Dermadry

Iontophoresis Device

INSTRUCTIONS FOR USE

This device is the sole property of:

READING THE INSTRUCTIONS FOR USE IS MANDATORY BEFORE USING THE DEVICE.

Table of Contents

Section 1
INTENDED USE

Dermadry is a Tap Water Iontophoresis device for single patient use designed for home use. **Patient has to be a minimum of 13 years old**. Any qualified person, including the patient, with a minimum of 8 years of education can be the operator of the device (refer to Warnings section).
Treatments are performed by applying an electric current onto the targeted skin areas.

Indication for use

Dermadry is a Tap Water Iontophoresis device. Its intended use is to treat hyperhidrosis (excessive sweating) of the hands, feet and underarms. Using the device in any other way than its intended purpose may be dangerous.

Section 2
CONTRAINDICATIONS

DO NOT use this device if you have any of the following conditions:

- Cardiac pacemaker
- ICD (implantable cardioverter defibrillator)
- Suspected or diagnosed heart problems (e.g. cardiac arrhythmia)
- Seizure disorders (epilepsy)
- Pregnant or suspected pregnancy
- Metal-containing intrauterine device (IUD)
- Metallic implants
- Large skin lesions and lesions that cannot be covered with petroleum jelly
- Numbness in the treated areas
- Infections or irritated skin
- Impaired sensation in hands, underarms or feet (e.g. polyneuropathy)
- Malignant disorders in the area of application
- Severe vascular disorders (e.g. local inflammation or thrombosis)

NOTE: If in doubt, please contact your health professional.

Section 3
WARNINGS

1. Read the Instructions for Use thoroughly before use.
2. This device is intended to be operated by persons with a minimum of 8 years of education.
3. This device is not suitable for children under 13 years old.
4. This device should only be used with the AC adapter and accessories provided. Using parts that are not included may put you at risk of harm or even death and will lead to loss of warranty.
5. Ensure that the electrical outlet meets the following requirements: 100-240 V~ and 50-60 Hz.
6. In the event of a malfunction, contact Dermadry's Customer Service.
7. No modification of this device is allowed. Any modification of the device will void the warranty.
8. Ensure that all parts are damage-free before using the device. If any part of the device is damaged, do not use the device. Contact Dermadry's Customer Service. immediately.
9. Before starting treatment, remove any jewelry from the target areas to avoid risk of electrical burns, redness or irritation.
10. Thoroughly clean skin before starting a treatment. Remove any creams, deodorants, antiperspirants and cosmetics from the target areas.
11. This device must only be used on intact skin. If necessary, cover small lesions with petroleum jelly (Vaseline) to insulate them from the current. If current is applied on open wounds, it could cause vivid pain.
12. Use the appropriate current strength. Begin treatment at a lower current strength than needed.
13. Follow the appropriate treatment profile for the area of the body (hands, feet or underarms). The treatment profiles are safe only for the corresponding skin areas.
14. During treatment, never allow direct contact between skin and electrodes. Ensure electrodes are always covered with the towels or pockets provided. Direct contact between skin and electrodes may cause burns, redness or irritation.
15. Do not perform maintenance on the device while it is in use.
16. Always use potable water for the treatment.
17. Ensure that the device in not plugged to the wall outlet before starting the setup.
18. Dermadry is not intended to be used to deliver drugs and shall not be used for this purpose. Potential systemic adverse effects may result from the use of this device with drugs. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. If, despite this warning, a drug or solution is used with this device, carefully read all labeling of the drug to understand all potential adverse effects. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action, and contact your local emergency services.

Section 4
CAUTIONS

1. Place the device on a firm and stable surface.
2. Never use more than 500ml (17 fl. oz.) of tap water in each tray for treatment of hands or feet.
3. Disconnect the AC adapter during bad weather conditions such as thunderstorms.
4. If not in use, the device shall not be plugged in to an electrical outlet to avoid any damage or premature wear.
5. Always remove gloves or socks from targeted skin area before treatment.
6. Ensure the device is at room temperature (20-40 °C / 70-105 °F) before powering it up.
7. This device is for indoor use only. Avoid exposure to rain, excessive humidity, high temperatures, dust or direct sunlight.
8. Do not place the device within 2 meters (7 feet) of any short-wave or microwave source.
9. Keep the device away from sources of excessive humidity such as a hot kettle or running shower.
10. Do not place the device near a heat source such as a heater, a stove or a fireplace.
11. Keep this device out of reach from children and pets when in use. Unwanted electric shocks may occur if components are disconnected unintentionally.
12. Any tampering or abusive use of the device leads to loss of warranty.
13. Do not place the device in such a way that will make the disconnection of the AC adapter difficult.

Potential side effects

You may experience the following temporary side effects:

1. Irritation, skin reddening (erythema), burning sensation, small blisters (vesiculation), and itching (pruritus). Wait until symptoms disappear completely before starting your next treatment.
2. Tingling and stinging sensations.
3. Muscle numbness (paresthesia) may occur.
4. Slight pain could be felt at the beginning of the treatment or after the polarity alternating sequence.

