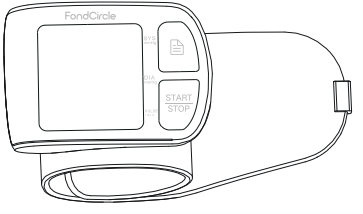
Manufactured for FondCircle Inc.
4695 MacArthur Court, 11th Floor, Newport Beach, CA 92660
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Web: www.fondcircle.com

FondCircle

Smart Devices. Connected Care.

Wrist Blood Pressure Monitor



User Manual

Model: FBP-W1

Version: 1.0.0_2508

FOREWORD

Thank you for purchasing the FondCircle Wrist Blood Pressure Monitor. This product uses the oscillometric method to measure blood pressure. Before each measurement, the device establishes a "zero pressure" equivalent to atmospheric pressure, then inflates the cuff while detecting pressure oscillations caused by pulse rates. These oscillations are used to calculate systolic and diastolic blood pressure, as well as pulse rate.
This user manual contains important safety and care information, and provides step-by-step instructions for using this blood pressure monitor. FondCircle assumes no liability and provides no warranty for any damage (including indirect damage) resulting from failure to comply with this user manual. Please read through this user manual carefully before using the product and strictly follow all safety precautions.

Video Tutorials

Scan the QR code to watch the tutorial videos, which demonstrate how to use the Wrist Blood Pressure Monitor safely.

Online Manual

Scan the QR code to get the manual as a PDF, which can be enlarged and viewed on your mobile device.

Quick Start Guide

Scan this QR code to download the Bluetooth Quick Start Guide as a PDF, which can be enlarged and viewed on your mobile device.

App Download
Scan the QR code with your phone or tablet to download the FondCircle App.

PACKAGE CONTENTS

NO.	Name	Quantity
1	Wrist Blood Pressure Monitor	1
2	User Manual	1
3	Quick Start Guide	1
4	AAA Batteries	2

CONTENTS

WARNINGS AND PRECAUTIONS 01
Precautions 01
Warnings 04
Caution 08
Notice 09
SYMBOLS 10
FEATURES 11
PRODUCT DESCRIPTION 12
General Description 12
Receiving and Inspecting your Monitor 13
Structure 14
Measurement Principle 17
Intended Use 17
HOW TO USE 18
Preparation Before Use 18
1. App 18
2. Installing the Battery 18
Function Setting 19
1. Setting Date, Time, and Voice 19
2. Setting a User ID 25

3. Applying the Cuff 27
Starting the Measurement 30
Recalling the Records 35
Deleting the Records 37
Tips for Measurement 41
CLEANING AND DISINFECTION 42
Cleaning 42
Disinfection Process 43
ABOUT BLOOD PRESSURE 44
Systolic and Diastolic Pressure 44
Standard Blood Pressure Classification 44
Irregular Pulse Rate Detector 46
Why Does My Blood Pressure Fluctuate Throughout the Day? 48
Why Do I Get a Different Blood Pressure at Home Compared to the Hospital? 49
Is the Result the Same When Measuring on the Right Wrist? 50
ERRORS AND TROUBLESHOOTING 51
SPECIFICATIONS 53
EMC GUIDANCE 55
FCC STATEMENT 62
WARRANTY AND CUSTOMER SUPPORT 65

WARNINGS AND PRECAUTIONS

PRECAUTIONS

- This device is intended for indoor, home use and is not intended for self-use in public areas.
- This device is portable, but it is not intended for use during patient transport.
- This device is not suitable for continuous monitoring during medical emergencies or operations.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
- This device is for adults. Do not use this device on newborns or infants. Do not use it on children and adolescents unless otherwise instructed by a medical professional.

• Consult with your physician before using this monitor if you suffer from the following conditions:
  - Common arrhythmias such as premature ventricular beats or atrial fibrillation.
  - Peripheral arterial disease, pregnancy, preeclamsia, or implantation of electrical devices.
  - Undergoing intravascular therapy, arteriovenous shunt, or mastectomy.

