact with the patient.

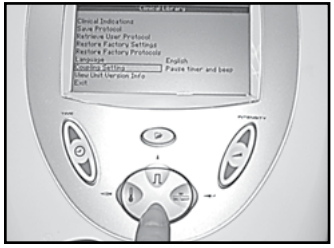
Also, while the sound head is in good contact with the patient, the  icon displays. However, when the sound head breaks contact with the patient's skin, the  icon displays (assuming the Coupling Setting feature is enabled).

To use the coupling feature, do the following:

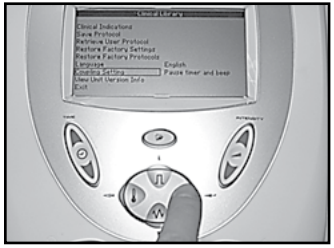


1. Press the Clinical Resources Folder button.
   The Clinical Resources menu displays.

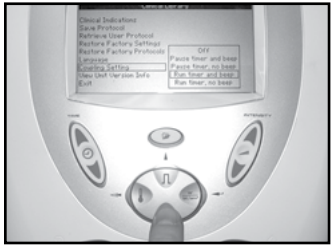
USING THE COUPLING FEATURE (CONTINUED)



2. Press the DUTY CYCLE (up arrow) or Frequency (down arrow) buttons until the Coupling Setting option is highlighted.



3. Press the Display (Enter) button to display the Coupling Settings menu.

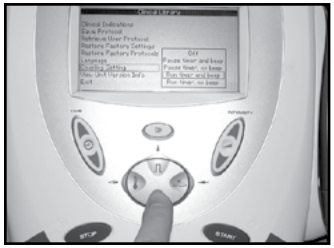


4. Press the Frequency (down arrow) or Duty Cycle (up arrow) buttons to select the manner in which you want to be notified when the sound head breaks contact with the patient's skin. The following list details these options:
   - Pause timer and beep - the timer stops and the unit beeps once. To resume treatment, simply make adequate contact with the patient's skin.
   - Pause timer, no beep - the timer stops but the unit does not give an audible tone. To resume treatment, simply make adequate contact with the patient's skin.

USING THE COUPLING FEATURE (CONTINUED)

- Run timer and beep - the timer continues to count down and the unit beeps once.
- Run timer, no beep - the timer continues to count down, but the unit does not give an audible tone.

NOTE: When the applicator becomes uncoupled during treatment, it continues to distribute ultrasound energy.



5. Press the Display (enter) button to accept the highlighted selection.

SYSTEM UTILITIES

Audible Tones

Audible tones will be heard in the following conditions:

- Any button is pressed.
- The Maximum Temperature for the sound head is exceeded.
- The rechargeable battery's power is low (in which case the Low Battery icon will display).
- Any error message is displayed.
- The sound head becomes uncoupled with the patient's skin and the appropriate coupling option is chosen (**pages 44-46**).
- The therapy time reaches 0:00.

Changing Protocol Parameters

You may change any user protocol or indication parameter prior to or during therapy. To change Frequency or Duty Cycle, do the following:

1. Press either the FREQUENCY (up arrow) or DUTY CYCLE (down arrow) buttons to browse through the provided options.

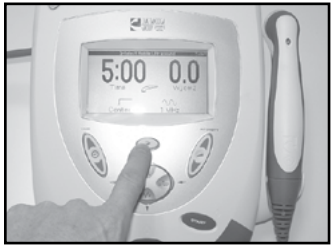
SYSTEM UTILITIES (CONTINUED)

2. To make INTENSITY and treatment TIME changes, touch the respective buttons and use the up or down arrows to advance to the desired settings.

Changing Power-Up Presets

The following power up presets can be changed and stored as new presets:

- Frequency
- Duty Cycle
- Treatment Time
- Intensity
- Pulse Frequency

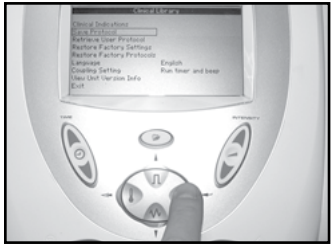


To change the power up presets, do the following:

1. Make the desired changes.

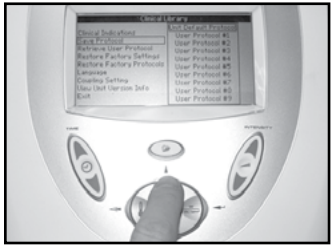
2. Press the Clinical Resources button.
   The Clinical Resources menu displays.

SYSTEM UTILITIES (CONTINUED)

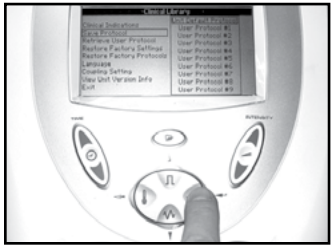


3. Press the DUTY CYCLE (up arrow) and FREQUENCY (down arrow) buttons to highlight Save Protocol, and press the DISPLAY (enter) button to accept the highlighted selection.

