

SAALMANN®

# User Manual

## Saalio® tap water-Iontophoresis-device

Item No. 07-01-000-02 Saalio UK (Hands & Feet)

Item No. 07-01-000-08 Saalio AX (Underarms)



We thank you for your confidence in Saalmann® therapy devices.

You made a wise choice: the Saalio® Iontophoresis device has been designed to combine maximum benefit with ease of use. It is easy to set up and simple to operate. This user manual will guide you through the setup procedure, familiarize you with its functions and offer advice and tips on the use of your new therapy system.

**Please review this user manual carefully!**

## Content

1 Scope of Delivery .....	3
2 Accessories and Spare parts .....	3
3 Safety Guidelines .....	4
4 Symbol Legend .....	6
5 Intended Use.....	7
6 Therapeutic Mode of Action .....	7
7 Indications .....	7
8 Contraindications and Side Effects .....	8
9 Initial Operation .....	9
10 Treatment Setup .....	9
11 Treatment Recommendation.....	12
11.1 Parameter Settings.....	12
11.2 Conducting Treatment.....	15
11.3 Treatment Phases .....	17
12 Cleaning and Disinfection.....	20
13 Transport and Storage .....	21
14 Error Checklist.....	21
15 Product Life Cycle and Service Life.....	22
16 Maintenance and Repair .....	22
17 Warranty.....	23
18 Electromagnetic Compatibility .....	24
19 Technical Data .....	25
20 Disposal Instructions .....	26
21 Manufacturer contact information.....	26
Appendix 1 – Electromagnetic compatibility .....	27
Appendix 2 - Patient Diary.....	30

## 1 Scope of Delivery

Saalio® DE (Hands & Feet)	Saalio® AX (Underarms)
1 control unit, 2 treatment basins, 2 silicone basin electrodes, 2 foam inserts, 2 electrode cables, 1 wide range power adapter, 1 user manual, textile bag.	1 control unit, 1 Set of silicone electrodes for armpits with sponge pads (1 pair), 2 electrode cables, 1 wide range power adapter, 1 user manual, 1 textile bag.

## 2 Accessories and Spare parts

Saalio® basin set for hands & feet	Art. No. 07-01-023-01
Saalio® set of electrodes for underarms (pair)	Art. No. 07-01-007-02
Saalio® face electrode	Art. No. 07-01-028-01
Electrode cable (pair)	Art. No. 07-01-004-02
Wide range power adapter	Art. No. 07-01-005-01
User manual (EN)	Art. No. 07-01-001-02
Textile bag	Art. No. 07-01-018-01

Spare parts (e.g. sponge pads or foam inserts) deliverable on request.

### 3 Safety Guidelines



The therapy system may only be powered by Saalio® power supply unit type FW7333SM/24 which has been specially designed for this device. The use of non-original parts may hazard the user and even lead to death. Using non-original spare parts and accessories also leads to immediate loss of warranty.



Place treatment device and trays on a firm, level surface.



Please always cover the treatment electrodes with the foam mats provided; otherwise, you might risk burns (electrical burn injuries, current marks). Avoid direct contact with the electrodes!



Make sure that the treatment device is at room temperature before you power it up.



Prior to starting a treatment session, please remove any metallic jewellery (rings, watches, bangles etc.), as current concentrations in these regions might result in local minor burns (electrical burn injuries, current marks).



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



Depending on the current strength selected, users may experience tingling or stinging sensations (discomfort) during the treatment.



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



You may remove your hands or feet safely from the treatment trays any time. In very rare cases, unpleasant electric shocks may occur; these are, however, absolutely harmless.



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



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 before further treatments are administered.



A patient may not be treated by two devices simultaneously.  
The device may not be modified.



The device may not be operated in the vicinity of short wave- and micro wave equipment. A minimum distance of 2 meters should be kept.



Disconnect the power supply from the socket if a thunderstorm approaches or if you do not plan to use the treatment device for an extended time.



Position the device so that you can unplug the power supply unit from the socket anytime.



This treatment device is designed for indoor use only. Do not expose it to rain or humidity.



