Instruction manual

iPress series 10

MEG017KP102

Pressotherapy device

Elliot Fournier le 06/05/2025

Usage instructions
&
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 safe until it is destroyed.

This equipment has been designed and manufactured for therapeutic use.
Use by trained professionals only.

In the event of a failure or misunderstanding with this manual, contact your distributor (see stamp on last page) or Électronique du Mazet at :

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

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

Table of contents

1 Introduction

This user and maintenance manual has been published to help you get to grips with your ***iPress series 10***, from the receiving it, through commissioning, to the subsequent stages of use and maintenance.
If you have any difficulty in understanding this manual, please contact the manufacturer, Électronique du Mazet, your dealer or distributor.

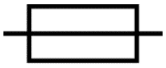
This document must be kept in a safe place, where it cannot be damaged.

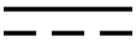
This document guarantees that the devices and their documentation are technically up to date at the time of marketing. However, we reserve the right to make changes to the device and its documentation without any obligation to update the present documents.

If the device is transferred to a third party, Électronique du Mazet must be informed of the new owner's contact details. It is imperative to provide the new owner with all documents, accessories, associated devices and packaging relating to the device.

Only personnel who have been informed of the contents of this document may operate the device. Non-compliance with any of the instructions contained in this document releases Électronique du Mazet and its authorized distributors from liability for the consequences of accidents or damage to personnel or third parties (including patients).

1.1 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 before using the device in complete safety
	**Applied part type B:** applied part in contact with the patient and which can be earthed.
	**Recycling**: this device must be disposed of at an appropriate recycling facility. Consult the manufacturer.
	**Protective earth**
	**Fuse**
	**Caution:** Switching unit off and on
	Alternating current
	Serial number
	Manufacturer
	Date of manufacture
	Product number

CE	CE marking (Conformité Européenne)
	Non-ionizing electromagnetic radiation
UDI	UDI (Unique Device Identifier)
	Temperature limit
	Operating instructions
	Direct current
MD	Medical devices

2 Device presentation

2.1 Description of pressotherapy device

iPress series 10 is a pressotherapy device.
As part of physiotherapy, it can be used to treat lymphedema. The device also offers programs for well-being and lazy bowel syndrome.
Please note that the use of the device for wellness and lazy bowel syndrome programs are not covered by a CE Medical 0459 mark issued under Regulation (EU) 2017/745 by the notified body. These are associated non-medical uses.
Pressotherapy is a treatment technique based on draining lymphatic massage techniques: a mechanical action based on physiological pressure movements using compression boots or sleeves to stimulate blood and lymph circulation.
Pre-set programs allow most pneumatic drainage techniques to be performed:
- Lymphoedemas (programs covered by a Medical CE Mark 0459 issued under Regulation (EU) 2017/745).
The pressotherapy technique can also be used to offer relaxing massage techniques, with predefined programs in the unit:
- Well-being and lazy bowel syndrome (programs not covered by a CE Medical 0459 mark issued under Regulation (EU) 2017/745).

The following parameters can be modified for all these programs:
- Pressure from 30 to 75 mmHg in 5 mmHg increments

- Treatment time from 1 to 60 min in 1 min increments
- Treated area (removal of cells)
- Targeted area (doubled dwell time on targeted cells) These parameters can be modified and saved.

The fixed parameters are :
- Working time (pressure hold) 3 s.
- Rest time (exhaust) of 5s.

The device offers a choice of 2 operating modes:
- The unit operates in "stand-alone" mode, with a predefined default program. This program is visible on the small display on the front of the device. If you wish to modify this program, you will need to download the "iPress" application (see "§ Downloading the application").
- The device operates in "connected" mode, and all parameters can be modified and saved. You will need to download the "iPress" application (see "Downloading the application") to discover the full range of programs available to you.

2.2 Expected performance

Pressotherapy is used to treat lymphedema.
The main benefit of using this pressotherapy medical device is the decongestion of lymphedema, with a significant reduction in the volume of the affected limb often observed, particularly as a complement to manual lymphatic drainage.
The main benefit of this decongestion is improved life quality: patients experience reduction in physical discomfort and improved mobility.

2.3 Intended use

Pressotherapy can be used to treat lymphedema.
Pressotherapy can also be used for well-being or lazy bowels syndrome. These uses are not covered by a CE Medical 0459 mark issued under Regulation (EU) 2017/745 by the notified body and are the sole responsibility of the practitioner.

2.4 Applications

These devices are intended for use with compression devices for the following applications:
- Treatment of lymphoedema of the lower limbs: legs and feet, thanks to compression boots.
- Treatment of lymphoedema of the upper limbs: arms and shoulders, using a compression sleeve.
The application of these compression devices generates a compressive movement on the various tissues of the human body. This compression activates lymphatic circulation.
A compression belt can also be used with the wellness and intestinal laziness programs available in the pressotherapy device.
These uses and applications are not covered by a CE Medical mark 0459 issued under Regulation (EU) 2017/745 by the notified body.

2.5 User profile

The user must be recognized as a healthcare professional. These devices are designed for use by physiotherapists.
This pressotherapy device must be used by trained medical personnel only.
with no disabilities whatsoever (motor, mental, cognitive or psychic).
The user must be aware of all the safety precautions, operating procedures and maintenance instructions provided in this user manual.

