Medray QuantumX
User Manual

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1. Introduction

The **Medray Quantum Series Medical Diode Laser Systems** (**Medray Quantum**, for short) **is a compact medical laser system**.It is designed for a wide variety of therapy procedures to relief pain.

Medray Quantum Quantum Series:

Mode	Specification	Max. Power
Medray Quantum QuantumX	640nm@0.2W, 808nm@15W, 915nm@15W, 1064nm@15W	45.2W
Medray Quantum Quantum	640nm@0.2W, 808nm@10W, 915nm@10W, 1064nm@10W	30.2W
Medray Quantum QuantumX60	640nm@0.2W, 808nm@30W, 980nm@30W	60.2W

The **Medray Quantum** utilizes a semiconductor laser module as the energy source for invisible infrared radiation.The energy is delivered to the treatment site via flexible a fiber threaded through a lightweight handpiece. Various types of Therapy Cover(s) for Smart Handle can be selected to connected with the handpiece(s), to use in different applications. The device is activated by means of a foot switch or a finger switch on the handpiece. A touchscreen display allows the user to adjust or set the treatment parameters, such as the laser output level,the laser can operate in continuous wave mode or controlled pulse mode.

The **Medray Quantum** is restricted to sale on the order of a licensed doctor and its use requires proper clinical and technical training. The manual provides instructions for those professionals who have completed the appropriate training.

When used and maintained properly, the **Medray Quantum** will prove a valuable addition to your practice.

1.1 System Packing List

The packing list of **Medray Quantum** Medical Diode Laser Systems includes the following:

1) Laser Console
2) Power Supply Adapter and Power Cord
3) Footswitch
4) Safety Goggles
5) Remote Interlock Connector
6) Therapy Cover(s) for Smart Handle
7) User Manual
8) Warranty Card

Please check carefully when you receive the device, and please contact Medray Laser and Technology if you have any questions.

NOTE:
Use proper care when transporting the unit. Refer to Section 8 in this User Manual for instructions.

WARNING: No modification of this equipment is allowed.

1.2 Facility Requirements

Electrical Supply:	Input:AC100-240V,50Hz-60Hz, 2.8A-1.6A
(Adaptor Model No.: PH260-24)	
Storage Temperature:	-20- 70ºC
Storage Humidity:	10- 90%, Non-condensing

Storage Atmospheric Pressure :	80kPa – 106kPa
Operation Temperature:	5- 35ºC
Operation Humidity:	10- 90%, Non-condensing
Operation Atmospheric Pressure:	80kPa – 106kPa

2. Equipment Description

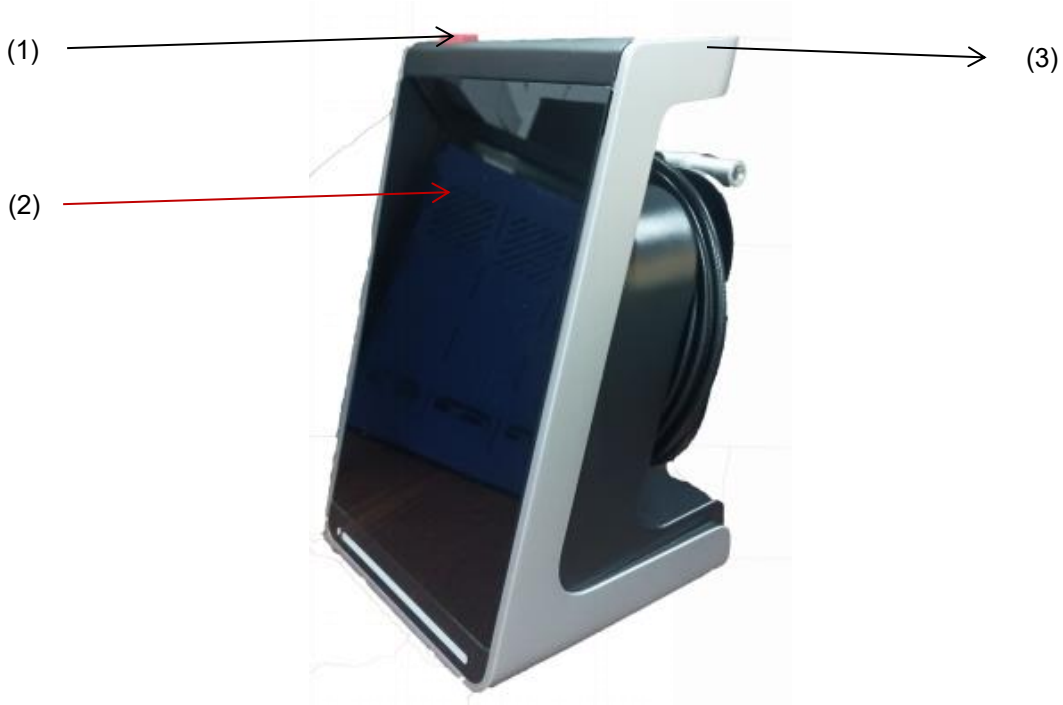
Product Composition:(1) Laser Console,(2) Power Cord with Power Supply Adapter, (3)Foot switch

Laser Console refers to the whole Main Unit of the Medical Device, which includes the Laser system and color touch Screen. The laser system consists of the fiber-coupled diode laser module, inner power supply, control panel, safety shutter and the embedded computer control system.

2.1 Base Console

The console has a display panel (Touch Screen and Emergency Laser Stop Button) in front. It can be powered by built-in rechargeable lithium-ion battery or AC-DC adaptor, the lithium-ion battery can be recharged by AC-DC adaptor connected to supply mains via the appliance coupler by a detachable Power Cord with mains plug.

The console has a display panel (Touch Screen and Emergency Laser Stop Button) in front. It can be powered by built-in rechargeable lithium-ion battery or AC-DC adaptor, the lithium-ion battery can be recharged by AC-DC adaptor connected to supply mains via the appliance coupler by a detachable Power Cord with mains plug.



(1) Emergency Laser Stop

(2) LCD Screen

(3) Handle

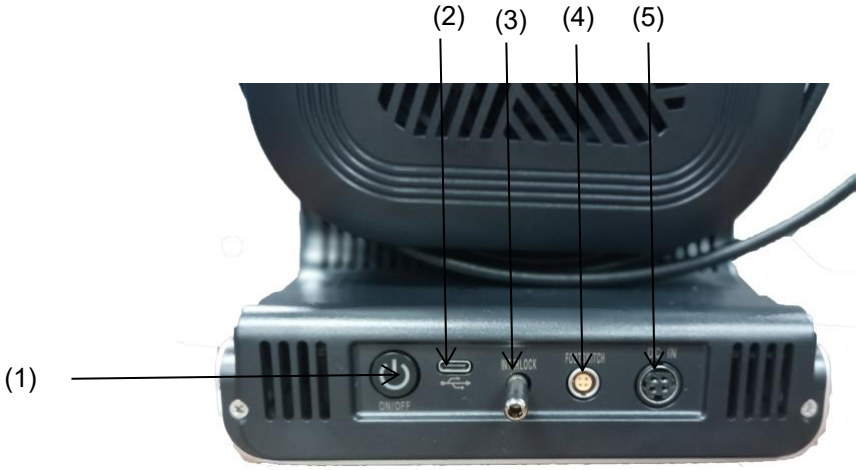
Figure 2.1 Front of the system

(1) Handpiece Holder

(2) Handpiece

(3) Fiber Cable Holder

Figure 2.2 Back of the system



(1) Power Switch

(2) Type C Port

(3) Remote Interlock Connector (Port)

(4) Footswitch Port

(5) DC Power Port

Figure 2.3 Left of the system

2.1.1 Electronic data interchange Interface

The Type C belong to electronic data interchange interfaces related to network security, which are used for the software upgrading. The software upgrading process is as followed approximately: Turn on the Medray Quantum

and put it in standby mode. Then insert the card reader, which stores the software application, and complete the software application upgrade..

CAUTION:
Never insert any unknown source or unauthorized reader into the above Electronic Interfaces.

2.2 Power Cord

Figure 2.4 Power Supply Module with cord

CAUTION:
Power Supply Adapter connector as a power grid disconnection measure, please ensure that the Medray Quantum is not placed in an area where it is difficult to operate the Power Supply Adapter connector.

2.3 Footswitch

Figure 2.5 Foot Switch

NOTE:

When the foot switch is in failure, please try to use the finger switch in the handpiece to control laser emission. If the finger switch can not control the laser emission too, please turn off the Medical Device using Power switch or Emergency Laser Stop Button, and contact Medray Laser and Technology to maintain or change the device and accessories.

2.4 Transmission System

The Transmission System of Medray Quantum is composed of a double sheathed optic fiber and a handpiece with replaceable treatment head(s). The actual laser transmission part is optical fiber. The fiber cable and the handpiece are connected to the laser console and can not be removed.

Figure 2.6 Therapy Cover(s) for Smart Handle

2.4.1 Installation requirements for Handpiece(s)

The procedure for installing handpiece is as followed:

1) Align with the direction of the buckle and press firmly to fix it, then the installation will be completed.

2) Hold the treatment handle part with one hand and the treatment head part with the other hand, and pull it out forcefully to complete the replacement.

3) In the handpiece after installation, the laser transmission system can be used.

2.4.2 Requirements for the Use of Handpiece

The Handpiece is a re-usable component and will require cleaning and disinfection prior to each patient treatment.

2.4.3 Finger Switch

In addition to the foot switch described, the laser output can also be controlled by the finger switch above the following handpiece. Its operation mode, the control effect is the same as the foot switch.

Figure 2.7 Finger switch

Single Touch:Press to hold laser emitting.

Double Touch:Press to keep the laser emitting, press to turn off the laser emitting.

