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# TRI

## POLLAR

USER MANUAL

# STOP VX2

MODEL: U

A HOME-USE DEVICE FOR TREATMENT  
OF MILD TO MODERATE FACIAL WRINKLES

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This User Manual refers to the product STOP VX2 MODEL U, for ease of reading it is referred to as STOP VX2 only.

## 1. WHAT IS THE STOP VX2?

Use the STOP VX2 at home to help reduce the appearance of mild to moderate facial wrinkles. STOP VX2 uses a mild energy source that heats the skin and treats the wrinkles.

### Indications for Use:

**The STOP VX2 device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types II-IV\*.**

**\* See section 3 for contraindications and safety information.**

The STOP VX2 device is a radio frequency (RF) device, based on the well-established TriPollar® technology. The technology is based on four electrodes designed to transmit thermal (heat) energy into the deep layers of the skin, in order to trigger collagen remodeling to reduce the appearance of wrinkles and improve your skin tone and texture. TriPollar® Radio Frequency does this by delivering controlled heat into the dermis while preserving the external layer, the epidermis.

STOP VX2 also delivers a mild vibration (VIB) while using the device as a reminder to keep the device in constant motion.

## 2. WHO CAN BENEFIT FROM STOP VX2 TREATMENTS?

Adults who have mild to moderate facial wrinkles and skin laxity, or anyone wishing to optimize collagen and elastin production using an at home device.

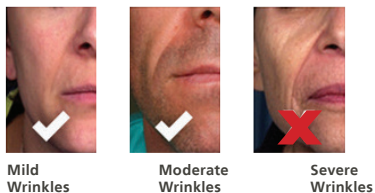


FIG.1 Who can benefit from STOP VX2 treatments

### 3. CONTRAINDICATIONS AND SAFETY INFORMATION

#### CONTRAINDICATIONS

**⚠ Do not use the STOP VX2 if you have any of the following:**

- An implanted pacemaker, arrhythmias, or any other severe known heart disorder. Flow of electrical energy through the body may damage the pacemaker and cause dangerous heart arrhythmias.
- An implantable metal device or body piercing in the treatment area. Flow of electrical energy through the implanted metal may heat the object and cause burns.
- You currently have or have had a history of cancer or pre-cancerous moles.
- You currently suffer from heart problems, cancer or other serious illness or disease.
- You have skin problems or irritations on your face.
- You are under 21 years of age.
- You are allergic to glycerin.
- Suffer from autoimmune disorders or diabetes.
- Currently using or used isotretinoin (Accutane) within the past six months. Using this device after using isotretinoin can cause severe scarring or more serious injury to your skin.
- Have Fitzpatrick skin type I (light, pale white skin) or V (brown, dark brown) or VI (very dark brown, black). The safety and effectiveness of the device when used in individuals with pale skin (type I) or darker skin (types V or VI) or may be prone to skin discoloration has not been established (See Fitzpatrick Scale - FIG.2).

**The Device should be used only for skin types 2,3,4.**



**FIG.2 Fitzpatrick Scale**

**Precaution is required before using the device if any of the following relate to you:**

- You use medications or cosmetic products that may cause fragile or dry skin.
- You currently have or have had in the past cold sores (Herpes) or other conditions sensitive to heat.
- You recently had any facial aesthetic procedure, such as fillers, Botox, skin peeling or other wrinkle treatments.

**Skin healing in these cases may be impaired:**

- Lesions on the treatment area.
- Blood clotting disorders.
- Use of blood thinning medications.

**Safety and effectiveness of the device was not tested in the following conditions or anatomical locations; therefore, DO NOT use STOP VX2 under the following circumstances:**

- If you have severe, deep wrinkles.
- If you are pregnant or breastfeeding.
- If you have moderate or severe wrinkles underneath the chin.
- Over the eyelids due to the potential damage to the eye structures.
- Over the eyebrows, eyeballs, lips, ears, thyroid, breasts or genital area.
- Use in subjects without total removal of facial hair may result in follicular burn in these areas.
- Do not use the STOP VX2 device over any areas other than the recommended areas in this user manual (**FIG.10**).
- Do not use the STOP VX2 device without the supplied treatment gel. The device may not operate properly if used without the TriPollar preparation gel or if used with another lotion or gel.
- Do not use TriPollar Preparation Gel after its expiration date.

