Since 1949

0459

Date of first EC marking certificate: 1998

PNEUMATIC TOURNIQUET

References : **G10803 - G10903**

Designation : **Pneumatic tourniquet with simple and d**

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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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
	Equalization of potentials (Terminal used in electrical tests)	Back of the unit
	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
	Battery charging status in increments 25 %	Display screen
	Manufacturer : 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 G10803 and G10903 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.
To enable to guarantee the traceability of operations through a USB cable or an optional printing port.
The model G10803 has only one pressure circuit and is intended to be used in operations using a single cuff, whereas G10903 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).

- -During its use, the device must be permanently connected to the power grid, the battery providing a security role only in case of failure on the power supply. The batteries should be used in case of doubt the system grounding protection in the installation.

-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.

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.

-Connect the power cord to the mains, make sure that the batteries are properly charged to compensate for any defects of the external grid.

-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 2007 version, the accompanying documents shall include the following information :
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 G10803-G10903 devices.

Electromagnetic conformity established with the following accessories :
Designation
Switching mode power supply card
Power supply cord 5 meters
Battery Pb 12v 4000 mAh
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 

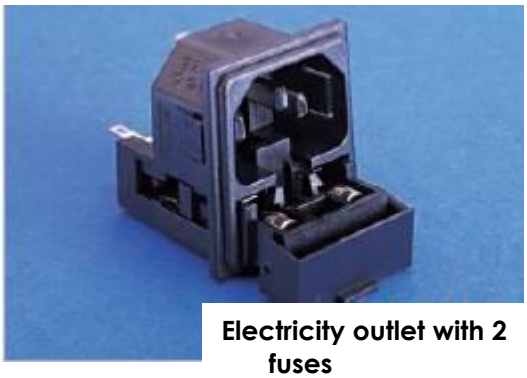
, long press the button is required.

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.
A reminder is given at the start of the device if the maintenance date is passed.

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 battery is protected by an external fuse with the following identification reach on the fuse holder :
Value of fuse **:** F8AH250V (rapid action, power cut 1500A).

The electronic card is protected by an external fuse : fuse value : F3.15AH250V (rapid action, power cut 1500A).

Change of battery

Lead acid battery do not present a hazard under normal conditions of use, however, and as a safety measure, prior to battery replacement is recommanded to guard against possible leakage from the battery by protecting hands with gloves and avoid inhaling the residual dust.

Technical characteristics of the battery : Pb - 4000 mAh.

Replacing the battery should only be performed by a biomedical technician trained for this activity by referring to the technical documentations DCT G10803-G10903.

Disconnect the power supply.
Remove the rear panel after unscrewing the 6 retaining screws.
Access to the 4 screws holding the battery holder.
Disconnect the battery, replace it and repeat the operations in reverse order for reassembly.

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 G10803)

IV. PRESENTATION OF THE MEDICAL DEVICE (model G10903)

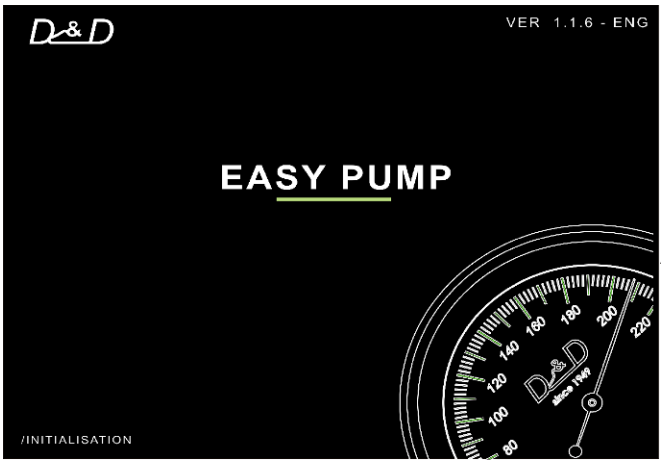
Connection coupling
For arm cuff
Blue circuit

