Sinoheart™ Automatic Upper Arm Blood Pressure Monitor

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EC REP
MedNet GmbH
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CE₁₂₈₂



BA-801

1 Important Notes

Specifications .

Blood Pressure Log.

- Only a physician is qualified to interpret changes in your blood pressure.
 This device is not intended to replace regular medical examinations.
 It is recommended that your physician review your procedure for using this monitor. Never make adjustments to your medication unless it is the advice of a physician.
- This Blood Pressure Monitor is intended to be used by adults. Children should not use this monitor unless it is under the supervision of an adult.
- 3. Don't instead other vendors cuff, Since these will affect Measurement
- Please read the entire instructions carefully before using this Blood Pressure Monitor.
- 5. A Warning Symbol
- 6. Type B Symbol
- 7. Class II Symbol

2 Measurement Accuracy

The blood pressure measuring device bears the CE (conformity) label" CE1282". The quality of the device has been verified and conforms to the provisions of the Eccouncil directive 93/42/EEC as well as the EMC directive 89/336/EEC:

EN 1060-

Non-invasive blood pressure measuring equipment General requirements

EN 1060-3

Non-invasive blood pressure measuring equipments Supplementary requirements for electro-mechanical blood pressure measuring system

EN 60601-

Safety requirements for medical electrical equipment

EN 60601-1-

Electromagnetic compatibility and safety for medical electrical equipment

EN 1497

Risk analysis for medical devices Accord with requirement in section $21\ \mbox{of}$ CMDR'S

3 Helpful Information

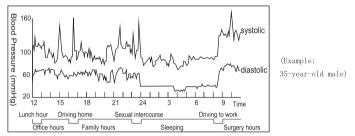
What is Blood Pressure?

Blood Pressure is the force that blood exerts on the arteries. This force is constantly changing as the heart beats. When the heart contracts, blood pressure reaches its highest value. This is called systolic blood pressure. When the heart relaxes between beats, the value of blood pressure is lower. This is called the diastolic blood pressure. The devie of measure for measure for blood pressure is the millimeter of mercury, abbreviated mmHg.

For example, an individual's blood pressure may be measured as 120 mmHg(systolic) and 80 mmHg (disatolic). This would be spoken as "120 over 80" and written as "120/80".

Remember that blood pressure varies throughout the day. Food intakes, smoking, time of day, stress, level of exercise and many other factors affect it.

Typical daily blood pressure fluctuations

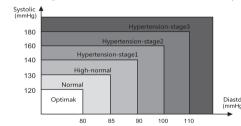


What is High Blood Pressure?

Hypertension, or high blood pressure, is a condition where an individual's blood pressure remains high over a long period of time. Untreated, Hypertension can cause many serious medical problems including strokes and heart attacks. To control hypertension, the American Heart Association recommends that you not smoke, reduce fat and salt intake, maintain proper weitht, exercise and get regular physical check-ups.

Blood Pressure Classification :

The world health Organisation (WHO) and the international Society of Hypertension (



Why is it Important to Measure Your Blood

Pressure at Home?

14

Having your blood pressure taken at the doctor's office may cause you to become nervous, thus artificially raipressure at home makes it easy to record a log of your daily readings

This will help you gain a greater understanding of your blood pressure reading and the factors that affect it. Be sure that you share your information with your physician.

Hints for Accurate Measurement

- 1. Relax and try to remain still for 5 to 10 minutes before a measurement.
- Remove any clothing on the upper arm so that the cuff can be placed directly on the skin. Constriction of the upper arm caused by rolling up a shirt sleeve may cause and inaccurate reading.
 - Avoid this condition by completely removing the garment causing the constriction.
- Refrain from eating, smoking, and drinling (especially alcoholic beverages) before a measurement since these activities can affect your blood pressure.
- Remember that blood pressure varies continuously throughout the day. Try to take your blood pressure at the same time each day.
- 5. Do not be concerned with the results of one measurement. Many measurements, recorded over a long period of time, will provide a better indication of your blood pressure.