2.6 Target population

For the treatment of lymphedema:
The device is intended for all adults 18 and over, regardless of weight, age or gender, suffering from lymphedema of the upper or lower limbs. For indications of well-being / lazy bowels syndrome:
Pressotherapy treatments for pregnant women have not been the subject of clinical studies, so treatment of these individuals is the responsibility of the practitioner.

2.7 Contraindications

This device must not be used in the following situations:

- Emboligenic deep vein thrombosis
- Acute limb infection
- Cardiovascular disease and untreated heart failure, severe arteriopathy (stage III AOMI)
- Epilepsy
- Dermal infection: eresipelas
- Febrile seizures
- Glaucoma
- Feverish state
- Severe peripheral neuropathy
- Skin rash: pressure urticaria
- Acute or chronic renal failure of any stage
- Dialysis patient
- Lymphangitis
- Systemic edema

Note: pressotherapy treatments for pregnant women have not been the subject of clinical studies, so treatment of these individuals is the responsibility of the practitioner.

2.8 Side effects

To date, the medical literature does not mention any side effects concerning the practice of pressotherapy.
A single-use hygiene sheath must be used.
If you experience any side effects from pressotherapy, please contact your distributor or the manufacturer.

2.9 Technical data

2.9.1 General features

- Operating temperature: 15°C to 35°C
- Storage temperature: -20°C to 60°C
- Operating relative humidity: 30% to 65%.
- Operating altitude:< 2000 metres
- Atmospheric pressure>80kPa.

2.9.2 Technical data

- Case dimensions: 360 x 320 x 115mm
- Case weight: 5.3 Kg
- Case color: White

- Power supply: 230VAC - 50Hz
- Power consumption: 50VA (230VAC)
- 2 Fuses size 5x20mm - T3.15AH-250V
- Class I electrical appliance
- Power-on indication: Illumination display and Logo.

- Bluetooth function: BLE 2.4 GHz

- Medical Class IIa equipment
- Applied part type B

2.9.3 Accessories

This device is supplied with the following accessories as standard:

Power cord

Sealing cap

Using non-manufacturer recommended accessories does not engage the manufacturer's liability.

Associated accessories/devices are not disposable.

The optional associated devices available are :

Designation	Ref	Manufacturer
- 10-cell straight boot - 10-cell left boot - 7-cell sleeve - 5-cell abdominal belt	- MEG009KP513DxZ - MEG009KP513GxZ - MEG009KP512xZ - MEG009KP511xZ	Electronique du Mazet

x= supplier name

2.9.4 Applied parts

Associated devices must not be placed in direct contact with the patient's skin.
A single-use hygiene sheath must be used at all times.
considered as a type B applied part.
Hygiene sheaths are not supplied with the unit.

2.9.5 Touch interface features

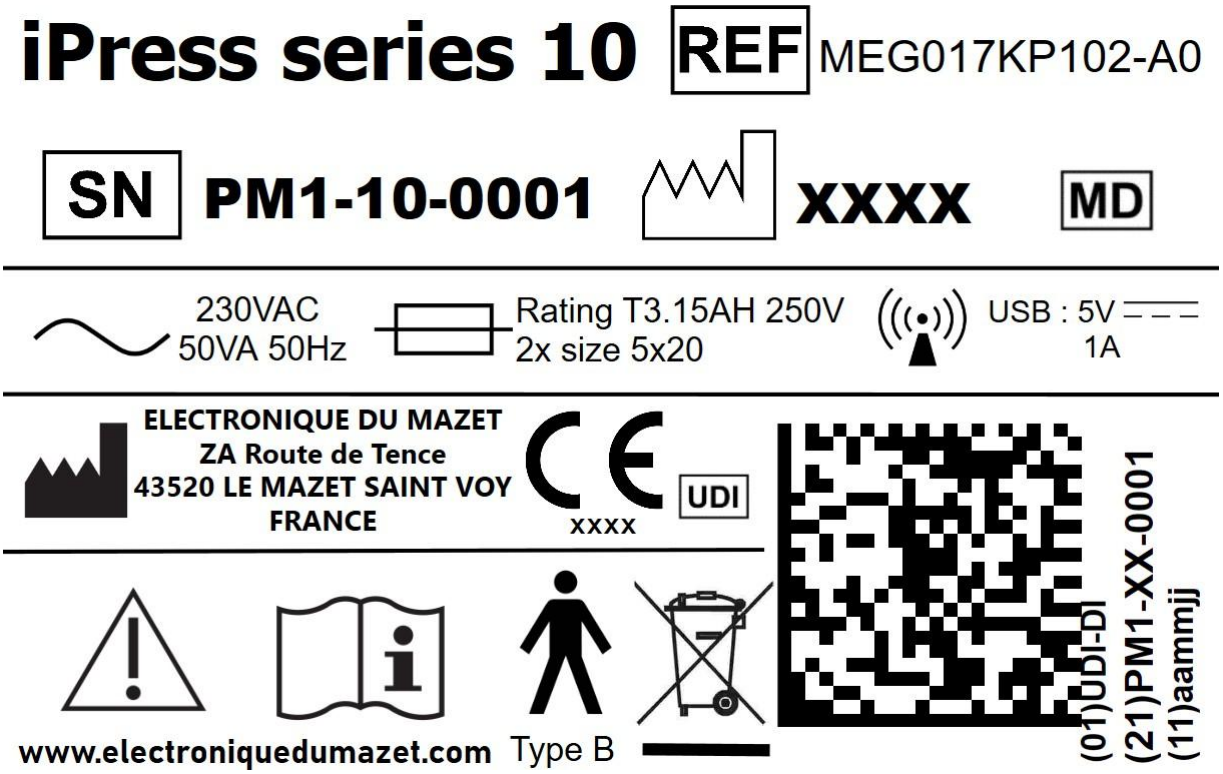
- Tablet or Smartphone with 6" to 10" screen;
- Android version: 8.0 or higher ;
- Application: *iPress* available on Play Store.

