Blood Pressure Monitor – Wrist
Tensiomètre de poignet
Blutdruckmessgerät Handgelenk
Sfigmomanometro da Polso
Tensiómetro de muñeca
Tensiómetro de Pulso

CE 0120 REF S150 ALV4725/0

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Attention: Consult the accompanying documents. Please read this manual carefully before use. For specific information on your own blood pressure, contact your physician. Please be sure to keep this manual.

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Introduction

What is blood pressure?

Your heart acts as a pump to circulate blood around your body and help supply it with oxygen. Blood pressure is the force needed for the heart to push blood through the arteries. The highest pressure in this cycle is when the heart contracts, this is called the SYSTOLIC BLOOD PRESSURE. Between contractions, the heart relaxes and blood flows into it since it is at its lowest pressure, which is called DIASTOLIC BLOOD PRESSURE.

Both blood pressure measurements, the systolic and diastolic, are necessary to enable a doctor to evaluate the status of a patient's blood pressure.

Many factors such as physical activity, anxiety, or simply the time of day, can influence your blood pressure.

Drinking caffeine (in tea or coffee) can also temporarily raise your blood pressure, as can the nicotine in cigarettes.

Blood pressure can also follow a daily pattern, varying from minute to minute and typically being at its lowest while we are asleep. These variations are even more pronounced in patients with high blood pressure.

Blood pressure is measured in millimetres of mercury (mmHg) and measurements are written with the systolic pressure before the diastolic e.g. a blood pressure written as 120/80 is referred to as 120 over 80.

Pulse Rate

This blood pressure monitor also measures your pulse rate. Your pulse reflects your heart rate and is measured in terms of the numbers of beats per minute. Pulse rate varies from minute to minute, and is affected by many things, including exercise, stress, anxiety, certain medicines and some foods.

Why is it beneficial to measure your blood pressure at home?

Monitoring your blood pressure at home gives you the advantage of taking blood pressure measurements at fixed times of the day, in familiar surroundings, without external influences. As a variety of conditions affect blood pressure, a single measurement is not sufficient for an accurate diagnosis. Home monitoring enables measurements to be taken over the course of weeks and helps to identify an ongoing trend.

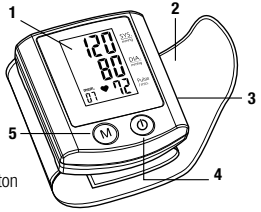
Here are a few tips to help you obtain more accurate measurements:

Blood pressure changes with every heartbeat and varies throughout the day. The measurements that you obtain from this blood pressure monitor will differ as a result.

- Blood pressure recording can be affected by the position of the user, his or her physiological condition and other factors. For greatest accuracy, wait one hour after exercising, bathing, eating, drinking beverages with alcohol or caffeine, or smoking to measure blood pressure.
- Before measurement, it's suggested that you sit quietly for at least 5 minutes as measurement taken during a relaxed state will have greater accuracy. You should not be physically tired or exhausted while taking a measurement.
- Do not take measurements if you are under stress or tension.

- During measurement, do not talk or move your arm or hand muscles.
- Take your blood pressure at normal body temperature. If you are feeling cold or hot, wait a while before taking a measurement.
- If the monitor is stored at very low temperature (near freezing), have it placed at a warm location for at least one hour before using it.
- Wait 5 minutes before taking the next measurement.

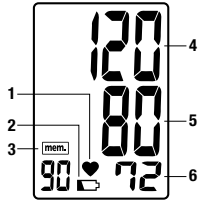
Product Features



1. LCD Display
2. Wrist Cuff
3. Battery Cover
4. ON/OFF/START Button
5. Memory Button

2 “AAA” size,
1.5V batteries

1. Pulse Indicator
2. Weak Battery Indicator
3. Memory Sequence
4. Systolic Pressure
5. Diastolic Pressure
6. Pulse Rate



Accreditation

This unit has been validated in accordance with requirements set by the European Society of Hypertension (ESH). This protocol tests the accuracy of blood pressure monitors to ensure measurements are comparable to those obtained by trained medical professionals

Comfort Inflation Technology

The unit will only inflate as high as necessary to provide greater comfort. It uses the oscillometric method to detect your blood pressure. Before the cuff starts inflating, the device will establish a baseline cuff pressure equivalent to the air pressure. This unit will determine the appropriate inflation level based on pressure oscillations, followed by cuff deflation. During the deflation of the wrist cuff, the monitor is detecting the pressure oscillations generated by the beat-to-beat pulsatile. Any muscle movement during this period of time will cause measurement error. After detecting the amplitude and the slope of the pressure oscillations during the deflation process, your S150 will determine for you the systolic and diastolic pressures, and your pulse rate is detected at the same time.