Connection coupling
For arm cuff
Red circuit

V. ACTIVATION OF THE DEVICE

A. START OF DEVICE

The pneumatic tourniquet is operational and turned off by pressing switch aside.
At start-up the screen lights up, if message is appearing on the page below refer to the "Error Startup" section :

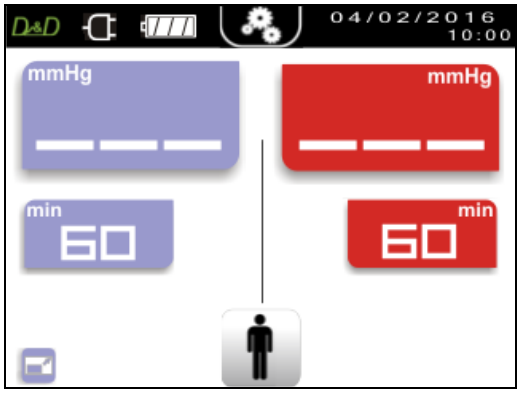


B. INFORMATIONS REGARDING OPERATION WAYS

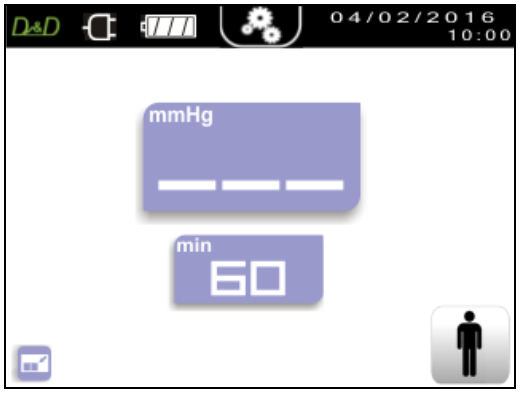
To simplify the reading of this document and the general use of the device "zones" of operations are defined by colors :

* Blue : for the left circuit (G10903) and for the single circuit pressure (G10803-G10903).
* Red : for the right circuit (G10903).

G10903 (Dual circuit)



G10803 and G10903 (Single circuit)



These pressure circuits are completely separated.
The settings of the pressure and of the timer are independents, the setting procedure is identical to the pressure and the timer (Only the color changes for a G10903).

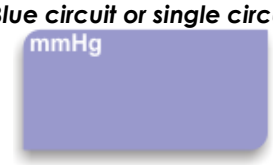
C. PRESSURE ADJUSTMENT

Changing the pressure (outside off surgery)

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

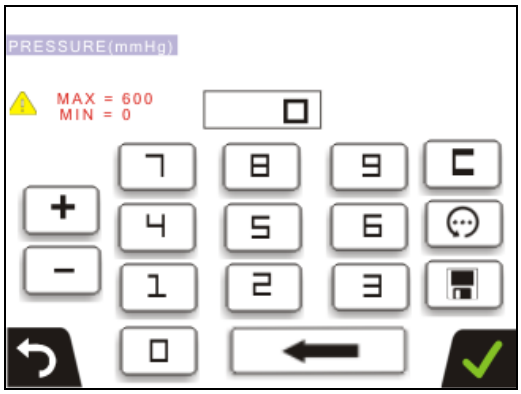
1) Press the key "PRESSURE"

Blue circuit or single circuit



Red circuit

2) Enter a set point value on the key board



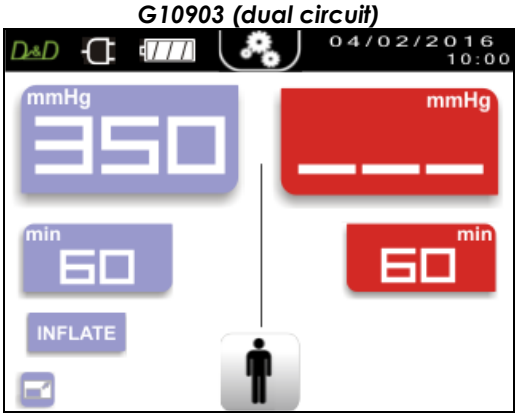
ex : 350 mmHg  or using the keys  and  .

