SaliPen

THE HIGH-TECH MOUTH MOISTENER

Clinician Guide

CONTENTS

Version 6.0 September 2023

Intended use: Relief of oral dryness

SaliPen is an electrical salivary stimulator system, and is identified as an 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).

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:

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

Maximal Frequency and Length of Use

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

The safety of SaliPen is not known beyond these time periods.

Those time limits are applicable for the **cumulative use,** i.e., when a first device is replaced by one or more devices.

Precautions

The following medical conditions need special precautions and require medical-specialist attention **prior** to using the device.

- 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)
- Risk for jawbone necrosis, a complication rarely taking place in: (a) patients after head and neck radiotherapy (especially high-dose), called Osteoradionecrosis (ORN) and (b) patients receiving medications to treat osteoporosis or bone tumors (such as bisphosphonates and denosumab), called Medication-related osteonecrosis of the jaw (MRONJ). Although we are not aware of such complications caused by SaliPen wearing, we encourage you to be alert of any injury to the tissue. In such a case, you are kindly requested to discontinue the use of SaliPen and to consult your doctor. Do not use Salipen again until receiving approval from your doctor.
- Presence of erosive or ulcerative oral lesions, which are chronic or recurrent.

Safeguards for patients

- If you feel any adverse effect, such as a sensation of a strong electrical current, injury in the mouth, swelling or others, **stop using the device immediately** and seek medical consultation.
- Do not use SaliPen in conjunction with other active medical therapeutic or diagnostic devices such as microwave therapy, EEG, ECG, etc.
- Do not use SaliPen if you have an implanted-electronic device like a deep brain stimulation (DBS) device, a cardiac pacemaker, a cardiac defibrillator, etc., unless an opinion by a medical specialist allows explicitly its use.
- 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. Please inspect it carefully before its re-use.
- 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 exercised 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.

Indications for Use

SaliPen is an electrical salivary stimulator system, indicated for use in patients with xerostomia (dry mouth).

Background

Salivary-gland function is controlled by the salivary reflex of the autonomic nervous system. Xerostomia (the sensation of oral dryness) is mostly attributed to damage of the salivary glands and their related nerves, although sometimes such a damage may not be apparent.

SaliPen is a device for **electrostimulation of the lingual nerve in the vicinity to the mandibular third molar**. At this point, this nerve carries efferent fibers for the innervation of the submandibular, sublingual and several minor salivary glands and afferent fibers of the salivary reflex. Thus, excitation of these fibers potentially leads to an increased secretion of all salivary glands, and hence to the relief of oral dryness.

Saliwell Ltd. manufactures a device that fits most users, commercially known as "SaliPen". Clinical studies have shown the following:

- The configuration (shape, distance, materials) of the electrodes should be as implemented in Saliwell devices.
- The **positioning of the electrodes** (near to the lingual nerve path) should remain **as stable as possible during each electrostimulation session**.

- A short-term (minutes) stimulatory effect is manifested by increased salivary secretion and is mostly felt immediately after starting the use of the devices.
- A lasting (hours) stimulatory effect is typically felt after long-term, persistent (weeks, months) use of the devices.
- Gradual improvement in the oral dryness relief is usually experienced over a period of few months of continuous use (typically up to eight months).
- Saliwell devices carry the potential to induce the regeneration of damaged salivary glands in the long run.

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), is autoclavable and 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 connector 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.

SaliPen Usage

The position of SaliPen in relation to the lingual nerve

The distance from the mandibular third molar area to the lingual nerve varies between 5.1 and 19.9 mm. In addition to the variances in the lingual nerve

path, the absence or presence of the third molar influences the position of the nerve in relation to the alveolar crest, as well. Thus, the exact location of the lingual nerve for every single patient cannot be established. Therefore, the electrical field generated by the SaliPen electrodes is designed to be effective at those distances and affect the lingual nerve, yet, the closer the nerve is to the stimulation electrodes, the better.

The next illustration shows the location of the electrostimulation site in relation to relevant anatomic structures: third molar, lingual nerve, submandibular ganglion and gland, sublingual gland and the excretory duct.

