JUNERA

980nm / 1470nm Diode Laser System

USER MANUAL

Version V1.1

ONYXA MEDICAL

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Wavelength: 980nm±10nm, 30W | 1470nm±10nm, 17W

Designed in conjunction with safety standards:
IEC 60601-1:2005+A1:2012+A2:2020 | IEC 60601-2-22:2007+A1:2019
IEC 60601-1-2:2014+A1:2020 | IEC 60825-1:2014

www.onyxamed.com

Device Information

Model	JUNERA
Serial Number	Check the sticker label on the machine body
Software Version	2025
Date of Sale	Check the sticker label on the machine body

Contact Information

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Table of Contents

1 Introduction

Thank you for choosing the JUNERA 980/1470nm laser.

JUNERA is a class 4 laser and care must be taken to avoid hazards or injury. Please read the operation manual carefully before operation. If you have any further questions about the safety, use or operation of the device that are not answered in these instructions, please contact ONYXA Medical (see Sales and Service Information, Section 14) or your local representative.

Indication for Use:
The "JUNERA" is indicated for the treatment of Facial Contouring and Lipolysis.

1.1 Copyright

The appearance, hardware control system, control software and other related parts are part of ONYXA Medical's copyright and all rights are reserved. Any person or company bears the legal liability for counterfeiting.

Under copyright law, this manual may not be copied in whole or in part without the express written permission of ONYXA. Authorized copies must bear the same ownership and copyright notices as are affixed to the original. The manual will be updated as changes and updates are made to the device.

1.2 Warnings and Safety Precautions

WARNING - CLASS 4 LASER PRODUCT
Visible and Invisible Laser Radiation Avoid Eye or Skin Exposure to Direct or Scattered Radiation 1470nm±10nm, 30W 980nm±10nm, 17W IEC 60825-1:2014 & IEC 60601-2-22:2007+A1:2019

WARNING
Always wear protective eyewear when using this device. The optical power emitted by this system can cause serious eye damage or other injury. Exercise extreme caution to avoid injury.

This device is intended for use by trained physicians or scientists only and should only be operated by qualified personnel who have familiarized themselves with the operating parameters of this product prior to use.

The "JUNERA" is a Class 4 laser according to IEC 60825-1:2014. A class 4 laser is dangerous to the eye both by direct beam and by diffuse reflection of the beam. It also represents significant skin and fire hazards.

DANGER

Do not use the unit near flammable anesthetics or other flammable substances. Avoid exposure of eyes and skin to direct or scattered radiation. Take all necessary precautions in areas where the laser is being used.

The near-infrared light (980nm, 1470nm) of the "JUNERA" penetrates the transparent parts of the eye and is focused on the retina at the back of the eye. This can inadvertently cause a retinal burn.

Only safety eyewear designed to protect against cw diode laser radiation with a wavelength of 980nm ±10nm and 1470nm ±10nm and an optical density of OD ≥ 4 should be used. Glasses that do not meet this specification are not suitable as eye protection. Suitable glasses are available from your ONYXA representative.

Nominal Ocular Hazard Distance (NOHD) is 10.5 m from the distal end of the fiber.

ATTENTION

Do not stare into the aiming beam or view the aiming beam directly through optical instruments. Avoid direct exposure to the aiming beam. Avoid placing reflective material, such as metal and glass, into the beam.

ATTENTION

Accidental irradiation to other than the target tissue may result in laser burn.

ATTENTION

The "JUNERA" is only to be used in combination with a foot-switch and specified application and light delivery systems appendant to the device.

ATTENTION

Please avoid touching the patient and the foot switch / door contact simultaneously.

ATTENTION

Please avoid electromagnetic interference. Electromagnetic interference will affect the normal use of medical devices.

NOTE:

A minimum distance of 25 cm should be maintained between the ventilation slots and the walls.

To avoid the risk of electric shock, the cover must not be removed. All maintenance work should be carried out by ONYXA or by qualified personnel authorized by ONYXA. After the warranty period has expired, maintenance can also be carried out by suitably qualified persons.

