B E A U T Y

Instructions For Use

Read this completely prior to using your NIRA BEAUTY Skincare Laser

Part number: 820-001, Rev G

WELCOME TO NIRA BEAUTY

Your journey to beautiful, better-looking skin.

The NIRA BEAUTY Skincare Laser is an innovative device for wrinkles skincare treatment, delivering lasting results*, easily and conveniently in your own home. With just a few minutes each day, your NIRA BEAUTY Skincare Laser visibly reduces the appearance of fine lines, wrinkles to restore smooth, radiant skin.

Collagen is a protein naturally produced by the body to give skin youthful elasticity and firmness. As we age, the production of collagen slows, which can result in wrinkles and imperfections, especially around the eyes. The NIRA BEAUTY Skincare Laser is specially designed to bo ost collagen stores and rejuvenate skin cells for the healthy, beautiful skin you deserve.

The NIRA BEAUTY Skincare Laser provides lasting results* to reverse the signs of aging using advanced dermatologist-tested technology to produce noticeable results in as little as 8 to 12 weeks.

Before using your device for the first time, it is important to read the instructions and safety information in this booklet to ensure proper use, and to achieve your best results. We recommend saving these instructions for future reference.

*based on clinical results with 3-months post-treatment observations



Watch the NIRA Beauty Instructional Video at: <u>www.nirabeauty.com/video</u>



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SYMBOLS

The following symbols are used within this manual or on the NIRA BEAUTY Skincare Laser and its packaging:



Consult Instruction For Use



Protection against finger-sized objects. Protected against dripping water. The device is not submersible.



Type BF Applied Part



Temperature Range



Relative Humidity Range





Serial Number



Date of Manufacture

Fragile, Handle with Care



Keep Dry



Caution – see Safety Information in this document

Standby & Ready



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Class II Double Insulation Electrical Appliance



Non-ionizing Radiation

ÐH⊦

Use only with NIRA BEAUTY Supply Unit



Read Operator's Manual

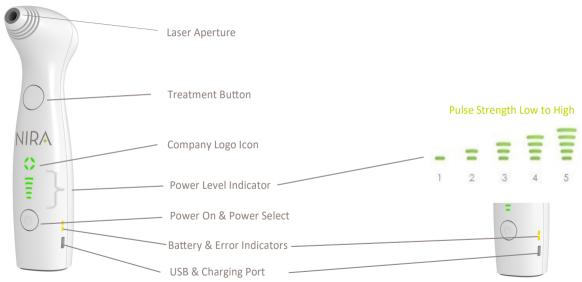
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Laser Radiation Warning



WARNING: Do not use this appliance near bathtubs, showers, basins or other vessels containing water.

ABOUT NIRA BEAUTY SKINCARE LASER



Contents: NIRA BEAUTY Skincare Laser, USB cable, wall plug adaptor, plug adaptor blades, Instructions for Use, Quick Reference Guide

SAFETY INFORMATION

Read all important safety information on pages 7 and 8 prior to using the NIRA BEAUTY Skincare Laser.

WHEN TO USE (INDICATIONS)

The NIRA Beauty Laser is an over-the counter device intended to treat:

Periorbital wrinkles—wrinkles around the eyes

WHEN NOT TO USE (CONTRAINDICATIONS)

Do not use on skin that is cut, burned, or infected. Only use on skin that is intact.

Do not use if under 12 years of age or with reduced physical, sensory or mental capabilities.

Do not use if you are pregnant, nursing or undergoing fertility treatments.

Do not use if have a history of skin cancer, or any other type of cancer, or pre-malignant moles.

Do not use if you have any active skin condition in the treatment area, such as sores, psoriasis, eczema, and rash and rosacea.

SAFETY INFORMATION - WARNINGS

To prevent serious injury, you must follow these Instructions for Use when using the NIRA BEAUTY Skincare Laser.

Changes or modifications not expressly approved by Dermal Photonics Corporation could void the user's authority to operate the equipment. If you experience skin color darkening, discontinue use and check with your doctor.

Do not treat if you have tanned skin. Tanned skin is at an increased risk of adverse effects with light-based devices.

Avoid sun tanning bed exposures and apply SPF 30 or greater when outside within 6 weeks of treatment.

The NIRA BEAUTY Skincare Laser is not intended for use by individuals (including children) with reduced physical, sensory, or mental capabilities. Children should be supervised to ensure they do not play with the appliance.

For use only with adolescents 12 and over.

Do not point or place the treatment tip over your eye or eyelid; serious or permanent eye damage may result.

