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FDA DECLARATION

APOLLO Desktop Laser Control Unit

Pivotal Health Solutions, Inc. confirms that the APOLLO AP2-DT 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.

The APOLLO Laser unit and probes, as detailed in this operating manual, have been cleared for medical use by the FDA as "Infrared Heating Devices" under 510K application K060134.

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.

Standard System

APOLLO AP2-DT Desktop Control Unit with your choice of one of the following probes.

- APOLLO 3000-C Laser Cluster Probe
- APOLLO 4000-C Laser Cluster Probe
- APOLLO 5000-C Laser Cluster Probe
- APOLLO AP2-500-S Laser Probe

Standard Accessories:

2 - 6 foot Probe CablesAC Power Adapter 12V2 pair Safety GogglesLight and Laser Therapy: Clinical Proceduresor Veterinary Laser Therapy

Optional Accessories:

APOLLO FINETIP Fine Tip Light Guide (Acu-tip)



INTRODUCTION APOLLO Desktop Laser Control Unit

The APOLLO AP2-DT Desktop 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 Desktop 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 with the ability to run two probes simultaneously.

Fast, Effective Treatment

With the APOLLO Desktop you can experience the future of laser therapy today. Only Apollo brings you power and performance at a reasonable price point.

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



OUTWARD APPEARANCE

The APOLLO AP2-DT Desktop 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 connectors & 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 aluminum, 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-DT Desktop Laser Therapy System:

Back Panel





APOLLO QUICK-START GUIDE



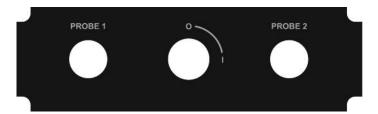
READ THE OPERATING MANUAL BEFORE USING THE APOLLO LASER

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 '0' 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:

You may use the unit immediately with the AC power adapter.

Carefully unpack the APOLLO Control Unit and place on a sturdy and level surface. 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, X-rays, 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. Note that the end of each connector has a half oval design that corresponds to the "top" of the connector (opposite the orientation lug).

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

SWITCHING ON APOLLO Desktop Laser Control Unit

Turn the key in a clockwise direction to the 'I' position. The green 'Power On' LED will illuminate and the LCD display will come on. The display will show the startup screen which shows the version number of the software, for 4 seconds.

The Display will then show the main menu screen, if no probes are connected.

Connect a probe in either "Probe 1" or "Probe 2" socket. The display will then show the treatment time screen.

After a 4-second delay the LCD display will change from "WAIT" to "READY" and a beep will be heard. The LCD display will also show the power rating of the probe that is connected on the right of the display window.

The unit is now ready for use. Pressing the "Scroll" switch will change the position of the arrow head to either Probe 1 or Probe 2 treatment time. Press the "Select" switch to change the time selected. **NOTE:** pressing the "Select" or "Scroll" switch will put the Laser Unit back in the "WAIT" mode.

After 4 seconds of either the "Scroll" or "Select" switches not being pressed, the Laser Unit will beep and revert to the "READY" mode.

Apollo Physical Therapy Products LLC (c) 2010 DT2 Version 1.1

MAIN MENU →Beep Frequency Display Options Dia9nostics

Probe	1	-	0mW
→2m00 Probe 0m20	2	-	250mW WAIT

Probe 1 - 0mW →2m00 Probe 2 - 250mW 0m20 READY STARTING TREATMENT

APOLLO Desktop Laser Control Unit

Starting Treatment:

Before beginning treatment read the entire manual and understand the precautions and treatment protocols to be followed. Specific treatment protocols and precautions for each probe type are provided on pages 11-12

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.

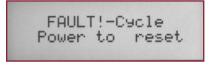
Probe →2m00	1	-	ØmW
→ZM00 Probe	2	_	250mW
0m16			ON

During emission the LCD display will count down and a beep will be heard every 10 seconds as a warning. **NOTE:** this can be changed, see ADVANCED OPERATION — Laser Probe Warning Beep. When the treatment time counter reaches zero, the probe will automatically switch off and the timer will re-set to its pre-set time.

