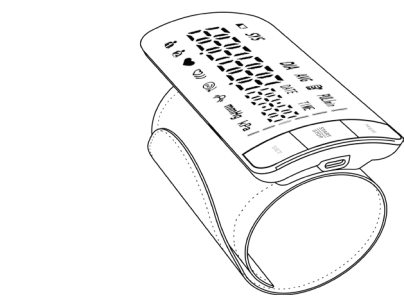


SEAGULL®

Upper Arm Blood Pressure Monitor

USER MANUAL FDBP-A13



- Subject to our actual product.**
- Thank you for purchasing the upper arm electronic blood pressure monitor.
 - Please read the instruction manual carefully before use to ensure safe use of this product.
 - After reading, please keep it properly for reference at any time.
 - A warranty card is included. Please keep it safe.

CONTENT

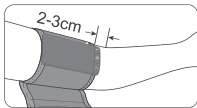
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1. Quick instructions

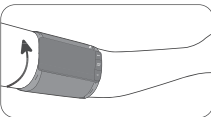
1. Correct posture for measurement posture.



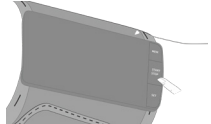
2. As indicated on the cuff, wrap the cuff around the upper arm. The arrow should point towards the hand, and the cuff's bottom edge should be 2-3 cm above the elbow joint.



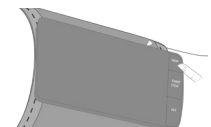
3. Tighten the cuff and secure the adhesive strip fastener.



4. Press the [START/STOP] button to start measuring blood pressure.



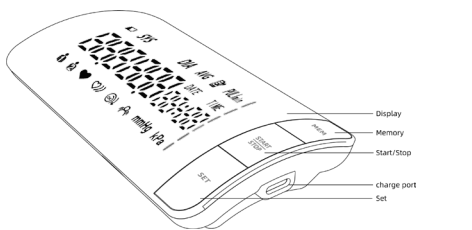
5. Press the [MEMORY] button to view measurement records.



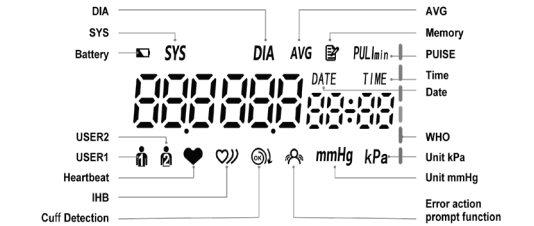
2. Product Structure Description

Structure and Composition: The product consists of the main device (including air pump, pressure sensor, deflation valve, power supply, microcomputer controller, display module, and software) and the cuff.

2.1 Upper Arm Blood Pressure Monitor



2.2 Explanation of Display Indications



3. Warnings and precautions

3.1 WARNING!

- This product is not suitable for newborns.
- This product is intended for home use only. If you have questions regarding the measurement results after measurement, please consult your doctor. Do not self-diagnose or self-treat based on the measurement results. The blood pressure readings should be interpreted by healthcare professionals!When common arrhythmia (such as atria premature beats, premature ventricular and atrial fibrillation) occurs, it will affect the measurement accuracy of blood pressure. If it is only sporadic, please take a rest for two hours before measuring. If it is a frequent nature, please go to the hospital for confirmation and treatment immediately.
- The presence of common arrhythmias (e.g., atrial premature beats, ventricular premature beats, and atrial fibrillation) may affect the accuracy of blood pressure measurement. If the conditions are occasional, please rest for two hours and measure again. If the conditions are frequent, seek immediate medical attention at a hospital for diagnosis and treatment.
- If the cuff remains continuously inflated, immediately press the [START/STOP] button manually to stop the measurement. Prolonged inflation may cause numbness in the upper arm.
- Do not allow children to use the device unsupervised. Some small parts may pose a swallowing (choking) hazard.
- Blood pressure measurement is prohibited on the side of the breast removed.
- Arm-based electronic blood pressure monitors should not be used in close proximity to or stacked with other devices, such as high-frequency equipment.