If you feel any of the above side effects, reduce intensity during next treatment.

5. Increased sweating: After the first few treatments, you may experience an increase in sweating. This symptom will subside after a few treatments.
6. Small electric shocks during treatment: In very rare cases, a harmless electric shock may occur if treatment is interrupted suddenly. To avoid this risk, remove your hands, feet or underarm electrodes slowly. Hands, feet and underarms electrodes can be safely removed at any time during treatment.
7. Skin dryness: Skin may become dry, small lesions or scaling may occur. To reduce these symptoms, use a moisturizing cream after treatments.
8. Aluminum may cause minor allergic reactions for some users. They may develop red, bumpy, scaly, itchy or swollen skin at the point of contact. If you notice any allergic reaction developing on the treated area of skin, stop using the device and contact Dermadry's Customer Service.

Section 5
INDICATIONS

There are varying severity levels of hyperhidrosis (excessive sweating). Understanding ones severity will help gauge the expected response time before results are seen. The greater the severity, the longer it will take to see results.

Clinical classification[1] of **hands and feet** (palmoplantar) hyperhidrosis:

LEVEL I **Mild** hyperhidrosis	Palms and soles are very moist.
LEVEL II **Moderate** hyperhidrosis	Pearls of sweat form, but sweating remains strictly limited to palms or soles.
LEVEL III **Severe** hyperhidrosis	Pearls of sweat also form on the distal dorsal surfaces of fingers or toes as well as on the sides of the feet. Sweat drips.

Clinical classification[1] of **underarm** (axillary) hyperhidrosis:

LEVEL I **Mild** hyperhidrosis	The skin is moderately moist. Sweat spots in clothing measure 5 to 10 cm (2 to 4 inches) in diameter.
LEVEL II **Moderate** hyperhidrosis	Pearls of sweat form on the skin; sweat spots measure 10 to 20 cm (4 to 8 inches) in diameter.
LEVEL III **Severe** hyperhidrosis	Sweat drips. Sweat spots measure over 20 cm (8 inches) in diameter.

[1] Refer to reference 1 in the section 21 - Bibliography.

Treatment schedule

PHASE 1	**Initial Phase**

Treatment should take place at equal intervals, from 3 (e.g. Monday, Wednesday, Friday) to 5 (e.g. Monday to Friday) times per week, at the highest comfortable current level.
Follow this schedule until sweating has significantly reduced, or the desired level of dryness has been reached. Do not perform more than one treatment per day, nor more than 5 treatments per week on each treated area. More than one area can be treated on the same day.

Initial Phase duration before experiencing results[2,3]:

LEVEL I **Mild** hyperhidrosis	From 3 to 5 times per week for about **1 to 2 weeks**.
LEVEL II **Moderate** hyperhidrosis	From 3 to 5 times per week for about **2 to 3 weeks**.
LEVEL III **Severe** hyperhidrosis	From 3 to 5 times per week for about **4 to 6 weeks**.

Using a higher, but still comfortable, current will help reach results faster. Treatment effectiveness can vary from one individual to another.

PHASE 2	**Maintenance Phase**

The Maintenance Phase is required to maintain the achieved results. This phase will require fewer treatments than the Initial Phase.

Frequency of Maintenance Treatment to maintain sweat reduction results[2,3]:

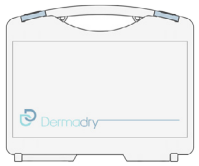
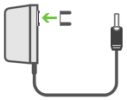
LEVEL I **Mild** hyperhidrosis	About 1 treatment every 2 to 3 weeks at the highest comfortable current level.
LEVEL II **Moderate** hyperhidrosis	About 1 treatment per week at the highest comfortable current level.
LEVEL III **Severe** hyperhidrosis	Up to 3 treatments per week at the highest comfortable current level.

Do not perform more than one treatment per day, nor more than 5 treatments per week on each treated area. More than one area can be treated on the same day.

[2, 3] Refer to references 2, 3 in the section 21 - Bibliography.

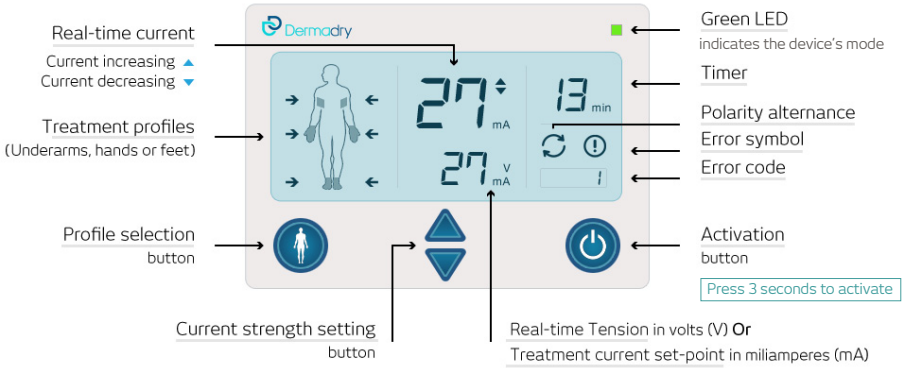
Section 6
DEVICE DESCRIPTION

Dermadry Tap Water Iontophoresis device components

	 consumable
Controller	**Hand and foot electrode** (pair) *
	 consumable
Case	**Towel** (pair) *
	 consumable
Cable (pair)	**Underarm electrode** (pair) *
	 consumable
AC adapter and blade (plug adapter)	**Underarm pocket** (pair) *
	
