MEG009XN102-A7
DATE 2023/01
EN

User's manual

I-Press 10C Pressure Therapy Device

Instructions for use
&
Technical description

Please read these instructions carefully before using your new device!
This manual is an integral part of the device and must be kept until it is destroyed.

This equipment has been designed and manufactured for therapeutic use.
The use is reserved for professionals Physiotherapists

If you have a problem or do not understand this manual, contact your distributor (see stamp on the last page) or contact Électronique du Mazet at :

Tel : (33) 4 71 65 02 16 - Fax : (33) 4 71 65 06 55

Please return the warranty certificate located on the last page of this manual within 15 days of installation or receipt.

Electronique du Mazet

1 Presentation of the device

The i-Press 10C is a pressure therapy device that helps in the practice of physical therapy, to treat venous disorders and lymphedema. It can also be used for wellness programs.

The computerized technology used in the i-Press 10C allows for ease of use and easy menu navigation.

The programs, predefined in the device, allow to perform most of the pneumatic drainage techniques:

- 1. venous system: venous insufficiency, varicose veins, water retention problems "heavy legs", ulcers, prevention of deep vein thrombosis (DVT).
- 2. lymphatic system:
  Lower limb zone Lymphatic system dysfunction: Secondary Lymphoedema, Edema
  Upper limb area: Lymphedema
- 3. wellness: relaxation (non-therapeutic program will not be included in the clinical evaluation), recovery after exercise

For all these programs, the parameters that can be modified are the following:

- Exerted pressure (in mmHg)
- Duration of treatment
- Treated area
- Working time
- Rest time

These settings can be changed and saved.

The i-Press 10C offers a choice of 2 operating modes:

- Access to the treatment by a clinical guide according to the pathologies with preset parameters, but modifiable and recordable
  This option allows a great ease of use and gives a guarantee of safety for the user.

- Access through the personalized processing base where all parameters can be modified and saved.
  This option allows you to adapt the program to a particular need.

Table of Contents :

2 Description and technical information

-This Operation and Maintenance Manual is published to assist you in getting started with your i-Press 10C from the initial acceptance phase, through commissioning, and on to subsequent operation and maintenance.
If you have any difficulty in understanding this manual, contact the manufacturer, Électronique du Mazet, your dealer or distributor.

-This document must be kept in a safe place, protected from atmospheric agents, where it cannot be damaged.

This document guarantees that the devices and their documentation are technically up-to-date at the time of marketing. However, we reserve the right to make changes to the device and its documentation without any obligation to update these documents.

-In the case of transfer of the device to a third party, it is mandatory to inform Électronique du Mazet of the details of the new owner of the device. It is imperative to provide the new owner with all documents, accessories and packaging related to the device.

-Only personnel who have been informed of the contents of this document may operate the equipment. Failure to comply with any of the instructions contained in this document will release Électronique du Mazet and its authorized distributors from the consequences of accidents or damage to personnel or third parties (including patients).

2.1 Symbols used

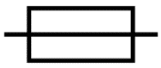
Warning: this logo draws your attention to a specific point

Operating Instructions: This logo informs you that the operating instructions must be read for safe use of the device

Type B applied part: applied part in contact with the patient and which can be connected to the ground.

Recycling: This device should be disposed of at an appropriate collection and recycling facility. Consult the manufacturer.

Protective earth



Fuse

O / I **Caution: Switching** off / on the device

Alternating current

SN Serial number

Manufacturer

Date of manufacture

REF Country of manufacture

CC Product reference

2.2 Technical specifications

2.2.1 General characteristics

- Operating temperature: 0°C to 40°C.
- Storage temperature: -40°C to 70°C.
- Operating relative humidity: 30% to 75%.
- Operating altitude: < 2000 meters
- Operating pressure: between 80 and 110 kPa

2.2.2 Technical characteristics of the device

- Housing dimensions: 340 x 320 x 140 mm
- Weight of the case : 3.5 Kg
- Case color: white - metallic grey screen

- Power supply: 230VAC - 50Hz
- Power consumption : <50VA (230VAC)
- Fuses: 2x size 5x20mm - T2AH-250V
- Class I electrical equipment
- Power on indication: Display illumination

- Medical Class IIa equipment.
- Type B applied part

2.2.3 Accessories

This device is delivered with the following accessories as standard:

-1 Power cord
-1 Pair of 10 cell boots
-1 User's Manual
-1 Clinical Guide

The optional accessories available are :
- 7-cell sleeve
- 7-cell abdominal belt
- Pair of 10-cell hip braces

The use of accessories not recommended by the manufacturer does not engage his responsibility