Please note that any of these conditions may affect measurement readings, in addition to patient motion, trembling or shivering.

• Do not use this device for diagnosis or treatment of any health problems or diseases. Please consult with your physician first whether the blood pressure or pulse rate readings can be used as an input in determining clinical actions. Please note that clinical actions can only be determined by the physician, otherwise it may lead to delayed treatment or other dangerous situations.

• If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
• This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
• Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
• The device may require up to 30 minutes to warm up/cool down from the minimum/maximum storage temperature before it is ready for use.
• The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment.
• Do not wash the cuff in a washing machine or dishwasher.
• The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure

measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
- Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
- The blood pressure monitor is intended for use by medical staff and laypersons, and the patient is also an intended user or operator.

WARNINGS

- Do not self-diagnose the measurement results and start treatment by yourself. The measurement results given by this device is not a diagnosis. Always consult your doctor for evaluation of the results and treatment.

- Do not adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat high blood pressure.
- Do not apply the cuff on an wrist that has an intravenous drip or a blood transfusion attached.
- Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
- Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
- Do not place the cuff on the wrist of a person whose arteries or veins are undergoing medical treatment, i.e. Intra-vascular access or intra-vascular therapy or an arteriovenous (a-v) shunt, which could disrupt blood circulation and cause injuries.
- Do not place the cuff on the wrist on the same side of a mastectomy (especially when lymph nodes have been

removed). It is recommended to take measurements on the unaffected side.

- Do not wrap the cuff on the same wrist to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
- Check (by observation of the concerned limb) that the operation of the device does not result in prolonged impairment of patient blood circulation.
- On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the wrist (cuff pressure >300 mmhg or constant pressure >15 mmhg for more than 3 minutes) might lead to bruising and discolored skin.
- Do not use this device with high-frequency (hf) surgical equipment at the same time.

- This device is not used in conjunction with oxygen rich
- Environments, not intended for use with flammable anaesthetics, not intended for use in conjunction with flammable agents.
- Do not touch output of the batteries and the user simultaneously.
- Do not use this device if you are allergic to polyester, nylon, or plastic.
- Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
- If you experience discomfort during a measurement, such as pain in the wrist or other complaints, press the power button immediately to release the air from the cuff.
- Do not use the device while under maintenance, or being serviced.
- Sensor degradation or looseness may reduce performance of device or cause other problems.

CAUTION

- Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized service centers.
- It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg). Please contact manufacturer or distributor for authorized service personnel.
- Store your device and cuff in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
- Dispose of accessories, detachable parts, and the device according to the local guidelines.

NOTICE

- You can use this device to take your own measurement, no third-party operator is required.
- Adapter is specified as a part of ME EQUIPMENT.
- At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
- The expected lifetime of the cuff may vary by the frequency of washing, skin condition, and storage state.
- Please report to the manufacturer and the competent authority of the Member State/the FDA in which you are established about any serious incident that has occurred in relation to this device.

SYMBOLS

The signs below may be in the user manual, labeling, or other components. They are required for standard use.

	Date of manufacture		Type BF applied part
	Manufacturer		Serial number
	Recyclable		Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Direct current		
	Refer to instruction manual/booklet Note: The background color of the symbol is blue.		MR Unsafe To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	Batch code		Consult instructions for use or consult electronic instructions for use.
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.		

FEATURES

- Measurement during inflation
- Systolic, Diastolic Blood Pressure, and Pulse Display
- Date/Time Indication
- Maximum 199 records per user

PRODUCT DESCRIPTION

GENERAL DESCRIPTION

The monitor features blood pressure measurement, pulse rate measurement, and result storage. Readings taken by the FBP-W1 are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product. Read the manual thoroughly before using the product.

