

DDM

Since 1949

Comprimètre (Automatique manette)
5 piekimo dalis
Automatinis turniketas

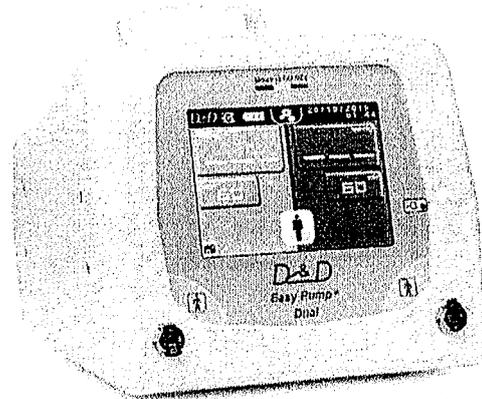
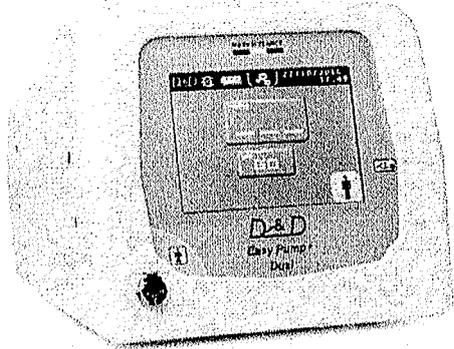
CE
0459

Date of first EC marking certificate: 1998

PNEUMATIC TOURNIQUET

References : **G10803 - G10903**

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



G10903

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

Posleitis

Intended to use

The device is designed to operate continuously.

The tourniquet 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:

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

Tourniquets

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) :

$$Op = \frac{(SBP - DBP) \times M}{L \times 3} + DBP \cong [(SBP - DBP) \times 2.5] + DBP$$

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

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

Modelis G10803 turi vieng slėpio palaikymo kanalą ir skirtas nau-
doti per operacijas naudojant vieng manžetę.
1.1. Modelis G10903 yra dviejų portų ir dviejų kanalų.

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 independent 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.

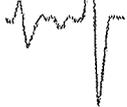
-To avoid the risk of strangulation or patient people, ensure that the power cord or extension tires are in reasonable distance.

- 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.

DDM



ISO 13485

**G
MED**

DESSILLONS & DUTRILLAUX

TECHNICAL CHARACTERISTICS

CT 047

Pneumatic tourniquet G10803 Easy Pump 1
tube

Index 7

PRESSION		
Type		1.7 bar
Service		0 to 600 mmHg
Setting range		± 1 mm Hg
Setting precision		± 5 mm Hg
		An audible and visual alarm
		1
TIMER	Units	minutes
	Alarm	Programmable audible and visual alarm
CONNECTION		
	Pneumatic	1 female coupler CPC type
	Electric	Connector CEE22
MAXIMUM SOUND LEVEL WHILE FUNCTIONING		52 dB

*Troubleshooting
(max)*

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Date of first EC marking certificate :
1998

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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 <i>59 inch = 15 cm</i>		
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	<i>manometeris pūpūtiņo raucis</i> 4.6 l/mn		
PRESSION			
Type	mmHg <i>slēpīo manometre</i>		
Service	1.7 bar <i>regulācijai / ušos</i>		
Setting range	0 to 600 mmHg		
Setting precision	± 1 mm Hg <i>slēpīo nustatījums</i>		
Display accuracy	± 5 mm Hg <i>slēpīo</i>		
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		

*2. Gali
diebt
is bale
cips.*

*slēpīo nustatījums
slēpīo*

*slēpīo manometre
regulācijai /
ušos*

Maksimālais gaisa spiedis darba laikā

DDM



DESSILLONS & DUTRILLAUX

TECHNICAL CHARACTERISTICS

CT 047

Pneumatic tourniquet G10803 Easy Pump 1 tube

Index 7

Technical characteristics Easy Pump G10803

STORAGE CONDITIONS		T : -5° à 40°C, Humidity : 20- 80 %
CONDITIONS OF USE		T : 5° à 40°C, Humidity : 20 – 80 % Maximum altitude 2000 m Atmospheric pressure 79.0 kPa to 106 kPa
CASE MATERIALS		ABS (Acrylonitrile Butadiene Styrene)
	Density	1.112 g/ cm ³
	Shock resistance	> 25 KJ / m ²
	UL flammability test	UL94 V-0
	Heat stability	85°C
	Hardness	78
DIMENSIONS		CASE
	Height (mm)	250
	Width (mm)	300
	Depth (mm)	190
		SCREEN
	Width (mm)	120
	Height (mm)	90
WEIGHT kg		4.2 KGS
LINE VOLTAGE	6.1 Electrumis	100 - 240 V AC
LINE FREQUENCY	6.1 maintenance	50 – 60 Hz
POWER PLUG		60 VA
FUSE		
Input power card		FT2AH/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	6. Vidine perrouenne betarife	Rechargeable
	Type	Pb
	Voltage	12 Volts
	Ampere	4000 mAh
	Charging time	8 h
	Autonomy	10 h
PUMP	6.2.2. Autonomie pompe integrate Darbo lactos	Membrane pump
	Type	
	Pump flow	4.6 l/mn

Exercice dydi's

5,9 inch → 15 cm

6.

