

# All Purpose

Durable BP Cuff

English



82-0093-00-RevF

SunTech Medical's All Purpose Clinical Grade Blood Pressure Cuffs

**INDEX** Index Line

**ARTERY** Cuff index line must fall within range markings

**ARTERY** Artery symbol and arrow should be placed over brachial or femoral artery

**RVP** Not made with PVC

**LATEX** Not made with natural rubber latex

**CE** Product in compliance with Council Directive 93/42/EEC Medical Devices Directive

**Symbol** Symbol indicating arm circumference

**Symbol** Symbol indicating manufacturer

**LOT** Symbol indicating lot code of cuff

**!** Symbol indicating Caution

## RANGES / COLORS

Size:	Color:	Range:
Infant	Orange	8-13 cm
Child	Green	12-19 cm
Child Long	Green	12-19 cm
Sm Adult	Royal Blue	17-25 cm
Sm Adult Long	Royal Blue	17-25 cm
Adult	Navy Blue	23-33 cm
Adult Long	Navy Blue	23-33 cm
Lg Adult	Burgundy	31-40 cm
Lg Adult Long	Burgundy	31-40 cm
Thigh	Brown	38-50 cm

## WARNINGS

Pressurization of the cuff can temporarily cause loss of function if simultaneously used with monitoring equipment on the same limb.

The cuff should not be placed on the patient's arm on the side of a mastectomy. In the case of a double mastectomy use the side of the least dominant arm.

If luer lock connectors are used in the construction of tubing, there is a possibility to connect the cuff to intravenous fluids, allowing air to be pumped into a blood vessel, potentially causing serious injury.

Do not attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.

Following the application of the BP cuff, petechia formation (a minute reddish or purplish spot containing blood that appears in the skin) or Rumpel-Leede phenomenon (multiple petechiae) on the arm, which may lead to idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets, associated with hemorrhagic conditions) or phlebitis (inflammation of a vein) may be observed.

## CAUTIONS

After washing ensure the size indication on the bladder and cuff shell match. Make sure that the cuff hose is threaded through one of the hose openings in the cuff.

Minimize limb movement during the measurement. The cuff should not be applied over a wound as this can cause further injury.

Federal (US) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Do not use cuff if there are any signs of damage. Failure to do so could affect measurement accuracy.

Do not machine wash the cuff bladder. Water could be trapped in the cuff and cause damage to the NIBP module and/or inaccurate BP readings.

Avoid contact with the cuff, other than that of the patient's limb, while measurement is in progress.

A compressed or kinked connection hose may

# All Purpose

BD-Manschette „Durable“

Deutsch

# All Purpose

Manguito de PA Durable

Español

# All Purpose

Brassard de prise de tension artérielle «Durable»

Français



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Do not machine wash the cuff bladder. Water could be trapped in the cuff and cause damage to the NIBP module and/or inaccurate BP readings.

Avoid contact with the cuff, other than that of the patient's limb, while measurement is in progress.

A compressed or kinked connection hose may

cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.

Using an incorrect cuff size could result in erroneous and misleading BP measurement results.

## APPLICATION

Follow the application instructions for use to ensure the correct size cuff for the patient. Failure to do so will adversely affect the accuracy of the reading.

1. Place open cuff around the inner portion of the upper arm (or thigh).
2. Align artery symbol ARTERY to the brachial (or femoral) artery.
3. Use the RANGE indicator with the INDEX line to check that the arm falls within the specified range of that cuff. If it does not, select a cuff that better accommodates the limb circumference.
4. Wrap the cuff snugly around the arm (or thigh).

Promptly remove cuff from patient when monitoring is not in progress.

## CLEANING INSTRUCTIONS

The following cleaning methods have been applied 20 times to the cuff without any apparent negative effects.

The cuff may be sprayed with a mild disinfectant solution (e.g. Cidezyme® ENZOL®, or 10% bleach solution), rinsed with distilled water and line dry. Ensure that no liquid enters tubing.

