

FORE-CARE™

ADVANCED WRIST BLOOD PRESSURE MONITOR



♥ SE-315

USER MANUAL



READ BEFORE USE

CE 0123

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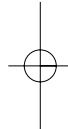


GENEXEL MEDICAL

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1. Caution

This device is designed to make automatically rapid exhaust if cuff pressure is 320 mmHg or more. If the cuff doesn't make automatically rapid exhaust when cuff pressure is 320 mmHg or more, please detach the cuff from the wrist.

2. Introduction

Thank you for purchasing the SE-315 Full Auto Wrist Digital Blood Pressure Monitor. The SE-315 is a compact, and light device which is easy to use due to an oscillometric method of measurement, in addition to a small, pre-formed wrist cuff of the unit, which is easy to apply. With the touch of a button the compact Wrist unit measures your blood pressure and pulse and displays the reading on a clear digital panel. Perfect for quick, easy readings at home, at work, almost anywhere!

The Compact Wrist unit uses the oscillometric method of blood pressure measurement. This means the unit detects your blood's movement through the artery in your wrist and converts the movements into a digital reading. An oscillometric unit does not need a stethoscope so that unit is simple to use and measurements are easy to obtain.

Clinical research has proven a direct relationship between blood pressure in the wrist and blood pressure in the arm.

Changes in Wrist blood pressure reflect changes in arm blood pressure because the arteries in the wrist and the arm are connected. Frequent wrist blood pressure measurement will provide you and your doctor with an accurate indication of changes in your true blood pressure.

Blood pressure measurement is determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard for Electronic or Automated Sphygmomanometer. (ANSI/AAMI SP10-1992)

The fifth Korotkoff sound was used to determine diastolic blood pressure.

3. Important Information before Blood Pressure Measurement

- To ensure accurate measuring result, carefully read these use instructions.
- This product is intended for household use only. Keep product and batteries away from children.
- People suffering from cardiac arrhythmia, vascular constriction, arteriosclerosis in extremities, diabetes or users of cardiac pacemakers should consult their doctor before measuring their blood pressure themselves, since deviations in blood pressure values may occur in such cases.

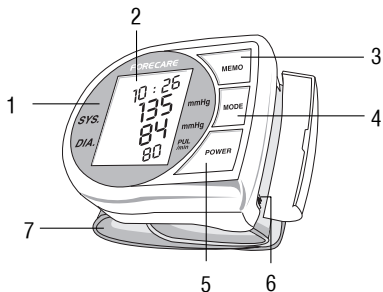
- If you are under medical treatment or taking any medication, please consult your doctor first.
- The use of this blood pressure monitor is not intended as a substitute for consultation with your doctor.
- Hold the monitor at heart level when measuring.
- Wait approximately 5 minutes before repeating a measurement.
- Always take readings at the same time of the day, ideally in the morning under same conditions,
- Do not measure within 30 minutes after smoking, coffee or tea consumption.
- Take off wrist watch and jewelry before fitting the monitor on the measuring arm.
- While taking a measurement, sit down, relax, keep still, especially the hand of the measuring arm, do not move or speak.
- It is recommended that the performance should be checked every two years after maintenance and repair according to the requirements in 7.1.1 of EN 1060 - 1:1995 and 7.4.1 of EN 1060 - 3:1997

4. Operation Guide

See the steps below for your convenience.

Battery Installation	See page 8
▼	
Attaching pressure cuff	See page 9
▼	
Correct measurement position	See page 10
▼	
How to measure	See page 11
▼	
Displaying measurements	See page 13
▼	
Memory recall function	See page 14
▼	
Description of display symbols	See page 18

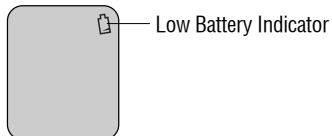
5. Parts Identification



- | | |
|----------------|-----------------|
| 1. Main frame | 5. POWER Switch |
| 2. Display | 6. Battery |
| 3. MEMO Switch | 7. Cuff |
| 4. MODE Switch | |

6. Battery Installation / Replacement

- If the Low Battery Indicator appears on the display, replace both batteries.



