Afib Talk Blood Pressure Monitor

Instruction Manual

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1. Introduction

1.1. Features of Afib Talk

Afib Talk BP Monitor (with integrated time/date display) is a fully automatic, digital blood-pressure measuring device for use on the arm, which enables very fast and reliable measurement of the systolic and diastolic blood-pressure as well as the pulse frequency by way of the oscillometric method of measuring. The device offers very high and clinical tested measurement accuracy and has been designed to provide a maximum of user-friendliness.

The device is intended for self-use in home.

Before using, please read through this instruction manual carefully and then keep it in a safe place. For further questions on the subject of blood-pressure and its measurement, please contact your doctor.

Attention!

1.2. Important information about self-measurement

- Substitution of a different component might result in measurement error.
- Cuff is replaceable only by an original.
- Do not use with neonatal patients.
- Do not intend to use with pregnant or pre-eclamptic patients
- It will cause harmful injury to the patient or affect the blood pressure due to connection tubing kinking.
- Too frequent measurements can cause injury to the patient due to blood flow interference.
- The application of the cuff over a wound can cause further injury.
- The application of the cuff and its pressurization on any limb where intravascular access or therapy, or an arteriovenous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury to the patient.
- Do not let the cuff and its pressurization on the arm on the side of a mastectomy
- Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring ME equipment on the same limb.
- The need to check that operation of the automated sphygmomanometer does not result in prolonged

impairment of patient blood circulation.

- Not intended to be used together with HF surgical equipment.
- Do not forget: self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with your doctor. Under no circumstances should you alter the dosages of any drugs prescribed by your doctor.
- The pulse display is not suitable for checking the frequency of heart pacemakers!
- In cases of IHB (Irregular Heart Beat), measurements made with this instrument should only be evaluated after consultation with the doctor.

Electromagnetic interference

The device contains sensitive electronic components (Microcomputer). Therefore, avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave cookers). These can lead to temporary impairment of the measuring accuracy.

2. Important information on the subject of blood-pressure and its measurement

2.1. How does high/low blood-pressure arise?

As your heart beats, it pumps your blood round your body so that your muscles can get all the energy and oxygen they need. To do this, your heart pushes your blood through a network of blood vessels called arteries. As the blood travels through the arteries it pushes against the sides of these blood vessels and the strength of this pushing is called your blood pressure.

As your heart squeezes and pushes your blood through your arteries, your blood pressure goes up. As your heart relaxes, your blood pressure goes down. So, with each heartbeat, your blood pressure will rise to a maximum level and then fall to a minimum level.

2.2. Which values are normal?

Blood pressure is too high if at rest, the diastolic pressure is above 90 mmHg and/or the systolic blood-pressure is over 160 mmHg. In this case, please consult your doctor immediately. Long-term values at this level endanger your health due to the associated advancing damage to the blood vessels in your body.

Should the systolic blood-pressure values lie between 140 mmHg and 160 mmHg and/or the diastolic

blood-pressure values lie between 90 mmHg and 100 mmHg, likewise, please consult your doctor. Furthermore, regular self-checks will be necessary.

With blood-pressure values that are too low, i.e. systolic values under 100 mmHg and/or diastolic values under 60 mmHg, likewise, please consult your doctor. Even with normal blood-pressure values, a regular self-check with your blood-pressure monitor is recommended. In this way you can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, please keep a record of the level of your blood pressure by carrying out regular self-measurements at specific times of the day. Show these values to your doctor. **Never use the results of your measurements to alter independently the drug doses prescribed by your doctor.**

Table for classifying blood-pressure values (unit: mmHg) according to World Health Organization:

Range	**Systolic Blood-pressure**	**Diastolic Blood-pressure**	**Measures**
Hypotension	lower than 100	lower than 60	Consult your doctor
Blood pressure optimum	between 100 and 120	between 60 and 80	Self-check
Blood pressure normal	between 120 and 130	between 80 and 85	Self-check
Blood pressure slightly high	between 130 and 140	between 85and 90	Consult your doctor
Blood pressure too high	between 140 and 160	Between90and 100	Seek medical advice
Blood pressure far too high	between 160 and 180	Between100and 110	Seek medical advice
Blood pressure dangerously high	Higher than 180	Higher than 110	Urgently seek medical advice!

