apollo

APOLLO Portable Laser Control Unit

Operator Manual

Model AP2-PT

PIVOTAL Health Solutions

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FDA DECLARATION

Pivotal Health Solutions, Inc. confirms that the APOLLO AP2-PT Desktop Laser unit and probes as specified in this operating manual meet and fully comply with the following Federal guidelines:

21 CFR 1002.10
21 CFR 1040.10
21 CFR 1040.11

Furthermore, the APOLLO unit does not cause radio interference with other equipment and complies with Federal guidelines on Radio Interference as defined in IEC60601-1-2:2001.

Curtis Turchin, MA, DC
Managing Member
Pivotal Health Solutions, Inc.
January 2011

Indications of use:
The Apollo IR Heat Lamp System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/ or promoting relaxation of muscle.

APOLLO PACKAGE CONTENTS

Maximum POWER System:
APOLLO AP2-PT Portable Control Unit
APOLLO 3000-C Laser Cluster Probe

Standard Accessories:
6 foot Probe Cable
AC Power Adapter
Battery Charger/ Alternate Battery
Safety Goggles (x2)
Leatherette Carrying Case
Light and Laser Therapy: Clinical Procedures
or Veterinary Laser Therapy

Optional Accessories:
APOLLO AP2-500-S Laser Probe
APOLLO PT-FINETIP Fine Tip Light Guide (Acu-tip)

INTRODUCTION

The APOLLO AP2-PT Portable Laser Therapy System:
Apollo, the Greek God of Sun and Healing, brought warmth and life to Earth. Now the Apollo Engineering Team has harnessed these powerful forces to create state-of-the-art laser therapy devices at a popular price. The system is FDA cleared as an "Infrared Heating Device". The AP2 Portable Laser Unit is a redesigned and enhanced version of the original APOLLO unit, with advanced programmable features, an LCD display and a built in optical power meter.

Fast, Effective Treatment: With the APOLLO Portable you can experience the future of laser therapy today. Only Apollo brings you power, performance and portability in such a compact, sleek design.

The APOLLO is also a easy to use therapeutic laser. Just turn the key, wait 4 seconds, press the probe switch and experience the performance of a powerful cold lasers. No complicated settings or adjustments..

Improved Patient Outcomes: The APOLLO harnesses laser technology. Using Apollo's perfect marriage of power and wavelength, you are assured of fast, comfortable treatments, exceptional clinical results and an impressive bottom line.

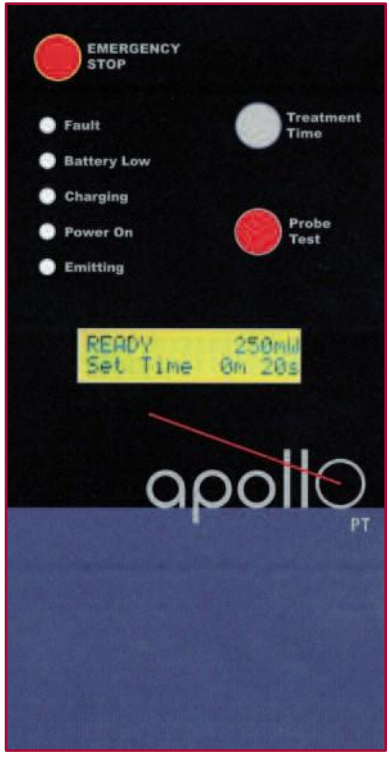
OUTWARD APPEARANCE

The APOLLO AP2-PT Portable Control Unit

The APOLLO AP2-PT Portable Control Unit is housed in an anodized, extruded-aluminum case. The LCD display, LED's and switches are located on the top panel. The Laser Probe connector & key switch are located on the front; the Remote Interlock and DC inlet are located on the back panel. APOLLO Laser Probes are precision-machined from aerospace-grade, then anodized for enhanced protection.

The Product/Manufacturer ID label and Certification label are located on the bottom panel of the APOLLO case. Warning labels are located on the front panel of the APOLLO case and on the Laser Probe.

Weight and measurements are described in **Technical Parameters**.



OUTWARD APPEARANCE

The APOLLO AP2-PT Portable Laser Therapy System:

Back Panel

INDICATIONS AND CONTRAINDICATIONS

Intended Use: The Apollo IR Heat Lamp System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

Contraindications:

- **Direct Irradiation of the eyes:** Class 3b and 4 lasers are potentially harmful to the eyes. Laser safety goggles must be worn by both patient and practitioner.
- **Pregnancy:** Although there are no studies showing any dangerous side effects, we advise avoiding the user of laser during pregnancy.
- **Carcinoma:** Do not use the laser over known primary or secondary tumors.
- **Thyroid:** Do not use directly over the thyroid gland.
- **Infections:** The laser is not intended to treat viral or bacterial infections. The probe should not be used in contact with bodily fluids (such as open wounds). Alternatively, treatment through a disposable protective barrier, such as Smith and Nephew OpSite Transparent Dressing, may be applied before treatment then discarded.
- **Immune Suppressant Drugs:** Although there are no studies showing any dangerous side effects we advise avoiding use of the laser since it can stimulate the immune system.

a drug will trigger a response, however we suggest "at risk" patients or patients with a history of such reactions be "patch tested" for the minimum recommended treatment time.

