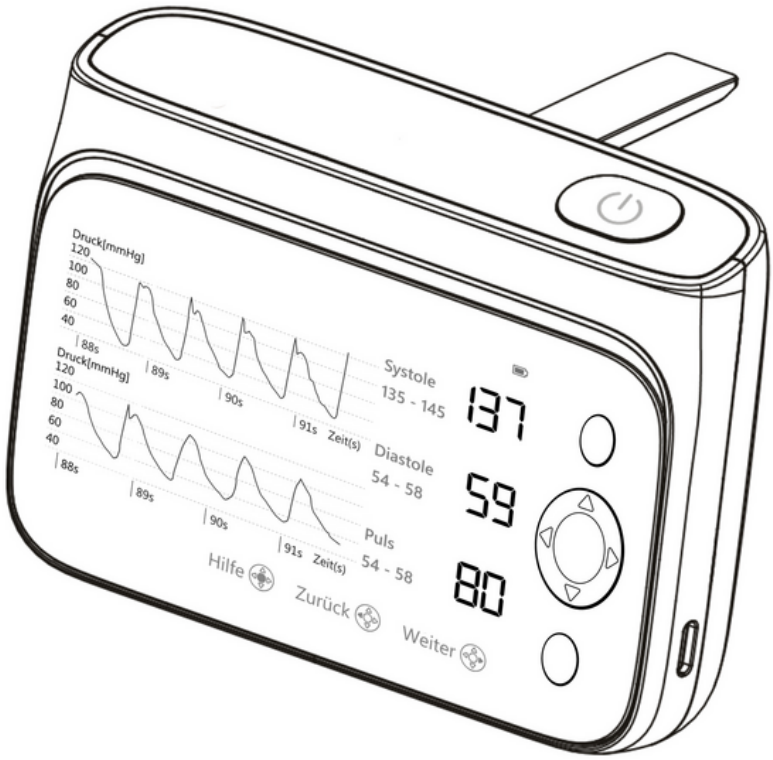
Arm Blood Pressure Monitor

User Manual



Model: ARM-30H

Manual Version: A1

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Table of Contents

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.

Packing List

No.	Name	Quantity
1	Arm Blood Pressure Monitor	1
2	Cuff 22-42cm (8.7~ 16.5 inches)	1
3	Pouch	1
4	User manual (English and German)	1
5	USB-charging cable	1

2. 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 0123	CE mark
	Manufacturer
	Date of manufacture
SN	Serial number
LOT	Batch code
EC REP	Authorized representative in the European Community
MD	Medical device
	Indicates the entity importing the medical device into the local
UDI	Unique device identifier

3. 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.

4. Contraindication

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

1. This device has not been tested on individuals with implanted electrical devices such as pacemakers or implantable defibrillators. Since the cuff is not electrical, there is no known risk of interference. However, oscillometric blood pressure measurements may be inaccurate in these patients. If you have a pacemaker or defibrillator, consult your doctor before use.

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.

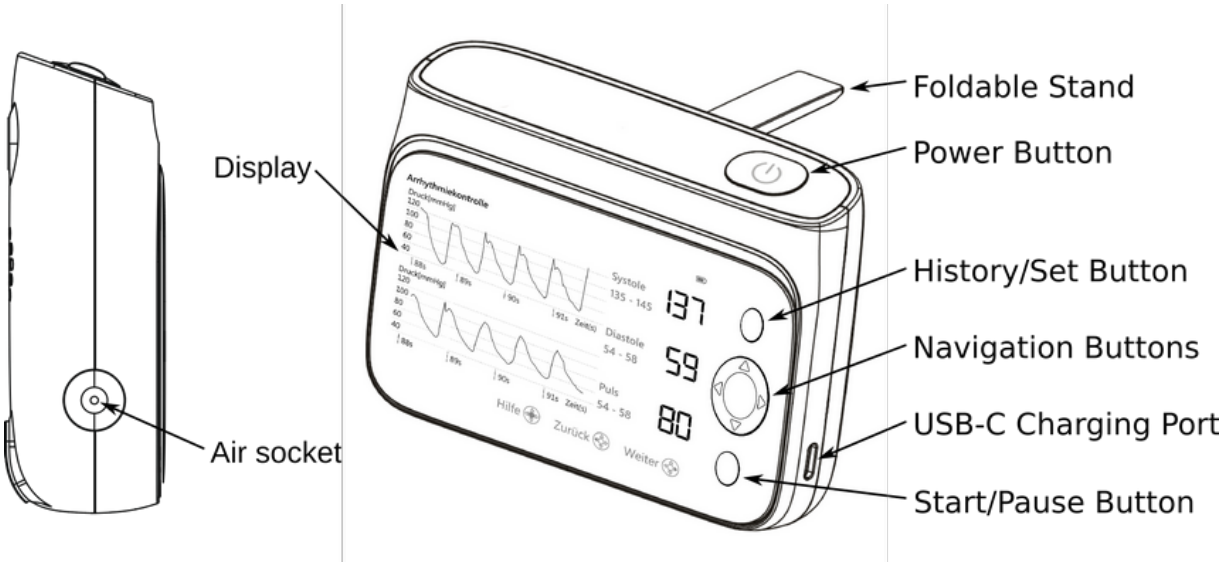
4. Avoid taking measurements of patients with conditions, diseases, and susceptible to environment conditions that lead to incontrollable motions (e.g. trembling or shivering) and inability to communicate clearly (for example children and unconscious patients).

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.

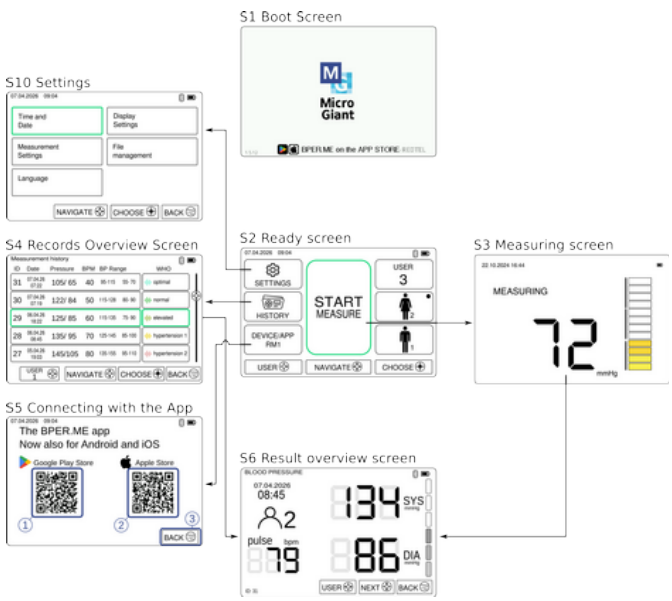
5. Product Parts

1. Main Body



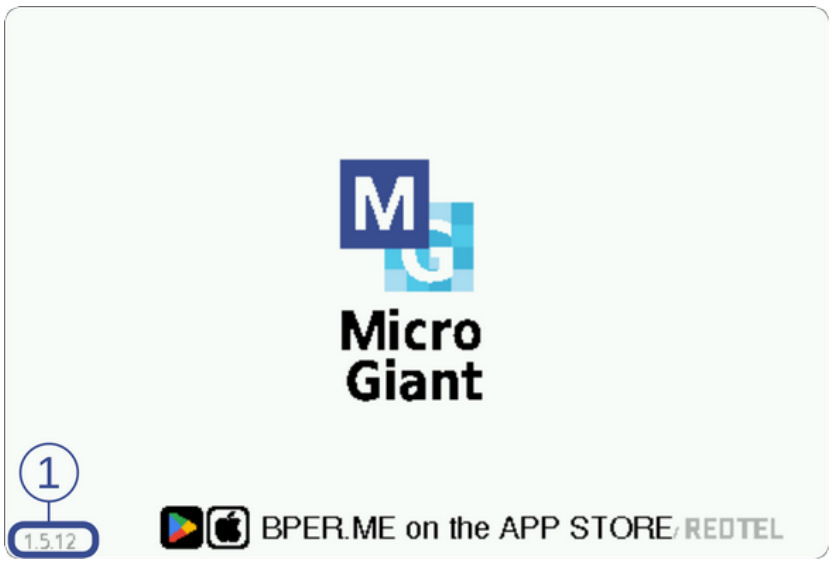
2. Display and User Interface

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 or App 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.

