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Sensilift Pro Instructions for Use - US		RD 21026 A0	Page 1 of 23

# Sensilift Pro

## Instructions for Use - US

Authorization				
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### **List of Revisions**

Revision	Paragraph	Change Description	Date	Issued by
A0	All	Initial release	Oct 07th, 2024	Stephanie Khoury

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**Carefully read the information below before you begin your first treatment. If you still have any doubts or are unsure that the device is safe for your use, please consult with your physician.**

## **PRECAUTIONS:**

- Never use flammable liquids, such as alcohol (including perfumes, sanitizers, or other applications containing alcohol) or acetone to clean the skin in the hour before using the device, as it may cause burning of the skin.
- Do not open or repair the device, as it may expose you to dangerous electrical components.
- Do not place, store or use the device near bathtubs, showers, basins or other vessels containing water, as this may cause severe electrocution.
- Do not leave the device unattended while plugged into the electricity supply, as it may lead to electrocution.
- Keep out of reach of children and pets.
- Not to be used by persons under 18 years of age.
- Children must not play with the appliance. Cleaning and maintenance by the user must not be carried out by children without supervision.
- Use the device only in accordance with these Instructions for Use and for its intended use.
- Do not use the device if any part of the device is missing, damaged or lost, if the device is not working properly, if you see or smell smoke, or if the device becomes damp or wet.
- Make sure the device is clean, dry and intact before each use. Cleaning instructions are detailed in the **Cleaning and Storage** section below.
- Do not use the device without first applying the Base Gel.
- Do not use the Base Gel after its expiration date.

**Note:** The Base Gel is for external use only - avoid direct contact with eyes. In the event that such contact does occur, wash the eyes immediately with water.

- To ensure the optimal performance of your RF device, be aware of the following potential sources of interference: microwave ovens, cordless phones, Bluetooth devices, wireless video cameras, baby monitors, wireless routers and access points, wireless speakers, other wireless networks, power lines and electrical substations, and CRT monitors and electric motors
- The Patient is the intended operator.
- Don't do any service or maintenance while the device is in use.
- Warning: RF devices may cause electromagnetic interference with other medical equipment, potentially affecting their performance and patient safety; ensure proper shielding, monitoring, and adherence to manufacturer guidelines.
- Dispose of the RF device, power supply, and any residues at designated e-waste recycling centers, following local regulations to ensure environmental safety.
- Instructions provided indicate not to position Sensilift Pro to make it difficult to operate the disconnected device.

## **CONTRAINDICATIONS**

Do NOT use the device if you:

- have an active implant, such as a pacemaker or insulin pumps, or if you have any known severe heart disorder, such as arrhythmias.
- Are pregnant or breastfeeding.
- suffer from severe or uncontrolled endocrine or metabolic conditions, such as diabetes or uncontrolled thyroid disease.
- have a damaged immune system or autoimmune disorder, such as AIDS or Lupus, or if you use drugs that influence the immune system.
- suffer from blood clotting disorders, excessive bleeding or bruising, damaged wound healing or if you routinely take blood-thinning medication.
- suffer from a history of deep vein thrombosis.
- have a history of collagen disorders or suffer from keloid scarring (growth of extra scar tissue where the skin has healed after an injury).
- have a general extreme illness, such as hepatitis, liver disease or epilepsy.
- suffer from sensitive or damaged skin, such as in cases of frequent redness or rash, inflammations, breakouts (such as psoriasis), blisters, sores, infections, acne or extra dry skin.

- have diminished or exaggerated perception of temperature change.
- have taken Accutane in the past 6 months.
- have a heat-induced disease or an active skin disease, such as herpes, eczema, rashes etc., in the treatment area.
- have skin cancer, areas at risk of malignancy, or if you have received radiation therapy or chemotherapy within the past 3 months.

## **WARNINGS**

Do NOT use the device:

- If you have any permanent implants in the designated treatment area, including but not limited to: silicon or injected chemical materials, metal plates or other metal materials.
- If you had plastic surgery, such as face lifting or eyelid surgery, or if you had aesthetic injections of fillers such as: Hyaluronic Acid, Collagen, fat or Botulinum Toxin, in the treatment area within the past 3 months.
- If you have had a professional chemical peel within the past 3 months with Alpha Hydroxyl Acids (AHA), such as glycolic acid, or Beta Hydroxyl Acid (BHA), or if you had a professional facial abrasion such as: dermabrasion, facial resurfacing, deep chemical peeling (phenol, Trichloroacetic acid-TCA), and/or ablative laser treatments within the past 3 months.
- Over nostrils, lips of the mouth, ears, breast or genital area, or areas not recommended in this user manual.
- Over the thyroid since it may cause adverse events.
- Over the eyelids, eyes or sides of the eyes (next to your nose), since it may cause eye damage.