Do not place or drop your device or charger near or into water or liquid. Do not use the device while bathing. Doing so could result in serious injury.

Always keep the cord away from heated or wet surfaces to prevent damage to the device.

Ensure the skin and treatment tip are dry before treatment. The device may not operate properly if the treatment tip is wet. Such failure to operate properly may cause serious side effects or device malfunction.

Do not treat the same spot more than once within a 1 minute period and do not treat more than twice within a 1 hour period. Multiple immediate treatments may result in discomfort or increased side effects.

Do not share the NIRA BEAUTY Skincare Laser with other people. Sharing the device could transfer bacteria or other pathogens from one person to another and may cause harmful infection.

Use only with the power supply unit and USB cable provided.

SAFETY INFORMATION - WARNINGS

Do not use the NIRA BEAUTY Skincare Laser if the device or the charger is visibly damaged. Never attempt to open or repair the device or charger; doing so could result in a serious eye or skin injury, or possibly fatal electrical shock.

Stop using the device and consult your doctor if you feel pain or your skin gets uncomfortably hot during treatment. Continued use of the device could result in serious skin injury.

Stop using the device if you see unwanted hair growth. Application of lasers and IPL for hair reduction to the lower face, particularly near the side burns, has been associated with a risk of paradoxical hair growth. This risk is proposed to arise from low level heating of the hair follicles.

SAFETY INFORMATION - PRECAUTIONS

¹ If you have a skin condition or are undergoing professional cosmetic treatments such as injectable toxins (such as Botox) or fillers, please check with your doctor or clinician prior using the NIRA BEAUTY Skincare Laser.

Only use the charger and USB cord supplied to recharge the device. Using a different charger or USB cord could cause device malfunction or serious injury. Do not drop the device on hard surfaces as the device could be damaged.

The NIRA BEAUTY Skincare Laser complies with standards regarding electromagnetic fields (EMF). If handled properly and according to the instructions in this booklet, the device is safe to handle based on scientific evidence available today.

Store the NIRA BEAUTY Skincare Laser in the supplied box to prevent lint or dust collection inside the laser aperture. Lint or dust inside the laser aperture may degrade the performance. Clean the device periodically as instructed on page 16.

Store the NIRA BEAUTY Skincare Laser in the supplied box in a secure location away from household animals and children.

POTENTIAL SIDE EFFECTS

Side effects that may appear include: skin warmth, redness and stinging. Rarer side effects that may appear include: dryness, roughness, tanned appearance to the skin, swelling, flaking, itching, crusting, bruising, pimple-like rash, irritated skin, blistering, scarring, infection, and skin color changes where your skin may become darker or lighter in color.

WHO SHOULD USE NIRA—WRINKLES

When used as directed, the NIRA BEAUTY Skincare Laser visibly smoothes and diminishes fine lines and wrinkles around the eyes

TREATMENT GUIDELINES - WRINKLES

- The NIRA BEAUTY Skincare Laser is intended to treat periorbital wrinkles—wrinkles around the eyes.
- Typically 2-3 rows of treatment are needed for each eye, moving the device slightly lower for each row of use, until the entire area is covered. Overlap each pulse slightly to ensure complete coverage. 50 pulses per eye area are recommended.
 Use a mirror when treating around the eyes.
- See the illustration to the right for clear treatment area definition.
- If you would like to accelerate your results, we recommend waiting 1 minute and retreating each area. Do not treat more than twice within a 1 hour period.



CHARGING INSTRUCTIONS

- First, connect the USB cable to the charging port of the device.
- If using your computer to charge, connect the large end of the USB cable to the USB port of your computer.
- Alternately, connect the large end of the USB cord to the wall plug adaptor and plug into a wall outlet.
- When your NIRA BEAUTY Skincare Laser is connected to a power source, the battery indicator lights will flash until the battery is fully charged. Once the battery is fully charged, the battery indicator lights will stop flashing. It should take no longer than 5 hours to fully charge the device.
- A fully charged device will last approximately 4 hours of continuous use. This time will vary with settings and will lessen as the battery ages.



Note: Treatment is disabled during charging.

Charger State	Battery Indicators	Condition	
	Top is ON Bottom is ON	Normal operation—Battery over half charge	
Charger disconnected	Top is OFF Bottom is ON	Normal operation—Battery less than half charge	
	Top is OFF ⇒ Bottom is Blinking	Very low charge. May stop functioning.	
Charger connected	☐ Top is OFF Bottom is Blinking	Still charging. Less than half charge.	
	E Top is Blinking Bottom is ON	Still charging. More than half charge.	
	Top is ON Bottom is ON	Charge complete. Discon- nect and treat.	