   The Save Protocol window displays.



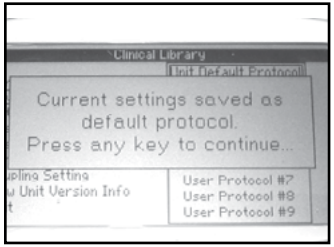
4. Press the DUTY CYCLE (up arrow) or FREQUENCY (down arrow) buttons to highlight Unit Default Protocol.



5. Press the DISPLAY (enter) button to accept the highlighted selection.

   The User Default Protocol confirmation window displays.

SYSTEM UTILITIES (CONTINUED)



6. Press any key to confirm the settings.

   You are returned to the Clinical Resources menu.

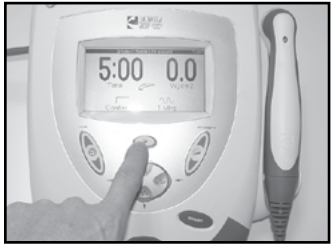
Brightening or Dimming the LCD

To brighten or dim the LCD, turn the contrast control dial until the display contrast is optimal.

SYSTEM UTILITIES (CONTINUED)

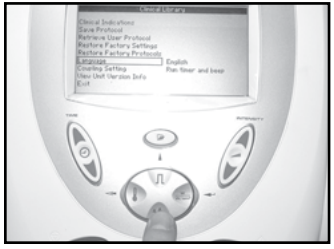
Changing Languages

To change the language displayed on the LCD, do the following:



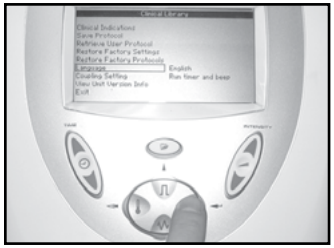
1. Press the Clinical Resources button.

   The Clinical Resources menu displays.

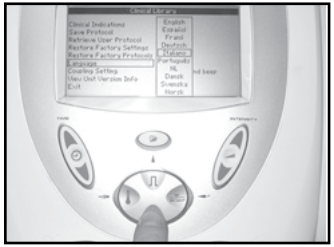


2. Use the FREQUENCY (down arrow) and DUTY CYCLE (up arrow) buttons to highlight the Language option.

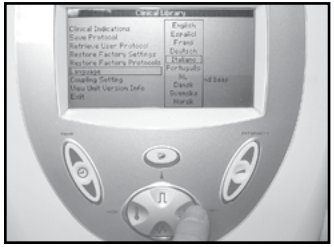
SYSTEM UTILITIES (CONTINUED)



3. Press the DISPLAY (enter) button to accept the highlighted selection.



4. Press the FREQUENCY (down arrow) and DUTY CYCLE (up arrow) buttons to highlight the appropriate language.



5. Press the DISPLAY (enter) button to accept the highlighted selection.
   Your unit now displays the language you selected.

SYSTEM UTILITIES (CONTINUED)

Using the Sound Head Warming Feature

To use the Head Warming feature on the unit, do the following:

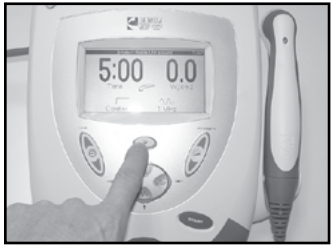
1. Press the Head Warming button.
   The sound head will warm to slightly above body temperature. A small icon of a thermometer will appear on the LCD.

2. Press the Head Warming button again to disable the feature.

SYSTEM UTILITIES (CONTINUED)

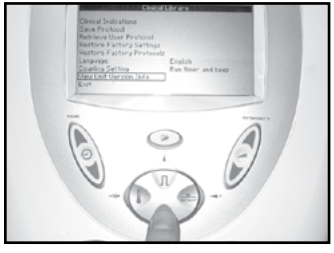
Viewing Unit Version Information

Use this utility to verify that the unit is using the latest software available. To do this, do the following:



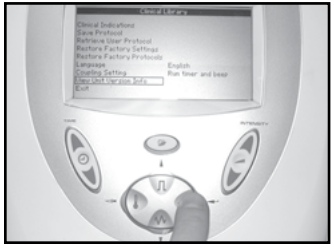
1. Press the Clinical Resources button.

   The Clinical Resources menu displays.



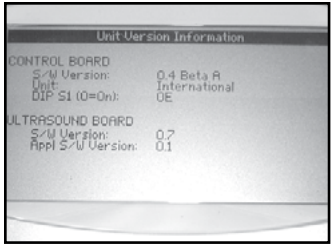
2. Use the FREQUENCY (down arrow) and DUTY CYCLE (up arrow) buttons to highlight the View User Info option.

