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Regulatory information

CE Marking	Index of classification	PHTALATES LATEX
CE	I	

The range of cuffs Nox Black is intended to be used to measure non invasive blood pressure associated with electronic or manual blood pressure.

This flexible and robust design can be cleaned in a washing machine to clean them by immersion with the requirement to remove the pocket.

- Reliability : an Index and a range "Min-Max" can quickly validate if the product is adapted to the size of the patient.

The indication "artery" can perfectly position the cuff, pocket located automatically centered on the passage of the artery.

1 - Device identification

Blood pressure cuff 1 tube



Blood pressure cuff 2 tubes



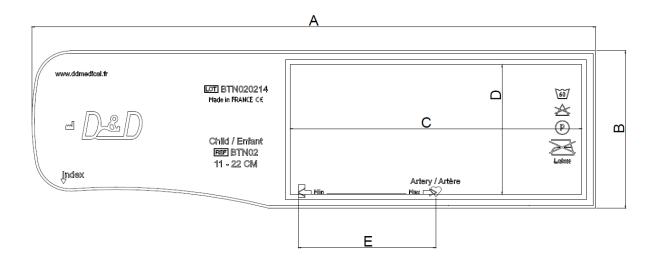


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2 - References

According to EN 1060-1 EC, the optimal size of the inflation bag must be at least equal in width to 40% of the circumference of the arm, and a length between 80 and 100% of the circumference of the arm (see markings shown on cuffs Soft Cuff).

Reference	Designation 1	Tube	Circumference in cm		Dimensions in mm				Tube color	
			Min	Max	Α	В	С	D	E	
BTN101	New born	1	6	12	173	55	95	40	43	GREY
BTN102	Child	1	11	22	348	97	180	80	85	GREY
BTN103	Small adult	1	16	28	458	130	230	110	120	GREY
BTN104	Adult	1	26	33	528	149	260	129	70	GREY
BTN105	Adult large	1	33	41	633	174	330	150	75	GREY
CTN104	Lower limb cuff adult	1	39	55	828	214	440	190	145	GREY
BTN201	New born	2	6	12	173	55	95	40	43	GREY
BTN202	Child	2	11	22	348	97	180	80	85	GREY
BTN203	Small adult	2	16	28	458	130	230	110	120	GREY
BTN204	Adult	2	26	33	528	149	260	129	70	GREY
BTN205	Adult large	2	33	41	633	174	330	150	75	GREY
CTN204	Lower limb cuff adult	2	39	55	828	214	440	190	145	GREY

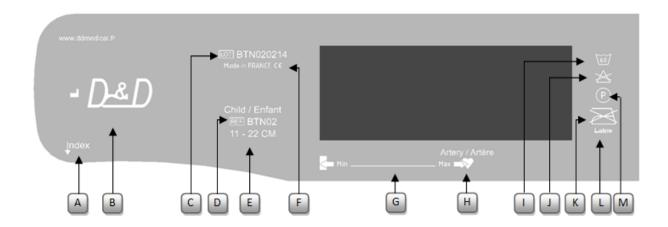




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Α	Index	Position indication index
В	- D-& D	Product Brand
С	LOT BTN020214	Number of batch
D	Child / Enfant	Name and product number
	REF BT02	
Ε	11 - 22 CM	Range of the product
F	Made in FRANCE C €	Original product marking
G	◯ ■ Min Max □	Validity range of product use
Н	Artery / Artère Max □ S	Indication for placement of the artery
1	\ <u>60</u> /	Machine wash at 60 ° C
J	<u>A</u>	Do not use bleacher
K		Do not iron
L	Latex	Latex free
M	P	Can be dry cleaned using any solvent
N	/ 1 Tube	Indication of the number of tube

A label indicates whether the device has one or two tubes (/ or tube 1/2 tubes).