3.2 CAUTION!

- Avoid high temperatures, humidity, dust, and direct sunlight. Do not disassemble this device without authorization! Otherwise, the manufacturer's calibration voltage will be invalid!
- Avoid dropping or subjecting the device to strong vibration/impact.
- The normal measurement cycle lasts approximately 1 minute. If the device remains in a continuous measurement state without stopping, manually press the [START/STOP] button to end the measurement. Avoid prolonged pressure on the upper arm to prevent limb numbness.
- Use the original power adapter from manufacturer or one that complies with medical standards (e.g., IEC 60601-1). Non-original accessories may result in unpredictable risks.
- For better reading of the display, please note the following visible conditions:
 - Ambient brightness: 100lm to 1500lm
 - Line of sight: less than 30cm
 - View: Normal display ±30°
- Extreme temperature, humidity, and altitude conditions can affect the performance of measurements, and the blood pressure monitor may not meet the claimed performance specifications.
- Do not apply the cuff over a wound, as this may cause further injury.
- Do not measure blood pressure on an arm with existing intravascular access or therapy, or an arteriovenous (A-V) shunt.

3.3 Scope of Application

It is suitable for measuring the systolic, diastolic and pulse rate of adults by oscillography, and the values are for reference in diagnosis.

3.4 Contraindications

Electronic blood pressure monitors are not suitable for patients with severe arrhythmia.

4. Explanation

4.1 Product Features

This fully automatic arm-type electronic blood pressure monitor

features. It measures both high and low blood pressure along with pulse rate using pressure oscillation technology. Designed for home healthcare, its user-friendly interface ensures greater convenience for users.

4.2 Measuring your own blood pressure

- Remember: self-measurement is for the purpose of self-control, not diagnosis or treatment. If you have abnormal blood pressure readings, consult your doctor immediately and take your medication as directed.The pulse displayed by this unit is not suitable to be a fixed frequency detector that identify heart rate!
- The pulse rate displayed by this blood pressure monitor cannot be used as a fixed-frequency device for heart rate measurement!
- If the user has a history of severe arrhythmia, the blood pressure readings should be confirmed by a professional doctor.

4.3 Electromagnetic Compatibility (EMC)

The blood pressure monitor contains sensitive electronic components. For accurate measurements, avoid using the device in environments with strong electromagnetic interference (e.g., near mobile phones or microwave ovens), as this may lead to measurement inaccuracy.

4.4 Product Operation Instructions

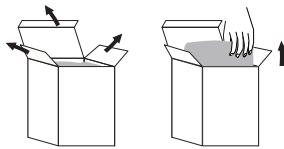
Cautions :

- Do not use the blood pressure monitor when using USB charging.
- For any questions about adapter, please consult the dealer at the point of purchase.

5. Product operation instructions

5.1 Unpacking

Open the outer packaging box, take out the product, and place it flat on table.

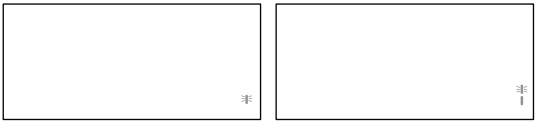


5.2 Product Charging

If the display shows a low power signal, charge the product.

- Icon lit: Battery is low.
- Icon lights up: The battery is depleted. Connect the adapter for charging (ensure it is the same type as specified).

When charging the product, the first blood pressure monitor indicator flashes once per second. When the battery reaches 50%, the second indicator flashes once per second. The battery icon flashes during charging and stops flashing after charging.



⚠Do not use the product while it is charging.

Please Be Attention !

Once the low battery indicator appears, the blood pressure monitor cannot be used unless it is charged.

5.3 Using the Power Adapter

Please use a USB 5V adapter for charging. Adapters that do not meet the requirements may compromise product safety. Ensure the adapter selected complies with relevant medical-grade safety certifications (e.g., IEC 60601-1).

6.Applying the Cuff

Wrap the cuff correctly.

- Do not start inflation before the cuff is wrapped around the upper arm.
- Please measure with the cuff placed directly against the skin or over thin clothing.
- If you are wearing thick clothing, do not roll up the sleeve. Remove the thick clothing before measurement.
- Measurements can be taken on either the left or the right arm.arms and the heart on the same level to relax and measure in a relaxed and natural posture.

