Since 1949

CE 0459

Date of first EC marking certificate: 1998

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.

Dessillons & Dutrillaux
Zone Industrielle La Tuque
47240 CASTELCULIER – FRANCE
Tél : +335 53 48 30 66 Fax : +335 53 47 24 64
Email : technique@ddmedical.fr
Web site : www.ddmedicall.fr

ISO 13485 G MED

INDEX

I. GENERAL INFORMATIONS

Symbols used

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
	Fabricant : Dessillons&Dutrillaux Z.I. La Tuque 47240 Castelculier - France	

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 -5°C to +50°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 

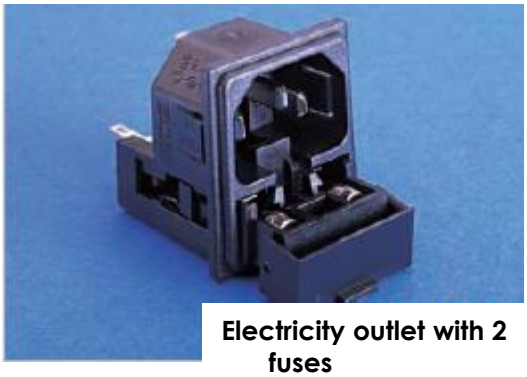
during 1 second.

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.



