

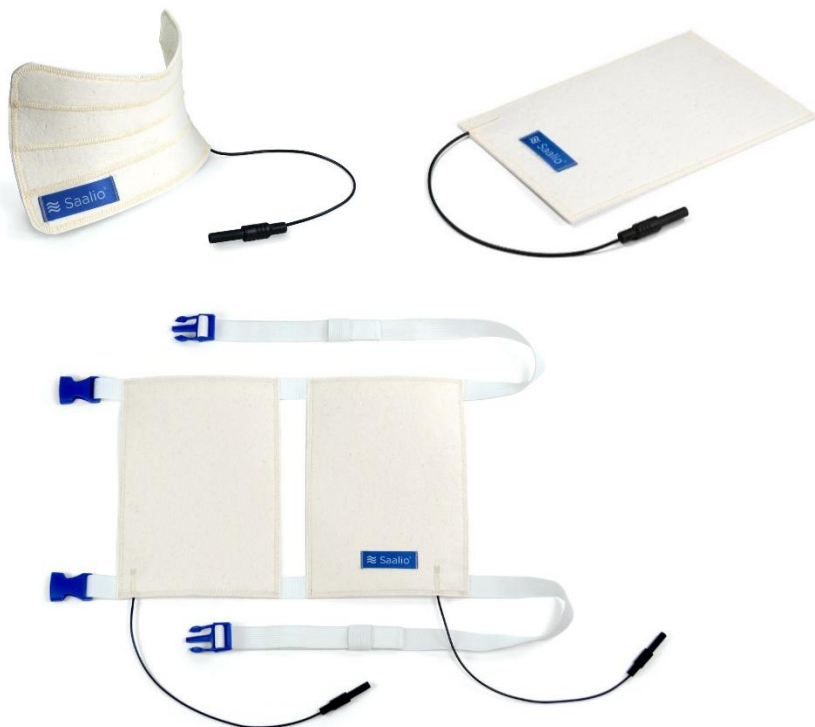


Instructions for Use

Saalio® Textile Electrodes

- Saalio® Face Electrode (item No. 07-01-028-01)
- Saalio® Forehead Electrode (item No. 07-01-028-04)
- Saalio® Neck Electrode (item No. 07-01-028-03)
- Saalio® Universal Electrode (item No. 07-01-028-02)
- Saalio® Pair of Body Electrodes (item No. 07-01-028-05)





We thank you for putting your trust in Saalman[®] therapeutic devices.

The Saalio[®] textile electrodes may only be combined with the following two Saalio devices:

- Saalio[®] DE (hands & feet) item No. 07-01-000-01
- Saalio[®] AX (underarms) item No. 07-01-000-07

You will find important information on how to carry out therapy in these instructions for use as well as in the instructions for use of the Saalio units.

Please carefully review both user instructions!

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1 Scope of Delivery

Saalio® Face electrode	tem No. 07-01-028-01
Saalio® Forehead electrode	item No. 07-01-028-04
Saalio® Neck electrode	item No. 07-01-028-03
Saalio® Universal electrode	item No. 07-01-028-02
Saalio® Pair of body electrodes	item No. 07-01-028-05

2 Combination products, Accessories and Spare Parts

The Saalio textile electrodes may only be combined and operated with the Saalio DE or the Saalio AX sets.

(no accessories and no spare parts)

3 Safety Guidelines



The textile electrodes may only be operated in combination with the Saalio DE or Saalio AX sets. Combination with other devices or electrodes may endanger the user or even cause death and will result in the immediate loss of the warranty.



Please remove any metal jewellery (rings, watches, bracelets, etc.) or metal-framed glasses before starting a treatment if these objects are near the electrodes or along the direct current path through the body. Metal objects may cause localised burns or current traces.



Any small skin lesions (wounds) must be covered with petroleum jelly (Vaseline) to insulate them from the current flow.



Injuries to the skin can heal more poorly in immunocompromised and elderly patients as well as diabetics or can even lead to serious infections.



After shaving, these areas of skin must not be treated for at least 24 hours to allow any cuts to heal.



Only switch the unit on or off when **no electrodes** are applied. All safety functions of the unit are only guaranteed when it is switched on.