1. As indicated on the cuff, apply the cuff to the upper arm being measured, with the arrow pointing toward the hand and the lower edge of the cuff positioned 2 cm to 3 cm above the elbow joint.
2. The main device of blood pressure monitor is positioned on the cuff above the artery area, pull the cuff tight and secure the fastener.

Note: Ensure the cuff is snug but comfortable. Avoid wrapping it too tightly or too loosely.

7.Correct Posture for Measurement

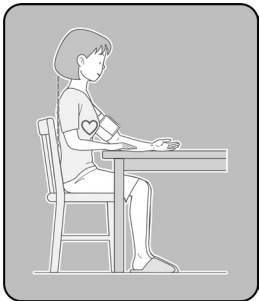
Avoid eating, smoking, or any form of activity before measurement, as all of these activities will affect the measurement results.Try to relax in a quiet environment and rest for at least 10 minutes before measurement.

- If you are wearing heavy clothing, please remove it from your upper arms.
- Choose one arm for measurement (usually the left). For consistent results, always measure on the same arm and position thereafter.
- Take your blood pressure at the same time every day, as it varies over time.

Common Factors Leading to Erroneous

Note: Comparative blood pressure measurements should be taken under the same conditions (usually resting conditions)!

- If the arm artery is positioned lower (higher) than the heart level, the measured blood pressure value will be higher (lower). (Each 15 cm difference in height will produce an error value of 1.3 kPa (9.7 mmHg))!
- This device is not suitable for newborns.
- Note: Please use the original manufacturer's cuff that has been clinically tested!
- A loose or exposed cuff can lead to incorrect blood pressure readings.
- Repeated measurements can cause vascular compression in the arm, which may also result in biased blood pressure values.Therefore, when performing repeat measurements, be sure to rest for 3 to 5 minutes first, or raise the arm for 3 minutes to relieve the state of congestion.
- Do not shake the arm muscles during measurement. If necessary, use a soft cushion can be used under the arm for support.



8.Measuring blood pressure

8.1 Starting the Measurement

Press the [START/STOP] button to begin the automatic measurement.

Stopping the Measurement

If any discomfort occurs or for any other reason (for example, if the cuff remains excessively inflated for a prolonged period), and a potential may occur, you must stop the measurement. At this time, you can press the [START/STOP] button, and the blood pressure monitor will immediately release the air pressure from the cuff.

8.2 Confirmation of Measurement Results

Measurement results are automatically stored after the measurement is complete.

1) Irregular Heartbeat Indication (IHB)

♥ If heartbeat intervals are irregular during the measurement, the irregular heartbeat symbol will be displayed along with the results.When the irregular heartbeat symbol is displayed, it may not be possible to measure correctly. Please remain still and take the measurement again.If the irregular heartbeat symbol appears frequently, please consult your physician.

2) Misoperation alert function:

⚠ This indicates that talking or moving your body during the measurement may cause incorrect results. Try measuring again.

8.3 Removing the Cuff

If you feel numbness in your upper arm after the measurement, loosen the cuff and swing your arm from side to side to promote blood circulation.

8.4 Automatic shutdown

The number will remain visible until the device automatically shuts down.

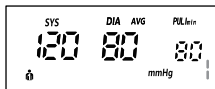
Note: This product displays pressure in millimeters of mercury (mmHg) or kilopascals (kPa) depending on the region. Use the product by referring to this manual according to the selected display mode.

This blood pressure monitor automatically records 2x99 measurements. When the memory is full, earlier records will be overwritten with new ones.

9.View measurement results

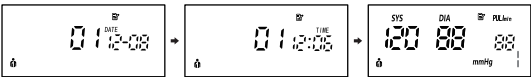
9.1 Reviewing Memory

Press the [Memory] key in power-off mode to display the average value (last three readings).



Query memory value

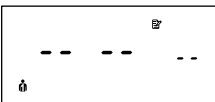
Press the [Memory] key again to show the next stored measurement value with date and time



9.2 Deleting Memory

This blood pressure monitor can only delete all records at once;

individual records cannot be deleted. While in memory display mode, press and hold the [Memory] button and simultaneously press and hold the [START/STOP] button for approximately 3 seconds.

