Saalio®

User Manual

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

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 pouches (1 pair), 2 electrode cables, 1 wide range power adapter, 1 user manual, 1 textile bag.

2 Accessories, Combination Products and Spare Parts

The Saalio® DE and Saalio® AX can be operated without separate accessories.

To treat other parts of the body such as the face, forehead, neck and trunk, the Saalio® DE and Saalio® AX can be combined with additional Saalio® textile electrodes (see page 33).

The sponge pouches and foam inserts are wear parts. The following components can be ordered subsequently at www.saalmann-medical-shop.de.

Electrode cable pair (length each 1.5 m)	Art. No. 07-01-004-02
Wide range power adapter	Art. No. 07-01-005-01
Foam insert (pair)	Art. No. 07-01-006-03
Sponge pouches (pair)	Art. No. 07-01-021-03
User manual (EN)	Art. No. 07-01-001-02
Textile bag	Art. No. 07-01-018-01

3 Safety Guidelines

The therapy system may only be powered by Saalio® power supply unit which has been specially designed for this device. The use of non-original parts may hazard the user and even lead to death. The use of non-original parts may also result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and may result in incorrect operation. The use of non-original parts will result in the immediate loss of the warranty.

The use of this device next to other equipment should be avoided, as it may result in improper operation. If the use as described above should nevertheless be necessary, this equipment and the other equipment should be checked for proper operation.

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

Please always cover the black electrodes with the foam mats or sponge pouches provided; otherwise, you might risk electrical burn injuries or current marks. Always avoid direct contact with the electrodes!

Make sure that the treatment device is at room temperature before you power it up. Depending on storage conditions the temperature adaptation may take up to 2 hours.

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 electrical burn injuries or current marks.

Any small skin lesions (wounds) 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.

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

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.

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 treatments, 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.

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

The device may not be operated in the vicinity of short wave- and micro wave equipment. RF communications equipment (radios) and their accessories (such as antennas) should not be used within 30cm of the Saalio equipment components and wiring. Observe the recommended EMC protective distances in Appendix 1. Failure to do so may lead to a reduction in the performance of the device.

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.

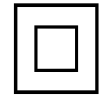
Make sure you do not kink the cable too much and do not expose the cable to heat or chemicals. If a cable is damaged, unplug it from device or electrode, respectively, and have it checked by Saalmann®.

Do not open the device. There are no control elements inside. The treatment system may only be serviced by Saalmann®.

According to EN60601-1-2 the Saalio® Iontophoresis device does not have any essential performance characteristics that are not related to the basic safety.

4 Symbol Legend

Symbols used in the user manual and on the device:

	Caution: important note!		Medical Device
	Read the user manual!		Manufacturer's CE-declaration with no. of Notified Body
	Manufacturer		Protection class II – double insulated
	Device serial number		Applied part type BF
	Lot. No.		Disposal instructions: Do not dispose of the equipment with domestic waste!

5 Proper Use

The unit is to be used in closed rooms and a dry environment. Allow the unit to reach room temperature before conducting a treatment. The required minimum distance to shortwave microwave devices depends on their frequency and transmission power and is defined in the EMC tables (see attachment 1). For additional information, please refer to item 9 in the operating instructions.

The unit may only be used on a power supply that matches the supply voltage specified on the rating plate. The cables, plugs, operating elements and housing parts on the unit must be in faultless condition to ensure safe operation of the unit. Before each start-up, the unit must be checked for possible damage; a defective unit must not be operated. The instructions on the unit and in the operating instructions manual must be observed. After completion, the unit must be switched off. For cleaning and disinfecting the unit, follow the operating instructions in point 12.

Any use beyond this scope is considered „not according to proper 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 „proper 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 Indication

The device is used to treat **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 sponge pouches 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 of hands, feet and armpits 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. The treatment of children and adolescents must only be carried out under the supervision of an adult. 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 Side Effects

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

- 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
- 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
- Hands and feet: children up to 6 years
- Armpits: children up to 12 years

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)

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.

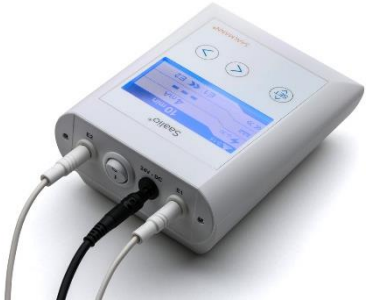
10 Treatment Setup

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.