2.5 BEAM DELIVERY SYSTEM

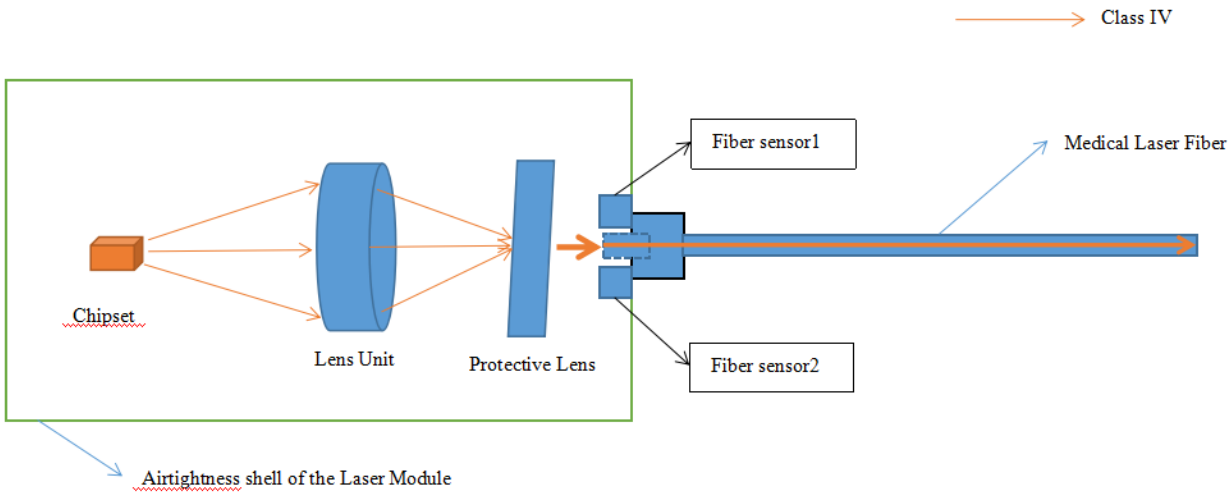


Figure 2.8 Diagrammatic sketch for Laser Radiation Fields and Paths

As the above diagrammatic sketch shows, the Laser Module is composed with Chipset, Lens Unit, Protective Lens, Fiber Sensors and Airtight shell, which is assembled inside the laser product. The Chipset is used to control semiconductor material to emit laser. The defocusing laser beam is focused on the Protective Lens through the focusing function of lens Unit. Because there is an Airtight shell, the laser can only emitted out by the Laser Aperture of the laser module. The fiber sensors are used to monitor fiber connection status. When the Laser Module is connected with a Medical Laser Fiber, the laser will be coupled into the fiber and the laser will emitted out through the end of the Medical Laser Fiber. The level of laser radiation is Class IV. The failure tolerance time is 1 ms, monitoring carried out at intervals less than 10 μs.

2.6 Battery Safety

The Medray Quantum can be powered by lithium-ion battery as well as external grid power. The main parameters of the lithium-ion battery is as follows:

Model:DBT-03; Nominal Capacity:3000mAh; Nominal Voltage: 10.8V; Charging Current: 15VDC, 9.6A.

The built-in lithium-ion battery indicator is located on the bottom left side of the Medray Quantum, as shown below. When the battery is charged, the indicator is steady red. When the battery is fully charged, the indicator is steady green; When the battery power is too low, the indicator blinks red and green at a frequency of 1Hz, and the software screen displays a message indicating that the battery power is low, please connect the power or turn off the machine. If other faults occur to the battery (for example, the temperature is abnormal or the connection is disconnected), the indicator blinks red and green at a frequency of 1Hz, and the software screen displays a message indicating that the battery Status is Abnormal.

WARNING:

If it is not possible to use Medray Quantum for a certain period of time, remove the battery to prevent an unacceptable risk of battery leakage.

WARNING:

Before replacing the battery, turn off the power.

WARNING:

Only maintenance personnel can use the tool to replace the battery.If the battery is replaced by an untrained person, the device may fail to start.

WARNING:
Using an incorrect method to replace the battery may cause the device to fail to turn on.

WARNING:
Replacing a battery without training may damage the battery interface cable, Improper operation may cause fire and other hazards.

WARNING:
Please use the battery provided by the manufacturer. It is forbidden to use the battery purchased by oneself.

WARNING:
The battery is expected to be maintained by anyone other than the maintenance personnel. Adequate maintenance instructions are required to ensure adequate maintenance. Please refer to Section 8 of this user manual for detailed instructions.

2.7 Replace the battery

The battery is installed at the bottom of the device and requires a tool screwdriver.

Step 1: Use tools to remove battery cover (bottom of device).

Step 2: Remove the battery pack first, and then unplug the battery cable.

Step 3 : Install the new battery.

Install the battery pack first, insert the battery cable, put the red line on the left, put the black line on the right,If the cable is not inserted in the queue, it cannot be inserted into the Screen.(The red line is positive and the black line is negative. The positive is on the left, the negative is on the right).

Step 4 : Use a tool to close the lid and secure the battery cover .

Step 5 : Charge the Medray Quantum. When Medray Quantum is charging, the Charging Indicator will be red.

Step 6 : When the charging is complete, the Charging Indicator will turn into green.

3. Safety

3.1 Precautions

Failure to comply with precautions and warnings described in this User Manual may lead to exposure to dangerous optical radiation sources. Please comply with all safety instructions and warnings.

3.2 Safety Instructions

Follow these safety instructions before and during treatments:

Do not operate in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before laser is used. Attention should also be drawn to the danger of ignition of endogenous gases.

NOTE:

All persons present in the treatment room must wear laser safety goggles. The protection scope of safety goggles must suitable for working laser wavelength (810nm, 915nm, 980nm and 1064nm).

CAUTION:

Periodically inspect safety goggles for pitting and cracking.

WARNING:

Do not use this unit if you suspect it of functioning improperly or other than described here in.

CAUTION:

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

CAUTION:

This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate the interference.

CAUTION:

Always ensure that the proper laser parameters are set before the Medray Quantum laser system is used in a clinical setting.

LASER WARNING:

Do not look directly into the beam or at specular reflections.

Never direct or point the beam at a person's eyes.

LASER WARNING:

Don't exchange the handpiece(s) when the device is in Ready Mode, switch the power off or place the system into Standby mode before exchanging.

Toggle the power switch (located on the back of the console) to the OFF(O) position before leaving unit unattended.

LASER WARNING:

Do not open unit housing at any time. Danger from optical radiation may exist.

LASER WARNING:

Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. If aimed directly at these surfaces the laser beam will reflect and create a potential hazard.

CAUTION:

There is a risk of fire and/or explosion if the laser output is in the presence of flammable materials, solutions or gases, or when used in an oxygen-rich environment.

CAUTION:

The metal/plastic sleeve on the optical fiber may become hot during use. Avoid casing contact with any tissue.

CAUTION:

The smoke and/or smoke emitted by the laser may contain biological tissue particles. Masks must be worn.

3.3 Safety Features

1) System Monitor

The system monitors the Emergency Laser Stop Switch, Remote Interlock Connection, foot switch Connection, and output power. An error in any one of these will stop the system. The text display will indicate the type of error. Operation will not resume until the error is cleared.

2) Power Switch

The laser console can be switched ON(I) or OFF (O) using the Power Switch on the left of the console (see Figure 2.3)

CAUTION:

Use only the Power Supply Module supplied with the Medray Quantum laser system.

3) Access Key Code

The Access Key Code prevents unauthorized use of the system. It is activated every time system is turned on with the Power Switch (refer to Section 4 for code).

4) Foot Switch

The Medray Quantum emits laser energy when the foot switch is pressed down and while the laser is in READY mode. The foot switch is protected by a metal cover. To access, first press down on the cover to unlatch it, then the foot switch can be pressed to fire the laser. (The foot switch function can be replaced by the finger switch on the handpiece).

Figure3.1 Footswitch

5) Remote Interlock Connector

This feature allows the laser console to be connected to the remote sensor, preventing its operation when triggered (e.g., by opening door). The electric cable from this connector should be wired to the normally closed switch, sensing the opening of a door and turning the laser console off when the switch is open.
To override this feature, don't connect the plug.

Figure 3.2 Remote Interlock Connector and the device port

6) Emergency Laser Stop

Press the red Emergency Laser Stop Button (see Figure 2.1) to instantly turn off the laser console. The error Screen will display an "Emergency Switch Error" message and the LED turns to red. To clear the error, turn off the power switch on the back of the laser console then restart the device.

7) Functional Display

The System Color Display with touchscreen and LED indicator on the control panel show the functional conditions of the system.The green color means power on, orange color means laser is emitting, red color means warning.

8) Sound Energy

The sound produced by Medray Quantum during normal use does not exceed the following levels: 83dBA, sustained for 12h over a 24-hour period. No special protective measures are required when testing acoustic energy.

3.4 Safety Classification

The following safety classifications are applicable to the device:

- Laser Radiation – Class4

- Aiming Beam–Class1
- Type of protections against electrical shock– Class Ⅰ
- Degree of protection against electrical shock– Type B Applied Part
- Not protected against water ingress– Ordinary Equipment
- Not suitable for use in presence of flammable anesthetic mixture
- Operation Mode –Continuous Wave and Pulse Mode
- Footswitch – IPX8

3.5 Maximum Permissible Exposure (MPE)

Maximum Permissible Exposure (MPE) is the highest power density (in W/cm2) from a light source that is considered safe. For the infrared radiation from this laser system, the MPE at the cornea for direct ocular exposure is determined by the wavelength, bam divergence, and exposure time. For Medray Quantum, the wavelength is 650nm,810nm,915nm,980nm and 1064nm; the beam divergence is 314mrad to 443mard. For exposure times between 10 and 3000seconds, the MPE at the cornea for Medray Quantum is 16.60 W/cm2; the skin MPE is 3319.2 W/m2.

3.6 Nominal Ocular Hazard Distance (NOHD)

Nominal Ocular Hazard Distance (NOHD) represents the distance at which the intensity or amount of exposure of the laser falls below the corresponding Maximum Permissible Exposure (MPE) under ideal conditions. This distance is a guide for the user security and is not a strict dividing line between safety and danger. In other words, it is not harmless to the human eye beyond the NOHD. In any case, the human eye should receive the minimum amount of laser exposure. The wavelengths of Medray Quantum is 650nm, 810nm, 915nm,980nm and 1064nm; The beam divergence is 314mrad to 443mard. The Nominal Ocular Hazard Distance (NOHD) is 6.25 m.

4. Operation Instructions

CAUTION:

To avoid the risk of electric shock, the Medray Quantum must be connected to a power grid with protective grounding.

CAUTION:

Medray Quantum must be connected to a suitable power supply; It can be connected to the power supply network or run from an internal power supply (lithium-ion battery, model: DBT-03). When the software prompts that the lithium-ion battery is low, connect it to the network power supply in time.

CAUTION:

The plug should not be inserted in a difficult position, so that the user can disconnect the network power in case of an accident.

