Portable Ultrasound

US PRO 2000™ 2nd Edition
INSTRUCTION MANUAL

Model # DU3035

CAUTION: Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner

This manual is valid for the DU3035 US PRO 2000™ 2nd Edition
Portable Ultrasound Unit

Declaration of conformity:
Roscoe Medical,Inc. declares that the US Pro 2000™ 2nd Edition complies with the following normative documents:
IEC60601-1, IEC60601-1-2, IEC60601-2-5, IEC61689, ISO 7010, ISO14971, ISO10993-1, ISO10993-5, ISO10993-10, IEC 60601-1-11

Complies with MDD 93/42/EEC and Amended by directive 2007/47/EC requirements.

It is important that you read all the warning and precautions included in this manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the device.

CAUTION: United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner by the law of the State in which he/she practices, according to 21 CFR 801.109.

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FORWARD

This manual contains general information on the operation, precautionary practices, and maintenance information of the DU3035 US Pro™ 2000 2nd Edition. In order to maximize the use, efficiency, and life of the device, please read the manual thoroughly and become familiar with it before operating the device. In particular, pay attention to:

1. Keep yourself informed of the contraindications.
2. The device may not be used in close proximity (i.e. less than 2 meters) to shortwave equipment.
3. The device may not be used in so-called "wet rooms" (hydrotherapy rooms).

The manufacturer cannot be held responsible for the results of using this apparatus for any purposes other than those described in these operating instructions.

INTENDED USE

The US PRO 2000™ 2nd Edition is a portable ultrasound device that generates deep ultrasonic waves within body tissues for the treatment of selected medical conditions such as pain relief, muscle spasms, and joint contractures, but not recommended for the treatment of malignancies. This is an FDA regulated product available by prescription only. Keep out of reach of children.

EXPLANATION OF ULTRASONIC STIMULATOR EFFECT

The US PRO 2000™ 2nd Edition is an ultrasonic therapeutic device that generates pulsed high frequency sound waves (1MHz) that are transferred to a specific body area via a sound head probe. The pulsed sound waves travel deep into the tissue to generate vasodilation, which helps increase blood flow to the treated area.

Therapeutic ultrasound is found to help relieve pain and reduce muscle spasms and is one of the most frequently used therapies by physicians and physical therapists. Most patients will feel nothing at all during treatment, while some patients may feel slight warmth.

CONTRAINDICATIONS

1. Do not use over or near bone growth centers until bone growth is complete.
2. Do not use over a healing fracture.
3. Do not use over the eyes.
4. Do not use on patients with implanted neurostimulation systems because tissue damage can occur at the location of the implanted electrodes resulting in severe injury or death. This can also damage the system components.
5. Do not use to treat malignancies, nor in the region where malignant tumors are present.
6. Do not use on patients with demand type cardiac pacemakers.
7. Do not use on someone who is pregnant.
8. Do not use over ischemic tissues in patients with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and may result in tissue necrosis (tissue death).
9. Do not use over the carotid sinus nerves or arteries, laryngeal or pharyngeal muscles.

PRECAUTIONS

1. Do not use on patients with hemorrhagic diatheses (excessive bleeding disorders).
2. Do not use over an area of the spinal cord following a laminectomy, i.e., when major covering tissues have been removed.
3. Do not use over areas that are under anesthesia.
4. Avoid bony prominences.
5. When using ultrasound, keep the sound head moving while maintaining contact with the skin.
6. If treatment becomes uncomfortable, stop treatment and contact your physician.
7. Do not immerse the portable ultrasound in water or other solvent.
8. Do not use over metallic implants, especially prostheses with a cement-matrix.
9. Only use the UL certified AC adapter that is included in the product case.