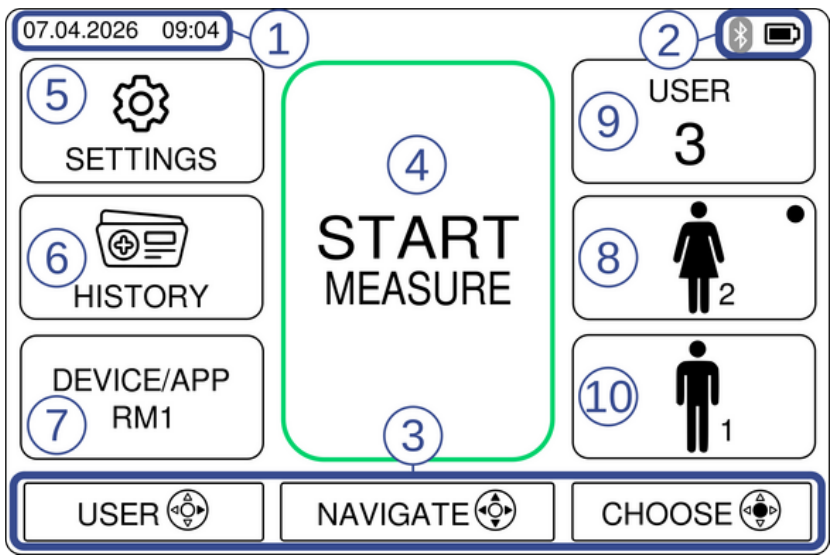
S1 Boot Screen



After the Power Button has been pressed the boot screen indicated that the device is working. Wait until the screen changes to “Ready Screen” (The screen S2 opens). The animation can be skipped with any button.

1. Firmware version of the device.

S2 Ready screen



1. Current date and time.

2. Device State: Bluetooth symbol appears when the device is connected to the app. The battery symbol shows the state of charge if the battery: green: battery is full, orange: measurement possible, but after that please start charging, red: battery empty, measurement may fail, please charge

3. Navigation overview: Select the user option using the right button. The other options can be accessed using the arrow buttons. The selected option is activated using the center button.

4. Select this option to start a measurement.

5. Select this option to open the settings (The S11 screen opens).

6. Select this option to load and display previous measurements (the S4 screen opens).

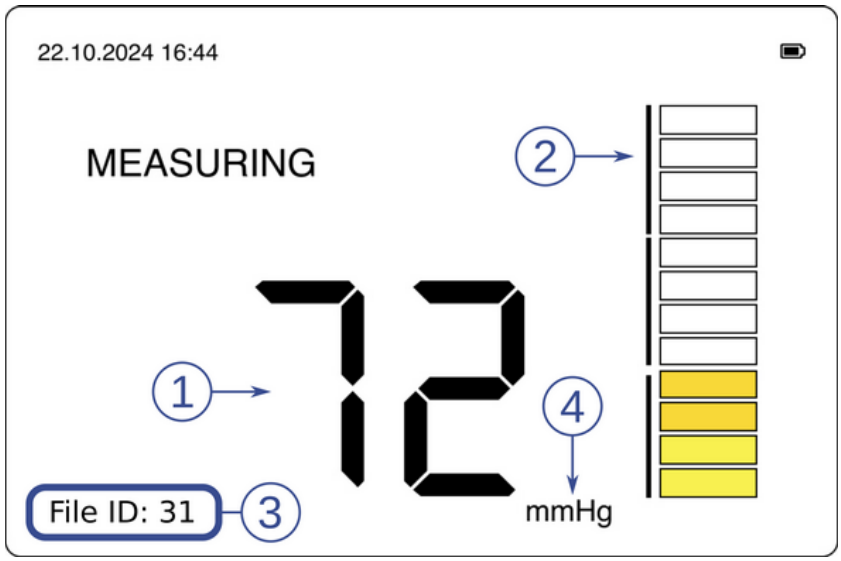
7. This option displays the device name, which can be changed using the app. When this button is tapped, a screen with information about the app appears (the S5 screen opens).

8. This option displays the selected user. This user is assigned to the data record, allowing multiple people to use the device. You can choose between the users "Female," "Male," and three additional users (User 3, User 4, and User 5).

Once the button is selected, the user can be changed using the up and down buttons. Pressing the up button moves option 9 to the middle position, and the selected user is changed. In the image shown, this would select “User 3”.

Similarly, pressing the down arrow button moves option 10 to the middle position and selects the displayed user. In the image shown, this would select “Man.”

S3 Measuring screen



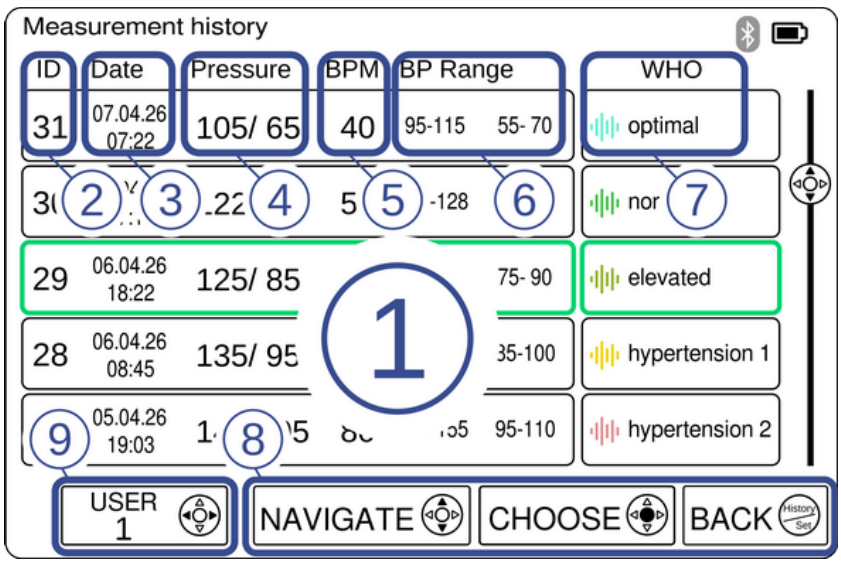
1. Actual pressure in the cuff

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 (see S4 screen)

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

S4 Records Overview Screen



1. A tabular of all recordings

2. ID of the recording, as indicated during measurement (see S3, 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.

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

9. Display and navigation prompt for the user whose measurement values are listed. Use the right and left buttons to view data from other users.

