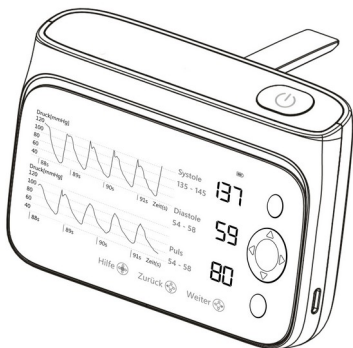


Arm Blood Pressure Monitor User Manual



Model: ARM-30H

Manual Version: A0

Issue date: Mar. 10, 2025

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Thank you for purchasing the Arm Blood Pressure Monitor.

The monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

The monitor also records the movements itself. With that information your blood pressure and your pulse can be analyzed more deeply.

In case of acute problems, the heart activity can be recorded and later checked by a doctor.

The device can be used in homecare environment, and the patient is an intended operator, and all the functions can be safely used.

This monitor complies with the requirements of ISO81060-2.

1. Unpacking Inspection










Before use, please open the package carefully and check whether all the parts are available according to the following packing list and whether the parts are damaged during transportation, and then install and operate in strict accordance with the user manual.









2. Packing List

| No. | Name | Quantity |
|-----|---------------------------------|----------|
| 1 | Arm Blood Pressure Monitor | 1 |
| 2 | Cuff 22-42cm (8.6~ 16.5 inches) | 1 |
| 3 | Pouch | 1 |
| 4 | User Manual | 1 |

3. Safety Precautions

Knowledge of the warning signs and symbols is crucial to the safe and proper use of this device. Kindly get informed on the following signs and symbols which you might encounter within this user manual or on the label:

| | |
|---|---|
|  | Warning information, refer to the attached document |
|  | Device classification: type BF applied part |
|  | Symbol for the marking of electrical and electronics devices according to Directive 2012/19/EU. |
|  | Consult the instructions for use |
|  | Keep dry |
|  | Low voltage prompt |
|  | Keep away from the sunlight |
|  | Vertical upward |
| IP21 | The device is protected against splashing water. Water splashed against the enclosure from any direction shall have no harmful effects. |
| RoHS | RoHS mark |
|  | CE mark |

| | |
|---|--|
|  | Manufacturer |
|  | Date of manufacture |
|  | Serial number |
|  | Batch code |
|  | Authorized representative in the European Community |
|  | Medical device |
|  | Indicates the entity importing the medical device into the local |
|  | Unique device identifier |

4. Product Composition

This product is composed of the main body and cuff.

5. Intended Use / Instructions for Use

The Arm Blood Pressure Monitor is intended to measure the systolic blood pressure and diastolic blood pressure, as well as the pulse rate of an adult person via non-invasive oscillometric technique at medical facilities or at home.

Intended users

Layperson or clinical professionals.

Clinical benefit

Patients can monitor systolic pressure, diastolic pressure, and pulse rate at home at any time, greatly reducing the number of visits to the hospital, reducing the risk of travel and improving the quality of patient's life.

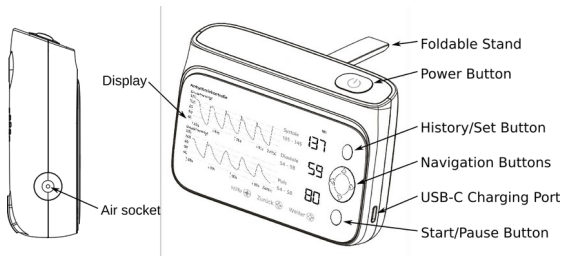
6. Contraindication

Do not use this device if the patient's condition meets the following contraindications, to avoid inaccurate measurements or injuries.

1. The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, and defibrillators.
2. Avoid taking measurement on the arm on the side of a mastectomy or lymph node clearance.
3. The device measures blood pressure using a pressured cuff. If the measuring limb suffers from injuries (for example open wounds) or under conditions or treatments (for example intravenous drip) making it unsuitable for surface contact or pressurization, do not use the device, to avoid worsening of the injuries or conditions.
4. Avoid taking measurements of patients with conditions, diseases, and susceptible to environment conditions that lead to uncontrollable motions (e.g. trembling or shivering) and inability to communicate clearly (for example children and unconscious patients).
5. The device uses oscillometric method to determine blood pressure. The arm being measure should have normal perfusion. The device is not intended to be used on a limb with restricted or impaired blood circulation. If you suffer with perfusion or blood disorders, consult your doctor before using the device.
6. This device is not for infants or mentally-impaired individuals who cannot express their thoughts.

7. Product Parts

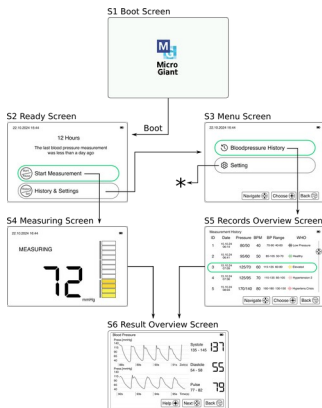
1. Main Body



2. Display and User Interface

The device is equipped with a multipurpose display to show results, reports and saved measurements. Also settings (*) can be adjusted and information about the measurement can be shown.

