INSTRUCTIONS FOR USE

OZO-OZO Ionto-MINI

Medical device - a device for reducing excessive sweating

Version: 4.7 EN

CE 1023

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Content

Caution! Please read these operating instructions carefully before connecting the device for the first time! The manufacturer is not liable for any health complications or damage to the product or property caused by improper use that is contrary to these instructions.

Basic safety instructions

- **The appliance is intended exclusively for the reduction of excessive sweating by following these instructions for use!**
- **Take note of all warnings and instructions for later use.**
- **ATTENTION, this device must not be used unsupervised by children, or people who are unable to express their feelings sufficiently.**
- **If the machine is damaged, do not use the device.**
- **Do not use iontophoresis if you are feeling unwell.**
- **Do not expose the device to extreme environmental conditions - *see below*.**
- **The device is not intended for use in combination with any other medical device.**
- **Only use the device for its intended purpose.**
- **Do not touch conductive objects while using the device.**
- **If you are unsure about your medical condition, consult your doctor about the use of iontophoresis.**
- **Use of the device by children and people under 18 years of age must be checked with a doctor and performed under the supervision of an adult.**
- **In case of damage, repairs or other problems, please contact the supplier.**
- **Only carry out iontophoresis treatment if you feel well. Reduce the current strength if you experience any pain or unpleasant sensation. Do not directly touch any metal parts of the device.**
- **Do not throw the device away with your normal household waste at the end of its working life. Send it back to the manufacturer or dispose of it at your local recycling centre.**

Contraindication

The use of iontophoresis is associated with a low incidence of side effects. Side effects are mainly due to improper use of the machine or because too high a current setting is used which may cause skin irritation, redness, itching, or even skin burns. Nevertheless, manufacturers have prevented the use of iontophoresis in a wide range of health conditions where the potential effect of the current is not well known.

The use of iontophoresis is contraindicated in the following conditions, i.e. the following patients must not use the Ionto-MINI:

1. **People with metal implants or prostheses or other metal objects such as rings or piercings which are in the path of the electric current**
   Metal objects can interfere with the electrical iontophoresis current and could theoretically act as electrodes with associated effects which could lead to the electrolytic dissolution at the implant's surface, a change in pH in the vicinity of the object, and/or a change of its temperature. The electric current passes from one electrode to the other electrode through the body, via the path of least resistance. E.g., in the treatment of hands, the current flows through the chest, but does not interfere with the legs or head. But a metal necklace or chest piercing must be removed before treatment.

2. **People with an implanted pacemaker, cardiovascular defibrillator, or electrically active element (e.g., insulin pump with glucose detector)**
   If an element (stimulator, etc.) with its own electrodes were placed in the electric iontophoresis current, the current could cause an undesirable effect by, for example, altering the measured values or damaging the device.

3. **Women with intrauterine devices containing non-insulated metal elements** See point 1

4. **Pregnant or breastfeeding women**
   An electric current as low in intensity as iontophoresis is not known to directly affect foetal development or milk production. However, consideration must be taken for the effect of possible substances which may be released from body tissue as a result of iontophoresis. From a preventive point of view, it is advisable to avoid iontophoresis in pregnant and lactating women.

5. **People with neuropathy / polyneuropathies**
   These conditions may cause a change in the perception of pain, leading to a risk of burns from setting the electric current to an intensity which would be perceived as painful in healthy people.

6. **People with hypersensitivity of the skin on the hands, feet and armpits**
   In these individuals, the use of iontophoresis may be painful and burns may occur more easily at higher current settings.

7. **People with allergies to stainless steel, chrome, nickel or any metal.**
   These metals can be present in trace amounts in the electrodes and can cause allergic contact dermatitis. However, since the patient and their skin do not come into direct contact with the electrodes, the possibility of the release of substances from the electrode on the basis of electrolysis is only hypothetical.

8. **People who have wounds / abrasions / pain / irritation / damage / unnatural discoloration / itching in the area to be treated.**
   Wounds, abrasions and other skin damage are much more sensitive to the current, which can cause a painful sensation. If the patient has abrasions, soreness or minor injuries on their hands, feet or armpits, the patient can prevent discomfort by applying an emollient cream to the wound before starting the procedure (this isolates the affected area from the passage of the current). If the discomfort does not go away even after applying the cream, the patient should not continue treatment until the injury has healed. In case of any health problems, please seek medical advice immediately and contact the manufacturer or distributor.

9. **People under 14 years of age**
   Increased sweating is normal in childhood and adjusts itself with age, so it is not necessary to treat such cases. More serious cases of hyperhidrosis should be discussed with a specialist doctor.

10. **People who feel unwell, people who are ill, or people with reduced cognitive functions**
    In these cases, there is a risk of the device being used incorrectly, which can lead to discomfort when performing iontophoresis or even burns if the instructions in the manual are not well understood and followed.

Safety instructions for using the device

- Always use the protective net sleeves on the hands/feet electrodes and the fabric covers on the underarm electrodes. To avoid skin burns, never touch the electrodes or their conductive parts (plug pin) directly when the device is turned on. Metal on the body must be removed before starting treatment. **The device is set up correctly if you can feel a slight, painless tingling.**
  Never ignore any feelings of discomfort!
- The device is exclusively for indoor use. Ensure the device is operated in a dry and warm environment. Avoid using the device near a fireplace, infrared heater, humidifier (nebuliser), or electric kettle. Do not operate your device at a distance of less than one meter from short-wave and microwave sources (e.g., microwave ovens, transmitters, mobile phones). Do not use the device if there is any sign of damage.
- The appliance and trays must be placed on a horizontal and stable surface.
- If the procedure is being carried out on your feet, the trays must be placed on the floor and the user must sit securely. Never stand with your feet in the trays.
- To avoid burns to the hands/feet, never fill the trays with water warmer than 40°C. Fill the trays with drinking water only and no other additives (under no circumstances should you add ingredients such as fragrances, disinfectants or other substances to the water). After use, always clean or disinfect the device and accessories according to the instructions below and dry them thoroughly so they are always ready for further use.
- Only use the device with the supplied accessories and the recommended type of batteries.
- After use, always place the device back in its thoroughly dried case.
- The device is designed for operation without the help of another person (the patient is the designated operator). If you should encounter any difficulties during treatment, you may wish to ask somebody else to help you with the control of the device. In such instances, you must ensure that the second person does not touch any other electrical appliances.
- If the current setting is changed during the procedure, it will not take immediate effect; it rises gradually. Do not touch, pull or disconnect the cable to the electrodes during treatment.
- Do not touch electrically conductive objects during treatment.
- Stop using your device if it has been dropped from a height, remove the batteries and send the device to an authorised service centre for them to inspect it. Apart from the battery cover, do not open any other part of the control unit.
- The device or its accessories must not be serviced or undergo

maintenance at the time of use.

