

*i*ONECARE

Portable iontophoresis device



User's Manual

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**IMPORTANT: READ THIS USER’S MANUAL
THOROUGHLY BEFORE USING**

Chap. 1 - INTRODUCTION

1.1 – What is Ionecare?

Ionecare is a new portable iontophoresis system for everyday wellbeing that is particularly suitable for treating the commonest forms of pain. The memory contains 20 preset iontophoresis and microcurrent treatment programmes.

Ionecare has two independent channels for connecting up to four electrodes to stimulate two different parts of the body simultaneously. The unit can also be used on two different persons at the same time, adjusting the treatment intensity independently in accordance to each subject's sensations.

1.2 – Who can use Ionecare?

Ionecare may be used by anyone who wishes to carry out specific pain relief treatments themselves at home or while travelling. It is so easy to use that treatments may be performed anywhere and at any time, to take full advantage of its beneficial effects and to achieve extraordinary results.

1.3 – Applications of Ionecare

Ionecare may be used for a wide variety of applications, ranging from the analgesic treatment of joint and muscle pains to cervical and lumbar pains, tendonitis, etc. In addition to pain relief, Ionecare may also be used to obtain a relaxing effect.

1.4 - Iontophoresis

Iontophoresis is used to promote the migration of medicinally active compounds into tissues in the form of ions, which cross the cutaneous barrier when a direct current is applied.

The medications used, which are responsible for the actual effects of the treatment, ionise in an aqueous solution and are applied either directly on the sponge, if already in liquid form, or dissolved in distilled water first and then applied on the sponge if in powdered form.

It is extremely important that you know the correct concentration and, unless you are using an amphoteric compound (one with no polarity), the polarity of the medication before starting, so that it may be applied to the sponge on the electrode of the same polarity. Additionally, an excessively strong concentration may cause skin irritation, whereas an excessively weak concentration may allow a predominance of parasite ions, deposited on the skin or on poorly cleaned sponges. The effect of the iontophoresis therapy is strictly dependent on the type of drug used and the effective quantity that crosses the cutaneous barrier. The latter factor is determined by the intensity of the current used, the duration of the therapy, the concentration of the solution and the surface area of the electrode. This form of therapy, which is used in a wide variety of medical areas, is indicated for the treatment of pathologies of **structures located close to the skin and not surrounded by substantial layers of**

muscular or fatty tissue, such as the **elbow, hand, wrist, knee, shoulder, cervical area and the tibia-tarsus area**. Depending on the drug used, iontophoresis may be used to achieve analgesic, anti-inflammatory, antiedemic or muscle relaxant effects (see drugs listed in the following table).

Table of drugs used in iontophoresis

Drug	Polarity	Pharmaceutical action	Indications
Calcium chloride (Sol. 1% 2%)	+	Sedative and recalcifying	Osteoporosis, Spasmophilia, algodystrophic syndrome DO NOT USE in cases of arteriosclerosis
Magnesium chloride (sol. 10%)	+	Analgesic, sedative, fibrolytic	Substitute for calcium chloride in cases with arteriosclerosis
Potassium iodide	-	Sclerolytic, emollient	Scars, adhesions, Dupuytren's disease, cheloidis
Lysine acetylsalicylate	-	Antiphlogistic and analgesic	Artrrosis
Flectadol, Aspegic	-	Analgesic	Artrrosis, extra/intra-articular rheumatism
Local anaesthetics (Novocaine, Lidocaine)	-		Local anaesthesia, trigeminal neuralgia
Benzydamine	+	Antiphlogistic and analgesic	Rheumatoid arthritis
Diclofenac sodium	+/-	Antiphlogistic and analgesic	Bruising
Orudis, Voltaren, Feldene, Lometacen, Arfen, Tilcotil, Axerol, Naprosyn	-	Anti-inflammatory	Degenerative and extra-articular rheumatism, gout
Piroxicam	+	Antiphlogistic and analgesic	Sprains
Sodium salicylate (1%-3%)	-	Analgesic	Articular rheumatism, acute decongestant, myalgia
Ketoprofene - Lysine salt	+/-	Anti-inflammatory	Arthrosis, arthritis
Thiomucase	-	Antiedemic	Post-trauma and post surgical edema and edema due to venous insufficiency

NOTE: if the drug used is not included in the above list, determine the polarity from the package or consult the prescribing doctor or dispensing pharmacist.

