
IDROSTAR

Please read this instruction leaflet carefully.
The results and guarantee for this machine depend on its proper use.

(M.a.j. 09/05)

GB



INDICATIONS

Treatment of hands and feet hyperhidrosis.

CONTRA-INDICATIONS

- Pregnancy
- Cardiac pacemakers
- Metal orthopaedic implants

i2M®

Manual Contents

Warnings	3
Introduction to Idrostar	3
Contents	3
Description of the controls	4
Maintenance of Idrostar	5
Setting up the Idrostar	5
Treatment of Hyperhidrosis	6
Warnings	6
Getting Started	6
Frequency of Treatment	7
Duration of Treatment	7
Treatment of Children	7
Side effects / Precautions	7
Important Battery Information	8
Condition of Guarantee	9
Accessories	10

Warning

- 1. The simultaneous connection of the machine with high frequency electrical equipment may result in burns to the side of the machine electrodes and possible damage to the machine.**
- 2. Do not use the machine within one metre of short wave or microwave equipment as this may produce instability in the machine output.**
- 3. Only use the accessories delivered with the Idrostar, other accessories may cause a fault with the machine.**
- 4. Do not allow liquids to get onto the machine.**
- 5. Do not open the machine. There are no serviceable parts inside. Service should only be done by a qualified person.**



: This standard graphical symbol means that you have to read the document before using the machine.



: This standard graphical symbol means that you are using a BF electrical class equipment.

== : This standard graphical symbol means DC Voltage.

Introduction to the Idrostar

The Idrostar machine is for the maintenance treatment of hyperhidrosis and allows treatment of two extremities at any one time. The treatment works by introducing a mild electrical current to the affected extremities via the water baths. The affected areas of the extremities should be placed on the plastic grills within the baths with the electrodes below and submerged in sufficient tap water to cover the affected area.

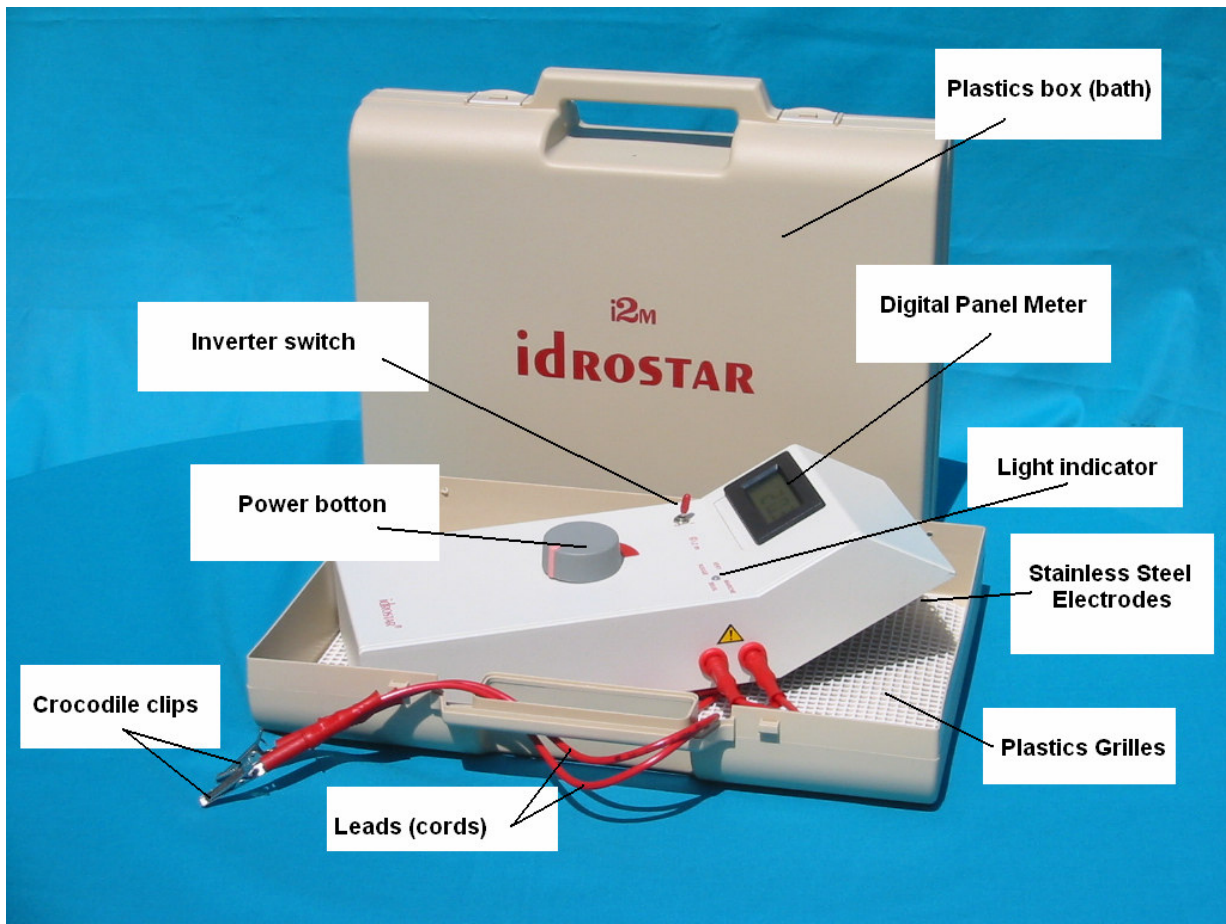
The Idrostar is designed to be portable. It runs off four Standard AA batteries and can be carried by the baths interlocking together and become the carrying case. The machine, electrodes, plastic Grills and Leads all fit in the case.