S5 Link to the App

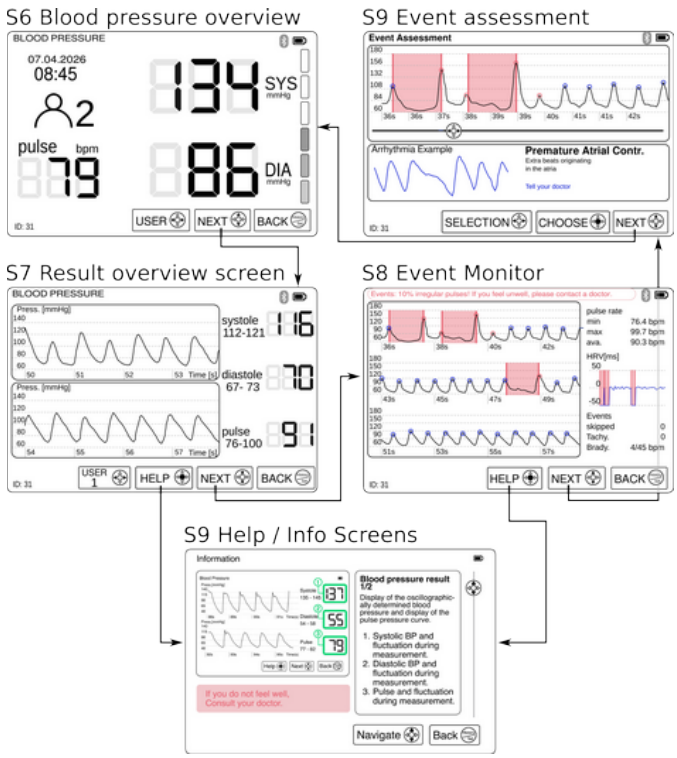
This screen allows you to use your smartphone to find the app.

1. If you are using an Android smartphone, scan this QR code.

2. If you are using an Apple smartphone, scan this QR code.

3. Navigation: Use the "History/Set" button to return to the previous screen.

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.

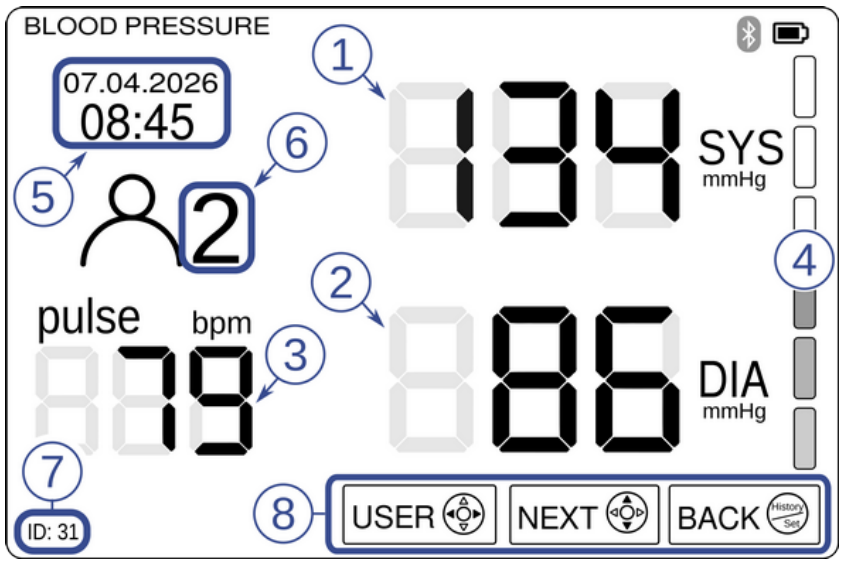
A detailed screen (S7) also shows the detected blood pressure and heart rate variations, as well as a snapshot of the pulse pressure rhythm.

The event monitor (S8) displays details of detected heart rate irregularities that were identified during the measurement.

The Event Assessment (S9) is an interactive screen that shows the same waveform as S8 (upper section) in an enlarged view. This screen allows measured data to be compared with examples of arrhythmia patterns (below).

It also allows you to navigate to an informational screen. This help menu describes, in a manner analogous to the descriptions in this manual, the meanings of the elements on the result display screens.

S6 Blood Pressure Overview

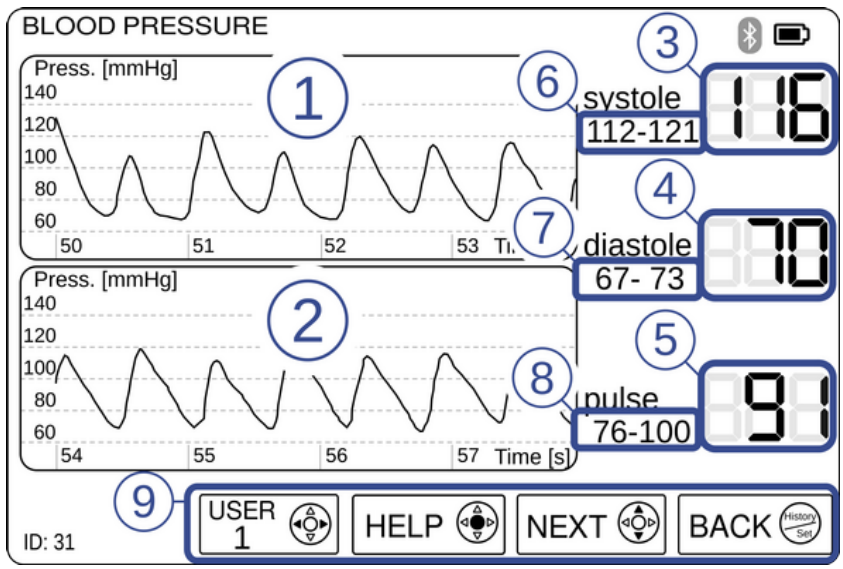


This screen displays the standard readings for blood pressure, similar to conventional devices.

1. Oscillometric systolic pressure reading.
2. Oscillometric diastolic pressure reading.
3. Pulse rate
4. Blood pressure classification (see Chapter 8. Blood Pressure Classification)
5. Date and time when the data record was collected.
6. Assignment of the data record to a user (1: Male, 2: Female, 3-5 other users). This user number was previously set in the standby screen (S2). This assignment can be changed later using the right/left buttons.
7. ID of the data record, which enables assignment (along with date and time) in the data record overview (S4).
8. Navigation: Use the left/right buttons to change the assignment of the data record to the user. The up/down buttons take you to a different results view. Use the History/Set button to return to the standby screen (S2).

S7 Result overview screen

This detailed results screen also shows a snapshot of the pulse pressure rhythm, as well as the detected blood pressure and heart rate variability.



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

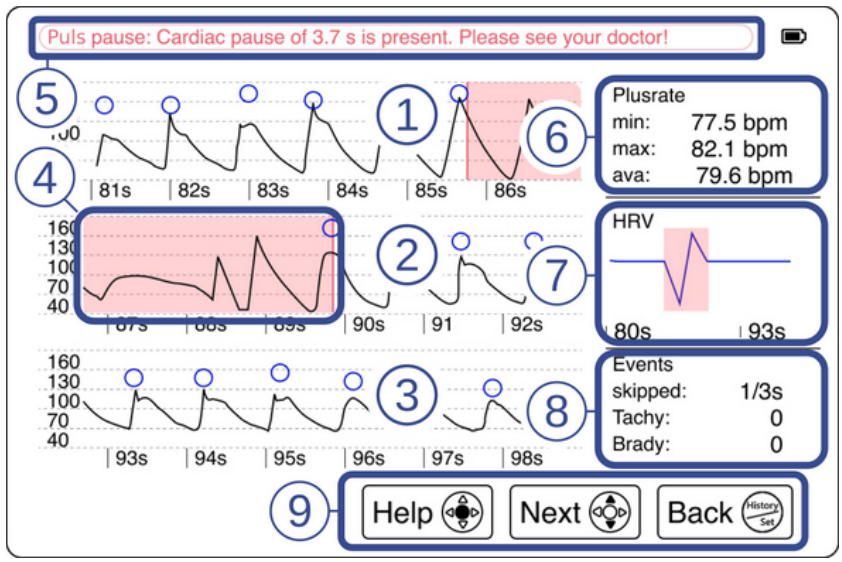
6. Recorded systolic blood pressure range during the measurement.