The device should be routinely cleaned and disinfected as described in the section "Cleaning and disinfecting the device" in this manual.

2 Transportation and Storage

2.1 Information on the Packaging

NOTE:
Please keep the packaging in case you need to return the product for servicing or repair.

The symbols printed on the outside are for transportation and storage, and have the following meaning:

- This end up
- Keep away from moisture
- Do not turn over
- Temperature extremes
- Limit of relative humidity 10%~90%
- Limit of atmospheric pressure 80KPa~106KPa
- Fragile – handle with care
- Not to be stowed under other cargo

The "JUNERA" should only be transported and stored in its original packaging to avoid damage. Drastic shaking during transportation should be avoided. Please do not throw or hit the device.

The device should not come into contact with acids, alkalis or corrosive substances. Protect it from direct sunlight or rain.

2.2 Transportation and Storage Conditions

The ambient air has to be dry (10%~90%) and clean. The temperature ranges from -20°C to 70°C, and the atmospheric pressure ranges from 80kPa to 106kPa.

3 Installation

3.1 Unpacking and Installation

In most cases, the device should be unpacked and installed by ONYXA or one of its representatives, responsible for on-site testing and inspection.

The product is well packed before transportation. Please check carefully for the package after you receive it.

When unpacking, please check that all items are included according to the packing list and keep them carefully, as they will be needed when you return the product to ONYXA. If you have any questions, please contact ONYXA or your representative immediately.

3.2 Requirements for the Room

The use of a medical Class 4 laser requires warning logos on the unit itself and clear markings at the entrances to the room. Please refer to the information below for further instruction.

3.2.1 Labeling of the Entrance

Each entrance door must be clearly marked so that the laser room can be immediately recognized from the outside.

- A laser warning logo indicating the laser wavelength must be affixed to all entrance doors.
- Each entrance door must be fitted with a warning light. Each time the laser is switched on, the warning light must light up and shine outwards.
- It is strictly forbidden to enter the room while the laser is in operation.

3.2.2 Laser Protection at Windows

During the procedure, it is important that no laser light can escape from the room. All openings to the outside of the laser room, including windows, must be properly secured to prevent laser beams from escaping. If you need information or assistance in designing the room, please contact ONYXA or your local dealer.

3.2.3 Protection Against High Reflective Surface

To avoid any direct or indirect scattered radiation from the laser beam, no highly reflective material should be found in the surgery room. This includes mirrors, picture frames, polished chromium surfaces and windows. All such surfaces have to be removed or protected by non-reflective material.

3.3 Safety Indicators

Safety indicators must be affixed to all entrances, exits and places, including windows, from

where the laser or laser radiation could escape.

4 Safety Tips and Technical Acceptance

4.1 General

The "JUNERA" is a precise medical laser device and can only be used for medical or Medical Aesthetic application. The system has been thoroughly developed and will be thoroughly tested before shipment. To enjoy your product through the lifetime and to protect you and your personnel from laser radiation we recommend reading this chapter very carefully. In addition, the person to operate the unit should get relative professional training before using.

The "JUNERA" is classified as class 4. Class 4 describes only high energy lasers and therefore needs certain precautions before switching on the system to allow a safe and trouble-free operation. Additionally we highly recommend not using any flammable materials close to the laser.

CAUTION

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

ATTENTION

(1) The temperature of the tip of laser fiber may be up to 70°C. This high temperature can be used for coagulation of soft tissue.

(2) The temperature at the tip of the laser fiber can be up to 300°C. This high temperature can be used for the carbonization of soft tissue.

(3) The temperature of the tip of laser fiber may be up to 1000°C. This high temperature can be used for vaporization, incision of soft tissue.

4.2 Eye Protection

ATTENTION

Do not look into the laser beam or reflected or scattered light of the laser beam. Never look directly into the output of the fiber optic. Otherwise damages of the retina could occur.

To avoid any eye injuries, in the treatment room where safety goggles are placed has to be clearly marked. All the people including patients and the operator have to wear safety goggles as soon as the laser is turned on.

Various types of safety spectacles are available for the corresponding wavelengths to protect the eyes. If you have any further questions about safety eyewear, please contact ONYXA or your local representative.