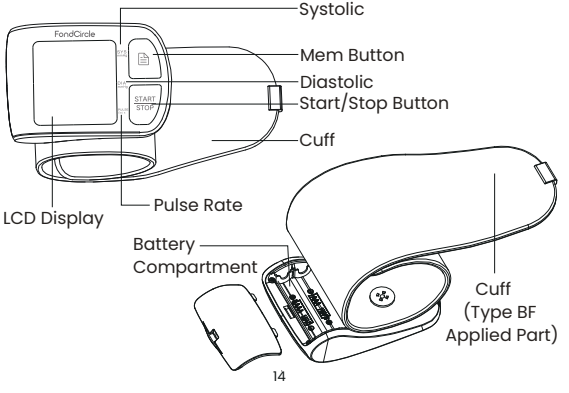
RECEIVING AND INSPECTING YOUR MONITOR

Check that the device packaging has not been tampered with and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed.

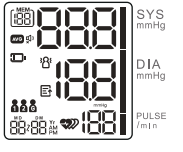
If you have any doubts, do not use the device and contact your retailer or the specified customer service address.

STRUCTURE

Monitor Components



LCD Display Symbol



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	The high pressure measured
DIA	Diastolic Blood Pressure	The low pressure measured
PULSE /min	Pulse Display	Pulse in beats per minute
1 2 G	User ID	User 1/2/Guest
	Current Time	Time (year:month:day:hour:minute)
	Pulse Rate	Pulse rate dectetion during measurement
	Irregular Pulse Rate	Irregular pulse rate detected during measurement

SYMBOL	DESCRIPTION	EXPLANATION
	Battery Indicator	Indicate the current battery level
	Data Transmitting	Data is transmitting; If the data transmission fails, this symbol will be show in next measurement.
	Excessive Body Motion Detector	Appears when talking, moving, or hand shaking is detected during the measurement. NOTE: The measured blood pressure reading may not beaccurate if the icon is displayed.
	Blood Pressure Level	Indicate blood pressure level
	Average Value	Displays average of last 3 readings
	Memory Display	Indicates memory mode and which group of memory
mmHg	mmHg	Unit of measurement of blood pressure
	Voice Broadcast	Turn voice broadcast on and off

MEASUREMENT PRINCIPLE

This product uses the oscillometric measuring method to detect blood pressure.

Before every measurement, the unit establishes a "zero pressure" equivalent to the air pressure. It starts inflating the arm cuff while the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure and pulse rate.

INTENDED USE

This blood pressure monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with a wrist circumference ranging from 13.5-21.5 cm (5.33-18.5 in). It is intended for adult indoor use only.

HOW TO USE

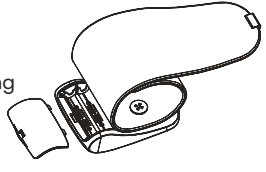
PREPARATION BEFORE USE

1. App

Before using the Blood Pressure Monitor, download and install the FondCircle® app. Always use the latest version of the app. You can download it from Google Play or the App Store.

2. Installing the Battery

- Open the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- Replace the battery cover.



⚠ CAUTION

- New and used batteries, or different types of batteries shall not be used together.
- Remove batteries if the device is not likely to be used for some time.
- Do not heat or deform the batteries, or dispose of them in fire.
- Batteries should not be disposed of with household waste.
- Please check with your local authority for battery recycling advice.

FUNCTION SETTING

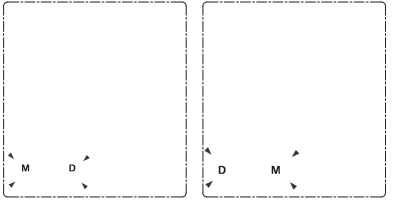
1. Setting Date, Time, and Voice

It is important to set the date, time, and voice settings before using your blood pressure monitor, so that each recorded measurement has an accurate timestamp. (Year Range: 2022–2052; Time Format: 12/24-hour)

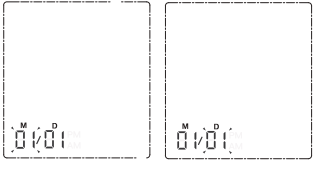
- **Initiate Settings**
  - When the monitor is off and you install the batteries for the first time, it automatically enters the settings mode. The wireless symbol will appear first.
  - Short-press the **"START/STOP"** button to move to the year setting.
  - If voice is on, the monitor will announce, "Please set the year."
  - Press the **"MEM"** button to adjust the year.



