

**MADE IN FRANCE** 

**Regulatory information**



CE Marking	Index of classification	Notified body	<del>PHTALATES LATEX</del>	
CE 0459	Im	G-MED		

Sphygmomanometer hand-held type with aneroid membrane, very light.

This precision manometer graduated from 0 to 300 mmHg is fixed on an anodized aluminum valve, equipped with a decompression knob.

Reading of measured values is facilitated by the size of the dial. Accuracy of  $\pm 3$  mm guaranteed over the entire measuring range.

This flexible and robust design and can be cleaned by machine and decontaminated by immersion after:

- \* Remove the Nox Black bladder from cuffs.
- \* Seal the connection pipes for Easy Cuff cuffs

- Reliability: an INDEX and a Min Max range allow to quickly validate whether the cuff or the cuff is adapted to the patient's limb.

- The indication "artery" carried on the cuff makes it possible to perfectly position this one, the pocket being automatically centered on the passage of the artery.

- Security : to fight against nosocomial infections, Easy Cuff fabric underwent an antimicrobial treatment.

## 1 - Device identification

**Sphygmomanometer with Easy Cuff**



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Date of first EC marking certificate :  
2004

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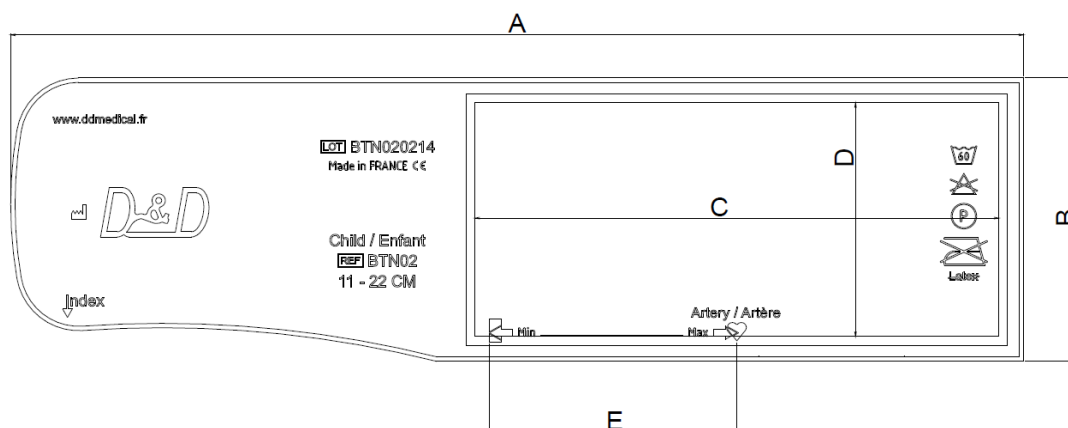
## 2 – References
















### Reference sphygmomanometer with cuff :

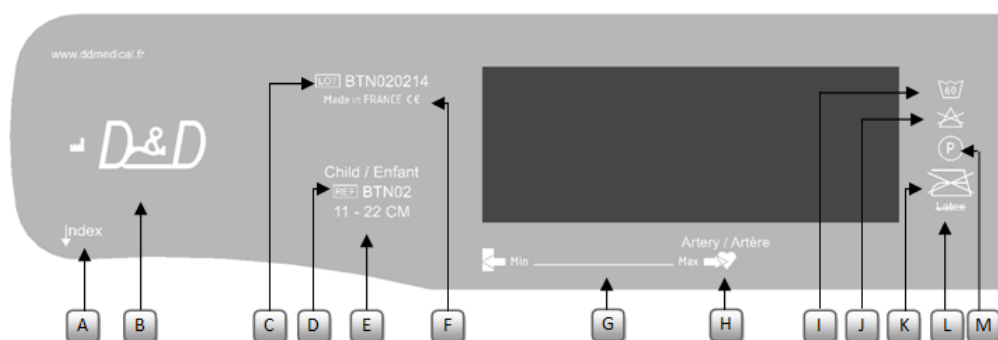
Designation	Ref with Nox Black cuff	Ref with Easy Cuff (immersible)	Ref with Easy Cuff (disposable)
Manometer	A10371		
New born	T60001	TI60001	TU60001
Child	T60002	TI60002	TU60002
Small adult	T60003	TI60003	TU60003
Adult	T60004	TI60004	TU60004
Adult large	T60005	TI60005	TU60005
Lower limb cuff adult	T60006	TI60006	TU60006

