(de) Gebrauchsanweisung

(en) User's Manual

(fr) Mode d'emploi

(it) Istruzioni per l'uso

(es) Instrucciones de empleo

(pt) Manual de operação

(ru) Руководство по применению

SwiSto3

CE
1304

MEDIZINTECHNIK
seit 1890
KaWe

de Bitte lesen Sie diese Gebrauchsanweisung vor der Benutzung sorgfältig und vollständig durch und beachten Sie die Pflegehinweise.

en Please read this User's Manual thoroughly and carefully before attempting to use this product and heed the given care instructions.

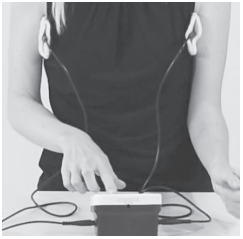
fr Lisez ce mode d'emploi attentivement et entièrement avant d'utiliser l'appareil et respectez les consignes d'entretien.

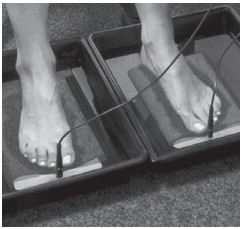
it Si prega di leggere attentamente queste istruzioni per l'uso prima di utilizzare lo strumento e di seguire i consigli per la manutenzione.

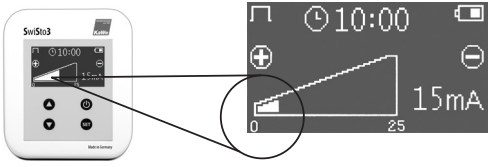
es Por favor, lea con atención las presentes instrucciones de empleo en su totalidad y siga las indicaciones referentes al cuidado del aparato.

pt Antes de utilizar este produto pela primeira vez, favor de ler com muita atenção todo este manual de operação e observar as indicações relativas à manutenção.

ru Перед использованием следует полностью и внимательно прочитать настоящее руководство по применению и соблюдать указания по уходу!







de

Wichtiger Hinweis vor jeder Anwendung:

1. Bitte jede Behandlung mit der niedrigsten Stufe der Behandlungsstromstärke beginnen.
2. Bitte nie mit den Finger-/Fußspitzen voraus sondern vollflächig und mit gleichmäßigem Druck in die Wannen eintauchen.

en

Important information to read before each use:

1. Please begin each treatment at the lowest setting for the treatment current intensity.
2. Please to not put your finger tips or toes into the water trays first, but steadily immerse the whole surface of your hands/feet at the same time.

fr

Remarque importante à lire avant chaque utilisation :

1. Commencer chaque traitement avec la plus petite intensité du courant de traitement réglable à l'affichage.
2. Ne jamais introduire les bouts des doigts/pointes des pieds en premier dans le bac, sinon mettre les mains/pieds avec toute la surface dans l'eau en appliquant une pression uniforme.

it

Da osservare prima di ogni utilizzo:

1. Iniziare ogni trattamento dal livello più basso dell'intensità di corrente per il trattamento.
2. Non immergere mai nella vasca prima le dita/punte dei piedi, bensì direttamente tutta la pianta esercitando una pressione uniforme.

es

Nota importante a leer antes de cada utilización:

1. Comenzar el tratamiento con la intensidad más pequña de la corriente de tratamiento ajustable en la visualización.
2. Nunca introducir primero los puntos de los dedos/de los pies en la bandeja, sino poner las manos/los pies con toda la superficie en el agua aplicando una presión uniforme.

pt

Chamada de nota importante antes de proceder a cada aplicação:

1. Favor de iniciar cada tratamento com a intensidade de corrente de tratamento mais baixa.
2. Favor de nunca imergir as pontas dos dedos/pés primeiro, mas sim imergir as mãos/os pés completamente nas bacias, aplicando pressão uniforme.

ru

Важные указания! Учитывать перед каждой процедурой!

1. Каждую процедеру начинайте с самого нижнего уровня шкалы настройки.
2. Никогда не погружайте руки или ноги в воду, начиная с кончиков пальцев. Всегда погружайте ладони или ступни в ванночку полностью и одновременно.