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



Make sure you do not kink the cable too much and do not expose the cable to heat or chemicals. If a cable is damaged, unplug it from device or electrode, respectively, and have it checked by Saalman<sup>®</sup>.



Do not open the device. There are no control elements inside. The treatment system may only be serviced by Saalman<sup>®</sup>.

## 4 Symbol Legend

Symbols used in the user manual and on the device:



Caution: important note!



Protection class II – double insulated



Read the user manual!



Manufacturer's declaration



Disposal instructions:  
Do not dispose of the equipment with domestic waste!



Applied part type BF



Manufacturer

SN

Device serial number

## 5 Intended Use

The Saalio® therapy system has been designed to treat hyperhidrosis (excessive sweating of hands/feet and under the armpits) („intended use“). The Saalio® treatment device is intended for use in dry rooms in a home setting. Any use beyond this scope is considered „not according to intended use“. The manufacturer cannot accept any responsibility for personal injury or material damage that is or might be caused by usage beyond the scope of „intended use“.

## 6 Therapeutic Mode of Action

Treatment with the Saalio® is conducted by directing a treatment current to the affected body regions. The water bath facilitates this current flow which leads to a reduction of the sweat secretion of the skin regions that are submerged in the water.

This therapeutic effect 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 Indications

The Saalio® treatment device is used to treat hyperhidrosis (excessive sweating) of hands and feet. The system may also be used in the treatment of axillary hyperhidrosis, provided the optional axillary electrodes with sponge pouches are utilized.

## 8 Contraindications and Side Effects



Under no circumstances should Iontophoresis be performed if any of the following applies:

- User/s with a pacemaker
- User/s with an ICD (implanted cardioverter defibrillator)
- Pregnancy
- Metal-containing intrauterine pessary
- Metallic implants present in the current path (arms or legs)
- Large skin defects / wounds that cannot be covered with Vaseline
- Impaired sensibility in hands or feet (e.g. polyneuropathy)
- User/s with palpitations (cardiac arrhythmia)
- User/s with seizure disorders (epilepsy)
- 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



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 after the treatment
- Short-term reddening of the skin following the iontophoresis treatment, caused by a stimulated circulation (hyperemia), amongst others

- Blistering and electric burns caused by excessively high current strength

## 9 Initial Operation

The device may only be used with a power supply unit that corresponds with the power supply specified on the rating plate. To ensure safe operation of the unit, all its cables, plugs, control elements and housing components must be in faultless condition. Prior to each use, check the device for possible damage; a defective unit may not be operated. Pay attention to the references in unit and user manual. Please switch the unit off after you finished a treatment session.

## 10 Treatment Setup

### Setup for hands and/or feet

Set up your device as follows:

- Place the treatment trays on a level and firm surface. If you only treat your hands, place both trays next to each other on a table. If you only treat your feet, place both trays next to each other on the floor. If you treat hands and feet simultaneously, position one tray on the table and one on the floor.



- Connect an electrode cable to every electrode and plug each into connectors E1 and E2 at the back panel of the device. The selected connection configuration (e.g. right electrode to E1 and left electrode to E2) should be adhered to for the next treatment sessions.
- Place an electrode into each treatment tray.
- Carefully cover each electrode with a blue foam mat.



- Now fill both treatment trays with enough tap water (0.8 to 1.0 l per tray) so that the foam mat is covered with a few millimetres of water. The optimal water level has been reached when upon immersion of hands or feet, the palms or soles, respectively, are completely wetted by water and the outsides of fingers or toes are partially covered – about one third.

**Tip:**

You can use lukewarm water to make the treatment more pleasant.

## Setup for the armpits

Prior to applying the sponge electrode (= silicon electrode in sponge pouch), clean skin areas. Remove ointments, creams, and cosmetics.

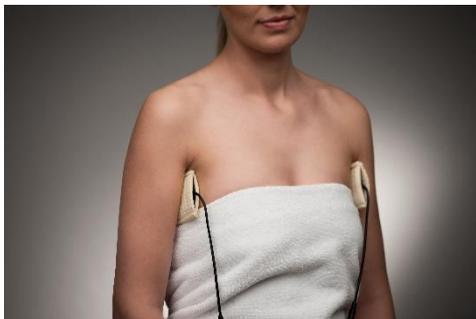
For reasons of hygiene, the sponge pouch should only be used by one person.