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 household rubbish. This product should be discarded 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 Ila complying with the Requirements of Directive 93/42/EEC modified by 2007/42/CEE.	Identification plate
	Pressure unit is measured in millimetres of mercury (1 mmHg equal to 1.33 hPa -(hectopascal)	<i>patētiama informācija ekrānā</i> Display screen
	Specified time expressed in min	<i>patētiama informācija ekrānā</i> Display screen
	Battery charging status in increments 25 %	<i>patētiama informācija ekrānā</i> Display screen
	Manufacturer : Dessillons&Dutrillaux Z.I. La Tuque 47240 Castelculier - France	

↑

*mīkulināsi perspējums
signāli*

INS 94 – Index V13 – 06/10/2021

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

VIII. CONFIGURATION

Šiame pateikiama informacija - data, laikas, baterijos lygis ir ar prietaisas yra prijungtas prie elektros.

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).

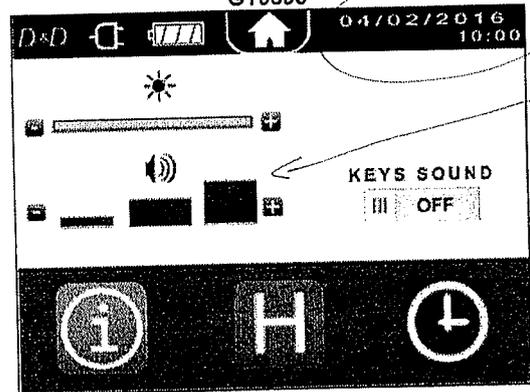
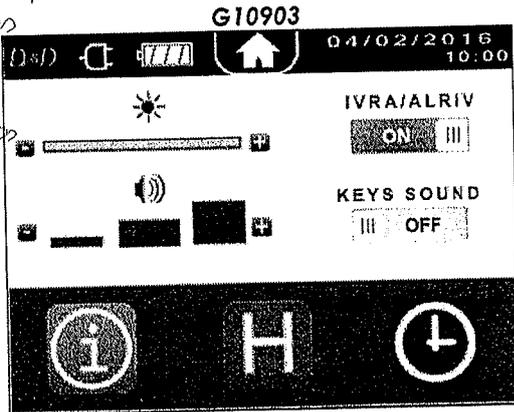


B. OPTIONS MENU

Introduction

Golimybi Reisti parametrus.

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



Changing the brightness of the screen

po ikone  mygtukai  and  , the current level is represented by the color yellow in the bar between the two keys.

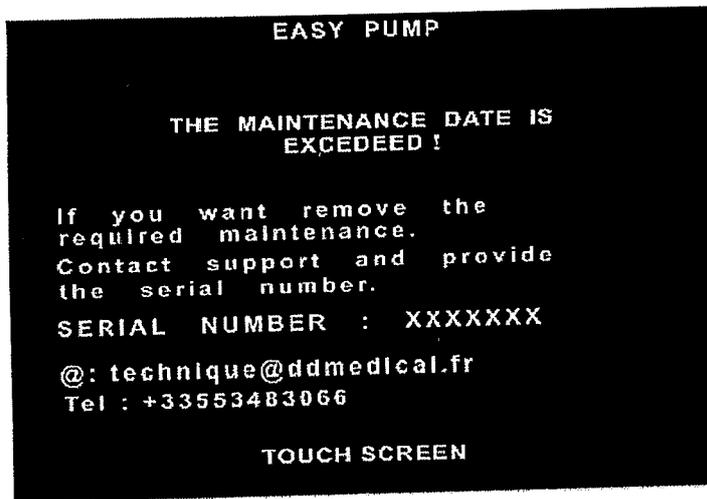
If modified, the brightness level will save and then reapply every time you start the unit.
 ⚠ You can't change the brightness of the device during surgery.
 Prietaiso ryškumo reguliavimas reikioti operacijos metu.

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.

