

Blood Pressure Monitor

Model : B21

User Manual



Questions or Concerns? info@alcedohealth.com · (833)682-8655

Table of Contents

Introduction and Intended Use	3
Important Information on Blood Pressure and its Measurement	6
Components of Your Blood Pressure Monitor	10
Using Your Monitor for the First Time	12
Measurement Procedure	16
Care and Maintenance	27
Warranty	28
Certifications	28
Technical Specifications	29
EMC Declaration	30

Introduction and Intended Use

This manual is for B21 models. It is a fully automatic digital blood pressure measuring device for use by adults on the upper arm at home or in your doctor's/nurse's office. It enables very fast and reliable measurement of systolic and diastolic blood pressure as well as pulse through the oscillometric method. This device offers clinically proven accuracy and has been designed to be user friendly.

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

 ${\ensuremath{\mathbb A}}$ **Warning**: Not suitable for neonatal and infants.

▲ **Warning**: Not suitable for people who cannot express their ideas correctly.

This device cannot be used together with high frequency surgical equipment.

Note:

- Only a health-care professional is qualified to interpret blood pressure measurements.
- This device is **not** intended to replace regular medical checkups.
- It is recommended that your physician review your procedure for using this device.
- Blood pressure readings obtained by this device should be verified before prescribing or making adjustments to any medications used to control hypertension. Under no circumstances should you alter the dosages of any drugs prescribed by your doctor.
- This monitor is intended for use by adults **only**. Consult with a physician before using this instrument on a child.
- In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with your doctor.
- Familiarize yourself with the section titled "Important Information on Blood Pressure and Its Measurement". It contains important information on the dynamics of blood pressure readings and will help you to obtain the best results.

• Host products, including accessories, shall be processed in accordance with local regulations after reaching the life cycle.

Note:

- This device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens) during use. These can lead to erratic results.
- **Do not** attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.

∆ Warning:

- Too frequent measurements can cause injury to the PATIENT due to blood flow interference.
- **Do not** place the cuff over wound part.
- Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb.

Contraindication

Use of this instrument on patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids could cause internal bleeding.

M Warnings and Precautions

- The device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens). These can lead to temporary impairment of the measuring accuracy.
- **Do not** use cuffs, AC adapters or batteries other than those included with this product or replacement parts supplied by the manufacturer.
- This system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.

- The separate ac adapter which is intended to connect USB interface of Blood Pressure Monitor has not been evaluated according to IEC 60601-1. The safety of the product shall be reappraised when it power supply by a separate ac adapter.
- Remove the battery if the ME EQUIPMENT is not likely to be used for some time.
- The user must check that the equipment functions safely and see that it is in proper working condition before being used.
- No modification of this equipment is allowed.
- The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- This equipment shall not be serviced or maintained while in use with the patient.
- The patient is an intended operator, the functions of monitoring blood pressure and pulse rate can be safely used by patient. The routine clean and changing batteries can be performed by the patient.
- Use of power adapters
 - ✓ Adapter: input 100-240v, 50/60hz output DC 5V 1A.

- ✓ Do not position the device to make it difficult to operate the disconnection device while using adaptor.
- Do not be prone to water leakage, high temperature, moisture, direct sunlight or more corrosive gas environment. Do not use this product in the above environment.

\mathbb{A} Cautions:

- To avoid any possibility of accidental strangulation, keep this unit away from children and **do not** drape tubing around your neck.
- To avoid damaging the device, keep this unit away from children and pets.
- The standard material used for the bladder and tubing is latex-free.
- 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, measurements made with this instrument should **only** be evaluated after consultation with your doctor.

Note:

- To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within the specified temperature and the relative humidity, please see the Technical Specifications.
- The cuff is treated as the applied part. The user should contact the manufacturer for assistance, if needed, in setting up, using or maintaining the device.

Important Information on Blood Pressure and Its Measurement

How Does High or Low Blood Pressure Arise?