### Reference and size arm cuff Nox Black :

Reference Nox Black cuff	Reference Soft cuff	Designation	Tube	Circumference in cm		Dimensions in mm					Tube color
				Min	Max	A	B	C	D	E	
BTN101	BT101	New born	1	6	12	173	55	95	40	43	BLACK
BTN102	BT102	Child	1	11	22	348	97	180	80	85	BLACK
BTN103	BT103	Small adult	1	16	28	458	130	230	110	120	BLACK
BTN104	BT104	Adult	1	26	33	528	149	260	129	70	BLACK
BTN105	BT105	Adult large	1	33	41	633	174	330	150	75	BLACK
CTN104	CT104	Lower limb cuff adult	1	39	55	828	214	440	190	145	BLACK



A		Position indication index
B		Product Brand
C		Number of batch
D	 	Name and product number
E		Range of the product
F		Original product marking
G		Validity range of product use
H		Indication for placement of the artery
I		Machine wash at 60 ° C
J		Do not use bleacher
K		Do not iron
L		Latex free
M		Can be dry cleaned using any solvent
N		Indication of the number of tube

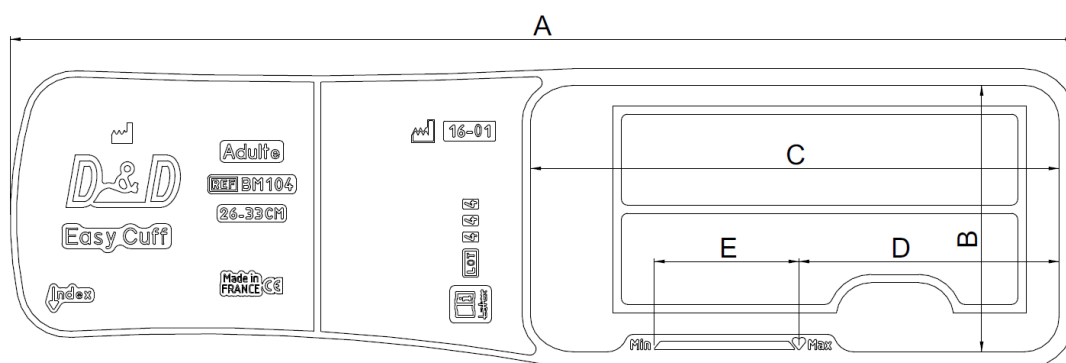


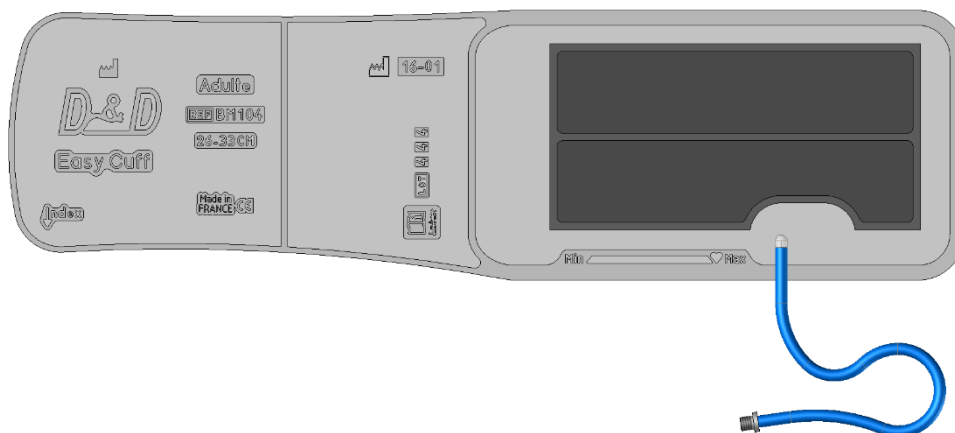
**Reference and size for Easy Cuff :**





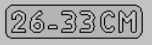



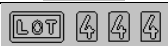


Reference	Designation	Tube	Circumference in cm		Dimensions in mm					Tube color
			Min	Max	A	B	C	D	E	
BM101	New born	1	6	12	170	40	95	47,5	43	WHITE
BM102	Child	1	11	22	338	80	180	90	85	PINK
BM103	Small adult	1	16	28	423	110	230	115	120	PARMA
BM104	Adult	1	26	33	516	129	256	129	70	BLUE SKY
BM105	Adult large	1	33	41	616,8	150	330	165	80	TURQUOISE
CM104	Lower limb cuff adult	1	39	55	816,5	190	440	220	160	PURPLE