To avoid possible current-induced skin damage, the silicon electrode must be completely and firmly pushed into the sponge pouch.

Before starting a treatment session, thoroughly soak the sponge pouches and do not wring them out! To ensure current flow, the sponge pouches must be soaking wet. It might be necessary to re-soak them in the course of a treatment session. Shortly interrupt and soak the sponge pouches again. Insert the re-moistened sponge pouches, with the connector cables pointing to the front, into your armpits and keep them in place by applying slight pressure with your arms. If possible, avoid abrupt movements during the treatment, since these can cause current fluctuations. Should you experience irregular tingling or a strong burning sensation, soak the sponge pouches again and lower the treatment dose.

### Tip:

You can wrap a towel around your chest and protect yourself from the leaking water.



### Note

It is imperative that after every treatment you keep the sponge pouches clean and pull the electrodes out of the pouches for drying.

## 11 Treatment Recommendation

### 11.1 Parameter Settings

Before you place hands/feet into the filled basin or insert the axillary electrodes with the wet sponge pouches into your armpits, turn on the device on the main switch located at the back panel of the device. The display now shows all treatment parameters. By pressing the **buttons < >** you can adjust the current setting which is always shown in blue in the display. Pressing the **SET-button** will take you to the next line and you can change these settings accordingly.



#### Treatment Duration [min:sec]

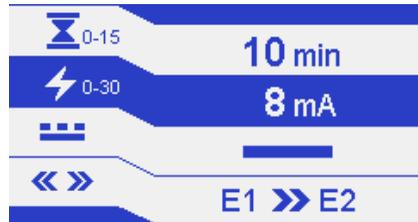
The initial factory setting for treatment duration and current strength is „1“. In the course of later treatments, the device stores the last parameter settings used. These automatically appear when the device starts up for the next treatment.



Now set the treatment duration in minutes. Successful treatment requires a sufficient duration but the latter can be limited by your individual current sensation. If possible, select a maximum duration of 15 minutes, but at least 10 minutes. In case current or duration become too unpleasant, reduce the treatment current rather than the treatment time.

## Current Setting [mA]

**For the first treatment, adjust the setting to a low current from 1 to 3 mA.** Thereafter, increase it according to personal perception in the course of a treatment session as well as between the treatments. The electricity should be incrementally increased to a value where a tingling or heat sensation is felt. Under no circumstances may the current be pre-set to a value that causes unpleasant or even painful sensation to the skin. The current strength is displayed in mA (milliampere) units.



We know from experience that personal electric current perception, actual body resistance as well as skin compatibility varies greatly from patient to patient. Especially at the onset of the therapy, the user must determine for him/herself which current strength is tolerable. Within limits, the individual tolerance can also fluctuate between the applications or change in the course of the treatment so that higher current values are accepted.

### **Tip:**

For your first treatment sessions and in order to find your individual current setting, you can ask a second person to gradually increase the current. This way you do not have to interrupt the therapy – especially if you are treating your hands – and the adjustment is done more quickly.

The electric current perception also depends on the limbs being treated – frequently, the feet are the least sensitive, the underarms on the other hand the most tender.

The combined hand/foot treatment requires significantly higher currents than the according individual treatment of the extremities. Due to the doubling and thus larger skin surface to be treated, higher currents are required to obtain a comparable therapeutic effect (current density).

## **Current form [DC (direct) /PC (pulsed)]**

The Saalio® gives you the option to choose between a treatment with direct current or pulsed current. The direct current setting is symbolised by a solid bar, the pulsed one by a broken bar (see illustration).



**Direct current (DC)** is more effective than pulsed current based on experience. To expeditiously achieve visible therapeutic success, the therapy starts preferably with direct current and is continued with direct current until a satisfactory reduction and normalization of the perspiration has been achieved.

**Pulsed current (PC)** is less effective than direct current. On the other hand, the electric current perception is significantly reduced when pulsed current is applied so that higher currents can be tolerated. To sum it up: pulsed current is usually less effective than direct current.

