

## ABOUT US

Driven by the passion for innovation, we at Dr Trust endeavour to provide our customers with the latest medical inventions with an objective to promote good health and wellness all around the world. All the medical devices and health monitors provided by Dr Trust are supported by accurate, latest and ground breaking technologies, innovated at our headquarter in NY, USA. All our products adhere to the most stringent CE and FDA guidelines and are strongly recommended by doctors and health practitioners. Our products are designed in the utmost exemplary ways to ensure that their accuracy and convenience are unrivalled. The ease of their use and operation makes them even more suitable for users of all age groups.

Dr Trust strives to enhance the quality of lifestyle by providing with the most trusted and innovative health care and wellness products. Being a renowned global leader in health care products, Dr Trust ensures that our technically efficient team works dynamically and tirelessly to provide the best of the medical devices to our clients. The products that we have to offer are suitably designed for use at homes, laboratories and hospitals.

Our ground breaking solutions allow you to monitor your health in the easiest ways possible. In today's era when all of our lives are too hassled to handle, it becomes a bit difficult to pay attention to our health. But it has now become easier with the coming of the monitoring devices which can be

We bring to you a variety of best self medical devices, trusted and used by Doctors, medical professionals and home users all over the world.

Dr Trust

Blood Pressure Monitor A Fib Talk-104

## QUICK STARTUP GUIDE

### Step 1

Check batteries and insert the air tube from the cuff into the air jack.


### Step 2

Before starting the measurement, select mode and make settings for user no., time, and date etc.


### Step 3

Position the cuff on your arm 1-2 inches above your elbow joints and tighten it in a way so that it fits comfortably around your arm.

### Step 4

After the cuff has been appropriately positioned, press the  button to measure blood pressure in the standard mode. Afib detection not possible in this mode.

### Step 5

To measure in Afib mode, press  The monitor will take 2 measurements in succession and the result is then automatically analyzed and displayed. the symbol appears in the display. The device will take two reading in 15 seconds gap and average them for final reading.



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## 1. INTRODUCTION

Your blood pressure is an important parameter that can be used to monitor your health. Dr Trust Afib Talk Blood Pressure Monitor enables you to monitor your blood pressure regularly and maintain a record of your blood pressure measurements. The device uses a unique AFIB technology to provide a reliable measurement of systolic and diastolic blood pressure as well as heart rate using the fuzzy logic technology and oscillometric measurement method. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with the measurement result. It also detects atrial fibrillation with high accuracy during blood pressure measurements in the «AFib» mode.

### 1.1. Features of Afib Talk BP Monitor

- The Dr Trust Afib Talk BP Monitor (with integrated time/date display) is a fully automatic, digital blood-pressure measuring device for use on the arm.
- The device offers very high and clinical tested measurement accuracy.
- It enables very fast measurements of the systolic and diastolic blood-pressure as well as the pulse frequency by way of the oscillometric method of measurement.
- It has been designed to provide a maximum of user-friendliness.
- The device is intended for self-use in home.
- It helps you to detect AFIB and hypertension at an early stage, even though you may not experience any symptoms.
- AFIB -Atrial Fibrillation Detector technology icon is displayed when atrial fibrillation is detected during a blood pressure reading.
- This powerful device automatically stores 2 users X 60 blood pressure readings. By clicking the viewing options the user can review the readings with date and information.

- Dual talking (Hindi & English) feature can be used if you have weak eyesight. If you do not want to use this sound feature, you can switch off to mute voice feedback.

### To Be Noted

Appropriate treatment can reduce your risk of suffering a stroke. AFIB detection is the world's leading digital blood pressure measurement technology for the early detection of atrial fibrillation (AFIB) and hypertension. For this reason, it is recommended that you need to visit to your doctor if the device gives an AFIB signal during your blood pressure measurement.

### 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 to pressurize your 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.
- Not intended to be used together with HF surgical equipment.
- For perfect measurements, please tie the provided universal conical cuff (arm circumference of 22-42 cm) to your left or right wrist in a right manner.
- Cuff OK' icon indicates whether the cuff is correctly wrapped or not. Whereas 'Arm Movement' indicator appears if the arm is not stationary.