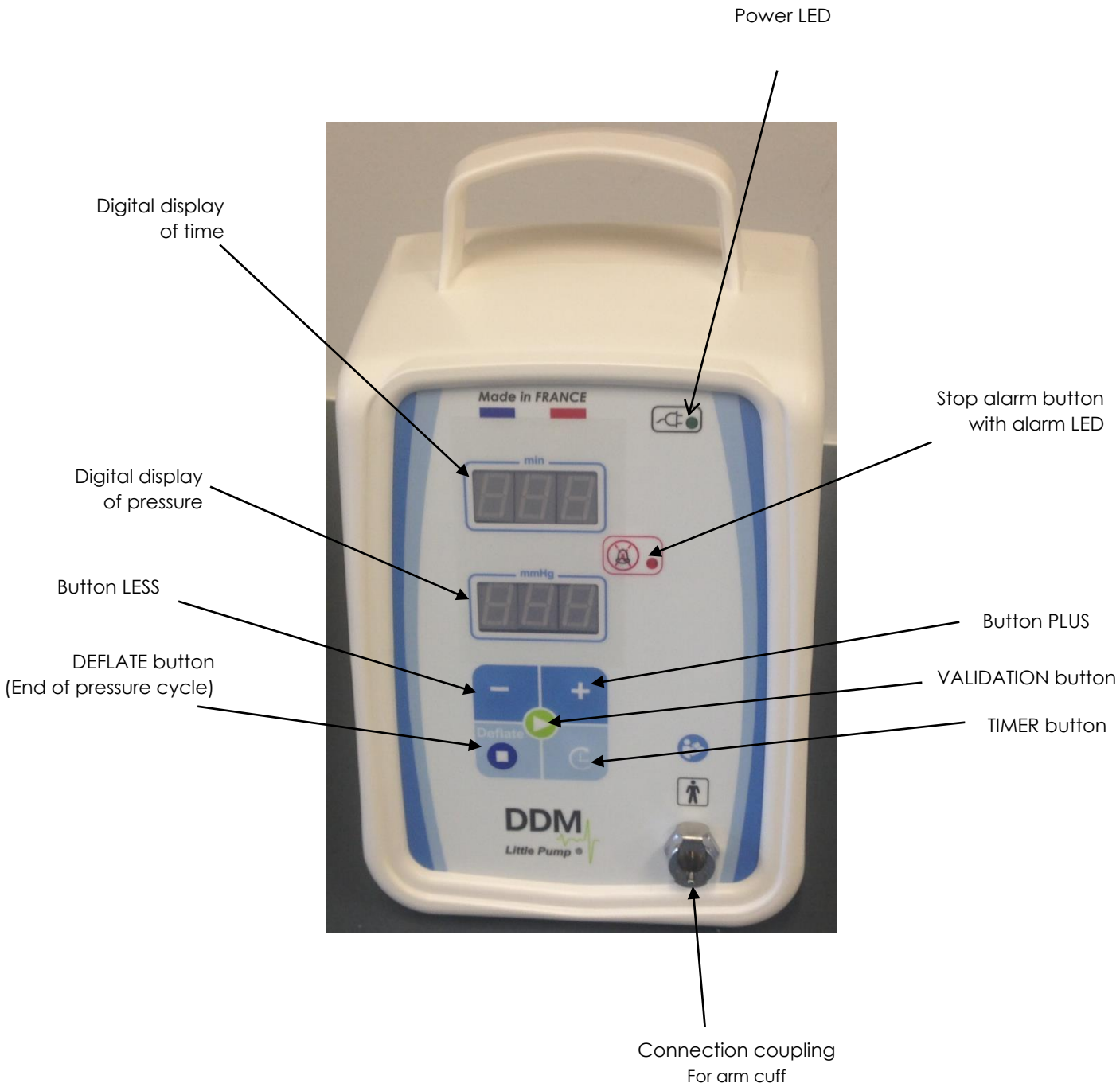
Electricity outlet with 2 fuses

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

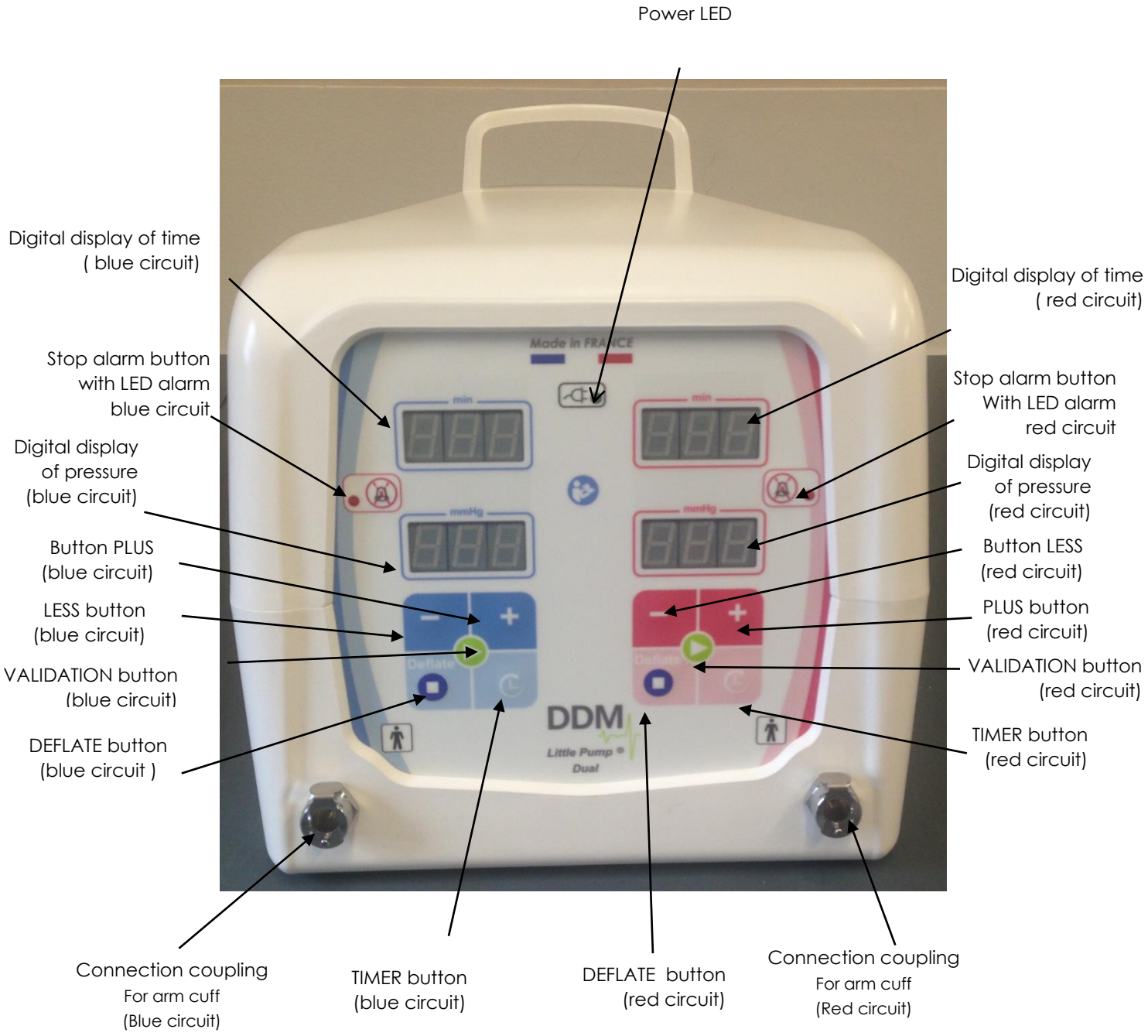
Equipotential bonding conductor

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 :

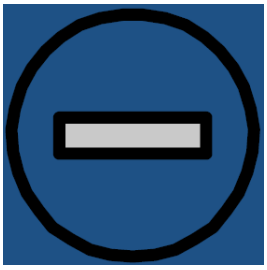
B. SETTING THE PRESSURE

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)

1) **Press the PLUS or MINUS buttons**
2) **Keep pressing the + or - button until the desired value**
3) **Validation by pressing VALIDATION button**
4) **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).

