

NIRA

Instructions For Use



HOW TO USE



1 Wash & Dry Face

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



2 Power On Device & Learn Reject Tone

- Turn on the device by pressing the power button.
- Identify the reject tone: While holding the device in front of you, briefly contact the device with your skin and immediately lift the device away from your skin. You will hear a low-pitched beep that indicates a rejection pulse.
- The rejection tone indicates that the device tip did not have full contact with the skin for the full treatment cycle. If you hear this tone, lift the device tip and place on the skin making sure there is full skin contact for the full treatment cycle.



Important: Read all instructions before first use.

3

Find Your Ideal Power Level

- Press and release the power button to adjust the power level. Set your NIRA Pro to level 1 (see power levels illustration).
- Place the device tip on the skin. The laser will automatically fire the laser once. A successfully delivered pulse is confirmed by two beeps. The first beep indicates the laser has begun firing. The second beep indicates the laser finished firing for that one spot.
- Move the laser, 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 laser to a new spot for each pulse, even if the pulse is rejected. 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. This is not recommended and should be avoided.

4

Treatment

- Using the chosen power level, hold the device tip against the skin beginning at the desired treatment area.
- Hold the device tip in place until you hear a series of two beeps approximately one second apart, indicating that the pulse has been completed.
- Lift and move the laser so it is slightly overlapping with the previous spot (see application pattern illustration).
- Following the application pattern shown in the illustration, repeat this process for 10 pulses on desired treatment area. Once 10 successful pulses have been completed, you will hear a set of three fast-paced jingle-like tones that indicate the treatment for that area is complete.
- Repeat this process for all desired treatment areas.
- Power down the device by holding down the power button until the power lights turn off. NIRA will automatically power down after 2 minutes without use.
- Continue with daily skincare regimen.



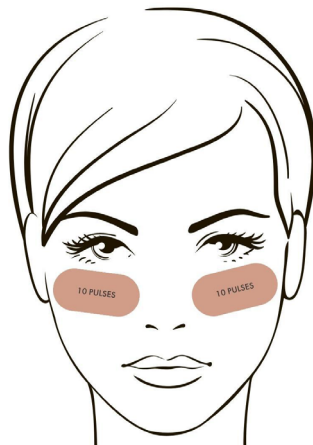
Application Pattern

For Best Results: Use the device daily for 90 days or more according to the instructions. For possible enhanced results, you may treat twice a day; waiting at least 1 minute before retreating each area. Do not treat more than twice within a 1 hour period. Daily usage is recommended on an ongoing basis to maintain results.

APPLICATION GUIDELINES



Application Pattern



Application Area

NIRA

As we age, our bodies naturally stop producing collagen, causing the skin to wrinkle and sag.

NIRA's patented non-fractional, non-ablative laser technology works by gently heating the dermis, stimulating natural collagen production and reducing the signs of aging. Over time, NIRA Pro provides more power than most professional treatments offer in a single visit - resulting in clinical-grade wrinkle reduction at home in just 90 days.

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



Watch the NIRA Pro Instructional Video:
www.niraskin.com/pages/how-to-use-nira-pro



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NIRA Pro is an at-home laser device for the treatment of facial wrinkles.*

WHO CAN USE

- All skin types and tones from light to dark.

WHEN TO USE

- When the face is fully clean and dried.
- NIRA Pro can be used in the morning or at night.
- Use NIRA Pro daily. For accelerated results repeat twice daily, but do not apply more than twice within a 1-hour period.

WHAT TO EXPECT

- You should start to see lasting wrinkle improvements within 60 days of regular treatments. You should see good, lasting results within 90 days of use.
- The first application session is usually the longest, so it's best to start when you have more time. After a few sessions, most users are able to complete a full session (10 pulses per eye) in 1 minute.
- Immediately after application, 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 application. If you find it uncomfortable, reduce the power levels in subsequent sessions.

HOW TO ACHIEVE THE BEST RESULTS

- Use daily for 90 days or more to achieve good, long-lasting results.
- Always use NIRA Pro on clean and dry skin.
- During your application sessions, use the highest power level where you feel warmth without pain.
- Use a facial moisturizer after each session. Daily use of a sunscreen with at least SPF 30 is recommended.
- Daily usage is recommended on an ongoing basis to maintain results.