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 the treatment to re-start and the treatment time will continue counting down from where it was stopped.

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.

NOTE: Beam power measurement can only be made when one probe is being used. If both probe outputs are on, then the beam power measuring circuit is disabled.

Precautions and Treatment Protocol for Probe Type

CAUTION: A higher probe power requires more movement of the probe during treatment, a technique call 'painting'. To maintain patient comfort and to reduce the chance of the patient feeling extreme heat during treatment, it is important that the clinician understands the proper technique and precautions to be followed for each probe type.

PROBE POWER	TIME PER SPOT	TIME PER AREA	TECHNIQUE	CAUTION
500 Point	20-30 seconds	2 minutes	Hold on spot	Standard Precautions
3000 Cluster	30 seconds	2 minutes	Hold on spot	Standard Precautions
4000 Cluster	20 seconds	1 1/2 minutes	Half painting, half spots	Avoid when possible or use extreme care over tattoos or suboccipital region
5000 Cluster	10 seconds	1-2 minutes	75% painting, 25% spots	Avoid when possible or use extreme care over tattoos or suboccipital region

Apollo 500 mW Probe:

FULL BODY DOSE:

For a typical patient, the dose per spot with this probe lasts approximately 30 seconds. This assumes that the clinician will multiple points of the body, sometimes 10-20 spots, for 20-60 seconds per spot.

TREATING ONE AREA:

Most of the time, in shallow areas like the ear and wrist, an average spot will be treated for 20-30 seconds. However, in deep areas like the knee and the lower back, will require that you treat multiple spots to achieve a physiological effect.

CAUTION:

 With this probe and you must be somewhat careful over tattoos. Avoid any dark tattoos or treat over them using caution, leaving the probe on the area no more than 10 seconds. This will reduce the chance of the patient feeling any heat.

DOSAGE:

The Apollo 500 mW probe produces 30 Joules per minute

 $(.5W \times 60 \text{ seconds})$. Thus, the average area will receive approximately 100-500 Joules.

Apollo 3,000 mW Probe:

FULL BODY DOSE:

For a typical patient, the full body dose with this probe takes approximately 4-8 minutes. This assumes that the clinician will treat two areas of the body for approximately 3-4 minutes per area. An area is defined as a small region of the body such as the lower back, knee, ankle, etc.

TREATING ONE AREA:

25% of the time, the clinician will keep the probe moving. This is called "painting." You will paint a typical area of the body by moving the probe about half the speed of ultrasound, around 1-2 inches per second (2-3 cm per sec.)

Most of the time, in deep areas like the knee and the lower back, will require that you either move the probe more slowly or treat points around the area for approximately 30-60 seconds per spot. In some cases, less sensitive areas can accept 40-60 seconds per spot.

CAUTION:

- With this probe and you must be careful over sensitive areas such as over tattoos and the suboccipital region. Avoid any dark tattoos or treat over them by continually moving the probe to reduce the chance of the patient feeling any heat.
- 2. Acutely painful areas require less time and more painting than chronic less painful regions.
- 3. If you are uncertain about the sensitivity of an area, hold the probe about ¼" above the skin and gently move the probe. Then, slowly move the probe closer to the skin to assess if direct contact is comfortable to the patient.

TREATMENT PROTOCOL:

When you first treat any area of the body treat with the following protocol:

- Place the laser on a spot for 30 seconds or more, and then gently move the probe around a small area for 30-40 seconds:
- Do not leave it on an area for more than 40-60 seconds before moving it to another area or spot.

DOSAGE:

The Apollo 3,000 mW probe produces 180 Joules per minute (3W x 60 seconds). Thus, the average area will receive approximately 200-900 Joules and the full body dose will be approximately 400 to 900 Joules.

Apollo 4,000 mW Probe:

FULL BODY DOSE:

For a typical patient, the full body dose with this probe takes approximately 4-8 minutes. This assumes that the clinician will treat two areas of the body for approximately 3-4 minutes per area. An area is defined as a small region of the body such as the lower back, knee, ankle, etc.