The button History/Set, Navigation buttons, and Start/Pause can be used to change the displayed screen, or to start a measurement.



S1 Boot Screen

After the Power Button has been pressed the boot screen indicated that the device is working. Wait until the screen changes to "Ready Screen" (S 2).



S2 Ready screen

1. Current date and time.

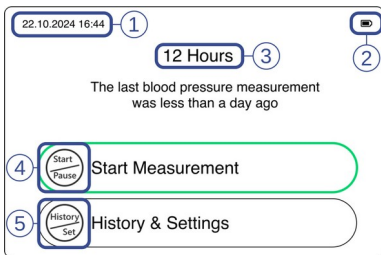
2. Battery state:
green: battery is full,
orange:
measurement
possible, but after
that please start
charging,

red: battery empty, measurement may fail, please charge

3. Time since last measurement

4. Navigation hint to start a measurement

5 Navigation hint to show the second menu screen (S3)



S3 Menu Screen

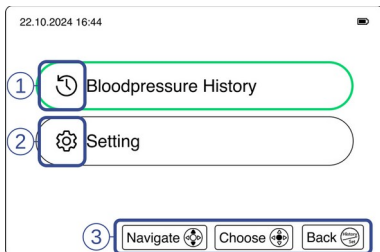
1. Navigation hint to open the records overview screen (S5).

2. Navigation hint to open the settings screen (S10).

3. Navigation overview:

Navigate up and

down with the up and down arrow buttons; Open selected with center button; Go to previous screen with History/Settings Button.



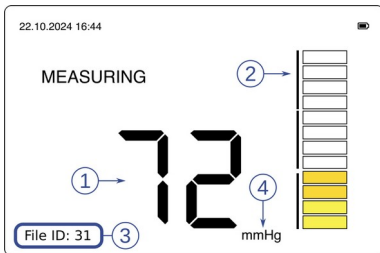
S4 Measuring screen

1. Actual pressure in the cuff

2. Graphical indicator of the actual value of the pressure in the cuff

3. Recording file ID, which can later be loaded with the records overview screen (S5)

4. Unit of the pressure value (mmHg or kPa)



S5 Records Overview Screen

1. A tabular of all recordings

2. ID of the recording, as indicated during measurement (see S4, reference 3)

3. Date and time of the recording

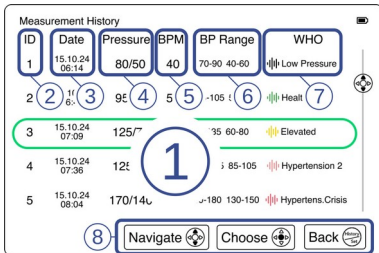
4 Oscillometric blood pressure value of the recording.

5. Heart pulse value of the recording

6. Pressure value range of the recording; systolic range and diastolic range

7. Classification of the oscillometric blood pressure of the recording according to WHO standard

8. Navigation overview: Navigate up and down to select recording; Open selected with center button; Go to previous screen with History/Settings Button.



3 Result Views and Help Screen

The result of a measurement or a recorded measurement can be viewed in different representations.

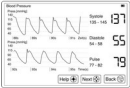
The classical representation (S6) is focused on showing systole, diastole, and pulse.

The Arrhythmia Overview (S7) details on possible arrhythmia during the measurement.

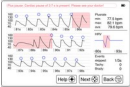
The Arrhythmia Assessment (S8) show the same curves (top) as S7 zoomed. With that screen measured data can be compared with examples of arrhythmia cures (bottom).

Also one can navigate to an informative screen. This screen helps to understand the user interface. It therefore serves the same purpose as this manual regarding the result representation screens.

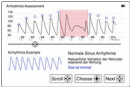
S6 Result Overview Screen



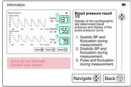
S7 Arrhythmia overview



S8 Arrhythmia Assessment



S9 Help / Info Screens



S6 Result overview screen

1/2. Partial reproduction of the pressure fluctuation due to heart pulse beneath the cuff during the recording.

3. Oscillometric systolic pressure value.

4. Oscillometric diastolic pressure value.

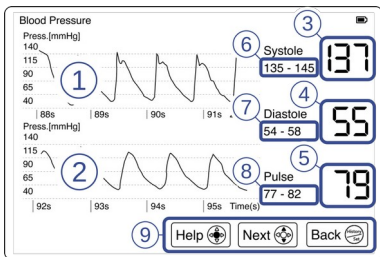
5. Pulse rate value

6. Recorded systolic blood pressure range during the measurement.

7. Recorded diastolic blood pressure range during the measurement.

8. Recorded range of pulse rate during the measurement.

9. Navigation overview: Show help screen with center button, Navigate up and down to select other view of this recording; Reset device screen with History/Settings Button.



S7 Arrhythmia overview screen

1./2./3. Reproduction of the pressure fluctuation due to heart pulse beneath the cuff during the recording.

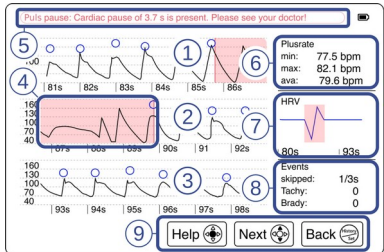
4. Marker of conspicuous parts of the pressure wave. If such a marking is been displayed, Please show it to your professional on you next meeting.