**⚠ WARNINGS****Eye damage, damage to glands, sensitive and delicate skin and other tissue may occur.****Follow instructions for use exactly as directed for your safety:**

- The device is intended only for a single user to prevent contamination between users.
- During treatment, in case of excessive redness or swelling, stop treatment and cool the area using a wash cloth and cold water for at least 15 minutes. Temporary, mild redness is expected.
- If redness persists for more than 24 hours after the treatment, please consult your physician.
- Patients with visual difficulties should use the device only while wearing corrective vision aid.

**Skin injury can occur under this condition:**

- Using blood thinning medications may induce skin hematomas due to the mechanical massage by the device.

If in doubt about any other medical condition or medication that might affect the treatment, please consult with your physician or contact us at [info@pollogen.com](mailto:info@pollogen.com).

## ⚠ PRECAUTIONS AND SAFETY INSTRUCTIONS

**Remember, this is an electric device using radio frequency waves. Please adhere to the following precautions:**

- Use this device only for its intended use as described in the user manual.
- Use the device for personal use only.
- Do not use the device if it is damaged or an item is missing.
- Turn the device on only during treatment.
- Do not use the device if it is disassembled, cracked or if the electric cord is damaged.
- Do not use the device in the vicinity of flammable liquids (alcohol, acetone).
- Always thoroughly dry your hands and face before treatment.
- Keep out of reach of children.
- Do not place, store or use the device near sources of water such as the sink or bathtub.
- Do not touch the device if it is wet or falls in to water. Unplug the power supply from the electrical outlet immediately and then take the device out of the water. This situation could damage the device or power supply, or cause an electric shock that may lead to serious injury or death.
- Immediately after use, or before cleaning the device, turn the device off and unplug it from the electrical outlet.
- Only use the power supply supplied with the STOP VX2 device. Using a different power supply can damage the device.
- The sensation while using the device should be warm and pleasant. If you experience discomfort, discontinue use immediately.

## ⚠ FIRE HAZARDS

- Do not use the device close to explosive or highly flammable materials (alcohol, methanol, acetone, etc.).
- If alcohol is used for cleaning the device, it must be allowed to dry thoroughly before the device is used and then move the alcohol away from the device.

## 4. WHAT'S INSIDE THE STOP VX2 BOX

### STOP VX2 kit includes:

- STOP VX2 DEVICE
- POWER SUPPLY
- TRIPOLLAR PREPARATION GEL

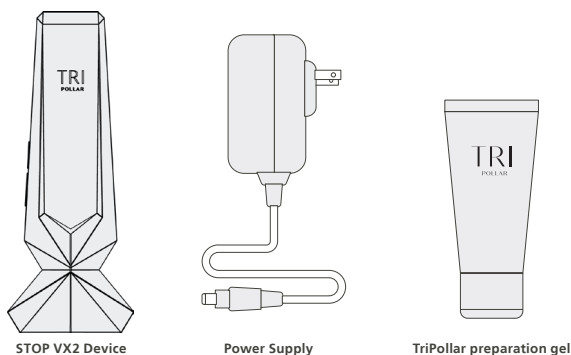


FIG.3 In the box.

Check that the box includes all items.

### ⚠ Important

Do not use the device if it is damaged or an item is missing. Check that there is a sticker on the protective cover. If your device does not have this sticker, DO NOT USE and contact STOP VX2 customer service at [info@pollogen.com](mailto:info@pollogen.com)

## 5. GETTING TO KNOW YOUR STOP VX2 DEVICE

The STOP VX2 device consists of a body and a protective cover.