SYSTEM UTILITIES (CONTINUED)



3. Press the Display button to accept the highlighted selection.

   The Unit Version Information window displays.



4. Press any key to return to the Clinical Resources menu.

STANDARD ACCESSORIES

5 cm^2 Applicator (Blue)-27335

Ultrasound Transmission Gel 9 oz bottle-4248

Power Supply Cord (Euro)-21284

Power Supply Cord (US)-27325

Power Supply Cord (Australian)-20971

Power Supply Cord (Swiss)-20972

Power Supply Cord (UK)-20973

Power Supply Cord (Danish)-20974

Power Supply Cord (Japanese)-20975

Power Supply Cord (Indian)-20976

Power Supply Cord (Israeli)-20977

OPTIONAL ACCESSORIES

1 cm^2 Applicator (Blue)-27333

2 cm^2 Applicator (Blue)-27334

10 cm^2 Applicator (Blue)-27336

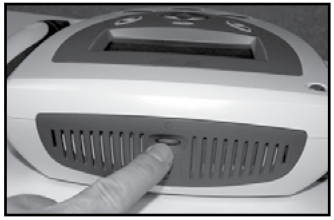
Battery Pack-27478

Intelect Mobile Carrying Bag-27467

Ultrasound Transmission Gel 5 liters-4238

ERROR MESSAGES

Troubleshooting the Display



If you press the Power On/Off button, and the LCD remains blank longer than a few seconds, the contrast may require adjusting. To adjust it, turn the contrast control dial clockwise until the display contrast is optimal.

Troubleshooting Error Messages

The following messages are displayed in the "Status Area" of the LCD under the following conditions.

Message	Displayed When
 Head Over Temp.	sound head reaches a temperature which could damage the crystal
 No Head Detected	sound head not plugged in or faulty sound head

NOTE: Any error encountered by the unit will stop therapy immediately.

MAINTAINING THE INTELECT MOBILE ULTRASOUND

The following items should be checked at least monthly to ensure proper operation of this unit:

- Power cord and plug: Check to make sure the cord is not frayed, kinked, and does not have torn or cut insulation.
- Applicator cable: Check to make sure the cable is flexible, free of kinks, not frayed, and the insulation is intact.
- Sound head face: Check to see that there is no build-up of gel or foreign material on the aluminum face.

Cleaning

To clean the accessories, use only soap and water. Alcohol may be used to disinfect the aluminum surface, but avoid the plastic area.

The Intelect Mobile Ultrasound case may be cleaned by wiping with a damp cloth or mild cleaning solution. Avoid abrasive cleansers.

NOTE: The sound head must be cleaned with alcohol between each therapy session.

Service

The Intelect Mobile Ultrasound must be recalibrated annually. It is recommended that all DJO ultrasound products be returned to the factory or an authorized servicing dealer for repairs or recalibration. Recalibration is also recommended after the replacement or repair of any major component. Should the unit require service, warranty, or repair, please contact the selling dealer or your local DJO customer service.

EU Directive on Waste Electrical and Electronic Equipment (WEEE), ensures that product is appropriately disposed of or recycled at the end of its life.

DJO, LLC ("Company"), warrants that the Intelect Mobile Ultrasound ("Product") is free of defects in material and workmanship. This warranty shall remain in effect for three years (36 months) from the date of original consumer purchase. If this Product fails to function during the three year warranty period due to a defect in material or workmanship, at the Company's option, Company or the selling dealer will repair or replace this Product without charge within a period of thirty days from the date on which the Product is returned to the Company or the dealer.

All repairs to the Product must be performed by a service center certified by the Company. Any modifications or repairs performed by unauthorized centers or groups will void this warranty.

The warranty period for applicators is one year (12 months).

This Warranty Does Not Cover:

Replacement parts or labor furnished by anyone other than the Company, the selling dealer or a certified Company service technician.

Defects or damage caused by labor furnished by someone other than Company, the selling dealer or a certified Company service technician.

Any malfunction or failure in the Product caused by product misuse, including, but not limited to, the failure to provide reasonable and necessary maintenance or any use that is inconsistent with the Product User's Manual.
DJO, LLC is not responsible for injury or damage resulting from modifications or service performed by non-authorized DJO, LLC service personnel.

COMPANY SHALL NOT BE LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

To Obtain Service From Company or the selling dealer under this warranty:

1. A written claim must be made within the warranty period to the Company or the selling dealer.
2. The Product must be returned to the Company or the selling dealer by the owner.

This warranty gives you specific legal rights and you may also have other rights which vary from state to state or location to location.

The Company does not authorize any person or representative to create for it any other obligation or liability in connection with the sale of the Product. Any representation or agreement not contained in the warranty shall be void and of no effect.

**THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED,
INCLUDING ANY WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

chattanooga™

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