TREATING ONE AREA:

50% of the time, the clinician will keep the probe moving at all times. This is called "painting." You will paint a typical area of the body by moving the probe about half the speed of ultrasound, around 1-2 inches per second (2-3 cm per sec.)

Some deep areas like the knee and the lower back require that you either move the probe more slowly or treat points around the area for approximately 20 seconds per spot. In some cases, less sensitive areas can accept 30 seconds per spot.

CAUTION:

- This is a powerful probe and you must be careful over sensitive areas such as over any tattoo, the suboccipital region, or the ear. Avoid any dark tattoos or treat over them by quickly moving the probe to reduce the chance of the patient feeling extreme heat.
- Acutely painful areas require less time and more painting than chronic less painful regions.
- 3. If you are uncertain about the sensitivity of an area, hold the probe about ¼" above the skin and gently move the probe. Then, slowly move the probe closer to the skin to assess if direct contact is comfortable to the

patient

TREATMENT PROTOCOL:

When you first treat any area of the body treat with the following protocol:

- Paint over one area: make sure this does not feel "hot" to the patient;
- If painting is comfortable, try placing the laser on a spot for 20 seconds or gently move the probe around a small area for 20-30 seconds;
- 3. When painting or slow movements in a small area produce no sensation of heat, you can ask the patient if leaving the probe in one spot is comfortable. If so, do not leave it on an area for more than 20-30 seconds before moving it to another area or spot.

DOSAGE:

The Apollo 4,000 mW probe produces 240 Joules per minute (4W x 60 seconds). Thus, the average area will receive approximately 200-500 Joules and the full body dose will be approximately 500 to 1000 Joules.

Apollo 5,000 mW Probe:

FULL BODY DOSE:

For a typical patient, the full body dose with this probe takes approximately 2-4 minutes. This assumes that the clinician will treat two areas of the body for approximately 1-2 minutes per area. An area is defined as a small region of the body such as the lower back, knee, ankle, etc.

TREATING ONE AREA:

75% of the time, the clinician will keep the probe moving at all times. This is called "painting." You will paint a typical area of the body by moving the probe about half the speed of ultrasound, around 1-2 inches per second (2-3 cm per sec.)

Some deep areas like the knee and the lower back require that you either move the probe more slowly or treat points

around the area for approximately 10 seconds per spot. In some cases, less sensitive areas can accept 20 seconds per spot.

CAUTION:

- This is a very powerful probe and you must be careful over sensitive areas such as over any tattoo, the suboccipital region, or the ear. Avoid any dark tattoos or treat over them by quickly moving the probe to reduce the chance of the patient feeling extreme heat.
- Acutely painful areas require less time and more painting than chronic less painful regions.
- 3. If you are uncertain about the sensitivity of an area, hold the probe about ¼" above the skin and gently move the probe. Then, slowly move the probe closer to the skin to assess if direct contact is comfortable to the patient.

TREATMENT PROTOCOL:

When you first treat any area of the body treat with the following protocol:

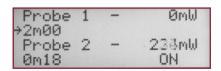
- Paint over one area: make sure this does not feel "hot" to the patient;
- If painting is comfortable, try placing the laser on a spot for 10 seconds or gently move the probe around a small area for 20 seconds:
- 3. When painting or slow movements in a small area produce no sensation of heat, you can ask the patient if leaving the probe in one spot is comfortable. If so, do not leave it on an area for more than 10-20 seconds before moving it to another area or spot.

DOSAGE:

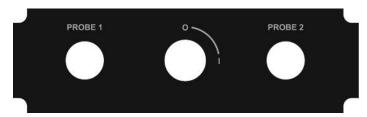
The Apollo 5,000 mW probe produces 300 Joules per minute (5W x 60 seconds). Thus, the average area will receive approximately 300-600 Joules and the full body dose will be approximately 600 to 1200 Joules.