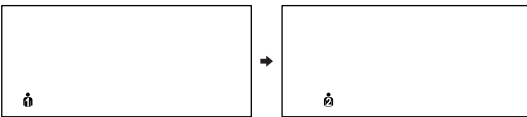


Note: Do not press the [START/STOP] button first, as it will activate other functions.

10. Setting Functions

10.1 User Selection

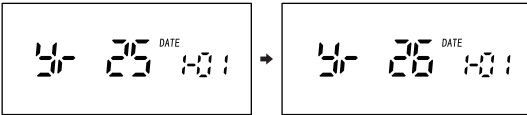
The system defaults to User 1. In shutdown mode, press the [SETTING] button to switch to User 2. The selection can be cycled (between User 1 and User 2).



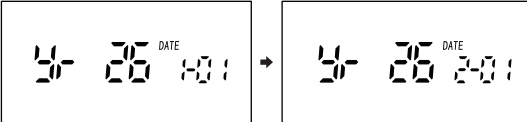
10.2 Setting Time, Date, and Measurement Unit (mmHg/ kPa)

This blood pressure monitor automatically records the date and time of each measurement. This feature is crucial as blood pressure fluctuates daily, so we recommend setting the correct time when using the device for the first time. To configure the time, follow these steps (e.g., set the time to 13:02 on February 13, 2026)

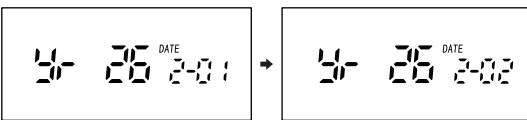
1.Press and hold the [Settings] key for 3 seconds in power-off mode to enter the function setting mode (if not selected, the system defaults to the factory year). The last two digits of the year will flash on the screen. You can input the year by pressing the [MEM] button (e.g., pressing once increases the year from '25'to'26')



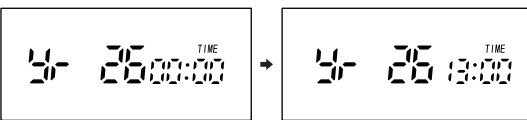
2.Press the [SETTING] button. The month will begin flashing at the bottom of the screen. The first digit of the month starts flashing. You can enter the month by pressing the [MEMORY] button (e.g., pressing once increases the month from '1'to'2').



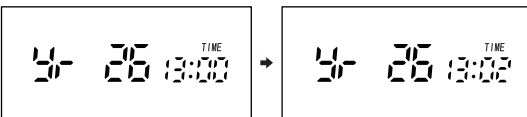
3.Press the [SETTING] button again to switch to date setting. The last two digits of the date will start flashing. You can enter the date by pressing the [MEMORY] button (e.g., pressing once changes the date from '01'to '02').



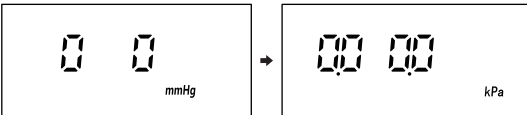
4.Press the [SETTING] button again to switch to time setting. At this time, the first two digits (representing the hour) will start flashing. 4.Press the [Memory] key to input the time (for example, pressing the [MEMORY] button 13 times changes the time from 00:00 to 13:00).



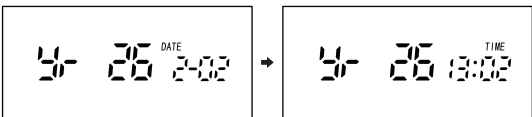
5.Press the [SETTING] button again, and the last two digits (indicating minutes) will flash. You can input minutes by pressing the [Memory] button (for example, pressing the button twice increases the time from 0 minutes to 02 minutes).



6.Press the [SETTING] button again to select the unit (mmHg or kPa). Press the [Memory] button to choose kPa or mmHg. When selecting mmHg, the display shows "0"; when selecting kPa, it shows "0.0" .



7. The final step is to set the date by pressing the [SETTING] button . After setting, the date will be displayed (displayed first, then automatically switch to time in 3 seconds). If no operation is performed, the device will automatically shut down in 30 seconds.