- 6. Please relax for 5 to 10 minutes before taking another measurement
- 7. Many factors can affect your blood pressure such as exercising, eating ,talking, moving, nervousness, environment and temperature changes, emotional stress can cause an increase in blood pressure Daily fluctuations of 25 to 50 mmHg

Please note:

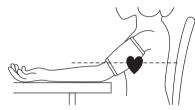
Some individuals with hypertension, diabetes, kidney disorders, arterioscierosis or por circulation may see a significant difference in blood pressure readings taken from the wrist as compared to readings from the upper arm.

It is recommended that you consult with your physician concerning the use of this monitor.

4 Correct Method of Measurement

To obtain the most accurate blood pressure measurement, please follow these important directions.

- . Be seated in a chair with back support.
- .Rest your arm on a table so the cuff is at the same level as your heart.
- .Place both feet on the ground



IMPORTANT:

The arm cuff must be at the same level as your heart, or accurate measurement will not possible. (Your heart is located slightly below your left armpit.)

5 Parts Identification

Monitor:



Description of Display Marks

Constriction

Deflating Measurement Error Measuring Battery Display *The battery indicator will redue when power redue. Please replace with new batteries when the battery indicator flashes. Arrhythmia detection Function

6 Preparation before Taking a Measurement

Battery Installation / Replacement

- 1. slide the battery cover off in the direction of the arrow.
- 2. Install or replace the four alkaline"AA"batteries, noting the proper orientation of positive(+) and negative (-) terminals of the batteries in the battery compartment.

- 3. Replace th battery cover.
- 4. If the Low Battery Symbol appears on the display, replace all batteries with new ones.
- 5. Remove the batteries if the device will not be used for an extended period of time.

Note

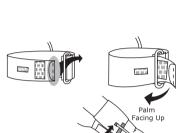
Batteries are hazardous waste.Do not dispose them together with the household garbage.



How to Apply the Arm Cuff

(Preferably the left arm.)

- 1. Insert the end of the cuff through the D-Ring to make a loop. (Makes sure that the Velcro stays outside when it is done.)
- 2. Ware the arm cuff with the hose downward. Pull the end of the cuff and secure it snugly with the velcro.
- 3. Adjust the cuff that the bottom edge is about 1 inch above the elbow on the inside of the left arm. Please mind the colored area on the cuff covers the brachia artery.
- 4. Plug in the air tube connector to the monitor.







10 Er Indicators and Troubleshooting

Error indicators

Error indicators		Possible sources of errors				
Ec	Indication:	Incomplete inflation				
ີ ປ	Correction:	Check the cuff has been connected with device firmly, if same Er message indicated, request a repair				
Er	Indication:	cuff over inflated and release automatically				
_ H	Correction:	Take a break, and reposition the cuff and measure again				
Er	Indication:	Could not obtain the pulse rate				
	Correction:	Reposition the cuff and measure again				
Er	Indication:	Strong Electromagnetic interference (Mobile phone and computer)				
2	Correction:	Relax and take a break, and then measure again.				
Er	Indication:	irregular pulse rate or blood pressure,				
3	Correction:	Relax and take a break, and then				

measure again

Taking a measurement

Please read the previous section on proper placement of the cuff and proper arm

- 1. After the cuff has been properly placed on the arm, please press the start/stop button to start a measurement.
- 2. After the display reads "00", the cuff will automatically inflate to an appropriate pressure. After the inflation, it slowly deflates to take the measurement. When the heart mark " appears which indicating the measurement is in process. The cuff will be quite snug for a short while, this is normal. Try to remain relaxed, refrain from talking, and be as still as possible during the measurement.

Note: If the device determined that the initial inflation pressure was insufficient, it will re-inflate to a higher pressure.

3. The device will completely deflate when measurement is finished. The systolic and diastolic pressure and pulse rate will be displayed.



TO end a measurement for any reason, just press Start/stop button to turn off the unit and release the cuff pressure.

If during a measurement the power drops to an insufficient level, the device will end the measurement and display the low battery symbol. Please replace the batteries and repeat the measurement.

If the device can not detect your pulse, it will end the measurement attempt. Please wait a few minutes make sure that the cuff is positioned properly, and try again.

The device will automatically shut off 1 minute after a measurement finished. You can also press Start / Stop button to shut the device off.

