

# SaliPen

THE HIGH-TECH MOUTH MOISTENER

## User Guide

### Intended use: Relief of oral dryness

SaliPen is a device for short term applications of electro-stimulation to increase salivary secretion.

#### Description:



SaliPen consists of two main modules: a command unit and a stimulating unit.

The command unit (the white part) includes the electronic circuit with a battery compartment and stays always outside the mouth.

The stimulating unit (the blue part) includes a stem and two flexible arms. The stem is used to hold SaliPen between the lips. The flexible arms carry the stimulating electrodes.



Both modules are connected together with a pin and can be separated by pulling away one from the other.



The package contains (from left to right):

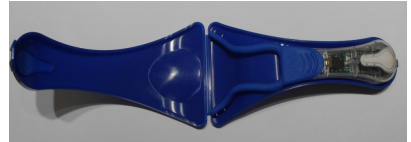
- a case for daily carrying of SaliPen,
- a SaliPen device.

## Basic usage

Wash your hands with soap and water before handling the device.

Wearers of a removable denture on the lower jaw should remove it before using SaliPen.

1. Take SaliPen out from its case.



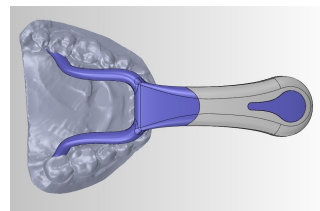
2. Press the ON-OFF button once. SaliPen green light flashes indicating that the device is turned on. If the light does not flash, press the button again.



3. Open your mouth and lift up your tongue.  
4. Slightly press the flexible arms one to the other.  
5. Insert SaliPen flexible blue arms into your mouth, under the tongue.



6. Push SaliPen arms **as back as possible** and release them to allow contact with the gums.



7. Relax your tongue and close your lips (not your teeth) over the SaliPen stem  
8. Keep SaliPen in your mouth a few minutes (see length of use below).



9. To take it out, slightly press the flexible arms one to the other, in order to detach the electrodes from the gums. After that, **gently** pull SaliPen out of your mouth.
10. Press the ON-OFF button once. SaliPen light stops flashing, indicating that the device is turned off.
10. Wipe the stimulating arms with a wet towel.
11. Place the SaliPen unit inside the daily carrying case.  
(Wearers of a removable denture may now wear it again.)

## Frequency and Length of Use

You should adjust the number of times using the SaliPen in a day and the duration each time, according to your condition and needs. The following list provides some possible usage examples:

- Intensive use: 10 times a day for up to 10 minutes each time
- Moderate use:
  - Five times a day for 1 minute each time
  - Twice a day for 5 minutes each time
- Light use: twice a day for 1-2 minutes each time



You may use SaliPen whenever you feel dryness in your mouth. However, it is recommended not to use it more than once every hour.

At initial use, it is recommended to start using SaliPen ten (10) minutes each time. If you are satisfied with the results, you can gradually decrease the length of use. For some users, one (1) minute of use induces satisfactory results for several hours; others may need more intensive stimulation.

Many other variants are possible. You may adjust the frequency and length of usage to your particular condition and convenience. However, use should be consistent even if only little effect is felt. Clinical trials showed that it may take a few months of persistent use until reaching satisfactory results.

## Care and Maintenance

- If the device stops working, please change the battery, which is contained in the battery compartment (see instructions below).
- Clean SaliPen stimulating unit at least once a day with a soft-bristle toothbrush.

- After each use, clean the stimulating arms with wet towel.
- If rinsing is needed, separate the stimulating arms from the control unit, and rinse **ONLY** the stimulating arms. Keep all other parts **DRY!**
- Visually check the device before using it to make sure it is not broken or has cracks. **Do not use it if any internal part of the stimulating unit is exposed!**
- It is recommended to replace the stimulating unit about every **6 months** or earlier or if it has physical damage.

## Replacing the battery

1. If you notice that the green LED flashes weakly or does not flash at all, this indicates that the battery should be replaced. SaliPen uses coin cell battery type CR2032, 3V Lithium. Use only fresh batteries.

2. Open the battery compartment by pressing with your nail or a coin as shown.

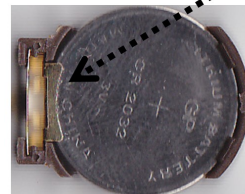
3. Extract the used battery from its holder using your nail or a sharp pin. It should pop up easily.



Extract from this side



Insert this side first



4. Place the fresh battery inside the holder, place the left side first and press it in.
5. Return the cover of the battery compartment to its place.
6. Test the device by pressing the ON-OFF button. If the LED flashes, it is OK.