- Fill each treatment tray with only enough tap water so that when immersing the hands or feet, the palms or soles are completely wetted with water, as well as the lower third of the outer sides of the fingers and toes (about 0.8 to 0.9 l per tray).

  Tip:
  Use lukewarm water - this makes the therapy more pleasant and the skin pores open.

Setup for the armpits

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

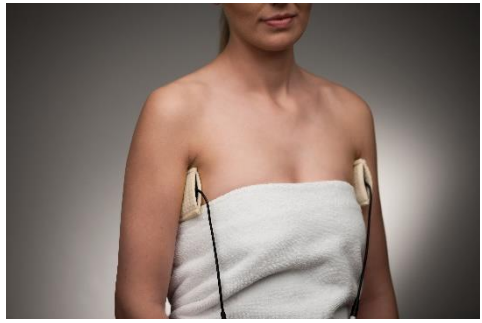
For reasons of hygiene, the sponge pouch should only be used by one person.

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 pause 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.

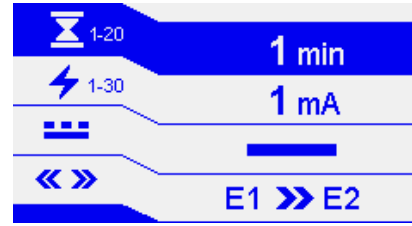
11 Treatment Recommendation

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.

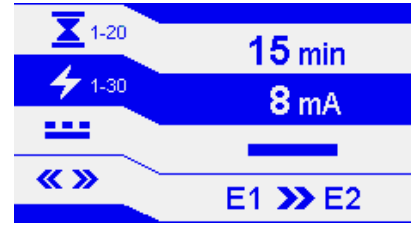
Treatment Duration [min:sec]

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 you have selected constant current flow (E1 << E2) or (E2 << E1), choose a treatment duration of 10 to 15 minutes. If you chose the AUTO setting (automatic change of the direction of current flow), select a treatment duration of 15 to 20 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 children with small extremities or maintenance therapy, when the introduction of less electricity is sufficient to maintain the reduction of perspiration.

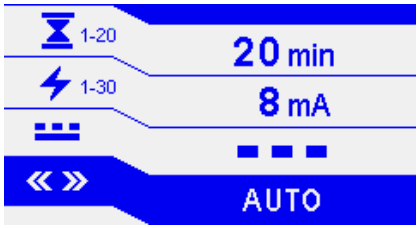
Direction of Current Flow [E1/E2]

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 continuously!

You can change the direction of current flow either manually between treatment sessions by alternating between the modes (E1 >> E2) and (E1 << E2). The

double arrow indicates the selected direction of current between jacks E1 and E2 on the rear of the device.

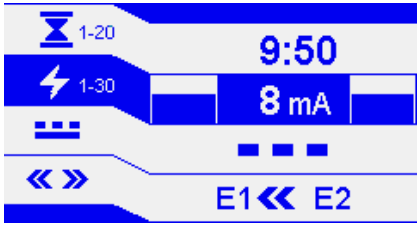
Alternatively, the direction of current flow can be automatically reversed when in (AUTO) mode. Half way through the duration of therapy, the current flow is automatically reduced, the direction of current flow is reversed and the current is again increased to its previous value. In individual cases, the automatic polarity change may be accompanied by discomfortable sensations.



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

11.2 Treatment Session

The device is ready to operate after you have set the parameters on the device or after you have confirmed the saved parameters by pushing the SET-button at least. The therapy starts by closing the electric circuit, which means by placing your hands / feet into the treatment trays or placing both underarm electrodes with sponge pouches (**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.



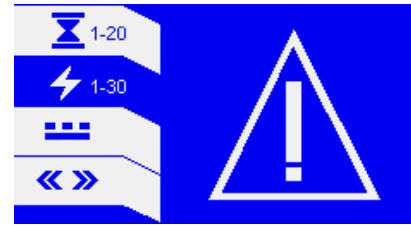
At the onset of the therapy, the current flow is slowly increased until the value indicated has been reached. A bar display right and left of the set current value helps you visualize the booting of the therapy current. A completely filled bar indicates full current flow according to the value indicated.

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. Now, continuously reverse the direction of current flow to ensure that both parts of the body are treated equally well. You can reverse the direction of current flow either manually between treatment sessions or select the automatic option to reverse the direction of current flow (see chapter 11.1 – Direction of Current Flow E1/E2). 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.