Instructions for use	

*: The items identified with an * are consumables and have a limited number of uses as per the indications of the Section 10 - Maintenance & Cleaning. Consumables can be obtained from Dermadry's website or authorized distributors.

Controller



Functioning modes

Dermadry has **4 modes** of function:

Mode	Functionality	Visual indication on the controller
SETTINGS	Default mode at device start-up. The user can set the treatment profile and current strength . At the end of the treatment, or if the user ends the treatment voluntarily, the device will automatically switch to Settings mode.	Treatment profile and treatment current setpoint are flashing.
ACTIVE	Press on and hold the **activation button** for **3 seconds** to switch the device to Active mode. The device is on standby, ready for the user to place its hands or feet in the trays or to apply the underarm electrodes.	Green LED flashes. Real-time current displays zero. Treatment profile and treatment current setpoint are displayed.
TREATMENT	When device detects that the user has placed their hands or feet in the trays, or has applied underarm electrodes, it will automatically switch to Treatment mode. It will begin to deliver the treatment current. Treatment profile cannot be changed while device is in use, but the current strength setpoint can be increased or decreased within the range allowed for the treatment profile.	Green LED is on. Real-time treatment current begins increasing toward the current setpoint. After two seconds of switching to this mode, the current setpoint is replaced by the real-time tension in volts.
PAUSE	If the user removes their hands, feet or the underarm electrodes during treatment, the device will automatically switch to Pause mode. This mode allows the user to adjust the current strength during the hands treatment. It also prevents having to restart the treatment should the user have to move position for a short time. Pause mode will last for 2 minutes. If the user does not replace their hands, feet or underarm electrodes, the treatment will end and the device will switch to Settings mode.	Green LED flashes. Real-time current and real-time tension display zero (0) Treatment timer is stopped.

Section 7
DEVICE SETUP

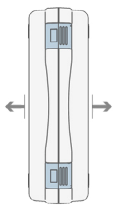
- Make sure that you've read the contraindications and that they do not apply to you.
- Ensure that all parts are damage-free before using the device. If any part of the device is damaged, do not use the device.
- This device should only be used with the AC adapter and accessories provided. Using parts that are not included may put you at risk of harm or even death and will lead to loss of warranty.
- During treatment, never allow direct contact between skin and electrodes. Ensure electrodes are always covered with the towels or pockets provided. Direct contact between skin and electrodes may cause burns, redness or irritation.
- Always use clean, potable tap water. Do not add any products or drugs to the water.
- This device must only be used on intact skin. If necessary, cover small lesions with petroleum jelly (Vaseline) to insulate them from the current.
- Ensure that the device in not plugged to the wall outlet before starting the setup.

7.1 For hands and feet

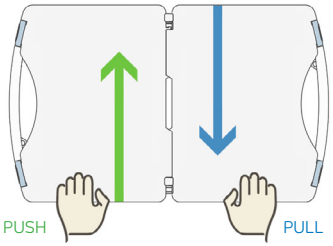
- Before starting treatment, remove any jewelry from the target areas to avoid risk of electrical burns, redness or irritation.
- Thoroughly clean skin before starting a treatment. Remove any creams, deodorants, antiperspirants and cosmetics from the target areas.

1. Separate the case into two trays and place the trays on a flat, firm surface (e.g. table for hands, floor for feet) in order to avoid water spillage.

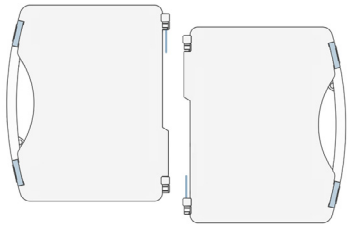
Place both trays side by side on a low table if you intend to treat hands. Place both trays side by side on the floor if you intend to treat feet.



Open the case.



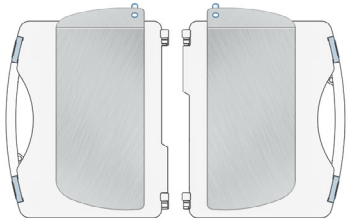
Apply opposing forces on each tray.



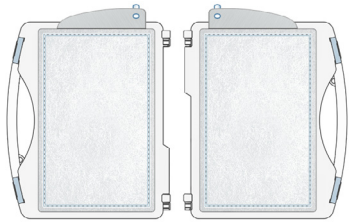
Trays will separate.