1) **Press the key MIN**

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

2) **Keep pressing the + or - button until the desired value**
3) **Validation by pressing VALIDATION button**
4) **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

E. KEYBOARD MANAGEMENT

Conditions for taking into account the pressing buttons :

- The keys  ,  ,  ,  and  are taken into account by pressing
- The key  is taken into account at the end of a second.

F. DEFAULT MANAGEMENT

Conditions of triggering an alarm				
Display		Causes	Priority	Actions
Flashing upper display	+ 2 slows beeps	Defined time expired	Medium	No action – Information signal
Flashing upper display	+ 7 beeps	Surgery time reached 180 minutes	Visual medium, Audible High	No action – Information signal
Flashing lower display	+ 7 beeps	Getting pressure not established within 20 seconds	High	The cuff is not tight enough around the limb or not connected
Flashing lower display	+ 7 beeps	Pressure leak : pressure below the setpoint since 5 seconds	High	Connect the cuff
Flashing lower display	+ 7 beeps	Over pressurization : pressure display above the set pressure and not stabilized since five seconds	High	Check that there is no support element on the cuff

The visual alarm also includes led light, flashing with the tempo of the audible alarm.

For the operator, the perception of a visual alarm condition can be established only being in front of the device, to overcome this requirement tourniquet is equiped with an audible alarm signal.

Alarm deactivation :

In case of high prority alarm, by pressing the key  the user disables the alarm tone during 30 seconds, during this time the visual alarm is always displayed.

In case of medium priority alarm, pressing the key  stops current alarm.

If there is an electrical power failure, the alarm system is immediatly unable to restore the alarm settings.

In case of power failure, the alarm is no longer functional.

VII. Configuration

A. MAINTENANCE

A menu protected by a password is accessible via a specific hardware configuration.
Only a qualified technician Dessillons & Dutrillaux can intervene on the settings of the device.

This menu allows :

- Set the calibration of pressure sensors.
- Check the configuration of the pneumatic tourniquet

B. USER SETTING

Volume setting :

The user can adjust the volume level of the device, it will be saved and re-applied at every boot.
To adjust the volume, proceed as follows :

1) **Being out of operation cycle**

2) **Holding down the button "STOP ALARM"** 

3) **Keep pressing buttons**  **or,**  **- until the volume desired value**

4) **Wait 2 secondes to confirm**

⚠ **Note** : On the model G10706 setting is to be performed on each circuit.

Default pressure setting :

A user can set the default pressure, it will be recorded and reapplied at each start.
To set the default pressure, proceed as follows:
1) Be out of the operating cycle
2) Press the or buttons  or  until the desired volume value is reached.
3) Simultaneously press the buttons  or 
4) The message "SAVEd" indicates the recording

⚠ **Note** : On the model G10706 setting is to be performed on each circuit.

Default timer setting :

A user can set the default timer, it will be saved and reapplied at each start.
To set the default timer, proceed as follows:

1) Be out of the operating cycle
2) Press the or buttons 

3) Simultaneously press the button  or  until the desired volume value is reached.

4) Simultaneously press the button  and 

5) The message "SAVEd" indicates the recording

Note : On the model G10706 setting is to be performed on each circuit.

VIII. USE WITH CUFF

A. USE THE DEVICE WITH A CUFF WITH A SINGLE BLADDER

1) Connect the power cord to the power grid

Press the switch ON / OFF to turn on the device.

2) Apply a skin protection on the limb

To do before placing a sufficiently tightened cuff around the limb and adapted to the patient's morphology. (The width of the cuff / by the circumference of the member should be less than or equal to 0.3).

3) Connect the pneumatic tourniquet connecting tube

To the quick coupler device ensuring that the extension cord is not folded, bent, pinched and that no node may hinder pressuring the cuff.

4) Exsanguinate the limb

By raising or by winding an Esmarch bandage at the base of the limb.

5) Pressure set point adjustment

Proceeding as described in section IV-B by ensuring that the cuffs is normally swells.

6) Proceed if necessary by setting a time

As described in section IV-C.

7) After the surgery, deflate the tourniquet

Pressing the key deflate.

B. INSTRUCTIONS FOR USE THE IVRA MODE

1) Connect the power cord to the power grid

Press the switch ON/OFF to turn on the device.