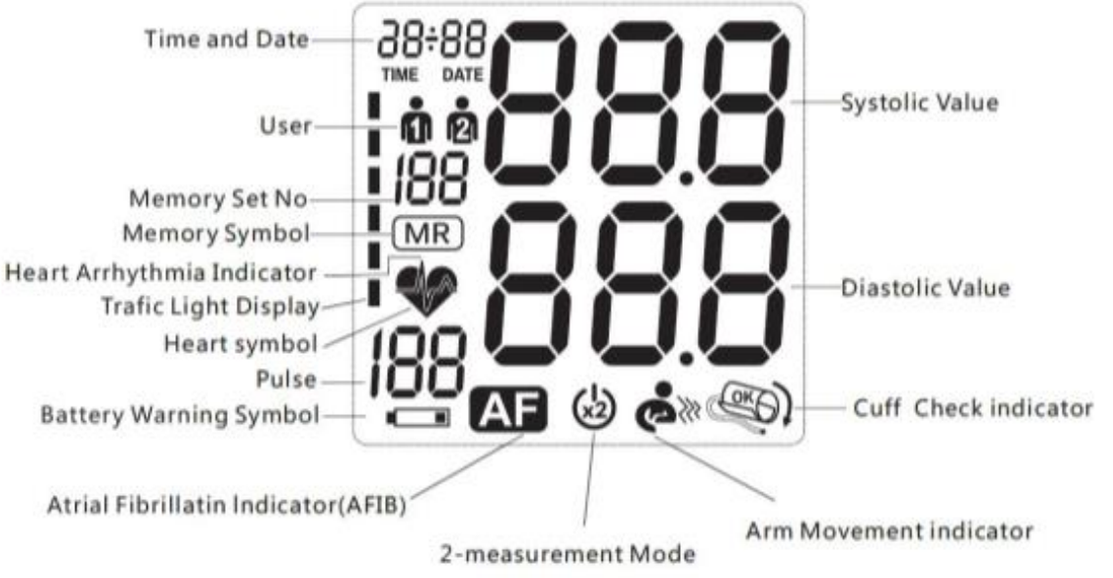
3. Important Facts about Atrial Fibrillation (AFIB)

What is Atrial Fibrillation (AFIB)? Normally, your heart contracts and relaxes to a regular beat. Certain cells in your heart produce electrical signals that cause the heart to contract and pump blood. Atrial fibrillation occurs when rapid, disorganized electrical signals are present in the heart's two upper chambers, called the atria; causing them to contract irregularly (this is called fibrillation). Atrial fibrillation is the most common form of IHB (Irregular Heart Beat) or irregular heartbeat. It often causes no symptoms, yet it significantly increases your risk of stroke. You'll need a doctor to help you control the problem.

How does AFIB impact my family or me?

People with AFIB have a five-fold higher risk of getting stroke. Since the chance of having a stroke increases with age, AFIB screening is recommended for people over 65 years and older. However, for people from the age of 50 years with high blood pressure (hypertension), diabetes, coronary heart failure or have had a previous stroke AFIB screening is also recommended. Early diagnosis of AFIB followed by adequate treatment can significantly reduce the risk of getting stroke. In young people AFIB screening is not recommended as it could generate false positive results and unnecessary anxiety. In addition, young individuals with AFIB have a relatively low risk of getting stroke as compared to elder people. Knowing your blood pressure and knowing whether you or your family members have AFIB can help reduce the risk of stroke. Risk factors you can control High blood pressure and AFIB are both considered «controllable »risk factors for strokes. Knowing your blood pressure and knowing whether you have AFIB is the first step in proactive stroke prevention.

4. Various components of the blood-pressure monitor



5. Putting the blood-pressure monitor into operation

5.1 Inserting the batteries

a) Insert the batteries (4 x size AA 1.5V), thereby observing the indicated polarity.

b) If the battery warning icon appears in the display, the batteries remain 20% power to warn user the batteries will be run out.

c) If the battery warning icon appears in the display, the batteries are empty and must be replaced by new ones

Attention! • After the battery warning icon appears, the device is blocked until the batteries have been replaced.