7. Recorded diastolic blood pressure range during the measurement.

8. Recorded range of pulse rate during the measurement.

9. Navigation overview: Display and changing of the user assignment with the keys left/right, Show help screen with center button, Navigate up and down to select other view of this recording; Reset device screen with History/Settings Button.

S8 Event Monitor



This display shows detected irregularities in the pulse pressure rhythm. These may include prolonged or shortened heartbeats, as well as systolic or diastolic values for individual heartbeats that deviate from the average.

1./2./3. Reproduction of the pulse pressure rhythm, which consists of pressure fluctuations caused by the 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 of inconspicuous (not marked) heart pulses).

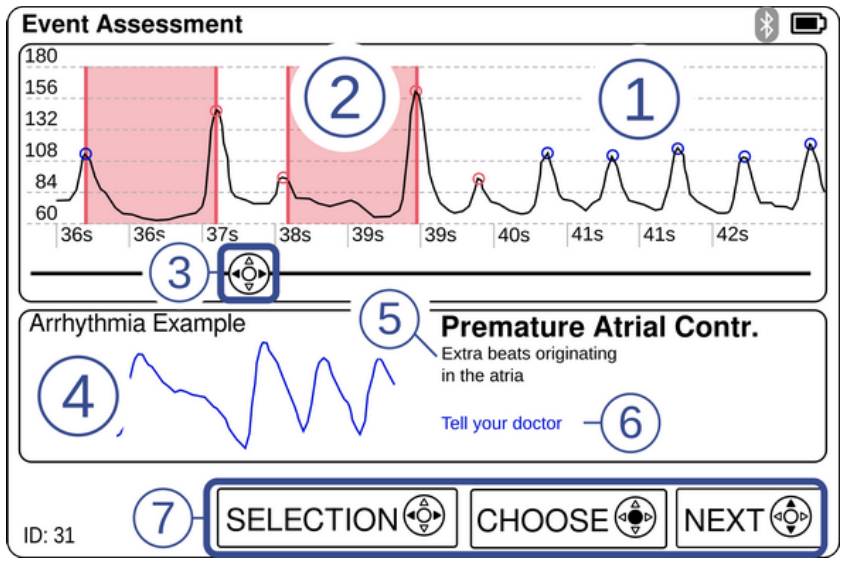
7. HRV: Heart rate variability; Beat to beat change of the heart pulse as graphical representation. A regular variation is a indicator of normal changes to respiration. Elevated variation above the usual

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 (S10) with center button; Go to previous screen (S2 when a actual measured recording is displayed or S4 when recording was selected from records overview screen) with History/Settings Button.

S9 Arrhythmia assessment screen



This is an interactive screen that allows you to compare the measured data with known heart rhythm irregularities.

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.

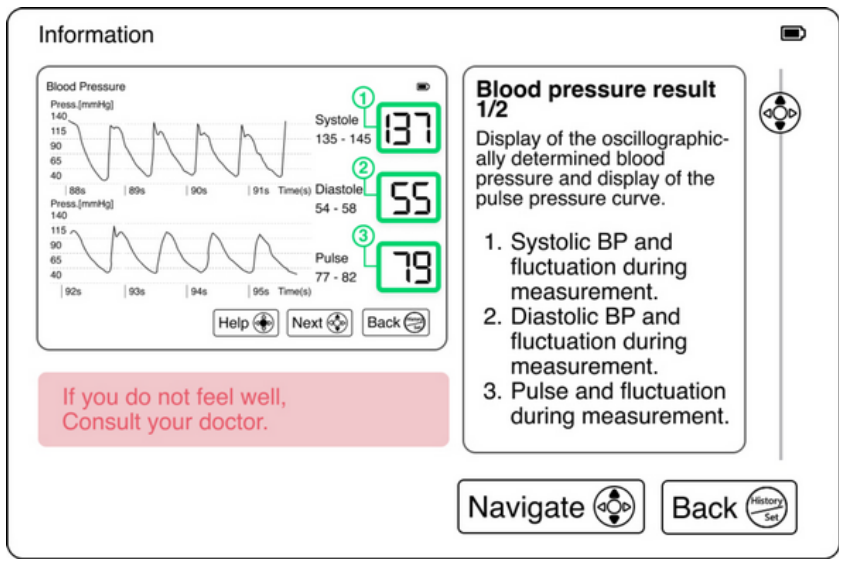
5. Name and information of that example data.

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).

S10 Help/Information screens

This screen show information about the values represented on the screens (S7, S8, and S9).



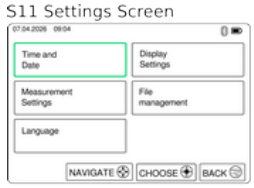
4 Setting Screens

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

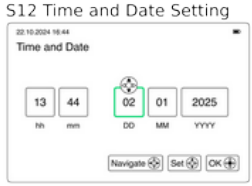
From the main setting screen (S11) the particular setting can be chosen with the navigation buttons and displayed with the central button.

Adjustments are possible using the navigation buttons. For confirmation of a adjustment the central button is used.

