

BASELINE®

EVALUATION

INSTRUMENTS

Electronic Blood Pressure Monitor

Wrist Model

Instruction Manual

REF 12-2151

U60E

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Introduction

▲ Thank you for purchasing the Baseline® Wrist Blood Pressure Monitor. Please read the manual carefully before you use the unit, and keep the manual after using.

▲ The unit is compact and easy to use, and adopts the oscillometric principle. It measures your blood pressure using advanced "Intellisense" for comfortable controlled inflation without the need for pressure presetting or reinflation. This unit is only intended for users age 12 and older.

▲ This unit stores results for 2 users, 90 measurement readings per user. Measurements are displayed on the screen and automatically stored. This unit has a blood classification index, it is easy to check your blood pressure.

Contraindication:
Do not use this product on patients with severe heart insufficiency to avoid risk of suffocation or death. This product is not suitable for infants and children.

INTENDED USE
This automatic blood pressure monitor intends to measure systolic pressure, diastolic pressure and pulse rate through the wrist. It is expected to be used at home or in the hospital, intended for people age 12 and older.

Safety Information

To ensure the correct use of the product, basic safety measures should always be followed including the warnings and the cautions listed in the instruction manual:

Symbol Descriptions

The following symbols may appear in this manual, on the label, on the device, or on its accessories. Some of the symbols represent standards and compliances associated with the device and its use.

▲ **WARNING:** This alert identifies hazards that may cause serious personal injury or death.

⚠ **CAUTION:** This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

Safety Information

⚠ Type BF applied part

🏭 Manufacturer

SN Specifies serial number

EC REP Authorized Representative in the European Community

CE CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

🗑 DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

⚡ Direct Current

📖 Follow instructions for use

⚠ CAUTION: Consult accompanying documents

Safety Information

⚠ Those with arrhythmia, diabetes, blood circulation or apoplexy problem, should only use the monitor under physician instruction.

⚠ Contact your physician for specific information about your blood pressure. Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your physician or licensed health care provider.

⚠ Store in a high place where children cannot reach.

⚠ No modification of this equipment is allowed.

⚠ Do not modify this equipment without authorization of the manufacturer.

⚠ If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

⚠ The cuff hose around neck may cause suffocation.

⚠ The swallowing of small part like packaging bag, battery, battery cover and so on may cause suffocation.

Safety Information

⚠ Do not use a dilution agent, alcohol or petrol to clean the unit. Do not hit heavily or knock down the product from a high place. Use the right cuff otherwise it will not work.

⚠ Never leave a low battery in the battery compartment, as it may leak and cause damage to the unit.

⚠ Remove the battery if you will not be using the device for 3 months

⚠ Replace batteries if the unit displays a low battery symbol.

⚠ Do not mix old and new batteries.

⚠ Do not use a cellular phone near the unit. It may result in operational failure.

⚠ Avoid use in high radiant area to ensure your measuring data is correct.

⚠ Do not use the equipment where flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) are present.

Safety Information

⚠ **WARNING:**
Do not dispose of electrical appliances as unsorted municipal waste; use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

Classification
1. Internally powered equipment;
2. Type BF applied part;
3. Protection against ingress of water or Particulate matter: IP21;
4. Not category AP / APG equipment;
5. Mode of operation: intermittent operation.

⚠ The user must check that the equipment functions safely and see that it is in proper working condition before being used.

Product Structure

UNIT

① LCD Display
② Start/Stop Button
③ Memory Button
④ Battery Cover
⑤ CUFF

DISPLAY

① User
② Year/month/date/time
③ Systolic Blood Pressure
④ Irregular Heart Beat
⑤ Diastolic Blood Pressure
⑥ Memory Times
⑦ Pulse
⑧ Memory Symbol
⑨ Low Battery
⑩ Pulse Rate
⑪ Blood Pressure Classification

Components

BATTERY

1.5X2AAA
alkaline batteries

STORAGE BOX

Battery Installation

Battery Installation And Replacement

1. Push the hook on the bottom of the battery cover as pictured.

2. Insert two 1.5V AAA batteries (included) in the battery compartment. Place the batteries "+" and "-" in the correct spots and facing in the right direction.