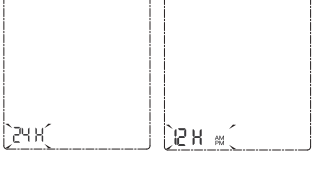
- **Confirm Year & Set Date Format**
  - When the correct year is selected, press the **"START/STOP"** button to confirm.
  - The date format (month/day or day/month) will appear.
  - Press the **"MEM"** button to switch between the two date formats.



- **Set Month & Day**
  - Follow the same steps to set the month and day.
  - If voice is on, the monitor will announce, “Please set the date.”



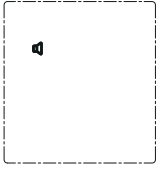
- **Set Time Format**
  - Follow the same steps to select the 12-hour or 24-hour time format.



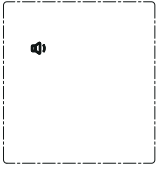
- **Set Hour & Minute**
  - Follow the same steps to set the hour and minute.
  - If voice is on, the monitor will announce, "Please set the time."



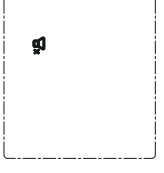
- **Set Voice Volume**
  - After confirming the time, the monitor enters the Voice setting.
  - If voice is on, the monitor will announce, "Please set the voice for you."
  - Press the **"MEM"** button to adjust the voice volume. (Default: Volume 1)



Voice On: Volume 1

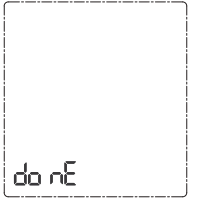


Voice On: Volume 2



Voice Off

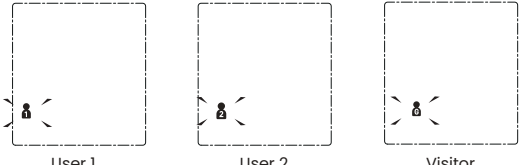
  - After setting the voice, the LCD displays **"do nE,"** then the monitor will automatically turn off.



2. Setting a User ID

There are 3 user IDs 1 2 G available. The user 1 and 2, each with 199 memory spaces, are designed for 2 different people to save the measured values separately. The user G, with no memory space, is reserved for guest.

- **Activate User Selection**
  - When the monitor is off, press and hold the **"MEM"** button. The current user ID will appear and begin to flash on the display. If voice is on, the monitor will announce "Please select a user." Press the **"MEM"** button again to switch between user 1, 2, and G.



User 1 User 2 Visitor

- **Confirm the User ID**
  - When your desired user ID is displayed, press the **"START/STOP"** button to confirm. The user ID will stop flashing, and the monitor will turn off automatically.

3. Applying the Cuff

Use only a cuff approved by the manufacturer for this device model. Confirm that the cuff fits your wrist circumference before use.

- **Remove Accessories**
  - Remove all accessories (e.g., watch, bracelet) from your wrist.
  - If your physician has diagnosed poor circulation in one wrist, use the other wrist.

- **Expose the Skin**
  - Roll or push up your sleeve so the cuff can be placed directly on your skin.

- **Apply the Cuff**
  - With your palm facing up, wrap the cuff around your wrist.

- **Position the Cuff**
  - The edge of the cuff should be about 1–2 cm (½–¾ in) from the wrist joint.
- **Secure the Cuff**
  - Fasten the cuff firmly, leaving no extra space between the cuff and your skin.
  - A loose cuff will result in inaccurate measurements.
- **Prepare for Measurement**
  - Sit comfortably with the tested wrist resting on a flat surface and your elbow supported on a table so the cuff is at heart level.
  - Turn your palm upwards, sit upright in a chair, and take 5–6 deep breaths to relax.

