Reusable Blood Pressure Cuff

English

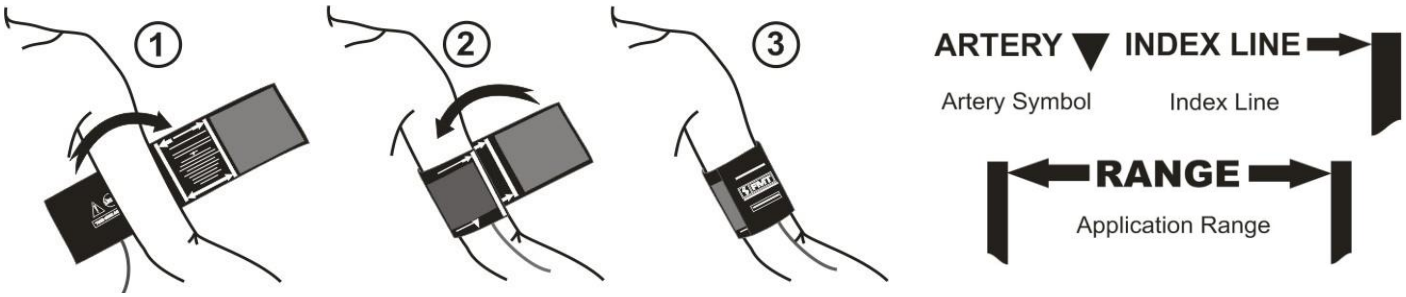
Product Description:
Blood pressure cuffs are used to determine systolic and diastolic blood pressure with non-invasive mechanical or electro-mechanical sphygmomanometers.

FMT- SX Single Tube Cuff with bladder (X is cuff size; 6 Thigh, 5 Large Adult, 4L Adult Extra Long, 4 Adult, 3 Small Adult, 2 Pediatric and 1 Infant size)
FMT- DX Double Tube Cuff with bladder (X is cuff size; 6 Thigh, 5 Large Adult, 4L Adult Extra Long, 4 Adult, 3 Small Adult, 2 Pediatric and 1 Infant size)
FMT- SBX Single Tube Bladderless Cuff (X is cuff size; 6 Thigh, 5 Large Adult, 4L Adult Extra Long, 4 Adult, 3 Small Adult, 2 Pediatric and 1 Infant size)
FMT- DBX Double Tube Bladderless Cuff (X is cuff size; 6 Thigh, 5 Large Adult, 4L Adult Extra Long, 4 Adult, 3 Small Adult, 2 Pediatric and 1 Infant size)

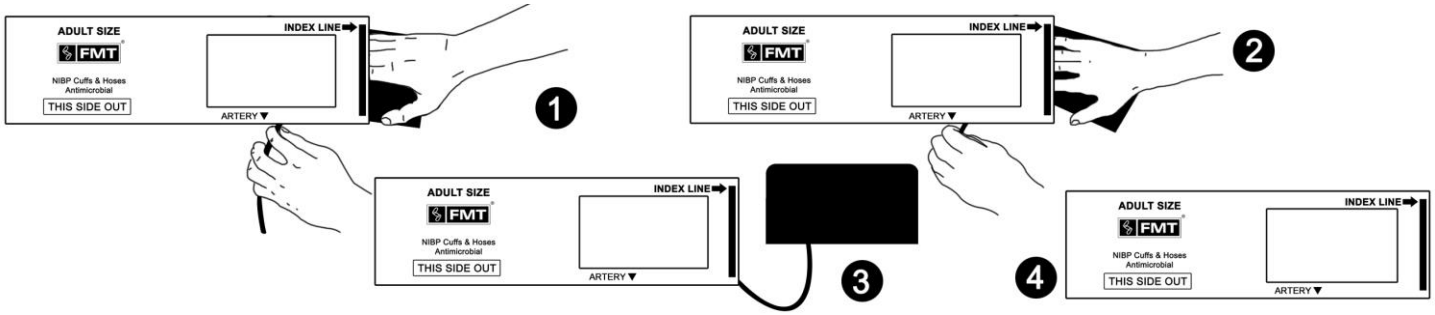
Directions for Use:
Blood pressure measurements should be taken by trained personnel following established procedures. Blood pressure measurements can be affected by the position of patient and their physiologic condition. Before beginning a procedure, ensure that the patient rests for at least five minutes, has support of their back and feet, and does not cross their legs. Passively support the patient's lower arm and keep the upper arm at heart level. The procedure needs to take place in a quiet environment with no talking. Failure to follow these recommendations can result in inaccurate blood pressure measurements.

