US PRO 2000 2ND EDITION

INSTRUCTION MANUAL

Richmar®

This manual is valid for the

US Pro™ 2000 2nd Edition Portable Ultrasound

This user manual is published by Richmar.

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

Conformity to safety standards

Richmar declares that the device complies with following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-2- 10, IEC60601-1-4, ISO10993-5, ISO10993-10, ISO10993-1

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1. GENERAL INFORMATION

1.1 Device Information

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.

1.2 Medical Background

EXPLANATION OF PAIN

Pain is a warning system and the body's method of telling us that something is wrong. Pain is important; without it abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies. Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design.

Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until the coded message travels to the brain where it is decoded, analyzed, and then reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is then interpreted, referred back and the pain is felt.

1.3 Foreword

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. Information regarding contraindications for using the device.
2. **DO NOT** use in close proximity (i.e. less than 2 meters) to shortwave equipment.
3. **DO NOT** use in "wet rooms" (hydrotherapy rooms).

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

2. IMPORTANT SAFETY INFORMATION

Read instruction manual before operating. Be sure to comply with all "Contraindications", Warnings", "Cautions" and "Adverse reactions" in the manual. Failure to follow instructions may cause harm to user or device.

Safety Symbols Used in this Manual	
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device or other property.

2.1 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 sever injury or death. This can also damage the system components.
5. **DO NOT** use to treat malignancies, not 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.

2.2 Warnings and Cautions

⚠ WARNINGS:

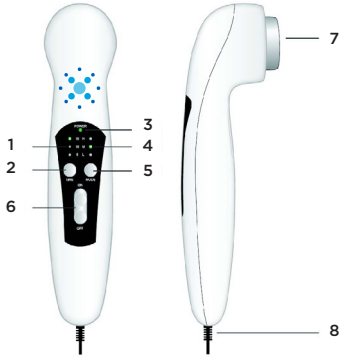
1. **DO NOT** use on patients with hemorrhagic diatheses (excessive bleeding disorders).
2. **DO NOT** use over an area of the spinal cord following a laminectomy, i.e., when major covering tissues have been removed.
3. **DO NOT** use over areas that are under anesthesia.
4. Avoid bony prominences.
5. 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.
10. The device complies completely with all parts of 21 CFR 1050.10 under the performance standard for sonic, infrasonic and ultrasonic radiation-emitting products.
11. Use of controls or adjustments to performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

⚠ 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.
   - Production 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 requirement.
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.

3. PRESENTATION

3.1 Construction



1. Time Indicator Light
2. Time Button
3. Power Indicator Light
4. Intensity Indicator Light
5. Mode Button
6. Power Switch
7. Ultrasound Head

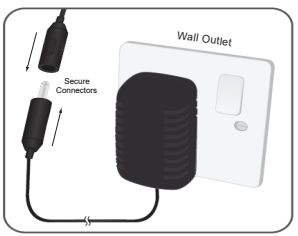
3.2 Features and Benefits

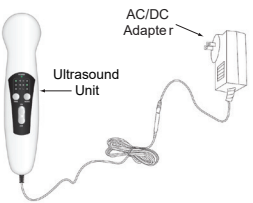
1. All the ultrasound parts are assembled and tested under strict process controls.
2. To ensure quality, the device has been designed with a single chip microprocessor.
3. Precious alloy round-headed probe created a smooth surface on the skin.
4. Produces both pulsed and continuous ultrasound therapy.
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. Head warming feature that PRE-HEATS (does not continually heat during treatment) the sound head prior to starting treatment for increased patient comfort.

3.3 Steps to Connect the Adapter

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 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

This device can only be used safely with the original adapter it came with. **DO NOT** reassemble or change the adapter to meet other requirements (including converters or adapters to meet outside US, countries) Doing so may cause damage to the unit and/or personal injury and will void the warranty on the device.