11.WHO Blood Pressure Classification and Voice Broadcast Function

WHO Blood Pressure Classification Function

The device is equipped with a Hypertension Indicator and a Risk Category Indicator bar. By referring to the WHO blood pressure classification, we can interpret whether blood pressure falls into the categories of Optimal, Normal, High-Normal, Grade 1 Hypertension (Mild), Grade 2 Hypertension (Moderate), or Grade 3 Hypertension (Severe).

After measurement, the blood pressure indicator will display at the corresponding position based on the blood pressure level.

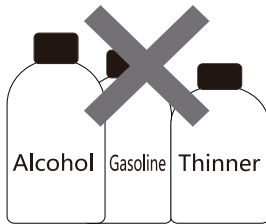
Note: Blood pressure values above 140 mmHg (18.7 kPa) systolic or 90 mmHg (12.0 kPa) diastolic indicate hypertension.

12.Maintenance and Storage

12.1 Storage Recommendations

Do not place the main unit in the following locations:

- Areas where water is likely to splash.
- Places with high temperatures, humidity, direct sunlight, a lot of dust, and high salt content.
- subject to high temperatures, humidity, direct sunlight, excessive dust, or high salt concentration.
- Areas subject to tilting, vibration, or impact.
- Areas used for storing chemicals or where corrosive gases are generated.(more than 3 months).



12.2 Maintenance Recommendations

⚠ Please note:

- When not in use, store the blood pressure monitor and accessories properly to avoid strong impacts or vibrations.
- As the cuff contains a well-sealed airbag, use it carefully and avoid folding, pulling, or twisting the cuff.
- If the device is dirty, clean and disinfect it by wiping with a soft dry cloth soaked in 75% medical-grade disinfectant alcohol. Avoid using wet cloths to wipe the socket. Similarly, wipe the cuff and rubber air tube with a soft dry cloth soaked in 75% medical-grade disinfectant alcohol. Ensure the liquid does not penetrate the device or cuff to prevent damage. It is recommended to clean the device once a month.

12.3 Maintenance

- Our company does not authorize any organization or individual to perform maintenance.
- Do not disassemble or repair this blood pressure monitor without authorization.
- Do not replace internal parts without authorization.
- Avoid falling or violent shaking of the body.
- Do not use autoclaves or gas sterilization (formaldehyde, ozone, etc.) equipment. Otherwise, it may damage the device.
- Do not use diluents, volatile oils, or other solutions to wipe this device, as it may damage the exterior surface.
- If you have any questions about the product during the warranty period, please contact the distributor or manufacturer for assistance.

12.4 calibration

This electronic blood pressure monitor was calibrated at the time of manufacture.We recommend an accuracy static pressure test every 2 years. This calibration can be performed by an authorized distributor. If you question the accuracy of measurements at any time, please contact your distributor or the manufacturer for assistance.

13. Blood pressure measurement Q & A (when the measurement is high / low)

-Q:Why is the blood pressure reading at home lower than that at the hospital?

-Answer: It is common to feel nervous when you measure blood pressure in the hospital, so the reading will be higher. Because you are in a relaxed state at home, so sometimes the reading will be 20mmHg~30mmHg (2.7kPa~4.0kPa) lower than the reading in the hospital. It is very important to know your blood pressure reading when you measure at home. If the measurement position is higher than the heart, the measurement value will also be low. If the table where the Upper Arm Blood Pressure Monitor is placed is too high, it will cause the armband to be higher than the heart, and the blood pressure value measured at this time will also be low.

-Q: Why is the blood pressure reading at home higher than at the hospital?

-Answer: If you are taking antihypertensive medication, its effectiveness may diminish, potentially causing your blood pressure to rise. The medication's effects usually wear off within a few hours, and your blood pressure may then increase accordingly. For

specific guidance, please consult your physician.

-Answer: If the cuff is not in the correct position, it may result in an elevated reading. When the cuff is misaligned, the blood pressure monitor may fail to detect the arterial signal, leading to a higher reading. Please check the cuff position again.

-Answer: An overly loose cuff can also result in a high reading. When the cuff is too loose, it prevents pressure from reaching the artery, leading to a higher blood pressure measurement than the actual value. Make sure there is no gap between the cuff and your arm when binding it.

