

Quick Start & Instructions For Use

Part number: 820-005, Rev C

QUICK START

NIRA SKINCARE LASER

HOW TO TREAT



► Wash & Dry Face

- Remove all makeup thoroughly.
- Cleanse your skin with your preferred skin cleanser.
- Dry your face completely before beginning treatment.





Power On Device

- Turn on device by pressing the power button for roughly 1 second.
- Identify the reject tone: While holding the device in front of you and making sure the device tip has NO direct contact with the skin, press and release the treatment button. You will hear a set of quick low-pitched beeps that indicate a rejection pulse.
- NIRA CHE
- The rejection tone indicates that the device tip did not have full contact with the skin. If
 you hear this tone during treatment you need to reposition the device tip making sure
 there is full skin contact.







- Press and release the power button to adjust the power level. Set your NIRA Laser to level 1.
- Place the device tip on the skin as shown to the right. Press and release the treatment button with your thumb; you will hear a series of 2 beeps. The first beep indicates the laser has begun firing and the second beep indicates the laser finished firing for that one spot.
- Repeat this process and continue to increase the power level until you have reached a power level where you feel warmth without pain.





CAUTION: Be sure to move the NIRA to a new spot for each treatment. If you treat the same spot twice in a row, the heat in your skin may build up to a point where you feel discomfort or pain. This is not recommended and should be avoided.



- Using the chosen power level hold the device tip against the skin starting at the outer corner of your eye.
- Press and release the treatment button while holding the device tip in place until you hear a series of two beeps approximately one second apart indicating that spot has been successfully treated.



Illustration of treatment pattern

- Reposition the device so it is slightly overlapping the previous treatment spot (See illustration for overlapping pattern) then press and release the treatment button again.
- Repeat this process for 40 pulses on one eye following the 2-3 row pattern shown in the illustration. Once 40 successful pulses are completed, you will hear a set of three fast-paced jingle-like tones that indicate the treatment for that eye is complete.
- Repeat this process for the opposite eye.
- Power down the device by holding down the power button until the NIRA logo and power level lights turn off.
- · Continue with daily skincare regimen.
- For Best Results, repeat this process daily for 90 days or more. To enhance your results
 you may treat twice daily.

WELCOME TO NIRA—INSTRUCTION FOR USE

Your journey to beautiful, better-looking skin.

NIRA's revolutionary new technology holds 6 patents, is FDA cleared, and clinically proven to deliver dramatic lasting results in as little as 2 minutes a day, at home, without pain, redness, skin damage or downtime.

As we age our bodies naturally stop producing collagen that causes wrinkles and sagging of the skin. The NIRA Skincare Laser reverses the impact of aging by warming the deeper layers of your skin, activating the skin to produce collagen like it did decades ago to give you the healthy, beautiful and youthful looking skin that you deserve.

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

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



CONTENTS

INSTRUCTION FOR USE	4
SYMBOLS	6
USER EXPERIENCE AND SAFETY INFORMATION	7
POTENTIAL SIDE EFFECTS	9
WHO SHOULD USE, WHEN TO USE, ACHIEVING BEST RESULTS, WHAT TO EXPECT	10
PRE-TREATMENT INSTRUCTIONS	11
TREATMENT GUIDELINES	
CHARGING INSTRUCTIONS	14
CLINICAL STUDY RESULTS	
CLEANING, STORAGE, SERVICE, AND MAINTENANCE	16
LABELS AND SPECIFICATIONS	
TRAVEL AND DISPOSAL	18
TROUBLESHOOTING	19
EMC INFORMATION	20
CONTACT INFORMATION	24