5. A text label explaining the findings of conspicuous parts in your measurement. This is not a diagnosis, please discuss this with your professional.

6. Summary of the value of the regular heart pulses (minimum value, maximum value and average value during the measurement)

7. HRV: Heart rate variability; Beat to beat change of the heart pulse as graphical representation. A regular variation is a indicator of normal changes to respiration. Elevated variation above the usual level are marked. This marks are usually links to the markings of reference 4. If your measurement show those markings, please discuss this on your next meeting with your professional.

8. A summary of events recorded. First line shows the count of missing beats i.e. gaps and the time of the longest gap. Second line shows the count of fast (tachycardia) heart pulses and the pulse



rate of the fastest recorded. Third line shows the count of slower than average pulses (bradycardia) and the pulse rate of the slowest pulse recorded.

9. Navigation overview: Navigate up and down to select an other view screen of this recording; Show help screen (S9) with center button; Go to previous screen (S2 when a actual measured recording is displayed or S5 when recording was selected from records overview screen) with History/Settings Button.

S8 Arrhythmia assessment screen

1. Partial reproduction of the pressure fluctuation due to heart pulse beneath the cuff during the recording.

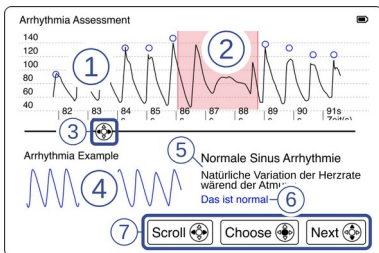
2. Marker of conspicuous parts of the pressure wave.

If such a marking is been displayed, please show it to your professional on you next meeting.

3. Positional indicator, which indicated which part of the recording is been shown.

4. A graphical representation of an example of a pressure ware of a medical condition. This is not your data! This is only an example.

5. Name and information of that example data.

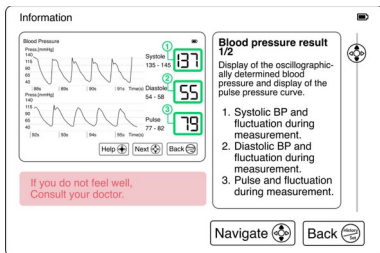


6. A suggestion what you should do when your data looks similar to an example.

7. Navigation overview: Navigate up and down to select an other view screen of this recording; Show an other example (reference 4 and 5) with center button; Show an other part of you measurement with left and right button (changing view of reference 1).

S9 Help/Information screens

This screen show information about the values represented on the screens (S6, S7, and S8).



4 Setting Screens

The settings allows to adjust time and date, the display, the measurement, file records, and the displayed language of the user interface.

From the main setting screen (S10) the particular setting can be chosen with the navigation buttons and displayed with the central button.

Adjustments are possible using the navigation buttons.

For confirmation of a adjustment the central button is used.

S10 Settings Screen



S11 Time and Date Setting



S12 Display Setting



S13 Measurement Setting



S14 File Manager Setting

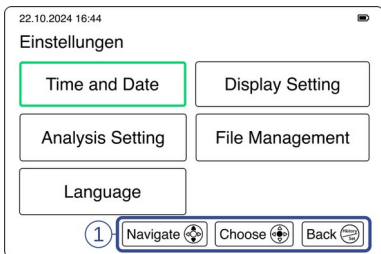


S15 Language Setting



S10 Settings screen

1. Navigation
overview: Navigate with the arrow buttons to select an other setting; Open the screen for the selected setting with

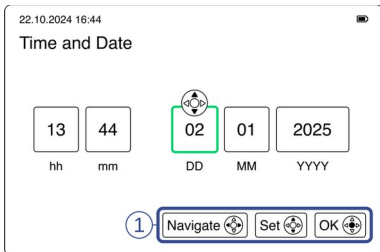


center button; Go to the previous screen with History/settings Button (S2).

S11 Time and date setting

1. Navigation

overview: Change the setting of the selected time or date item with up and down arrow button; Change selected time or date item with left and right button; Accept setting and go to the previous screen with center button (S10).

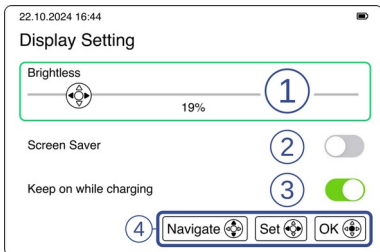


S12 Display setting

1. Setting of the brightness of the screen

2. Toggle whether the device should go off after a minute

3. Toggle whether the device should go off when the device is charging.



4. Navigation overview: Change the setting of the selected item with left and right arrow button; Change selected item with up and down button; Accept setting and go to the previous screen with center button (S10).