The device's body has a treatment head and a control panel.

### TREATMENT HEAD

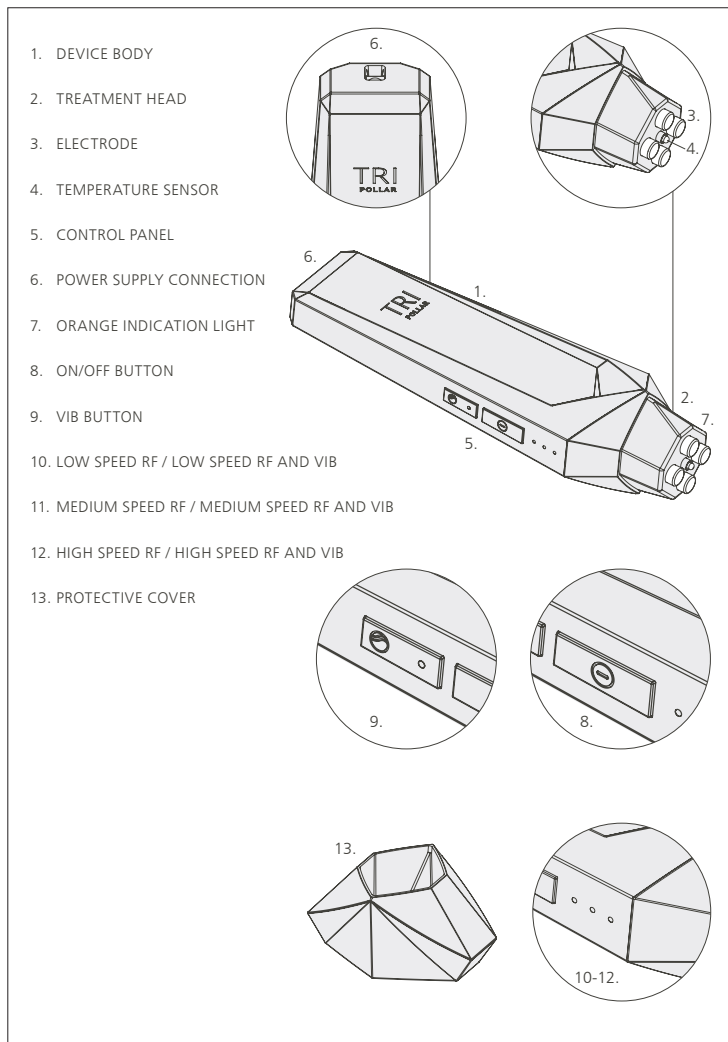
The treatment head has four energy tips (electrodes) and a temperature sensor. When not in use, the treatment head should be covered with its protective cover (FIG.4 #13).

### CONTROL PANEL

The control panel includes the ON/OFF power button, VIB button and heating level indicator light (white).

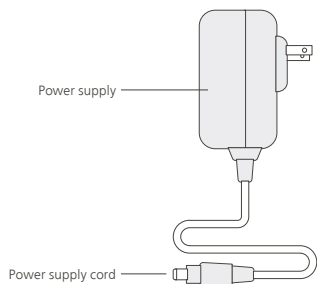


**FIG.4 Shows the components comprising the TriPollar Stop VX2 device**



## POWER SUPPLY

The power supply is equipped with a built-in electric plug adapter and power supply cord (**FIG.5**)



**FIG.5 Power Supply**

## TRIPOLLAR PREPARATION GEL

TriPollar preparation gel is required for use with the STOP VX2. After opening the tube, the TriPollar preparation gel can be used for 12 months.

## 6. STOP VX2 TREATMENT PROCEDURE

### HOW OFTEN TO USE YOUR STOP VX2

For best results, use the STOP VX2 device 2-3 times (not consecutive days) a week for a period of 8-12 weeks. For maintenance: additional treatments are recommended once a week.

