MEDIC
THERAPEUTICS

BLOOD PRESSURE MONITOR

USER MANUAL

Prior to use, please read this manual

Product Description:

The Medic Therapeutics blood pressure monitor measures heartrate and blood pressure with an arm circumference ranging from 22cm to 32cm. Readings are aligned with those taken by a medical professional with a cuff and stethoscope.

Features:

100mmx68mm Digital LCD Display
Stores up to 60 readings per user

Safety Precautions:

1. Should not be used if pregnant.
2. Not suitable for use on anyone with implanted electrical devices such as, pacemaker or defibrillator.
3. Intended for use by adults only.

Measurement Readings:

This product uses an Oscillometric Measuring method. Before each measurement, the device establishes a 'zero pressure' equivalent to atmospheric pressure. While the arm cuff inflates, the device detects pressure oscillations generated by, beat-by-beat pulsation. This process detects the systolic and diastolic pressure as well as the pulse rate.

Indications for Use:

The Medic Therapeutics blood pressure monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22 cm to 32 cm (about 8¾˝-12½˝). It is intended for adult indoor use only.

Contraindications:

1. The device should not be used by any person who may be suspected of, or is pregnant .
2. The device is not suitable for use on patients with implanted,electrical devices, such as cardiac pacemakers, defibrillators.

Safety Information:

The signs below might be in the user manual, labeling 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"
	Symbol for "MANUFACTURE DATE"		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"		Symbol for "RECYCLE"
	Caution: These notes must be observed to prevent any damage to the device.		The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods.

CAUTION

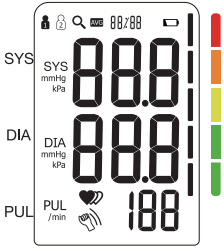
* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing 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.
* 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 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.

CAUTION

* 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. Prolonged high pressure (cuff pressure > 300mmHg or constant pressure > 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
* Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, 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 was 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 fetus 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 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.
* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic 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 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, 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.

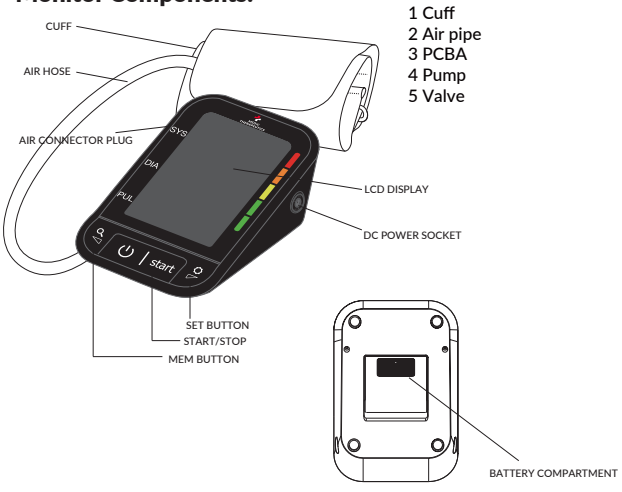
* Adaptor is specified as a part of ME EQUIPMENT.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* If the cuff pressure reaches 40 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 plug/adapter plug pins insulate 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 Medic Therapeutics. 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.
* 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 MANUFACTURE. 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, 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.

LCD Display:



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High blood pressure
DIA	Diastolic blood pressure	Low blood pressure
PUL /min	Pulse display	Pulse in beats per minute
	Memory	Indicate it is in the memory mode and which group of memory it is.
	Motion indicator	Motion may result in an inaccurate measurement
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
	Blood pressure level indicator	Indicate the blood pressure level
	Current Time	Year/Month/Day, Hour : Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	User 1	Start measurement,save and transmit the measuring results for User 1
	User 2	Start measurement,save and transmit the measuring results for User 2
AVG	Average value	The average value of blood pressure

Monitor Components:



Parts Overview:

1. Blood Pressure Monitor

2. Cuff (Type BF applied part) (22cm~32cm)

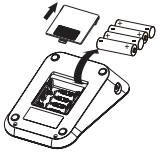
3. 4×AAA batteries

4. User manual

5. Carry bag

Power Supply:

Battery-Powered :
6VDC 4×AAA batteries.



Caution

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

Installing and Replacing Batteries:

1. Open battery cover.
2. Install batteries according to polarity symbols.
3. Replace battery cover.

Replace Batteries When:

- The Low Battery icon appears. 
- The display is dim.
- The display does not light up.

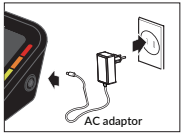
Caution

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

Authorized Component:

1. Please use the authorized adapter (not included).
2. AC adaptor powered mode:
   6V 1A (not included)
   (Please only use the recommended AC adapter model).