OR

To machine wash the cuff, remove the bladder and fully engage the hook and the loop. Machine wash warm with a mild detergent (50 - 130°F or 1 - 54°C) and line dry.

Disposal: Please dispose of cuff according to local regulations

## ENVIRONMENTAL CONDITIONS

Operating Ranges

Temp: 0 - 50°C

RH: 15 - 95% non-condensing

Storage Ranges

Temp: -20 - 65°C

RH: 15 - 95% non-condensing

## WARRANTY

SunTech Medical warrants our blood pressure cuff products to be free from defects in material and workmanship 24 months from the original date of purchase. This limited warranty covers the no charge replacement of the cuff under normal wear and tear conditions when returned to the attention of Service Department at the address below depending on location.

Contact the Service Department at either of these locations to receive a Return Material Authorization number before sending any product. Cuffs should be returned to the attention of the appropriate Service Department at the addresses below.

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82-0093-00-RevF

Universal-Blutdruckmanschetten von SunTech Medical für den klinischen Einsatz

**INDEX** Index-Linie

**ARTERY** Index-Linie der Manschette muss im markierten Bereich liegen

**ARTERY** Symbol für Arterie und Pfeil müssen über der Arteria brachialis oder femoralis liegen

**RVP** Nicht mit PVC hergestellt

**LATEX** Nicht mit Naturlatex hergestellt

**CE** Produkt erfüllt die Anforderungen der Medizinproduktrichtlinie 93/42/EWG des Rates

**Symbol** Symbol gibt den Armumfang an

**Hersteller-Symbol**

**LOT** Symbol gibt die Los-Nummer der Manschette an

**!** Symbol kennzeichnet Vorsichtsmaßnahmen

## GRÖßen/FARBEN

Größe: Farbe: Umfang der Extremität:

Kleinkind orange 8-13 cm

Kind grün 12-19 cm

Kind, lang grün 12-19 cm

Kl. Erwachsene königblau 17-25 cm

Erwachsene, lang dunkelblau 23-33 cm

Gr. Erwachsene, lang dunkelrot 31-40 cm

Oberschenkel braun 38-50 cm

oder zu ungenauen Blutdruck-Messwerten führen.

Während der Messung darf nur der Arm, an dem gemessen wird, mit der Manschette in Kontakt sein.

Ist der Manschettenschlauch gequetscht oder geknickt, übt die Manschette eventuell ständigen Druck aus und beeinträchtigt den Blutfluss. Dies kann den Patienten möglicherweise gefährden.

Hat die Manschette die falsche Größe, können die Messergebnisse falsch und irreführend sein.

## MANSCHETTE ANLEGEN

Beachten Sie die Hinweise zum Anlegen der Manschette, damit Sie die richtige Größe wählen.

Eine falsche Manschettengröße beeinträchtigt die Genauigkeit der Messung.

## 1. Legen Sie die aufgeklappte Manschette um die Innenseite des Oberarms (

# All Purpose

Bracciale "Durable" per la misurazione della pressione arteriosa



Italiano

Bracciali multifunzione per la misurazione della pressione arteriosa a uso clinico di SunTech Medical



Linea Index

La linea Index sul bracciale deve rientrare nelle marcature del range

Il simbolo dell'arteria e la freccia devono essere posizionati sull'arteria brachiale o femorale

Prodotto senza PVC

Prodotto senza lattice in gomma naturale

Prodotto in conformità con la Direttiva del consiglio 93/42/CEE (Direttiva sui dispositivi medici)

