AED IONOMAT

USER MANUAL

27/12/18

Anglais / English

IONOMAT 1

1 General description and expected use of the IONOMAT ..........................1 3
2 Contents of box ......................................................................................3
1 General description and intended use of IONOMAT 1

IONOMAT 1 is intended for the treatment of perspiration of the hands, feet or armpits by ionophoresis, it also allows the treatment of warts of the feet and hands.

Iontophoresis is one of the most effective methods to combat sweating. It works with water to transmit a small flow of 10 to 20 mA electrical current to the skin surface (through the feet or hands placed on electrodes with 2 cm of ordinary water).

The electrical current released by the machine has one purpose: to microscopically thicken the surface layer of the skin in order to block the production of perspiration.

The ionophoresis method consists of placing the areas to be treated (feet, hands, etc.) in tanks containing water and operating the device.

For the armpits, it is a matter of placing small electrodes on wet sponges, putting them under your arms and activating the machine.

The treatment of perspiration gives satisfactory results after a period of between 4 and 10 weeks, respecting the frequency of sessions indicated in this manual.

For the treatment of warts, one tablespoon of sodium salicylate is added to the water on the affected side.

2 Contents of the box

| → The Generator | → 2 Cables with crocodile clips | → 2 Stainless steel electrodes |
| → Bins (2 or 3 litres) | → 2 Cables with crocodile clips | → 2 Storage Case |
| → Biocompatible grids | | |
2 Product Features

Device name: IONOMAT 1
The medical device for the treatment of hypersudation by iontophoresis.

The functions are ensured by the electronic assembly allowing the production of a stable and precise current.

![Generator of IONOMAT 1](image)

Figure 1: Generator of IONOMAT 1

⚠️ It is strictly forbidden:
- to use accessories, spare parts, and equipment not described in this manual.
- to connect this unit to other equipment not described in this manual
- to modify this device

3 User Manual

For assistance, if necessary, in the assembly, use or maintenance of the device, please contact AED IONOMAT.

3.1 Unpacking the device and starting the device

1 Remove the medical device from its transport package.

⚠️ The red wire must be connected to the red plug, the black wire must be connected to the black plug.

⚠️ Risk of Strangulation - Special attention should be paid to the use of cables

4 Once the generator and bins are positioned at your convenience, pour 2cm of tap water into each tray (for hand and foot treatment)
**Wet the sponges abundantly (for underarm treatment).**

The device must be positioned so that you can easily access the mains plug to ensure separation to the power supply.
4  Hand perspiration treatment

1) Place on a coffee table: the generator in the middle,
On the left is a tray with the electrode covered with the biocompatible grid.
On the right the other tank with the electrode covered with the biocompatible grid.
2) Connect the electrodes to the cables with the clamps to the generator,
3) Plug in the generator; the green LED lights up and you read 00.0
Pour about 2 cm of water into the bins. (hands must not be fully immersed).
Sit comfortably on a chair in front of the table.
4) Adjust the current to the supported value according to the table of recommended values, start
with the minimum value, gradually increase over the sessions until the maximum value is easily
supported).
5) Turn the right knob to "IONO 20" and put your hands in the water immediately.
6) After 15 seconds, the current rises slowly and then stabilizes. It cancels out after 10 minutes
and then slowly increases again as it reverses.
7) After 20 minutes the device rings, you can then remove your hands and stop the ringing by
setting the right button to 0.

⚠️ You can stop the treatment at any time by gradually removing the extremities
and finishing with a palm.

⚠️ During the first use, it is recommended to use 20min to determine the
effectiveness of the treatment, switch to the 30 mn position in case of insufficient
effectiveness.

<table>
<thead>
<tr>
<th>Children (From 7 years old)</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>HANDS</td>
<td>2 à 8 mA</td>
<td>5 à 20 mA</td>
</tr>
</tbody>
</table>

Frequency of sessions: In attack treatment 3 to 5 sessions the first week, then 2 sessions per week for
4 weeks and 1 maintenance session per week all year round.

Treatment of foot tranpiration

1) Place on a coffee table: the generator.
Place 1 tray on the floor on the left with the electrode covered with the biocompatible grid.
Place the other tray on the right side of the floor with the electrode covered with the biocompatible grid.

2) Connect the electrodes to the cables with the clamps to the generator,
3) Plug in the generator, the green LED lights up and you read 00.0
4) Pour about 2 to 3 cm of water into the bins. (The feet should not be fully submerged).
5) Connect the electrodes to the cables with the clamps to the generator,
6) Plug in the generator, the green LED lights up and you read 00.0
7) Sit comfortably on a chair in front of the table.

Pour about 2 to 3 cm of water into the bins. (The feet should not be fully submerged).

Sit comfortably on a chair in front of the table.

4) Adjust the current to the supported value according to the table of recommended values, start with the minimum value, gradually increase over the sessions until the maximum value is easily supported
5) Turn the right knob to "IONO 20" and put your feet in the water.
6) After 10 seconds, the current rises slowly and then stabilizes. It cancels out after 10 minutes and then slowly increases again as it reverses.
7) After 20 minutes the device rings, you can then remove your hands and stop the ringing by setting the right button to 0.

