INSTRUCTION MANUAL FOR

THE fischer®

Tap Water Iontophoresis Device

User Manual

The Fischer® Tap Water Iontophoresis Device

Item No. 07-80-000-10

Thank you for choosing RA Fischer Co.

The Fischer® has been designed to be more powerful and easier to use than conventional iontophoresis devices. Setup and start treating in less than 5-minutes! This user manual will guide you through setting up The Fischer®, familiarize you with its 3-button interface and functions, and provide hyperhidrosis treatment recommendations. Please read the following carefully.

1 Scope of Delivery

The Fischer® Tap Water Iontophoresis Catalog No. 07-80-000-10
Main control unit, 2 water bath trays, 2 silicone-graphite electrodes, 2 foam inserts, 2 electrode cables, power adapter, user manual, storage bag.


2 Accessories and Spare parts

The Fischer® can be supplemented with the following add-ons:

Set of silicone-graphite electrodes with sponge pads for underarms, (size sponge pad: 3.7” x 2.6”) Catalog No. 07-80-007-02 Material (electrode): silicone-graphite-compound	
Buffer: none	

The foam inserts and sponge pads are wearable parts and need to be replaced approx. every 18-months. Any spare parts are deliverable upon request.

3 Safety Guidelines

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician. In other words, if you live in the U.S. you need a prescription to purchase The Fischer®.

The Fischer® may only be powered by the adapter provided, which has been specially designed for this device. The use of non-original parts may be hazardous to the user and even lead to death. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could also result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Using non-original spare parts and accessories immediate voids warranty.

Use of this equipment adjacent to or stacked with other equipment should be avoided because added pressure could result in accidental damage. If stacking of equipment becomes

necessary, The Fischer® and any other equipment should be observed to verify that they are operating normally.

Place The Fischer® and water bath trays on a firm, level surface.

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

Do not use the wearable parts (foam inserts and sponge pads) for more than 18-months and replace them on time.

Make sure that The Fischer® is stored at room temperature before you power it up. Depending on storage conditions, the temperature adaptation may take up to 2 hours.

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

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

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

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

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

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

The treated skin can show signs of dehydration like flaking or small lesions. Should this be the case, please apply a rehydrating cream **after** treatment.

Immediately following a treatment session, occasional redness may be observed. This is temporary and a sign that the treatment is working (stimulating capillaries). In rare cases, blistering may occur. Reducing the treatment intensity can minimize the appearance of these symptoms. Before administering a new treatment session, the skin has to heal completely. In case of an unexpectedly strong skin reaction, a medical professional must be consulted before further treatments are administered.

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

Keep out of reach of children unless otherwise supervised. Do not leave the device unattended. Risk of strangulation and injuries.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of The Fischer® could result. Follow the recommended separation distances listed in appendix 1.

Disconnect the power supply from the socket if a thunderstorm approaches or if you do not plan to use The Fischer® for an extended period of time.

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

The Fischer® is designed for indoor use only. Do not expose it to rain or humidity.

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

Make sure you do not pull the cable too hard and do not expose the cable to heat or chemicals. If a cable is damaged, unplug it from device or electrode, respectively, and have it checked by RA Fischer Co.

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

Warning: Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labelling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labelling for appropriate action.

Warning: Do not use when a thunderstorm is in the vicinity.

Warning: The long-term effects of chronic electrical stimulation have not been established.

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

4 Symbol Legend

Symbols used in the user manual and on the device:

Specific warnings, are not otherwise found on the label

Prescription use only

Read the user manual!

Applied part type BF

Catalog No.

Protection class II – double insulated

Batch Code

Manufacturer

UDI (Device and product identification)

5 Intended Use

The Fischer® is a Tap Water Iontophoresis (TWI) device intended to treat hyperhidrosis (pathological sweating) affecting hands, feet, underarms, or all three. Any other use or usage beyond this scope is considered un-intended use and may have dangerous consequences.