ADVANCED OPERATION

APOLLO Desktop Laser Control Unit



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



ADVANCED OPERATION

Treatment Timer: Eleven preset treatment times of between 5 seconds and 2 minutes are available. To adjust each time press the "Scroll" switch until the arrowhead is next to the timer to be adjusted. Then press the "Select" switch to select the desired treatment time. **NOTE:** pressing and holding the "Select" 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

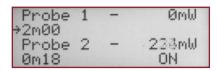
the probe switch. **NOTE:** Treatment time selection is stored in EEPROM memory in the microcontroller, therefore the last treatment time selected is remembered when the laser unit is switched off

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 "WAIT" 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

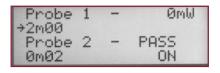
Probe Power Measurement: The APOLLO laser unit features a built in laser power meter. This is a useful device for ensuring the laser output is functioning normally. To measure power output, switch the probe on and aim the probe at the "Probe Test" window. The probe needs to be touching the window for accurate results. You will then see that the emission indicator is flashing and the power reading is displayed on the right of the display, instead of the rated power of the probe.

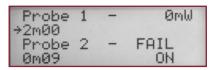
Move the laser probe up, down left and right for the highest reading. The power reading should be the probe power rating +/-20%. **NOTE:** For the 2000mW, 3000mW & 4000mW Cluster Probes, each individual laser output must be measured, and therefore the reading will be 500mW or 750mW or 1000mW or 4000mW, not 2000mW or 3000mW. as cluster probes have four laser diodes. Measure the laser output for each laser in the Cluster Probe the same way as for a single laser probe, adjusting the probe position for the highest reading. NOTE: Treatment Time countdown is stopped while in the "Test Mode". NOTE: The 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 Test Mode, then you can presume that the laser probe is producing less than 10mW of output. NOTE: Beam power measurement can only be made when one probe is being used. If both probe outputs are on, then the beam power measuring circuit is disabled. This is because the laser unit has no way of knowing which laser probe

is being tested, therefore the internal calibration factor for each probe cannot be correctly applied.



To simplify probe power measurement, an automatic measuring system can be selected as an option. To select this, remove all probes. Switch the laser unit off, then switch on while holding the "Scroll" switch down for at least 2 seconds. The automatic probe PASS/FAIL option is now selected. This can be toggled back off by repeating this procedure. Once selected, this option functions as follows: Switch the probe on and aim the beam at the photodiode test window. Adjust the probe for the maximum reading on the display. When the probe is removed, the display shows "PASS" or "FAIL" depending on whether the reading was within +/-20% of the correct output.

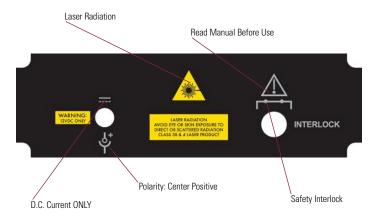




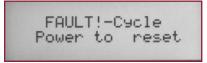
Alternatively, switch the probe off once the maximum reading has been achieved. The display will then show the last reading for 4 seconds before reverting back to the normal display. NOTE: if two probes are being used at once the probe power circuit is disabled, as the laser unit has no way of knowing which probe is being measured.

Remote Interlock Connection: A remote interlock connector is a legal requirement for all class 3B and 4 laser devices. 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 mono jack plug which can be plugged into the remote interlock connector. If the door is 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.



Switch the power off then back on to re-set the laser unit.

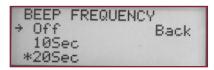
Main Menu Settings:

To access the main menu remove both probes

MAIN MENU →Beep Frequency Display Options Dia9nostics

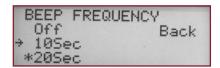
ADVANCED OPERATION

Beep Frequency: To adjust the beep frequency, scroll the arrow to "beep frequency" using the "Scroll" switch and then press the "adjust switch. The display will then show the beep menu.

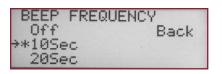


When the laser probe is on, the emission indicator on the front panel of the laser unit and in the probe is on and the LCD display shows "ON". As an extra safety feature, a warning beep is sounded by default every 10 seconds. This can be changed if required, to one of the following settings: off, 10 seconds or 20 seconds.

