

MADE IN FRANCE 

Regulatory information



CE Marking	Index of classification	Notified body	PHTALATES LATEX
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 ± 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 Soft Cuff bladder from cuff.
- * 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, this fabric underwent an antimicrobial treatment.

1 - Device identification

Sphygmomanometer with Soft Cuff



Sphygmomanometer with Easy Cuff



Dessillons & Dutrillaux

Zone Industrielle La Tuque
 Tél : +33 5 53 48 30 66
technique@ddmedical.fr

47240 CASTELCULIER
 Fax : +33 5 53 47 24 64
www.ddmedical.fr

Date of first EC marking certificate :
 2004

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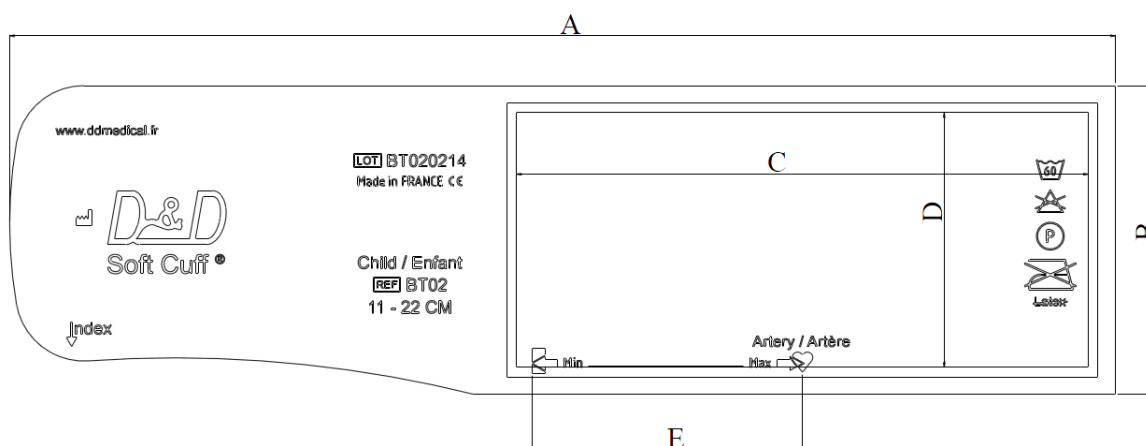
2 – References




Reference sphygmomanometer with cuff :

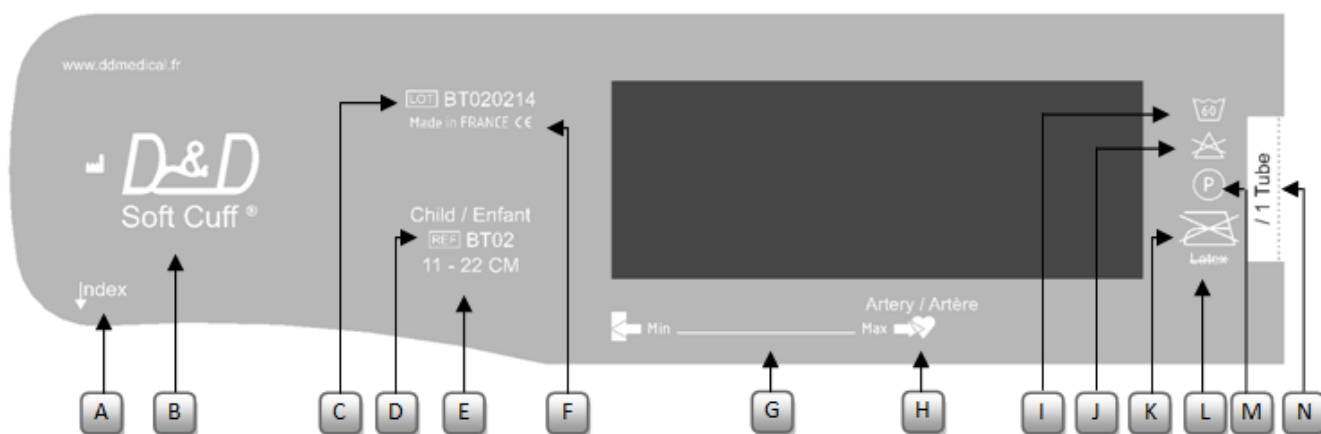
Designation	Ref with Soft Cuff	Ref with Easy Cuff
Manometer	A10370	
New born	TS50001	TI50001
Child	TS50002	TI50002
Small adult	TS50003	TI50003
Adult	TS50004	TI50004
Adult large	TS50005	TI50005
Lower limb cuff adult	TS50006	TI50006

Reference and size of Soft Cuff :

