

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 conveniently used at homes and even on the go.

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 Goldline with MDI - 103

QUICK START GUIDE

Step 1

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

Step 2

Before starting the measurement, make sure to do settings for the user no., language, time, and date.

Step 3

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

Step 4

After the cuff has been appropriately positioned, press the ON/OFF button and the symbols on the display light up for a few seconds to indicate the machine is ready.

Step 5

After the cuff fully inflates, air will automatically start flowing back out. Look at the screen to get your blood pressure reading.

Step 6

Wait for few seconds to get final readings for the measured systolic and diastolic blood-pressure values as well as the pulse frequency. Afterward, switch off the machine or it will switch itself off after some time.



1. INTRODUCTION

- 1.1. Measurement Principle- MDI Technology
- 1.2. Features
- 1.3. Important Information About Self-Measurement

2. IMPORTANT INFORMATION ON THE SUBJECT OF BLOOD-PRESSURE AND ITS MEASUREMENT

- 2.1. How does high/low blood-pressure arise?
- 2.2. Which values are normal?

3. THE VARIOUS COMPONENTS OF THE BLOOD-PRESSURE MONITOR

4. PUTTING THE BLOOD-PRESSURE MONITOR INTO OPERATION

- 4.1. Inserting the batteries
- 4.2. Reading the set date
- 4.3. Setting the time and date and user selection

5. CARRYING OUT A MEASUREMENT

- 5.1. Before the measurement
- 5.2. Common sources of error
- 5.3. Fitting the cuff
- 5.4. Measuring procedure
- 5.5. Discontinuing a measurement
- 5.6. Memory – storage and recall of the measurements
- 5.7. Memory full
- 5.8. Memory – cancellation of all measurements

6. APPEARANCE OF THE HEART ARRHYTHMIA INDICATOR FOR EARLY DETECTION

7. ERROR MESSAGES / MALFUNCTIONS

8. CARE AND MAINTENANCE, RECALIBRATION

9. BATTERY LIFE

10. SAFETY, CARE AND DISPOSAL

11. REFERENCE TO STANDARDS

12. TECHNICAL SPECIFICATIONS

13. MANUFACTURER'S DECLARATION

14. CONTACT US

ABOUT US



● 1. INTRODUCTION ●

Your blood pressure is an important parameter that can be used to monitor your health. Dr Trust BP Goldline with MDI enables you to monitor your blood pressure regularly and helps you to maintain a record of your blood pressure measurements. You can then use this record to assist your physician in diagnosing and maintaining a healthy blood pressure level. This is digital BP measuring device is fully automatic and comes with integrated time/date display. Intended for use on the arm, the device gives very fast and reliable measurements of the systolic and diastolic blood-pressure as well as the pulse frequency through Measurement During Inflation (MDI) technology. This device can be used at health facilities, fitness centers and other public facilities for blood pressure measurements of the visitors. It can also be used in outpatient clinics of general hospitals for BP measurements of patients. The device offers a very high and clinically tested measurement accuracy and has been designed to provide a maximum of user-friendliness.

1.1. Measurement Principle- MDI Technology

Dr Trust BP Goldline with MDI is a BP monitor with Measurement During Inflation (MDI) technology. MDI is a new technology which is faster and gives extra comfort to the arm of the patient. This product uses the Oscillometric Measuring method to detect blood pressure during inflation without creating any pressure on the arm. It allows accurate consecutive blood pressure measurements on the upper arm with minimal deviation. Better accuracy is ensured in case of repeated measurements. It measures diastolic blood pressure first during inflation and gives instant result without deflating. It classifies measurements according to the WHO evaluation system using Traffic-Light Colour scale. Also, it allows for immediate repeat measurement for comparison with least difference.