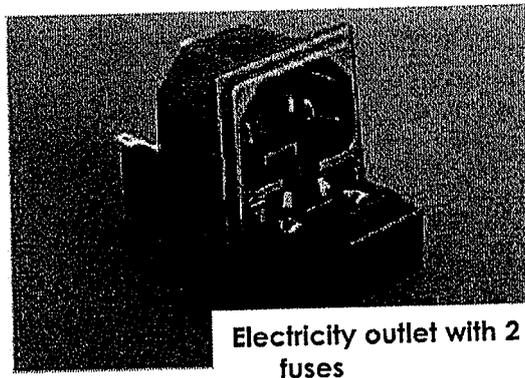
⚠ You can't change the sound level of the device during surgery.

Garsas lygis yra reguliuojamas po garsu ikone mygtukais + ir - .

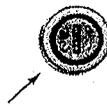


Replacing fuses general protection

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



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  

Baterijas testimas

Lead acid battery do not present a hazard under normal conditions of use, however, and as a safety measure, prior to battery replacement is recommended 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.

Inticomator baterijos keitimas gali būti atliktamas biomedicinos techniko,

Replacing the battery should only be performed by a biomedical technician trained for this activity by referring to the technical documentations DCT G10803-G10903. *kuris yra apmokytas kaip tai atlikti pagal techninės dokumentacijos reikalavimus.*

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

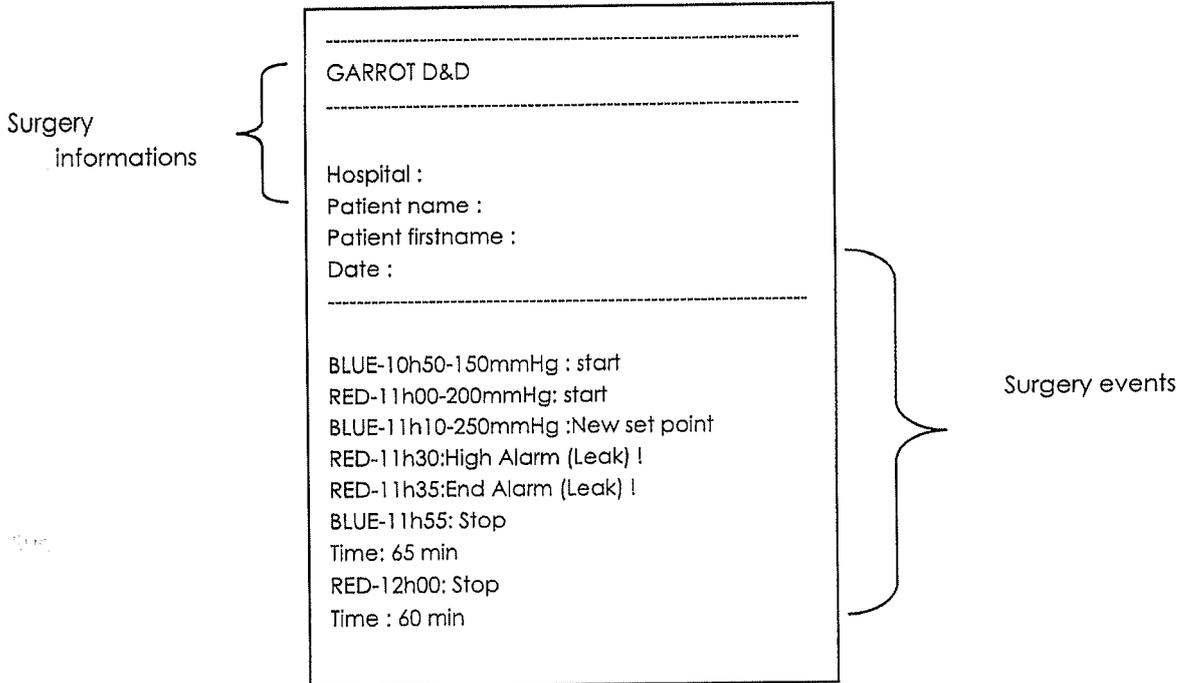
← Nidinė baterija

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.

10

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 *Operacijos metu atpažįsta tikrinę vertimą.*

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

*perspektyvo
signalai*

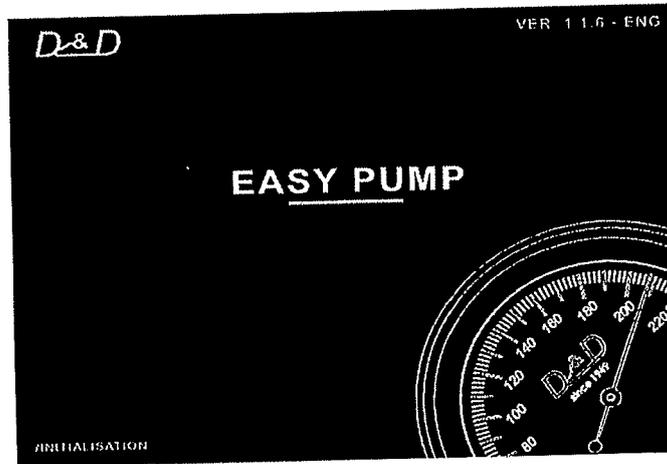
Events	Description
Start	Start of surgery
Stop time : 000min	Stopping a cycle of surgery and indication of the operating time
New set point	Changing the pressure set point
High Alarme (Cdt) !	Indicates a high priority alarm Cdt :alarm condition
End Alarm(Cdt) !	Indicates the end of an alarm Cdt : alarm 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