- Please use «AA» Long-Life or Alkaline1.5V Batteries.
- The use of 1.2V Accumulators is not recommended.
- If the blood-pressure monitor is left unused for long periods, please remove the batteries from the device.

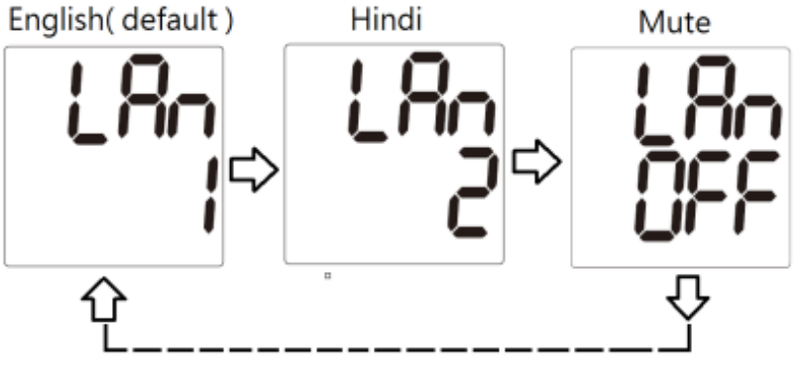
5.2 Reading the set date

Please press the TIME button and the date will be shown in the display.

5.3 Language selection, User selection and setting the time / date

Talking Language selection: Bilingual of English and Hindi

You can select either English or Hindi to check your BP. Press and hold (x1) or (x2) button for around 5 seconds, to enter into language selection mode. A default language is English. Press Memory button, to switch language to Hindi and to mute (voice off). Again press (x1) or (x2) button to save your selection and to exit.



User selection: This advanced blood pressure monitor allows you to track blood pressure readings for 2 individuals independently.

a) Before measurement, make sure you set the unit for the intended user. The unit can track results for 2 individuals. (User 1, User 2)

b) Press the TIME button for at least 3 seconds. The display now indicates the set user, during which the set user blinks. To confirm, press ON/OFF button.

c) Click the MEMORY button to select User.

d) We suggest the first person to take their pressure to be User 1.

Setting the Time & Date

This blood-pressure monitor incorporates an integrated clock with date display. This has the advantage, that at each measurement procedure, not only the blood-pressure values are stored, but also the exact moment of the measurement. After new batteries have been inserted, the clock begins to run TIME 12:00 and DATE 1-01.You must then re-enter the date and current time. For this, please proceed as follows.

1. Press the TIME button for at least 3 seconds firstly, user icon will blink. Then press TIME button again the display now indicates the set year, during which the four characters blink.
2. The correct year can be entered by pressing the MEMORY button
3. Press the TIME button again. The display now switches to the current date, during which the first character (month) blinks.
4. The corresponding month can now be entered by pressing the MEMORY button.
5. Press the TIME button again. The last two characters (day) are now blinking
6. The corresponding day can now be entered by pressing the MEMORY button.
7. Press the TIME button again. The display now switches to the current time, during which the first character (Hour) blinks
8. The corresponding hour can now be entered by pressing the MEMORY button.
9. Press the TIME button again. The last two characters (Minutes) now blink.
10. The exact time can now be entered by pressing the MEMORY button
11. Press TIME button (or TIME / DATE or TIME): the unit of measurement will flash.
12. Once you have made your settings, press the TIME button (or TIME / DATE or TIME). The setting is confirmed and the clock starts running.
13. Now after all settings have been made, press the TIME button once again. The date is briefly

displayed and then the time. The input is now confirmed and the clock begins to run.

Further Information

With each press of the button (TIME, MEMORY) one input is made (e.g. switching over from hours to minutes mode, or altering the value by +1). However, if you keep the respective button depressed, you can switch more quickly to find the desired value respectively.

6. Carrying out a measurement

6.1 Before the measurement

- Avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Try and find time to relax by sitting in an armchair in a quite atmosphere for about ten minutes before the measurement.
- Measure always on the same arm (normally left).
- Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the course of the day.