Only discard empty batteries. They should not be disposed of in the household waste, but at appropriate collection sites or at your retailer.

- To do so, remove the cover from the battery compartment and insert the batteries as shown. Be sure to pay attention to the polarity of the batteries.

IMPORTANT

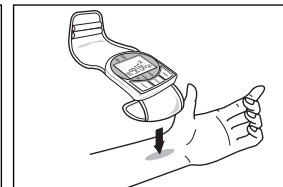
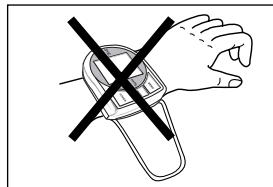
In order to ensure that the device functions properly, the cover of the battery compartment must fit tightly.

“Take the battery out of the main unit when this device will not be used for a long time. If the batteries are not used any more, please dispose of them in accordance with National Regulation.”

7. Attaching Pressure Cuff

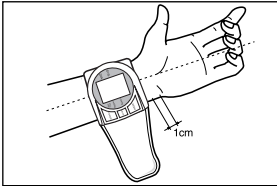
Wrap the pressure cuff around the wrist.

- The display should be placed on the palm side of the wrist.
- The wrist should be bare skin.



Fasten the pressure cuff snugly.

- Do not pull the pressure cuff.
- Do not tighten the pressure cuff too much.
- The cuff edge should be approximately 1cm above from your palm.

**NOTE**

Please use only a cuff supplied by Genexel Medical Instrument, Inc. using other cuffs may impede measurement.

8. Correct Measurement Position**Measurement values vary according to your posture.****Measure your blood pressure in the sitting position**

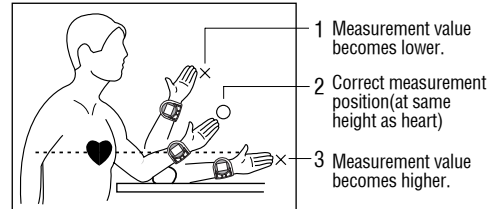
- Place your elbow on a table or other object.
- Use the storage case to position the arm so that the pressure cuff is at the same height as the heart.
- Open your hand and fingers slightly, and relax.
- Blood pressure will vary in relation to the level of the cuff

from the heart. A 10cm difference will result in an 8mmHg measurement error.

- Relax your hand with the palm facing up.

NOTE

Your heart is located slightly below your armpit.

**For successive readings, wait 5 to 8 minutes between measurements.**

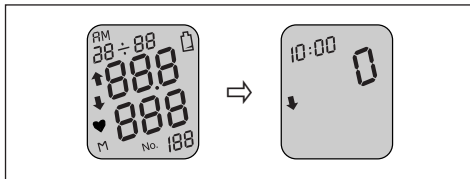
- Waiting allows the engorged blood vessels to return to normal before each new measurement is taken.

9. How to Measure

Please read “IMPORTANT INFORMATION BEFORE BLOOD PRESSURE MEASUREMENT” and “CORRECT MEASUREMENT POSITION” and “ATTACHING PRESSURE CUFF” before measuring.

Turn Power On

- When Power is turned on, all display symbols appear for approximately 1 second.
- The display symbols disappear and the deflation Indicating symbol(↓) starts to flash. Release air in the wrist cuff.
- When the “0” is displayed, the unit is ready for measurement. When the “↓”symbol appears, the air in the cuff is released automatically



Automatic Inflation

- In 1 second, the pressure cuff inflates after the “0” is displayed on the window.
- When the power switch is subsequently pressed during pressurization, the unit is turned off and the cuff deflates.

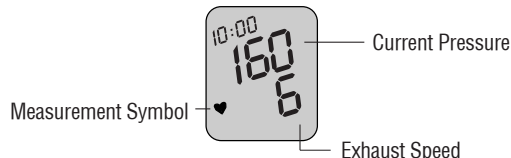
When inflation is completed, the “♥”symbol will appear indicating that measurement is in progress.