### TREATMENT SAFETY GUIDELINES

- Be sure that all four energy tips firmly touch the skin at all times during treatment.
- It is important to keep the device moving at all times during treatment.  
**Leaving the device on the same spot without movement may result in skin overheating and possible excessive skin redness.**
- For most effective treatment, use slow, circular movements.

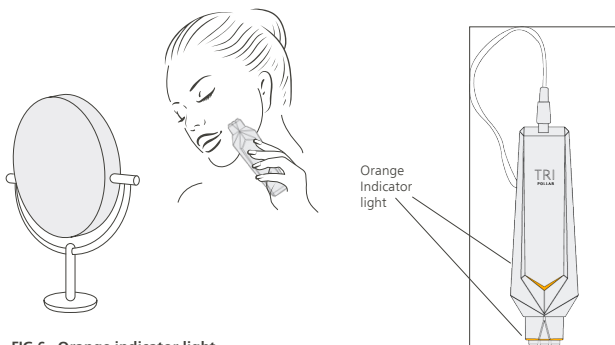
## FIRST TIME TEST

Before your first treatment, perform a test on a small area of skin (forearm, 2"x2"). This will help to determine whether or not your skin will have a negative reaction to the gel or treatment and that the device is operating correctly.

- Apply a small amount of TriPollar preparation gel on the test area.
- Connect the power supply (**FIG. 8**)
- Treat the area with the STOP VX2. Follow the steps below:
  1. Remove the protective cover.
  2. Shortly press the On/Off button.
  3. Make sure the white indicator light is on (**FIG. 9**).
  4. Place the device on the skin, and using slight pressure ensure that all 4 energy tips touch the skin.
  5. Move the device slowly in circular motions until the orange indicator light comes on (it may take a few minutes). If the orange indicator light does not illuminate, move the device more slowly and/or in smaller circles.
  6. Once the orange indicator light comes on, followed by a 'beep' sound, continue treating the same area for a few more seconds.
  7. Check if your skin has a negative reaction (excessive redness and/or swelling), if not proceed to the treatment.

## BEFORE STARTING THE TREATMENT

- Remove all jewelry, piercing and eye glasses (if you wear them).
- Sit in front of a mirror during treatment so you can see the orange temperature indicator light.
- Clean your face with soap and water and dry thoroughly.
- Make sure your hands are clean and dry.



**FIG.6 Orange indicator light**

## HOW TO APPLY TRIPOLLAR PREPARATION GEL

1. Dab a small amount of gel on your fingertip (to allow smooth movement of the device).
2. Dab small spots of gel around the face.

### ⚠ Important

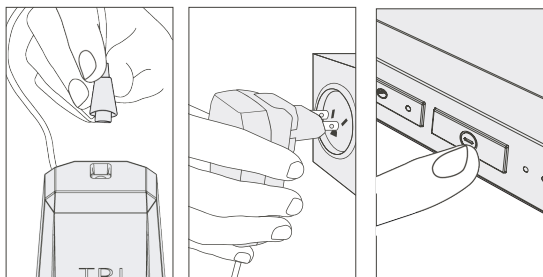
Be careful not to apply gel into your eyes.

3. Evenly spread a thin layer of the gel onto the face.
4. Clean your hands.
5. Close the gel tube after usage.



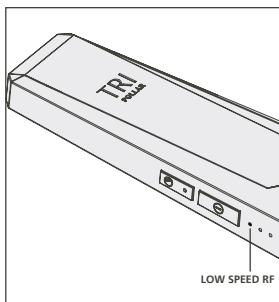
FIG.7 Applying TriPollar preparation gel

## HOW TO CONNECT THE POWER SUPPLY AND START THE DEVICE



**FIG.8** How to connect the power supply and start the device

1. Connect the power supply cord to the device. You should hear a "click" indicating that the connector is in place.
2. Plug the power supply into an electrical outlet.
3. Shortly press the On/Off button to turn the device on.
4. Make sure the heating level white indicator light is on.