3. Push the battery cover back over the main unit.

Battery Installation

Low battery and replacement
When the power is on, the low battery symbol will display and the unit will not work until the batteries are changed.

Battery type and replacement
Use (2) 1.5V AAA batteries. Do not use the batteries beyond their expiry date. If the monitor is not in use for a period of time, remove the batteries.

WARNING
Dispose the batteries in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the batteries.

Setting Mode

HOW TO SET USER
Press and hold the MEM button to turn on. The screen will display or . Press the START/STOP button to change between users. The device will then enter into year-setting mode.

User 1

User 2

YEAR SETTING
After the above step, the screen will display the year. Press the START/STOP button to increase the numbers. Press the MEM button to confirm the year. The device will then enter into date-setting mode.

20 20

Year Setting

Setting Mode

MONTH AND DATE SETTING
After the above step, the screen will display month-day (XX/XX). Press the START/STOP button to set the number from 01 to 12. Press the MEM button to confirm the month.

20 20
1/0 1

Month Setting

Same as the month settings, press the START/STOP button to set the day number from 01 to 23. Press the MEM button to confirm the date. The device will then enter into time-setting mode.

20 20
1/0 1

Date Setting

Setting Mode

TIME SETTING
After the above step, the screen will display time (XX:XX). Press the START/STOP button to set the number from 0 to 23. Press the MEM button to confirm the hour. Same as the hour settings, press the START/STOP button to set the number from 00 to 59. Press the MEM button to confirm the minute. The time setting mode is now complete.

Note:
You will need to reset the date and time if the battery has been removed for more than 30 seconds.

8:08
1/0 1

Hour Setting

8:08
1/0 1

Minute Setting

Proper Use of The Unit

Measurement

Pre-measurement
Relax for about five to 10 minutes prior to the measurement. Avoid eating, drinking alcohol, smoking, exercising and bathing for 30 minutes before taking a measurement. All these factors will influence the measurement results.

Remove any garment that fits closely to your wrist. Always measure on the same wrist (normally left).

Take measurements regularly at the same time every day, as blood pressure changes throughout the day.

Proper Use of The Unit

Common factors of wrong measurement
All efforts by the patients to support their arm can increase blood pressure.

Make sure you are in a comfortable, relaxed position and do not activate any of the muscles in the measurement arm during measurement. Use a cushion for support if necessary.

If you put your wrist lower or higher than your heart, a false reading will occur.

Note:
Only use clinically-approved cuffs!

A loose cuff or a exposed bladder causes false reading.

With repeated measurements, blood accumulates in the arm, which can lead to false reading.

Consecutive blood pressure measurements should be repeated after 1 minute pause or after the arm has been held up in order to allow the accumulated blood to flow.

Proper Use of The Unit

1. Roll up your sleeve. Make sure your sleeve is not rolled up too tightly on your arm; this may constrict the flow of blood in your arm.

2. Wrap the cuff directly against your skin. Hold the bottom part of the cuff and wrap it around the wrist so it fits comfortably and securely around your wrist as the picture shows.

3. Sit in a chair and assume an upright body posture. Place the monitor at the same level as your heart.

Too low

Too high

Correct position

Proper Use of The Unit

4. Press the START/ STOP button; the monitor will measure your blood pressure automatically, remain still while the monitor is in use.

Note:
If it is not possible to fit the cuff to your left wrist, it can be placed on your right wrist. However, all measurements should be made using the same wrist.

Proper Use of The Unit

NOTE:
The symbol is displayed along with the reading if an irregular heartbeat is detected during the measurement.

Discontinuing a measurement
If it is necessary to interrupt a blood pressure measurement for any reason (ex. the patient feels unwell) the START/STOP button can be pressed at any time. The device will immediately decrease the cuff pressure automatically.

