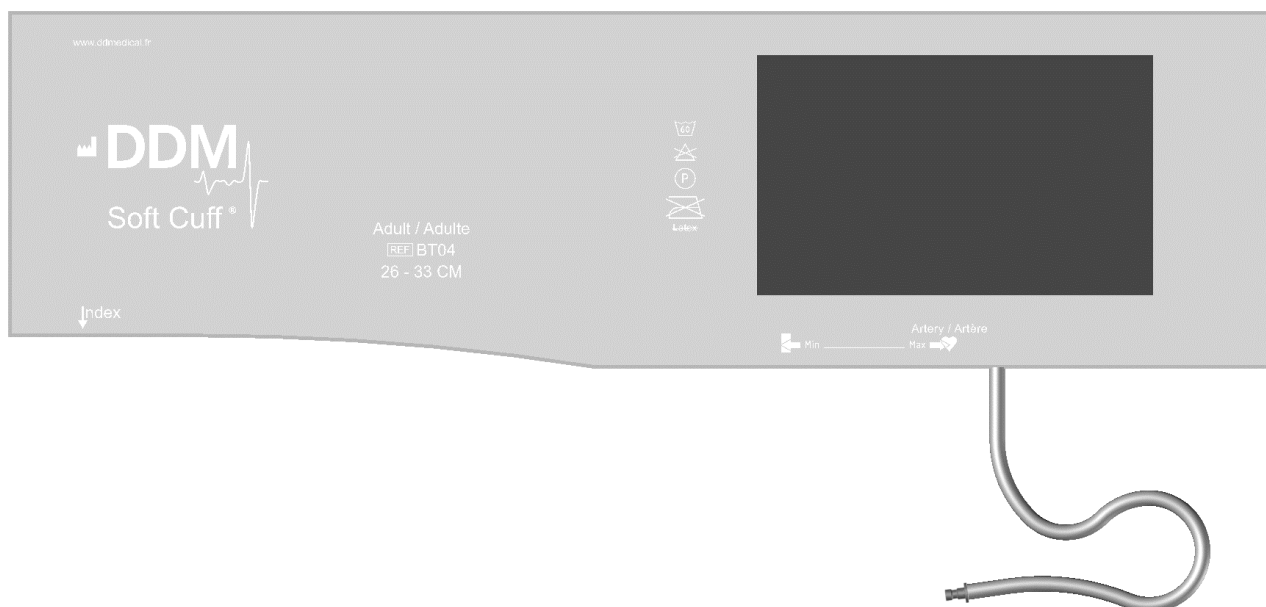


# INSTRUCTIONS FOR USE



# SOFTCUFF®



MADE IN FRANCE

INS123 – V7 – 2023-05



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Created in 1949 by Lucien Dessillons. Since its inception, DESSILLONS & DUTRILLAUX has been developing and manufacturing equipment for medical diagnosis, orthopedic surgery and medical resuscitation.

# 1. Summary

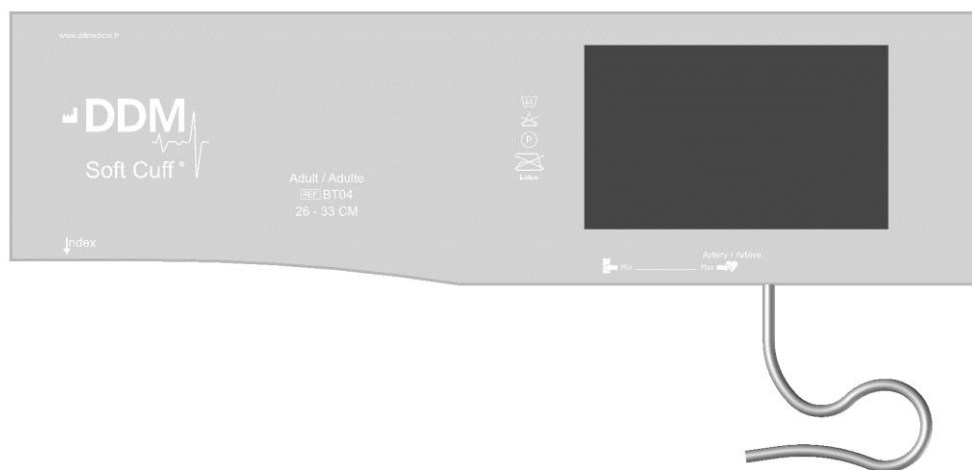
1.	SUMMARY.....	3
2.	DEVICE IDENTIFICATION .....	4
3.	REFERENCE .....	6
4.	INSTRUCTIONS FOR USE .....	7
5.	TERMS OF USE.....	8
6.	MAINTENANCE .....	8
7.	CLEANING AND DECONTAMINATION .....	9
8.	STORAGE .....	9
9.	SECURITY, RELIABILITY, COMPATIBILITY AND WARRANTY .....	10

## 2. Device identification

The SOFTCUFF® range of cuffs is intended to be used for non-invasive blood pressure measurement associated with electronic or manual blood pressure monitors. Flexible and robust design.