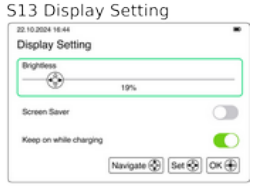
S11 Settings Screen



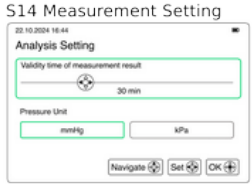
S12 Time and Date Setting



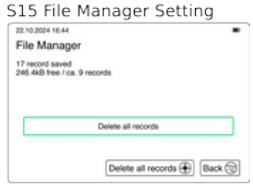
S13 Display Setting



S14 Measurement Setting

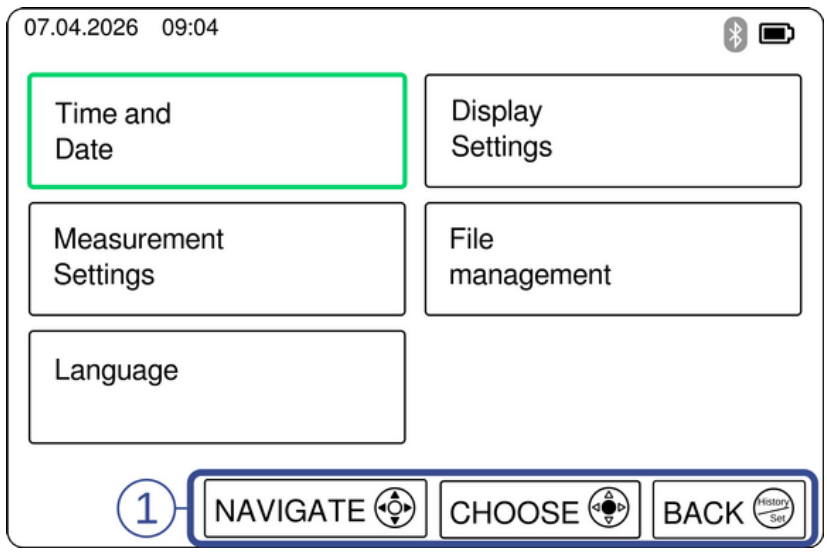


S15 File Manager Setting



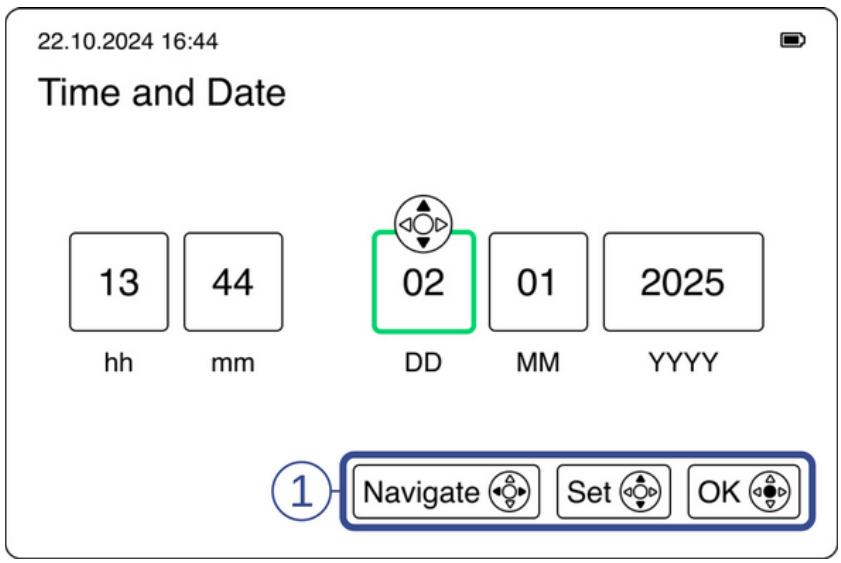
S16 Language Setting

S11 Settings screen



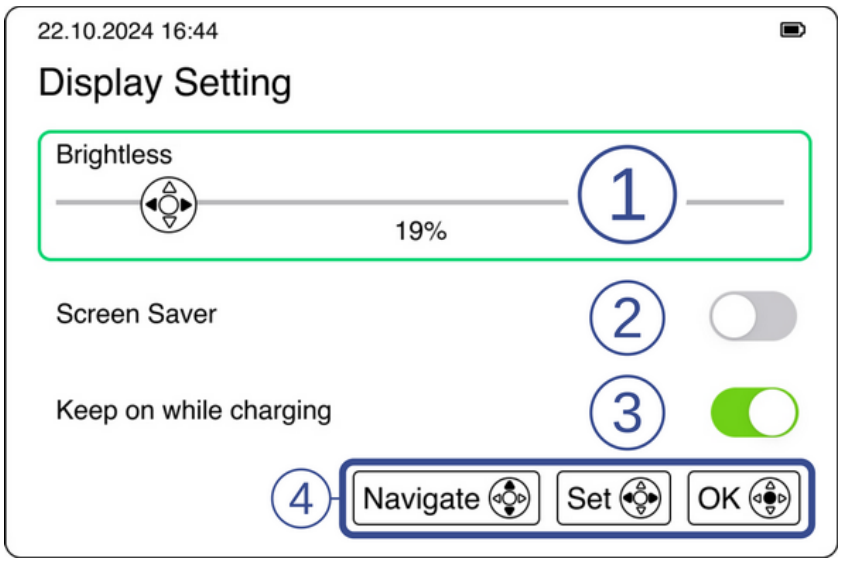
1. Navigation overview: Navigate with the arrow buttons to select an other setting; Open the screen for the selected setting with center button; Go to the ready screen with History/settings Button (S2).

S12 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 (S11).

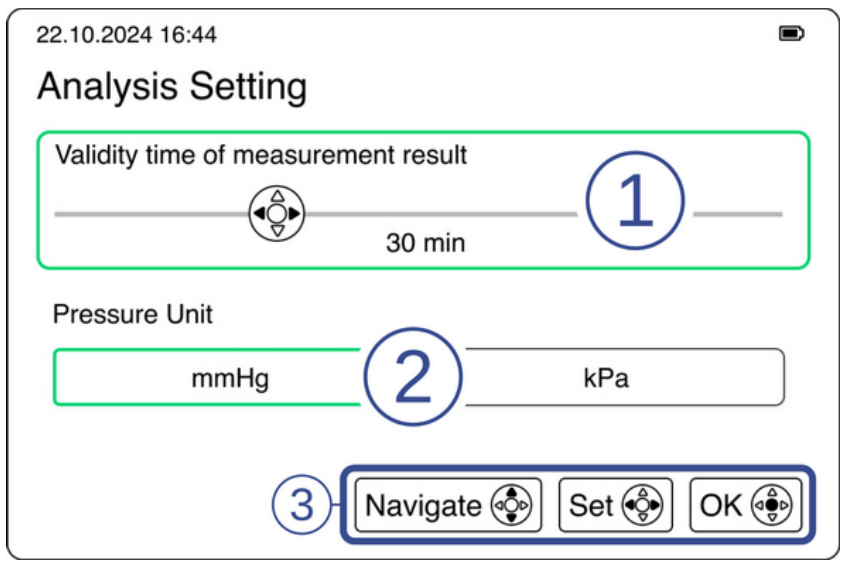
S13 Display setting



1. Setting of the brightness of the screen
2. Toggle wether the device should go off after a minute
3. Toggle wether 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 (S11).

S14 Measurement setting

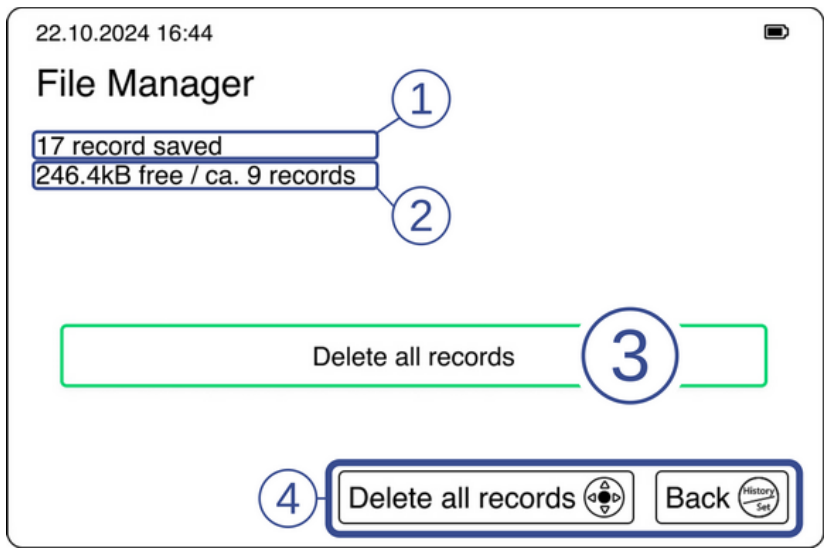


1. Time in minutes when a displayed measurement should be marked as “old”.

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

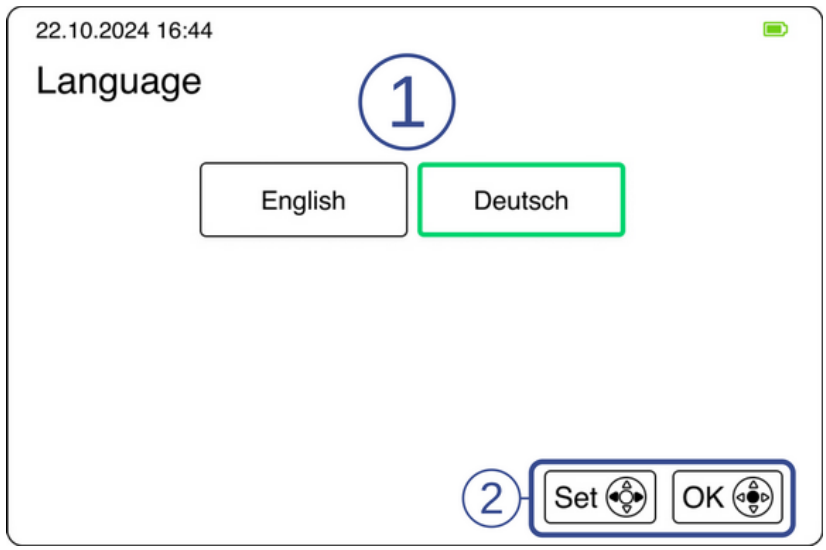
3. Navigation overview: Change the setting of the selected item with left and right arrow button; Change selected item with up and down button; Accept setting and go to the previous screen with center button (S11).

