DDM

CE
0459

PNEUMATIC TOURNIQUET

References : **G10705 - G10706**

Designation : Electromechanical pneumatic tourniquet with simple and dual regulated pressure circuit

USER GUIDE

Before using these devices for clinical applications, maintenance and troubleshooting please read carefully this manual and understand all information about their features by observing imperatively instructions described.

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MADE IN FRANCE

INDEX

I. GENERAL INFORMATIONS

Symbols used

	Description	Location
	The operations instructions must be read, written on the back of the appliance	Back of the unit
	Fragile, handle with care	Adhesive package
	Humidity limit	Adhesive package
	Temperature limit	Adhesive package
	Warning message	User guide
	Safety message	User guide
	Separate electronics components from houshold rubbish. This product should be discared at a collection point for recycling of electrical and electronic waste	Identification plate User guide
	Medical device type BF- applied parts constituted by the cuffs and extension in the patient's environment	Front side
	Earth (ground)	Inside the device
	Medical device class IIa complying with the Requirements of Directive 93/42/EEC modified by 2007/42/CEE.	Identification plate
mmHg	Pressure unit is measured in millimetres of mercury (1 mmHg equal to 1.33 hPa -(hectopascal)	Display screen
min	Specified time expressed in min	Display screen
	Manufacturer: SPENGLER SAS 30 rue Jean de Guiramand 13290 Aix en Provence - France	Packaging label

	Medical Device	Packaging
	Catalogue number	Packaging
	Batch number	Packaging
	Date de fabrication et pays d'origine	Packaging
	Do not use is package is damaged	Packaging
	Temperature limitation	Packaging
	Atsmospheric Limitation	Packaging
	Authorised Representative in the European Community	Packaging

Intended to use

The device is designed to operate continuously.
The touniquet is used exclusively in the operating room to temporarily block blood flow in the upper and lower limbs of the patient to perform surgery on the ends of members and include but are not limited to achieve :

- Reduction of certain fractures
- Replacement of the knee joints, wirst, hand and elbow
- Knee arthroscopy, wirst, hand and elbow
- Subcutaneous fasciotomy
- Amputation of members
- Tumor excisions, cysts

The tourniquets G10705 and G10706 are medical devices to be used with one or two cuffs for bloodless operation areas or bilateral surgery or with dual cuffs for operations using local anaesthesia (intravenous loco-regional anaesthesia).

The parameters of pressure and tourniquet time are defined by practitioners, this manual can never be a substitute for operative techniques usually performed. The usable range of pressure is between 0 and 600 mmHg.

An informal basis and with reference to various medical publications, the inflation pressure should be as low as possible : from 50 to 75 mmHg above the occlusion pressure sufficient for the upper limb 100 to 130 mmHg and above the occlusion pressure to a lower extremity.

Using the Graham's formula, the occlusion pressure (Op) is depended of the circumference of the member (M), the width of the withers (L), the systolic blood pressure (SBP) and diastolic(DBP) :

$$Op = \frac{(SBP - DBP) \times M}{Lx3} + DBP \cong [(SBP - DBP) \times 2{,}5] + DBP$$

Patient population

Any person may resort to surgery requiring the use of a tourniquet, only contraindications described below or decision of the medical profession may lead to a rejection of this surgical technique.

User profil

Tourniquet devices are intended to be used only by medical professionals trained accordingly to the intended use, and described below. It is commonly Nurse of Operating Room State graduate or Nurse Anesthetist graduate of State.

Contra-indications

Contra-indications are described in the medical literature include :

- If excessive skin fragility
- Open fracture of the leg
- Venous thromboembolism
- Acidosis
- Severe crushing injuries

In all cases the final decision of the use of a pneumatic tourniquet is the responsability of the practising doctor.

Specifics of the models

These medical devices are electronically managed, they are designed and manufactured in France.
The model G10705 has only one pressure circuit and is intended to be used in operations using a single cuff, whereas G10706 has 2 independend pressure circuits, thus enabling the inflation of 2 cuffs at different pressures in the scope of a bilateral surgery or using loco-regional anaesthesia.

It is possible to adapt a mobile stand on wheels with a basket to put the accessories.

Medical devices Directive

Medical device class IIa complying with the requirements of Directive 93/42/CEE.

Storage and transport conditions before use.