## Safeguards

- Do not use SaliPen in conjunction with other active medical therapy or testing such as short or microwave therapy, EEG, ECG, etc.
- Do not use SaliPen if you wear an implanted electronic device like a deep brain stimulation device, a cardiac pacemaker, a cardiac defibrillator, etc., unless specialist medical opinion allowing the use has first been obtained.

- Store SaliPen in its carrying case while not in use.
- Do not expose SaliPen to heat or direct sunlight.
- Do not expose SaliPen to liquids other than water or saliva.
- Do not clean SaliPen using ultrasound/ultrasonic devices.
- If SaliPen is dropped, it may get fractures or cracks and hence damage to the electronic module.
- Don't use the equipment in the presence of flammable mixtures with air or with oxygen or nitrous oxide.

## Frequently Asked Questions

### How does SaliPen work?

SaliPen sends electrical pulses of specific patterns that stimulate the nerves associated with salivary glands secretion. The stimulated nerves excite both the salivary glands directly to secrete more natural saliva, and stimulate the salivation control center of the brain to further command the salivary glands to secrete more saliva.

### Can I feel the electrical pulses?

No. The pulse intensity is below the human sensitivity level.

### Can I sleep with SaliPen?

No.

### How long does the power source of the intra-oral device last?

SaliPen has been designed to operate for about 6 months. However, based on the frequency and intensity of use, the power source may run out of power earlier. If the SaliPen is out of power please replace the battery.

### What if I break the SaliPen?

If the SaliPen is broken, you should stop using it.

### Can I use other dry mouth treatment methods in parallel with SaliPen?

This question should be addressed to your treating clinician.

### How often should the SaliPen be replaced?

The command unit can be used indefinitely, until it stops functioning or it breaks. Like a toothbrush, it is recommended to replace the stimulating unit about every 6 months or earlier or if it has physical damage.

**Where can I get a new stimulation unit?**

The stimulating unit can be purchased at Saliwell site ([www.Saliwell.com](http://www.Saliwell.com)).

**How effective is electro-stimulation in relieving dry-mouth?**

A series of scientific clinical trials conducted by several independent groups, in multiple leading medical centers, have shown high effectiveness of electro-stimulation in increasing natural saliva secretion.

**How fast can I feel the relief?**

It is very individual; some feel the relief immediately, for others it takes a few days or weeks.

**After I use SaliPen for a few minutes, how long the effect lasts?**

It is very individual; for some the effect lasts a day, for others an hour. On average it lasts about 3 hours.



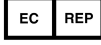


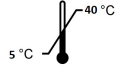










**Will I feel continuous improvement over time?**

Yes, a clinical study shows a growing effectiveness upon using electro-stimulation over time. Typically it is improved up to 8 months and then stabilizes.

**Specifications**

<b>Size</b>	13 cm (5.1") x 5.5 cm (2.2")
<b>Weight</b>	22 grams
<b>Color</b>	White and Blue
<b>Battery Type</b>	Lithium 3V CR2032
<b>Packaging</b>	SaliPen is packed in a protective plastic package
<b>Power source</b>	One CR2032 Lithium battery, 3 V, replaceable
<b>Output signal</b>	±3V bi-phase pulses, 5Hz, 0VDC, 1mSec
<b>Operating temperature</b>	From +5 °C to +40 °C
<b>Storage Temperature</b>	From 0 °C to +65 °C
<b>Atmospheric Pressure Range</b>	700 hPa to 1060 hPa
<b>Humidity</b>	Humidity: 0-93% RH Non-condensation
<b>Mode of operation</b>	ON/OFF
<b>Battery life</b>	Approximately 12 months
<b>Degree of Protection</b>	IP00 – no protection

## Legend & Graphic Symbols

	MANUFACTURER		On/Off TOGGLE SWITCH
	EUROPEAN REPRESENTATIVE		CONSULT INSTRUCTIONS FOR USE
	DATE OF MANUFACTURING		OPERATING TEMPERATURE LIMITATION
	BATCH CODE		SERIAL NUMBER
	CAUTION, CONSULTING ACCOMPANYING DOCUMENTS		DEGREE OF PROTECTION AGAINST ELECTRICAL SHOCK
	CE CERTIFICATION AND SUPERVISING NOTIFIED BODY CODE		RECYCLE PROPERLY IN ACCORDANCE TO WEEE REGULATIONS
	CLASS IIa DEVICE		KEEP DRY
	FCC FEDERAL COMMUNICATIONS COMMISSION		KEEP OUT OF SUNLIGHT

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.

**Manufacturer contact details:** Saliwell Ltd., 65 Hatamar St., Harutzim 60917, Israel, e-mail: [service@saliwell.com](mailto:service@saliwell.com)




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# SaliPen

**DRY MOUTH RELIEF**



<div style="border: 1px solid black; padding: 2px; display: inline-block;">LOT</div>	S/N	 <b>Date</b>