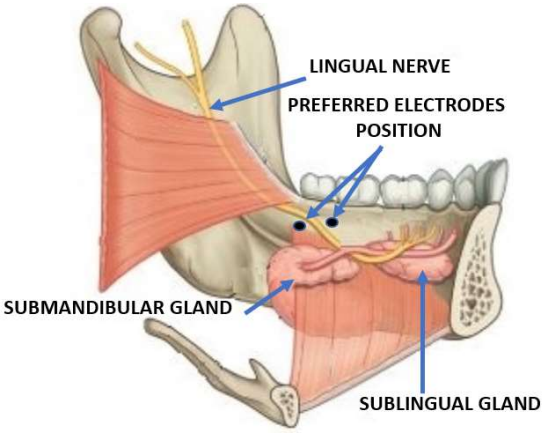


Figure 1 - The lower-jaw anatomy and the preferred positioning of the SaliPen electrodes

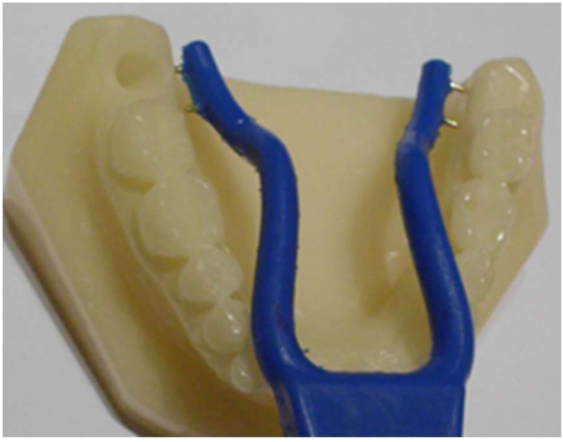


Figure 2 - An upper view of SaliPen proper positioning, with the electrodes placed lingually to the mandibular third molar, which may be either absent (right) or present (left).

The position of the device in different mandible sizes

Whether the distance between the mandibular third molar and the incisive teeth is short or long, the electrodes should be positioned close to the third molar region while the stem is placed between the lips to stabilize and hold the whole device in place during the treatment session.

The SaliPen device is designed to fit most mandibles, small and large. The next figure depicts the positioning of SaliPen in a small and in a large mandible. In a small jaw patient (upper pictures) the stem protrudes more outwards the lips than in a large jaw individual (lower pictures).

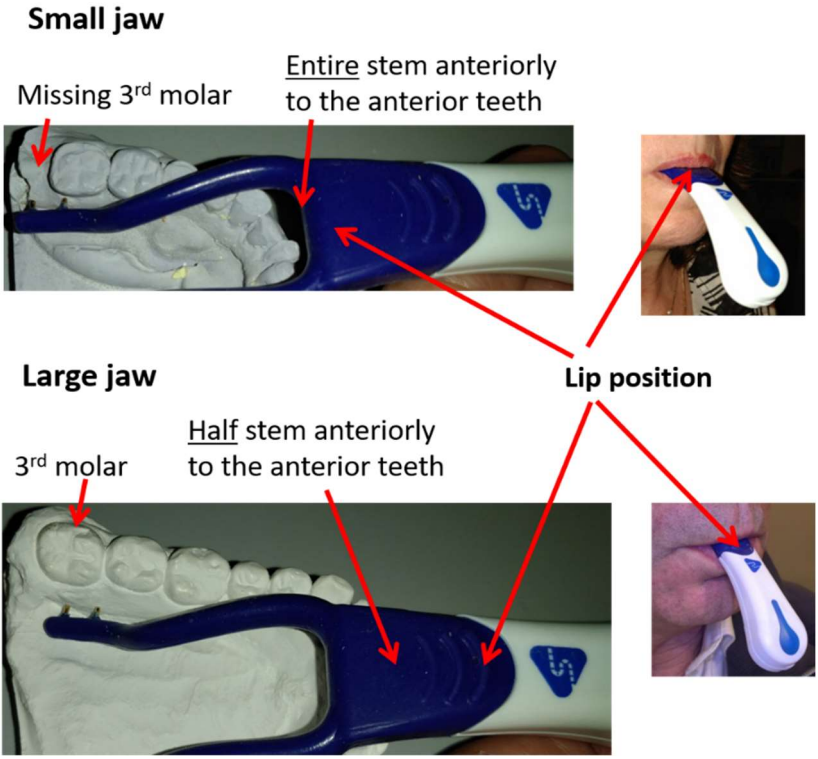


Figure 3 - Positions of the electrodes on the in patients with small (upper) and large (lower) mandibles.

Note that the stem has marks to help indicating the correct positioning. The picture to the right zooms in the SaliPen's stem. Please show your patient the position of his/her upper lip in relation to the protruding lines. It is advisable that until getting used, the patient inserts the device in front of a mirror.

Influence of the varying distance of the electrodes in relation to the lingual nerve

As the user cannot know the exact subcutaneous location of the neuro-sensitive organ or tissue, the effectiveness of the therapy relies on the electrode positioning and the spread of the stimulus signals. This limitation is compensated in all electronic stimulating devices by generating an electrical field strong enough to excite the nerves at varying distances. The concept is utilized in almost all non-invasive electrical stimulation devices, such as TENS, etc.

