

SaliPen

THE HIGH-TECH MOUTH MOISTENER

User Guide

Certifications: FDA, CE, TGA

Intended use: Relief of oral dryness

SaliPen is an electrical salivary stimulator system, intended to electrically stimulate a relative increase in saliva production. It is an intraoral device indicated for use in patients with xerostomia (dry mouth).

Contents

Certifications: FDA, CE, TGA	1
Intended use: Relief of oral dryness	1
Specific labeling for the US market	2
Contraindications	2
Precautions	3
Safeguards	3
Potential adverse events	4
General tips for the treatment of Dry Mouth	4
Description	6
Basic Usage	6
SaliPen insertion and removal	8
Recommended frequency and length of use	10
Care and maintenance	10
Replacing the battery	11
Frequently Asked Questions	11
Specifications	13
Declaration on Electromagnetic Emissions	13
Legends & Graphic Symbols	15
Manufacturer contact details	15

Version 3.0 September 2020

Specific labeling for the US market

in accordance with the FDA certification (K180838)

R_x Only

Caution: Federal law restricts this device to sale by or on the order of a dental practitioner or a physician.

Warning

You **MUST** receive professional training on the use of SaliPen by a dental practitioner. It is emphasized that the safety and effectiveness of the device may be affected if untrained patients start using it.

Intended use: Relief of oral dryness

SaliPen is an electrical salivary stimulator system, and is identified as a prescription intraoral device intended to electrically stimulate a relative increase in saliva production.

Indications for Use

SaliPen is an electrical salivary stimulator system, indicated for use in patients with xerostomia (dry mouth), under prescription of a dental practitioner or physician.

Maximal frequency and length of use

SaliPen should NOT be used for more than:

- 5 minutes per time
- 5 times per day
- 50 months (4 years and 2 months)

The safety of SaliPen is not known beyond these time periods. The limits above are also applicable for the cumulative use of more than one device, i.e. when a first device is replaced by one or more devices.

Contraindications

SaliPen shouldn't be used by:

- Children and adolescents (persons under 18 years of age).
- Epileptic disorder.
- Persons that are allergic to the surface materials of the device:
 - Electrodes: coated with gold.
 - Body: made of methyl vinyl silicone rubber.

Precautions

It is recommended to consult a specialist in the specific area of the conditions listed below regarding use of SaliPen. The following medical conditions should be considered as a basis for special precautions prior to the use of SaliPen:

- Use of a pacemaker
- Pregnancy
- Psychiatric or psychological disorders
- Involuntary muscle movement disorder (for example Parkinson's disease)
- Neurologic disorder in the head and neck area (for example trigeminal neuralgia)

Safeguards

- If you feel any adverse effect, such as electrical current, injury in the mouth, swelling or others, stop using the device and seek medical consultation.
- 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 the opinion of a medical specialist 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 saturated oxygen or nitrous oxide.

The safety of SaliPen use can be seriously affected if these safeguards are not internalized by the user.

Potential adverse events

Potential adverse events of SaliPen use include: discomfort in the areas of the mouth that are in contact with the device, infection, inflammation, and allergic reaction of the oral tissues.

General tips for the treatment of Dry Mouth

(Recommendations from Dr. Andy Wolff, Specialist in Oral Medicine)

The secretion of saliva is influenced by multiple factors that are independent and may, in fact, oppose the positive effect of SaliPen. I, thus, recommend a holistic approach to treat your dry mouth that would minimize the negative effects. Some of these negative factors can be reduced or even neutralized by simple measures.

“Negative” factors

Chronic medications: Many drugs have a drying effect on the mouth. Examples include medications for chronic diseases like high blood pressure, Parkinson’s disease, depression, anxiety, urological problems and others. Those types of drugs cannot typically be avoided, but may be replaced by similar ones that may have a less drying effect. Please consult your physician.

Short-term medications: Please be aware that some other drugs that are taken occasionally to treat temporary conditions, like for cough and cold, nausea and allergy, may have also a drying effect that counteracts the effect of SaliPen.

Habits: Smoking and excessive consumption of alcohol have a drying effect on the mouth.

Body hydration: Insufficient fluid intake can lead to the sensation of a dry mouth. Try to drink water as much as possible.

Mouth breathing: This has a negative effect on oral wetness. Seek medical advice to overcome this problem.

Mood: Being “down”, anxious or nervous has a negative effect on the secretion of saliva. Improving the mood helps salivary glands to secrete more saliva.

Ambient humidity: Staying in a dry room increases the sensation of oral dryness. The use of a humidifier is helpful.

Time of the day: Secretion of saliva is highest at evening hours and lowest just before waking up early in the morning.

Season and temperature: Secretion of saliva is lower in summer and when the temperature is high, leading to increased oral dryness.