Chap. 2 - SAFETY GUIDELINES

2.1 – General guidelines

Before using the device for the first time, read this user's manual thoroughly. Furthermore, before switching the device on or connecting to a patient, always perform the following checks:

- (1) check the unit visually for **signs of damage**;
- (2) read and make note of all **warnings** printed on the unit;
- (3) keep unit away from any **spillage hazards**, as the unit is not impermeable (IP 20);
- (4) check that you have the **right accessories necessary** for the intended stimulation treatment (see Chap. Standard Equipment).

2.2 – Counter-indications

Iontophoresis may not be used in the following cases:

- (1) on persons wearing pacemakers or suffering from heart disease or arrhythmia;
- (2) on the front of the throat, as this may provoke laryngeal spasm;
- (3) on the sides of the neck, as the carotid body is particularly sensitive;
- (4) on the abdomen or in the lumbar sacral area of pregnant women;
- (5) in areas with skin lesions, mucosa, altered localised sensitivity, infection, inflammation, phlebitis or thrombophlebitis;
- (6) in the case of implanted electronic devices (e.g. pacemakers) located immediately beneath the treated area;
- (7) when using near areas with metallic implants (prostheses, osteosynthesis materials, screws, plates, etc.);
- (8) in the proximity of tumours and in abdominal and lumbar areas in the event of liver or kidney stones;
- (9) in areas afflicted with dermatitis or with cutaneous hypoesthesia, allergies to the substances used or in conjunction with thermal anaesthesia
- (10) Keep away from children.

2.3 - Precautions for use

Consult a doctor and use the electro-stimulator only under medical supervision in the following instances:

1. should the symptoms not subside after a few days of treatment with iontophoresis;
2. when applying electrodes to the face;
3. when using near areas with metallic implants (prostheses, osteosynthesis materials, screws, plates, coils, etc.);
4. in patients suffering from epilepsy or Parkinson's disease, as their sensitivity threshold may be altered;
5. in the case of suspected or confirmed pregnancy and applying only to the extremities;

6. when applying electrodes to areas near tendon or muscle injuries;
7. with patients suffering from spastic paralysis.

Do not apply electrodes in the following areas:

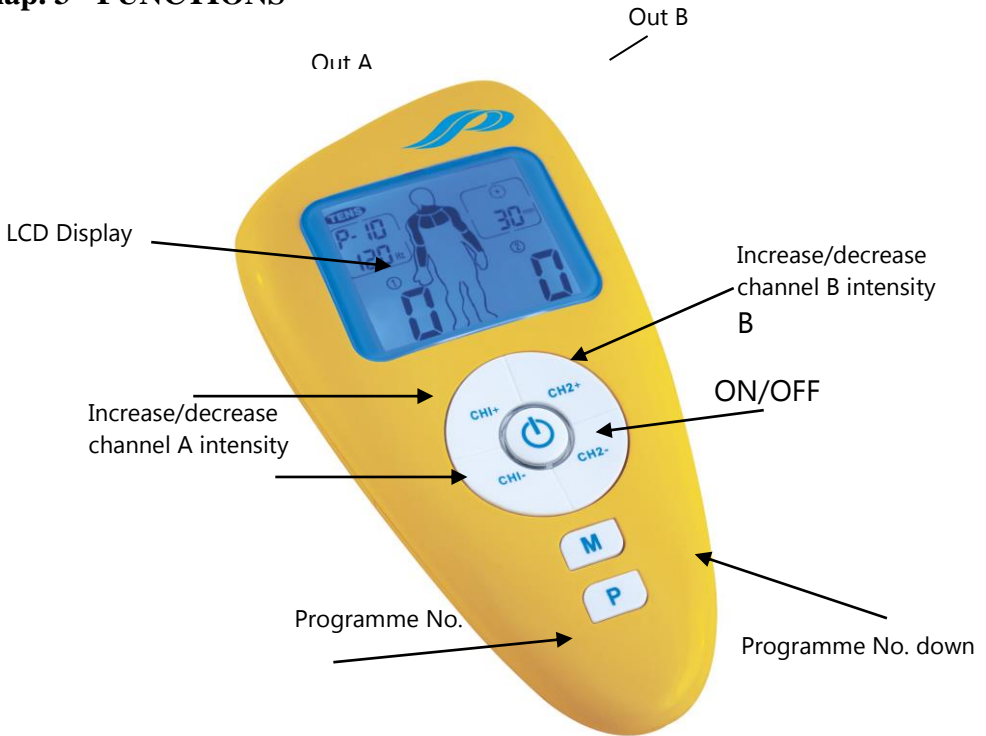
1. above the eyeball;
2. directly onto sensitive areas, such as the centre of the breast, the groin or the armpit.
3. The heart must never be situated between the positive and negative electrodes. Never apply an electrode on the front of the chest and one on the back near the heart.