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

When starting treatment, sessions should be performed four times per week and not more than once daily for approx. 15-minutes each. After about 10 treatments, sweat secretion decreases to normal levels. Due to the reversible character of the therapy, a long-term treatment (maintenance schedule) is indicated with sessions lasting approx. 15-minutes, to be conducted once or twice per week, depending on the severity of the clinical symptoms. For cleaning and disinfecting, please refer to item 12 in the user manual.

Any use beyond this scope is considered “not according to intended use.” The manufacturer cannot accept any responsibility for personal injury or material damage that is or might be caused by usage beyond the scope of “intended use.”

6 How Iontophoresis Works

Treatment with The Fischer® is conducted by directing an electric current to the affected body regions. A contact of water (by means of a water bath or wet sponge) facilitates this current flow which leads to a reduction of the sweat secretion of the treated skin regions.

To put it simpler: imagine your skin is a sponge. The Fischer® uses an electric current to push the natural minerals found in tap water into the holes (your sweat pores) “plugging them up” to create a long-lasting dryness barrier.

This therapeutic effect has been validated in numerous medical studies; a scientifically unambiguous explanation for its mechanism of action is still outstanding. Medical experts assume that the electrical current irritates the synaptic connections between sweat-inducing nerves and sweat glands to such an extent that the sweat glands are no longer stimulated to secrete sweat. This means the sweat gland itself is not impacted but merely the “supply line“ to the nerves. **The therapeutic effect only occurs after repeated treatment and is of reversible nature, hence, treatment is to be repeated regularly.**

The intensity (amperage) of the current must be adjusted according to the individual’s sensitivity. There is no danger or risk to you as the current is limited to certain maximum values.

7 Indications

The Fischer® is used to treat hyperhidrosis, a medical condition marked by excessive sweating of the hands, feet, underarms, or all three.

8 Contraindications and Side Effects

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

- User/s with a pacemaker
- User/s with an implanted cardioverter defibrillator (ICD)
- Pregnancy
- Metal-containing intrauterine pessary (only relevant in case of feet treatment)
- Metallic implants present in the current path (hands or feet)
- Large skin defects / wounds that cannot be covered with Vaseline
- Any area where sensation is absent or impaired (e.g. polyneuropathy)
- User/s with palpitations (cardiac arrhythmia)
- User/s with seizure disorders (epilepsy)
- User/s with potentially malignant lesions, acute localized infections, skin eruptions, or swollen, broken, or inflamed areas
- User/s with severe local inflammation or thrombosis (blood clots)
- User/s with severe vascular disorders

The following side effects may occur:

- A tingling and burning sensation during the treatment caused by excessive current settings or open areas of the skin
- Slight, but harmless, shocks when treatment is interrupted
- Dry skin after the treatment

- Short-term reddening of the skin following the iontophoresis treatment, caused by a stimulated circulation (hyperemia), amongst others
- Blistering and electric burns caused by excessively high current strength

9 Initial Operation

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

10 Treatment Setup

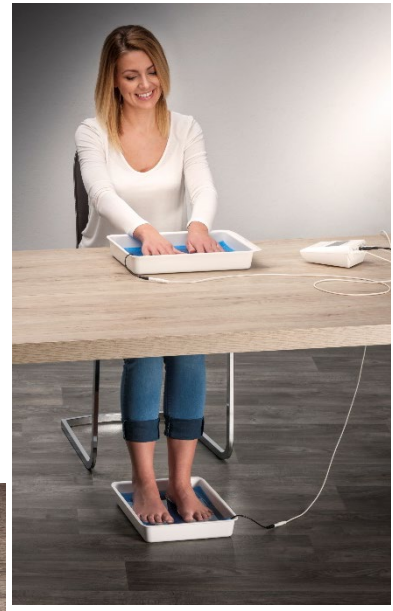
10.1 Setup for hands and/or feet

Set up your device as follows:

- Place the water bath trays on a level and firm surface. If you only treat your hands, place both trays next to each other on a table. If you only treat your feet, place both trays next to each other on the floor. If you treat hands and feet simultaneously, position one tray on the table and one on the floor.
- Connect an electrode cable to each electrode and plug them into connectors E1 and E2 at the back panel of the main control unit (see picture). The selected connection configuration (e.g. left electrode to E1 and right electrode to E2) should be adhered to for the next treatment sessions.

