ESH Protocol Embedded

AHA Protocol Embedded

WatchBP home T

Accurate home blood pressure measurements with the WatchBP Home T.

Instruction Manual

EN → 3

microlife

Federal Communications Commission (FCC) Statement

changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

Note: 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 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.

This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance.)

Microlife WatchBP Home T is the world's first digital blood pressure measurement device that strictly follows European Society of Hypertension (ESH)[1, 2] and American Heart Association (AHA) recommendations for home blood pressure measurement. Using the WatchBP Home T device helps you collect accurate home blood pressure measurements your doctor can trust. This WatchBP Home T device has been clinically validated according to the ESH protocol [3].

Indications For Use

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home T (BP3MX1-3T) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual with arm cuff circumference sizes ranging from 22 -42 cm by using a non-invasive oscillometric technique in one inflatable cuff being wrapped around the upper arm.

The memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer Home software by connecting the monitor via cable. The device can also be used in connection with smart mobile devices running the APP and via Bluetooth.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal with the reading once atrial fibrillation is detected. It is intended for use in individuals previously diagnosed with AFib. The feature has not been tested for and is not intended for use in people under 22 years of age.

Table of Contents

Cuff Socket

Serial Port

Mode Switch

Power Socket

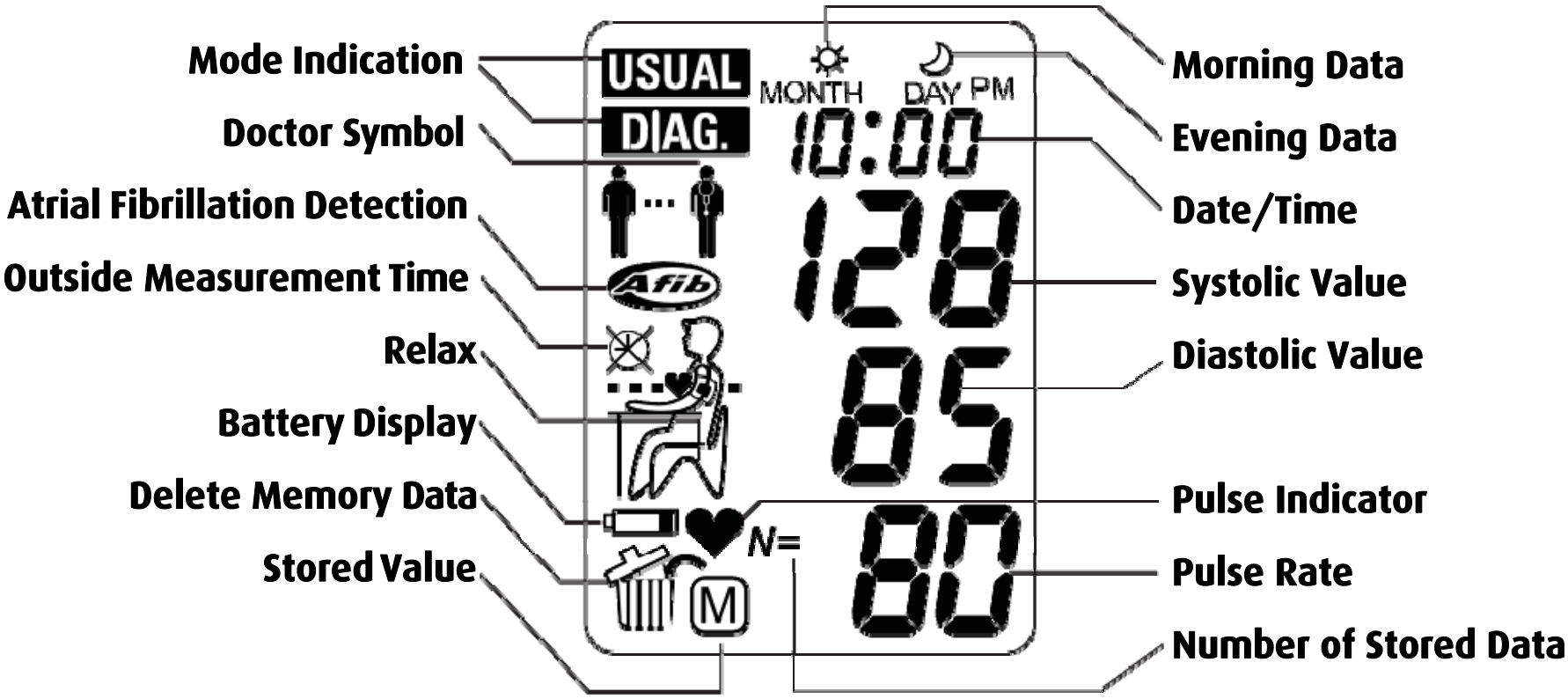
Bluetooth symbol

Display

ON/OFF Button

Battery Compartment

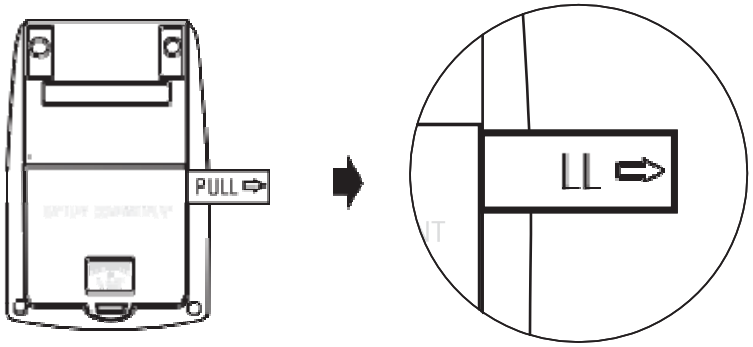
M Button (Memory)


Mode Indication
Doctor Symbol
Atrial Fibrillation Detection
Outside Measurement Time
Relax
Battery Display
Delete Memory Data
Stored Value
USUAL
DIAG.
MONTH
DAY
PM
10:00
128
85
80
N=
M
Afib
Morning Data
Evening Data
Date/Time
Systolic Value
Diastolic Value
Pulse Indicator
Pulse Rate
Number of Stored Data

Before using WatchBP Home T for the first time

Activating the Device

Pull out the protective strip from the battery compartment.