Simbolo indicante la circonferenza del braccio

Simbolo indicante il produttore

Simbolo indicante il codice di lotto del bracciale

Simbolo indicante un avviso

RANGE / COLORI

Misura: Colore: Range:  
Lattante Arancione 8-13 cm  
Bambino Verde 12-19 cm  
Bambino lungo Verde 12-19 cm  
Adulto picc. Blu reale 17-25 cm  
Adulto picc. lungo Blu reale 17-25 cm  
Adulto Blu marino 23-33 cm  
Adulto lungo Blu marino 23-33 cm  
Adulto gr. Bordeaux 31-40 cm  
Adulto gr. lungo Bordeaux 31-40 cm  
Coscia Marrone 38-50 cm

È possibile spruzzare il bracciale con una soluzione disinfettante delicata (per es. Cidezyme®, ENZOL®, oppure una soluzione con candeggina al 10%), per poi risciacquare con acqua distillata e stendere ad asciugare. Assicurarsi che nessun liquido entri nei tubi.

OPPURE

Per lavare in lavatrice il bracciale, rimuovere la camera d'aria e chiudere completamente la parte in Velcro. Lavare in acqua tiepida (1-54 °C) con un detergente delicato e stendere ad asciugare.

Smaltimento: Smaltire il bracciale attenendosi alle normative vigenti a livello locale

AVVERTENZE

La pressurizzazione del bracciale può provocare una perdita temporanea di funzionalità dell'apparecchio di monitoraggio se applicato simultaneamente allo stesso arto.

Il bracciale non deve essere posizionato sul braccio della paziente sul lato di una mastectomia. In caso di doppia mastectomia utilizzare il lato del braccio meno dominante.

Se per la costruzione dei tubi vengono utilizzati connettori Luer Lock, c'è la possibilità di collegare il bracciale a fluidi intravascolari, con la possibilità di pompare dell'aria in un vaso ematico, con il rischio di provocare lesioni gravi.

Non utilizzare il bracciale su un arto utilizzato per infusioni IV o per qualsiasi altro accesso intravascolare, terapia oppure per uno shunt artero-venoso. Gonfiando il bracciale si potrebbe bloccare temporaneamente il flusso ematico, con possibili danni al paziente.

A seguito dell'applicazione del bracciale PA, possibile manifestazione di petechie (minuscule chiazze di colore rossastro o violaceo contenente sangue che compare sulla cute) o fenomeno di Rumpel-Leede (petechie multiple) sul braccio, che potrebbe provocare l'insorgenza di trombocitopenia idopatica (riduzione spontanea persistente del numero di piastrine circolanti associate a condizioni emorragiche) o flebitis (infiammazione di una vena).

AVVISI

Dopo il lavaggio, verificare che l'indicazione della misura sulla camera d'aria corrisponda a quella riportata sull'involucro del bracciale. Verificare che il tubicino sia infilato in una delle apposite aperture del bracciale.

Ridurre al minimo il movimento degli arti durante la misurazione.

Il bracciale non va applicato sopra una ferita perché così facendo si possono provocare ulteriori lesioni.

La legge federale statunitense limita la vendita del presente dispositivo ai medici o su prescrizione medica.

Non usare il bracciale in presenza di segni di danneggiamento. La mancata osservanza di quanto sopra può intaccare l'accuracy delle misurazioni.

Non lavare in lavatrice la camera d'aria del bracciale. L'acqua potrebbe restare intrappolata nel bracciale e provocare danni al modulo NIBP e/o lettura inaccurate della PA.

Mentre è in corso la misurazione, evitare il contatto con il bracciale, ad eccezione di quello con l'arto del

# All Purpose

"Durable" bloeddrukmantel

Nederlands

# All Purpose

manguito de PA "Durable"

Portuguese (Brazil)

Universelle bloeddrukmantelten van medische kwaliteit van Suntech Medical



Indexlijn

De indexlijn van de mantel moet vallen tussen de bereikmarkeringen

Het arterie-symbool en de pijl moeten zich boven de brachiale of femorale arterie bevinden

Bevat geen PVC

Bevat geen natuurlijk rubberlatex

Dit product voldoet aan richtlijn 93/42/EEG van de Raad betreffende medische hulp middelen