**FIG.9**

## TREATMENT PROCEDURE

Treatment time is up to 2-3 minutes for each treatment area. Total treatment session should not exceed 20 minutes.

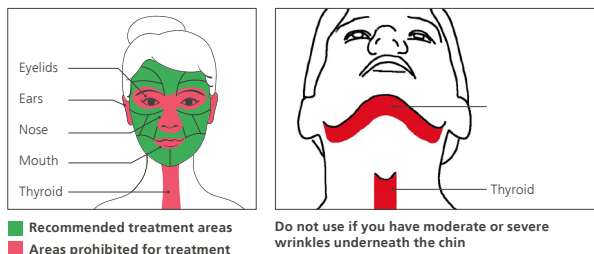
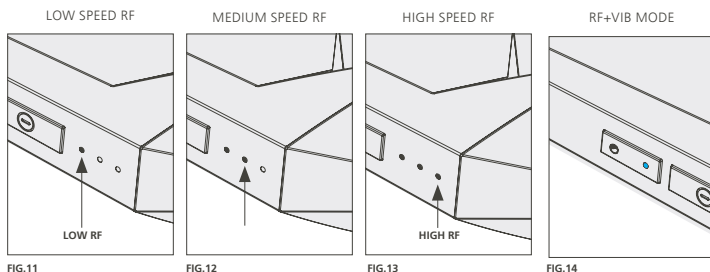


FIG.10 Recommended and prohibited treatment areas

### ⚠ Important

**Never treat directly on eyes / eyelids, lips, nose, ears or thyroid.**



## TREATMENT PROCEDURE

1. Remove the protective cover.
2. Shortly press the On/Off button.
3. Select the RF speed setting (Low/Medium/High) that is most comfortable for you. When the white led shows a single light illuminated (FIG.11), the device is operating at the Low RF heating speed profile. You can press the Power button again to change the heating speed profile (FIG.12, FIG.13) the white LEDs will light up according to the level chosen.
4. Once the device is placed on the skin, the Turbo RF will start. Turbo RF will be initiated once at the beginning of the treatment or if a new heating speed profile / mode is chosen.

5. To switch to RF + VIB mode, press on the VIB button, Make sure that the Blue indicator light turns ON (FIG.14).

The VIB level will start to operate according to the last RF heating speed profile chosen. You can press the Power button again to change the RF+VIB level, the white LEDs will light up according to the level chosen. It's recommended to start at the Low RF+VIB.

6. Place the device on the gel covered skin and ensure all 4 energy tips touch the skin. Move the device slowly (FIG.16) in circular motions until the orange light turns on, accompanied by a "beep" sound. This indicates that the skin has reached the desired temperature. This can take 2-3 minutes. You will feel a warm sensation on your skin. The orange light may remain illuminated if the device is moved slowly and in small increments (which is the desired progression of treatment). If this is the case, device will not beep continuously.

- **During the treatment you must keep the device constantly moving. A mild vibration will be felt on the face, to remind you to keep the device in constant motion (only when working with RF+VIB mode).**
- If your skin begins to feel too hot, expand the treatment area or move slightly faster.
- If the orange light does not turn on, perform a slower movement (FIG.17).

#### ⚠ Important

Do not stop the motion of the device on the skin.

7. After the orange light turns on, continue treating the same area for a few more seconds.  
 8. Expand the treatment to include the adjacent area.  
 9. Repeat steps 6-8 until the entire face is treated.

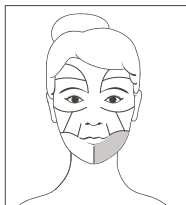


FIG.15 Start treatment on the lower cheek and jawline



FIG.16 Circular motions

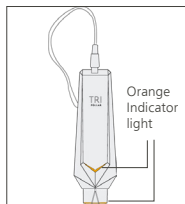


FIG.17 Orange indicator light

#### Safety feature that protects the skin from overheating

The device has a safety feature that protects the skin from overheating. When the skin has reached the maximal temperature, the energy source will shut down automatically. You will know it is activated when the orange light is on, the white light is on and the mild vibration will stop (when using VIB mode). The device will turn back on when you move to the next treatment area.