Memory-recall of measurements
This blood pressure monitor stores measurements for 2 users, with 90 measurements recorded per user. The oldest measurement will be replaced by the latest measurement when each user exceeds 90 readings.

Read memory record
Press the MEM button when powered off; the average of the latest 3 readings will be shown. Press the MEM button again: the last measurement will be shown. Subsequent measurements can be displayed one after the other by pressing the MEM button each time.

Proper Use of The Unit

123
82
73

120
80
78

128
82
70

121
84
71

Clear all measurements
If you are sure that you want to permanently remove all stored measurements. Long press the MEM button to enter into setting mode. When powered off, press the MEM button 6 times until CL appears. Press the START/STOP button; CL will flash 3 times to clear the measurements. Press MEM button again: M and "no" will be shown on the display, which means the memory has been cleared.

CL

About Blood Pressure

About Blood Pressure

Blood pressure is the pressure that is exerted in the arteries. Systolic blood pressure value represents the blood pressure produced by contraction of the heart muscle.

Diastolic blood pressure value represents the blood pressure produced by relaxation of the heart muscle.

Systolic blood pressure

Diastolic blood pressure

About Blood Pressure

■ According to the blood pressure classification by the WHO/ISH.

■ SYS lower than 100mmHg is considered hypotension.

Diastolic blood pressure (mmHg)

110
100
90
85
80

Severe hypertension

Moderate hypertension

Mild hypertension

High normal value

Normal blood pressure

Optimal blood pressure (target value)

120 130 140 160 180

Systolic blood pressure (mmHg)

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

About Blood Pressure

Blood Pressure Type

118

70

78

Optimal blood pressure

126

70

82

Normal blood pressure

135

75

88

High normal value

146

72

93

Mild hypertension

165

78

106

Moderate hypertension

182

76

118

Severe hypertension

25

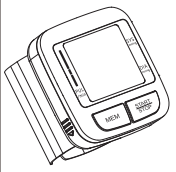
Care and Maintenance

Make sure the monitor is off prior to cleaning. Use a mixture of distilled water and 10 percent bleach.

Using a spray bottle, moisten a soft cloth towel with the bleach or detergent mix until it is fully saturated. Squeeze any excess moisture from the cloth to avoid dripping or potential oversaturation of the cuff.

Wipe all surfaces of the blood pressure monitor cuff thoroughly, making sure to clean the inside and outside of the cuff. Be cautious not to get any moisture in the main unit.

Using a dry cloth, gently wipe away any excess moisture that may remain on the blood pressure cuff. Lay the cuff flat in an unrolled position and allow the cuff to air dry.



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Warranty Information

Statement

- The intended use: the unit is intended to be used by adults at home or at a medical center to measure blood pressure and pulse rate from the wrist.
- The device meets the requirements of IEC 80601-2-30 Part 2 for non-invasive blood pressure monitors.
- Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer.
- The cuff/stethoscope auscultatory method is within the limits prescribed by the American National Standard, manual, electronic, or automated sphygmomanometers.
- The risk of patient and user can be lowered to an acceptable level.

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EMC Declaration

Technical description

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not application
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not application

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EMC Declaration

Radiated RF IEC6100 0-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	710 745 780	704 — 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
	810 870 930	800 — 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	1720 1845	1700 — 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	2450	2400 — 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240 5500 5785	5100 — 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

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Exceptional Situation

Error indicators
The following symbols will appear on the display when measuring is abnormal.

Symbol	Cause	Correction
	Weak signal or pressure change suddenly	Wrap the cuff properly. Remeasure the correct way.
	External strong disturbance	When near cell phone or other high radiant device the measurement will fail. Keep quiet and no talking while measuring
	An error occurs during the process of inflating	Wrap the cuff properly. Make sure that the air plug is properly inserted in the unit. Remeasure.
	Abnormal blood pressure	Repeat the measurement after relaxing for 30 min. If you get an unusual reading 3 times, please contact your doctor.
	Low battery	Replace old batteries with new ones.