Symbool dat de omtrek van de arm aangeeft

Symbool dat de fabrikant aangeeft

Symbool met de batchcode van de mantel

Symbool dat een waarschuwing aangeeft

BEREIKEN/KLEUREN

Afmetingen: Kleur: Bereik:  
Baby Oranje 8-13 cm  
Kind Groen 12-19 cm  
Kind (lang) Groen 12-19 cm  
Volwassene (klein) Koningsblauw 17-25 cm  
Volwassene (klein, lang) Koningsblauw 17-25 cm  
Volwassene Marineblauw 23-33 cm  
Volwassene (lang) Marineblauw 23-33 cm  
Volwassene (groot) Bordeauxrood 31-40 cm  
Volwassene (groot, lang) Bordeauxrood 31-40 cm  
Bovenbeen Bruin 38-50 cm

WAARSCHUWINGEN

De druk in de bloeddrukmantel kan tijdelijk verlies van functie van gelijktijdig gebruikte bewakingsapparatuur op dezelfde ledemaat veroorzaken.

De mantel mag niet worden aangebracht op de arm van de patiënt aan de kant van een mastectomie. In het geval van een dubbele mastectomie gebruikt u de kant van de minst dominante arm.

Als er luer-lockconnectors worden gebruikt in een slangconstructie bestaat de mogelijkheid dat de mantel wordt aangesloten op intraveneuze vloeistoffen waardoor er lucht in een bloedvat kan worden gepompt, wat mogelijk leidt tot ernstig letsel.

Breng de mantel niet aan op een ledemaat die gebruikt wordt voor IV-infusies of een andere intravasculaire toegang, behandeling of een arterioveneuse (A-V) shunt. Het opblazen van de mantel kan de bloedsomloop tijdelijk blokkeren, wat letsel bij de patiënt kan veroorzaken.

Na het aanbrengen van de bloeddrukmantel kan petechie optreden (een kleine roodachtige of paarse puntvormige bloeding in de huid) of de Rumpel-Leede-fenomeen (meerder petechiae) op de arm, wat kan leiden tot idiopathische trombocytopenie (spontane persistende afname van het aantal bloedplaatjes, wat optreedt bij hemorragische toestanden) of kan flebitis (ontsteking van eenader) worden waargenomen.

OPMERKINGEN

Controleer na het wassen of de maatindicatie van het opblaasgedeelte en die van de overtrek van de mantel hetzelfde zijn. Controleer of de slang van het opblaasgedeelte van de mantel door één van de slangenopeningen van het overtrek van de mantel loopt.

Probeer de ledemaat tijdens het meten zo min mogelijk te bewegen.

Breng de bloeddrukmantel niet aan over een wond omdat dit tot meer letsel kan leiden.

Op grond van de fedrale wetgeving van de Verenigde Staten mag dit product uitsluitend door of op voorschrijf van een bevoegd arts worden verkocht.

Gebruik de mantel niet als er tekenen van beschadigingen zijn. Het gebruiken van een beschadigde mantel kan een negatieve invloed hebben op de meet nauwkeurigheid.

Het opblaasbare gedeelte van de mantel mag niet in de wasmachine worden gewassen. Er kan zich water ophopen in de mantel wat schade kan veroorzaken aan de NIBP-module en/of leiden tot onnauwkeurige bloeddrukmetingen.

Voorkom contact met de mantel, anders dan contact

REINIGINGSINSTRUCTIES

De volgende reinigingsmethodes zijn 20 keer op de mantel uitgevoerd zonder dat dit zichtbare negatieve effecten had.