● 1.2. Features ●

- The device is intended for self-use at home.
- The device offers very high and clinically tested measurement accuracy. It has been designed to provide a maximum of user-friendliness.
- BP measurement can be performed using either the right or the left arm.
- The arm cuff is inflated around the arm by pressing the START/STOP button and deflation speed is automatically controlled.
- Easy to operate as no special adjustment is required.
- Just insert your arm into the arm insertion section to the shoulder and press the START/STOP button. The rest of the procedure is done automatically for a quick and easy measurement of blood pressure.
- It is a fully automatic, digital, blood pressure measuring device with MDI technology and a large LCD screen with backlight and big font.
- It provides a fast and reliable measurement of systolic and diastolic blood pressure as well as heart rate using the oscillometric measurement method.
- It displays pulse irregularities measured during a blood pressure reading. However, if the irregularity appears several times a week with measurement taken daily, we advise you to consult your doctor.
- Hypertension Classification Indicator displays the range between which your blood pressure values lie.
- Memory feature allows to store up to 112 blood pressure readings of 2 users with time and date.
- Unique talking feature announces results in HINDI/ENGLISH. It allows visually impaired people to make health checkups independently.



1.3. Important Information About Self-Measurement

- Do not use with neonatal patients.
- Do not intend to use with pregnant or pre-eclamptic patients.
- Keep product in proper packing. Any inadequate use will cause harmful injury to the patient or would 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.
- Avoid pressurization of cuff on any limb where intervascular access or therapy or an arteriovenous (A-V) shunt is present. It could result in injury to the patients because of temporary interference to blood flow.
- Do not let the cuff and its pressure 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.
- There is a 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.

⚠ Attention!

Points to Be Noted

- *Substitution of a different component might result in measurement error.*
- *Cuff is replaceable only by an original.*
- *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 cardiac irregularity (Arrhythmia), 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 Causes High Blood Pressure?

While the cause of high blood pressure in most people remains unclear, inactivity, poor diet, obesity, older age, and genetics -- can all contribute to the development of hypertension.

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.



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. Which values are normal?

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 for appropriate action.

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 & broadcasting	Systolic Blood-pressure	Diastolic Blood-pressure	Diastolic Blood-pressure
Hypotension	lower than 100	lower than 60	Consult your doctor
Optimal	between 100 and 120	between 60 and 80	Self-check
Normal	between 120 and 129	between 80 and 84	Self-check
High to normal	between 130 and 139	between 85 and 89	Consult your doctor
Slight hypertension	between 140 and 159	Between 90 and 99	Seek medical advice

Medium hypertension	between 160 and 179	Between 100 and 109	Seek medical advice
Strong hypertension	Higher than 180	Higher than 110	Urgently seek medical advice!

⚠ Attention!

Points to Be Noted

If your values are mostly standard under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so-called «labile hypertension». Please consult your doctor if you suspect that this might be the case.

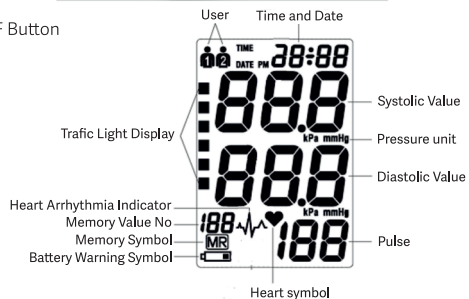
- Correctly measured diastolic blood-pressure values above 120 mmHg require immediate medical treatment.



3. COMPONENTS OF GOLDLINE BLOOD-PRESSURE MONITOR





Correct ON/OFF Button




4. OPERATIONS

4.1. Inserting the batteries

- Insert the batteries (4 x size AA 1.5V), thereby observing the indicated polarity.
- If the battery power reduces less than 20%, battery warning  appears.
- If the batteries are empty, battery warning  icon appears indicating immediate replacement by new ones.

⚠ Attention!

Points to Be Noted

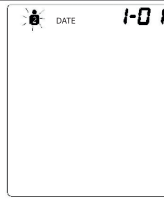
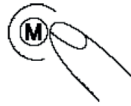
- After the battery warning  icon appears, the device is blocked until the batteries have been replaced.
- Please use «AA» long-life or alkaline 1.5v batteries.
- Please remove the batteries from the device if the blood-pressure monitor is left unused for a long period.

4.2 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 user no. for the intended user. The unit can track results for 2 individuals (User 1, User 2) with their identity.
- Press the TIME button for at least 3 seconds. The display now indicates the set user. To confirm, press ON/OFF button.
- Click the MEMORY button to select User 2.
- We suggest the first person to take their pressure to be User 1.