- Application: *iPress* available on App Store.

2.10 Identification label

Information and specifications are given a label on the back of each unit.

2.10.1 Identification label



3 Warnings

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

CAUTION: Multi-socket outlets must not be placed on the floor. No other electrical appliance or power strip may be connected to the power strip.

ATTENTION: The device must be plugged into an outlet with a suitable earth terminal (Class I electrical appliance).

ATTENTION: The device must be positioned so as to leave a free space for access to the power cable in case of emergency.

CAUTION: In an emergency, disconnect the mains cable directly from the unit.

ATTENTION: No modifications of the device are permitted. It is strictly forbidden to open the device casing.

CAUTION: This device complies with applicable electromagnetic compatibility standards. If you notice any malfunction due to interference or otherwise in the presence of another device, contact Électronique du Mazet or the distributor, who will give you advice on how to avoid or minimize possible problems.

ATTENTION: Operating altitude below 2000m. Performance decreases with altitude.

WARNING: The device must be used with the accessories and associated devices supplied by the manufacturer.

ATTENTION: The device has not been designed for use with creams, essential oils or any other product, which may cause premature wear.

CAUTION: The unit should be cleaned with a soft, dry cloth.

WARNING: The user must replace the associated devices as soon as their condition appears degraded.

WARNING: The user must not place anything on the unit.

CAUTION: Associated devices must not be placed direct contact with the patient's skin.
A single-use hygiene sheath must be used, it is considered a type B applied part.
Hygiene sheaths are not supplied with the unit.

4 Precautions

4.1 Environment

This device is intended for professional use only.
This pressotherapy unit is designed for indoor use only. Do not use in damp or potentially explosive environments.
This device is not intended for domestic use.

4.2 Residual risks

4.2.1 Mains failure

In the event of a power cut during treatment, it is advisable to disconnect the pneumatic connectors at the back of the unit to relieve pressure on the limbs.

4.2.2 Treated areas

The device treats the lower or upper limbs.
See §-Program for more information.

4.2.3 Applied parts

Associated devices must not be placed in direct contact with the patient's skin.
A single-use hygiene sheath must be used at all times. It is considered a type B applied part.
Hygiene sheaths are not supplied with the unit.

4.2.4 Operating environment

The risk of transmitting bacteria or viruses from one patient to another via the applied parts is possible. Be sure to observe the hygiene conditions recommended by the manufacturer (wearing hygiene sheaths).

4.2.5 Water infiltration

If water enters the unit, it may malfunction. In this case, unplug the unit and disconnect the cables. In any case, avoid the presence of water in the vicinity of the device.

5 Patient data confidentiality

The device does not collect any patient data from the mobile device (tablet or smartphone) to which it is connected.

It is the user's responsibility to apply and comply with the European Parliament's General Data Protection Regulation 2016/679.

If the tablet is returned with the device, the user must delete the patient's backup data when returning the device to the After-Sales Service department, so that it cannot be divulged. If the user wishes to keep this data, he/she can make a backup copy by saving it on an external medium before deleting it. In this case, please refer to the tablet's user manual.

6 Cybersecurity

As the device and its mobile application are computerized systems integrated into larger information systems, certain rules and best practices must be put in place to ensure the safety of patients and users.

Électronique du Mazet does not supply or control the operating environment for its products. It is therefore the user's responsibility to ensure that the following recommendations are followed.

6.1 Best practices for IT security

- Keep your software up to date, including the operating (Android).
- Use operating accounts to prioritize access.

- Use strong passwords to access accounts.
- Lock your smartphone/tablet when not in use.
- Check the authenticity of any third-party software you install.
- Check application regularly for updates.

6.2 Network communications

- The device does not require a network connection to operate.

7 Installation

7.1 Unpacking the unit

Open the carboard and remove the *iPress series 10* device.
Check the contents of the carton against the **packing list** included with the documentation.

Check that the contents of the cardboard are undamaged; if you have any doubts about the integrity of the device or its associated accessories/devices and the correct operation of the device may be in question, contact Électronique du Mazet.

If the unit has been stored in a cold place and there is a risk of condensation, **allow it to stand for at least 2 hours at room temperature** before switching it on.

Retain the original packaging to ensure safe transport of the unit in the event of an accident. maintenance or after-sales service (see § After-sales service and warranty).

Before using the device for the first time, we recommend that you clean the unit and its accessories/associated devices (see **§ Maintenance).**

Install the device on a stable support at working height and away from the patient’s environment.