- **Additional Guidelines for Hypertension Patients**
  - The middle of the cuff should align with the level of the right atrium of the heart.
  - Before measurement, sit comfortably with legs uncrossed, feet flat on the floor, and ensure your back and wrist are supported.
  - Rest for 5 minutes before measuring.
  - Wait at least 3 minutes between measurements to allow blood circulation to recover.
  - Take measurements in a quiet environment.
  - Remain relaxed and avoid movement or talking during measurement.
  - Keep the cuff at the same level as the right atrium of the heart throughout the measurement.
  - Do not cross your legs; keep your feet on the ground.
  - For meaningful comparisons, take measurements under similar conditions each time (e.g., at the same time of

day, on the same wrist, or as instructed by your physician).



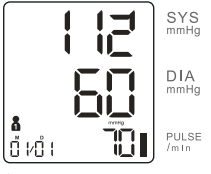
STARTING THE MEASUREMENT

1. When the monitor is off, press the **"START/STOP"** button on. The measurement will begin, and you should remain still and silent until the measurement is complete.

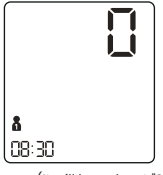
Note: If the voice function is on, the monitor will say, "Starting measurement, please remain still and quiet," before completing the measurement. (For example, with User 1 and voice on.)

Note: You can stop the measurement at any time by pressing the **"START/STOP"** button.

A step-by-step guide showing what you'll see while taking a measurement:



Display the latest record of current user



Adjust to zero (It will broadcast "Starting measurement, please remain still and quiet.")

2. After the measurement is finished, the wireless symbol and symbol will display, and the data will start transmitting.

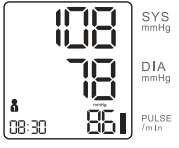


Inflating and measuring



Save amd read your measuring result
(Your systolic blood pressure is 108,
your diastolic blood pressure is 78, Pulse is 86.)

3. If the data transmits successfully, the wireless symbol and the symbol will disappear, and the monitor will turn off automatically.



4. If unsuccessful within 60 seconds, it will time out and the monitor will shut off.

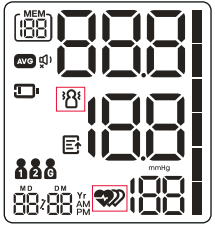
5. Press the **"START/STOP"** button to power off, otherwise it will shut off automatically.

6. Irregular pulse rate and excessive body motion during the measurement.

- During a measurement, if an irregular pulse rate is detected, the symbol will appear in the measurement result.

- During a measurement, if there is excessive body motion, the symbol will flash for about 5 seconds and then recheck. If the motion is no longer detected, the symbol will disappear; if still detected, the symbol remain displayed in the final measurement result.

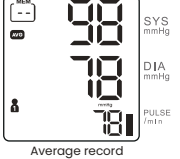
Note: The measured blood pressure reading may not be accurate if this symbol is displayed.



RECALLING THE RECORDS

Recalling the Records

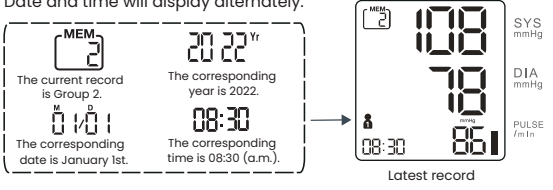
1. When the monitor is off, press the **"MEM"** button to select the user ID. Switch users by pressing **"MEM"** again. After choosing the desired user, press the **"START/STOP"** button to confirm. If there are less than 3 recorded measurements, it will display the latest record of the current user. If there are more than 3 measurements, it will show the average of the most recent 3 measurements. If there are no records, it will display "—."