User's Manual

Dear Customer, thank you for choosing a KaWe product. Our products are known for their high quality and longevity. This KaWe product fulfils the requirements of EC Directive 93/42/EWG (Medical Devices Directive). We assume no liability for improper or inadequate use of this device, or if the device is not checked before use. Please read these instructions carefully and completely before use and follow the maintenance instructions.

1. Application

The SwiSto3 is used in medical facilities and in the home by healthcare professionals as well as by non-professionals.

2. Intended use

The SwiSto3 iontophoresis set is designed to treat intense foot, hand and underarm perspiration. This is a proven and tested anti-perspiration system that uses tap water iontophoresis. A reduction in perspiration can be observed after as few as approx. 15 – 20 treatments, each lasting 20 to 30 minutes. Treatment is only to be administered two to three times per week.

3. Scope of delivery: SwiSto3

1 x SwiSto3 iontophoresis device
2 x water trays
2 x plate electrodes (150 x 220 mm) incl. cable
2 x electrode sponge pads
1 x charging plug

4. Accessories

2 x plate electrodes with sponge pockets for underarm perspiration treatment,

2 x replacement sponge pockets (ca. 90 x 110 mm)

5. Manufacturer responsibility

The manufacturer only assumes responsibility for the safety, reliability and efficient operation of the SwiSto3 iontophoresis device if:

1) repairs, modifications, readjustments or enhancements are performed by the manufacturer or by a person authorised by the manufacturer and

2) the electrical system installed in the treatment room meets the requirements of ICE-stipulations and

3) the SwiSto3 iontophoresis device is used in accordance with the instructions given in the user's manual.

The manufacturer is not liable for damages resulting from improper use. Only use the plate electrodes and connection cables supplied by KaWe and/or the original KaWe-brand spare parts and accessories.

6. Symbol key

	Power button
	Anode
	Cathode
	Increase current
	Decrease current
	Menu button for selecting settings
	Continuous current
	Pulsed current
	Treatment time
	Battery symbol
	Electromagnetic field warning
	Charge symbol

	Type BF device according to DIN IEC 601 Part 1 / VDE 0750 Part 1
	Heed the user's manual
	Warning!
	Separate disposal of electric and electronic devices
	Manufacturer
	Date of manufacture
LOT	Lot code
CE	Complies with relevant EU guidelines
IP41	Protected against water droplets and solid matter with a diameter of greater than or equal to 1.0mm
REF	Product reference number
SN	Series number
	Temperature limit
	GOST-R certification of exports to Russia

7. Contraindications/side effects and preventative measures

IMPORTANT! Vital information:

Consult your physician before using this device to receive an individualised treatment plan. Tap water iontophoresis may not be performed under the following circumstances or if the patient has one of the following conditions (contraindications):

- implanted electronic devices (i.e. pacemaker)
- pregnancy
- metal implants in the areas of the body through which the current is conducted (arms or legs)
- metal-containing intrauterine devices (contraceptive coils) when treating the feet
- large-sized skin defects that cannot be covered with Vaseline or isolating bandages/wraps
- heart murmurs or insensitivity to pain.

Note for Allergy Sufferers:

The electrode plates (for hands/feet and armpits) are made of nickel-containing stainless steel and the sponge pockets are made of synthetic fibers. An allergy to any of these materials can cause skin irritation. To rule this out, a doctor should be consulted before use.

The device may only be installed and operated in accordance with the instructions given in the user's manual. Radios, mobile telephones or other similar devices that may affect the device must be placed at least 2 metres away from the device. The device may not be used by unsupervised children and must be stored out of reach of children. The cables pose a risk of strangulation. Small parts may become loose and could be swallowed or inhaled.

Only use standard accessories provided by KaWe. The use of other cables, charging devices, electrodes, water trays etc. is not allowed. The use of non-standard parts can influence the EMC interference immunity and electrical safety of the unit.

Simultaneous treatment with another high-frequency surgical instrument may cause skin burns under or near the electrodes.

The operation of the iontophoresis device within close range (approx. 1 m) of a short-wave or a microwave therapy unit can cause fluctuations in the output readings of the iontophoresis device and therefore, should be avoided.