S15 File manager setting



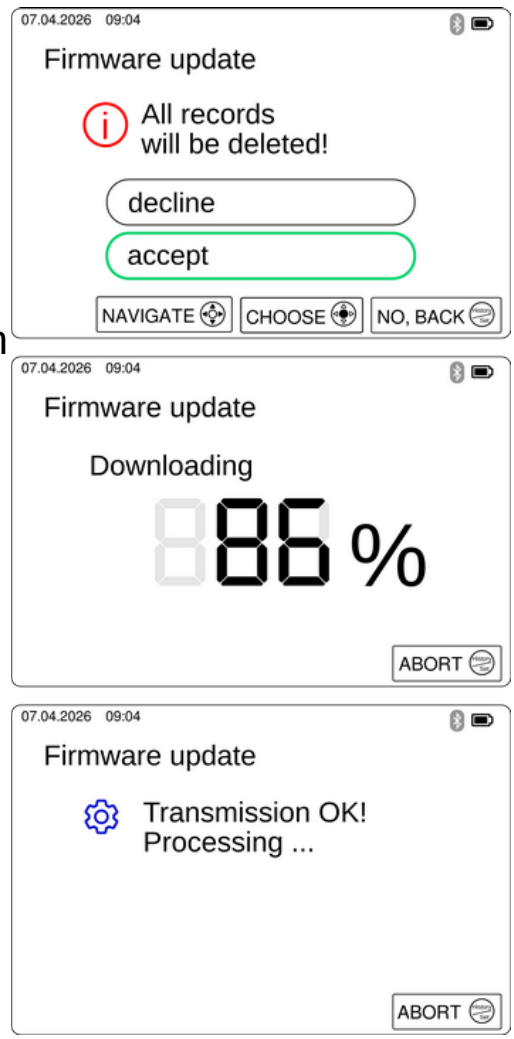
1. Count of saved recordings
2. Free flash space and estimation of recording which can the stored without deleting the oldest recording.
3. Select this to delete all recordings
4. Navigation overview: Go back to the settings overview with history/settings button; Delete all recordings with the center button (you will be asked again) and go back to the previous screen.

S16 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 (S11).

5 Screens during Device Updates



As part of our ongoing product improvement efforts, the companion app may suggest a firmware update. This provides new features and fixes bugs.

You should perform an update as soon as possible at a time when you do not have any measurements scheduled. Before performing an update, please make sure that all measurements you wish to keep have been transferred to your smartphone, as the update process will delete all measurements from the device.

To perform an update, connect the device to a charger and start the update process in the app.

An update takes about 10 minutes and uses your smartphone's Bluetooth feature.

You can cancel the update at any time, and the old version will remain. However, if a transfer has already started, the saved measurements will be deleted.

6. Use with the BPER.ME companion app (optional)

6.1 Notes on using the app

Use of the smartphone app is optional. Measurements and all medical functions are performed independently of the app, using only the blood pressure monitor. The app does not influence or control the measurement, nor does it interpret the readings.

Medical decisions should always be based on the readings displayed on the device and in consultation with your doctor.

The app is not intended to be a medical device and does not perform any diagnostic or therapeutic functions.

6.2 Intended Use of the App

The current version of the app performs the following functions:

- Downloading and storage of measurement data
- Display of measurement values
- Export of measurement data as a PDF
- Sharing of measurement data
- Transfer of firmware update data to the device

The app establishes a Bluetooth connection to the device and transfers measurement data from the device. This measurement data is displayed as a list and can be exported individually or as a consolidated PDF, which you can then share with third parties, such as your doctor, using the share function.

In the event of an update, the app serves solely as a communication interface for transferring firmware files to the device. The entire update process, including verification and validation, is handled by the device itself.

6.3 Where can I download the app?

The app is available for Android and iOS and can be found in the respective app stores by searching for BPER.ME.

You can access the app directly by using your smartphone’s QR scanner to scan the QR code for your platform:

6.4 Using the App

Separate instructions are provided for using the app. These can be found within the app or on the manufacturer’s website (https://bper.me/).

7. Blood Pressure Classification

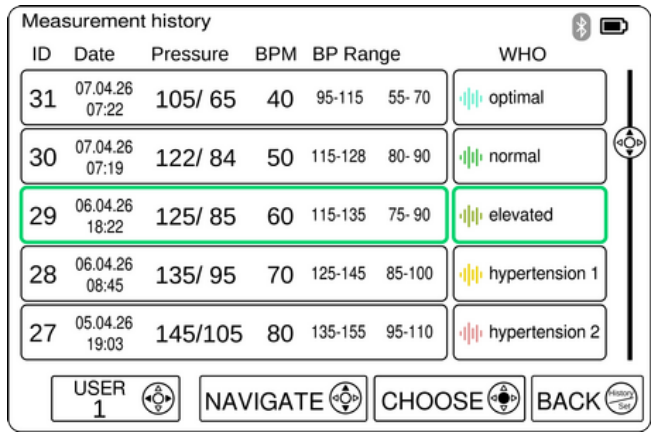
The recorded measurements are classified according to the guidelines of the European Society of Cardiology[1].

The meanings of the colors in the WHO column are:

Green: Normal blood pressure

Yellow: Elevated blood pressure

Red: High blood pressure



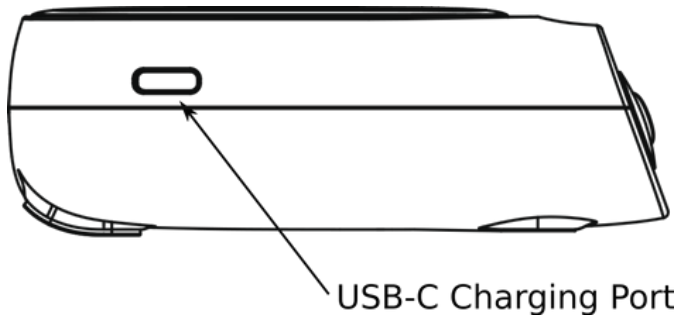
Systolic Blood Pressure (mmHg)		Diastolic Blood Pressure (mmHg)	Color Display	Classification
<120	and	<80	Green	Optimal
120-129	and/or	80-84	Green	Normal
130-139	and/or	85-89	Green	Elevated
140-159	and/or	90-99	Yellow	Stage 1 Hypertension
160-179	and/or	100-109	Red	Stage 2 Hypertension
≥180	or	≥110	Red	Stage 3 Hypertension

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

1 2018 ESC/ESH Guidelines for the management of arterial hypertension, European Heart Journal, Volume 39, Issue 33, 01 September 2018, Pages 3021–3104, https://doi.org/10.1093/eurheartj/ehy339

8. 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:

- A power adapter is not included in the package.
- Use a 5V USB power adapter from a reputable manufacturer. The device cannot take blood pressure measurements while charging, but stored data can still be safely accessed.