2. Long press the SET button for 3-5 seconds, and the individual figure will start

1. The device with time and date displayed on the LCD, please set them per

blinking sequentially from month, date, hour to minute

Note: Press Memory button once will cause the display to advance by one digit.

9 Memory function

following method.

8 Setting date and Time

Memory input

When a valid measurement is made, the result (systolic, diastolic, pulse rate, date and time) will be stored in the memory automatically as soon as the device is turned off or when another measurement is initiated.

The device is capable to store 2×90 readings, and also compute the average of the latest 3 readings. When readings stored more than 90, the oldest ones will be

Memory recall

By pressing Memory button, AVG will be shown in the down left hand corner, which means you entered into memory function. AVG means the average of all recorded readings. Now press the Memory button again, 01 will be shown in the down right hand corner, which is your latest reading in the memory, when you press it again, 02 will be shown which is the one before the latest reading. When you press the button repeatedly, the records will be displayed sequentially

Memory erase

Press memory button and hold it down more than 3 seconds, you will erase the records of readings of the selected memory aroup.



Care and Maintenance

11 Sensor Calibration Mode

can send back to our company for calibration

mmHg and kPa transferring instruction

- . Keep the device away from high temperautresor high humidity, and direct sunliaht.
- . Keep sharp objects away from the cuff.
- . Do not press the Start/Stop button without the cuff around your arm to avoid excess presure build up that may damage the cuff.

The blood pressure device should be calibrated by the qualified company. And you

when the device powered on and finished a measurement, the systolic and

diastolic pressure will be displayed, which unit is mmHg; if you want to change

the measurement unit, you can press Start / Stop button for 10 seconds when

the device powered off, and then press "Memory" button select mmHq or Kpa.

- . Use the device at a sufficient distance from devices with strong electrical fields such as television, microwave ovens, X-ray equipment, etc.
- . Do not subject the device to strong impacs or drop it onthe floor.
- . Do not disassemble or modify the device or the cuff.
- . Remove the batteries when the device is to be stored for extended periods of

Note:

Removing the batteries will erase all readings in memory.

. Use only a soft dry cloth to clean the unit. Do not use solvents or other petroleum based cleaners.

DA 001

. Circuit diagram and repairable part can provided if it's nessary.

Specifications

Model:	BA-8U1					
Measuring method:	Oscillometric					
Memory function:	Storage and recall 90 measurements with average					
Display:	Digital LCD					
Measuring range:	Pressure: 0-280 mmHg Pulse: 40-199/minute					
Sensor accuracy:	Pressure:±3 mmHg Pulse:: ±5%					
Inflation system:	Electro-pneumatic pump					
Arm size ranges:	24-34 cm(9.4-13.4 inches)					
Batteries:	1.5V alkaline (LR6/AA)X4					
Automatic power-off:	Approx. 1 minute after measurement					
Reference method for clinical trials:	Auscultatory measurement					
Weight:	Approx. 460g(NO batteries)					
Storage and transport condition:	+5°C~+40°C 10%~90%RH					
Operating condition:	-20℃~+65℃ 10%~95%RH					
Standard cited:	EN 1060-1 EN 60601-1-2 EN 1060-3 EN 14971					
	EN 60601-1 YY-0670					

Troublachaating

Troubleshooting							
Problem	Recommended method						
No display	Make sure that the batteries are installed in the proper direction. (Polarity matches to the indication in the battery case.)						
No measurement occurs	Check that the cuff is positioned properly, pgo over the measurement procedure again.						
Blood pressure	Check if the arm is positioned properly Position your arm on a table, so the cuff is						
readings are too high or too low	at the same level as your heart Remain seated during the entire measurement						
	period Refrain from hand and body movements during measurement						
Blood pressure reading	Your blood pressure can fluctuate considerably throughout the day, all of the following factors can influence your blood pressure						
are vaiable	Emotional state						
valubic	Daily activities or exercise						
	Smoking						
	Drinking alcoholic beverages						
	Eating						
	Taking certain medications						

14 Blood Pressure Log

Date	1/1	1/1	1/1				
Time	7:00	13:30	20:00				
mmHg 240							
220							
200							
180							
160							
140							
	128	134					
120			123				
100							
		90					
80	84	/					
			ļ				
60							
Pulse	70	73	69				
Body Condition							

