

Regulatory information

CE Marking	Index of classification	Notified body	PHTALATES LATEX
CE 0120	Ila	SGS	

The specific design of the pressure cuff can be wrapped around the liquid bag and thereby makes it very easy implementation and cleaning. The pressure is controlled by manometer. Depression is controlled by a valve.

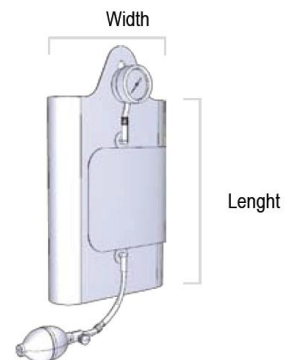
1 - Device identification:

Visual face



2 - References :

Reference	Designation	Size	The bladder dimensions in mm	
			Length	Width
M30500	Transparent polyurethane cuff	500 cc	220	191
M31000	Transparent polyurethane cuff	1 000 cc	333	222
M34000	Transparent polyurethane cuff	4 000 cc	420	440



3 – Use of the device - Mode of employment

- Open the pressure cuff.
- Place the liquid bag to the center of the pressure cuff, output tubes oriented to bulb.
- Insert the fastening system of pressure cuff in the opening of the liquid bag before insert it into the opening made on the pressure cuff.
- Close the pressure cuff by squeezing the movable portion around the liquid bag.
- Using the bulb, breathe the pressure required to maintain the cuff around the liquid bag, suspend all on a drip stand.
- As to the flow of product irrigated, the pressure displayed by the manometer falls gradually : it is necessary to restore order to ensure complete emptying of the liquid.

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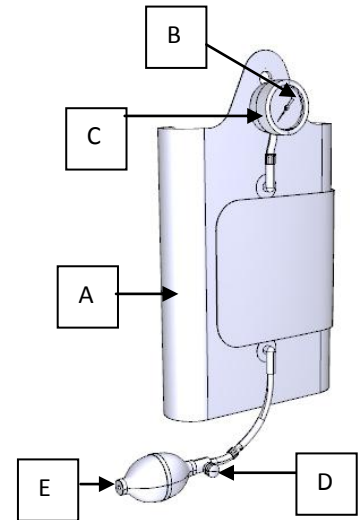
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Certifié ISO 13485

4 – Identification and characteristics of different subsets :

Identifiant	Référence	Dénomination	Caractéristique
A	MS3050	Pressure cuff only 500 cc	Polyurethane
A	MS3100	Pressure cuff only 1000 cc	Polyurethane
A	MS3400	Pressure cuff only 4000 cc	Polyurethane
B	A10807	Manomètre	ABS + glass plexiglass
C	PM50B	Protecteur de manomètre	Silicone
D	A10259	Robinet de poire	ABS
E	A10219	Poire	PVC
E/F	A10226	Poire complète	ABS + PVC



5 - Maintenance :

Visual inspection / watertight : before each use
 Calibration test : every 12 months for manometer.

6 – Cleaning and disinfection :

Surface cleaning	Disinfection with decontamination solution
Complete device	Complete device

7 – Stockage

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 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.

9 - Warning :

Do not use the device near a heat source.

This use could cause device failure and a risk of complications for the patient.