For this reason, pulsed current should only be selected in those cases where direct current is perceived as painful even at relatively low current values or if the skin is sensitive. Pulsed current lends itself to maintenance therapy, when the introduction of less electricity is sufficient to maintain the reduction of perspiration.

## **Direction of Current Flow [E1/E2]**

In general, Saalio® treatments are not impacted by the direction of current flow. The results achieved on that part of the body where the current flows from water to body are, however, somewhat better. In



order to ensure a uniform sweat reducing effect on the extremities, you should reverse the direction of current from one treatment session to the next but never within one treatment session!

The selected direction of current is indicated by the double arrow. You can reverse the direction of current by pressing the buttons < or > between jacks E1 and E2 on the rear of the device.

**Pressing the „Set“ button will take you back to the top line (treatment time).**

## 11.2 Conducting Treatment

Only after you have set or confirmed the above parameters on the device, you can start the treatment by placing your hands / feet into the treatment trays (treatment start: short beep). As soon as current flows, the current symbol flashes and the time display showing the remaining treatment time starts counting down.

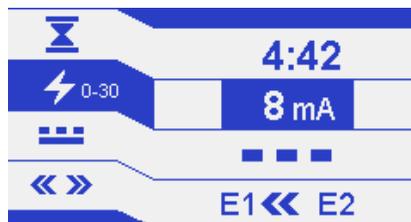


At the onset of the therapy, the current flow is slowly increased until the value indicated has been reached. A bar display right and left of the set current value helps you visualize the booting of the therapy current. A completely filled bar indicates full current flow according to the value indicated.

Should the Saalio® detect irregularities in the power circuit within a treatment session, e.g. caused by movements of hands or feet, the device shuts down the therapy current and then slowly reboots to the set point (safety component).

Within the parameters of a treatment session, only the treatment dose can be adjusted. All other parameters can only be changed at the next session after having activated the on/off switch.

The device switches to „**pause**“ **mode**, when you remove your hands/feet from the tray and thus interrupt the current flow. The current symbol stops blinking, the treatment timer is halted and the remaining time appears blinking in the display. Moreover, the device „beeps“ to indicate that the „pause“ mode has been activated. Once hands and/or feet are placed in the tray again, the treatment session continues.



The treatment dose is reduced towards the end of the treatment. Do not remove your hands/feet from the tray until the device has beeped 3 times, thus indicating that the treatment session is finished.

The device switches to **short-circuit mode** if it detects an unnaturally low total resistance, e.g. because 2 electrodes have been placed in a tray. The short-circuit mode is indicated by a continuous beep as well as the „Caution“ symbol appearing in the display. Once the error has been fixed, the device returns to the icon for setting treatment parameters.



**Only after the treatment session** is finished, turn off the device at the main switch.

### 11.3 Treatment Phases

In the initial part of the so-called **therapy initiation**, adjust the Saalio® device accordingly to let you experience the sweat-reducing effect on an extremity as quickly as possible. If you see for yourself the efficacy of the device, you will be motivated to carry on with the additional therapy. In the course of 10 to 14 days, first results should be noticeable.

As soon as you notice any positive effect, the second part of the initial phase begins. Reverse the direction of current after every application to ensure that both parts of the body are treated equally. Continue the therapy strictly and without any change in frequency and duration until the perspiration is reduced to the desired degree. This phase can take an additional 3 to 4 weeks.

After conclusion of the initial phase, switch to the so-called **maintenance therapy**. The Saalio® device is now to be applied continuously but less frequently to maintain the status quo. As a rule, it is sufficient to conduct treatments 1 - 2 times per week.

**Tip:**

In the initial phase, treat hands and feet separately: this will help you determine the according optimum parameters which will speed up the visible effect.

Only if the electric current perception and the actual current values for hands and feet are comparable, does a combined treatment of hands and feet make sense.