You can stop the treatment at any time by gradually removing the ends and ending with the heel, or reset with the current adjustment knob.

During the first use, it is recommended to use 20min to determine the effectiveness of the treatment, switch to the 30 mn position in case of insufficient effectiveness.

You will read 00.0 if one or both feet are not water.

<table>
<thead>
<tr>
<th>Feets</th>
<th>Children (From 7 years old)</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
</table>

|                | 3 à 10 mA                   | 5 à25 mA    | 10 à 25 mA   |

Frequency of sessions: In attack treatment 3 to 5 sessions the first week, then 2 sessions per week for 4 weeks and 1 maintenance session per week all year round.

7 Underarm perspiration treatment

1) Connect the alligator clips to the width of the stainless steel armpit electrodes.
2) Thread the stainless steel underarm electrodes into the biocompatible sponges when wet thoroughly.
3) Hold them under the arms horizontally, letting the crocodile clip extend well beyond the arms, which should not touch the skin.
4) Set the right button to "Iono 20" and gradually increase to read between 3 and 6 on the display.

⚠️ When using, do not exceed 6 mA read on the display; a higher current may cause small burns that heal spontaneously. Wait for complete recovery before resuming treatment.

⚠️ You will read 00.0 if the electrodes are not in place under the arms or are not sufficiently wet.

⚠️ Wet the biocompatible protective sponges thoroughly.

<table>
<thead>
<tr>
<th></th>
<th>Children (From 7 years old)</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underarms</td>
<td>1 à 3 mA</td>
<td>4 à 6 mA</td>
<td>4 à 6 mA</td>
</tr>
</tbody>
</table>

Frequency of sessions: In attack treatment 3 to 5 sessions the first week, then 2 sessions per week for 4 weeks and 1 maintenance session per week all year round.

Warts treatment

7.1 Treatment of warts unilaterally (on one side)

1) Add one tablespoon of sodium salicylate to the water on the electrode side connected to the red cable, the other end is immersed in ordinary water
2) Use the "Lock" position of the right button.
3) Then refer to the instructions for the treatment of sweating on your hands or feet.

7.2 Treatment of bilateral warts (both sides)
1) Add one tablespoon of sodium salicylate to each tray.
2) Use the "Iono 30" position of the right button.
Then refer to the instructions for treating hand or foot perspiration.

<table>
<thead>
<tr>
<th></th>
<th>Children (From 7 years old)</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hands</td>
<td>2 à 8 mA</td>
<td>5 à 22 mA</td>
<td>8 à 25 mA</td>
</tr>
<tr>
<td>Feet</td>
<td>5 à 10 mA</td>
<td>8 à 25 mA</td>
<td>12 à 25 mA</td>
</tr>
</tbody>
</table>

Frequency of sessions: Two sessions per week are necessary until the wart(s) disappears completely, the skin must be clear.

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8 Cleaning and disinfection of the device

8.1 IONOMAT maintenance

Do not use acetone solvent
The cleaning of the device is limited to the external parts with a non-abrasive sponge soaked in alcohol or a dry cloth
Never immerse the unit in water or clean it with ether.

Device :
- The cleaning of the device is limited to the external parts with a non-abrasive sponge soaked in alcohol or a dry cloth.
- Never immerse the device in water or clean it with ether.

Accessories :
- Dry the electrodes.
- Dry the biocompatible grids
- Dry the bins after each use.
- Renew the electrodes every month with a scouring pad to maintain their shine.
- Never put the cables in water or disinfectant.

8.2 Disinfection

8.2.1 Home use:
Treatment of hyperhidrosis:
- Disinfect the trays, biocompatible grids and electrodes every 10 sessions with diluted bleach.
Warts treatment:
- Disinfect the trays, biocompatible grids and electrodes between each session with diluted bleach.

8.2.2 Use in a professional environment:

Treatment of hyperhidrosis or warts:
- Disinfect the tubs and sponges and electrodes between each patient with water using the recommended products: Steranios 2%, Hexanios G+R or Alcohol 70%.
- Refer to the instructions for the products used.

4.1 Storage of the Dispenser

1) Once the treatment is complete, disconnect the medical device, empty the water from the trays and dry the electrodes and trays
2) Store the device in its case (if applicable) in this order:
   - Place the electrodes at the bottom of the case.
   - Place over the bins
   - Place the generator in the trays and surround the trays with the power cable and the cables connecting the electrodes
   Or store the device in a suitable place so as not to damage it.
5 Troubleshooting

Only AED IONOMAT personnel are authorized to carry out repairs to the IONOMAT 1. For any incident, contact AED IONOMAT. In any case, unplug the power cord from the wall outlet.