- **Reaction to Treatment:** Sensations such as localized feelings of warmth, tingling, or an increase or decrease in symptoms may be reported within the 24-hour period immediately following treatment. Sensations such as nausea or dizziness may be experienced in response to laser therapy. In patients with severe treatment reactions the Laser treatment should be discontinued.
- **Topical Lotions:** Lip balms, creams, lotions, etc. can contain chemicals that attract light and can cause smoking or burns. Always clean skin thoroughly before laser treatment.
- **Tattoos, Pigmented Tissues, and Sensitive Regions:** Dark pigments, tattoos, marker-pen inks, melanin, and other natural or man-made pigments may absorb light. Use caution when treating over a dark tattoo as the patient may feel a sensation of heat. Sensitive areas with dense hair follicle distribution, such as the hairline, upper neck, top lip, etc. may also cause discomfort or a sensation of heat, especially on individuals with darker-colored hair.
- **Pins, Metal Plates, Plastics, and Pacemakers are not contraindicated.** The laser may be safely used over metal implants, plastics, and stiches and on patients with a pacemaker.

SAFETY INFORMATION AND PRECAUTIONS

Do not connect non-Apollo probes or accessories. The use of non-Apollo components is potentially dangerous and will void the warranty.

Do not alter the unit or attempt self-repairs. Do not open the control unit (except for battery replacement with an Apollo supplied replacement battery) or disassemble the probe. Contact Pivotal Health Solutions to obtain authorized service center information.

Remote Interlock: A remote interlock connector is available on the back panel of the Apollo for attachment of this optional safety circuit. If the safety circuit is installed the Apollo will not operate when the circuit is broken (i.e. the door is open).

Safety Accessories: The Apollo is a Class 3B and 4 laser product. Appropriate eyewear is supplied with the Apollo device and additional eyewear is available from your Apollo dealer.

Safety Warnings:

- Read the user manual carefully before using the laser.
- This equipment is to be used only under the prescription and supervision of a licensed practitioner.
- Remove key when not in use to prevent unauthorized access.
- Use only the AC adapter provided. Replace if damaged only with Apollo dealer or service center provided parts.
- Apollo should be used only in appropriate work environment. Do not use where there is danger of explosion or water damage.
- Use Apollo on a solid, horizontal surface.
- Do not place Apollo in proximity of devices that emit strong electric, magnetic, or electro-magnetic fields (motors, transformers, x-rays, etc.) which can cause interference.
- Do not place in direct sunlight.
- Do not use the Apollo if mechanical or water damage is apparent.
- The Apollo should be checked periodically (recommended monthly) for loose cable, loose connections, damaged cords and cables, damaged diodes, and damaged display functions. Contact Pivotal Health Solutions for repair instructions.
- Do not irradiate sensitive areas such as eyes, head, thyroid gland or other endocrine glands. Do not use over cancer or pre-cancerous tumors, with patients on immune suppressant drugs, or if patient is pregnant.
- The probe should not contact potentially infectious bodily fluids (such as open wounds). Treatment for such areas may be done with use of Smith & Nephew OpSite Transparent Dressing, or an equivalent protective barrier.
- Patients should be monitored for skin changes over the course of laser treatments and changes in skin should be evaluated and treatment protocols adjusted or discontinued as appropriate.
- Wear appropriate safety eyewear during treatment.
- Do not use the Apollo is areas that contain flammable gases and/or explosive compounds.
- Display appropriate warning signs outside the immediate laser work area.
- Do not disconnect the probe or turn the unit off while irradiating.
- Handle probes with care. Probes are not water (or oil) resistant.
- The user is responsible for compliance with State and/or Federal laws that apply to the ownership or user of the Apollo device.
- **The Apollo emits a class 3B or 4 laser beam. During therapy with the Apollo you must follow all instructions in this manual. The manufacturer will not accept responsibility for damage due to improper use of the instrument.**
- **Not for use in an oxygen-rich environment.**
- **During use, storage, and transport of APOLLO, no toxic radiation is emitted.**

MAINTENANCE, ROUTINE MAINTENANCE AND UNIT CARE

With appropriate care and maintenance your Apollo should provide years of reliable operation. However, as the Apollo ages laser components may require service to maintain optimal operating condition.

Replacement of laser diodes can be your most expensive maintenance item and care of the power system and probe should increase the life of the diodes and decrease your overall maintenance expenses.

Unit Care:

- **Storage and Use**: It is recommended to use and store the device in a dry, dust-free location. This device should never be placed in water. Do not use the device if there is any visible damage, especially to the power adapter.
- Refer to the SERVICE AND CLEANING section for complete cleaning and disinfection instructions.
- **Do not store power cords or probe cables tightly wound.** Permanent bends may develop and weaken or damage the cord and cable wires. Damaged wires decrease the stability of electrical signals and laser diode damage may result.
- **Replace damaged power supply units and probe cables.** Power fluctuations from use of damaged cords or cables may decrease the life of the laser diodes.
- **Surge Protector:** Use of a surge protector can decrease the risk of damage from mains power fluctuations.
- Protect probe from contact with oil, water, and other liquids that could damage the laser diodes.
- Avoid buildup of hair on probe, damage can result.

Routine Maintenance:

- **Cleaning/Disinfection:** Periodic cleaning and disinfection may be needed. Full details are in the SERVICE AND CLEANING section of this manual. The user is responsible for providing and using cleaning and disinfecting materials.
- **Inspection:** Inspect device monthly for loose cables, loose connections, damaged cords and cables, display issues, or other damage. Contact Pivotal Health Solutions if issues are found.
- Battery maintenance: See the "Battery Care and Use" section for full details on battery use and maintenance.
- Battery replacement: Typical batteries last 18-24 months. If you are getting less life review the sections on the battery or call Pivotal Health Solutions to discuss if your process can be optimized.
- **Calibration:** Laser diodes age with use and power output may change slightly over time. Routine (annual is recommended) calibration of your unit and will keep your probe output at the expected output and will also help identify any potential service issues early. Pivotal Health Solutions has rental laser units available for use during calibration and/or service. Call Pivotal Health Solutions for availability of a rental.