If the dose is set too high, you may experience painful sensations all over the treated extremities.



During the first treatments, a patient may experience increased sweat production; these symptoms will spontaneously abate after the next few treatment sessions.



The electrodes can be removed safely at any time. In very rare cases, unpleasant electric shocks may occur, but they are absolutely harmless.



The treated skin can show signs of dehydration like flaking or small lesions. Should this be the case, please apply a rehydrating cream **after** treatment.



Immediately following a treatment session, occasional redness and rarely also blisters can be observed in the treated area. These phenomena completely recede. Reducing the treatment doses can minimize the appearance of these symptoms. Before administering a new treatment session, the skin has to heal completely. In case of an unexpectedly strong skin reaction, a medical professional must be consulted first.



Make sure you do not kink the electrodes or cable too much and do not expose the cable to heat or chemicals. If an electrode or a cable is damaged have it checked by Saalman.



If you wish to clean the device, pull all plugs from the socket and switch it off. Use a soft, damp cloth and a mild cleaning solution.



Protect from access by children, do not leave the device unattended, risk of strangulation and injuries.



The textile electrodes are subject to natural wear and should be replaced regularly (every 12 months).



The electrodes may not be modified.



This electrode is made of cotton fleece and is subject to natural wear and tear by frequent use. This can impair the function and safety of the electrode. **It is therefore in your own interest to replace the electrode every 12 months during normal use.**

4 Symbol Legend

Symbols used in the user manual and on the label:



Caution:
important note!



Medical Device



Read the user
manual!



Manufacturer's CE-
declaration



Device serial
number



Lot. No.



Manufacturer

5 Intended Use

The Saalio® therapeutic device in combination with the Saalio® textile electrodes has been designed for the treatment of focal hyperhidrosis („intended use“). The Saalio® therapeutic device is to be used in dry rooms in a home setting. Any application beyond that scope is considered „improper use“. The manufacturer does not accept responsibility for any personal injury or material damage resulting from or likely to result from an application beyond the scope of „intended use“.

6 Therapeutic Mode of Action

This effectiveness of tap water iontophoresis has been validated in numerous medical studies; a scientifically unambiguous explanation for its mechanism of action is still outstanding. Medical experts assume that the electrical current irritates the synaptic connections between sweat-inducing nerves and sweat glands to such an extent that the sweat glands are no longer stimulated to secrete sweat. This means the sweat gland itself is not impacted but merely the „supply line“ to the nerves. **The therapeutic effect only occurs after repeated treatment and is of reversible nature, hence, treatment is to be repeated regularly.**

The amperage of the treatment current must be adjusted according to individual sensitivity. There is no danger of a safety risk as the current is limited to certain maximum values.

7 Intended Purpose and Indications

The Saalio® textile electrodes are intended to be combined with the Saalio® DE set (hands and feet) or the Saalio® AX set (armpits) and to allow the use of the tap water iontophoresis device on other parts of the body: face, neck, back, breast, abdomen etc.

Tap water iontophoresis is used for the treatment of primary hyperhidrosis by passing a direct or pulsed treatment current through the affected body sites. This current flow is ensured by a water bath or by previously soaked textile electrodes or sponge pads and leads to a temporary reduction of the sweat secretion on the skin regions contacting the water.

The treatment is applied to persons who suffer from excessive, pathological sweating in defined areas of the body (e.g. hands, feet and armpits, face etc.) regardless of gender. The persons must be able to perceive current-induced pain and decide independently about the intensity of treatment and whether to discontinue treatment. Furthermore, the contraindications must be observed (see item 8).

The device can also be used by lay persons and does not require training or separate instruction. Only start the treatment after you have carefully read and understood the entire instructions for use. In case of any uncertainties, contact the manufacturer or the attending physician.