Do not store the package outside, avoid mechanical vibrations.
Storage and transport conditions : temperature -20°C to +60°C relative humidity 20% to 80 % maximum.
Operating conditions : temperature 5°C to +40°C relative humidity 20 % to 80 % maximum.
Handle the package carefully to avoid dropping.

II. GENERAL WARNING 

Any modification may cause a hazard to the patient or user. Under no circumstances and in no way the device must not be changed.

Caution

The environmental conditions of use must be respected.

-To avoid electric shock pneumatic tourniquet should only be connected to a power network with a protective earth with the power cord of 5 meters provided. It is not permissible to use a base of multiple sockets or extension cord.

-To prevent electrical hazard to the patient, do not use the medical device in the immediate environment of the patient (less than 2 meters).

-Pneumatic tourniquet and particularly its electrical connection must be protected from water and moisture. Never turn on the device if the liquid has been spilled on it.

-To prevent damage, do not use metal or sharp objects on the front of the pneumatic tourniquet.

-Do not pull on the AC power or pneumatic extensions to change the device instead.

-Any movement of the device must be disconnected for the power supply.

-To avoid the risk of strangulation or patient people, ensure that the power cord or extension tires are in reasonable distance.

- To prevent risk of device falling, do not propel the unit mounted on mobile stand, a handle is provided to make any manoeuvre secure by pulling or pushing the device to cross in front of any obstacles. The moving is done by pushing forward. Keep one hand on the handle in case of uneven ground.

- To prevent inadvertent movement, it is strongly recommended to lock the wheels brakes.

-Separate the electrical power cord to the castors.

-Do not use the device in areas where is risk of explosion induced by anesthetics and disinfectants inflammable.

-Be sure to use accessories in good condition and suitable to members whom they are intended.

-The connector receptacle serves as a connection switch and must remain accessible at all times to enable the immediate disconnection of the power cord in the event of danger.

-For Switzerland, the plug will 12G1011 standard model of FELLER brand and the power cable must be H05VV-F FELLER brand.

Cleaning and disinfection

Disconnect the device from the mains supply before any intervention cleaning and disinfection of the unit, using only appropriate disinfectant wipes (Type Wip'anios). Apply wipe surfaces and extensions to deal with.

In case of severe soiling use a second wipe leaving for 5 to 15 minutes depending on the antimicrobial efficacy sought, however, leaving the screens.
There is no limit to use these applications. Rinsing is unnecessary.

It is also possible to use detergent foam using a non-woven cloth.
Procedure for cleaning the device as indicated for the wipe.

Never spray disinfectant directly on the device. Pneumatic tourniquets extensions must be dried before use.

Before each commissioning of the device

- Make sure the accessories are compatible for use with pneumatic tourniquet, it is forbidden to use cuff without appropriate connectors and change the output connectors.

-Check that the connexions are in good conditions, that they are not bent or pinched and that the air is output as soon as the system starts up.

-As a precaution to ensure that the medical device works properly and that the system is sealed with the cuff used by proceeding as described below.

-Put the cuff on a mandrel.

-Display the pressure instructions, e.g. 300 mmHg

-Wait until the cuff is correctly positioned to reach a stability of the pressure display, wait 2 minutes to see that the alarm does not go off.

-Disconnect the cuff of the device, the alarm must be activated after 3 seconds.

Precautions relating to electromagnetic compatibility

Pneumatic tourniquet should be installed and put into service according to EMC recommandations attached.
Operation of the device is guaranteed to all lower levels of compliance disturbances reported in annex.

Malfunctions can be caused by the proximity of RF communications equipment portable or mobile non EC.

According to the paragraph 5.2.2.1 (d) of the IEC International Standard 60601-1-2:2014 version, the accompanying documents shall include the following informations :
It is advisable not to use the EM device or system next to other devices or piled up with other devices. If it is not possible to avoid this, it is advisable to supervise the EM device or system in order to verify the normal functioning in the configuration in which it will be used.
The use of accessories, sensors or cables other than those specified below, except for those sold by Dessillons & Dutrillaux as a replacement part of internal elements, may cause an increase in the transmission levels or a decrease in the immunity levels of the G10705-G10706 devices.

Electromagnetic conformity established with the following accessories :
Designation
Switching mode power supply card
Power supply cord 5 meters
Connector receptacle CEE 22

Limits use of the medical device

Life time is estimated at 5 years, an appeared malfunction or accidental fall of the medical device requires to inform the biomedical department about risks in order to conduct a comprehensive review of functionality on the device and ensure the integrity of essential performance described below.