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

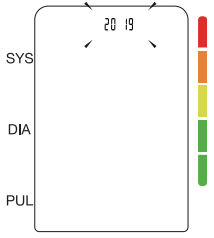


Input: AC 100-240V:
50/60Hz 0.2A Max
Output: 6V ⎓ 1000Ma

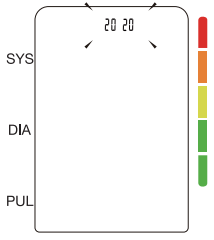
Setting Time, Date, Measurement Unit:

It is important to set the clock prior to use so a time stamp can be accurately assigned to each reading and stored in the device's memory.

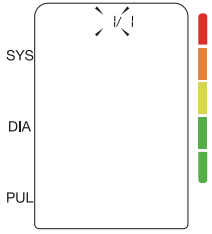
1. While off, press and hold the SET button for 3 seconds to set the year.



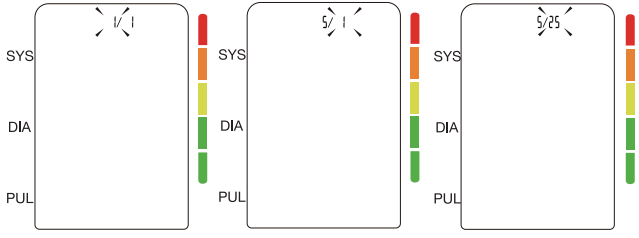
2. Press the MEM button to change the year. Each press will increase the year by one.



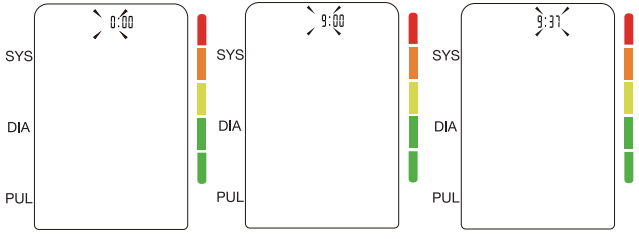
3. When you reach the correct year, press the SET button and move to the next step.



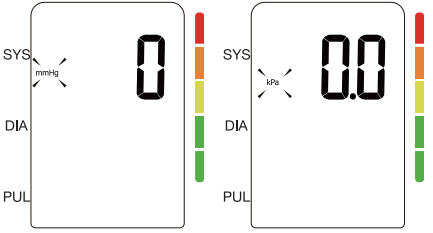
4. To set month and day, repeat steps 2 and 3.



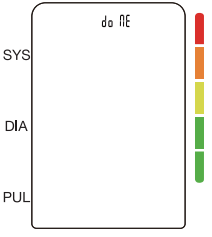
5. Again repeat steps 2 and 3 to set the hour and minute.



6. Repeat steps 2 and 3 to set the Unit.

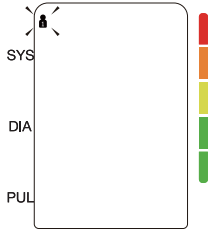


7. After the device is set, the LCD will display ‘Done’, then display the settings and turn off.

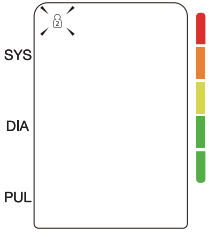


User Selection:

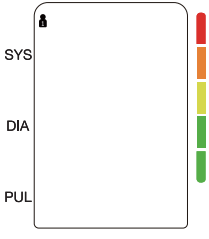
1. When the monitor is off, press and hold the 'MEM' to enter the user setting mode. The User ID will blink.



2. Press the 'MEM' button again to select User 1 or User 2.

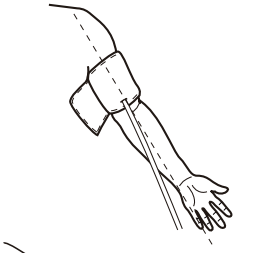


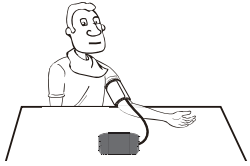
3. After User ID selection, press the 'SET' button to confirm. The User ID will stop blinking and the device will turn off.



Placing the Arm Cuff:

1. Remove any jewelry from your left arm. *Note: Use the right arm if user has been diagnosed with poor circulation.*
2. Roll or push up any sleeve and ensure the sleeve isn't too tight.
3. With your arm extended and hand facing up, wrap the cuff securely around your upper arm. Position the tube off-center toward the inner arm. Or position the artery mark directly over the main artery of the inner arm. *Note: Locate the main artery by pressing 2 fingers approx. 2cm above the bend of your elbow on the inside on your left arm.*
4. The cuff should be snug but not too tight. You should be able to slide a finger between your cuff and your arm.
5. Sit comfortably with your arm resting on a flat surface. Place your elbow on a table so that the cuff is level with your heart. Sitting fully upright, turn your palm upwards and take 5 to 6 deep breaths.