3) Validate :

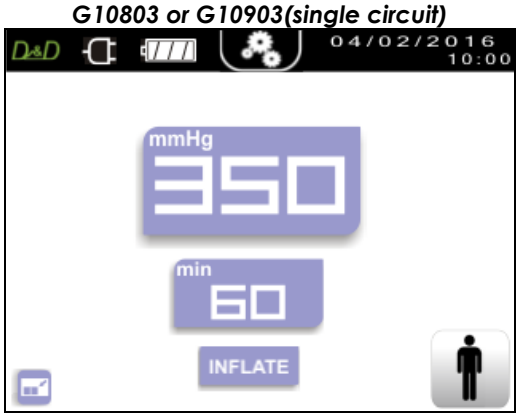
Validate by pressing the button  .

The desired pressure is displayed on the screen :

G10903 (dual circuit)



G10803 or G10903(single circuit)



Changing the pressure (during surgery)

During surgery, it is possible to modify the initial pressure by doing the same.

1) **Press the key PRESSURE**

2) **Entering a new value on the alphanumeric key board**

For example 380 mmHg 

3) **Validation :**

Press the key  on the key board, the new value is adjusted automatically.

Default setting pressure (outside off surgery)

Outside off surgery, it is possible for the user to save a default pressure for each circuit, this pressure will automatically reapply at the end of the operation.
For this, simply proceed as follows :

1) **Press the key PRESSURE**

2) **Entering a new value on the alphanumeric key board**

For example 380 mmHg 

3) **Press the key BACKUP**

 : a new page opens asking you to validate.

4) **Validation**

Press the key  on the key board, the value is stored in memory even after a device restart.

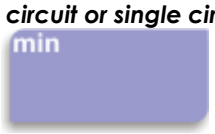
D. SETTING THE TIMER

Modification of the timer (outside off surgery)

The user can set a timer for surgery. An alarm is activated at the end of the timer delay. If the user doesn't have a timer program, the default timer is selected. (Factory setting : 60 minutes).

1) **Press the key MIN**

Blue circuit or single circuit



Red circuit

2) **Entering a new value on the alphanumeric key board**

For example : 50 min : 

3) **Validation**

Press the key  , the new value is configured and displays on the screen.

Modification of the timer (during surgery)

During surgery, it is possible to modify the initial timer by doing the same.
If the timer alarm is activated during modification, the alarm is turned off.

1) **Press the key MIN**

2) **Entering a new value on the alphanumeric key board**

For example : 20 min 

3) **Validation**

Press the key  , the value is configured, the timer alarm will go off 20 minutes after the modification.

Default setting timer (outside off surgery)

Outside off operation, it is possible for the user to save a default timer for each circuit, this setting will automatically reapply at the end of the operation. To do this, simply proceed as follows :

1) **Press the key MIN**

2) **Entering a new value on the alphanumeric key board**

For example : 25 min 

3) **Press the key BACKUP**

 : a new page opens asking you to validate.

4) Validation

Press the key  on the key board, the value is stored in memory even after a device restart.

E. TURNS THE SYSTEM ON AND OFF

Turns the system on (inflation)

When the setting pressure value is set on the circuit, the key 

displays on the screen (the color changes according to the pressure circuit used).
This button starts the operation cycle and allows pressurization of the cuffs.

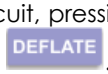
Turns the system off (deflation)

After the intervention cycle launched on the circuit, the key 

displays on the screen (the color changes according to the pressure circuit used). This button allows stopping operation cycle.
This as the effect of :

- Stops alarms on this pressure circuit
- Stops timer and freezes the value
- Deflation of the tourniquet

The button 

(color changes according to circuit G10903) appears when a pressurization fault * is detected on the circuit, pressing this button shortly causes the intervention cycle to stop with the same effects as the button 

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* see : **C.DEFAULT MANAGEMENT** (page 18).