Maintenance:

- The user may replace the battery pack with an Apollo authorized battery pack. See the section in this manual on "Replacing the Battery" for instructions.
- There is no other user maintenance. Do not attempt other repairs or disassemble the probe.
- If the unit goes to 'fault' during use of the unit (except when the Emergency Stop button was pressed) contact Pivotal Health Solutions for instructions on obtaining authorized diagnosis of the fault and/or repair.

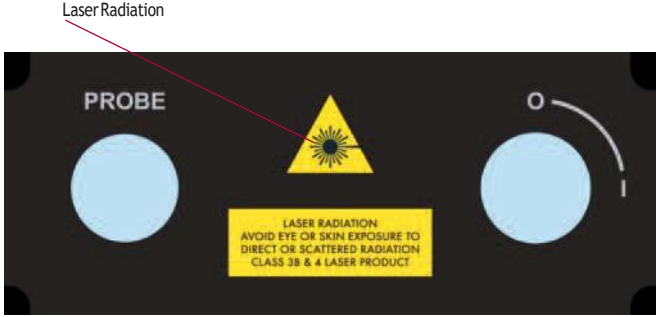
APOLLO QUICK-START GUIDE

READ THE OPERATING MANUAL BEFORE USING THE APOLLO LASER
CLASS 3B & 4 LASER EMISSION IS HAZARDOUS TO THE EYE SAFETY GOGGLES MUST BE WORN BY THE PATIENT & OPERATOR AT ALL TIMES DURING TREATMENT

Key Switch: When the key is in the 'O' position, the laser is 'safe', i.e., it cannot be operated.

When the key is in the 'I' position, the laser is 'ready for use', and must be treated with caution to prevent eye injury.

Ensure the key is in the 'O' position before following the instructions below.



Assembly: The APOLLO is shipped with the battery partially charged. You may use the unit immediately. The alternate battery should be charged for 30 hours on the stand alone charger before its first use.

Carefully unpack the APOLLO Control Unit and place on a sturdy and level surface, or in the optional carry bag. Place in a cool, dry environment out of direct sunlight. Do not place APOLLO in proximity of devices that emit strong electric, magnetic, or electro-magnetic fields (motors, transformers, etc.). The electromagnetic interference from such devices could cause damage to the APOLLO Laser Unit.

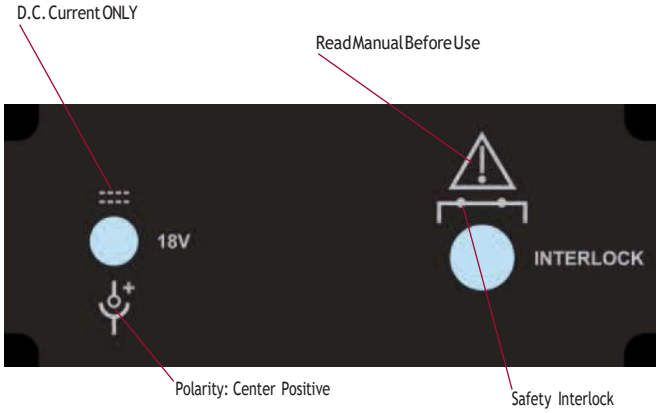
Carefully connect the Probe Cable to the Control Unit and Probe. Align the pins on the Probe Cable Connectors with the sockets on the Probe and Control Unit (there is a small orientation lug on the Probe Cable Connector that fits into a corresponding gap in the Probe and Control Unit Sockets) and press firmly until the plug is fully seated in the socket.

Do not twist the plug as this may damage the pins.

SWITCHING ON

Battery Operation: When battery power is low the yellow "Battery Low" LED on the Apollo unit will illuminate indicating it is necessary to switch to an alternate battery that has been fully charged. The depleted battery that has been removed from the Apollo Unit should be charged on the stand alone charger so that it is ready for use.

NOTE: For maximum battery performance, charge the alternate battery for 30 hours on the stand alone charger before first use.



Switching On: Turn the key in a clockwise direction to the '|' position. The green 'Power On' LED will illuminate and the LCD display will come on. After a 4-second delay the LCD display will change from "Standby" to "READY" and a beep will be heard. The LCD display will also show the power rating of the probe that is connected in the top right of the display window.

The unit is now ready for use. Pressing the "Treatment Time" switch will change the treatment time if required. NOTE: pressing the treatment time switch will put the Laser Unit back in the standby mode. After 4 seconds of the treatment time switch not being pressed, the Laser Unit will beep and revert to the "READY" mode.

TREATMENT

Starting Treatment: Place the patient on a treatment table, chair or stool in a stable position. They can be sitting, prone, supine or side-lying. The patient and clinician should be wearing safety goggles.

The control unit should be on a flat sturdy surface and positioned close to the patient. Hold the probe in one hand with your thumb positioned over the probe switch. Always be sure to have the rounded glass lens of the probe head flat against the area of the patient to be treated. The glass lens should be in direct contact with the patient's skin.

Press the Probe switch to begin emission. The yellow "Emitting" LED will illuminate while emission is in progress. Three short beeps will be heard as a warning that emission is about to start. Press the probe switch again to stop treatment.

Stopping Treatment: The output may be stopped at any time during treatment by pressing the Probe switch. Emission will cease, and the LCD display will stop counting down and two short beeps will be heard. Pressing the Probe switch again will cause treatment to re-start and the treatment time will continue counting down from where it was stopped. NOTE: pressing the "Treatment Time" switch after treatment was stopped, will re-set the treatment time to the original set time.

Emission may also be stopped immediately by pressing the red 'Emergency Stop' switch. This puts the unit into a "Fault" condition and the key switch will need to be switched off and then back on to reset the Laser Unit.

Probe Power Measurement: The probe power output can be measured during treatment by aiming the laser output at the "Probe Test" window. The power is displayed on the LCD display in milliwatts (mW). NOTE: for the Cluster Probe each individual laser output has to be measured. See ADVANCED OPERATION – Probe Power Measurement for further instructions.