PRE-USE INSTRUCTIONS

- Be sure battery is charged. If the battery is charged, unplug battery charger prior to use.
 The NIRA BEAUTY Skincare Laser will not operate while the device is connected to the USB.
- Turn on the device by pressing the power button located on the lower end of the device.
- You may wish to test on your forearm and adjust power setting to get familiar with the sensation experienced at each level. We recommend starting at the lowest level.
- Press the Laser Aperture fully against the skin, then press the Treatment Button to fire the laser.
- Press the power button again to increase power from levels 1 to 5, then back to 1 until you
 find the highest level that where <u>you feel warmth from the device without pain</u>. This setting
 will vary by treatment location.

Note: you may use different power settings on different parts of your body depending on the sensitivity of the treatment area. For example, areas such as under the eye should be treated starting at the lowest level to test the area then gradually increase the power level if desired.





RECOMMENDED USE INSTRUCTIONS

Before using the NIRA BEAUTY Skincare Laser read the entire Instructions for Use booklet. You may also wish to watch the instructional video at www.nirabeauty.com/ video.

PREPARE

- Cleanse your skin with your preferred skin cleanser.
- Dry your face thoroughly before you begin treatment.
- If your skin is already clean and dry, you can skip this step.

TREAT

- Turn on your NIRA BEAUTY Skincare Laser by pressing the power button once. You will hear a high-pitched beep and the lights will turn on. Press the power button again to increase the power level to the desired strength. Use the highest power level where you feel warmth without pain.
- Place the Laser Aperture (Applied Part) flat against the skin then press the Treatment Button. You will hear one high-pitched beep and see the power level lights flashing when the device starts treating. Keep the device tip pressed completely to skin during treatment.
- If you hear a lower pitch beep when pressing the treatment button or during the treatment, this means the tip does not have complete contact with the skin. If this occurs, lift the tip completely off the skin and reposition the tip and try again.
- After about one second you will hear another beep and you may move the device tip to the next spot and repeat.
- Treat the skin in a linear pattern so all areas of interest are treated evenly with slight overlap between pulses.
- When finished, hold the power button for about 2 seconds to power down the device. The unit will automatically power down after 2 minutes with no activity. It is recommended to clean the exterior of the NIRA BEAUTY Skincare Laser after each use with a damp cloth. Continue with your daily skincare routine.

WHAT TO EXPECT

Treatment with the NIRA BEAUTY Skincare Laser is easy when you know what to expect.

- The first treatment session is usually the longest, so it's best to start when you have more time. Within a few uses, most users complete a full treatment around the eyes in 2 3 minutes for wrinkle treatment.
- Immediately after treatment, you may feel a warming sensation similar to how a mild sunburn might feel. This is a normal reaction that will lessen within an hour following treatment. If you find it uncomfortable, reduce the power levels in subsequent treatments.
- During the first month, it is rare, but you may experience some temporary redness. If you treat yourself at night, the redness will diminish while you sleep.
- Some users may notice that their skin becomes rough and/or dry during the first month of use. Try applying a moisture cream after treatment to help soothe
 any dryness. You should continue to use moisturizing skincare products during the day. Daily use of a sunscreen with SPF 30 or greater is also recommended.

ACHIEVING BEST RESULTS

- Wash and completely dry treatment areas before using NIRA BEAUTY Skincare Laser.
- Treat each desired area once each day.
- During your treatment sessions, use the highest power level where you feel warmth without pain.
- To lessen possible skin dryness, use a facial moisturizer after each treatment.
- For the best results, daily usage is recommended for 4 months.
- After desired results are achieved, you may continue to use device daily to maintain desired results.

CLINICAL RESULTS

In a clinical study using the NIRA Skincare Laser, 3 medical professionals reviewed data in a blinded fashion and rated wrinkle treatment results on a 9-point scale and found on average:

- 61% of users saw 1 full wrinkle scale unit improvement within 3 months
- 12% of users saw 2 full wrinkle scale units improvement within 3 months
- 59% of users saw 1 full wrinkle scale unit improvement within 4 months
- 17% of users saw 2 full wrinkle scale units improvement within 4 months
- 57% of users saw 1 full wrinkle scale unit improvement within 5 months
- 20% of users saw 2 full wrinkle scale units improvement within 5 months
- 63% of users saw 1 full wrinkle scale unit improvement within 6 months
- 22% of users saw 2 full wrinkle scale units improvement within 6 months
- 69% of users saw 1 full wrinkle scale unit improvement within 7 months
- 36% of users saw 2 full wrinkle scale units improvement within 7 months
- 10% of users saw 3 full wrinkle scale units improvement within 7 months
- 81% of users where achieved wrinkle reduction maintained wrinkle improvement for at least 1 month after users stopped using NIRA as rated by 3 independent and blinded professional reviewers.
- 81% of users where achieved wrinkle reduction maintained wrinkle improvement for at least 2 months after users stopped using NIRA as rated by 3 independent and blinded professional reviewers.