VI. INFORMATIONS ABOUT THE OPERATION OF THE SYSTEM

A. KEYBOARD MANAGEMENT

Consideration of pression the "buttons" area on touchscreen :

- All keys are taken into account by pressing
- If the user is pressing a key, it is taken into account only once, except for 2 + an + keys can remain pressed to increment or decrement a value.
- The action of the button 

is active after pressing this button a long time.

B. BATTERY MANAGEMENT

For use, the pneumatic tourniquet should be permanently connected to the electricity grid of the hospital. From that moment, a "power outlet" icon  appears at the information on the screen headband 

to inform the user that the device is powered from the mains, the battery is charging and ensures the relay when problem on the grid.

The battery level is displayed on the screen as a more or less filled in the state of the charge status of the battery  . In case this level is less than 25 % of a full charge a battery fault is triggered, it is an early warning that is characterized by yellow triangle logo  + 1 beep, to alert the user once the battery at a low load.
If the charge is less than 10% of a full charge, a battery fault is triggered.

This is an alert that is characterized by an icon for battery 

+ a series of beeps to inform the user, the pressurization is not guaranteed if the device is not connected to the mains.

A break alarm is possible by pressing the key  .

If the operator does not connect the device to time, it blocks the pressure in the system then reboots.
When starting or restarting the device on battery, if the charge in the battery is insufficient that will display battery in red color struck out on a black background.

C. DEFAULT MANAGEMENT

Conditions for triggering an alarm				
Display		Causes	Priority	Actions
 Time Out	+ 2 beeps	Defined time expired	Medium	No action – Information signal
	+ 1 beep	Battery charging to 25 %	Low	No action – Information signal
 180min	+ 7 beeps	Surgery time reached 180 minutes	Visual medium, Audible High	No action – Information signal
 Battery!	+ 7 beeps	Battery charge 10 % Insufficient charge battery to ensure a secure response	High	Check that the device is plugged in- Replace the battery
 PRESSION	7 beeps	Setting pressure not established in less than 6 seconds	High	The cuff is not tight enough around the limb or not connected. Press the button "STOP" then restart a cycle
 PRESSION	7 beeps	Pressure leak: The pressure present in the circuit is less than the pressure setpoint for 5 seconds	High	Ensure proper connection of the cuff.
 PRESSION	7 beeps	Overpressure: The pressure present in the circuit is greater than the pressure setpoint for 5 seconds	High	Check than there is no element resting on the tourniquet
 PRESSION	7 beeps	Stabilization: The device fails to stabilize the pressure in the circuit.	High	Check that the tourniquet is correctly placed and conforms.

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.

 Note : Note: Holding down the button  allows you to know more precisely the type of alarm in progress, when the button is released the user instantly returns to the operation menu.

Alarm deactivation :

If 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.

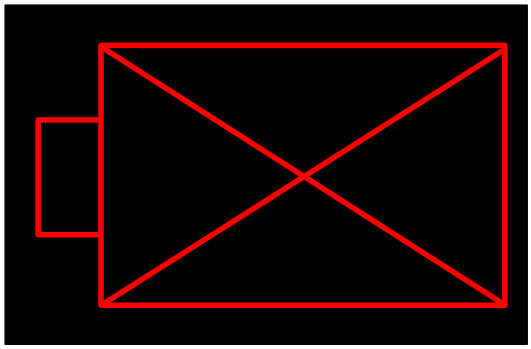
If there is an electrical power failure, the alarm system is immediatly unable to restore the alarm settings.

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

D. DEFAULT ON STARTING :

When the device is turned on, various tests are performed. In case of failure on one of these tests, the device informs the user about the problem.

Start up with a battery with too low load



Start up with a defective printer (optional) or disconnected

Maintenance date exceed (see II-Maintenance)

Memory failure or system file failure

Starting the device with pressure in the system

The device determines that a cycle was underway before the start of the device. The cycle restarts with a cycle pressure as a pressure setpoint, the pressure in the circuit.

Note : Surgery time is reset to 0 minute and the setpoint timer used is the default settings timer : 60 minutes.

Default of License Key

The license key is requested when the device is a lending device, a new key is requested to unblock the device for a certain duration or permanently.