When treatment is complete, return the key to the 'O' position.

BATTERY CHARGING AND CARE:

Battery Performance: Whenever wall power is available the AP2- PT portable laser should be plugged in during treatments to preserve the battery. In situations where wall power is not available, the AP2-PT portable laser has a NiMH battery that will provide enough power to operate the unit unplugged for approximately 60 treatment minutes (thirty 2-minute treatments) depending on probe wattage. An additional battery and external charger are provided with the unit so that a fully charged battery can be available when the battery in use is depleted. When the 'low battery' LED on the control unit illuminates the battery in use needs charging. It is recommended the stand alone charger be used to charge batteries off-line so that a fully charged battery can be ready when needed. Additional batteries and chargers may be purchased through Pivotal Health Solutions.

The Apollo Control Unit also has a built-in battery charger intended for overnight charging, or whenever the Control unit is not in use for an extended period of time.

Charging Setup: Charging a battery installed in the Apollo Unit requires the supplied AC power adapter to be connected to the DC inlet on the Laser Control Unit. The power adapters on the Control Unit and External charger will operate from any electrical outlet supplying voltage from 100 to 240V AC, 50 or 60Hz.

CAUTION: The power adapter provided with your Unit is a medical grade power adapter and the only type that is approved for use with the APOLLO Portable Laser Unit. Do not use a non-Apollo provided portable power adapter. Doing so could compromise the electrical safety of the product and cause an electric shock hazard. It could also damage the laser diodes.

Charging Methods:

1) **Built-in Charger**:
   The control unit has a built-in charger that will charge a fully depleted battery to full capacity in 18 hours. To use the built-in charger the unit must be plugged in and the key in the 'off' position. The 'Charging' light will illuminate when charging. The built-in charger can be used with the unit unattended, such as overnight, since the key is removed and authorized use cannot occur.

2) **Stand-Alone Charger**:
   The standalone charger will charge a fully depleted battery to capacity in 18 hours. The charging LED on the power adapter is red while charging, and will turn green when the battery is fully charged.

Note: Before first use, charge the alternate battery for 30 hours using the stand alone charger.

Instructions for changing the battery are provided on page 29.

BATTERY CHARGING AND CARE:

For most situations, the user will charge both batteries overnight utilizing both the built in charger, and the standalone charger. This allows both batteries to be fully charged and ready for use the next day. The standalone charger can then be used to charge depleted batteries off line and alternate to the unit as needed. To prevent shortening battery life, do not leave a battery charging for more than 2 days.

Charging Guidelines:

Infrequently Used Batteries: The batteries are meant to be used regularly. Infrequently used batteries may decrease their response to charging, may decrease treatment time provided and may lead to more frequent battery replacement.

Battery Low LED:
The "Battery Low" LED will illuminate when the battery voltage is low and at the point where laser output will start to reduce. When probe output decreases by 20% the "Fault" LED also illuminates and the anthe laser is put into fault condition, preventing further use. (This safety feature is a regulatory requirement and prevents ineffective treatment due to low output.)

Both the External and built-in chargers utilize a Slow (trickle) charge which applies a low current to the NiMH battery over an extended period of time. This protects the battery cells from damage and ensures extended battery life. The Slow charge current means the battery can be left on for up to 2 days in this trickle charge mode without damaging the battery. Leaving the battery on charge for longer than this on a regular basis could shorten the battery life, and is not recommended. A battery does not need to be completely depleted before charging and does not need to be fully charged before use.

However, it is recommended for maximum battery life that the External charger and additional battery be utilized to fully charge batteries off-line so that they can be inserted into the unit to replace a worn out or undercharged battery. The Apollo Unit's built-in charger should be used primarily for overnight charging with the key in the off position.

Battery Life:
Appropriately charged, used, and maintained batteries can be expected to provide consistent power for 18-24 months. User replaceable battery packs are available. Contact Pivotal Health Solutions or your dealer. Do not use non-Apollo batteries in the laser.

Treatment Timer: Seven treatment times of 10 seconds, 20 seconds, 30 seconds, 45 seconds, 1 minute, 1 minute 30 seconds and 2 minutes are available. To select a specific time, press the treatment time switch when a probe is connected. NOTE: pressing and holding the treatment time switch will scroll through the times. The switch can be released when the desired treatment time is displayed. When the probe is switched on the treatment time will count down. Treatment can be stopped and re-started at any time by pressing the probe switch. Pressing the Treatment Time switch, when the probe has been switched off mid treatment, will re-set the timer to the programmed time. Pressing the treatment time switch again will select another time.

Laser Probe Warning Beep: When the laser probe is on, the emission indicator flashes and the LCD display shows "LASER ON". As an extra safety feature, a warning beep is sounded every 10 seconds. This can be changed if required, to one of the following settings: a beep every second, a beep every 10 seconds (default), a beep every 30 seconds, or no beep at all.

To change the settings proceed as follows: remove the probe and switch the laser unit off. Switch the laser unit back on while holding down the emergency stop switch. Keep the switch depressed for two seconds or until the second beep is heard. This will "toggle" the probe warning beep to the next setting. Repeat the procedure, if required, until the desired setting has been reached. NOTE: Laser Probe Warning Beep selection is stored in EEPROM memory in the microcontroller, therefore the setting is remembered when the laser unit is switched off.

Laser Ready Delay: A 4 second delay is incorporated into the laser unit as a safety precaution, to stop sudden unexpected laser output, which could cause a hazard. When a probe is plugged into the laser unit the display shows "Standby" and operation of the laser probe is inhibited. After 4 seconds the display changes to "READY" and a beep is heard, at this point the laser is ready for use and can be switched on by pressing the probe switch. As a further safety precaution, when the probe switch is depressed, 3 short beeps are sounded as a warning before the laser output is enabled. There is also a half second delay before laser emission. When switching the probe off, two short beeps are sounded.