⚠ CAUTIONS

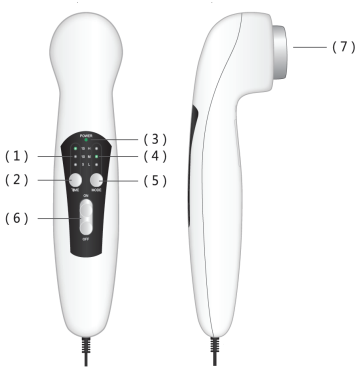
1. Always use this device under the directions of a physician.
2. Patients with the following diseases, symptoms or conditions should not use the device:
   - During pregnancy or menstrual cycle.
   - Acute disease, heart disease, tubercle disease, facial neuralgia (sharp facial pain), pernicious tumor, hemophilia, high fever, abnormal blood pressure, or under any unhealthy conditions.
   - On patients with sensitive physical conditions, ringworm, dermatitis, and any infectious disease.
   - On persons who are unable to effectively express themselves such as: infants/small children, mentally disabled individuals, individuals under the influence of alcoholic beverage, or during extreme fatigue.
   - Product should not be applied on the following areas: any wounds, the mouth, neuralgia (sharp painful) spots, surgical areas, sunburned skin, sensitive skin and over skin implants made of metal, plastic or silicone materials.
   - Do not use with other electronic equipment, such as ECG machine etc., even if this device conforms to the EMC requirements.
3. **DO NOT** use on the thoracic region if you have a pacemaker.
4. **DO NOT** use on areas where malignant tumors are present.
5. **DO NOT** use on the areas of blood inhibited tissue, because there is not enough blood supplied to the area to meet the metabolic demand, and this could result in tissue necrosis (tissue death).
6. **DO NOT** use the device on persons with bleeding issues/disorders.
7. **DO NOT** use on areas under anesthesia.

⚠ WARNING

- The device complies completely with all parts of 21 CFR 1050.10 under the performance standard for sonic, infrasonic and ultrasonic radiation-emitting products.
- Use of controls or adjustments to performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

PARTS OF THE DEVICE

(1) TIME INDICATOR LIGHT
(2) TIME BUTTON
(3) POWER INDICATOR LIGHT
(4) INTENSITY INDICATOR LIGHT
(5) MODE BUTTON
(6) POWER SWITCH
(7) ULTRASOUND HEAD



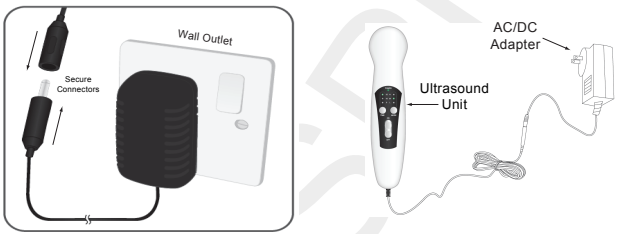
SPECIAL FEATURES

1. All the ultrasound parts are assembled and tested under strict process controls.
2. To ensure quality, the device has been designed with a single chip microprocessor.
3. Precious alloy round-headed probe creates a smooth surface on the skin.
4. The device has an attractive exterior and was ergonomically designed so that it fits to the human hand and is easy to hold and convenient to use.
5. Single-button control, microcomputer makes the device easy to use.
6. Designed with three output intensities and three treatment time selections to meet a wide range of therapy requirements.
7. The device has a head warming feature that pre-heats the sound head applicator for increased patient comfort.

STEPS TO CONNECT THE ADAPTOR

US Pro™ 2000 2nd Edition requires the following steps for proper setup:

1. Ultrasound transmission gel is required when treating a patient with the US Pro™ 2000 2nd Edition portable ultrasound device.
2. The AC/DC adapter is required to power the device. No battery is used.
3. Join the male connector of the AC/DC adapter to the female connector of the ultrasound unit. Be sure you have a secure fit. Then plug the AC/DC adapter into a wall outlet to power the unit. The DU3035 US Pro™ 2000 2nd Edition is now ready for treatment.
4. Follow the "INSTRUCTIONS FOR USE" section of this manual.

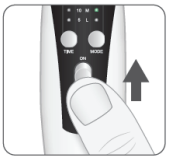


⚠ WARNING

The device can only be used safely with the original adapter it came with. DO NOT re-assemble or change the specification of the adapter. Doing so may cause damage to the unit and/or personal injury. Be sure to follow the specific assembly instructions stated above.

INSTRUCTIONS FOR USE

Please read this instruction manual carefully before using the US Pro 2000™ 2nd Edition Portable Ultrasound Unit.



1. Turning on the device and head warming feature:
Turn the device on by sliding the power switch upwards (towards "ON"). The power indicator light will illuminate. The device will automatically enter the preheat mode. The six indicator lights will flash alternately during this period.

When the preset temperature is reached or the maximum preheat time has ended (3 minutes), all of the indicators lights will flash five times. Once complete, the device enters standby mode. This head warming feature takes approximately three minutes from a cold/room temperature start to finish.

If the warming feature is not needed, press both the "MODE" button and the "TIME" button simultaneously. The device will go back to standby mode. When the device is in standby mode, the modulation duty cycle is defaulted at 5% and the (L) indicator light will be illuminated.

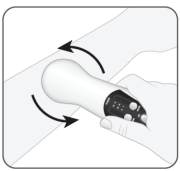
⚠ **WARNING:** During the head warming period, the following items should be noted:

- The device will automatically exit the head warming feature if any load is detected in the preheating process. Therefore, do not apply the ultrasound head to the patient during the warming period.
- To restart the warming feature, you will have to power off the device and turn it back on again.

