PNEUMATIC TOURNIQUET

References: **G10904**

Designation: **Electronic pneumatic tourniquet with double regulated pressure circuits**

USER MANUAL

Before using these medical devices for clinical applications, troubleshooting or maintenance of these, please read this manual carefully and assimilate all the information relating to their functionalities by observing the instructions described.

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SUMMARY

I. DEVICE IDENTIFICATION

tourniquet **G10904** is used exclusively in the operating room to temporarily block blood flow to the patient's upper or lower limbs in order to perform extremity surgery and includes but is not limited to:

- Reductions of certain fractures;
- Replacement of knee, wrist, hand or elbow joints;
- Arthroscopy of the knee, wrist, hand or elbow;
- Amputation of limbs;
- Tumor excisions, cysts.

MEDICAL DEVICE: PNEUMATIC TOURNIQUET

Code : 14074

CND Code (European Nomenclature of Medical Devices) : Z12139006 - PNEUMATIC TURNSTILES

Reference	***Designation***	***UDI-ID***
G10904	**Dual circuit pressure electronic model**	37004682GAESE

II. DEVICE DESTINATION

Indication

tourniquet **G10904** is a medical device to be used with one or two simple tourniquets for bloodless operating fields, in bilateral surgery or with double tourniquets for operations under local anesthesia (loco-regional anesthesia or ALRIV) .
It is the surgical responsibility to establish the indication for use of the tourniquet and to specify the site of application, the insufflation pressure used and the duration.
tourniquet **G10904** in association with a double pocket cuff allows the realization of an intravenous locoregional anesthesia (ALRIV).
The various tourniquets (armbands and thigh straps) and the extensions constitute the applied parts of the device. These elements are listed in the appendix.

Area of use

tourniquet **G10904** associated with an armband/shorts makes it possible to establish around a limb, a circumferential pressure in order to interrupt the blood circulation, downstream of the tourniquet and thus to make the operating field bloodless.
The electro-pneumatic tourniquet pump blows air into the cuff or deflates it to generate the pressure desired by the user.
The pressure in the cuff allows the compression of the limb on which it has been positioned, thus interrupting the blood circulation for a defined period. The retention of blood flow thus reduces the influx of blood to the area on which the surgeon operates, thus leaving the operating field cleaner.
The use of a tourniquet therefore gives the doctor essential visual comfort, thus offering him better operating conditions and the assurance of precise surgical gestures.

Patient population

Any human being can have recourse to a surgical intervention requiring the use of a pneumatic tourniquet, only the contraindications described below or a decision of the medical profession can give rise to a rejection of this operative technique.

User profile

The G10904 Pneumatic Tourniquet is intended for use only by trained medical professionals for the intended use described below. This is usually a State Certified Operating Room Nurse (IBODE) or a State Certified Nurse Anesthetist (IADE).

Hygiene rules to follow for entering the block

All members of the surgical team who have direct contact with the operating field, sterile instruments or equipment used in the operating field perform surgical disinfection of the hands and forearms before putting on a sterile gown and sterile gloves
.

III. CONTRAINDICATIONS, COMPLICATIONS AND PRECAUTIONS

Contraindications :

- infection of one extremity;
- an open fracture;
- a tumor located distal to the place of use of the tourniquet;
- haemoglobinopathy (eg sickle cell anaemia);
- blood circulation disorders ;
- revascularization of one extremity;
- extremities provided with access for dialysis;
- a venous thrombo -embolism;
- pressure ;
- acidosis ; _
- medication or use of supplements (e.g. creatine)

- Local :
    - bypasses ;
    - arteriosclerosis ;
    - calcifications , other arteriopathies;
    - arteriovenous fistula ;
    - flap ;
    - morbid obesity ;
    - clinical or ultrasound DVT;
    - localization in the operated limb;
    - dissection with ATCD of lymphoedema;

- General:
    - edema (ICH, head trauma, etc.);
    - failure ;
    - respiratory ;
    - Diabetes with neurological damage;
    - sickle cell disease;
    - Advanced rheumatoid arthritis.

In all cases the final decision on the use of a tourniquet rests with the surgeon.

Complications / undesirable side effects

- Nerve damage;
- Superficial infection;
- Deep vein thrombosis;
- Traumatic wound dehiscence
- Exudation from the wound;
- Erythema;
- Skin blisters;
- Skin bruises and hematomas.

- General effects:
    - The use of the tourniquet leads to a painful syndrome whose mechanism remains complex.
    - Under general anesthesia, after 20-30 minutes, the pneumatic tourniquet is responsible for a gradual increase in blood pressure and heart rate.
    - Increased thromboembolic risk linked to the use of the tourniquet.

- On the respiratory level, in addition to the embolic phenomena, the lifting of the tourniquet is responsible for the recirculation of the products of anaerobic and hypoxic metabolism.
- Finally, more delayed, the phenomenon of ischemia-reperfusion by local activation of polymorphonuclear can be responsible for an acute respiratory distress syndrome (ARDS) by oxidative lung burn.

- Local effects:
  - Reported in the literature, limb ischemia-reperfusion syndrome is responsible for an increased risk of local infection.
  - Moreover, the ischemic pain of the limb is responsible for the appearance of a reperfusion edema which will evolve in two phases. The first phase immediately follows the lifting of the tourniquet and corresponds to a vasodilatation effect of the ischemic limb. This first phase is generally responsible for a 10% increase in member volume.
  - The second edematous phase will set in more gradually due to the activation of polymorphonuclear cells in the hypoxic tissues.
  - Vessels may also be injured below the tourniquet.
  - Muscular pain is detectable from the end of the first hour of tourniquet.
  - These muscle lesions lead to dynamic abnormalities responsible for postoperative instability and poor functional recovery.

IV. DEVICE USE, PERFORMANCE, CLEANING, STORAGE AND DISPOSAL

Principle of operation

tourniquet **G10904** associated with an armband/shorts makes it possible to establish around a limb, a circumferential pressure in order to interrupt the blood circulation, downstream of the tourniquet and thus to make the operating field bloodless.
The electro-pneumatic tourniquet pump blows air into the cuff or deflates it to generate the pressure desired by the user.
The pressure in the cuff allows the compression of the limb on which it has been positioned, thus interrupting the blood circulation for a defined period. The retention of blood flow thus reduces the influx of blood to the area on which the surgeon operates, thus leaving the operating field cleaner.
The use of a tourniquet therefore gives the doctor essential visual comfort, thus offering him better operating conditions and the assurance of precise surgical gestures.

