

# STOP VX

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

USER MANUAL

MODEL: U

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#### 1. WHAT IS THE STOP VX?

Use the STOP VX at home to help reduce the appearance of mild to moderate facial wrinkles.

STOP VX uses a mild energy source that heats the skin and treats the wrinkles.

#### **Indications for Use:**

The STOP VX 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 VX 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 that will reduce the appearance of wrinkles and improve your skin tone and texture. TriPollar® Radio Frequency technology combines the delivery of controlled heat deep into the skin, while preserving the external layer - the epidermis.

Electronic Vibration (ELV) - this feature delivers a tingling sensation while using the device as a reminder to keep the device in constant motion.

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

Adults who have mild to moderate facial wrinkles and want to decrease them using a home device.



Mild Wrinkles



Moderate Wrinkles



Severe Wrinkles

FIG.1 Who can benefit from STOP VX treatments

#### 3. CONTRAINDICATIONS AND SAFETY INFORMATION

#### CONTRAINDICATIONS

#### ∆ Do not use the STOP VX 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 have diseases such as heart problems, autoimmune disorders,

cancer and use of immunosuppressive medications.

- 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.



#### Type 1 Light, pale

white Always burns. never tans

Type 2 White, fair

Usually burns, tans with difficulty



#### Type 3 Medium white to olive Burns mildly.

tans gradually



### Type 4

Olive, mid brown Rarely burns, tans with ease



### Type 5

Brown, dark brown Very rarely burns, tans tans very very easily easily





Type 6

Verv dark brown, black Never burns.

# 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 VX 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 VX device over any areas other than the recommended areas in this user manual (FIG.10).
- Do not use the STOP VX 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.

#### **↑ 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.
- 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.

#### **⚠ 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 inflammable 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 VX device. Using a different power supply can damage the device.

#### **↑** 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 VX BOX

#### STOP VX kit includes:

- STOP VX DEVICE
- POWER SUPPLY
- TRIPOLLAR PREPARATION GEL

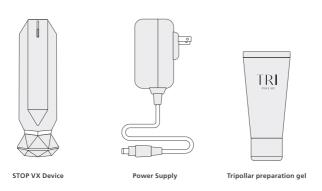


FIG.3 In the box.

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 VX customer service at info@pollogen.com

#### 5. GETTING TO KNOW YOUR STOP VX DEVICE

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

The device's body has a treatment head on one side and a control panel on the other side.

#### 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 #14).

#### **CONTROL PANEL**

The control panel includes the ON/OFF power button, power supply connection, heating level indicator light (green/blue) and temperature orange indicator light.

FIG.4 Shows the components comprising the TriPollar® Stop VX device

FIG.4 1. DEVICE BODY 2. TREATMENT HEAD 3. ELECTRODES 4. TEMPERATURE SENSOR 5. CONTROL PANEL 6. POWER SUPPLY CONNECTION 7. GREEN/BLUE INDICATION 8. ORANGE INDICATOR LIGHT 9. ON/OFF BUTTON 10. 11. 10. LOW SPEED RF 11. HIGH SPEED RF 12. LOW SPEED RF + ELV 14 13. HIGH SPEED RF + ELV 14. PROTECTIVE COVER

#### POWER SUPPLY

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

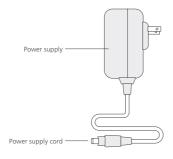


FIG.5 Power Supply

#### TRIPOLLAR PREPARATION GEL

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

#### 6. STOP VX TREATMENT PROCEDURE

#### HOW OFTEN TO USE YOUR STOP VX

For best results, use the STOP VX 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 ensure that your skin does not have a negative reaction (excessive redness and/or swelling) 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 VX. Follow the steps below:
  - 1. Remove the protective cover.
  - 2. Shortly press the On/Off button.
  - 3. Make sure the green indicator light is on (FIG 4. #10).
  - 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).
  - Once the orange indicator light comes on, followed by a 'beep' sound, continue treating the same area for a few more seconds.
  - 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.