FAIXAS E CORES

Tamano: Cor: Intervalo:  
Infantil pequeno Laranja 8-13 cm  
Infantil Verde 8-13 cm  
Infantil longo Verde 12-19 cm  
Adulto pequeno Azul-escuru 17-25 cm  
Adulto pequeno longo Azul-escuru 17-25 cm  
Adulto Azul-marinho 23-33 cm  
Adulto longo Azul-marinho 23-33 cm  
Adulto grande Vinho 31-40 cm  
Adulto grande e longo Vinho 31-40 cm  
Coxa Marrom 38-50 cm

ADVERTÊNCIAS

A pressurização do manguito pode afetar o funcionamento de outros equipamentos de monitoramento usados na mesma extremitade.

O manguito nunca deve ser usado no braço do mesmo lado no qual tenha sido realizada uma mastectomia. Em caso de mastectomia bilateral, use o lado do braço menos dominante.

Se forem usados conectores Luer nos equipos, o manguito pode ser conectado a bolsas de fluidos. Isso pode levar à introdução de ar na circulação sanguínea e causar lesões graves.

Não coloque o manguito na mesma extremitade usada para infusões IV ou outros acessos vasculares, tratamentos ou fistulas arteriovenosas (AV). A insuflação do manguito pode bloquear temporaneamente a circulação do sangue, o que pode causar lesões ao paciente.

Após colocação do manguito de PA, pode haver formação de petéquias (pequenos pontos avermelhados ou arroxeados contendo sangue visível no nível da pele) ou o fenômeno de Rumpel-Leede (petéquias múltiplas) no braço, que podem causar trombocitopenia idiopática (diminuição espontânea e persistente da contagem de plaquetas associada a afecções hemorrágicas) ou flebitis (inflamação em uma veia).

Antes de enviar qualquer produto, entre em contato com o Departamento de Assistência Técnica em qualquer desses locais para solicitar um número de Autorização de Devolução de Material (RMA). Os manguitos devem ser devolvidos aos cuidados da Assistência Técnica apropriada nos endereços abaixo.

GARANTIA

SunTech Medical garante que os manguitos de pressão por ela produzidos estarão livres de defeitos usados na mesma extremitade.

O manguito nunca deve ser usado no braço do mesmo lado no qual tenha sido realizada uma mastectomia. Em caso de mastectomia bilateral, use o lado do braço menos dominante.

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Não coloque o manguito sobre lesões, pois isso pode agravá-las.

Nos EUA, a lei federal proíbe a venda deste produto a ou sob ordem de profissionais de saúde licenciados.

Não use manguitos com quaisquer sinais de danos. Caso contrário, a medição pode ser imprecisa.

Não lave a bolsa do manguito em máquina. A água pode ficar retida no interior do manguito e danificar o módulo de PANI e/ou afetar a precisão das leituras de PA.

Coloque o manguito em contato apenas com o braço do paciente ao realizar a aferição.

Se a mangueira da conexão for comprimida ou estiver dobrada, o manguito pode ser pressurizado continuamente, interferindo na circulação e podendo causar lesões ao paciente.

Se o manguito não tiver o tamanho correto, as

afirções podem produzir resultados errados e enganosos.

MODO DE COLOCAR O MANGUITO

Siga as instruções de uso para escolher o manguito de tamanho apropriado para cada paciente. Caso contrário, as aferições podem produzir resultados imprecisos.

ARTERY

O símbolo da arteria e a seta precisam estar sobre a artéria braquial ou femoral

RVE

Fabricado sem PVC

LATEX

Fabricado sem latex de borracha natural

CE

O produto está de acordo com a Diretiva do Conselho 93/42/CEE relativa a dispositivos médicos

Symbol

Símbolo indicador da circunferência do braço

Symbol

Símbolo indicador do fabricante

LOT

Símbolo indicador do código de lote do manguito

Symbol

Símbolo indicador da advertência

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Adulto grande e longo Vinho 31-40 cm  
Coxa Marrom 38-50 cm

CONDICÕES AMBIENTAIS

Intervalos de operação

Temperatura: 0 - 50 °C

UR: 15 - 95% não condensante

Intervalos de armazenamento:

Temperatura: 20 - 65 °C

UR: 15 - 95% não condensante

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