## Overview of the treatment phases:

Phase	Initial phase part 1	Initial phase part 2	Maintenance phase
Goal	Recognizing the therapeutic effects on <b>one</b> extremity	Reducing/normalising sweating on <b>both</b> extremities	Maintaining the status
Duration	10 to 14 days	3 to 4 weeks	Continuous
Extremities	Hands, feet and armpits each paired, <u>no</u> combination treatment)	Hands, feet and armpits each paired, <u>no</u> combination treatment)	hands, feet and armpits each paired or combination treatment
Number/duration of applications	10 min. daily or 4 x week 15 min. each	10 min. daily or 4 x week 15 min. each  (in the transition to maintenance phase incrementally less)	15 min. 1 to 2 times per week
Direct (GS), pulsed (PS) current	preferably GS, PS if required	preferably GS, PS if required	GS or PS
Direction of current	<b>constant</b>	<b>alternating</b>	alternating
Current:	<p><b>It is impossible to provide reliable guide values for therapeutically effective and simultaneously tolerable current strengths since these can fluctuate very strongly from individual to individual.</b></p> <p>Start your very first application (for each part of the body) with very low values of 1 to 3 mA. Increase the current during the application incrementally, so that the electricity is noticeable, but not unpleasant.</p> <p>In the following applications always re-adjust this value according to your individual sensation and your experience. The electric current should be noticeable and simultaneously tolerable.</p> <p>Reduce the electricity if this is painful or the skin displays irritations which do not completely subside again after a few hours!</p>		



## 12 Cleaning and Disinfection

The Saalio® treatment system is generally maintenance free. Please wring out the foam mats or sponge pouches thoroughly. **It is essential to dry the treatment electrodes after every treatment to prevent calcium deposits on the electrodes!**

### Note:

Discoloration of water and trays after the first treatment sessions is common (leaching of the electrode materials). Foam mats, silicon electrodes as well as sponge pouches can change colour in the course of use.

**Please only store completely dry accessories in the trays!**

### Cleaning (if required)

Clean control unit, treatment trays and electrodes with a damp cloth. Also acceptable are surface disinfectants suitable for acrylic glass, like.

- Esemfix des
- Descosept Spezial
- Mikrozyd sensitiv liquid
- Sani Cloth Active

### **Cleaning the tray electrodes and axillary electrodes with sponge pouches**

For hygienic reasons, clean sponge pouches and silicon electrodes after every treatment session under clear running water (max. 30° C). To this end, remove the silicon electrodes from the sponge pouches. Afterwards, wring the sponge pouches out and let them dry. Dry the silicon electrodes with a cloth.

If necessary, you can wash sponge pouches and foam mats as well as the textile bag in the washing machine at 30 degrees C.

You may also use suds (non-ionic tensides) and disinfectants to clean sponge pouches and silicon electrodes. Store sponge pouches and foam mats as well as all other materials in a dry place to avoid possible mould growth

## 13 Transport and Storage

When transporting the Saalio® treatment device, protect it from unnecessary shocks. Store the therapy system in a dry room and do not expose it to high temperatures.

## 14 Error Checklist

Should prior to, during, or after a treatment session the functionality of the device not comply with what is described in the user manual, please work through this checklist before you send us the device for repair. You could save yourself and us a lot of expense and inconvenience. Thank you kindly!

- Verify if the power supply unit is properly connected with the control unit and your power grid. The green LED on the power supply unit is lit.
- Verify if the plugs of the electrode cables have been pushed far enough into the receptacles of the treatment electrodes and if they make secure contact.
- The therapy current will only boot up to the selected set point if treatment time has been set to more than 1 minute **and** the skin areas to be treated have closed the treatment circuit

### Rule out a device defect:

For further diagnosis, it is very useful to verify that the unit is basically working, i.e. also without any body resistance. Prepare a basin for the hand treatment as described above. Now, instead of a hand, place the second basin electrode on the foam insert moistened with water and adjust the device for automatic start of the treatment. Now observe if the unit actually commences with the treatment (countdown running, energy symbol flashing)?

**YES**, treatment is initiated. Consequently, the device works correctly. In your case, water and/or body resistance is too high. In order to determine which of the two types of resistance is too high and possibly remedy the situation, proceed as follows:

Determine body resistance:

The first step is to make sure that your skin is free of oily or greasy residue from creams, cosmetics or cream soaps. Also, make sure the water level is sufficient. Try once more to initiate the treatment on yourself. Should the device still not start automatically, ask someone else to conduct the treatment on him/herself. If the device works properly for another person, your personal body resistance is too high and the device does not start for safety reasons.