8 Contraindications and Adverse Reactions



Iontophoresis with the textile electrodes must not be used under any circumstances in the following cases:

- User/s with a pacemaker
- User/s with an implanted cardioverter defibrillator (ICD)
- Pregnancy
- Metal-containing intrauterine pessary (only relevant in case of feet treatment)
- Metallic implants or other conductive objects present in the current path between the two electrodes (this includes, for example, dental implants, inlays, braces, piercings).
- Pathologically altered skin or large skin defects (wounds) that cannot be covered with petroleum jelly
- User/s with palpitations (cardiac arrhythmia)
- User/s with neurological diseases (e.g. epilepsy or limited sensitivity)
- User/s with malignant disorders in the area of application
- User/s with severe local inflammation or thrombosis (blood clots)
- User/s with severe vascular disorders
- Children and youths up to the age of 18



The following side effects may occur:

- A tingling and burning sensation during the treatment caused by excessive current settings or open areas of the skin
- Slight, but harmless, shocks when treatment is interrupted
- Dry skin or itching after the treatment
- Short-term reddening of the skin following the treatment, among other things as a result of stimulated circulation (hyperemia) or through higher current densities along the water line
- Reversible blistering
- Electricity burns or current marks due to high punctual current strengths (e.g. direct skin contact with the electrode)
- Metallic taste in the mouth when using the face or forehead electrode, avoidance by changing the polarity.

Concurrent skin conditions or the simultaneous use of antiperspirants may increase the likelihood of side effects.

9 Activation

The textile electrodes must be in excellent condition. Prior to every usage, the electrodes must be checked for possible damages; a defective electrode may not be operated. Please pay close attention to the information on the device itself and in the user manual. Once the therapy session is finished, turn off the device.

10 Device Setup

The Saalio device can only be operated with one electrode and one counter electrode at a time. For safe use, only the following electrode configurations are permitted.

Body Site	Electrode	Counter Electrode
Face	Face electrode	Treatment basin for hands or feet*
Forehead	Forehead electrode	Treatment basin for hands or feet*
Neck	Neck electrode	Treatment basin for hands or feet*
Other Body Sites	Universal electrode	Universal Electrode or Treatment basin for hands or feet*
Back, Breast, Abdomen	Body electrodes (pair of universal electrodes)	

* Treatment basin means single basin equipped with basin electrode and foam insert)



Treatment basin as counter electrode

10.1 Face, Forehead, Neck and Universal Electrode

While the textile electrode (face, forehead, neck or universal electrode) constitutes an electrical contact surface with the device, your hands or feet (treatment tray) are required to serve as second contact surface in order to facilitate the flow of electricity through the body. Basically, this configuration is similar to the application of a combined hand/foot treatment. Conduct the device setup in the following sequence:

1. Once you have connected the power supply unit, switch on the control unit.
2. Prepare a treatment tray according to the user manuals for Saalio® sets for hand or foot treatment. It serves as so-called counter electrode to the textile electrode. Connect the electrode to the control unit.



3. Fill the other treatment tray with tap water as well. Place the textile electrode into this tray and allow it to completely get soaked. Subsequently, the textile electrode is also connected to the control unit.

Tip:

Use warm tap water. It is much more pleasing to the skin.

4. Counter electrode

- 4.1. In case you intend to use either both your hands or only one hand as counter electrode, place the treatment tray on a table in front of your body.
- 4.2. Should you want to use your feet as counter electrode, place the prepared treatment tray (with electrode and foam mat inside) on the floor in front of you. Next, take the second tray in which the textile electrode is soaking and place it on the table in front of your body.
5. Cover adjacent parts of the body with a towel in order to catch any water that might be leaking.
6. At this time, remove the textile electrode from the water. Wring it gently to a point where water barely drips from the textile electrode and then attach the textile electrode to your body.
7. Textile electrodes can be fixed with straps (if available). Tighten the straps only as much as is necessary to ensure that the sponge holds a maximum amount of water while simultaneously achieving a current density that is as consistently constant as possible. The textile electrode should be evenly attached, particularly to those areas where you experience excessive sweating.

Should you initially experience a less than perfectly close fit in some areas of the textile electrode (e.g. the outline of the nose when using the face electrode), use your hands to press against the according area for a while. If the electrode is wet enough and the geometric discrepancy is not too significant, the sponge will usually stick to the body contour.