9. Function Setting

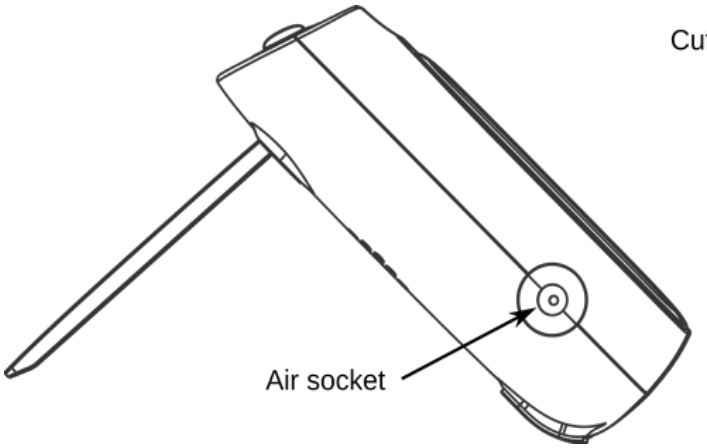
Please refer to the screens S11-S16.

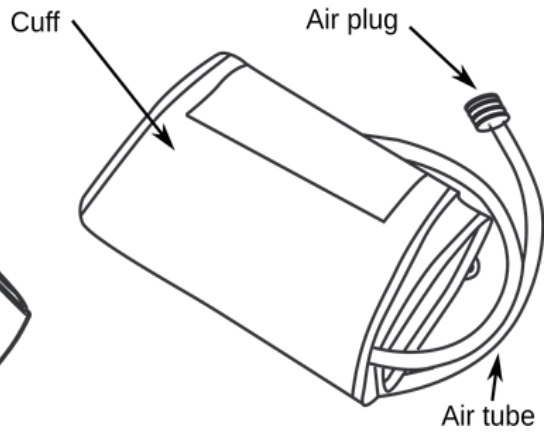
The following settings can be changed with those screens:

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

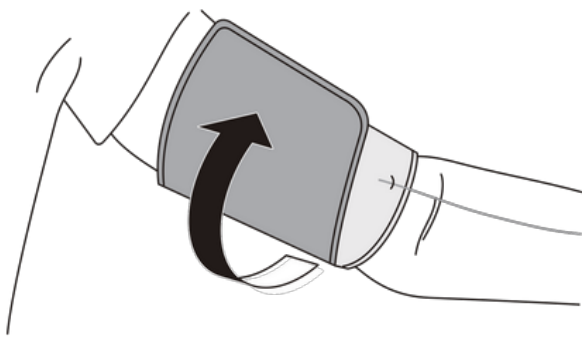
10. How to apply the arm cuff

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



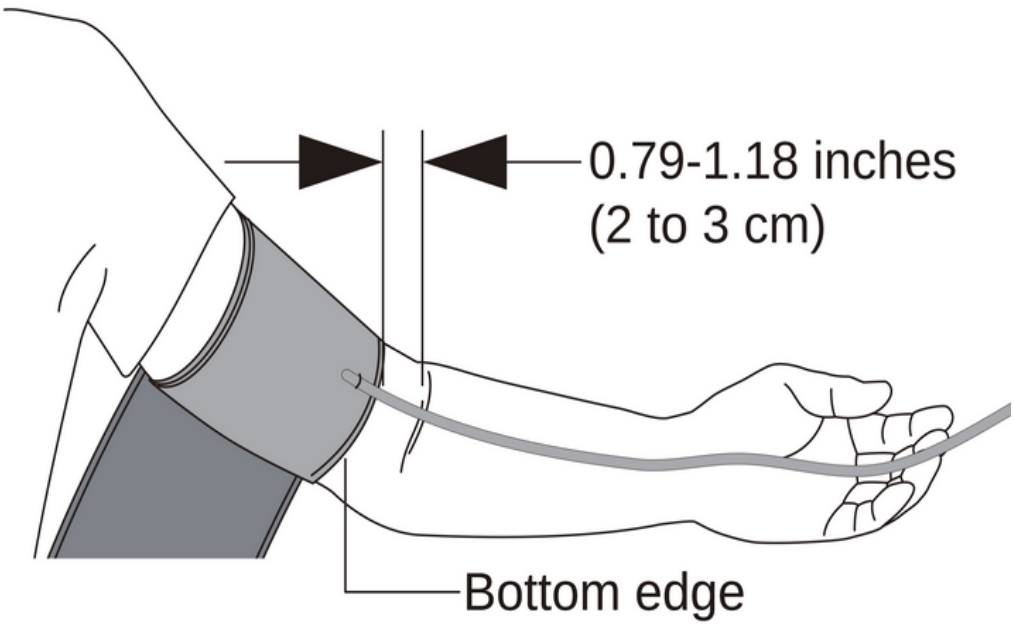


2. Place your hand through the cuff loop. Pull the cuff until it reaches your upper arm.



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.

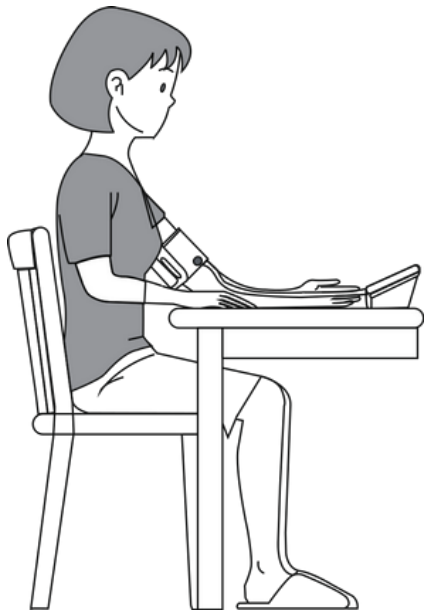
How to avoid blood congestion and ensure the repeated measurement is accurate?

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.

11. 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 "10. 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 S3). 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 S4. A recording can be selected by date or ID.

3. Delete Memory: Recordings can be deleted by the records settings screen (refer screen S15)

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.

12. 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	±5%	
Low Battery	When the power is lower than 3.4V±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 x1.2 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℃~55℃ 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:

   ±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.

13. 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.

14. 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 has 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.

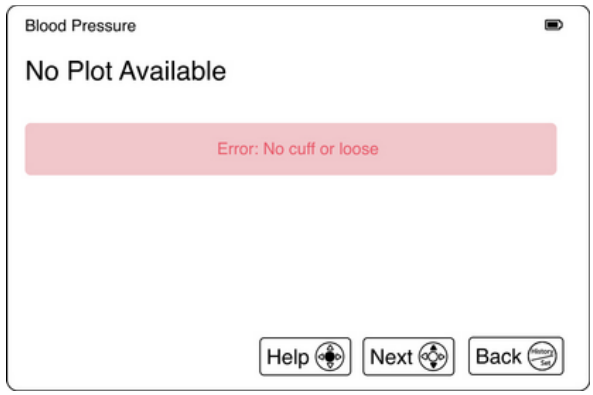
-- Please note when measuring multiple times: There might be extravasated blood because the arm is compressed, resulting that the fingertip blood does not flow smoothly, if you continue the measurement in case of extravasated blood, you cannot obtain the correct measured value. Loosen the arm band, raise 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.

15. 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 unexpected.
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
The battery indicator does not turn "green" even after prolonged charging.	This is a known hardware issue that does not affect functionality.	If the indicator is "yellow," this means the device is fully charged and can be used without any further restrictions.
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.
The blood pressure readings are strange and have a decimal place	The device is set to kPa.	In the settings menu "Measurement Settings" (see Chapter 5, Display S14), you can switch between the pressure units "mmHg" and "kPa".

The time is incorrect or not displayed	The time hadn't been synchronized for a long time.	Connect the device to the companion app so that the time is updated automatically. Alternatively, you can set the time in the "Time and Date" settings menu (see Chapter 5, Figure S12).
 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.		