ADVANCED OPERATION

Probe Power Measurement: The APOLLO laser unit features a built in laser power meter. This is useful for verifying that laser output is functioning normally. To measure power output, switch the probe on and aim the probe at the "Probe Test" window. The probe needs to be touching the window for accurate results. The display reverts to "Output Test Mode" and the emission indicator is flashing at twice its normal rate during this test. The power reading is displayed in the top right of the display. Move the laser probe up, down left and right for the highest reading. The power reading should be the probe power rating +/-20%. **NOTE:** On cluster probes you cannot measure all four laser diodes at once and it is very difficult to measure individual diodes. Cluster probe readings should be considered approximate. For cluster probe output measurement, the four diodes are located equally around the perimeter of the probe so adjust the probe position for the highest reading for each diode. NOTE: Treatment Time countdown is stopped while in the "Output Test Mode". NOTE: The "Output Test Mode" is only activated when the "Probe Test" photodiode sees a power of greater than 10mW. Therefore, if you aim a probe at the "Probe Test" window and the Laser Unit does not change to "Output Test Mode", then you can presume that the laser probe is producing less than 10mW of output.

Remote Interlock Connection: A remote interlock connector is provided for practitioners who desire to install a door interlock system. The connection is designed to be connected to a door switch in the treatment room. A normally closed magnetic or micro switch can be used, which should be wired so the connection is closed when the door is closed. This door switch should then be terminated with a ¼ inch audio jack plug (such as Amphenol part number ACPM-GB) which can be plugged into the remote interlock connector. Should the door be opened when the laser probe is emitting, the laser probe will automatically be switched off and the laser unit will be put into a fault condition. NOTE: if the door is opened when the laser probe is not emitting, then the normal operation of the laser unit is unaffected.

Emergency Stop Switch: The Emergency Stop switch is designed for use in an emergency when the laser output needs to be shut off immediately. Pressing the emergency stop switch during treatment will put the laser unit into fault condition and disable the laser output. **NOTE:** pressing the emergency stop switch has no effect unless the laser probe is on.

Fault Conditions: For product safety and in order to meet the regulatory requirements, certain safety features are built into the laser unit to shut down and disable the output. If a fault condition occurs, the laser cannot be used and the output is switched off. The key switch must be turned off and then back on to re-set the fault condition and enable normal operation to resume. These fault conditions can also help to diagnose problems with the APOLLO laser unit. Each type of "Fault" condition is subtly different in order that the cause of the "fault" can be identified.

The following circumstances will cause a fault condition:

1. Operation of the "Emergency Stop" switch when the laser probe is on. "FAULT! - Cycle power to reset" is shown on the LCD display, the "Fault" LED is illuminated and a fast warning beep is heard.

Corrective Action – Turn the key switch "Off" and then "On" to reset the system.

2. Operation of the "Remote Interlock Connector" when the laser probe is on. "FAULT! - Cycle power to reset" is shown on the LCD display, the "Fault" LED is illuminated and a fast warning beep is heard.

3. Unplugging the laser probe from the laser unit when the laser probe is on. "FAULT! - Cycle power to reset" is shown on the LCD display.

Corrective Action – Turn the key switch "Off" and then "On" to reset the system.

4. Operating the Laser probe when the battery voltage is so low that laser output power is reduced by more than 20%. "FAULT! – Cycle power to reset" is shown on the LCD display, the "Fault" LED is illuminated, together with the "Battery Low" LED.

Corrective Action – Connect the power adapter and then turn the key switch "Off" and then "On" to reset the system.

5. Operating the Laser unit when the battery voltage is so low that continued use could discharge the battery below the recommended voltage. The "Fault" LED is illuminated, together with the "Battery Low" LED.

Corrective Action – Change to the alternate charged battery or use wall power.

SERVICE AND CLEANING

Use and Storage: It is recommended that you use and/or store your APOLLO in a dry, dust free environment, preferably in the APOLLO carry bag. This device should never be placed in water. DO NOT use the APOLLO if there is any damage visible, especially to the power supply.

Cleaning: Surfaces of the APOLLO should be cleaned using a cloth moistened with water or a diluted detergent. Never use abrasive cleaners, or chemicals that contain ammonia, acetone, benzene or thinners. When cleaning do not allow water or liquid to enter the device.

Clean patient contact surfaces (glass lens) before and after each patient treatment to ensure hygienic safety. An appropriate disinfectant should be used to prevent cross infection.

Acceptable cleaning solutions include: Alcohol, hydrogen peroxide, chlorine bleach (3% concentration), or chlorine mixed one part bleach to 10 parts water. Wipe surface thoroughly using a moistened swab. Do not submerge.

The probe should not be used in contact with the patient where contamination from bodily fluids or pathogens is likely (such as open wounds). Alternatively treat though a disposable protective barrier, such as Smith & Nephew OpSite Transparent Dressing. This is an adhesive disposable sterilized film which can be applied to probes before treatment and then removed and disposed of afterwards

It is recommended that you have the APOLLO serviced, calibrated and tested for electrical safety by Apollo or an Apollo-authorized Service Center every 12 months.

Transport: To avoid damage, transport APOLLO only in its original packaging. Remove the power adapter, key and probe cable before packing. Avoid rough handling.

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Outside the USA: 011 605-753-0110

APOLLO PRODUCT WARRANTY

A. Limited Warranty: Pivotal Health Solutions, Inc. hereby warrants that this Product shall be free from material defects in materials and workmanship for a maximum period of 2 (two) years from the date of purchase subject to the following condition:

i. The warranty on probe cables and accessories is limited to a period of 12 (twelve) months from the date of purchase.

ii. The warranty on user replaceable batteries is limited to ***OUT OF BOX**** failures.

