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sensiLift	RD-11118 B1

# sensiLift

## INSTRUCTIONS FOR USE

Authorization				
	Name	Title	Signature	Date issued
Updated by:	Veronika Kravtsov	RA/ QA Associate		June 6 <sup>th</sup> , 2017
Reviewed by:	Martin Gurovich	VP R&D		June 6 <sup>th</sup> , 2017

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### List of Revisions

Revision	Paragraph	Change Description	Date	Issued by
A0	All	Initial release	January 12 <sup>th</sup> , 2014	Segman Shlomit
B0	Cleaning	Maintenance title was added as headline	June 12 <sup>th</sup> , 2014	Shlomit Segman
	FCC declaration	added		
	FCC warnings	added		
C0	All	According to FDA requirements, comments from FDA pre-submission and Dr. Man review	Oct 14 <sup>th</sup> , 2014	Segman Shlomit
D0	All	Updating treatment times according to clinical trial results	Jan 10 <sup>th</sup> , 2016	Yael Liebes-Peer
	Recommended treatment	Addition of maintenance protocol		
E0	All	According to FDA comments (Q160059) and Prof. Shemer Review	Oct 31 <sup>st</sup> , 2016	Yael Liebes-Peer
F0	All	According to FDA comments (K17499): Addition of indication for use statement, restriction to use near the eyes and on thyroid, clearer language, removal of "unique" sensor description	April 18 <sup>th</sup> , 2017	Yael Liebes-Peer

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GO	All	According to FDA comments (K170499/S001)	June 6 <sup>th</sup> , 2017	Veronika Kravtsov
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**What is sensiLift**

sensiLift is a home use device intended for non-invasive treatment of mild to moderate facial wrinkles and rhytides.

sensiLift brings a completely new approach to non-invasive skin treatment using Dynamic RF™ technology combining RF (Radio Frequency) used by doctors professionals worldwide with the comfort of moving treatment fingers.

**Indications for Use:**

The sensiLift is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult women who have Fitzpatrick Skin Types I-IV.

**How does it work?**


**Introducing the new Dynamic RF technology**

A major cause of skin wrinkles is the reduction in the quantity and quality of collagen fibers in the dermis and hypodermis (skin layers).

**Radio Frequency (RF)** is a form of electromagnetic energy. RF energy is being used in doctors’ clinics for a long time. RF treatments were found to produce a highly efficient thermal effect on biological tissue. Heat is generated as a result of tissue resistance to the movement of electrons within the RF field. The sub-cutaneous heat generates new collagen and enhances existing collagen, leading to wrinkles reduction.

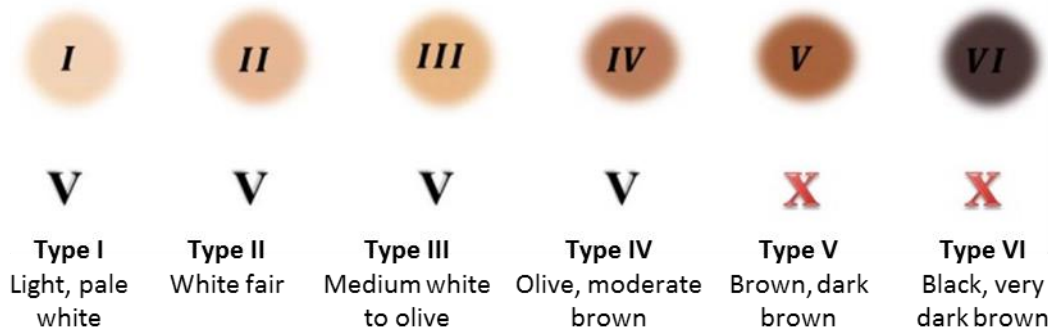
The sensiLift™ treatment creates enough thermal effect to induce collagen remodeling with no ablative thermal damage of the epidermis or dermis.