2. Place a hand and foot electrode into each tray.
3. Cover each electrode with a towel.

NOTE: The case can be reassembled by reversing the steps when device is ready to be stored.



Place electrodes.



Cover electrodes with a towel.

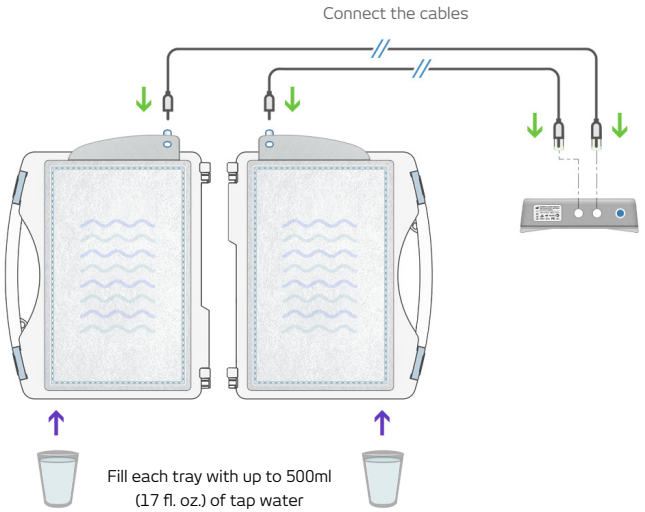
4. Connect a cable to each electrode while plugging the other cable end into the connectors on the back panel of the controller.

The device is designed to automatically alternate the current's polarity during treatment without the need to manually reverse the cables. No difference is made between plugging the right or left electrode into the right or left connector on the back panel of the controller.

NOTE: Make sure cables are fully plugged into the electrodes to prevent unstable connections. This may cause current fluctuations and minor electric shocks during treatment.

5. Carefully fill both treatment trays with enough tap water, up to a maximum of 500 ml (17 fl. oz.) per tray.

Ensure that the entire skin surface intended for treatment is in contact with water. Use water between room temperature and warm (20-40 °C / 70-105 °F) according to user comfort.



Fill each tray with up to 500ml (17 fl. oz.) of tap water

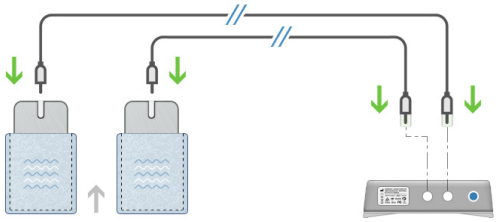
7.2 For underarms

- Thoroughly clean skin before starting a treatment. Remove any creams, deodorants, antiperspirants and cosmetics from the target areas.
- Avoid sudden movements during treatment. These can cause current fluctuations and may lead to minor electric shocks.

1. Connect a cable to each underarm electrode.
2. Soak each pocket with tap water. The pockets must be completely wet to ensure the current is spread evenly over the targeted skin of the underarms. Use water between room temperature and warm (20-40 °C / 70-105 °F) according to user comfort.
3. Insert an underarm electrode in each pocket ensuring it is covered by the pocket in its entirety. If skin comes into contact with the electrode during the treatment, redness or erythema to the exposed skin could ensue.

NOTE: If pockets become dry during treatment, tap water can be used to remoisten them. Ensure that the treatment is paused during this process. The treatment will remain paused for two minutes only. If the underarm electrodes are not placed back, the treatment will terminate automatically. The device will then switch to 'Settings' mode. If you feel unpleasant tingling, electric shocks or burning sensations, stop the treatment and make sure the underarm electrodes are sufficiently moist. Lower the treatment current level if necessary.

4. Plug the other cable end into the connectors on the back panel of the controller. The device is designed to automatically alternate the current's polarity during treatment without the need to manually reverse the cables. There is no difference between plugging the right or left electrode into the right or left connector on the back panel of the controller.



Setup for underarms

NOTE: Make sure connectors are fully plugged into the electrodes to prevent unstable connections. This may cause current fluctuations and minor electric shocks during treatment.

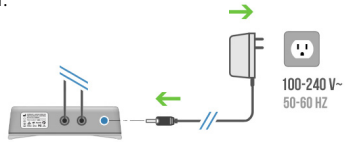
Section 8
PERFORMING THE TREATMENT

8.1 Device start-up

- Ensure skin is intact before treatment.
- The device must only be used with the AC adapter provided. If a different AC adapter is used, harm may occur.

1. Place the controller on a table in front of the user.
2. If necessary, install the blade to the AC adaptor.
   If another blade (plug adapter) is required, contact Dermadry's Customer Service.
3. Plug the AC adapter into the wall and connect it to the controller.

NOTE: Before connecting the device to the AC adapter, ensure that it has been at room temperature for at least the last 6 hours.



The controller's display will light up and start its automatic internal testing (all the display symbols and green LED will flash once).

The internal testing will take 1-2 seconds to complete, the device will then switch to 'Settings' mode.