Contents

Your Idrostar is delivered with:

- 1 pair of plastic baths (The carrying case):
- 1 pair of stainless steel electrodes to fit the baths
- 1 pair of plastic grills to fit the baths.
- 1 pairs of electric leads with stainless steel crocodile clips
- 4 x AA Batteries
- 1 Instruction Manual.

Photo and Description of the machine and its controls



Plastic Box:	This is the carry case and water baths.
Stainless Steel Electrodes:	These are placed in the bottom of the baths
Plastic Grills:	These are placed over the top of the Stainless Steel Electrodes to avoid skin contact with the electrodes.
Leads:	These connect into the sockets on the machine and by connecting the crocodile clips to the Stainless Steel Electrodes supply the current to the Electrodes
Display Panel Meter:	Display shows the current intensity in mA (from 1 to 30).
Inverter Switch:	Switch to change the polarity (only when the current is at zero).
Power Button:	This has two functions firstly it turns the machine on and then by turning it gradually in a clockwise direction it increases the intensity of the current. (Before using the machine ensure the switch is turned off, fully anti clockwise)
Light Indicator:	The light comes on green when the machine is switched on and changes through orange to red as the intensity of current increases.

Maintenance of the Idrostar

1. The baths, steel electrodes and grills can be disinfected with dilute Milton or similar and then dried by using hand towels.
2. The machine must only be cleaned with a soft cloth, slightly moistened with water or a mild detergent solution. Do not use solvents such as alcohol, benzine or thinner, as they may affect the finish.
3. Never immerse the machine in water.
4. When the machine is not in use, remove the leads from the machine.
5. When the treatment is finished, never place the machine and accessories in the baths if they are still wet.
6. If you do not use the machine for some time, it is best to remove the batteries so that they do not leak in the case.

Setting up the Idrostar

Insert batteries: 4 x alkaline AA batteries are to be inserted into the battery compartment located on the back of the machine. To do this remove the cover, place the 4 batteries within the housing, ensuring they are the correct way round as shown on the bottom of the battery housing. (If the batteries are not inserted correctly, the green indicator light, marked, "ON/MARCHE" will not light up).

Once the batteries are in place replace the battery cover and place the machine on the table.

(4 alkaline AA batteries should last for 3 sessions, depending on the quality of the batteries. You can use rechargeable batteries of 1.2 volts these should be recharged after each session.)

Place one of the stainless steel electrodes in the bottom of each bath.

Place one of the plastic grilles over the top of each of the stainless steel electrodes. *(These are to ensure your skin does not come in direct contact with the stainless steel electrode.)*

Plug the leads into the output sockets on the machine and take the crocodile clips, that are connect to the other end, and attach them to the corners of the electrodes. (one clip per electrode).

