GE Healthcare

ENGLISH

GE CRITIKON* Blood Pressure Cuffs and Accessories

DESCRIPTION

Blood pressure (BP) is measured by inflating a flexible cuff placed around the patient's limb. As it inflates, the cuff blocks blood flow in the limb's artery. When the air is gradually let out of the cuff, blood flow resumes. The pressure inside the cuff is provided directly on an aneroid gauge in manual BP measurement. Automated systems use a software algorithm to provide a Systolic/Diastolic/Mean Arterial BP measurement.

GE CRITIKON BP products are to be used by persons with knowledge or training of noninvasive blood pressure measurement. Intended conditions/environments for use are clinical settings such as a hospital, surgery center or a physician office and during patient transport.

GE CRITIKON Cuffs are available in 1-tube and 2-tube configurations. Cuffs are color coded for size selection. Inflation systems include a cuff, tubing, inflation bulb and valve.

Nominal range for the cuff pressure is 0-150mmHg for neonatal BP measurement and 0-300mmHg for Adult /Pediatric.

The operating conditions of NIBP products in normal use are 0° to +46° C (+32 to +115°F); 15-90% humidity. Store within the conditions of -20° to +55° C (-4° to 131°F); 15-95% humidity.

Refer to documentation provided by the gauge manufacturer for gauge accuracy information.

Comply with regional law when non-automated sphygmomanometer or accessory is discarded.

Note: Limited reuse is a term that applies to a cuff that may be reused but is less durable than a standard reusable cuff.

INDICATIONS

GE CRITIKON blood pressure cuffs are accessories used in conjunction with noninvasive blood pressure (NIBP) measurement systems. SOFT-CUF*, CLASSIC-CUF* cuffs and inflation systems are non-sterile and semi-disposable (may be single-patient use or optional limited reuse). They are available in neonatal, pediatric and adult sizes. DURA-CUF* and SENSA-CUF* cuffs and inflation systems are non-sterile and may be reused. They are available in pediatric and adult sizes. The devices are not designed, sold or intended for use except as indicated.

GENERAL BP MEASUREMENT GUIDELINES

Patient should be comfortably seated with legs uncrossed, back and arm supported. The middle of the cuff should be at the level of the right atrium during BP measurement. The patient should relax as much as possible and not talk or move during the measurement procedure. It is recommended that 5 minutes elapse before the first reading is taken. It is recommended that the operator is standing or seated next to the patient during a manual BP measurement.

During manual BP measurement, it is recommended K5 be used in auscultation of adults, and K4 in auscultation of children aged 3 to 12. For pregnant women, K5 should be used unless sounds are audible with the cuff deflated in which case K4 should be used.

NOTE: K5 is the point at which the Korotkoff sounds can no longer be heard. K4 is the change in the tones heard through a stethoscope from a clear tapping sound to a muffled sound.

Some symbols may not appear on all products.

SYMBOLS	DESCRIPTIONS
Rx Only	CAUTION: Federal law restricts this device to sale by or on the order of a physician.
	Indicates which side of cuff is applied to patient
	Not made with PVC
REF	Catalog or orderable part number
LONG	Long cuff size
ARTERY 	Artery symbol and arrow should be placed over brachial artery
	Not made with DEHP
CE	European Union Conformity Mark (First CE Marked 2013)
 OR LATEX FREE	Not made with natural rubber latex
	Date of Manufacture
LOT	Lot/Batch number, DDD(Ordinal Day)YY(Year)XXXX or Lot/Batch number (Package)
– Index Line –	Index Line
	Cuff index line must fall within range markings
	Caution
	Consult Instructions for Use
	Identifies a device providing an interface between equipment
	Manufacturer name and address
UDI	Unique Device Identification

SYMBOLS	DESCRIPTIONS
GTIN	Global Trade Item Number
EC REP	European Authorized Representative
	1-tube cuff configuration
	2-tube cuff configuration
	Bulb configuration
Single Patient Use	For Single Patient Use Only

NEONATAL CUFF SIZES

SYMBOLS	DESCRIPTIONS (cuff size)	COLOR	RANGE: (limb circumference)
	#1 3 - 6 cm #1	Orange	3 - 6 cm
	#2 4 - 8 cm #2	Light Blue	4 - 8 cm
	#3 6 - 11 cm #3	Green	6 - 11 cm
	#4 7 - 13 cm #4	Blue	7 - 13 cm
	#5 8 - 15 cm #5	Rose	8 - 15 cm

ADULT/PEDIATRIC CUFF SIZES

SYMBOLS	DESCRIPTIONS (cuff size)	COLOR	RANGE: (limb circumference)
INFANT	Infant	Orange	8 - 13 cm
CHILD	Child	Green	12 - 19 cm
SMALL ADULT	Small Adult	Light Blue	17 - 25 cm
ADULT	Adult	Navy Blue	23 - 33 cm
LARGE ADULT	Large Adult	Rose	31 - 40 cm
THIGH	Thigh	Brown	38 - 50 cm