Never perform treatments during thunderstorms. If necessary, immediately discontinue the treatment and turn off the unit.

The maximum current and the maximum voltage are limited by safety values that are determined by the regulations for electrical medical devices, thereby eliminating the risk of harm to the patient.

Electrical shocks are primarily caused by contact failures between the connector cables and the electrodes. Over time, transfer resistance occurs between the electrodes and the connector cables due to the direct contact with water. This can be avoided by disconnecting the cable on the electrode just before beginning treatment and then reinserting it with a twisting motion. The friction thereby produced creates a clean metal-to-metal contact which is essential for a constant flow of current. This practically eliminates uncomfortable current peaks that could otherwise be felt by the patient.

Persons with prosthetics must remove these before treatment. They must also consult a doctor before using this device.

It is essential that the patient ensure that the success of the treatment is not affected by any type of disturbance. Due to this reason as well for electrical safety reasons, it must be ensured that no children or house pets are allowed in the room at the time of treatment.

The patient should be aware of the fact that – especially during underarm perspiration treatment – any rash movement during the treatment can alter the surface on the body being used for the current transfer. As a result, the current load on the affected body part may exceed the allowed value, which although it cannot cause actual harm, could potentially cause discomfort, skin irritation and/or slight burns. Such complications can be best avoided by:

- Avoiding direct metal contact between the electrodes and the body by using the foam pads or sponge pockets.
- Removing the hands and/or feet slowly from the water trays while the treatment current is flowing.
- Ensuring that the electrodes are always fully inserted into the sponge pockets during underarm perspiration treatments.
- Ensuring that during underarm perspiration treatment the contact pressure between the sponge pocket and the underarm remains as constant as possible for the entire treatment time.

Direct current tap water iontophoresis is not suitable for sensitive users as it may cause skin irritation or paraesthesia. In order to minimize these side effects, this device is to be used with pulsed current and the current must not exceed given amperage. Nevertheless, while using pulsed current, slight stinging, burning or tingling sensations or a slight reddening of the treated skin areas may still occur. In order to prevent these side effects, the sponge pockets should only be lightly and evenly moistened and not soaked before they are placed under the armpits.

Cover damaged/rough areas of the skin on the palms of the hands, the soles of the feet and the grooves of the nails with Vaseline or another greasy ointment, since there is increased electrical current transmissibility through these areas.

Using this device too often may lead to minor skin irritation in some cases.

If the treatment is intentionally performed with a very high electric current, an uncomfortable tingling can occur in the extremities through which the current is flowing.

The complete surface of the body parts being treated must rest with uniformly-distributed pressure on the foam pads and/or sponge pockets. A non-uniform distribution of the surface and of the pressure may cause a current density (>0.2mA/cm2) that is too high in some areas, which can cause skin irritation or minor burns.

Jewellery and wrist watches should be removed before treatment.

The optimum therapy results are achieved by selecting the highest possible (however, different for each individual) current intensity in the water bath during the treatment.

The influence on sweat inhibition is much more pronounced on the positive (+) pole than on the negative (-) pole. Therefore, if applicable, it is recommended that the patient change the polarity of the electrodes after each treatment.

The hands and the feet cannot be treated simultaneously. In accordance with the user's manual, hand, feet and underarm treatments are to be carried out as separate procedures.

In order to avoid skin irritation or burns, only electrodes recommended by KaWe are to be used.

Please ensure that the electrode plates are always covered with the included foam pads!

In order to reduce the skin's natural resistance and if necessary, to make the treatment current feel more comfortable to the user, the hands or the feet should be massaged in a warm water bath prior to being treated.

Replace the water in the trays with fresh water before each use.

Ensure that the display can be read during treatment and is not illegible due to lighting conditions.

The device and its parts (such as the keypad etc.) are to be checked before each use to ensure that they are in sound condition. Should there be any apparent problems such as wear etc., please send the device in to the manufacturer.

The expected operational life time of the device is, depending on use and maintenance, between 4 and 8 years. The built-in recharge-able battery is designed for 800 complete charging cycles. With a fully-charged battery, approx. 10, 20 minute-long treatments can be performed at full power.