1) **Set the year** – Upon removing the protective strip or installing new batteries, the Year number flashes in the display. Use the M Button to select the Year. Press the ON/OFF Button to confirm your selection.

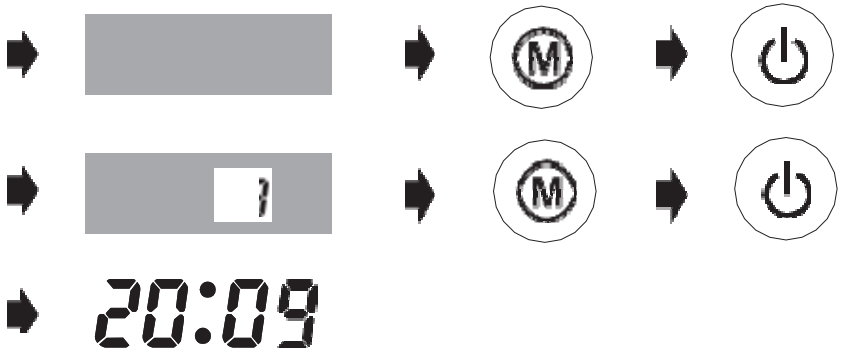
Press M Button to make selection

Press ON/OFF Button to confirm

2) **Set the month** – Press the M Button to set the Month. Press the ON/OFF Button to confirm.

3) **Set the day** – Press the M Button to set the Day. Press the ON/OFF Button to confirm.

4) **Set the time –** Once you have set the Hour and Minutes and pressed the ON/OFF Button, the date and time are set, and the current time is displayed.

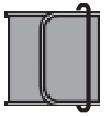


5) If you want to change the date and time, take out one battery from the battery compartment briefly and put it back. The Year number will flash. Complete the process as described above.

Selecting the correct cuff

The WatchBP Home T device is available with different cuff sizes. If the cuff provided with the device is an unsuitable size , please consult your doctor.

⁘ *please use only Microlife cuffs!*



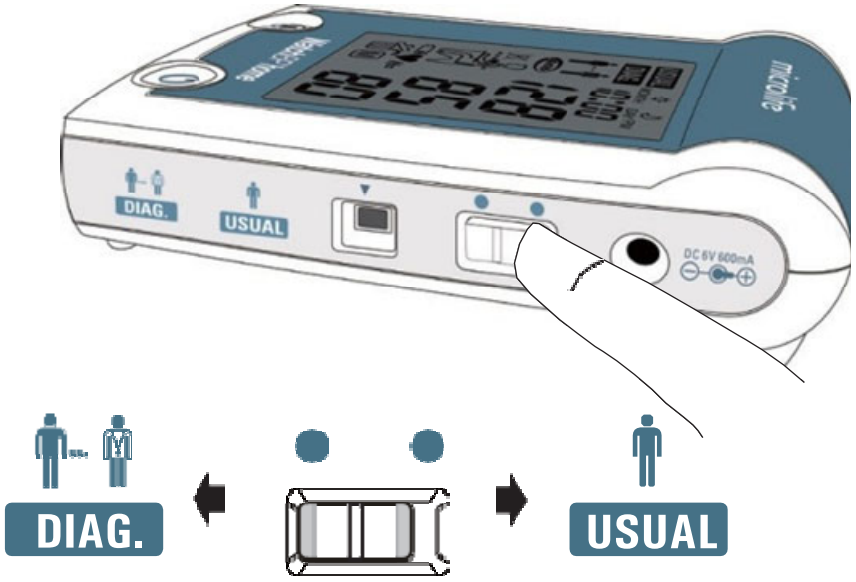
M (Mediumsize)
22 - 32 cm (8.7 - 12.6 inches)
M is the correct size for most people.

L (Large size)
32 - 42 cm (12.6 - 16.5 inches)

Taking measurements using WatchBP Home T

Prior to each measurement, use the Mode Switch on the right side of the device to select the proper measurement mode. The two options include:

«**DIAG.**» (Diagnostic) or «**USUAL**» (Usual) mode.



«DIAG.» Mode

The «**DIAG.**» mode should be selected as requested by your doctor when blood pressure is measured in accordance with the measurement guidelines of the European Society of Hypertension (ESH).

ESH
Protocol Embedded

No measurements on non-work days

In «**DIAG.**» mode, blood pressure measurements are taken **on 7 consecutive working days** (or normal week days). **No readings should be taken on «non-working» days** (or particularly relaxing days) in this mode!

Two sets of measurements per day

ESH guidelines recommend one double measurement taken in the morning between 06:00 - 09:00 and one in the evening between 18:00 - 21:00. **Always perform measurements before taking your medication, unless otherwise directed by your doctor.**

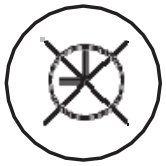
ESH Guidelines

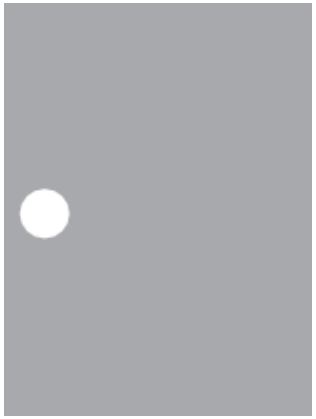
Taking measurements using WatchBP Home T (cont.)

Extended measurement period

WatchBP Home T has an extended measurement period and allows morning measurements between 04:00 - 12:00 and evening measurements between 18:00 - 24:00.

Extended Time

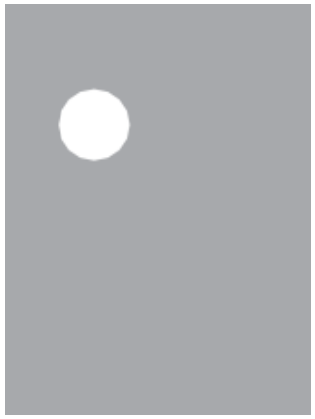




Outside these times, measurements cannot be taken and the symbol on the right will be displayed on the screen.

