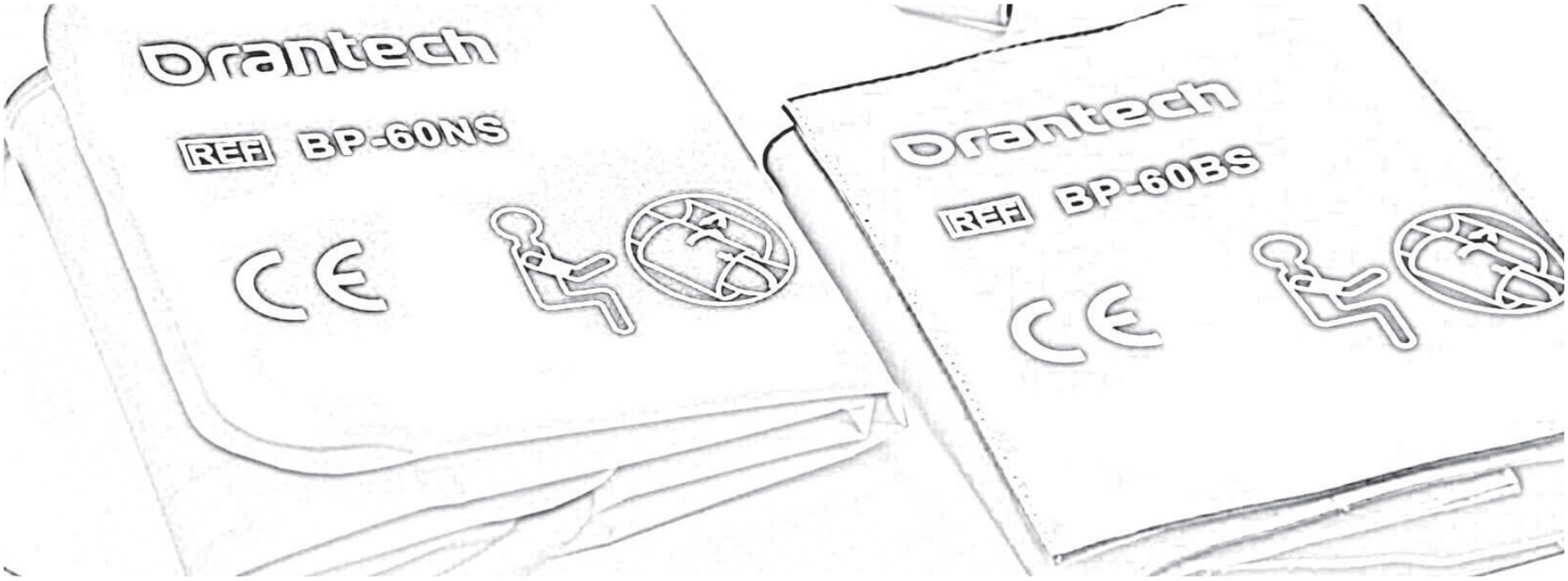
Drantech

The **difference** you can **sense**

CE



Reusable 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 and may be reused. It is available in neonate, infant, child and adult sizes.

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

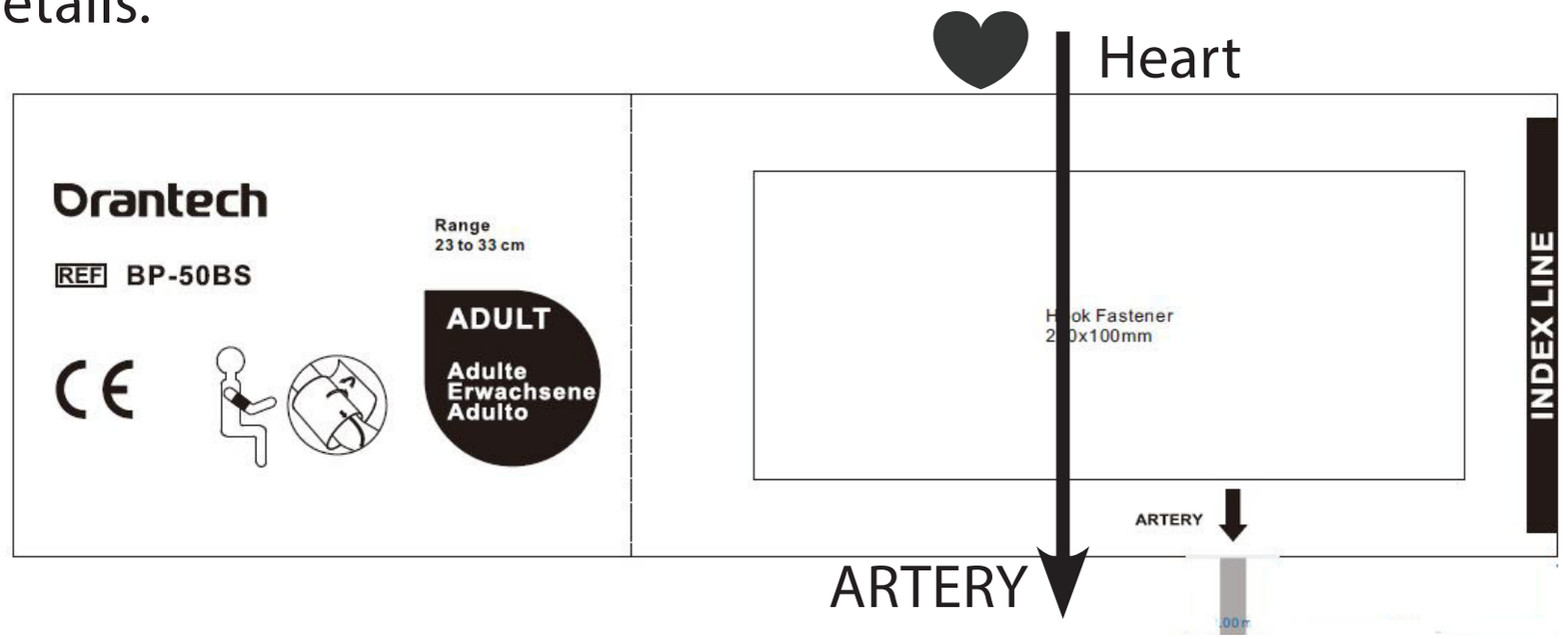
5 years.