- Place an electrode into each water bath tray.

- Carefully cover each electrode with a blue foam insert.
- Now fill both water bath trays with enough tap water (approx. 2-5 cups) so that the foam mat is covered with enough water to cover the area being treated. A good sign that you've added the right amount of water: the palms of your hands and/or soles of your feet are completely wetted by water and the outsides of your fingers and/or toes are partially covered. Unless you suffer from sweating on the tops of your hands and/or feet, refrain from submerging your entire hand/foot in water.



Tip: Use lukewarm water to make the treatment more pleasant and help keep your skin pores open.

10.2 Setup for the underarms

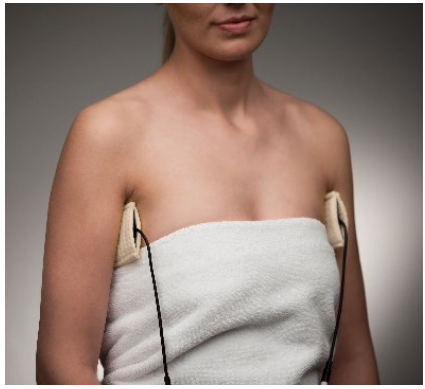
Prior to applying the axillary electrode, clean skin areas. Remove ointments, creams, and cosmetics.

For hygienic reasons, the sponge pad should only be used by one person.

To avoid possible current-induced skin damage, the silicone-graphite electrode must be completely and firmly pushed into the sponge pad sleeve.

Before starting a treatment session, thoroughly soak the sponge pad and **do not wring them out!** To ensure current flow, the sponge pad must be soaking wet. It might be necessary to re-soak them during the course of a treatment session. If necessary, simply pause treatment and soak the sponge pad again.

When ready, insert the moistened sponge pad sleeves, with the connector cables pointing to the front, under your arms. Keep them in place by applying slight pressure with your arms. If possible, avoid abrupt movements during the treatment, since these can cause current fluctuations.
Should you experience irregular tingling or a strong burning sensation, soak the sponge pouches again and lower the power level.



Tip:

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

Note

It is imperative that after every treatment you keep the sponge pads clean and pull the electrodes out of the pads for drying. Do not store the silicone-graphite electrodes in the sponge pad sleeves.

11 Treatment Recommendation

11.1 Parameter Settings

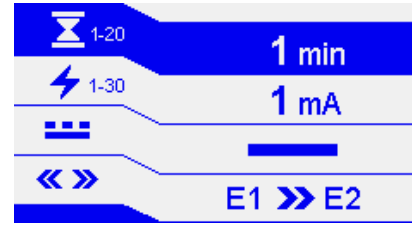
Before you place your hands/feet into the water bath trays, or insert the axillary electrodes with the wet sponge pads under your arms, turn on the device. The main power switch is located on the back panel of the main control unit (pictured right). The display now shows all treatment settings.

Adjust the current setting (which is always shown in blue) by pressing the **buttons < >**. Pressing the **SET-button** will take you to the next line and you can change these settings (including treatment time, direct or pulsed current, and automatic or manual polarity switch).

There is no start button. Once the main control unit has been turned on and the current level has been set, you're ready to begin treatment. Place your hands/feet into the water bath trays. You should feel a mild tingly sensation. On screen, you'll notice the Active Treatment Display (ATD) generating a bar graph as the current level slowly ramps up.

Treatment Duration [min:sec]

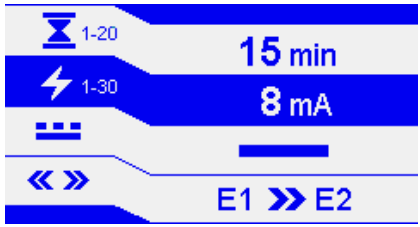
The initial factory setting for treatment duration and current strength is "1 min" and "1 mA" respectively. After your first treatment, The Fischer® automatically saves the last settings used.