NOTE:

For detailed installation instructions for Medray Quantum accessories and components, please refer to the service manual or contact the qualified person designated by the manufacturer to perform installation.

4.1 System Setup

(1) Place the unit in a clean, dry, and well-ventilated area.

(2) Set warning sign on the treatment room entrances.

(3) Make sure all persons present in the treatment room wear laser safety goggles.

(4) Medray Quantum power box with power cord socket and foot switch and remote interlock connector ports.

(5) Verify that the power switch is in the OFF (O) position.

(6) Take out the power cord and power supply adapter,insert one end of the power cord connector into the power supply adapter socket completely.

(7) Connect the power cord to the laser console and plug into a wall outlet.Medray Quantum will work using DC power.

(8) Connect the Remote Interlock Connector to the laser console.

(9) Connect the foot switch to the console by inserting the connector of the foot switch to the back of the console .

(10)Connect the suitable Therapy Cover(s) for Smart Handle on the handpiece handle if necessary. You should choose

the Therapy Cover(s) for Smart Handle according to you clinical need. Details can refer to 2.4 Transmission System.

(11)Wind any excess fiber optic cable onto the fiber spool counter clockwise around the base of the console.

(12)The handpiece is now ready to use. To store the handpiece, place it in the handpiece holder located at the top of the laser console.

CAUTION:

Do not connect or disconnect the handpiece or Therapy Cover(s) for Smart Handle while the laser console is turned on.

CAUTION:

Do not cover or block ventilation channels. these channels provide an air-flow path to cool the unit.

CAUTION:

Do not bend the fiber optic at a sharp angle, as it can be broken, the bend radius must more than 15cm.

Make sure it is not caught or pinched between the housing and the fiber optic access plug.

LASER WARNING:

Never point the laser at a person’s eyes.

LASER WARNING:

Never operate the laser without handpiece or Therapy Cover(s) for Smart Handle attached.

CAUTION:

Laser fume and/or plume may contain viable tissue particulates. the aperture protective hat acts as the protection for the laser aperture. When the handpiece is removed, please cover up the laser aperture with aperture protective hat immediately to prevent the aperture from being contaminated.

CAUTION:

Do prevent the laser aperture from the contamination of dust, liquid, oil or any other material. Otherwise, the output power of the laser will decrease or even the inner laser system will be damaged.

Clean the aperture protective hat with alcohol before using it. But do care not to leave cotton yarn or other funicle inside the hat during the cleaning.

4.2 Operation - Turn ON the Medray Quantum

Ensure the built-in lithium-ion battery of the device is enough power.If the built-in lithium-ion battery of the device is low power ,connect the power supply adapter with cord to the power connector on the laser console and plug the cord into a wall outlet.

4.2.1 Welcome Screen

Turn on the Power Switch at the back of the console to the ON (I) position. The Welcome Screen will appear (Figure 4.1).

Figure 4.1 Welcome Screen

4.2.2 Login Screen

After about 10 seconds, there will be a “Android” logo animation, and then the LOGIN Screen will appear (Figure 4.2).

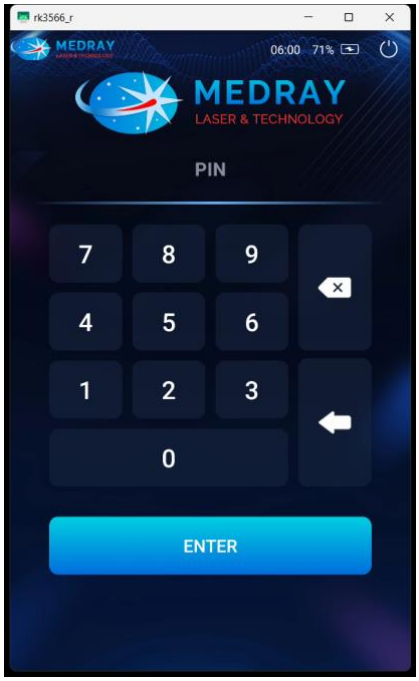


Figure 4.2 LOGIN Screen

The Password is 1234 or 0000 by default. Input the correct password, then you can enter the Selection Mode Screen,

(Figure 4.3).

4.2.3 Select mode Screen

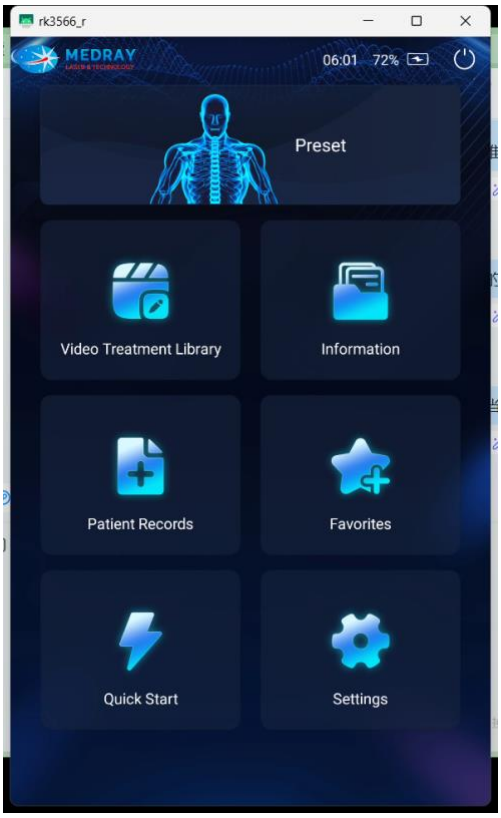
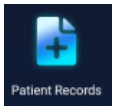


Figure 4.3 Selection Mode Screen

In the Selection Mode Screen, you can click the icons to enter the corresponding screens. By clicking 

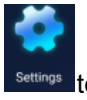
to enter the Preset Screen, which is showed in Sec.4.2.4 Preset Screen; By clicking 

to enter the VIDEO Treatment Library Screen, which is showed in Sec.4.2.5; By clicking 

to enter the Information Screen, which is showed in Sec. 4.2.6; By clicking 

to enter the Patients Record Screen, which is showed in Sec. 4.2.7; By clicking the 

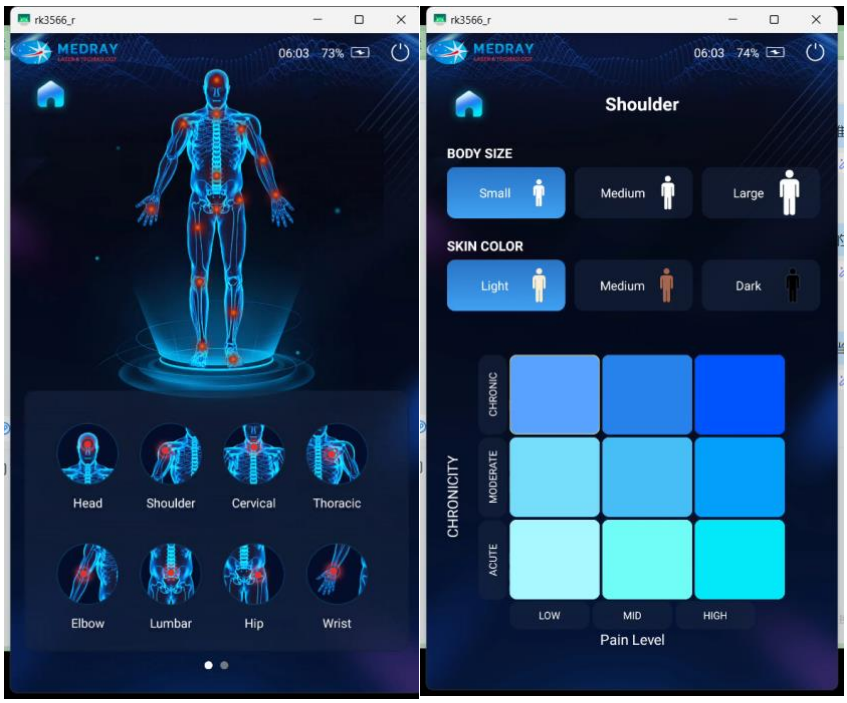
to enter the Favorites Screen, which is showed in Sec. 4.2.12; By clicking the 

to enter the Quick start Screen, which is showed in Sec. 4.2.13; By clicking the 

to enter the Setting Screen, which is showed in Sec. 4.2.14;

4.2.4 Pre-set Protocols

By clicking the Body Picture on the Selection Mode Screen, you can enter the Select Parameter Screen, which is showed in Figure 4.4.



(1) Body site selection (2) Other treatment selection

Figure 4.4 Select Parameter Screen

In this screen, you can select the treatment body site from the figure 4.4 (1), After entering the body site screen, you can select, skin color, chronicity and the Pain level, as needed. After the parameter are selected, the software will provide you the preset protocol, and you will enter the Treating Screen, which is show in Figure 4.5.

