medicare
LIFESENSE

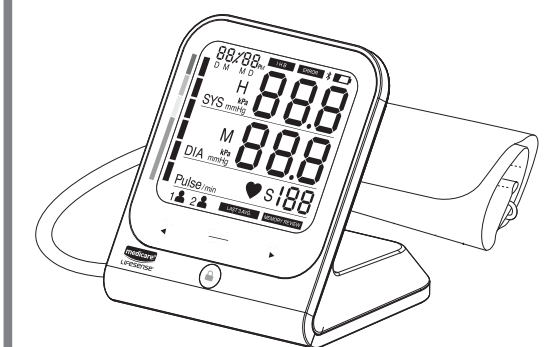
CE 0197

Version 4.0

User Manual

A4 Blood Pressure Monitor Wireless

Upper Arm



- Please read the user manual carefully and thoroughly so as to ensure the safe usage of this product, and keep the manual well for your further reference in case you have problems.

CE 0197

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CATALOGUE

Table of Contents

♥ General Description

Thank you for selecting MEDICARE LIFESENSE arm type blood pressure Monitor (MD1809). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.
Readings taken by the MD1809 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.

Features:

- 84mm×73 mm Digital LCD display
- Maximum 60 records
- 3rd technology Measuring during inflation (The updated technology in the world)

♥ Indications for Use

The Medicare Lifesense Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22 cm to 42 cm (about 8¾″-16½″).
It is intended for adult indoor use only.

♥ Safety Information

The signs below might be in the user manual, labelling or other component. They are the requirement of standard and using.

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS"
CE 0197	Symbol for "COMPLIES WITH MDD 93/42/EEC REQUIREMENTS"		Symbol for "ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
	Symbol for "MANUFACTURER"		
SN	Symbol for "SERIAL NUMBER"		
⎓	Symbol for "DIRECT CURRENT"		For indoor use only
	Symbol for "MANUFACTURE DATE"		Symbol for "Class II Equipment"
F1	T1A/250V Φ3.6*10CCC		Symbol for "Including RF transmitter"
	Caution: These notes must be observed to prevent any damage to the device.		Symbol for humidity limitation
	Symbol for "RECYCLE"		The Green Dot is the license symbol of a European network of industry-funded system for recycling the packaging materials of consumer goods.

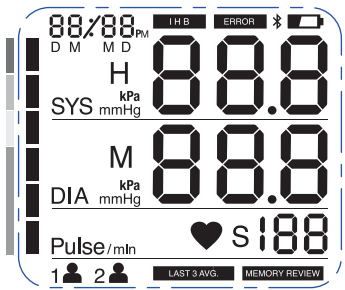
⚠ CAUTION

The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
The device is not suitable for use on pregnant women, patients with implanted, electronical devices, patients with pre-elcampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses
At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use.
Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.

⚠ CAUTION

* This device is intended for adult use in homes only.
* The blood pressure monitor, and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensation or irritation reaction.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure.
It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment without asking a physician for treatment advice.
* If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* When the device is used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
* Warning: Do not apply the cuff over a wound;otherwise it can cause further injury.
*Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
*On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate.
Should the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measuring, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER is clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the foetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* When not in use, store the device with the adapter in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
*This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
*If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff.
*Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners
*Do not wash the cuff in a washing machine or dishwasher!