Set the treatment duration in minutes. If you have selected the manual polarity switch (E1 << E2 or E2 << E1), choose a treatment duration of 10 to 15 minutes. If you chose the AUTO setting (automatic polarity switch), select a treatment duration of 15 to 20 minutes. If the

sensation during treatment becomes too unpleasant, reduce the current level rather than the duration time.

Current Setting [mA]



For the first treatment, adjust the setting to a low current from 1 to 3 mA. Thereafter, increase it according to your personal preference. Everyone's body resistance to iontophoresis is different, so some patients can start out treating at a higher level, while others have to start low and work their way up gradually. Iontophoresis should not hurt. Always treat within acceptable comfort levels. A tingling or warming sensation is normal and means the treatment is working. The current strength is displayed in mA (milliampere) units.

Especially at the onset of the therapy, the user must determine for him/herself which current strength is tolerable. Within limits, the individual tolerance can also fluctuate between the applications or change over the course of multiple treatments until a higher current level can be tolerated.

Sensitivity also depends on the extremities being treated – notably, your feet are the least sensitive, while your underarms and palms of your hands are more sensitive.

Patients treating both hands and feet at the same time require a higher current level due to the doubling of skin surface area being treated.

Tip:
For your first treatment session, ask a second person to gradually increase the current while your hands/feet are in the water bath trays. This helps establish a baseline for your sensitivity to the treatment. Don't worry if you start low. You can always increase over time as you acclimate to iontophoresis.

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

The Fischer® gives you the option to choose between direct current or pulsed current treatments. The direct current setting is symbolized by a solid bar; pulsed by a broken bar (pictured right).

Direct current (DC) is more effective than pulsed current based on experience. With direct current, power slowly ramps up and maintains the maximum value throughout the treatment.

Pulsed current (PC), on the other hand, it's perceived as being more comfortable because patients can tolerate higher currents. However, pulsed current is not as effective because you is only receiving a small portion of the treatment at the maximum value. Instead of maintaining the maximum value throughout the treatment, pulsed current fluctuates the current up and down.

Put it this way: what's the more effective way of driving down the highway? Accelerating to 65 mph and keeping a steady speed until you reach your destination and then slowing to a stop? (direct current) Or accelerating to 100 mph, then decelerating down to 0, then re-accelerating back up to 100, all the way down the highway? (puled current) Sure, you were technically "going faster" in our pulsed current metaphor (100 mph vs 65 mph), but did it really get you to your destination any faster?

Pulsed current should only be selected in those cases where direct current is perceived as being too painful even at relatively low current values, or if your skin is highly sensitive. Additionally, patients who are seeing a reduction in sweating may choose to switch to pulsed current for their regular maintenance sessions.

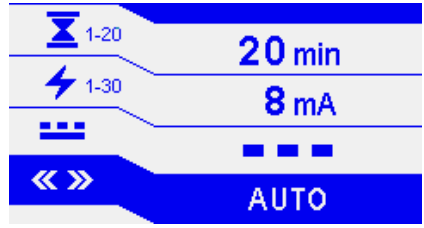
Direction of Current Flow [E1/E2]

We recommend starting out in the AUTO mode. This will automatically switch the polarity from positive to negative between the two silicone-graphite electrodes (labeled E1 & E2).

Note: It does not matter if E1 is on the right or left; the electrodes can be placed interchangeably in either water bath tray.

You can also change the direction of current flow manually by alternating between the modes (E1 >> E2) and (E1 << E2). The arrows indicate the selected direction of current between jacks E1 and E2 on the rear of the device.

Why would anyone want to switch polarities manually? Some patients have reported seeing a faster sweat reduction in the extremity being treated on the positive polarity.



TIP: the arrows always point to the positive electrode. While it doesn't matter which electrode is placed on the left/right or table/floor (for patients treating hands and feet at the same time), knowing which electrode is positive can help you focus the treatment for faster results.

For example, instead of taking 2-weeks to see drier results in both hands on AUTO, you could see a reduction in sweat in your right hand in less than a week by treating it with the positive electrode on manual.

Pressing the "Set-button" will take you back to the top line (treatment duration).