SYMBOLS

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

$\square \mathbf{i}$	Consult Instruction For Use	SN	Serial Number	$((\overset{\bullet}{\blacksquare}))$	Non-ionizing Radiation
IP22	Protection against finger-sized objects. Protected against dripping water. The device is not submersible.		Date of Manufacture	⊅ ∏	Use only with NIRA Supply Unit
†	Type BF Applied Part	Ī	Fragile, Handle with Care		Read Operator's Manual
35°C (95°F)	Temperature Range	7	Keep Dry		Laser Radiation Warning
(59°F) 75% 30%	Relative Humidity Range	Ţ	Caution – see Safety Information in this document		WARNING: Do not use this appliance near bathtubs, showers, basins or other vessels containing water.
	Pressure Range	<mark></mark>	Standby & Ready		
70kPa	Ü		Class II Double Insulation Electrical Appli-		

ance

USER EXPERINCE

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

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

For best results, use the device daily according to the instructions for 90 days or more. Lasting results should become apparent after 4 weeks and become more noticeable after 8 - 12 weeks of use. Excellent results require patience and persistence along with daily treatments to allow your skin's natural mechanisms to repair and improve your skin from within.

SAFETY INFORMATION

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

WHEN TO USE (INDICATIONS)

The NIRA Skincare 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 you 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 rosace a.

REGULATORY COMPLIANCE

NIRA Skincare Laser is FDA Cleared for home use for periorbital wrinkles (wrinkles around the eye) and is CE marked for the same.





SAFETY INFORMATION - WARNINGS

- To prevent serious injury, you must follow these Instructions for Use when using the NIRA 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 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 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-C cable provided.





Do not use the NIRA 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

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 Skincare Laser. Only use the charger and USB-C cord supplied to recharge the device. Using a different charger or USB-C cord could cause device malfunction or serious injury. Do not drop the device on hard surfaces as the device could be damaged. The NIRA 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 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 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. Less frequent 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

- All skin tones.
- Anyone with wrinkles around the eyes.
- Anyone that wants to decrease the appearance of wrinkles around the eyes.

WHEN TO USE NIRA

- When the face is fully clean and dried.
- The NIRA laser can be used in the morning or at night when you are not in a hurry or tired.
- Use the NIRA skincare laser daily. For accelerated results repeat twice daily, but do not treat more than twice within a 1-hour period.

ACHIEVING BEST RESULTS

- Wash and completely dry treatment areas before using the NIRA Skincare Laser.
- Treat each under eye area once each day.
- During your treatment sessions, use the highest power level where you feel warmth without pain.
- Use a facial moisturizer after each treatment.
- For the best results, daily usage is recommended for 4 months.

WHAT TO EXPECT

- Users typically experience improvements within the first few weeks but notice the most dramatic results after 2–3 months of daily use.
- 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 (40 pulses per eye) in 2 3 minutes.
- 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, you may experience some temporary redness, which is rare. 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 a fter treatment to help soothe any dryness. Continue to use moisturizing skincare products during the day. Daily use of a sunscreen with at least SPF 30 is recommended.

PRF-TREATMENT INSTRUCTIONS

Step One

- Remove all makeup thoroughly
- Cleanse your skin with your preferred skin cleanser.
- Dry your face completely before you begin treatment.



Step Two

Unplug battery charger prior to use. The NIRA Skincare Laser will not operate while the device is connected to the USB C.

Step Three

Turn on device by pressing the power button for approximately 1 second; you will hear a set of beeps and the NIRA Star logo and power level lights will turn on.

Step Four

- Identify the reject tone: While holding the device in front of you and making sure the device tip has NO direct contact with the skin. press and release the treatment button. You will hear a set of quick low-pitched beeps that indicate a rejection pulse.
- The rejection tone indicates that the device tip did not have full contact with the skin. If you hear this tone during treatment you need to reposition the device tip making sure there is full skin contact.

Power Levels Low to High



Step Five

- Set the treatment power level to 1 by pressing and releasing the power button quickly until only one light displays in the power level setting area. (Illustration of power levels low to high is shown to the right)
- Test this power level by placing the device tip on the skin under the outer corner of your eye. While holding the device tip in place, press and release the treatment button until you hear two high pitched beeps approximately 1 second part from another. Note: If you hear the rejection tone when pressing the treatment button this may be because the device tip lost contact with the skin.
 - Reposition the device tip making sure there is full skin contact and try again.
- For best results use the highest power level setting where you feel warmth without pain. You can adjust the power level setting by pressing and releasing the power button.