16. 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

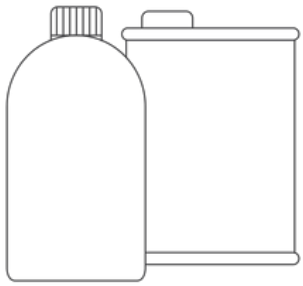
● Do not bend or crease the air tube excessively.

● 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.

4. 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.

17. 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	800-960	GSM 800/900,	Pulse modulati	2	0.3	28	28
	870							

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

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.

18. Glossary

Term	Explanation
arrhythmia	Irregular heart rhythm of one or more pulses.
Arterial pressure	Pressure within the arteries, basis for blood pressure measurement.
blood pressure	Force with which the blood pushes against the walls of the arteries; measured as systolic and diastolic values in mmHg or kPa.
Blood pressure chart	Overview for classifying measured values.
Blood pressure classification	Classification of blood pressure values according to WHO standards: Optimal, Normal, High-normal, Hypertension Stage 1 – 3
Blood pressure measurement	Measurement of systolic and diastolic pressure.
Blood pressure monitor	Device for manual or automatic measurements.
Blood pressure peak	Above-average blood pressure reading of a single pulse.
Blood pressure trend	Long-term log of measured values.
BPER.ME App	Companion app for Android and iOS for transferring, storing, displaying and exporting measured values as well as firmware updates of the device.
Cardiac cycle	An action of the heart to generate pressure; the pressure changes between diastole and systole.
Cardiac risk factors	Accompanying conditions such as diabetes, lipid metabolism disorders, which affect blood pressure levels.
Cardiovascular parameters	Combination of blood pressure, pulse, heart rate.
cuff	Inflatable wrist cuff for measuring blood pressure on the upper arm; size 22 – 42 cm.

Cuff size	Suitable size for precise measurements.
Cuff wear detection	Warning system that sounds an alarm if the cuff is incorrectly aligned or loose.
Daily profile	Measurement data taken at different times of day.
Data set / Measurement data set	Individual measurement including date, time, blood pressure values and pulse.
Data set overview (S4)	A screen where all measurements can be displayed in tabular form, selected, and managed.
Diastolic blood pressure (DIA)	Minimum blood pressure value during the relaxation phase of the heart (diastole).
Display	The device's LED screen displays measurements, settings, and information.
Event assessment (S9)	Interactive display that compares measurement results with examples of known pulse irregularities.
Event Monitor (S8)	Display for showing heart rhythm deviations and abnormal pulse values during measurement.
Firmware update	Device software update that provides new features or fixes bugs; transferable via the app.
Heart level	Position the upper arm at the same level as the heart for accurate measurement.
Heart rate (pulse)	Number of heartbeats per minute.
Heart rate variability (HRV)	Measurement of beat-to-beat changes in heart rate, displayed as a graphical representation.
High normal blood pressure	Classification of blood pressure when systolic pressure is between 130 and 139 mmHg and/or diastolic pressure is between 85 and 89 mmHg
Hypertension / Hypertension	Elevated blood pressure above the normal range.

Hypotension	Low blood pressure below the normal range.
IP21	Protection class: protected against dripping water.
Irregular pulse	Temporal deviation of one or more pulses beyond the natural fluctuation.
Korotkoff sounds	Noises when the cuff pressure drops.
Lifestyle factors	Factors such as exercise, stress, diet, caffeine or smoking affect blood pressure.
Long-term measurement	24-hour measurement or repeated daily measurements.
Mean arterial pressure (MAP)	Average pressure during the cardiac cycle.
Measurement accuracy	Precision of the measured values.
Measurement interval	Time interval between measurements.
Measurement protocol	Recording of measurements, time, date and any remarks.
Measurement screen (S3)	Displays current cuff pressure, pressure graph, measurement ID and unit.
Medical check-up	Regular evaluation by specialists.
Medication control	Monitoring of blood pressure lowering medications.
Non-invasive measurement	Measurement without invasive procedures.
Normal blood pressure	Classification of blood pressure when systolic pressure is between 120 and 129 mmHg and/or diastolic pressure is between 80 and 84 mmHg
Normal range	Standard range for systolic/diastolic values.
Optimal blood pressure	Classification of blood pressure when systolic < 120 mmHg and diastolic < 80 mmHg
Oscillometric measurement	Blood pressure is measured via pressure fluctuations in the artery.

pacemaker	An implant that can influence measurements.
Pneumatic pressure measuring range	Working range of the cuff from 0 to 295 mmHg (0 – 39.3 kPa).
positioning	Correct arm and cuff positioning for accurate measurements.
Pressure sensor	Electronic component for measuring cuff pressure.
pulse	Pressure signal of a heart contraction at the measuring point.
Pulse measurement	Heart rate measurement during or independently of blood pressure measurement.
Pulse pressure	Difference between systolic and diastolic blood pressure.
Pulse pressure rhythm	Graph showing the pressure change within the arteries under the cuff during the measurement period.
Pulse rate / Heart rate	Number of heartbeats per minute (bpm).
Readiness indicator (S2)	Standby screen, displays date, time, battery status, navigation and user assignment.
Repeat measurement	Check in case of unclear values.
Risk assessment	Assessment of cardiac comorbidities.
Risk indicators	Accompanying diseases such as diabetes, cholesterol.
RoHS / CE marking	Compliance with European directives.
Seat measurement	Blood pressure measurement while seated for consistent readings.
Stage 1 hypertension	Classification of blood pressure when systolic pressure is between 140 and 159 mmHg and/or diastolic pressure is between 90 and 99 mmHg
Stage 2 hypertension	Classification of blood pressure when systolic pressure is

	between 160 and 179 mmHg and/or diastolic pressure is between 100 and 109 mmHg
Stage 3 hypertension	Classification of blood pressure if systolic pressure is greater than or equal to 180 mmHg or diastolic pressure is greater than or equal to 110 mmHg
Stress factors	Emotional or physical stress that affects values.
Systolic blood pressure (SYS)	Maximum blood pressure during heartbeat (systole).
Target audience	Laypeople or clinical professionals using the device.
Target values	Individually defined measurement objectives.
Technical data	Overview of measuring range, accuracy, power supply, screen size, protection class and operating environment.
Upper arm measurement	Standard measurement on the upper arm.
User	Person using the device; the device can be assigned to multiple users.
Vascular changes	Arteriosclerosis or thrombosis, which can affect the measurement.
Warning	Safety instructions to prevent damage to the device or injury to the user.
Battery warning	Warning that the battery voltage has dropped below 3.4 V ± 0.1 V and the device will automatically switch off.
Contraindication	Conditions or situations in which the device should not be used.

19. Changes from the previous version of the manual (from A0 to A1)

- Updated illustrations of device screens (Chapter 5)
- Description of the update process (Chapter 5.5)
- Addition of a glossary (Chapter 18)
- New chapter added on the optional companion app (Chapter 6)
- Revision and standardization of the chapter structure
- Adjustment of blood pressure classification in accordance with the 2018 ESC/ESH Guidelines
- Addition of further troubleshooting tips (Chapter 15)
- Editorial revisions to improve clarity

EC REP

Share Info GmbH

Address: Heerdter Lohweg 83, 40549 Düsseldorf, GERMANY

Tel: 0049 179 5666 508

E-mail: EU-Rep@share-info.com

Shenzhen AOJ Medical Technology Co., Ltd.

Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, PEOPLE’S REPUBLIC OF CHINA

Email: info@aojmedical.com

Website: www.aojmedical.com

Tel: 86-755-2778 6026

Made in China