- Do not attempt to disassemble the device. In the event of damage, service or any other problem, contact the manufacturer or distributor.
- Do not dispose of the device in household waste. At the end of the device's life, send it to the manufacturer or dispose of it at your local recycling centre.
- Always dry your hands before touching the control knob on the device.
- Protect your device against moisture; it must not be immersed in water (if this happens, stop using your device, remove the batteries and send the device to an authorised service centre for them to inspect). If you have any queries regarding the device's features or usage, please contact the distributor or manufacturer.
- If you experience any adverse reactions, discontinue use.
- **Withdrawal of hands/ from the trays during the therapy session, can cause discomfort from intense electrical stimulation. Avoid the fast withdrawal of hands/feet.** After removing your hands/feet from the trays, wait at least 2 seconds before immersing them again.
- It is completely normal and healthy to sweat, so make sure you do not overdo the treatment.
- Do not use the device if your skin is irritated or damaged or if you have an adverse reaction, feel pain or your skin is irritated/damaged/injured. In particular, young patients will need to find an intensity they are comfortable with. We recommend using lower currents at a comfortable level, which do not cause unpleasant feelings or burns.

The plug on the front of the device is only intended for connecting the electrodes supplied with the device.

Connecting another device or system may destroy the device or injure the patient.

Beware of the risk of strangulation to infants or children from becoming entangled in the connection cable.

The edges of the electrodes can cause cuts; please be careful when handling them.

Batteries and charger

- The plugged-in battery charger must never be left unattended.
- The charger is only designed to charge the supplied batteries (Li-Ion 14500, 3.7 V, 700 - 850 mAh).
- If there is a switch on the charger, it must be switched to 4.2 V.
- If the device is not used for more than 1 month, remove the batteries from the device and charge them every 3 months.
- Do not use the charger at ambient temperatures above 40 ° C.
- Batteries may become hot during charging.
- Do not use or store the charger near heat sources.
- Do not use the charger if its cover is damaged.
- Do not expose the charger to rain, snow, high temperatures, frost, water or other chemicals.
- Do not use the charger near flammable liquids or flammable materials.
- Do not disassemble the charger or batteries.
- The charger must not be used by children without adult supervision.
- Only use batteries according to the specifications in Chapter 5. When inserting the batteries, make sure the polarity is correct.
- **Leaving batteries in the control unit with the incorrect orientation leads to the malfunction of the device's display screen.**
- Ensure the batteries are always charged with the supplied charger. When charging, follow the instructions given separately in Chapter 6 - How to operate the charger.
- Never short-circuit, open or dispose of batteries in a fire.
- For more information, see Chapter 5 "Information on compatible batteries" and 6 "Information on the supplied Li-Ion battery charger".

Symbols used on the device or in the instructions for use

	Warning See Safety Instructions for using the device		"Conformité Européene" (European Conformity) Mark of conformity and number of notified body
	Read instructions for use		It is necessary to read the warning given in the Instructions for Use
	Serial number		Applied part type BF
	Do not dispose of in household waste, separate as hazardous waste		Manufacturer
	Protect from rain and Keep dry		Date of manufacture
	Catalogue number (Ionto - MINI)		

Producer

Merebit s.r.o.
Tyršova 942
691 23 Pohořelice
Czech Republic

Product label

Model:	**OZO-OZO Ionto-MINI**
Classification of medical device: device (ČSN EN 60601-1):	IIa Safety class - with internal power supply
Type (ČSN EN 60601-1):	BF

The device is designed for continuous operation

1. Introduction, safety instructions

Thank you for purchasing an Ionto-MINI electrical device.

OZO-OZO Ionto - MINI is a medical device designed to treat hyperhidrosis - excessive sweating of the hands, feet and armpits.

OZO-OZO Ionto-MINI is a microprocessor-controlled direct current source using the principle called iontophoresis, which is a clinical proven method to reduce excessive sweating and is recommended by dermatologists as a non-invasive alternative to drugs, botulinum toxin or surgical treatment. Electrodes are conductively (water layer) attached to the affected site (e.g., hands, legs, armpits) without directly touching the treated parts (e.g., they are separated by a water-soaked cover or plastic net sleeves) and a low intensity electric current is applied. In most cases, it is sufficient to use tap water, which has enough ions to conduct the electrical current (this method is called tap-water iontophoresis). Through the electrodes, a weak electrical current is applied to the skin. The current is controlled by the iontophoresis. The benefits of the therapy can be seen after 1 to 3 weeks of use (but can vary according to the individual) and the positive effects can last for several months. After such time, the therapy can be repeated in order to prolong its effects.

Because conductivity in fluids (as well as in biological systems) is caused by the movement of ions, the current flow passes via the path of least resistance, preferably through the sweat channels. As the total surface area of the sweat channels is small, higher currents can be achieved which selectively reduce the sweat glands. The direct mechanism of this action is not yet fully known; in medical literature, coagulation of proteins in the channels or their thermal deactivation is reported, which in turn reduces perspiration.

The device is designed for professional and home use. Most users observe the positive effect of the therapeutic procedure after only ten applications. However, it is important to acknowledge that different individuals will react in different ways. If the results of iontophoresis treatment, according to the recommended schedule, do not show after 20 sessions, please email your local distributor info@sweatguard.co.uk and they will do their best to help you achieve the desired results.

The maximum current and maximum voltage of the device were designed according to the safety limits set for medical electrical devices. This device

is intended both for professional and home use, therefore its operation and control are simple and easy to follow. For improved safety and comfort during use, the following advanced systems have been incorporated into the Ionto-MINI: an electronic control of the current; a timer which will automatically change electric current polarity and an audio indicator of electrical current intensity. Furthermore, the device is equipped with a mode of automatic switch-off after inactivity, which saves the batteries.