Evaluation

After measurements have been carried out for a total of 7 working days, take the device to your doctor for evaluation of your home blood pressure data.

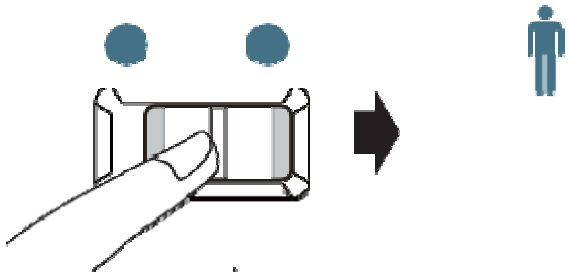


When measurements have been carried out for the full 7 days, the doctor symbol will flash on the screen.

«USUAL» Mode

The «**USUAL**» mode is selected for regular blood pressure measurement with Afib detection. In «**USUAL**» mode, One measurement is taken. The results of the blood pressure is displayed and, if atrial fibrillation is detected, the Afib icon is displayed. The readings are automatically stored for later evaluation by your doctor.

Anytime



250 measurements safely stored

The WatchBP Home T device can store up to 250 measurement readings in «**USUAL**» mode.

250

Measurements

⁘ *When memory is full, each new reading will automatically overwrite the earliest measurement.*

Eight steps for measure blood pressure properly

Step 1

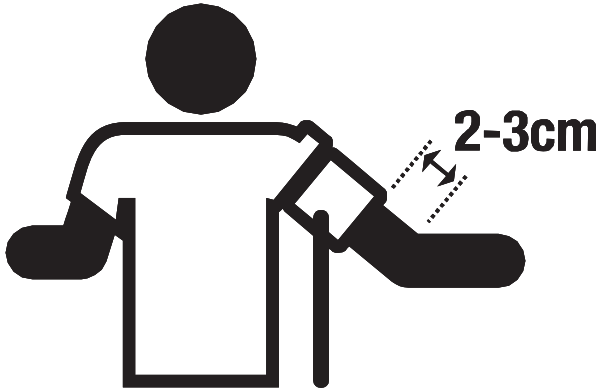
Avoid taking measurements directly after eating, drinking or smoking. Allow at least one hour between these activities and measurement of your blood pressure.

Step 2

Prepare a chair and table for the measurement. The chair should have a vertical back-rest and the table should allow your upper arm to rest at the same height as yourheart.

Step 3

Remove all clothing covering or constricting the arm to be measured. Apply the cuff. Make sure the lower edge of the cuff is exactly 2–3cm from the inner fold of your arm. The tube connecting the cuff to the device should be placed on the inside of the arm. (*Additional visual instruction can be found on the cuff*)



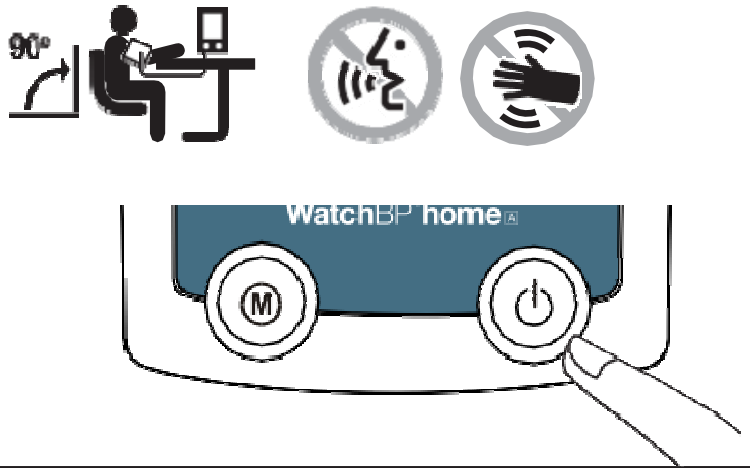
Step 4

Sit down and relax for at least five minutes prior to the measurement.

Eight steps for measure blood pressure properly (cont.)

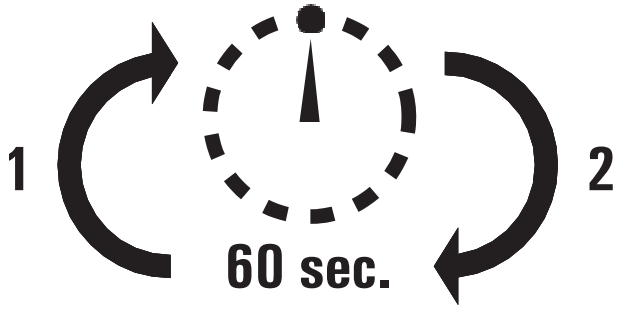
Step 5

Sit upright and lean comfortably against the chair's backrest. Press the start button. The device will initiate a 60-second countdown in «**DIAG.**» mode or a 15-second countdown in «**USUAL**» mode. During the measurement do not move, cross your legs, or tense your arm muscles. Breath normally and do not talk.



Step 6 (in «**DIAG.**» mode)

One measurement cycle includes two measurements. Once the first measurement is complete, continue to relax as you wait for the second measurement. The second measurement will start after 60-seconds. During this time avoid any movement.



Step 7 (in «**DIAG.**» mode)

Once the two readings are complete, measurement data is automatically stored for future reference by your doctor. If an error displays after the readings, please repeat the first six steps once again.

Automatically stored

Step 8 (in «**DIAG.**» mode)

When seven days of measurements have been collected, the Doctor Symbol will flash on the display. Do not forget to take your WatchBP Home T device with you on your next visit to the doctor. (*Note: the doctor symbol is only displayed for measurements in «DIAG.» Mode.*)

Special Function

Atrial fibrillation detection

This device is designed to screen for atrial fibrillation during blood pressure measurements.

If atrial fibrillation is detected during blood pressure measurement, the Afib icon is displayed.

⁘ *Atrial fibrillation, a major cause of stroke can be detected by this device. However, not all risk factors for stroke, including atrial flutter, may be detected by this device.*

⁘ *This device may not detect atrial fibrillation in people with pacemakers or defibrillators. People with pacemakers or defibrillators should therefore not use this device to detect atrial fibrillation.*

⁘ *Joseph Wiesel, et al. Detection of Atrial Fibrillation Using a Modified Microlife Blood Pressure Monitor.*
American Journal of Hypertension 2009; 22, 8, 848-852.