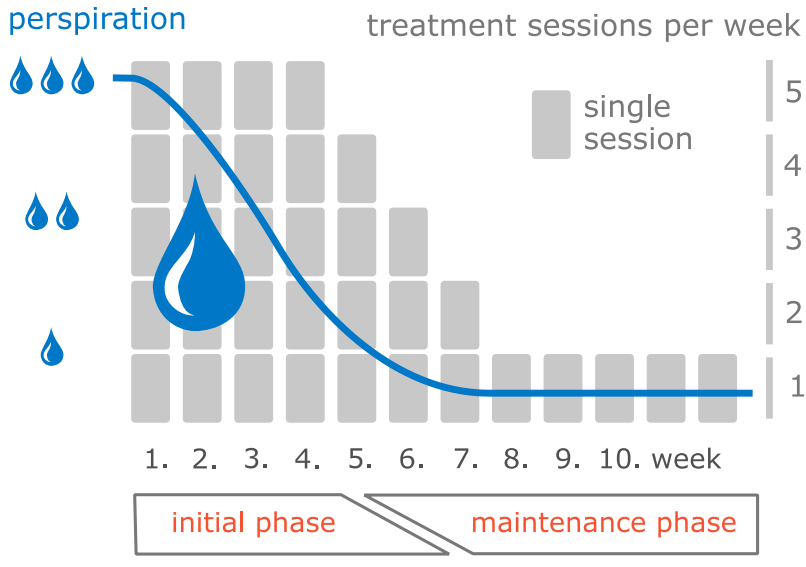
Tip:
In the initial phase, treat hands and feet separately: this will help you determine the according optimum parameters which will speed up the visible effect.

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.

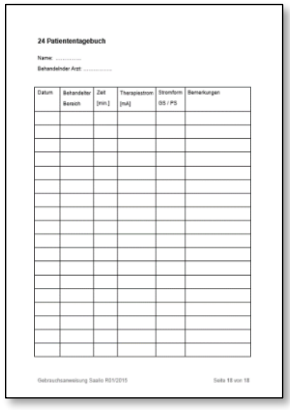
Overview of the treatment phases:

Phase	**Initial phase part 1**	**Initial phase part 2**	**Maintenance phase**
Goal	Recognizing the therapeutic effects on **one** extremity	Reducing/ normalising sweating on **both** extremities	Maintaining the status
Duration	10 to 14 days	3 to 4 weeks	Continuous
Extremities	Hands, feet and armpits each paired, no combination treatment)	Hands, feet and armpits each paired, no 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 minutes daily or 4 x/week for 15 to 20 min. each (in the transition to maintenance phase incrementally less)	1 to 2 times a week for 15 to 20 min. each
Direct (GS), pulsed (PS) current	preferably GS, PS if required	preferably GS, PS if required	GS or PS
Direction of current	**constant**	Manual / automatic reversal	Manual / autom. reversal
Current:	**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.** 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. 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. Reduce the electricity if this is painful or the skin displays irritations which do not completely subside again after a few hours!		

Schematic Therapy Procedure:



Tip:



Use the patient diary to record the treatments as well as possible changes or personal settings and also to note side effects.

12 Cleaning and Disinfection

Before cleaning and disinfecting switch off the device and unplug it from the mains. Clean control unit, treatment trays and electrodes with a damp cloth.

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.

When using the device by several patients, the sponge cloths and foam inserts must always be used by only one single user. The other components, such as the trays, silicone electrodes, the cables and the control unit, must be cleaned and disinfected before any patient change, in order to prevent infections between patients. The disinfectant must be approved for cleaning and disinfecting medical devices with sensitive surfaces (Plexiglas). The following disinfectants can be used for this purpose: Cleanisept®, mikrozid® sensitiv liquid or Sani-Cloth™ Active.

For a sufficient disinfecting effect, the application instructions of the respective manufacturers, in particular the exposure times, must be observed.

13 Transport and Storage

After each treatment wring out the foam mats or sponge pouches thoroughly. It is essential to dry the treatment electrodes and trays after every treatment to prevent calcium deposits on the electrodes. Please only store completely dry components in the trays.

Store the therapy system in a dry room and do not expose it to high temperatures or direct sunlight. Store sponge pouches and foam mats as well as all other materials in dry conditions and places to avoid possible mould growth.

When transporting the Saalio® treatment device, protect it from unnecessary shocks. Follow the transport and storage conditions (item 20).