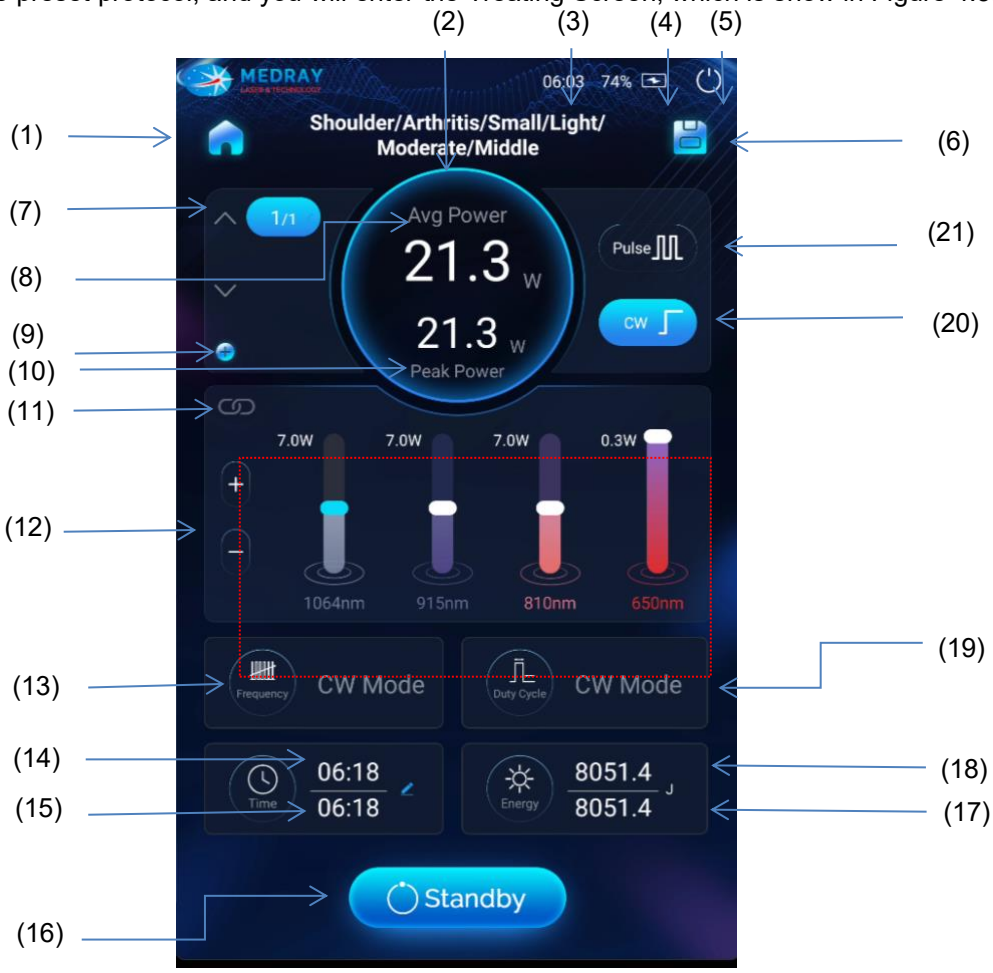


Figure 4.5 Treating Screen

(1)	*Return, return to the previous Selection Parameters Screen*	(2)	*The selected parameters*
(3)	*Time*	(4)	*The batter capacity*
(5)	*Power icon, to close the Screen*	(6)	*Save, save the parameters as Favorites Protocols Records*
(7)	*Treatment Phases*	(8)	*Average Power*
(9)	*Phase addition button, by click the icon ,the treatment phase can be added.*	(10)	*Peak Power*
(11)	*Lock icon, by click the icon, the laser output power can be adjust synchronously. After the max. Output reaches, the power of the wavelength can not be adjusted continuously.*	(12)	*Power adjust icons, including the increasing ico decreasing icon and the slide button*
(13)	*Frequency, in CW mode and Pusle mode*	(14)	*Phase time, the time of the current treating phase*
(15)	*Total time of the Preset protocols*	(16)	*Standby/Ready*
(17)	*Total Energy*	(18)	*Total Energy*
(19)	*Duty cycle, in CW mode and Pusle mode*	(20)	*CW mode, CW can be selected*
(21)	*Pulse mode, Pulse can be selected*		

As Figure 4.4 shows, the parameters of treatment body site, body size, skin color, chronicity and the Pain level are selected as Head, Small, Light, Moderate and low, correspondingly. The selected parameters will show on the screen. On this screen, several treating parameters can be set and the set parameters will show. Details are as followed.

(a) Treating Phases

The whole treatment may be divided up to different treating phases, the treatment phase can be added as needed. The parameter can be set as different for different phases. The screen will show the treating parameters of the current phase, the icon of which will turn into blue..

(b) Laser Output Power

The peak power for different wavelength can be set by the Power adjust icons (and) . The peak power range can be set are different for different wavelength of different models, details please refer to 5 Specification. After the peak power was set, the total peak power will show on the screen and the average power will be calculated automatically and show on the screen at the same time.

In addition, when the Lock icon is selected, the laser output power can be adjust adjust synchronously. After the max. Output reaches, the power of the wavelength can not be adjusted continuously.

(c) Operation mode

There are two kinds of operation modes can be selected, CW and Pulse.

CW-In this Continuous Mode (CW), the laser will emit continuously.

Pulse – In this Repeat Pulse Mode, the laser will be emitted by pulse. Selecting the pulse will allow the User to set the frequency and working parameters.

(d) Frequency

Frequency is the number of periodic changes in the laser pulse completed in one second. It can be set ranges from 1 Hz to 20000 Hz. Click the frequency box and the soft keyboard will display, allowing the user to manually input the value in Hz.

(e) Duty cycle

Duty Cycle is the percentage of the pulse width (laser emission time) in a pulse cycle. It can be set ranges from 1% to 99%. Click the Duty Cycle box and the soft keyboard will display, allowing the user to manually input the value.

(f) Phase treating time and the Total Time

The Phase treating time range is 1-7200 seconds, click the area of the time box, a keyboard will display, on the screen, allowing the user to manually set the Phase treating time. After the treating time of each phase are set, the total time will be calculated automatically and shown on the screen. The laser emission of each phase will stop when the phase treating time reaches.

(g) Phase Energy and Total Energy

After the laser output power and the treating time are set, the energy will show on the screen. The Phase Energy is calculated by the average power multiply by the treatment phase time for each treatment time. The Total Energy is the sum of all the phase energy.

(h) Save

After the treating parameter are changed or set completely, you can click the Save icon to save the parameters as Favorites or/ and Records. To save, click the option button 

. The Favorite protocol or the record can be named as you wish. After saved, the protocols will be listed in the Patients List (Records) Screen which is show in sec.4.2.7, the records will be listed in the Favorite List Screen which is show in Sec.4.2.8.

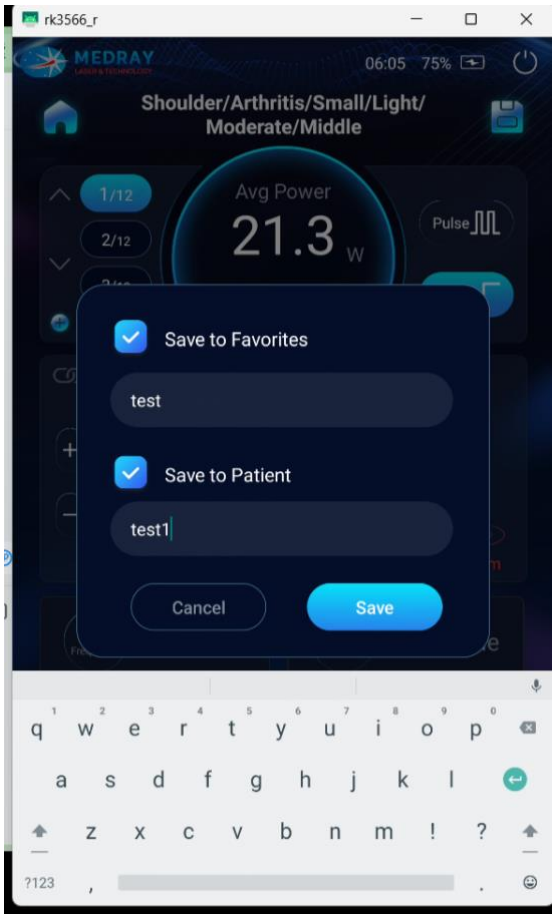


Figure 4.6 Save

4.2.5 VIDEO Treatment Library Screen

By clicking 

on the Selection Mode Screen, you will enter the following VIDEO Treatment Library Screen Screen.

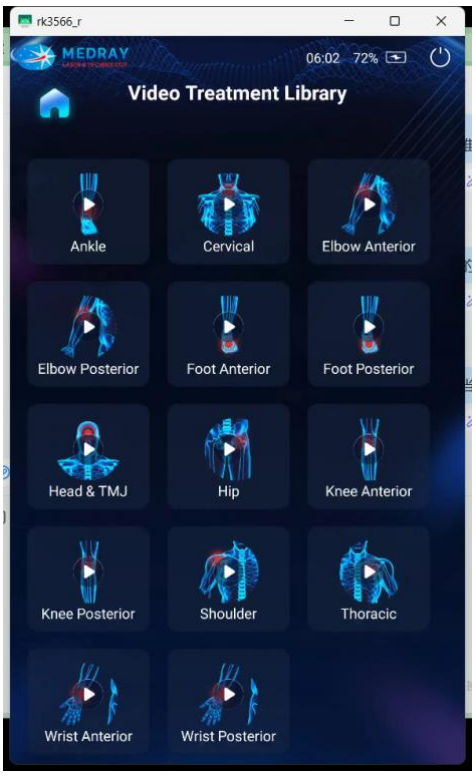
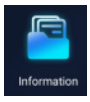


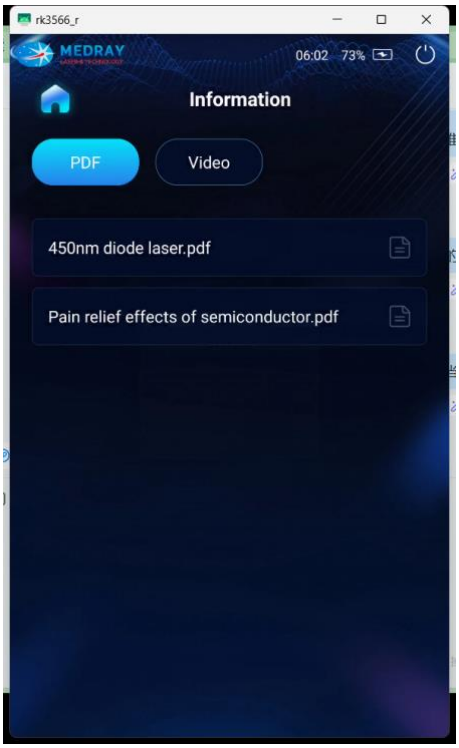
Figure 4.7 VIDEO Treatment Library Screen

In this screen, there will some VIDEO Treatment Library Screen saved. You can refer to the training files as you needed.

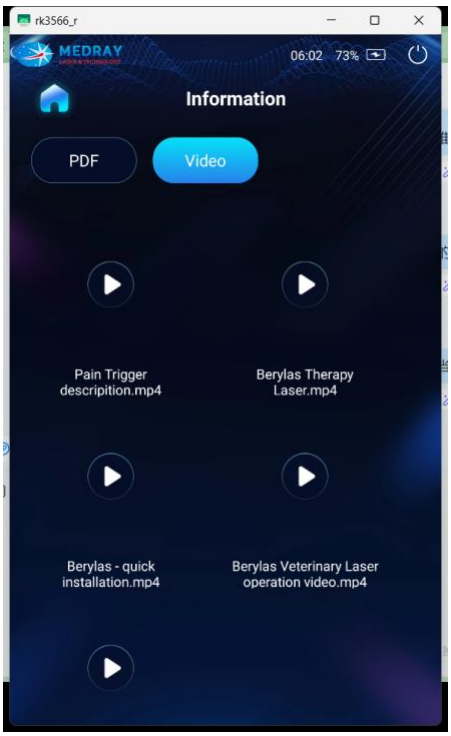
4.2.6 Information Screen

By clicking 

on the Selection Mode Screen, and you will enter the Quick Start Screen. The function icons are the same with the Treating Screen, details please refer to Sec.4.2.6, Figure 4.8.