The sensiLift device is based on the unique Dynamic RF™ technology. The unique technology combines RF with moving treatment fingers. This maximizes the effectiveness and safety of the RF treatment, allowing multiple RF waves to reach wider range of skin layers and assist in getting best possible visible and ongoing, lasting results.

 **Please carefully read this user manual before you start using *sensiLift*<sup>TM</sup>.**

### Who should use and how to decide to use *sensiLift*

- *sensiLift*<sup>TM</sup> is intended for women, 30-70 years old who desire to reduce mild to moderate facial wrinkles and rhytides.
- *sensiLift*<sup>TM</sup> is intended for use on the cheeks, around mouth, the “crow’s feet” next to your eyes, and the chin (as also demonstrated in the “treatment area” section).
- *sensiLift*<sup>TM</sup> is intended for use on Fitzpatrick skin type I-IV, as demonstrated below:



Note: *sensiLift* is especially designed for your own personal treatment! It is intended for a single user only.

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## sensiLift's safety

sensiLift has two built in thermal sensors, constantly measuring your skin temperature. When the temperature rises to the maximal allowed (104°F), the RF energy will automatically stop. When temperature is low enough, the RF energy will be automatically re-activated.

In addition, the RF electrodes constantly move. This prevents local over-heating of your skin.

No over-heating due to the temperature sensors and the movement of the treatment fingers. Altogether, follow the instructions for use and your treatment will be comfortable and pleasant.

## sensiLift Device Description

The sensiLift device kit has the following main components:

1) External power supply

2) sensiLift hand-held device:

Two treatment fingers including the electrodes applying RF while moving.  
The treatment fingers also include safety temperature sensors.

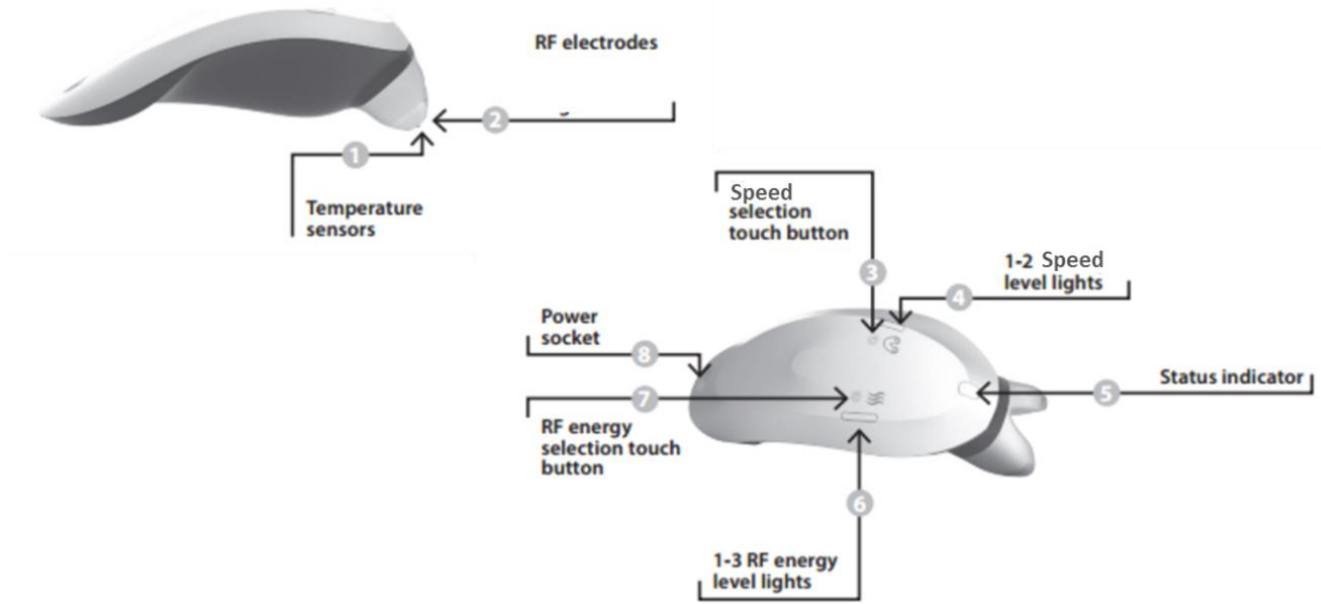
3) sensiLift Base:

Specially designed to improve contact between the device and the skin and enhance skin conductivity.

sensiLift Base ingredients: Glycerin, Aqua, Phenoxyethanol, Ethylhexylglycerin, Triethanolamine and Carbomer.





### Hand-held description



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## User interface description

<b>Status Indicator</b>	Blinking yellow light	sensiLift is on <b>Stand-by</b> mode. In case of no light, make sure the power cord is plugged-in properly.
	No indicator light – before treatment	When energy (1-3) or speed (1-2) level are selected and ON – you can start your treatment.
	Steady green light	sensiLift is in <b>Treatment mode</b> , RF is activated, skin contact is detected and the treatment is ongoing.
	Blinking alternating green and yellow	sensiLift is in <b>Error mode</b> , the device has detected a malfunction and prevents the activation of the RF and speed functions.
RF energy level selection touch button 	1-3 Energy levels lights	Green light on, indication of RF energy level. Press the RF energy level selection button repeatedly until you reach the desired level: 1, 2, 3 or off. *
Electrodes speed level selection touch button 	1-2 speed level lights	Green light on, indication of speed function level. Press the speed level selection button repeatedly until you reach the desired level: 1, 2, or off. *
<p>*Note: The activation of either the RF or Speed function will automatically activate the other function at level 1. You can select other levels based on the “preliminary test”.</p> <p>Notice that you cannot use RF function alone or speed function alone. They always work together!</p>		

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## When shouldn't sensiLift be used?

sensiLift™ is designed to allow you safe and effective treatment. However, sensiLift™ might not be appropriate for everyone. Please read the information below before use. If you still have any doubts, and you are unsure that sensiLift™ is safe for your use, please consult with your physician.

## Who cannot use the sensiLift - CONTRAINDICATIONS

Do NOT use **sensiLift™** device if you have any of the following conditions:

- If you have an active implant such as a pacemaker or insulin pumps or if you have any severe known heart disorder such as arrhythmias.
- If you are pregnant or breastfeeding.
- If your skin is Fitzpatrick skin type V or type VI (dark skin).
- If you suffer from severe or uncontrolled endocrine or metabolic conditions (such as diabetes and uncontrolled thyroid disease).
- If you have a damaged immune system or autoimmune disorders such as AIDS, or Lupus, or if you use drugs that influences the immune system.
- If you suffer from blood clotting disorders or excessive bleeding or bruising or damaged wound healing or if you routinely taking blood thinning medications.
- If you suffer from a history of deep vein thrombosis.
- If you have history of collagen disorders or suffer from keloid scar (growth of extra scar tissue where the skin has healed after an injury) formation.
- If you have extreme general illness, such as hepatitis, liver disease or epilepsy.
- If you suffer from sensitive skin such as in cases of frequent redness, inflammations, breakouts, infection and acne or extra dry skin.
- If you have diminished or exaggerated perception of temperature changes.
- If you have been taking Accutane in the past 6 months.
- If you have heat induced disease or an active skin disease (Herpes, Eczema, rash etc.) in the treatment area.

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- Do not use the device if you have skin cancer or on areas at risk of malignancy or if you have received radiation therapy or chemotherapy within the past 3 months.