If necessary, non-expert users are to contact the manufacturer or their representative in order to receive help with the device or to report unexpected functional operation or occurrences.

The treatment success rate is approx. 97%

8. Start-up/preparation

Caution, condensation can cause a safety hazard! If the device

becomes very cold during storage or transport, ensure that it reaches room temperature before using it.

When operating the device, heed the instructions given in "Guidelines and manufacturer declaration – Electromagnetic immunity".

To charge the battery, first plug the low-voltage connector into the socket on the back side of the unplugged SwiSto3 iontophoresis device. The plug-in charger is to be stored in a location that is easily accessible and easy to reach.

Ensure that the connector cable between the adapter and the iontophoresis device is not a tripping hazard!

Charge only with the KaWe REF 05.19170.002 charging plug!

Charge the battery completely before using for the first time. The charging time for a completely discharged battery is approx. 10 hours. When charging, the battery symbol blinks and the charging symbol on the display appears in the middle of the screen. The device cannot be used while it is being charged. The charging progress can be seen on the battery symbol.

To perform a treatment, place the SwiSto3 iontophoresis device on a flat and dry surface.

Place the water trays in an appropriate location.

Place the electrodes (REF 05.19040.021) in the water trays.

Place the foam pads on the electrodes such that the electrodes are completely covered.

Use the connector cables to connect the electrodes with the output jacks (+ and -) on the side of the device. When connecting the cables to the electrodes, they should be plugged in with a simultaneous twisting motion.

Fill both of the tubs with a minimum of 3-4 cm of lukewarm tap water. Take special care that the trays do not overflow or have the potential to overflow when the hands or feet are put into the water.

For the underarm perspiration treatment, insert the plate electrodes into the sponge pockets and soak them well in water.

Power-on the SwiSto3 iontophoresis device by pressing the push-button switch. Hold the button down for approx. 1 second until the display illuminates. Current treatment values will be shown on the display.

The SET button is used to select each of the individual settings. Each of the blinking values can be changed with the up and down buttons. The following can be changed: the current intensity in steps of 1 mA, continuous current / pulsing current and the treatment time in min:sec.

If the display is not readable or the unit appears to be damaged in any way, send the device in to the manufacturer immediately.

9. Treatment of foot, hand and underarm perspiration

Prepare device for use as described in Section 8 "Start-up/ preparation".

Power the device on by pressing the power button for one second.

- Treatment of foot and hand perspiration: In each of the tap water-filled trays, place the palm of a hand or the sole of a foot onto the foam pad-covered plate electrode. Directly touching the electrodes is not dangerous; in order to avoid spots of excessive current density, it is recommended however, that as much of the surface of the body part to be treated as possible rests on the electrodes and the pressure is uniformly distributed.
- Treatment of underarm perspiration: Wet the sponge pockets evenly with tap water! In order to avoid excessively high current densities, care should be taken to ensure that the contact area is as large as possible and that the pressure is evenly distributed. Insert the plate electrodes (REF 05.19080.001) into the sponge pockets.

The parameters that can be selected will begin to blink on the display. The current intensity for the treatment can be selected using the UP and DOWN buttons. --> Confirm selection by pressing the SET button. --> Select pulsing current with the UP button and continuous current with the DOWN button. --> Confirm selection by pressing the SET button. --> Set the treatment time in minutes (MIN) using the UP and DOWN buttons. --> Confirm selection by pressing the SET button. --> Set the treatment time in seconds (SEC) using the UP and DOWN buttons. --> Confirm selection by pressing the SET button. --> Setting selection is completed when the treatment starts, the time countdown begins and the clock symbol begins to blink.

Beginning the treatment

For foot or hand perspiration: The treatment begins by closing the circuit by immersing the hands or feet in the water tubs.

For underarm perspiration: The treatment for underarm perspiration begins by closing the circuit by inserting the electrodes (encased in the sponge pockets) under the armpits.

1) Raise the upper arm and insert the electrode into the arm pit.
2) The electrode is then held in place by the lowered upper arm. Insure before you lower the upper arm that the electrode and connecter cable are completely inserted into the sponge pocket, as direct contact between metal and skin can lead to localised burns. Especially when treating underarm perspiration, please keep the pressure created by the upper arm as constant as possible for the entire duration of the treatment, which can be up to 30 minutes.