Default image file

The image file contains some display elements, this message is displayed when the file is unavailable.
This does not prevent the proper operation of the device only certain graphical (non-essential) elements will not appear.

VII. TRACEABILITY

A. DATA RECORDING

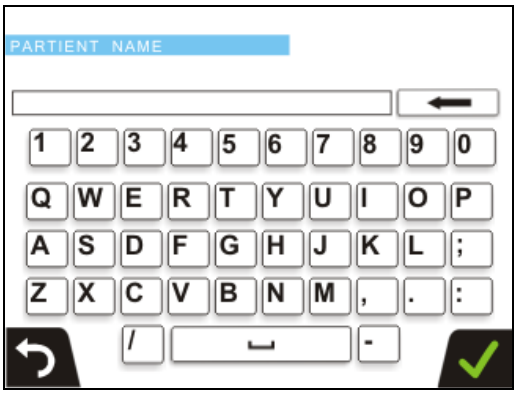
Traceability should enable to control and to check the cuff pressure during a cycle. This is a time-stamped record of the various pressures of the cuff during the surgical procedure. These data are printed during the pressurization cycle of the cuffs. Data to be recorded are :

- The patient's name
- The patient's surname
- The hospital's name or the number of the operating room
- Pressures are stamped during the intervention. They are recorded at each event.

B. ALPHANUMERIC KEYBOARD

Generally

The alphanumeric keyboard allows the user to change some information like service's name, hospital or operating block's name, and the full name of the patient.



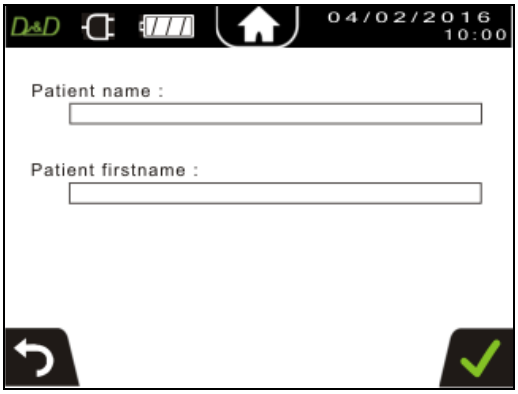
Changing the name and surname of the patient

1) No pressure cycle in progress

The key **Patient name**  is displayed.

2) Press the key patient name

Allows the user enter in the "patient name" menu :



3) Press the white rectangle

Located under « Patient name » or « Patient firstname », provides access to the keyboard and change respectively, the patient's name and patient's surname.

4) Now simply enter a name or a surname (max 20 characters)

Example : Bob,  , in case of error to delate the last letter, just press the key  .

5) To return to the previous menu

Confirming selection by the validate key  , without confirming by the return key  .

6) To confirm the patient's full name

Pressing the key validation is required. Not validate : just press the back key .

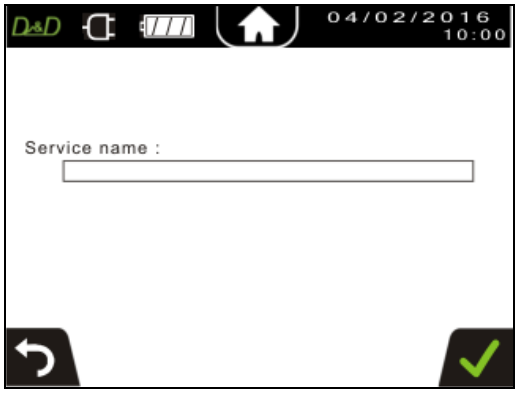
Changing the service's name, or hospital operating block

1) **Enter in the menu Hospital**

Icon (see options)