Choice of armband or shorts

Armbands come in different sizes and shapes.
The choice of cuff depends on the surgical intervention, the type of anesthesia and the morphology of the patient. The following elements are taken into account:

- The morphology of the limb: shape of the straight or conical cuff, length to limit the risk of overlapping.
- The occlusion pressure: a larger width of the cuff reduces the occlusion pressure.
- In case of intravenous locoregional anesthesia (ALRIV) use of the double pocket cuff.

The choice of cuff is the responsibility of the surgeon.

Selected pressure

The parameters of pressure and time of tourniquet are defined by the practitioners, this user manual can in no way replace the operating techniques usually performed. The usable pressure range is between 0 and 600 mmHg .

Informally and with reference to various medical publications, the inflation pressure should be as low as possible; 50 to 75 mmHg above the occlusion pressure is sufficient for an upper limb and 100 to 130 mmHg above the occlusion pressure for a lower limb.

According to Graham's formula, the occlusion pressure (Po) depends on the circumference of the limb (M), the width of the withers (L), the systolic (SAP) and diastolic (PAD) blood pressure:

$$Po = +\overline{PAD} \; \frac{(PAS - PAD) \times C}{[(PAS - PAD) \times 2.5] + PAD}$$

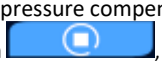
Lx3

Duration of the intervention

Because of the risks, the duration of continuous garroting of a limb should not exceed 150 minutes, preferably no more than 90 minutes for an upper limb, and no more than 120 minutes for a lower limb.
The procedure duration parameter is set by the surgeon and configurable in the device. An alarm will sound at the end of the set time.

The tourniquet is not in direct contact with the patient's body but is in limited contact with the user. Only the cuff used with the **Pneumatic Tourniquet G10904** will be in direct contact with the patient.

Essential device performance

- Pressurization of a tourniquet according to a value defined by the operator
- Maintenance of this pressure throughout the duration of the intervention
- Display of the duration of intervention with audible and visual information of the set time
- Trigger an audible and visual alarm in the event of failure of the rated pressure compensation system
- Return tourniquet pressure to 0 after operator intervention on button  , a long press is required.

V. USE WITH A CUFF

A. INSTRUCTIONS FOR USE OF THE DEVICE WITH SIMPLE TOURNIQUET

1. Connect the mains plug to the electrical network	Press the on/off switch to turn on the device.
2. Apply skin protection to the limb	To be done before positioning a sufficiently tight tourniquet around the limb and adapted to the patient's morphology. (the width of the withers / by the circumference of the limb must be less than or equal to 0.3)
3. Perform limb exsanguination	By raising or winding an Esmarch band from the end of the limb.
4. Connect the tourniquet connecting tube	To the quick coupler of the device, ensuring that the extension is not bent, bent, pinched and that no knot risks hindering the pressurization of the tourniquet
5. Adjustment of the pressure setpoint	By proceeding as described in paragraph IV-C, ensuring that the tourniquet inflates normally.
6. If necessary, set a time	As described in paragraph IV-D.
7. At the end of the intervention, deflate the tourniquet	by pressing the Deflate key

B. INSTRUCTIONS FOR USE IN LOCO-REGIONAL ANESTHESIA (ALRIV)

Help from the device for this type of intervention is available in the **option menu** (see VI-B) via the **IVRA button** 

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	Without assistance	With assistance	
1-Connect the mains plug to the electrical network	Press the on/off switch to turn on the device.		
2-Apply skin protection to the limb	To be done before positioning a double pocket tourniquet , the proximal pocket being towards the root of the limb.		
3-Proceed to exsanguination of the limb	By elevation or by winding an Esmarch band from the extremity of the limb.		
4-Connect the tourniquet connecting tube	Connect the tubes of the proximal pocket to the left coupler (blue sector), the tube of the distal pocket to the right coupler (red sector) ensuring that the extension is not bent, bent, pinched and that no knot risk of hindering the pressurization of the tourniquet.		IVRA button Push the button 
5-Setting the pressure setpoint	From the upper pocket by applying the method defined above. If necessary, set a time as described in paragraph IV-D.	**5- Adjust the circuits** Applying the adjustment method defined above, adjust the pressure on each circuit. If necessary, set a time as described in paragraph IV-D.	
6-After injection of the anesthetic and its effect obtained	Inflate the distal pocket in the same way. The distal tourniquet is thus inflated on an anesthetized part.	**6-Press the inflate button**	Press the **Inflate button**  of the blue circuit.
7-Deflation of the lower pocket	At the end of the operation, deflate the distal pocket by pressing the Deflate key on the keyboard, disconnect the tourniquet from the electro-tourniquet, cut off the power supply by pressing the on /off switch .	**7-Follow the appearance cycle of pimples**	

Note: the user can withdraw the aid at any time by accessing the **option menu** (see VI-B) and pressing the **IVRA button** 

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VI. PUT IN FUNCTION

A. STARTUP

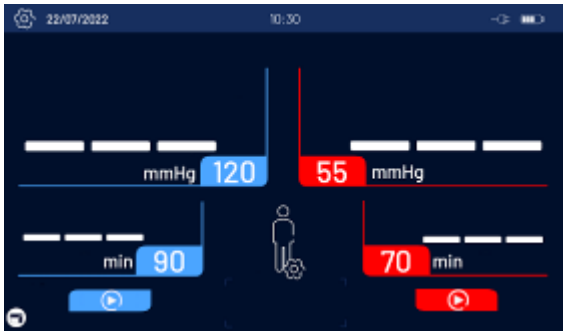
The electro-tourniquet is operational and is switched off by pressing the side switch.
At startup, the screen lights up, when a message appears on the page below, refer to the "Startup Error" section:

B. INFORMATION ON OPERATION PAGES

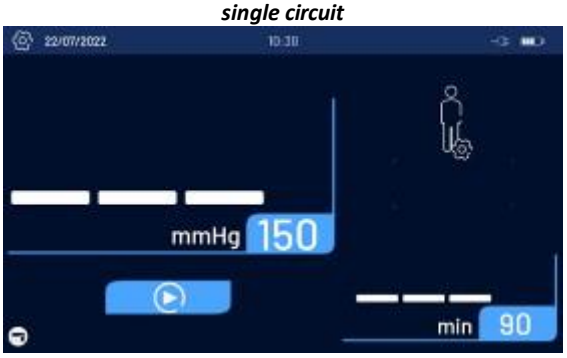
In order to simplify the reading of this document and the general use of the device, "zones" of operations have been defined by color:

- Blue: for the left circuit and for the single circuit
- Red: for the right circuit

dual circuit



single circuit



The pressure circuits are completely separated.
The pressure and timer settings are independent, the setting procedure is the same for pressure and timer (Only the color changes) .