2. Apply transmission gel:
Wash the area to be treated so that it is free of oil and dirt. Apply a generous layer of ultrasound transmission gel on the treatment area. The gel acts as a coupling substance and ensures effectiveness. The area treated should be two times the diameter of the sound head.

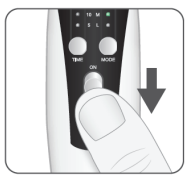
3. Set ultrasound intensity:
Press the “MODE” button to select the modulation duty cycle. The mode button has three levels, Low (L) - 5%, Medium (M) - 50% and High (H) - 100%, each level corresponds to a LED light indicator.

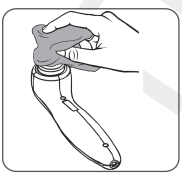
4. Set treatment time:
Press the "TIME" button to cycle through the treatment time (5, 10 and 15 minutes), as shown by the “TIME” indicators. When the time is chosen, the system will start working. During working time, the user can press the "TIME" button to adjust the treatment time.



5. Place sound head on treatment area and begin treatment:
Move the sound head in a slow, flat, circular motion over the skin surface of the treatment area. Apply the sound head evenly (in time) over the treatment area (see page 11 for **Load Detection System Caution**).

6. Turn off the device:
After completing the treatment session, the device will automatically shut off and all indicator lights will be off. Power off the device physically by sliding the power switch downwards (towards “OFF”). Unplug the unit from its power source.





7. Clean the device after every use:
With device turned off, clean the ultrasound head / probe with a wet towel or soft tissue. Do not immerse the device in water. Always store device in its protective case at room temperature in a dry location.

⚠ LOAD DETECTION SYSTEM CAUTION:

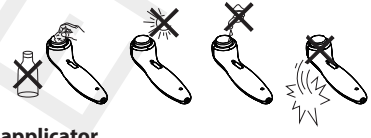
1. The device has a **load detection system** for safety. When the treatment head does not have good contact with the skin, the device will stop treatment automatically, and the time indicator light will flash one time. The device will not continue the treatment program until good contact is made.

2. The device has a temperature protection function. When the temperature of the treating head exceeds 107°F (42°C), the treatment will automatically stop and the time indicator light will flash two times. The device will not continue the treatment program until the temperature is below 104°F (40°C).

MAINTENANCE

Switch off the device and disconnect it from the power supply. The device can be cleaned with a damp cloth. Use lukewarm water and a non-abrasive liquid household cleaner (no abrasive, no alcohol content solution). If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

CAUTION: Do not submerse the device in liquids. Should the unit accidentally become submersed, contact the dealer or Authorized Service center immediately. Do not attempt to use the device that has been submersed in any liquid substrate until inspected and tested by a Service Technician certified by an Authorized Service Center.



Cleaning of the applicator

The applicator should be regularly inspected for damage, e.g. hairline cracks, which could allow the penetration of liquids. Clean the contact surface immediately after each treatment. Make sure that no ultrasound gel remains on the applicator. We further recommend cleaning the head, cable and adapter daily, using a soft cloth damped with lukewarm water. The applicator can be disinfected using a cloth moistened with an antimicrobial cleaner.

STORAGE CONDITIONS

When not in use, store the device with the adapter in a dry room and protect it against extreme moisture, heat and direct sunlight. Never place any heavy objects on the storage case.

- STORAGE CONDITIONS: 14°F ~ 122°F; 20% - 93% RH

TROUBLESHOOTING

The device is manufactured through complete quality assurance system. If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the device should be serviced.

Problem	Possible Cause	Solution
POWER LED fails to light up	✧ The plug of the adaptor is not inserted into the socket properly. ✧ The DC plug of the adaptor is not inserted into the DC receptacle on the device correctly. ✧ Did not press the ON/OFF button.	✧ Insert the plug of the adaptor into the socket again. ✧ Connect the adaptor with the device again correctly. ✧ Press the ON/OFF button again.
POWER LED is performing normally, but no output function occurs.	✧ Output intensity button setting is incorrect.	✧ Please make sure and set it again.