• 68% of users where achieved wrinkle reduction maintained wrinkle improvement for at least 3 months after users stopped using NIRA as rated by 3 independent and blinded professional reviewers.

Side effects that may appear include: skin warmth and stinging. Less frequent side effects may appear include: dryness, and temporary skin color changes where your skin may become darker or lighter in color.

Clinical study users were trained on the use of the device.

User Experience

In a clinical study users of the NIRA Skincare Laser completed anonymous surveys about their experiences and found:

- 99% of users felt the NIRA Beauty Skincare Laser was easy to use.
- 87% of users enjoyed using the NIRA Beauty Skincare Laser.

ENVIRONMENT CONDITIONS

The NIRA BEAUTY Skincare Laser should be used in a comfortable environment.

Temperature: 15°C to 35°C (59°F to 95°F) Relative Humidity: 30-75% Atmospheric Pressure: 70-106 kPa

REQUIRED SHIPPING AND STORAGE CONDITIONS

The NIRA BEAUTY Skincare Laser should be stored in a dry place at normal room temperature.

Shipping Temperature: -40°C to 50°C (-40°F to 122°F) Storage Temperature: -20°C to 35°C (-4°F to 95°F) Relative Humidity: 10-100% Atmospheric Pressure: 50-106 kPa

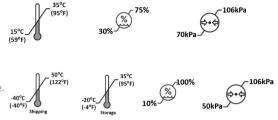
SERVICE AND MAINTENANCE

The device does not require assembly or regular maintenance. Never attempt to service it in any manner. If you have any questions regarding servicing or maintenance, please call Dermal Photonics Corporation. The NIRA BEAUTY Skincare Laser will operate for more than one year of recommended use.

CLEANING AND DISINFECTION

The interior of the tip should be cleaned once a week with a cotton swab. Gently place the cotton swab into the opening on the Laser Aperture to clean the glass lens and remove any debris. If debris has fallen into the laser output window and it will not come out using the cotton swab, gently shake the device to let the debris fall out.

Disinfect all surfaces with 70% alcohol solution between each use.



LABELING AND SPECIFICATIONS

The NIRA BEAUTY Skincare Laser is a Class 1 laser operating at the specifications listed in the table below. The laser aperture integrates a touch sensor requiring contact in order to treat.

Specifications		
Wavelength	1450nm (+/- 20nm)	
Pulse Duration	0.8 s	
Maximum Power Output	1.8 W	



FCC ID 2ADZENIRA

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference, and
- 2) This device must accept any interference received, including interference that may cause undesired operations.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation... This equipment generates, uses and can rad late radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer of an experienced radio/TV technician for help.

TRAVEL

If traveling with NIRA BEAUTY Skincare Laser, be sure to pack the device in its original packaging to prevent damage. Always check the country's voltage requirements when traveling outside the United States. The device can operate between 100 - 240 VAC and 50 - 60 Hz. You may need a wall plug adapter or different wall plug blades to charge the NIRA when traveling abroad.

DISPOSAL

As appropriate disposal of the device at the end of its life is an integral part of our sustainability policy, we ask you to observe the following:

- Do not throw away the device with the normal household waste at the end of its life, but hand it in at an official collection point for recycling.
- This device contains a built-in lithium-ion rechargeable battery that cannot be removed. This rechargeable battery contains substances that may pollute the environment.
- To ensure proper disposal, take the device to an official collection point or return to Dermal Photonics Corporation. Staff at the collection point or the Dermal Photonics service center will ensure the battery is removed and disposed of in an environmentally safe way.



TROUBLESHOOTING

Refer to this table if you are having problems operating the device. If you still have questions, please visit www.nirabeauty.com or call NIRA Customer Service at 781-451-1700.