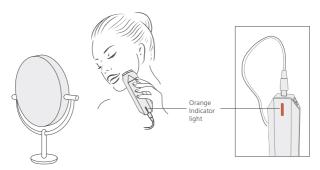


FIG.6 Orange indicator light

#### 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



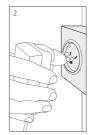




FIG.8 How to connect the power supply and start the device

- 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 green indicator light is on.

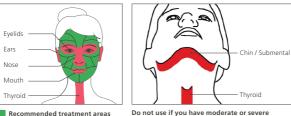


FIG.9 Control panel

#### TREATMENT PROCEDURE

Identify the parts of your face that you wish to treat. Divide your face into several treatment areas.

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



wrinkles underneath the chin

FIG.10 Recommended and prohibited treatment areas

#### **△** Important

Areas prohibited for treatment

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/High) that is most comfortable for you. Once the device is turned ON, it is operating at the Low speed level and the indicator shows a single green light bar (FIG.11). To switch to the High-speed level, press the power button again- the
- indicator light shows 2 green light bars (**FIG.12**).

  4. To switch to the RF+ELV mode, press the power button once again. The
- indicator light will show a single blue light, representing Low speed level (FIG.13). To change to High speed level, press the power button again- the indicator light will show 2 blue light bars (FIG.14).
- 5. 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.
  - During the treatment you must keep the device constantly moving. A tingling sensation will be felt on the face, to remind you to keep the device in constant motion (only when working with RF+FIV 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.

- After the orange light turns on, continue treating the same area for a few more seconds.
- 7. Expand the treatment to the adjacent area.
- 8. Repeat steps 6-7 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. You will know it is activated when the orange light is on, the green/blue light is off and tingling sensation will stop (when using ELV 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

- Turn OFF the device by pressing continuously 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. Gently clean your skin and 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 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.
- 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.

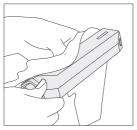


FIG.18 Cleaning the device





FIG.19 Attach the protective cover

#### 8. TROUBLESHOOTING

In the event that your STOP VX 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.
- 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 green indicator light is on.
- 4. Make sure you have applied the Tripollar preparation gel according to the instructions above. The STOP VX will not work properly if the Tripollar preparation gel is not applied.
- 5. If the orange light does not turn on:
  - Move the device slower.
  - Be sure there is not too much gel applied on the face.
- If you feel the device stops heating the skin, the orange light is on and the green light is off, move to the next treatment area and check that device turns back on.
- 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 when both orange LEDS are not operating, the device will turn itself off when overheated & will turn off the Green/Blue LED.
- 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.

#### 9. TECHNICAL SPECIFICATIONS

#### **Technical Specifications**

Weight: 102gr

Physical Dimensions: H=146mm L=40mm W=20mm

TriPollar RF Frequency: 1MHz

Input: 100-240VAC 50/60 Hz 0.4A

Output Voltage: DC 8V
Output current: 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

$\triangle$	Caution
[]i	Consult instructions for use
LOT	Batch code
REF	Catalogue number
SN	Serial number
À	Type BF applied part (Degree and type of protection against electric shock)
	Date of Manufacture
3	Manufacturer
F	Floating Connection
<u> </u>	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.
IP22	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 / 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:

- 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.
- 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 VX 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 VX 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.

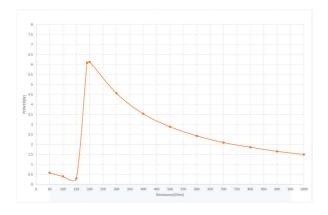
#### Risks

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 VX 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			
Emission (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			
Immunity (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 ÷2.7 GHz, 80% AM, 1 kHz	Complies			
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies (Table 9), 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	± 2.0 kV on 230 VAC mains (PA), Tr/Th – 5/50 ns, 100 kHz	Complies			
Immunity from Surge	IEC 61000-4-5	±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÷ 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			

### STOP VX

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