TREATMENT GUIDELINES

While looking in a mirror and keeping both eyes open, treat each wrinkle with a series of individual pulses.

Step One

• Using the chosen power level, hold the device tip against the skin under the outer corner of your eye.

Step Two

- Press and release the treatment button with your thumb while holding the device tip in place until you hear a series of 2 beeps approximately 1 second apart. The first beep indicates the laser has begun firing and the second beep indicates the laser finished firing for that one spot.
 - Note: Be sure you are hearing the treatment tone and not the rejection tone. Follow step 4 in the "Pre-Use Instructions" section to make sure you can correctly identify the reject tone.
- Reposition the device so it is slightly overlapping the previous treatment spot (See illustration for overlapping pattern) then press and
 release the treatment button again. Repeat this process for 40 pulses on one eye following the 2-3 row pattern shown in the illustration. Once completed, you will hear a set of three fast-paced jingle-like tones that indicate the treatment for that eye is complete.

For best results, use the device daily according to the instructions for 90 days or more. Lasting results should become apparent after 4 weeks and become more noticeable after 8 and 12 weeks of use. Excellent results require patience and persistence along with daily treatments to allow your skin's natural mechanisms to repair and improve your skin from within.

CAUTION: Be sure to move the NIRA to a new spot for each treatment. If you treat the same spot twice in a row, the heat in your skin may build up to a point where you feel discomfort or pain. This is not recommended and should be avoided.





Illustration of treatment pattern

TREATMENT GUIDELINES

Step Three

- Repeat this process on the opposite side for 40 pulses or until you hear the jingle-like tone again.
- Repeat twice daily to accelerate results. Do not treat more than twice within a 1-hour period.

Step Four

- When finished, check your device battery level to determine if recharging is necessary.
- Press and hold the power button for approximately 2 seconds to power down the device. You will hear a power down set of beeps and the lights will turn off. The device will automatically power down after 2 minutes with no activity.
- It is recommended to clean the exterior of the Laser after each use with a damp cloth.

Step Five

• Continue with your daily skincare routine. The use of a moisturizer and sunscreen with SPF of 30 or greater on the treatment area is recommended.

For Best Results

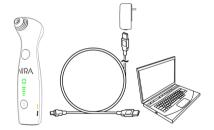
Repeat this process daily for 90 days or more. You may use twice daily for possible enhanced results; we recommend waiting 1 minute before retreating each area. Do not treat more than twice within a 1-hour period.





CHARGING INSTRUCTIONS

- First, connect the USB C 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 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 3 hours to fully charge the device.
- A fully charged device will last approximately 4 hours of continuous use. This equates to several weeks of daily usage between charges. This time will vary with settings and will lessen as the battery ages.
- Your NIRA Skincare Laser will not work when it is plugged into the battery charger.
 Unplug your NIRA Skincare Laser before treatment.



Note: Treatment is disabled during charging.

Accessories: Micro USB 2.0 Type C Cable, 5V 2A Fixed Blade Wall Plug-in Power Supply

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.
	Top is Blinking Bottom is ON	Still charging. More than half charge.
	Top is ON Bottom is ON	Charge complete. Disconnect and treat.

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 unit improvements within 3 months
- 59% of users saw 1 full wrinkle scale unit improvement within 4 months
- 17% of users saw 2 full wrinkle scale unit improvements within 4 months
- 57% of users saw 1 full wrinkle scale unit improvement within 5 months
- 20% of users saw 2 full wrinkle scale unit improvements within 5 months
- 63% of users saw 1 full wrinkle scale unit improvement within 6 months
- 22% of users saw 2 full wrinkle scale unit improvements within 6 months
- 69% of users saw 1 full wrinkle scale unit improvement within 7 months
- 36% of users saw 2 full wrinkle scale unit improvements within 7 months
- 10% of users saw 3 full wrinkle scale unit improvements within 7 months
- 81% of users maintained wrinkle improvement for at least 2 months after users stopped using NIRA
- 68% of users maintained wrinkle improvement for at least 3 months after users stopped using NIRA

Side effects that may appear include: skin warmth and stinging. Less frequent side effects that 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.