2) Apply a skin protection on the limb

To do before placing a cuff with double bladder : placing the proximal bladder at the base of the limb.

3) Exsanguinate the limb

By raising or by winding an Esmarch bandage at the base of the limb.

4) Connect the pneumatic tourniquet connecting tubes

Connect the tubes of the proximal bladder to left coupler (blue area), the tube of the distal bladder to right coupler (red area) ensuring that the cord is not folded, bent, pinched and that no node may hinder the presurization of the pneumatic tourniquet.

5) Setting the pressure setpoint

Perform the pressurization of the upper bladder by applying the method defined above. Proceed possibly setting a time as described in section IV-B, IV-C.

6) After injection of the anesthetic and its resulting effect

Perform the pressurization to inflate the distal bladder in the same way. The distal pneumatic tourniquet cuff is inflated on an anesthetized part.

7) Deflate the upper bladder tourniquet cuff

The upper bladder (proximal) can now be deflated by pressing the key Deflate of corresponding pressure circuit.

8) Deflate the lower bladder tourniquet cuff

After the surgery, deflate the distal bladder by pressing the Deflate key, disconnect the cuff to pneumatic tourniquet, cut power by pressing the switch ON/OFF.

IX. ANNEX

TECHNICAL CHARACTERISTICS OF PNEUMATIC TOURNIQUET G10705

STORAGE CONDITIONS	T : -5°à 40°C, Humidity : 20- 80 %
CONDITIONS OF USE	T : 5°à 40°C, Humidity : 20 – 80 % Maximum altitude 2000 m Atmospheric pressure 79.0 kPA to 106 kPa
CASE MATERIALS	ABS (Acrylonitrile Butadiene Styrene)
Density	1.112 g/ cm^3
Shock resistance	> 25 KJ / m^2
UL flammability test	UL94 V-0
Heat stability	85°C
DIMENSIONS	G10705
Height (mm)	238
Width (mm)	167
Depth (mm)	160
WEIGHT kg	2.200
Dimensions of the display	
Width (mm)	38.4
Height (mm)	16.4
Quantity	2
LINE VOLTAGE	100 - 240 V AC
LINE FREQUENCY	50 – 60 Hz
POWER PLUG	60 VA
SWITCH MODE POWER SUPPLY	Entry : 90-264 Vac, 47-63 Hz, 1.8 – 1 A - Exit : 15 Vdc, 4A
FUSE	
Input power card	FTT2AH/250V
Output power card	F1,6AH/15V
PUMP	
Type	Membrane pump
Pump flow	4.6 l/mn
PRESSION	
Type	mmHg
Service	1.7 bar
Setting range	0 to 600 mmHg
Setting precision	± 1 mm Hg
Display accuracy	± 5 mm Hg
Alarm	An audible and visual alarm
Number of independant pressure circuit	1
TIMER	
Units	Minutes
Alarm	Programmable audible and visual alarm
CONNECTION	
Pneumatic	1 female coupler CPC type
Electric	Connector CEE22
MAXIMUM SOUND LEVEL WHILE FUNCTIONING	52 dB

TECHNICAL CHARACTERISTICS OF PNEUMATIC TOURNIQUET G10706

STORAGE CONDITIONS	T : -5°à 40°C, Humidity : 20- 80 %
CONDITIONS OF USE	T : 5°à 40°C, Humidity : 20 – 80 % Maximum altitude 2000 m Atmospheric pressure 79.0 kPA to 106 kPa
CASE MATERIALS	ABS (Acrylonitrile Butadiene Styrene)
Density	1.112 g/ cm^3
Shock resistance	> 25 KJ / m^2
UL flammability test	UL94 V-0
Heat stability	85°C
DIMENSIONS	G10706
Height (mm)	250
Width (mm)	300
Depth (mm)	190
WEIGHT kg	4.2
Dimensions of the display	
Width (mm)	38.4
Height (mm)	16.4
Quantity	4
LINE VOLTAGE	100 - 240 V AC
LINE FREQUENCY	50 – 60 Hz
POWER PLUG	60 VA
SWITCH MODE POWER SUPPLY	Entry : 90-264 Vac, 47-63 Hz, 1.8 – 1 A - Exit : 15 Vdc, 4A
FUSE	
Input power card	FTT2AH/250V
Output power card	F1,6AH/15V
PUMP	
Type	Membrane pump
Pump flow	4.6 l/mn
PRESSION	
Type	mmHg
Service	1.7 bar
Setting range	0 to 600 mmHg
Setting precision	± 1 mm Hg
Display accuracy	± 5 mm Hg
Alarm	An audible and visual alarm
Number of independant pressure circuit	2
TIMER	
Units	Minutes
Alarm	Programmable audible and visual alarm
CONNECTION	
Pneumatic	2 female coupler CPC type
Electric	Connector CEE22
MAXIMUM SOUND LEVEL WHILE FUNCTIONING	52 dB

DIRECTIVES AND DECLARATION OF THE MANUFACTURER - ELECTROMAGNETIC IMMUNITY

D&D pneumatic tourniquets are intended to be used in the electro-magnetic environment detailed below. It is convenient that the user of these devices makes sure that they are used in such an environment.