7.2 Getting started

1- Mains socket
2- On / Off switch
3- Fuse location
4- Connectors for associated devices
5- USB port for smartphone or tablet charging
6- Screen
7- Play button (Process start/stop)
8- Bluetooth pairing button

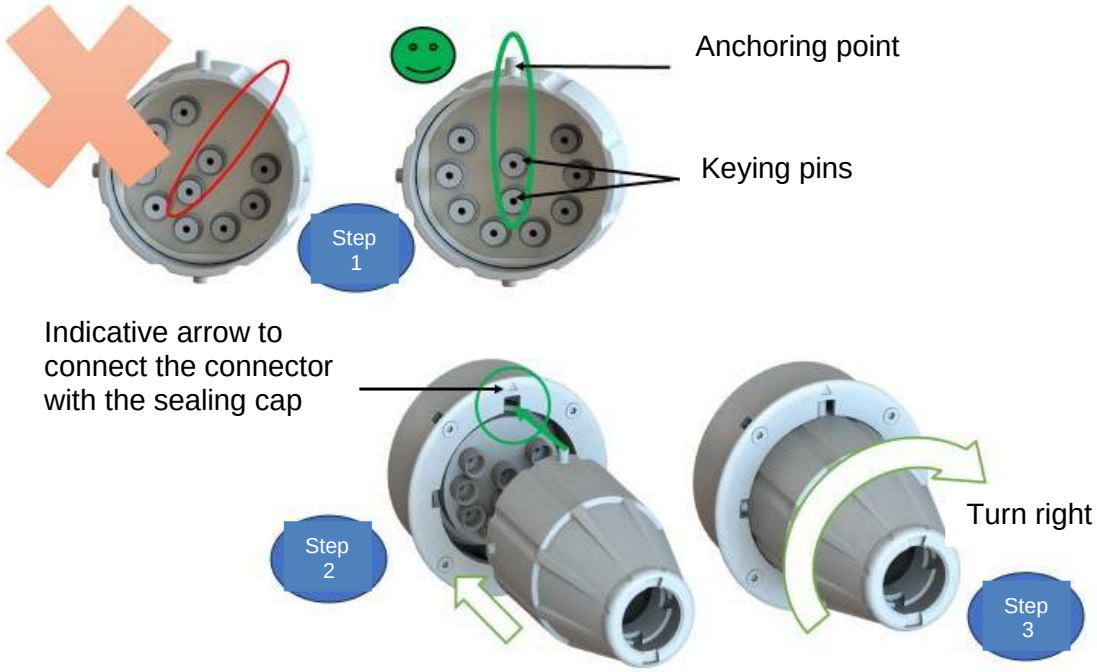
7.2.1 Power on

Connect the power cord as follows:

- Connect the power cord to the mains socket,
- Connect the mains plug to the wall socket.

Switch on the unit using the switch on the rear of the unit.
(Position I: On / position 0: Off) (See **§ Device installation**).
Display and Logo light up. Play button indicator flashes.

7.3 Connecting associated devices



To insert the accessory connector into the unit :

1. Align the keying pins (inside of connector) with the anchoring point (contour of connector).

2. Insert the connector into the device base. An arrow on the base of the device will guide you.

3. Lock the connector by turning it to the right

Repeat this step to connect the second accessory.

If you wish to use only one accessory, you need to insert the blanking plug into the device base on the second remaining plug by following the 3 steps described above.

To unplug the connector, do the opposite maneuver.

7.4 iPress application

Note: it is possible to operate the device without using the application,
but its functionality is limited.

7.4.1 Download

The "iPress" application must be downloaded onto the user's smartphone/tablet.
by scanning the QRcode below:

GET IT ON Google Play

The smartphone/tablet used must be equipped with an Android system version 8 or higher.

If you encounter any difficulties, please refer to §9-Malfunctions.

To connect the device and the application, *see §Application Getting Started*.

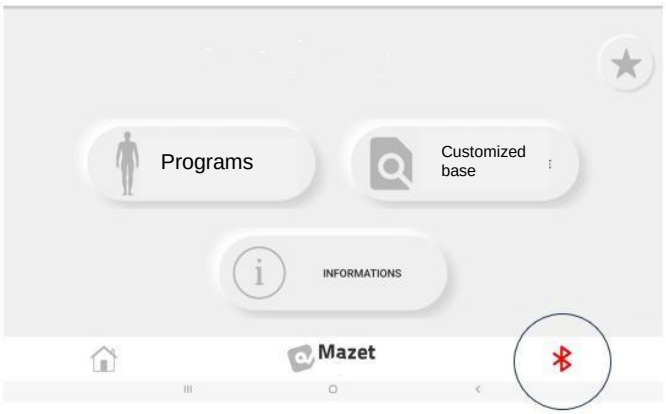
7.4.2 Connecting the device to application

➔ Switch on the pressotherapy unit
➔ Activate geolocation on tablet/smartphone
➔ Connect the device to application :

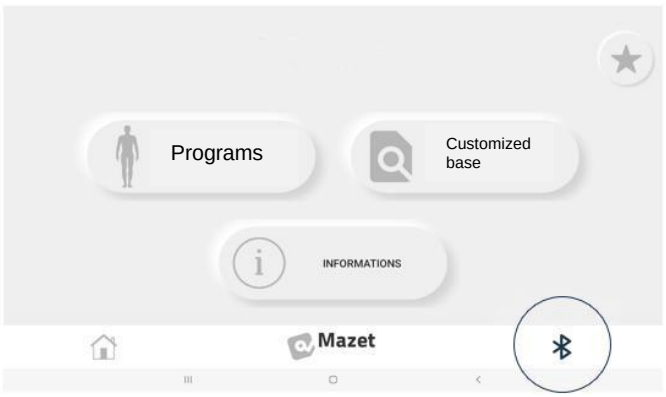
- Press the Bluetooth logo on application: the logo should change color from red to blue.
- Press the Bluetooth button on the device (flashes blue)

The LOGO appears when the device is linked to the application.