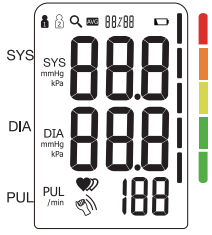


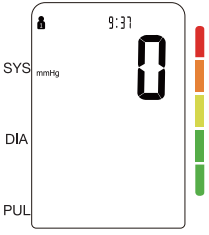
Tips for Users with Hypertension:

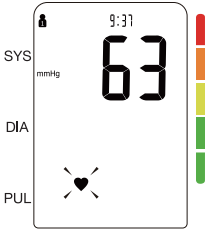
- Rest for 5 minutes prior to measuring.
- Take measurement in a quiet room.
- Wait 3 minutes between measurements so blood circulation can recover.
- Relax and do not talk or move while taking measurement.
- Keep the cuff level with the heart's right atrium.
- Sit comfortably with uncrossed legs and keep feet flat on the ground.
- Keep back against the chair.
- For accurate comparison, take all measurements under similar conditions: Same time, same position, same arm, etc...

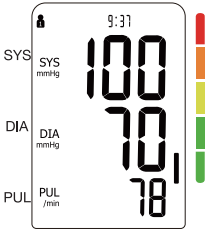
Measurement Reading:

1. With the device off, press the 'Start/Stop' button and the full measurement will be taken.









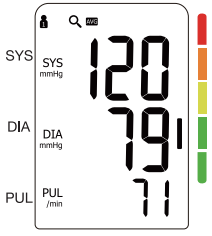
2. Press 'Start/Stop' button to turn off the device or the device will turn off automatically after 1 minute.

Tips:

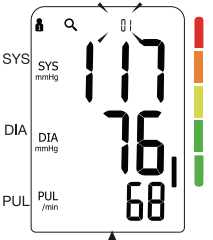
- A Maximum of 60 records are stored for both User 1 and User 2.
- If the measurement result is out of the measurement range (SYS: 60mmHg to 230mmHg; or DIA: 40mmHg to 130mmHg;or Pulse: 40-199 pulse/minute), the LCD will display the word "out".

Reading Recall:

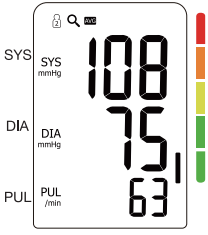
1. When the monitor is off, press the "MEM", button to display the last 3 readings. *Note: If fewer than 3 readings are stored, the most recent will be displayed.*



2. Press the "MEM" or "SET" button to locate the desired record. The order, date and time will be shown alternately.



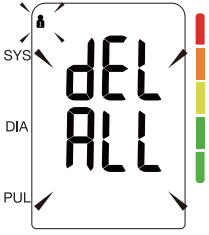
3. To check another user's record, press the "Start/Stop" button to turn off the monitor. Press and hold the "MEM" button to enter User Selection Mode. Then press and hold the "MEM" button to select, User 1 or User 2 and press "SET" to confirm selection. Next, press "MEM" button to recall the records.



* Please Note: The most recent record is shown 1st. With each new reading, all other records will be pushed back a digit with the last being dropped if the number of readings surpasses 60.

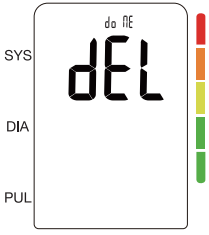
Deleting Records:

1. When the monitor is in Recall Mode, press and hold the "MEM" button for 3 seconds. The display will flash, "User ID+dEL ALL" will show.

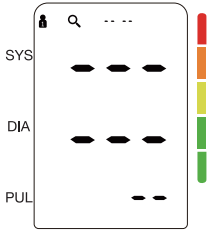


* Note: To exit Delete Mode without removing any records, press the "Start/Stop" button before pressing "SET" button to confirm any deletions. *

2. Pres "SET" button to confirm deletion. The monitor will dis play "dEL + donE" and turn off.



3. If there is no record, the following will appear on the display:



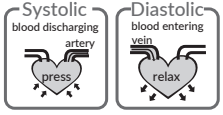
For Accurate Readings, DO NOT Use:

1. Within an hour of eating or drinking.
2. After smoking or drinking coffee or tea.
3. Withing 30 minutes of taking a bath.
4. When talking or using your fingers.
5. In a cold environment.
6. While using the bathroom.

Maintenance:

1. Store in a dry, cool place.
2. Avoid shaking or bumping/striking a hard surface.
3. Use a soft cloth to clean.
4. Do Not use or submerge on water or liquid.
5. Avoid dirty/dusty environments and avoid environments with fluctuating circumstances.