About Atrial Fibrillation

Atrial fibrillation is a common heart rhythm problem and a common cause of major strokes. It affects more than 2 million people in North America. It is more common in old age and found in 10% of people over 80 years old. About 20% of all strokes are caused by atrial fibrillation. The elderly, or those with high blood pressure, diabetes or heart disease are more likely to get a stroke if they have atrial fibrillation.

Atrial fibrillation is a rhythm problem that can last from a few minutes to days or weeks and even years. Atrial fibrillation can lead to the formation of blood clots in the upper chambers of the heart (the atria).These clots can break off and flow to the brain causing a stroke.The use of blood thinners, such as warfarin or eliquis ® and others, can lower the risk of stroke in patients with atrial fibrillation.

A doctor can confirm the presence of atrial fibrillation by using an EKG. Atrial fibrillation can sometimes come and go.So a doctor may not see it on regularly scheduled visits.

One sign of atrial fibrillation is palpitations. But, many people don’t feel anything.These people can still get a stroke. If someone has even one episode of atrial fibrillation, they may be at increased risk of a stroke. The decision to take blood thinners to prevent a stroke should be made by the patient and his doctor.

Atrial Fibrillation Detector

The Watch BP home T can screen for atrial fibrillation during blood pressure measurement. The device displays the Afib icon if atrial fibrillation is detected at the time of the blood pressure measurement.

People with a history of atrial fibrillation may have atrial fibrillation on occasion or they may have it all the time. Using the device regularly can help people keep track of how often they are in atrial fibrillation. If the device detects atrial fibrillation in someone who is not on a blood thinner, that person should contact their doctor to determine if they need to be on a blood thinner.

Sometimes the device might detect atrial fibrillation when it is not there. This is usually caused by other rhythm abnormalities. Occasionally, the device might not detect atrial fibrillation even when it is there. On a repeat reading the device should detect atrial fibrillation.

The device may not detect atrial fibrillation in people with pacemakers or defibrillators. It is not recommended to use for detecting atrial fibrillation in people with pacemakers or defibrillators.

Atrial fibrillation detection instructions

• Use this device regularly to keep track of the recurrence of atrial fibrillation.

• People with atrial fibrillation are at risk of stroke and most should be treated with anticoagulation.

• If atrial fibrillation is detected in someone who is not on anticoagulation, the physician should be contacted to discuss appropriate evaluation and treatment

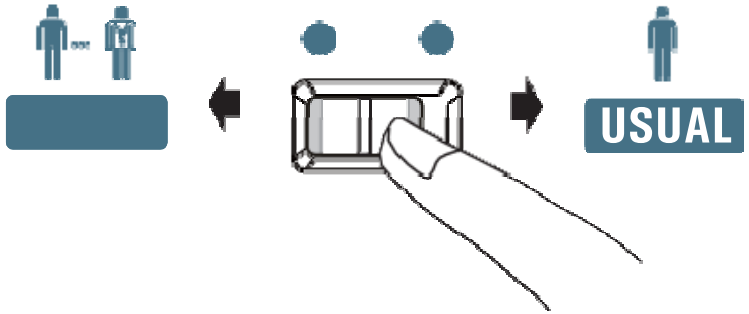
Information for the doctor

This device is designed to detect atrial fibrillation for patients previously diagnosed with atrial fibrillation. Though it is programmed to specifically detect atrial fibrillation, frequent premature beats, marked sinus arrhythmia or other rhythm abnormalities might cause false positive readings. False negative readings can occur infrequently.

Viewing, deleting and transferring measurements

Viewing measurements

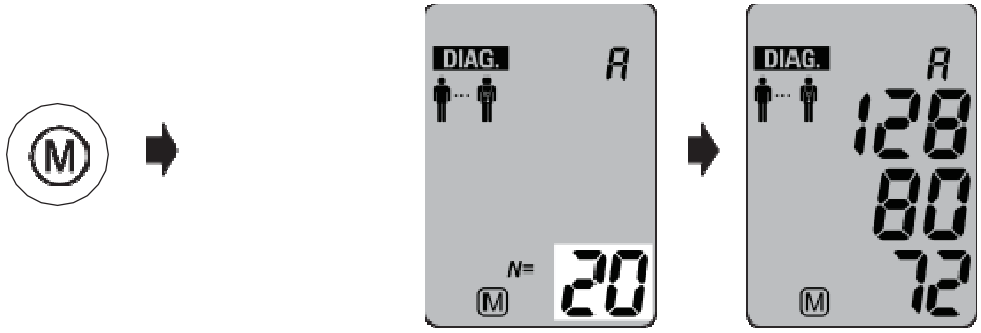
1) Use the Mode switch to first select the type of measurements you wish to view.



2) Then press the M Button.

In «DIAG.» Mode

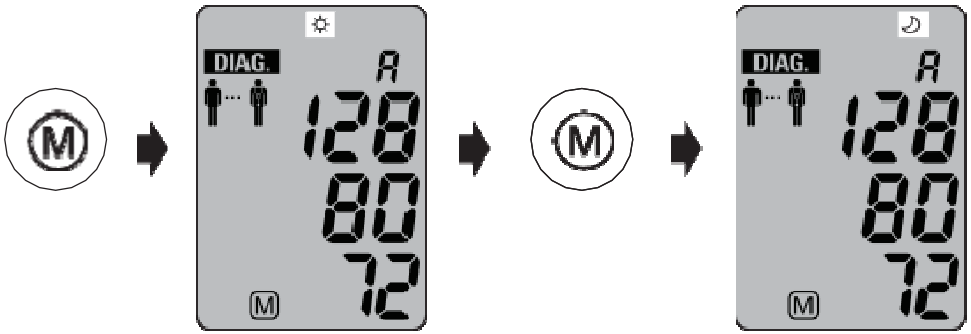
1) When the M Button is pressed, it briefly displays the total number of measurements stored, e.g. N=20 and then switches to the average of all readings.



