TECHNICAL CHARACTERISTICS



ALLTIME®

WITH SOFTCUFF® OR EASYCUFF®





DESSILLONS & DUTRILLAUX ZI La Tuque – 47240 Castelculier – France www.ddmedical.fr technique@ddmedical.fr

Created in 1949 by Lucien Dessillons. Since its inception, DESSILLONS & DUTRILLAUX has been developing and manufacturing equipment for medical diagnosis, orthopedic surgery and medical resuscitation.

1. Summary

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2. Device identification

The aneroid blood pressure monitor is a medical device that measures blood pressure using a cuff.

The mano-pear type sphygmomanometer with aneroid membrane, very light.

This precision pressure gauge graduated from 0 to 300 mmHg is fixed on an anodized aluminum valve, equipped with a pressure relief wheel.

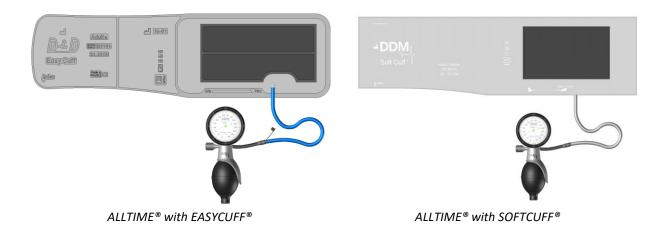
The reading of the measured values is facilitated by the size of the dial. Guaranteed accuracy of \pm 3 mm over the entire measuring range.

The device is available in 6 references:

- ALLTIME[®] with aluminium case only.
- ALLTIME[®] with aluminium case with EASYCUFF[®] cuff.
- ALLTIME[®] with aluminium case with SOFTCUFF[®] cuff.
- ALLTIME[®] with ABS case only.
- ALLTIME[®] with ABS case with EASYCUFF[®] cuff.
- ALLTIME[®] with ABS case with SOFTCUFF[®] cuff.



ALLTIME®



| ALLT | IME® |
|--|----------------------------|
| 40 consticuter PRANCE 260 10 constituter Prance 200 10 constituter Prance | Measuring range 0-300 mmHg |
| 20 DDM 18 since 1949 10 Alltime ® | Product brand |
| Castelculler FRANCE C€ 0459 2 | Manufacturer's address |
| | See instructions for use |
| mmHg | Unit of measurement |
| 00000 | Serial Number |

| EASYCUFF® | | | | | | |
|----------------|---|--|--|--|--|--|
| Index | Index position indication | | | | | |
| | Product brand | | | | | |
| $D \sim D$ | | | | | | |
| Easy Cuff | | | | | | |
| Adulte | Product name and part number | | | | | |
| (REF BM 104) | | | | | | |
| Made in CC | Product origin marking | | | | | |
| (26-33CM) | Range of use of the product | | | | | |
| <u>M</u> 16-01 | Date of manufacture | | | | | |
| | See instructions for use | | | | | |
| Learner | Latex Free | | | | | |
| Lot 4 4 | Batch number | | | | | |
| (Min) Max \ | Range of validity of use of the product | | | | | |
| Max` | Artery placement indication | | | | | |

| ↓ndex | Index position indication | | |
|----------------------------|---|--|--|
| DDM Soft Cuff * | Product brand | | |
| LOT 214 | Batch number on the bladder | | |
| Child / Enfant REF BT02 | Product name and part number | | |
| 11 - 22 CM | Range of use of the product | | |
| Made in FRANCE CE | Product origin marking | | |
| Kan Min Max 🖘 | Range of validity of use of the product | | |
| Artery / Artère Max 🖘 | Artery placement indication | | |
| $\sqrt{60}$ | Machine wash at 60°C maximum | | |
| \bowtie | Do not use a whitener | | |
| \ge | Do not iron | | |
| Latex | Latex Free | | |
| P | Can be dry cleaned with all solvents | | |

3. Reference

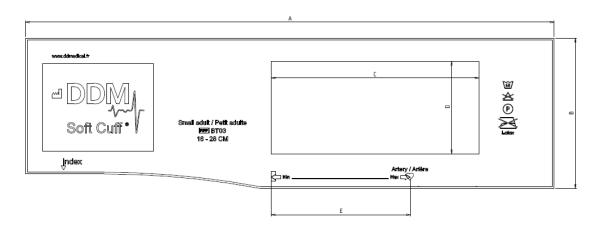
ALLTIME® reference with aluminium body and aluminium case and SOFTCUFF® or EASYCUFF®:

| Designation | Reference with SOFTCUFF® cuff | Reference with EASYCUFF® cuff |
|------------------------|----------------------------------|----------------------------------|
| Pressure gauge alone | A10 | 370 |
| Infant | TS50001 | TI50001 |
| Child | TS50002 | TI50002 |
| Small adult | TS50003 | TI50003 |
| Adult | TS50004 | TI50004 |
| Adult L | TS50005 | TI50005 |
| Adult thigh | TS50006 | TI50006 |
| Manometer with 3 cuffs | TS53000 | TI53000 |