By pressing the button on the membrane keypad on the upper side of the device, the treatment current can be increased until a mild to strong tingling can be felt. The intensity of the current can be seen on the display. Similarly, the current can also be reduced during the treatment by pressing the button. When the current is being changed during the treatment, the current reading on the display does not blink.

CAUTION: Do not exceed the recommended maximum current (see table)!

The treatment stops automatically after the set treatment time has been reached or when the current circuit is broken before the set time has elapse. The treatment will resume for the remainder of the set treatment time when the current circuit has once again been closed. The clock symbol blinks and the time countdown resumes.

If the clock showing the treatment time has run down to 00:00 and the current circuit is still complete, the + / - symbols on the display both begin to blink. Once the set treatment time has expired, none of the settings can be changed until the circuit has been interrupted by removing the hands or feet from the water trays. The + / - symbols then stop blinking and the MIN symbol begins to blink, signalling that new settings can now be selected. The previously set treatment time will be saved.

Turn the SwiSto3 iontophoresis device off after completing treatment by pressing the power button. The device will also turn off automatically after two minutes.

The last-used treatment settings are automatically saved and used when the device is restarted for the next treatment. These settings can be changed with an open current circuit as described in Section 9.

The SwiSto3 iontophoresis device can also be plugged into the local power supply network to be charged using the charging plug. The battery symbol shows the battery charge up in the top right-hand corner of the display.

The charging symbol appears when the charging plug is plugged in. After testing the rechargeable battery for at most one minute, the charging function begins and the battery symbol begins to blink.

If the charging plug is plugged in during treatment, the treatment will be interrupted.

10. Important information

If the treatment circuit is broken, the treatment current is automatically shut off so that electric shock does not occur. When the battery charge is low, the battery symbol begins to blink. Treatment is only to be carried out after first charging the battery. When the battery is empty, the device turns off automatically.

If the rechargeable battery has an extremely low charge, the display will blink while charging. After being charged for max. 30 minutes, the display will illuminate normally without blinking.

11. Troubleshooting

11.1 Treatment does not start – possible causes

Treatment circuit is not closed. Eliminate possible contact failure between the connector cables and the electrodes by unplugging the electrode connection pin and reinserting it into its socket with a twisting motion. Then close the treatment circuit through your body by placing your hands or feet into the water onto the foam pad-covered electrodes, or when treating underarm perspiration, by placing the sponge pockets under your arms.

Sponge pockets (for underarm perspiration treatment) are not wet enough. The entire surface of the sponge pockets must be uniformly moistened.

Too little tap water in the trays. The level of the water in the trays must be approx. 3-4 cm.

The electric conductivity of the tap water is not sufficient. In this case, the conductivity of the tap water must be increased by adding minerals to the water.

Electrodes are worn out. After prolonged use, the condition

of the electrodes can deteriorate (due to calcium deposits on their surface, for example) to such an extent as to inhibit the power output of the device. The electrodes are to be replaced.

The battery charge is low. The battery symbol blinks, + and - symbols blink when the treatment circuit is complete.

11.2 Treatment is interrupted – possible causes

Disruption of the treatment circuit – such as by suddenly removing hands/feet from the trays or raising your arm during an underarm perspiration treatment.

Electrode contact failure. Eliminate possible contact failure between the connector cables and the electrodes by unplugging the electrode connection pin and reinserting it into its socket with a twisting motion.

The battery charge is low. The treatment current is turned off. The battery symbol blinks, + and - symbols blink when the treatment circuit is complete. Charge the battery as described in Section 8.

11.3 Treatment current feels too weak – possible causes

Electrodes are worn. After prolonged use, the condition of the electrodes can deteriorate (due to calcium deposits on their surface, for example) to such an extent as to inhibit the power output of the device. The electrodes are to be replaced.

11.4 Display does not illuminate – possible causes

Battery is completely discharged. First charge the battery with the supplied charging plug. The charging symbol will appear on the display. Soon after the battery has begun charging, the device switches automatically to charging mode.