Determine water resistance:

If the device also does not start properly for another person, the water resistance is probably too high (e.g. in case of very soft water). Replace the tap water by still mineral or table water and re-try initiating the treatment. Additionally or alternatively, you can also put a very thin fleece or sponge cloth as cover on the electrodes instead of the foam insert as this measure will reduce the water path and thus the resistance.

In case of a device failure or if the above-mentioned measures to reduce resistance remain unsuccessful, please contact us by phone.

## **15 Product Life Cycle and Service Life**

The service life of the medical device is determined to be 5 years. Consumables are excluded. The manufacturer has to inspect the medical device not later than by the end of this deadline. Every successful reconditioning measure by the manufacturer extends the service life of the medical device by one year.

## **16 Maintenance and Repair**

To avoid transport damage, please always put the device in the treatment trays provided. If possible, ship in the original packaging. Please make

sure that the device is protected against shocks and that packaging is suitable for the method of shipment selected.

In case of a malfunction, we can only take responsibility for safety, performance, and reliability of the device if it is repaired by us or by persons contracted by us. Any manipulation on or repair of the device by persons not authorised by us renders our warranty and liability null and void.

**Please don't forget to clean and dry the device and accessories prior to shipping it!**

It is imperative that you please also send us all of the electrical accessories (power supply unit, tray electrodes or electrode cables, respectively) along with the Saalio® control unit.

## **17 Warranty**

The Saalio® therapy system has been manufactured and tested with the greatest care. Should, however, a malfunction occur, we grant you a manufacturer warranty for all defects caused by material deficiency or manufacturing error. The manufacturer warranty extends over 4 years for final customers/consumers and 2 years for commercial customers (the provisions of the manufacturer's general terms and conditions in the version in force at the date of purchase are applicable).

Any intervention on the therapy device by buyer or third parties renders the warranty claim void. Any defects or faults which are or might be caused by improper handling or disregard for the „intended use“ or the instructions in the user manual result in the immediate loss of warranty claims against the manufacturer.

Categorically excluded from all warranty claims are wear parts. Should you have any reason for a claim, please get in touch with us. The contact information is specified in the user manual.

## **18 Electromagnetic Compatibility**

As a matter of course, the Saalio® treatment device has been developed and manufactured according to the mandatory guidelines for electromagnetic compatibility (EMC).

### **Note:**

With regard to EMC, medical electrical equipment is subject to particular precautions. Please follow the corresponding instructions in appendix 1.

## 19 Technical Data

<b>Dimensions Control Unit</b>	L x B x H	200 x 150 x 60 mm
<b>Weight</b>	0,3 kg	
<b>Input</b>	Supply Voltage:	24 V DC
	Current Input:	max. 80mA
	Performance Input:	max. 1,92 W
<b>Ambient Temperature Relative Humidity of Air Barometric Pressure</b>	+10°C till +30°C 30% till 70 % 700hPa till 1060hPa	
<b>Output Direct Current</b>	Treatment Voltage	max. 58 V=
	Treatment Current	max. 30 mA
<b>Output Pulsed Current</b>	Treatment Voltage	max. 58 V=
	Treatment Current	max. 30 mA
	Pulse Rate	10 kHz Rectangular

### Power Supply unit

<b>Input</b>	Input Voltage:	100-240 V~ / 50-60 Hz
	Max. Current Input:	200 mA
<b>Output</b>	Rated Output Voltage:	24 V=
	Current Output:	max. 330mA
	Max. Output Rating:	8 VA

## 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



Saalmann medical GmbH & Co. KG  
Suedbahnstrasse 34  
D-32547 Bad Oeynhausen  
Germany

Internet: [www.saalmann-medical.de](http://www.saalmann-medical.de)

Mail: [info@saalmann-medical.de](mailto:info@saalmann-medical.de)