ALLTIME® reference with aluminium body and ABS case and SOFTCUFF® or EASYCUFF® :

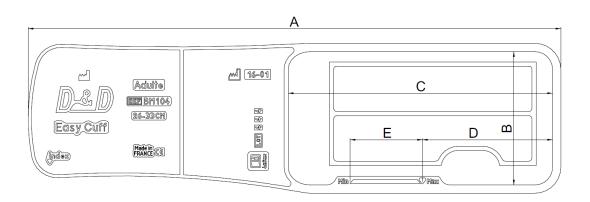
| Designation | Reference with SOFTCUFF [®] cuff | Reference with EASYCUFF® cuff |
|------------------------|--|----------------------------------|
| Pressure gauge alone | A10 | 371 |
| Infant | T60001 | TI60001 |
| Child | T60002 | TI60002 |
| Small adult | T60003 | TI60003 |
| Adult | T60004 | TI60004 |
| Adult L | T60005 | TI60005 |
| Adult thigh | T60006 | TI60006 |
| Manometer with 3 cuffs | T63000 | TI63000 |

Reference and size of SOFTCUFF® cuffs:



| Reference | Designation | Evi+ | Circum in | Dimensions in mm | | | | Tube color | | | |
|------------------------|--------------------------|-------------|--------------|------------------|------|------|-----|------------|-----|------|---|
| With connector and cap | | Designation | Designation | esignation Exit | Min. | Max. | А | В | С | D | E |
| BT101A11313 | Infant size cuff | 1 | 6 | 12 | 173 | 55 | 95 | 40 | 43 | GREY | |
| BT102A11313 | Child-size cuff | 1 | 11 | 22 | 348 | 97 | 180 | 80 | 85 | GREY | |
| BT103A11313 | Small adult size cuff | 1 | 16 | 28 | 458 | 130 | 230 | 110 | 120 | GREY | |
| BT104A11313 | Adult size cuff | 1 | 26 | 33 | 528 | 149 | 260 | 129 | 70 | GREY | |
| BT105A11313 | Large adult size cuff | 1 | 33 | 41 | 633 | 174 | 330 | 150 | 75 | GREY | |
| CT104A11313 | Adult lower limb cuff | 1 | 39 | 55 | 828 | 214 | 440 | 190 | 145 | GREY | |

Reference and size of EASYCUFF® cuffs:



| Reference | Designation | Ev:t | Circum in | Dimensions in mm | | | | Tube color | | | |
|---------------------------|--------------------------|-------------|--------------|------------------|-------|------|-----|------------|-----|-----------|---|
| With connector and cap | | Designation | Designation | Designation Exit | Min. | Max. | А | В | С | D | E |
| BM101A11313 | Infant size cuff | 1 | 6 | 12 | 170 | 40 | 95 | 47,5 | 43 | WHITE | |
| BM102A11313 | Child-size cuff | 1 | 11 | 22 | 338 | 80 | 180 | 90 | 85 | ROSE | |
| BM103A11313 | Small adult size cuff | 1 | 16 | 28 | 423 | 110 | 230 | 115 | 120 | PARMA | |
| BM104A11313 | Adult size cuff | 1 | 26 | 33 | 516 | 129 | 256 | 129 | 70 | SKY BLUE | |
| BM105A11313 | Large adult size cuff | 1 | 33 | 41 | 616,8 | 150 | 330 | 165 | 80 | TURQUOISE | |
| CM104A11313 | Adult lower limb cuff | 1 | 39 | 55 | 816,5 | 190 | 440 | 220 | 160 | VIOLET | |