- Constant-speed deflation

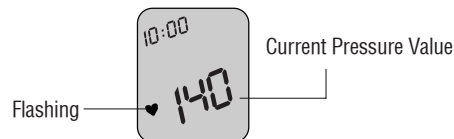
The pressure reducing function starts by opening the solenoid valve for a short time. After the pressure is

reduced and pulse is detected, pressure reduction is synchronized with patient’s pulse cycle and deflation is carried out.

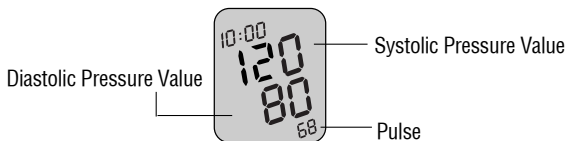
- ① The pressure value appears on the upper part, and exhaust speed on the lower part of the display.



- ② When a pulse is detected, the pressure value moves to the lower part of the display. At this time the “♥” symbol flashes at the same rate as pulse rate.



- ② When the measurement is completed and the buzzer sounds (beeps), Systolic pressure is displayed on the upper part and diastolic pressure is displayed on the middle of the display, and pulse on the lower part of the display.



Turn Power OFF

Press the Power switch to turn Power off.

Automatic Power OFF Function

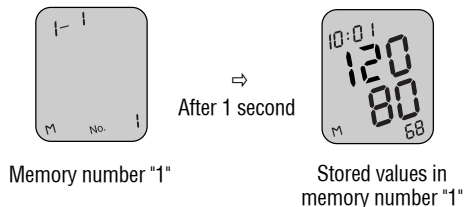
If the unit is left on after measurement an automatic POWER OFF function turns the power off after approximately 1 minute.

Memory Recall Function

- ① To confirm previous measurement value, press Memory switch while current measurement value or time is displayed.
- ② After "M no.1" and date of the measurement are displayed for 1 second, the measurement value in

Memory No.1 is displayed for 5 seconds, and the display automatically returns to the previous.

- ③ Memory No. is increased by 1 once Memory switch is pressed while memory No. or measurement value is displayed.
1 second after Memory No. is displayed, stored value in the memory No. is displayed.
- ④ When new measurements is performed, the new measurement value is stored in Memory No.1 and the measurement value which was stored in Memory No. 1 moves to Memory No. 2. automatically.
Measurement value stored in Memory No.58 disappears.



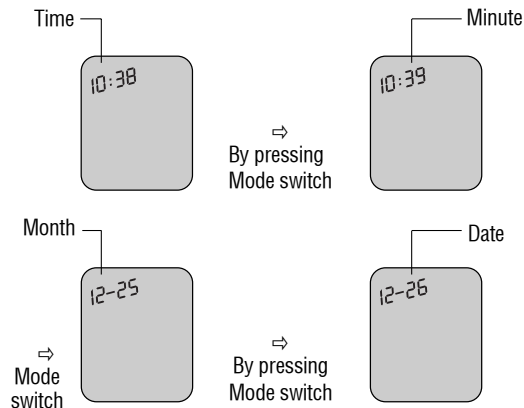
Change of Time and Date

(Press MODE S/W and change with MEMORY S/W)

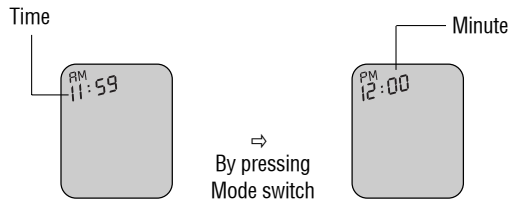
- ① To change time and date, press MODE switch while time or measurement value is displayed.
- ② Flashing refers to the changeable.