Tips:

- Use your feet as counter electrode. This frees both hands to change the current strength, correct the position of the textile electrode or initially press it down against individual areas.
- Use a mirror to check and optimize the fit of the textile electrode or ask a second person for assistance.
- Initiate the treatment very soon after you have applied the wet textile electrode. The wetter the electrodes, the better their conductivity and thus distribution of the current on the skin.
- Pressing down on the nose contour is easily done at the onset of the therapy session. If applicable, remove one hand from the basin (counter electrode).

10.2 Pair of Body Electrodes

Electricity enters and exits the body via the two body electrodes which are connected by a strap. An additional counter electrode is not required.

Conduct the device setup in the following sequence:

1. Once you have connected the power supply unit, switch on the control unit. Set the desired treatment parameters on the device. Push the SET button at least once to automatically initiate the treatment.
2. Connect both electrode cables to the control unit.
3. Allow both universal electrodes to get completely soaked.
4. Now, apply both body electrodes to your body and fasten them with the flexible straps. Take care to reduce the length of the straps just far enough as to ensure that the electrodes do not slip. (If the straps are too tight, an inhomogenous current feed-in might occur.)
5. Now connect both universal electrodes with the electrode cables. As soon as the second electrode is connected, the electric circuit is closed and the treatment session is automatically initiated.

Tips:

- Use warm tap water. It is much more pleasing to the skin.
- Skin contact with the electrodes should be as even as possible in order to facilitate extensive homogenous current feed-in. The wet, heavy electrodes best attach to the skin when in a vertical position.

You best lie down for a treatment session so that the electrodes are positioned on top.

- Initiate the treatment very soon after you have applied the wet textile electrode. The wetter the electrode, the better its conductivity and thus the distribution of current on the skin.
- Cover adjacent parts of the body with a towel in order to catch any water that might be leaking.



11 Conducting the Treatment

Basically, treatment with a textile electrode resembles that of hands, feet and armpits. Since the treated body sites or skin, respectively, might react with a more sensitive current perception and might be prone to dehydration, special precautions and recommendations should be observed, particularly at the outset of treatment.

If you have shaved your underarms, this should have been done at least 24 hours ago. Antiperspirants should not be used at the same time. The last application should have been at least 5 days ago.

Prior to the treatment session, remove any cosmetics and oily care products. It is prudent to wash the skin areas prior to treatment with regular soap and water and thus remove oil and sebum from the skin. Even minute oil films can locally result in significantly higher contact resistance which greatly hampers the current flow in these areas. Do not use any liquid soap.

11.1 Device Settings

Treatment time [min:sec]

Limit your initial treatment session to 2 minutes, to detect possible undesired skin reactions early on. Remove the textile electrode to check. Due to the stimulated circulation, a slight reddening of the skin is not unusual. It should, however, subside within 1 to 2 hours. Only then gradually increase the duration of your treatment by 5 minutes and examine the skin every time. If after the first 12 minutes (2 + 5 + 5 min) no additional skin changes occur other than the normal reddening, you can increase the duration to a maximum of 15 minutes for the next treatment session.



Should you experience any skin changes, wait until they have completely abated until you re-initiate the treatment with a lower current strength.

Treatment Current [mA]

For the very first use, set the current to 1 mA before applying the dripping wet textile electrode. The device will start automatically after you close the circuit with your hands or feet. Then, gradually increase the current during operation until you experience neither an unpleasant tingling sensation nor pain.

Current sensitivity greatly differs from person to person and usually also changes in the course of the treatment (habituation effect). We categorically recommend the use of current strengths above **10 mA for direct current or 15 mA for pulsed current only after you have gained some previous experience (at least 10 sessions).**

Current Type [PC / D/C]

Due to its better efficacy, direct current (D/C) is preferable - especially at the onset of the treatment. Should a sensation of pain already be evident at low current strengths (a few mA) or should a hypersensitive skin reaction occur, pulsed current (PC) is always the better choice.

Moreover, in the course of the subsequent maintenance therapy, pulsed current can be a viable alternative to direct current.