Screen before BT connection



Screen after BT connection



7.5 Operating device

7.5.1 Default use

After switching on the device, simply press the 'Play' button to start processing in the device's memory.
The default setting is the "decongestion phase" treatment (**§ - Program guide**), with a pressure setting of 50 mmHg and a treatment time of 25 minutes.

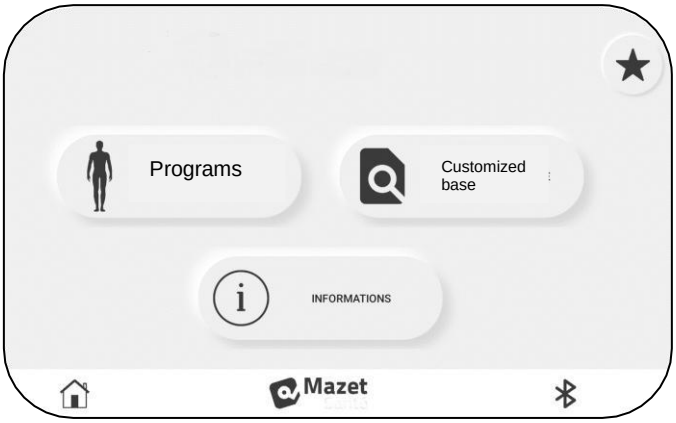
To change the default program, simply connect the device to the
and change the desired parameters.

To stop during the treatment: press the 'Play' button to stop the treatment.

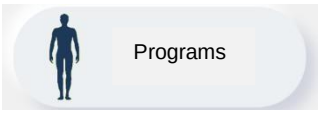
7.5.2 Application use

- Starting a treatment

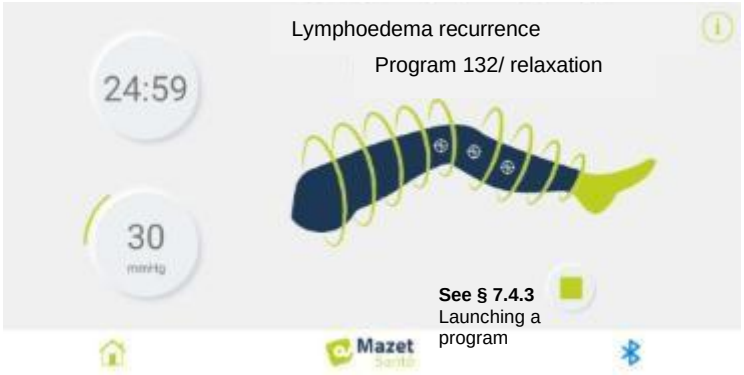
The main screen features a list of choices accessible via buttons which you simply press to access the desired program.



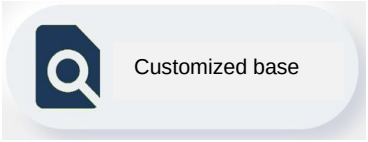
7.5.3 Programs



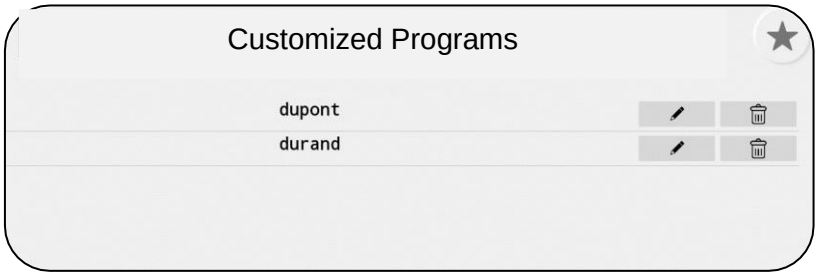
The main menu is used to select the work area.
Then select the body zone and the specific treatment you wish to perform.
Once you've made your choice, you'll be taken to the processing launch screen:



7.5.3.1 Customized base



Press the corresponding button to access the list of predefined programs (if any)



The icon is used to change the program name.

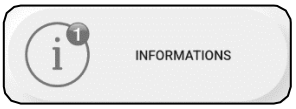
The icon deletes the program.

Clicking on the name, it takes you to the screen with the saved custom settings.

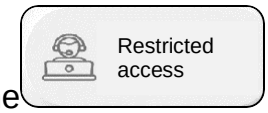
7.5.3.2 Information

- pressing the corresponding button, this menu allows you to access the device serial number and the software versions for both the device and the tablet.

If a small '1' appears on the information button :
There is an *iPress* application update.



