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.

SPENGLER SAS
30 rue Jean de Guiramand
13290 AIX EN PROVENCE – FRANCE
Tél : +33(0)4 42 90 31 31
Email : info@gsh-med.fr
Web site : www.gsh-med.fr

MADE IN FRANCE

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
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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:

(PAS – PAD) x C
Po = + PAD ⍰ [(PAS - PAD) x 2.5] + PAD

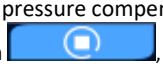
Lx3

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:

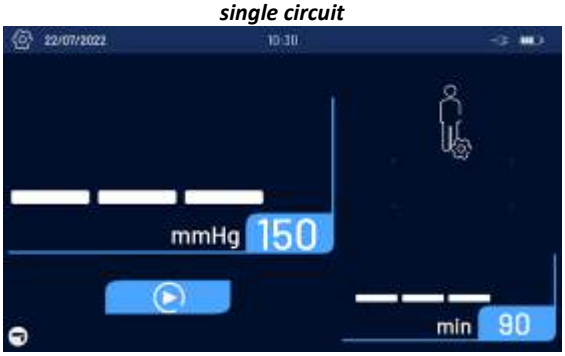
B. INFORMATION ON OPERATION PAGES

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) .

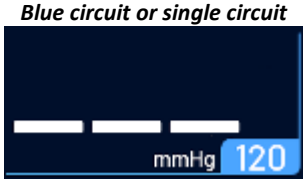
C. PRESSURE ADJUSTMENT

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**

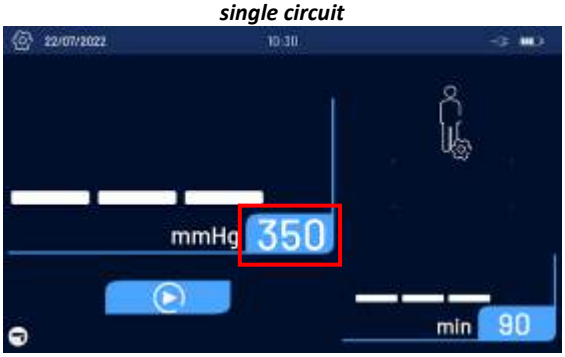
ex: 350 mmHg    or using the keys  and  (can be activated in the advanced options (see VI-B) .

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.

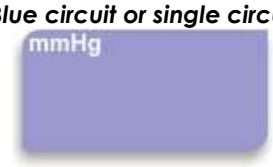
This setting can be configured from the advanced options (See VI-B)

D. DEFINITION OF OPTIMAL OCCLUSION PRESSURE (excluding intervention)

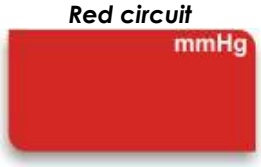
Definition of optimal occlusion pressure (excluding intervention).
The "optimal occlusion pressure" menu is used to determine the optimal occlusion pressure for the patient.

1) Press the key "PRESSURE"

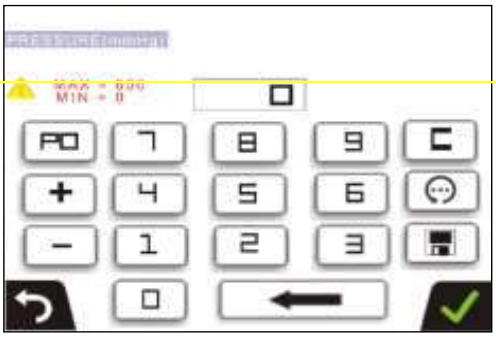
Blue circuit or single circuit



Red circuit



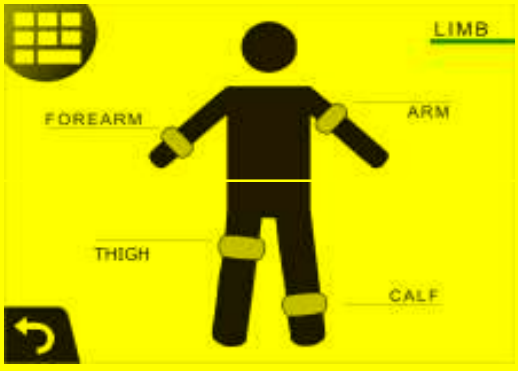
2) Press the key "PO" on the keypad



3) Selection the morphology of the patient

The selection of the morphology is one of the factors taken into account in the calculation of the optimal occlusion pressure.

4) Selection of the limb to operate



The selection of the limb to be operated is one of the factors taken into account in calculating the optimal operating pressure.

5) Automatic mode

The automatic mode is used to determine the optimal occlusion pressure by detecting the heartbeat inside the cuff.

To do this, install the cuff used for the operation on the patient's limb.
Select the cuff corresponding to the one placed on the patient in the menu No. 5 "Selection of operated limb".

- Press the "START" button.
- Wait for the end of the detection.
- At the end of detection, press the button 

6) Results

The "results" menu displays a summary of the information entered by the user and determines the occlusion pressure.

- Press the button  to confirm the optimal occlusion pressure.

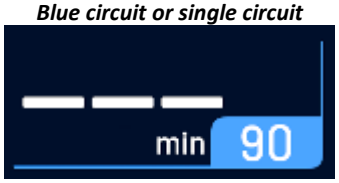
D. TIMER SETTING

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  (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