M

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 :

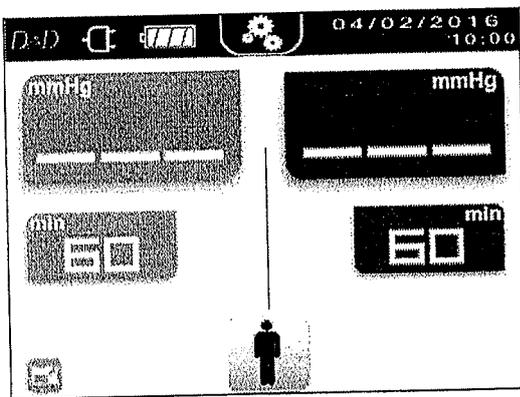


B. INFORMATIONS REGARDING OPERATION WAYS

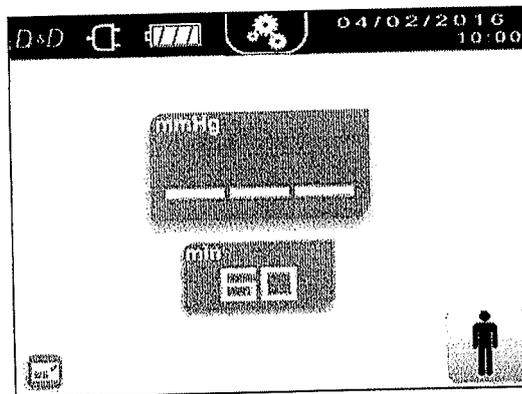
To simplify the reading of this document and the general use of the device "zones" of operations are defined by colors :

- * 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 independent, the setting procedure is identical to the pressure and the timer (Only the color changes for a G10903).

slépia is laiko nustatymas yra vienas nuo kito, nepriklausomai

C. PRESSURE ADJUSTMENT

Changing the pressure (outside off surgery)

slépia nustatymas 3

Step 3

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"

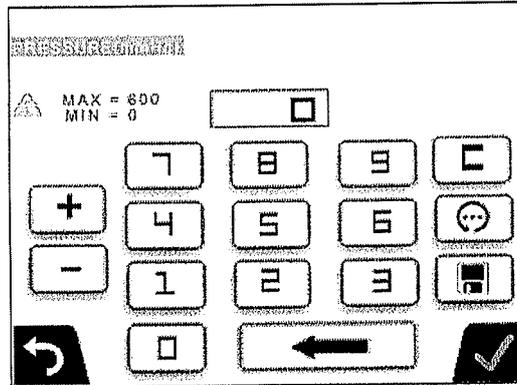
Blue circuit or single circuit



Red circuit



2) Enter a set point value on the key board



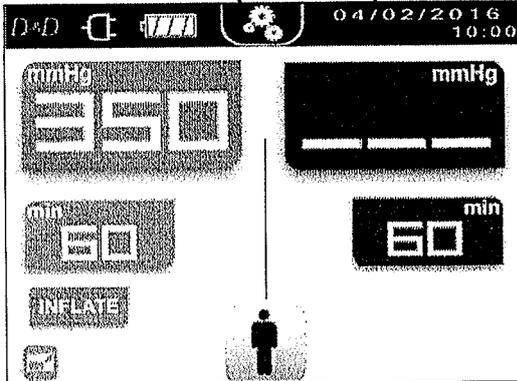
ex : 350 mmHg    or using the keys  and .

3) Validate :

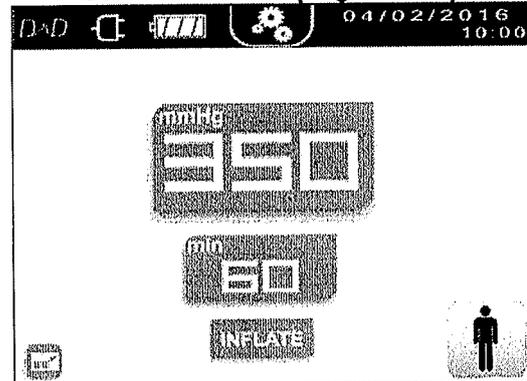
Validate by pressing the button .