(1) Clinical literature



(2)Clinical training videos
Figure 4.8 Information Screen

4.2.7 Record List Screen

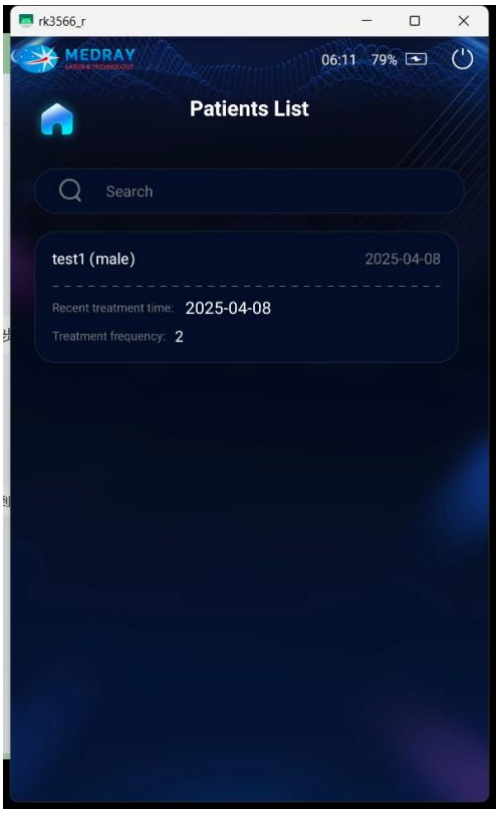


Figure 4.9 Record List Screen

Click the Save icon to save the parameters as Records, and then the protocols will show on the Record List Screen. Some parameter, such as the treatment site, treat time and applied energy will show on the screen when clicking the Drop down arrow . And you can also add some description for the records.

CAUTION:

Do not save sensitive information in the Description, when the product is repaired or scrapped, back up and delete relevant information.

4.2.8 Favorite List Screen

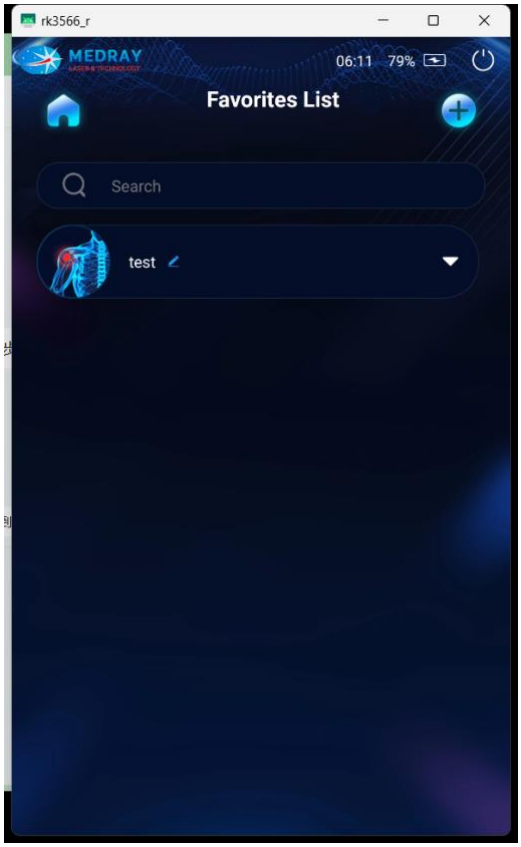
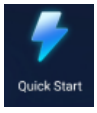


Figure 4.10 Favorites List Screen

Click the Save icon to save the parameters as Favorites, and then the protocols will show on the Favorites List Screen. Some parameter, such as the average power, operation mode, treat time and applied energy will show on the screen when clicking the Drop down arrow  .

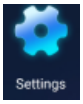
4.2.9 Quick Start

By clicking 

on the Selection Mode Screen, and you will enter the Quick Start Screen. The function icons are the same with the Treating Screen, details please refer to Sec.4.2.9, Figure 4.11.

Figure 4.11 Quick Start Screen

4.2.10 Setting Screen

Click the 

on the Screen, you will enter the following Setting Screen.

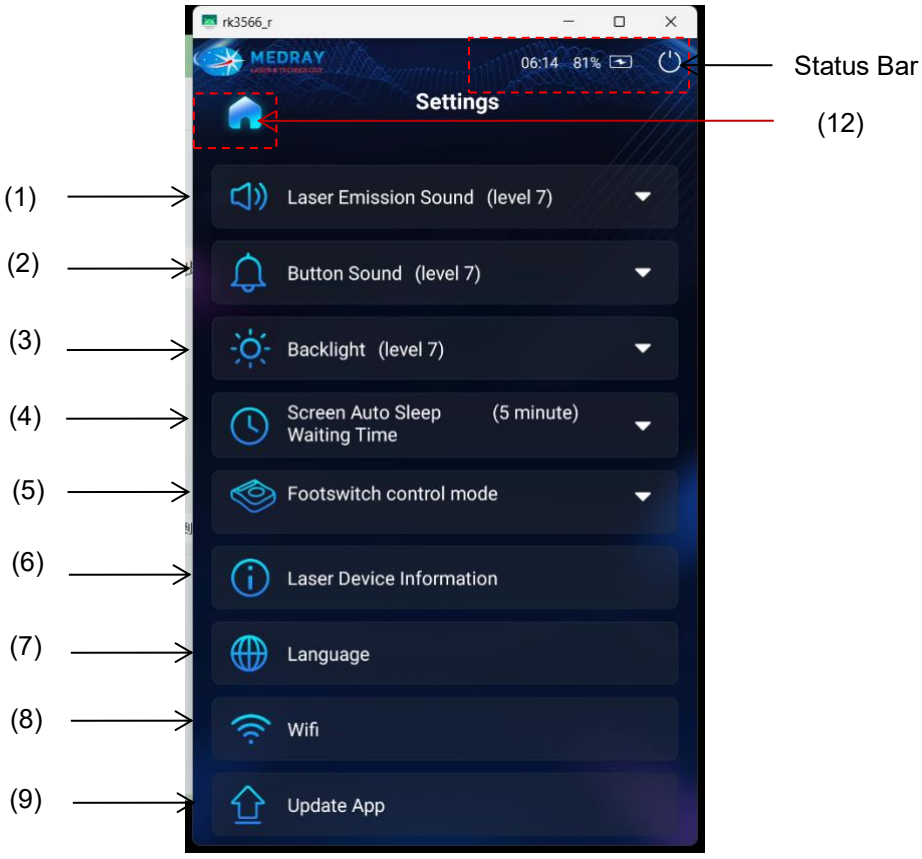


Figure 4.12 Setting Screen

(1) Emission sound, to adjust the sound warning the laser is emitting

(2) Button Sound, the adjust the sound clicking the icons

(3) Back Light, to adjust the brightness of the screen

(4) *Screen Auto Sleep Waiting Time, to set the screen auto sleep waiting time, when the time was set, the software will be locked if the time when there is no any operation on the screen reaches the set time*

(5) *Footswitch Controlled Laser Emission, to set the controlled method of footswitch. When "Hold" was selected, the laser will keep emitting when the footswitch is hold by the users, when "Release" was selected, the laser will keep emitting when the footswitch is released*

(6) Laser device Information, to get the information of the device, details refer to Sec.4.2.11 Information

(7) *Languages, to select different languages for the screens*

(8) Wifi, to connect the reliable wifi when needed, details refer to Sec. 4.2.11 WIFI Connection

(9) Update, to update the version of APK

(10) *Firmware Update, to update the software of the firmware*

(11) Change Password, to change the system password.

(12) *Back , to back the front page.*

4.2.11 Information Screen

By clicking the 

on the setting screen, the information of the device will show on the screen. The information including the model, Serial Number, Wavelength, Power, software version, manufacturing date and APP version.

Figure 4.13 Information Screen

4.2.12 WIFI Connection Screen

By clicking the WIFI cion 

on the setting screen, you can enter the following WIFI Connection Screen. The users can choose which WiFi they want to connect to or choose to turn off WIFI function.

> **CAUTION:**
> It is prohibited to connect to unsafe WIFI access nodes, and it is prohibited to access public WIFI.

Figure 4.14 WIFI Connection Screen

4.2.13 Standby and Ready

Click this button 

can switch the status form Standby to Ready.

Pressing the **READY** or **STANDBY** buttons, changes from one status to another.

STANDBY: In this mode, the laser power supply is disabled. User can set the parameters above.
READY: In this mode, the laser power supply is enabled. User can not set the parameters above. Pressing the Foot Switch the laser energy emits. Pressing the On / Off Switch on the Hand Piece instead, the laser energy emits (infrared), there will be laser beep sound. And the LED indicator color will change from green to orange.

> The power output (joules) level and treatment times are lower for the Conservative Settings versus the Aggressive Settings

4.3 Error

When the device is in Ready Mode, keep pressing the footswitch, the device will emit laser light, if the Footswitch/Remote Interlock Connector is not connected, the error message below (Figure 4.26) will appear. Other errors may also happen when the Medray Quantum is in use, please refer to the troubleshooting instructions to solve the problems.

Figure 4.15 Errors

4.4 Emergency Laser Stop

When the device needs to stop in an emergency, the user can press the Emergency Laser Stop Button on the top of the laser console (Figure 4.16). Pushing the Emergency Laser Stop Button terminates laser emission. Before restarting, turn as indicated by the arrow at the knob to bounce up the emergency stop.