#### ⚠ Attention

#### To Be Noted

- 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 Irregular Heartbeat (IHB), 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. What Is Blood Pressure?

As your heart beats, it pumps your blood around 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. How does high/low blood-pressure problem arise?

The level of blood-pressure is determined in a part of the brain, the so-called circulatory Centre, and adapted to the respective situation by way of feedback via the nervous system. To adjust the blood-pressure, the strength and frequency of the heart (Pulse), as well as the width of circulatory blood vessels is altered. The latter is affected by way of fine muscles in the blood-vessel walls. The level of arterial blood-pressure changes periodically during the heart activity: During the «blood ejection» (Systole) the value is maximal (systolic blood-pressure value), at the end of the heart's «rest period» (Diastole) minimal (diastolic blood-pressure value). The blood-pressure values must lie within certain normal ranges in order to prevent particular diseases.



### 2.3. What Health Problems Are Associated with High Blood Pressure?

Hypertension contributes to several serious health conditions. Atherosclerosis, Heart Diseases or Heart Failure, Stroke, Kidney Disease and Eye Disease are few among several potentially serious health conditions which are linked to high BP.

### 2.4. What Circumstances Can Increase or Decrease Blood Pressure?

Your blood pressure increases and decreases under the following circumstances

#### Blood pressure is higher than normal:

- When you are excited, nervous, or tense
- While taking a bath
- During and after exercise or strenuous physical activity
- When it is cold
- Within one hour after meals
- After drinking tea, coffee, or other caffeinated drinks
- After smoking tobacco
- When your bladder is full

#### Blood pressure is lower than normal:

- After consuming alcohol
- After taking a bath

### 2.5. 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. If the systolic blood-pressure values lie between 140 mmHg and 159 mmHg and/or the diastolic blood-pressure values lie between 90 mmHg and 99 mmHg, likewise, you need to consult your doctor. Furthermore, regular self-checks will be necessary.

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 119	between 60 and 80	Self-check
Blood pressure normal	between 120 and 129	between 80 and 84	Self-check



Blood pressure slightly high	between 130 and 139	between 85 and 89	Consult your doctor
Blood pressure too high	between 140 and 159	Between 90 and 99	Seek medical advice
Blood pressure far too high	between 160 and 179	Between 100 and 109	Seek medical advice
Blood pressure dangerously high	Higher than 180	Higher than 110	Urgently seek medical advice!

**△ Attention**

**To Be Noted**

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.

**3. IMPORTANT FACTS ABOUT ATRIAL FIBRILLATION (AFIB)**

**3.1. 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 Heartbeat) or irregular heartbeat. It often causes no symptoms, yet it significantly increases your risk of stroke. You'll need a doctor to help you to control this problem.

**3.2. How does AFIB impact?**

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.

**3.3. How Dr Trust AFIB Talk can help?**

Knowing your blood pressure and knowing whether you or your family members have AFIB is the first step in proactive stroke prevention. Dr Trust AFIB Talk Blood Pressure Monitor with implemented AFIB technology, allow patients to be screened for AF during blood pressure measurements at home, using a sophisticated algorithm. If AF is detected during blood pressure measurements, the AFIB symbol is displayed. However, the BP monitor does not make a diagnosis, but it provides important information for your doctor, who can refer you for further diagnose to confirm the presence of AF.

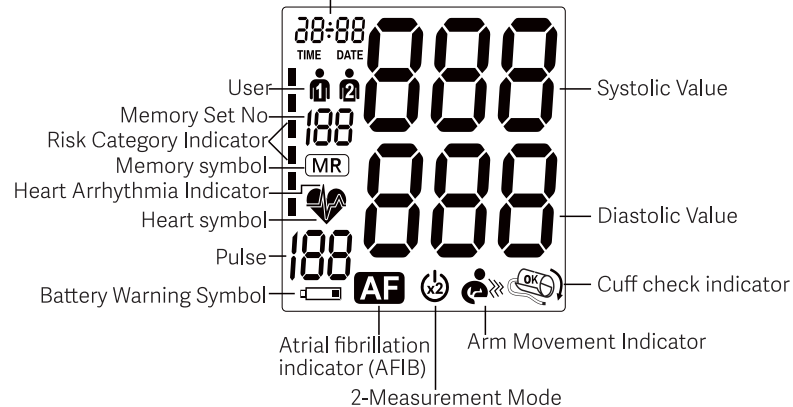


#### 4. VARIOUS COMPONENTS OF THE BLOOD-PRESSURE MONITOR





- Memory Button
- I/O Button in Afib mode  
(2-Measurement Mode)
- I/O Button in Standard mode
- Time/Date Setting