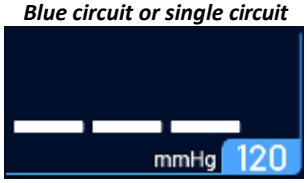
C. PRESSURE ADJUSTMENT

Modification of the pressure (outside intervention)

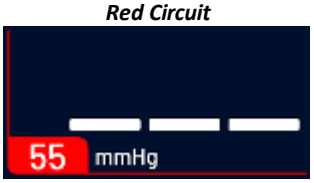
The user must select the pressure parameter, enter a setpoint value, and validate this setpoint in order to pressurize the tourniquet.

1. **Press the "PRESSURE" area**

Blue circuit or single circuit



Red Circuit



2. **Enter an instruction on the numeric keypad**

ex: 350 mmHg 

or using the keys 

and 

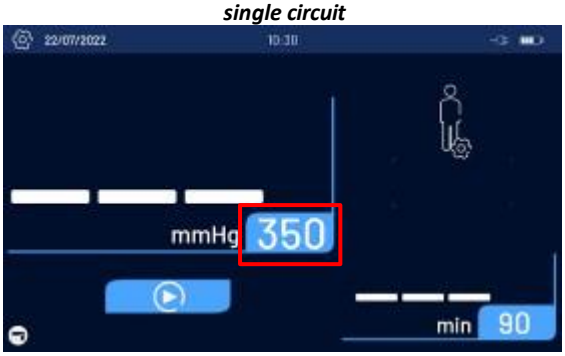
(can be activated in the advanced options (see VI-B) .

3. **Validation**

Press the key  . The setpoint entered appears on the operation page.

dual circuit

single circuit



Change in pressure (during surgery)

During the operation, it is possible to modify the initial pressure by proceeding in the same way.

1. **Press on the area " PRESSURE "**

2. **Enter an instruction on the numeric keypad**

For example: 380 mmHg 

3. **Approval:**

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

Setting a default pressure (outside intervention)

Out of operation, it is possible for the user to save a default pressure for each circuit, this pressure will be automatically reapplied at the end of the operation.

This setting can be configured from the advanced options (See VI-B)

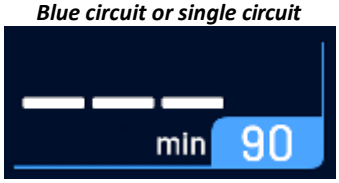
D. TIMER SETTING

Changing the timer (excluding intervention)

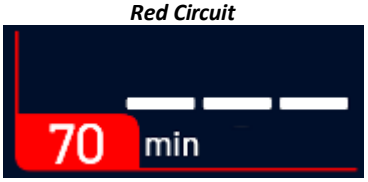
The user can configure an operation timer, the device will trigger an alarm after the set number of minutes. If the user does not program a timer, the default timer is then selected (factory setting: 60 minutes).

1. **Press on the area " MIN "**

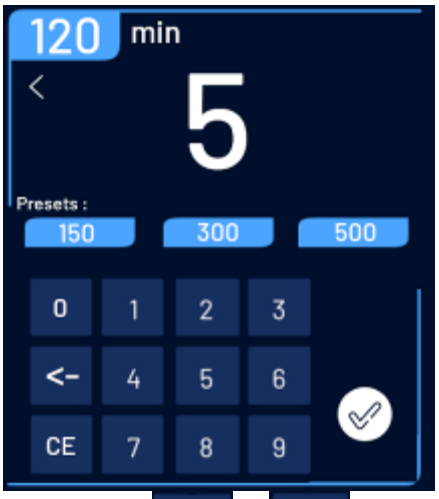
Blue circuit or single circuit



Red Circuit



2. **Enter an instruction on the numeric keypad**



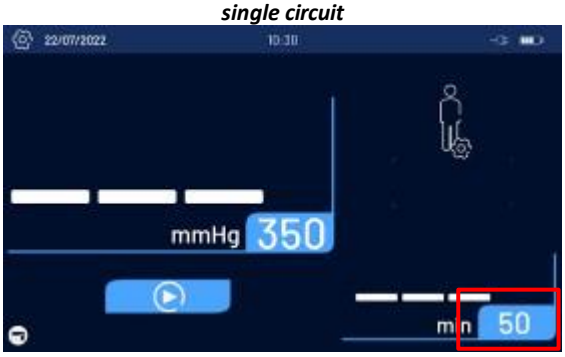
For example: 50 mins  or using the keys  and  (can be activated in the advanced options (See VII-E)) .

3. **Validation**

Press the key  , the value is configured and appears on the operation page.

dual circuit

single circuit



Modification of the timer (in the course of intervention)

During the intervention, it is possible to modify the initial timer by proceeding in the same way.
If the timer alarm is active during the change, it deactivates.

1. **Press on the area " MIN "**

2. **Enter an instruction on the numeric keypad**

For example: 20 mins 

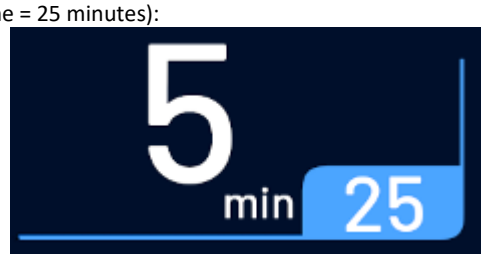
3. **Validation**

Press the key  , the value is configured, the user time alarm **will be triggered within 20 minutes following the modification.**

Example :

The effective operation time is 5 minutes, the user sets a time alarm in 20 minutes.