Immunity testing	Level of testing in accordance with CEI 60601-1-2:2014	Level of conformity	Electromagnetic environment - directives
Conducted RF disturbances EN 61000-4-6	3 Veff of 150 kHz at 80 MHz outside ISM tapes	3 Veff	It is convenient that portable instruments and RF mobile devices are not too close to any part of these devices, including cables; it is advisable to respect the recommended separation distance, calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** *d* = [3.5/ *3*] *?P* *d* = [3.5/ *3*] *?P* of 80 MHz at 800 MHz *d* = [7/ *3*] *?P* of 800 MHz at 2,5 GHz where *P* is the characteristic of the maximum output power of the transmitter in watts (W), according to the manufacturer of the transmitter and *d* is the recommended separation distance in meters (m). It is convenient that the field intensity of the RF fixed transmitters, determined by an electromagnetic research on site(a), are less than the level of conformity, in each frequency band(b).
Radiated RF disturbances EN 61000-4-3	3 V/m of 80 MHz at 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and at 800 MHz, the highest frequency band is applied.

NOTE 2: These directives may not be applicable in every situation. The electromagnetic propagation is affected by the absorption and by the reflection of structures, objects and people.

(a) The field intensity of the fixed transmitters, such as the base stations for radiotelephones (mobiles/wireless) and land mobile radios, amateur radios, radio broadcasting and TV broadcasting cannot be theoretically planned with accuracy. In order to evaluate the electromagnetic environment due to fixed RF transmitters, it is convenient to consider an electromagnetic research on site. If the field intensity, measured in the place where the devised is **used, exceeds the RF level of conformity applicable above, it is advisable to observe the device to make sure that** it works normally. If abnormal performances are observed, additional measures may be taken, for the reorientation or reposition the device.

(b) In the band frequency of 150 kHz to 80 MHz, it is convenient that the field intensities are less than **3 V/m**.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE INSTRUMENTS AND RF MOBILE DEVICES AND G10705--G10706 PNEUMATIC TOURNIQUET

These devices are aimed to be used in an electromagnetic environment where radiated RF disturbances are under control. The user of these devices may help to prevent electromagnetic interferences by keeping a minimal distance between portable instruments and RF mobile devices (transmitters) and these devices, as recommended below, according to the maximum emission power of the communication device.

	Separation distance according to the frequency of the transmitter **M**		
Maximum emission power assigned of the W **transmitter**	**from 150 kHz to 80 MHz** *d* = [3.5/ *3*] *?P*	**from 80 MHz to 800 MHz** *d* = [3.5/ *3*] *?P*	**from 800 MHz to 2.5 GHz** *d* = [7/ 3] *?P*
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3

In the case of transmitters which have a maximum emission power assigned that is not indicated below, the recommended separation distance *d* in meters (m) may be determined by using the equation applicable to the frequency of the transmitter, where *P* is the characteristic of the maximum transmission power of the transmitter in watts (W), according to the manufacturer of the transmitter.

NOTE 1: At 80 MHz and at 800 MHz, the separation distance for the highest frequency band is applied.

NOTE 2: These directives may not be applicable in every situation. The electromagnetic propagation is affected by the absorption and by the reflection of structures, objects and people.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The G10705 and G10706 pneumatic tourniquets are provided for use in the electromagnetic environment specified below. He agreed that the customer or the user of these devices ensure that they are used in such an environment.

Emissions test	***Conformity***	***Electromagnetic environment - directives***
Emissions RF *CISPR 11*	*Group 1*	*G10705 and G10706 pneumatic tourniquets use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
Emissions RF *CISPR 11*	*Class B*	
Harmonic emissions *EN61000-3-2*	*Class A*	*G10705 and G1706 pneumatic tourniquets are suitable for use in all premises, including domestic establishments and those directly connected to public low-voltage power supplies buildings used for domestic purposes.*
Emissions of voltage fluctuations flicker *EN 61000-3-3*	*Conform*	

TABLE MANUFACTURER'S INSTRUCTIONS AND DECLARATION - ELECTROMAGNETIC IMMUNITY FOR ALL DEVICES AND EM SYSTEMS OTHER THAN MAINTAINING LIFE