Average record

2. Press the **"MEM"** button to select the desired measurement. If the wireless symbol and appears along with the record, that means the record pending to transmit.

Date and time will display alternately.



⚠ CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (199) is dropped from the list.

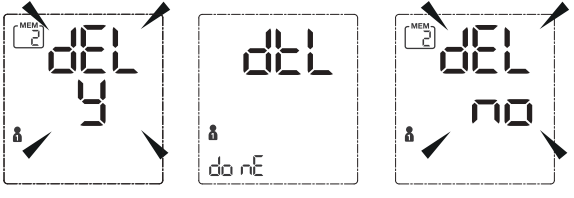
DELETING THE RECORDS

If you did not obtain a correct measurement, you can remove it by following these steps:

A. Delete a Single Measurement

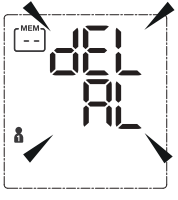
- **Enter Memory Recall Mode**
  - When the monitor is off, press the **"MEM"** button.
  - This will display the Memory Recall mode for the current user (you can press **"MEM"** again to switch between User 1 and User 2).
- **Select the Desired Record**
  - After a few seconds, press the **"MEM"** button repeatedly to find the measurement you wish to delete.
  - Press and hold the **"MEM"** button for 3 seconds. The display will show a blinking dEL and the memory number of that reading.

- **Confirm Deletion**
  - Press the **"MEM"** button to toggle between Y (Yes) and NO.
  - Press the **"START/STOP"** button to confirm your choice.
  - If Y is selected, the reading is deleted.
  - The remaining records will shift forward by one (for example, record 03 becomes record 02).

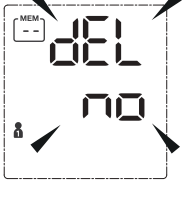


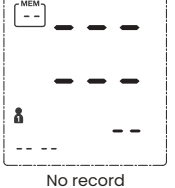
B. Delete All Measurements

- **Enter Memory Recall Mode**
  - When the monitor is off, press the **"MEM"** button.
  - This displays the Memory Recall mode (use the **"MEM"** button to switch between User 1 and User 2 as needed).
- **Initiate Full Deletion**
  - After a few seconds, press and hold **"MEM"** + **"START/STOP"** together for 5 seconds.
  - The display will blink dEL AL along with the user ID.
- **Confirm Full Deletion**
  - Press the **"MEM"** button to toggle between AL (All) and NO.
  - Press the **"START/STOP"** button to confirm.
  - If dEL AL is selected, the unit will display do nE + User ID and then delete all records for that user.
  - After a few seconds, the screen will show ---.









No record

TIPS FOR MEASUREMENT

Measurements may be inaccurate if taken in the following circumstances.



Within 1 hour after dinner or drinking



Immediate measurement after tea, coffee, smoking



Within 20 minutes after taking a bath



When talking or moving your fingers



In a very cold environment



When you want to discharge urine

CLEANING AND DISINFECTION

CLEANING

- **Power Off**

In order to get the best performance, follow the instructions below:
Step 1: Make sure to switch off and unplug the device prior to cleaning.
Step 2: Use a soft cloth with soapy water to clean the cuff first, then use a soft cloth with clean water to remove residual soap until there is no visible residual contaminants. Make sure that no liquid gets into the cuff.
Step 3: Use a dry, soft cloth to wipe the cuff and to remove residual moisture.
Step 4: Dry the cuff in a well-ventilated place after cleaning.

DISINFECTION PROCESS

Step 1: Make sure to turn off and unplug the device prior to disinfection.
Step 2: Use a soft cloth with 70% isopropanol to disinfect the cuff for about 10 minutes. Make sure that no liquid gets into the cuff.
Step 3: Use a clean, dry cloth or towel to wipe off the disinfectant until there is no visible residue.
Step 4: Dry the cuff in a well-ventilated place after disinfection.