The desired pressure is displayed on the screen :

G10903 (dual circuit)



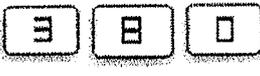
G10803 or G10903 (single circuit)



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 

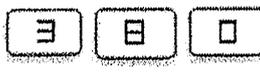
- 3) Validation :

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.

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

*2.1. Spalvotas lietimui
pautrus ekranas*

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.

*spalvos keičiasi
pildavomai nuo naudojimo
slėgio*

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 .

* 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 :

- o All keys are taken into account by pressing
- o 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.
- o 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.

15

C. DEFAULT MANAGEMENT

garsiškai perspėjimo signalai

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 that 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.

*4.1
manžetės ar
karnelis oro
nuotėkų
stebejimas.*

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 equipped 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 priority 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.

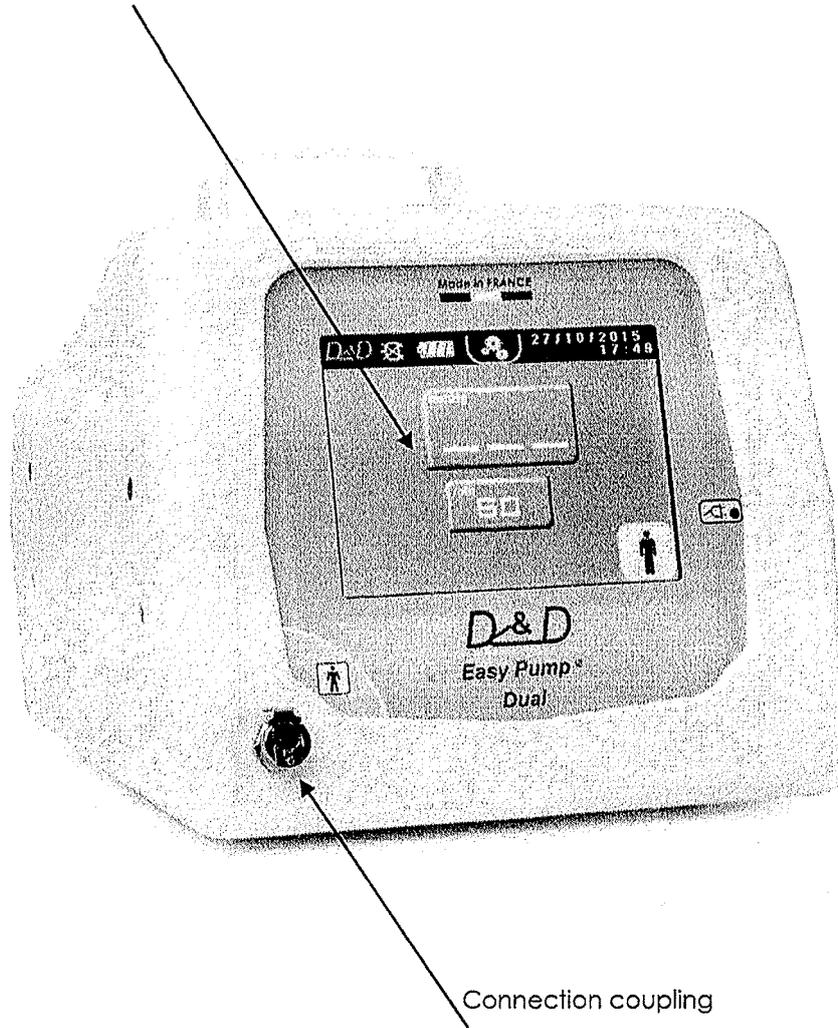
If there is an electrical power failure, the alarm system is immediately unable to restore the alarm settings.