- ③ Flashing value increases by 1 once Memory switch is pressed.
- ④ Flashing moves from Time, Minute, Month to Date in turn once MODE switch is pressed.
- ④ The change is completed by pressing Mode switch once more after Date change.
- ④ To stop change, leave the unit without pressing any switch, 10 seconds later the display returns to the previous and current time is displayed





24-hours system with military hour



12-hours system with AM and PM



10. Description of Display Symbols

Display symbol	Condition/Cause	Corrective action
 Measurement in progress	Appears in the measurement condition and flashes when pulse is detected.	Measurement in progress-remain quiet.
 Exhaust	flashes when power is applied and there is air remaining in the cuff.	Automatic exhaust is performed.
 Insufficient pressure	Measurement has begun but the pressure was insufficient.	Automatic repressurization is performed.
 Replace batteries	Appears when the battery voltage is excessively low.	Replace both batteries with new ones.
<i>Err</i> Insufficient pressure	Appears when the accurate blood pressure could not be obtained.	Wait a further 5 minutes and then remeasure. Loosen cuff to allow circulation of blood in the wrist and hand
<i>PUL Err</i> Exhaust	Appears when the accurate pulse rate could not be obtained.	
<i>AM PM</i>	In a 12-hours system AM and PM are displayed.	

11. More about Blood Pressure Measurements

What is Blood Pressure ?

Blood pressure is the force of blood flowing against the walls of the arteries. Arterial blood pressure varies during the course of the cardiac cycle. The highest pressure in the cycle is called the **SYSTOLIC BLOOD PRESSURE** ; the lowest the **DIASTOLIC BLOOD PRESSURE**. Both pressure readings, the **SYSTOLIC** and **DIASTOLIC**, are necessary to enable a physician to evaluate the status of a patient's blood pressure. Many factors such as physical activity, anxiety, or the time of day, can influence your blood pressure. Blood pressure is typically low in the morning and increases from afternoon to evening. It is lower in the summer and higher in the winter.

Why is it important to measure your Blood Pressure at home?

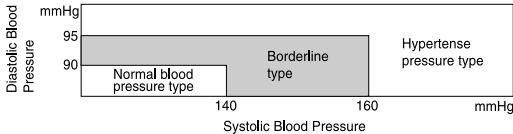
blood pressure measurement by a doctor in a hospital or a clinic, and group health checks, tends to stimulate nervousness in the subject and may even create higher blood pressure. Also blood pressure varies in accordance with a variety of conditions, and so judgment is not possible on the basis of a single measurement.

The blood pressure measured in the morning just after getting up, before taking any food, and with the subject still, is known as the fundamental blood pressure. In practice, it is rather difficult to record the fundamental blood pressure, but to come as near as possible to measuring the blood pressure in

the environment that is close to this, is why it is useful to take the measurement at home.

Who Blood Pressure Classifications

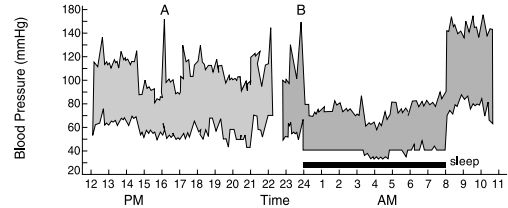
Standards for assessment of high or low blood pressure, without regard to age, have been established by the World Health Organization (WHO), as shown in this chart.



Reference Material : Investigation into Adult Diseases Report by the Ministry of Health and Social Security, 1971.

Variations in Blood Pressure

Individual blood pressures vary greatly both on a daily and a seasonal basis. These variations are even more pronounced in hypertensive patients. Normally the blood pressure rises while at work and is at its lowest during the sleeping period. The graph below illustrates the variations in blood pressure over a whole day with measurement taken every five minutes.



Shown is data for measurements taken every 5 minutes. The thick line represents sleep. The rise in blood pressure at 4 PM(A in the graph) and 12 PM(B in the graph) correspond to an attack of pain and sexual intercourse. (Beven, Honor & Stott : Clin. Sci. 36 : 329,1969)

12. Care and Maintenance

1. Avoid storing the unit where it will be exposed to direct sunlight, dust or high humidity.
2. Do not Wash the main unit or pressure cuff.
3. Do not disassemble the unit.
4. Do not drop the unit. Protect it from sudden jars or shocks.
5. Do not clean the unit with volatile liquids.
The unit and pressure cuff may be wiped clean with a soft, dry cloth.