2) **Press the white rectangle**

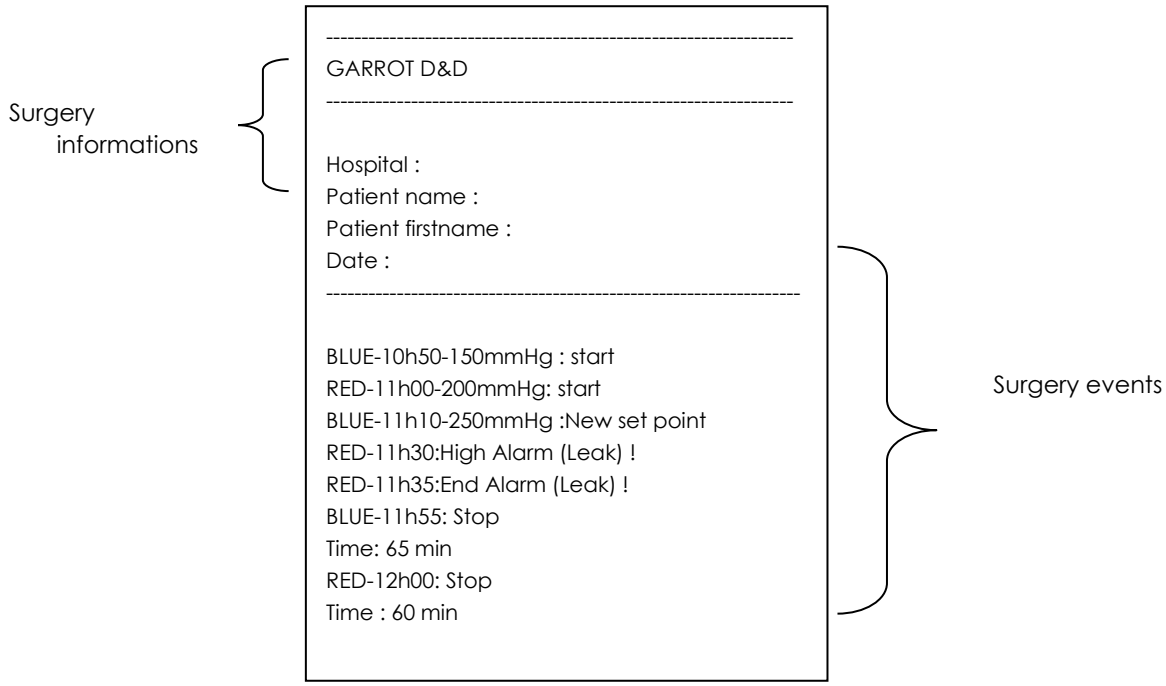
Located under « Service name» , wich allows access to the keyboard.



3) **Perform the actions N°4 to 6described in VII-B-Changing the name and surname of the patient**

C. DATA PRINTING

Printing is done automatically during the cycle, if the unit is equipped with a printer (optional).
The printed ticket is in this form :



- You can change the surgery informations via :
  - Hospital menu (see option), Hospital modification field that indicates the hospital's name or the Operating block's number.
  - Patient name menu (see VII-B), changing fields patient's name and surname's patient.
  - Date and Time menu (see option), change in the date field

Events during surgery

- The operating events indicate all the events that occur during surgery.

Events	Description
Start	Start of surgery
Stop time : 000min	Stopping a cycle of surgery and indication of the operating time
New set point	Changing the pressure set point
High Alarme (Cdt) !	Indicates a high priority alarm Cdt :alarm condition
End Alarm(Cdt) !	Indicates the end of an alarm Cdt : alarm condition
Medium Alarme(Cdt) !	Indicates the end of a medium priority alarm Cdt : alarm condition
IVRA ON	Indicates that the IVRA mode is operational (see option)
IVRA OFF	Indicates that the IVRA mode is no longer operational (see option)
RESTART...	Indicates that the device has started a pressure cycle at starting of the device
-Error : Too short cycle...	Indicates that the cycle was

	launched and immediately stop.
Printer Stop	Indicates that the printer has stopped
Printer Restart	Printer is back to normal

VIII. CONFIGURATION

A. INFORMATION PANEL

The panel information at the top of most pages allows the date, time, battery level, and if the device is connected to the mains via a power outlet.