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

III. PRESENTATION OF THE MEDICAL DEVICE (model G10803)

spalvotas lietimui patarus ekranas

Touch screen



DDM



TECHNICAL CHARACTERISTICS

CT 047

Pneumatic tourniquet G10803 Easy Pump 1 tube

Index 7

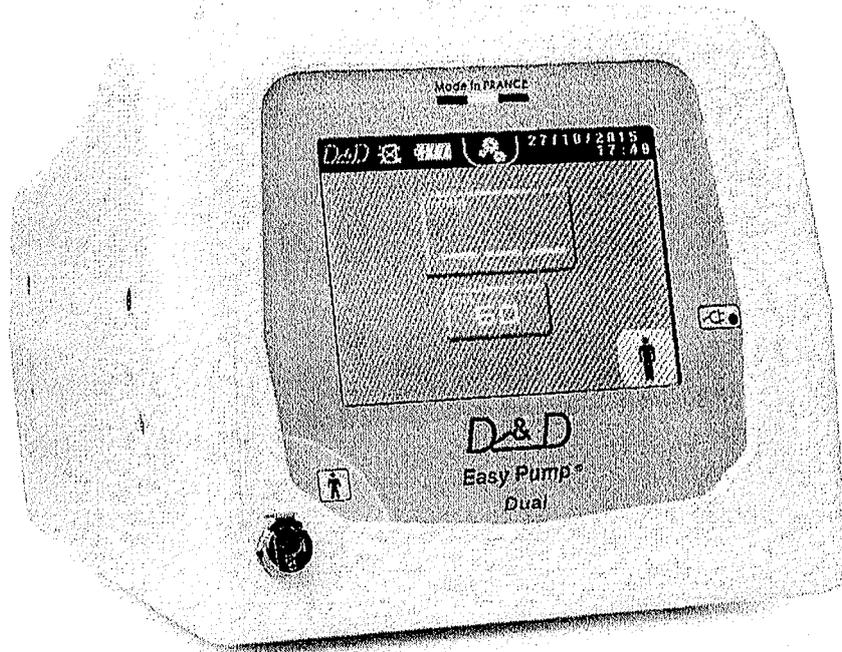
MADE IN FRANCE ■ ■

Regulatory information

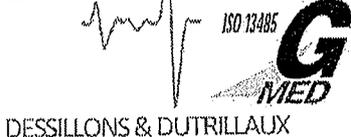
CE Marking	Index of classification	Notified body	PHTALATES	LATEX
CE 0459	Ila	G-MED		

Comprimetas su ventene prietaiso pernestimul

ventene ↓



DDM



TECHNICAL CHARACTERISTICS

CT 044

Mobile stand for pneumatic tourniquet

Index 4

Regulatory information

The mobile stand is for use exclusively with the pneumatic tourniquets D & D.

He's delivered with : *montareno platei specialia remountate*

- A mounting plate specially designed for pneumatic tourniquets D & D
- An arm equipped with a handle to facilitate movement.
- A walk with 4 braked castors *4 rotucari cu frictiuni*
- A storage basket for the pneumatic armbands and extension cords.

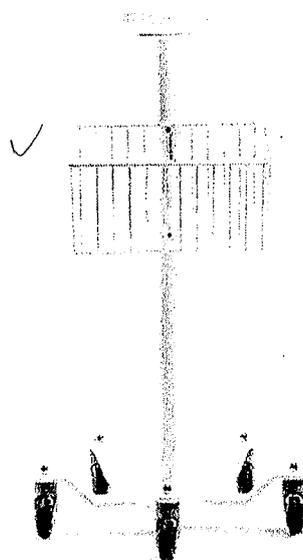
1.3

*pneumatici
turniceti*

treptu pneumatici maneteni in pozitie
laxei laterali

1 - Device identification

Mobile stand



1.4

Transportin stavar cu 5
rotucari, filtrariu
mechanism compozitru
prutintinti in cu bupcia
manetems.

2 - References

Reference	Designation	Dimensions in m		Weight in kg
		Height	Footprint	
A10701	Mobile stand for pneumatic tourniquet	1	Ø 0.56	14

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Date of first EC marking certificate :
2004

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DDM

TECHNICAL CHARACTERISTICS

CT 044

**Mobile stand for pneumatic
tourniquet**

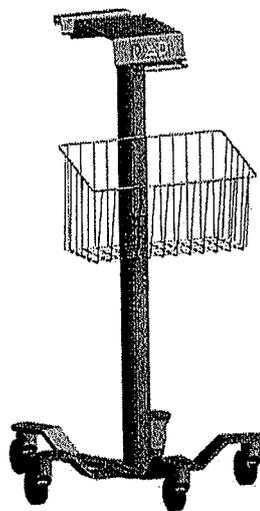
Index 4

3 - Instructions for use

- 1.3
- The mobile stand is used with pneumatic tourniquets D & D.
pneumatisches Tourniquets zur proximalen Gefäßverengung
 - The pneumatic tourniquet is maintained on the mounting plate by screws.
 - 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.
 - Any movement of the device must be disconnected for the power supply.
 - Separate the electrical power cord to the castors.

4 - Identification and characteristics of different subsets

Identifier	Designation	Characteristics
A	Gallows with platinum	Steel + epoxy paint
B	Basket	Rilsan-coated steel
C	Base with 5 branches	Steel + shockproof plastic coating
D	Castors	Clevis and high quality nylon wheel. Polypropylene wheel body, gra thermoplastic rubber bandage



_____ A

_____ B

_____ C

_____ D

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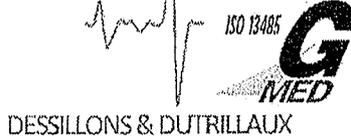
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DDM**TECHNICAL CHARACTERISTICS**

CT 044

Mobile stand for pneumatic tourniquet

Index 4

5 - Cleaning and disinfection

Spray disinfectant solutions.