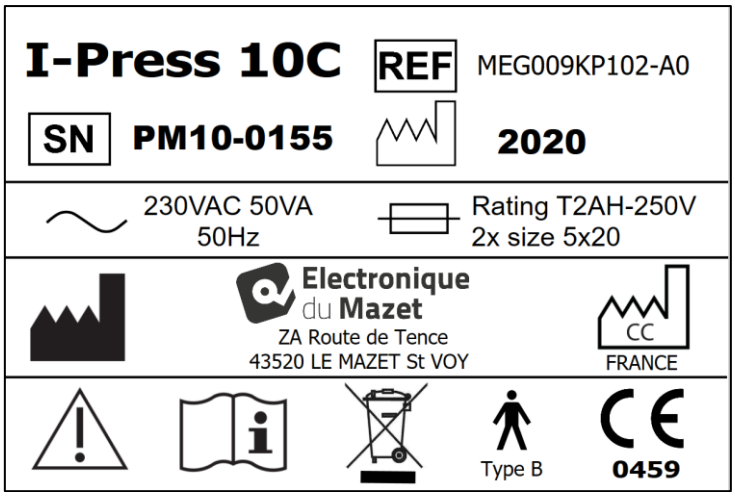
2.2.4 Applied parts

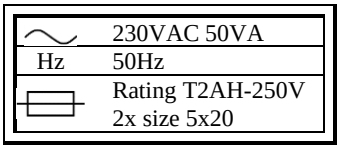
Treatment accessories should not be placed in direct contact with the patient's skin.
A single-use hygiene sheath must be used, it is considered as a **type B applied part.**
Hygiene sheaths are not supplied with the unit.

2.3 Nameplate label

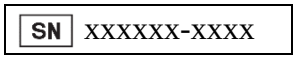
The information and characteristics are reported on the back of each device on a label

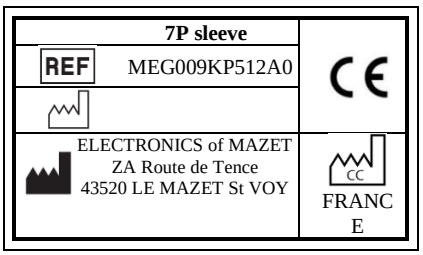
2.3.1 Device identification labels

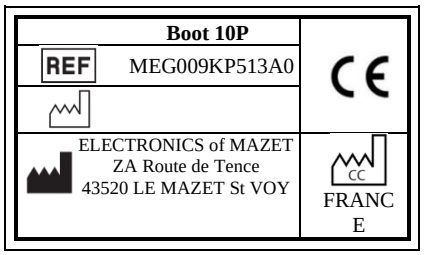


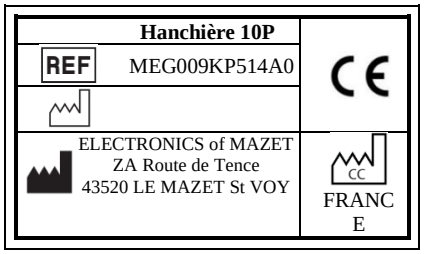


2.3.2 Accessory identification labels









2.4 Warnings

CAUTION: Install the unit on a flat, stable surface. Do not obstruct the ventilation openings (no objects closer than 4cm).

CAUTION: Power strips must not be placed on the floor. No other electrical appliances or power strips should be connected to the power strip.

CAUTION: The appliance must be connected to an outlet with a grounding terminal (Class I electrical appliance)

CAUTION: The unit must be positioned so as to allow free access to the power cable in case of emergency.

CAUTION: In case of emergency, disconnect the power cable directly from the unit.

CAUTION: No modifications to the device are permitted. It is strictly forbidden to open the housing of the device.

CAUTION: This device complies with applicable electromagnetic compatibility standards. If you experience interference or other problems with another device, contact Électronique du Mazet or the distributor for advice on how to avoid or minimize the problem.

CAUTION: This equipment is not intended for use in residential environments and may not provide adequate protection for radio reception in such environments.

CAUTION: Operating altitude below 2000m.
The performance of the device decreases with altitude.

CAUTION: The device must be used with the accessories supplied by the manufacturer.

CAUTION: The device must not be accessible to the patient.
It should not be placed in contact with the patient.

2.5 Precautions

2.5.1 Residual risks

2.5.2 Mains failure

In case of power failure during treatment, it is preferable to disconnect the pneumatic connectors on the back of the device in order to release the pressure on the limbs.

2.5.3 Treated areas

The areas treated by the device are the lower or upper limbs.
See **§7-clinical guide** for more information.

2.6 Confidentiality of patient data

The device collects data when a treatment is saved. The data is stored in the device. It is the responsibility of the practitioner to apply and be in compliance with the European Parliament's General Data Protection Regulation 2016/679.
When returning to the After Sales Service, the practitioner must delete the patient data so that it is not disclosed.