Directives and declaration of the manufacturer – electromagnetic immunity			
D&D electronic pneumatic tourniquets are intended to be used in the electro-magnetic environment detailed below. It is convenient that the user of these devices makes sure that they are used in such an environment			
Immunity testing	**Level of testing CEI 60601-1-2:2014**	**Level of conformity**	**Electromagnetic environment - directives**
Electrostatic discharge (DES) EN 61000-4-2	±6 kV in contact ±8 kV in air	±6 kV ±8 kV	It is advisable that the floors are made of wood, concrete or ceramic tiles. If the floors are covered with synthetic materials, it is convenient that the relative humidity is of at least 30%.
Electrical Fast transient / burst EN 61000-4-4	±2 kV for electric lines ±1 kV for input/output lines	±2 kV Non applicable	It is advisable that the quality of the power supply network is that of a typical commercial or hospital environment.
Impulse waves EN 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	It is advisable that the quality of the power supply network is that of a typical commercial or hospital environment.
Voltage dip, brief voltage outsets and voltage variation in the power supply input lines EN 61000-4-11	<5 % *U*T for 10 ms 40 % *U*T for 100 ms 70 % *U*T for 500 ms <5 % *U*T for 5 s	<5 % *U*T for 10 ms 40 % *U*T for 100 ms 70 % *U*T for 500 ms <5 % *U*T for 5 s	It is advisable that the quality of the power supply network is that of a typical commercial or hospital environment. If the user of these devises requires the continuous operation during the power cuts in the supply network, it is advisable to feed these devices by means of a power supply without cuts or a battery.
Magnetic field at the frequency of the electric network (50/60 hertz) EN 61000-4-8	3 A/m	3 A/m	It is advisable that the magnetic fields at the frequency of the electric network have the levels of a representative place located in a typical commercial or hospital environment.
NOTE : *U*T is the voltage of the alternative network before the application of the level of testing			

DECLARATION OF CONFORMITY

DDM DESSILLONS & DUTRILLAUX	**DECLARATION DE CONFORMITE** selon la directive 93/42/CEE modifiée par la directive 2007/47/CEE **DECLARATION OF CONFORMITY** *According to directive 93/42/EEC modified by directive2007/47/EEC*	Indice 18

Nous, DESSILLONS & DUTRILLAUX - Z.I. de la Tuque - 47240 CASTELCULIER - France

Déclarons sous notre entière responsabilité que le ou les dispositifs médicaux décrits ci-dessous sont conformes aux exigences de la directive 93/42/CEE, modifiée par la directive 2007/47 CE, qui leurs sont applicables.

We declare under our responsability that the products or product groups described below conform to the requirements of the European Directive 93/42/EEC, modified by the Directive 2007/47 EEC applicable at materiel devices.

DISPOSITIF MEDICAL : — **Electro-garrot pneumatique à pression constante**
Medical Device Group : — *Pneumatic/electric tourniquet at constant pressure*
Code GMDN: — *14074*

MODELE :
Model:

G10705	**Modèle électromécanique simple circuit de pression** *Electromechanical model with 1 regulated pressured circuit*
G10706	**Modèle électromécanique double circuit de pression** *Electromechanical model with 2 regulated pressured circuits*
G10803	**Modèle électronique simple circuit de pression** *Electronic model with 1 regulated pressured circuit*
G10903	**Modèle électronique double circuit de pression** *Electronic model with 2 regulated pressured circuits*
LOP	**Avec option LOP** *Option LOP*

INDICE DE CLASSEMENT : — **Classe IIA, règle 9**
selon annexe IX de la directive

Index of classification : — *Class IIA, rule 9*
Appendix IX, of the European directive

Procédure de marquage CE : — **Annexe II.3**
CE marking process

MARQUAGE CE : — **CE 0459**
CE marking :

Cette déclaration est basée sur les éléments suivants :
This declaration is based on the following elements:

- **Documentations techniques (réf DTC G10705-G10706 et G10803-G10903) démontrant la conformité des dispositifs médicaux aux exigences de la directive**
  Technical documentation (ref. DTC G10705-G10706 & G10803-G10903) showing the conformity of these devices to the requirements of the directive.