Ensure that the power button is off (turned fully anti clockwise).

Cover each grill with warm tap water to a depth of at least 1cm, approximately 1 litre of water.

Treatment of Hyperhidrosis

Warnings

Ensure all jewellery, watches etc are removed.

The skin surface to be treated must be free of all lesions (if any are present, cover with a small amount of Vaseline).

Never remove your extremities from the baths when the power is switched on.

Getting Started

If you suffer from both hands and feet hyperhidrosis then it is recommended that you treat the extremities on one side of your body first then the other, for example place the right hand in one bath and the right foot in the other, this allows you to use the free hand to control the machine.

If you suffer from feet hyperhidrosis only then treat both feet together placing one foot in each bath.


If you suffer from hands hyperhidrosis only, then treat both hands together placing one hand in each bath. You will require someone to help you with the controls.

1. Ensure the inverter switch is in position "1" and the machine is switched off.
2. Place the extremities to be treated into the baths ensuring to press only lightly on the plastic grills avoiding all contact with the Stainless Steel Electrodes.
3. Turn the power button slowly clockwise to the maximum tolerable level. You should feel a 'pins and needles' sensation, but this should not be uncomfortable.

At a certain level you will feel a slight discomfort or pricking. During the early sessions the sensations may quickly become difficult to tolerate, if this occurs reduce the intensity of the current by turning the power button anti clockwise until it becomes tolerable.

With repeated sessions the skin will improve and the current can be increased towards, but never beyond 20 mA on the digital panel meter. ***The Indicator Light will become red at 18 mA as a precaution to prevent the user passing level 20 mA.***

4. After 10 or 15 minutes (See Duration of Treatment page 7), very slowly turn the power controller anti clockwise to the "STOP " position. ***Ensure that the green indicator light has gone out.***
5. Change the inverter switch to the "2" position.
6. Restart the treatment for the same extremities following steps 3 to 4 above and after 10 or 15 minutes; again very slowly turn the power controller anti clockwise to the "STOP" position. ***Ensure that the green indicator is switched off.*** The treatment is now complete for this side.
7. Dry off the extremities and if treating hands and feet then repeat sections 1 to 6 with extremities untreated.

: ***The digital panel meter will remain at zero unless your extremities are in the baths and the machine is switched on.***

⚡: please note that the power may increase without help by about 1-3 mA every 2 minutes or more

⚡: once the treatment is in progress, do not remove hand or foot from the bath.

Frequency of treatments

The treatment protocol below is for patients that have had no Iontophoresis treatment before, or it is a considerable time since you have had treatment and the condition has returned to how it was before treatment. If you have had treatment before by a Hospital or Clinic and you are using the machine for maintenance then treatment is only necessary when the sweating cessation returns.

For new patients or patients that have let treatment lapse for a long time period you should follow the schedule shown below:

First week	- treatment on Day 1, Day 2 & Day 4.
Second week	- treatment on Day 7 & Day 10.
Third week	- treatment on Day 15.
Fourth week	- treatment on Day 22.

In practice an almost complete cessation of sweating can be achieved after the fourth treatment. After the seventh treatment session, further sessions will only be needed if sweating restarts. It is then best to commence therapy immediately. At this stage, only one or two treatments may be necessary.

⚡: There is no benefit in multiplying and extending the time of the treatment, please respect the prescribed advise.

Duration of Treatment

20 minutes in total for hands and feet - reverse polarity after 10 minutes

30 minutes in total for feet only - reverse polarity after 15 minutes

Treatment of Children

The basic treatment is the same as for adults, but because the skin is thinner the power level should not exceed 15mA.

Please seek medical advice before commencing treatment on children.

Side Effects / Precautions

These are always benign and mild

- An unpleasant electric shock (approximately 30V, but not dangerous) if the patient breaks the circuit during treatment by lifting a hand or foot out of the water.
- Sensation of mild burning if the metal electrode is touched.
- Microbruising if the intensity of treatment is too great.
- Moderate hyperkeratosis (hardening of the skin, callus) if treatment sessions are too frequent.