- For single patient multiple use, it's recommended to clean the device surface once a month or whenever it's necessary.
- For multiple patient multiple use, it's recommended to clean the device before and after usage. Maintenance procedures should be taken as per instruction.

ABOUT BLOOD PRESSURE

SYSTOLIC AND DIASTOLIC PRESSURE

- When the ventricles contract and pump blood out of the heart, blood pressure reaches its maximum value, called **systolic pressure.**
- When the ventricles relax, blood pressure reaches its minimum value, called **diastolic pressure.**

STANDARD BLOOD PRESSURE CLASSIFICATION

The chart provided is based on the standard blood pressure classification published by the American Heart Association (AHA).

This chart reflects blood pressure categories defined by American Heart Association.			
Blood Pressure Category	Systolic mmHg (upper #)		Diastolic mmHg (lower #)
Normal	less than 120	and	less than 80
Elevated	120-129	and	less than 80
High Blood Pressure (Hypertension) Stage 1	130-139	or	80-89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis (Consult your doctor immediately)	Higher than 180	and/or	Higher than 120

⚠ CAUTION

- Only a physician can tell your normal BP range.
- Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

IRREGULAR PULSE RATE DETECTOR

An irregular pulse rate is detected if there is an irregular rhythm during blood pressure measurement. The monitor records pulse intervals and calculates an average.

- **If two or more pulse intervals** are recorded and each differs from the average by more than ±25%, the irregular pulse symbol will appear with the results.
- **If four or more pulse intervals** are recorded and each differs from the average by more than ±15%, the same symbol will appear.

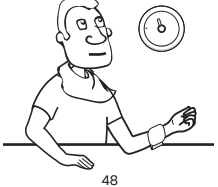
⚠ CAUTION

- The appearance of the irregular pulse rate (IPR) icon indicates a pulse irregularity was detected during the measurement.

- This is **not necessarily** a cause for concern. However, if the symbol appears frequently, consult a healthcare professional.
- Results from the irregular pulse rate detector **cannot** be used for clinical judgment on their own. Seek medical advice before making any health-related decisions.

WHY DOES MY BLOOD PRESSURE FLUCTUATE THROUGHOUT THE DAY?

- Individual blood pressure varies multiple times every day. It is also affected by how you tie the cuff and your measurement position. Take measurements under the same conditions whenever possible.
- If the person takes medication, blood pressure may vary more.
- Wait at least 3 minutes before taking another measurement.



WHY DO I GET A DIFFERENT BLOOD PRESSURE AT HOME COMPARED TO THE HOSPITAL?

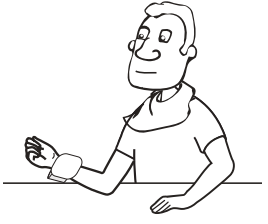
Blood pressure can differ throughout the day due to weather, emotions, exercise, etc. There is also the "white coat" effect, which means blood pressure often increases in clinical settings.

Key factors that affect measuring blood pressure at home:

- If the cuff is tied properly.
- If the cuff is too tight or too loose.
- If the cuff is tied on the upper arm.
- If you feel anxious.
- Taking 2-3 deep breaths before measuring can help.
- Advice: Relax yourself for 4-5 minutes until you are calm.

IS THE RESULT THE SAME WHEN MEASURING ON THE RIGHT WRIST?

It is generally okay to measure on either arm, but results may vary for different individuals. We recommend measuring on the same arm each time for consistency.



ERRORS AND TROUBLESHOOTING

Problem	Symptom	Potential Cause	Solution
No power	Display does not light up.	Batteries are depleted.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
High battery	bAt H shows	The battery is too high.	Replace with new batteries.
Low battery	bAt Lo+ shows	The battery is too low.	Replace with new batteries.
Error message	E 01 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 02 shows	The monitor detected motion, talking, or the pulse is too weak while measuring.	Movement can affect the measurement. Relax for a moment and then measure again.
	E 03 shows	The measurement process does not detect the pulse.	Loosen the clothing on the wrist and then measure again.
	E 04 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.