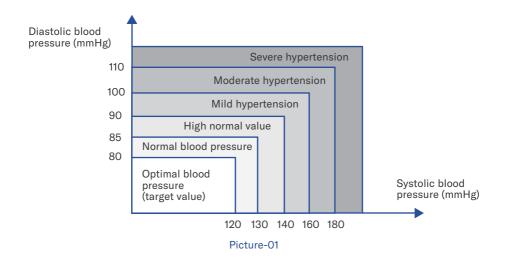
Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and speed of the heart (Pulse), as well as the width of circulatory blood vessels is altered. Blood vessel width is controlled by fine muscles in the blood vessel walls.

Your level of arterial blood pressure changes periodically during heart activity: During the "blood ejection" (Systole) the value is highest (systolic blood pressure value). At the end of the heart's "rest period" (Diastole) pressure is lowest (diastolic blood pressure value).

Blood pressure values must lie within certain normal ranges in order to prevent particular diseases.

Which Values are Normal?

Please refer to the diagram below (Picture-01)



There are six grids in the display of device. Please refer to the Table-01. Different grids represent different interval scales of WHO.

Blood Pressure Value	WHO Grids in Device	WHO Classification
DIA <80 & SYS <120	1	Optimal blood pressure
DIA <85 & SYS <130	2	Normal blood pressure
DIA <90 & SYS <140	3	High normal value
DIA <100 & SYS < 160	4	Mild hypertension
DIA <110 & SYS <180	5	Moderate hypertension
DIA >=110 or SYS >=180	6	Severe hypertension

Table-01

Blood pressure is very high if your diastolic pressure is above 90 mmHg and/or your systolic blood pressure is over 160 mmHg, while at rest. In this case, please consult your physician immediately. Long-term values at this level endanger your health due to continual damage to the blood vessels in your body. If your systolic blood pressure values are between 140 mmHg and 159 mmHg and/or the diastolic blood pressure values between 90 mmHg and 99 mmHg, consult your physician. Regular self-checks are necessary.

If you have blood pressure values that are too low, (i.e., systolic values under 105 mmHg and/or diastolic values under 60 mmHg), consult your physician. Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. You can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, keep a record of values along with time of day and date. Show these values to your physician. Never use the results of your measurements to independently alter the drug doses prescribed by your physician.

Further Information

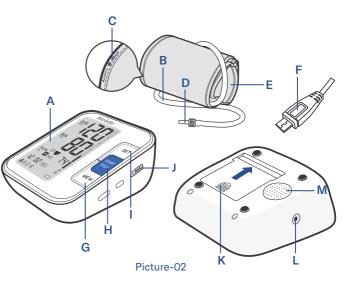
- If your values are mostly normal under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so-called "labile hypertension." Consult your doctor.
- Correctly measured diastolic blood pressure values above 120mmHg require immediate medical treatment.

What Can be Done if Regular High or Low Values are Obtained?

- Consult your doctor.
- Increased blood pressure values (various forms of hypertension) are associated with considerable health risks over time. Arterial blood vessels in your body are endangered due to constriction caused by deposits in the vessel walls (Arteriosclerosis). A deficient supply of blood to important organs (heart, brain, muscles) can result from arteriosclerosis. Furthermore, the heart will become structurally damaged with increased blood pressure values.
- There are many different causes of high blood pressure. We differentiate between the common primary (essential) hypertension, and secondary hypertension. The latter group can be ascribed to specific organ malfunctions. Please consult your doctor for information about the possible origins of your own increased blood pressure values.
- There are measures which you can take to reduce and even prevent high blood pressure.