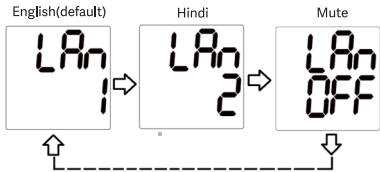


4.3. Language Selection, Time / Date Settings

Language Selection

User can select either of the two languages i.e., English & Hindi, if talking required. Else user can also mute the unit.

- 1) Press & hold on/Off button for 3 seconds. Default Language 1(Language English) will appear.
- 2) To change language to Language 2 (Hindi), press memory button one time. Press this button twice to mute. To go back to English press setting button.



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 from the following setting: 2010-06-20 09:30 o'clock. 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. Press the "MEMORY to set the unit of measurement (mmHg or kPa)



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 work

14. Rapid user select button press the user button, then  is blinking, press again to change user



Attention!

Points to Be Noted

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 pressed, you can switch more quickly to find the desired value respectively.

5. CARRYING OUT A MEASUREMENT

5.1. Before the Measurement

To ensure a reliable reading follow these recommendations:

- Avoid eating, drinking alcohol, bathing, smoking as well as any form of exertion directly before taking the measurement as all these factors influence the measurement result.
- Try to rest for 15-30 minutes by sitting in an armchair in a quite atmosphere prior to taking a measurement.
- Always take measurements in a quiet place.
- Stress raises blood pressure. So, do not take measurements during stressful times.
- Measure always on the same arm (preferably left).
- Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the day.
- Avoid wearing tight clothing on your arm.
- Do not talk, just remain still during the measurement.
- The cuff (arm) should be at the same level as your heart.



⚠ Attention!

To Be Noted

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

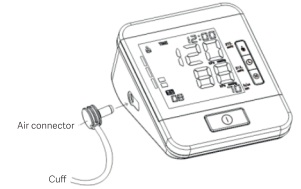
5.2. Common Sources of Error

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

- 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 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).

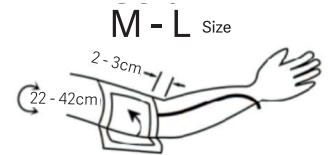
5.3. Fitting the cuff

Insert air connector into air outlet shown in the given picture and make sure the air connector is fitted properly to avoid air leakage.

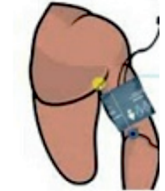


Positioning the Cuff on The Arm Correctly

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.



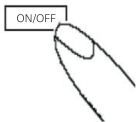
- e) Keep the legs uncrossed with feet flat on the floor and back & arm supported.



5.4. Start Taking BP Measurement

After the cuff has been appropriately positioned, the measurement can be started:

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



- b) As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation. The Heartbeat Symbol (♥) flashes with every heartbeat.

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

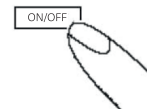


Example (Fig.): Systole 118, Diastole 73, Pulse 75

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.

5.5. Discontinuing a Measurement

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



5.6. Memory – Storage and Recall of The Measurements

The blood-pressure monitor automatically stores each of the last 60 measurement values.

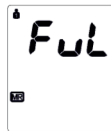
By pressing the MEMORY button, an average value of the last 3 measurements as well as the last measurement (MR1) and the further last 59 measurements (MR2, MR3, ..., MR60) can be displayed one after the other.



(MR1: Values of the last measurement) (MR2-MR60: Values of the measurement before MR1)

5.7. Memory full

Pay attention that the maximum memory capacity is not exceeded. When the memory is full, the old values are automatically Overwritten with new ones. When memory is full, the display shows the following picture for 1 sec to remind you memory is full.

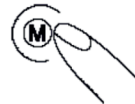


5.8. Memory – Cancellation of All Measurements


Before you delete all readings stored in the memory, make sure you do not need refer them for future reference. Keeping a written record is prudent and may provide additional information for your doctor's visit.



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 clear the memory permanently, press the MEMORY button while «CL» is flashing to indicate deletion of stored data.



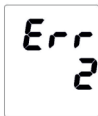
6. Appearance of the Heart Arrhythmia Indicator for Early Detection

this symbol  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.



7. ERROR MESSAGES/MALFUNCTIONS

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



(Example: Error No. 2).