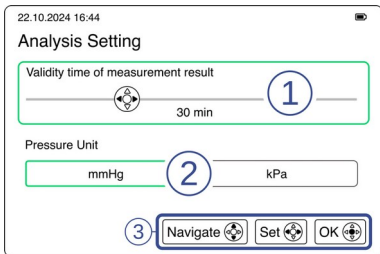
S13 Measurement setting

1. Time in minutes when a displayed measurement should be marked as “old”.

2. Selection of the pressure unit used by the device.

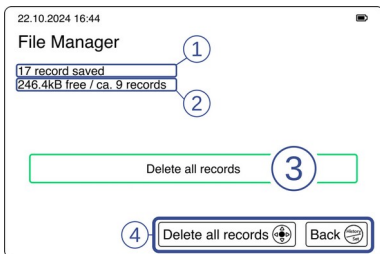
3. Navigation overview: Change the setting of the

selected item with left and right arrow button; Change selected item with up and down button; Accept setting and go to the previous screen with center button (S10).



S14 File manager setting

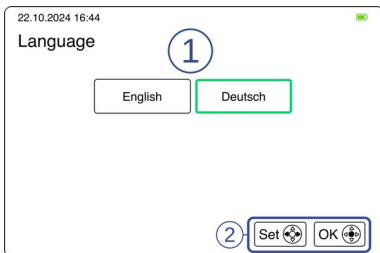
1. Count of saved recordings
2. Free flash space and estimation of recording which can be stored without deleting the oldest recording.
3. Select this to delete all recordings



4. Navigation overview: Go back to the settings overview with history/settings button; Delete all recordings with the center button (you will be asked again) and go back to the previous screen.

S15 Language setting

1. Selection of the device language.
2. Navigation overview: Use left and right button to select device language; Use center button to change language and go back to settings screen (S10).



8. WHO Blood Pressure Indicator

The recorded measurements will be evaluated according to the WHO standard.

The meaning of the colors in the WHO column are:

Green: Normal blood pressure

Yellow: mild elevated blood pressure

Red: high blood pressure

| Measurement History | | | | | |
|---------------------|-------------------|----------|-----|-----------------|------------------|
| ID | Date | Pressure | BPM | BP Range | WHO |
| 1 | 15.10.24 06:14 | 80/50 | 40 | 70-90 40-60 | Low Pressure |
| 2 | 15.10.24 06:41 | 95/60 | 50 | 85-105 50-70 | Healthy |
| 3 | 15.10.24 07:09 | 125/70 | 60 | 115-135 60-80 | Elevated |
| 4 | 15.10.24 07:36 | 125/95 | 70 | 115-135 85-105 | Hypertension 2 |
| 5 | 15.10.24 08:04 | 170/140 | 80 | 160-180 130-150 | Hypertens.Crisis |

Navigate Choose Back

| Systolic Blood Pressure (mmHg) | | Diastolic Blood Pressure (mmHg) | Color Display | WHO classification |
|--------------------------------|--------|---------------------------------|---------------|----------------------|
| ≥180 | and/or | ≥120 | Red | Hypertensive crisis |
| ≥140 | or | ≥90 | Red | Stage 2 Hypertension |
| 130-139 | or | 80-89 | Red | Stage 1 Hypertension |
| 120-129 | and | ≤80 | Yellow | Elevated |
| ≤120 | and | ≤80 | Green | Normal |



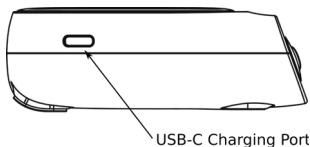
Warning: Never diagnose or treat yourself based on the readings. Please always consult with your physician.

9. Power Connection

Please check whether the power of the device is sufficient before using.

When you find the battery runs out, please use the manufacturer-provided

Type-C charging cable to recharge the device. (The Type-C charging cable is included in the package.)



NOTE:

- Optional AC adapter should comply with the requirement of IEC 60601-1 standard.
- Use only the exclusive AC adapter specified by authorized dealers. Other AC adapter may vary in output voltage and polarities and may represent a risk on your life and damaging the device.

10. Function Setting

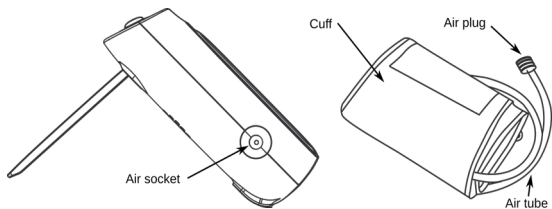
Please refer to the screens S10-S15 (Sections 2 S10 – 2 S15).

The following settings can be changed with those screens:

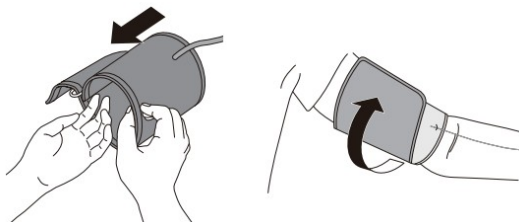
1. Time and Date
2. Display settings
3. Measurement related settings
4. File and recordings related settings
5. Language

11. How to apply the arm cuff

1. Connect the arm cuff to the monitor by inserting the air plug into the air socket securely.

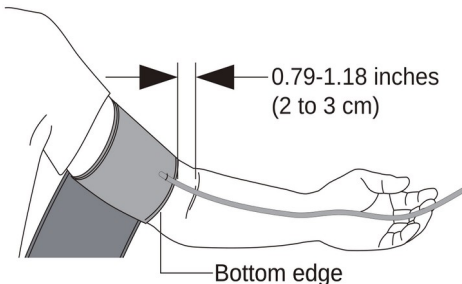


2. Place your hand through the cuff loop. Pull the cuff until it reaches your upper arm.



Note:

The bottom edge of the arm cuff should be 0.8-1.2 inches (2-3cm) above the inside elbow. The air tube should be on the inside of your arm and aligned with your middle finger.