Essential characteristics of the medical device

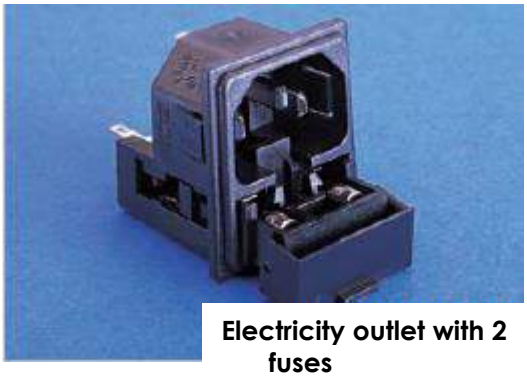
- Set a tourniquet pressure following a value defined by the operator
- Maintain this pressure throughout the duration of the intervention
- Display operating time with sound and visual information in the defined time
- Audible and visual alarm can be set up in case of failure of the compensation system rated pressure
- Bring the pressure down to 0 after surgery by pressing this button  during 1 second.

Maintenance

An annual preventive maintenance is recommended for the control of essential performance described below, and electrical safety.
To overcome any malfunction, this service must be performed by Dessillons & Dutrillaux.
The minimum qualification required by maintenance personnel for maintenance operations : biomedical technician level.

Replacing fuses general protection

The fuses power (2 units) are located on the electricity outlet.
Replace them in accordance with the values : FT2A H250V.