“Positive” factors

Type of food: Chewing is a strong stimulator of saliva secretion. Therefore, I recommend eating food that needs to be chewed. Eating soft food that doesn't require chewing enhances only poorly saliva secretion.

Consistency of SaliPen usage: The ultimate goal of SaliPen use is to restore the salivary gland function in order to increase the amount of saliva in your mouth. Salivary glands are much like muscles. If you want to build your muscles you have to work out consistently. Similarly, the more you use SaliPen, the better it restores the salivary gland function and the stronger is its counteractive effect against the “negative” factors set forth above. Please, be consistent and persistent in the SaliPen use. See “Recommended frequency and length of use” on page 10.

Improvement over time: Our clinical studies show improvement in saliva secretion until, typically, eight months of use, then it stabilizes. Thus, it is important to persist in the use of SaliPen, even if at the beginning your mouth feels not moist as you would like it to be. Please be aware that the longer you use SaliPen, the stronger is its positive effect.

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 always stays 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 with a pin and can be separated by pulling away one from the other.



The package contains (from left to right):

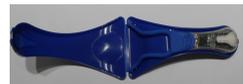
- a case for daily carrying of SaliPen,
- a SaliPen device.



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.)

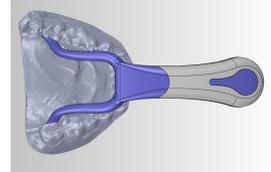
1. Take SaliPen out from its case.
2. Press the ON-OFF button once. SaliPen green light flashes indicating that the device is turned on. If the light does not flash, press the button again.



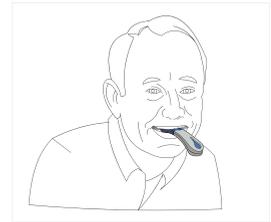
3. Open your mouth and lift up your tongue.
4. Slightly press the flexible arms one to the other.
5. Insert SaliPen flexible blue arms into your mouth, under the tongue.



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. You should feel the contact of the electrodes on the inner gums (those that face the tongue) at the back of the lower jaw.
9. Keep SaliPen in your mouth a few minutes (see length of use below).



10. When the time is due to take it out, slightly press the flexible arms one to the other, in order to detach the electrodes from the gums. Then, **gently** pull SaliPen out of your mouth.
 11. 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 tissue paper.
 11. Place the SaliPen unit inside the daily carrying case.
- (Wearers of a removable denture may now wear it again.)

Consult with your dental practitioner or the Saliwell company if you believe or are not sure that you follow the steps above in the right way or if you feel discomfort with the use of the device, beyond a foreign object sensation in your mouth.

SaliPen insertion and removal



1- Approach SaliPen to your mouth while squeezing its arms with your fingers



2- Lift the tongue, move SaliPen as deep as possible into the oral cavity, and then down along the molar teeth. Squeeze the arms firmly to avoid contact between the electrodes and the teeth.



4- Relax the tongue and hold SaliPen firmly on its white command unit.



5- Stabilize SaliPen in place while pressing it with the lips (NOT with the teeth!).

step by step



3- Once the electrodes are below the level of the teeth gently release the pressure of your fingers and let the electrodes touch the gums that are below and behind the rearmost teeth.



6- To remove SaliPen, squeeze firmly its arms, lift it gently without contacting the gums and the teeth, and finally pull it out of the mouth.

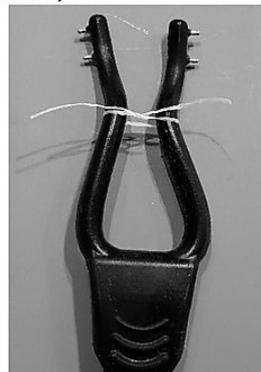
IN CASE ELECTRODES BOTHER

At the beginning of SaliPen use, the gums may be sensitive since they are not used to the electrodes. This problem may be overcome by any of these ways:

A- Covering the electrodes with a small amount of toothpaste and then inserting SaliPen in the mouth.



B- Releasing the pressure. In such a case, start using SaliPen with its arms bound by dental floss or a zip tie. Over time, you may loosen the ligature or remove the floss completely.



Recommended 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. Please use SaliPen only when you are awake.

The following list provides some possible usage examples:

- Intensive use: 5 times a day for up to 5 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 should use SaliPen in a fixed routine, and not only when 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 five (5) minutes each time. If you are satisfied with the results, you can gradually decrease the length of use. This is individual, i.e., 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 use to your particular condition and convenience. However, **use should be consistent even if only little effect is felt**. Clinical trials showed gradual improvement over time and that 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 wet tissue paper.
- After each use, clean the stimulating arms with a wet tissue paper.
- If rinsing is needed, separate the stimulating arms from the control unit, and rinse **ONLY** the stimulating arms. Keep the white control unit **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 **six** 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.