4. Instructions for use

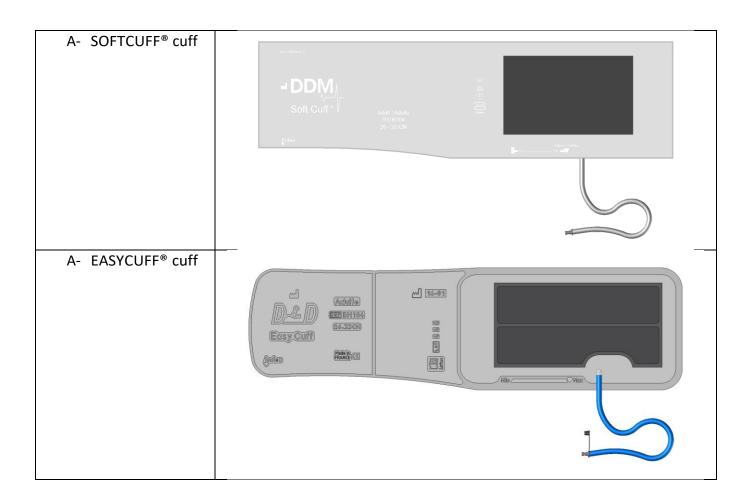
- It is imperative that the cuff has the right connectors for the blood pressure monitor.
- Select a cuff adapted to the patient's morphology. The size and range of use are indicated on the cuff.
- Position the center of the bladder represented by a heart on the axis of the humeral artery.
- Wrap the cuff around the limb.
- Once the cuff is positioned and ready for use, the INDEX must be between the Min and the Max (heart axis). If the INDEX exceeds the Max index at the heart axis, replace the cuff with the larger size model. If the INDEX exceeds the Min index at the tip of the range, replace the cuff with the model of the smaller size.
- When the cuff and INDEX are correctly positioned the blood pressure measurement procedure can begin.
- Wrap the cuff properly around the limb and ensure its retention using the intended fastening system.
- Position the tips of the stethoscope lyre to your ears, the microphone in the listening position, just below the cuff, on the path of the artery.
- Ensure that the pear pressure relief screw is in the closed position and inflate to 30 or 40 mmHg above the assumed pressure. The blood no longer circulates at the microphone, no sound is audible to the stethoscope.
- Lightly unscrew the pear decompression screw to slowly reduce the inflation pressure and allow blood to flow again, the first beats are noticeable to the stethoscope.
- Read at this moment the pressure indicated by the manometer, this value corresponds to the maximum pressure or systolic pressure.
- Continue decompression, the beats perceived with the stethoscope amplify and then fade to become inaudible.
- Read at this time the indicated pressure, this reading corresponds to the minimum pressure or diastolic pressure.
- Unscrew the decompression wheel further to completely purge the remaining air in the bladder.
- Remove the cuff.

5. Terms of Use

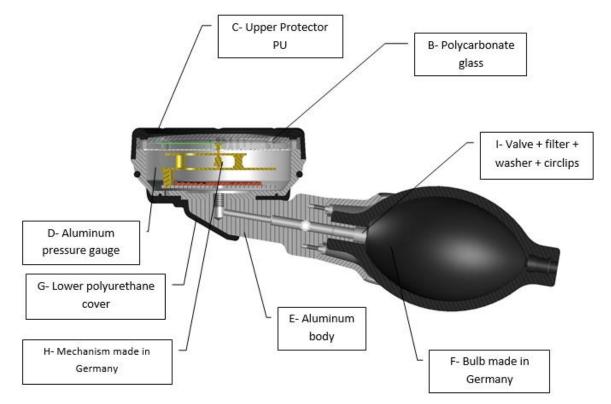
| Ambient temperature | Relative humidity | Atmospheric pressure |
|---------------------|-------------------|----------------------|
| + 10° C to + 40° C | 30% to 100% | 700 hpA to 1060 hpA |

6. Identification and characteristics of the different sub-assemblies

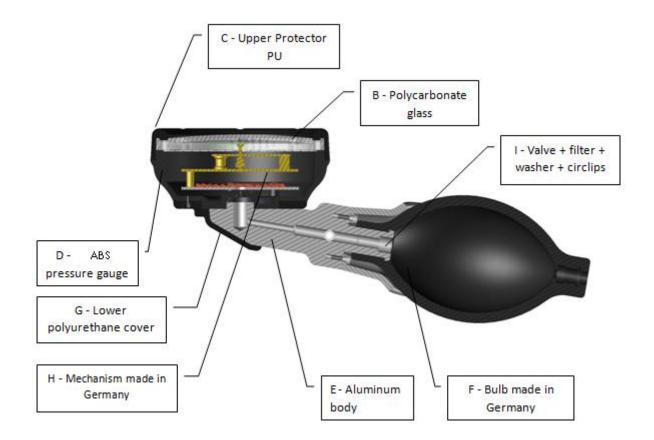
| Identifier | Reference | Denomination | Characteristic |
|------------|----------------------------|------------------------------------|--|
| А | SOFTCUFF [®] cuff | Velcro cuff + bladder | Fabric with antibacterial coating and treatment and PU coated |
| A | EASYCUFF [®] cuff | Monobloc cuff | HF welded PU coated fabric |
| В | A10362 | Glass | Polycarbonate |
| С | A10363 | Upper pressure gauge protector | Polyurethane |
| D | A10364 | Pressure gauge case | Aluminium |
| D | A10369 | Pressure gauge case | ABS |
| E | A10365 | Body | Aluminium |
| F | A10226 | Inflation pear | Phthalate-free PVC |
| G | A10366 | Lower pressure gauge protector | Polyurethane |
| Н | A10367 | Mechanism 0-300 mmHg | Brass |
| I | A10368 | Valve + filter + washer + circlips | Silicone – polyamide – steel – steel |