-Answer: Incorrect sitting posture during measurement can sometimes lead to higher readings. Sitting cross-legged, on a sofa, or bending forward at a low table may cause abdominal pressure or place the cuff below the heart, resulting in elevated blood pressure readings.

-Q: Why do my blood pressure readings vary each time?

-Answer: Blood pressure varies depending on when it is measured. Even within the same day, it can fluctuate. To manage your blood pressure effectively, measure it at the same time each day.

-Q: Why do I feel pain and numbness when the cuff wraps around my arm?

-Answer: This is a temporary and normal phenomenon, please don’ t worry. When measuring blood pressure, the cuff tightens to temporarily stop blood flow in the artery, which may cause some pain and numbness in the arm. These sensations usually subside after removing the cuff and resting briefly.

-Q: What is the key to effective blood pressure management?

-Answer: Please document your medication regimen and lifestyle details. Tracking daily blood pressure fluctuations helps you better understand your blood pressure trends, which is essential for personal health management. This record is also crucial for doctors’ diagnosis. Therefore, we recommend recording both the blood pressure readings and the relevant measurement context (e.g., antihypertensive medication use, lifestyle status, etc.).

-Q: When is the best time to measure blood pressure?

-Answer: The best time to measure blood pressure is within 1 hour after waking up in the morning or before going to bed at night. It is also recommended to measure blood pressure at the same time every day.

14. About Blood Pressure

14.1 High Pressure and Low Pressure

The highest blood pressure value, when the heart contracts to pump blood into the arteries, is known as “high pressure.” The lowest value, when the heart expands to reserve blood for the next beat, is referred to as “low pressure.” These are professionally termed Systolic Pressure and Diastolic Pressure, respectively. The World Health Organization (WHO) has established a standard classification method for blood pressure, as shown in the table below. Unit: mmHg

Scope	systolic blood pressure (high) SYS	Diastolic pressure DIA	corresponding measures
hypopiesia	<100	<60	Get a doctor to check
ideal blood pressure	100~120	60~80	Self-test
normal pressure	120~130	80~85	Self-test
Normal high blood pressure	130~139	85~89	Self-test
mild hypertension	140~159	90~99	ref.phys
moderate hypertension	160~179	100~109	ref.phys
severe hypertension	≥ 180	≥ 110	Danger! See a doctor immediately

In conjunction with this, the 1988 Joint National Committee (JNC) on Hypertension recommended that an individual’ s blood pressure (both Systolic/high pressure and Diastolic/low pressure) must be measured at least three times before any further diagnosis can be made, if the readings are found to be above normal levels.

14.2 What measures should be taken when blood pressure is too high or too low?

1) Please consult your doctor.
2) Prolonged gradual blood pressure elevation (across various hypertension types) poses serious health risks. The buildup of deposits in blood vessel walls restricts blood flow, leading to arteriosclerosis—a highly dangerous condition. This can result in insufficient blood supply to vital organs (heart, brain, muscles, etc.), and in severe cases, may even cause structural damage to the heart.
3) There are many factors that can lead to hypertension, which we classify into common primary hypertension and secondary hypertension. Secondary hypertension may cause organ dysfunction. If your blood pressure keeps rising, consult your doctor to identify potential causes.

Chasing your lifestyle habits can also help prevent or lower high blood pressure. These changes must be an integral part of a healthy life, and include:

Chasing your lifestyle habits can also help prevent or lower high blood pressure. These changes must be an integral part of a healthy life, and include:

A: Dietary Habits

Follow your doctor’ s advice and maintain your normal weight.Avoid excessive salt intake; be mindful that many “packaged foods”

contain high levels of salt.Avoid fatty foods (Note: packaged foods often contain high levels of fat content).

B: Disease Prevention

Stick to medical advice to prevent certain diseases, such as diabetes, fat metabolism disorders, and gout.

C: Lifestyle Habits

Refrain from smoking and avoid consuming excessive alcohol or spirits with high alcohol concentration; limit your caffeine intake (coffee, tea, chocolate, etc.).

D: Physical Exercise

After a medical check-up, engage in regular physical exercise by choosing dynamic activities that require endurance rather than high intensity, and avoid pushing beyond your physical limits. For individuals over 40 with medical history, consult a doctor before starting any exercise regimen.