6.2 Common sources of error

Note: Comparable blood-pressure measurements always require the same conditions! These are normally always quiet conditions.

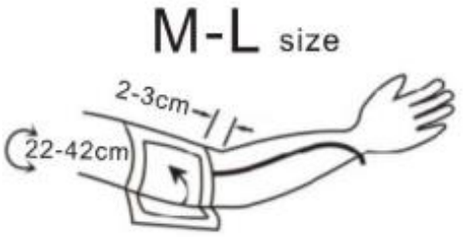
- All efforts by the patient to support the arm can increase the blood-pressure. Make sure you are in a comfortable, relaxed position and do not activate any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
- The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- Avoid compression or restriction of the connection tubing.
- A loose cuff causes false measurement values.
- With repeated measurements, blood accumulates in the respective arm, which can lead to false results. Correctly executed blood-pressure measurements should therefore first be repeated after a 5 minute pause or after the arm has been held up in order to allow the accumulated blood to flow away (after at least 3 minutes).

6.3 Fitting the cuff

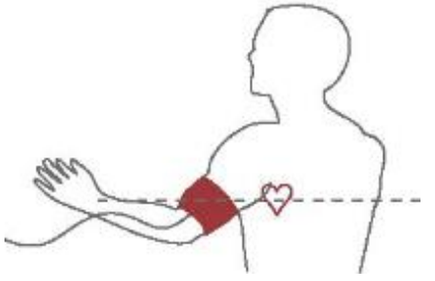
Insert air connector into air outlet shown in left photo and please make sure the fitting of the air connector completely and properly to avoid air leakage.

a) The distance between the edge of cuff and the elbow should be approx. 2~3cm.

b) Secure the cuff with the Velcro fastener, so that it lies comfortably and not too tight, whereby no space should remain between the cuff and the arm.



c) Lay the arm on a table, with the palm upwards. Support the arm a little with a rest (cushion), so that the cuff rests at about the same height as the heart. Take care, that the cuff lies free. Remain so for 2 minutes sitting quietly, before beginning with the measurement.



d) Let legs uncrossed, feet flat on the floor, back and arm supported.

6.4 Measuring procedure

6.4.1Measuring in standard mode

In this mode has IHB (Irregular Heart Beat) detection but no Afib detection

After the cuff has been appropriately positioned, the measurement can begin:

a) Press the  button, the pump begins to inflate the cuff. In the display,  the increasing cuff-pressure is continually displayed.

b) Cuff fitting detection: the icon  will appear and blink during measuring, if cuff was fit too loose. The icon  will appear during measuring , if cuff was fit well

c) Arm movement detection during measuring: the icon  will appear , if a movement was detected which may influence accuracy . due to the movement not too serious , the measuring can be continuous (if the movement is too serious , Err2 displayed)

d) After reaching the inflation pressure, the pump stops and the pressure slowly falls away. The cuff-pressure (large characters) is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display begins to blink

e) When the measurement has been concluded, the measured systolic and diastolic blood-pressure values as well as the pulse frequency are now displayed.

Example 1

Example 1: Systole 120, Diastole 80, Pulse 70,

And IHB (Irregular Heart Beat) detected, cuff fit well.

Example 2 : Systole 120, Diastole 80, Pulse 70 ,

And IHB (Irregular Heart Beat) detected, cuff fit too loose .

Example 2

Example 3: Systole 128, Diastole 86, Pulse 68,

And a movement detected, cuff fit well

Example 3

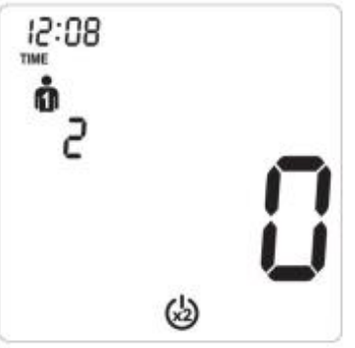
The measurement results are displayed, until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off, to save the batteries.