The display will be as follows (set time = 25 minutes):



Setting a default timer (outside intervention)

Out of operation, it is possible for the user to save a default timer for each circuit, this setting will be automatically reapplied at the end of the operation.

This setting can be configured from the advanced options (See VII-E).

E. ON/OFF CYCLE

Starting a cycle (inflation)

When the pressure setpoint is set on the circuit , the button appears (the color changes according to the circuit), this button launches the intervention cycle and therefore allows the pressurization of the tourniquet . 

Stopping a cycle (Deflation)

Once the intervention cycle has been launched on a circuit , the button  appears (the color changes according to the circuit), a long press on this button allows the intervention cycle to be stopped, which has the effect of :

- Stopping alarms on the circuit concerned
- Timer stop (value freezes)
- Tourniquet decompression

VII. OPERATING INFORMATION

A. BUTTON MANAGEMENT

Conditions for taking into account pressing on the so-called "button" areas of the touch screen:

- All keys are taken into account when pressed.
- If the user remains pressed on a key, it is taken into account only once , except for the 2 keys + and - which can remain pressed to increase or decrease a value.
- The action of the button  is active after a certain pressing time.

B. BATTERY MANAGEMENT

For any use, the electro-tourniquet must be permanently connected to the electrical network of the establishment. From this moment, a "mains socket" icon  appears in the information banner 

on the screen to inform the user that the device is powered by the mains, the battery is charging and thus takes over in the event of a problem on the electrical network.

The charge level is displayed on the screen in the form of a more or less full battery depending on the state of charge of the battery  . If this level is less than 25% of a full charge, a battery fault is triggered, this is a pre-alert characterized by a yellow triangle on the battery logo +  1 beep, in order to warn the user the first time the battery has a low charge level.
If the charge level is less than 10% of a full charge, a battery fault is triggered. This is an alert which is characterized by the banner displayed alternately in red with the message "Battery"


+ A red flashing of the front LED and a series of beeps to inform the user, pressurization will not be ensured if the device is not connected to the mains.

If the operator does not connect the device in time, it blocks the pressure in the circuit and then restarts.

When switching on or restarting the device on battery, if the charge present in the battery is insufficient, it will display a red battery crossed out on a black background.

C. STARTING ERROR

When the device is powered up, a series of tests is carried out, in the event of failure on one of these tests, the device indicates to the user the problem encountered.

to start :

When starting is impossible, the front LED flashes **red** to indicate the type of fault.

Default	Blink	Remedies
The screen is not detected	Fast flashing LED	Back after-sales service
Screen memory fault	LED flash: 2 short 1 long	Back after-sales service
System memory fault	LED flash: 3 short 1 long	Back after-sales service
Power supply board detection fault	LED flash: 4 short 1 long	Back after-sales service
Battery level too low fault	LED flash: 2 short every 30 seconds	Charge the device

Fault with indication on the screen:

Fault code	Default	Remedies
TAC001	No touch screen detection.	Back after-sales service
MEM002	Error in system memory files.	Back after-sales service
DTE001	Invalid date and time	Back after-sales service
MD001	Maintenance date passed	Perform maintenance or enter an unlock code.
MD002	The system was unable to retrieve the maintenance date.	Back after-sales service
CV001	The software license has expired (if on loan)	Enter an unlock code
CV002	System unable to retrieve software license status.	Back after-sales service
PR001	System unable to retrieve sensor calibration data.	Back after-sales service

Starting with pressure in the circuit:

The device determines that a cycle was in progress before the start and therefore restarts a cycle with the pressure in the circuit as the pressure setpoint.

Note: the operation time is reset to 0 min and the timer set point used is the default one (factory setting: 60 minutes)
.

D. TRACEABILITY

Data recording:

The traceability must make it possible to control, check the pressure of the tourniquet during a cycle. This is a time-stamped recording of the different pressures of the tourniquet during the surgical intervention. This data is printed during the tourniquet pressurization cycle. The data to be recorded are:

- The patient's name
- The patient's first name
- The device name entered by the user.
- Time-stamped pressures during the intervention. They are recorded at each event.

E. ALPHANUMERIC KEYBOARD

In general

The alphanumeric keyboard allows the user, if he wishes, to modify certain information such as the name of the department, hospital or block, as well as the patient's surname and first name.

Change patient information

1. **When no pressure cycle is in progress**

The **"Patient" button**  appears.

2. **Pressing the "Patient" button**

Allows access to the "Patient" menu :

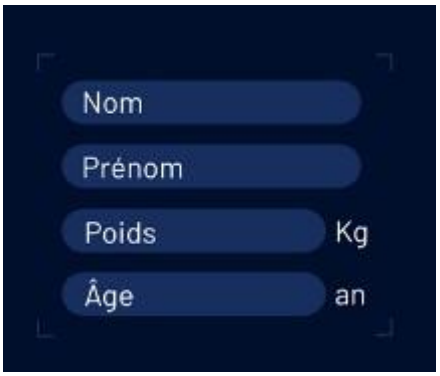
3. Setting the patient type

The patient type is selected by touching the associated button, see table below:

Button	Type of patient
	Infant
	Child
	Adult
	Adult Large

4. Setting Name / First name / Age / Weight

Pressing the corresponding text field gives access to the alphanumeric keyboard .



5. **Now just enter the desired information.**

Example: Bob, B O B, if you make a mistake to delete the last letter, just press the key ←.

6. **To return to the previous menu**

By validating your choice with the validate button ✓, without validating the back button <.

7. **To validate the new patient information**

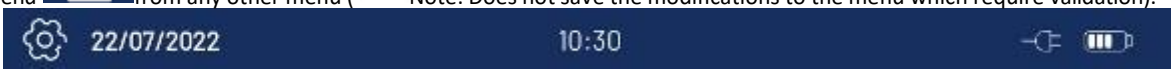
Pressing the validate button ✓ is necessary. To not validate it, just press the back button <.

VIII. CONFIGURATION

A. INFORMATION STRIP

The banner at the top of the pages allows you to: find out the date, the time, the battery level of the device, and whether the device is connected to the electrical network via a mains socket.