2. Important information

2.1. Ionto-MINI device and its accessories

Please check you have received the following - see Fig. 1:

- Control unit and electrode cable (a, m)
- Pair of electrodes (i)
- Pair of trays, which are also the case of the device (h)
- Pair of Li-Ion 14500 batteries, 3.7 V, 700-850 mAh (b)
- Pair of protective foam cylinders (g)
- Battery charger (s)
- Battery charger power cord (f)
- Instructions for use (l)
- Protective nets for electrodes (k)

Picture 1 Package contents and description of device controls

2.2. Optional accessories

Pair of armpit electrodes - attachment part (Picture 2)

Pair of armpit electrode covers - attachment part (Picture 2)

Picture 2 A pair of armpit electrodes with covers

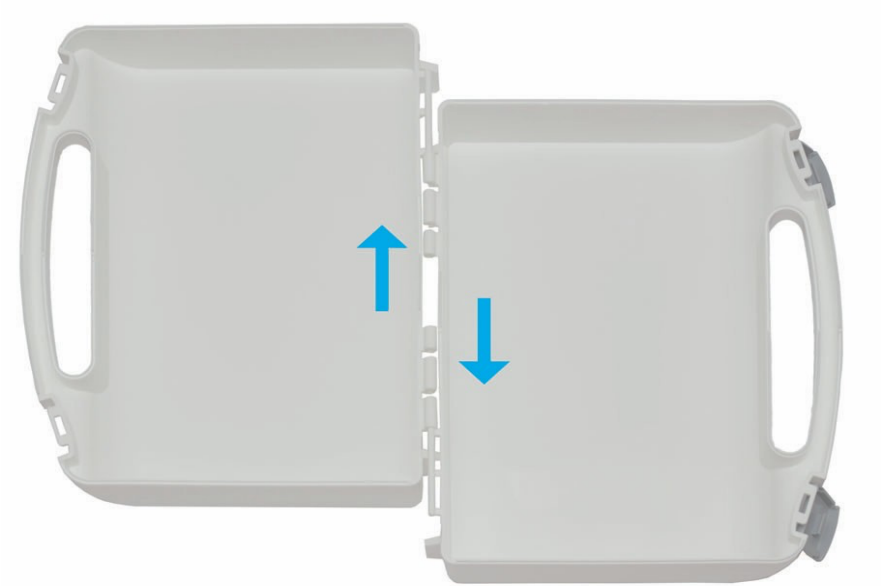
3. Introduction to OZO-OZO Ionto-MINI

3.1. Device assembly

3.1.1. Device assembly for hand and feet treatment

Make sure your hands are dry. Place the case on a flat surface. Empty the case and make sure there are no other objects near the case. Open the pair of trays that also form the device package - the iontophoresis case - and remove the control unit and accessories from the trays. With both sections of the case (two trays) lying down on a flat surface, gently and carefully slide

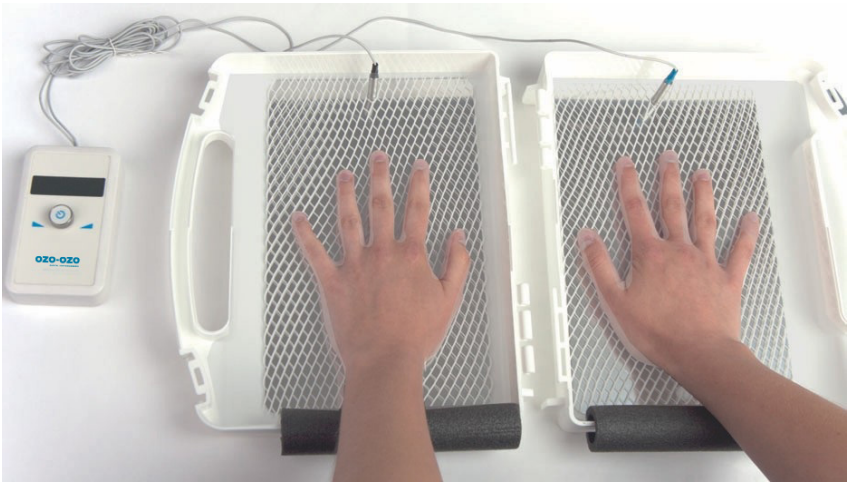
the right tray towards you (see Picture 3). By doing this, it will be easier to empty separated trays after the treatment.



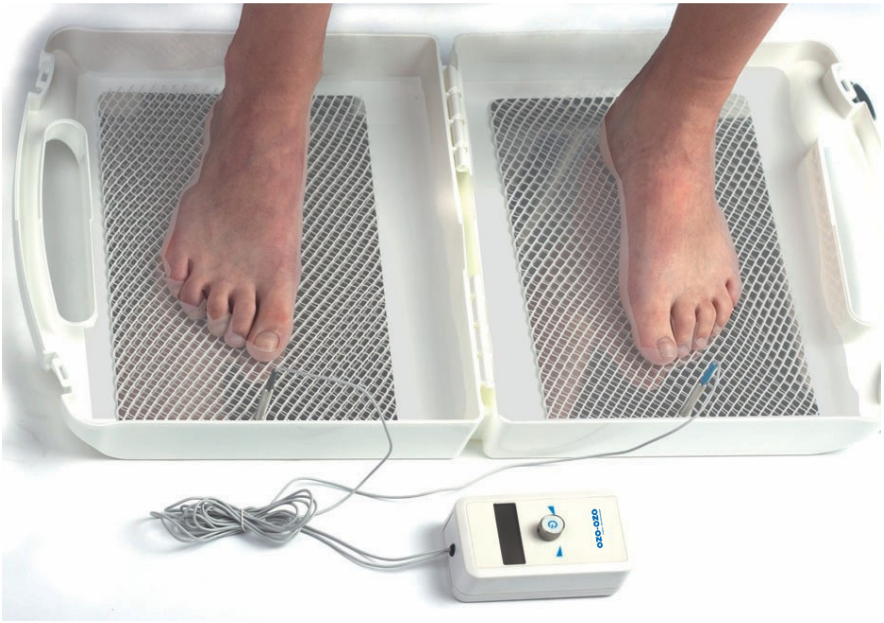
Picture 3 The principle of disconnection of trays

Separate the electrodes, leaving them in their protective plastic net sleeves and place each electrode into the tray. The connector pin of the electrode must be pointing away from the body. Protective plastic foam (g in Picture 1), protect the skin of your wrist from being scratched by the tray edge, should be attached to the tray edges.
Place the control unit beside the trays and connect the pins of the electrodes to the cable connectors of the main unit (see Picture 4 – Device connection). The colours of the connectors are unimportant in connecting the electrodes. Make sure that the batteries are correctly orientated in the Ionto-MINI. Pour pure tepid tap water (which must not have passed through a filter or softener) into each tray, enough to keep your feet or hands completely submerged under water (see Picture 5 and Picture 6). Always follow the system of connection of individual components as displayed in the Instructions for Use. Only switch the device on after correctly connecting all components; never touch the metal electrode.

