Intelect® Legend Ultrasound

USER MANUAL

chattanooga™

ISO 13485 Certified Company

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Welcome to the Intelect Legend Ultrasound

The Intelect Legend US, designed and manufactured by Chattanooga offers a new dimension in 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 Legend US allows you to select a frequency of 1 or 3.3 MHz without changing sound heads. Sound heads are available in 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.

Features of the Intelect Legend Ultrasound

- **Electronic Signature™**
  Automatically calibrate the system to any size Intelect Legend 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.
- **Easy as *One-Two-Go***
  In just two steps you are ready to start treatment, just **set "Intensity" and press "Start."**
- **Tactile Touch Control**
  Digital electronics and new user interface design give you simple tactile touch control of all system parameters.
- **Programmable Start-Up Presets**
  All power-up presets can be individually customized to meet the clinician's needs.

Foreword

This manual has been written for the owners and operators of the Intelect Legend Ultrasound. It contains general instructions for operation, precautionary instructions and maintenance recommendations. In order to obtain maximum life and efficiency from your Intelect Legend Ultrasound and to assist in the proper operation of the unit, read and understand this manual thoroughly and become familiar with the controls on the panel as well as the various accessories that come with the unit before operation of the unit.

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.

Liability Disclaimer

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.

Precautionary Instructions

1. **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.
2. **CAUTION:** DO NOT operate the Intelect® Legend Ultrasound when connected to any unit other than Chattanooga devices. DO NOT operate the unit in an environment of shortwave diathermy use.
3. **WARNING:** Federal law restricts this device to sale by, or on the order of, a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.
4. **CAUTION:** The Ultrasound generator should be routinely checked before each use to determine that all controls function normally; especially that the intensity control does properly adjust the intensity of the ultrasonic power output in a stable manner. Also, determine that the treatment time control does actually terminate ultrasonic power output when the timer reaches zero.
5. **CAUTION:** Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.
6. **CAUTION:** 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.
7. **WARNING:**  Explosion hazard if used in the presence of flammable anesthetics. The warning symbol for this hazard is prominently displayed on the cabinet.
8. **WARNING:** For continued protection against fire hazard, replace fuses only with ones of the same type and rating.
9. **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.
10. **WARNING:** This device should be kept out of the reach of children.
11. **WARNING:** This device should be used only under the continued supervision of a licensed practioner.
12. **CAUTION:** Meets IEC/EN 60601-1-2 Electromagnetic Compatibility/Interference safety standard. (Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.)
13. **WARNING:**  Type B Equipment
14. **CAUTION:** This unit should be operated, transported and stored in temperatures between 15° - 40° C, with relative humidity ranging from 30% - 60%.
15. **ATTENTION:**  Consult accompanying documents.
16. **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."

Principles of Operation

- Initial Setup Instructions
- System Components
  - Standard and Optional Accessories
- Operator Interface
  - Operating Controls

Initial Setup Instructions

Remove the Intelect® Legend US unit and any additional items ordered from the carton and inspect for damage that may have occurred during shipment. Check the voltage rating on the serial decal located on the bottom of the unit. Plug the system power supply in to a 120 Volt to 220/240 Volt AC outlet, as required. DO NOT attempt to use Direct Current (DC). DO NOT attempt to use the unit if it is not properly grounded. DO NOT place unit in a location where the power cord could be tripped over or pulled out during treatment. Follow the procedures listed in the precautionary instructions located later in this section.

System Components

The following accessories are included (standard) with your Intelect Legend Combo.

Item	Part#	Description
1	78047	Applicator, Ultrasound 5 cm^2
2	4248	Conductor™ Gel
3	78201	Operator's Manual

Optional Accessories

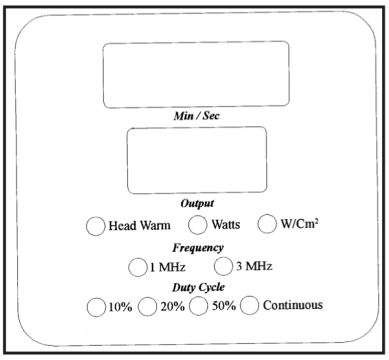
The following is a list of optional accessories available for the Intelect Legend Combo.

