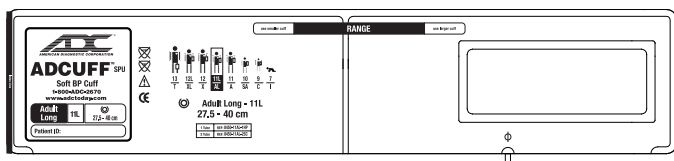


ADCUFF™ SPU

Soft BP Cuff

Instructions for Use



ADC®
55 Commerce Drive
Hauppauge, NY 11788
U.S.A.

Inspected in the U.S.A.

Made in China

tel: 631-273-9600

toll free: 1-800-232-2670

fax: 631-273-9659

www.adctoday.com

info@adctoday.com

EU REP

SC Cattus SRL
Str. Baneasa Nr. 10 C
Târgu-Mures, Jud. Mures
România, EU

UK REP

Vera Global Ltd.
86-90 Paul Street 3rd Floor
EC2A 4NE, London, United Kingdom

CH REP

MedLife S.A.
Chemin du Pont-du-Centenaire 109
1228 Plan-les-Ouates
Suisse



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

Standards

ANSI/AAMI/ISO 81060-1:2007 • EN / ISO 81060-1:2012

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 between patient and cuff. Two fingers should fit in this space if the cuff is correctly positioned.

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.

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.

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 manometer pressure 250 mmHg with thigh size disposable cuffs, at or above 86°F (30°C).

CAUTION: Extreme altitudes may affect blood pressure readings. Your device has been designed for normal environmental conditions.

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: Patient should remain still during measurement to avoid erroneous readings.

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)
Infant	Orange	9-14.8
Child	Green	13.8-21.5
Small Adult	Royal	20.5-28.5
Adult	Navy	27.5-36.5
Adult Long	Navy	27.5-40
Large Adult	Burgundy	35.5-46
Large Adult Long	Burgundy	35.5-50
Thigh	Brown	45-56.5

Size	Color	Range (cm)
Neonatal 1	Orange	3-6
Neonatal 2	Lt Blue	4-8
Neonatal 3	Green	6-11
Neonatal 4	Navy	7-13
Neonatal 5	Burgundy	8-15

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).
3. Align artery symbol ARTERY to the brachial (or femoral) artery.
4. 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.

5. Wrap the cuff snugly around the arm (or thigh) allowing 1-2 fingers between cuff and limb.
6. Promptly remove cuff from patient when monitoring is not in progress.

Disposal: Please dispose of the cuff according to local regulations.

Environmental Conditions

Operating Ranges:

Temp: 41°F - 104°F (5°C - 40°C), relative humidity 15% - 80% (non-condensing)

Storage Ranges:

Temp: 14°F - 104°F (-10°C - 40°C), relative humidity 10% - 85% (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

A printed copy of this manual can be sent to you at no charge within seven calendar days. To request a copy, e-mail us at info@adctoday.com.

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.

To register your product visit us at:
www.adctoday.com/register

This manual is available online in a variety of languages,
follow the links for language options:
www.adctoday.com/care

FOR QUESTIONS, COMMENTS, OR SUGGESTIONS CALL TOLL FREE:
1-800-ADC-2670

OR VISIT:
www.adctoday.com/feedback