3 Installation of the device

Open the carton, remove the accessories and the i-Press 10C

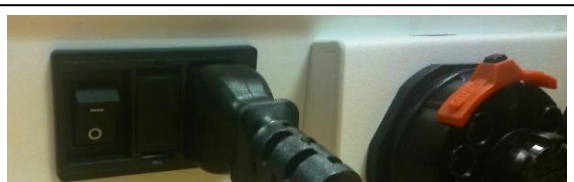
Remove the light plastic wrappings that cover the unit.
Check the contents of the box against the **packing list** included with the documentation.

Check that the contents of the box are not damaged; if you have any doubts about the integrity of the device or its accessories and that the proper functioning of the device could be questioned, contact Électronique du Mazet

If the unit was stored in a cold place and there was a risk of condensation, **let the unit rest for at least 2 hours at room temperature** before turning it on.

Before the first use, it is recommended to clean the device and its accessories, see **§8 Maintenance.**

Install the device on a stable support at working height and out of the patient's environment.



-Connect the power cord
-Flip the switch :
Position 0: Off
Position 1: On

-Connect the accessories: **Lock (red) on the left**, position the connector by respecting the coding. **Lock** by sliding the **lock to the right**.
-Disconnect accessories: Slide the **Lock to the left** to release the connector

Example of connection of 2 accessories: **Boots**

Example of connection 1 accessory: **Sleeve** (the other outlet remains free)

4 User's manual

4.1 Handling the device

4.1.1 Power on / start / stop

Turn on the device with the switch located at the back of the device (Position I: On / position 0: Off) (See §5 Installation of the device).
The home screen will turn on and display the software version.

Choice of the display language

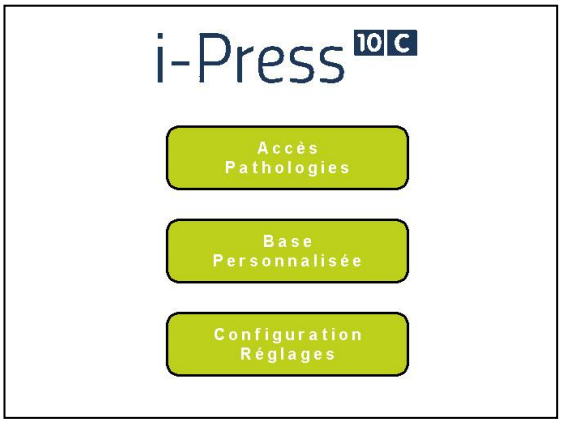
4.1.2 Use of the touch screen

The lists of choices displayed on the screen and the validations as well as the navigation in the menus are indicated by "action" buttons on the touch screen. To access the desired function, press in the indicated area.

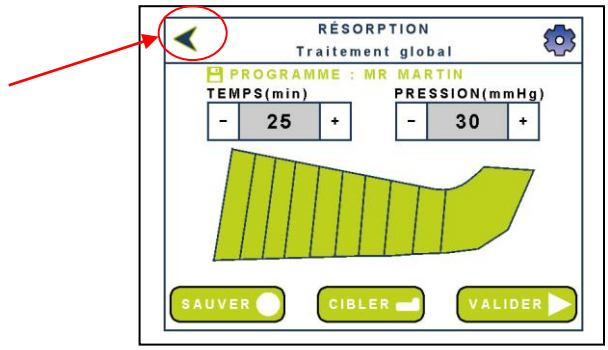
4.1.3 Menu main

By pressing the corresponding key, this menu allows you to access :

- To the "**Pathology Access**" treatment database
- To personalized treatments: "**Personalized Base**
  (See §6.2.3 Choosing a treatment from the personalized programs)
- Technical information and settings: "**Configuration and settings**" (See §6.6)



All the menus accessible afterwards will be equipped with a button allowing the return to the main menu (placed at the top left)



4.2 Choice of treatment

4.2.1 From the last treatment performed

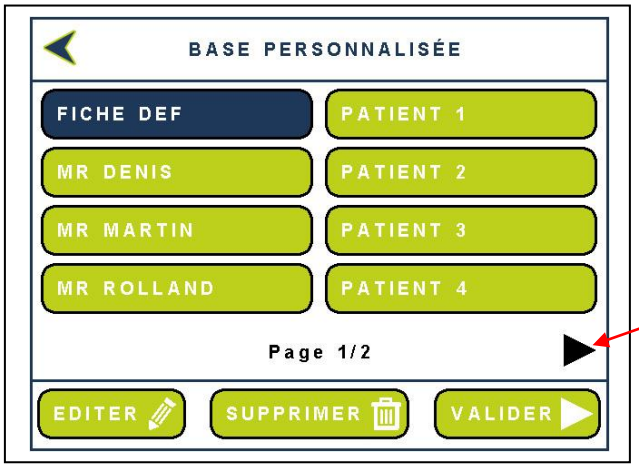
To select the last treatment performed, press the screen at the bottom left when the start page is displayed.