6.4.2Measuring in Afib Mode (2-measurement mode)

In Afib mode, 2 measurements are automatically taken in succession and the result is then automatically analyzed and displayed. Because blood pressure constantly fluctuates, a result determined in this way is more reliable than one produced by a single measurement.

- After pressing the button , the symbol appears in the display.
- The middle, left hand section of the display shows a 1, 2 to indicate which of the 2 measurements is currently being taken.
- There is a break of 15 seconds between the measurements

(15 seconds are adequate according to «Blood Pressure Monitoring, 2001, 6:145-147» for oscillometric instruments). A countdown indicates the remaining time.



- The individual results are not displayed. Your blood pressure will only be displayed after all 2 measurements are taken.
- Do not remove the cuff between measurements.
- If one of the individual measurements was questionable, a third one is automatically taken.

In the measuring:

After reaching the inflation pressure, the pump stops and the pressure slowly falls away. The cuff-pressure is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display begins to blink

Measured result:

The measured systolic and diastolic blood-

Pressure values as well as the pulse are now displayed.

Example 1:

Systole 128, Diastole 86, Pulse 68, Afib detected.

Icon of IHB (Irregular Heart Beat) and Afib AF will be appeared

Arm movement detected and cuff fit too loose detected

Example 1

Example 2:

Systole 128, Diastole 86, Pulse 68, IHB (Irregular Heart Beat) detected , but no Afib detected.

Arm movement detected and cuff fit well

Example 2

The measurement results are displayed until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off

6.5 Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the power button or can be pressed at any time. The device then immediately lowers the cuff-pressure automatically.

6.6 Memory – storage and recall of the measurements

The blood-pressure monitor automatically stores each of the last 120 measurement values. By pressing the MEMORY button, an average value of the last 3 measurements as well as the last measurement and the further last 120 measurements (MR119,MR118,…,MR1)can be displayed one after the other

measured under mode
the last 9th memory

measured under mode
the last 8th memory

measured under mode
the last 6th memory

the indicate "A" means an average value for the last 3 measurements

Measured under (x1) mode

the last 3rd memory

(MR1: Values of the last measurement) (MR2-MR120: Values of the measurement before MR1)

6.7 Memory– cancellation of all measurements Attention!

Before you delete all readings stored in the memory, make sure you will not need refer to the readings at a later date. Keeping a written record is prudent and may provide additional information for your doctor's visit. In order to delete all stored readings, depress the MEMORY button for at least 5 seconds, the display will show the symbol «CL» and then release the button. To permanently clear the memory, Press the MEMORY button while «CL» is flashing.

7. Appearance of the Heart IHB (Irregular Heart Beat) Indicator for early Detection

This icon indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal blood pressure – repeat the measurement. In most cases, this is no cause for concern. However, if the symbol appears on a regular basis (e.g. several times a week with measurements taken daily) we advise you to tell your doctor.

Please show your doctor the following explanation: Information for the doctor on frequent appearance of the IHB (Irregular Heart Beat) indicator. This instrument is an oscillometric blood pressure monitor that also analyses pulse frequency during measurement. The instrument is clinically tested. The IHB (Irregular Heart Beat) symbol is displayed after the measurement, if pulse irregularities occur during

measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) we recommend the patient to seek medical advice.
The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage

8. Appearance of the Atrial Fibrillation Indicator for early Detection

This device is able to detect atrial fibrillation (AFIB). This icon AF indicates that atrial fibrillation was detected during the measurement. If the AFIB symbol appears after having performed a full blood pressure measurement episode (triplicate measurements), you are advised to wait for one hour and perform another measurement episode (triplicate measurements). If the AFIB symbol appears again, then you are advised to visit your doctor. If after repeated measurement the AFIB symbol is no longer displayed there is no cause for concern. In such case it is recommended to measure again the next day. Keep the arm still during measuring to avoid false readings. This device may not detect atrial fibrillation in people with pacemakers or defibrillators.

9. Error messages /malfunctions

If an error occurs during a measurement, the measurement is discontinued and a corresponding error code is displayed.