4. Place the fresh battery inside, 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.

Frequently Asked Questions

How does SaliPen work?

SaliPen sends electrical pulses of specific patterns that stimulate the nerves associated with salivary gland secretion. The stimulated nerves excite the salivary glands to secrete more natural saliva.

Can I feel the electrical pulses?

Normally not. The pulse intensity is below the human sensitivity level. However, some patients may feel a mild pulsation.

Can I feel discomfort from the contact of the electrodes with my gums?

Yes, especially when starting to use the device. To overcome this, you may cover the electrodes with a small amount of tooth paste or bind the two arms together with dental floss in order to allow only slight contact with the gums.

Can I sleep with SaliPen in my mouth?

No.

How long does the power source of the SaliPen last?

SaliPen has been designed to operate for about 12 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 six 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).

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

Clinical trials conducted by several independent groups, in leading medical centers, have shown high effectiveness of electro-stimulation in increasing natural saliva secretion in people suffering from chronic dry mouth due to several causes.

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?

Probably yes. The clinical studies show growing effectiveness upon using electro-stimulation over time. Typically, it is improved up to 8 months and then stabilizes.

Specifications

Size	13 cm (5.1") x 5.5 cm (2.2")
Weight	22 grams
Color	White and Blue
Battery Type	Lithium 3V CR2032
Packaging	SaliPen is packed in a protective plastic package
Power source	One CR2032 Lithium battery, 3 V, replaceable
Output signal	±3V bi-phase pulses, 5Hz, 0VDC, 1mSec
Operating temperature	From +5 °C to +40 °C
Storage Temperature	From 0 °C to +65 °C
Atmospheric Pressure Range	700 hPa to 1060 hPa
Humidity	Humidity: 0-93% RH Non-condensation
Mode of operation	ON/OFF
Service life	10 years
Battery life	Approximately 24 months
Degree of Protection	IPX0 – no protection

Warning: Testing revealed that SaliPen functioning is not affected by or does not affect the functioning of devices emitting electromagnetic fields, such as diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors. Nevertheless, it is recommended not to activate the SaliPen device together with any of the above-mentioned devices.

Declaration on Electromagnetic Emissions

In order to regulate the requirements for EMC (electromagnetic compatibility) with the aim of preventing unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference, as well as the maximum levels of electromagnetic emissions for medical devices. The SaliPen device has been tested and conforms to the requirements of the

standard. SaliPen is intended for use in the electromagnetic environment specified below. The user of SaliPen should assure that it is used in such an environment.

Immunity (Stimulation mode) table according to IEC 60601-1-2

Immunity Test Standard	IEC 60601 test level	Electromagnetic environment – guidance
Electrostatic discharge (ESD). IEC 61000-4-2 "Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test"	Air Discharge - 15kV. Contact Discharge - 8kV.	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated immunity. IEC 61000-4-3:2006 Amendment A1:2007, Amendment A2:2010 "Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test"	10V/m 80-2600Mhz	Portable and mobile RF communications equipment should be used no closer to any part of SaliPen than the recommended separation distance.
Immunity to magnetic field. IEC 61000-4-8 "Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency"	30A/m, 50Hz & 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radio-frequency disturbance. CISPR 11:2009 +Amendment A1:2010, Class B "Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement"	The margin between the emission level and the specifications limit is 11.1dB, in the worst case, at the frequency of 113.5Mhz, horizontal polarization.	SaliPen uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Legends & Graphic Symbols

	MANUFACTURER		On/Off TOGGLE SWITCH
R_x Only	PRESCRIPTION ONLY		CONSULT INSTRUCTIONS FOR USE
 2019	DATE OF MANUFACTURING		OPERATING TEMPERATURE LIMITATION
LOT	BATCH CODE	S/N	SERIAL NUMBER
	CAUTION, CONSULTING ACCOMPANYING DOCUMENTS		DEGREE OF PROTECTION AGAINST ELECTRICAL SHOCK
 KEEP DRY	KEEP DRY		RECYCLE PROPERLY IN ACCORDANCE TO WEEE REGULATIONS
FC	FCC - FEDERAL COMMUNICATIONS COMMISSION		KEEP OUT OF SUNLIGHT
	CLASS IIa DEVICE (in Europe)	CE 2460	CE CERTIFICATION AND SUPERVISING NOTIFIED BODY CODE

Manufacturer contact details:

Saliwell Ltd., 65 Hatamar St., Harutzim 6091700, Israel, e-mail: service@saliwell.com, Fax: +972773534338



European Representative:

Saliwell Ltd. Gewerbepark Eschberger Weg, Im Helmerswald 2, Gebäude 4, POB 102719, 66121 Saarbrücken, Germany. www.saliwell.com

**SaliPen Label &
Unique Device Identification (UDI)**

See back cover