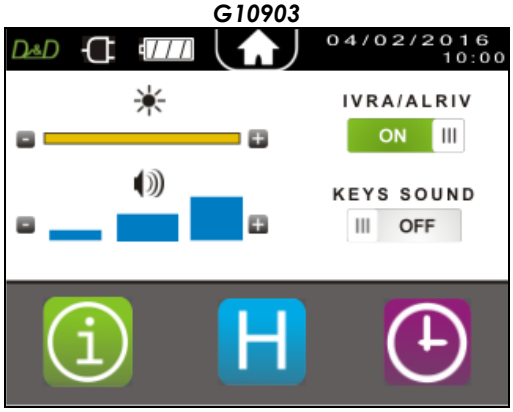
It also allows using the key  to access the options (from the operation menu) or quickly return to the operation menu  from any other menu (Note : Do not save changes to the menu that require validation).

B. OPTIONS MENU

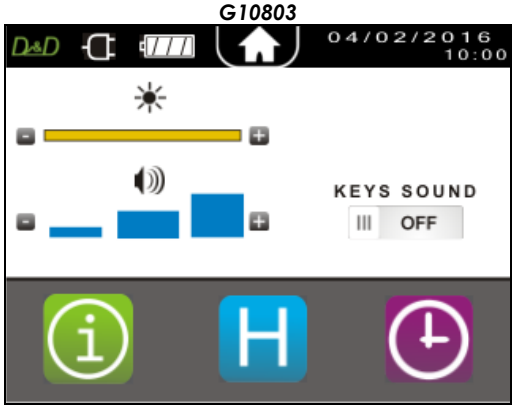
Introduction

An option menu is accessed by pressing this key  located at the panel information.

G10903



G10803



Changing the brightness of the screen

Below the icon  , by the keys  and  , the current level is represented by the color yellow in the bar between the two keys.
If modified, the brightness level will save and then reapply every time you start the unit.

You can't change the brightness of the device during surgery.

Changing the sound level

Below the icon  , by the keys  and  , the current level is represented by vertical white bars between the two buttons.
If modified, the sound level will save and then reapply every time you start the unit.

You can't change the sound level of the device during surgery.

Changing the surgery mode

By the key 

or 

located below the words IVRA/ALRIV.

surgery mode IVRA/ALRIV is activated

surgery mode IVRA/ALRIV is deactivated.

Changing the touch sound level

By the key 

or 

located below the words SOUND TOUCH, this parameter allows you to enable or disable the sound emitted by the device when pressing the button.

If changing the setting, it will save and then reapply every time you start the unit.

level sound activated

level sound desactivated.

You can't change the touch sound level of the device during surgery.

To access to the date and time menu

Acces to this menu is by 

To access to the hospital menu

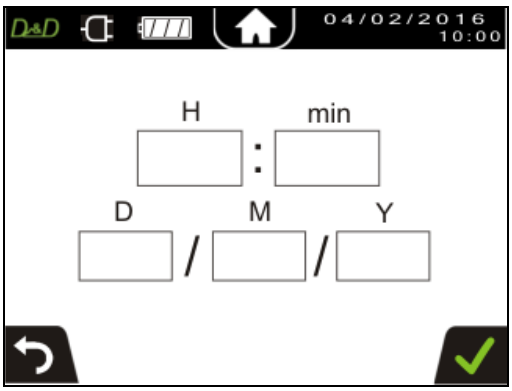
Acces to this menu is by 

To access to information menu of the casing

Acces to this menu is by 

C. DATE AND TIME

This menu is accessible via the **option menu** (see VIII-B), changes the date and time of the tourniquet.



Pressing each white rectangle opens the numeric keyboard wich can change each field.

Pressing the key **validate**  to confirm the change.

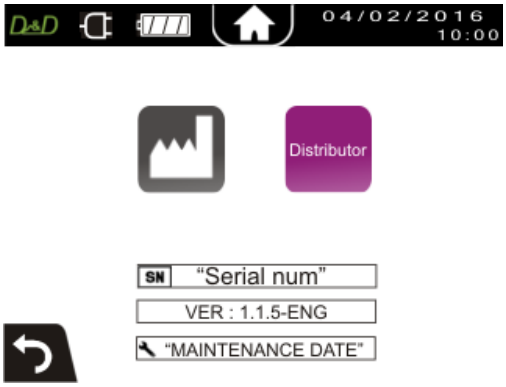
Pressing the key **return**  lets not save changes.