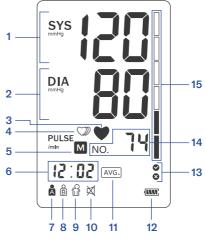
Components of Your Blood Pressure Monitor

- A. LCD Display
- B. Air Hose
- C. Artery Mark
- D. Air Plug
- E. Cuff
- F. Micro USB Power Cable
- G. Memory Button
- H. Start / Stop Button
- I. Set Button
- J. AC Adapter Port
- K. Battery Compartment
- L. Cuff Connector Port
- M. Speaker



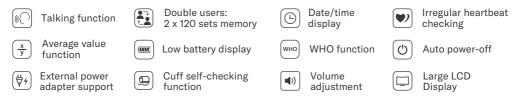
The Symbols on the LCD Display

- 1. Systolic Blood Pressure
- 2. Diastolic Blood Pressure
- 3. Heartbeat Symbol (Flashes During Measurement)
- 4. Irregular Heartbeat Symbol
- 5. Memory Symbol
- 6. Date/Time Display
- 7. USER A
- 8. USER B
- 9. Movement Error Symbol
- 10. Mute Symbol
- 11. Average Value Symbol
- 12. Low Battery Symbol
- 13. Cuff Self-Checking Function
- 14. Pulse Unit Symbol
- 15. WHO Function Symbol



Picture-03

Features of Model B21



Note: Arm circumference should be measured with a measuring tape in the middle of the relaxed upper arm. Do not force cuff connection into the opening. Make sure the cuff connection is not pushed into the AC adapter port.

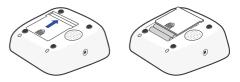
Using Your Monitor for the First Time

Battery Installation

Use only 1.5V "AAA" alkaline batteries with this device.

1. Press the hook on the bottom of the battery cover and lift the cover off in the direction of the arrow.

2. Install 4 "AAA" size batteries so the + (positive) and - (negative) polarities match the polarities of the battery compartment, replace the battery cover. Make sure that the battery cover is securely in position.



Battery Replacement

Low Battery Indicator



- 2. To prevent the damage of monitor from leaked battery fluid, please take out of battery if the monitor unused in a long time (generally more than 3 months). If battery fluid get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.
- 3. Attached battery is only for testing the function of the monitor. Long-life alkaline batteries are recommended.

- 4. Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
- 5. Battery is dangerous stuff, do not mix it with other rubbish.

Micro USB Power Cable

You may also use the monitor with the 5V micro USB power cable. Only use an approved micro USB power cable to avoid damaging the monitor.



- 1. Make sure the power cable is not damaged.
- 2. Plug the cable into the power socket on the right side of the blood pressure monitor.
- 3. Plug the USB into a 5V powered USB port.

Note:

- No battery power is consumed while the micro USB power cable is plugged in.
- If electrical power is interrupted (such as by accidentally unplugging the monitor from the power socket), the monitor must be reset by removing the power cable from the power socket on the monitor and reinserting it.

System Settings

Press the **SET** button and hold it for more than 3 SECONDS. The User symbol will then flash. Set User, Date and Time, and Talking Volume follow the steps below.

Setting the User:





- 1. Press the **MEM** button to select User A or User B.
- 2. Then press **SET** button to confirm.

Setting the Year:

When the year display is flashing, press the **MEM** button, the year will increase by 1 year each, hold the **MEM** button and it will increase continuously 1 by 1, and then rollover to initial year, once the year set is OK, press **SET** button to confirm.

Setting Month/Date:

Initial Month/Date is 1/01, when the Month display is flashing, press the **MEM** button, the month will increase by 1, press **SET** button to confirm, and follow the same way to set the date. Press **SET** button to confirm.

Setting Time:

When the hour display is flashing, press the **MEM** button, the hour will increase by 1, press **SET** button to confirm, and follow the same way to set the minute. Press **SET** button to confirm.



Setting Volume:

When display with SP is flashing, press **MEM** button to switch volume 1, volume 2, volume 3 or OFF. Press **SET** button to confirm.



Delete All Saved Results:

Select a user. Press **MEM** button to display results. Press and hold again until all measurements turn 0.



Note:

- You can't delete individual results. All results will be deleted at once.
- Taking out the batteries will not delete saved results. However, it will reset some of your settings, such as date, time, and speaker volume.