13. Limited Three Year Warranty

Your SE-315 Full Auto Wrist Digital Blood Pressure Monitor is warranted to be free from manufacturing defects for a period of three years under normal use. This warranty extends only to the original retail purchaser.

Should repair be needed within the warranty period, ship the unit prepaid to **Genexel Medical Instrument, Inc. #196, Anyang7-Dong, Manan-Gu, 430-017 Anyang-City, Kyunggi-Do, KOREA.**

ATTN : Service Dept. Be sure to include the model number of your unit and your phone number on any correspondences. We will either repair or replace (at our option) free of charge any parts necessary to correct defects in the materials or workmanship. The above Warranty is Complete and exclusive. The warrantor expressly disclaims liability for incidental, special, or consequential damages of any nature some states do not allow the exclusion or limitation of incidental or consequential damages, so the above warranty may not apply to you.

Any implied warranties arising by the operation of law shall be limited in duration to the term of this warranty. (Some states do not allow limitations on how long an implied warranty lasts, So the above limitation may not apply to you)

This warranty gives you specific legal rights and you may have other rights which vary from state to state. As a

condition to operation of your warranty, the enclosed registration card must be completed and sent to us within one month from the date of purchase.

FOR CUSTOMER SERVICE CALL 82-2-575-1141 (EXT : 201)

14. FCC Information

Warnings

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Note

Potential For Radio/ Television Interference (for U.S.A. only) This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or


more of the following measures: Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Potential For Radio/Television interference (for Canada only)
This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the interference-causing equipment standard entitled "DigitalApparatus", ICES-003 of the Canadian Department of Communications.

Cet appareil numérique respecte les limites de bruits radioélectriques applicables aux appareils numériques de Classe B prescrites dans la norme sur le matériel brouilleur: "Appareils Numériques", NMB-003 édictée par le ministre des communications.

15. Specifications

Name and model number	Full Auto Wrist Digital Blood Pressure Monitor SE-315
The degree of protection against electric shock	Type BF equipment 
Display system	Digital display system/LCD 13 digits SYS, DIA, PULSE, TIME, DATE
Power source	LR03(AAA) 1.5V x 2 batteries
Measuring range	20-300 mmHg (Pressure) 40-199 Pulses/minute (Pulse)
Accuracy	±3 mmHg (pressure) ±5%(Pulse)
Pressurization	Automatic pressurization using a micropump.
Rapid air release	Solenoid valve
Deflation	Solenoid valve, Constant air release
Memory	Built-in memory enabling display of the previous measurement values of 58 Times.
Automatic Power OFF	To be automatically cut off after 1 minute of non use to save energy.
Automatic repressurization	To be automatically repressurized when the cuff pressure is insufficient.
Battery life	Approximately 200 measurements
Operating environment	+10°C ~ +40°C , less than 85% RH
Storage environment	-10°C ~ +60°C , less than 95% RH
Unit Dimensions	125mm(W) x 81mm(D) x 31mm(H)
Weight	Approx. 150g (including 2 batteries)
Cuff Dimensions	Approximately 304(L) x 70(W) mm
Wrist Circumference Range	Approximately 130 ~ 210mm
Accessories	Carrying Case, Instruction Manual, AAA 1.5V x 2 batteries.

These specifications are subject to change without notice for purposes of improvement.

Subject to change without notice.

This device conforms to the following standards :

DIN EN 60601-1 : 3/96 <Medical electrical equipment> -

Part 1 : General requirements for safety

DIN EN 1060-1 : 12/95, AMD 1 09/02 <Non-invasive sphygmomanometers> -

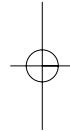
Part 1 : General requirements

DIN EN 1060-3 : 9/97 <Non-invasive sphygmomanometers> -

Part 1 : General requirements

DIN EN 1060-3 : 9/97 < Non-invasive sphygmomanometers> -

Part 3 : Supplementary requirements for electro - mechanical blood pressure measuring systems



MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC. For detailed description of EMC requirements please contact the Genexel Medical Instrument, Inc.

Potable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.



At the end of the product's useful life, please disposal of it at appropriate collection points provided in your country.