8.2 Settings mode

The default treatment profile is set for treatment of the underarms, which has the lowest current strength.
In 'Settings' mode, the current setting point (in mA) and the profile will flash on the screen.
Depending on the desired treatment, users can select from the following profiles: underarms, hands or feet.
Each treatment profile has its own settings with specific maximum current level and treatment duration.
Current strength can be modified depending on sweat level.

Parameter	Hands	Feet	Underarms
Current strength range	1-15 mA	1-25 mA	1-8 mA
Treatment duration (predefined)	20 min	20 min	15 min
Polarity alternating frequency (predefined)	Each 5 min	Each 5 min	Each 2 min 30 sec

For the first treatment, the current level must be set lower than intended. Users should adapt current level according to comfort. Sensitivity to the current varies from user to user. A built-in safety feature will stop the device from delivering a current level of more than 25 mA.

8.3 Active mode

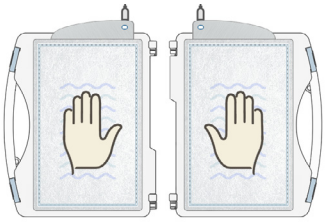
During 'Active' mode, the device is ready to deliver treatment.

Press the activation button for 3 seconds to activate the device. The green LED will begin to flash. The treatment profile and current strength setpoint will stop flashing. .

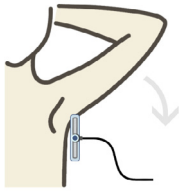
In 'Active' mode, the treatment profile cannot be changed but the setpoint current strength can be modified if necessary. If the treatment profile is not correct, the device should be switched to 'Settings' mode by pressing the activation button.

8.4 Treatment mode

Place your hands or feet in the trays, or place the underarm electrodes in the underarms.



Place your hands **or** feet in the tray



Place the underarm electrodes in the underarms

The device will then automatically switch to 'Treatment' mode and start delivering current.

- The green LED will turn on.
- The current will begin to rise slowly towards the setpoint value.
- The treatment timer will begin to decrease. When less than a minute is left, the display will be in seconds.
- The current setpoint display will change to show the real-time tension in volts. L5 will be displayed when the tension is lower than 5 volts.

During the treatment, the device will automatically alternate the current polarity . Refer to Section 13 'Integrated Safety Features' for more details.

The treatment can be paused or stopped at any time as per the instructions of Section 9 – End of Treatment.

NOTE: If the tap water does not contain enough minerals, the treatment will not be as effective. Use non-carbonated bottled or mineral water instead. If this does not work, contact Dermadry's Customer Service. immediately.

Slight pain could be felt at the beginning of the treatment or after the polarity alternating sequence.

Section 9
END OF TREATMENT

If not in use, the device shall not be plugged into an electrical outlet to avoid any damage or premature wear.

Just before the timer reaches zero, the current strength will begin to decrease slowly until reaching zero. The device will then switch to 'Settings' mode.

The treatment can be stopped at any time by pressing the activation button. The current strength will begin to decrease until reaching zero. The device will then switch to 'Settings' mode.

Hands, feet, and underarm electrodes can then be removed completely without any risks.

PAUSE: If hands or feet are removed from the water or the underarm electrodes are removed from the underarms during treatment, the current strength will immediately reach zero and the device will switch to 'Pause' mode (the green LED will start flashing and the timer will stop).

NOTE: The device will remain in 'Pause' mode for two minutes only. If after this time, the device does not detect a re-application of the treatment (e.g. hands in the trays), the treatment will terminate automatically. The device will then switch to 'Settings' mode.
It is not recommended to stop the treatment this way. In rare circumstances, minor electric shocks may ensue.

RESTART: To restart the treatment, place hands or feet back into the water, or place back the underarm electrodes. Once the hands, feet or underarm electrodes are back in place, treatment will return to the previous current level set before pausing. The timer will continue from where it was paused.

When the treatment is completed, disconnect the controller from the AC adapter. Disconnect the AC adapter from the wall plug. Empty the water from the trays or the pockets. The device must be cleaned as soon as possible to avoid any degradation of the components. The cleaning must be done as per the indications of the Section 10 - Maintenance and cleaning.

Section 10
MAINTENANCE AND CLEANING

Important Notices

Your device will not need to be serviced by Dermadry Laboratories during its expected lifetime provided instructions for use and precautions are followed.

Do not repair or disassemble the device yourself. Do not use the device with components that are not provided by Dermadry.

To ensure the adequate functioning of this device, the provided Instructions for Use must be adhered to. If in any doubt, contact Dermadry's Customer Service.

Any prohibited use of this device or failure to adhere to the provided Instructions for Use, constitutes a violation of the warranty conditions and will lead to irrevocable loss of warranty.

Do not perform maintenance on the device while it is in use.

Consumables and Service Life

The device's expected service life is 5 years provided it is used and maintained as per the instructions for use.

Components listed below are consumables and have a limited number of uses.

	Recommended duration of use under normal conditions
Towels	1 to 2 years
Hands and Feet electrode	1 to 2 years
Underarm pockets	30 treatments
Underarm electrode	1 to 2 years

Cleaning procedure

The device is intended only for single-patient use in home therapy. The cleaning procedure as per this section is sufficient.