4.3 Electrical Protection

- Opening the device to repair or maintain should only be carried out by certified person from ONYXA. ONYXA will not take any responsibility if any other person opens the device without the approval of ONYXA and the warranty will be voided.
- "JUNERA" Endolaser system has already been set limitation of current before shipment so as to prevent the dangerous output in a non-normal condition.
- Please make sure that the device is firmly grounded when it is in operation.

The room where the device is installed should be clean and dry. Please make sure that there is no water drop or water vapor when the device is turned on.

4.4 Fire Hazards

DANGER

Do not work with the device and the laser beam close to flammable, anesthetic or any other solvents which are easily flammable. Remove the paper and plastics from the laser working area, within a certain distance.

When the laser is not in use or patients are changed or a break in the treatment occurs please turn the device into "stand-by" status. In this mode the laser cannot be activated by the foot switch.

4.5 Protection Against Scattered Light

To prevent any triggering of the laser during connecting fiber optics, please follow the connection sequence described below:

1. Install the fiber optic
2. Switch the laser on

As already mentioned, the laser beam must not be directed at flammable materials. The foot switch must be placed in the doctor's working area and can only be operated by the doctor responsible for the treatment. Never have the laser triggered by a third person.

4.6 Main Switch

The main switch of the device is a power switch on the left side of the device. Press the power button to start the system. The system then performs a self-test. After entering the password, you can access the main user interface.

4.7 Manual Reset

If the system malfunctions, the power supply to the laser is interrupted immediately and the entire device is switched off. To restart the device, the main switch must be pressed again to jump up and then pressed down again. If the error occurs repeatedly, please contact ONYXA or

the dealer immediately.

4.8 External Interlock Connector

There is an external interlock connection on the back of the unit, which is connected to the room's door interlock via a cable. The appliance is switched off as soon as the door is opened. The connection for the external locking device is not connected by default.

4.9 Safety Signs

The following safety signs are used on the JUNERA device:

- Warning: Danger for laser
- Laser output window
- Emergency Laser Stop
- Manufacturer
- External interlock connector
- Fiber
- B type applied part
- Refer to operator manual
- Serial number
- Equipotentiality Terminal
- Production date
- EEE Marking

4.10 EMC Guidance

1) This product requires special precautions with regard to EMC and must be installed and commissioned in accordance with the EMC information provided; this device may be affected by portable and mobile RF communications equipment.

2) Do not use cell phones or other devices that emit electromagnetic fields near the device. This may result in incorrect operation of the device.

3) Caution: This device has been thoroughly tested and inspected to ensure proper performance and operation!

4) Caution: This appliance should not be used adjacent to or stacked with other appliances. If used adjacent to or in a stack is necessary, the appliance should be observed to verify normal operation in the configuration in which it is used.

CAUTION

Do not use "JUNERA" in an environment where RF emitters such as diathermy, electrocautery and RFID are present. If "JUNERA" is affected by hidden RF emitters, please press the laser emergency stop button immediately. "JUNERA" can only be used again once the hidden RF emitters have been removed.

NOTE:

The essential performance of "JUNERA" is Laser Output. The performance limit is the actual LASER OUTPUT measured in the WORKING AREA shall not deviate from the set value by more than ±10%.

5 Environmental Protection

Fiber is single use and should be abandoned in accordance with the disposal of medical waste which contact with the human body.

WARNING

It is prohibited to reuse the disposable sterile medical fiber. It may become an important means of disease transmission.

The "JUNERA" will not generate any wastes during normal use. When scrapping, the host can be disposed of as conventional electric products.

6 Indication for Use

The "JUNERA" is indicated for the treatment of Facial Contouring and Lipolysis.

The physician should be aware of the clinical applications of the laser when the exact therapy of the diode laser is not clearly known in each clinical case.

Prohibited Applications:

Patients with heart problems, psychosis, high blood pressure or patients who have been shown to be unsuitable for laser therapy.

7 Product Description

7.1 General Overview

The "JUNERA" consists of four main components:

1. Laser Console
2. Power Cord
3. Foot switch
4. Transmission System

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.