⁘ *«A» is displayed when the number shown is the average of all data.*

⁘ *«- -» will display when the number of measurements is less than 12.*

2) Press the M Button again to display the average of all morning data. Press the M Button once again to show the average of all evening data.



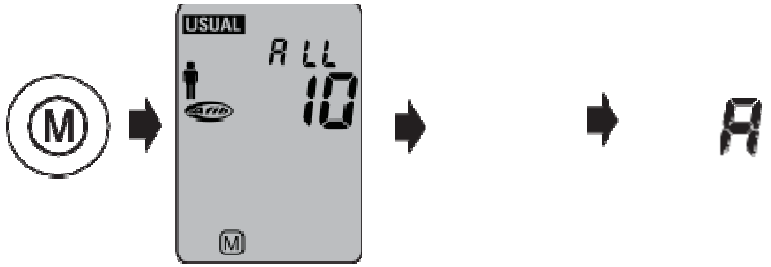
3) Press the M Button repeatedly to review all the individual readings one by one.

4) The daily average is displayed after the individual readings of the day.

In «USUAL» Mode

1) When the M Button is pressed, the number of readings detected with Afib are displayed.

2) Press M Button again, the number of total readings stored, e.g. N=63, is displayed; followed immediately by the average of all measurements stored in memory.

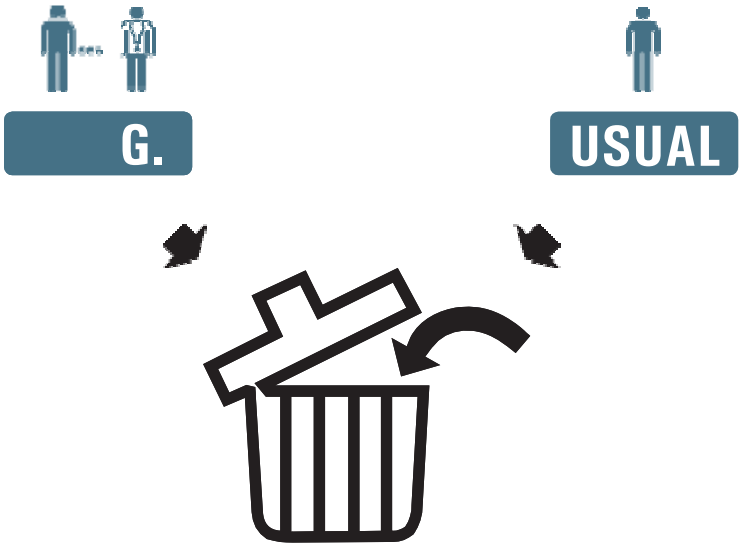


3) All individual readings can be viewed by repeatedly pressing the M Button.

Individual Reading

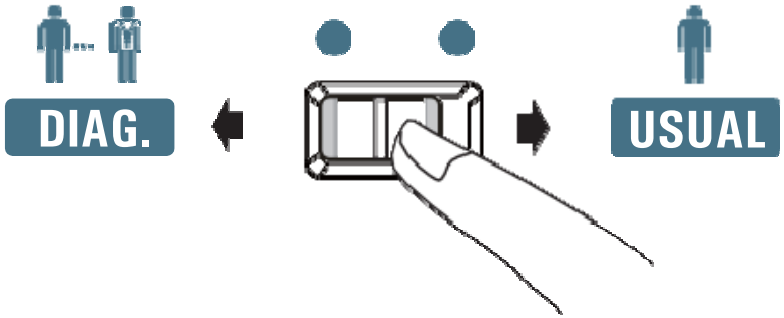
Deleting measurements

Data from «**DIAG.**» and «**USUAL**» can be deleted independent of each other.



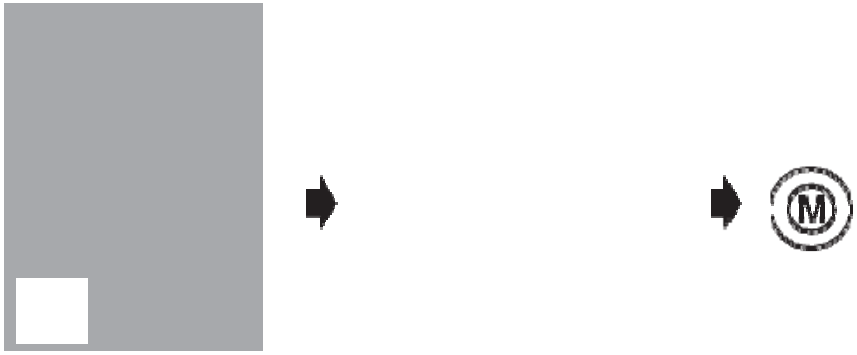
⁘ *Only delete the stored measurements when you are sure that you no longer need the data.*

1)Use the Mode switch to select the mode of measurements you want to delete.



2)Press the M Button and hold it for 7 seconds until the Delete symbol flashes.

3)Release the M Button and press it once more while the Delete symbol flashes. The deleting is confirmed by the beep sound.



⁘ *Only measurements in the selected mode will be deleted.*

Installation of the software program

The latest WatchBP Analyzer Home Software is available from the Microlife website.

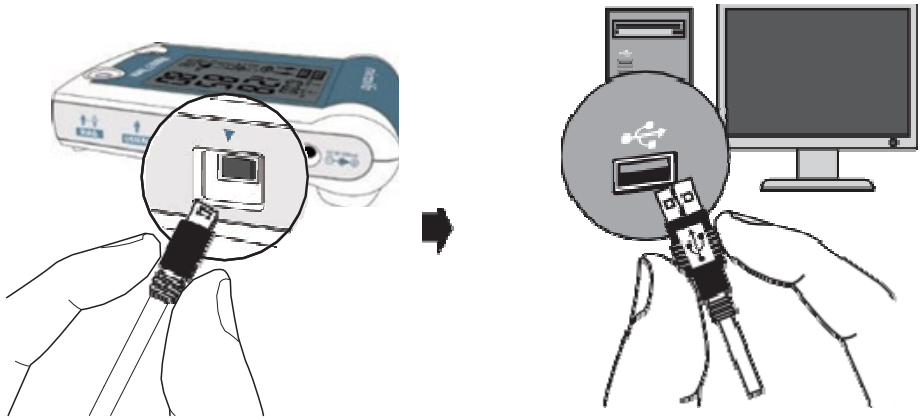
https://www.microlife.com/support/softwareprofessional-products

Double click the download installer and simply follow the instructions provided in the installation window on the PC screen.