The device should be cleaned after each use as per the following procedure:

1. Clean hands or wear gloves before installing and uninstalling the device.
2. Always use a soft cloth for cleaning.
3. Before cleaning, ensure the device is turned off and all the cables are disconnected from the controller.
4. Wipe the case and controller with a clean, moist cloth. For best results, use a mild regular dish soap. For difficult to reach areas, gently rub with a soft brush or toothbrush.
5. Air dry the case and controller.
6. Wash electrodes under running water. Use a soft cloth and a mild dish detergent. Remove soap with a cloth.
7. Air dry the electrodes.
8. For towels: hand or machine wash with common detergent. Squeeze out water and air dry.
9. For pockets: clean with dish soap under running water. Squeeze out water and air dry.

Do not use any other cleaning method to clean your device. The provided cleaning procedure was designed to maximize the lifespan of the device.

Warnings

Follow these instructions to prevent damage or premature wear of your device:

- Never use other chemicals, plastic solvents or abrasives to clean the device. Never use solvents such as alcohol, acetone or wax remover to clean the device.
- The device controller and the AC adapter must never be submersed in water or placed under running water.
- Care must be taken when using the trays filled with water to avoid spillage on electrical parts (controller and AC adapter) and to minimize the risk of slipping.
- Always store the device and its components in clean, dry areas protected from direct sunlight and extreme temperatures.
- Underarm pockets are consumable. They need to be replaced after a maximum of 30 uses. If they appear to be contaminated after cleaning, do not use them. Contact Dermadry Laboratories' Customer Service.
- Excessive corrosion on the electrodes can hinder the treatment current. To avoid excessive corrosion, ensure to thoroughly clean and air-dry the electrodes after completing treatment.
- Discoloration of the electrodes after the first treatment session is normal.

Section 11
TRANSPORT AND STORAGE

The device is accompanied by a case that fits all of its components.

The device is intended to be a reusable device. It can be stored between -25 to 70 °C / -13 to 158 °F between uses in the device's case which was designed for this purpose. Ensure the device is at room temperature (20-40 °C / 70-105 °F) before powering it up.

For repackaging, please follow these instructions to avoid damage and premature wear:

- Always clean and dry the device and its components before storing.
- Always place the device and its components in the provided case.

Section 12
TROUBLESHOOTING

Device not delivering current

- Make sure to press the activation button for at least 3 seconds to activate the device.
- Ensure the AC adapter is properly connected to the controller and to the wall outlet.
- Ensure that the green LED on the AC adapter is light on.
- Ensure the cables are securely connected. Connections between the electrode and cable may become loose with time. This could cause the device to function incorrectly.
- The water may lack minerals. If this is the case, use non-carbonated mineral water instead.
- If the device is activated but the treatment does not start (the green LED continues to flash), remove excess water from the trays or pockets so that the towels or pockets are just barely saturated. In extreme cases of excessive sweating, or when the skin is inflamed (e.g., due to athlete's foot on the feet or hands), the skin's resistance may be so low that it prevents the device from starting treatment.
- Completely corroded electrodes can prevent the device from delivering current. They are consumables and should be replaced when necessary. New electrodes can be purchased from Dermadry's website or authorized distributors.

If the treatment still does not work as expected, contact Dermadry's Customer Service.

UNDERARMS	Treatment is inefficient or you don't feel the current at all

The current might not pass properly through the skin.

- Ensure that the pockets are adequately soaked with water.
- Ensure the AC adapter is properly connected to the controller and to the wall outlet.

FUNGAL INFECTION

Tap water iontophoresis treatment might not be efficient or might not reach its full efficiency if the treated skin is affected by a fungal infection. The most prevalent form of fungal infection is tinea pedis, commonly called Athlete's foot.

Those types of infections affect a large portion of hyperhidrosis sufferers. Fungal infections can occur on hands and feet. Symptoms might be apparent, but not always. Known symptoms are blisters, acute sensitivity to heat, itching, stinging, and burning sensations on the affected skin.

The easiest way to detect Athlete's Foot is by looking for small craters in the skin of the palms, soles and particularly between the toes.

WHAT TO DO ? Treat the fungal infection first.
Please refer to your pharmacist or physician for a treatment that suits you.

Once the fungal infection is completely treated, resume the treatments starting from the Initial Phase.