The  icon refers to the online user manual.

The 

icon is used by our customer service department to analyze a problem.

7.5.3.3 Specific buttons

The  icon takes you back to the start-up page.

The  icon provides access to the favorite menu stored in the device.

7.6 Performing a treatment

7.6.1 Patient installation

The patient is either lying down or sitting up, depending on the treatment.

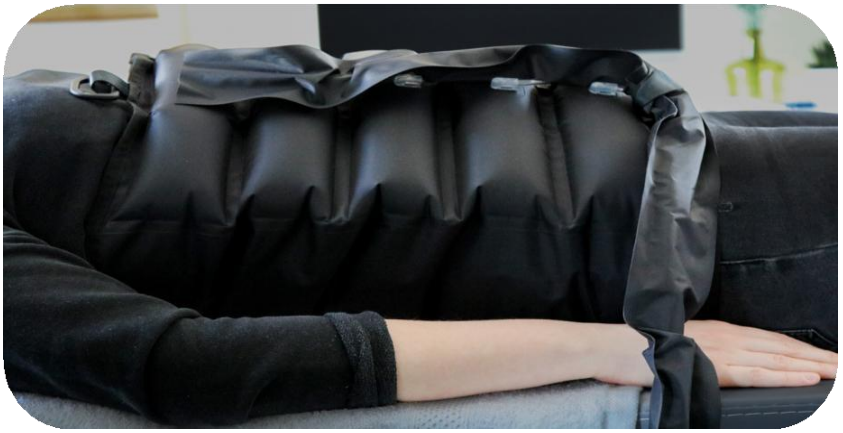
7.6.2 Setting up associated devices

The user must place the associated device on the patient, depending on the treatment being administered. Associated treatment devices ***must not be placed in direct contact with the patient's skin*.** A hygiene sheath or protective clothing must be used.
If the associated device used is too large, it can be rolled up and unused cells deactivated (***§* Starting a program**).

BOOTS :

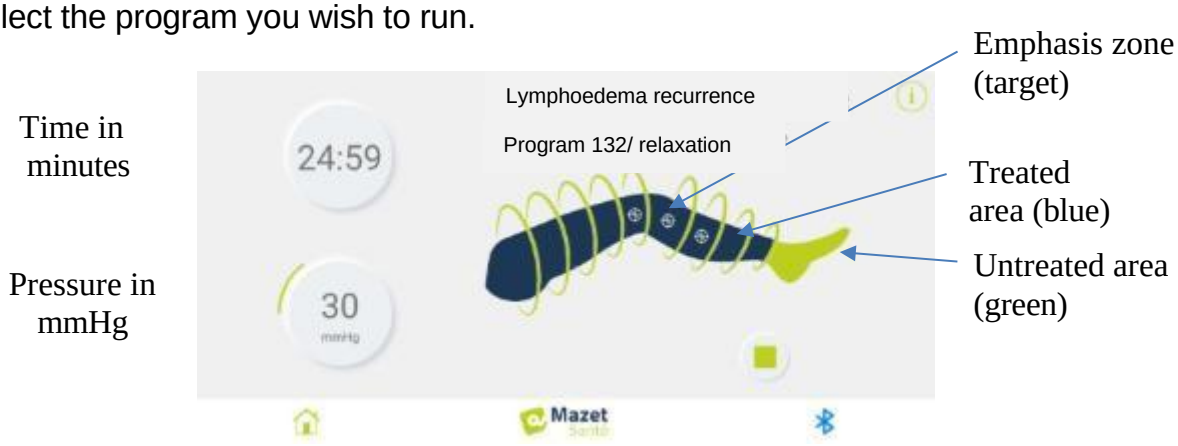
SLEEVE :

BELT:



7.6.3 a program

Select the program you wish to run.



Once the treatment has been selected and the parameters adapted to the patient, press the PLAY' button on the front panel or the icon on the display to start processing.

In this mode, the icon allows you to save this treatment in the device as a favorite. pressotherapy.

Press the icon to save customized programs.

Stop during cycle: press the stop button to end the treatment and deflate the associated device.
Working time 3 seconds (Cell pressure hold)
5-second **rest time** (deflation between 2 inflations or 2 cycles)
Emphasis zone: double the working time of the targeted zone.

An information icon ⓘ , in the top right-hand corner of the program page, provides access to the bag inflation/deflation diagram.

7.6.4 End of treatment

End of treatment is signaled by an audible signal on the tablet (if connected) and active deflation of the associated devices.

Once the associated devices have been deflated, the logo goes out and you can disconnect them and remove them from the patient, along with the hygiene sheath.