If the charging plug is plugged in and still no charging symbol appears on the display, check the voltage of the electrical outlet that is being used with appropriate equipment. If the electrical outlet is functioning properly, the SwiSto3 and the charging plug must be inspected at a location authorised by KaWe – see as well the Section "Safety Inspections".

12. Recurring safety inspections pursuant to §11 of the Medical Products Ordinance for SwiSto3 devices

The SwiSto3 device must be inspected at least every two years by individuals able to perform such safety inspections properly due to their training, knowledge and practical experience, and do not require any special instructions with regard to these inspection activities.

- Visually inspect the device and accessories for mechanical damage that would adversely affect their functionality.
- Check safety-related labels and the display to insure that they are legible.
- Perform function check as instructed in the user's manual.
- Test the iontophoresis current with a load resistance of 1.5 KΩ.
- The SwiSto3 device contains no parts that require maintenance by the user.
- The housing may not be opened!

When the (+) button is pressed, the current intensity is set to 25 mA. For this, a current of 25 mA ± 2 mA is necessary. Then a short-circuit test is performed on the output, whereby the values must not change.

When the (-) button is pressed, the current intensity output of the device gradually diminishes. Here, the current value must decrease with each decreasing display increment. The treatment current is tested with a reference instrument.

During technical safety inspections, an electrical safety inspection pursuant to IEC 62353 (Medical Electrical Devices - Repeat Tests and Tests After Repair of Medical Electrical Equipment) or IEC 60601-1 is to be performed.

The equivalent leakage currents may be up to 1.5 times that of the first measured value and at the same time may not exceed the limiting value. The first measured values are given in the enclosed test reports. The safety inspection must be entered into the technical manual in accordance with § 6 MPG of the regulations pertaining to the sale of iontophoresis devices and the inspection results must be documented. If the device is found to not be functional and/or safe to operate, it is to be repaired or the user of the device is to be notified of the risks of using the device.

13. Cleaning and disinfection

Empty the water trays.

Wipe the water trays, electrodes and connector cables with a dry cloth and then disinfect them as follows: use any commonly-used disinfecting agent such as Bode Bacillol®, BRAUN Meliseptol® or orochemie B30. The instructions given by the manufacturer of the disinfecting agent are to be followed. The surface that is to be disinfected must be wiped with the disinfectant using light pressure, such that the surface is wet enough and enough of the active ingredient of the disinfecting agent is deposited. The applied disinfectant

solution is to be allowed to dry on the surfaces and they may not be wiped dry. The reaction/wait time for the above-named disinfecting agents is 5 minutes and must be observed.

The SwiSto3 iontophoresis device is to be wiped down weekly with a disinfecting agent.

Water trays, electrodes and connector cables are to be disinfected before each use!

Sponge pockets can be rinsed with warm water, but not with any kind of cleaning agent and for hygienic reasons, are each to be used only by one and the same patient.

Important information!

Parts such as electrodes, foam pads, sponge pockets and connector cables are subject to a certain amount of wear and may require replacement after prolonged use. Check all parts for damage before each application, especially the connecting lines. If corroded, the cables are to be replaced. If the contact plugs on the SwiSto3 become corroded, send the device in for inspection.

The integrated rechargeable battery may only be replaced by the manufacturer. Should the battery be defective (will not charge, discharges too quickly), send the device in for inspection/repair.

Warning: Modifying the SwiSto3 medical electrical device is not allowed! In order avoid the risk of electric shock, only the included charging plug (REF 05.19170.002) may be used to charge the unit.

14. Storage while not in use

In order to prevent the SwiSto3 iontophoresis device from becoming damaged, it should be stored along with its accessories in its original packaging if not in use for a prolonged period of time.

15. Transport and storage

When transported, the SwiSto3 iontophoresis device is to be packaged such that it is protected from damage. If the device is not to be used for a prolonged period of time, it should be charged completely before being stored. The device and accessories are to be stored in a dry location between 0 °C and +40 °C.

16. Disposal

The non-accessible part of the SwiSto3 iontophoresis device contains electrical and electronic components. For this reason, at the end of its service life, the device must be brought to an appropriate waste disposal site in accordance with local regulations or returned to the manufacturer.