The default setting is 10 seconds. The above screen shows 20 seconds is selected by the "*" symbol. To change this back to 10 seconds, scroll the arrowhead to 10 seconds using the "Scroll" switch.



Then press the "Select" switch. You will see the "*" symbol has moved to the 10 second position.



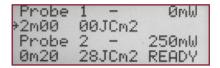
Scroll the arrow to "Back" using the "Scroll" switch. The laser unit will then re-start and store the new settings in memory.

Display Options:

To adjust the display options, scroll down to "display options" using the "Scroll" switch in the main menu andpress "Select" to select the Display Options menu.

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The secondary display can be set to Joules Cm² (J/Cm² or JCm²), Total Joules or off. The Joules Cm² display will automatically calculate the J/Cm² and display it for the probe being used. Initially the display will show zero. As the treatment time counts down the J/Cm² display will start counting up showing the dosage delivered. At the finish of treatment the total dosage will be shown. This is zeroed when the next treatment is started



If total Joules are selected, the total number of Joules is calculated and shown for the probe being used and this counts up as treatment time counts down. This does not reset at the end of each treatment, but continues to total up the joules indefinitely to a maximum reading of 25599 joules. To reset this, switch the power off and back on.

Probe	1	-	0mW
+2m00		00J	
Probe	2	-	-250mW
0m20		05J	READY

Diagnostics:

Selecting "Diagnostics" in the main menu shows the diagnostics screen.



This is primarily intended for engineers. A total hour meter shows the total number of treatment hours that the laser unit has done. The top line shows the last fault code that triggered a fault condition, which can be off use to an engineer diagnosing problems.

Fault code 0 - No faults

Fault code 1

- Emergency stop switch depressed, or safety micro shutdown.

Fault code 2 - Probe disconnected during treatment.

Fault code 3

- Power meter reading high on power up (power meter fault).

Press the "Select" switch to exit the diagnostics screen.

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

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 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 sterilised 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.

Calibration of the Optical Power Meter Calibration of the built in optical power meter is by adjustment of VR1 mounted on the PCB. This should only be attempted by qualified engineers with a suitable optical power meter that is calibrated to national standards.



Pivotal Health Solutions

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APOLLO PRODUCT WARRANTY

APOLLO Desktop Laser Control Unit

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.

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. so utside 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. sfacility 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.'s 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

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.

shipped to 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.

APOLLO SAFETY WARNINGS AND NOTES

APOLLO Desktop Laser Control Unit

Do not connect non-APOLLO laser probes or accessories:

Use of non-APOLLO probes and accessories is potentially dangerous and will void this product's warranty.

Remote Interlock: There is a remote interlock connector on the back panel of the APOL-LO for attachment to an optional safety circuit. If the safety circuit is installed and the interlock circuit is broken (e.g. open treatment room door), the APOLLO will not operate.

Use of Safety Accessories: The APOLLO is a Class 3B & 4 Laser Product. Appropriate eyewear is supplied with the APOLLO device, and additional eyewear is also available from your APOLLO dealer.

Safety Warnings:

Before turning on the APOLLO, read the manual carefully and observe all operation instructions.

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 power adapter provided with your APOLLO.

Replacement power adapters should only be obtained from

Apollo Physical Therapy Products or an authorized APOLLO

dealer or service center.

APOLLO should be used in a proper work environment.

It should not be used in an environment where there is danger

of explosion and/or water damage.

During use, storage and transport of APOLLO, no toxic radiation is emitted.

During use, place the APOLLO unit 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 APOLLO in direct sunlight.

Do not use the APOLLO if mechanical or water damage is noticed

The user is responsible for the use of materials and accessories

that are not supplied by Apollo Physical Therapy Products.

This includes cleaning and disinfecting liquids.

It is advisable to thoroughly check the APOLLO once a month for

loose cables, damaged diodes and damaged display functions.