## What you must do to avoid serious harm – WARNINGS

In some cases sensiLift™ safety and effectiveness has not been tested or established yet. Therefore, if you have any of the following conditions, it is NOT advised that you use the device:

- Do not use over 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) 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 had professional chemical peel within the past 3 months (Alpha hydroxyl acids (AHA) such as glycolic acid or Beta hydroxyl acid (BHA), or professional facial abrasion (such as dermabrasion, facial resurfacing, or deep chemical peeling (Phenol, Trichloroacetic acid-TCA, and/or ablative laser treatments) within the past 3 months.
- Do not use over nostrils, lips of the mouth, ears, breast or genital area, or areas not recommended in this user manual.
  - Do not use over the thyroid since it may cause adverse events.
  - Do not use over the eyelids, eyes or sides of the eyes next to your nose) since it may cause eye damage.
- Do not use the sensiLift over any metal items (such as earrings, jewelry or piercing) or on tattoos or permanent make up in the designated treatment areas.
- Do not use over sunburns, dark brown or black spots such as freckles, birth marks, around the nipples, moles or blisters in the treatment area.
- If you are allergic or sensitive to chrome, nickel or any component of the base gel.
- If you are male.

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- If you are under the age of 30 or over the age of 70.
- This appliance is not intended for use by persons with compromised physical, sensory or mental capabilities.
- Do not use sensiLift without facial hair removal from treatment areas, since it may result in burn in these areas.

Note: If you have undergone any other aesthetic procedures in the designated treatment area or any uncertainty regarding potential side effects, consult your physician before using sensiLift™.

### **What you must do to avoid other harm - CAUTIONS:**


- Never use flammable liquids such as alcohol or acetone (including perfumes, sanitizers, or other products containing) to clean the skin one hour before using sensiLift™ 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 sensiLift near bathtubs, showers, basins or other vessels containing water as this may cause severe electrocution.
- Do not leave sensiLift™ unattended while plugged into the electricity as it may lead to electrocution risk.
- Use the sensiLift only according to the instructions for use and for the intended use.
- Do not use the device if any part of the device is missing, damages or loose, if the device is not working properly, if you see or smell smoke or if the device becomes damp or wet.
- Do not use the sensiLift device without applying the “sensiLift base” before use.
- Do not use “sensiLift Base” after its expiration date.

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- Before using sensiLift, make sure the device is clean, dry and intact. Cleaning instructions are detailed in the cleaning section.

Note: sensiLift is designed to be used by a single user.

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

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## Possible Side Effects

When using the sensiLift device according to the instructions for use, side effects are rare. However, any aesthetics procedure, including home use devices, may cause side effects. Therefore it is important that you understand and accept the risks and complications that can occur with RF wrinkle reduction device:

Degree of Side Effects	Side Effects
<b>Minor Side- Effects</b>	Local pain Skin Irritation Skin Redness Skin Sensitivity Allergic contact eczema or sensitivity to the sensiLift Base
<b>Rare Side- Effects</b>	Skin mild Burns Pigment Changes Excessive Redness and Swelling Urticaria (hives/ severe red rash), Purpura (purple spots beneath the skin) or Ecchymosis (discoloration of the skin) Hematoma (swelling of clotted blood)
<b>Extremely Rare Side- Effects</b>	Severe Burns Infection Bruising Blistering

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## Benefits

sensiLift Dynamic RF features in a unique treatment fingers. The treatment fingers enable multiple RF wave lengths to penetrate different skin layers, while gently moving along the treated area, together with continuous temperature sensing. This combined action has been proven to be an intense, effective and safe treatment.

sensiLift also includes dedicated thermal sensors that constantly “reads” your skin’s condition. The sensors adjust the temperature to provide you a more personalized and safe treatment for your convenience and ease of use. When you use sensiLift on your face you’ll be able to see and feel the improvement in facial wrinkles and rhytides reduction, with every single treatment.

As an extra precaution, the RF electrodes has been designed to only emit RF energy only when it is in contact with your skin.

Response to sensiLift differs between individuals depending on biological factors and how closely treatment instructions are followed.