Figure 4 Device connection



Picture 5 Hand care



Picture 6 Foot care

3.1.2. Device assembly for armpit treatment

Wash the electrode fabric covers before use. Before using the electrodes, remove the fabric covers and soak the covers in drinking water (do not use filters or water softeners). The fabric covers should be kept moist throughout, but water should not drip from them. Then, ensure the electrodes are completely covered by the electrode fabric covers. The edges of the electrodes can cause incisions; please be careful when handling them. Connect the cable connectors of the main control unit to the pins of the electrodes (see Picture 7 – Application of axillary electrodes). The colour of the connectors is unimportant in connecting the electrodes. Make sure the batteries are correctly orientated in the Ionto-MINI. Always observe the system of connection of individual components as displayed in the Instructions for Use. Switch the device on only after correctly assembling all components; never touch the metal electrode.

Picture 7 Application of axillary electrodes

3.2. Starting up and controlling the device - basic instructions

3.2.1. Starting and operating the device - hands and feet treatment

1. Assemble the device.
2. Pour water into the trays.
3. Briefly press the rotary knob on the control unit (for 1 second).
4. Turn the knob to set the desired current level.
5. Check the display shows a non-zero value for the output current (OUT).
6. Put your hands/feet in the trays and the program will start automatically with a slow increase of current intensity until it reaches the desired intensity level.
7. The device is set correctly if you feel a slight painless tingling. If you feel any discomfort, reduce the current level. If, on the other hand, you feel nothing, increase the current level.

8. If the treatment is unpleasant, reduce the current level.
9. During the treatment of your feet or armpits, the set current level can be easily changed as needed. Adjust the current level so the treatment is not uncomfortable. If you experience discomfort during hand treatment and do not have another person available to assist you, slowly remove one hand from the tray, dry it, and reduce the required current to a level that does not cause excessive discomfort. Then slowly put your hand back in the tray and the program will start again automatically with a gradual increase in current.
10. The factory setting of the device timer is 10 minutes, while the polarity of the current is reversed in the middle - after five minutes. (You can change the timer in the settings). As the polarity is switching, you will hear an audible signal and a click, accompanied first by a reduction in the sensation of tingling and then by an intensification.
11. After the set time has elapsed, the program ends automatically. If necessary, you can slowly remove your hands from the tray, dry them and switch off the appliance by pressing the knob on the control unit before the set time has elapsed.

3.2.2. Starting up and operating the device - armpit treatment

Once you have soaked the electrode covers, place the underarm electrodes in the electrode covers and put them under your armpits, in a comfortable horizontal position with the cables facing forward. Do not press hard against the electrode cover. Please then follow the same instructions as above.

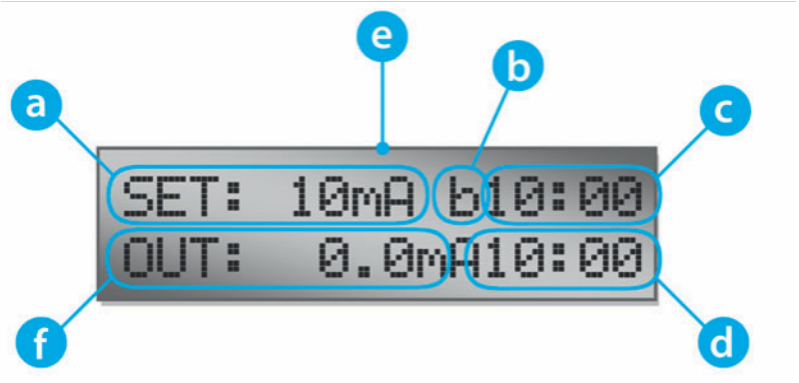
1. Assemble the device.
2. Place the electrodes into the wet electrode covers and put them under your armpits in a comfortable horizontal position, with the wires facing forward. Do not apply excessive force to the electrodes.
3. Briefly press the rotary knob on the control unit (for 1 second).
4. Turn the knob to set the desired current level.
5. Check the display shows a non-zero value for the output current (OUT).
6. If you experience any discomfort, reduce the current to a level that does not cause discomfort.
7. After the set time has elapsed, the program ends automatically. If necessary, you can switch off the device by pressing the knob on the control unit before the set time has elapsed.
8. If you want to end the therapy before the timer runs out, first reduce the current intensity to zero before switching the device off.

3.3. Detailed manual

To start the Ionto-MINI, press the raised rotary knob with push button function on the control unit (see Picture 8).

Picture 8 Starting the device

Then a "welcome sound" (beep) will sound and the information will appear on the display (Picture 9). The Ionto-MINI has two control modes - automatic and manual. The default setting is automatic mode. To switch between automatic and manual mode, see the next chapter.



Picture 9 Display description

3.3.1. Automatic mode - recommended

The display on Picture 9 shows the option when the device is set to 10 mA (row beginning with the word SET (a)). The row beginning OUT (f) indicates the value of real output current, i.e., the current travelling through the circuit of electrodes during iontophoresis therapy. (c) indicates the pre-set time and (d) is the actual duration of your therapy. By turning the knob to the right/left you can increase/decrease the current (a) flowing through the trays. If you turn the knob to the right, the current will be increased; if you turn it to the left, the current will be decreased until zero, which is confirmed by a beep. Continuing the rotation to the left past zero will change the polarity to negative values, and further turning of the knob will again increase the level of current but with the opposite polarity. Change of polarity (pole shift) is indicated by the "–" sign. See the example of the device pole shift to negative values of 10 mA on Picture 10. The option to reverse the polarity feature, enables balanced therapy of both hands/feet as the cathode and the anode have somewhat different properties of action. The factory setting of the device performs the pole shift automatically in the middle of the set time.

Picture 10 Reverse polarity of the device

After setting the required current level and having placed your hands/feet into the trays, the device recognises when the extremities are in place and starts to automatically increase the current to your pre-set value. Launch of the session is indicated by a flashing "OUT".

Sensations

The device is set correctly if you feel a slight tingling and/or a slight burning sensation during the procedure. **If these feelings are uncomfortable, reduce the current.** If, on the other hand, you do not feel anything, increase the intensity carefully. The current setting does not take effect immediately, but rises gradually. If you do not notice a slight tingling and/or a slight burn even at the maximum current, check that the device is working**. Never ignore discomfort, but change the current setting**. During treatment of your feet or armpits, the set current level can be easily changed as needed. Adjust the current level so treatment is not unpleasant. If you experience any discomfort during hand treatment and do not have another person available to assist you, slowly remove one hand from the tray, dry it and

reduce the required current to a level that does not cause too much discomfort. Slowly put your hand back in the tray and the program will start again automatically with a gradual increase in current. Even if your hand/foot is slowly removed from the tray during the procedure, you may feel a slightly unpleasant pulsing sensation. If you pull your hand/foot out quickly despite our warnings, the intensity of the impulse will increase and the discomfort will be more intense.