During the deflation, the device will detect the amplitude and slope of the pressure oscillations and thereby determine for you the systolic blood pressure, diastolic blood pressure, and pulse.

Hypertension Risk

Hypertension can be classified into 4 stages[1].

	Systolic Pressure		Diastolic Pressure
Normal	<120	And	<80
Suspected Hypertension	120~139	Or	80~89
Suspected Stage 1 hypertension	140~159	Or	90~99
Suspected Stage 2 hypertension	≥160	Or	≥100

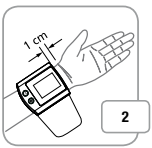
These blood pressure classifications are based on historical data, and may not be directly applicable to any particular patient. It is important that you consult with your physician regularly. Your physician will tell you your normal blood pressure range as well as the point at which you will be considered at risk. For reliable monitoring and reference of blood pressure, keeping long-term records is recommended.

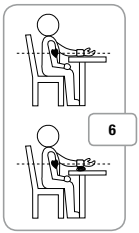
[1] As defined by The United States National High Blood Pressure Education Program Coordinating Committee (7th report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure-Complete Report JNC-7, 2003).

Using your Alvita Blood Pressure Monitor

Applying the Cuff

1. Remove all watches, jewellery, etc. prior to attaching the wrist monitor. Clothing sleeves should be rolled up and the cuff should be wrapped on bare skin for correct measurements.
2. Apply the cuff to your left wrist with your palm facing up as shown in fig. 1.
3. Make sure the edge of the cuff is about 1 cm from the palm as shown in fig. 2.
4. In order to ensure accurate measurements, fasten the velcro strap securely around your wrist so there is no extra space between the cuff and the wrist as shown in fig. 3. If the cuff is not wrapped tight enough, the measurement values may be inaccurate.
5. If your physician has diagnosed you with poor circulation in your left arm, carefully place the cuff around your right wrist as shown in fig. 4.





Correct Measuring Posture

1. Place your elbow on a table so that the cuff is at the same level as your heart as shown in fig. 5. Note: Your heart is located slightly below your armpit and slightly to the left of the middle of your chest. Relax your entire body, especially the area between your elbow and fingers.

2. If the cuff is not at the same level as your heart or if you can not keep your arm completely still throughout the measurement, use a soft object such as a folded towel to support your arm as fig. 6. Do not allow hard objects to come in contact with the wrist cuff.

3. Turn your palm upwards.

4. Sit upright in a chair, and take 5-6 deep breaths. Avoid leaning back while the measurement is being taken as fig. 7.

Measurement Procedures

1. Press the ON/OFF/START button. All digits will light up, checking the display functions. The checking procedure will complete in 2 seconds.
2. After all symbols appear, the display will show a flashing “0”. At this time, the monitor is ready to measure.
3. The monitor will automatically inflate to approximately 180 mmHg and measurement will begin.
4. When the measurement is completed, systolic blood pressure, diastolic blood pressure, and pulse will be shown simultaneously and be saved automatically in the memory system.

Press the ON/OFF/START button to turn the monitor off. If no button is pressed, the monitor will automatically shut off after 1 minute.

This monitor will re-inflate automatically to approximately 220 mmHg if the system detects that your body needs more pressure to measure your blood pressure.

Note:
1. To interrupt the measurement, simply press ON/OFF/START button or Memory button; the cuff will deflate immediately.
2. During the measurement, do not talk or move your arm or hand muscles.

Recalling values from memory

1. To recall stored blood pressure measurements from memory, simply press the Memory button. The last measurement will be shown first. Every new press of the Memory button recalls the previous measurement stored.

Note: The memory bank can store up to 90 measurements per memory zone. When the number of measurements exceeds 90, the oldest data will be replaced with the new measurement

Clearing Values from Memory

1. The data in the memory will not be lost when the Blood Pressure Monitor is switched off.
2. You can erase the memories stored by:
   a. Remove the batteries
   b. Press and hold the memory button for more than 5 seconds
3. The data in the memory zone can be erased if any of the batteries are removed. It is recommended that users record their measurements in a log book before replacing the batteries.