Time and Date



## 5. PUTTING THE BLOOD-PRESSURE MONITOR INTO OPERATION

- Insert the batteries (4 x size AA 1.5V), after observing the indicated polarity.
- This battery symbol  is the warning display of 20% battery only
- If the battery warning  icon appears in the display, the batteries are empty and must be replaced by new ones

### ⚠ Attention To Be Noted





- After the battery warning  icon appears, the device is blocked until the batteries have been replaced.
- Please use «AA» Long-Life or Alkaline 1.5V Batteries.
- The use of 1.2V Accumulators is not recommended.
- If the blood-pressure monitor is left unused for a long period, please remove the batteries from the device.

### 5.2. Reading the Set Date

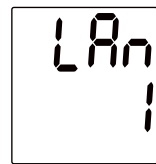
Press the TIME button and the date will be shown in the display.

### 5.3. Language Selection, User Selection and Setting The Time / Date

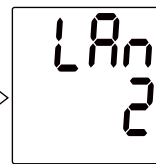
Language Selection: Bilingual English/ Hindi

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

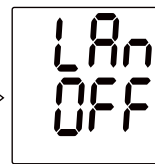
English(Default)



Hindi



Mute



### User Selection

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

- Before measurement, make sure you set the unit for the intended user. The unit can track results for 2 individuals. (User 1, User 2)
- 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.
- Click the MEMORY button to select User.

### 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.





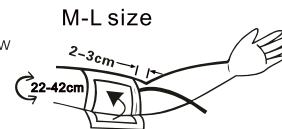
- All efforts by the patient to support the arm can increase the blood-pressure. Make sure you are in a comfortable, relaxed position and do not activate any of the muscles of the arm during the measurement. Use a cushion for support, if necessary.
- The performance of the automated sphygmomanometer 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. Make sure the air connector is fitted properly to avoid air leakage.

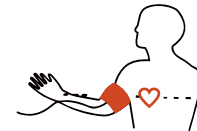


- a) The distance between the edge of cuff and the elbow should be approx. 2-3cm.



- b) Secure the cuff with the Velcro fastener, so that it lies comfortably and not too tight. Ensure that 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. Sit in the same position for 2 minutes quietly, before beginning with the measurement.



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





### 6.4. Measuring procedure

#### 6.4.1 Taking Measurement in standard mode

The standard mode only detects IHB (Irregular Heartbeat). Afib detection not possible in this mode.



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

- Press the  button, the pump begins to inflate the cuff. In the display, the increasing cuff - pressure is continually displayed.
- Cuff fitting detection: the icon  will appear and blink during measuring if cuff is too fit too loose. The icon  will appear during measuring, if cuff was fit well
- Arm movement detection during measuring: the icon  will appear, if a movement is 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)

- 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



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:** Systole 120, Diastole 80, Pulse 70,  
And IHB (Irregular Heartbeat) detected, cuff fit well.



Example 1

**Example 2:** Systole 120, Diastole 80, Pulse 70,  
And IHB (Irregular Heartbeat) detected, cuff fit too loose.



Example 1



#### To Be Noted

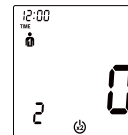
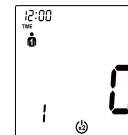
The measurement results are displayed, until you switch the device off. If no button is pressed for 3 minutes, the device switches automatically off, to save the batteries.

#### 6.4.2 Taking Measurement 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 seems to be questionable, a third one is automatically taken.

#### During the measurement:

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.