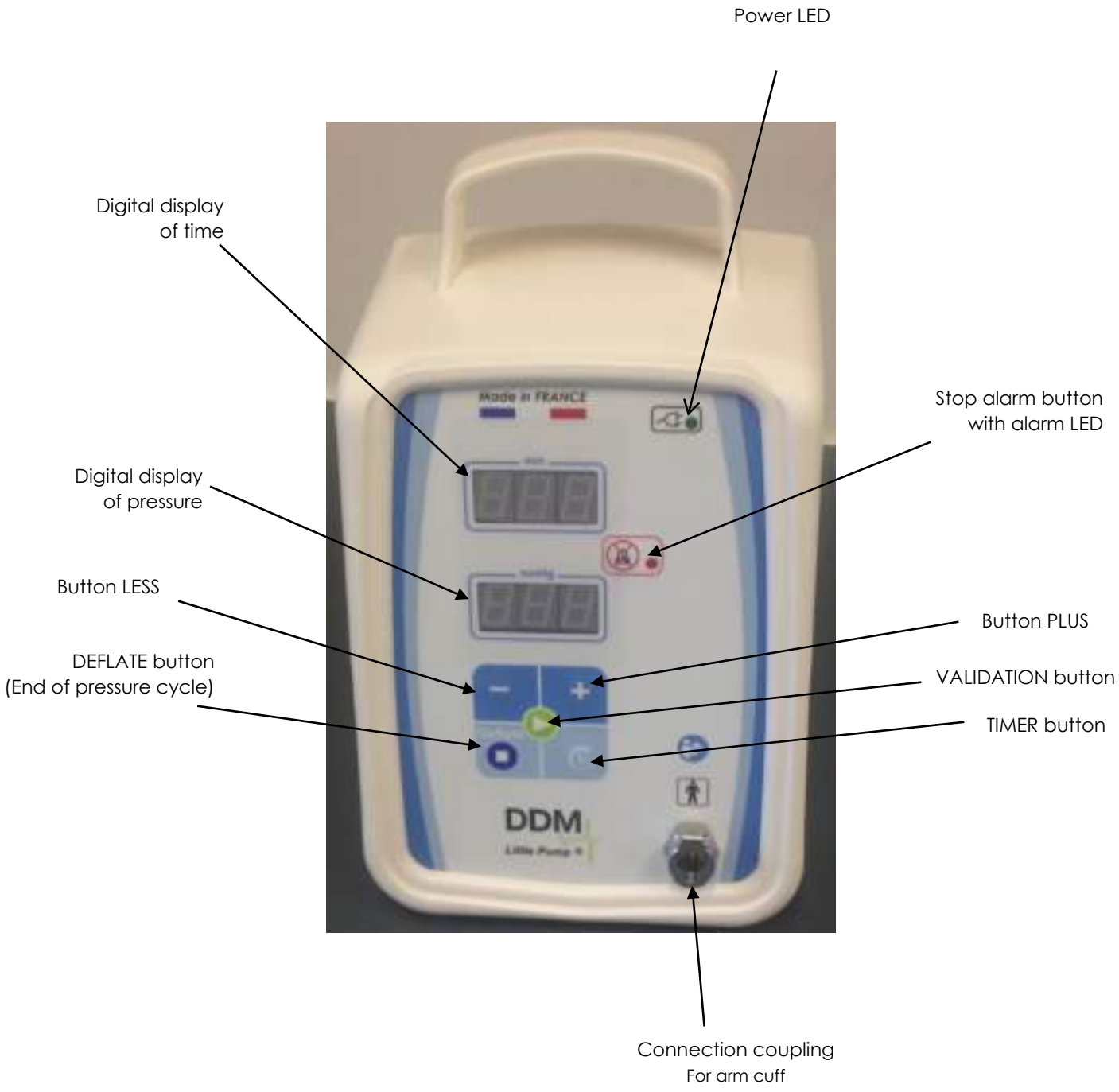
Electricity outlet with 2 fuses

The circuit board is protected by an external fuse : fuse value : F1.6AH250V (rapid action, power cut 1500A).