Item	Part#	Description
1	78046	Applicator, Ultrasound 10 cm^2
2	78048	Applicator, Ultrasound 2 cm^2

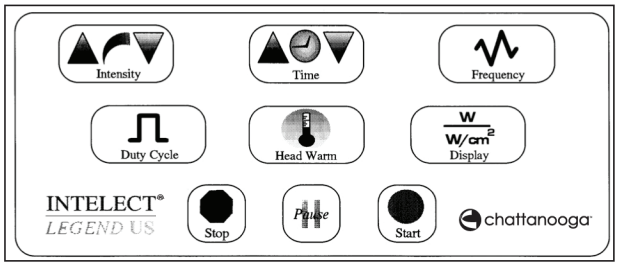
Operator Interface

The operator interface consists of an illustrated control panel with light emitting diodes (LED) and a liquid crystal display (LCD). The operator is able to view parameter options on the LED and LCD readouts and make selections by touching the designated area of the control panel. The displays will provide continual information during the treatments concerning amplitude and elapsed time. Ultrasound and stimulation intensities are adjusted with control panel buttons adjacent to the corresponding LED display. The stimulation / ultrasound output can be stopped by pressing the "PAUSE" or "STOP" buttons located at the bottom of the control panel.

LED Display



Illustrated Control Panel



Operating Controls

1. **LED Screen Display - LED Parameter Display Field.**
   - Displays Treatment Time, Output Intensity, Frequency, Duty Cycle, Display and Head Warm.
2. **Illustrated Control Panel**
   - Membrane switches control LED screen display and treatment parameters.
3. **Intensity (Power)**
   - Select this prompt to set or modify output power intensity.
4. **Time**
   - Select this prompt to set or modify treatment time in minutes.
5. **Frequency**
   - Select this prompt to change to a frequency of 1 MHz or 3.3 MHz.
6. **Duty Cycle**
   - Select this prompt to change to a duty cycle of 10%, 20%, 50% or Continuous.
7. **Head Warm**
   - Select this button to warm the head of the ultrasound applicator prior to treatment.
     NOTE: Turning Head Warm on will be accompanied by a fan turning on and the lighting of the Head Warm LED on the LED display. The fan and the LED will turn off when Head Warm is turned off. A low level of output will be displayed in the output LED display when Head Warm is active.
8. **Display**
   - Select this button to change output display from W/cm^2 (Intensity) to Watts (Power).
9. **Stop**
   - Select this prompt to stop a treatment session.
10. **Pause**
    - Select this prompt to pause a treatment session.
11. **Start**
    - Select this prompt to begin a treatment session.

Indications/Contraindications

Indications

Ultrasound for use in applying deep heat can be used for treatment of selected medical conditions such as the relief of pain, muscle spasms and joint contractures. Those conditions may be associated with adhesive capsulitis, bursitis with slight calcification, myositis and soft tissue injuries. The Intelect® Legend Ultrasound can provide therapeutic deep heating between 40° and 45° C in all of its operating modes, while using any of the applicators available for this device.

Contraindications

Ultrasound should not be used over:

- An area of the body where a malignancy is known to be present.
- The eyes
- The reproductive organs
- An acute infection or sepsis
- A pregnant uterus
- A deep vein thrombosis
- An arterial disease
- An anesthetized area or condition that causes impairment of sensation, such as chemotherapy.
- The epiphyses of skeletally immature children.
- The thoracic area if the patient is using a cardiac pacemaker.
- A healing fracture
- 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.
- 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."

Precautions

Precautions should be taken when used:

- For acute conditions of bursitis and tendonitis that can be exacerbated by the use of ultrasound.
- Over an area of the spinal cord following a laminectomy (i.e., when major covering tissues have been removed).
- On patients with a tendency toward hemorrhaging.