If an exclamation mark is shown on the display, it means the pre-set current cannot be achieved. This may be due to a lack of natural salts in the water (try using another water source) or due to excessive resistance of your skin. Skin resistance may change over the years and is very individual. However, good results can also be achieved with a low level of current.
By default, the device timer is set to 10 minutes with polarity reversal in the middle of this time, i.e., after five minutes. As you reverse the polarity, you will hear a beep and a click, and you will feel the intensity of the tingling decrease and increase again. After switching the polarity, the current intensity feeling may change. If you feel uncomfortable, reduce the current. Timer settings and turning the automatic pole shift function on/off can be changed in the SET UP MENU. The ideal connection of an iontophoretic device is shown for hands in Picture 5, for feet in Picture 6 and in Picture 7 for the armpits.

The appropriate length and frequency of procedures using the assembled device are given in Chapter 4.

3.3.2. Manual mode

Some users may have a higher electrical skin resistance and the automatic mode will then not work properly (the device may not detect the presence of hands/feet in the trays and will not not start the procedure automatically). In this case, use manual mode. To treat your hands, you will need another person to operate the device while your hands are immersed in the water.

Keep the current set at zero when immersing your hands in the water. The display will show SET: 0, OUT: 0.0 mA.

Set the desired current level or, in the case of hand treatment, ask another person to set it.

Never remove your hands/feet from the water during therapy. This could cause a strong electrical impulse, which is not dangerous, but can be unpleasant, especially for more sensitive people.

Likewise, at the end of therapy, the current must drop to zero before removing hands/feet from the water. When the time limit is reached, the current is automatically reduced to zero, so you no longer have to regulate the current with the help of another person. If necessary, before the set time expires you can ask the person assisting you to decrease the current to SET: 0 and then wait until it drops to OUT: 0.0 mA.

Differentiation between automatic and manual mode

The display in Picture 11 shows the device in automatic mode. Picture 12 shows the device in manual mode. In automatic mode you can select the current level, whereas in manual mode you choose the intensity of the treatment. Therefore, the unit does not display SET: as in automatic mode. OUT: displays the actual current value in both modes.
The display is the same as Picture 9, except the SET value is shown with no unit and shows only power (see Picture 12).

Picture 11 Display in automatic mode

Picture 12 Display in manual mode

Adjusting the current intensity

Turning the knob to the right or left regulates the current intensity. Turning the knob to the right increases the intensity of the therapeutic current. If someone is assisting you, they can increase the power until you feel a slight tingle which is not uncomfortable for you. If you reach a level which is

uncomfortable, ask the person assisting you to lower the current. Never ignore feelings of discomfort. After setting the power to a level which is comfortable for you, keep your extremities in the water. As soon as the timer reaches halfway, the power automatically decreases to zero. At this point the person assisting you can reverse the polarity by turning the knob to the left to the equivalent minus value (e.g., if power was at number 8, the minus value will be -8). Halfway through the session, the device will automatically decrease to zero value and you can remove your extremities from the water. Be sure to turn the knob slowly in order to adjust the power by single degrees.

3.4. Settings menu

To activate the settings menu when the device is switched off, press and hold the rotary knob on the control unit (for 5 seconds). You can switch between menu items (functions) by turning the knob. To change a particular function, briefly press the knob to select the menu item and turn it again to set the function to the desired value. Then confirm the value by pressing the button again.

To exit the setup menu, either press and hold the rotary knob on the control unit or select EXIT in the MENU.

In the MENU you will find the following items:

- TIME - timer setting for the entire treatment period.
- SOUND - turn the sound on / off.
- CHANGE POLARITY - activation/deactivation of automatic polarity switch during treatment session (we highly recommend this function is switched on and utilised).
- CURRENT LIMIT - maximum current setting.
- CONTROL MODE - switching between automatic and manual control mode.
- ABOUT - firmware version.
- EXIT - exits the MENU and switches to ’turned on’ state.

3.5. Switching off the device

After using the device, dry your hands/feet and then switch off the Ionto-MINI by pressing the control knob as in the case of switching the device on. You do not have to return the current to the initial zero value before this step.

Next, disconnect the pair of cables from the electrodes. Remove the protective foam covers from the edges of the trays, carefully remove the water and treat the electrodes and immersion trays as described in Chapter 4.3 – Cleaning and Maintenance. When fully dry, return all parts to the attached trays and everything should be stored in the case which encloses all the equipment.

4. Ionto-MINI treatment

4.1. Ionto-MINI treatment for adult users (18 years and older)

We are all different, so everyone has to choose the intensity of current that suits them. When setting the intensity, always start at the lowest value of the recommended current range and increase the intensity very carefully. At the right current intensity, you will feel a slight tingling sensation. The selected current intensity must be easily tolerated, must not be unpleasant and must not cause skin irritation. If irritation or persistent discomfort occurs, even after reducing the current, stop treatment immediately.

The therapy is divided into two phases. The **Start-up or "Stage 1"** phase is the initial period with prescribed parameters to support successful initiation of treatment. The **Maintenance or "Stage 2"** phase is a regular maintenance regime. During the "Stage 1" phase, sweating will be significantly reduced. Once this happens, discontinue "Stage 1" and go on to "Stage 2". In exceptional cases, reduction of sweating may not occur after 20 treatment sessions in "Stage 1". In this case, please email your local distributor info@sweatguard.co.uk and they will do their best to help you achieve the desired results.

Within "Stage 2" you need to find the treatment rate that suits you. Each individual reacts differently when undergoing iontophoresis, so the treatment frequency in "Stage 2" depends on the specific needs of the user. To identify the appropriate frequency of therapies in this phase, we recommend trying an interval between treatments of 6 days, then 8 days,10 days, and so on. Stop increasing the length of the interval if you feel your sweating is starting to return. The usual maintenance treatment period for individual users is 7 to 28 days.
In "Stage 1" we recommend you only treat one part of the body (e.g., hands only). When you go into "Stage 2", you can begin to treat another part of the body (e.g., feet). Treatment of other parts of the body will start again with "Stage 1". We would not recommend to treat multiple parts of the body on the same day. During the start-up phase of treatment, carry out iontophoresis treatment with the following recommended parameters:

Hands / Feet Treatment

		age		
		adults	**13 - 18**	**under 13**
Stage 1 week 1	**day 1**	3mA – 15mA 30 min	3mA – 10mA 14 min	3mA – 6mA 6 min
	day 2	3mA – 15mA 30 min	- -	- -
	day 3	3mA – 15mA 30 min	3mA – 10mA 14 min	- -
	day 4	3mA – 15mA 30 min	- -	3mA – 6mA 6 min
	day 5	3mA – 15mA 30 min	3mA – 10mA 14 min	- -
	day 6	3mA – 15mA 30 min	- -	- -
	day 7	3mA – 15mA 30 min	- -	- -

If there is a reduction in sweating then continue the therapy in Stage 2, now only once a week according to the schedule below. If sweating reduction has not occurred, repeat Stage 1 again.

