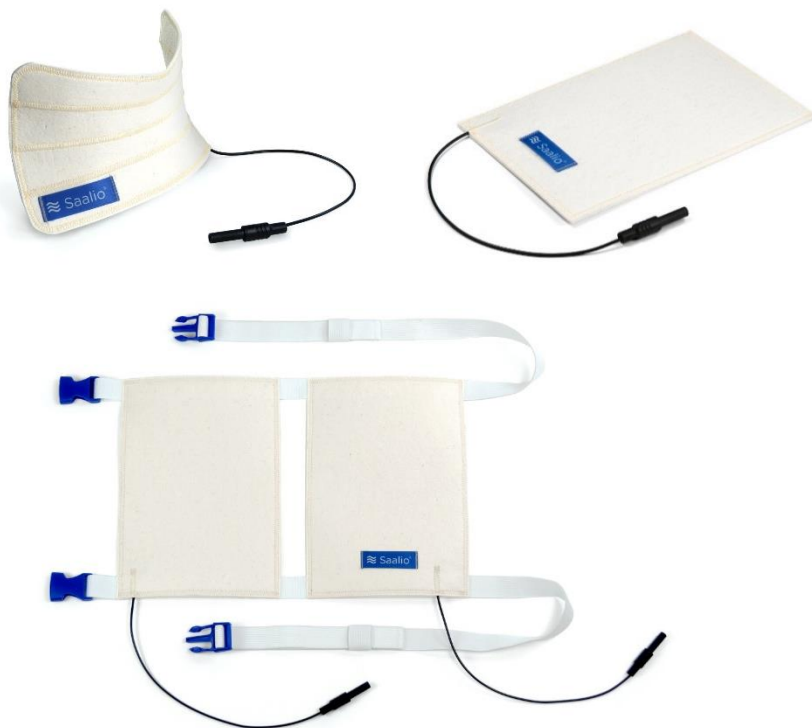


# Instructions for Use

## 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<sup>®</sup> therapeutic devices.

The Saalio<sup>®</sup> textile electrodes are not an independent medical device but rather an accessory electrodes for the following Saalio sets and may exclusively only be used with these:

- Saalio<sup>®</sup> DE (hands & feet)                    item No. 07-01-000-01
- Saalio<sup>®</sup> AX (underarms)                    item No. 07-01-000-07

These instructions for use contain supplementary information in addition to the general user manual for the Saalio sets in order to ensure safe and convenient use of the product.

**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

To be used with following device configurations:

- Saalio® DE (Hands & Feet)
- Saalio® AX (Armpits) plus Saalio® iontophoresis tray set

## 2 Accessories and Spare parts

In addition to the user manual of the Saalio® set:

Saalio® treatment basin for hands & feet                      Item No. 07-01-023-01

## 3 Safety Guidelines

(see user manual for Saalio® sets)

## 4 Symbol Legend

(see user manual for Saalio® sets)

## 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**

(see user manual for Saalio® sets)

## **7 Indications**

The Saalio® therapeutic device is used for the treatment of focal hyperhidrosis (excessive sweating).

## **8 Contraindications and Adverse Reactions**

(see user manual for Saalio® sets)

The same contraindications and side effects apply to the textile electrodes as to the Saalio® sets. Bear in mind contra induced metallic implants and objects, for example dental implants, inlays, braces and piercings.

## **9 Activation**

The device may only be used with a power supply that corresponds with the power adapter listed on the type plate. To ensure safe operation of the device, all electric cables, plugs, controls and housing components of the device must be in excellent condition. Prior to every activation, the device is to be checked for possible damages; a defective device 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

### 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.

Do not conduct any treatment of the face immediately after shaving. The current increasingly penetrates small skin defects and can locally lead to unfamiliar sensations of pain.

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.

Especially in the initial phase, tap water iontophoresis can result in dry skin, if applied frequently. It is advisable to treat your skin with a suitable care product immediately following the therapy session.

### 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]**

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

(see instructions for the Saalio® sets)

**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 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 Error Checklist**

(see user manual for Saalio® sets)

### **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 Electromagnetic Compatibility**

(see user manual for Saalio® sets)

## **19 Technical Data**

(see user manual for Saalio® sets)

## **20 Disposal Instructions**

### **Disposal of packaging materials and waste electrical equipment**

The device may not be disposed of in the domestic waste. Dispose of the device in a waste facility that accepts electronics/electrical appliances or contact the manufacturer.

## 21 Manufacturer contact information



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