

Single-patient-use NIBP Cuffs

User Manual

Intended Use & Indications for Use

The NIBP cuffs are accessories be used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile. It is available in neonate, infant, child and adult sizes.

Contraindication

Blood pressure cuffs for children to adults of all ages are strictly prohibited for use on neonates.

Operating Conditions

- Ambient temperature: 0°C to +40°C
- Relative humidity: 15% to 85%
- Atmospheric pressure: 86 kpa ~ 106 kpa

Storage & Packaging

Each cuff is individually packaged.

Cuffs must be stored in their original packaging and within the storage conditions to maximize the storage life.

Storage conditions are as follows:

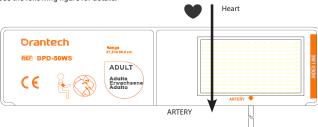
- Ambient temperature: -10°C to +40°C
- Relative humidity: 15% to 85%
- Atmospheric pressure: 86 kpa ~ 106 kpa

Shelf Life

2 years.

Instructions for Use

- Select appropriate blood pressure measurement site. Because normative values are generally
 based on this site and as a matter of convenience, upper arm is preferred. When using the upper
 arm choose correct cuff accordingly, taking into account the patient's cardiovascular status and
 the effect of alternative site on blood pressure values, proper cuff size and comfort.
- If patient is standing, sitting, or inclined ensure that cuffed limb is supported to keep cuff level
 with patient's heart. If cuff is not at heart level, the difference in systolic and diastolic values due
 to hydrostatic effect must be considered.
- Select appropriate cuff size. Measure patient's limb and select appropriately sized cuff according
 to size marked on cuff or cuff packaging. When cuff sizes overlap for a specified circumference,
 choose the larger size cuff. Accuracy depends on use of proper size cuff.
- Before use, check that the cuff, cuff tubing and hose are clean and free of damage. Replace cuff
 when ageing, tearing or weak closure is apparent. Do not inflate cuff when unwrapped. Do not
 use cuff if structural integrity is suspect.
- Inspect patient's limb prior to application. Do not apply cuff to areas where skin is not intact or tissue is injured. Ensure hook does not contact skin; contact may cause irritation.
- Palpate artery and place cuff so that patient's artery is aligned with cuff arrow marked "artery".
 See the following figure for details.



- Squeeze all air from cuff and confirm that cuff is connected to a non-invasive blood pressure
 measurement device. Ensure that connection is secure and that tubing is not kinked.
- Wrap cuff snugly around the patient's limb. Cuff index line must fall within range markings.
 Ensure that hook and loop closures are properly engaged so that pressure is evenly distributed throughout cuff. If upper arm is used, place cuff as far proximally as possible.
- Proper cuff wrapping should be snug but should still allow space for a finger between patient
 and cuff. Cuff should not be so tight as to prevent venous return between determinations.

Warning

- Connect cuffs and inflation systems only to systems designed for non-invasive blood pressure monitoring.
- Do not connect cuff to intravascular fluid systems which may allow air to be pumped into a blood vessel which could lead to serious patient injury.
- Do not apply external pressure against cuff while monitoring. This may cause inaccurate blood pressure values.
- ▲To optimize performance and accuracy, minimize limb movement/cuff motion.
- Avoid contact with the cuff while monitoring since it may cause inaccurate blood pressure values.
- Devices that exert pressure on tissue have been associated with purpura, skin avulsion, compartmental syndrome, ischemia and/or neuropathy.
- Do not obtain readings more frequently than clinically indicated, weighing benefits of frequent measurement against risk.
- Check cuff site and extremity frequently for signs of impeded blood flow, especially when monitoring at frequent intervals and/or over extended periods of time. Rotate site if appropriate.
- ARemove cuff from patient when monitoring has been suspended.
- Do not apply cuff to limb used for intravenous infusion or areas where circulation is compromised.
- \(\text{\Delta}\) Use care when placing cuff on extremity used to monitor other patient parameters.
- ▲Do not apply cuff to areas where skin is not intact or tissue is injured. Ensure that the rough side

- of the closure does not contact skin; contact may cause irritation.
- Do not obtain readings more frequently than clinically indicated, weighting benefits of frequent measurement against risk.
- · Apply cuff according to instructions.



Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

Waste Disposal

Please refer to your local laws and regulations for information on how to dispose of NIBP Cuffs.

Title of Symbol



Manufacturer



Catalogue number



Batch code



Serial number



Not made with natural rubber latex



Refer to instruction manual /booklet



Non-sterile

Rx only(U.S.)

Federal (U.S.) Law restricts this device to sale by or on the order of a physician



Use-by date



Caution



Warning



Date of manufacture



Crossed out wheelie bin indicates separate treatment from general waste at end of life. Waste of Electrical and Electronic Equipment Directive (WEEE).



Authorized Representative in the European Community



CE Mark



Single patient use



Medical device



Unique Device Identifier

Support

To get the support, please contact the representative of manufacturer or local distributor. The categories shown below are available for sale through the local distributors or e-commerce.







Orantech Inc.

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