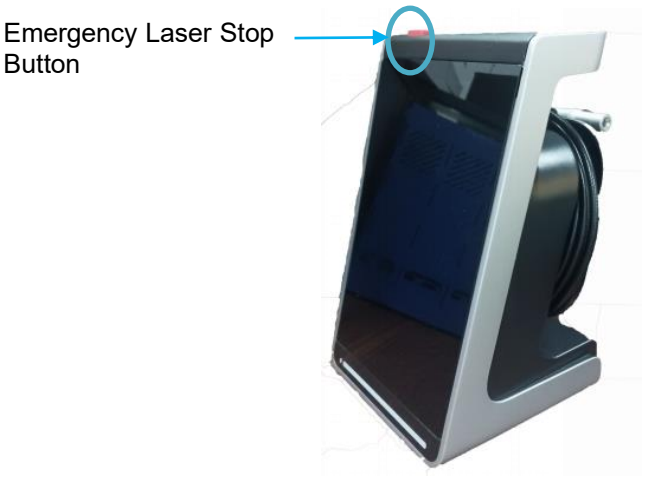
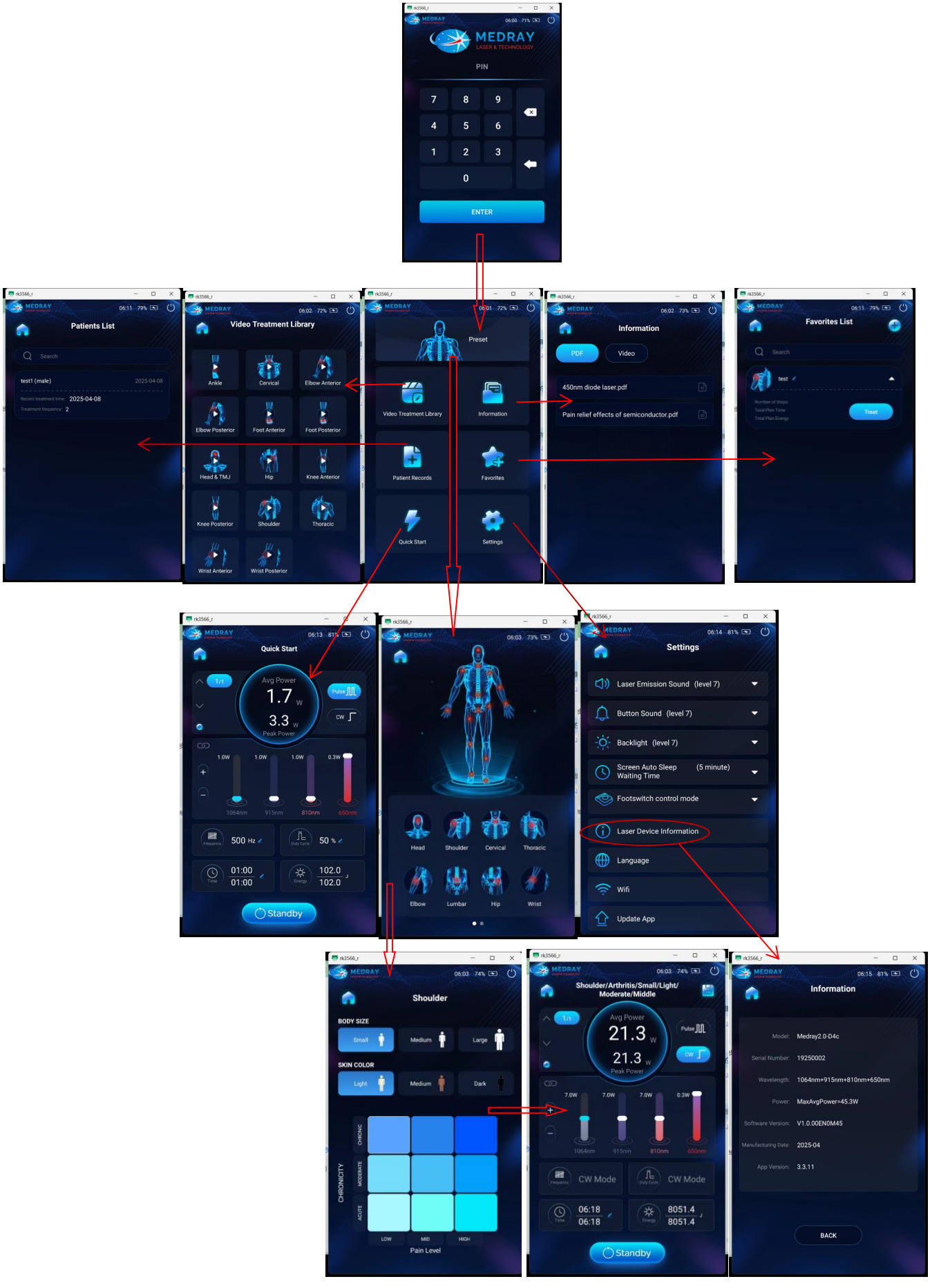


Figure 4.16 Emergency Laser Stop Button

4.5 Quick preview of main operation screens



4.6 Turn the Laser Console Off

After the device stops to emit laser light, switch the power switch (located on the back of the console) to the OFF (O) position to turn off the laser console and unplug the power cord. Wind the fiber cable onto the fiber spool counterclockwise around the base of the console.

Place the handpiece on the handpiece holder.

CAUTION:

Verify that the fiber optic tubing assembly is not twisted once the fiber is returned to the holder. The fiber may break if it is twisted.

Refer to Chapter 8 for the maintenance if the laser system will not be used for a long period of time.

5. Specifications

Electrical Specifications

Operating Voltage	100V -240V ~
Adapter	(Model No.: PH260-24): Input:AC100V-240V 2.8A-1.6A; Output: 24V, 8.67A-10.83A
Frequency	50/ 60Hz
Main Control	Power Switch
Disable Control	Emergency Laser Stop Button

Laser System Specifications

Laser Type	GaAlAs Diode Laser System
Wavelength and Maximum Power	Medray Quantum QuantumX: 640nm@0.2W, 808nm@15W, 915nm@15W, 1064nm@15W; Max.45.2W Medray Quantum Quantum: 640nm@0.2W, 808nm@10W, 915nm@10W, 1064nm@10W; Max.30.2W Medray Quantum QuantumX60: 640nm@0.2W, 808nm@30W, 980nm@30W; Max.60.2W
Operation Mode	CW, Pulse
Duty Cycle	1%-99%
Repetition Rate	1Hz- 20KHz
Transmission System	A non-removable handpiece with interchangeable Therapy Cover(s) for Smart Handle attached to a flexible optical fiber. Fibers of 400μm With SMA905 Connector
Control Mode	10.1 "Android Color LCD Touch Screen
Dimensions	210(W)*210(L)*290(H) mm
Weight	3.55Kg
Power Accuracy	± 20%
Laser Class	Class 4 laser Product per IEC/EN 60825-1
Safety Class	Class I Type Device per EN/IEC 60601-1
Waterproof level	IPX0
Footswitch Waterproof	IPX8

level	

Environmental Specifications

Storage Temperature	-20- 70ºC
Storage Humidity	10- 90%, Non-condensing
Storage Atmospheric pressure	80kPa – 106kPa
Operation Temperature	5- 35ºC
Operation Humidity	10- 90%, Non-condensing
Operation Atmospheric pressure	80kPa – 106kPa

6. Contraindications, Warnings & Precautions

6.1 Contraindications

All clinical procedures performed with the Medray Quantum must be subjected to the same clinical judgment and care used with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, or an immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/ laser type sources associated with this device.

WARNING:

- Do not apply infrared light to abdominal or lumbosacral points in pregnant females.
- Do not apply infrared light to the epiphyseal lines in children.
- Do not apply infrared light to the thoracic region or over the pacemaker itself in patients with pacemakers.
- Do not apply infrared light over the thyroid gland, ovaries or testicles.
- Do not apply infrared light to patients who are taking drugs that have heat or light sensitive contraindications, such as but not limited to certain types of steroids.

6.2 Warnings and Precautions

1) Safety Goggles

All personnel inside the treatment room must wear appropriate laser safety goggles for the diode laser wavelength of 810nm, 915nm, 980nm and 1064nm. Before you wear the safety goggles, please check if the wavelength and protection grade are matched with the following table.

Item	Wavelength	VLT%	Protection grade	Recommend Manufacturer
Safety goggle	800-1100 nm	50%	OD6+	SOKY

2) Clinical Use

Use your clinical judgment to determine all aspects of treatment including, but not limited to, the laser treatment protocol, technique, power settings, pulse duration and interval settings, mode of operation as well as the accessories(*e.g.*, tip type) and other procedural requirements.

Closely observe and monitor clinical effects and use your judgment to determine clinical parameters and approach for the treatment. Make appropriate power, pulse length, and interval adjustments to compensate for varying tissue compositions, density, and thickness. Always start treatment at the lowest power setting for that specific indication and increase as required.

Medray Laser & Technology assumes no responsibility for parameters, techniques, methods or results.

3)Training

Only licensed professionals who have reviewed and understood this User Manual should use this device. Medray Laser & Technology assumes no responsibility for parameters, techniques, methods, or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc.

LASER WARNING:

Never point the laser at a person's eyes. All persons present in the treatment room must wear safety goggles when the laser is in operation.

7.Clinical Applications

7.1 Introduction

WARNING:

Only operators who have been trained in the use of lasers and are thoroughly familiar with this Operator Manual should use Medray Quantum. Medray will provide the training ,however, training provided by Medray is limited to the use of the Medray Quantum and does not replace the necessary medical training and experience required to perform pain treatment.

CAUTION:

Medray Quantum should only be used by professionals trained in pain treatment.

7.2 Indications for Use

Medray Quantum is intended to emit energy near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; the temporary relaxation of muscle.

Indications:minor muscle and joint pain and stiffness; minor arthritis pain; muscle spasm.

Patient populations: Adult, and meet the requirement of indications and contraindications.

Intended user: Doctors, healthcare professionals or carers,who must be trained to how to use the device.

Organs / parts of the body / tissues or body fluids contacted by the device:the treatment heads may contact with the human body. There are 5 models treatment heads for optional. The nature of contact is as followed: Direct contact, contact body: the intact skin, the contact materials are different.

Side-effects:Discomfort or redness of the skin.

WARNING:

Do never treat the patients who do not match the requirements of indications and contraindication, which may lead to burn patients or other adverse reactions.

A NOTICE TO THE USER and/or PATIENT :

Any serious incident that has occurred in relation to the device should be reported to the Medray and the competent authority of the Member State in which you are established.

8. Maintenance

WARNING:

No modification of this equipment is allowed. No maintenance while in use.Improper maintenance may result in equipment damage or even electric shock.

CAUTION:

Medray Quantum contains no parts that are serviceable by the user. Any attempt to repair, adjust, or modify the system (outside of the procedures outlined in this manual) by any person not authorized by Medray is strictly forbidden and will invalidate the warranty.