Note:
Foam mats, silicon electrodes as well as sponge pouches can change colour in the course of use.

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 parameters have been confirmed by pushing the SET-button once **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) or the short-circuit symbol appears (triangle in the display, warning tone)?

YES, treatment is initiated or the short circuit symbol appears. 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. Spare parts (see item 2) 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

The Saalio® treatment system is generally maintenance free. Nevertheless the manufacturer recommends a maintenance at least every 2 years for commercial use. The commercial user is responsible for compliance with the required inspection resulting from national operator obligations and occupational health and safety regulations.

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 its components prior to shipping it!

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

17 Warranty

The manufacturer grants a 4-year warranty for the Saalio® therapy device from the date of delivery. (The manufacturer's terms and conditions apply in the version valid on the date of delivery).

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 spare parts (foam inserts and sponge pouches).

18 Electromagnetic Compatibility

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

19 Technical Data

Control Device

Dimensions Control Unit [L x B x H]		150 x 120 x 65 mm
Weight		0,3 kg
Input	Supply Voltage:	24 V DC
	Current Input:	max. 130 mA
	Performance Input:	max. 3,1 W
Output Direct Current	Treatment Voltage	max. 58 V=
	Treatment Current	max. 30 mA
Output Pulsed Current	Treatment Voltage	max. 58 V=
	Treatment Current	max. 30 mA
	Pulse Rate	10 kHz Rectangular
Protected against solid foreign objects ≥ 12,5 mm and vertically falling water drops (power supply excluded)		IP21

Power Supply unit type FW8002M/24(1) or FW8000M/24(2)

Input	Input Voltage:	100-240 V~ / 50-60 Hz
	Max. Current Input:	200 mA
Output	Rated Output Voltage:	24 V=
	Current Output:	max. 300(1) oder 500(2) mA
	Max. Output Rating:	7,2(1) oder 12,0(2) VA

Overall System

Requirements for:	Operation	Transport and Storage
Temperature	+10°C to +30°C	-20°C to +70°C
Relative Humidity	30 % to 70 %	< 90 %, non-condensing
Atmospheric Pressure	700 hPa to 1060	700 hPa to 1060 hPa

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

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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Appendix 1 – Electromagnetic compatibility

Electromagnetic emissions 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.		
interference emission	**Compliance**	**Electromagnetic surrounding - Guidance**
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	

Electromagnetic immunity 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.			
Immunity test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD); IEC 61000-4-2	**± 8 kV** contact discharge **max. ± 15 kV** air discharge	**± 8 kV** **± 15 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	**± 2 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)	**± 1 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	**0 %** U_T for 0.5 cycle **0 %** U_T for 1 cycle **70 %** for 25 cycles **0 %** U_T for 250/300 cycles	**0 %** U_T for 0.5 cycle **0 %** U_T for 1 cycle **70 %** for 25 cycles **0 %** U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Saalio device requires continued operation during power mains interruptions, it is recommended that the Saalio device is powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field; IEC 61000-4-8	**30 A/m**	**30 A/m**	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.			

Electromagnetic Immunity

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.

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Saalio device, including cables, than the recommended separation distance (d in meter) calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	**3 V rms** 150 kHz to 80 MHz **6 V rms** 150 kHz to 80 MHz within ISM bands and amateur radio bands	**3 V rms** **6 V rms**	
Radiated RF IEC 61000-4-3	**10 V/m** 80 MHz to 2700 MHz	**10 V/m**	
Radiated RF according IEC 61000-4-3 in close proximity to wireless communication devices	according to IEC 60601-1-2:2014 Table 9	**passed**	(corresponds to a recommended safety distance of 0.3 m to the devices of the corresponding radio services)
			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.			

Appendix 2 - Patient Diary

Name: _____

Attending physician: _____

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

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

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

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

The Saalio® sets can be combined with following products:

Art. No. 07-01-023-01 Saalio® treatment basin for hand or feet
(counter electrode for face, forehead, neck or body)
Art. No. 07-01-007-02 Saalio® armpit electrodes with sponge pouches (pair)
Art. No. 07-01-028-01 Saalio® face electrode*
Art. No. 07-01-028-02 Saalio® universal electrode*
Art. No. 07-01-028-03 Saalio® neck electrode*
Art. No. 07-01-028-04 Saalio® forehead electrode*
Art. No. 07-01-028-05 Saalio® body electrodes (pair)*
(* for users from 18 years)






More information on: www.saalmann-medical.de

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