2.4 - Special Precautions

1. Do not use the iontophoresis after a **large meal**.
2. If symptoms of **tachycardia**, **extrasystole** or **intolerance to stimulation** arise, **suspend** treatment to restore normality.
3. After treatment, a slight **reddening** of the skin where the sponge was applied is possible. If, however, a burning sensation is noted during the treatment, interrupt the therapy, check that the sponges are still wet and reposition correctly in full contact with the skin.

NOTE: Apply the sponges carefully so that they adhere completely with the skin as poor contact may lead to reddening and, eventually, burns.

Chap. 3 - FUNCTIONS



Use Ionecare as follows:

1. **fit batteries** in the battery compartment at the back of the unit: ensure that the polarity is as indicated in the compartment,
2. **put in charge the battery charger and connect it to the device for 12 hours;**
3. **disconnect the battery charger**

NOTE: instructions 2 and 3 must be followed only before first use or every time the display shows low battery indication.

4. **wash** the application area and remove any creams or lotions;
5. **attach leads** as required (from 1 to 2), with the respective connectors inserted in the sockets in the upper part of the unit;
6. **connect electrodes;**

7. Wet the sponges thoroughly with water and squeeze so that they do not drip.
8. Prepare the medicinal compound (dilute to the correct concentration if necessary) and apply to one of the two sides of the sponge containing the electrode of the polarity indicated on the package of the drug or specified by the prescribing doctor or physiotherapist; **positive poles are the red plugs, whereas negative poles are the black plugs;**
9. Apply the sponge with the drug to the area you intend to treat and apply the other sponge on the opposite side of the relative body part or at a distance of approximately 10 cm (see Figure 'APPLICATION');
10. Secure the electrodes with the elasticised strap supplied so that their surfaces are completely in contact with the skin;
11. **switch on** the unit by pressing ON/OFF;
12. choose a **programme** with the increase/decrease programme number buttons (see **Table 1**);
13. **set the intensity** of stimulation with the + and – buttons for the channels used (A or B); The treatment will now start;

NOTES: the stimulation intensity may fluctuate as the treatment is in progress; should this occur, adjust the intensity to maintain a constant level of stimulation; On the display the output current is indicated from 0 to 60. Each step is 0,33mA. When the display shows 60, the output current is 20mA.

WARNING: if the stimulation becomes uncomfortable or painful, reduce the intensity or interrupt the treatment by pressing the ON/OFF button.

14. Press P- or P+ to temporarily pause the programme. Press ON/OFF to stop the programme.
15. once a programme has **completed**, you may select another **programme** with the programme number up/down buttons (see **Table 1**);
16. the unit switches off automatically after 2 minutes of inactivity;
17. **return electrodes and sponges to their respective bags.**

Chap. 4 - PROGRAMMES

Ionecare comes with 20 preset iontophoresis and microcurrent therapy programmes, with adjustable stimulation levels. Each program produces different effects and can be used for specific objectives. Table 1 lists all programs with relative use.