**An Out of Box failure is defined as follows: Immediate failure of the battery to function properly during its initial use. Improper charging, operation, or other occurrence as defined in paragraph E, shall terminate the warranty.*

Out of Box warranty period: The customer must immediately notify Pivotal Health Solutions in writing of an Out of Box failure. Any notification received beyond (30) days of the initial shipment date will not be accepted.

B. Limitation of Remedies: PIVOTAL HEALTH SOLUTIONS, INC. and Customer acknowledge and agree that the Customer's sole remedy under this Limited Warranty shall be, at the sole option of PIVOTAL HEALTH SOLUTIONS, INC., the repair or replacement of the Products or any components thereof which are determined by PIVOTAL HEALTH SOLUTIONS, INC. to be materially defective in material or workmanship or, at the sole option of PIVOTAL HEALTH SOLUTIONS, INC., the refund of the purchase price of the Products in question. PIVOTAL HEALTH SOLUTIONS, INC. shall not be liable for injury to property other than the Products themselves.

C. Disclaimers from Warranty: THIS LIMITED WARRANTY IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THIS LIMITED WARRANTY.

D. Products Covered by This Warranty: This Limited Warranty shall extend to the Products and components thereof manufactured, supplied or repaired by PIVOTAL HEALTH SOLUTIONS, INC..

E. Automatic Termination of Warranty Obligations: Any obligation of PIVOTAL HEALTH SOLUTIONS, INC. under this Limited Warranty shall automatically and immediately terminate, without notice from or any further action by PIVOTAL HEALTH SOLUTIONS, INC. and PIVOTAL HEALTH SOLUTIONS, INC. shall have no responsibility for damages of any kind as a result of the occurrence of any of the following:

i. accident, misuse, abuse or negligent use of the Products or any component thereof;

ii. any repair or alteration of the Products or any component thereof made outside Pivotal Health Solutions, Inc.'s facility, except by an employee of PIVOTAL HEALTH SOLUTIONS, INC. authorized to do so;

iii. improper installation or operation (including both mechanical and electrical) of the Products or any component thereof, which includes operation of the Product not in accordance with the Product's operating manual;

iv. failure to provide normal maintenance for the Products or any component thereof in accordance with the Product Operating Manual.

v. Alteration or obliteration of any identifying marks.

F. Limitation on Damages (Consequential Damages Excluded): PIVOTAL HEALTH SOLUTIONS, INC. shall not be responsible for, nor does this Limited Warranty extend to, any consequential or incidental damages or expenses of any kind including, without limitation, injury to persons or property, loss of use of the Products, lost goodwill, lost resale profits, work stoppage, impairment of other goods, breach of contract, negligence or such other actions as may be deemed or alleged to be the cause of a loss or damage to the Customer or any other persons.

G. No Other Warranties, Statements are Opinions: This Limited Warranty is in lieu of all other express or implied warranties of PIVOTAL HEALTH SOLUTIONS, INC. and PIVOTAL HEALTH SOLUTIONS, INC. does not assume, nor does it authorize any person to assume on its behalf, any other obligation or liability, either verbally or in writing. PIVOTAL HEALTH SOLUTIONS, INC. and Customer agree that any statements and representations made by PIVOTAL HEALTH SOLUTIONS, INC. outside of this Limited Warranty are only PIVOTAL HEALTH SOLUTIONS, INC.'s opinion, and are not warranted to be accurate. PIVOTAL HEALTH SOLUTIONS, INC. and Customer further agree that if any statement by PIVOTAL HEALTH SOLUTIONS, INC. in this Limited Warranty or in any agreement or correspondence, whether oral or written, between PIVOTAL HEALTH SOLUTIONS, INC. and Customer is construed as an affirmation or promise, it shall nevertheless not constitute a warranty that the Products or any component thereof will conform to such affirmation or promise.

H. Enforcement of Limited Warranty: The Customer will immediately notify PIVOTAL HEALTH SOLUTIONS, INC. in writing of any Product or component thereof to be repaired or replaced pursuant to Paragraph A hereof. Customer's written notice shall specify the Product or component thereof as well as list the facts or reasons supporting or underlying Customer's claim for relief under this Limited Warranty. Allegedly defective Products or components thereof shall be returned to PIVOTAL HEALTH SOLUTIONS, INC.'s facility at the sole cost of Customer. In the event that PIVOTAL HEALTH SOLUTIONS, INC. elects to repair or replace the allegedly defective Product or component thereof, PIVOTAL HEALTH SOLUTIONS, INC. shall ship, at PIVOTAL HEALTH SOLUTIONS, INC.'s expense, said replacement or repaired Product or component to Customer via the lowest priced transportation available to PIVOTAL HEALTH SOLUTIONS, INC.; provided, however, that PIVOTAL HEALTH SOLUTIONS, INC. shall be obligated to ship and pay for deliveries only to the address from which the Product was shipped to PIVOTAL HEALTH SOLUTIONS, INC..

I. Strict Construction Rule Waived: The Customer hereby waives the benefit of any rule that disclaimers of warranty shall be construed against PIVOTAL HEALTH SOLUTIONS, INC. and agrees that the disclaimers in this Limited Warranty and in the Agreement shall be construed liberally in favor of PIVOTAL HEALTH SOLUTIONS, INC..

J. Other Rights: This Limited Warranty gives the Customer specific legal rights, and the Customer may also have other rights which may vary from state/province to state/province.

TECHNICAL PARAMETERS

The APOLLO System comprises a battery-operated, hand-held Control Unit and up to two interchangeable hand-held Laser Probes, only one of which may be connected to the Control Unit at any time. The desired Probe is connected to the Control Unit via a detachable 6 foot cable.