Systolic vs. Diastolic Pressure



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

Standard Blood Pressure

The chart on the right details the standard 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

Warning

Consult your physician if your measuring falls outside the AHA range. Only your doctor can determine and confirm whether blood pressure has reached a dangerous point.

Irregular Heartbeat Detector:

An irregular heartbeat is detected when the rhythm varies while measuring the systolic and diastolic pressures. During each measurement, pulse intervals are recorded and calculated to provide an average. If there are 2 or more intervals where the difference between each interval and the average is more than the average value of ±25%, or 4 intervals where the average exceeds the value of ±15%, the irregular heartbeat symbol will appear on the display with the measurement result.

Warning

While the detection of the IHB is generally not cause for concern, if it does appear, always consult your physician. The monitor should not be used to diagnose or treat any condition.

Why Blood Pressure Fluctuates Throughout the Day:

1. Mild fluctuation is normal. However, readings can vary depending on how you tie the cuff so always take the measurement in the same position.
2. Medication can cause variations.
3. Wait at least 3 minutes between measurements.

Why Your Measurement at Home is Different Compared to the Hospital or Doctor's Office:

Weather, activity, and emotion can impact readings. Also, blood pressure usually increases in clinical settings.

Is the Result the Same if Measuring on the Right Arm?

The use of both arms is ok, but we suggest measuring with the same arm each time.

Tips for At-Home Measurement:

- Ensure cuff is tied properly.
- Ensure fit (not too loose or too tight).
- Ensure cuff is place in the correct spot on the upper arm.
- Ensure you are relaxed.
- Take 2-3 deep breaths before measuring.

Troubleshooting:

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the product is 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.	Check Batteries' Life & Battery Placements.	Replace batteries & ensure proper position.
Low batteries	Display is dim or show	Low Battery.	Replace Batteries.
Error message	E 01 shows	Cuff is not secure.	Solution: Refasten cuff.
	E 02 shows	Motion, talking, poor pulse is detected.	Relax for a moment and then measure again.
	E 03 shows	No pulse detected.	Loosen clothing on the arm.
	E 04 shows	Measurement fail.	Relax and try again.
	EExx,shows on the display.	A calibration error occurred.	If persistent, refer to the warranty and contact the retailer.
Warning message	"out" appears on display.	Your Measurement results fall out of measurement range (SYS:60mmHg to 230mmHg; or DIA: 40mmHg to 130mmHg; or Pulse: 40-199 pulse/minute).	Retake measurement and contact your physician.

Specifications:

Mode Number:	MT-BPM-001
Power supply	Battery powered mode: 6VDC 4×AAA batteries AC adaptor powered mode: 6V ⎓1A (not included) (Please only use the recommended AC adaptor model).
Display mode	Digital LCD V.A.100mm×68mm
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°C-40°C within±3mmHg(0.4kPa) Pulse value:±5%
Normal working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An 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~32cm
Weight	Approx.281g(Excluding the dry cells and cuff)
External dimensions	Approx.154.6mm×106mm×57.1mm
Attachments	4×AAA batteries, user manual and a carrying bag
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Software Version	A01

WARNING: No modification of this equipment is allowed.

FCC Statement:

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, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Complied Standards List:

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	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/ 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 active this device near HF surgical equipment or near 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 TMB-1585-S, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical Description of the Blood Pressure Monitor:

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

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 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°.0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 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.		

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
	710 745 780	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Limited Lifetime Warranty:

Your Medic Therapeutics Blood Pressure Monitor is backed by a limited lifetime manufacturer's warranty. Medic Therapeutics will repair or replace your device at any time should it fail due to a defect in material or workmanship, subject to the certain limitations.

This limited warranty does not cover any damage that results from unauthorized or improper use, service, or repair. Further, it does not cover damage caused by accident, impact, negligence, or normal wear and tear. Should you discover your Medic Therapeutics Blood Pressure Monitor is not functioning properly, please send your device to our repair center for evaluation. If your product cannot be repaired or serviced, we will reserve the right to change it for a similar or newer model.

Please note that a flat rate of $35.00 will be charged to cover a service evaluation fee and return shipping of your device. All warranty claims must be accompanied by a copy of your proof of purchase from an authorized retailer. Please send your device, proof of purchase, and a check or money order in the amount of $35.00 made out to Medic Therapeutics to:

Address:
Medic Therapeutics Service Center
3069 Taft Street
Hollywood, FL 33021

Contact:
warranty@medictherapeutics.com

Distributor Information:

HUB Emergency Services, LLC
Medic Therapeutics
3069 Taft Street,
Hollywood, FL 33021

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