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 (Artefact).
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 another reading following directions carefully. Contact your doctor if you continue to get unusual readings.
ERR8	Pressure in cuff is over 290mmHg

Further Information-

The level of blood-pressure is subjected to fluctuations even with healthy people. Important thereby is, that comparable measurements always require the same conditions (Quiet conditions)! If, in spite of fulfilling all these factors, the fluctuations are larger than 15mmHg, and/or you hear irregular pulse tones on several occasions, please consult your doctor. The MEMORY button while «CL» is flashing to indicate deletion of stored data.

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.	<ol style="list-style-type: none"> 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).	<ol style="list-style-type: none"> 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.



103

Every measurement produces a different value although the instrument functions normally and the values

1. Please read the following information and the points listed under «Common sources of error». Repeat the measurement.

Displayed are normal

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.

8. CARE AND MAINTENANCE, RE-CALIBRATION

- 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 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 Re-calibration

Sensitive measuring devices must be checked for time to time for accuracy. We therefore recommend a periodical inspection of the static pressure display every 2 years.

9. BATTERY LIFE

1000 times measurement with 4-size "AA" alkaline Batteries.

10. 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.
- This instrument comprises 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, dry cloth

Disposal



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

11. 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



12. TECHNICAL SPECIFICATIONS


Measurement Procedure	Oscillometric , corresponding to Korotkoff method: Phase I : systolic , Phase V : diastolic
Display	Digital Display
Measuring range: SYS/DIA Pulse	30 to 280 mmHg (in 1 mmHg increment) 40 to 200 beat/minute
Static accuracy: SYS/DIA Pulse	±3mmHg ±5% of reading
Measuring resolution	1mmHg
Inflation	Automatic inflation by internal pump
Memory function	Up to 199 memories (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
Measuring resolution	1mmHg
Inflation	Automatic inflation by internal pump
Memory function	Up to 199 memories (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 pressures display range	0-299mmHg/0-39.9KPa
Electrical shock protection:	Internal power unit
Safety classifications	Type BF equipment
Measuring resolution	Continuous operation
Protection against ingress of water	IPX0
Accessories	M-size Cuff, 4 "AA" batteries, instruction manual

Notice: The provided adapter is complied with EN60601-1, EN60601-1-2



13. MANUFACTURER'S DECLARATION

The Blood Pressure Monitor Goldline with MDI is intended for use in the electromagnetic environment specified below. The user of this device should need to assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	The BP Monitor Goldline with MDI 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	The BP Monitor Goldline with MDI 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 % U_T) 95% dip in U_T . (for 0.5 cycle 40 % U_T) 60% dip in U_T (for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T) 95% dip in U_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 stlye requires continued operation during power mains interruptions, it is recommended that the BP Monitor Goldline 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	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 the BP Monitor Goldline, including cables, than therecommended separation distance calculatedfrom the equation applicable to the frequency of the transmitter. Recommend separation distance 3V $d = 1.2 \times P_{1/2}^{1/2}$ 80MHz to 800 MHz $d = 2.3 \times P_{1/2}^{1/2}$ MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency rangeb . 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	



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 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 BP Monitor Goldline with MDI is used exceeds the applicable RF compliance level above, the BP Monitor Goldline with MDI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BP Monitor Goldline with MDI.

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 the BP Monitor Goldline with MDI.

The BP Monitor Goldline with MDI is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BP Monitor Goldline with MDI can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BP Monitor Goldline with MDI 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

Note1: For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

CUSTOMER SUPPORT

CONTACT ADDRESS

USA

Nureca INC.USA
276 5th Avenue, Suite 704-397,
New York (NY) - 10001, USA

INDIA

Corporate Office (Mumbai)

Nureca Limited
128 Gala Number Udyog Bhavan,
1st Floor Sonawala Lane, Goregaon East
Mumbai City Maharashtra 400063

Contact us

India: +91-7527013265 / +91-9356658436

Website: www.drtrust.in

Corp Website: www.nureca.com

Email: customercare@nureca.com

Connect with us on social networks

Facebook: @drtrust

Instagram: @drtrustisin

Youtube: NurecaUsa

COPYRIGHT©2021 NURECA LTD ALL RIGHTS RESERVED



Scan to View
Product Demo Video
www.drtrustusa.com/103