It also allows via the button  to access the options (from the operation menu), or to return quickly to the operation menu  from any other menu ( Note: Does not save the modifications to the menu which require validation).



B. OPTION MENU

Presentation

The option menu is accessible by pressing the button  on the strip.

Changing screen brightness

Below the image  , by moving the slider  .
If changed, the brightness level will be saved and then reapplied each time the device is started.

Changing the sound level

Below the image  , by moving the cursor. 
If modified, the sound level will be saved and reapplied each time the device is started.

Modification of the operating mode

Via the button 

or 

located below the words IVRA/ALRIV.

IVRA/ALRIV operating mode activated.

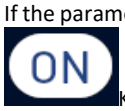
IVRA/ALRIV operating mode disabled.

Changing the key sound

Via the button 

or 

located below the words "Key sound" , this parameter allows you to activate or deactivate the sound emitted by the device when the buttons are pressed.
If the parameter is modified, it will be saved and then reapplied each time the device is started.



Key sound activated.

Key sound off.

Access to the manufacturer information menu

Access to this menu is via the button  .

Access to the distributor information menu

Access to this menu is via the button  .

Access to the advanced options menu

Access to this menu is via the button  .

C. Manufacturer Information

This menu, accessible via the option menu (see VI-B), is used to obtain all the information on the manufacturer of the device .

D. Distributor Information

This menu, accessible via the option menu (see VI-B), is used to obtain all the information on the device distributor.

E. Advanced options

This menu, accessible via the option menu (see VI-B), is used to consult information concerning the device or to configure device parameters:

The menu is made up of 8 sub-menus described in the table below:

Submenu	Description
Dispositif	View **device information** and configure **device name.**
Date et heure	Allows you to configure the date and time indicated by the device.
Par défaut	Allows you to configure the default pressure and operating time at device start-up (when no pressure is detected at start-up).
Pre-réglages	Allows you to configure presets for pressure and time.
Langues	Allows you to configure the language of the device.
Claviers	Allows you to configure the layout of the alphanumeric keyboard as well as special characters. Allows you to configure the type of numeric keypad (Numpad or Incremental)
Maintenance	Allows you to view the date of the next maintenance, the status of the software license, or enter a device code.
Aide	Allows you to consult the quick guide of the device

IX. PRECAUTIONS FOR USE AND GENERAL WARNINGS

Any modification may cause danger to the patient or user. Under no circumstances and in any way should the device be modified.

Caution for use

The environmental conditions of use must be respected

- **CLASS I device** : To avoid any risk of electric shock, the electro-tourniquet must only be connected to a power supply network equipped with a protective earth with the 5-meter power cord provided. It is prohibited to use a multiple socket outlet or an extension cord.

- In order to prevent any electrical risk with the patient, do not use the medical device in the environment close to the patient (less than 2 meters).

- When in use, the device must be permanently connected to the power supply network, the battery only ensuring a safety role in the event of an anomaly on the mains power supply. The battery should be used if in doubt of the protective earthing system in the installation .

-The electro-tourniquet and particularly its electrical connection must be protected from water and humidity. Never operate the device if liquids have been spilled on it.

- To prevent any risk of damage, do not use metallic or pointed objects to enter display values on the keypads.

-Do not pull on the mains power cord or the pneumatic extension cords to change the device's location.

- Any movement of the device must be carried out disconnected from its mains supply.

-To avoid any risk of strangulation of persons or the patient, ensure that the electrical cord or the pneumatic extensions are at a reasonable distance.

- At the risk of dropping it, do not propel the device mounted on a mobile base, a handle is provided to carry out any secure maneuver by pulling or pushing the device to overcome any obstacle on the ground. Moving the moving foot is done by pushing forward. Keep one hand on the handle to overcome any unevenness .

- To avoid accidental movement, it is strongly recommended to lock the caster brakes.

-Move the power cord away from the rollers of the device.

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

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

- The connection base acts as a disconnector and must remain accessible at all times to allow immediate disconnection of the power cord in the event of danger.

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

Before each commissioning

- Make sure that the accessories to be used are compatible with the electro-tourniquet, it is forbidden to use tourniquets that do not have appropriate connectors and to modify the output connectors .

- Check that the extensions are in good condition, that they are not bent or pinched and that the air arrives at the outlet of the tubing as soon as it is put into operation.

- As a preventive measure, ensure that the medical device works correctly, and that the system is sealed with the cuff used by proceeding as described below:

-Connect the mains plug to the electrical network, ensure that the battery is correctly charged to compensate for any fault in the external electrical network.

-Position a tourniquet on a mandrel

- Display a pressure setpoint ex: 300 mmHg

-As soon as the pressure has stabilized, wait 2 minutes to ensure that the device is sealed.

-Disconnect the armband from the device, the alarm should activate after 3 seconds

Electromagnetic Compatibility Precaution 

The electro-tourniquet must be installed and put into service in accordance with the EMC recommendations attached in the appendix. Operation of the device is guaranteed for all disturbances below the compliance levels declared in the appendix.

Malfunctions may be caused by proximity to non-CE portable or mobile RF communications equipment.

The EM device or system should not be used adjacent to or stacked with other devices. If this is not possible, the ME equipment or system should be observed to verify normal operation in the configuration in which it will be used.

During EMC tests, it has been identified that electrostatic pulses greater than or equal to 8 kV can cause the touch screen to malfunction. As the rest of the system performs its role, this has not been identified as a major risk and does not constitute a patient risk. When this happens, restarting the device is required .