This device is not intended to be used in a clinical setting. This device was developed to be used at home with the guidance and prescription from a physician for no more than 2-3 times a day at 15 minute intervals. Be sure to follow all assembly and use instructions.

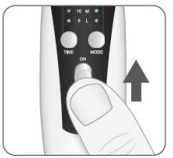
4. SPECIFICATIONS

	Item	Description
Ultrasound Probe	Ultrasound Modulation Frequency	1.0MHz±10%
	Max. Output Power	6.4W±20% (Modulation duty cycle at 100%)
	Output Power	L: 0.32W±20% M:3.20±20% H: 6.40W±20%
	Pulse Repetition Rate	100Hz±10%
	Modulation Duty Cycle	L(5%), M(50%), H (100%)
	Effective Radiating Area	4.0cm²±20%
	Waveform	Pulsed
	BNR (Max):	5.0
	Max. Effective Intensity:	1.6Wcm²±20% (Modulation duty cycle at 100%
	Effective Intensity:	L:0.08W/cm²±20% M: 0.80Wcm²±20% H:1.60Wcm²±20%
	Working Time:	Adjustable at 5 minutes, 10 minutes, 15 minutes
	Preheat Temperature: (Pre-treatment warming only. Does not warm during treatment)	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:	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)
Operation Conditions		5°C - 40°C; 30% - 75%RH; 800-1060hPa

5. INSTRUCTIONS FOR USE

5.1 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 had 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.
Note: Head warming feature that PRE-HEATS 9does not continually heat during treatment) the sound head prior to starting treatment for increased patient comfort.

5.2 How to Cancel the Warming Feature

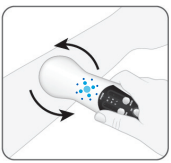
If the warming feature is not needed, press both the “MODE” button and the “TIME” button simultaneously. The device will go back to standby mode. When the device is in standby mode, the modulation duty cycle is defaulted at 5% and the (L) indicator light will be illuminated.

⚠ **WARNING**:

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

1. 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.
2. To restart the warming feature, you will have to power off the device and turn it back on again.

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 get on the treatment gel. The gel acts as a coupling substance and ensures effectiveness and safety. The area treated should be two times the diameter of the sound head.

	**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.
	**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.
	**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. ⚠ **WARNING:** If the motion is not consistent enough or stops, it could cause potential harm. Keep the ultrasound moving while in contact with the treatment area.
	**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.
	**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.

5.3 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 once. 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 twice. The device will not continue the treatment program until the temperature is below 104°F (40°C)

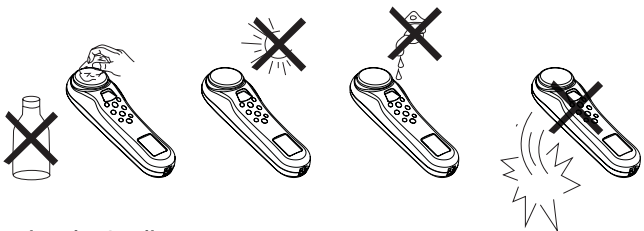
6. Program

PROGRAM	MODULATION DUTY FACTOR	WAVE CHARACTER	OUTPUT POWER W/cm²
L	5%	Low	0.08±20%
M	50%	Medium	0.8±20%
H	100%	High	1.6±20%

7. MAINTENANCE AND CLEANING

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 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.

8. STORAGE

1. For prolonged pauses in treatment, store the device in a cool dry room and protect it against heat, sunshine and moisture.
2. Store the device in a cool, well-ventilated place.
3. **NEVER** place any heavy objects on the device.
4. Storage Conditions: 14°F ~ 122°F, 20% ~93% Relative Humidity

9. TROUBLESHOOTING

The device is manufactured through complete quality assurance system. If there are any performance problems, please check the chart below for problems you can fix. Performance problems often result from little things that you can find and fix at home without tools. This can save you the cost of a service call.