Error No.	Possible cause(s)
ERR 1	No pulse has been detected.
ERR 2	Unnatural pressure impulses influence the measurement result. Reason: The arm was moved during the Measurement (Artifact).
ERR 3	The inflation of the cuff takes too long. The cuff is not correctly seated.
ERR 5	The measured readings indicated an unacceptable difference between systolic and diastolic pressures. Take other reading following directions carefully. Contact

	you doctor if you continue to get unusual readings.
ERR8	Pressure is over 290 mmHg

Further Information - The level of blood-pressure is subject to fluctuations even with healthy people. Important thereby is, that comparable measurements always require the same conditions (Quiet conditions)! If, in spite of observing all these factors, the fluctuations are larger than 15mmHg, and/or you hear irregular pulse tones on several occasions, please consult your doctor. For licensing, the device has been subjected to strict clinical tests, by which the computer program used to measure the blood-pressure values was tested by experienced specialist doctors in Germany. The same computer program is used in every individual device, and has thus also been clinically tested. The manufacture of the devices takes place according to the terms of the European standard for blood-pressure measuring devices (see technical data) you must consult your specialist dealer or chemist if there are technical problems with the blood-pressure instrument. Never attempt to repair the instrument yourself! Any unauthorized opening of the instrument invalidates all guarantee claims!

Other possible malfunctions and their elimination

If problems occur when using the device, the following points should be checked and if necessary, the corresponding measures are to be taken:

Malfunction	Remedy
The display remains empty when the instrument is switched on although the batteries are in place.	1. Check batteries for correct polarity and if necessary insert correctly. 2. If the display is unusual, re-insert batteries or exchange them.
The device frequently fails to measure the blood pressure values, or the values measured are too low (too high).	1. Check the positioning of the cuff. 2. Measure the blood-pressure again in peace and quiet under observance of the details made under point 5.
Every measurement produces a different	1. Please read the following information and the points

value although the instrument functions normally and the values displayed are normal	listed under «Common sources of error». Repeat the measurement. **Please note: Blood pressure fluctuates continually so successive measurements will show some variability**.
Blood pressure measured differs from those values measured by the doctor.	1. Record the daily development of the values and consult your doctor. **Please note: Individuals visiting their doctor frequently experience anxiety which can result in a higher reading at the doctor than obtained at home under resting conditions.**

10. Care and Maintenance, Recalibration

a) Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.

b) The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of straining through twisting or buckling.

c) Clean the device with a soft, dry cloth. Do not use petrol, thinners or similar solvent. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff must not be washed!

d) Do not drop the instrument or treat it roughly in any way. Avoid strong vibrations.

e) Never open the device! Otherwise the manufacturer calibration becomes invalid!

Periodical recalibration

Sensitive measuring devices must from time to time be checked for accuracy.

We therefore recommend a periodical inspection of the static pressure display every 2 years. Your specialist dealer would be pleased to provide more extensive information about this.

11. Safety, care and disposal

Safety and protection

- This instrument may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for the damage caused by incorrect application.
- These instruments comprise sensitive components and must be treated with caution. Observe the storage and operating condition described in the “Technical specifications” section!
- Protect it from water and moisture, extreme temperatures, impact and dropping, contamination and dust, direct sunlight, heat and cold
- The cuffs are sensitive and must be handled with care
- Only pump up the cuff once fitted
- Do not use the instrument close to strong electromagnetic fields such as mobile telephones or radio installations
- Do not use the instrument if you think it is damaged or notice anything unusual.
- If the instrument is not going to be used for a prolonged period the batteries should be removed.
- 

Read the additional safety instructions in the individual sections of this booklet. Ensure that children do not use the instrument unsupervised: some parts are small enough to be swallowed
- Must use the recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety
- A warning to remove primary batteries if the instruments is not likely to be used for sometime

Instrument care

Clean the instrument only with a soft, dry cloth

Disposal

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

12. Reference to Standards

Device standard: Device corresponds to the requirements of the European standard for non-invasive blood- pressure monitor

EN1060-1

EN1060-3

EN1060-4 – clinical investigation

IEC/EN 60601-1-11

ANSI / AAMI SP10, NIBP,

IEC80601-2-30:2009 + corrigendum 2010

Electrical compatibility: Device fulfils the stipulations of the

IEC/EN 60601-1,

IEC/EN 60601-1-2

The stipulations of the EU-Guidelines 93/42/EEC for Medical Products Class IIa have been fulfilled.