⁘ *System Requirements for Software: 1GHz CPU, 512MB Memory, 4.5GB free hard disk space, Microsoft Windows 7 SP1 / 8 / 10*

Transferring data to the computer

1) Start the software program and connect the device to the computer using the cable supplied.
2) The date and time on the device automatically synchronize with the date and time on the PC when successfully connected with WatchBP Analyzer Home PC software.
3) Click <**Download**> button in the WatchBP Analyzer Home to transfer the measurement data on the device to a PC.



⁘ *See instruction manual of the WatchBP Analyzer Home for details.*

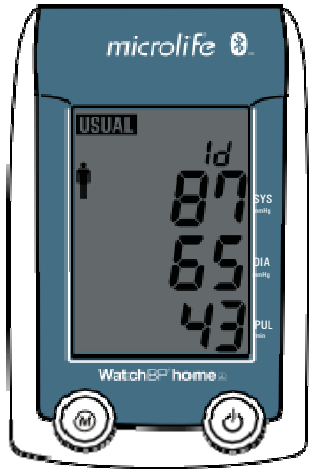
Bluetooth connectivity

The measurement data in «**DIAG.**» and «**USUAL**» can be transferred to a Bluetooth enabled cell phone (android, iphone). Make sure that the phone has Bluetooth turned on before transferring measurements. Before connecting with the phone, please check if Bluetooth pairing is necessary.

Press and hold the M button for around 5 seconds, the unique 6-digit device ID of the unit is displayed. Open the «Microlife WatchBP Home» app on your smartphone. Go to «Dashboard». Click «Sync data» icon. Connect the device and confirm pairing. The measurement data on the device will upload to smartphone automatically when the connection is established.

WatchBP Home App Compatibility:

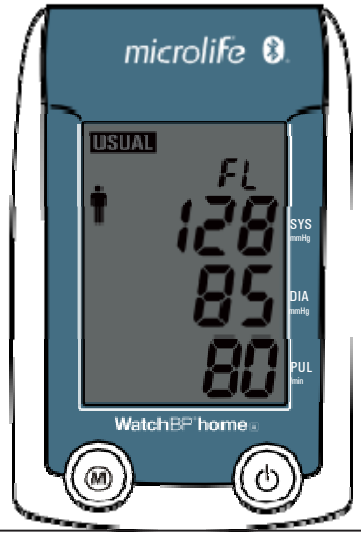
iPhone 6 or above running iOS 12.0 or higher. Android phones running Android 8 or above.



Bluetooth

Questions?
To access the tutorial, go to the App home screen (Microlife WatchBP Home) and press the "Settings and & help" button. •Press "Tutorial" and select your topic.

After the finish of a blood pressure measurement, the Bluetooth also turns on and displays the 6-digit device ID awaiting the connection.
The screen will show “FL” if the connection fails.



※If the Bluetooth connection keeps failing, please reset the Bluetooth Bonding by pressing and holding the Start/Stop button of the device for 7 seconds and start the connection again.

Bluetooth is not active when the blood pressure monitor device is recording data. The blood pressure monitor device will not sound any alarm with or without Bluetooth. The Bluetooth is used only to transfer data from point A to point B.

Batteries and power adaptor

Battery indicator

When the batteries have ¼ power supply left, the Battery Symbol will flash each time the device is switched on.

Replacing low batteries

When the batteries need to be replaced, the Battery Symbol will flash each time the device is switched on.

1) Open the battery compartment at the back of the device.
2) Replace the batteries – ensure correct polarity as shown by the symbols in the compartment.

- *Use 4 new, 1.5V, size AA alkaline batteries.*
- *Do not use batteries beyond their date of expiry.*
- *Remove batteries, if the device will not be used for a prolonged period.*

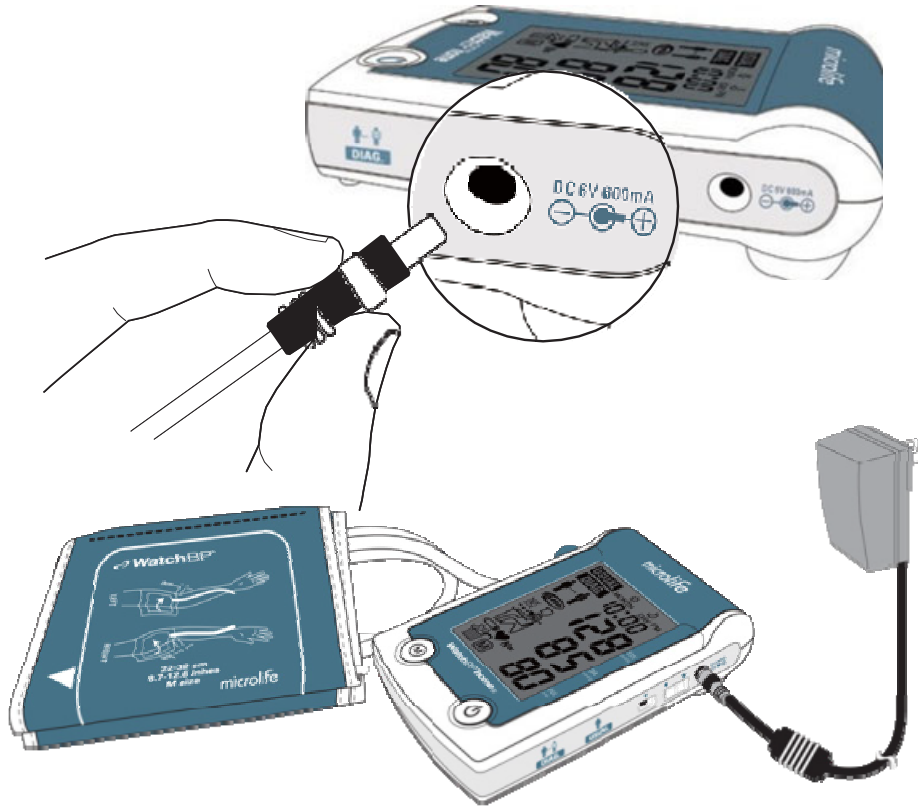
Using a power adaptor

The WatchBP Home T device can also be operated using a Microlife power adaptor (DC 6V, 600mA).