Warnings

- Always keep the applicator 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 sound head on hard surfaces. DO NOT cool the sound head with ice water or ice packs. DO NOT allow the sound head to overheat repeatedly. All of these conditions are likely to damage the sound head crystal.
- **CAUTION:** Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

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 applicator 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 knowing it. 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.

To Prevent Overheating of the Sound Head

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

- **Applicator Movement**
  If movement of the ultrasound applicator is too slow, the patient may feel perosteal pain characterized by a deep ache or pain. If motion is too fast, or if the applicator 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**
  NOTE: Head Max. Temp. is for the protection of the equipment, not for the protection of the patient.

Handle the Ultrasound Applicator(s) with Care

- DO NOT drop the sound head on hard surfaces.
- DO NOT allow the sound head to reach maximum temperatures repeatedly.
- DO NOT cool an overheated sound head with ice water or ice packs.
- All of these conditions are likely to damage the sound head crystal.
- Damage resulting from these conditions is not covered under the warranty.

US - Ultrasound

- Introduction to ultrasound
- Intelect® Legend Clinical Features
- General Setup Steps and Quick Start
- Detailed Setup Steps

Introduction to 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 literature as a reference on the appropriate frequency for your clinical needs.

There are three ultrasound applicators available with the Intelect US: 2cm^2, 5 cm^2 and 10cm^2. You may select either 1 or 3.3 MHz frequencies for each ultrasound applicator. Frequency may be selected either before or during treatment.

Intelect Legend Ultrasound Clinical Features

- **Electronic Signature™**
  Automatically calibrates the system to any size Intelect Legend sound head.
- **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.
- **Ergonomic Applicators**
  A new easy to handle applicator that offers a 20 degree contour in the hand grip. This ergonomic extra will help deliver uniform ultrasound wiht greater clinician comfort.
- **Tactile Touch Control**
  Digitial electronics and new user interface design give you simple tactile touch control of all system parameters.
- **One-Two-Go Format**
  In two steps you are ready to start therapy.
- **Programmable Start-Up Presets**
  All power-up presets can be individually customized to meet the clinician's needs.

General Setup Steps

The unique design of the front panel allows you to set up a treatment faster than ever. Careful grouping of treatment options allow you to easily indentify and select from the appropriate options for a specific mode of treatment. Two simple steps are all that's needed prior to touching Start and initiating treatment.

Power-Up Preset Parameters

Frequency:	1 MHz
Duty Cycle:	20%
Treatment Time:	5 Minutes
Power:	Clinician Controlled

Quick Start

The following is a quick step by step procedure for using ultrasound (US). Before proceeding refer to treatment cautions.

Procedure	**Comments**
Turn power on	The unit will go through self diagnosis, followed by the main menu.
Apply ultrasound gel	Follow steps in preparation for treatment.
Set "Intensity"	Set intensity level for your treatment.
Press "Start"	To begin treatment
End Treatment	Clean area of residual gel.

Detailed Setup Steps

1. Turn System power "**ON**."
2. To preset parameters, as described above, will be displayed on the LED display. To change the power-up presets, see System Utilities (on page 12).
3. Select "**FREQUENCY**."
   Press the Frequency icon to select 1 or 3.3 MHz. When the icon is pressed, frequency will toggle from 1 to 3.3 MHz and back again as long as the icon is being pressed.
   NOTE: With the 2 cm^2 and 5cm^2 heads, switching from 1 to 3.3 MHz results in no change in power. When using a 10 cm^2 head at 11 Watts or greater, changing from 1 to 3.3 MHz reduces power 50%.
4. Select "**DUTY CYCLE**."
   Press the Duty Cycle icon to select 10%, 20%, 50% or Continuous Duty Cycle. When the icon is pressed, the Duty Cycle toggles through the options on the LED display.
5. Select "**TREATMENT TIME**."
   Raise or lower treatment time using the up and down arrow keys in the Time box.
   NOTE: The time section of the parameter display field shows set values only.
6. Increase "**INTENSITY**."
   Raise or lower power using the up and down arrow keys in the Intensity box. Output intensity will be displayed in the Output LED Display.
7. Select "**START**."
   Press Start. The timer will count down and ultrasound power will ramp up.