OPERATING WARNINGS

- **Apply cuff according to instructions.**
- **Connect cuffs and Inflation systems only to systems designed for noninvasive blood pressure monitoring.**
- **Do not connect the cuff to intravascular fluid systems which could allow air to be pumped into a blood vessel, which could lead to serious patient injury.**
- **Do not apply cuff to limb used for intravenous infusion, arterial monitoring, where AV fistulas are present, or areas where circulation is compromised. Assess limb for risk of lymphedema (due to mastectomy,etc.).**
- **Do not apply cuffs to areas where skin is not intact or tissue is injured, or where dermal disruption is at greater risk. Ensure that the rough side of the closure does not contact skin; contact may cause irritation.**
- **Do not apply the cuff to the upper arm if the width of the cuff is greater than the length from the armpit to the elbow of the patient.**
- **Do not obtain determinations more frequently than clinically indicated, weighing benefits of frequent measurement against risk.**
- **Check cuff/adapter/air hose, cuff site, and cuff limb frequently. Signs of impeded blood flow, especially when monitoring at frequent intervals and/or extended periods of time should be checked frequently. Rotate site if appropriate.**
- **Devices that apply pressure on tissue have been associated with purpura, skin avulsion, compartment syndrome, ischemia, thrombosis, and/or neuropathy.**
- **Avoid contact with the cuff while monitoring, since it may cause inaccurate blood pressure values.**
- **To assure accuracy, minimize limb movement/ cuff motion.**
- **Use care when placing the cuff on limbs used to monitor other patient parameters.**
- **Remove cuff from patient when monitoring has been suspended.**
- **The performance of the non-automated sphygmomanometer can be affected by extremes of temperature and humidity beyond those defined within this document.**
- **No modification of this equipment is allowed.**
- **Single Patient Use Cuff is designed to be used on a Same Single Patient during a normal hospital stay. It is not designed or validated to be used on multiple patients. Discard Cuff after use. Reuse may cause a risk of cross-contamination.**

INSTRUCTIONS FOR USE

1. Measure patient's limb and select appropriately sized cuff according to the size marked on the cuff or on the cuff packaging. When cuff sizes overlap for a specified circumference, choose

the larger size cuff. Accuracy depends on use of a properly sized cuff.
2. Before use check that the cuff, cuff tubing and hose are clean and free of damage. Replace cuff when aging, tearing or when weak closure is apparent. Do not inflate cuff when not on patient.
3. Select the appropriate blood pressure measurement site. Inspect patient's limb prior to application (read Operating Warnings).
4. Apply the cuff by wrapping it around the limb ensuring the INDEX LINE (INDEX LINE) falls between the RANGE (RANGE) marks on the cuff. If it does not, either a larger or a smaller cuff should be used. Make sure to align arrow marked ARTERY (ARTERY) over the patient's brachial artery (or popliteal artery for thigh measurement). Press the rough and soft sides of the closure together.
5. The cuff should be snug, but not too tight; allowing space for two fingers to fit between the patient and the cuff.
6. For automated BP measurement, connect the cuff to the hose/adapter ensuring proper engagement of the connectors.
7. For manual BP measurement, the valve is closed by rotating the control knob clockwise. Squeeze the bulb repeatedly until the desired pressure is obtained (shown on the gauge). Rotate the control knob counter-clockwise to release the air in the cuff.

CLEANING AND DISINFECTION

- Consider discarding any product grossly contaminated with blood or other bodily fluids.
- The user has the responsibility to validate any deviations from the recommended method of cleaning and disinfection.
- When cleaning, liquid cannot enter any tubing. Liquid in the airway may affect blood pressure determination accuracy and damage automatic or manual monitors. User can either isolate that area or use wash plugs.

CLEANING INSTRUCTIONS

(For Cuffs, Adapters, Hoses and inflation Systems)
Note: When rinsing, care should be taken to prevent liquid from entering the cuff orifices like tubing etc.

Note: Limited reuse is a term that applies to a cuff that may be reused but is less durable than a standard reusable cuff.

Use one of the following methods and allow to air dry before reuse:

1. Clean with Enzymatic detergent, such as ENZOL® enzymatic detergent (US) or Cidezyme® enzymatic detergent (UK) prepared according to the manufacturer's directions. Rinse.
2. Clean with 10% solution of household bleach (5.25% sodium hypochlorite) (diluted with distilled water). Rinse.
3. Clean with 70% isopropyl alcohol.
4. Clean with a wipe consisting of one or more of the following chemical composition.
   a. n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides - 0.25%
   b. n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides - 0.25%
   c. Sodium Hypochlorite - 0.60%
   d. Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium Chloride - 0.07%
   e. Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium Chloride - 0.07%

LOW-LEVEL DISINFECTION INSTRUCTIONS

(For Limited Reuse and Reusable Cuffs Only)
Exposed surfaces of the cuff withstand the successive number of disinfection cycles shown below with no apparent negative effect.

CUFF STYLE	DISINFECTION CYCLES ALLOWED
SOFT-CUF	1000
CLASSIC-CUF	1000
SENSA-CUF	1500
DURA-CUF	2000

1. Fill a spray bottle with Enzymatic detergent, such as ENZOL® enzymatic detergent (US) or Cidezyme® enzymatic detergent (UK), prepared according to the manufacturer's directions.
2. Take precautions to avoid liquid from entering the cuff tubing. Liquid in the tubing may affect blood pressure determination accuracy and damage automatic or manual monitors. Either isolate that area from the spray, or consider using wash plugs.
3. Spray the detergent solution as prepared in step 1 liberally on the cuff and tubing. On heavily soiled areas or areas where soil is dried on, allow the cleaning agent to sit on the cuff and tubing for 1 minute.

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.

4. Wipe smooth surfaces with soft clean cloth. Use a soft-bristled brush on visibly soiled areas and irregular surfaces.
5. Rinse with copious amounts of water, distilled is preferred.
6. Repeat as necessary.
7. To disinfect, fill a spray bottle with 10% solution of household bleach (5.25% sodium hypochlorite) in distilled water. Spray this solution on the cuff until saturated and allow to sit for 5 minutes.
8. Wipe away excess solution with soft clean cloth.
9. Rinse with copious amounts of distilled water.
10. Allow cuff to air dry before reuse on multiple patients.

Product in compliance with applicable sections of EN 1060 - Specification for Non-Invasive Sphygmomanometers
Part 1: General requirements
Part 2: Supplementary requirements for mechanical sphygmomanometers
Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

Rx Only CE

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