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 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.



ENVIRONMENT CONDITIONS

The NIRA 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 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









LABELING AND SPECIFICATIONS

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

Specifications					
Wavelength	1450nm (+/- 20nm)				
Pulse Duration	0.8 s				
Maximum Power Output	2.0 W				



FCC ID 2ADZENIRD

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 radi ate 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 t hat 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 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 Skincare Laser 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.niraskin.com or call NIRA Customer Service at 781-451-1700.

Power lights on but Usage lowest level blinking Power lights on but All Usage lowest level blinking Power lights on but All Usage lowest level blinking Bilinking FAST Bilinking FAST Call NIRA Customer Service 5 Bilinking SLOWLY B-T-B-TT Call NIRA and Turn back on. If not resolved, call Customer Service 7	Front Light Indicates		Battery Indicators	User Action	Reference Code
B-T-B-T Replenish Usage 3 B-T-B-T Blinking FAST Call NIRA Customer Service 5 Blinking SLOWLY BB-T-BB-T Customer Service 7 Blinking SLOWLY Customer Service 7		*	Normal	Replenish Usage	2
Call NIRA Customer Service 5 Blinking SLOWLY BB-T-BB-T Customer Service 7 Customer Service 7			B-T-B-T	Replenish Usage	3
BB-T-BB-T Customer Service			<u>¥</u> в-тт-в-тт ¥	Call NIRA Customer Service	5
			DD T DD T		7
at the same time Charge NIRA by plugging into electrical outlet 8			Blinking SLOWLY at the same time	Charge NIRA by plugging into electrical outlet	8
All Front lights off - can't treat Silinking FAST B-TTT Call NIRA Customer Service 9			D TIT D TIT	Call NIRA Customer Service	9
Call NIRA Customer Service 10			漢 <u>孝</u>	Call NIRA Customer Service	10
B-TITT-B-TITT B-TITT Service Bilinking FAST Release Treatment button. Call NIRA Customer 11					11
Blinking FAST BB-TT-BB-TT Call NIRA Customer Service 12			Blinking FAST	Call NIRA Customer Service	12
Blinking FAST B-TTTT-B-TTTTT Release Power button. Call NIRA Customer Service 13				Release Power button. Call NIRA Customer Service	13

B—Bottom LED T—Top LED

EMC INFORMATION

The NIRA Skincare Laser needs special precautions regarding EMC and needs to be installed according to EMC information. The device contains hardware capable of Bluetooth Low Energy (BLE) communication. This hardware can receive and transmit RF energy in 2400—2483.5 MHz frequency range with DSSS modulation. It is compliant with CFR Title 47, FCC part 15.249 and ETSI EN 300-400 standards, and equivalent isotropically radiated power is less than 10 dBm (10mW).

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

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

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

Electromagnetic Immunity Declaration

The NIRA Skincare Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the NIRA Skincare Laser 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	±8 kV contact ±15 kV air	Complies	
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines.	Complies	Mains power quality should be that of a typical home, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical home commercial 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	
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 or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Е	lectrom	agnetic	Immunit	y Dec	laration
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the NIRA Skincare Laser including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
			$d = 1.17 \sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.17 \sqrt{P} 80 MHz to 800 MHz
IEC 61000-4-6	150 KHZ (0 80 IVIHZ		d = 2.33 \sqrt{P} 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	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.
			Interference may occur in the vicinity of equipment marked with the following symbol:
			((·•))

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, 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 NIRA Skincare Laser is used exceeds the applicable RF compliance level above, the NIRA Skincare Laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NIRA Skincare Laser.

b 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 Skincare Laser

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

	Separation distance according to frequency of the transmitter M				
Rated maximum output power of transmitter W	150 kHz to 80 MHz	150 kHz to 80 MHz	150 kHz to 80 MHz		
	$d=1,17\sqrt{\textbf{\textit{P}}}$	d = 1,17 \sqrt{P}	$d = 2,33\sqrt{P}$		
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		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using 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 applies.

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

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