Cuff Tube Connection

Insert the cuff tube into the opening on the left side of the monitor indicated by the drawing of a cuff.



Measurement Procedure

Note: You should always be seated and calm before and during measurement.

Before Measurement:

- Avoid eating and smoking as well as all forms of exertion directly before measurement. These factors influence the measurement result. Find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before taking a measurement.
- Remove any garment that fits closely to your upper arm.
- Always measure on the same arm (normally left).
- Always compare measurements taken at the same time of day, since blood pressure changes during the course of the day, as much as 20-40 mmHg.

Common Sources of Error:

Note: Comparable blood pressure measurements always require the same conditions.

- Conditions should always be quiet.
- All efforts by the user to support the arm can increase blood pressure. Make sure you are in a comfortable, relaxed position and do not flex any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
- If the arm artery lies considerably lower or higher than the heart, an erroneously high or low blood pressure will be measured. Each 25-30 cm difference in height between your heart and the cuff results in a measurement error of 10 mmHg.
- Cuffs that are too narrow or too short result in false measurement values. Selecting the correct cuff is extremely important. Cuff size is dependent upon the circumference of the arm (measured in the center). The permissible range is printed on the cuff.

Cuff works under the pressure range 0-300 mmHg. The wide range rigid cuff is: 8.7" – 15.7" (22 - 40 cm).

Note: Only use approved cuffs!

- A loose cuff or a sideways protruding air pocket causes false measurement values.
- With repeated measurements, blood accumulates in the arm, which can lead to false results. Consecutive blood pressure measurements should be repeated after a 1 minute pause or after your arm has been held up in order to allow the accumulated blood to flow away. If you decide to take your Averaging Mode measurement again, be sure to wait at least one minute beforehand.

Fitting the Cuff

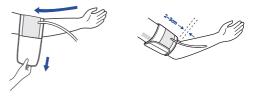
Please refer to Picture-04

- 1. The cuff is pre-formed for easier use. Remove tight or bulky clothing from your upper arm.
- Wrap the cuff around your upper left arm. The rubber tube should be on the inside of your arm extending downward to your hand. Make certain the cuff lies approximately 1/2" to 3/4" (2 to 3 cm) above the elbow.

Important! The **①** on the edge of the cuff (Artery Mark) must lie over the artery which runs down the inner side of the arm.

- **3.** To secure the cuff, wrap it around your arm and press the hook and loop closure together.
- 4. There should be little free space between your arm and the cuff. You should be able to fit 2 fingers between your arm and the cuff. Cuffs that don't fit properly result in false measurement values. Measure your arm circumference if you are not sure of proper fit.
- 5. Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked.
- 6. Remain seated quietly for at least two minutes before you begin the measurement.





Picture-04

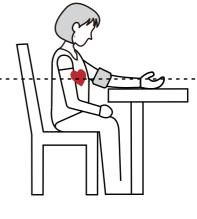
Measure Procedure

Please refer to Picture-05

Sit comfortably in a chair with your feet flat on the floor. Stretch your arm forward on the desk and keep relaxing, make sure the palm of hand is upturned. Make sure arm is in correct position, to avoid body movement. Sit still and do not talk or move during the measurement. After the cuff has been appropriately positioned on the arm and connected to the blood pressure monitor, the measurement can begin:

- 1. Select your User ID (A or B).
- 2. Press the **START/STOP** button. The pump begins to inflate the cuff. In the display, the increasing cuff pressure is continually displayed.
- 3. After automatically reaching an individual pressure, the pump stops and the pressure slowly falls. The cuff pressure is displayed during the measurement.
- 4. When the device has detected your pulse, the heart symbol in the display begins to blink.

5. When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse will be displayed.



Picture-05

Memory

At the end of a measurement, this monitor automatically stores each result with date and time. Each unit stores 120 sets measurements for 2 users, totally 240 sets (User A and B).