7.2 Front and Side Panel

The front and side panel includes the following components:

1. Color Touch Screen
2. Protection Hat for Laser Aperture
3. Fiber support
4. Switch button

7.2.1 Laser Aperture

The laser aperture is designed with a standard SMA-905 connector. Make sure that the fiber connection is right and well.

WARNING

Do not remove the fiber during the use of the device.

Fiber cannot be steeply bent; the bend radius must be more than 15cm.

The aperture protective hat acts as the protection for the laser aperture. When the fiber is removed, please cover up the laser aperture with aperture protective hat immediately to prevent the aperture from being contaminated.

ATTENTION

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 funicles inside the hat during the cleaning.

7.2.2 Color Touch Screen

The LCD touch screen of the unit features high sensitivity and high resolution. It is the man-machine interface. You can touch the icons on the screen with a finger or professional pen to open the corresponding program.

ATTENTION

Do not put heavy objects or apply excessive pressure on the touch screen to prevent distorting the touch screen display. Also avoid touching the screen with sharp materials in case there's any scratch too.

7.2.4 Power Indicator

The power indicator on the power button will be green if the power supply of the laser is normal.

The laser emission indicator also lights up when the system is in an emergency or abnormal state. At this time, the system stops all outputs and the touch screen displays the error information while the system displays a warning signal.

ATTENTION

Press the emergency stop to terminate laser emission if the laser emission meets a problem. Cautions have to be taken that don't sprinkle any liquid directly on the surface of the touch screen.

7.2.8 Fiber

Even though fiber is not a component of "JUNERA", a suitable fiber is necessary to be connected with "JUNERA" to transfer laser energy to the patient.

The suitable fiber must meet the following requirements:

- Fiber core diameter: 200μm-800μm
- NA = 0.2
- Single use
- Sterile

7.3 Rear Panel

The rear panel includes the following components:

1. Foot switch outlet
2. Power outlet
3. Fan

7.3.1 Connect/Disconnect Foot Switch and Remote Interlock

ATTENTION

Please pay attention to inserting and pulling out the foot switch and the interlock.

There is a dot on the connector and a notch on the outlet. When inserting the foot switch or interlock, the dot must be directed at the protrude.

When pulling out the foot switch or interlock, please hold the right place.

Connection steps: 1. Align the socket, 2. Insert vertically, 3. Tighten

7.4 Accessory List

Model: JUNERA

No	Name	Quantity
1	Handle piece	Depend on order
2	Fiber	Depend on order
3	Safety goggles	1 Piece
4	Safety goggles (patient)	1 Piece
5	Foot switch	1 Piece
6	Test card	1 Piece
7	Fiber stand	1 Piece
8	Power cord	1 Piece
9	Aluminum suitcase	1 Piece

8 Specifications

Laser type	GaAlAs diode laser
Model	JUNERA
Wavelength	1470nm±10nm, 980nm±10nm
Output power	1470: 0-30W, 980: 0-17W
Irradiance	240 W/cm²
Beam divergence	314 mrad to 443 mrad
Operation mode	Continuous, Pulse, Single
Fiber core diameter	400μm, 600μm
NA	>0.22
Application systems	With SMA905 connector, before use must sterile, FDA/CE Marking
Transmission system	Contact: fibers of 200μm-800μm with SMA905 connector; Non-contact: fi
Aiming beam	Diode laser of 650nm, power Max. 3mW, adjustable brightness
Operation interface	Color LCD touch screen
Power supply	100-240VAC, 50/60Hz, 2.6-1.0A
Laser Class	4
Safety classification	Class I Type B
Cooling	Air
Fuse	F15AL250V
Waterproof level	IPX1
Foot switch waterproof level	IPX8
Transportation & Storage	Temperature: -20°C~70°C, Humidity: 10%~90%, Pressure: 80KPa~106KPa
Application environment	Temperature: 10°C~40°C, Humidity: 10%~90%, Pressure: 80KPa~106KPa
Dimensions	570(W) × 380(L) × 350(H) mm
Machine Weight	2.4 Kg

9 Operating the Instrument

ATTENTION

The JUNERA should only be operated by a physician or qualified healthcare practitioner, who has been instructed in the use of the instrument during installation.