The final decision will rest with with Medray in all cases.

To avoid risk of electric shock, do not open the housing. During the warranty period, servicing and maintenance may only be carried out by Medray or by qualified personnel authorized by Medray.

CAUTION:

The Medray Quantum repair process may produce energy hazards, such as electrical energy, electromagnetic interference, mechanical energy, laser radiation, etc. When replacing a component, refer to the circuit diagram, component list, or other maintenance documents.

CAUTION:

Medray may provide circuit diagrams, component lists, drawing notes, calibration instructions, or other materials upon request which may help maintenance personnel repair the Medray Quantum which can be repaired by the maintenance personnel designated by Medray.

8.1 Daily Maintenance

The following checks should be performed regularly:

- Check customer has applied to the doctor and patient is suitable for laser protective glasses models.
- Check the device and treatment room enough air circulation between the walls.
- Check the integrity of the laser transmission system launch port.
- Check the function of the LED Indicator.
- Check that all labels and markings can be read and are positioned correctly.
- Check whether all of the power input connection is good and safe and reliable
- Check the foot switch connection.
- Check that an Remote Interlock Connector the laser into standby mode.
- Check that the Emergency Laser Stop Button is working.

●Check aiming beam integrity.

● At the lowest possible power setting, check that the laser switches to standby when the connector of the application fiber is loosened.

8.2 General Cleaning

Attention: Unplug the device before cleaning.

1. After each operation, power should be turned off and put in a dry and ventilated place to keep the instrument clean,Chemical cleaning agents, abrasive cleaning agents, and rough cleaning cloths may damage the surface of the housing and therefore should not be used.To avoid liquid leakage into the machine caused by the machine circuit failure.
2. Foot switch: dust should be forced to avoid bad contact. Do not tread too hard, so as not to damage the foot switch. Foot switch absolutely prohibited water, soaking.
3. Do not twist the connecting joint of the foot switch and avoid frequent insertion and removal to avoid poor contact or damage.
4. Connect the power cable to the device plug and Remote Interlock Connector. Do not frequently insert or remove the power cable to avoid bad contact or damage.
5. Handpiece: Before each use, it should be sterilized by professional users according to the requirements of the operation. Before sterilization, clean and disinfect as required. When optical fibers are not in use, place them properly to prevent pollution.

8.3 Transportation

The Medray Quantum is susceptible to damage if not handled properly. The unit should always be handled carefully and never banged, jarred, jolted, dropped or knocked.

Do not transport the unit unless it is completely packaged inside its shipping box. If you have any questions regarding transportation please contact Medray.

8.4 Storage

The Medray Quantum should be stored in a cool, dry place when not in use. Storage temperature -20°C-70°C, relative humidity 10%- 90%, non-condensing. Cover the unit when not in use for extended periods of time. Store the system in a place where it will not be accidentally bumped or banged.

CAUTION:
Make sure the distal end of the handpiece shaft is protected from dirt with the protective tip plug and handpiece.

The Medray Quantum is shipped inside a custom shipping box. Please save and store the box in a cool, dry place for use when transporting the laser, or for long-term storage.

8.5 Battery maintenance

The battery can be recharged 300 times and can be replaced when the user feels the battery is low.

When the battery level is less than 20%, the device will send out an alarm signal to remind you to charge.It takes 3-5 hours to fully charge.

8.6 Safe Disposal

If you plan to discontinue the use of this laser and intend to dispose of it, make sure to observe the applicable legal provisions. Please contact your local distributor, authorized service center, or Medray customer service for the disposal of this laser.

9. Calibration

Calibration procedure is recommended to be performed every twenty-four (24) months in order to maintain the required accuracy of output power versus displayed power. Bi-annual calibrations can be performed at a certified depot repair facility. Please contact Medray Laser and Technology. or your Authorized Service Representative to schedule an appointment. For calibration, the instrument used is Laser Power Meter. The recommended Laser Power Meter is LP-3C manufactured by Physcience Opto-Electronics, Beijing. LP-3C is composed of two parts: Laser Receiving Part and Output Power values Displaying Part. The steps of calibration procedure are as followed.

Step 1: Make the Medray Quantum power on, handpiece connected and in the Standby Status.

Step 2: Make the Laser Power Meter power on, and select the suitable test range.

Step 3: Connect the tip of fiber to the Output Power Values Displaying Part. There should be 2-3cm between the tip and the Displaying Part.

Step 4: Adjust the parameters for each wavelength of Medray Quantum as followed in sequence: Operation CW mode, output power: Minimum, median and maximum; and Operation repeat mode duty cycle with 50%, output power: Minimum, median and maximum.

Step 5: Make Medray Quantum Medical diode laser emitting, and read the power values in the Output Power values Displaying Part.

The error between the preset and measured power should be less than ±20%. If not, you are requested to call Medray for maintenance.

The following output power values and pulse duration values are recommended to be calibrated.

No	Setting Output Power	Permissible Output Power Range	Measured Output Power	Verdict
1				
2				
3				
4				

No	Setting pulse Duration	Permissible Pulse Duration Range	Measured Pulse Duration	Verdict
1				
2				
3				

CAUTION:

No need to calibrate the pulse width during the expected lifetime, The above data is for reference only.

10.Software Specification

Medray Laser & Technology respects the intellectual property of others, and we ask our users to do the same.
The Medray Quantum series software is protected by copyright and other intellectual property laws.
This product contains proprietary ,copyrighted software developed by Medray Quantum all rights reserved in U.S.A. and other countries.

11.Troubleshooting

Should any of the on-Screen messages listed in Figure11.1 appear, follow the trouble shooting instructions for the specific message as noted below.

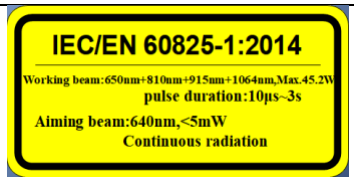
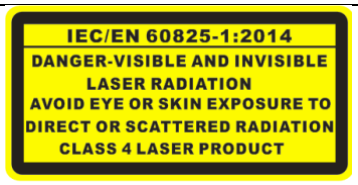
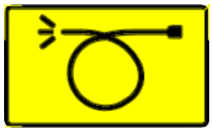
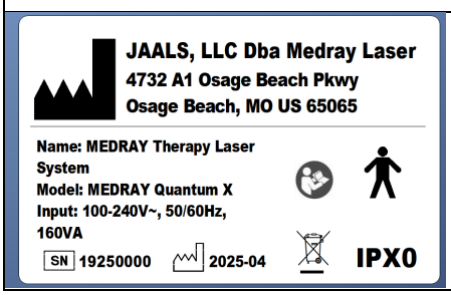
NOTE:

For any on-screen message not listed in Figure 11.1, re-power the laser console; if the message does not clear, please contact Medray Laser & Technology at info@medraylaser.com or (573) 745-1086.

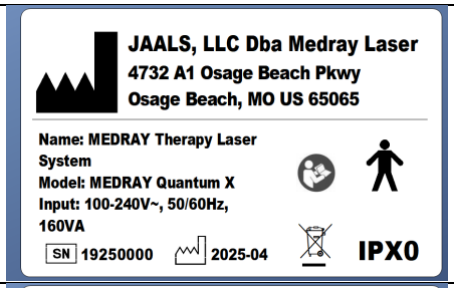
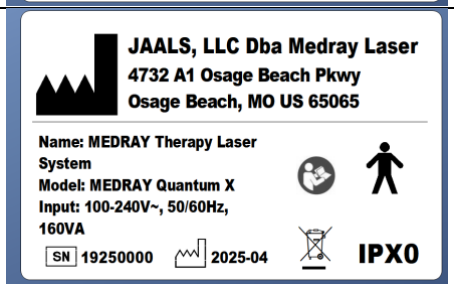
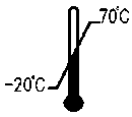
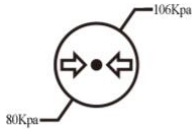
Title	Message !	Reason ?	Fix ✓
Error 1 	Laser Temperature too High	System too hot	Allow 5-10 mins for laser to cool down
Error 2 	Laser Temperature too Low	Environment temperature too low	Raise the environment temperature
Error 3 	Laser Temperature Sensor open circuit	Laser Temperature Sensor open circuit	Call Medray Laser Service
Error 4 	Laser Temperature Sensor short circuit	Laser Temperature Sensor short circuit	Call Medray Laser Service
Error 5 	Controller Overheat	System too hot	Allow 5-10 mins for laser to cool down
Error 6 	Controller Temperature Sensor open circuit	Controller Temperature Sensor open circuit	Call Medray Laser Service
Error 7 	Controller Temperature Sensor short circuit	Controller Temperature Sensor short circuit	Call Medray Laser Service
Error 8 	Fiber not connected	Fiber not inserted	Connect the Fiber
Error 9 	Footswitch not connected	Footswitch not connected	Connect the foot switch
Error 10 	Laser light Emergency Laser Stop	Laser light Emergency Laser Stop	Switch off the power and restart the system
Error 11 	Power Error	Power Error	Restart the device, call Medray Laser Service if error not cleared
Error 12 	Foot switch not released	Foot switch not released	Release the foot switch
Error 13 	Remote Interlock Connector not connected	Remote Interlock Connector open	Check Remote Interlock closed
Error 14 	Duration time or Frequency setting error.	Duty Cycle〈1% or the interval time〉3s	Duty Cycle should ≥1%; Re-enter the Phase Time
		Other unknown error	Call MedrayLaser Service

Figure11.1

APPENDIX A–Labeling

Graphic	Title	Description
	Emergency Laser Stop	Top indicate the Emergency Laser Stop Button location, the switch used in emergencies to stop laser output.
	Warning Lable-Hazard Symbol	Warning, there is laser radiation.
	Explanatory label for Laser specification	Explanatory label, indicates specification of laser output power, wavelength of diode and aiming beam and the applicable Standard
	Explanatory label for laser emission	To indicate the medical device is a class 4 Laser Product, be careful to avoid eye or skin exposure to direct or scattered radiation
	Aperture Label	Optical fiber applicator, to indicate the laser aperture is on the end of the applicator(handpiece).
	Medical Device	Indicate the item is a medical device
	Unique device identifier	To indicate carrier that contains unique device identifier information. For example: for Medray Quantum, UDI:06974214160XXX Manufacturing Date:YYYY.MM.DD, SN:19XXXXXXX;the issue agency:GS1; the UDI carrier is as followed: and the UDI Carrier will be placed adjacent to the UDI symbol. 
	Nameplate	To provide the basic information of the medical device, including the manufacturer information.