**NIRA Pro is FDA-Cleared and clinically proven to reduce wrinkles around the eyes. NIRA Pro is Model 2 of Dermal Photonics Corporation, Massachusetts, USA.*

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 to using NIRA Pro. Only use the Medical grade/electrical safety certified charger and supplied USB-C cord to recharge the device. Using an uncertified 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. NIRA Pro 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 NIRA Pro 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. Store NIRA Pro in the supplied box in a secure location away from household animals and children.

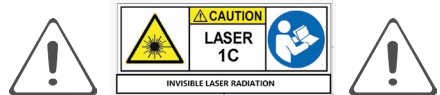
Warnings

Do not use NIRA Pro if the device or the charger is visibly damaged. Never attempt to open or repair the device; 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 application. 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. 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.

In most cases such side effects are transient and will disappear with time, but in some rare cases they may persist. If you notice any of these problems do not disappear within one day, please discontinue the treatment for a few days, and then continue treatments again when comfortable. If such side effects continue, we recommend discontinuing treatment and to seek professional advice from a skin care specialist before using the NIRA further.

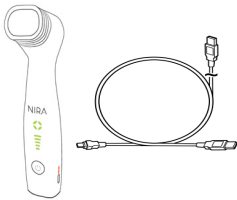
Warnings (continued)

- To prevent serious injury, you must follow these Instructions for Use when using NIRA Pro.
- Changes or modifications not expressly approved by Dermal Photonics Corporation could void the user's authority to operate the equipment.
- Do not use on skin that is cut, burned, or infected. Only use on skin that is intact.
- 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.
- If you experience skin color darkening, discontinue use and check with your doctor.
- Do not apply after long-term UV exposure. Sunburned 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 application.
- NIRA Pro 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 ages 22 and over.
- Always keep the cord away from heated or wet surfaces to prevent damage to the device.
- Do not point or place the application 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.
- Ensure the skin and application tip are dry before application. The device may not operate properly if the application tip is wet. Such failure to operate properly may cause serious side effects or device malfunction.
- Do not share NIRA Pro 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 USB-C cable provided.
- Use only with a Medical grade/electrical safety certified charger. AC input 110 V/60 Hz (or 100-240 V/50-60 Hz) and DC output 5 V current 1 A or more.









CHARGING INSTRUCTIONS

- First, connect the USB-C cable to the charging port of the device. Next connect the large end of the USB cable to a wall plug adaptor and plug into a wall outlet. Battery indicator lights on the device will start to flash.
- 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 40 mins of continuous use. This equates to 3 days of daily usage between charges. This time will vary with settings and will lessen as the battery ages.
- Your NIRA Pro will not work when it is plugged into the battery charger. Unplug your NIRA Pro to begin application.



Note: Application is disabled during charging.

Accessories: Micro USB 2.0 Type C Cable, AC input 110 V/60 Hz (or 100-240 V/50-60 Hz) and DC output 5 V current 1 A or more Fixed Blade Wall Plug-in Power Supply (not supplied in the SKU)












Charger State	Battery Indicators	Condition
Charger Disconnected	 Top is ON Bottom is ON	Normal operation. Battery over half charge.
	 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 use.

TROUBLESHOOTING

Refer to this table if you are having problems operating the device.

If you still have questions, please visit www.niraskin.com or contact NIRA Customer Support.

B—Bottom LED
T—Top LED

	Battery Indicators	Other	User Action	Reference Code
	Bottom Light Blinking SLOWLY	N/A	Charge for > 1 hour. If not fixed, contact NIRA Customer Support.	1
	Blinking SLOWLY B-T-B-T	N/A	Turn off device for > 5 minutes for cooling. If not fixed, contact NIRA Customer Support.	2
	Blinking FAST B-TT-B-TT	N/A	Reboot device. If not fixed, contact NIRA Customer Support.	4
	Normal	Device makes a single monotone sound that is different from the normal tones	Reboot device. If not fixed, contact NIRA Customer Support.	5
	Blinking SLOWLY BB-T-BB-T	N/A	Reboot device. If not fixed, contact NIRA Customer Support.	7
	Blinking FAST BB-TT-BB-TT	N/A	Reboot device. If not fixed, contact NIRA Customer Support.	12
	Blinking FAST BB-TTT-BB-TTT	N/A	Reboot device. If not fixed, contact NIRA Customer Support.	14
	Blinking SLOWLY at the same time	N/A	Charge for > 2 hours. If not fixed, contact NIRA Customer Support.	8
	Blinking FAST B-TTT-B-TTT	N/A	Reboot device. If not fixed, contact NIRA Customer Support.	9
	N/A	Device will not power on	Charge for >2 hours. Press Power button for 15 seconds, then release. If not fixed, call NIRA Customer Support.	