Don't touch the signal port when another hand contacts the patient.

This part of the manual only describes the technical use of the instrument without detailing the medical use.

9.1 Introduction

To guarantee a faultless operation of the device during surgery the following requirements have to be met:

- The device has already been plugged into electricity.
- The safety goggles are available for the people in the room.
- The fiber has already been fixed to the laser aperture.
- The remote interlock connector has been used.
- The foot switch has already been connected.
- The emergency stop has already been popped out.

To start the laser unit, turn the main switch ON. Immediately the power indicator will be green with the system fans working. At the same time, the LCD screen lights up.

9.2 How to Use the Device

1. System will take about 3 seconds to start up, and then touch the screen for the next interface.
2. Input password: 1004
3. Click the functions and then enter (Click the Enter Button) to next parameters setting interface.

NOTE:

Choose the correct hand piece to enter correct functions.

9.3 Main Menu

1. Please choose the treatment area: JAW FAT, NECK, EYES, CHEEKS

2. Laser emission mode:

- CW Mode - continuous laser output

- Pulse Mode - press the foot switch, multiple pulses laser out
- Single Mode - press the foot switch, only one pulse laser out

ATTENTION

1. For safety in CW mode, after emitting for 5 minutes (when peak power is above 12W), the laser should be stopped for 1 minute at least.

2. In Pulse mode, the laser will emit by pulse when you don't release the foot switch.

3. In Single mode, the laser will emit one pulse when you don't release the foot switch.

3. Wavelength: Choose the wavelength 980nm or 1470nm, or both.

4. Power: Click "W", Enter the ideal power in keyboard. 980nm Power: 1-30W adjustable, 1470nm Power: 1-17W adjustable.

5. Under Pulse Mode, please input value of "Pulse width" and "Pulse interval".

6. Increase or decrease setting value stepwise.

7. Aiming beam intensity (1-5 Level): Adjust the density of the aiming beam.

8. Start and stop work by clicking the corresponding button.

9. Working Panel displays current operation status.

10. Save the treatment parameter for future use.

9.4 Laser Fiber

1. Before use, please check whether the fiber's package is in good condition, if there is any breakage, please change it.
2. Do not bend the fiber excessively.

9.5 Shutdown of the Unit

1. Firstly, please change the device to "Return" status.
2. Secondly, please close the key switch.
3. Thirdly, please rotate the fiber optic connector to remove the optical fiber, and cover the aperture protective hat immediately.
4. Lastly, please turn off the power supply and unplug the power cord.

10 Failure Detection

Problem	Possible Cause	Solution
Unit does not start, power indicator off	Emergency Stop pressed	Turn Emergency Stop back to normal
Unit does not start	Fuse is burned	Check and replace fuse
TEMPERATURE HIGH	Temperature > 35°C	Stop laser and wait
TEMPERATURE LOW	Temperature < 10°C	Increase room temperature
POWERSUPPLY ERROR	Laser current too high	Check laser current
Remote INTERLOCK	Interlock not connected	Connect the interlock
FIBER NOT CONNECTED	Fiber not connected	Connect the fiber
Foot switch opened	Foot switch not connected	Connect foot switch
No aim light	Fiber not connected	Check fiber connection
No aim light	Intensity too low	Send back to ONYXA
No aim light	Aim beam status OFF	Set aim beam to ON
No laser light	Foot switch issue	Check foot switch

11 Cleaning and Disinfecting the Instrument

Separate the unit from the power supply before cleaning and disinfecting.

1. Clean (disinfect) the aperture protective hat with alcohol before using it. But do care not to leave cotton yarn or other funicles inside the hat during the cleaning.
2. Clean the LCD touch screen with clear water carefully after use. Don't touch the screen with hard or sharp materials. Don't scrub the screen with reagent. You can clean it softly with soft tissue.
3. Clean the shell with a cleaner carefully after using. Please prevent the liquid into the laser or the fiber connector.
4. Before the cleaning, please make sure the device is turned off and the power cord is unplugged.