The device is available in 2 references:

- SOFTCUFF® without connector.
- SOFTCUFF® with A11313 connector.
















*SOFTCUFF® without connector*



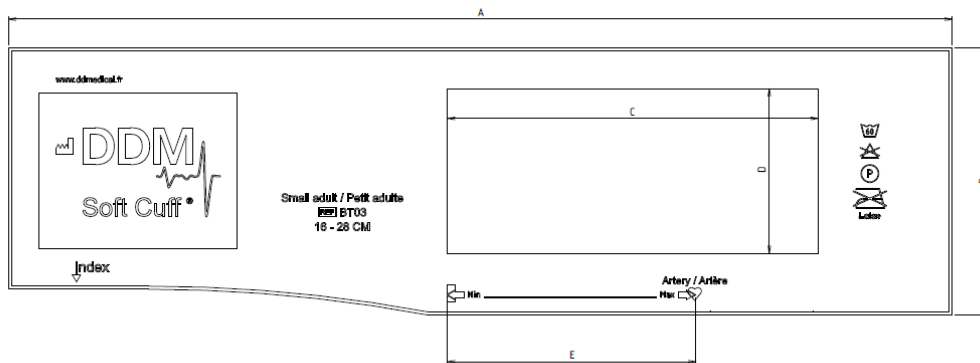
*SOFTCUFF® with A11313 connector*

**Indication on the device:**

	Index position indication
	Product brand
	Batch number on the bladder
	Product name and part number
	Range of use of the product
	Product origin marking
	Range of validity of use of the product
	Artery placement indication
	Machine wash at 60°C maximum
	Do not use a whitener
	Do not iron
	Latex Free
	Can be dry cleaned with all solvents

### 3. Reference

According to EN CE 1060-1, the optimal size of the inflation bladder must be at least equal in width to 40% of the circumference of the arm, and in length between 80 and 100% of the circumference of the arm (refer to the markings indicated on the SOFTCUFF® cuffs).



Reference		Designation	Exit	Circumference in cm		Dimensions in mm					Tube color
Without connector	With connector			Min.	Max.	A	B	C	D	E	
BT101	BT101A11313	Infant size cuff	1	6	12	173	55	95	40	43	GREY
BT102	BT102A11313	Child-size cuff	1	11	22	348	97	180	80	85	GREY
BT103	BT103A11313	Small adult size cuff	1	16	28	458	130	230	110	120	GREY
BT104	BT104A11313	Adult size cuff	1	26	33	528	149	260	129	70	GREY
BT105	BT105A11313	Large adult size cuff	1	33	41	633	174	330	150	75	GREY
CT104	CT104A11313	Adult size lower limb cuff	1	39	55	828	214	440	190	145	GREY
BT201	BT201A11313	Infant size cuff	2	6	12	173	55	95	40	43	GREY
BT202	BT202A11313	Child-size cuff	2	11	22	348	97	180	80	85	GREY
BT203	BT203A11313	Small adult size cuff	2	16	28	458	130	230	110	120	GREY
BT204	BT204A11313	Adult size cuff	2	26	33	528	149	260	129	70	GREY
BT205	BT205A11313	Large adult size cuff	2	33	41	633	174	330	150	75	GREY
CT204	CT204A11313	Adult size lower limb cuff	2	39	55	828	214	440	190	145	GREY

## 4. Instructions for use

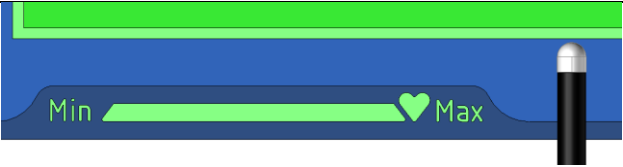
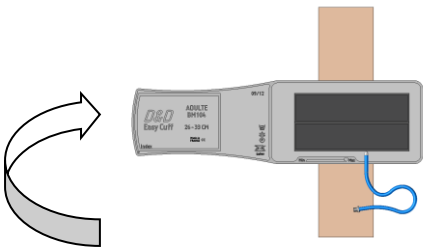
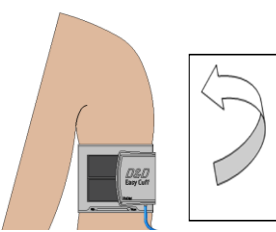

### a. Application

DDM cuffs for non-invasive blood pressure measurement are connectable to the main types of electronic monitors and manual devices (blood pressure monitors) using a pneumatic circuit as a means of mechanical signal transmission.