Table 1: Programmes

1	IONO.ARM. LEV.2
2	IONO.ARM. LEV.3
3	IONO.ABDOMEN-HIPS LEV.1
4	IONO.ABDOMEN-HIPS LEV.2
5	IONO.ABDOMEN-HIPS LEV.3
6	IONO.BUTTOCKS LEV.1
7	IONO.BUTTOCKS LEV.2
8	IONO.BUTTOCKS LEV.3
9	IONO.THIGHS LEV.1
10	IONO.THIGHS LEV.2
11	IONO.THIGHS LEV.3
12	MICROCURRENT LEV.1
13	MICROCURRENT LEV.2
14	MICROCURRENT LEV.3
15	IONTOPHORESIS LEV.1
16	IONTOPHORESIS LEV.2
17	IONTOPHORESIS LEV.3
18	MICROCURRENT LEV.1
19	MICROCURRENT LEV.2
20	MICROCURRENT LEV.3

* Medical programmes with CE0476 certification.

4.1 - Programming treatment sessions

For effective therapy with Ionecare, apply the most appropriate programme for the pathology in question to the relative area of the body daily, **following the instructions of the prescribing doctor**. In general, a cycle of 10 sessions is performed, which may be repeated two or three times if the desired results are not achieved. Seek medical advice if the problem persists.

Chap. 5 - APPLICATIONS

As a guideline, apply two electrodes with sponges to the area you intend to treat. **Avoid areas specified in the counter-indications and follow the instructions given by your doctor.**

With **iontophoresis**, if the pain is widespread or deep, the position in which the drug is applied is indifferent: apply the electrodes at a distance of approximately 10 cm from each other to demarcate the treated area. If the pathology or pain is felt in a well defined and superficial part of the body, apply the electrode with the drug directly onto the pain and place the other electrode in the immediate vicinity (approximately 4 – 5 cm away).

IMPORTANT: read the counter-indications before using

5.1 - Positioning the electrodes

Examples of applications with iontophoresis



NOTE: for any applications not specified here, follow the indications of the prescribing doctor attentively.

Chap.6 - TECHNICAL SPECIFICATIONS

6.1 - Characteristics

Power supply: 4 x 1,2V Ni-Mh AAA batteries

Waveform: microcurrents and iontophoresis

Channels: 2 independent

Intensity: 0-20 mA

Frequency: 100-120 Hz

Pulse amplitude: 100-350 μ s

6.2 - Standard equipment

Unit

2 dual core leads

4 silicone electrodes

4 sponge pockets

2 elasticised securing straps

4 x 1.5 V AAA batteries

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Carrier case

6.3 - Replacement parts and accessories

Silicone electrodes

Sponge pockets

Elasticated securing straps

Chap. 7 - SYMBOLS



CLASS II DEVICE



TYPE BF DEVICE



READ THE DOCUMENTATION INCLUDED



IN ACCORDANCE WITH DIRECTIVE 93/42EEC CONCERNING MEDICAL EQUIPMENT, THIS DEVICE BEARS THE CE MARK, REGISTERED AS N° MED9904, ISSUED BY THE AUTHORISED CERTIFYING ORGANISATION N°0476.

Chap. 8 - MAINTENANCE

- **Unit:** clean with a moist cloth. To ensure that the unit performs as specified, use only at environmental temperatures between 5 and 40° C and with humidity levels less than 80%. The same conditions are required for transporting and storing the unit.
- **Batteries:** remove the batteries from the unit for prolonged periods out of use. Replace dead batteries with batteries of the same type or rechargeable batteries; **do not use different types of battery together.**
- **Electrodes:** always return to their respective bags after use.
- **Sponge pockets:** always rinse and return to their respective bags after use.

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