11.2 Conducting Treatment

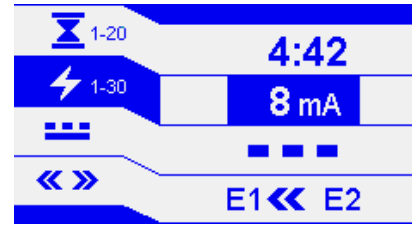
The device is ready to operate after you confirm the settings are correct by pushing the SET-button at least once. Start by placing your hands/feet into the water bath trays or by placing the wet axillary electrodes under your arms (you'll hear a short "beep" that indicates you've completed the circuit and treatment has begun). As soon as

current flows, the Active Treatment Display (ATD) flashes and the treatment timer starts counting down.

At the onset of therapy, the current flow is slowly increased until the value indicated has been reached. The ATD shows bars to the left and right of the set current value, helping you visualize the treatment as it ramps up. A full-bar indicates that the current flow maximum value has been reached.

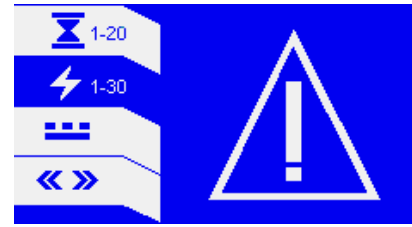
Should The Fischer® detect irregularities in the power circuit during a treatment session (e.g. caused by movements of the hands or feet) the device shuts down the current and then slowly reboots to the set point. This is the Anti-Shock Guard.

During treatment, only the milliamperes can be adjusted. All other settings can only be changed after having turned the device off/on.



The device switches to **"pause mode"** when you remove your hands/feet from the tray and thus interrupt the current flow. You'll notice the current symbol stops blinking on the ATD; the treatment timer stops and the remaining time blinks. Additionally, the device beeps to indicate that the treatment has been paused. Once your hands and/or feet are placed in the water bath trays again, the treatment session continues.

The milliamperes are ramped down towards the end of the treatment to allow your body to gradually readjust. Do not remove your hands/feet from the tray until the timer reaches zero and the device has beeped three times, thus indicating that the treatment session is complete.



The device switches to **short-circuit mode** if it detects an unnaturally low total resistance, e.g. because two electrodes have been placed in a tray. The short-circuit mode is indicated by a continuous beep as well as the "Caution symbol" appearing on screen (pictured right). Once the error has been fixed, the screen displays treatment settings again.

Only after the treatment session is complete should you turn off The Fischer® using the main on/off switch.

11.3 Treatment Phases

Success comes in two phases. First is **therapy initiation**, lasting 10-14 days. During this phase, most patients use The Fischer® every other day, slowly working their way up in milliamperes. On average, most patients start out in the 1-3 mA range and end the phase treating at 10-15 mA.

Note: while these recommended ranges and schedule may work for most patients, some may need to use The Fischer® every day for the first 10-14 days until they see results.

As soon as you notice a reduction in sweat, the second phase begins – staying consistent. For the next 2-3 weeks, you'll want to continue treating at the settings you established at the end of therapy initiation. Most patients treat at 10-15 mA for 15-minutes 3x a week during this phase. However, remember that everyone's bodily resistance is different, so whatever settings and routine you've established, you want to stay consistent.

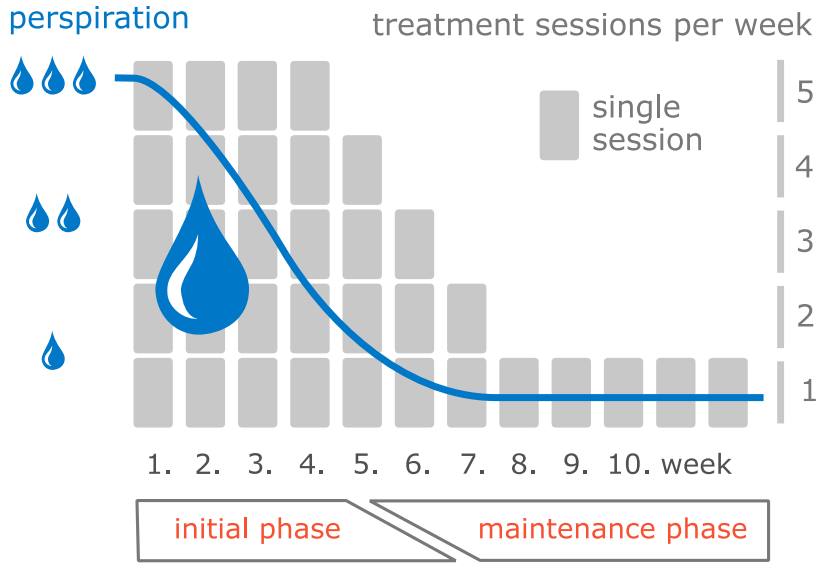
The third and final phase is your **maintenance schedule**. You can begin to reduce the frequency of use, settling into an "as needed" routine. Most patients end up needing to treat once every 2-4 weeks, while some may even go longer between sessions.