Based on the treatment regime followed in this User's Manual you should expect to see some improvement already after 4 weeks.

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## User Instructions

sensiLift is intended for use on cheeks, around mouth, the “crow’s feet” next to your eyes, and the chin, as illustrated in the treatment areas below.

### Device Set-Up

1. Remove all components from the box (handheld device, power supply and sensiLift Base).
2. Check expiration date of the sensiLift base.
3. Make sure the treatment fingers are clean, dry and intact.
4. Plug the power supply end into an electrical outlet and the cord end into the device socket.

**The sensiLift is now ready to be used**

### How to prepare yourself

1. Make sure your skin is dry, clean and free of topical products (such as moisturizers), liquids or lint.
2. Remove jewelries from the treatment areas.
3. Excessive or long facial hair should be shaved before using sensiLift.
4. Use a mirror to assist you during treatment.
5. Never use flammable liquids such as alcohol (including perfumes, sanitizers, or other applications containing alcohol or acetone) to clean the skin one hour before using sensiLift as it may cause burning of the skin.
6. Perform a preliminary test on a small patch of skin in the intended treatment area 48 hours before the first use of the sensiLift. In the preliminary test, you can determine energy and speed level settings optimal for your treatment (see preliminary test section).



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## Preliminary Test

The preliminary test is intended to determine your skins reaction to the sensiLift treatment and help you to find the best sensiLift setting for each treatment area.

Do a preliminary test on each area you intend to treat 48 hours prior to the full first treatment.

1. Apply a thin, even layer of "sensiLift Base", included in your kit, on the area to be treated.
2. Select RF energy level 3 and speed level 1.
3. Place the sensiLift device on the desired treatment area and start moving it in circular motion in the treatment area, for 3 minutes.
4. The treatment will create a warm sensation on your skin. If you feel your skin is heated too fast for you, reduce the RF energy level. The energy level should be adjusted according to you own comfort.
5. Select the speed level to 1 or 2 according to your own comfort.
6. Stop the test if you do not feel comfortable or if you see adverse effects such as severe redness or blistering.
7. Wait 48 hours and examine the tested area.

If the skin in the test area seems normal (no adverse effects) you can proceed with a full treatment in the highest comfortable energy level and speed level you have 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 you faster heating. You can achieve maximum results with all RF energy levels (for lower levels, it will just take longer time to reach the effective temperature). Therefore, select your optimal RF energy level according to your level of comfort.



## How to Use the sensiLift device

\*Note: Perform a preliminary test before proceeding to a full treatment for the first time.  
See “preliminary test section” above.

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See treatment areas, treatment time and treatments schedule in the “treatment protocol” section below.

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1. Apply a thin, even layer of the “sensiLift Base” included in your kit, on the area of your skin intended for treatment.
2. Set the RF energy level and the speed to the level you have selected in your preliminary test treatment. Press the RF energy level selection button  repeatedly until you reach the desired level: 1, 2, or 3. Press the  button repeatedly until you reach the desired level: 1 or 2.
  - ✓ The activation of either the RF or speed function will automatically activate the other function at level 1. Select different levels based on your “preliminary test”.
  - ✓ sensiLift is equipped with safety sensors which will keep the temperature in the effective and safe range during the whole treatment.
3. Place the treatment fingers on the intended area, ensuring full contact with your skin during the entire treatment. sensiLift will indicate the proper skin contact by the green indicator light. If the sensiLift is not properly placed, the RF energy will not be delivered and the indicator light will be off.
4. If you do not feel sensations of warmth after approximately 10 seconds, try moving sensiLift on a smaller treatment area, and/or increasing the RF energy level.
5. Move the device on the treated area with slow circular or back and forth motion. Make sure constantly and firmly contacting the skin during the whole treatment.
6. Turn off the device and then unplug at the end of each treatment session.
7. After completing the treatment, wipe off the "sensiLift Base" from the treated area.