In vitro experiments have shown that electrostimulation applied on the lingual side of the mandibular molar region is strong enough to stimulate, as it propagates several millimeters around the stimulation source (the electrodes). In addition, despite the variable, the relative positioning of the lingual nerve and the electrodes, clinical trials have shown that electrostimulation on the oral mucosa on the lingual side of the mandibular next to the third molar, is effective for the treatment of dry mouth.

It means that as long as the electrodes are on the lingual side in the vicinity of the third molar, the required efficacy is typically achieved.

Patient Training in SaliPen Usage

Please be familiar with the section "Basic Usage" of the User Guide.

The following videos posted on YouTube may be helpful to understand the use:

"How to use the SaliPen device to stop dry mouth"
(https://www.youtube.com/watch?v=MIk6Vv9DJg8&ab_channel=Saliwell-DryMouthReliefTechnologies)

"Learn how SaliPen stops dry mouth naturally"

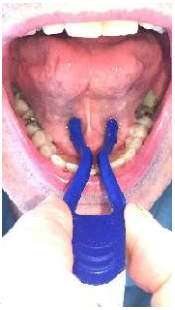
(https://www.youtube.com/watch?v=C2hziLrqRkE&t=14s&ab_channel=Saliwell-DryMouthReliefTechnologies)

SaliPen should be positioned in the mouth so that the electrodes are in contact with the lingual mucosa near the third molar area, and kept in this position by the lips and not the teeth, during the use, up to 5 minutes per use.

Thus, kindly instruct your patient how to insert SaliPen in such a way that eventually the electrodes contact the mucosa of the lower dental arch, at the lingual side of the third molar (either present or absent), and it stays stable at this position. Please, let the patient practice the insertion and removal of SaliPen until he/she can do it in a safe and effective manner.

The next figures shows the steps of insertion, wearing and removal of SaliPen.


1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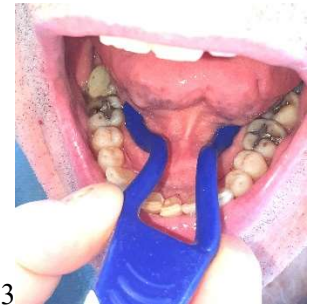
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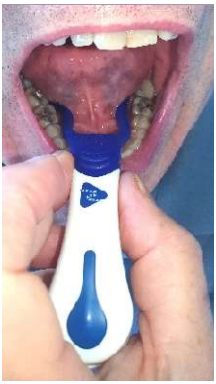
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Figure 4 – SaliPen usage: (1) arms are squeezed together, (2) tongue is lifted, (3) arms are inserted and pushed distally on the lingual side until the end of the gingiva, (4) arms are released and allowed to contact the oral mucosa, (5)

device's stem is held by the lips, and (6) after up to 5 minutes, the device is removed by squeezing again the arms one to the other.

Please instruct your patient step by step with the procedures above.

At the beginning of SaliPen use, the oral mucosa may be sensitive to the electrodes until getting used to their presence (like in orthodontic appliances).

This issue may be overcome in 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, it is recommended to bind SaliPen arms with dental floss or a zip tie. Over time, the ligature may be loosened or even removed completely.

Clinical Conditions that May affect the SaliPen Usage

Some clinical conditions may interfere with or impact the patient's ability to position and maintain SaliPen in place. Those conditions are:

1- Very small mandible
2- Limited opening of the mouth
3- Macroglossia
4- Severely resorbed mandibular posterior edentulous ridge
5- Gag reflex
6- Hyperalgesia of the oral mucosa
7- Predisposition to oral sores

Before recommending the SaliPen, it is advisable to discuss with the patient the expected difficulties (including a possible inability) in using the device.

Recommended Frequency and Length of Use

The patient should adjust the number of times using the SaliPen in a day and the duration each time, according to his/her condition and needs. **However, SaliPen shouldn't be used for more than 25 minutes every day (accumulated) and up to five minutes in one session. In addition, SaliPen should not be used while sleeping and not under the influence of drugs or alcohol.**

The following list provides some possible usage examples:

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

Patients should use SaliPen in a fixed routine, and not only when they feel oral dryness. However, it is recommended not to use it more than once every hour.

During the initial use, it is recommended to use SaliPen five (5) minutes each time. If the results are satisfying, the patient can gradually decrease the length of use. Yet, it 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. The patient may adjust the frequency and length of usage to his/her condition and convenience. However, the use should be consistent even if only a small effect is felt.