■ The upper arm is the preferred site for the placement of the cuff. The forearm and ankle can also be used. If a large cuff does not fit to the upper arm adequately, use an alternate site.
■ Select the appropriate size cuff based on the patient's arm circumference. The applicable range, in centimeters, is printed on each cuff.
■ The bladder (or inflating part of the cuff) width should be 40% of the arm circumference with the bladder length encircling at least 80 percent of the arm; 100 percent for a child's arm. Use of the wrong size cuff can affect the accuracy of the measurement.
■ Remove clothing from the limb before positioning cuff. Place the cuff on a bare limb.
■ Apply cuff to the arm (or thigh) such that the side labeled **"THIS SIDE AGAINST SKIN"** contacts the patient. Align the artery symbol (▼) labeled **ARTERY** to the brachial (or femoral) artery.
■ Wrap cuff snugly around the limb, allowing room for no more than two fingers underneath. Close the hook and loop fasteners.
■ Verify white line marked with **INDEX LINE** at the end of cuff closes to tubing falls within the size **RANGE** lines printed on the cuff interior. The INDEX LINE at the edge of the cuff should reach into, but not extend beyond, the RANGE marking on the cuff. If they do not line up, use a different size cuff.
■ When using electronic NIBP units; attach the cuff tubing connector(s) to the extension hose connector. Ensure that the hose is routed to avoid kinking or compression. Attach the NIBP extension hose to the NIBP pneumatic fitting on the patient monitor.
■ When using manual manometers; attach one tube to a bulb and valve. Attach the other tube to the coiled tubing on the blood pressure manometer or to the tube fitting on the aneroid gauge.
■ Take blood pressure in the normal manner. For electronic blood pressure monitoring, be sure to follow the monitor manufacturer's instructions.

Notice: Use proper size cuff; if two cuff sizes fit, use the larger one.



Cleaning:
■ Before washing the cuff, remove other inflation system parts (bladder, bulb, valve) if available. Remove the bladder according to the steps shown in the below diagram. For bladderless cuffs, remove the tube fitting(s) and close off tube(s) with the plug(s) (available as accessory P/N BP00) to prevent fluid from entering tubing. Fluid in tubing will damage monitoring equipment.
■ Close the hook and loop fasteners.
■ Machine wash in warm water, then dry at warm setting. Wash and rinse temperatures should not exceed 30 ºC / 86 ºF.
■ Cuff may be hand washed with mild detergent and drip-dried.
■ When the cuff completely dried, reassemble the tube fitting(s).



FRM.85/REV.08 (28/06/2019)

Metko Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.
İvedik O.S.B. Ağaç İşleri Sanayi Sitesi 1354. Cad. 1358. Sok. No:9
06378 Yenimahalle - Ankara / Turkey Tel: +90 312 3871246 (pbx)
Fax: +90 312 3871251 www.metkoltd.com metko@metkoltd.com

Disinfection and Sterilization:
Do not use steam or heat to sterilize the cuff. Ethylene oxide (EtO) gas sterilization may be used if necessary. FMT cuffs have been determined to withstand cleaning with classes of cleaners listed below when used in accordance with labeled instructions. Prolonged use of these disinfectants at full strength may cause discoloration and degradation. Ensure that no liquid enters tubing.

Anionic Cleaners (e.g., Alconox), Isopropyl Alcohol 70%, Quaternary Ammonium Cleaners (e.g., Steris Coverage Plus NPD), Mild Soap and Water, Enzymatics (e.g., Metrazyme).