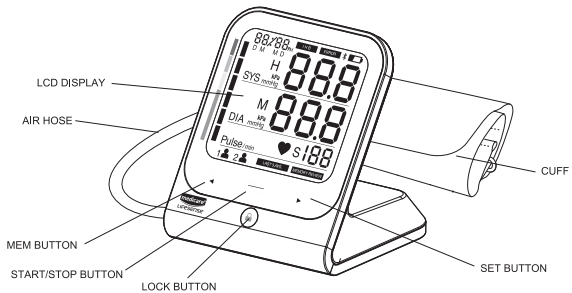
♥ LCD display signal



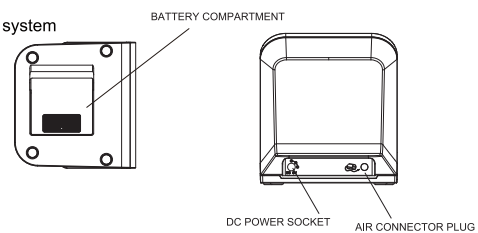
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pulse /min	Pulse per minute	Beats per minute, BPM
LAST 3 AVG.	Average value	The average value of the latest three records
MEMORY REVIEW	Memory	The displayed measurement values is from the memory.
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
Lo +	Low battery	Batteries are low and need to be replaced
I H B	Irregular heartbeat	Irregular heartbeat Detection
	Grade	The grade of the blood pressure
88:88 PM D M M D	Current Time	Year/Month/Day(M/D or D/M), Hour/Minute

SYMBOL	DESCRIPTION	EXPLANATION
ERROR	Error	Error
H	Hour	The hour in the clock mode
M	Minute	The minute in the clock mode
S	Second	The second in the clock mode
♥	Heartbeat	Heartbeat detection during the measurement
1	User 1	Start measurement,save and transmit the measuring results for User 1
2	User 2	Start measurement,save and transmit the measuring results for User 2
ᛒ	Bluetooth icon	The bluetooth icon blinks when the bluetooth is working

♥ Monitor Components



Component list of pressure measuring system
1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve

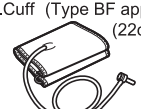


♥ Content List

1.Blood Pressure Monitor (MD1809)

2.Cuff (Type BF applied part) (22cm~42cm)

(Please use MEDICARE LIFESENSE authorized cuff. The size of the actual cuff please refer to the label on the attached cuff.)



3. 4×AAA batteries

4.User manual

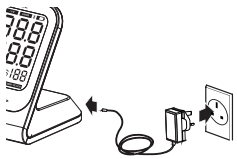
5. AC Adaptor (6V ⎓ 1A)

♥ The Choice of Power Supply

1.Battery powered mode:
6VDC 4×AAA batteries

2.AC adaptor powered mode:
6V ⎓ 1A
(Please only use the recommended AC adaptor model).

Please unplug the adaptor to depart from the using utility power.



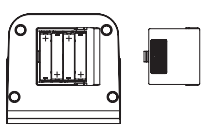
AC adaptor

⚠ CAUTION

In order to get the best effect and protect your monitor,please use the right battery and special power adaptor which complies with CE safety standard.

♥ Installing and Replacing the Batteries

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



Replace the batteries whenever the below happen

- The shows
- The display dims
- The display does not light up

⚠ CAUTION

- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, do not dispose with other daily trash.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.
- Do not use new and used batteries together.
- Do not use different types of batteries together.

♥ Measurement Principle

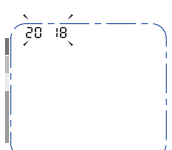
This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the air pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval then calculates standard deviation. The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

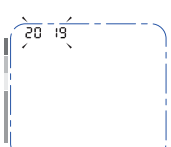
♥ Setting Date, Time, Measurement Unit and Clock Mode

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year : 2018—2058 time format:12H/24H)

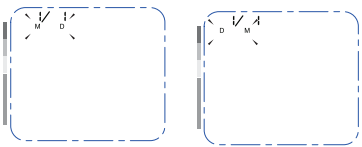
1.When the monitor is off, hold pressing “SET” button for 3 seconds to enter the mode for year setting.



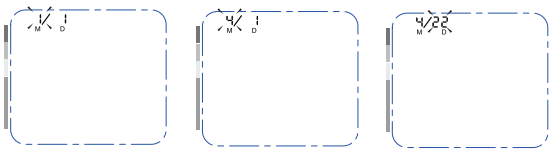
2.Press the “MEM” button to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.



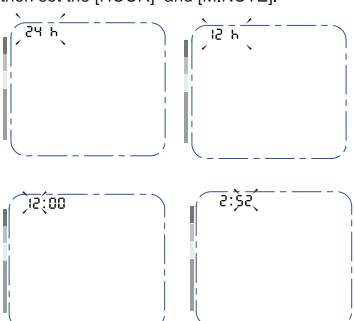
3.When you get the right year, press “SET” button to set down and turn to next step to set the date format between “M/D” or “D/M”.