Stage 2

week 2	3mA – 15mA 30 min	3mA – 10mA 14 min	3mA – 6mA 6 min
week 3	3mA – 15mA 30 min	3mA – 10mA 14 min	3mA – 6mA 6 min
week 4	3mA – 15mA 30 min	3mA – 10mA 14 min	3mA – 6mA 6 min

Maintenance phase

If you are satisfied with the result, continue with the maintenance therapy once a month with the same settings as before, or depending on the severity of your condition, sometimes it is sufficient to perform the therapy only when sweating occurs.

When sweating is significantly reduced, exit Stage 1 and move on to Stage 2.

4.2. Ionto-MINI application for users under 18 years of age

During adolescence, excessive sweating may be natural and temporary and may not necessarily mean that the patient is suffering from excessive sweating (hyperhidrosis). For this reason, iontophoresis treatment is possible for people under 18 years of age, only if they are positively diagnosed with excessive sweating (hyperhidrosis). The treatment of children and adolescents must be supervised by an adult. For people under the age of 18, we recommend to set lower current levels and a lower frequency of treatment sessions than for people over the age of 18. Other instructions are the same as for persons over 18 years of age (see chapter 4.1). Underarm treatment

Only use the armpit electrodes which come with the Ionto-MINI.

Wash the electrode fabric covers before the first use. Wash and dry the fabric electrode covers after each use. Dry the electrodes after use and keep them dry.

Remove the electrode from the fabric cover before using it; soak the electrode cover in drinking water. Then insert the entire electrode into the fabric cover. The edges of the electrodes may be sharp; be careful when handling the electrodes. Make sure the electrodes are fully inserted into the fabric covers. Only use the electrodes under the armpits. To ensure the procedure has the correct effect, it is necessary to keep the electrode covers wet and in the armpit throughout the treatment. You will need to resoak the electrode (if they dry out too much the set current cannot be reached).

Place the electrodes (covered with the electrode covers) securely under your armpit, in a comfortable position (horizontally) with cables facing forward. Do not press hard against the electrode covers. Place a towel around your abdomen in order to catch any drips.

Set the treatment time to 10 minutes (when buying a new device, 10 minutes is the factory default setting and therefore it is not necessary to change the settings). Perform 3 treatment sessions, each lasting 10 minutes (perform a total of 30-minute daily treatment sessions in Stage 1. Always resoak the fabric electrode covers between treatments. This will ensure the electrodes are soaking wet throughout the duration of therapy.

Handle the uncovered electrodes carefully, so as not to injure yourself against their edges or cut the fabric electrode covers.

Be especially careful after shaving your armpits. The skin may be sensitive and may react painfully. In this instance postpone the procedure until lateror treat the skin with an emollient cream before the procedure.

During the initial phase of armpit treatment, carry out iontophoresis treatment within the following recommended parameters:

Undearm treatment

		age		
		adults	**13 - 18**	**under 13**
Stage 1 week 1	**day 1**	3mA – 10mA 10 + 10 min	3mA – 5mA 10 + 10 min	3mA – 5mA 10 min
	day 2	3mA – 10mA 10 + 10 min	- -	- -
	day 3	3mA – 10mA 10 + 10 min	3mA – 5mA 10 + 10 min	- -
	day 4	3mA – 10mA 10 + 10 min	- -	3mA – 5mA 10 min
	day 5	3mA – 10mA 10 + 10 min	3mA – 5mA 10 + 10 min	- -
	day 6	3mA – 10mA 10 + 10 min	- -	- -
	day 7	3mA – 10mA 10 + 10 min	- -	- -

If there is a reduction in sweating then continue the therapy in Stage 2, now only once a week according to the schedule below. If sweating reduction has not

Stage 2

week 2	3mA – 10mA 10 + 10 min	3mA – 5mA 10 + 10 min	3mA – 5mA 10 min
week 3	3mA – 10mA 10 + 10 min	3mA – 5mA 10 + 10 min	3mA – 5mA 10 min
week 4	3mA – 10mA 10 + 10 min	3mA – 5mA 10 + 10 min	3mA – 5mA 10 min

Maintenance phase

If you are satisfied with the result, continue with the maintenance therapy once a month with the same settings as before, or depending on the severity of your condition, sometimes it is sufficient to perform the therapy only when sweating occurs.

4.3. Cleaning and maintenance

As a sanitary standard, this device should only be handled with clean and dry hands and used in a clean environment. Do not store any items other than the device's components and accessories in the device's case. To keep the device free of any impurities, wipe it with a slightly moistened cloth without any detergents, having ensured the batteries are removed.

The pairs of electrodes and trays should be cleaned after each session, ideally with a kitchen sponge and mild soap and water solution. Do not remove the protective sleeve from the hands/feet electrodes during cleaning, as this can cause damage to the protective sleeves. Finally, rinse the electrodes and trays thoroughly with pure running water and wait until they are fully dry before storing them in the case.
Handle the uncovered electrodes carefully, so as not to injure yourself against their edges.
If required, the surfaces of the device and all its accessories can be treated with a disinfectant based on ethyl alcohol; electrodes and trays should be rinsed thoroughly with pure water before their next use. Disinfection of both the device and accessories must also be performed in the case of a change of user. Do not expose the device to any organic solvents; these can significantly compromise the device or accessory surfaces.
Discoloration of device, electrodes or trays or presence of spots after several initial sessions is quite natural and does not represent any problem.

Maintenance of armpit electrode covers

- – Hand wash after each use.
- – Machine wash at 30–40°C using a good quality detergent.
- – Do NOT use a fabric softener.
- – Max spin speed 800 RPM.
- – Do not tumble dry.
- – Dry the armpit electrode covers naturally and thoroughly before placing armpit electrodes back into the armpit electrode covers.