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- If you have any metal items, such as jewelry or piercings, or tattoos or permanent make up on the designated treatment area/s.
- Over sunburns, dark brown or black spots such as: freckles, birth marks, moles or blisters in the treatment area.
- If you are allergic or sensitive to chrome, nickel or any component of the Base Gel.
- The appliance may be used by persons with reduced physical, sensory or mental capabilities or lack of experience and knowledge provided that they are under supervision or have been instructed in the safe use of the appliance and that they understand the hazards involved.
- Do not use the device over hairy areas of the body, as this may result in the hairs being burnt.

Note: If you have undergone any other aesthetic procedures in the designated treatment area, or if you have treated the skin with a prescribed drug within the past 3 months, or if you have any concerns regarding potential adverse effects, please consult your physician before using the device.

## **Introducing DRF (Dynamic radio frequency) Technology – How does it work?**

This device brings a new approach to non-invasive skin rejuvenation featuring Sensica proprietary Dynamic RF™ technology, combining clinically proven RF (Radio Frequency), commonly used by doctors, with advanced facial speed.

Radio Frequency (RF) is a form of electromagnetic energy intended to reduce wrinkles. It is suitable for adults with Fitzpatrick Skin Types I-IV, easy to use, and provides noticeable, long-lasting results.

RF technology has been used in doctors' clinics for several years and was found to be highly effective. The device has two electrodes that deliver the RF energy into the skin to contract collagen fibers and stimulate the natural production of collagen, which decreases as we age. If used correctly and according to the Recommended Treatment Protocol, the

device will reduce the appearance of wrinkles. Results may be visible after just one treatment.



***Please make sure to carefully read this user guide before you start***

***treating with the device.*** The user guide can also be found at [www.sensica.com](http://www.sensica.com)

## **Intended Use**

The device is intended:

- For women and men who want to: reduce mild to moderate facial wrinkles
- Fitzpatrick Skin Types I-IV
- For use on the perioral region (nasal labial or lower cheek), periorbital region (around the eyes or upper cheek), and the chin.
- For use on mild to moderate depth wrinkles.
- To be used with the Base Gel. This gel is specially designed to work with Sensica RF devices and ensures proper delivery of RF energy. This will provide the best possible results by improving contact between the device and the skin to improve skin conductivity.

**Note:** Sensilift PRO is an over-the-counter device specially designed for your treatment and is intended for a single user and home use only.

## **Possible Adverse Effects**

When using the device according to the Instructions for Use, adverse effects are rare. However, every aesthetic procedure, including the usage of home-use devices, may cause some degree of adverse effects (as listed in the table below).

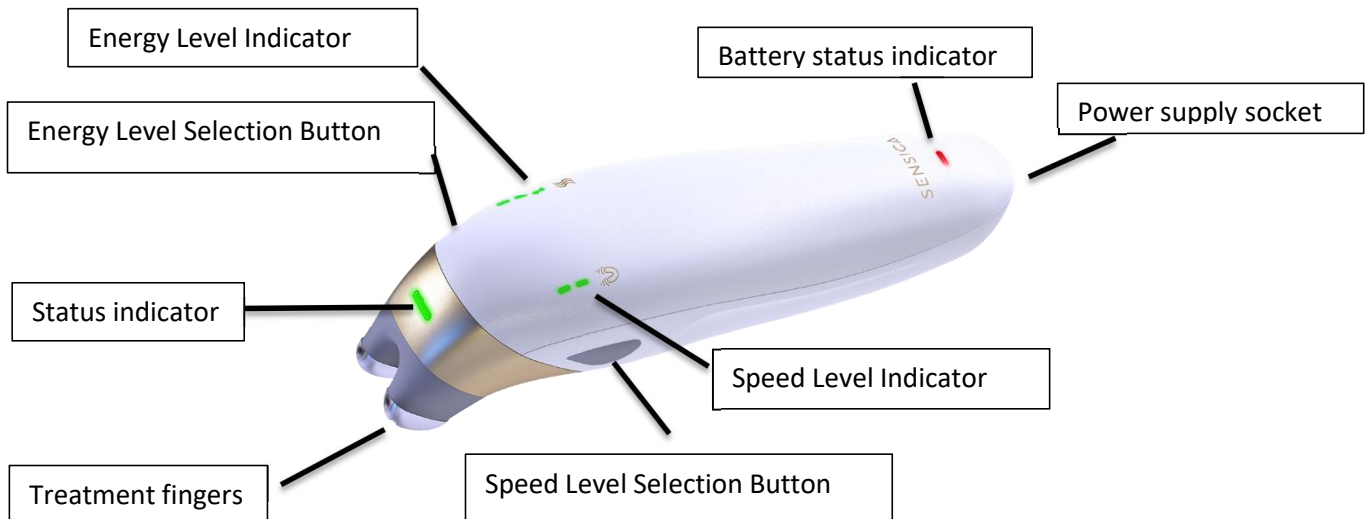
In case adverse effects appear, stop using the device and consult with your physician if necessary.