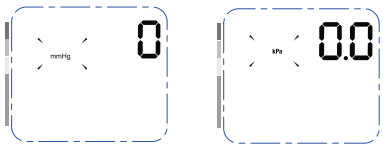
4.Repeat steps 2 and 3 to set the [DATE FORMAT], then set the [MONTH] and [DAY].



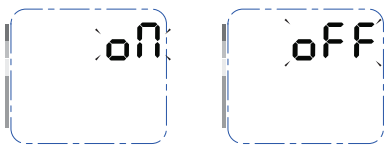
5.Repeat steps 2 and 3 to set the [TIME FORMAT] between 12H or 24H, then set the [HOUR] and [MINUTE].



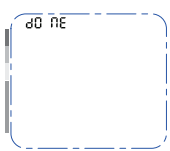
6.Repeat steps 2 and 3 to set the [UNIT].



7.Repeat steps 2 and 3 to set the clock mode.

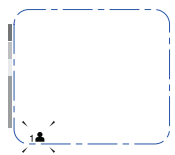


8.After the clock mode is set,the LCD will display “done” and then turn off.

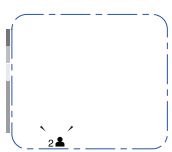


♥ Select the User

1.When the monitor is off , press and hold the MEM button to enter user setting mode. The user ID will blink.



2.Then press MEM button again, select the user ID between user 1 and user 2.

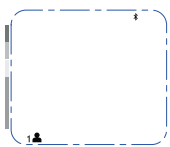


3. After selecting the suitable user ID, press SET button to confirm. Then the LCD will turn off.

♥ Pair-up the Blood Pressure Monitor with Your Device

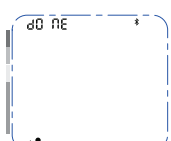
1.Turn on Bluetooth and the app. Make sure both are ON when pair-up is proceeding.

2.When the monitor is OFF, press and hold the START/STOP button to start pair-up. The bluetooth symbol ᛒ will blink, indicating pair-up is proceeding.

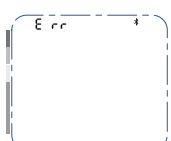


3.Then please select the user ID you want to connect with your smartphone on the app to continute the pair-up.

If SUCCEED, symbol dO nE will be shown on the LCD.



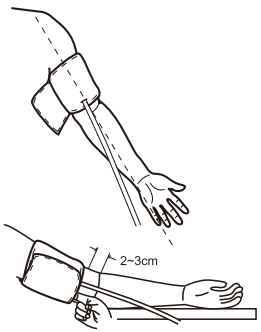
If FAIL, only bluetooth symbol E rr will be shown on the LCD.



4.The monitor will shut off after Pair-up process is complete.

Bluetooth Module No.: LS51802
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: -1 dBm
Supply Voltage: 2V-3.6 V
Transmitting Distance: 10 meters

♥ Tie the cuff



1 .Tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger.

2 .The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.

3 .Sit comfortably with your tested arm resting on a flat surface.

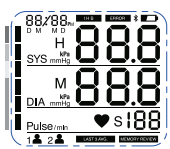
4 .Patients with Hypertension:
The middle of the cuff should be at the level of the right atrium of the heart;
Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.

• Rest for 5 minutes before measuring.
• Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
• For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, position of upper arm, or as directed by a physician.

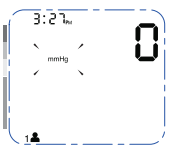
♥ Start the Measurement

1.When the monitor is off, press the “START/STOP” button to turn on the monitor, and it will finish the whole measurement.
(Take user 1 for example)

LCD display



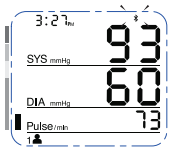
Adjust to zero.