#### Immediate skin response

During the treatment, your skin may become slightly red and /or swollen. This is normal and will disappear soon after the treatment is finished.

#### ⚠ Important

In case of excessive redness or swelling, stop treatment and cool the area using a wash cloth and cold water for at least 15 minutes.

### After treatment

1. To turn OFF the device, press and hold the On/Off button for 2-3 seconds.
2. Unplug the power supply from the power outlet.
3. Disconnect the power supply from the device.
4. Cleanse your skin with warm water and a gentle face wash to remove the TriPollar Preparation Gel.

### Possible side effects

Possible side effects may appear either at the time of treatment or shortly after. Side effects may include any of the following: prolonged pain, damage to natural skin texture (such as crusting, blister, burn, bruising, and fragile skin), excessive skin redness or swelling, and mild headache. Although these effects are extremely rare and expected to be temporary, if they continue for more than 24 hours, please consult your physician.

## 7. CLEANING AND STORAGE

1. Use 2-3 disposable baby wipes to remove any gel residues.
2. Use a soft cloth, moistened with detergent solution disinfectant for 5 minutes, to clean the treatment head and electrodes until they are visibly clean.
3. Use a new soft cloth, moistened with tap water for 15 seconds, to remove detergent residue.
4. Use a dry soft cloth to dry the treatment head and electrodes.
5. Use a soft cloth, moistened with medical grade 70% alcohol solution for 1 minute, to wipe the treatment head and electrodes.
6. Spray the treatment head and electrodes with medical grade 70% alcohol solution, then wipe with a dry soft cloth. Be careful not to spill any liquids into the device.
7. If dirt residues are not fully removed, repeat cleaning steps 1-6.
8. Attach the protective cover to the device and store the device in a safe place.

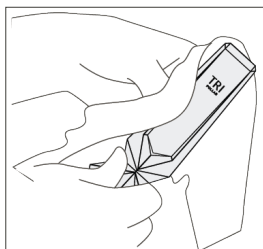


FIG.18 Cleaning the device

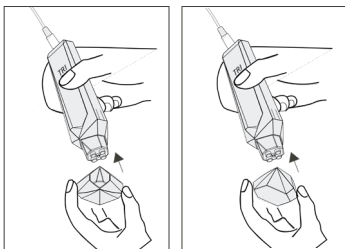


FIG.19 Attach the protective cover

### Warning

Do not place the TriPollar STOP VX2 device in water or under running water. This situation could damage the device or power supply, or cause an electric shock that may lead to serious injury or death.



## 8. TROUBLESHOOTING

In the event that your STOP VX2 device is not working, prior to contacting the service center, take the following precautions:

1. Make sure you have removed the device's protective cover before use.
2. Make sure the electric cord is securely connected to the device until "click" is heard.
3. Make sure that the ON/OFF button was pressed and the white indicator light is ON.
4. Make sure you have applied the TriPollar preparation gel according to the instructions above. The STOP VX2 will not work properly if the TriPollar preparation gel is not applied.
5. If the orange light does not turn ON:
  - Move the device more slowly and/or in smaller circles.
  - Be sure there is not too much gel applied on the face.
6. If you feel the device stops heating the skin, the orange light is ON and the white light is ON, move to the next treatment area and check that the device is heating the skin.
7. In case of voltage interruption, the device will turn OFF. Wait until the voltage supply returns and then you can turn the device back ON by pressing the ON/OFF button.
8. In case both orange LEDs are not operating, the device will turn itself OFF when overheated.
9. In case of non-operative orange LEDs, consult service.
10. In case of ON/OFF button stays in OFF position, consult service.
11. In case of ON/OFF button stays in ON position, Unplug Power Supply from the electrical inlet & consult service.
12. In case headlight LEDs blinking white or orange, discontinue use immediately & consult service.