3. Make sure that the air tube is positioned on the inside of your arm and wrap the cuff securely, so it can not move around your arm.

Note: Repeated measurement will result in blood congestion in the arm, which will affect the measurement result.

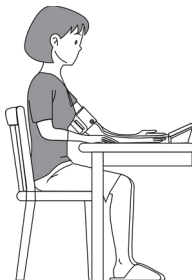
How to avoid blood congestion and ensure the repeated measurement is accurate?

You can raise the left hand and hold the fist several times, or takeoff the cuff and rest for at least 2-3 minutes before taking the measurement.

4. Sitting correctly

To take a measurement, you need to be relaxed and comfortably seated in a room with a comfortable temperature.

- Sit in a comfortable chair with your back and arm supported.
- Keep your feet flat and your legs uncrossed.
- The arm cuff should be placed on your arm at the same level as your heart, with the arm resting comfortably on a table.



Warning: Do not kink the connecting tubing, as the resulting continuous cuff pressure can cause interference with blood flow and harmful injury to the patient.

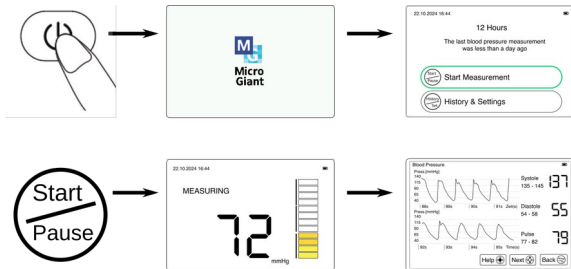
12. How To Take Proper Measurements

1. Preparation before measurement:


- Take off the clothes on the arm.
- Always measure in the same arm (generally the left arm).
- Remain still and keep quiet during the measurement.
- Relax as much as possible and do not talk during measurement.
- Measure your blood pressure at about the same time every day.
- Do not measure the blood pressure immediately after physical exercise or a bath. Rest for 20-30 minutes before taking the measurement.
- Measurements under the conditions listed below may affect results:


Within an hour after dinner, after drinking wine, coffee, tea; doing sports, talking, being nervous, being in unsteady mood, bending forward, moving, room temperature dramatically changing; inside a moving vehicle, repeated and continuous measuring.

2. Taking A Measurement




1. Fasten the arm cuff following the instruction of "11. How to apply the arm cuff". Start the measurement after wearing the cuff correctly.

2. Start the device with the power button  and wait until it has booted.

3. Press the START/STOP Button . The monitor will start inflating for measurement and displaying the pressure (refer to screen 2. S4). Check the measured values after the measurement finished.

Note: If you feel uncomfortable during the measurement,

press the START/STOP Button  immediately to stop the measurement. Please consult your doctor if unexpected readings are obtained.

3. Memory Function

1. Each measured value is stored automatically. This device can store up to 200 sets of measurements. Once the memory is full, the old records will be refreshed with new ones.
2. For displaying previous measurements please refer to the Screen S5. A recording can be selected by date or ID.
3. Delete Memory: Recordings can be deleted by the records settings screen (refer 2 S14)


4. "Cuff Worn" Detection

In case of a misaligned cuff or a loose cuff a warning will be displayed on the screen.

5. "Keep Still" Indication

In case of a movement a warning will be displayed on the screen.

6. Turn off the unit

Press power Button  to turn off the Arm blood pressure monitor. Also the monitor automatically turns off after 1 minutes.

13. Specifications

| | | |
|------------------------------------|---|--|
| Model | ARM-30H | |
| Display | LED screen | |
| Measuring method | Oscillometric measurement | |
| Measuring part | Upper arm | |
| Pneumatic pressure measuring range | 0~295 mmHg (0~39.3 kPa) | |
| Maximum pressure protection | 300 mmHg (40.0 kPa) | |
| Measurement range | Blood pressure value | SYS: 60-240 mmHg (8.0-32.0 kPa); DIA: 30-180 mmHg (4.0-24.0 kPa); |
| | Pulse rate | 40-250 bpm |
| Accuracy of the cuff pressure | ± 3 mmHg (± 0.4 kPa) | |
| Accuracy of the pulse rate | $\pm 5\%$ | |
| Low Battery | When the power is lower than $3.4V \pm 0.1V$, the device will be turned off automatically. | |
| Power source | 3.7V rechargeable lithium battery | |
| Charging method | Type-C charging port; Charging voltage: d.c. 5V | |
| Memory | 3500 kB, 200 recordings | |
| Dimension | 128 mm (L) x 89.8 mm (W) x 30.8 mm (H) (5 inches x 3.54 inches x 1.2 inches) | |
| Screen size | 75 mm (L) x 50 mm (W) (3.5 inches) | |
| Cuff size | 22~42 cm (8.6~16.5 inches) | |
| Weight | 195g | |