UNIT SPECIFICATIONS

Specifications		
Item		Description
Ultrasound Probe	Ultrasound Modulation Frequency:	1.0MHz±10%
	Max. Output Power:	6.4W±20% (Modulation duty cycle at100%)
	Output Power:	L: 0.32W±20% M: 3.20W±20% H: 6.40W±20%
	Pulse Repetition Rate:	100Hz±10%
	Modulation Duty Cycle:	L (5%), M (50%), H (100%)
	Effective Radiating Area:	4.0cm^2± 20%
	Waveform:	Pulsed
	BNR (Max):	5.0
	Max. Effective Intensity:	1.6Wcm^2±20% (Modulation duty scycle at 100%)
	Effective Intensity:	L: 0.08W/cm^2±20% M: 0.80Wcm^2± H:1.60Wcm^2±20%
	Working Time:	Adjustable at 5 minutes, 10 minutes, 15 minutes
	Preheat Temperature:	Max. 35±5 degree centigrade (NOTE: Actual preheat temperature will be influenced by the environmental temperature and preheat time.)
	Preheat Time:	Max. 3 minutes
	Dimension:	202 mm (L) x 49 mm (W) x 70 mm (H)
	Weight:	193g (without adapter)
	Material of Applicator:	Aluminum Alloy
	Beam Type:	Collimated
	Degree of Protection against Water:	IPX7 (Only for Treatment Head)
Power Adapter	Input:	Voltage: AC 100--240V Frequency: 50Hz/60Hz
	Output:	Output voltage: DC 15V, Max. Currency: 1.2A
Buttons	Time:	Choose working time: 5m — 10m —15m —0m (stop)
	Mode:	Choose modulation duty cycle: 5% —50% — 100%
Indication Lights	Time Indication Lights:	5, 10, 15 minutes
	Duty Cycle Indication Lights:	Low (L), Medium (M), High (H)

Program Lists

PROGRAM	MODULATION DUTY FACTOR	WAVE CHARACTER	OUTPUT POWER W/cm^2
L	5%	Low	0.08±20%
M	50%	Medium	0.8±20%
H	100%	High	1.6±20%

Operating Conditions: 5°C ~ 40°C; 30% ~ 75%RH; 800~1060hPa

PRESCRIPTION STATEMENT

CAUTION: United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner by the law of the State in which he/she practices, according to 21 CFR 801.109.

GLOSSARY OF SYMBOLS

Type BF Applied Part

Caution

Type of protection against electric shock: Class II Equipment

Electrical devices are recyclable material and should not be disposed of with household waste after their useful life. Help us to protect the environment and save resources by taking this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in area if you have any questions.

Refer to instruction manual

IPX7 Only for treatment head: Protected against the effects of temporary immersion in water.

SN Serial number

LOT Batch code

ELECTROMAGNETIC COMPATIBILITY (EMC)

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices. In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by Roscoe Medical, Inc. conform to this IEC60601-1-2:2007 standard for both immunity and emissions. Refer to EMC table guidance supplied in this manual regarding the EMC environment in which the device should be used.

Special precautions need to be observed:

- The use of accessories and cables other than those specified by Roscoe Medical may result in increased emission or decreased immunity of the device.
- Care must be taken when operating this device adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
- The performance of the device was determined to be essential performance. This device has been thoroughly tested according to tested and inspected to assure proper performance and operation.

TABLE 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The DU3035 device is intended for use in the electromagnetic environment specified below. The customer or the user of the DU3035 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The DU3035 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The DU3035 device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Applicable	

TABLE 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The DU3035 device is intended for use in the electromagnetic environment specified below. The customer or the user of the DU3035 should assure that it is used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line (s) to line (s)	±1 kV line (s) to line (s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commerical or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is needed that hte device be powered from an uninterruptible power supply.

TABLE 3

Guidance and manufacturer's declaration - electromagnetic emissions

The DU3035 device is intended for use in the electromagnetic environment specified below. The customer or the user of the Du3035 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DU3035 device, including cables, than the recommended seperation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended seperation distance:** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$, 80MHz to 800MHz $d=2.3\sqrt{P}$, 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE I: At 80 MHz ends 800 MHz the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3]V/m.

TABLE 4

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

LIMITED WARRANTY

We warranty each new US Pro™ 2000 2nd Edition (excluding gel, wires and adapter) for one year from defects in materials and workmanship from the original date of purchase. This warranty applies only to the original purchaser. The original invoice or receipt must accompany all returns.

This warranty does not cover abuse, accident, or damage resulting from failure to follow operating instructions. The warranty is voided if the unit has any alterations or has been disassembled. We shall not be liable for any direct or indirect consequential damages resulting from the use of this unit.

Some states do not allow limitations on how long an implied warranty lasts or the exclusion or limitation of incidental or consequential damages, so the above limitations may not apply to you. This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

Product: US Pro™2000 2nd Edition

Model: DU3035

Serial Number: _____

Date of Purchase: _____

Distributor: _____

ROSCOE MEDICAL™

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