4.2.2 From u diagnosis

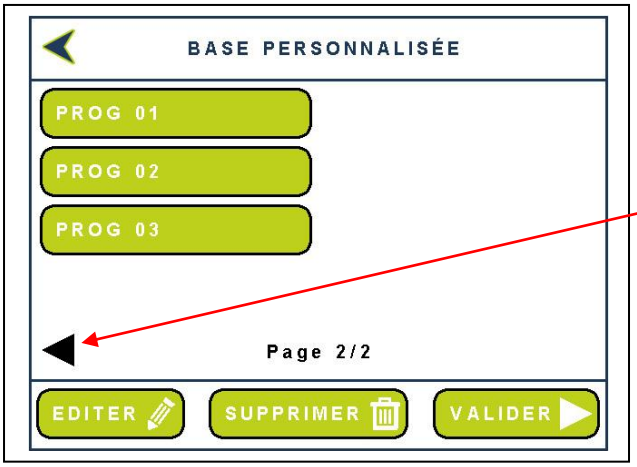
Selecting the pathology to be treated, by pressing the corresponding action button, allows access to the **§6.3 Parameter modification** menu.

The details of the predefined parameters for each pathology are detailed in **§7 Clinical Guide**.

4.2.3 From the customized programs



Goes to the next page
(5 pages / 40 patient cards)



Allows you to return to the previous page

Your own programs (up to 40 slots), distinguished by the name you assign to them (16 characters available), can be assigned to some of your patients or to specific pathologies .

Press the chosen treatment to access the menu **§6.3 Modification of parameters**.

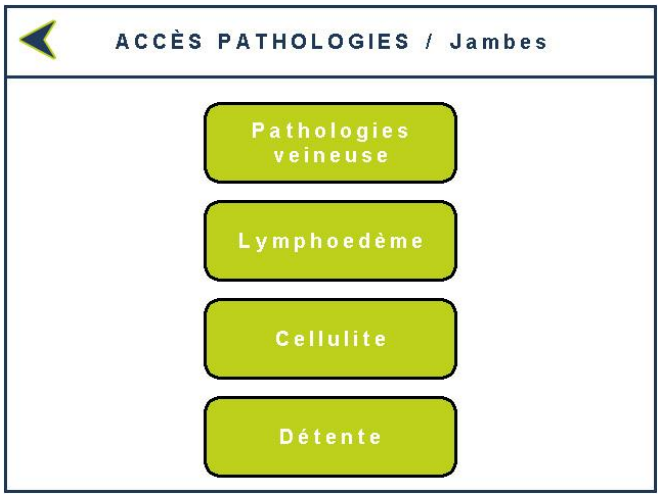
4.3 Modification of parameters

When accessing the treatment, and before starting it, it is possible to modify the "Time" (treatment) and "Pressure" (in the cells) parameters by pressing the "+" or "-" key of the one you wish to set.

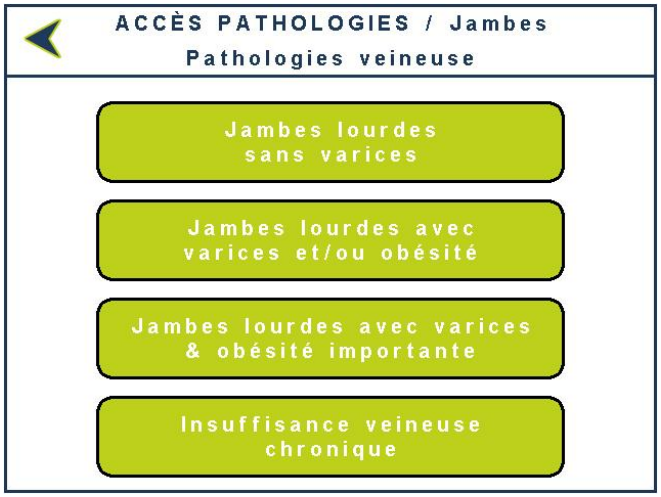
4.4 Run a treatment

4.4.1 Start the treatment

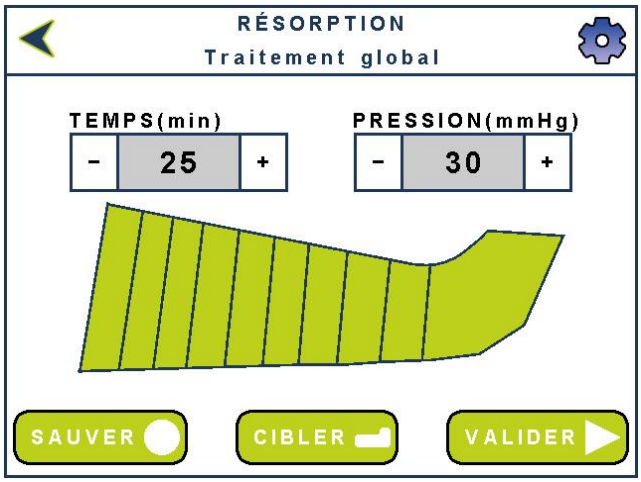
Choose the treatment category you want.