The electrode covers for the electrodes are made from a fabric with the following properties and composition: 420g/m2 100% bio cotton. During washing and further maintenance, take the material properties into account in order to maintain the service life of the electrode covers.

5. Information on compatible batteries

Product specification: Li-Ion 14500, 3.7 V, 700–850 mAh, Type: Li-Ion Batteries.

Perform regular inspections of the batteries in the device to prevent damage. If their voltage drops below the desired level, a warning will appear on the display showing the letter **"b"** (BATTERY). In this case, remove the batteries from the unit, leave them idle for 30 minutes and then charge them.

Batteries are consumer goods. You can purchase replacement batteries on the website of the manufacturer or your distributor (www.sweatguard.co.uk). When purchasing from another retailer, bear in mind that batteries must comply with IEC 62133.

Batteries should not be placed in the hands of children, so never leave them lying around - there is a risk that children or pets will swallow them. When charging or inserting into the device, observe the specified polarity (the polarity of the batteries is marked on their packaging). The battery contacts must not be short-circuited - they may catch fire or rupture. Only use the batteries in the supplied device. Do not put batteries in fire or water. Only charge the batteries in the supplied charger. If the charger is equipped with a switch, it must be set to 4.2 V. Leaking or damaged batteries can cause burns when in contact with the skin; Be sure to wear suitable protective gloves when handling damaged batteries. Keep batteries charged. Follow the diagram at the bottom of the battery compartment when inserting them into the device.

If you do not plan to use the device for more than 1 month, remove the batteries from the device and charge them every 3 months. Do not dispose of unusable, damaged or end-of-life batteries in household waste, but hand them in at an electrical waste collection point. Only replace batteries with a new pair, never combine a used battery with a new one.

Check regularly that the batteries in the device are secure. If the display shows the letter "b" Fig. 10, the battery is empty - replace or charge the batteries.

Batteries can be removed from their compartment using a non-conducting, blunt object (e.g., battery cover) inserted between the contact of the device and the side of the battery without the spring. Applying pressure, pull the battery from its housing - see Picture 13

Picture 13 Removal of batteries

6. Information on the supplied Li-Ion battery charger

Identification

Manufacturer, type: Shenzen TrustFire Technology Co., Ltd., TR-001
Output voltage: 4.2 V
Maximum power: 2.1 W
Protection class: II
The device is not designed for continuous operation.

6.1. Instructions for use of the Li-Ion battery charger

Load both the batteries into the chamber as indicated by the polarity symbols. Symbol + and – on each battery must correspond with the symbols inside the chamber of the charger. The switch must be switched to 4.2V.

Insert the batteries into the charger as indicated by the polarity symbols (+/-) marked inside, connect the provided power cable to the charger and plug the charger into a power outlet.

Each charging slot is equipped with an LED indicator. After loading the

batteries and plugging the charger into the outlet, a red LED indicates charging is in process. A green LED indicates either completed charging (battery is fully charged), or if it lights immediately after connecting the charger, the battery is either fully charged or damaged; a damaged battery should not be used - replace both batteries with a new pair.

The batteries can become a little warm while charging (warmer than their surroundings).

Fully discharged batteries need to be charged for approx. 2 hours.

Do not leave the batteries in the charger for more than 2 hours.

Battery chargers must never be left unattended.

7. Troubleshooting

This chapter provides solutions to the most frequent issues which might occur during the use of the Ionto-MINI. Please proceed, keeping to the order of steps; do not skip over or omit individual steps. There is a general rule in the error message procedure that if a problem is self-detected by the device, an error is displayed together with a beep and the device is shut down. If the error persists, it will still be displayed when the device is switched on again. Problems are self-detected only after setting the device at a non-zero level of electric current.

Device cannot be switched on:
1. Check that batteries are loaded correctly.
2. Ensure that batteries are inserted with the correct orientation.
3. Try to charge the batteries.
4. Contact technical support.

During the session, no current is conducted through the patient, but data is shown on display
At the beginning of the procedure, the device is checking whether your hands or feet are in the water trays. If no current is conducted through the patient, but data is shown on display, you can try the following:
1. Test your cables. Switch the device on, set any level of current and connect the connectors together (make a short circuit). If the cables are in order, the display shows: SHORT CIRCUIT. If SHORT CIRCUIT does not appear after several attempts, try to reconnect the cable to the device and try the Short Circuit Test again.
2.Try to charge the batteries.
Resistance of the skin can change over time. If the resistance of the skin is too high, the device will not start automatically.
3. Use water from another source.
4. Try the device on another person.
5. Add more water to the trays (more skin submerged = lower total resistance)
6. Add a few crystals (5 small ones are enough) of table salt to each tray (sometimes the conductivity of the water is low)
7. Have a few days rest (this usually helps your skin properties recover)
8. You can switch the device to manual mode, (please see the manual first) this will bypass the initial test. With manual mode, you have to be careful not to put/pull out the hands or feet from the water trays during a treatment session. For hand treatment you will need some assistance by another person.
9. Contact customer support on info@sweatguard.co.uk

Display shows ERROR:
1. Turn the device off and on again.
2. Remove the batteries from the device for 2 minutes, then reload them and turn the device on.

The display is blank:
1. Turn the device off and on again.
2. Check the batteries are loaded.
3. Ensure the batteries are inserted with the correct orientation.
4. If you hear a sound when turning the control unit on, the device is working, but the display is damaged and needs to be replaced. *(Leaving batteries in the control unit with the incorrect orientation leads to the malfunction of the device's display screen.)*
5. Contact technical support.

Display shows INT ERROR:
1. Turn the device off and on again.
2. An internal error has occurred; it is necessary to contact technical support.

Display shows SHORT CIRCUIT:
1. Connectors/electrodes have short-circuited. Connect the device as per its instructions and then switch it off and on again.
2. Reconnect the cable to the device and try the Short Circuit Test again.
3. Remove the batteries from the device for 2 minutes, then reload them and turn the device on.
4. Contact technical support.

Display shows letter "b" Picture. 9 – letter "b"
Batteries installed in the device are discharged, remove them and recharge. Ensure you have installed them with the correct orientation.

Display shows LOW ERROR:
Batteries installed in the device are discharged (the battery level is less than 3.05 V), remove them and recharge. Ensure you have installed them with the correct orientation.

Display shows BATTERY ERROR:
Batteries installed in the device are discharged (the battery level is less than 2V), remove them and recharge. Ensure you have installed them with the correct orientation.

Display shows EXCLAMATION POINT "!" after the current value
This occurs if the current has been set too high and due to skin resistance,

the instrument fails to reach the specified value. In this case the device starts the therapy session with the maximum current available. It is worth noting good results can still be achieved at lower current levels.