Tip:
In the initial phase, treat hands and feet separately: this will help you determine appropriate settings for each extremity. Because the palms of your hands are more sensitive than the soles of your feet, you'll need to find a current value you can tolerate for both. When treating separately, most patients can tolerate a higher setting for their feet than they can for their hands.

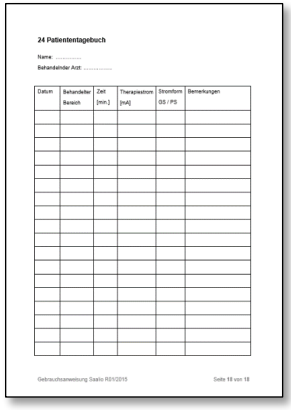
Overview of the treatment phases:

Phase	Therapy Initiation (phase 1)	Staying Consistent (phase 2)	Maintenance Schedule (phase 3)
Goal	Recognizing the therapeutic effects on **one** extremity	Reducing/ normalising sweating on **both** extremities	Maintaining the status
Duration	10 to 14 days	2 to 3 weeks	Continuous
Extremities	Hands, feet and armpits each paired, no combination treatment)	Hands, feet and armpits each paired, no combination treatment)	hands, feet and armpits each paired or combination treatment
Number/duration of applications	10 min. daily or 4 x week 15 min. each	10 min. daily or 4 x week 15 to 20 min. each (in the transition to maintenance phase incrementally less)	As needed for 15 to 20 min. each
Direct (DC), pulsed (PS) current	preferably DC, PC if required	preferably DC, PC if required	DC or PC
Direction of current	Auto	Auto / manual reversal	Auto / manual reversal
Current:	It is impossible to provide reliable guide values for therapeutically effective and simultaneously tolerable current strengths since these can fluctuate very strongly from individual to individual. Start your very first application (for each part of the body) with very low values of 1 to 3 mA. Increase the current during the application incrementally, so that the electricity is noticeable, but not unpleasant. In the following applications always re-adjust this value according to your individual sensation and your experience. The electric current should be noticeable and simultaneously tolerable. Reduce the electricity if this is painful or the skin displays irritations which do not completely subside again after a few hours!		

Schematic Therapy Procedure:



Tip:


24 Patiententagebuch

Name: .....

Behandelnder Arzt: .....

Datum	Behandelter Bereich	Zeit [min.]	Therapiestrom [mA]	Stromform DS / PS	Bemerkungen

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Use your Treatment Journal to record each session, from milliamperes to side-effects.

12 Cleaning and Disinfection

Before cleaning and disinfecting, switch off The Fischer® and unplug it. Clean the main control unit, water bath trays and electrodes with a damp cloth.

For hygienic reasons, clean foam inserts, sponge pad sleeves, and silicone-graphite electrodes after every treatment session under running water (max. 30° C, 86° F). To this end, remove the silicon electrodes from the sponge pads. Afterwards, wring the sponge pads and foam inserts out and let them dry. Dry the silicone-graphite electrodes with a cloth.

If necessary, you can machine wash the sponge pad sleeves, foam inserts, and storage bag (max. 30° C, 86° F). A subsequent centrifuging or spinning is to be avoided by all means – items should be drip-dried. Due to its textile structure, the sponge pads should only be washed if needed so as not to unnecessarily shorten its service life.