PROBLEM	CHECK POINTS	POSSIBLE SOLUTION
LED light does not turn on.	1. The plug adapter is not inserted into the socket properly 2. The DC plug of the adapter is not inserted into the DC receptacle on the device correctly. 3. Did not press on the ON/OFF button	1. Insert the plug of the adapter into the socket again. 2. Connect the adapter with the device again correctly. 3. Press the ON/OFF button again
LED is performing normally but no output function occurs	Output intensity button setting is incorrect	Please make sure and set it again.

For technical documentation or support, please contact your local distributor or the manufacturer as shown on the label.

10. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

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 Compass Health Brands Corp. conform to this IEC50501-1-2:2007 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:

1. The use of accessories and cables other than those specified by Compass Health Brands Corp. may result in increased emission or decreased immunity of the device.
2. Care must be take when operating this device adjacent to or stacked with other equipment. Potential electromagnetic or other interference by not using other equipment in conjunction with it.
3. 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.

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user assures that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The 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	Group B	The device is suitable for use in all establishments including 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	

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

Guidance and manufacturer's declaration - electromagnetic emissions.

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

Immunity test	IEC 60501 test level	Compliance level	Electromagnetic environment guidance
Conduct-ed RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF Communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=[\frac{3.5}{V1}]\sqrt{P}$ $d=[\frac{3.5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E1}]\sqrt{P}$ 800 MHz to 2.5 MHz 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 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.

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM 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.
2. Over the frequency range 150 kHz to 80 MHz, field strength should be less than (3i) W/m.

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) as recommended below, according to the maximum output power of the communications equipment

Rate maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	800 MHz to 2,5 GHz $d=[\frac{3.5}{V1}]\sqrt{P}$
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 9m0 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) accordable to the transmitter manufacturer.
NOTE 1: 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 propogation is affected by absorption and reflection from structures, objects and people.

11. GLOSSARY OF SYMBOLS

SN	Serial number
	Attention: Read the operating instruction before use! Equipment capable of delivering output values in excess of 10mA r.m.s. or 10V r.m.s. averaged over any period of 5s.
	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 and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.
	Type BF Applied Part
	Type of protection against electric shock: Class II Equipment
	Refer to instruction manual
IPX7	Only for treatment head: Protected against the effects of temporary immersion water.

12. WARRANTY

Please contact your dealer in case of a claim under the warranty. If you have to send the unit back to your provider, enclose a copy of your receipt and state what the defect is.

The following warranty terms apply:

1. The warranty period for device is one year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs or replacement under warranty **DO NOT** extend the warranty period either for the device or for the replacement parts.
3. The following is excluded under the warranty:

    - All damage which has arisen due to improper treatment, e.g. non-observance of the user instruction.
    - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
    - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the retailer.
    - Accessories are not included in device warranty.
    - If used in a clinic setting and not for intermittent home use.
    - If adapter was modified or replaced with adapter not supplied by the manufacturer

Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

1. All products must be returned in original packaging and must contain all components, accessories and user manuals. If any components are missing, you will be responsible for the cost of the replacement component and the 25% restocking fee.
2. All returns must be approved with a Return Authorization Number. Please call our Customer Service Team at (800) 376-7263 to obtain a Return Authorization Number. Provide the following information when calling:
    - Item Number
    - Original Order Number
    - Product Serial Number/Lot Number
    - Reason for Return
3. The Return Authorization Number must be marked clearly on the returned carton and is valid for 10 business days from the date of issue.

4. Returned merchandise must be in the same unit of measure as originally purchased.
5. Return Labels or Call Tags can be issued by our customer service department to return merchandise.
6. Associated fees and return freight charges will apply. All returns of dropshipped items are subject to a restocking fee as well as inbound and outbound freight charges.
7. Returns will not be accepted on items that are:
    - Missing their serial number
    - Special order items
    - Returned more than 30 days after delivery
    - Returned without notification

Manufactured for:

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