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Regulatory information

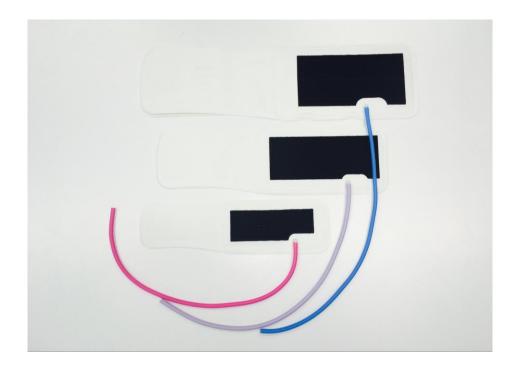
CE Marking	Index of classification	PHTALATES LATEX
CE	I	

The range of armbands EasyCuff for single use patient is intended to be used for non invasive blood pressure measurement associated with electronic or manual blood pressure.

This device is intended to be used for only one patient, however, its design is very reliable but adapted to use for only one patient.

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

1 - Device identification



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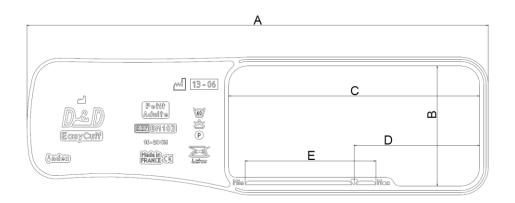


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2 - References

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	Tube	Circumference in cm		Dimensions in mm			Tube color		
			Min	Max	Α	В	С	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
BMU201	New born	2	6	12	170	40	95	47,5	43	WHITE
BMU202	Child	2	11	22	338	80	180	90	85	ROSE
BMU203	Small adult	2	16	28	423	110	230	115	120	PARMA
BMU204	Adult	2	26	33	516	129	256	129	70	BLUE SKY
BMU205	Adult large	2	33	41	616,8	150	330	165	80	TURQUOISE
CMU204	Lower limb cuff adult	2	39	55	816,5	190	440	220	160	PURPLE



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CT 045

Non invasive blood pressure cuff "Easy Cuff" for single use patient only

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Connectors for non invasive blood pressure cuffs

Screw con	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	rn 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 L	uer 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						
Luer lock C	onnection					
Reference	<u> </u>	Material	Designation			
		Material Nylon	Designation Male luer lock			
Reference						
Reference A11050		Nylon	Male luer lock			
A11050 A11356		Nylon Nylon/ Nylon Chrome-plated brass	Male luer lock Male / Female luer lock connection			
A11356 A11357		Nylon Nylon/ Nylon Chrome-plated brass /Nylon	Male luer lock Male / Female luer lock connection Male / Female connector luer lock			
A11356 A11357 A11400		Nylon Nylon/ Nylon Chrome-plated brass /Nylon Chrome-plated brass Chrome-plated brass/	Male luer lock Male / Female luer lock connection Male / Female connector luer lock Male luer lock male connection			
A11356 A11357 A11400 A11358 A11359		Nylon Nylon/ Nylon Chrome-plated brass /Nylon Chrome-plated brass Chrome-plated brass/ Chrome-plated brass Nylon/ Chrome-plated	Male luer lock Male / Female luer lock connection Male / Female connector luer lock Male luer lock male connection Male / Female connector luer lock			
A11356 A11357 A11400 A11358 A11359	Design Colin connection	Nylon Nylon/ Nylon Chrome-plated brass /Nylon Chrome-plated brass Chrome-plated brass/ Chrome-plated brass Nylon/ Chrome-plated	Male luer lock Male / Female luer lock connection Male / Female connector luer lock Male luer lock male connection Male / Female connector luer lock			

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La Turque 47240 CASTELCULIER



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Protective caps for Luer lock connection					
Reference	Design	Material	Designation		
A45000	Ī	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

Designation	Characteristics
Submersible monobloc assembly cuff adult	PU coated fabric - high-frequency welding
Velcro	Loop Astrakan high-frequency welding
Angled connecting tube	Molded PU, welding HF, angle 90 °
Connecting hose	Compound vinylique phtalates free 58 shore A
Velcro	Hoop Astrakan high-frequency welding

5 - Cleaning and disinfection

The device is designed for a single use, it is not expected protocol cleaning and disinfection.

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6 - Packaging

Reference	Packaging unit
BMU101	1
BMU102	1
BMU103	1
BMU104	1
BMU105	1
CMU104	1
BMU201	1
BMU202	1
BMU203	1
BMU204	1
BMU205	1
CMU204	1

7 – 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

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.

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