**Reference and size for Easy Cuff disposable :**

Reference	Designation	Tube	Circumference in cm		Dimensions in mm					Tube color
			Min	Max	A	B	C	D	E	
BMU101	New born	1	6	12	170	40	95	47,5	43	WHITE
BMU102	Child	1	11	22	338	80	180	90	85	ROSE
BMU103	Small adult	1	16	28	423	110	230	115	120	PARMA
BMU104	Adult	1	26	33	516	129	256	129	70	BLUE SKY
BMU105	Adult large	1	33	41	616,8	150	330	165	80	TURQUOISE
CMU104	Lower limb cuff adult	1	39	55	816,5	190	440	220	160	PURPLE





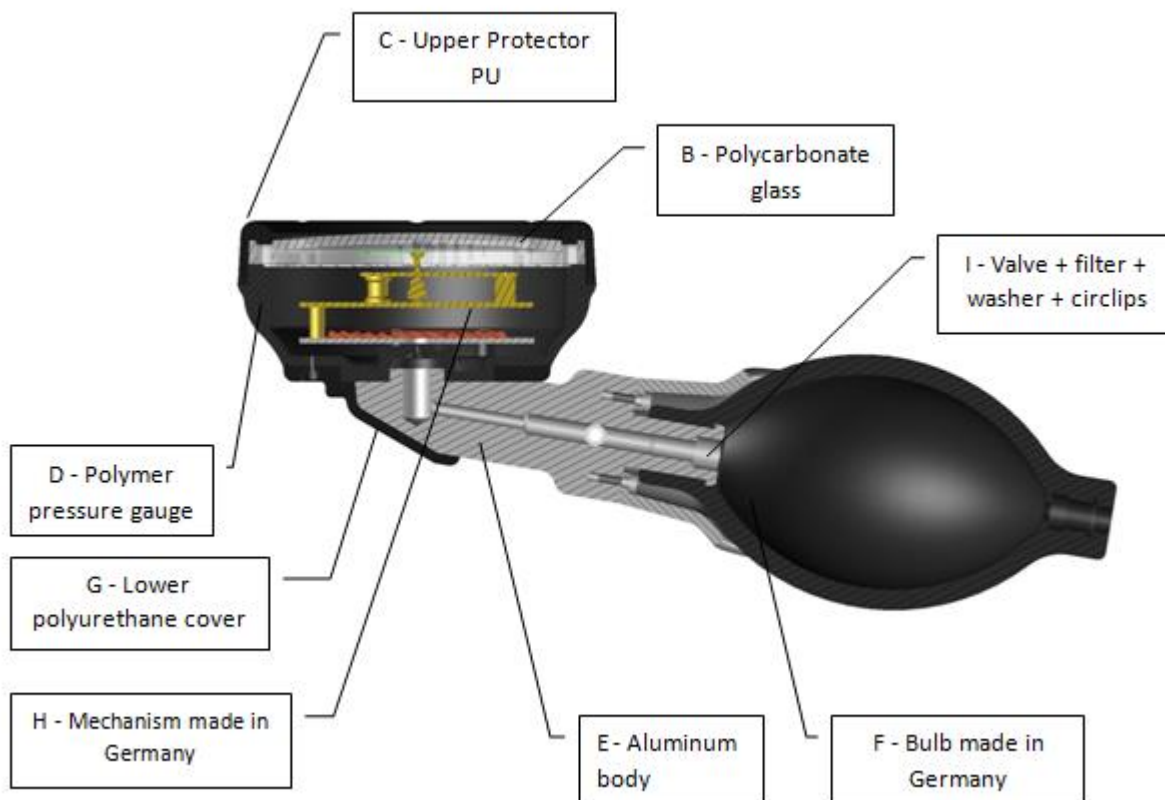
A		Indication of the position of the index
B		Product Brand
C		Name and product number
D		Original product marking
E		Range of product use
F		Date of manufacture
G		See operating instructions
H		Latex free
I		Manufacturing Lot Number
J		Validity range of product use
K		Indication for placement of the artery