### b. Procedure

Before any proper installation and use of the cuff, it is imperative to consult the instructions for use of the electro-medical device, or manual device concerned.

#### Placing the cuff on the limb:

<p><b>A</b></p>	<p>Place the inside of the cuff on the chosen limb, aligning the artery index finger with the patient's artery.</p>	
<p><b>B</b></p>	<p>Orient the cuff inlet tube towards the patient's hand or foot and position the cuff so that the tube inlet is away from the brachial (or femoral) artery.</p>	
<p><b>C</b></p>	<p>Secure the cuff with the Velcro strap, making sure that the index mark is within the "mini-maxi" zone. Otherwise, choose another size of cuff more appropriate for the patient.</p>	
<p><b>D</b></p>	<p>Once the cuff is positioned and ready for use, the INDEX must be between the Min and the Max (heart axis). Connect the cuff to the connecting tube of the electromedical device.</p>	

### **Precautions:**

- The cuff should not be placed on a limb receiving another appliance (infusion, blood transfusion, SpO2 sensor ...)
- Avoid tightening the cuff too tightly at the time of application, so as not to block the patient's blood circulation.
- During frequent blood pressure measurements, regularly check the condition of the patient's skin at the measurement site.
- Place the connecting tube to the monitor in such a way that it does not interfere with the patient's movement.
- Make sure there are no leaks in the cuff connector.
- The inflatable part of the cuff must completely surround the limb chosen for measurement.

### **Activation of the electro-medical device:**

- Connect the PNI extension cord to the appropriate electromedical device.
- Activate the electromedical device and ensure its operation (consult the instructions for use of the device).

## **5. Terms of Use**

<b>Ambient temperature</b>	<b>Relative humidity</b>	<b>Atmospheric pressure</b>
+ 10° C to + 40° C	30% to 100%	700 hpA to 1060 hpA

## **6. Maintenance**

- Under no circumstances should a liquid penetrate inside the pneumatic part of the cuff, as this could partially or totally damage the electromedical device or manual measuring device to which the cuff are connected.
- Under no circumstances should a tubing be "clamped" using pliers or other unsuitable instruments.
- Under no circumstances should the cuff be handled with any sharp object.
- Under no circumstances should the cuff be inflated without being wound and closed with the two Velcro parts on a round limb or tube without a stop and sharp part.



## 7. Cleaning and decontamination

SOFTCUFF® are not sterilizable.

Reference	Dry cleaning
BT101	X
BT102	X
BT103	X
BT104	X
BT105	X
CT104	X
BT201	X
BT202	X
BT203	X
BT204	X
BT205	X
CT204	X
BT101A11313	X
BT102A11313	X
BT103A11313	X
BT104A11313	X
BT105A11313	X
CT104A11313	X
BT201A11313	X
BT202A11313	X
BT203A11313	X
BT204A11313	X
BT205A11313	X
CT204A11313	X

### a. Dry cleaning

Recommended product: DETERQUAT / ANIOS.

<b>A</b>	Spray a detergent, disinfectant, bactericidal foam on the cuff, taking care to distribute the product well.
<b>B</b>	Leave on for 15 minutes.
<b>C</b>	Rinsing is useless, wipe with a single-use wipe.

## 8. Storage

Any cuff awaiting use must be kept under the conditions below:

Type of packaging	Local	Temperature	Humidity	Pressure
Origin	Ventilated room	+ 10° C to + 70° C	10% to 100%	500 hpA to 1060 hpA

## **9. Security, reliability, compatibility and warranty**

### **a. Security**

DDM cuffs are made in accordance with European and National standards IEC 601-2/30.

DDM cuffs do not contain latex.

The class and type of protection against electric shock are also related to those of the electromedical device or manual device to which the cuff can be connected.

Cuffs can in no way be responsible for incidents occurring in the event of non-compliance with the rules of installation and use in this documentation.

Classification according to the recommendations of European Directive 93/42 Class I.

### **b. Reliability**

The performance of DDM cuffs is directly related to that of the electromedical or manual device to which they are connected. Failure to comply with the rules for the application of this documentation may lead to erroneous measures.

### **c. Compatibility**

DDM cuffs must be used with compatible connectors indicated by the manufacturer of the measuring medical device.

### **d. Guarantee**

Dessillons & Dutrillaux guarantees that the cuffs comply with the specifications of the safety and performance standards applicable to it and currently in force.

All unused DDM cuffs, kept in their original packaging and without damage are guaranteed for 12 months from the date of delivery.

All DDM cuffs are warranted against design defects for the duration of their use.