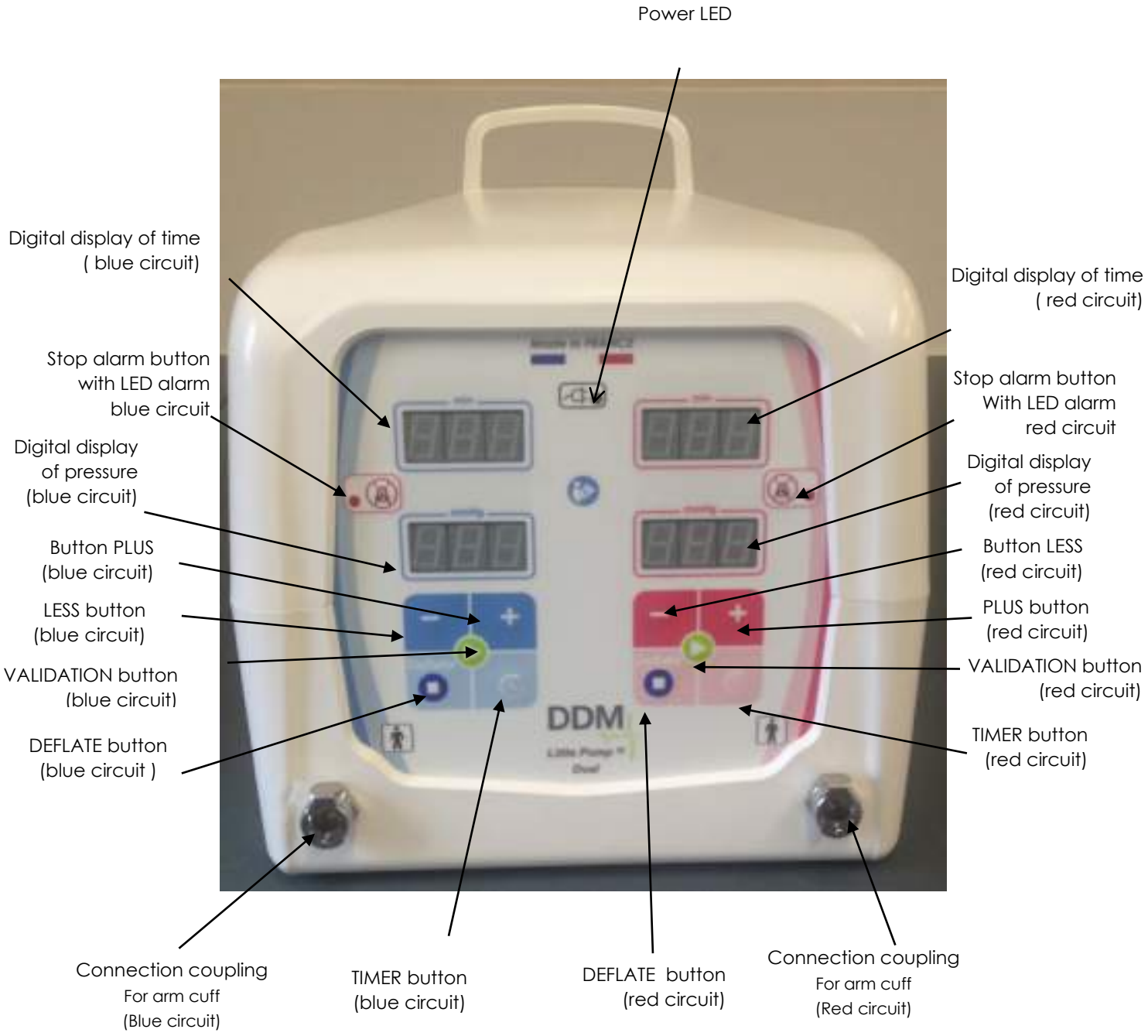
Equipotential bonding conductor

The equipotential bonding terminal, on the back of the device and symbolized by this logo  is used in the electrical tests carried out by D & D MEDICAL

III. PRESENTATION OF THE MEDICAL DEVICE (model G10705)



IV. PRESENTATION OF THE MEDICAL DEVICE (model G10706)



V. ACTIVATION OF THE DEVICE

A. START OF DEVICE

The pneumatic tourniquet is operational and turned off by pressing switch aside.
A sound produced when the device is turned on, the LED alarm and displays light up. The upper display indicates scroll left the software version:

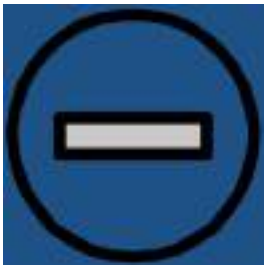
The lower display shows scrolling to the left :

B. SETTING THE PRESSURE

Changing the pressure (outside off surgery)

The user has to select the pressure parameter, setting a value and validate these instructions to perform a pressurization of the pneumatic tourniquet.

1) **Press the PLUS or MINUS buttons**


OR


The lower display will be flashing

2) **Keep pressing the + or - button until the desired value**

3) **Validation**

By pressing VALIDATION

The lower display stops flashing

Info : By waiting 5 seconds the user can validate information entered.

4) Example : 350 mmHg

Press the buttons boutons  or  to  confirm by pressing the button  or wait 5 seconds

Changing the pressure (during surgery)

Press the PLUS or MINUS buttons
Keep pressing the + or - button until the desired value
Validation by pressing VALIDATION button
Exemple 380 mmHg :

Press the buttons boutons  or  to  confirm by pressing the button  .

Note : Wait for the flashing to stop (5 seconds), does not validate the pressure change, only pressing VALIDATION button validate setting.

C. SETING THE TIMER

Changing the timer (outside off surgery)

The user can select a duration for surgery; then an alarm will sound when the time allowed for surgery has expired.
If the user doesn't program a duration, the default setting timer is selected (default setting configured in the factory : 60 minutes).

Press the key MIN

Press the key  above the upper display (it will be flashing).

Keep pressing the + or - button until the desired value
Validation by pressing VALIDATION button
Exemple for 50 minutes :

Press the button  and on the buttons  or  until it is indicated  at the upper display and wait for 5 seconds or press the button  .

Changing the timer (during surgery)

During surgery, it is possible to change the initial timer by proceeding in the same way.
If the alarm timer is active during modifications, it is turned off.

1) **Press the key min**

2) **Keep pressing the + or - button until the desired value**

3) **Validation by pressing VALIDATION button**

4) **Exemple new setting to 45 minutes**

The upper display indicates the elapsed time is :  minutes

The timer has been setting by default and will ring on  minutes, but the operator would like the alarm goes off at  minutes. To do this, please observe the following instructions :

Press the button  and on the buttons  or  until it is indicated displayed  at the upper display and wait for 5 seconds or press the button  .

⚠ Note : Wait for the flashing to stop (5 seconds), does not validate the pressure change, only pressing  validate setting.

D. SYSTEM SHUT-DOWN/DEFLATION OF THE TOURNIQUET

Launching a pressure cycle (inflate)

When the pressure setpoint is set on the circuit and therefore there is no display flashing. The vacuum cycle can be started by pressing the VALIDATION button.

End of a pressure cycle (deflate)

At the end of the surgery, the user has to press the key  during 1 second to perform the deflation of the cuff.

- Stop the pump and decompression of the cuff
- Stop the timer : the value freezes
- Stop the cycle alarm.

VI. Information about operation