- **Certificat CE d'approbation du système de management de la qualité de DESSILLONS & DUTRILLAUX n° 32763 rev 4 émis par GMED :**

  CE certificate n° 32763 rev 4 of approval of the system of management of the quality of DESSILLONS & DUTRILLAUX emitted by GMED

  ORGANISME NOTIFIE CE n°: 0459 GMED – 1 Rue Gaston Boissier – 75724 PARIS CEDEX 15
  Notified Body number 0459

Date : 06/04/2021

Vanessa HILBERT / Responsable Qualité

DESSILLONS & DUTRILLAUX
ZI De Tuque
47240 - CASTELCULIER
Tél. 05 53 48 10 [illegible] 05 53 47 24 64
SIREN 571 [illegible] 218

CE marking

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 32763 rev. 4**
Délivrée à Paris le 19 mars 2021
Issued in Paris on March 19th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

DESSILLONS DUTRILLAUX
ZI La Tuque
47240 CASTELCULIER FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Manchette à pression, garrots électro-pneumatiques et électroniques à pression constante avec option LOP, aspirateurs de fluides chirurgicaux ou biologiques

Pressure cuff, electronic and electro-pneumatic tourniquets with constant pressure with option LOP, aspirators for surgical or biological fluids

Voir document complémentaire GMED / See GMED additional document
n° 38203

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600792, P601429, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P600792, P601429, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date* : **March 19th, 2021 (included)**
Valable jusqu'au / *Expiry date* : **May 26th, 2024 (included)**

GMED 0459 GMED 0459
GMED
DocuSigned by:
Lionel DREUX
1D8DE0BCB0D47A...

Lionel DREUX
Certification Director

GMED - 32763 rev. 4
Modifie le certificat 32763-3

Ce document complémentaire GMED n° 38203 rev. 0 atteste de la validité du certificat CE n° 32763 rev. 4 au regard des informations listées ci-dessous.

This GMED additional document n° 38203 rev. 0 attests to the validity of CE certificate n° 32763 rev. 4 with regard to the information listed below.

Fabricant / *Manufacturer:*

DESSILLONS DUTRILLAUX
ZI La Tuque
47240 CASTELCULIER FRANCE

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Manchette à pression BLUE FUSE 500 cc	M20085	IIa
Manchette à pression BLUE FUSE 1000 cc	M20080	IIa
Manchette à pression BLUE FUSE 3000 cc	M20075	IIa
Manchette à pression CLEAR FUSE 500 cc	M30500	IIa
Manchette à pression CLEAR FUSE 1000 cc	M31000	IIa
Manchette à pression CLEAR FUSE 3000 cc	M34000	IIa

GMED | 0459

GMED - 38203 rev. 0

DocuSigned by:
Lionel DREUX

Lionel DREUX
Certification Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Manchette à pression EASY FUSE 500 cc	**M10500**	**IIa**
Manchette à pression EASY FUSE 1000 cc	**M11000**	**IIa**
Manchette à pression EASY FUSE 3000 cc	**M13000**	**IIa**
Manchette à pression GREY FUSE 500 cc	**M20500**	**IIa**
Manchette à pression GREY FUSE 1000 cc	**M21000**	**IIa**
Manchette à pression GREY FUSE 3000 cc	**M23000**	**IIa**
Manchette à pression GREY FUSE 5000 cc	**M25000**	**IIa**
Garrot électro-pneumatique Little Pump à 1 circuit de pression régulée	**G10705**	**IIa**
Garrot électro-pneumatique Little Pump dual à 2 circuits de pression régulée	**G10706**	**IIa**
Garrot électronique Easy Pump à 1 circuit de pression régulée	**G10803**	**IIa**
Garrot électronique Easy Pump dual à 2 circuits de pression régulée	**G10903**	**IIa**
Aspirateur de fluides chirurgicaux ou biologiques LITTLE VAC	**LV705**	**IIa**

Site couvert et Activités / *Location and Activities*

DESSILLONS DUTRILLAUX - ZI La Tuque - 47240 CASTELCULIER - FRANCE
Siège social – responsable de la mise sur le marché, conception, fabrication et contrôle final
Headquarters – legal manufacturer, design, manufacture and final control

GMED 0459

GMED - 38203 rev. 0

GMED
DocuSigned by:
Lionel DREUX
Lionel DREUX
Certification Director

ACCESSORIES AND CONSUMABLES LIST

ACCESSORIES	
Reference	Designation
A10701	Mobile stand on wheels with basket for cuff
A11008	Acetal male connector with O-ring
A11012	Female coupler online fluted Ø 4.8
A11322	O-ring for acetal mal connector (reference A11008) - Cdt : 10 units
A20001	Blue tubing 2 m for tourniquet and cuff with male and female connectors
A20006	Blue tubing 2 m for tourniquet and cuff with male and female connectors
A90004	Mains fuse F1.6AH250v
A11362	Mains fuse F2AH250v
A10726	Power cord ; Lenght : 5 meters