Phone +49 (0)5731 25450 0

Fax +49 (0)5731 25450 11

## Appendix 1 – Electromagnetic compatibility

<b>Electromagnetic emissions</b>		
The Saalio device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.		
<b>interference emission</b>	<b>Compliance</b>	<b>Electromagnetic surrounding - Guidance</b>
RF emission according CISPR 11	Group 1	The Saalio device unit 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.
RF emission according CISPR 11	Class B	The Saalio device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission according IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

<b>Electromagnetic immunity</b>			
The Saalio device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601-test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transients / bursts IEC 61000-4-4	± 2 kV for power supplies ± 1 kV for input/output lines	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV for line(s) to line(s) ± 2 kV for line(s) to earth	± 1 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<b>&lt; 5 % <math>U_T</math></b> (> 95 % dip in $U_T$ ) for 0.5 cycle <b>40 % <math>U_T</math></b> (60 % dip in $U_T$ ) for 5 cycles <b>70 % <math>U_T</math></b> (30 % dip in $U_T$ ) for 25 cycles	<b>&lt; 5 % <math>U_T</math></b> (> 95 % dip in $U_T$ ) for 0.5 cycle <b>40 % <math>U_T</math></b> (60 % dip in $U_T$ ) for 5 cycles <b>70 % <math>U_T</math></b> (30 % dip in $U_T$ ) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Saalio unit requires continued operation during power mains interruptions, it is recommended that the Saalio device is powered from an uninterruptible power supply or a battery.

	<b>&lt; 5 % <math>U_T</math></b> (> 95 % dip in $U_T$ ) for 5 s	<b>&lt; 5 % <math>U_T</math></b> (> 95 % dip in $U_T$ ) for 5 s	
Power frequency (50/60 Hz) magnetic field  IEC 61000-4-8	<b>3 A/m</b>	<b>3 A/m</b>	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: $U_T$ is the a. c. mains voltage prior to application of the test level.			

<b>Electromagnetic Immunity</b>			
The Saalio device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601-test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
			Portable and mobile RF communications equipment should be used no closer to any part of the Saalio device unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b>
Conducted RF IEC 61000-4-6	<b>3 Vrms</b> 150 kHz to 80 MHz	<b><math>V_1 = 3 \text{ Vrms}</math></b>	$d = 1,2\sqrt{P}$
Conducted RF IEC 61000-4-3	<b>3 V/m</b> 80 MHz to 2,5 GHz	<b><math>E_1 = 3 \text{ V/m}</math></b>	$d = 1,2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ for 800 MHz to 2,5 GHz
			where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol  
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			

**Recommended separation distances between portable and mobile RF communications equipment and the Saalio device**

The Saalio device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Saalio device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Saalio device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 kHz to 800 MHz $d = 1,2\sqrt{P}$	800 kHz to 2,5 GHz $d = 2,3\sqrt{P}$
<b>0,01</b>	<b>0,12</b>	<b>0,12</b>	<b>0,23</b>
<b>0,1</b>	<b>0,37</b>	<b>0,37</b>	<b>0,74</b>
<b>1</b>	<b>1,17</b>	<b>1,17</b>	<b>2,33</b>
<b>10</b>	<b>3,69</b>	<b>3,69</b>	<b>7,38</b>
<b>100</b>	<b>11,67</b>	<b>11,67</b>	<b>23,33</b>

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Appendix 2 - Patient Diary

Name: \_\_\_\_\_

Attending physician: \_\_\_\_\_

date	treated area	parameter: mA, PC/DC	length of time (min)	notes



## Accessories and Spare parts for the Saalio® Sets:



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



Saalio® set of electrodes for underarms (pair)  
with sponge pouches (1 pair)  
Item No. 07-01-007-02



Saalio® face electrode  
Item No. 07-01-028-01



Saalio® fresh & natural 75 ml  
(Plant-based odor-inhibiting gel)  
Item No. 07-03-002-01

The sweat reducing treatment with the Saalio® device is ideally complemented by Saalio fresh & natural, an odor-reducing gel based on purely plant-derived substances.

More information on: [www.saalmann-medical.de](http://www.saalmann-medical.de)

or directly order on: [www.saalmann-medical-shop.de](http://www.saalmann-medical-shop.de)