Mute/Unmute



- 1. When the monitor is OFF, press the **SET** button. The time and user symbol will display.
- 2. Press SET button to turn on the mute.
- 3. Press the SET button again to turn off the mute.

Switch User

A B

- Press **SET** button and hold it for more than 3 seconds until the User Symbol flash.
- Press **MEM** button to select user A or B.
- Then press **START/STOP** button to turn off the device.

Viewing the Stored Values



- 1. Press the **MEM** button. Select a user (A or B).
- 2. The first display reading with AVG symbol AVG. is the average of the last 3 results.
- 3. Press **MEM** again to view each result, beginning with the most recent measurement taken.
- 4. Press MEM again to view the next result.
- 5. Alternatively, press and hold **MEM** to scroll to any result.

Discontinuing a Measurement

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

Display Readings

The measurement results are displayed until you switch the device off. If no button is pressed for 60 seconds, the device switches off automatically.

Cuff Placement Indicators



Cuff is placed correctly



Cuff is placed incorrectly

If S is displayed, make sure the cuff is plugged in, and check to see if the cuff is too lose or too tight. Adjust accordingly until S is displayed.

Movement Error Indicator

ഷ

This will display if the monitor has detected movement. Remove the cuff and wait 2-3 minutes. Replae the cuff and measure again. Do not move during measurement.

Irregular Heartbeat Indicator



This will display if an irregular heartbeat is detected during measurement. The result may differ from your normal basal blood pressure.

This indicator is only a caution. In most cases. there is no cause for concern-simply repeat the measurement. Stay relaxed, remain still, and avoid talking during measurement.

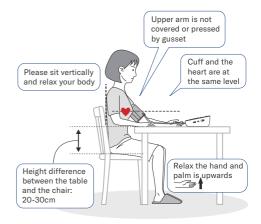
If you see the irregular heartbeat indicator regularly (such as several times a week with measurements taken daily), contact your physician.

Note: Patient Position

- · Comfortably seated
- Legs uncrossed
- Feet flat on the floor .
- Back and arm supported •
- Middle of the cuff at the level of the right atri-. um of the heart

Recommended Use Methods

- Recommend that the patient relax as much as possible and not talk during the measurement procedure.
- Recommend that take a 5 min break between measurements.
- Any reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition.
- Performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- To stop the inflation or measurement, push the **START/STOP** button. The monitor will stop inflating, start deflating, and will turn off.
- After the monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed.
- The monitor will automatically turn off after one minute.



Picture-06

Display Error Readings

Symbol	Cause	Solution
No display appears	Weak battery or improper placement	Replace both batteries with new ones. Check the bat- tery installation for proper placement of the battery polarities.
Enl	Sensor abnormal	Check if the pump is working or not. If it is working, then the problem is sensor abnormal. Please send it to the local distributor.
Er2	Monitor could not detect pulse wave or cannot calculate the blood pressure data	Check if the air releasing is too slow or not. If it is too slow, please check if there is any dust in the tube plug of the cuff and the cuff port in the device. If yes, please clean and start the measurement again. If no, please send the device back to the local distributor.
Er3	Measurement result is abnormal (SYS≦45 mmHg, DIA≦24 mmHg)	Occasionally - measure for one more time/Always - send it to local distributor.
ErM	Too loose cuff or air leakage (Cannot inflate to 30 mmHg within 15 s)	Tie the cuff correctly and make sure the air plug is properly inserted in the unit.
EnS	The air tube is crimped	Correct it and make the measurement again.
Erő	The sensor is sensing great fluctuation in the pressure	Please keep quiet and don't move.

Symbol	Cause	Solution	
Erl	The pressure that the sensor sensing is over the limit	Please send back to the local distributor.	
ErB The demarcation is incorrect or the device has not been demarcated		Please send back to the local distributor.	