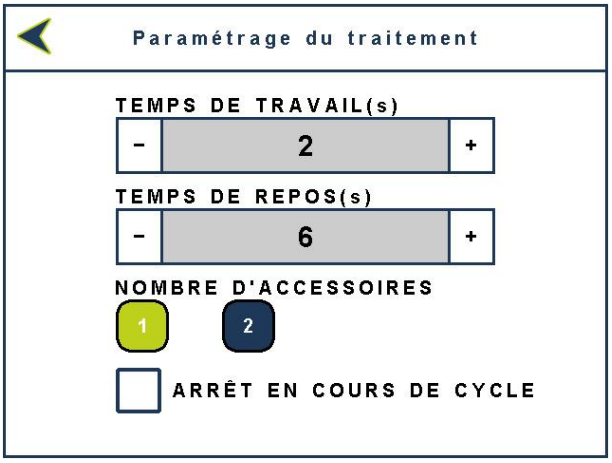
Choose the desired treatment.



Once the treatment has been chosen, adapt the parameters to the patient and press validate.



This icon gives access to the treatment settings:

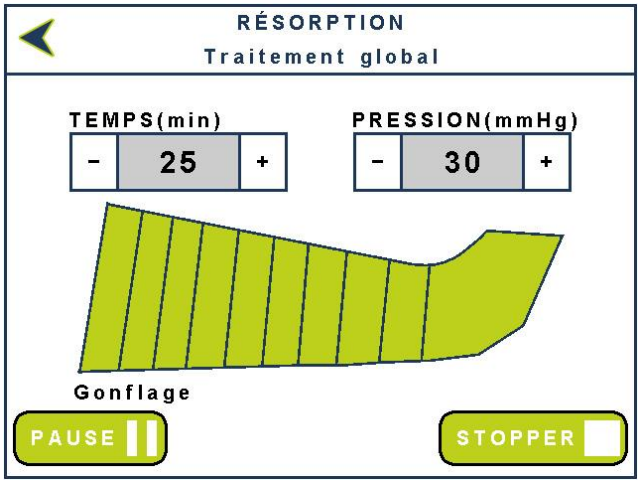


-Working time from 0 to 15 seconds
(keeping the cell pressurized)
-Rest time of 4 to 15 seconds
(Deflation between 2 inflations)
- Number of accessories: (setting available with leg programs) Default set to 2.
- Stopping during the cycle:
-Valid: end of treatment at the end of the timer.
-Otherwise the program stops at the end of a complete cycle.

4.4.2 During treatment

All parameters can be changed during processing by selection on the touch screen.

The treatment can be stopped or restarted by selection on the touch screen.



4.4.3 End of treatment

End of treatment

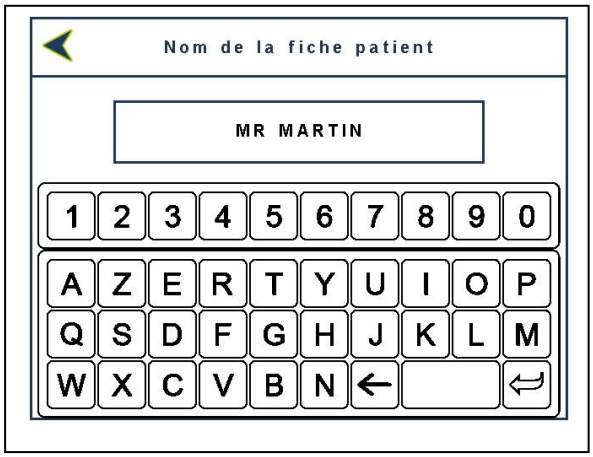
The end of the treatment is signaled by a succession of beeps.

You can stop the active deflation to return to the general menu

4.5 Saving a treatment

After stopping, at the end of a treatment or before starting the treatment, the user has the possibility to save the parameters of his treatment in one of the programs of the personalized database (see **§ 6.2.3**).

To do this, the user must press the "save" button from the processing launch screen.