7.7 Program guide

Body Area	Program type	Program	Phases	Phases name	Program number	duration/Pressure
Legs	lymphedema	Thérapie décongestive	Phase décongestion	Appel-Résorption large	1311	25min/50mmHg
			Phase consolidation LO	Drainage péristaltique	1312	25min/30mmHg
		Récidive LO	0	Résorption détente	132	25min/30mmHg
		LO persistant	0	Fragmentation	13	50min/50mmHg
		LO transitoire/Prévention LO	0	Appel-Résorption large	134	25min/50mmHg
	Well-being	Elimination des toxines	0	Drainage péristaltique	141	25min/30mmHg
		Détente	0	Résorption détente	14	25min/30mmHg
		Récupération musculaire	0	Résorption détente	143	25min/30mmHg
	CE	Récupération musculaire intense	0	Drainage péristaltique	144	25min/30mmHg
Arms	lymphedema	Thérapie décongestive	Phase décongestion	Appel-Résorption	2111	25min/50mmHg
			Phase consolidation LO secondaire	Résorption	2112	25min/30mmHg
		LO persistant	0	Fragmentation	21	50min/50mmHg
		LO transitoire	0	Appel-Résorption	213	25min/50mmHg
	Well-being	Détente	0	Résorption détente	231	25min/30mmHg
		Récupération musculaire	0	Résorption détente	232	25min/30mmHg
	CE	Récupération musculaire intense	0	Drainage péristaltique	233	25min/30mmHg
Abdomen	Well-being	Détente	0	Résorption détente	311	25min/40mmHg
		Massage stimulant	0	Résorption	312	25min/50mmHg
CE	Lazy bowel	0	0	Résorption	32	25min/50mmHg

CE Non-medical programs which are not covered by the CE marking

Uses of the medical device concerning :

- " Leg programs : Venous pathologies: venous insufficiency : heavy legs without varicose veins / venous ulcer / Deep venous thrombosis prevention / chronic venous insufficiency ".
- "Leg programs: Venous pathologies: Circulatory disorders: Varicose veins (normal BMI) / varicose veins BMI >30 / Post-thrombotic syndrome".
- "Leg programs: Well-being: Toxin elimination / Relaxation / Sports recovery and Intense sports recovery".
- "Arm programs: Well-being: Relaxation / Sports recovery and Intense sports recovery".
- "Abdomen Programs: Well-being: Relaxation and Stimulating Massage".
- "Abdomen programs: intestinal laziness".

The programs in this leaflet are not medical programs. They are non-medical programs, not covered by CE mark 0459 issued Regulation (EU) 2017/745.

In the table above, this logo  specifies programs that not medical programs covered by the CE0459 mark issued under Regulation (EU) 2017/745.

8 Maintenance, upkeep

The **iPress series 10** is designed to last 5 years.

To ensure that the unit retains its performance throughout its lifetime, Electronique du Mazet technicians should verify the unit's intergrity every 2 years.

8.1 Housing

The housing only requires normal, periodic cleaning of its external surface, which could become soiled. The same applies to cords, pipes, etc.

The screen should be wiped clean with a soft, dry cloth**, free of any detergent 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.

8.2 Associated devices

Associated devices must not be placed in direct contact with the patient's skin.
A single-use hygiene sheath must be used at all times, and isconsidered as a type B applied part.
Hygiene sheaths are not supplied with the unit.

8.3 Sterilization

This device is not sterile.
The associated devices are not sterile, nor are they intended for sterilization.

9 Malfunction

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

When shipping the unit, please observe the following instructions:

- Decontaminate and clean the unit and its associated devices.
- Use original packaging.
- Attach all associated devices/accessories.
- Set the various elements.
- Make sure the packaging is securely closed.

Shipping address :

Électronique 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
E-mail sav@electroniquedumazet.com

Possible malfunctions :

Anomaly description	Possible causes	Actions
Screen not turning on	Power grid problems	Check mains connection
	Getting started	Check position of start/stop button (position I)
	Fuses out of order	Check and replace fuses
	Other cause	Contact customer service
Pockets don't bulge	Accessory/associated device not properly connected	Check that pneumatic connectors are locked
	Faulty accessory/associated device (leak)	Contact customer service
	Pneumatic problem (pump or solenoid valve) defective)	Contact customer service
Pockets do not deflate (active deflation) defective)	Pneumatic problem (pump or solenoid valve) defective)	Contact customer service
Other anomaly	Unknown	Contact customer service

In the event of the device falling or water entering the device, it is imperative to have the device inspected by Électronique du Mazet to exclude any risk (patient and user) associated with the use of the device.

10 After-sales service and warranty

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

- Only use accessories/associated devices supplied by Électronique du Mazet or its distributors.
- Any modification, repair, extension, adaptation or adjustment of the device must be carried out by Électronique du Mazet or its authorized distributors.
- The working environment complies with all legal and regulatory requirements.
- The unit may only be operated by competent and qualified personnel. Use must comply with the instructions in this manual.
- Treatments are to be used only for the applications for which they are intended and which are described in this manual.
- The unit must be serviced regularly in accordance with the manufacturer's instructions.
- All legal requirements concerning the use of this device are complied with.
- The device uses only consumables or semi-consumables 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 releases Électronique du Mazet and its authorized distributors from all liability for defects, breakdowns, malfunctions, damage, injury and the like...

Failure to comply strictly with the operating instructions contained in this manual will invalidate the warranty.

The warranty period is 24 months from the date of delivery
Accessories/associated devices are guaranteed for 6 months from the date of delivery.
Consumables and semi-consumables are not guaranteed.
Transport and packaging costs are not included in the warranty.

Électronique du Mazet, or its distributor, undertakes to supply the drawings, spare parts list, instructions and tools needed to repair the device, on the sole condition that qualified technical personnel have been trained on this specific product.