## 9. TECHNICAL SPECIFICATIONS

### Technical Specifications

Weight:	94gr
Physical Dimensions:	H=154mm L=40mm W=60mm
TriPollar RF Frequency:	1MHz
Input:	100-240VAC 50/60 Hz 0.4A
Output Voltage:	DC 8V
Output current:	MAX 1.5A

### Operating conditions











Temperature:	+5°C to +30°C
Humidity:	20RH to 80RH
Atmospheric pressure:	80 kPa to 106 kPa

### Transport and Storage

Temperature:	0°C to 40°C
Humidity:	10RH to 90RH
Atmospheric pressure:	50 kPa to 106 kPa
Electrical Safety:	Medical Grade Power supply classified as Class II
Product Lifetime:	7 Years
Output power	5.7W @ 200 OHM

Preparation gel contains 1.7 oz/50ml.

## 10. SYMBOLS AND LABELS GLOSSARY

	Caution
	Consult instructions for use
	Batch code
	Catalogue number
	Serial number
	Type BF applied part (Degree and type of protection against electric shock)
	Date of Manufacture
	Manufacturer
	Floating Connection
	WEEE wheeled bin. This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. This product must be disposed or recycled in accordance with local laws or regulations that apply.
<b>IP22</b>	2 - protection against particulate matter; 2 - protection against ingress of water

## 11. CUSTOMER SUPPORT

Prior contacting your local distributor for service and support, please have the device serial number ready. The serial number can be found on the top panel of the device.

Customer satisfaction is our top priority. If for some reason you are not satisfied with the product, we want to know about it. You may contact Pollogen directly via:

**International e-mail: [service@pollogen.com](mailto:service@pollogen.com) / Tel: +972-3-5104110**

 Pollogen Ltd., 6 Kaufman St., PO Box 50320, Tel Aviv 6801298 Israel

## 12. WARRANTY TERMS

This product has been subjected to strict quality control performed by the manufacturer. For this reason, the distributor in your country guarantees proper function of your product for 12 months from date of actual purchase. If you use the device properly, follow all instructions outlined in the user manual, you can enjoy the product to your ultimate satisfaction.

This policy warrants the support that the distributor provides for the device, should it happen that failures attributable to manufacturing defects be found. In such case, you shall be entitled to make full use of the benefits of this warranty. This implies the reason and replacement of parts, free of charge (regarding both service and parts) at any Authorized Service Center. Within its validity term, you are entitled to make use of the warranty if necessary to have a fully enjoyable product, provided the above-indicated conditions are fully met. This warranty is valid for the device marketed by the distributor in your country.

### **The warranty is not valid when:**

1. Amendments in the warranty policy, sales receipt or invoice, or the absence of any of these original documents.
2. Damage or deterioration of the device due to improper use or if the device has been modified or repaired by an unauthorized third party.
3. Damage of the product due to defects incurred during transportation, such as bumps, bangs or improper handling.
4. Damage due to humidity or any kind of liquids, foreign bodies inside the device or the use of unapproved, unadvised accessories with the device contradictory to the user manual.
5. When the device is not used in accordance with the respective user manual or with its supplied accessories.
6. Partial or total damage or loss of the device, due to natural disasters (such as earthquakes, floods, fire, lightening, etc.), force majeure or accident.
7. Damage to the device after being subjected to high dust environments, humidity or application of excessive voltage from the power inlet.
8. If the product's serial number has been amended or erased.
9. To cosmetic damage, including but not limited to scratches and dents.

### 13. APPENDIX I - WRINKLE FORMATION

Collagen and elastin fibers are components in the deeper layer of the skin that give the skin its shape. The collagen fibers are responsible for skin strength and tone. The elastin fibers allow skin flexibility or elasticity. With aging, the collagen and elastin fibers weaken and the production of new fibers slows down. These structural changes cause the skin to loosen causing skin sagging and wrinkles (FIG.20).