Note: FMT does not make any claims as to the efficacy of these chemicals for infection control. Please consult your hospital's Infection Control Officer for applicable disinfection policies.

Warning: Clean or disinfect the cuff before attaching to a new patient.
Caution: Do not press with hot iron.
Caution: Do not wash cuff with natural fibers such as cotton or wool, as these fibers will cling to the hook and loop.

Warnings:
1- Limb circumference ranges are printed on each cuff. Be sure cuff is correctly matched to patient type and size. Cuffs that are too small may produce false high blood pressure measurements; cuffs that are too large may produce false low pressure measurements.
2- Never connect intra-arterial or intra-venous lines, or any other Luer connectors, to the NIBP tubing. This can cause serious injury or death. Do not use Luer connectors.
3- Do not attach the cuff to a limb being used for intra-venous infusion or SpO2 monitoring. Cuff inflation might block the infusion, causing harm to the patient and in accurate measurements.
4- Do not repeat NIBP measurements at intervals less than 3-5 minutes over an extended period of time. Rapidly repeating measurements can impair circulation in the monitored limb.
5- Do not place an NIBP cuff on an extremity with impaired circulation. It can lead to further compromise in patient's circulation if the cuff inflated too high.
6- It is recommended to change the cuff site every four (4) hour if blood pressure is being monitored frequently.
7- Check patient regularly for signs of skin irritation or impaired circulation in the monitored limb.
8- Ensure that the tube is not kinked or obstructed before taking measurements. This may cause inaccurate measurements.
9- As with all medical equipment, carefully route hoses to reduce the possibility of patient entanglement or strangulation.
10- Do not allow a blood pressure cuff to remain on patient for more than 10 minutes when inflated above 10 mm Hg. This may cause patient distress, disturb blood circulation, and contribute to the injury of peripheral nerves. Promptly remove cuff from patient when monitoring is not in process.
11- Periodically inspect and replace damaged or deteriorated cuffs. Replace cuffs if hook and fastener fails to hold during inflation. If artery, index or ranges markings are not visible, do not use the cuff. Replace cuff when damaged, clogged or visibly contaminated. Replace cuff if the monitor displays a message that a leak has been detected.
12- Dispose cuffs according to local laws and regulations.
13- Follow your institution's guidelines for long-term patient care.

Storage:
The packed product should be stored at a temperature between 0°C to 50°C (32°F to 122°F) and relative humidity between 20%-80%.
During the storage the products should be protected from sun light. It is recommended to store the products in original packages until the first use.

Warranty:
FMT reusable cuffs are under twelve (12) months warranty against material and workmanship defects from the date of original purchase. In warranty period, METKO will be responsible for repairing the cuff or change the cuff free of charge if the defect is proven. This warranty does not extent to any product that has been subject to misuse, neglect or accident; or that has been damaged by causes external to the product; or that has been used in violation of the operating instructions supplied with the product.

The information in this instruction insert has been carefully checked and it is believed to be accurate. In the interest of continued product development, METKO reserves the right to make changes and improvements to this insert and the product it described any time, without notice or obligation.

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

Definition – Label Symbols:

Consult electronic instructions for use


Follow instructions of use

Catalog number or part number

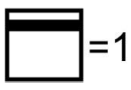
Batch code or Lot code


Date of Manufacture

Non Sterile

Latex free


Reusable, do not throw away



Contains 1 piece

Patient Size


Manufactured by


Single Tube Cuff


Double Tube Cuff


Cuff with Bladder


Cuff without Bladder


Storage Temperature


Operating Temperature

Operating Humidity

Mark of Conformity to European Medical Directive 93/42/EEC

Authorized European Representative

Federal Law restricts this device to sell by or on the order of a physician (USA audiences only)

FMT® is a registered trademark of METKO Ltd.

All FMT products are Latex free.

Metko Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.
İvedik O.S.B. Ağaç İşleri Sanayi Sitesi 1354. Cad. 1358. Sok. No:9
06378 Yenimahalle - Ankara / Turkey Tel: +90 312 3871246 (pbx)
Fax: +90 312 3871251 www.metkoltd.com metko@metkoltd.com