Mild adverse effects should be spontaneously relieved within a few hours.

Severity of Adverse	Frequency of Adverse Effect	Adverse Effects
---------------------	-----------------------------	-----------------



Effect		
Mild	Common	Local pain Skin irritation Skin redness Skin sensitivity Allergies or sensitivity to the Base Gel
Moderate	Rare	Mild skin burns Pigment changes Excessive redness and swelling Urticaria, purpura or ecchymosis Hematoma
Severe	Extremely Rare	Severe burns Infection Bruising Blistering




**Device Accessories:**


1. Power Supply cable

**Device Description****User interface description**

**1. ON/OFF and energy selection button** – Pressing the button will turn the device ON at energy level 1, shown by 1 illuminated light in the energy level display. Once it reaches the highest level, another press will turn the device OFF. The device will switch to standby mode when left unattended for 45 seconds.

**2. Status indicators**

Status indicator	No light	The device is OFF or no skin contact
	One time yellow-green light	The device is ' <b>ready to use</b> ' after ON and internal Bluetooth module is detected.
	Steady green light	The device is in <b>treatment mode</b> . RF is activated, skin contact is detected, and the treatment is undergoing.
Battery status indicator	Steady Red	Battery charging and the device is connected to the external power supply.
	Steady Green	The battery is done charging, and the device is connected to the external power supply.
	One time red	The device is ON.
	Blinking red	The battery needs to be charged.
RF energy level selection button, also turning on the device 	1-3 energy level lights	To turn on the device, briefly press this button. When the green light is on, it indicates that the RF energy is active. Touch the RF energy level selection button repeatedly until you reach the desired level: 1, 2, 3 ,1,.. To turn off - hold this button

		down for 3 seconds
Speed level selection button, also turning on the device 	1-2 speed level lights	<p>To turn on the device, briefly press this button. When the green light is on, it indicates that the speed function is active. Touch the speed level selection button repeatedly until you reach the desired level: 1, 2, or off.</p> <p>To turn it off - hold this button down for 3 seconds</p>

## User Instructions

### What to Expect When Using Sensilift PRO

During your treatment, it is normal to experience:

- Sensations of warmth created by the RF energy.
- Some mild red or pink color on the skin – during and just after each treatment.

### Preliminary Test

The preliminary test is intended to determine your skin's reaction to the treatment and help you find the best settings for each treatment area. Perform a preliminary test on each area you intend to treat 48 hours prior to the full treatment.

- Prepare your skin as described below in "**Step 1: Prepare your skin**". Instructions for operating the device can be found below in "**Step 2: Device operation**".
- Before using the device, apply a thin, even layer of the Base Gel on the treatment area.
- Start your test with energy level 1 and move the device in small circular motions.
- Increase the energy levels according to your comfort. Stop the test if you do not feel comfortable or if you see adverse effects.
- Perform the preliminary test for a total time of about 3 minutes.
- Wait 48 hours and examine the tested area.

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- If the skin in the tested area appears normal and no adverse effects are present, you can proceed with a full treatment at the highest comfortable energy level that you tested.

\*Note: The RF energy level indicates the rate at which the temperature rises when in heating mode. A high RF energy level will enable faster and more even heating. You can achieve maximum results with all RF energy levels but for lower levels it will take more time to reach the effective temperature. Therefore, you may select any RF energy level that you find comfortable.

## Getting Started

### Step 1: Prepare Your Skin

1. Prior to use, make sure your skin is dry, clean and free of topical products such as: moisturizers, liquids or lint.
2. Remove all jewelry from the treatment area and from your hands.
3. Never use flammable liquids such as alcohol (including perfumes, sanitizers, or other applications containing alcohol) or acetone on the skin one hour before using the device as it may cause burning of the skin.
4. The device is suitable for men. However male users should make sure their skin is clean-shaven before treatment.

### Step 2: Device Operation

**Note:** A preliminary test should be conducted separately for each area you intend to treat before proceeding with a full treatment in that area. See the “**Preliminary Test**” section above.