   NOTE: When treatment time has expired a tone will sound. Wipe excess coupling medium from patient's skin.

Modifying Treatment Parameters

Treatment parameters can be modified prior to or during a treatment session. To modify a parameter, select that parameter on the control panel. Treatment time and output intensity are changed using their designated up or down arrow buttons. Frequency, duty cycle and output display toggle from choice to choice with repeated touches of their respective buttons. You have the choice to make changes on-line while a session is in progress, or you may pause the session by pressing the Pause button and make desired changes. If Pause is your choice, press Start to resume the session after changes are made.

Changing Power-Up Preset Parameters

First, change the parameters to your desired settings. Next, simultaneously touch and hold the Intensity key and the Display key.

Head Warm

Select this option prior to starting a treatment session and the sound head will warm using a percentatge of the unit's power. The Head Warm LED will activate and a fan will turn on indicating heat warming is on.

NOTE: Head Warm is only possible *prior* to pressing the Start button, thereby initiating a treatment. When the start button is pressed, Head Warm is turned off.

Basic Guidelines for Ultrasound Utilization

- **Patient Position**
  - Position the patient in a correct anatomical posture to allow for effective treatment.
  - For example, when attempting to treat the bicipital groove of the humerus, be sure to position the arm in an externally rotated position to expose the target tissue to the ultrasound waves.
- **Importance of Transducer to Skin Contact**
  - Ultrasound energy will not pass into the target tissue if the angle of the transducer head to the surface of the skin is greater than or equal to 15 degrees (Summer and Patrick, 1964).
  - If air is trapped in the coupling agent or between the skin and the transducer, attenuation of the ultrasound energy will occur resulting in diminshed results.
  - The transducer head may be damaged if there is poor contact during treatment because the crystal develops standing waves when the ultrasound vibration is not unloaded (Griffin, 1992).

Appendix

- Warranty
- System Utilities
- Maintenance
- System Troubleshooting
- Technical Specifications

Intelect® Legend Ultrasound
Two Year Limited Warranty

DJO, LLC ("Company") warrants that the Intelect Legend US ("product"), excluding accessories, is free of defects in material and workmanship.

This warranty shall remain in effect for two (2) years from the date of the original consumer purchase of this and extends to any owner of the product during the warranty period. Accessories that are included as standard with the product (as listed in the users manual) are warranted for 90 days. Ultrasound applicators 2 cm^2, 5 cm^2 or 10 cm^2 are warranted for one (1) year. If this product fails to function during the two year warranty period because of defect in material or workmanship, at the Company's option, the company or the selling dealer will replace or repair this product without charge within a period of 30 days from the date on which the defective product is returned to the company or the dealer. The company or the dealer will ship the replacement or repaired product to the owner. All calibration and repairs must be performed by a service center certified by DJO, LLC. Any modifications or repairs performed by unauthorized centers or groups will void this warranty. To participate in warranty coverage, the product's warranty registration card (included with the product) must be filled out and returned to DJO, LLC by the original owner within 10 business days of purchase.

This warranty does not cover:

1. Replacement parts or labor furnished by anyone other than the company, the dealer or an approved company service agent.
2. Defects or damage caused by labor furnished by someone other than the company, the dealer or an approved company service agent.
3. Any malfunction or failure in the product while it is in the possession of the owner during the warranty period, if the malfunction or failure is not caused by a defect in material or workmanship. This includes but is not limited to a malfuntion or failure caused by unreasonable use, applications in which the product was not intended or the failure to prove reasonable or necessary maintenance.

The Company Shall Not be Liable for Incidental or Consequential Damage.

Warranty Registration

Complete the warranty registration card and return it to DJO, LLC within 10 days of purchase. The warranty registration card should be filled out completely with the system serial number and serial number of the included ultrasound applicator. Warranty registration will ensure that you will not be billed for services that are covered by the warranty policy. Complete the entire card included with your system and return postage paid to DJO, LLC.