Clinical trials showed gradual improvement over time. It may take a few months (up to eight months) of persistent use until reaching satisfactory results.

Care and Maintenance Instructions for the Patient

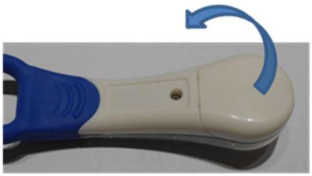
- If the device stops working, please change the battery, which is contained in the battery compartment (see instructions below).

- After each use, and at least once a day, 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 (6)** months or earlier or if it has physical damage.

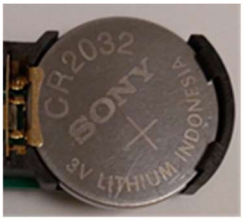
Battery Replacement Instructions for the Patient

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 standard coin cell battery type CR2032, 3V Lithium. Use only fresh batteries.

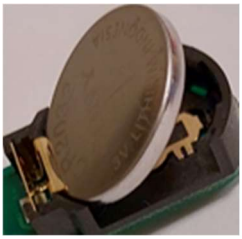
2. Open the battery compartment by pressing with your nail or a flat screwdriver as shown.



3. Extract the used battery from its holder using your nail or a flat screwdriver. Push gently the metal holder to the left. 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.

Questions that Patients May Ask Frequently

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 24 months using a single battery. 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. The stimulating arms, like a toothbrush, replacing is recommended about every six (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 the 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 around the world, 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 even weeks.

After I use SaliPen for a few minutes, how long does the effect last?

It is very individual; for few, the effect lasts a day, for others an hour. On average it lasts about three 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 eight months and then stabilizes.

Does the SaliPen stimulation induce regeneration of salivation capabilities?

Initial clinical indications suggest such regeneration process is possible, but it is yet to be proved scientifically.

About Dry Mouth

Saliva facilitates the patient's speech, taste, chewing, swallowing, digestion, and teeth protection. Insufficient saliva production may lead to xerostomia, which is the symptom of suffering from dry mouth.

Prevalence of Dry Mouth

Xerostomia is a common symptom that may affect about 10% of the adult's population. Oral dryness is more common among the elderly, and more common in women than in men.

Etiology of Dry Mouth

Dry mouth is primarily caused by a compromised function of the salivary glands, often induced by:

- Medications
- Head and neck radiotherapy
- Autoimmune diseases, for example, Sjögren's Syndrome
- Anxiety states
- Diabetes
- HIV infection
- Other causes

Dry Mouth Diagnosis

SaliPen is indicated for the treatment of dry mouth. The term “dry mouth” reflects two conditions that may or may not be related:

Xerostomia - the individual's subjective sensation of dry mouth

Hyposalivation - reduced salivary flow rate.

Anamnesis

It is recommended to record and document the following details:

- Patient's chief complaint
- Dental and oral diseases history (including xerostomia treatment)

- If the patient suffers from xerostomia, its etiology and severity
- Patient's expectations from the treatment with SaliPen
- Evaluation of the expected compliance with the SaliPen treatment.

Oral Signs and symptoms related to Dry Mouth

Patients suffering from dry mouth may complain about any of the following symptoms:

- Decrease in the amount of the saliva
- Change in the characteristics of the saliva (foamy, viscous, ropy)
- Dry and/or cracked lips
- Burning mouth
- Swelling and/or pain of the salivary gland
- Frequent necessity of fluid intake when eating or when in bed
- Difficulty eating dry food, using dentures, swallowing, speaking, tasting food
- Bad breath or taste
- Frequent waking up from sleep due to dry mouth

Some patients express no complaint of xerostomia despite suffering from hyposalivation. In these cases, the signs of salivary gland hypofunction may help you diagnose the condition. A patient suffering from the following conditions should be suspected of reduced salivation:

- History of rampant or cervical caries
- Halitosis
- Bad taste sensation
- Fungal infection
- Burning mouth

Xerostomia diagnosis

Several symptoms are reliable indicators of xerostomia. The following questionnaire may help assess your patient's condition:

- Do you need to do something to keep your mouth moist?
- Do you get out of bed at night to drink water?
- Do you have difficulties speaking due to lack of mouth lubrication?
- Do you have difficulties swallowing dry food?

Hyposalivation diagnosis

The diagnosis of hyposalivation is based on a simple in-office saliva flow rate measurement. The most common measurement method is Whole Saliva Collection, in which saliva is collected in a tube for at least five minutes after having nothing in the mouth for at least 90 minutes. The patient is asked to expectorate into the tube during the collection period and to refrain from swallowing saliva. The tube is weighed prior and after saliva collection and the difference in weight (measured in grams) indicates the volume of saliva collected (in milliliters). This volume is finally divided by the number of minutes during which saliva has been collected to obtain to flow rate value.