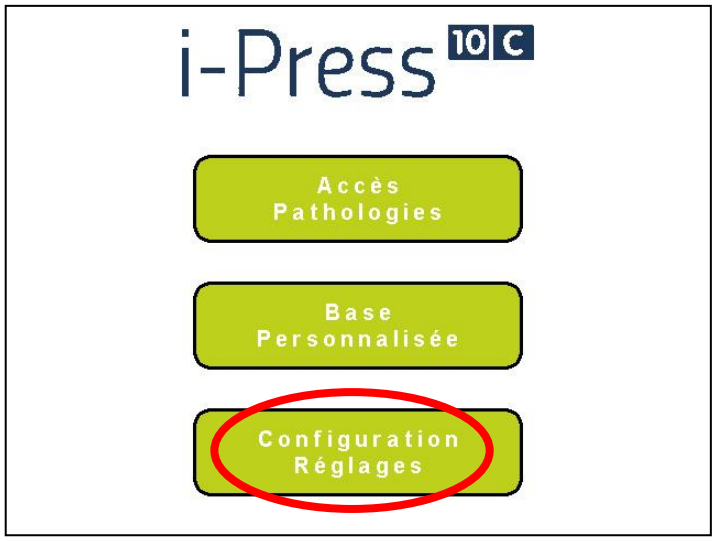


Choosing a program for the custom base :

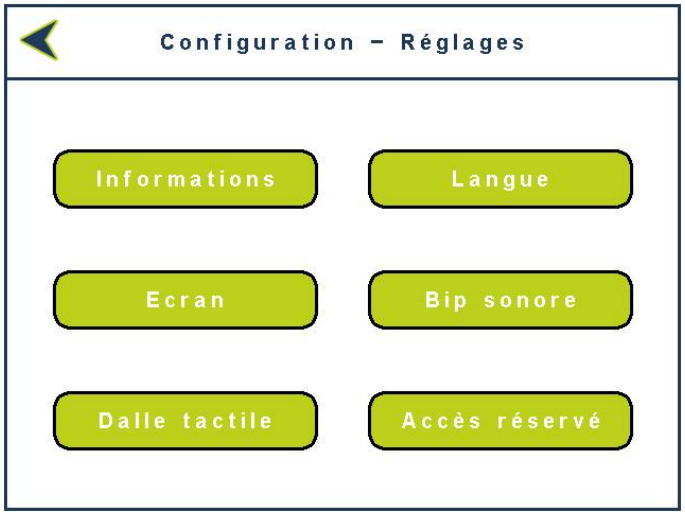
-Enter the name of the treatment (16 characters max) for a total of 40 records.

4.6 Technical Information, Configuration & Settings

This screen provides access to technical information about the equipment, menu language selection, screen brightness adjustment, sound information selection and testing.



You will then have access to the following menu:



- **Information** indicates you our coordinates as well as those of our SAV

- **Language:** allows you to select the language of the device (French, English or Spanish)
- **Screen:** allows you to adjust the contrast
- **Audible beep:** allows you to activate or deactivate the audible information when a key is pressed (the beep at the end of the treatment cannot be deactivated)
- **Touch Panel:** allows you to adjust the sensitivity of the touch panel

- **Reserved access:** allows you to launch a self-diagnosis of the device using a code that will be communicated to you by our after-sales service (Information button) in the event of a failure or malfunction of the device.

5 Clinical Guide

5.1 Target population

The device is intended for all adults over 18 years old, regardless of gender.

5.2 Expected performance

The **i-Press 10C is** a pressotherapy device that helps in the treatment of venous and lymphatic pathologies by performing mechanical lymphatic drainage.
This technique allows to promote the circulation known as "return". Indeed, the interest of lymphatic drainage is no longer to be demonstrated. The lymphatic system is a major function of our body. The transport of lymph is not always ensured adequately, moreover, it is rather slow. This can have many repercussions on the circulatory system, as well as on the general state of the body. When we know the importance of lymph in the proper functioning of our defense system and the elimination of toxins, we understand better the interest of optimizing lymphatic drainage. Manual drainage (MD) is commonly used and practiced by a good number of physiotherapists. This technique is very widespread and does not always offer all the keys to the various lymphatic pathologies. A specific case of chronic edema shows the need to treat it in synergy with other techniques: bandaging and pneumatic drainage (PD).