To obtain service from company or selling dealer under this warranty, the owner must do or abide by the following:

1. A written claim must be made within the warranty period to company or selling dealer.
2. If the claim is made to the company, the written claim should be sent to:

DJO, LLC
1430 Decision St
Vista, CA 92081 USA
T: 1-800-592-7329 USA
T: 1-317-406-2209
F: 1-317-406-2014

3. The product must be returned to the company or 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.

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.

System Utilities

Audible Tones

Audible tones will be heard in the following conditions: Changing Frequency, Duty Cycle or when Max. Head Temp. is exceeded.

Changing Power-Up Preset Parameters

Change the parameters to your desired settings. Simultaneously touch and hold down the Intensity and Display keys.

Changing Power-Up Preset Parameters

Prior to or during a treatment session, any parameter may be changed. To change Frequency or Duty Cycle, press the respective button to scroll through the provided options. As you scroll, an audible tone will be heard to make you aware of the change. Intensity and Treatment Time changes are made by touching their respective buttons then using the up or down arrow keys to advance to the desired settings.
NOTE: Intensity display will first be viewed in the smaller Intensity display box of the parameter display field, after touching Start, the in-treatment display of Intensity will ramp up to your desired setting.

Head Warm

Touch this option prior to starting a treatment session and the sound head will warm, using a percentage of the unit's power. The Head Warm LED will activate, and a fan will turn on, indicating Head Warming is on.
NOTE: Head Warm is only possible *prior* to touching the Start button initiating a treatment. When the Start button is pressed, Head Warm is turned off.

Maintenance Instructions

To fully maintain compliance with Federal Regulation Title 21 (21 CFR), this unit must be recalibrated annually. It is recommended that all Chattanooga 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.

The following items should be 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 or does not have torn or cut insulation.
- **Power Supply:** Check to be sure all connections are secure and there is no build-up of material in the connection area.
- **Sound Head Cable:** Check to make sure the cable is flexible, free of kinks, not frayed and that insulation is in tact.
- **Sound Head Face:** Check to see that there is no build-up of gel or foreign material on the aluminum face.

Cleaning Ultrasound Applicators

To clean these accessories, use only soap and water. Alcohol may be used to disinfect the aluminum surface, but avoid the gray plastic area.
CAUTION: When cleaning, plug input cable into the unit to prevent wetting electrical contacts.

Cleaning Intelect® Legend Ultrasound Case

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

DO NOT immerse unit or power supply and DO NOT spray directly on unit or power supply. It is best to dampen cloth, then wipe surface.

System Troubleshooting

Display Case

The following messages are displayed in the LED display panel under the following conditions:

Ultrasound Message	Displayed When:
HHH	Applicator head reaches a temperature which could damage the crystal.
noHd	No ultrasound head detected.
E 03	An attempt to setup an address on the onewire device failed.
E 04	An attempt to read data from the onewire device failed.
E 05	An attempt to program the onewire device failed.
E 06	The onewire EPROM is full (during cal).
E 08	A device ID was returned from the onewire device that is unknown (i.e., not a 2502 or 2505).
E 08	The ultrasound head is uncalibrated.

Technical Specifications for Intelect® Legend US

Intelect Legend Ultrasound

Dimensions:	8.25″ x 11″ x 2.5″
Weight:	2.9 lbs
Applicators:	2 cm^2, 5 cm^2 and 10 cm^2
Input:	~100 - 250V, 1.0A 50/60 Hz
Output:	⎓ +12V. 4.1A
Fuse:	4.0 A

2 cm^2 Applicator

Frequency (MHz):	1.0 MHz, 3.3 MHz (all +/- 5%)
Power (Watts):	0 to 4 Watts
ERA (cm^2):	1.8 cm^2
Effective Radiating Area:	1.8 cm^2 -0.4/+0.2 cm^2 for the 2 cm^2 crystal
Maximum beam non-uniformity ratio:	5.0:1
Beam Type:	Collimating