The internally rechargeable battery pack is charged via an external switchmode plugpack, which may also supply operating current to the Control Unit in the event that the batteries are discharged.

The APOLLO features a programmable treatment timer, and incorporates a number of safety features as required for a Class 3B & 4 Laser device, including a key operated master switch, watchdog circuitry, 4- second standby/ready emission delay and emission warning indicator.

The APOLLO System incorporates an optical power meter. This feature conveniently measures laser power in order to verify the correct operation of APOLLO probes.

AP2-PT Portable Control Unit Specifications and Laser warning labels:

Emission Timer:	10sec, 20sec, 30sec, 45sec, 1min, 1min 30 sec, 2min.
Timer Accuracy:	Better than ±1second
Standby/Ready: Delay:	4 seconds
Display:	32 digit LCD
Power Meter:	6mm x 6mm Silicon Photodiode
Calibration Accuracy:	Better than ±15%.
Battery:	10x 1.2V 2500mAH NiMH rechargeable cells
Laser Class:	Class 3B & 4 Laser Product (probe dependant)
Weight:	2.5lb
Dimensions:	9.5L x 5W x 2.2H Inches
Compliance Standards:	IEC60601-1:2006; IEC60601-1-2:2001; IEC60825-1:2007 21CFR1040.10; 21CFR1040.11
Max Operating Altitude:	2000 M

OPTICAL HAZARD: Laser operators should be aware of the potential hazards of Lasers, such as optical injury caused by unintended irradiation of the eye. Hazard reduction, such as the provision of appropriate safety eyewear, removal or covering of reflective surfaces in the treatment area, and adequate signage and removal of the key when not in use is the responsibility of the Laser user.

ENVIRONMENTAL This unit should be operated in temperatures between 0˚c and 40˚c max humidity 90%. This unit should be transported in/ stored in temperatures between -20˚c to 50˚c max humidity 90%.

APOLLO LASER PROBE SPECIFICATIONS

500mW Probe Specifications and warning labels:

Applicator Type:	500-S
Emitter Type:	GaAlAs Semiconductor Laser
Emitter Wavelength:	810nm
No. of Emitters:	1
Beam Divergence:	9° x 38°
Total Power Output:	500mW
Aperture:	9.5mm
Polarization:	Linear
Laser Classification:	Class 4
Spot Size:	1.7 x 9.5mm, 0.161Cm^2
1/e^2 Power Density (Irradiance):	2.68W/Cm^2 (26,800Wm-2)
Treatment Time for 4 J/Cm^2:	1.49 seconds
Total Energy delivery per minute:	30 Joules, 160.8 J/Cm2
NOHD:	80Cm
Safety goggle requirement:	OD4 minimum @ 810nm

APOLLO LASER PROBE SPECIFICATIONS

3000mW Probe Specifications and warning labels:

Applicator Type:	3000-C
Emitter Type:	GaAlAs Semiconductor Laser
Emitter Wavelength:	810nm
No. of Emitters:	4
Beam Divergence:	9° x 38°
Optical Output Power per emitter:	750mW
Total Power Output:	3000mW
Aperture:	25mm
Polarization:	Linear
Laser Classification:	Class 4
Spot Size:	2.7 x 21mm, 0.567Cm2
1/e^2 Power Density (Irradiance):	1.14W/Cm2 (11,400Wm^{-2})
Treatment Time for 4 J/Cm^2:	3.51 seconds
Total Energy delivery per minute:	180 Joules, 68.4 J/Cm^2
NOHD:	120Cm
Safety goggle requirement:	OD4 minimum @ 810nm

APOLLO LASER PROBE

Laser Safety Goggle Specifications:

EN207 Classification	Continuous D 785-830 L4
	Pulsed I 785-830 L5
	Pulsed I 800-820 L6
CEI 825 Classification	785-830 OD5+
ANSI Classification	785-830 OD5+

NOTE: use of laser safety goggles, other than those supplied or meeting the above specification, could result in hazardous eye exposure.

GLOSSARY OF TECHNICAL TERMS

$1/e^2$ spot size . . . . . .The size of the spot that contains $1/e^2$ of the source power. This is approximately 86.5%.

Beam divergence . . . .The angle that the emitted Laser or LED beam deviates from a perfect right angle to the source. Normally shown in degrees in the x and y plane but can also be shown in radians. (360 deg = 3.14( ) radians)

Coherent . . . . . .A monochromatic source that has all emitted wavelengths of light in phase to each other.

Irradiance . . . . . .The ratio of power to area. Also known as power density.

Joule . . . . . .The product of power and time. 1 Joule = 1 Watt for 1 second.

LASER . . . . . .An acronym for Light Amplification by Stimulated Emission of Radiation.

Monochromatic . . . . . .Substantially the same wavelength i.e. a narrow spectral width.

MPE . . . . . .Maximum Permissible Exposure, as defined in EN60825. There is an MPE for the eye and for the skin. Only the MPE for the eye is considered a safety issue in Laser therapy, as the MPE for skin is often exceeded during a typical treatment.

NOHD . . . . . .Nominal ocular hazard distance. The distance at which the Laser output is safe to view without safety spectacles i.e. below the MPE.

OD . . . . . .Optical Density. The resistance of an optical filter to pass light. An OD of 1 would reduce power by a factor 10. An OD of 2 would reduce power by a factor of 100.

Polarization . . . . . .Linear polarization occurs when all wavelengths of light emitted from a source are emitted at the same angle to each other. Generally, when no filtering is mployed, Laser sources are polarized and LED sources are not (or randomly polarized).

Power . . . . . .The intensity of the source, normally measured in Watts.

Power density . . . . . .The ratio of power to area. The correct term is Irradiance.