| | | | |
|--|--|--------------|---|
| | | | |
| Anti electronic shock type | Internal power supply | | |
| Auto power-off | 1 minute without operation | | |
| Anti electronic shock degree | Type BF | | |
| Operation mode | Continuous operation | | |
| Protection against harmful ingress of water or particular matter | IP21 | | |
| Service life | 5 years | | |
| Protection against electric shock | Internally powered supply | | |
| Operating environment | Temperature condition | 5°C~40°C | If stored or used beyond the designated temperature and humidity range, it will not be used properly. |
| | Humidity condition | 15%~90%RH | |
| | Atmospheric condition | 70kPa~106kPa | |
| Transportation and storage environment | Avoid strong impact, direct impact, exposure or rain during transportation. The device shall be stored indoors at the temperature of -20°C~55°C and the relative humidity of 10%~93%. Atmospheric condition: 70kPa~106kPa without corrosive gas and with good ventilation. | | |

The product was clinically investigated according to the requirement of ISO 81060-2.

Essential performance

1. Measurement Range (Blood Pressure):

Systole: 60-240 mmHg (8.0-32.0 kPa);

Diastole: 30-180 mmHg (4.0-24.0 kPa);

2. Pulse rate:

40-250 bpm

3. Accuracy of the cuff pressure :

± 3 mmHg (± 0.4 Kpa)

4. Accuracy of the pulse rate:

$\pm 5\%$

Note: The specified power supply should meet the following condition:

- Output voltage: DC 5V,
- Output current: 1000mA, Class II
- Comply with IEC 60601-1,
- Provide at least two MOPP insulation between ac input and dc output,
- Comply with US and Canadian deviation requirements.

14. Contraindications, Precautions, Warnings and Emergency Instructions

- No maintenance or servicing when using.
- Too frequent measurements can cause injury to the PATIENT due to blood flow interference.
- Consult with your physician before using this monitor on an arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy or lymph node clearance.
- Do not use other medical equipment for monitoring on the same limb simultaneously. This could temporarily cause loss of function or an inaccurate measurement.
- Please check whether the operation of the Arm blood pressure monitor leads to prolonged impairment of patient's blood circulation by observing the limb concerned.
- Please use component (e.g. cuff) provided by manufacturer. Otherwise, the measurement accuracy will be affected.
- No modification of this equipment is allowed.
- To avoid strangulation, please keep the air tube away from the infants, toddlers and children.
- Do not leave the small parts where children can reach them. Children may swallow them. If a child accidentally swallows them please contact a doctor immediately.
- The cuff complies with the requirements of ISO 10993-5, ISO 10993-10, ISO 10993-23. But few sensitive people may have allergies.

- DO NOT use this monitor on an injured arm or an arm under medical treatment.

Caution

- Do not perform measurements more frequently than necessary. Due to the interference of blood flow, some bruising may occur.
- Maintenance should be done by the manufacturer as suggested.
- When the ambient temperature is less than 5°C, please take the device to the place where the ambient temperature is between 5°C~40°C at least 1 hour; When the ambient temperature is higher than 40°C, please take the device to the place where the ambient temperature is between 5°C~40°C at least 2 hours.
- DO NOT use this monitor for infants, toddlers, children or persons who cannot express themselves.
- DO NOT take medicine based on readings from the device. Contact your physician for specific information about your blood pressure. The patient should not self-diagnose or self-medicate per measured results. Kindly adhere to the instructions of your physician or health provider.
- DO NOT use the device while you are on an intravenous drip or blood transfusion.
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Make sure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular therapy, or an arteriovenous (AV) shunt.

- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pregnancy, pre-eclampsia or renal disease.
- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders, because the cuff inflation can cause bruising.
- DO NOT use this monitor for any purpose other than measuring blood pressure and pulse rate.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.
- DO NOT use this monitor in a moving vehicle such as in a car.
- DO NOT drop or subject this monitor to strong shocks or vibrations.
- Do not use or store the monitor outside the manufacturer's specified conditions (extremely high or low temperatures and humidity), as this may affect the performance or cause inaccurate measurements.
- When the performance changes (such as: inaccurate measurement or abnormal display), please stop using it immediately and contact the sales service personnel in time.

15. Common Q & A on Blood Pressure

Q1: Why is the blood pressure value obtained at home lower than that obtained at the hospital?

- The blood pressure difference between home and hospital measurements is about 20 mmHg-30 mmHg (2.7 kPa-4.0 kPa). This is because individuals tend to be more relaxed at home than at the hospital.
- In addition, when the device is placed at a position over the heart, the blood pressure value tends to be much lower than it actually is. Ensure the device is positioned right at the heart level.

Q2: Why is the blood pressure value obtained at home higher than that obtained at the hospital?