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Connectors for non invasive blood pressure cuffs

Screw connection							
Reference	Design	Material	Designation				
A11306		Acetal	Male connector screw connection				
A11307		Chrome-plated brass	Female connector screw connection				
A11350		Acetal/ Chrome-plated brass	Male/Female screw connection				
Quarter-tu	ırn connection						
Reference	Design	Material	Designation				
A11301		Acetal	Female connector quarter-turn conection				
A11300		Acetal	Female connector quarter-turn conection with sealing valve				
A11308		Acetal /EPDM	Male connector quarter-turn connection with O-ring				
A11351		Acetal/EPDM	Male / female with quarter-turn connection				
Connection	n with clip system						
Reference	Design	Material	Designation				
A11305		Chrome-plated brass	Female connector with clip system				
A11313		Chrome-plated brass	Male connector with clip system				
A11352		Chrome-plated brass	Male / female with clip system				
A11304		Nylon	Male connector with clip system				



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A11353		Chrome-plated brass /Nylon	Male / female with clip system						
Standard Luer lock connection									
Reference	Design	Material	Designation						
A11312		Chrome-plated brass	Female connector with luer lock connection						
A11311		Chrome-plated brass	Male connector with luer lock male connection						
A11354		Chrome-plated brass	Male / female connector luer lock						
A11303		Nylon	Female connector luer lock female connection						
A11302		Nylon	Male connector luer lock male connection						
A11355		Nylon/ Nylon	Male / female connector luer lock						
Luer lock connection									
Reference	Design	Material	Designation						
A11050		Nylon	Male luer lock						
A11356		Nylon/ Nylon	Male / Female luer lock connection						
A11357		Chrome-plated brass /Nylon	Male / Female connector luer lock						
A11400		Chrome-plated brass	Male luer lock male connection						
A11358		Chrome-plated brass/ Chrome-plated brass	Male / Female connector luer lock						
A11359		Nylon/ Chrome-plated brass	Male / Female connector luer lock						
uer lock Colin c	onnection								



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A11051		Chrome-plated brass	Luer femelle Colin							
Protective	Protective caps for Luer lock connection									
Reference	Design	Material	Designation							
A45000	Ť	PVC	Protective caps for female luer lock connection							
A11360		PVC	Female connector luer lock female connection + stopper cap for cleaning and desinfection							
A11631		PVC	Female connector luer lock female connection + stopper cap for cleaning and desinfection							

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.

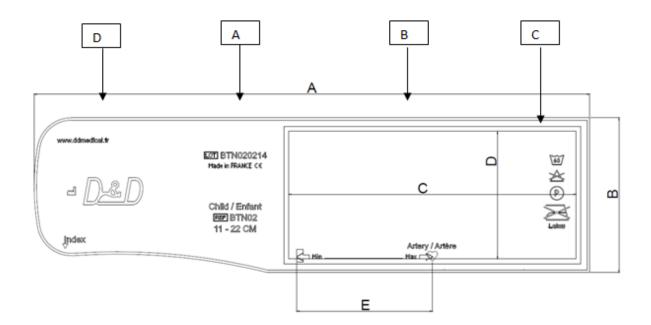


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- Loosen the vent screw the bulb to slowly reduce the inflation pressure and allow blood to flow again, the first beats are perceptible stethoscope.
- Read this pressure gauge reading now, this value corresponds to the maximum pressure or systolic 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 differents subsets

Identifier	Designation	Characteristics		
А	Fabric enveloppe	Nylon fabric		
В	Bag	PU coated fabric - High frequency welded		
С	Velcro closure	Loop sewn		
D Velcro closure		Hook sewn		





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5 - Cleaning and disinfection

1) 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.

2) Cleaning by immersion (after removing the bag):

- 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 - Packaging

Reference Designation		Packaging unit
BTN101	New born	1
BTN102	Child	1
BTN103	Small adult	1
BTN104	Adult	1
BTN105	Adult large	1
CTN104 Lower limb cuff adult		1
BTN201 New born		1
BTN202	Child	1
BTN203	Small adult	1
BTN204	Adult	1
BTN205	Adult large	1
CTN204 Lower limb cuff adult		1

8 - 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 1 (one) year 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.

7 – 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