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Care and Maintenance

Maintenance



Do not clean the body and cuff with gasoline or other flammable substances

Do not wet the cuff or attempt to clean the cuff with water.



Store the unit in a clean and dry location. Do not subject the unit to extreme hot or cold temperature, humidity or direct sunlight.

Remove the batteries if the unit will not be in use for 3 months or longer.



⚠ We are not responsible for any quality-related problems if the device is not maintained as instructed.

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Warranty Information

Warranty Information

- The unit is guaranteed to be free of defects in workmanship and materials under normal use for a period of two years from the date listed on the purchase record.
- For repair under this warranty, our authorized service agent must be advised of the fault with the period of the warranty. This warranty covers part and labor only under normal operations. Any defect resulting from natural causes, eg. flood, hurricane etc, is not within this guarantee. This guarantee does not cover damage incurred by use of the unit not in accordance with the instructions, accidental damage, or being tampered with or serviced by unauthorized service agents.
- Monitor subjected to misuse, abuse, and neglect of these manual content, non-instructional purposes; unauthorized repair or modifications will be excluded from this warranty.

⚠ The device is not repairable and contains no user-serviceable parts.

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EMC Declaration

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines ±2 kV input/output lines ±1 kV 100 kHz repetition frequency	Not application
Surge IEC 61000-4-5	line(s) to line(s) ±0.5 kV ±1 kV. 0% 0.5 cycle At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	Not application
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11		Not application

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Exceptional Situation

Trouble removal

Problem	Check	Cause and solutions
No power	Check the battery power	Replace with new ones
	Check the polarity position	Reinstall batteries and ensure proper polarization
Error and stops working	Moved the wrist when inflating	Keep the body still
	Check if talking when measuring	Keep quiet when measuring
Cuff leak	If the cuff wrap is too loose	Wrap the cuff tightly
	If the cuff is broken	Change to a new cuff
⚠ Please contact the distributor if you cannot solve the problem. Do not disassemble the unit by yourself!		

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Specification

Description	Automatic wrist blood pressure monitor	
Display	LCD digital display	
Measuring principle	Oscillometric method	
Measuring localization	Wrist	
Measurement range	Pressure	0~299 mmHg
	Pulse	40~199 pulses/min
Accuracy	Pressure	±3mmHg
	Pulse	±5% of reading
LCD indication	Pressure	3 digit display of mmHg
	Pulse	3 digit display
	Symbol	Memory/Heartbeat/Low battery
Memory function	2x90 sets memory of measurement values	
Power source	2pcs AAA alkaline battery DC 3V	

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EMC Declaration

IEC 60601-1-2 2014 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product

Instructions for use
The ME EQUIPMENT or ME SYSTEM is suitable for home health care environments and so on.

Warning Do not use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, when the intensity of EM disturbances is high.

Warning Use of this equipment adjacent to or stacked with other equipment should be avoided because it may result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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EMC Declaration

Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Not application
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz

NOTE U_r is the a.c. mains voltage prior to application of the test level.

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Care and Maintenance

Keep the unit in the storage case when not in use.

Clean the unit with a soft, dry cloth.

Do not use any abrasive or volatile cleaners.

Never immerse the unit or any component in water.



⚠ We are not responsible for any quality-related problems if the device is not maintained as instructed.

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Specification

Automatic power off	In 3 minutes	
Main unit weight	Approx. 96g (batteries not included)	
Main unit size	L69.5mm • W66.5mm • H60.5mm	
Battery life	Can be used for 300 times for normal condition	
Accessories	Cuff, instruction manual	
Operating environment	Temperature	5~40°C
	Humidity	15%~93%RH
	Air pressure	86kPa~106kPa
Storage environment	Temperature -20°C~55°C, Humidity: 10%~93%RH avoid impact, sun or water exposure during transportation.	
Cuff size	Wrist circumference approx. Size 13.5~21.5CM	

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EMC Declaration

Warning Portable RF communications equipment (included peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the blood pressure monitor, included cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

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EMC Declaration

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380~390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
	450	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0,3	28

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