Battery Installation

1. Open the battery cover in the right direction. Install battery in the right position. Battery Type: 2 AAA size. Replace the cover and click in the other end to secure the battery cover.
2. Replace the batteries in pairs.
3. Remove batteries when unit is not in use for extended periods of time.

You need to replace the batteries when
1. The low battery icon appears on display.
2. The ON/OFF/START button is pressed and nothing appears on the display.

⚠ Caution:

1. Batteries are hazardous waste. Do not dispose them together with the household garbage.
2. There are no user serviceable parts inside. Batteries or damage from old batteries are not covered by warranty.
3. Always use branded batteries. Always replace all of the batteries at the same time. Use batteries of the same brand and same type.

Troubleshooting

Display Explanations

EE / Measurement Error: Measure again. Wrap the cuff correctly and keep wrist steady during measurement. If the error keeps occurring, return the device to your local distributor or service centre.
E1 / Air Circuit Abnormality: Measure again. If the error keeps occurring, return the device to your local distributor or service centre.
E2 / Pressure Exceeding 300 mmHg: Switch the unit off and measure again. If the error keeps occurring, return the device to your local distributor or service centre.
E3 / Data Error: Remove and reload the batteries. If the error keeps occurring, return the device to your local distributor or service centre.
Er / Exceeding Measurement Range: Measure again. If the error keeps occurring, return the device to your local distributor or service centre.

If any abnormality arises during use, please check the following points.

Symptoms	Check Points	Correction
No display when the ON/OFF/START button is pressed	Have the batteries run down?	Replace them with new batteries.
	Have the batteries' polarities been positioned incorrectly?	Re-insert the batteries in the correct positions.
EE mark shown on display or the blood pressure value is displayed excessively low or high	Is the cuff positioned correctly?	Wrap the cuff properly so that it is positioned correctly.
	Did you talk or move during measurement?	Measure again. Keep arm steady during measurement.
	Did you vigorously shake the cuff during measurement?	

Note: If the unit still does not work, return it to your pharmacist. Under no circumstance should you disassemble and repair the unit by yourself.

Cautionary Notes

1. The unit contains high-precision assemblies. Therefore, avoid extreme temperatures, humidity, and direct sunlight. Avoid dropping or strongly shocking the main unit, and protect it from dust.
2. Clean the blood pressure monitor body and the cuff carefully with a slightly damp, soft cloth. Do not press. Do not wash the cuff or use chemical cleaner on it. Never use thinner, alcohol or petrol (gasoline) as cleaner.
3. Leaky batteries can damage the unit. Remove the batteries when the unit is not used for a long time.
4. The unit should not be operated by children so to avoid hazardous situations.
5. If the unit is stored near freezing, allow it to acclimate at room temperature before use.
6. This unit is not field serviceable. You should not use any tool to open the device nor should you attempt to adjust anything inside the device. If you have any problems, please contact the store or the doctor from whom you purchased this unit.
7. As a common issue for all blood pressure monitors using the oscillometric measurement function, the device may have difficulty in determining the proper blood pressure for users diagnosed with common arrhythmia (atrial or ventricular premature beats or atrial fibrillation), diabetes, poor circulation of blood, kidney problems, or for users suffered from stroke, or for unconscious users.
8. To stop operation at any time, press the ON/OFF/START button, and the air in the cuff will be rapidly exhausted.
9. Once the inflation reaches 300 mmHg, the unit will start deflating rapidly for safety reasons.

10. Please note that this is a home healthcare product only and it is not intended to serve as a substitute for the advice of a physician or medical professional.
11. Do not use this device for diagnosis or treatment of any health problem or disease. Measurement results are for reference only. Consult a healthcare professional for interpretation of pressure measurements. Contact your physician if you have or suspect any medical problem. Do not change your medications without the advice of your physician or healthcare professional.
12. Electromagnetic interference: The device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens These may lead to temporary impairment of measurement accuracy.
13. Dispose of device, batteries, components and accessories according to local regulations.
14. This monitor may not meet its performance specification if stored or used outside temperature and humidity ranges specified in Specifications.