Problem	Symptom	Potential Cause	Solution
Error message	EExx, shows on the display.	A calibration error occurred.	Retake the measurement.If the problem persists,contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.
Warning message	"outa" shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

Note: If the product still does not work, contact customer service. Under no circumstance should you disassemble or attempt to repair the unit by yourself.

SPECIFICATIONS

Measurement Mode	Oscillographic testing mode
Measurement Range	Cuff Pressure: 0-299 mmHg (0-39.86 kPa) SYS: 60-230 mmHg, DIA: 40-130 mmHg Pulse Value: 40-199 bpm
Measuring Accuracy	Pressure: ±3 mmHg (±0.4 kPa) Pulse Value: ±5%
Power Supply	2 AAA batteries
Operating Conditions	Temperature: 5-40°C (41-104°F) Humidity: 15-90% RH, non-condensing Atmospheric Pressure: 70-106 kPa
Storage & Transportation Conditions	Temperature: -20-60°C (-4-140°F) Humidity: 0-93% RH, non-condensing Atmospheric Pressure: 50-106 kPa
Display	Digital LCD V.A.43 x 46 mm
Cuff Size	13.5-21.5 cm
Device Dimensions	86.6 × 60.6 × 46 mm

LCD Size	43 × 46 mm
Weight	Approx. 106 g (excluding batteries)
Mode of Operation	Continuous operation
Degree of Protection	Type BF applied part
Device Classification	Internally Powered ME Equipment
IP Classification	IP22 protected against solid foreign objects of 12.5 mmΦ and greater, and against vertically falling water drops when enclosure titled up to 15°.
Software Version	A01
Expected Lifetime	Device: 3 years or 30,000 measurements (may vary based on usage conditions) Cuff: 10000 times
Type of Use	Multiple patient use

EMC GUIDANCE

Essential performance: Accuracy of measuring blood pressure and pulse rate.

Measurement Range	Systolic pressure: 60-230 mmHg Diastolic pressure: 40-130 mmHg Pulse: 40-199 beats/minute
Rated Cuff Pressure	0-299 mmHg (0-39.9 kPa)
Accuracy	Pressure: ±3 mmHg / 0.4 kPa Pulse: ±5%

The Basis Safety of the Blood Pressure Monitor (FBP-W1) is as following:

Deviation from normal operation that poses an unacceptable risk to the patient or operator.

The ME Equipment or ME System is suitable for home healthcare environments.

Warning:

- Don't be near the 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.
- 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.
- 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.

Technical description:

1. All necessary instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration - electromagnetic emissions and immunity.

Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions	
Emissions Test	**Compliance Level**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Surge IEC61000-4-5	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	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	Not applicable	Not applicable
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and Manufacturer's Declaration - Electromagnetic Immunity								
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance Level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for enclosure port immunity to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5k Hz 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, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							

	1720	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
	1845							
	1970							
	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	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							

FCC STATEMENT

FCC ID: OU9TMB2285BT

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference.
(2) This device must accept any interference received, including interference that may cause undesired operation.

FCC Regulatory Compliance

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide

the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

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

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

WARRANTY AND CUSTOMER SUPPORT

Warranty

The device is covered by a 12-month warranty from the date of purchase, subject to the following terms and conditions.

The warranty does not cover:

- The batteries, packaging, or any other consumables.
- Damage resulting from improper use, including but not limited to:
  - Unauthorized disassembly or modification of the device.
  - Accidental dropping or impact during use or transportation.
  - Failure to follow the instructions provided in the user manual.

To claim warranty service, users must provide proof of purchase and comply with the terms outlined in the user manual.

Customer Support:

Email: support@fondcircle.com
Tel: 1-877-899-7770 (US) (Mon-Fri, 8:00 AM-5:00 PM PST)
Web: www.fondcircle.com