Pneumatic drainage should be used as a complement, not a replacement, to manual techniques. It provides practitioners with an additional aid to the treatment of their patients, and is even an indispensable tool in the treatment of edemas. Pneumatic drainage leads to decongestion, it will then be used before a manual drainage, while in other cases it can be used simultaneously, or even after a manual drainage to reinforce and prolong its effects

Thanks to the new possibilities of programming and adjustment that allow many movements, we speak of sequential and programmable pressotherapy, the indications for the use of pneumatic drainage are numerous and can be classified into 3 categories:

1. ***Venous system:*** Venous insufficiency, Varicose veins, Water retention problems "heavy legs", Ulcers, Prevention of deep vein thrombosis
2. ***Lymphatic system:***
   Lower limb zone Lymphatic system dysfunction: Secondary Lymphodemas, Edema
   Upper Extremity Zone: Lymphodema
3. ***Well-being:*** Relaxation, Recovery after exercise

5.3 Major contraindications

This device **must not be used** in the following cases:

- Emboligenic deep vein thrombosis
- Untreated heart failure, Severe arterial disease
- Skin infection (Erespele, urticaria, ...)
- Sensitivity disorder
- Severe renal failure
- Febrile state (fever, ...)
- Lymphangitis
- Systemic edema

Note: Pressotherapy treatments for pregnant or breastfeeding women have not been clinically studied, therefore the treatment of these individuals is the responsibility of the practitioner.

The contraindications are not exhaustive and we advise the user to inquire in case of doubt.

5.4 Side effects

To date, the medical literature does not mention any side effects of pressotherapy.

6 Maintenance, upkeep

The I-press 10C is designed to last for 5 years.

To ensure that the performance of the device is maintained throughout its life, it is necessary to have the device checked by Électronique du Mazet technicians every 2 years.

6.1 Housing

The case only requires normal periodic cleaning of its external surface which may become dirty. The same applies to the power cord.

The touch screen should be cleaned with a soft, dry cloth, **without any product or water**.
Clean the rest of the unit only with a dry or slightly damp cloth.
Be sure to unplug the power cord before cleaning.

6.2 Accessories

The treatment accessories must not be placed in direct contact with the patient's skin. A hygiene sheath must be used.

The treatment accessories can be cleaned with a dry or slightly damp cloth.

6.3 Sterilization:

This device is not sterile,
Accessories are not sterile, nor are they intended to be sterilized.

7 Malfunction

If you notice a malfunction that is not commented on in the documents accompanying the device (see below), please inform your distributor or the manufacturer.

In the case of a shipment of the device, please observe the following instructions:

- Decontaminate and clean the unit and its accessories.
- Use the original packaging, including the retaining flanges.
- Attach all accessories to the unit.
- Set up the different elements.
- Make sure the package is properly closed.

Shipping address:

Electronique du Mazet
ZA Route de Tence
43520 Le Mazet St Voy

Tel : (33) 4 71 65 02 16
Fax: (33) 4 71 65 06 55
Email: sav@electroniquedumazet.com

Possible operating anomalies:

Description of the anomaly	Possible causes	Actions
Screen off	Problem of the electrical network	Check the power connection
	Starting up the device	Check the position of the on/off button (position I)
	Fuses out of order	Check and change the fuses
	Other cause	Contact the service department
Pockets do not bulge	Poorly connected accessory	Check the locking of the pneumatic connectors
	Defective accessory (leak)	Contact the service department
	Pneumatic problem (defective pump or solenoid valve)	Contact the service department
Pockets do not deflate (defective active deflation)	Pneumatic problem (defective pump or solenoid valve)	Contact the service department
Other anomaly	Unknown	Contact the service department

If the device is dropped or if water penetrates, it is imperative to have the device checked by Électronique du Mazet to exclude any risk (patient and user) related to the use of the device.

8 After-sales service and warranty

This device is warranted by your supplier under the conditions specified in this document, provided that:

- Only accessories supplied by Électronique du Mazet or its distributors should be used.
- Any modification, repair, extension, adaptation and adjustment of the device must be carried out by Électronique du Mazet or its authorized distributors for these operations.
- The work environment meets all regulatory and legal requirements.
- The device may only be used by competent and qualified personnel. Use must be in accordance with the instructions in this user's manual.
- Treatments should be used only for the applications for which they are intended and which are described in this manual.
- The device must be regularly maintained according to the manufacturer's instructions.
- All legal requirements for the use of this device are met.
- The device uses only the accessories supplied or specified by the manufacturer.
- Machine parts and spare parts must not be replaced by the user.

Inappropriate use of this device or neglect of maintenance relieves Électronique du Mazet and its authorized distributors of all responsibility for defects, malfunctions, damage, injuries and the like.

The warranty is void if the operating instructions in this manual are not strictly followed.

The warranty is 24 months from the date of delivery of the device.

The accessories are guaranteed for 6 months from the date of delivery of the device.

Shipping and handling costs are not included in the warranty.

9 Disposal

9.1 Accessories

As soon as any deterioration of an accessory is noted, the product must be cleaned with a broad spectrum disinfectant and then returned to the manufacturer.