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- Clean the device with soft damp cloth or paper towel, according to cleaning instructions (see Cleaning section).

## Recommended treatment protocol:

### Typical sensiLift Treatment Interval

Use the sensiLift device once a week on each desired area for a period of 8 weeks.

To sustain optimal long term results, you can repeat sensiLift™ treatment protocol as needed.

#### Notes:

- Response to sensiLift device differs between individuals depending on biological factors, heredity and aging.
- For long term results, additional treatments may be repeated for maintenance.
- You may use the treatment log at the end of this manual, to assist you with recording your treatment areas, dates and duration.
- In rare cases, treating the chin and sideburn can lead to paradoxical effect of hair regrowth.

### Treatment Areas



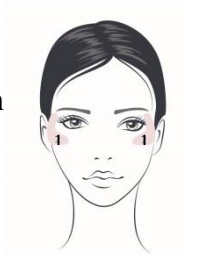

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**Do not treat full areas with energy levels you have not tested before in a preliminary test.**

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"Crow's feet" (beneath and sides of the eyes) treatment (Treatment area 1)

- Place the treatment fingers on the area as indicated in the picture.
- Keep moving the device in continuous slow 'side to side' circular motion.
- Avoid areas such as inside the nostrils, eye cavity and oral cavity, as treatment in these areas may cause adverse effects.
- Avoid contact with the eyes and eyelashes.
- The recommended treatment time for this area is 5 minutes (on each side).



- ⚠ Do not use the device in the inner side of the eye (next to the nose) or on the eyelids. Keep a distance of 1 inch from your eyelids and corners of the eyes.**

Cheek and around mouth treatment (Treatment area 2)

- Place the treatment fingers on the area as indicated in the picture.
- Move in slow circular motions across the cheek area and up and down over the "smile folds"
- The recommended treatment time for this area is 5 minutes (on each side).



- ⚠ Do not use the device on the lips of the mouth.**

Chin treatment (Treatment area 3)

- Place the treatment fingers on the area as indicated in the picture.
- Keep the device moving from one side of the chin to the other.
- The recommended treatment time for this area is 5 minutes.

- ⚠ Do not use the device on the thyroid area (bottom middle area of the neck).**

**What to expect when using sensiLift**

During your facial wrinkle and rhytides reduction treatment it is normal to experience:

- Sensations of warmth during session of treatment – created by the RF energy.
- Some mild red or pink color to the skin – during and just after using the sensiLift device.

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## Post facial treatment care

- After completing the treatment, wipe off the "sensiLift Base" from the treated area.
- Apply a high-factor sunscreen (at least 30 SPF) and protect the treated area from sunlight for two weeks following treatment.
- Following treatment, avoid the use of extremely hot water and discontinue use of abrasive or harsh products for two days.
- In cases where superficial crusting or scabbing occurs, do not rub, scratch or remove the scab. Cleanse the area gently and pat dry.
- Makeup may be applied immediately after treatment.
- Since skin aging is an ongoing process, you can repeat sensiLift treatment according to your needs.

## Cleaning and troubleshooting

### Cleaning

- Make sure to turn off and unplug the sensiLift before cleaning.
- It is recommended to clean the sensiLift device from excess of "sensiLift Base" with a soft damp cloth or paper towel. Make sure all electrodes area including the temperature sensors, silicone cover, are cleaned thoroughly.
- Keep the sensiLift dry. Never place, store or use sensiLift near bathtubs, showers, basins or other vessels containing water as this may cause severe electrocution.
- If you do not plan on using your sensiLift for a long period of time, it is recommended to keep it clean and stored.
- If you plan to travel and take your sensiLift with you, you should store it in the original box and follow the maintenance instructions.