(The device is working at a constant current source which means if you set 10mA, the device is always trying to stick to this value, even if the resistance is changing. This is done by changing the voltage. The device maintains a safe voltage of 1- 55V. Low skin resistance requires an estimated voltage of 20V for 10mA, while higher skin resistance may require a voltage which is higher than the maximum voltage of 55V, but if the skin resistance is higher, it is no longer possible to increase the voltage, therefore just reduce the current.)

Note:

Diagrams, parts lists, descriptions, calibration instructions or other information for service purposes or repair are available from the MANUFACTURER upon request. Applies only to the manufacturer-approved service specialist and parts of the instrument specified by the manufacturer as serviceable.

8. Technical parameters

Power supply	2 x 3.7 V
Li-Ion batteries capacity	(2 pcs.) 700 to 850 mAh
Minimum number of battery charge cycles	200
Minimum battery life for the specified use	6 months
Battery charger type	TrustFire, model TR-001
Power consumption in the "on" state, not operating	0.1 W
Power consumption during therapy	0.15 to 2.5 W
Output voltage range on the electrodes (DC), according to current setting and impedance between the electrodes	0 to 55 V
Output DC current, adjustable in steps	0 to 20 mA
Accuracy	max 5%
Load impedance	200 Ω to 16000 Ω
Safety class of the device (ČSN EN 60601-1)	with internal power supply
Application part type (ČSN EN 60601-1)	BF
Ingress protection	min. IP 20
Dimensions of the device	112x69x28 mm
Dimensions of the device with turn knob	112x69x42 mm

Dimensions of electrodes	XL 300x185 mm/ Armpit 150x80 mm
Weight of control unit	200 g
Total weight with accessories	1.500 g
Lifespan	10 years
Operating environmental conditions	
Storage and Transportation Temperature, Humidity, Air Pressure	-25 ° C to +5 ° C; +5 ° C to +35 ° C. Relative humidity up to 90% without condensation; > 35 ° C to 70 ° C at a water vapor pressure of up to 50hPa
Operating Temperature and Humidity	+5 ° C to +40 ° C; relative humidity range 15% to 90% without condensation, but partial water vapour pressure not required above 50hPa; air pressure 700 hPa to 1060 hPa.

Modifications to this device and its accessories is prohibited

9. Electromagnetic compatibility

User manual and declaration of manufacturer – electromagnetic emissions		
The OZO-OZO Ionto-MINI device is intended for use in the electromagnetic environment specified below. The patient or user of OZO-OZO Ionto-MINI is obliged to ensure that the device is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - instructions
CISPR high frequency radiation 11	Group 1	The equipment 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.
CISPR high frequency radiation 11	Class B	OZO-OZO Ionto-MINI is suitable for use in all institutions, including households and those buildings that are directly connected to the public low-voltage power supply network that supplies buildings for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

User manual and declaration of manufacturer – electromagnetic immunity			
The OZO-OZO Ionto-MINI device is intended for use in the electromagnetic environment specified below. The patient or user of OZO-OZO Ionto-MINI is obliged to ensure that the device is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - instructions
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact	+/- 6 kV contact	Floors should be wooden, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	+/- 8 kV air	+/- 8 kV air	

<table>
<tr><th colspan="4">User manual and declaration of manufacturer – electromagnetic immunity</th></tr>
<tr><td colspan="4">The OZO-OZO Ionto-MINI device is intended for use in the electromagnetic environment specified below. The patient or user of OZO-OZO Ionto-MINI is obliged to ensure that the device is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601
test level</td><td>Compliance level</td><td>Electromagnetic environment – instruction</td></tr>
<tr><td rowspan="4">Emitted RF IEC 61000-4-3</td><td rowspan="4">3 V / mOd 80 MHz to 2.5GHz</td><td rowspan="4">3 V / mOd 80 MHz to 2.5GHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the OZO-OZO Ionto-MINI, including cables, than the recommended separation distance calculated from the equation
applicable to the frequency of the transmitter.
Recommended separation distance</td></tr>
<tr><td>d=1,2√P 80MHz to 800MHz. d=2,3√P 800MHZ 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 from fixed RF transmitters as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency b.</td></tr>
<tr><td>Interference may occur in the vicinity of the device marked with the following symbol:</td></tr>
<tr><td>  </td></tr>
<tr><td colspan="4">NOTE 1: From 80 MHz to 800 MHz, the separation distance for the highest frequency range applies.</td></tr>
</table>

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

Recommended separation distances between portable and mobile radiocommunication equipment and OZO-OZO Ionto-MINI equipment

The OZO-OZO Ionto-MINI device is intended for use in an electromagnetic environment in which high-frequency interference is controlled. The patient or user of the OZO-OZO Ionto-MINI can help prevent electromagnetic interference by maintaining the minimal distance between portable and mobile high-frequency communication devices (transmitters) and the OZO-OZO Ionto-MINI device, as recommended below according to the maximum output power of the communication devices.

Rated maximum output power of transmitter mW)	Separation distance according to frequency of transmitter		
	From 150 kHz to 800MHz	From 80 MHz to 800 MHz	From 800 MHz to 2.5 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.17	0.17	0.23
0.1	0.32	0.32	0.74
1	1.17	1.17	2.3
10	3.16	3.16	7.4
100	11.7	11.7	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in metres (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: At 80MHz and 800MHz, 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.

10. Warranty

The iontophoresis control unit and battery charger are covered by a two-year warranty from the date of purchase by the customer and is valid if all instructions in this manual are followed correctly. Batteries and other accessories are considered consumables and are not covered by the warranty.

11. Manufacturer and distributor contact details

If necessary, contact the manufacturer or distributor for assistance in using or maintaining the equipment, or to report adverse events or occurrences. Please also fill in the satisfaction questionnaire at www.ozo-ozo.cz

Producer
Merebit s.r.o.
691 23 Pohořelice
Czech Republic
EU
Tax ID: CZ 29290406
Tel: +420 774 848 833
e-mail: info@merebit.com
web: www.merebit.com;
www.ozo-ozo.cz

Distributor

SweatGuard Ltd
The Limes, 1
Pulteney Road, Bath BA2 4HD
United Kingdom
info@sweatguard.co.uk

Company Number 05998898.
VAT Registration Number 895246188.
SweatGuard ® is a British company registered in England and Wales.

Notes on treatment:

MEREBIT

ROBOTICS AND MEASUREMENT
IN MEDICINE, RESEARCH
AND BIOTECHNOLOGY