### 3 - Use of the device – Operating instructions

- Select a cuff adapted to the morphology of the patient. The size and range of use are indicated on the cuff.
- Position the center of the bladder pocket represented by a heart on the axis of the brachial artery.
- Roll the cuff around the limb.
- Once the cuff positioned and ready to use, the INDEX must be between the Min and Max (axis of the heart). If INDEX exceeds the Max index located at the axis of the heart, replace the cuff by the model of the larger size. If INDEX exceeds Min index located at the tip of the range, replace the cuff by the model of smaller size.
- When the cuff and INDEX are positioned correctly the procedure for measuring blood pressure can begin.
- Correctly roll the cuff around the limb and ensure its continuation with the fastening system provided.
- Place the tips of the lyre of the stethoscope in your ears, the microphone in the listening position, just below the cuff, on the passage of the artery.
- Ensure that the vent screw of the pear is in the closed position 30 and to inflate or 40 mmHg above the estimated pressure. Blood no longer circulates at the microphone, no sound is heard with a stethoscope.
- Loosen the vent screw the bulb to slowly reduce the inflation pressure and allow blood to flow again, the first beats are perceptible stethoscope.
- Read this pressure gauge reading now, this value corresponds to the maximum pressure or systolic pressure.
- Continue decompression beats levied stethoscope amplify then fade to become inaudible.
- Read this moment the pressure indicated, this reading corresponds to the minimum pressure or diastolic pressure.
- Unscrew the knob further relief to completely purge the remaining air in the bladder.
- Remove the cuff.

**4 - Identification and characteristics of different subsets**

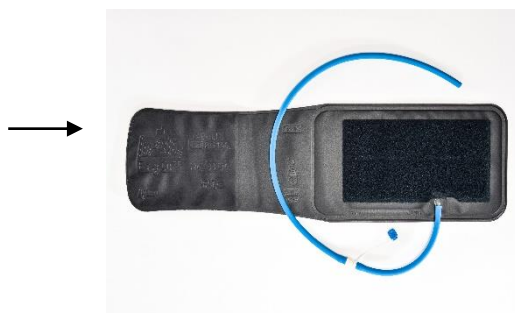
Identifier	Reference	Denomination	Characteristics
A	Nox Black	Arm cuff Velcro + bladder	Nylon cuff and PU coated fabric bladder
A	Easy Cuff	Monobloc cuff	Welded PU coated fabric + antibacterial treatment
B	A10362	Glass	Polycarbonate
C	A10363	Upper protector	Polyurethane
D	A10369	Casing	Polymer
E	A10365	Body	Aluminium
F	A10226	Bulb	Phtalates - free PVC
G	A10366	Lower cover	Polyurethane
H	A10367	Mechanism 0-300 mmHg	Brass
I	A10368	Valve + filter + washer + circlips	



A- Nox Black



A- Easy Cuff



## 5 – Cleaning and disinfection

### 1/Cleaning of manometer :

Spray disinfecting solutions. do not use detergent, do not immerse.

### 2) Cleaning of arm cuff by dry cleaning :

- A) Spray a foam detergent, disinfectant, bactericidal on the arm cuff, taking care to distribute the product well on the surface.
- B) Leave 15 minutes.
- C) Do not rinse.
- D) Product recommended: Surface'Safe / Anios.

### 3) Cleaning of arm cuff by immersion (after removing the bladder) :

- A) Remove the arm cuff bag
- B) Clean the arm cuff with water or with washing machine. Washing machine at 40 ° (60 ° being the maximum), without a spin cycle. The number of washing machine and the washing temperature decreases the life of the cuff.
- C) Immerse the arm cuff assembly in a decontaminating solution.
- D) Immersion time : 15 minutes.

Rinse thoroughly with water, renewing the dipping bath after each use. Product recommended : Aniosyme DD1 manufactured by Anios



## 6 – Maintenance :

Control calibration every 12 months for the manometer.

## 7 – Packaging

Reference			Packaging unit
T60001	TI60001	TU60001	1
T60002	TI60002	TU60002	1
T60003	TI60003	TU60003	1
T60004	TI60004	TU60004	1
T60005	TI60005	TU60005	1
T60006	TI60006	TU60006	1

## 8 – Storage

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

## 9 – Warranty

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.