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CONTEC Contec08A

CONTEC CONTEC08A Automatic Blood Pressure Monitor User Manual

Model: CONTEC08A

1. INTRODUCTION

This manual provides essential instructions for the safe and effective operation of your CONTEC CONTEC08A Automatic Blood Pressure Monitor. Please read this manual thoroughly before first use and retain it for future reference. This device is designed for household use to measure blood pressure and pulse rate.

2. PRODUCT OVERVIEW

2.1 Key Features

- High-definition color LCD display for clear readings.
- Fully automatic blood pressure measurement.
- Multi-user storage: Automatically stores results for three users, up to 100 items per user.
- Data review interface: Displays data in list, trend graph, and large font formats.
- PC software support: Connects via USB for data viewing, analysis, and report printing.

2.2 Components

The standard package includes:

- CONTEC08A Main Unit
- Adult Cuff (22-32cm arm circumference)
- USB Cable
- User Manual

Note: A charger is not included in the package. The device operates on batteries or an external AC adapter (not included).



What are these? (Note: There is no charger)

- › Blood Pressure Monitor
- › Packing Box
- › Download PC Software
- › Adult Cuff
- › Instruction Manual
- › USB Cable

Figure 2.2.1: Package contents of the CONTEC08A Blood Pressure Monitor.