The controller will run an automatic troubleshooting process each time it starts up.
Dermadry has many safety features which will detect malfunctions. Any malfunction detected by the device will stop the current to prevent harm to the user. In this case, one of the following error codes will appear on the controller screen:

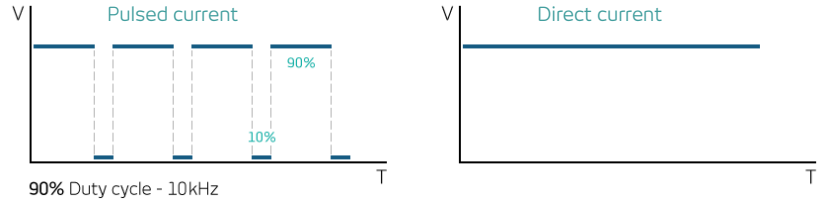
Error Code 1	Error during diagnostic
Unplug and plug back the controller from the AC adapter. If problem persists, contact Dermadry's Customer Service.	
Error Code 2	**Tension or current exceeded profile limit**
Unplug and plug back the controller from the AC adapter. If problem persists, contact Dermadry's Customer Service..	

Section 13
INTEGRATED SAFETY FEATURES

PULSED CURRENT

The device works using pulsed current. Although equally as effective as direct current, the pulsed current ensures user comfort. It also reduces the risk of irritation and pain when treating the underarms.

NOTE: All Dermadry devices use pulsed current for treatment. Pulsed current at duty cycle of 90% have been shown to have the same efficiency and to be more comfortable[4].



90% Duty cycle - 10kHz

SHORT CIRCUIT PROTECTION

The device will detect short circuits (e.g., the electrodes come into contact) and stop delivering current.

[4] Refer to reference 4 in the section 21 - Bibliography.

ALTERNATING POLARITY DURING TREATMENT

Dermadry incorporates a feature that automatically alternates the polarity of the current. When doing so, the symbol of polarity alternating loop will appear on screen and the current strength will start decreasing. Once the current strength reaches zero, the device will automatically alternate the polarity and the current strength will start rising again. This process eliminates risk of harm due to the variation of the pH level of the tap water. A tingling sensation might be felt during this process, especially at high current strength. This is particularly important when treating the underarms. It also helps to ensure a smooth treatment is carried out.

SAFETY & CHILD LOCK

The device will not start treatment until the activation button is pressed for 3 seconds. This allows the user to verify the device settings before starting treatment. It also prevents treatment being started unwantedly by a child if the device has been left unattended.

Section 14
MECHANISM OF ACTION

Many studies[5,6,7] have emitted hypotheses on the mechanism of action of tap-water iontophoresis. They mostly suggest that current directed through the skin irritates connections between sweat nerves and sweat glands. While the sweat gland is not affected, the sweating stops.

This effect only happens after several treatments and is not permanent. Treatment is to be repeated regularly to maintain this effect.

The use of tap water ensures uniform treatment over the target regions. Providing an adequate level of current on the target area will stop the sweat in the majority of cases.

The success of treatment depends on the current strength. Higher current levels work better and should be used for intense sweating. The treatment strength should be changed based on skin sensitivity. Hands and feet can tolerate a higher current strength than the underarms.

[5,6,7] Refer to references 5,6,7 in the section 21 - Bibliography.

Section 15
WARRANTY

- The Dermadry device expected service life is 5 years provided it is used and maintained as per the instructions for use.
- The warranty provided for the device is 1 year. The controller, AC adapter, cables, electrodes and the case are covered for this period.
- The Dermadry controller and components are not intended to be repaired and the warranty does not cover any breakages due to physical shock, water or heat damage or any damage resulting from unintended use. The warranty covers only defects caused by manufacturing problems and those which occurred through normal use of the device.
- The towels and the pockets for the underarm electrodes are consumables and are not included in the product warranty. Please contact Dermadry's Customer Service. or visit Dermadry Laboratories website for more information.
- Underarm pockets should be replaced after 30 uses.
- Any repair, manipulation or damage beyond the warranty conditions renders the warranty null and void.

Section 16
DISPOSAL

The device must not be disposed of in domestic waste. It must be taken to the nearest collection facility that accepts electronics/electrical appliances. If the location of such is unknown, please contact your municipality. They will be able inform you of the disposal options at a facility in your area.

Special precautions for Europe: The Directive on Waste Electrical and Electronic Equipment (WEEE) requires you as an end-user to dispose of any WEEE separately.

WEEE waste may contain hazardous substances that should not end up in the (human) environment and can have adverse effects if they do.

Section 17
TECHNICAL DATA

Essential Performance

In order to perform its functions (essential performance), the device must be able to deliver up to 25mA and 55V DC, without going over these values by more than 5V or 5mA, for a duration of 15 to 20 min.

AC adapter

Input	**Input Voltage**	100-240 V~ / 50-60 Hz
	Max. Current Input	600 mA
Output	**Rated Output Voltage**	5 V
	Current Output	Max 1.2 A
	Max. Output Rating	Max 6 W
Operating temperature	**In ° Celsius:** **In ° Fahrenheit:**	20-40 °C 70-105 °F
Environmental conditions of transport and storage between uses	**In ° Celsius** (Fahrenheit)	-25 °C to +5 °C (-13 °F to 41 °F) and +5 °C to +35 °C (+41 °F to 95 °F) at a relative humidity up to 90%, non-condensing; > 35 °C to 70 °C (95 °F to 158 °F) at a water vapour pressure up to 50 hPa

