

- Align artery symbol \oplus to the brachial (or femoral) artery.
- Use the RANGE indicator with the INDEX line to check that the limb falls within the specified range of that cuff. If it does not, select a cuff that better accommodates the limb circumference.
- Wrap the cuff snugly around the arm (or thigh) allowing 1-2 fingers between cuff and limb.
- Promptly remove cuff from patient when monitoring is not in progress.

Disposal: Please dispose of cuff according to local regulations.

Environmental Conditions

Operating Ranges:

Temp: 32°F - 122°F (0°C - 50°C)
RH: 15 – 95% non-condensing

Storage Ranges:

Temp: -4°F - 149°F (-20°C - 65°C)
RH: 15 – 95% non-condensing

Limited Warranty

ADC warrants our blood pressure cuff products to be free from defects in material and workmanship 24 months from the original date of purchase. The warranty shall only cover out-of-box failures, as this is a single patient use product. It is not intended for repeated use.

Contact the ADC Service Department at **1-800-ADC-2670** to receive a Return Material Authorization number before sending any product. Cuffs should be returned to the attention of the Service Department at the address below.

To Obtain Warranty Service: Send item(s) postage paid to ADC, Attn: Repair Dept., 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, phone no., proof of purchase, and a brief note explaining the problem.

For Australian Consumers

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonable foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

For our European Customers

On request, send to ADC by e-mail (info@adctoday.com), we can send to you this manual on paper form within 7 calendar days at no additional cost to the user.

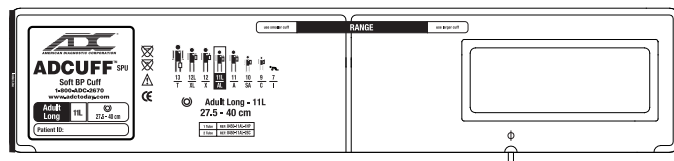
Our website, <https://www.adctoday.com>, where these instructions for use are available fulfills the requirements of personal data protection, according to Directive 95/46/EC and GDPR on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Any serious incident that has occurred in relation to this medical device should be reported to ADC and the competent authority of the Member State in which the user and/or patient is established.

ADCUFF™ SPU

Soft BP Cuff

Instructions for Use



Introduction

Intended use

ADC® Adcuff SPU pediatric through adult Blood Pressure Cuffs are noninvasive blood pressure cuffs intended for use in conjunction with non-automated and automated sphygmomanometers to determine blood pressure in pediatric through adult patients.

Contraindications

ADC Adcuff SPU

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

Symbol Definitions

The following symbols are associated with your SPU cuff.

Symbol	Definition	Symbol	Definition
	Important caution		Catalog Number
	Warning/Caution		Manufacturer
	Not made with natural rubber latex		Date of Manufacture
	Phthalate free		Batch Code
	Circumference Size		Temperature Limit
	Meets the general safety and performance requirements of Regulation (EU) 2017/745 of the European Union		Humidity Limitation
	Consult instructions for use		Medical Device
	Unique Device Identifier		Non-Sterile
	Cuff index line		Do not use if package is damaged
	Artery symbol - should be placed over brachial or femoral artery		Importer
	Authorized representative in the European Community/European Union		Distributor
	UK Representative	 Cuff index line must fall within range markings for an accurate measurement	

General Warnings

A warning statement in this manual identifies a condition or practice that, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

WARNING: Patient injury risk. Never install luer lock connectors on ADC blood pressure tubing. Using these connectors on blood pressure cuff tubing creates the risk of mistakenly connecting this tubing to a patient's intravenous line and introducing air into the patient's circulatory system.

WARNING: Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.

WARNING: 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.

WARNING: Allow space for 1 to 2 fingers between patient and cuff.

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

WARNING: 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.

WARNING: 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 petechia) 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.

WARNING: A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.

General Cautions

A caution statement in this manual identifies information within the manual to avoid equipment failure.

CAUTION: Possible measurement error. Use only approved blood pressure cuffs and accessories; substitution might result in measurement error.

CAUTION: Inaccurate measurement risk. Using an incorrect cuff size could result in erroneous and misleading BP measurement results. Only use the cuff when the artery index marker falls within the printed range indicated on the cuff, otherwise erroneous readings may result.

CAUTION: Do not inflate cuff unless the hook and loop is engaged.

CAUTION: Do not allow foreign debris to ingress into tubes.

CAUTION: Do not use steam or heat to sterilize the cuff or tubing.

CAUTION: Do not exceed 250 mmHg with thigh size disposable cuffs at or above 30 °C/86 °F.

CAUTION: Intravenous Systems (IV) - Do not connect cuffs with luer lock connectors to intravenous fluid systems or fluid may enter the cuff.

CAUTION: Ensure an airtight seal at all connection points prior to use.

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

CAUTION: Minimize limb movement during the measurement.

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

Ranges / Colors

Size	Color	Range (cm)	Size	Color	Range (cm)
Infant	Orange	9-14.8	Neonatal 1	Orange	3-6
Child	Green	13.8-21.5	Neonatal 2	Lt Blue	4-8
Small Adult	Royal	20.5-28.5	Neonatal 3	Green	6-11
Adult	Navy	27.5-36.5	Neonatal 4	Navy	7-13
Adult Long	Navy	27.5-40	Neonatal 5	Burgundy	8-15
Large Adult	Burgundy	35.5-46			
Large Adult Long	Burgundy	35.5-50			
Thigh	Brown	45-56.5			

Application

Use the ADC ADCUFF SPU Blood Pressure cuff the same as a traditional blood pressure cuff. The blood pressure cuff works with manual and automated sphygmomanometers. 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.

Operational Pressure Range: 0 to 300 mmHg

1. Select cuff size appropriate for the patient's arm circumference. The applicable range, in centimeters, is printed on each cuff.
2. Place open cuff around the inner portion of the upper arm (or thigh).