B—Bottom LED T—Top LED

Description	Battery Indicators	User Action	Reference Code	
Power lights on but Usage light lowest level blinking	Normal	Replenish Usage	2	
All front lights off	Blinking SLOWLY	Replenish Usage	3	
	Blinking FAST	Call DPC Customer Service	5	
	Blinking SLOWLY	Turn off NIRA and Turn back on. If not resolved, call Customer Service	7	
	Blinking SLOWLY	Charge NIRA	8	
	Blinking FAST	Call DPC Customer Service	9	
Front lights not on - can't treat	Blinking SLOWLY BB-TT-BB-TT	Call DPC Customer Service	10	
	Blinking FAST	Release Treatment button. Call DPC Customer Service	11	
	Blinking FAST	Call DPC Customer Service	12	
	Blinking FAST	Release Power button. Call DPC Customer Service	13	

EMC INFORMATION

The NIRA BEAUTY Laser needs special precautions regarding EMC and needs to be installed according to EMC information.

Caution: Mobile RF communications equipment can affect the NIRA BEAUTY Laser device.

Warnings: The use of accessories and cables other than those specified in this document may result in increased emissions or decreased immunity of the NIRA Laser.

Warnings: The NIRA Laser should not be used adjacent to or stacked with other equipment treatments.

Warning: The charger may be damaged with electrostatic discharge through the air if the discharge voltage will be higher than 8 kV. If the device is not charging when connected to the charger and the cable is properly connected contact the company (information on page 25) and order a new charger.

		Electromagnetic Emissions Declaration
The NIRA BEAUTY is inten that it is used in such an e		magnetic environment specified below. The customer or the user of the NIRA BEAUTY should assure
RF emissions CISPR 11	Group 1	The NIRA BEAUTY uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NIRA BEAUTY is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies
Harmonic emissions IEC 61000-3-2	Complies	buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The NIRA BEAUTY is intended for use in the electromagnetic environment specified below. The customer or the user of the NIRA BEAUTY should assure that it is used in such an environment.			
Immunity test	IEC 60601test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	<u>+</u> 8 kV contact <u>+</u> 8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be a least 30%
Electrical fast transient/ burst IEC 61000-4-4	<u>+</u> 2 kV for power supply lines <u>+</u> 1 kV for input/output lines.	Complies	Mains power quality should be that of a typical home, commercia or hospital environment.
Surge IEC 61000-4-5	<u>+</u> 1 kV differential mode <u>+</u> 2 kV common mode	Complies	Mains power quality should be that of a typical home commercia or hospital environment.
Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) For 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NIRA BEAUTY requires continued operation during power mains Interruptions, it is recommended that the NIRA BEAUTY be powered from an uninterrupted power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial o hospital environment.

THE MILLION DERIO		ie electromagnetic em	ironment specified below. The customer or the user should assure that it is used in such an environment.
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2,5 GHz	3 V 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the NIRA BEAUTY including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ $d = 2.33 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in 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: ((j))
	z and 800 MHz, the higher freq delines may not apply in all situ	7 0 11	ropagation is affected by absorption and reflection from structures, objects and people.
theoretica which the	ally with accuracy. To assess the	e electromagnetic environ the applicable RF complian	(cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted ment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in ice level above, the NIRA BEAUTY should be observed to verify normal operation. If abnormal performance is observed, additional measures TY.

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

Recommended separation distances between portable and mobile RF communications equipment and the NIRA BEAUTY

The NIRA BEAUTY is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NIRA BEAUTY can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NIRA BEAUTY 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 the transmitter M			
	150 kHz to 80 MHz	150 kHz to 80 MHz	150 kHz to 80 MHz	
	d = 1,17 \sqrt{P}	d = 1,17 √ P	d = 2,33 √ P	
0,01	0,12	0,12	0,23	
0,1	0,37	0,37	0,74	
1	1,17	1,17	2,33	
10	3,70	3,70	7,37	
100	11,70	11,70	23,30	

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

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

GLOSSARY

Inflammatory/Inflamed:Red and sensitive to the touch.Periorbital Wrinkles:Wrinkles around the eyes.

QUESTIONS?

Our Dermal Photonics Corporation Customer Care representatives are available to help. Contact us at:

Dermal Photonics Customer Care 5 Elm Street, Suite 10 Danvers, MA 01923 Phone: 781-451-1700 Email: info@nirabeauty.com Or visit <u>www.nirabeauty.com</u> European Authorized Representative Obelis s.a Boulevard Général Wahis 53 1030 Brussels, BELGIUM Phone: +(32) 2.732.59.54 Fax: +(32) 2.732.60.03 E-Mail: mail@obelis.net



Watch the NIRA Beauty Instructional Video at: <u>www.nirabeauty.com/video</u>



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