⁘ *Only use Microlife branded power adaptors.*

1) Plug the adaptor cable into the Power Plug in the WatchBP Home T device.
2) Plug the adaptor plug into the wall socket. When the power adaptor is connected, no battery power is consumed.

⁘ *External power adaptor shall be fulfilled in compliance with the requirements of IEC 60601-1:2005.*



Safety, care, accuracy test and disposal

"Read the instruction manual carefully before using this device, especially the safety instructions, and keep the instruction manual for future use."

Safety and protection

This device may be used only for the purpose described in this booklet. The device comprises of sensitive components and must be treated with caution. The manufacturer cannot be held liable for damage caused by incorrect application.

Observe the storage and operating conditions described in the "Technical specifications" section of this manual.

Protect the device from water and moisture

Protect the device from direct sunlight

Protect the device from extreme heat and cold

Do not use this device close to strong electromagnetic fields such as mobile telephones or radio installations.maintain a minimum distance of 3.3m from such devices when using this unit.

Never open device

Protect device from impact and drops

IP21

Protected against solid foreign objects of 12.5 mm diameter and greater. Protected against the ingress of vertically falling water drops with the device positioned on a turntable.

Device care and disinfecting

Use a soft cloth with one of the following recommended cleaning solutions to wipe the exterior of the device:

· Ethyl or isopropyl alcohol (70% solution)
· Hydrogen peroxide 7.5% solution
· Sodium hypochlorite solution (5.25-6.15% household bleach diluted 1:500 provides >100 ppm available chlorine)

Accuracy test

We recommend the WatchBP Home T device be tested for accuracy every 2 years or after mechanical impact (e.g. being dropped). Please contact Microlife to arrange for an accuracy test.

Cuff cleaning and disinfecting

DO NOT wash the cuff. DO NOT iron the cuff cover. Wipe the cuff with 70% ethyl or isopropyl alcohol. Do not immerse hose. Allow to air-dry thoroughly before next use.

DO NOT iron the cuff cover

DO NOT wash the cuff.

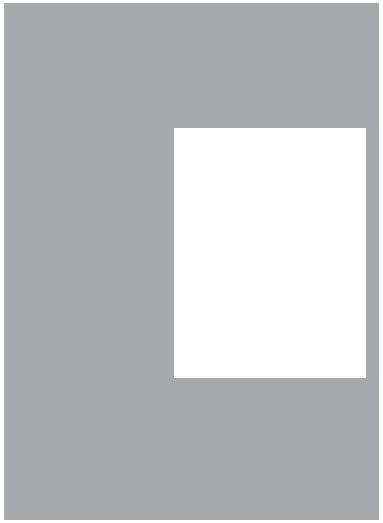
Disposal

Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, and not as domestic waste.

Error messages

If an error occurs during measurement, the measurement is interrupted and an error message «Er» is displayed.

- *Please consult microlife, if this or any other problem occurs repeatedly.*
- *If you think the results are unusual, please read through the information in this instruction manual carefully.*

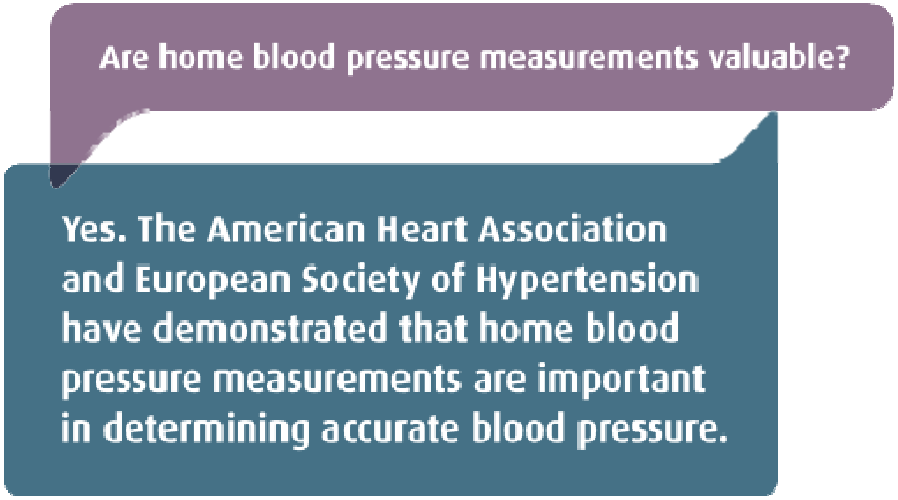


Error	Description	Potential cause and remedy
«**Er 1**»	**Signal too weak**	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.
«**Er 2**»	**Error signal**	During the measurement, error signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.

«**Er 3**»	**No pressure in the cuff**	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the batteries if necessary. Repeat the measurement.
«**Er 5**»	**Abnormal result**	The measuring signals are inaccurate and no result can therefore be displayed. Read through the checklist for performing reliable measurements and then repeat the measurement.

«**HI**»	**Pulse or cuff pressure too high**	The pressure in the cuff is too high (over 300 mmHg) OR the pulse is too high (over 200 beats per minute). Relax for 5 minutes and repeat the measurement.
«**LO**»	**Pulse too low**	The pulse is too low (less than 40 beats per minute). Repeat the measurement.

Important facts about blood pressure and home measurements



- **Blood pressure** is the pressure of the blood flowing in the arteries generated by the pumping of the heart. Two data readings, the **systolic** (upper) value and the **diastolic** (lower) value, are always measured.
- The **pulse rate** is the number of times the heart beats in aminute.
- **Permanent high blood pressure can damage your health and therefore must be treated!**
- Always discuss your home blood pressure measurement data with your doctor and tell him/her if you have noticed anything unusual or feel unsure. **Never rely on single blood pressure readings**.
- There are many causes of excessively **high blood pressure**. Your doctor will explain them in more detail and offer treatment when appropriate.
- Blood pressure is subject to wide fluctuations as the day progresses, and can be impacted by emotions, physical exertion and other conditions .