6 - Maintenance

Cleaning rollers to remove any residual dust or materials which might interfere with the movement of the apparatus.

7 - Packaging*Transportarimo vežimēlio Ref. Kodes*

Reference	Packaging unit
A10701	1

8 - Storage

Type of packaging	Storage area	Temperature	Humidity	Atmospheric pressure
Original packaging	Ventilated area	-10° à 40 ° c	30 to 40 %	500 to 1060 hpA

9 - Warrentee

This warranty provides assurance for the customer who purchases a D & D product that should the product fail to function to D & D published specifications during the term of this warranty, will either replace or repair.

The guarantee period is 2 (two) years from the date of purchase.

The product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.

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CUFFS

Marking	Class
CE	I

MONOBLOC

Decontaminable

- Colour coding per size
- Antimicrobial treatment

Cuff with 1 bladder

Base	References		Designation	Color of tube	Dimensions in cm		
	With fastening strap				Cuff width	Cuff length	Overall length
GBDM101	GBDMS101		Cuff new born straight	White	3.5	29	38
GBDM102	GBDMS102		Cuff child straight	Pink	4.5	35	48
GBDM103	GBDMS103		Cuff small adult straight	Parma	6	46	61
GBDM104	GBDMS104		Cuff adult straight	Blue sky	8	46	67
GBCM105	GBCMS105		Conical cuff adult large	Orange	10	47	70
GCDM103	GCDMS103		Lower limb cuff adult straight	Yellow	8	76	97
GCDM104	GCDMS104		Lower limb cuff adult straight	Purple	10	62	76
GCDM105	GCDMS105		Lower limb cuff adult straight L	Green	10	76	90
GCDM106	GCDMS106		Lower limb cuff adult straight XL	Gray	10	82	100
GCDM107	GCDMS107		Lower limb cuff adult straight XXL	Red	10	107	122
GCCM104	GCCMS104		Conical lower limb cuff adult	Purple	10	62	76 ←
GCCM105	GCCMS105		Conical lower limb cuff adult L	Green	10	76	90 ←
GCCM106	GCCMS106		Conical lower limb cuff adult XL	Gray	10	82	100 ←
GCCM107	GCCMS107		Conical lower limb cuff adult XXL	Red	10	107	122 ←

*purpurine
Zafix
pille
raudone*

*5.3
5.3
5.3
5.3*

Komplektuojamos manžetės su spalviniu lodeniniu pagal dydį.

Cuff with 2 bladders

Base	References		Designation	Dimensions in cm		
	With fastening strap			Cuff width	Cuff length	Overall length
GBDM204	GBDMS204		Cuff adult straight	8	46	67
GBDM202	GBDMS202		Cuff child straight	4.5	35	48
GCDM204	GCDMS204		Lower limb cuff adult straight	10	62	76



del

Precautions relating to electromagnetic compatibility



Pneumatic tourniquet should be installed and put into service according to EMC recommendations 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

- toos verduino laets su gervo in vaiedo informacija nustatyti laiku.*
- o Set a tourniquet pressure following a value defined by the operator
- o Maintain this pressure throughout the duration of the intervention
- o Display operating time with sound and visual information in the defined time
- o Audible and visual alarm can be set up in case of failure of the compensation system rated pressure
- o 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.

D. SETTING THE TIMER

laikmečio nustatymas

Modification of the timer (outside off surgery)

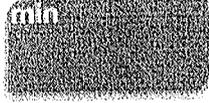
Naudotojas gali nustatyti operacijos laikmatį. Pasibaigus laikmečiui
The user can set a timer for surgery. An alarm is activated at the end of the timer delay. If the user doesn't have a timer program, the default timer is selected. (Factory setting : 60 minutes).

delsai įjungiamas alarmas. Jėgu naudotojas neturi savo laikmečio

sprengiamas, numatytas laikmatis atly-
muojasi. (60 min.)

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.

2. Device identification

Arm cuffs and lower limb cuffs are medical devices used with a pneumatic tourniquet during surgery of the upper or lower limbs.