The use of accessories, sensors or cables other than those sold by the manufacturer as replacement parts or internal components may lead to increased emission levels or decreased immunity levels of electro-medical devices

Electromagnetic compliance established with the following accessories:
Designation
Switching power supply board
5 meter mains lead
Pb battery 12v 4000 mAh
CEE 22 connector socket

X. DEFECT MANAGEMENT

Conditions for triggering an alarm

Display		Causes	Priority	Remedies	Alarm Determination Time
	TIME OVER	Defined time expired	Mean	Press the stop alarm button	No deadlines
	-	25% battery charge	Weak	Without - Information signal	No deadlines
	180 MINUTES	Operative time arrived at 180 minutes	average visual, High Sound	Stop the pressure cycle.	No deadlines
See “B – BATTERY MANAGEMENT”	BATTERY	Battery charge at 10% Insufficient battery charge to ensure safe intervention	High	Check that the device is connected to the mains	No deadlines
	PRESSURIZING	Pressurization not possible	High	Tourniquet not connected	~5 seconds
	STABILIZATION	The device struggles to stabilize the pressure in the tourniquet	High	The tourniquet has a leak or the pressure is not suitable for its size.	~25 seconds
	LEAK	Pressure leak: Pressure below set point for 5 seconds	High	Connect the cuff	~5 seconds
	OVERPRESSURE	Overpressure: Display of pressure higher than the set pressure and not stabilized for 5 seconds	High	Check that there is no element resting on the tourniquet	~5 seconds
	REGUL. PRESSURE	A fault in the pressure regulation circuit has been detected	High	Back after-sales service	~15 seconds

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

When several alarms with the same priority are triggered, all alarms are displayed.

Disabling the alarm

In the event of a high priority alarm, pressing the key  deactivates the ringing of the current alarm for 30 seconds; the visual alarm is always displayed.

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

If there is a power outage, the alarm system is immediately unable to restore the alarm settings.

In the event of a power cut, the alarm system is no longer functional.

XI. MAINTENANCE AND REPAIRS

Maintenance

Annual preventive maintenance is recommended to check the essential performance described below, and electrical safety .
To remedy any possible malfunction, this service must be provided by Dessillons & Dutrillaux .
The minimum qualification required by maintenance personnel to carry out maintenance operations: biomedical technician level.
A reminder is made when the device is started if the date has passed.

A menu protected by a password is accessible via the Advanced options menu (See VI-B).

This menu allows:

- Enter device information
- Adjust the calibration of the pressure sensor(s).
- Set the so-called “original” maintenance date.

Replacement of general protection fuses

Disconnect mains power

The power supply protection fuses (2 units) are located on the power outlet. Replace these, respecting the values indicated: FT2A H250V.

Prise avec 2 fusibles

The battery is protected by an external fuse with the following identification on the fuse holder **:** Value of the fuse **:** F8AH250V (fast action, breaking capacity 1500A).

The electronic board is protected by an external fuse: fuse value: F3.15AH250V (fast action, breaking capacity 1500A).

Equipotential bonding terminal

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

Battery replacement 

The lead-acid battery does not present any danger under normal conditions of use, however, and as a safety measure, before replacing the battery, it is recommended to protect yourself against any risk of leakage from the battery by protecting yourself. hands with gloves, and avoiding inhaling residual dust.

Technical characteristics of the battery: Pb – 4000 mAh - 12 Volts

The replacement of the battery must be carried out only by a biomedical technician trained for this activity by referring to the technical documentation INS185 Battery replacement instruction G10904.

Disconnect mains power
Remove the rear panel after unscrewing the 6 retaining screws.
Access the 4 battery support retaining screws.
Disconnect the battery, replace it and repeat the operations in the reverse order for refitting.

Device cleaning and disinfection

Although the touch screen contains a waterproof lexan , clean and disinfect the device disconnected from its mains supply before each intervention, using only appropriate disinfectant wipes (Wip'anios type). Apply the wipe to the surfaces and extensions to be treated.

In the event of heavy soiling, use a second wipe, leaving it to act for 5 to 15 minutes depending on the antimicrobial effectiveness desired, while sparing the screens.
There is no usage limit for these applications. Rinsing is unnecessary.

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

Never spray disinfectants directly on the device. Pneumatic tourniquet extensions must be dried before use.

Storage and transport conditions before use

Do not store the package outside, avoid mechanical vibrations.
Storage and transport conditions: Temperature -20°C to +60°C relative humidity 20 to 80% maximum
Conditions of use: Temperature 5°C to +40°C relative humidity 20 to 80% maximum
Handle the package with care to prevent it from falling.

Limits of use of the medical device (lifespan)

The end of life (estimated at approximately 5 years), a malfunction that appeared previously or the accidental fall of the medical device requires informing the biomedical department of the risks generated in order to carry out a general review of the functionalities before any restoration of the device. device and ensure critical performance integrity.

This lifetime is defined according to the DDVE GAE document and takes into account the obsolescence of components and aging as a result of operations that can degrade the device (manufacturing and cleaning)

Environmental protection – Disposal of the device at end of life

1. Risks of infections and microbial risks:

The medical device must be discarded after being decontaminated and following the practices in force in your establishment.

It must be thrown in a specific container:

- WEEE (Waste Electrical and Electronic Equipment)

2. Physical risks (sharp or sharp objects):

Not applicable.

XII. TECHNICAL CHARACTERISTICS

Technical description

The device is an electro-pneumatic tourniquet.
The tourniquet consists of the following elements:

- a pump to inject the necessary pressure
- a pressure regulator controlling the pressure sent to the cuff to maintain a constant pressure.
- a microprocessor managing the pressure display and the pressure regulator to limit fluctuations, even minimal pressure.
- of 2 connecting tubes with locking systems. These connectors are incompatible with other tubes in the operating room such as infusion tubes to avoid any risk of error by operating room staff.

It is used with an inflatable armband/shorts

Technical characteristics of pneumatic tourniquets G1 0904

STORAGE CONDITIONS	T - 20° to 60°C, RH: 20 to 80%
TERMS OF USE	T: 5° to 40°C, RH: 20 to 80% Maximum altitude 2000 meters Atmospheric pressure 79.0 kPa to 106 kPa
HOUSING MATERIAL Density Impact resistance Fire resistance Hardness (shore D)	ABS 1.112 g/cm ^{3} >25 KJ/ ^{m2} UL94 V-0 78
DIMENSIONS	
Height (mm)	250
Width (mm)	300
Depth (mm)	190
WEIGHT kg	5.5
	Screen
Width (mm)	153
Height (mm)	85
NETWORK VOLTAGE	100-240VAC
NETWORK FREQUENCY	50 – 60Hz
POWER TAKE-OFF	60VA
SWITCHING POWER SUPPLY	Input: 90-264 Vac, 47 -63 Hz, 1.8- 1A Output: 15Vdc, 4A
FUSES	