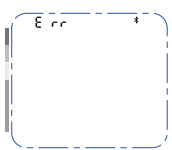
Inflating and measuring.

Display and save the measurement results.

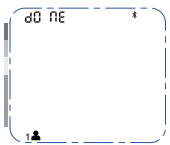
2.This device will proceed to data transmission after measurement. The Bluetooth symbol blinks on the LCD indicates data is transmitting.



If the data transmission fails, the LCD will display E rr.



If the data transmission succeeds, the LCD will display dO nE.



3.Press the “START/STOP” button to power off, otherwise it will turn off within 1 minute.

Tips: Maximum 60 records are both for User 1 and User 2.

⚠ CAUTION

• Interference may occur in the vicinity of equipment marked with the following symbol .And MD1809 may interfering vicinity electrical equipment.
• Sensitive people, including pregnant women pre-eclamptic and those who implanted medical electronic instruments, should avoid using the unit whenever possible.
• Keep the monitor at least 20 centimeters away from the human body (especially the head) when the data transmission is proceeding after measurement.
• To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

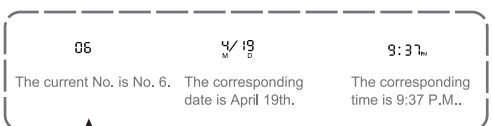
How to mitigate possible interference?

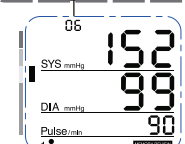
1. The range between the device and BT end should be reasonably close, from 1 meter to 10 meters. Please ensure no obstacles between the device and BT end so as to obtain quality connection and to lower the RF output range.
2. To avoid interference, other electronic devices (particularly those with wireless transmission / Transmitter) should be kept at least 1 meter away from the monitor.

♥ Recall the Records

1. When the monitor is off, please press “MEM” button to show the average value of the latest three records. (Take user 1 for example)

2. Press “MEM” button or “SET” button to get the record you want.





The order, date and time of the record will be shown 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 (60) is dropped from the list.

♥ Delete the Records

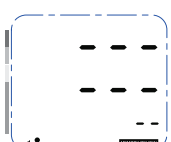
If you did not get the correct measurement, you can delete all results by following steps below. (Take user 1 for example)

1.Hold pressing “MEM” button for 3 seconds when the monitor is in the memory recall mode ,the flash display “ User ID+ dEL ALL” will show.

2.Press “SET” button to confirm deleting and the monitor will display “dEL dOnE” and then turn off.

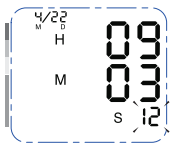
Note: To exit out of delete mode without deleting any records, press START/STOP button before pressing "SET" to confirm any delete commands.

3. If there is no record. the following display will show.

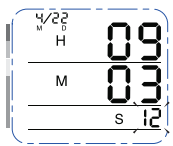


♥ About the Clock mode

If you set the clock mode on in the setting mode, when you turn off the blood pressure monitor, the backlight of the LCD will turn off, the LCD will display the current time.



When the backlight of the LCD is off, press any buttons to light it up, the following display will show.

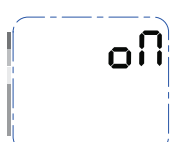


♥ About the Lock Button

The unnecessary keys’ touch will make the blood pressure monitor turn on and waste electricity. To avoid this, you can press the Lock button to lock the keys if necessary.

Hold pressing the Lock button until the LCD displays “OFF”, this indicates the touch keys (such as MEM, START/STOP, SET) have been locked.

Hold pressing the Lock button until the LCD displays “ON” to unlock the keys.



♥ 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

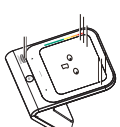
In a very cold environment

When you want to discharge urine

♥ Maintenance

In order to get the best performance, please follow the instructions below.

Put in a dry place and avoid the sunshine



Avoid intense shaking
and collisions

Using wet cloths to remove dirt

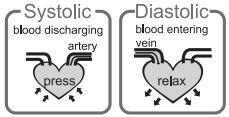
Avoid touching water,
clean it with a dry cloth in case.