Store between 10 – 90% RH	
Store between 700 – 1060hPa	

Specifications

Blood pressure measurements determined with S150 are equivalent to those obtained by a trained observer using cuff/ stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometers. This unit is to be used by adult consumers in a home environment. Do not use this device on infants or babies.

Power source	DC 3V Two AAA batteries
Measurement Method	Oscillometric
Measurement Range	Pressure: 30~260 mmHg; Pulse: 40~199 beats/ minute
Accuracy	Pressure: ± 3mmHg; Pulse: within ±5% of measurement
Pressure Sensor	Semi conductor
Inflation	Pump Driven
Deflation	Automatic Pressure release valve
Memory capacity	90 memories
Auto-shut-off	1 minute after last button operation
Operation Environment	10°C~40°C (50°F~104°F); 40%~85% RH; 700~1060 hPa
Storage and Transportation Environment	-10°C~60°C (14°F~140°F); 10%~90% RH; 700~1060 hPa
Dimensions	82(L) x 69(W) x 66(H) mm

Weight	115g (w/o batteries)
Wrist circumference	13.5~22cm (5.3”~8.7”)
Cuff materials	Outer fabric: Nylon Air bag: PVC
Limited Users	Adult users
	Type BF: Device and cuff are designed to provide special protection against electrical shocks.
IP Classification	IP22: Protection against harmful ingress of water and particulate matter
*Specifications are subject to change without notice.	

This Blood Pressure Monitor complies with the European regulations and bears the CE mark “CE 0120”. The quality of the device has been verified and conforms to the provisions of the EC council directive 93/42/EEC (Medical Device Directive), Annex I essential requirements and applied harmonized standards.
EN 1060-1: 1995/A2: 2009 Non-invasive sphygmomanometers - Part 1 - General requirements
EN 1060-3: 1997/A2: 2009 Non-invasive sphygmomanometers - Part 3 - Supplementary requirements for electro-mechanical blood pressure measuring systems
EN 1060-4: 2004 Non-invasive sphygmomanometers - Part 4: Test Procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.
This blood pressure monitor was designed for long service time. To ensure accurate measurements, this monitor is recommended to be re-calibrated every 2 years.

EMC guidance and manufacturer's declaration

Guidance and manufacturer's declaration-electromagnetic emissions		
The S150 is intended for use in the electromagnetic environment specified below. The customer or the user of the S150 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The S150 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The S150 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity. The S150 is intended for use in the electromagnetic environment specified below. The customer or the user of the S150 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input line IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the S150 requires continued operation during power mains interruptions, it is recommended that the S150 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity			
The S150 is intended for use in the electromagnetic environment specified below. The customer or the user of the S150 should assure that is used in such and environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80MHz to 2,5 GHz	Not applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the S150, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$, $d = 1,2\sqrt{P}$ 80MHz to 800 MHz, $d = 2,3\sqrt{P}$ 800MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the S150 is used exceeds the applicable RF compliance level above, the S150 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the S150.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the S150

The S150 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the S150 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the S150 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz / $d=1,2\sqrt{P}$	80MHz to 800MHz / $d=1,2\sqrt{P}$	800MHz to 2,5GHz / $d=2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING: The symbol on this product means that it's an electronic product and following the European directive 2012/19/EU the electronic products have to be dispose on your local recycling centre for safe treatment.

This instrument is covered by a 2 year guarantee from the date of purchase. Batteries, cuff and wearing parts are not included. Opening or altering the instrument invalidates the guarantee. The guarantee does not cover damage, accidents or non-compliance with the instruction manual. Please contact your pharmacist.

S150 is protected against manufacturing defects by an established International Warranty Program. For warranty information, you can contact your pharmacist.

Blood Pressure Log / Fiche de suivi de votre tension artérielle / Blutdruckprotokoll / Registro della pressione arteriosa / Cuaderno de registro de la presión arterial / Registo de medição da pressão arterial

☐1 ☐2

mmHg

220

200

180

160

140

120

100

80

60

Pulse/Pouls/ Puls/Pulsazioni/ Pulsaciones/ Pulsação

Blood Pressure Log / Fiche de suivi de votre tension artérielle / Blutdruckprotokoll / Registro della pressione arteriosa / Cuaderno de registro de la presión arterial / Registo de medição da pressão arterial

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