MEDICAL DEVICE: PNEUMATIC TOURNIQUET CUFF

GMDN Code: 17231
 CND Code (European Nomenclature of Medical Devices) : V9003 Turnstile, manually- operated
 Basic IUD : 37004682B2CGRX

➤ **Monoblock cuffs:**
 These arm cuffs and lower limb cuffs of very robust design are composed of a single monobloc assembly, which facilitates their maintenance and decontamination. Owing to their impervious connector, it is possible to immerse them in a decontaminating solution. To ensure secure Velcro fixing, a ribbon to the keeps the whole. *5.1 Monzette's double fixation methodology*

1-monoblock cuffs		LATEX-FREE REUSABLE NOT STERILE 14 SIZES				
Reference	Optional retaining strap	Designation	tube color	Dimensions in cm		
				AT	B	VS
GBDM101	GBDMS101	Cuff new born straight	White	3.5	2.9	3.8
GBDM102	GBDMS102	Cuff child straight	White	4.5	3.5	4.8
GBDM103	GBDMS103	Cuff small adult straight	Palms Skin tones	6	4.6	6.1
GBDM104	GBDMS104	Cuff adult straight	Grey Skin tones	8	4.6	6.7
GBCM105	GBCMS105	Conical cuff adult large	Yellow	10	4.7	7.0
GBDM103	GBDMS103	Lower limb cuff adult straight	Purple	8	7.6	9.7
GBDM104	GBDMS104	Lower limb cuff adult straight	Purple	10	6.2	9.0
GBDM105	GBDMS105	Lower limb cuff adult straight L	Green	10	7.6	10.0
GBDM106	GBDMS106	Lower limb cuff adult straight XL	Red	10	8.2	12.2
GBDM107	GBDMS107	Lower limb cuff adult straight XXL	Purple	10	10.7	12.2
GCCM104	GCCMS104	Conical lower limb cuff adult L	Green	10	6.2	7.6
GCCM105	GCCMS105	Conical lower limb cuff adult XL	Green	10	7.6	9.0
GCCM106	GCCMS106	Conical lower limb cuff adult XXL	Green	10	8.2	10.0
GCCM107	GCCMS107	Conical lower limb cuff adult XXXL	Red	10	10.7	12.2

2-monoblock cuffs		LATEX-FREE REUSABLE NOT STERILE 3 SIZES			
Reference	Optional retaining strap	Designation	Dimensions in cm		
			AT	B	VS
GBDM204	GBDMS204	Cuff child straight	6	4.6	5.7
GBDM202	GBDMS202	Cuff adult straight	4.5	3.5	4.8
GCCM204	GCCMS204	Conical lower limb cuff adult	7	6.2	7.6

➤ **IUD monoblock cuffs:**

Reference	IUD-ID	Reference with fastening strap	IUD-ID	Tube	Lifetime
GBDM101	03700468207924	GBDMS101	03700468208877	1	5 years
GBDM102	03700468207917	GBDMS102	03700468208440	1	
GBDM103	03700468207856	GBDMS103	03700468208105	1	
GBDM104	03700468207719	GBDMS104	03700468208112	1	
GBCM105	03700468206699	GBCMS105	03700468208129	1	
GCDM103	03700468207207	GCDMS103	03700468208907	1	
GCDM104	03700468207558	GCDMS104	03700468208947	1	
GCDM105	03700468207597	GCDMS105	03700468208143	1	
GCDM106	03700468207665	GCDMS106	03700468208624	1	
GCDM107	03700468207672	GCDMS107	03700468208631	1	
GCCM104	03700468207320	GCCMS104	03700468209294	1	
GCCM105	03700468207733	GCCMS105	03700468209457	1	
GCCM106	03700468207757	GCCMS106	03700468208464	1	
GCCM107	03700468207764	GCCMS107	03700468209195	1	
GBDM204	03700468208044	GBDMS204	03700468208778	2	
GBDM202	03700468208690	GBDMS202	03700468209492	2	
GCCM204	03700468211303	GCCMS204	03700468211259	2	

➤ **Arm cuffs with silicone bladder:**

Owing to their special, robust design, it is possible to sterilize these arm cuffs and lower limb cuffs. They are composed of an envelope and a removable silicone bladder, which facilitates their maintenance.

Reference	Designation	Dimensions of the bladder in cm
Sterilizable arm cuff		
LATEX-FREE REUSABLE NOT STERILE 3 SIZES		
Arm cuff and lower limb cuff with single bladder		
GBS101	Arm cuff and lower limb cuff new born	19x4
GBS102	Cuff child	26.5x5
GCS102	Lower limb cuff child	35.5x6
GBS103	Cuff small adult	35.5x6
GCS103	Lower limb cuff small adult	53x6
GBS104	Cuff adult	53x6
GCS104	Lower limb cuff adult	69x9
GCS105	Lower limb cuff adult L	81x9
GCS106	Lower limb cuff adult XL	85.5x12
Arm cuff and lower limb cuff with double bladder		
GBS202	Double cuff child / small adult	2x (35.5x6)
GBS204	Double cuff adult	2x (53x6)
GCS204	Lower limb double cuff adult	2x (69x9)
Conical cuffs for lower limb		
GCCS104	Adult thigh	69x9
GCCS105	Adult thigh L	81x9
GCCS106	Adult thigh XL	85.5x12