Power board input	FST2AH/250V
Power board output	F3.15AH/15V
Battery	F8AH/12V
BATTERY	Refillable
Kind	bp
Tension	12 volt
Amps	4000mAh
Loading time	10am
Autonomy	8am
PUMP	
Kind	membrane _
Debit	4.6 l/min
PRESSURE	
Unit	mmHg
On duty	1.7 bar
Adjustment range	0 to 600mmHg
Setting accuracy	±1mmHg
Display accuracy	±5mmHg
Alarm	Sound and visual
Number of independent pressure circuit	2
TIMER	
Unit	Minutes
Alarm	Audible and visual programmable
CONNECTIONS	
Pneumatic	2 CPC-type female couplers
Electric	CEE22 connector
MAXIMUM SOUND LEVEL IN OPERATION	52db

Main materials used

The device consists of an ABS PC casing in which the components are fixed on a frame and then fixed on the case. The materials of the main components are in the table below:

Identification of the materials making up the DM	Chemical name
Anti-UV anti-abrasion front panel film	X190 TREATED POLYESTER
Housing	Polycarbonate ABS (PC-ABS)
Frame	Trovidur EC
Chassis bracket	Aluminum 5083
Tube to Tube fittings	Nylon
Tube (ref SI60)	Silicone
lead battery	ABS (UK94 :HB)
Connector for equipotential bonds	Nickel-plated brass
female connector	Acetal
CPC male connector	Acetal
Pipe (ref 29)	PVC
Power board	-
Pump bracket	Galvanized steel
pump vibration damper	Synthetic rubber (CR)
ON/OFF switch	Nylon 6.6 computer copper alloy silver alloy
Battery hatch	Aluminum 5083
Front female connector	Brass

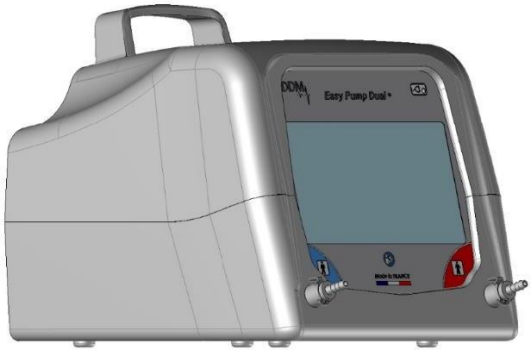
USB connector cable	PVC

Device visuals

1. Front visual - G10904

2. Rear visual - G10904

3. Visual three-quarter left - G10904



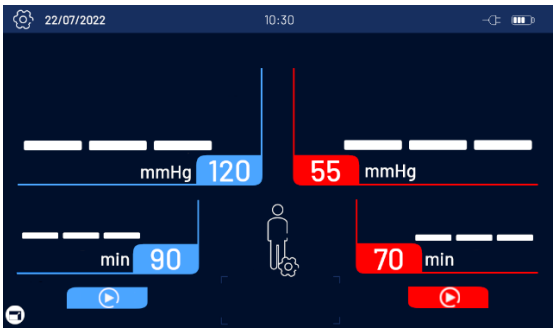
Operation software

"Zones" of operations have been defined by the manufacturer according to two colors:

- Blue: for the left circuit and for the single circuit;
- Red: for the right circuit .

single circuit

dual circuit



List of accessories and consumables

ACCESSORIES	
Ref	Description
A10701	Mobile base on wheels with basket
A11008	Male acetal fitting with O-ring
A11012	Splined in-line female coupler Ø 4.8
A11322	Pouch of 10 O-rings for fitting A11008
A20001	Blue extension with male and female connectors
A20006	Red extension with male and female connectors
A90004	Mains fuse F1.6AH250v
A11362	Mains fuse F2AH250v
A10726	Power cord Length 5 meters

One-piece decontaminable cuffs for pneumatic tourniquet – 1 tube

Reference	Optional: retaining strap	Designation	tube color	Dimensions in cm		
				AT	B	VS
GBDM101	GBDMS101	right infant cuff	White	3.5	29	38
GBDM102	GBDMS102	right child cuff	Pink	4.5	35	48
GBDM103	GBDMS103	Right small adult one-piece cuff	Parma	6	46	61
GBDM104	GBDMS104	right adult arm cuff	Sky blue	8	46	67
GBCM105	GBCMS105	One-piece adult arm cuff L tapered	Turquoise	10	47	70
GCDM103	GCDMS103	Straight adult one-piece shorts	YELLOW	8	76	97
GCDM104	GCDMS104	Straight adult one-piece shorts	Purple	10	62	76
GCDM105	GCDMS105	One-piece adult shorts L right	Green	10	76	90
GCDM106	GCDMS106	One-piece adult XL straight shorts	Gray	10	82	100
GCDM107	GCDMS107	Straight XXL adult one-piece shorts	Red	10	107	122
GCCM104	GCCMS104	Tapered adult one-piece shorts	Purple	10	62	76
GCCM105	GCCMS105	One-piece adult shorts L conical	Green	10	76	90
GCCM106	GCCMS106	One-piece adult XL tapered shorts	Gray	10	82	100
GCCM107	GCCMS107	Conical XXL adult one-piece shorts	Red	10	107	122

One-piece decontaminable cuffs for pneumatic tourniquet – 2 tubes

Reference	Optional: retaining strap	Designation	Dimensions in cm		
			AT	B	VS
GBDM204	GBDMS204	right adult arm cuff	8	46	67
GBDM202	GBDMS202	right child arm cuff	4.5	35	48
GCDM204	GCDMS204	Straight adult one-piece shorts	10	62	76

Fabric armbands with silicone pouch for pneumatic tourniquet

Reference	Designation	Dimensions of the pocket in cm
Armband Single pocket shorts		
GBS101	Armband / Infant shorts	19x4
GBS102	Child Armband	26.5x5
GCS102	Child shorts	35.5x6
GBS103	Small adult cuff	35.5x6
GCS103	Small adult shorts	53x6
GBS104	Adult armband	53x6
GCS104	Adult shorts	69x9
GCS105	Adult shorts L	81x9
GCS106	XL adult shorts	85.5x12
Armband Double pocket shorts		
GBS202	Double child / small adult cuff	2x (35.5x6)
GBS204	Double adult cuff	2x (53x6)
GCS204	Adult double shorts	2x (69x9)
Conical shorts		
GCCS104	Adult conical shorts	69x9
GCCS105	Adult conical shorts L	81x9
GCCS106	XL adult tapered shorts	85.5x12

XIII.INFORMATION IN THE EVENT OF A SERIOUS INCIDENT

Any serious incident occurring in connection with the device should be notified to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

XIV. GUARANTEE

Guarantee	DDM replaces or repairs any device that does not work as indicated in the instructions. The duration of this warranty is 24 months.
Warranty limit	The product must be used in accordance with the instructions and for the indications provided; it must not have been modified or accidentally damaged before use.