Do not irradiate sensitive areas such as eyes, head, thyroid gland and other endocrine glands. Do not use over cancer or pre-cancerous

tumors, with immune-suppressant drugs or if the patient is pregnant. 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 sterilised film which can be applied to probes before treatment

and then removed and disposed of afterwards. Clean patient contact surface before and after each patient treatment to ensure hygienic safety.

See Maintenance Section for cleaning instructions.

During therapy it is necessary for the patient and the practitioner to use appropriate safety eyewear.

Do not use the APOLLO in areas that contain flammable gases and/or explosive compounds.

Display appropriate warning signs outside the immediate laser workplace.

Do not disconnect the probe or turn the APOLLO off while irradiating. Do not attach non-APOLLO accessories to the laser probe connector.

Handle probes with care! Probes are not water-resistant.

Do not open the APOLLO control unit case or disassemble the laser probe.

The user is responsible for compliance with State and/or Federal laws that apply to the ownership or use of the APOLLO device.

APOLLO emits a class 3B and 4 laser beam. During therapy with the APOLLO, you must follow all instructions written in this operating manual. The manufacturer will not accept responsibility for damage due to improper use of the instrument.

Not intended for use in an oxygen rich environment.

TECHNICAL PARAMETERS

APOLLO Desktop Laser Control Unit

The APOLLO System comprises a Desktop Control Unit and several interchangeable hand-held Laser Probes, any two 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 Control Unit is powered by the external 12 volt universal power adapter. NOTE: if you are using an Apollo portable laser unit as well, note that the DT desktop laser uses a different voltage adaptor with a higher power rating. Do not use the adaptor for the portable laser unit.

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-DT Desktop Control Unit Specifications and Laser warning labels:



Emission Timer: 5sec, 10sec, 15sec, 20sec, 30sec, 45sec, 1min, 1min 15sec,

1min 30sec, 1min 45sec, 2min.

Timer Accuracy: Better than ±1second

Standby/Ready Delay: 4 seconds

Display: 80 digit backlit LCD

Power Meter: 6mm x 6mm Silicon Photodiode

Calibration Accuracy: Better than ±15%.

Laser Class: Class 3B & 4 Laser Product (probe dependant)

Weight: 3.5lb

Dimensions: 9.5L x 11W x 3.5H 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%.

500mW Probe Specifications and warning labels:

Applicator Type: 500-S

Emitter Type: GaAlAs Semiconductor Laser

Emitter Wavelength: 810nm No. of Emitters: 1

Beam Divergence: 9º x 38º Total Power Output: 500mW
Aperture: 9.5mm
Polarization: Linear

Laser Classification: Class 4

Spot Size: 1.7 x 9.5mm, 0.161Cm² 1/e² Power Density (Irradiance): 2.68W/Cm² (26,800Wm-2)

Treatment Time for 4 J/Cm²: 1.49 seconds

Total Energy delivery per minute: 30 Joules, 160.8 J/Cm2

NOHD: 80Cm

Safety goggle requirement: OD4 minimum @ 810nm







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

Polarization: Linear Laser Classification: Class 4

Spot Size: 2.7 x 21mm, 0.567Cm2 1/e² Power Density (Irradiance): 1.14W/Cm2 (11,400Wm²)

Treatment Time for 4 J/Cm²: 3.51 seconds
Total Energy delivery per minute: 180 Joules, 68.4 J/Cm²

NOHD: 120Cm

Safety goggle requirement: OD4 minimum @ 810nm







APOLLO LASER PROBE SPECIFICATIONS

APOLLO Desktop Laser Control Unit

4000mW Probe Specifications and warning labels:

Applicator Type: 4000-C

Emitter Type: GaAlAs Semiconductor Laser

Emitter Wavelength: 810nm No. of Emitters: 4

Beam Divergence: 9° x 38°
Optical Output Power per emitter: 1000mW
Total Power Output: 4000mW
Aperture: 25mm
Polarization: Linear
Laser Classification: Class 4

Spot Size: 2.7 x 21mm, 0.567Cm² 1/e² Power Density (Irradiance): 1.51W/Cm2 (15,100Wm²)