5 cm^2 Applicator

Frequency (MHz):	1.0 MHz, 3.3 MHz (all +/- 5%)
Power (Watts):	0 to 10 Watts
ERA (cm^2):	4.0 cm^2
Effective Radiating Area:	4.0 cm^2 +/- 1.0 cm^2 for the 5 cm^2 crystal
Maximum beam non-uniformity ratio:	5.0:1
Beam Type:	Collimating

10 cm^2 Applicator

Frequency (MHz):	1.0 MHz, 3.3 MHz (all +/- 5%)
Power (Watts):	1 MHz: 0 to 20 Watts, 3.3 MHz: 0 to 10 Watts
ERA (cm^2):	8.5 cm^2
Effective Radiating Area:	8.5 cm^2 +/- 1.5 cm^2 for the 10 cm^2 crystal
Maximum beam non-uniformity ratio:	5.0:1
Beam Type:	Collimating

Duty Cycle

Pulsed:	10%, 20%, 50%
Continuous:	100%

Pulse Duration

5 msec +/- 20%:	(50% Duty Cycle, pulsed mode)
2 msec +/- 20%:	(20% Duty Cycle, pulsed mode)
1 msec +/- 20%:	(10% Duty Cycle, pulsed mode)

Ultrasonic Power

Variable from 0 Watts to 20 Watts, 10 cm^2 crystal at 1.0 MHz, 1 - 10 Watts at 3.3 MHz

Variable from 0 Watts to 10 Watts, 5 cm^2 crystal

Variable from 0 Watts to 4 Watts, 2 cm^2 crystal

Output Meter Accuracy

+/- 20% for any output above 10% of maximum

Temporal Peak / Average Intensity Ratio

2:1 +/- 20% for 50% Duty Cycle

5:1 +/- 20% for 20% Duty Cycle

9:1 +/- 20% for 10% Duty Cycle

Output

Pulsed:	1 MHz or 3.3 MHz, modulated 100% by the 100 Hz rectangular wave with the selected Duty Cycle.
Continuous:	1 MHz or 3.3 MHz, nominal signal that is activated as long as the timer is operating

Timer Accuracy

+/- 0.2 minute

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 2.4 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.

Abbreviations

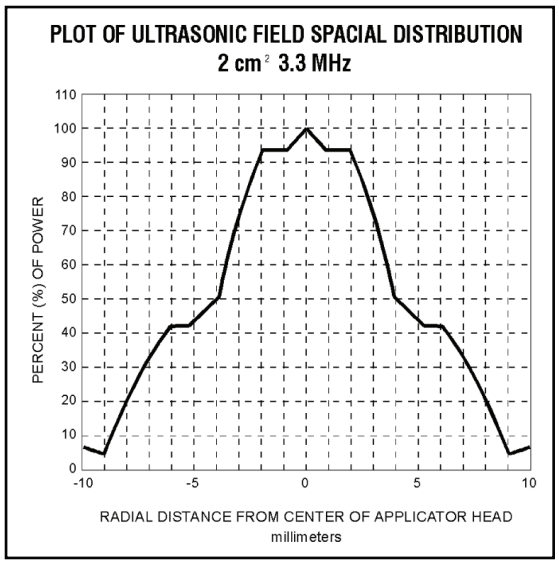
The following abbreviations are used on the sound head of the Intelect® Legend US.

Abbreviation	**Meaning**
Area	Effective Radiating Area
Coll.	Collimating
BNR	Beam Non-Uniformity Ration
Freq.	Frequency

Beam Profile of the 10 cm^2 Transducer Operating at 1 MHz

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.