Controller

Dimensions Control Unit	**L x B x H**	In cm: 10.1 x 13.1 x 3.9 In Inch: 3.98 x 5.16 x 1.54
Weight	**In grams** (In pounds)	197 g (0.434 lb)
Input	**Supply Voltage**	5 V DC
	Current Input	Max 700 mA
	Performance Input	Max 3.5 W
Ambient Temperature Relative Humidity of Air Barometric Pressure	**For Transport and Storage**	-25 °C to +70 °C 30% to 70 % 700 hPa to 1060 hPa
	For use	+10 °C to +30 °C 30% to 70 % 700 hPa to 1060 hPa
Output Current	**Treatment Voltage**	Max. 55 V
	Treatment Current	Max. 25 mA
	Pulse Rate	10 kHz Rectangular
Operating temperature	**In ° Celsius:** **In ° Fahrenheit:**	20-40 °C 70-105 °F
Environmental conditions of transport and storage between uses	**In ° Celsius** (Fahrenheit)	-25 °C to +5 °C (-13 °F to 41 °F) and +5 °C to +35 °C (+41°F to 95 °F) at a relative humidity up to 90%, non-condensing; > 35 °C to 70 °C (95 °F to 158 °F) at a water vapour pressure up to 50 hPa
Accuracy of displayed values	**Current**	+/- 1 mA
	Tension	Under 5 V: +/- 5 V | Over 5 V: +/- 1 V

Section 18
ELECTROMAGNETIC COMPATIBILITY

Dermadry has been developed and manufactured according to the Electromagnetic Compatibility (EMC) guidelines.

Please note that Medical-Electric devices are subject to particular EMC precautions.

Make sure to follow the warnings listed below.

Interference emission	Compliance	Electromagnetic surrounding - Guidance
RF emission according CISPR 11	Group 1	Only RF energy is used in the internal function of the device. Therefore, the radiation emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission according CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage AC adapter network that supplies buildings used for domestic purposes.
Harmonic emission according IEC 61000-3-2	Not applicable OR Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transients / bursts IEC 61000-4-4	± 2 kV for power supplies ± 1 kV for input/output lines	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV for line(s) to line(s) ± 2 kV for line(s) to earth	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on AC adapter input lines IEC 61000-4-11	**< 5 %** U_T (> 95 % dip in U_T) for 0.5 cycle **40 %** U_T (60 % dip in U_T) for 5 cycles **70 %** U_T (30 % dip in U_T) for 25 cycles **< 5 %** U_T (> 95 % dip in U_T) for 5 s		Mains power quality should be that of a typical commercial or hospital environment. If the user of Dermadry requires continued operation during power mains interruptions, it is recommended that the Dermadry is powered from an uninterruptible AC adapter or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

Electromagnetic immunity			
The Dermadry device is designed for operation in the electromagnetic environment specified below. 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 Dermadry, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: 2m
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 3 Vrms	Md = 1,2ÖP

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

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

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

Dermadry is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Dermadry device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Dermadry. The minimum distances to be observed are described below considering the maximum output power of the communication equipment:

Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d = 1.2ÖP	80 kHz to 800 MHz d = 1.2ÖP	800 kHz to 2.5 GHz d = 2.3ÖP
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

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

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

Section 19
SYMBOLS AND LEGEND

SYMBOL	DESCRIPTION
	For indoor use only.
	CLASS II equipment.
REF	Catalogue reference number.
	WEEE compliance symbol (Waste Electrical and Electronic Equipment Directive).
TÜV SÜD	TÜV SÜD symbol for Safety and EMC compliance.
	Keep dry.
IP21	Ingress Protection: IP XY X: 2 Protected against solid foreign objects of 12,5 mm Ø and greater Y: 1 Protection against vertically falling water drops.
RoHS	Short for **Directive on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment.** Indicates that none of the following ten substances was used in the manufacture of the medical device: Lead (Pb), Mercury (Hg), Cadmium (Cd), Hexavalent chromium (Cr6+), Polybrominated biphenyls (PBB), Polybrominated diphenyl ether (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP).

SYMBOL	DESCRIPTION
	Follow Instructions for use.
or	Warning.
	Type BR applied part.
	Indicates the medical device manufacturer .
	Indicates the date when the medical device was manufactured.
SN	Serial number.
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.
FC	Symbol to indicate compliance to the FCC rules for each type of electrical function that is contained in the product. As a general rule, products that, by design, contain circuitry that operates in the radio frequency spectrum need to demonstrate compliance through the applicable FCC equipment authorization procedure (i.e., Verification, Declaration of Conformity (DoC) or Certification) depending on the type of device as specified in the FCC rules.
	Fragile.

Section 20
CONTACT INFORMATION

20.1 Manufacturer

Dermadry Laboratories inc.
9223 boulevard Langelier, Montréal, QC H1P 3K9, CANADA
Email: support@dermadry.com

20.2 European Representative

CEpartner4U | Ton Pennings
Esdoornlaan 13, 3951DB, Maarn, The Netherlands

Section 21
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