13. Remark:

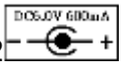
	Some electrical and electrical equipments forbid to abandon and disposal at will	CE 0197	TUV NO.
	Manufacturer's name and address		Reading Instruction Book before use

	Inapplicable baby		Type B equipment
	Cuff Connector		AC/DC Adapter
	Attention consult accompanying documents	EC REP	Wellkang Tech Consulting Suite B ,29 Harley Street, LONDON W1G 9QR ,United Kingdom
	Keep Dry		

14. Technical specifications

Measurement Procedure:	Oscillometric , corresponding to Korotkoff method: Phase I : systolic , Phase V : diastolic
Display:	Digital display
Measuring range:	Pressure: 30 to 280 mmHg (in 1 mmHg increment) Pulse: 40 to 199 beat/minute
Static accuracy:	Pressure: ±3mmHg / Pulse: ±5% of reading
Measuring resolution :	1mmHg
Inflation:	Automatic inflation by internal pump
Memory function:	2 x 120 memories for 2 users (SYS, DIA, Pulse)
Decompression:	Constant exhaust valve system
Power source:	4- size “AA” alkaline Batteries
Rated voltage:	DC 6.0V 4.0W (direct current)
Operation temperature:	5~40°C/41~104°F
Operation humidity:	15%~85%RH maximum

Storage temperature:	-10~55°C/14~131°F
Storage humidity:	10%~95%RH maximum
Dimensions :	135× 115× 72 ±1.0 mm
Weight :	540 g±5g (including batteries and cuff)
Cuff pressure display range:	0~290mmHg/0~38.7kPa
Electrical shock protection:	Internal power unit
Safety classifications:	Type B equipment
Mode of operation:	Continuous operation
Protection against ingress of water:	IP22
Accessories:	M-size Cuff , 4 “AA” batteries, instruction manual ,warranty card

Please be noticed the power adapter is not supplied from the origin, users can buy the adapter in the market which must comply to EN60601-1, EN60601-1-2 

15. Manufacturer's Declaration

Afib Talk is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

Electromagnetic Emissions: (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	Afib Talk uses RF energy only for internal functions. Therefore, this RF emission is extremely weak and there is little chance of it creating any kind of interference whatsoever with nearby electronic equipment.
RF emissions CISPR 11	Class B	Afib Talk 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
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker IEC	Not applicable	

61000-3-3		purposes.

Electromagnetic Immunity: (IEC60601-1-2)

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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 %.
Electric fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	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	<5 % U_T (95% dip inU_T.) for 0.5 cycle 40 % U_T(60% dip in U_T) for 5 cycles 70 % U_T(30% dip inU_T) for 25 cycles <5 % U_T (95% dip inU_T) for 5 sec.	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the upper arm style requires continued operation during power mains interruptions, it is recommended that Afib Talk be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC60601-1-2 test level	IEC60601-1-2 test level	Electromagnetic environment - guidance

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 80% AM (2Hz) 3 Vrms 80 MHz to 2.5 GHz 80% AM (2Hz)	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Afib Talk, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommend separation distance** 3V $d = 1.2 \times p^{1/2}$ 80Mhz to 800 MHz $d = 2.3 \times p^{1/2}$MHz to 2.5 GHz 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 meters (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: 

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a]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 broad cast 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 Afib Talk is used exceeds the applicable RF compliance level above, it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Recommended Separation Distances:

Recommended separation distance between portable and mobile RF communications equipment and Afib Talk.			
Afib Talk is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Afib Talk can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Afib Talk 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 $d = 1.2 \times p^{1/2}$	80 MHz to 800 MHz $d = 1.2 \times p^{1/2}$	800 MHz to 2.5 GHz $d = 2.3 \times p^{1/2}$
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 meters (m) can be determined 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. Note1:At 80MHz and 800MHz, the separation distance for the higher frequency range applies Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

For any other query contact: - **dr@drtrustusa.com**