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 contact NIRA Customer Support.



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.

ENVIRONMENTAL CONDITIONS

NIRA Pro 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

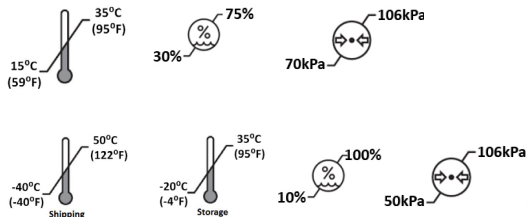
NIRA Pro should be stored in a dry place at normal room temperature.

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



CLINICAL RESULTS

In a clinical study using NIRA Precision*, three 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 had 1 full wrinkle scale unit improvement or more within 3 months
- 69% of users had 1 full wrinkle scale unit improvement or more within 7 months
- 81% of users who achieved wrinkle reduction maintained wrinkle improvement for at least 2 months after they stopped using NIRA

No difference was found in adverse events in Skin Type V or VI, thus the device is safe for all skin types.

User Experience:

- 99% of users felt that NIRA was easy to use
- 93% of users said NIRA met or exceeded their expectations
- 90% of users recommend the device
- 87% of users enjoyed using NIRA

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 a Dermal Photonics service center will ensure the battery is removed and disposed of in an environmentally safe way.

CE *NIRA Pro (Model 2) is a development of previously released and FDA-cleared NIRA Precision (Model 1). Calculations of the skin temperature changes during and after laser pulse found that such changes were very similar between NIRA Precision and NIRA Pro.

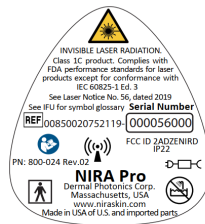
LABELING AND SPECIFICATIONS

NIRA Pro 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 activate the laser. Complies with FDA performance standards for laser products except for conformance with IEC 60825-1:2014 Ed. 3 and IEC 60601-2-2:2012 Ed. 3.1, as described in Laser Notice No. 56. dated May 8, 2019.

Specifications	
Wavelength	1450nm (+/- 20nm)
Pulse Duration	3.0 s
Maximum Power Output	2.0 W

The laser radiation hazard label can not be affixed to the product aperture but it is supplied here.

LASER RADIATION
FOLLOW INSTRUCTIONS
CLASS 1C LASER PRODUCT



EMC INFORMATION

NIRA Pro needs special precautions regarding EMC and needs to be installed according to EMC information.

Caution: Mobile RF communications equipment can affect NIRA Pro.

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

Warnings: NIRA Pro should not be used adjacent to or stacked with other equipment during application.

Electromagnetic Emissions Declaration		
NIRA Pro is intended for use in the electromagnetic environment specified below. The customer or the user of NIRA Pro should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	NIRA Pro 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	NIRA Pro 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 domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity Declaration


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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±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.

Electromagnetic Immunity Declaration

NIRA Pro is intended for use in the electromagnetic environment 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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V_{rms} 150 kHz to 80 MHz</p> <p>10 V/m 80 MHz to 2.5 GHz</p>	<p>3 V</p> <p>10 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of NIRA Pro including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p>$d = 1.17 \sqrt{P}$ 150 kHz to 80 MHz</p> <p>$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

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

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

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

^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 NIRA Pro

NIRA Pro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of NIRA Pro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and NIRA Pro 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 $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
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.

SYMBOLS

The following symbols are used within this manual or on NIRA Pro and its packaging:



Consult Instruction For Use



Fragile, Handle with Care



Read Operator's Manual

IP22

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



Keep Dry



Laser Radiation Warning



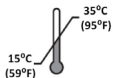
Type BF Applied Part



Caution – see Safety Information in this document



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



Temperature Range



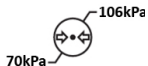
Standby & Ready



Relative Humidity Range



Class II Double Insulation Electrical Appliance



Pressure Range



Non-ionizing Radiation

NIRA

Customer Support
www.NIRAsk.in.com
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