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.

Cleaning

Product must be thoroughly cleaned with the specified detergent before reuse. The additional use of household bleach as described below provides at least low-level disinfection.

- Reusable NIBP cuffs have been subjected to 20 successive applications of the following cleaning/disinfection method with no apparent negative effect. While this procedure is adequate for disinfection, it may not remove all stains.
- Care must be taken to avoid liquid entering into the cuff tubing, air hose openings and inflation system valves. Liquid in the airway may affect blood pressure determination accuracy and damage automatic or manual monitors.

Materials

- Enzymatic detergent such as ENZOL® enzymatic detergent (US) or Cidezyme® enzymatic detergent (UK)
- Distilled water
- 10% solution of household bleach in distilled water
- Soft cloths and soft-bristled brushes
- Spray bottles

Procedure

- Prepare the enzymatic detergent (ENZOL® enzymatic detergent (US) or Cidezyme® enzymatic detergent (UK) or equivalent and distal water) according to the manufacturer's instructions, and 10% bleach solution, in separate spray bottles.
- Spray detergent liberally on product. If material is dried on, allow to sit for 1 minute.
- Wipe smooth surfaces with a soft cloth. Use a soft-bristle brush on visibly soiled areas and irregular surfaces.

Note: Take particular care when cleaning the bulb and control valve on a Complete Inflation System. Do not allow fluid to enter back valve or saturate knob.

- Remove visible contaminants from the periphery and the underside of the control knob.
- Rinse with copious amounts of distilled water.
- To disinfect, spray 10% bleach solution on affected area until saturated and allow sitting for 5 minutes.
- Wipe away excess solution and rinse product again with distilled water. Allow cuff to air dry.

Warranty & Liability

Orantech offers 6 months warranty against defects in material or

workmanship from the date of purchase. But does not include the damage or breakage due to the abusive use or negligent care of the cuffs.
Orantech reserves the right to perform warranty service at its own facility. We guarantee that the products conform to the specifications of the safety and performance standards currently in force and applicable to it.

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.
- Remove cuff from patient when monitoring has been suspended.
- Do not apply cuff to limb used for intravenous infusion or areas where circulation is compromised.
- 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.

Caution

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

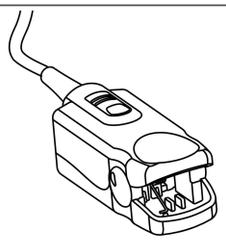
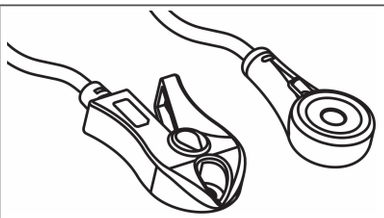
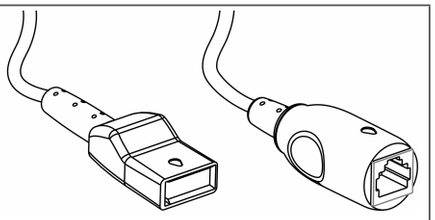
Title of Symbol

	Manufacturer
REF	Catalogue number
LOT	Batch code
SN	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
Index Line	Index Line

	Caution
	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)
EC REP	Authorized Representative in the European Community
CE	CE Mark
ARTERY 	Artery symbol and arrow should be placed over brachial or femoral artery
| ←RANGE→ |	Cuff index line must fall within range markings

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.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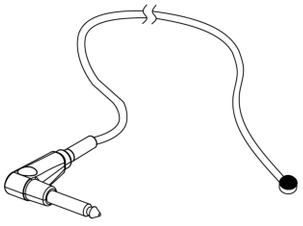	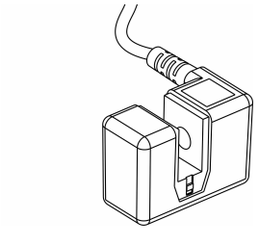	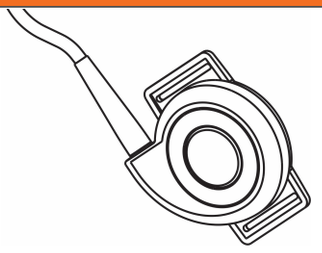	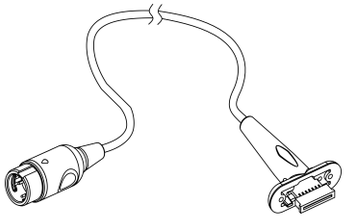
TEMP	$EtCO_2$	FETAL	EEG

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