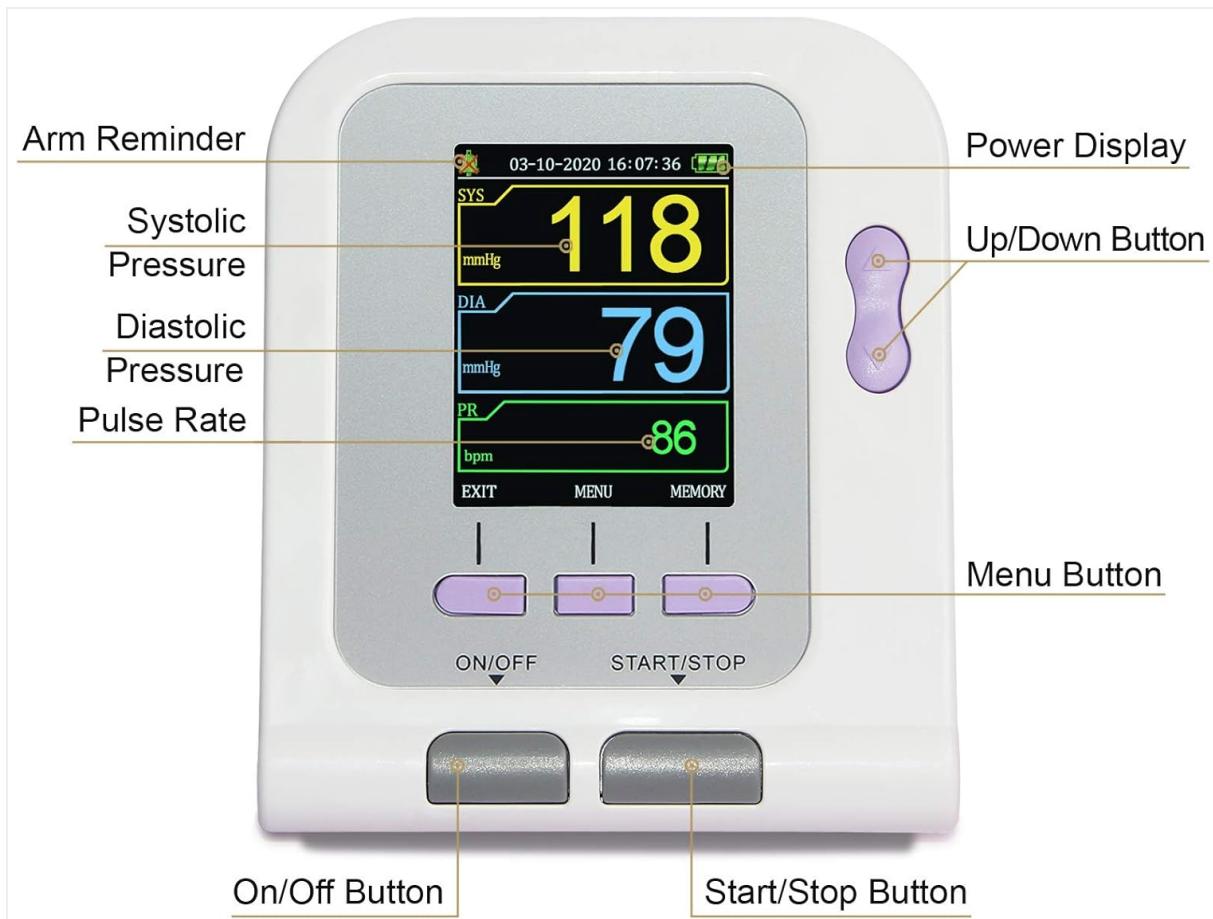


Figure 2.2.2: Key display elements and buttons on the CONTEC08A monitor.

3. SAFETY INFORMATION

This device is intended for non-invasive measurement of arterial blood pressure and pulse rate in adults. It is not intended for use in neonatal or infant patients unless specific cuffs are used and the device supports those modes. Always consult your physician for interpretation of blood pressure readings. Do not use this device for self-diagnosis or self-treatment.

3.1 General Precautions

- Do not apply the cuff over a wound or inflamed area.
- Avoid taking measurements immediately after drinking coffee or alcohol, taking a bath, or engaging in physical exercise. Wait at least 30 minutes.
- Ensure the cuff size is appropriate for your arm circumference.
- Keep the device away from strong electromagnetic fields.

April 28, 2020

Contec Medical Systems Co., Ltd.
% Ray Wang
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Re: K202757

Trade/Device Name: Electronic Sphygmomanometer, Automatic Blood Pressure Monitor
CONTEC08A/CONTEC08C/ABPM50

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: Class II

Product Code: DXN

Dated: March 24, 2021

Received: March 29, 2021

Dear Ray Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Figure 3.1.1: FDA clearance documentation for the CONTEC Electronic Sphygmomanometer.

4. SETUP

4.1 Battery Installation

1. Open the battery compartment cover on the back of the device.
2. Insert four AA batteries, ensuring correct polarity (+/-).
3. Close the battery compartment cover securely.

4.2 Cuff Connection

1. Locate the air tube connector on the side of the monitor.
2. Firmly insert the air tube from the cuff into the connector port.

Your browser does not support the video tag.

Video 4.2.1: This video demonstrates the battery installation and cuff connection process for the CONTEC blood pressure monitor, along with proper user positioning for measurement.

5. OPERATION

5.1 Preparing for Measurement

- Sit upright in a chair with your feet flat on the ground.
- Ensure your arm is resting comfortably on a flat surface, with your palm facing upwards.
- Relax and avoid talking or moving during the measurement.

5.2 Applying the Cuff

1. Slide the cuff onto your upper arm, ensuring the air tube is positioned on the inside of your arm, aligned with your brachial artery.
2. The bottom edge of the cuff should be approximately 1 inch (2 fingers) above your elbow.
3. Wrap the cuff snugly around your arm, but not too tightly.



• Adult cuff size: 8.7-12.6 inches upper arm

Figure 5.2.1: Correct cuff placement on the upper arm.

5.3 Taking a Measurement

1. Press the **ON/OFF** button to turn on the device.
2. Press the **START/STOP** button to begin the measurement. The cuff will inflate automatically.
3. Remain still and quiet until the measurement is complete and the results are displayed.
4. The device will display your Systolic Pressure (SYS), Diastolic Pressure (DIA), and Pulse Rate (PR).



Figure 5.3.1: Example of measurement results on the CONTEC08A display.

Your browser does not support the video tag.

Video 5.3.2: This video provides a comprehensive overview of the CONTEC Blood Pressure Monitor, including its features, different cuff sizes, and a demonstration of taking a measurement.