If The Fischer® is being used by several patients, the sponge pad sleeves and foam inserts may only be used to treat a single user. The other components, such as the water bath trays, silicone-graphite electrodes, the cables, and the control unit must be cleaned and disinfected before any patient change, in order to prevent infections between patients. The following disinfectants can be used for this purpose:

• Cavi Wipes (wiping disinfection)

• Microzid sensitive liquid (wiping disinfection)

• Sani Cloth Active (wiping disinfection)

Refer to the application instructions on the respective disinfectants. Otherwise, only cleaning products suitable for acrylic glass are to be used.

13 Transport and Storage

After each treatment, wring out the foam inserts and sponge pads thoroughly. It is essential to dry the silicone-graphite electrodes and water bath trays after every treatment to prevent calcium deposits on the electrodes. Please only store completely dry accessories in the trays.

Store The Fischer® in a dry room and do not expose it to high temperatures or direct sunlight. Store sponge pads and foam inserts, as well as all other accessories, in a dry place to avoid possible mold.

When transporting The Fischer®, protect it from unnecessary shocks. Follow the transport and storage conditions (item 19).

Note:
Foam inserts, silicone-graphite electrodes and sponge pads can change color over the course of use.

14 Troubleshooting Checklist

Should you encounter any errors prior to, during, or after a treatment session, please work through this troubleshooting checklist before contacting RA Fischer:

- Verify that the power supply cord is properly connected to the control unit and your power grid. The green LED on the power supply cord should be lit.
- Verify that the plugs on the electrode cables have been pushed all the way into the control unit and silicone-graphite electrodes.
- The current will only boot up to the selected current level if treatment time has been set to more than 1 minute **and** the settings have been confirmed by pushing the SET-button once **and** the skin areas to be treated have closed the treatment circuit.

Rule out a device defect:
Verify that The Fischer® is working by testing it without any body resistance. Prepare a water bath tray for the hand treatment as described above. Now, instead of a hand, place the second silicone-graphite electrode on the foam insert (moistened with water) and set the polarity switch to automatic. Now check the main control unit: is the timer counting down? The energy symbol flashing?

If YES, than the treatment is working and The Fischer® is working properly. So why is the treatment not working when you try it? Your body resistance may be too high, or you may life in a “soft water” area, meaning your tap water lacks the

mineral concentration that makes iontophoresis possible. Here's what you can do:

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

Determine water resistance:
If the device does not start properly for another person, you may live in a "soft water" area and the water resistance is probably too high. In place of using tap water, pick up a bottle of distilled mineral water or table water from your local grocery store and re-try the treatment. Additionally, you can use a very thin fleece or sponge cloth in place of the blue foam inserts over the silicone-graphite electrodes. This will reduce the water path and thus the resistance.

In case of a device failure, or if the actions mentioned above are unsuccessful, please contact RA Fischer Co. by phone. (800) 525-3467

15 Product Life Cycle and Service Life

The service life of The Fischer® is determined to be 5 years. Spare parts (see item 2) are excluded.

The manufacturer must inspect the medical device no later than the above mentioned deadline. Every successful reconditioning measure by the manufacturer extends the service life of the medical device by one year.

16 Maintenance and Repair

The Fischer® is generally maintenance free. Nevertheless, the manufacturer recommends a maintenance at least every 2 years.

To avoid transport damage when sending in for repair, please store the accessories for The Fischer® in the water bath trays provided. If possible, ship in the original packaging. Please make sure that the device is protected against shocks and that packaging is suitable for the method of shipment selected.

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

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

Please include all accessories (power supply cord, silicone-graphite electrodes, electrode cables, etc) along with The Fischer® control unit.

17 Warranty

The Fischer® has been manufactured and tested with the greatest care. Should a malfunction occur, our manufacturer's warranty covers all defects caused by material deficiency or manufacturing error. This manufacturer's warranty extends over 4 years.

Any intervention on The Fischer® by buyer or third parties renders the warranty null and void. Any defects which are, or might have been caused, by improper handling or disregard for the "intended use" listed in this user manual result in the immediate loss of warranty claims against the manufacturer.