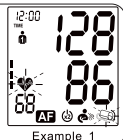
#### Measured result:

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 Heartbeat)  and Afib  will appear




#### 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

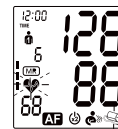
The blood-pressure monitor automatically stores each of the last 120 measurement values. By pressing the MEMORY button, an average value of the last 3 measurements as well as the last measurement and the further last 120 measurements (MR119, MR118,...,MR1) can be displayed one after the other




Measured under  mode the last 9th memory




Measured under  mode the last 8th memory



Measured under  mode the last 6th memory



Measured under  mode the last 3rd memory



The indicate "A" means an average value for the last 3 measurement



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

#### 6.7. Memory– Cancellation of All Measurements

Before you delete all readings stored in the memory, make sure you don't need them for future reference. In order to delete all stored readings, press 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

The device is clinically tested for accuracy. 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 in a week with measurements taken daily) we advise you to tell your doctor.

#### 8. APPEARANCE OF THE ATRIAL FIBRILLATION INDICATOR FOR EARLY DETECTION

This device is able to detect atrial fibrillation (AFIB). This icon  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 BP measurement 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)
Err1	No pulse has been detected.
Err2	Unnatural pressure impulses influence the measurement result. Reason: The arm was moved during the Measurement (Artifact).
Err3	The inflation of the cuff takes too long. The cuff is not correctly seated.
Err5	The measured readings indicated an unacceptable difference between systolic and diastolic pressures. Take other reading following directions carefully. Contact your doctor if you continue to get unusual readings.
Err8	Pressure is over 290 mmHg



#### 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 value although the instrument functions normally and the values displayed are normal	1. Please read the following information and the points 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

- Do not expose the device to extreme temperatures, humidity, dust, or direct sunlight.
- The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of straining through twisting or buckling.
- Clean the device with a soft, dry cloth. Do not use petrol, thinner or similar solvent. Spots on the cuff can be removed carefully with damp cloth and soapsuds. The cuff must not be washed!
- Do not drop the instrument or treat it roughly in any way. Avoid strong vibrations.
- Never open the device! Otherwise, the manufacturer calibration becomes invalid!

#### Periodical recalibration

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


We therefore recommend a periodical inspection of the static pressure display every 2 years.

## 11. SAFETY, CARE AND DISPOSAL

#### ⚠ Safety and protection

- This instrument should be used only for the purpose described in this booklet. The manufacturer would not be responsible 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 some time.

#### Instrument care

Clean the instrument only with a soft and dry cloth.

#### Disposal



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

## 12. REFERENCE TO STANDARDS

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


IEC60601-1-6:2010+A1:2013/ EN60601-1-6:2010+A1:2015
IEC60601-1:2005+A1:2012/EN60601-1:2006+A11:2011+A1:2013+A12:2014
IEC60601-1-2:2014/ EN60601-1-2:2015
IEC/EN60601-1-11:2015
IEC80601-2-30:2009+A1:2013/EN80601-2-30:2010+A1:2015

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

## 13. 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: $\pm 3$ mmHg / Pulse: $\pm 5\%$ 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:	136×112×71±1.0 mm
Weight:	540 g±5g (including batteries and cuff)
Cuff pressure display range:	0~290mmHg
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 ,adapter, string bag
<p>We are also providing the power adapter which comply to EN60601-1, EN60601-1-2 along the bp unit.</p> 	

• 14. MANUFACTURER'S DECLARATION •

Dr Trust 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	Dr Trust Afib Talk BP Monitor 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	Dr Trust 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 purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker IEC 61000-3-3	Not applicable	



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 % UT@95% dip in UT. 0 for 0.5 cycle  40 % UT@60% dip in UT 0 for 5 cycles  70 % UT(30% dip in UT) for 25 cycles  <5 % UT@95% dip in UT 0 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: UT 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	3 Vrms 150 kHz to 80 MHz 80% AM (2Hz)	3 Vrms	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 $3V$ $d = 1.2 \times \sqrt{P}$ 80MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 2MHz 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz 80% AM (2Hz)	3 V/m	

<p>Note1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>
<p>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 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 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.</p> <p>b) Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.</p>
<p><b>Recommended Separation Distances:</b></p>
<p>Recommended separation distance between portable and mobile RF communications equipment and Afib Talk.</p>
<p>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.</p>



Rated maximum output power of transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz	Separation distance according to frequency of transmitter m
	$d = 1.2 \times p^{1/2}$	$d = 1.2 \times p^{1/2}$	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.

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