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## Troubleshooting

If you experience any problems with the sensiLift device, please refer to the information below to try to resolve it:

- If the sensiLift device does not turn on:
  - a. Make sure that the power cord is plugged properly into the electrical outlet and into the device power socket.
  - b. Make sure that the power outlet has power.
- If the sensiLift does not deliver RF signal energy (you cannot feel a warm sensation):
 

Verify there is full contact with the skin and the “sensiLift Base” was applied on the skin. The RF signal will be activated only when both of the treatment fingers are in full contact with the skin. See Indicator stated in "User interface description" section.
- General error:
  - a. In case of dirt or debris are stuck on the treatment fingers, you should clean the electrodes according to the cleaning section. If you can't get the area clean, contact our Customer Service.
  - b. In case of a general error, reset the device – unplug the power cord from the electrical outlet on the wall, wait 10 sec and then reconnect it.
  - c. If you still have problems with your device, please contact our customer service.

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## Customer Service

- For more information about the sensiLift;
- If your sensiLift is broken, quits working, or you need more assistance;
- To order more “sensiLift Base” (for additional treatments or if your “sensiLift base” is expired);

Just call our order line, a toll-free number TBD by the company.

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## Device Specification Parameters

The RF handheld device is powered by (Bipolar RF) a  $6\pm 0.5$  [Watt]

Frequency:  $1\pm 0.05$  [MHz]

Selectable output power level: 3 levels

Mechanical speed: Implemented by moving RF electrodes Speed: 50-100 RPM

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

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

External Power Supply: Input 100-240 [VAC], 50-60 [Hz], Output 9[VDC], 1.5[A]

Device Size and Weight: 122 [g], 173[mm] X 56.8[mm] X 53.1[mm] LxHxW

4.3 [Oz], 6.8[In] X 2.23[In] X 2.09[In] LxHxW

## Storage Instructions

Storage and Transport Conditions	
<b>Temperature</b>	-25 $^{\circ}\text{C}$ to 70 $^{\circ}\text{C}$ (-13 $^{\circ}\text{F}$ to 158 $^{\circ}\text{F}$ )
<b>Humidity</b>	10% to 90% RH at 55 $^{\circ}\text{C}$ /131 $^{\circ}\text{F}$
<b>Pressure</b>	Non-condensing
Operational Conditions	
<b>Temperature</b>	5 $^{\circ}\text{C}$ to 40 $^{\circ}\text{C}$ (41 $^{\circ}\text{F}$ to 104 $^{\circ}\text{F}$ )
<b>Humidity</b>	20% to 80% RH
<b>Max Operating Altitude</b>	10,000 ft.

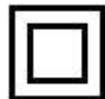


## Labeling

### Manufacturer or distributor information

Model: ST100 XX YY ZZ, add GUDID number

Power: 9 [V], 1.5 [A], 100-240 [VAC], 50-60 [Hz]



Double insulation



Type BF equipment



Consult Instructions for use



Do not dispose



Keep away from eyes



Please read all warnings and safety precautions prior to use



Do not use the sensiLift device on sensitive tanned skin or after sun exposure



Keep dry

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

**The FCC Wants You to Know:**







This equipment has been tested and found to comply the limits of ISM device, pursuant to Part 18 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential insulation. This equipment generates, uses and can radiated radio frequency energy and, if not installed and used accordance with the instructions, may cause harmful interference to radio communication. 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 encourage to try to correct the interference by one or more of the following measures:

- a. Reorient or relocate the receiving antenna.
- b. Increase the separation between the equipment and receiver.
- c. Connect the equipment to an outlet on a circuit different from that to witch the receiver is connected.
- d. Consult the dealer or an experienced radio/TV technician.

**FCC WARNING**

Modifications not expressly approved by the manufacturer could void the user authority to operate the equipment under FCC Rules.

***Treatment Log***

<b><i>Treatment Date</i></b>	<b><i>Treated Area</i></b>	<b><i>Comments</i></b>
		
		
		
		
		
		

***Treatment Log***

<i>Treatment Date</i>	<i>Treated Area</i>	<i>Comments</i>
	