XV. SYMBOLS USED

The different symbols

Symbols used	Description	Location
	It is essential to refer to the instructions for use	On the back of the device
	Fragile, handle with care	Packaging label
	humidity limit	Packaging label
	Temperature limit	Packaging label
	Warning message	instruction manual
	Security message	instruction manual
	Separate the medical device from household waste for recycling. This product must be disposed of in a specific container	Rating plate instruction manual
	Type BF Equipment – Applied Parts consisting of tourniquets and extensions in the patient's environment	Front facing
	Earth (mass)	Device interior
	Medical device compliant with the requirements of directive 93/42/EEC modified by the directive 2007/42/EEC	Rating plate
mmHg	Unit of pressure in millimeters of mercury (1 mmHg is equal to 1.33hPa (hectopascal)	Display screen
min	Unit of time expressed in minutes	Display screen
	Battery state of charge in 25% increments	Display screen
	Battery charging	Display screen
	Mains power supply	Display screen
	Power supply by disconnected mains plug	Display screen
	Manufacturer: SPENGLER SAS 30 rue Jean de Guiramand 13290 Aix en Provence - France	Packaging label

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

Medical Devices Directive

The medical device complies with the requirements of European Directive 93/42/EEC amended by Directive 2007/47/EEC relating to medical devices.

XVI. APPENDICES

Guidance and manufacturer's declaration – electromagnetic immunity			
Electro tourniquets are intended for use in the electromagnetic environment specified below. The customer or the user of these devices should assure that they are used in such an environment.			
Immunity test	***Test level according to IEC 60601***	***Compliance level***	***Electromagnetic environment – guidelines***
Disturbances *Conducted RF EN 61000-4-6* *Disturbances Radiated RF EN 61000-4-3*	*3 Vrms from 150 kHz to 80 MHz outside ISM bands* *3 V/m from 80 MHz to 2.5 GHz*	*3 Vrms* *3V/m*	*Portable and mobile RF communications equipment should not be used in close proximity to any part of the tourniquet equipment including cables; the recommended separation distance calculated from the equation applicable to the frequency of the transmitter should be observed.* ***Recommended Separation Distance*** *d = [3.5/ 3] √ P* *d = [3.5/ 3] √ P from 80 MHz to 800 MHz* *d = [7/ 3] √ P from 800 MHz to 2.5 GHz* *Or P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer and d is the recommended separation distance in meters (m) .* *Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b].* *Interference may occur near equipment marked with the following symbol:* 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. *NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and by reflections from structures, objects and people.*			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environm ent due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the tourniquet is used exceeds the applicable RF compliance level above, the tourniquet should be observed to verify normal operation. If abnormal performan ce is observed, additional measures may be necessary, such as reorienting or repositioning the electro-tourniquet. *(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*			

Table of recommended separation distances between portable and mobile RF communications equipment and pneumatic tourniquets G10904

Recommended separation distances between portable and mobile devices of RF communications and the *electro-tourniquet* block

The G10904 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of these devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and *electro-tourniquet* equipment as recommended below. , depending on the maximum transmit power of the communications device.

Rated maximum transmit power of transmitter W	**Separation distance according to frequency of transmitter** m		
	from 150 kHz to 80 MHz $d = [3.5/3] \sqrt{P}$	**from 80MHz to 800MHz** $d = [3.5/3] \sqrt{P}$	**800MHz to 2.5GHz** $d = [7/3] \sqrt{P}$ _
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

For transmitters rated maximum transmit power not given above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum transmit power rating of the transmitter in watts (W), according to the manufacturer of the transmitter.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and by reflec tions from structures, objects and people.

Guidance Table and Manufacturer's Declaration - Electromagnetic Immunity for All Non-Life Support EM Equipment and Systems

Guidance and manufacturer's declaration – electromagnetic emissions		
The G10904 device is intended for use *in the electromagnetic environment specified below. The customer or the user of these devices should assure that they are used in such an environment.*		
Emissions test	***Compliance***	***environment - guidance***
RF emissions *CISPR 11*	*Group 1*	*The G10904 electro-tourniquet block uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment .*
RF emissions *CISPR 11*	*Class B*	
Harmonic emissions *EN61000-3-2*	*Class A*	*The G10904 electro-tourniquet device is suitable for use in all premises, including domestic premises and those directly connected to the public low-voltage power supply network supplying buildings for domestic use.*
Emissions of flicker voltage fluctuations *EN 61000-3-3*	*Compliant*	

Guidance and manufacturer's declaration – electromagnetic immunity			
The G10904 device is intended for use in the electromagnetic environment specified below. The customer or the user of the electro tourniquet should assure that it is used in such an environment.			
Essay immunity	**test level IEC 60601**	**Level of compliance**	**Environment electromagnetic – guidelines**
Electrostatic Discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	±6kV ±8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients in bursts EN 61000-4-4	±2 kV for power lines electric ±1 kV for input/output lines	±2kV Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
shock waves EN 61000-4-5	±1 kV mode differential ±2 kV mode commmon	±1kV ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
voltage dip, interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% *U* T for 10ms 40% *U* T for 100ms 70% *U* T for 500ms <5% *U* T for 5 sec	<5% *U* T for 10ms 40% *U* T During 100ms 70% *U* T for 500ms <5% *U* T for 5 sec	Mains power quality should be that of a typical commercial or hospital environment . If the user of the electro-tourniquet device requires continuous operation during power outages, it is recommended to power the equipment electro- tourniquet from an uninterruptible power supply or battery.
Magnetic field at power grid frequency (50/60 hertz) EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a representative location in a typical commercial or hospital environment.
NOTE: *U* T is the AC mains voltage before applying the test level.			