11.1 Announcements

1. To ensure the device works well, you can clean/inspect it every month, and change the outer components if necessary.
2. Please make sure all the lenses are clear and firm before connecting.
3. After using the hand piece, please clean the lens.

12 Maintenance

12.1 The Main Unit's Maintenance

"JUNERA" is a precise medical instrument and should only be maintained by a professional engineer authorized by ONYXA.

When the fiber is removed, please cover the aperture with the protective hat. The protective hat should be cleaned with alcohol in advance.

Don't touch the screen with hard or sharp materials. Don't scrub the screen with reagent. You can clean it softly with soft tissue.

The unit should avoid drastic shaking and hitting during movement.

The laser output power is yearly calibrated by professional engineer from ONYXA.

12.2 Planned Preventative Maintenance

The "JUNERA" should be checked annually by a ONYXA Laser-accredited technician, the results of the maintenance should be recorded in the instrument log book. Failure to use an ONYXA Laser or other authorized ONYXA Laser technician during the guarantee period will result in the warranty being invalid.

12.3 Replacement of Fuse

ATTENTION

Please turn off the power supply before changing the fuse.

When changing the fuse, please refer to the following steps:

1. Pull out the electrical outlet from the wall.
2. Pull the electrical wire from the mainframe.
3. Take the insurance box out, if necessary, please use a knife.
4. Replace the disabled fuse with the same parameter one.
5. Close the insurance box.
6. Test the instrument.

13 Service

ATTENTION
No part can be serviced or maintained while in use with the patient.

Quick response within 24 hours, readily available accessories and equipment.

Regular maintenance and technique support on the spot.

Statement: We will provide circuit diagrams, component part lists, descriptions and calibration instructions to assist SERVICE PERSONNEL in parts repair.

14 Attachments

14.1 Device Master Record and Training Protocol

DEVICE MASTER RECORD

Model:	
S/N:	
Inventory-No.:	
Operator:	
Location:	

Training Protocol

Responsible: Name / Signature:	
Date:	
Checked:	
Name of person trained / signature:	

14.2 Annual Maintenance

Annual maintenance checklist includes: Visual Inspection, Inspection of functional capability, Inspection of Monitoring and Safety System, Electric Safety, and Measurement of Output Parameters.

15 Application Specification

CAUTION

Always wear safety goggles when performing this procedure.

15.1 Patient Population

a) Age: adult

b) Weight: no requirements

c) Health: If the patient has one of the situations as follows, he/she is not applicable for the JUNERA:

1. Patients who have used isotretinoin (Accutane) within the past month
2. Patients taking medication known to increase sensitivity to sunlight
3. Patients who have heart trouble
4. Patients who have psychosis
5. Patients who have hypertensive diseases
6. Patients who have been proved are not suitable for laser therapy

d) Nationality: Multiple

e) PATIENT state: PATIENT is OPERATOR: N/A; PATIENT is not OPERATOR: adult

15.2 Part of the Body or Type of Tissue Applied to or Interacted With

a) Treatment site: body surface (face and body).

b) Condition: health is suitable for surgery.

15.3 Intended Operator

a) Education: Doctors and healthcare professionals must be properly trained in how to use the device. The primary training resource for operators is the Instructions for Use (IFU), which is supplied with the device.

b) Knowledge: minimum - doctors, healthcare professionals, who must be trained on how to use the device

c) Experience: minimum - healthcare professionals who have been trained in the functions and indications of the JUNERA

e) Permissible impairments: average degree of aging-related short-term memory impairment

15.4 Application

a) Environment:

General:

- 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 use: 10°C to 40°C
- Environmental humidity for use: 10%-90%
- Environmental temperature for storage: -20°C to 70°C
- Environmental humidity for storage: 10%-90%
- Environmental pressure: atmospheric pressure (about 80KPa to 1060 KPa)
- Mains Supply: AC100~240V, 50/60 Hz, 1.4A

b) Frequency of use: The 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 ME equipment. Secure the JUNERA before use.