### Charging Instructions

1. Before first use or when the battery is empty, fully charge the device (charging takes up to 2 hours).

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2. When the battery is low, indicated by the blinking red battery status light, recharge the device. Fully charge the device every 3 to 4 months, even if it hasn't been used.
3. To charge, plug the power cord into an electrical outlet. The charging light will turn green when the battery is fully charged.
4. After charging, unplug the power adapter from both the outlet and the device.

**Notes about Charging:**






- It is normal for the device and power adapter to warm up during charging.
  - Charge the device in a cool or room-temperature environment, and never in a location above 40°C. The device has built-in battery-overheat protection and will not charge if the room temperature exceeds 40°C.
  - Do not cover the device or power adapter while charging.
  - You can use the device while it is charging.
5. Make sure the device is clean, dry, and intact before use.
  6. Set the Radio Frequency (RF) energy level and the massage speed to the level you selected in your preliminary test treatment. Gently touch the RF energy level selection button  repeatedly until you reach the desired level: 1, 2, or 3. Gently touch the speed level  button repeatedly until you reach the desired level: 1 or 2.
  7. The activation of either RF or speed functions can be done independently or together. Both functions will be activated at level 1. Select different levels based on the preliminary test.
  8. Sensilift PRO is equipped with 2 safety sensors which will keep the temperature in the effective and safe range during the entire treatment.
 







**Note:** The device stops the heating when the desired temperature is achieved; heating is re-activated when the temperature begins to drop.
  9. Place the treatment fingers on the intended area, ensuring full contact with your skin during the entire treatment. Sensilift PRO will indicate the proper skin contact by the green status light. If Sensilift PRO is not properly placed, the RF energy will not be delivered.
  10. Note: the device will automatically turn off after 45 seconds of no skin contact.

11. If you do not feel sensations of warmth after approximately 10 seconds, try moving the device to a smaller treatment area, and/or increasing the RF energy.
12. Move the device on the treatment area in a slow, circular, or back-and-forth motion while constantly and firmly staying in contact with the skin.
13. See treatment areas, treatment time, and treatment schedule in the "Recommended Treatment" section.
14. At the end of each treatment session turn off the device.
15. After completing the treatment, wipe off the remaining Base Gel from the treated area.
16. Cleaning instructions for before and after treatment are depicted in the Cleaning & Storage section.


## **Recommended Treatment**

- Place the treatment fingers as indicated in the picture of the chosen treatment area.
- Keep moving the device as described for the chosen treatment area.

<b>Treatment Area</b>	<b>Recommended Treatment Time</b>	<b>Recommended Device Movement</b>
Forehead 	10 minutes	Slow up and down motion across the forehead
"Eleven" 	5 minutes	Small circular movements or up and down
"Crow's feet" 	5 minutes for each side	Continuous, slow 'side to side' circular motions
Cheeks 	5 minutes for each side	Slow circular motions across the cheek
"Smile folds" 	5 minutes for each side	Slow up and down motions over the "smile folds"

		
Chin 	5 minutes	Side to side
Jawline 	5 minutes for each side	Slow up and down motions along the jaw
Neck 	5 minutes for each side	Slow up and down motions across the neck
Decolletage 	5 minutes for each 4cm <sup>2</sup> sub-area	Slow circular motions across decolletage
Hands 	5 minutes for each 4cm <sup>2</sup> sub-area	Slow circular motions across hands

**Warning:** avoid contact with the eyes, eye cavities, nostrils, and oral cavity, as treatment in these areas may cause adverse effects.

**Warning:** avoid treatment in the lower third of the neck since this area is more sensitive and avoid treating the thyroid area (marked ).

- For long-lasting results, use the device once a week on each desired area for a period of 8 weeks.
- Response to the treatment differs between individuals and depends on environmental and biological factors, heredity and aging.
- To sustain optimal long-term results, maintenance treatments may be performed as needed every 4-8 weeks

## Post-facial treatment care

- We recommend using Sensica's anti-aging cream to enhance treatment efficacy and ensure long-lasting results (available at [www.sensica.com](http://www.sensica.com)).
- Apply a high-factor sunscreen (at least SPF 30) and protect the treated area from direct sunlight for two weeks following treatment.
- After treatment, avoid using hot water on your face and discontinue the use of abrasive or harsh products for two days.
- Makeup can be applied immediately after treatment.

## Cleaning & Storage

- Ensure the device is turned off and unplugged before cleaning.
- Clean the device, particularly the treatment fingers, temperature sensors, and silicone cover, using a soft, damp cloth or wipes to remove any residual Base Gel.



***Do not rinse the device under running water, as it may cause device malfunction.***

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- Keep the device dry. Never place, store, or use the device near: bathtubs, showers, basins or other vessels containing water as this may cause severe electrocution.