Trouble Shooting

Problem	Check This	Solution
Check the battery power		Replace new batteries
No power	Check the polarity position	Installation batteries correctly
Whether the plug is inserted		Insert plug into the air socket tightly
No inflation	Whether move the arm when inflate	Change a new cuff
Error and stop Whether the plug is broken or leak		Keep the body peaceful
working Check if chatting when measured		Keep quite when measure
Cuff leak Whether the cuff wrap too loose		Wrap the cuff tightly
Whether the cuff broken		Change a new cuff

 ${\Bbb A}$ Please contact the distributor if you can't solve the problem. Do not disassemble the unit by yourself.

Symbol Descriptions

The following symbols may appear in this manual, on the Digital Blood Pressure Monitor, or on it's accessories. Some of the symbols represent standards and compliances associated with the Digital Blood Pressure Monitor and its use.

EC	REP

Authorized Representative in the European Community

- CF Mark: conforms to essential CE requirements of the Medical Device Directive 93/42/EEC.
- lm Date of manufacture.
 - Manufacturer
- SN Specifies serial number
- ★ Type BF applied part
- Direct current
 - Temperature range



Disposal: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treat ment is necessary.



Follow instructions for use



Put up



Fragile



Keep dry



Avoid the sun



Handle gently

No Sterilize requirement Not category AP / APG equipment Mode of operation: continuous

X

Replacing Batteries

When it is time to replace the batteries, ____ will flash on the display. You cannot take any further measurements and must replace the batteries.

To Replace the Batteries:

- **1.** Turn the monitor upside down and remove the battery compartment cover.
- 2. Remove the batteries and insert new batteries.
- 3. Replace the battery compartment cover.

Note:

- Use 4 new 1.5V AAA long-life, alkaline batteries. If using reusable batteries, only use "NiMH" reusable batteries.
- Taking out the batteries will reset the date and time but will not delete saved results. To reset the date and time, see Setting the Date and Time (page 14).
- Do not use batteries beyond their expiration date. If the monitor is not going to be used for a prolonged period the batteries should be removed.

- Do not allow batteries to run out of charge inside the monitor. This will damage the monitor. Always replace batteries once appears on the display.
- If you do not intend to use the device for a week or more, always remove or recharge batteries!

Using the AC Adapter

You may also operate this monitor using the AC adapter (output 5V DC/1A with Micro USB plug).

Note: AC Adapter is not included in this product. It is sold separately.

Use only the approved AC adapter to avoid damaging the unit.

- Ensure that the AC adapter and cable are not damaged.
- Plug the adapter cable into the AC adapter port on the right side of the blood pressure monitor.
- Plug the adapter into your electrical outlet. When the AC adapter is connected, no battery current is consumed.

Note: No power is taken from the batteries while the AC adapter is connected to the monitor. If electrical power is interrupted, (e.g., by accidental removal of the AC adapter from the outlet) the monitor must be reset by removing the plug from the socket and reinserting the AC adapter connection.

Care and Maintenance

- Wash hands after each time measurement.
- If one device is used by different patients, wash hands before and after each use.
- Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
- The cuff contains a sensitive air-tight bubble. Handle this cuff carefully and avoid all types of stress through twisting or buckling.
- Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.

- Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.
- Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.
- Never open the monitor! This invalidates the manufacturer's warranty.
- Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

Accuracy Test

Sensitive measuring devices must be checked for accuracy from time to time. We recommend a periodical inspection of your unit by an authorized dealer every 1 year. Please turn to local distributor or the manufacturer.

Warranty

Your blood pressure monitor is guaranteed for 1 year against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties.

Warranty only applies to the instrument. All accessories including the cuff are guaranteed for one year, USB charging cable is not included.

There are no user serviceable parts inside. Batteries or damage from old batteries is not covered by the warranty.

Note: According to international standards, your monitor should be checked for accuracy every year.