15. Error Warning/Troubleshooting

15.1 Error Warning

The display will show an error warning (indicated by an icon/symbol) if any of the following conditions occur:

Scope	Error Description	Possible Cause	Corrective Action
Er01	Measurement Error	The noise is too large to detect the effective pulse rate signal.	Please rest for 2 minutes, adjust the cuff, and remain still and silent during the measurement process.
	Measurement Error	No pulse rate signal detected	
	Measurement Error	The test results deviate from the normal range	
	The static pressure exceeds the set protection point.	Pressure exceeds the design limit for protection.	Blood pressure was measured again.
	reset timeout	1. The pressure fluctuation in the cuff of the zeroing process was continuous. 2. The sensor circuit is abnormal. 3. The sensor is damaged.	1. Keep the cuff still when resetting the time. 2. Check the power supply of the sensor. 3. Replace the sensor.
Er02	Incorrect cuff position	1. The armband was not worn. 2. Wearing too loose. 3. Wearing tight clothing. 4. abnormal cuff pressure.	Adjust the cuff to fit snugly around the upper arm, allowing just enough space for one finger to slide in, and position the cuff’s airway opening over the elbow crease. 2cm~3cm position.
Lo	Low battery	The power supply voltage is below the minimum operating voltage.	Charge promptly

15.2 Other information

Even in healthy individuals, blood pressure constantly fluctuates (exhibiting a “sawtooth pattern”). Therefore, comparative measurements must always be taken under consistent, standardized conditions (e.g., in a quiet environment and at rest). If the difference between readings taken under the correct conditions is greater than 2.0 kPa (15 mmHg), or if you detect irregular heartbeats in certain circumstances, please consult your physician.

15.3 Troubleshooting

If any malfunction or abnormal situation occurs during use, check and troubleshoot according to the items listed in the table below:

In conjunction with this, the 1988 Joint National Committee (JNC) on Hypertension recommended that an individual’ s blood pressure (both Systolic/high pressure and Diastolic/low pressure) must be measured at least three times before any further diagnosis can be made, if the readings are found to be above normal levels.

16. Reference Standards

The FDBP-A13 arm-type electronic blood pressure monitor complies with the following standards:
Performance and Safety Standard: IEC 80601-2-30
Electromagnetic Compatibility: IEC 60601-1-2
Safety Standard: IEC60601-1

Declaration: The blood pressure values measured by this device are equivalent to those obtained by the auscultatory method. The measurement error complies with the requirements specified in YY 0667-2008 (Medical electrical equipment - Part 2-30: Particular requirements for the safety and essential performance of automated non-invasive blood pressure monitor).

17. Disposal Advice

If the blood pressure monitor is damaged and requires disposal, please process electronic waste in accordance with relevant national laws and regulations. Do not dispose of batteries or the product directly into a household waste bin. If you have any questions, please consult the authorized dealer or local authority responsible for waste disposal.

18. Technical Specifications

Model	FDBP-A13
Display	LED
Measurement Principle	Oscillography
Measurement Range	Pressure : 0mmHg~295mmHg(0kPa~39.3kPa) Pulse rate: (40~199) beats per minute
Memory	Automatically stores 99 sets of measurements for each user
Resolution	1mmHg(0.1kPa)
Accuracy	static pressure: ±3 mmHg (±0.4 kPa) Pulse rate: within ±5% of the reading
Power Supply	Rechargeable 3.7V lithium battery
Special Accessories	The instruction manual (including product warranty card) and certificate of conformity are provided, along with a Type-C charging cable.

Dimensions	Dimensions: 127mm (length) × 67mm (width) × 100mm (height) (including cuff)
Weight	Approximately 221g
Maximum Cuff Pressure	360mmHg
Cuff	It has a service life of 5000 times and can be used for arm circumference of 220mm to 420mm.
Type of Protection Against Electric Shock	Internal power supply type
Degree of Protection Against Electric Shock	BF type application section
Service Life of the Main Unit	5 years
Operating Mode	Continuous duty
Operating Conditions	Temperature: 5°C ~40°C Humidity:15%RH-90%RH,No condensation Atmospheric pressure:70kPa~106kPa
Transportation and Storage Conditions	Temperature: -25°C to 55°C ; Humidity: 15% RH to 95% RH (no condensation); Atmospheric pressure: 70 kPa to 106 kPa Please strictly comply with the environmental conditions for transportation and storage, otherwise the accuracy of the equipment may be affected.