6. DATA MANAGEMENT

6.1 User Storage

The CONTEC08A automatically stores measurement results for up to three different users, with each user having a capacity of 100 readings. This allows for easy tracking of individual blood pressure trends over time.

6.2 PC Software

The device supports connection to a PC via the included USB cable. Dedicated PC software (available for download) allows you to:

- View stored data in detail.
- Analyze results through trend graphs and other visual representations.
- Generate and print comprehensive reports.



Figure 6.2.1: Multi-user data storage and review interface.

7. MAINTENANCE AND CARE

7.1 Cleaning

- Clean the device and cuff with a soft, dry cloth.
- Do not use abrasive cleaners or immerse the device in water.

7.2 Storage

- Store the device in a cool, dry place, away from direct sunlight and extreme temperatures.
- If the device will not be used for an extended period, remove the batteries to prevent leakage.

8. TROUBLESHOOTING

If you encounter issues with your CONTEC08A monitor, please refer to the following common solutions:

Problem	Possible Cause	Solution
Device does not power on.	Batteries are low or incorrectly installed.	Replace with new AA batteries, ensuring correct polarity.
Inconsistent or inaccurate readings.	Improper cuff placement, movement during measurement, or incorrect posture.	Ensure correct cuff placement, remain still and quiet, and maintain proper posture as described in Section 5.
Cuff does not inflate or inflates improperly.	Air tube not securely connected, or cuff is damaged.	Check air tube connection. If the cuff is damaged, replace it.
Difficulty reading the instruction manual.	Small print size.	Refer to the digital version of this manual for easier readability.

9. SPECIFICATIONS

Feature	Specification
Model Number	Contec08A
Product Dimensions	6.3 x 4.72 x 4.33 inches
Item Weight	0.65 Kilograms (1.43 Pounds)
Power Source	Corded Electric (via USB) / 4x AA Batteries
Display Type	LCD
Age Range (Description)	Adult
Band Size	22-32 centimeters (Adult Cuff)
UPC	604348345627, 756040906450

10. WARRANTY AND SUPPORT

For any questions or support regarding your CONTEC08A Blood Pressure Monitor, please contact the seller directly through the platform where the purchase was made. Specific warranty details are not provided in the product information. Please refer to your purchase documentation or contact the seller for warranty information.

Related Documents - Contec08A

	<p>CONTEC08C Electronic Sphygmomanometer User Manual</p> <p>User manual for the CONTEC08C Electronic Sphygmomanometer, detailing its functions, safety precautions, operation, maintenance, and specifications for accurate blood pressure measurement.</p>
	<p>Contec SP80B Spirometer User Manual and Technical Guide</p> <p>Comprehensive user manual for the Contec SP80B Spirometer, detailing operation, safety guidelines, technical specifications, maintenance, and troubleshooting for lung function testing.</p>
	<p>CONTEC ESB0059 Pulse Oximeter Probe User Manual</p> <p>User manual for the CONTEC ESB0059 Pulse Oximeter Probe, detailing its intended use, performance specifications, directions for use, maintenance, warnings, and electromagnetic compatibility information for healthcare professionals.</p>
	<p>Contec CMS1600B Color Doppler Ultrasound Diagnostic System User Manual</p> <p>This user manual provides comprehensive instructions for the Contec CMS1600B, a wireless handheld color Doppler ultrasound diagnostic system. It covers device operation, software functions, safety precautions, maintenance, and troubleshooting for healthcare professionals.</p>
	<p>Contec CMS50D1 Fingertip Pulse Oximeter User Manual and Specifications</p> <p>Comprehensive user guide for the Contec CMS50D1 fingertip pulse oximeter, detailing its features, operation, maintenance, troubleshooting, and technical specifications for SpO2 and pulse rate monitoring.</p>
	<p>RT-200 Universal Cable + TV Remote Control Programming and Operating Instructions</p> <p>Comprehensive programming and operating instructions for the Contec RT-200 Universal Cable and TV Remote Control. Learn how to install batteries, program for cable set-top boxes and TVs using code entry or point-and-press methods, manage volume and input, and troubleshoot common issues. Includes extensive TV setup codes for various brands.</p>