	Manufacturer	To indicate the medical device manufacturer
	Date of manufacture	To indicate the date when the medical device was manufactured
	Serial Number	To indicate the manufacturer's serial number so that a specific medical device can be identified
	Follow instructions for use	To signify that the instructions for use must be read
	Defibrillation-Proof Type B Applied Part	APPLIED PART complying with the specified requirements of IEC 60601-1 to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT
	THE MARKING OF EEE	To indicate the Medical Device is electrical and electronic equipment, the waste must be collect separately
IPX0	IP code	To indicate the degrees of protection provided by an enclosure against access to hazardous parts, ingress of solid foreign objects, ingress of water and to give additional information in connection with such protection. IPX 0 means the protection level for ingress of solid foreign objects is not specified, the protection level for ingress of water is 0.
	Authorized representative in the European community	To indicate the authorized representative in the European community
	CE marking	To indicate the Medical Device is considered to be in conformity with the requirements of MDR

	Footswitch label	To indicated the Manufacturer of foot switch, the main performance and the manufactured information of foot switch.
	Single unit packaging Label	Indicates the sales unit information
	Importer	Indicates the entity importing the medical device into the locale
Transport Packaging Label		
	Fragile, handle with care	Fragile, handle with care, indicates a medical device that can be broken or damaged if not handled carefully
	Keep dry	Keep dry, indicates a medical device that needs to be protected from moisture
	Humidity Limitation	Humidity limitation, indicates the range of humidity to which the medical device can be safely exposed
	Temperature Limit	Temperature limit, indicates the temperature limits to which the medical device can be safely exposed
	Atmospheric press limitation	Atmospheric pressure limitation, indicates the atmospheric pressure limits to which the medical device can be safely exposed

APPENDIX B–Spare Parts & Accessories

Medray offers the laser console, spare parts or optional accessories for Auralight-B system, users can select the optional accessories according to their applications, the other parts are standard parts include in the unit.

No.	Name	Specifications	Spare parts	Optional accessories
1	Laser Console	Medray Quantum	✓	
2	Power Cord	Mains plug:YG-102, Power supply cord: H05VV-F, Mains connector:YG-11	✓	
3	Adaptor	PH260-24: AC100-240V ; Output: 24V, 8.67A-10.83A	✓	
4	Footswitch	MF-10	✓	
5	Remote Interlock Connector	3.5mm-silver-3	✓	
6	Safety Goggles	Wavelength: 800-1100nm; VLT%: 50%; Protection grade: OD6+	✓	
7	Therapy Handpiece	/	✓	
8	Treatment head(s)	TYPE:DF-004B		✓
9	User Manual	/		
10	Warranty Card	/		

APPENDIX C–Electromagnetic compatibility

CAUTION:

Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in The following tables.

Portable and mobile Radio Frequency (RF) communications equipment can affect medical electrical equipment.

Accessories: Medical grade power cord, maximum length 2meters

Footswitch: Wired

WARNING:

No modification of the accessories and foot switch is allowed. As replacement parts for internal or external components, may result in increased EMMISSIONS or decreased IMMUNITY of the Medray Quantum medical diode laser system.

Guidance and manufacture's declaration----electromagnetic emissions		
The Medray Quantum is intended for use in the electromagnetic environment specified below. the customer or the user of Medray Quantum should assure it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
Class A or B	Class A	The Medray Quantum 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.
Group 1 or 2	Group 1	
CISPR 11,14-1,32 or ISO 7137	CISPR 11	
Conducted RF Emissions	Compliant	The Medray Quantum is not suitable for interconnection with other equipment.
Radiated RF emissions	Compliant	
Harmonic current Emissions IEC 61000-3-2	Compliant	The Medray Quantum is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage changes,voltage fluctuations and flicker Emissions IEC 61000-3-3	Compliant	

Guidance and manufacture's declaration----electromagnetic immunity			
The Medray Quantum is intended for use in the electromagnetic environment specified below. the customer or the user of the Medray Quantum should assure it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Continuous level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast Transients/bursts IEC61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency	Main power quality should be that of atypical commercial or hospital environment.
Surges (line to line) IEC 61000-4-5	±0.5kV , ±1 kV	±0.5kV , ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges (line to ground) IEC 61000-4-5	±0.5kV, ±1 kV , ±2kV	±0.5kV, ±1 kV , ±2kV	
Voltage dips, short interruptions and voltage variations IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle <5% U_T (>95% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25/30 cycles (50/60Hz) <5% U_T (>95% dip in U_T) for 250/300 cycles (50/60Hz)	<5% U_T (>95% dip in U_T) for 0.5 cycle <5% U_T (>95% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25/30 cycles (50/60Hz) <5% U_T (>95% dip in U_T) for 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Auralight-B requires continued operation during power mains interruptions, it is recommended that the Auralight-B be powered from an uninterrupted power supply.
RATED Power frequency magnetic fields IEC 61000-4-8	30 A/m 50Hz or 60 Hz	30 A/m 50Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. main voltage prior to application of the test level

Guidance and manufacture's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted Disturbances Induced by RF fields IEC 61000-4-6	3 V RMS 150 kHz to 80 MHz 6 V RMS in the ISM bands between 150 kHz to 80 MHz 80% AM at 1kHz	（V1）=3 V RMS	Portable and mobile RF communications equipment should be used no closer to any part of the Medray Quantum, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ **150 KHz to 80 MHz** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.7 GHZ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 8s there commended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] **Interference may occur in the vicinity of equipment marked with the following symbol:** 
Radiated RF EM fields IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	

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) telephone 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 Medray Quantum is used exceeds the applicable RF compliance level above, the Medray Quantum should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Medray Quantum.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] 3V/m.

Recommended separation distances between
Portable and mobile RF communications equipment and the Auralight-B

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.7 GHz** $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

APPENDIX D–Cleaning

WARNING:
Always turn off the system and unplug the power cord from the wall outlet before cleaning.

WARNING:
Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

Medray Quantum is a compact laser product. It is important to keep the unit and accessories free from dust. To clean the exterior surfaces on the unit or accessories:

CAUTION:
Ensure the solution is only 75% alcohol or less. Solutions of more than 75% alcohol can cause product damage. After cleaning the handpiece head, wipe it dry with a soft cloth. then leave it on a clean surface to dry.

LCD Panel

After each use, use a dedicated LCD screen to clean the LCD panel. Do not use bleach or lotion.

CAUTION:
Do not spray or dump the detergent directly on the LCD panel. This may cause damage to the equipment.

Device Shell

Use a dust-free cloth dampened with a small amount of a noncorrosive cleaning solution, such as isopropyl alcohol or a hospital-grade disinfectant, to wipe the device housing. Wipe and air dry.

Therapy Handpiece

To disinfect the Therapy Handpiece, with an appropriate such as alcohol (containing 75%), and wrap the handpiece with clean gauze.

NOTE:
The Handpiece is a re-usable accessory and will require cleaning and disinfection prior to each patient treatment.

CAUTION:
Handpiece must be disinfected prior to initial use.
handpiece(s) is reusable and must be cleaned and disinfected between patients to avoid cross-contamination.

APPENDIX E– Application Specification

E.1 Medical purpose

Medray Quantum is intended to use in emitting energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and the temporary relaxation of muscle and for temporarily increasing local blood circulation.

The device is intended to be used in Medical facilities, such as hospital and clinic, for inpatient or outpatient use.

E.2 PATIENT population

a) Age: adult

b) Weight: no requirements

c) Health: If the patient has one of the situations as follows or the treatment site is included in the following situation, he/she is not applicable for this Medical Diode Laser Systems.

(1) Abdominal or lumbosacral points in pregnant females;
(2) The thoracic region or over the pacemaker itself in patients with pacemakers;
(3) The thyroid gland, ovaries or testicles;
(4) Patients who are taking drugs that have heat or light sensitive contraindications, such as but not limited to certain types of steroids.
(5) Patients who have been proved are not suitable for the therapy of laser.

d) Nationality: multiple

e) PATIENT state:

- PATIENT is user: N/A
- PATIENT is not user: adult

E.3 Part of the body or type of tissue applied to or interacted with

a) Treatment site:
–intact skin, muscles and joints

b) Condition: health is suitable for treatment.

E.4 Intended user

a) Age: adult
b)Gender: no requirements
c)Education:

- doctors, healthcare professionals or carers, who must be trained to how to use the device. For training users, the main training document is the IFU, which is provided to users along with the device. After the sale personnel explain how to operate the device and the matters needing attention during the transport, storage, operate, maintenance and repair, and disposal process, an operating video about the particular problem can be provided.
- no maximum

d) Knowledge:

- minimum: doctors, healthcare professionals or carers, who must be trained to how to use the device

- no maximum

e) Language understanding:

- one of those in the instructions for use

f) Experience:

- minimum:

healthcare professionals and carers who have been trained in functions and indications of the Medical Diode Laser Systems.

- no maximum

g) Permissible impairments:

- average degree of aging-related short term memory impairment

E.5 Application

a) Environment:

– General:

- This product is intended for use in a medical facility, such as hospital, clinic, for inpatient or outpatient use
- Avoid using the device in the vicinity of flammable or anesthetic gases.
- Do not use the device in the direct vicinity of short-wave or microwave equipment.

– Physical: Conditions of visibility:

- Ambient luminance range: 100 lx to 1 500 lx
- Viewing distance: 20 cm to 40 cm.

– Physical:

- Environmental temperature for using: 5ºC to 35^{o}C
- Environmental humidity for using: 10-90%, Non-condensing
- Environmental temperature for storage: -20ºC to 70ºC
- Environmental humidity for storage: 10-90%, Non-condensing
- Environmental pressure: atmosphere pressure (about 80 Kpa to 106 KPa)
- AC adaptor (Model No.: PH260-24): Input:AC 100-240V ; Output: , 24V, 8.64A-10.83A

b) Frequency of use:

Medical device works in non-continuous operation (maximum activation (on) time: 5 min, minimum deactivation (off) time: 1 min). Suggest 0.5 hours per day.

c) Mobility:

– Portable MD equipment. Secure the Medical Diode Laser Systems before use.

Medray Laser and Techology

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