- The anti-hypertensive drug might have lost its efficacy. Kindly adhere to your doctor's instructions.
- The cuff might not be in the correct position. If it is not placed right, no arterial pressure value will be obtained, and the blood pressure value might be much higher than it is. Therefore, properly position the cuff.
- The cuff is not tight enough. If it is loose, the compression force might fail to transmit to the artery, causing the blood pressure value to be much higher than it is. Therefore, re-adjust and tighten the cuff further.
- The patient is not sitting correctly during the measurement. Slouching, tilting, bending, and sitting cross-legged are not encouraged while taking blood pressure measurements due to increased abdominal pressure or the arm position being below the heart. Kindly take readings in the correct posture.

Q3: When can I obtain better measurements?

- Measurements are best taken in the mornings right after you urinate or when your mind and body are stable. We recommend taking readings at the same time of the day, every time.

Q4. Why the blood pressure value measured each time is different?

1) The blood pressure will change to some extent. For example, a person with the pulse of 70 beats per minute will have 100,800 blood pressure changes every day. Because the blood pressure is constantly changing, it is difficult to obtain the correct blood pressure value by measurement only once. Please make measurement for 2-3 times. The first measurement will generally be higher due to nervousness or inadequate preparation, and then when the second measurement, the nervous emotion will be slightly alleviated, so generally, the second measurement will be 5 mmHg-10 mmHg

(0.7 kPa-1.3 kPa) lower than the first time. This will be more obvious for those with higher blood pressure.

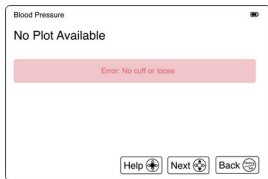
-- Please note when measuring multiple times: There might be extravasated blood because the arm is compressed, resulting that the fingertip blood does not flow smoothly, if you continue the measurement in case of extravasated blood, you cannot obtain the correct measured value. Loosen the arm band, raise your hand over the head and grasp and stretch your left and right palms for 15 times repeatedly. Then the extravasated blood can be dissolved and you can continue the blood pressure measurement

2) Cuff position and twining method. The measured value varies with the cuff size. Particularly, if the cuff is twined round the elbow, you cannot obtain the correct measured value.

-- Please use the correct cuff twining method for measurement. The arm circumference range of the enclosed cuff is 22-42 cm (center of the upper arm). If the model is inconsistent, please purchase separately.


16. Abnormal Phenomena and Handling

If the measurement is abnormal, a screen similar to this may appear. This screen is showing an error message. Kindly follow the recommended instructions.



| Error | Cause/Solution |
|---------------------------|---|
| Insufficient buildup | The pressure cannot reach 30 mmHg (4 kPa) in 15 s. |
| Overpressure | The inflation reaches 300 mmHg. |
| No pulse | The pulse rate is not detected correctly. |
| Pressure lost | The pressure dropped unexpectedly. |
| Movement | Too much disturbance (Move, talk, or magnetic disturbance during a measurement). |
| Cuff rearranged | Too much disturbance or cuff moves during inflating. |
| BP very high | The blood pressure probably exceeds the measurement range. |
| No cuff or loose | Please check the placement of the cuff. |
| Irregular heartrate | Blood pressure can not be estimated, due to a irregular measurement of the pulse. Please check the cuff placement and do not move during measurement. |
| No Sys/Dia | Blood pressure estimation failed, please measure again. |
| Pressure build up aborted | The pressure build up was incomplete. Please check the cuff placement and do not move during measurement. |
| Strange results | The measurement result is abnormal. |
| Aborted | The user stopped the measurement. |

* Troubleshooting

| Anomaly | Possible Faulty | Solution |
|---|---|---|
| Failure to power on | The battery is depleted | Recharge the device |
| No pressurizing | The air tube plug is not inserted tightly | Insert the air tube plug firmly into the socket. |
| | The air tube is broken or leaking | Please contact the dealer to replace the cuff with a new one. |
| Unable to measure indicated by an error on the display | The arm is moved during pressurization | Keep your arm and body still. |
| | Talking during the measurement | Keep quiet while measuring the blood pressure. |
| Air leakage of the cuff | The cuff is attached too loosely. | Please tighten the cuff |
| | The airbag of the cuff is ripped | Please contact the dealer to replace the cuff with a new one. |
|  If the blood pressure still cannot be measured after trying the above-stated solutions, please contact the dealer. Do NOT attempt to disassemble the device by yourself. | | |

17. Cleaning and Disinfection

1. Cleaning

The device can be cleaned with a soft, clean cloth dampened with a small amount of neutral detergent or water.

It is suggested to clean the monitor before and after each use.

Complete the cleaning in 3min each time. The number of repeated cleaning each time shall not exceed 3 times.



Do not use corrosive cleaning agents, and be careful not to immerse any part of the monitor to avoid liquid flow into the instrument.

2. Disinfection

Recommended disinfecting agent:

75% medical alcohol

1) Carefully wipe the device with a soft, clean cloth dampened with a small amount of the above disinfectant, and dry immediately with a soft, clean, dry cloth.

2) The body of the device can also be cleaned with a soft, clean cloth dampened with a small amount of 75% medical alcohol for disinfection.



Do not disinfect through methods like high-temperature steam or ultraviolet radiation. These might damage the device and reduce its service life.

It is suggested to disinfect the monitor before and after use each time. Each time of disinfection shall be completed within 1min. The number of repeated disinfection each time shall not exceed 2 times.