17. Technical specifications

Classification	Applied part: type BF
Protection classification	IP 41
Dimensions	W 110 x H 84 x L 120 mm
Nominal output current	Adjustable 1 ..... 25 mA
Load resistance	max. 1.5 kΩ
Power input	1.5 W
Power supply	Li-ion rechargeable battery
Operation mode	Continuous operation
Weight	Charging plug: approx. 0.10 kg iontophoresis device: approx. 0.36 kg
Safety features	Electronic current limiting device for the treatment current, Current is cut off when the treatment circuit is broken, System interrupt for when the treatment circuit is not closed
Current type	Continual current or pulsed current up to a max. of 25 mA

Operating temperature	+ 10 °C to + 40 °C
Storage temperature	0 °C to + 40 °C
Relative humidity	30 % to 75 %
Air pressure	700 hPa to 1060 hPa

18. Guarantee

We guarantee this product for 48 months (with the exception of the Li-Ion rechargeable battery). This guarantee is only valid however, if this product is handled properly and in accordance with this user's manual. This guarantee is valid from the date of purchase printed on the invoice.

Wear parts e.g. electrodes, foam pads, sponge pads - are not covered by the warranty!

Before returning the device in the event of any device malfunction, the device must be carefully checked for the cause of this malfunction as described in the "Troubleshooting" section. If, during our inspection of the SwiSto3 iontophoresis device you send in, we determine that one of the causes of the malfunction is described in this user's manual and could have been easily remedied by the customer, we will charge you a flat-rate inspection fee. (Costs for labor, postage, packing and VAT.)

EMC information: Medical electrical devices are subject to special precautionary measures to ensure their safe operation with regard to electromagnetic compatibility. The following information is important for ensuring safe operation.

Guidance and manufacturer's declaration – electromagnetic emmisions		
The SwiSto3 is designed to be used in the types of electromagnetic environments listed below. The customer or user is responsible for ensuring that this device is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – Guidance**
RF emissions CISPR 11	Group 1	The SwiSto3 device 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 emissions CISPR 11	Class B	The SwiSto3 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 emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The SwiSto3 is intended for use in the electromagnetic environment specified below.
The customer or user is to assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV voltage line to line ± 2kV voltage line to ground	± 1kV voltage line to line ± 2kV voltage line to ground	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	<5 % UT for 1/2 cycle (>95 % dip) 40 % UT for 5 cycles (60 % dip) 70 % UT for 25 cycles (30 % dip) <5 % UT for 5 seconds (>95 % dip)	<5 % UT for 1/2 cycle (>95 % dip) 40 % UT for 5 cycles (60 % dip) 70 % UT for 25 cycles (30 % dip) <5 % UT for 5 seconds (>95 % dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued OPERATION during a power mains interruption, it is recommended that the device be powered by an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If interference occurs, it may be necessary to place the SwiSto3 further away from the sources of power frequency magnetic fields or to install a magnetic shield: The power frequency magnetic field should be measured at the designated site to ensure that it is not large enough to cause interference.

Note: UT is the ac mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The SwiSto3 is intended for use in the electromagnetic environment specified below. The customer or user of the SwiSto3 is to assure that it 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 SwiSto3 device, including cables, than the recommended separation distance, which is calculated using the equation for the frequency transmission.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	$d = 1.2\sqrt{P}$ 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 meters (M). Field strengths (a) from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level (b) 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 propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SwiSto3 device is used exceeds the applicable RF compliance level above, the SwiSto3 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SwiSto3

The SwiSto3 is intended for use in the electromagnetic environment described below. The customer or the user of the SwiSto3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SwiSto3 as recommended below, according to the maximum output power of the communications equipment.

	Separation distance (meters) according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

Note 1: For the calculation of the separation distance for transmitters with a frequency range of 80 MHz to 2.5 GHz, an additional factor
of 10/3 is used in order to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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

MEDIZINTECHNIK
seit 1890
KaWe

KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstraße 56
71679 Asperg, Germany

Phone: +49 7141 68188-0
Fax: +49 7141 68188-11
e-mail: info@kawemed.de

QM-1-065H-1 / B-26300 / 2023-10

www.kawemed.com