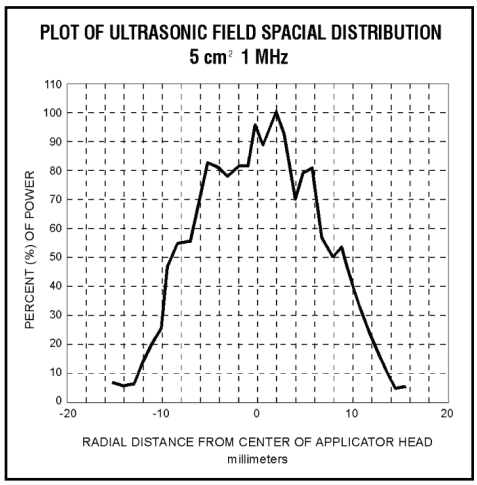
Energy distribution within the radiated field is 2.4 W/cm^2 maximum and it takes a generally conic shape, having decreasing intensity at progressively increasing distance from the face of the transducer. This field distribution applies for the radiation emitted into the equivalent of an infinite medium of distilled, degassed water at about 30° C and with power line variations in the range of +/- 10% of the rated voltage.

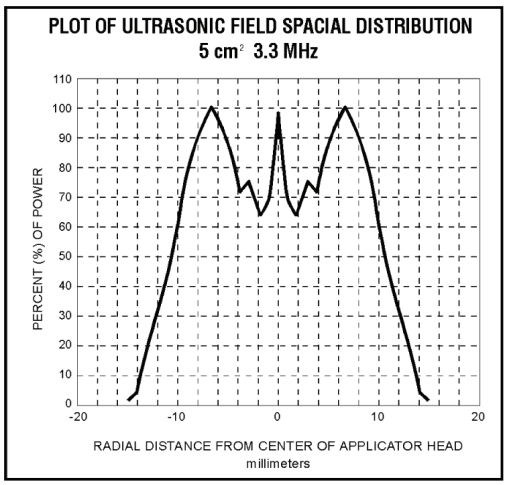


Beam Profile of the 5 cm^2 Transducer Operating at 1 MHz and 3.3 MHz

Spatial distribution of the radiated field is essentially a collimated beam of the ultrasonic energy having a cross-sectional area of 4.0 cm^2 for the 5 cm^2 sound head when measured at a point 5 mm from the transducer face.

Energy distribution within the radiated field is 2.5 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 about 30° C and with power line variations in the range of +/- 10% of the rated voltage.

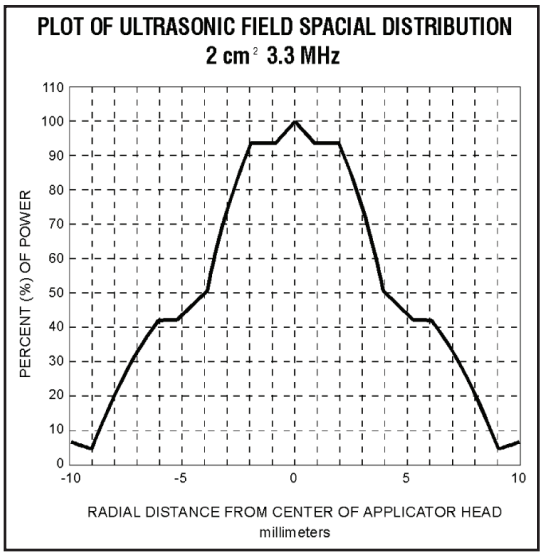




Beam Profile of the 2 cm^2 Transducer Operating 3.3 MHz

Spatial distribution of the radiated field is essentially a collimated beam of the ultrasonic energy having a cross-sectional area of 1.8 cm^2 for the 2 cm^2 sound head when measured at a point 5 mm from the transducer face.

Energy distribution within the radiated field is 2.22 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 about 30° C and with power line variations in the range of +/- 10% of the rated voltage.



Glossary

Beam Non-Uniformity Ration – 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 6.0:1. Because of the areas of increased intensity, the sound head is moved continuously during the treatment.

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 is recommended.

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 burst-on time in the Russian Waveform and 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 – Selectable to 1 or 3.3 MHz with the 5 cm^2 or 2 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) to 3,300,000 (3.3 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) or w/cm^2.

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 throughout the treatment period.

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 (Applicator) – The applicator used for delivery of ultrasound to the patient. An aluminum face contracts the patient's skin. It covers a transducer mechanism that converts electrical energy to mechanical energy in the form of a vibrating crystal.

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).

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