9.2 Electronics

Should the I-Press 10C device fail or become unusable, please return it to the manufacturer or drop it off at a Recylum collection point.
Indeed, as part of its commitment to the environment, Électronique du Mazet finances the recycling network Récylum dedicated to WEEE Pro, which takes back free of charge electrical lighting equipment, control and monitoring equipment, and used medical devices (More information on www.recylum.com).

10 Transport and storage

The device must be transported and stored in its original packaging or in packaging that protects it from external damage.

Store in a clean, dry place at room temperature.

11 CE declaration

ÉLECTRONIQUE DU MAZET can provide the CE declaration for this device on request.

The first affixing of the medical CE on this device took place on 14/10/2016

12 Manufacturer

Électronique du Mazet is a company located in the heart of the Massif Central. Originally a simple manufacturer of electronic cards, over the years it has developed its own brand of medical equipment, mainly for physiotherapy.

Today, EDM studies, develops, manufactures and markets pressotherapy, depressotherapy and electrotherapy devices (uro rehabilitation).

For any additional information, please contact us.

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Fax : +33 (0)4 71 65 06 55

facebook.com/mazet-santé

www.electroniquedumazet.com

13 EMC compliance table

EMC compliance according to IEC / EN 60601-1-2 (2014)			
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
Emissions test	**Standard**	**Compliance**	**Electromagnetic environment - guidelines**
RF emissions	CISPR 11	Group 1	The device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause interference in any nearby electronic device.
RF emissions	CISPR 11	Class B	The device is suitable for use in all premises, including domestic premises and those directly connected to the public low-voltage power supply network supplying buildings for domestic use.
Harmonic emissions	IEC 61000-3-2		Class A
Voltage fluctuations / Flicker	IEC 61000-3-3		Compliant
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
IMMUNITY test	**Test level IEC 60601**	**Level of compliance**	**Electromagnetic environment - guidelines**
Electrostatic Discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	The floors should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic materials, the relative humidity should be at least 30%.
Transients fast in bursts IEC 61000-4-4	± 2 kV for lines power supply electric ± 1 kV for lines input/output	± 2 kV for lines power supply electric	The quality of the power supply should be that of a typical commercial or hospital environment.
Surge voltage transitional IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and earth	± 1 kV between phases ± 2 kV between phase and earth	The quality of the power supply should be that of a typical commercial or hospital environment.
Tension dips, short cuts and variations of tension on input lines power supply electric IEC 61000-4-11	<5% UT (>95% UT trough) for 0.5 cycle 40% UT (60% UT trough) for 5 cycles 70% UT (30% UT trough) for 25 cycles <5% UT (>95% UT trough) for 5 s	<5% UT (>95% UT trough) for 0.5 cycle 40% UT (60% UT trough) for 5 cycles 70% UT (30% UT trough) for 25 cycles <5% UT (>95% UT trough) for 5 s	The quality of the power supply should be that of a typical commercial or hospital environment. If the user of the device requires continuous operation during power outages, it is recommended that the device be powered from an uninterruptible power supply or battery. NOTE UT is the AC system voltage before the test level is applied.
Magnetic field at the frequency of the electrical network (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the power system frequency should be at levels characteristic of a representative location in a typical commercial or hospital environment.
IMMUNITY test	**Test level IEC 60601**	**Level of compliance**	**Electromagnetic environment - guidelines**
			Portable and mobile RF communications devices should not be used closer to any part of the device, including cables, than the recommended separation distance,

Conducted RF disturbances IEC 61000-4-6 Radiated RF disturbances IEC 61000-4-3	3 Vrms 150kHz-80MHz 3V/m 80MHz-2.5GHz	3 Vrms 3V/m	calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.67.\sqrt{P}$ $d = 1.67.\sqrt{P}$ *80MHz-800MHz* $d = 2.33.\sqrt{P}$ *800MHz-2.5GHz* where *P is* the maximum output power characteristic of the transmitter in watts (W), according to the transmitter manufacturer, and *d* is the recommended separation distance in meters (m). The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be below the compliance level in each range of frequencies. b Interference may occur in the vicinity of the device marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the highest frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

a) The field strengths of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM broadcasting, and TV broadcasting, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic investigation should be considered. If the field strength, measured at the location where the device is used, exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or repositioning the device.
b) In the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications devices and the device

The device is intended for use in an electromagnetic environment in which radiated RF interference is controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications device (transmitters) and the device, as recommended below, based on the maximum transmit power of the communications device.

Power output maximum assigned value of the sender (W)	**Separation distance according to the frequency of the transmitter** (m)		
	150kHz - 80MHz	80MHz - 800MHz	800MHz - 2.5GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1	1.167	1.167	2.330
10	3.690	3.690	7.368
100	11.67	11.67	23.300

For transmitters with maximum rated transmit power not given above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum transmit power characteristic of the transmitter in watts (W), according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

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