11 Disposal

As soon as any deterioration of a treatment accessory/associated device is detected, the product must be cleaned with a broad-spectrum disinfectant and returned to the manufacturer.

If the device becomes inoperative or unusable, please return it to the manufacturer or dispose of it at a collection point.

Indeed, as part of its commitment to the environment, Électronique du Mazet finances the ecosystem recycling network dedicated to WEEE Pro, which takes back, free of charge, electrical lighting equipment, control and monitoring equipment, and used medical devices (more information at www.ecosystem.eco)".

12Transport and storage

The device must be transported and stored in its original packaging or in packaging that protects it from external risks. Store in a clean, dry place at room temperature.

13 CE declaration

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

The medical CE was first affixed to this device on 30/09/2009.

14Manufacturer

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

Today, EDM designs, develops, manufactures and markets pressotherapy, depressotherapy, electrotherapy (urological rehabilitation) and a range of otological diagnostic devices (Echodia brand).

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www.electroniquedumazet.com

15 EMC compliance

EMC compliance to IEC 60601-1-2 : 2014
Electromagnetic emission

Emissions	Compliance level	Guidelines
CISPR 11 RF emissions	Group 1	The device uses RF energy only to its internal functions.
CISPR 11 RF emissions	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 used for domestic purposes.

Electromagnetic immunity

Immunity	Standard	Test level	Guidelines
Immunity to electrostatic discharge (ESD)	IEC 61000-4-2	± 8 kV contact (indirect / direct) ± 2 kV,± 4 kV,± 8 kV± 15 kV air	Wooden, concrete or ceramic tile floors are all suitable. If floors are covered with synthetic materials, the relative humidity should be at least 30 %
Immunity to RF electromagnetic fields radiated	IEC 61000-4-3	80MHz at 2.7GHz: 3V/m 80% AM at 1kHz, 1% sec	Corresponds to the characteristic level of a typical commercial or hospital environment.
Immunity to proximity fields emitted by RF wireless communication devices	IEC 61000-4-3	Internal port Spot de frequency: Table 9 of the standard, table below: Modulation Pulse or FM Band	
Immunity to rapid burst transients	IEC 61000-4-4	+/-2 kV (100kHz)	The quality of the power supply should be that of a typical commercial or hospital environment.
Surge immunity	IEC 61000-4-5	+/-1kV	
Voltage dip immunity	IEC 61000-4-11	0% at 0.5 cycle 0% at 1 cycle 70% at 25/30 cycles 0% at 250/300 cycles	
Immunity to induced disturbances by conducted radio-frequency fields	Conducted RF 61000-4-6	3V at 0.15MHz - 80MHz 6V at ISM and radio band	
Magnetic field immunity at mains frequency (50/60Hz)	IEC 61000-4-8	Level: 30 A/m (50Hz/60Hz)	Magnetic fields at mains frequency should be those of a environment. typical commercial or hospital environment.
Immunity to proximity magnetic fields in the 9kHz to 13.56MHz range	IEC 61000-4-39	Level: 8A/m (30kHz) with CW modulation Level: 65 A/m (134.2 kHz) with pulse 2.1 kHz modulation Level: 7.5 A/m (13.56 MHz) with pulse 50 kHz modulation	

IEC60601-1-2 :2014 Table 9 - Test for ENVELOPE ACCESS IMMUNITY to RF wireless communications equipment

	Frequency of the test (MHz)	**Band (MHz)**	**Modulation**	**Level test immunity (V/m)**
Proximity fields for RF communications wireless	385	380 - 390	Pulse modulation: 18 Hz	27
	450	430 - 470	FM -± 5 kHz deviation 1 kHz sine	28
	710	704 - 787	Pulse modulation: 217 Hz	9
	745			
	780			
	810	800 - 960	Pulse modulation: 18 Hz	28
	870			
	930			
	1720	1700 - 1990	Pulse modulation: 217 Hz	28
	1845			
	1970			
	2450	2400 - 2570	Pulse modulation: 217 Hz	28
	5240	5100 - 5800	Pulse modulation: 217 Hz	9
	5500			
	5785			

Wireless communication

Transmission method	Bluetooth® Low Energy 4.2 or 5.0
Wireless communication	Frequency range: 2402 - 2480 MHz Modulation: FHSS Effective radiated power: <5 dBm

ELECTRONIQUE DU MAZET

ZA ROUTE DE TENCE
43520 LE MAZET SAINT VOY

Tél : +33 4 71 65 02 16
Mail : sav@electroniquedumazet.com

Your dealer / distributor :

16Warranty certificate

Warranty certificate

This form must be returned to Electronique du Mazet within 15 days of receipt. following installation or receipt of equipment.

I, ... Organization:

..... Address :

.....

.....

.....

Hereby declare that I have received the ***iPress series 10*** **no. …….**in working order.

I have received all the necessary instructions for its use, maintenance, servicing, etc...

I have read the instruction manual and noted the warranty and after-sales service conditions.

In the event that Electronique du Mazet or its distributors do not receive this duly completed and signed form within one month of delivery, Electronique du Mazet will be released from all liability with regard to the warranty and after-sales service, or any other consequence due to misuse of the device.

....

User signature :

Your distributor :

Please return to :
Electronique du Mazet
Z.A. Route de Tence
43520 Le Mazet St Voy