Important Battery Information

General Precautions

- . Keep batteries out of reach of children.
- . Insert the batteries in the proper direction as indicated by the positive (+) and negative (-) markings on the battery and battery compartment.
- . Do not mix old and new batteries or batteries of different types (for example, carbon and alkaline batteries).
- . Always remove old, weak, or worn-out batteries promptly and recycle or dispose of them in accordance with Local and National Disposal Regulations.
- . If a battery leaks, remove all batteries and recycle or dispose of them in accordance with the battery manufacturer's instructions and Local and National Disposal Regulations. Before inserting new batteries, thoroughly clean the battery compartment with a damp paper towel, or follow the battery manufacturer's recommendations for cleanup. If fluid from the battery comes into contact with skin or clothes, flush with water immediately.
- . Remove the batteries if your device is to be stored for longer than a month without being used, or better remove the batteries after used your device.

Special Precautions

Released battery electrolyte is corrosive, can cause damage to the eyes and skin, and may be toxic if swallowed. The precautions below are to prevent the sudden release of electrolytes, which these prohibited actions can cause.

- . Do not open, puncture, or mutilate the batteries.
- . Do not install the batteries incorrectly. Carefully observe the positive (+) and negative (-) markings on the battery for proper installation.
- . Do not heat batteries.
- . Do not use a fire to dispose of batteries.

Product Disposal Information

Dispose of this product in accordance with Local and National Disposal Regulations.

CONDITIONS OF GUARANTEE

I2M guarantee that this product is free of faults of materials or manufacture at the time of purchase, and during the following 2 years. However, the battery cannot be guaranteed.

If a fault occurs during the guarantee period by reason of defective materials, the manufacturer, I2M will take responsibility under the following conditions.

1. The guarantee will only be valid on production of the invoice with the following details filled in:-
 - a) The name of the purchaser
 - b) The name, address and stamp of the distributor
 - c) The name of the model and the product's serial number
 - d) The date of the purchase

I2M reserve the right to refuse this guarantee if all or part of these details are missing or modified after the original purchase.

2. This product cannot be considered defective in material or manufacture if it has been adapted or changed to conform to the technical or security standards of any country other than that for which it was designed.

This guarantee does not apply

- a) With any of these adaptations or changes whether or not correctly performed
- b) To any damage which results from the above

3. This guarantee will not cover any of the following points-

- a) The repair or replacement of parts worn out by normal use
- b) The costs and risks of transport to or from the place of repair
- c) Damage to this product resulting from:-
 - i) Abuse or misuse in particular, but not exclusively due to
 - (a) Negligence or fault by the user (used contrary to instructions or design, dropping, breakage or accidental cracking) and
 - (b) Installation or use of this product contrary to the technical or security standards that apply in the country of use.
 - ii) Repairs by non agreed personnel
 - iii) Accidents, natural disasters or all other causes out of the control of I2M in particular but not exclusively due to lightning, flooding, fire, public disturbance, batteries which have worn out and poor ventilation.

4. This guarantee in no way limits the statutory rights of the customer under the national laws in force. In the absence of such national laws this guarantee or its use within the E.U, will be the sole and exclusive legal recourse of the customer and I2M will not be held responsible for damage whether direct or indirectly resulting from failure to abide by the above conditions.

Please note

During the duration of the guarantee we advise you to keep the original packaging in case you need to return the machine - which must always be returned complete to STD Pharmaceutical Products Ltd., Plough Lane, Hereford, HR4 0EL. United Kingdom

I2M is a registered trade mark

IDROSTAR is a registered trademark

IDROSTAR is a registered model

I2M LTD (capital 16,000Euros) specialists in the Innovation, production and distribution of medical apparatus.

Accessories

- 1 x electronic box
- 2 x plastic baths
- 2 x stainless steel electrodes – dimensions: 325 x 200 x 0.6mm (w/h/d)
- 2 x stainless steel crocodile clips
- 2 x plastic grills
- 2 x cords – length: 1m50
- 1 x instructions for use
- 4 x AA batteries.

Weight: 2kg

Package dimensions: 350 x 275 x 85mm (w/h/d)

This machine conforms with the international standards:

EN 60601-1 / EN 60601-2-10 / EN 60601-1-2 / EN 55011 / IEC 801-3 / IEC 801-2

I2M est certifié ISO 9001-2000 & ISO 13485-2003,
Matériel aux normes CE,
Organisme notifié n°0499.