REUSABLE MONOBLOC ARM CUFF AND LOWER LIMB CUFF FOR PNEUMATIC TOURNIQUET – 1 Tube

Reference	Optional : fastening strap	Optional : protector	Designation	Color of tube	Dimensions in cm		
					A	B	C
GBDM101	GBDMS101	GBDMP101	Cuff new born straight	White	3.5	29	38
GBDM102	GBDMS102	GBDMP102	Cuff child straight	Pink	4.5	35	48
GBDM103	GBDMS103	GBDMP103	Cuff small adult straight	Parma	6	46	61
GBDM104	GBDMS104	GBDMP104	Cuff adult straight	Blue sky	8	46	67
GBCM105	GBCMS105	GBCMP105	Conical cuff adult large	Turquoise	10	47	70
GCDM103	GCDMS103	GCDMP103	Lower limb cuff adult straight	Yellow	8	76	97
GCDM104	GCDMS104	GCDMP104	Lower limb cuff adult straight	Purple	10	62	76
GCDM105	GCDMS105	GCDMP105	Lower limb cuff adult straight L	Green	10	76	90
GCDM106	GCDMS106	GCDMP106	Lower limb cuff adult straight XL	Grey	10	82	100
GCDM107	GCDMS107	GCDMP107	Lower limb cuff adult straight XXL	Red	10	107	122
GCCM104	GCCMS104	GCCMP104	Conical lower limb cuff adult	Purple	10	62	76
GCCM105	GCCMS105	GCCMP105	Conical lower limb cuff adult L	Green	10	76	90
GCCM106	GCCMS106	GCCMP106	Conical lower limb cuff adult XL	Grey	10	82	100
GCCM107	GCCMS107	GCCMP107	Conical lower limb cuff adult XXL	Red	10	107	122

REUSABLE MONOBLOC ARM CUFF AND LOWER LIMB CUFF
FOR PNEUMATIC TOURNIQUET – 2 Tubes

Reference	Optional : fastening strap	Optional : protector	Designation	Dimensions in cm		
				A	B	C
GBDM204	GBDMS204	GBDMP204	Cuff adult straight	8	46	67
GBDM202	GBDMS202	GBDMP202	Cuff child straight	4.5	35	48
GCDM204	GCDMS204	GCDMP204	Lower limb cuff adult straight	10	62	76

DISPOSABLE MONOBLOC ARM CUFF AND LOWER LIMB CUFF
FOR PNEUMATIC TOURNIQUET

Reference	Designation	Color of tube	Dimensions in cm		Overall length
			Width	Length	
GBU101	Cuff new born	White	3.5	29	38
GBU102	Cuff child	Pink	4.5	35	48
GBU103	Cuff small adult	Parma	6	46	61
GBU104	Cuff adult	Blue sky	8	46	67
GBCU105	Conical cuff adult large	Turquoise	10	47	70
GCDU103	Lower limb cuff adult straight	Yellow	8	76	97
GCDU104	Lower limb cuff adult straight	Purple	10	62	76
GCDU105	Lower limb cuff adult straight L	Green	10	76	90
GCDU106	Lower limb cuff adult straight XL	Grey	10	82	100
GCDU107	Lower limb cuff adult straight XXL	Red	10	107	122
GCCU104	Conical lower limb cuff adult	Purple	10	62	76
GCCU105	Conical lower limb cuff adult L	Green	10	76	90
GCCU106	Conical lower limb cuff adult XL	Grey	10	82	100
GCCU107	Conical lower limb cuff adult XXL	Red	10	107	122

STERILIZABLE ARM CUFF AND LOWER LIMB CUFF FOR PNEUMATIC TOURNIQUET

Reference	Designation	Dimensions of the bladder
Arm cuff and lower limb cuff with single bladder		
GBS101	Lower limb cuff new born	19 x 4
GBS102	Cuff child	26,5 x 5
GCS102	Lower limb cuff child	35,5 x 6
GBS103	Cuff small adult	35,5 x 6
GCS103	Lower limb cuff small adult	53 x 6
GBS104	Cuff adult	53 x 6
GCS104	Lower limb cuff adult	69 x 9
GCS105	Lower limb cuff adult L	81 x 9
GCS106	Lower limb cuff adult XL	85,5 x 12
Arm cuff and lower limb cuff with double bladder		
GBS202	Double cuff child / small adult	2 x (35,5 x 6)
GBS204	Double cuff adult	2 x (53 x 6)
GCS204	Lower limb double cuff adult	2 x (69 x 9)
Conical cuffs for lower limb		
GCCS104	Adult thigh	69 x 9
GCCS105	Adult thigh L	81 x 9
GCCS106	Adult thigh XL	85,5 x 12