Evaluating blood pressure data

The table on the right classifies blood pressure data for adults in accordance to the guidelines of the European Society of Hypertension (ESH). (Data in mmHg)

The higher value is the one that determines the evaluation. Example: a readout value between **150/85** or **120/98** mmHg indicates «Grade 1 Hypertension».

Category	Systolic	Diastolic
Optimal	**< 120**	**< 80**
Normal	**120 - 129**	**80 - 84**
High normal	**130 - 139**	**85 - 89**
Grade 1 Hypertension	**140 - 159**	**90 - 99**
Grade 2 Hypertension	**160 - 179**	**100 - 109**
Grade 3 Hypertension	**_ 180**	**_ 110**
lsolated Systolic Hypertension	**_ 140**	**< 90**

Technical specifications

Operating condition:	. 10 to 40 °C (50 to 104 °F) . 15 - 90 % relative maximum humidity, Air pressure 700 to 1040 hPa.
Storage condition.	. -20 to 55 °C (-4 to 131 °F) . 15 - 90 % relative maximum humidity
Weight:	• 385 g (including batteries)
Dimensions:	• 150 x 100 x 50 mm
Measuring procedure:	• Oscillometric, corresponding to Korotkoff
Method:	• Phase I systolic, Phase V diastolic
Measurement range:	• 30 - 280 mmHg – blood pressure • 40 - 200 beats per minute – pulse
Cuff pressure display:	• Range: 0 - 299 mmHg • Resolution: 1mmHg • Static accuracy: pressure within ± 3 mmHg • Pulse accuracy: ± 5 % of the readout value
Voltage source:	• 4 x 1.5 V Batteries; size AA • Mains adapter DC 6V, 600 mA (optional)
Battery life:	Approximately 250 measurements
Reference to standards:	. Device corresponds to the requirements of the standard for noninvasive blood pressure monitor. IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11, ANSI/AAMI/ISO 81060-2 ANSI/AAMI/IEC 80601-2-30
Electromagnetic compatibility:	• Device fulfills the stipulations of the standard IEC 60601-1-2.
Expected service life:	• 5 years or 10,000 measurements (batteries and cuff are not included.
Cuff service life:	• Approximately 2 years

Type BF
applied part

Microlife reserves the right to alter technical specifications without prior written notice.

Guarantee card

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Address: _____

_____

Date:

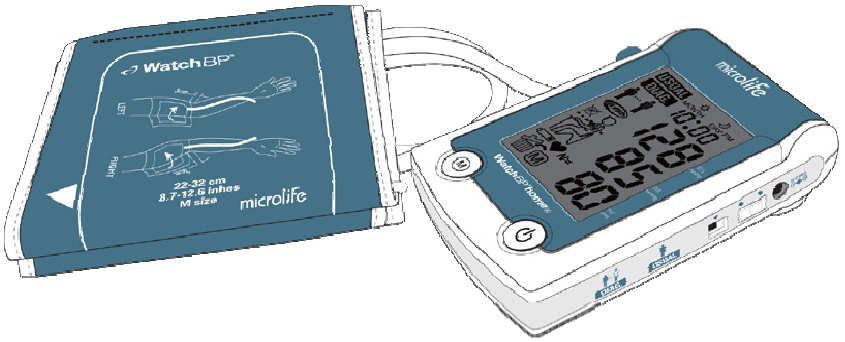
Telephone: _____

Email:

Model: WatchBP Home T

ERP Model Number: BP3MX1-3T

Date:



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Appendix

Manufacturer's Declaration of the Product (Altogether 10 pages)
Guidance and manufacturer´s declaration – electromagnetic emission –for all EQUIPMENT AND SYSTEMS Row

1	**Guidance and manufacturer´s declaration – electromagnetic emission**		
2	The model WatchBP Home T (BP3MX1-3T) is intended for use in the electromagnetic environment specified below. The customer or the user of the model BP3MX1-3T(WatchBP Home T) should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment – guidance
4	RF emissions CISPR 11	Group 1	The Model WatchBP Home A BT(BP3MX1-3C) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	The Model WatchBP Home T(BP3MX1-3T) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	A	
7	Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Model WatchBP Home T(BP3MX1-3T) are intended for use in the electromagnetic environment specified below. The customer or the user of the Model WatchBP Home T(BP3MX1-3T) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency± 1 kV for input/output lines	± 2 kV for power supply lines100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	± 0.5 kV, ± 1 kV differential mode line-line	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT)for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT)for 25/30 cycles at 0° 0 % UT(100 % dip in UT)for 250/300 cycle at 0°	0 % UT (100 % dip in UT)for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT)for 25/30 cycles at 0° 0 % UT(100 % dip in UT)for 250/300 cycle at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models WatchBP Home T(BP3MX1-3T) product name requires continued operation during power mains interruptions, it is recommended that the models WatchBP Home T(BP3MX1-3T) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The WatchBP Home T(BP3MX1-3T) is intended for use in the electromagnetic environment specified below. The customer or the user of the WatchBP Home T(BP3MX1-3T) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	Portable and mobile RF communications equipment should be used no closer to any part of the Models WatchBP Home T(BP3MX1-3T), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.7GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, 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

[a] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[C] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WatchBP Home T(BP3MX1-3T) is used exceeds the applicable RF compliance level above, the WatchBP Home T(BP3MX1-3T) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WatchBP Home T (BP3MX1-3T).

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

RecommendedseparationdistancesbetweenportableandmobileRFcommunicationsequipmentandthemodel WatchBP Home T (BP3MX1-3T)			
The Model WatchBP Home T (BP3MX1-3T) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model WatchBP Home T (BP3MX1-3T) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model WatchBP Home T (BP3MX1-3T) as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
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 80 MHz and 800 MHz, 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.

Recommended separation distances between RF wireless communications equipment

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 RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					

1720	2	0.3	28	28	Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNINGS!

- This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.
- The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.