To obtain a stimulated salivary flow rate, ask the patient to chew a piece of paraffin while collecting the saliva. Due to circadian variations in flow rate, repeated salivary collections should be performed at a similar time of the day.

The flow rate of saliva is a dynamic and variable parameter. The following table provides an indication of normally found salivary flow rates.

	Normal Flow Rate	**Abnormal Flow Rate**
Unstimulated whole saliva	0.3-0.4 ml/min	<0.1 ml/min
Stimulated whole Saliva	1-2 ml/min	<0.5 ml/min

Drugs Causing Dry Mouth

The sensation of dry mouth may be caused by the intake of dryness-inducing medications. Of the most 50 prescribed medications in the US in 2003, 64% were xerogenic. Altogether, there are 1,800 drugs in 80 drugs classes that are known to have the side effect of inducing dry mouth. More information in https://link.springer.com/content/pdf/10.1007%2Fs40268-016-0153-9.pdf (a downloadable article that can be found when searching the internet for Wolff Guide Medications). The xerogenic drugs belong to the following (and also other) drug categories.

Abusive Drugs	Gastrointestinal Agents
Aids Related therapeutic Agents	General Anesthetics
Alzheimer's Disease Management	Hemorrheologic Agent
Analgesics	Hormones
Anaphylaxis Emergency Kit	Hyperprolactinemic Disorders
Anorexiants	Hypertensive Emergency Agent
Anti-Arrhythmic Medications	Hypotension Management
Anti-Infective Agents	Immunologic Agents
Anti-Inflammatory Agents	Lou Gehring's Disease Therapy.
Anti-Neoplastic Agents	Multiple Sclerosis Management
Anti-Rheumatic Agents	Muscle Relaxants
Anti-Ulcer Agents	Nasal Decongestants
Anticholinergics & Antispasmodics	Nasal Inhalants
Antihistamines	Nausea Medications
Antihistamines and Decongestants	Nerve Agent Poisoning Treatment
Antihyperlipidemic Agents	Nutritional Supplements
Antihypertensives	Ophthalmic Preparations
Assisted Reproductive Technology	Opioid Antagonists
Benzodiazepene Antagonist	Osteoporosis Management
Blood Modifier	Paget's Disease Management
Bronchodilators	Parkinsonism Drugs
Central Nervous System Stimulant	Psychotropic Agents
Cervical Dystonia Treatment	Seizure Disorder Medication
Cold and Cough Preparations	Sleep Aids
Dermatological Preparations	Smoking Cessation Aids
Diagnostic Aids	Sympathomimetic Combination
Diarrhea Medications	Treatment of Attention
Digestives	Treatment of Gaucher Disease
Diuretics	Treatment of Migraine
Erectile Dysfunction Management	Vasodilators

Selected Literature

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Wolff A et al. A Guide to Medications Inducing Salivary Gland Dysfunction, Xerostomia, and Subjective Sialorrhea: A Systematic Review Sponsored by the World Workshop on Oral Medicine VI. *Drugs R D* 2017; 17:1–28

Zadik Y et al. Safety and efficacy of an intra-oral electrostimulator for the relief of dry mouth in patients with chronic graft versus host disease: Case Series. *Med Oral Patol Oral Cir Bucal*, 2014; 19(3): e212-219

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 activate the SaliPen device **together with** any of the above-mentioned devices.

Declaration on Electromagnetic Emissions

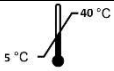
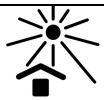
In order to regulate the requirements for electromagnetic (EM) compatibility with the aim of preventing unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to EM interference, as well as the maximum levels of EM emissions for medical devices. SaliPen conforms to the requirements of the standard and is intended for use in the EM 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	EM environment
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 a 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
	CLASS IIa DEVICE (in Europe) Class II in the USA.		CONSULT INSTRUCTIONS FOR USE
 2022	DATE OF MANUFACTURING		OPERATING TEMPERATURE LIMITATION
	BATCH CODE	S/N	SERIAL NUMBER
	CAUTION, CONSULTING ACCOMPANYING DOCUMENTS		DEGREE OF PROTECTION AGAINST ELECTRICAL SHOCK
	KEEP DRY		RECYCLE PROPERLY IN ACCORDANCE TO WEEE REGULATIONS
	**FCC** – FEDERAL COMMUNICATIONS COMMISSION		KEEP OUT OF SUNLIGHT
OTC	Over The Counter		

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:

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SaliPen Label & Unique Device Identification (UDI)