The foam inserts and sponge pads are wearable parts and thus excluded from any warranty claims. Should you, however, detect any material or manufacturing defects prior to your first use, please contact RA Fischer Co.

18 Electromagnetic Compatibility

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

19 Technical Data

Control Device

Dimensions Control Unit [D x W x H]		5.9” x 4.7” x 2.6”
Weight		0.66 lb
Input	Supply Voltage:	24 V DC
	Current Input:	max. 130 mA
	Performance Input:	max. 3,1 W
Output Direct Current	Treatment Voltage	max. 58 V=
	Treatment Current	max. 30 mA
Output Pulsed Current	Treatment Voltage	max. 58 V=
	Treatment Current	max. 30 mA
	Pulse Rate	10 kHz Rectangular
Protected against solid foreign objects ≥ 12,5 mm and vertically falling water drops (power supply excluded)		IP21

Power Supply unit

Input	Input Voltage:	100-240 V~ / 50-60 Hz
	Max. Current Input:	200 mA
Output	Rated Output Voltage:	24 V=
	Current Output:	max. 300mA
	Max. Output Rating:	8 VA

Overall System

Requirements for:	Operation	Transport and Storage
Temperature	+10°C to +30°C (+50°F to +86°F)	-20°C to +70°C (-4°F to +158°F)
Relative Humidity	30 % to 70 %	< 90 %, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa

20 Disposal Instructions

This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Dispose or recycle this product in accordance with local laws or regulations that apply.

21 Contact information

If necessary, contact us for assistance regarding the use or maintenance of The Fischer® device or to report unexpected operations or incidents.

Importer / Distributor:

RA Fischer Company
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Manufacturer:

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Appendix 1 – Electromagnetic compatibility

Electromagnetic emissions The Fischer® device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.		
interference emission	**Compliance**	**Electromagnetic surrounding - Guidance**
RF emission according CISPR 11	Group 1	The Fischer® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission according CISPR 11	Class B	The Fischer® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission according IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity The Fischer® device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.			
Immunity test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD); IEC 61000-4-2	**± 8 kV** contact discharge **max. ± 15 kV** air discharge	**± 8 kV** **± 15 kV**	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transients / bursts; IEC 61000-4-4	**± 2 kV** for power supplies	**± 2 kV**	Mains power quality should be that of a typical commercial or hospital environment.
Surge; IEC 61000-4-5	**± 1 kV** for line(s) to line(s)	**± 1 kV**	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines; IEC 61000-4-11	**0 %** U_T for 0.5 cycle **0 %** U_T for 1 cycle **70 %** for 25 cycles **0 %** U_T for 250/300 cycles	**0 %** U_T for 0.5 cycle **0 %** U_T for 1 cycle **70 %** for 25 cycles **0 %** U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of The Fischer® requires continued operation during power mains interruptions, it is recommended that The Fischer® is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz)	**30 A/m**	**30 A/m**	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

magnetic field; IEC 61000-4-8			
NOTE: U_T is the a. c. mains voltage prior to application of the test level.			

Electromagnetic Immunity

The Fischer® device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of The Fischer®, including cables, than the recommended separation distance (d in meter) calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	**3 V rms** 150 kHz to 80 MHz **6 V rms** 150 kHz to 80 MHz within ISM bands and amateur radio bands	**3 V rms** **6 V rms**	
Radiated RF IEC 61000-4-3	**10 V/m** 80 MHz to 2700 MHz	**10 V/m**	
Radiated RF according IEC 61000-4-3 in close proximity to wireless communication devices	according to IEC 60601-1-2:2014 Table 9	**passed**	(corresponds to a recommended safety distance of 0.3 m to the devices of the corresponding radio services)
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol 
NOTE: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			

Appendix 2 – Treatment Journal

Name: _____

Date	Area Treated	Settings (mA, DC/PC)	Duration (mins)	notes

Date	Area Treated	Settings (mA, DC/PC)	Duration (mins)	notes

Date	Area Treated	Settings (mA, DC/PC)	Duration (mins)	notes

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