Note : The date of service called "original" is retained in memory.

D. INFORMATION CASE

This menu is accessible via the **option menu** (see VIII-B), provides access to informations :

- From manufacturer (name, address, phone number, web address, email address) by pressing the key  .
- From Distributor (name, address, phone number, web address, email address) by pressing the key  .
- From device (serial number, software version and date of maintenance) at the bottom of the menu.



E. 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 :

- Consult the electrical of the device's power supply.
- Set the calibration of pressure sensors.
- Set maintenance time called "original"
- Check the configuration of the pneumatic tourniquet

IX. USE WITH ONE 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 a Esmarch bandage from the end of the limb.

5) Pressure set point adjustment

Proceeding as described in section V-C by ensuring that the tourniquet is normally swells.

6) Proceed if necessary by setting a time

As described in section 4-D.

7) After the surgery, deflate the tourniquet

Pressing the key deflate.

B. INSTRUCTIONS FOR USE THE IVRA MODE

An assistance by the tourniquet : this type of intervention is available in the **option menu** (see VIII-B) via the key **IVRA** III OFF .

Without assistance :

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 (to the root of the limb).

3) Exsanguinate the limb

By raising or by winding an Esmarch bandage from the end 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

By applying the adjustment method defined above, adjust the pressure on each circuit. If necessary, adjust the time as described in paragraph V-D.

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

With assistance :

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 (to the root of the limb).

3) Exsanguinate the limb

By raising or by winding an Esmarch bandage from the end 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) Key IVRA

Press the button 

until it becomes like this 

.

6) Set one of the two circuits

By applying the adjustment method defined above, adjust the pressure on each circuit. If necessary, adjust the time as described in paragraph V-D.

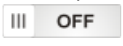
7) Press the key Inflate

Press the key **Inflate** 

on blue circuit.

8) Follow the cycle of appearance of keys

Note : anytime the user can remove the help option by accessing the **option menu** (see VIII-B) and pressing the key **IVRA** 

until it's become as 

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X. ANNEX

TECHNICAL CHARACTERISTICS OF PNEUMATIC TOURNIQUET G10803-G10903-G10903Z

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 Pression atmosphérique 79.0 kPA à 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		
Hardness	78		
DIMENSIONS	Case G10803	Case G10903	Case G10903Z
Height (mm)	250	250	250
Width (mm)	300	300	300
Depth (mm)	190	190	190
	SCREEN		
Width (mm)	120		
Height (mm)	90		
WEIGHT kg	4.2	4.2	4.5
LINE VOLTAGE	100 - 240 V AC		
LINE FREQUENCY	50 – 60 Hz		
POWER PLUG	60 VA		
FUSE			
Input power card	FTT2AH/250V		
Output power card	F3.15AH/15V		
Battery	F8AH/12V		
PULSED POWER SUPPLY	Entry : 90-264 Vac, 47-63 Hz, 1.8 – 1 A - Exit : 15 Vdc, 4A		
BATTERY	Rechargeable		
Type	Pb		
Voltage	12 Volts		
Ampere	4000 mAh		
Charging time	8 h		
Autonomy	10 h		
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	2	2
TIMER			
Units	Minutes		
Alarm	Programmable audible and visual alarm		
CONNECTION			
Pneumatic	1 female coupler CPC type	2 females coupler CPC type	4 females 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	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 G10803-G10903 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 G10803 and G10903 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*	*G10803 and G10903 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*	*G10803 and G10903 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**	**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 SIRET [illegible]

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 545
GMED
DocuSigned by:
Lionel DREUX
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

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Lionel DREUX
Certification Director

ACCESSORIES AND CONSUMABLES LIST

ACCESSORIES	
Reference	Designation
A10701	Mobile stand on wheels with basket for cuff
G13200	Printer G10803-G10903
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