Treatment Time for 4 J/Cm²: 2.65 seconds
Total Energy delivery per minute: 240 Joules, 90.6 J/Cm²

NOHD: 150Cm

Safety goggle requirement: OD5 minimum @ 810nm







5000mW Probe Specifications and warning labels:

Applicator Type: 5000-C

Emitter Type: GaAlAs Semiconductor Laser

Emitter Wavelength: 810nm No. of Fmitters: 4

Beam Divergence: 9º x 38º

Optical Output Power per emitter: 1250mW
Total Power Output: 5000mW

Aperture: 25mm
Polarization: Linear

Laser Classification: Class 4

Spot Size: 2.7 x 21mm, 0.567Cm² 1/e² Power Density (Irradiance): 1.87W/Cm² (18,700 Wm²)

Treatment Time for 4 J/Cm²: 2.13 seconds

Total Energy delivery per minute: 300 Joules, 112.2 J/Cm²

NOHD: 190Cm

Safety goggle requirement: OD5 minimum @ 810nm







APOLLO LASER PROBE

APOLLO Desktop Laser Control Unit



Laser Safety Goggle Specifications:

EN207 Classification Continuous D 785-830 L4

Pulsed I 785-830 L5 Pulsed I 800-820 L6 785-830 OD5+

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

APOLLO Desktop Laser Control Unit

1/e² spot size The size of the spot that contains 1/e² 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.

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

Laser therapy, as the MPE for skin is often exceeded during a typical treatment.

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

0DOptical 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

employed, 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.

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

WattThe 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)

CONTRAINDICATIONS

APOLLO Desktop Laser Control Unit

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 use of laser during pregnancy for obvious liability reasons.

CARCINOMA: Do not use the Laser over any known primary or secondary tumor.

THYROID: Laser should not be used 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 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.

IMMUNE SUPPRESSANT DRUGS: Although there are no studies showing any dangerous side effects, we advise avoiding the use of laser since laser can stimulate the immune system.

PHOTOSENSITIVITY REACTIONS: Some patients may be taking drugs or natural remedies known to cause photosensitivity reactions. It is unlikely that a combination of Laser and drug will trigger a response; however we suggest that "at risk" patients or patients with a history of such reactions be "patch tested" for the minimum recommended treatment time.

REACTIONS TO TREATMENT: Patients may report a number of sensations, such as localized feelings of warmth, tingling, or an increase or decrease in symptoms, within the 24-hour period immediately following Laser treatment. Other sensations that may be experienced in response to Laser therapy are nausea or dizziness. In patients with persisting or severe treatment reactions, Laser treatment should be discontinued.

TOPICAL LOTIONS: Lip balms and creams can contain chemicals that attract light and can cause smoking or burns. Always clean the skin thoroughly before laser treatment.

PINS, METAL PLATES, PLASTICS & PACEMAKERS ARE NOT CONTRAINDICATED: Laser may be safely used over metal implants, plastics and stitches and on patients fitted with a pacemaker.

TATTOOS, PIGMENTED TISSUES, AND SENSITIVE REGIONS:

Dark pigments, such as tattoos, marker-pen inks, melanin, and other natural or man-made pigments, may absorb light. Be very careful when treating over a dark tattoo as the patient can feel a sensation of heat. Sensitive areas with dense hair follicle distribution, such as the hairline, upper neck, top lip, and so on, may also cause discomfort or a sensation of heat, especially with individuals who have darker-colored hair.

Guidance and	l manufacturer	's declaratio	n – electroma	gnetic 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

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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 5 s	<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 5 s	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.

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				
power of transmitter vv	150 kHz to 80 MHz d = 1.17 √ P	80 MHz to 800 MHz d = 1.17 √ P	800 MHz to 2,5 GHz d = 2.33 √ 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.

SAFETY APPROVALS AND RECOGNITION

APOLLO Desktop Laser Control Unit

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	

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.

SERVICE APOLLO Desktop Laser Control Unit

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.



	DT
Rated Voltage	100-240V
Rated Frequency	47-63H _{2Z}
Current	1.5-0.7A
Output	12V DC 5A
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



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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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