The STOP VX2 device is designed to improve the existing collagen fibers while triggering new collagen and elastin formation by reaching the deep skin layers – the dermis, where new collagen and elastin fibers form.



FIG.20 How wrinkles form

### 14. APPENDIX II – CLINICAL TRIAL

The benefits and risks of the STOP VX2 model U device that is based on STOP U device, were tested in a clinical trial involving 40 participants, ages 35-65, in two sites within the United States, led by two investigators. Participants received 8 treatments by practitioners on the skin of their face for a 6 week period and there was follow up at 1 and 3 months after the last treatment. They were evaluated throughout the study for skin improvement and side effects.

#### Benefits

Over 80% (31/37) of the participants showed at least one grade improvement in Fitzpatrick wrinkle score at three months follow-up after treatment; There were no incidences of serious adverse events or complications; As expected, mild to moderate erythema and mild edema were detected at the site of treatment immediately after treatment; All cases resolved without treatment within few hours; Treatment was well tolerated with minimal to no pain in the majority of study subjects.

#### Risks

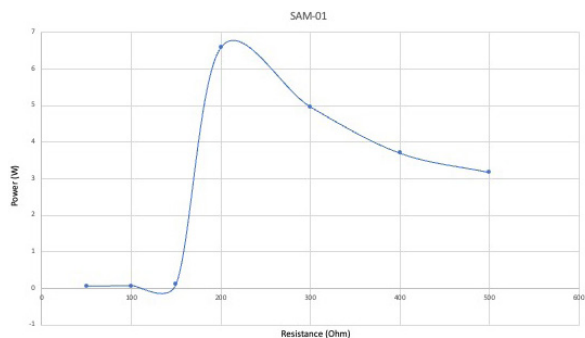
4 (1.3%) incidences of mild pain were reported in a total of 312 treatments;

The study used a small sample size; the users were professionals; the users did not choose the device for themselves.

### Summary of Clinical Data

The results of this study demonstrate that the STOP VX2 model U device provides a safe, tolerable and effective treatment for improvement of the appearance of facial wrinkles.

## 15. APPENDIX III – OUTPUT POWER VS. LOAD RESISTANCE



## 16. APPENDIX IV – ELECTROMAGNETIC COMPATIBILITY

Test	Standard	Class/ Severity level	Test result
<b>Emission</b> (IEC 60601-1-2 sections 7.1 & 7.2)			
Conducted emission Freq. range: 150 kHz - 30 MHz	CISPR 11	Group 2 Class B on 230 VAC and 120 VAC mains (PA)	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 2 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	AC mains. Test is not applicable	Exempted
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	AC mains	Complies
<b>Immunity</b> (IEC 60601-1-2 section 8.9 & 8.10)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m 80 MHz $\pm$ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies ( <b>Table 9</b> ), from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	$\pm$ 2.0 kV on 230 VAC mains (PA), Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	$\pm$ 1.0 kV DM on 230 VAC mains (PA); Tr/Th – 1.2/50 (8/20) ms	Complies
Immunity from conducted disturbances induced by radio- frequency fields	IEC 61000-4-6	3.0, 6.0 VRMS on 230 VAC mains (PA); 0.15 $\div$ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 Hz & 60 Hz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000- 4-11	0 % - 10 ms, 0 % - 20 ms, 70% - 500ms, 0% - 5 sec on 230 & 120 VAC mains (PA)	Complies

### TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO PROXIMITY MAGNETIC FIELDS

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz <sup>a)</sup>	CW	8
134,2 kHz	Pulse modulation <sup>b)</sup> 2,1 kHz	65 <sup>c)</sup>
13,56 MHz	Pulse modulation <sup>b)</sup> 50 kHz	7,5 <sup>c)</sup>

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.  
b) The carrier shall be modulated using 50 % duty cycle square wave signal.  
c) r.m.s., before modulation is applied







# STOP VX2

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