Avoid dusty and unstable
temperature environment

Do not attempt to clean the reusable cuff with water and never immerse the cuff in water.

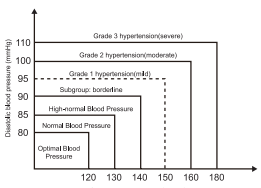
♥What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



♥What is the standard blood pressure classification?

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:



⚠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.

Blood Pressure (mm Hg) \ Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	≥180
DIA	<80	80-84	85-89	90-99	100-109	≥110

♥Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure.During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 25%, the irregular heartbeat symbol appears on the symbol when the measurement results are displayed.

⚠ CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.
2. If the person takes medicine, the pressure will vary more.
3. Wait at least 3 minutes for another measurement.

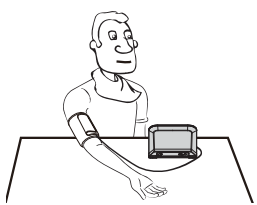
♥Why do I get a different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise etc, Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your 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 beginning will be better for measuring.
Advice: Relax yourself for 4-5 minutes until you calm down.

♥Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people. We suggest you measure the same arm every time.



This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

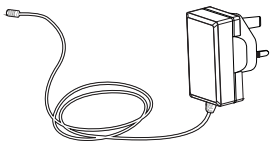
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or show Lo +	Batteries are low.	Replace with new batteries
Error message	+ Err shows	Data communication is failed.	Check if the App/Bluetooth is on or not,try data transmission again.
	E 1 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 2 shows	The cuff is very tight	Refasten the cuff and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E10 or E11 shows	The monitor detected motion,talking or the pluse is too poor while measuring.	Relax for a moment and then measure again.
	E20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	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.

Power supply	Battery powered mode: 6VDC 4×AAA batteries AC adaptor powered mode: 6V ⎓ 1A (Please only use the recommended AC adaptor model).
Display mode	Digital LCD V.A.84mm×73mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5℃-40℃within±0.4kPa(3mmHg) pulse value:±5%
Normal working condition	Temperature range of:+5°C to +40°C Relative Humidity range of: 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa Atmospheric Pressure range of:700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%,non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	About 22cm~42cm
Net Weight	Approx.255g(Excluding the dry cells and cuff)
External dimensions	Approx.107mm×103mm×118mm
Attachment	4×AAA batteries,user manual, AC Adaptor
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21
Software Version	A01
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

1. Please use the Fleming Medical authorized adapter.



Adapter
Input: 100-240VAC 50/60Hz 0.3A Max
Output: 6V ⎓ 1A

♥ Contact Information

For more information about our products, please visit www.flemingmedical.ie

Customer Support:
Company: Fleming Medical Ltd.
Address: Corcanree Business Park,
Dock Road,
Limerick.
Ireland.
Tel: +353 (0)61 304600
Email: pharmacy@flemingmedical.ie

♥ Complied Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labelling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013+A12:2014/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

	EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems IEC 80601-2-30:2009+A1:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

♥ EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments

Warning: Don't place 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.

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.

Warning: 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."

Warning: 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**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

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	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles; Single phase: at 0°.0 % U_T; 250/300 cycle	0 % U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles; Single phase: at 0°. 0 % U_T; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
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							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communica-tions equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	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
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmittters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\ \sqrt{P}$	80 MHz to 800 MHz $d = 1.2\ \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\ \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

⚠ CAUTION

* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anaesthetic mixture with air of with oxygen or nitrous oxide.
* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.
* The patient can measure, transmit data and change batteries under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
*The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensitisation or irritation reaction.
* Adaptor is specified as a part of ME EQUIPMENT.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The plug/adapter plug pins insulates the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains to safely terminate operation of ME equipment.
* The operator shall not touch output of batteries /adapter and the patient simultaneously.
* Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
* The device doesn't need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Fleming Medical. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
* Please report to Fleming Medical if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80 MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
* Please use ACCESSORIES and detachable parts specified/ authorised by MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no luer lock connectors are used in the construction of tubing. If there has, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* 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.