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

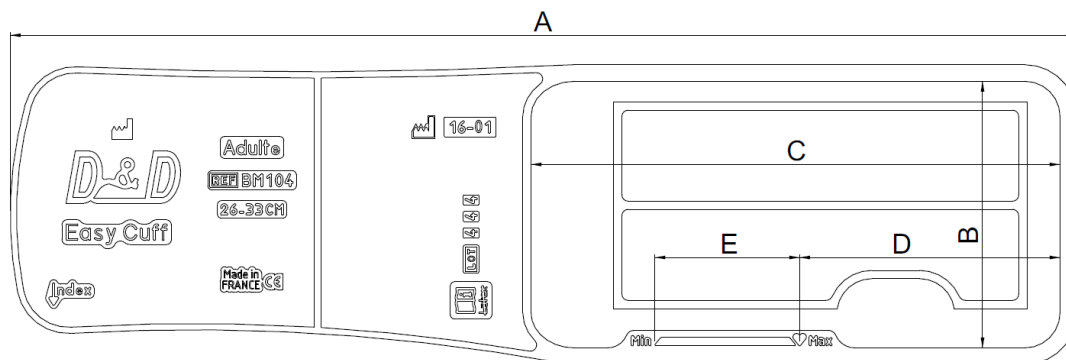


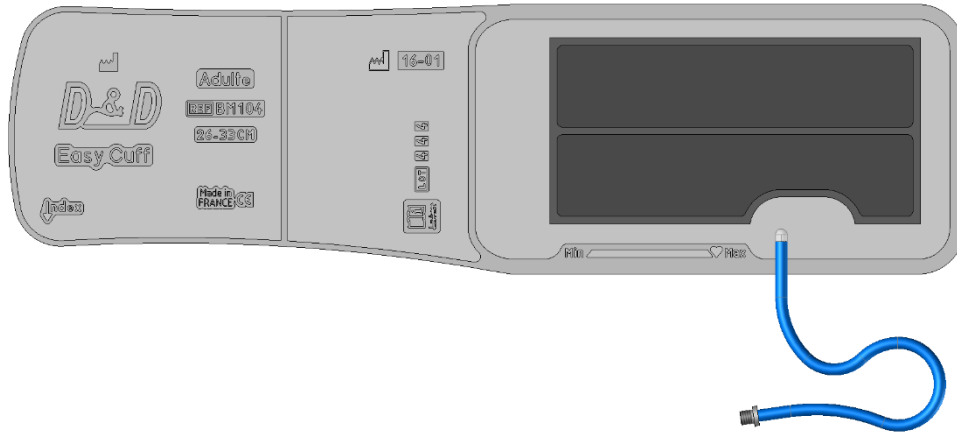
A	↓ Index	Position indication index
B		Product Brand
C	LOT BT020214	Number of batch
D	Child / Enfant REF BT02	Name and product number
E	11 - 22 CM	Range of the product
F	Made in FRANCE CE	Original product marking
G	← Min _____ Max →	Validity range of product use
H	Artery / Artère Max →	Indication for placement of the artery
I	60	Machine wash at 60 ° C
J		Do not use bleach
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





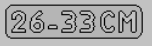



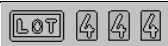
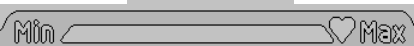



Reference and size for Easy Cuff :

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





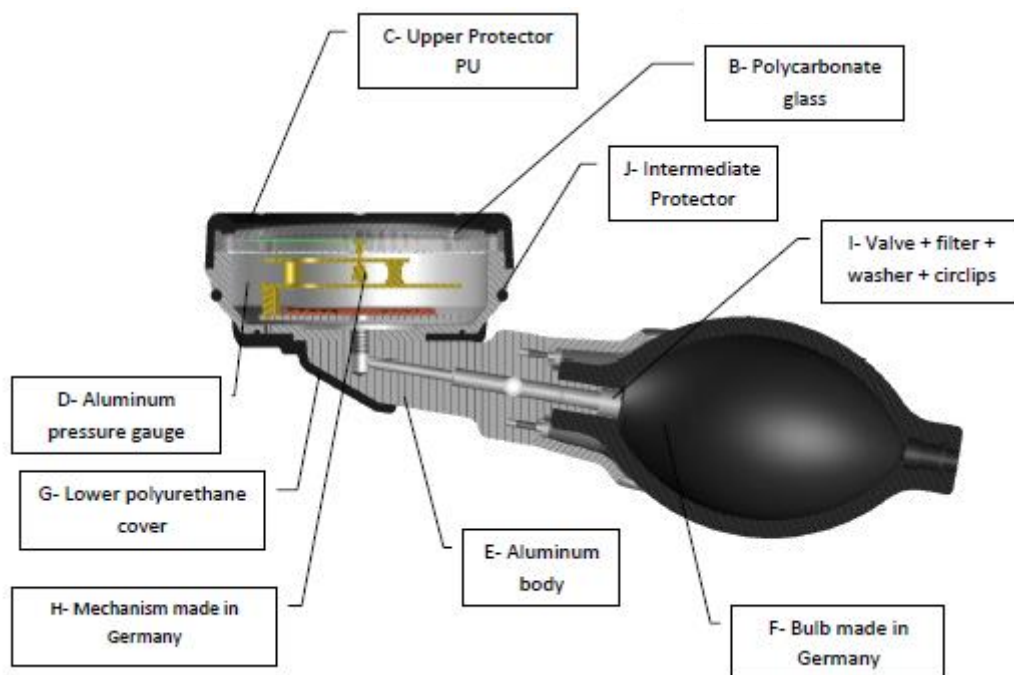
A		Indication of the position of the index
B		Product Brand
C		Name and product number
D		Original product marking
E		Range of product use
F		Date of manufacture
G		See operating instructions
H		Latex free
I		Manufacturing Lot Number
J		Validity range of product use
K		Indication for placement of the 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	Soft Cuff	Arm cuff Velcro + bladder	Fabric with coating and antibacterial treatment 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	A10364	Casing	Aluminium
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	
J	A10372	Intermediate protector	EPDM



A- Soft Cuff



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
TS50001	TI50001	1
TS50002	TI50002	1
TS50003	TI50003	1
TS50004	TI50004	1
TS50005	TI50005	1
TS50006	TI50006	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.