3. Disposal

Dispose of the monitor, other components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

Notes

- Do not bend or crease the air tube excessively.
- Do not store the monitor or its components:
 - When the monitor or its parts are wet.
 - In locations with extreme temperatures, humidity, direct sunlight, dust, or corrosive gases.
 - In areas with a high risk of vibrations or shocks.

18. Upkeep and Maintenance

- Always keep the surface of the device clean and tidy, helpful to prolong its service life.
- If the device is dirty, please wipe with a dry soft cloth. If the dirt cannot be eliminated easily, wipe with a soft cloth stained with water or neutral detergent, and then dry with a dry cloth.
- We suggest to calibrate the monitor once a year at least. Please contact manufacturer or agent if you need.



Water or neutral detergent



Warning: Do not allow water or other liquids to flow into the device. The arm pressure monitor should no longer be used when liquid has entered and damaged the device or the cuff.

19. Appendix 1 EMC Information

| Guidance and manufacturer's declaration - Electromagnetic emission | | |
|---|-------------------|---|
| The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Arm Blood Pressure Monitor should assure that it is used in such an environment. | | |
| Emissions | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The Arm Blood Pressure Monitor 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 Arm Blood Pressure Monitor 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 IEC61000-3-2 | N.A. | |
| Voltage fluctuations/- flicker emissions IEC61000-3-3 | N.A. | |

| Guidance and manufacturer's declaration - Electromagnetic immunity | | |
|---|--|--|
| The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Arm Blood Pressure Monitor should assure that it is used in such an environment. | | |
| Immunity test | IEC 60601 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 | ±1 kV signal input/output 100 kHz repetition frequency | ±1 kV signal input/output 100 kHz repetition frequency |
| Surge IEC 61000-4-5 | Not applicable | Not applicable |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | Not applicable | Not applicable |
| Power frequency magnetic field IEC 61000-4-8 | 30A/m, 50/60Hz | 30A/m, 50/60Hz |
| Conducted RF IEC61000-4-6 | 3V signal input/output; 0,15MHz-80MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1kHz | 3V signal input/output; 0,15MHz-80MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1kHz |

| | | |
|---|--|--|
| Radiated RF IEC61000-4-3 | 10 V/m 80 MHz - 2,7 GHz 80% AM at 1KHz | 10 V/m 80 MHz - 2,7 GHz 80% AM at 1KHz |
| NOTE: UT is the a.c. mains voltage prior to application of the test level | | |

| Guidance and manufacturer's declaration - electromagnetic Immunity | | | | | | | | |
|--|----------------------------|---------------|-------------------|-------------------------------------|----------------------|-----------------|--|------------------------------|
| The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Arm Blood Pressure Monitor should assure that it is used in such an environment . | | | | | | | | |
| Radiated RF0-4-3 (Test specifications for ENCLOSURE-PORT IMMUNITY to RF wireless communications equipment) | Test Frequency (MHz) | Band (MHz) | Service | Modulation | Max. Power (W) | Distance (m) | IEC 60601-1-2 Test Level (V/m) | Compliance level (V/m) |
| | 385 | 380-390 | TETRA 400 | Pulse modulation 18 Hz | 1.8 | 0.3 | 27 | 27 |
| | 450 | 430-470 | GMRS 460, FRS 460 | FM ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 | 28 |
| | 710 | 704-787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 | 9 |
| | 745 | | | | | | | |
| | 780 | | | | | | | |
| | 810 870 | 800-960 | GSM 800/900, | Pulse modulation | 2 | 0.3 | 28 | 28 |

| | | | | | | | | |
|--|------|---------------|--|-----------------------------------|-----|-----|----|----|
| | 930 | | TETRA 800, DEN 820, CDMA 850, LTE Band 5 | on 18 Hz | | | | |
| | 1720 | 1700- 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulati on 217 Hz | 2 | 0.3 | 28 | 28 |
| | 1845 | | | | | | | |
| | 1970 | | | | | | | |
| | 2450 | 2400- 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulati on 217 Hz | 2 | 0.3 | 28 | 28 |
| | 5240 | 5100- 5800 | WLAN 802.11 a/n | Pulse modulati on 217 Hz | 0.2 | 0.3 | 9 | 9 |
| | 5500 | | | | | | | |
| | 5785 | | | | | | | |

Guidance and manufacturer's declaration - electromagnetic Immunity

| | | | | |
|--|-------------------|--------------------------------|--------------------------------------|---------------------------|
| Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields) | Test Frequency | Modulation | IEC 60601-1-2 Test Level (A/m) | Compliance level (A/m) |
| | 30 kHz | CW | 8 | 8 |
| | 134.2 kHz | Pulse modulation 2.1 kHz | 65 | 65 |
| | 13.56 MHz | Pulse modulation 50 kHz | 7.5 | 7.5 |

Statement: "The ARM-30H of Arm Blood Pressure Monitor was tested according to the recommendations of Technical Report IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems."

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 equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
- Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Notice

If users or patients have occurred any serious incident that relation to the device, please report to manufacturer and the competent authority of the Member State in which you are established.



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