ALLTIME® with aluminium body and aluminium case:



ALLTIME[®] with aluminium body and ABS case:



7. Maintenance

- Calibration check every 12 months for the pressure gauge.
- Under no circumstances should a liquid penetrate inside the pneumatic part of the cuff, as this could partially or totally damage the electromedical device or manual measuring device to which the cuff is connected.
- In order to avoid any risk, we recommend DDM filling system: A11313 connector and cap.
- Under no circumstances should a tubing be "clamped" using pliers or other unsuitable instruments.
- Under no circumstances should the cuff be handled with any sharp object.
- Under no circumstances should the cuff be inflated without being wound and closed with the two Velcro parts on a round limb or tube without edges and sharp parts.

8. Cleaning and decontamination

EASYCUFF[®] and SOFTCUFF[®] are not sterilizable.

| Reference | Dry cleaning | Immersion cleaning |
|------------------|--------------|--------------------|
| A10370 | Х | |
| A10371 | Х | |
| EASYCUFF® | Х | Х |
| SOFTCUFF® | Х | Х |

a. Cleaning the pressure gauge

A Spraying of decontaminating solutions. Do not use detergent, do not immerse.

b. Dry cleaning SOFTCUFF® and EASYCUFF®

Recommended product: DETERQUAT / ANIOS.

| A | Spray a detergent, disinfectant, bactericidal foam on the cuff, taking care to distribute the product well. |
|---|---|
| В | Leave on for 15 minutes. |
| С | Rinsing is useless, wipe with a single-use wipe. |

c. SOFTCUFF[®] immersion cleaning

Recommended product: ANIOS'CLEAN EXCEL D / STERANIOS.

| Α | Remove the bladder from the cuff. | | | |
|---|---|--|--|--|
| В | Clean the cuff with water or in the washing machine at 40 $^{\circ}$ (60 $^{\circ}$ being the maximum), without | | | |
| | spinning. The number of machine washes as well as the washing temperature reduces the duration | | | |
| | of use of the cuff. | | | |

d. EASYCUFF[®] immersion cleaning

Recommended product: ANIOS'CLEAN EXCEL D / STERANIOS.

| Α | Seal the tube(s) with the closure system provided: | | | |
|---|--|--|--|--|
| | Connector with cap: A11313 | | | |
| В | Immerse the tube and cuffs in a solution. | | | |
| С | Immersion time: 15 minutes. | | | |
| D | Rinse thoroughly with water, renewal of the soaking bath after each use. | | | |

9. Storage

Any cuff awaiting use must be kept under the conditions below:

| Type of packaging | Local | Temperature | Humidity | Pressure |
|-------------------|--------------------|--------------------|-------------|------------------------|
| Origin | Ventilated room | + 10° C to + 70° C | 10% to 100% | 500 hpA to 1060 hpA |

10. Conditioning

| Refer | ences | Number of units per package |
|---------|---------|-----------------------------|
| A10 | 370 | 1 |
| TS50001 | TI50001 | 1 |
| TS50002 | TI50002 | 1 |
| TS50003 | TI50003 | 1 |
| TS50004 | TI50004 | 1 |
| TS50005 | TI50005 | 1 |
| TS50006 | TI50006 | 1 |
| TS53000 | TI53000 | 3 |
| A10 | 371 | 1 |
| T60001 | TI60001 | 1 |
| T60002 | TI60002 | 1 |
| T60003 | TI60003 | 1 |
| T60004 | TI60004 | 1 |
| T60005 | TI60005 | 1 |
| T60006 | TI60006 | 1 |
| T63000 | TI63000 | 3 |

11. Security, reliability, compatibility and warranty

a. Security

DDM cuffs are made in accordance with European and National standards IEC 601-2/30. DDM cuffs do not contain latex.

The class and type of protection against electric shock are also related to those of the electromedical device or manual device to which the cuff can be connected.

Cuffs can in no way be responsible for incidents occurring in the event of non-compliance with the rules of installation and use in this documentation.

Classification according to the recommendations of European Directive 93/42 Class I for cuffs and Class Im for the pressure gauge.

b. Reliability

The performance of DDM cuffs is directly related to that of the electromedical or manual device to which they are connected. Failure to comply with the rules for the application of this documentation may lead to erroneous measures.

c. Compatibility

DDM cuffs must be used with compatible connectors indicated by the manufacturer of the measuring medical device.

d. Guarantee

The warranty assures the Customer who purchases a DDM medical device that if the medical device does not function as indicated in the instructions for use, it will be replaced or repaired.

The duration of this warranty is 24 months for the pressure gauge and 12 months for the cuffs.

The product must be used in accordance with the labelling, it must not have been modified or has been the subject of an accident or erroneous, abusive or inappropriate use.