## Troubleshooting

If you encounter any issues with your device, please refer to the information below for troubleshooting solutions:

- If the device does not turn on:

Make sure that the device is charged.

- If you cannot feel heat:
  - Verify full contact with the skin (indicated by a green light).
  - Verify that you applied enough Base Gel.



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- Remember that the device reacts to your skin and may temporarily reduce heat for safety reasons.

See status indicator table in the **User Interface Description** section.

- In case of dirt or debris on the treatment fingers, you should clean them by the **Cleaning & Storage** section. If you can't get the area clean, contact our customer service.
- In case of a general error, reset the device by unplugging the power cord from the electrical outlet on the wall, wait 10 seconds and then reconnect it.

If you still have problems with your device, please contact our customer service.

In addition:

1. Beware of cable use as misuse could cause strangulation.
2. If you suffer from an allergic reaction to the device materials, please stop using the device.
3. Be aware from contact injuries

Any severe incident that has occurred in relation to the device should be reported to us (via customer service).



## **Disposal**

For environmental reasons, do not dispose of the device in the household waste. Dispose of it at a suitable local collection or recycling point by EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

## **Customer Service**

If your device has stopped working or if you need further assistance or information, please contact us.

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You can also reach out to order additional Base Gel or purchase it online at [www.sensica.com](http://www.sensica.com).

For customer service, please refer to the contact details on the inner back cover.

## **Device Specification Parameters**

The RF handheld device is powered by bipolar RF at  $6\pm 1$  [Watt]

**Shelf life:** 5 Years

**Battery:** Li-ion

**Frequency:**  $1\pm 0.05$  [MHz]

**Selectable output power levels:** 3 levels

**Mechanical speed:** implemented by moving RF electrodes. Speed: 50-100 RPM

**Temperature sensors:** RF heating is automatically deactivated when skin temperature reaches  $40\text{ }^{\circ}\text{C}/104\text{ }^{\circ}\text{F}$ . The heating is reactivated when the temperature decreases.

**Treatment area:**  $\sim 2.2\text{ [cm}^2\text{] / }0.34\text{ [In}^2\text{]}$

**External power supply:** Input 100-240 [VAC], 50-60 [Hz], Output 12[VDC], 1.8[A]

**Device size and weight:**

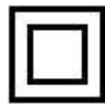
- 205 [g], 190[mm] X 55 [mm] X 51[mm] LxHxW
- 7.231 [Oz], 7.4[In] X 2.16[In] X 2[In]

## **Storage Instructions**

Storage and transport conditions	
Temperature	-20 °C to 70 °C (14°F to 158°F)
Humidity	10% to 90% RH at 55°C/131°F
Pressure	Non-condensing 70KPa to 106KPa
Operational conditions	
Temperature	10°C to 40°C
Humidity	(50°F to 104°F)

**Max operating altitude****30% to 70% RH****3,000 m.**

## **Labeling**

**Model: ST300****Power: 12 [V], 1.8 [A], 100-240 [VAC], 50-60 [Hz]**

Double insulation



Rechargeable battery



Consult Instructions for use



Waste Electronic and Electrical Equipment



Please read all warnings and safety precautions prior to use



Protect from moisture.



This device must not be used near to water or in water itself (e.g., in a wash basin, in the shower or bathtub) – risk of electric shock!



Our products and packaging are recyclable, do not throw them away!



**IP22**

IP2X: Object of 12.5 mm diameter, shall not penetrate.

IPX2: Vertically falling drops shall have no harmful effects.



Use the device only with the original power supply. For your safety, never use DC adapters which are not approved by the manufacturer.

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**Notes on battery handling**

- If your skin or eyes come into contact with fluid from the battery cell, flush out the affected areas with water and seek medical assistance.
- Protect batteries from excessive heat.
- Risk of explosion! Never throw batteries into a fire.
- Do not disassemble, open or crush the batteries.
- Some warming of the device and power adapter during charging is normal.
- Do not charge the battery in a room temperature above 40°C (104 °F). The device is equipped with battery-overheat protection and will not charge if the room temperature exceeds 40°C (104 °F).
- Never cover the appliance and the adapter during charging.
- Only use chargers specified in the instructions for use.
- Batteries must be charged correctly prior to use. The instructions from the manufacturer and the specifications in these instructions for use regarding correct charging must be observed at all times.
- Fully charge the battery prior to initial use (see Device Set-up section above).
- In order to achieve maximum battery service life, fully charge the battery at least twice a year.

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## **FCC Requirement**

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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 operation.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Note: 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 radiate 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 or more 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 or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.