Direction of Current [E1/E2]

A change in the direction of current as it is required for the parallel treatment of two extremities (hands, feet, armpits) is not useful when treating with a textile electrode. It is recommended to set the direction of current in such a way that the textile electrode produces a higher impact than the counter electrode. This can be achieved with the following required setting and cable connection:

E1 (textile electrode) >> E2 (hands or feet)

The direction of current may, however, also be changed in order to modify the current perception or to minimize the typical metallic taste in the mouth which arises as soon as a current flows. Experience shows that the metallic taste is not a result of dental fillings or the like but rather mainly of the direction of current.

11.2 Treatment Session

To carry out a treatment session, follow the instructions in the manual of the Saalio device (also chapter 11.2).

Before starting make also sure that any metal objects in the current flow (jewellery, watches, glasses, braces) have been removed and open skin sites are covered (see chapter 3).

Important note: When initiating a therapy session, the **first thing to do is always power up the control device**. Only then you put on the textile electrode or place your hands or feet in the basin. Once the treatment is finished, you first remove the textile electrode or take your hands/feet out of the basin and **as a last step you turn the control device off**.

11.3 Treatment Phases

For any application with a textile electrode, you should - in addition to the initial and maintenance phases (see instructions for the Saalio® sets) - conduct a third short test phase beforehand, to be able to recognize undesired adverse reactions and risks early on. Hence, the first applications should be conducted with shorter times (2, 5 and subsequently 10 minutes) and lower currents (2, 4 and 6 mA). Only then, in the course of the so-called initial phase, you gradually increase duration and possibly current strength of the treatment, to be able to achieve the desired therapeutic effect.

Then determine the „individual current value“ for your skin area, which – although noticeable – is always to be perceived as still comfortable and never unpleasant.

Similar to the other parts of the body, treatment with a textile electrode is subsequently divided into an initial and a maintenance phase. Please refer to the user manual of the Saalio device for the according duration and frequency.

Tip:

It is best to conduct your treatment in the early evening. First of all, the skin has had a relatively long time to recover after the morning shave. Secondly, skin reddening, which is caused by increased blood circulation and subsides again relatively quickly, is better tolerated in the evening.

12 Drying and Cleaning

After every treatment session, put the textile electrode into a dry towel and press both together so that the towel can absorb all humidity from the mask. Make sure you avoid vigorous wringing of the textile electrode, as this could harm it.

Put the (still) wet textile electrode in a warm, dry location to ensure it can dry quickly. During the drying phase, the textile electrode shrinks and becomes stiff. Please do not unnecessarily deform the dry, stiff textile electrode as it can easily tear. Once the textile electrode comes into contact with water again, it becomes soft and pliable.

The textile electrode can be hand or machine washed at 30°C (use a mesh/laundry bag). A subsequent centrifuging or spinning of the textile electrode is to be avoided by all means - it is rather to be drip-dried. Due to its textile structure, the textile electrode should only be washed if needed so as not to unnecessarily shorten its service life.

13 Transport and Storage

Always store the textile electrode only when it is completely dry. Once the textile electrode has dried, it should no longer be bent or twisted since it can easily tear.

Do not expose the textile electrode to direct sunlight.

14 Troubleshooting with the Saalio® Helpdesk

If you encounter any issues with the device or have further questions, please contact the **Saalio® Helpdesk**. You can open this app using a QR code, which is located on the back of the control unit.

The app answers questions regarding:

- Efficacy
- Side effects
- Contraindications
- Body parts
- Device & technology

The **Saalio® Helpdesk** does not replace these instructions for use, but merely supplements them.

15 Product and Service Life

Due to its textile structure, the service life of the textile electrode has been determined to be 12 months for standard application.

16 Maintenance and Repair

(no maintenance and repair)

17 Warranty

The Saalio® textile electrodes, just as sponge pockets and foam inserts, are wear parts and thus excluded from any warranty claims. Should you, however, detect any material or manufacturing defects prior to your first use, please get in touch with us, using the contact information specified in the user manual.

18 Disposal Instructions

Disposal of packaging materials and waste electrical equipment

19 Manufacturer contact information

If necessary, contact the manufacturer for assistance with regard to the use or maintenance of the Saalio device or to report unexpected operations or incidents. All serious incidents related to the device, as defined in Regulation (EU) 2017/745 on medical devices, shall be reported to the manufacturer and the competent authority of the Member State where the user and/or the patient is established.



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