6 Possible errors identified

<table>
<thead>
<tr>
<th>Errors Identified Information</th>
<th>Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>The generator does not display and the green light does not light</td>
<td>Check the power supply of the device</td>
</tr>
<tr>
<td>Low battery on display</td>
<td>Voltage on insufficient area</td>
</tr>
<tr>
<td>Display &quot;00.0&quot; during treatment</td>
<td>Check that both ends are well immersed in water</td>
</tr>
</tbody>
</table>

7 Recommendations for use

The use of IONOMAT 1 is not recommended for patients meeting one of these criteria:

- Pregnant women
- Children under 7 years
- People with heart problems
- Persons with metallic prostheses and / or orthoses
- Persons with metallic IUDs
- Persons with injuries at the extremities

13 Precautions for use

13.1 Transport of IONOMAT 1

The integrity of the transport is ensured by a transport package containing dunnage particles.

13.2 Precautions

- Carefully keep this user manual as it contains the information necessary for proper use of the equipment,
- Before connecting the appliance to an outlet, check the values given in the appliance's operating instructions (volts and Hz) and your distribution network,
- Medical device, fragile, to handle with precautions,
- Do not unscrew the visible nuts,
- Do not open the device,
- Do not place anything on the unit and do not bend the cables
- Always unplug the appliance after each use,
- Do not leave the cables within easy reach of children
• For children, the treatment is the same, but it is necessary to respect the recommended current values. We advise the presence of an adult during the treatment.

13.3 Disposal
At the end of life, the device is to be placed in a suitable reprocessing center. Under no circumstances should the device and disposable probe be disposed of with household waste or disposed of in the environment.

Pursuant to European Directive 2002/96 / EC, this electrical appliance must not be disposed of in household waste but must be brought to a waste disposal facility for processing for recovery.

13.4 Electromagnetic Sensitivity
This device complies with the requirements of EN 60601-1-2 which describes electromagnetic compatibility (EMC) requirements for medical devices. IONOMAT 1 requires precautions against EMC.

Interference Hazards: The use of accessories, sensors and cables other than those specified, with the exception of sensors and cables sold by the manufacturer as an internal component replacement part, may lead to increased levels of interference. Emission or a decrease in immunity levels of IONOMAT 1. Using IONOMAT next to other devices may cause interference. Especially in the vicinity of RF communication with higher immunity levels than the values in Table 9 of EN 60601-1-2.

13.5 Intended User Profile & User Environment
The device is intended to be used in an environment but medical and in patients' homes. It is intended for several users:
• Practitioner (Dermatologist / Physiotherapist / Podiatrist): Person who is currently using medical devices
• Patient: Person (> 7 years) using this medical device at home

13.6 Pictograms used on IONOMAT 1

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Mention</th>
<th>Symbols</th>
<th>Mention</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacture or place of manufacture" /></td>
<td>Manufacture or place of manufacture</td>
<td><img src="image" alt="Date of manufacture" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Displays the relative humidity limit between which the IONOMAT can be safely exposed" /></td>
<td>Displays the relative humidity limit between which the IONOMAT can be safely exposed</td>
<td><img src="image" alt="Applied part of type BF" /></td>
<td>Applied part of type BF</td>
</tr>
</tbody>
</table>
13.7 Technical Specifications

- Dimension of the generator: 220 x 155 x 70mm
- Generator weight: 0.8 kg
- Constant current generator
- Guaranteed current from 0mA to 25mA on a load of 2.2kohms
- Digital reading of current in mA and indication of polarity
- Residual ripple for 10mA 10mV nominal, warranty below 20mV
- 15 s +/- 1 current-delaying device at start-up
- Slow ((1-exponential) growth of the current to reach the preset value
- Automatic zero reversal
- Automatic shutdown, power cancellation and ringing at the end of the cycle
- Casing, buttons made of insulating material
IONOMAT 1

- Sealing of the generator: IP 21
- Class IIa medical device,
- 230 V / 50 Hz - 10VA
- 2 fuses of 0.5A (not accessible)
- 2 fuses of 0.1A (not accessible)
- IONOMAT 1 device does not have essential performance
- Cables 1m long and 0.75 sections

13.8 Device life
The lifetime of the device and its accessories is:
- Generator: 10 years
- Cables: 5 years
- 2 x plastic trays (30 cm x 20 cm x 6 cm): 5 years
- 2 x 3 cm plastic bins (34 cm x 23 cm x 7 cm): 5 years
- 2 pairs of stainless steel feet / hand electrodes: 5 years

Maintenance must be performed every 5 years to ensure the performance and safety of the device

13.9 Storage conditions
Storage conditions for IONOMAT 1 are described below.

<table>
<thead>
<tr>
<th>Transport, Storage and Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient temperature</td>
</tr>
<tr>
<td>0°C à + 38°C</td>
</tr>
<tr>
<td>Relative humidity</td>
</tr>
<tr>
<td>30% à 70%</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
</tr>
<tr>
<td>850hPa à 1060hPa</td>
</tr>
</tbody>
</table>

14 Administrative information concerning the company
For any incident (operation or unforeseen event), please contact AED IONOMAT

AED IONOMAT
Adress : 5 rue des Genêts 34269 La Tour Sur Orb - FRANCE

Telephone service from Monday to Friday only in the morning from 9am to 12pm.