19. Attachment List

component	quantity
Main Device	1 unit
Cuff	1 unit (installed on the main device)
Instruction Manual	1 copy (including product warranty card)
Certificate of Quality	1 sheet

20. Standardized symbolic description

	Caution! Consult accompanying.
	WARNING! A warning with this symbol and the signal word “WARNING” indicates a potentially hazardous situation which could result in death or serious injury if not avoided.
	: A note identifies additional information that facilitates the use of the device.
	Follow instructions for use
	Type BF applied parts
	Electric shock protection type : Class II equipment
	Disposal in accordance with Directive 2002/96/EC (WEEE)
	Medical Device Regulation (EU) 2017/745, Notified Body is SGS Belgium NV.
	Manufacturer

	Authorized representative in the European Community
	Serial number
	The value of SYSTOLIC BLOOD PRESSURE
	The value of DIASTOLIC BLOOD PRESSURE
	Level of protection for ingress of water or particulate matter into ME EQUIPMENT
	Medical Device
	Catalogue number
	Unique Device Identifier
	Date of manufacture

21. Electromagnetic compatibility information

① Note:

- The Upper Arm Blood Pressure Monitor FDBP-A13 meets the electromagnetic compatibility requirements of IEC60601-1-2, IEC60601-1-11, ISO80601-2-30;
- Users should install and use the electromagnetic compatibility information provided by the random files. Portable and mobile RF communication devices may affect the performance of the Upper Arm Blood Pressure Monitor FDBP-A13. Avoiding strong electromagnetic interference when used, such as Close to mobile phones, microwave ovens, etc.

⚠ Warning !

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could 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.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the FDBP-A13 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the FDBP-A13, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Attachment:

Guidance and manufacturer’s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer’s declaration – electromagnetic emission		
The FDBP-A13 is intended for use in the electromagnetic environment specified below. The customer or the user of FDBP-A13 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The FDBP-A13 uses RF energy only for its internal function. There for, 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 FDBP-A13 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	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer’s declaration – electromagnetic immunity – for all EQUIPMENT AND SYSTEMS			
Guidance and manufacturer’s declaration – electromagnetic immunity.			
The FDBP-A13 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDBP-A13 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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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%.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U _i ; 0,5 cycle U _i ; At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _i ; 1 cycle and 70 % U _i ; 25/30 cycles Single phase: at 0° 0 % U _i ; 250/300 cycle	0 % U _i ; 0,5 cycle U _i ; At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _i ; 1 cycle and 70 % U _i ; 25/30 cycles Single phase: at 0° 0 % U _i ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FDBP-A13 requires continued operation during power mains interruptions, it is recommended that the FDBP-A13 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U _i is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer’s declaration – electromagnetic immunity – for EQUIPMENT AND SYSTEM			
The FDBP-A13 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDBP-A13 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the FDBP-A13, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[\frac{3\sqrt{P}}{E_t}] \sqrt{P}$ $d=[\frac{3\sqrt{P}}{E_t}] \sqrt{P}$ $d=[\frac{3\sqrt{P}}{E_t}] \sqrt{P}$ 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).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			
^a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz. ^b 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 FDBP-A13 is used exceeds the applicable RF compliance level above, the FDBP-A13 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FDBP-A13. ^c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT AND SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the FDBP-A13.					
The FDBP-A13 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FDBP-A13 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FDBP-A13 as recommended below, according to the maximum output power of the communications equipment.					
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter				
	150 kHz to 80 MHz outside ISM and amateur radio bands $d=[\frac{3\sqrt{P}}{E_t}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d=[\frac{12}{V_t}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3\sqrt{P}}{E_t}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{2.7\sqrt{P}}{E_t}]\sqrt{P}$	
0.01	0.12	0.20	0.035	0.07	
0.1	0.38	0.63	0.11	0.22	
1	1.2	2.00	0.35	0.70	
10	3.8	6.32	1.10	2.21	
100	12	20.00	35	70	
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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.					



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