Spot size . . . . . .The size of the spot of light from a Laser or LED source, normally measured at the point of normal treatment.

Spectral width . . . . . .The variation in wavelength of a source, normally measured at 50% intensity.

Watt . . . . . .The unit of power. 1 Watt = 1 Ampere x 1 Volt

Wavelength . . . . . .The physical length of one cycle of an electromagnetic wave. For light at near infra red wavelengths this is normally measured in nm (nanometers, meters x 10^{-9})

SERVICE TECHNICAL SPECS

TECHNICAL SPECIFICATIONS:

Recycle and dispose of device properly in accordance with local, state and federal laws. Over the years, tons of electronics equipment with hazardous materials have been thrown away with standard garbage. Over time, these materials leech out of the electronic causing damage to the environment. It is important to try and properly dispose of retired devices in order to prevent damage to our environment.

	PT
Rated Voltage	100-240V
Rated Frequency	47-63H$_2$
Current	0.8-0.4A
Out Put	18V DC 1.67A
Duty Cycle	Continuous
Electrical Classification	Class II
Electrical Type	Type BF
Equipment is not suitable for use in the presence of flammable mixtures.	

Warning: No modification of this equipment is allowed.

SAFETY APPROVALS AND RECOGNITION

Guidance and manufacturer's declaration – electromagnetic emissions		
The Apollo is intended for use in the electromagnetic environment specified below. The customer or the user of the Apollo should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Apollo 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.s
RF emissions CISPR 11	Class B	The Apollo is suitable for use in all establishments other than domestic, and may be used in domestic establishments 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 per Ed. 3.2 (2009) (European limits)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Apollo is intended for use in the electromagnetic environment specified below. The customer or the user of the Apollo 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 ± 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 ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output 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) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Apollo requires continued operation during power mains interruptions, it is recommended that the Apollo be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT IS THE A.C. MAINS VOLTAGE PRIOR TO APPLICATION OF THE TEST LEVEL.			

SAFETY APPROVALS AND RECOGNITION

Guidance and manufacturer's declaration – electromagnetic immunity

The Apollo is intended for use in the electromagnetic environment specified below. The customer or the user of the Apollo 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Apollo, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.17 x P 150 kHz to 80 MHz d = 1.17 x P 80 MHz to 800 MHz d = 2.33 x P 800 MHz to 2,5 GHz 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 metres (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: 

NOTE 1 At 80 MHz and 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 Apollo is used exceeds the applicable RF compliance level above, the Apollo should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Apollo.

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

SAFETY APPROVALS AND RECOGNITION

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

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

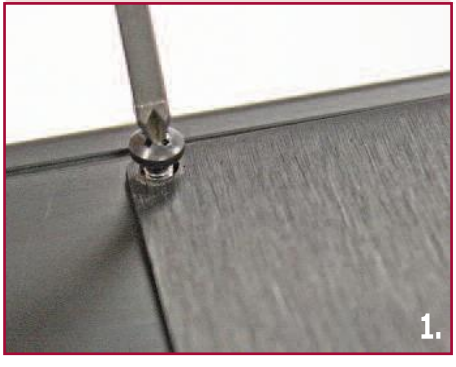
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.33\sqrt{P}$
0,01	.117	.117	.233
0,1	.37	.37	.737
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3

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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

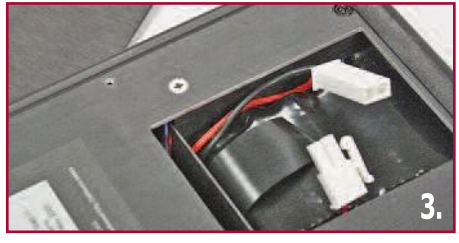
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

REPLACING THE BATTERY

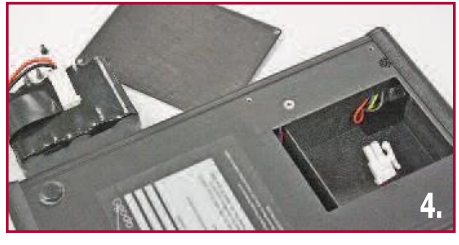


Using a small Phillips screw driver remove the battery cover.

Disconnect the battery from the unit.

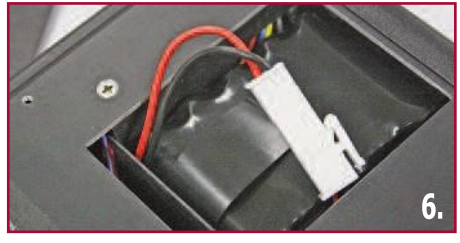


Remove the battery.



Replace the battery

Connect the battery to the unit.



Using a small Phillips screw driver replace the battery cover.

APOLLO operates a policy of continuous development. Therefore, it reserves the right to make changes and improvements to the Product described in this manual without prior notice.

The contents of this document are provided "as is ". Except as required by applicable law, no warranties of any kind, either expressed or implied, are made in relation to the accuracy, reliability or contents of this document. APOLLO reserves the right to revise this document or withdraw it at any time without prior notice.

Neither APOLLO, its officers, employees or agents, nor the author of this manual, hold that the application of Laser Therapy will achieve any or all of the benefits referred to or implied in this text or in any other materials prepared by APOLLO. There may be other dangers or consequences associated with the use of Laser Therapy which are not referred to in this text.

While APOLLO has taken all possible care in the design and manufacture of this device, no responsibility can be taken by APOLLO for the way in which it is used. The purchaser operates the APOLLO Laser Device at their own risk.

APOLLO will not accept any liability for any injury or damages resulting directly or indirectly from the use of the APOLLO device, any associated equipment or the information contained in this manual or any other materials or advice provided by APOLLO to the purchaser or any officer, employee, or agent of the purchaser.

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