Certifications

Device Standard

This device is manufactured to meet the European blood pressure monitors: IEC 80601-2-30 · IEC60601-1-11 · IEC60601-1

Electromagnetic compatibility:

Device fulfills the stipulations of the International standard IEC60601-1-2

Package Contents

- 1 × Blood Pressure Monitor
- 1 × Cuff
- 4 x AAA Batteries
- 1 x Micro USB Cable
- 1 x Storage Bag
- 1 × User Manual
- 1 × Quick Start Guide

Technical Specifications

Model	B21
Weight	228.1 g (Batteries are not included)
Display	64*95 mm【2.52"x3.74"】 LCD Digital Display
Monitor Size	11.8 x 11x 5.2 cm / 4.65 x 4.33 x 2.05 inch
Cuff Circumference	8.7" – 15.7" (22 - 40 cm)
Operating Conditions	Temperature: 5°C - 40°C / 41°F - 104°F Relative Humidity: 15% - 93%
Storage and Shipping Conditions	Temperature: -25°C to 70°C / -13°F to 158°F Relative Humidity: ≤ 93%
Atmospheric Pressure Range	70 kPa~106 kPa
Measuring Method	Oscillometric
Pressure Sensor	Resistive
Measuring Range	SYS:60-230mmHg DIA:40-130mmHg

Pulse	40 to 199 per minute	
Cuff Pressure Display Range	<300 mmHg	
Memory	Automatically stores the last 120 measurements for 2 users (total 240)	
Measuring Resolution	1 mmHg	
Accuracy	Pressure within ± 3 mmHg pulse ± 5 % of the reading	
Power Source	a) 4*AAA batteries, 1.5 V b) AC adapter INPUT: 100-240 VAC 50/60 HZ_OUTPUT: 5V DC 1A	
Automatically Power off	60 seconds	
Users	Adult	
Expected Service Life of the Device and Accessories	5 years	
Technical alterations reserved		

EMC Declaration

- This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
- 2. Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
- 3. Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation.
- 4. **Caution:** This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary. This machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission

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

Emission test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The device use RF energy only for its internal function. There- fore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B		
Harmonic emissions IEC 61000-3-2	Not applicable	The device is suitable for use in all establishments, including domestic establishments other than domestic and those di-	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	rectly connected to the public low-voltage power supply net- work that supplies buildings used for domestic purposes.	

Guidance and manufacture's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic ma- terial, the relative humidity should be at least 30%.	
Electrical 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 typ- ical commercial or hospital environment.	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270°, 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycle 0% UT; 250/300 cycle	Not applicable	Mains power quality should be that of a typ- ical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be pow- ered from an uninterruptible power supply or a battery.	

Guidance and manufacture's declaration – electromagnetic immunity			
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical lo- cation in a typical commercial or hospital environment.
NOTE : UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	ISM band 6 V RMS	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance cal- culated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance d=0.35 √p d=1.2 √p

Gui	dance and manufact	ure's declaration – e	lectromagnetic immunity
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	80 MHz to 800 MHz: d=1.2 \sqrt{p} 800 MHz to 2.7 GHz: d=2.3 \sqrt{p} Where, P is the maximum output power rating of the transmitter in watts (W) ac- cording to the transmitter manufacturer and d is the recommended separation distance. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance $\begin{pmatrix} (\cdot, \cdot) \end{pmatrix}$ level in each frequency range. Inter- ference may occur in the vicinity of equip- ment marked with the following symbol:
NOTE 2 These gui	z and 800 MHz, the high delines may not apply in stion from structures, ob	all situations. Electroma	lies. gnetic propagation is affected by absorption
land mobile ra theoretically wit tromagnetic sit device is used e normal operatio re-orienting or r	dios, amateur radio, AM chaccuracy. To assess th e survey should be cons exceeds the applicable F on. If abnormal perform relocating the device.	A and FM radio broadca e electromagnetic enviro sidered. If the measured RF compliance level abc ance is observed, addit	for radio (cellular/cordless) telephones and ast and TV broadcast cannot be predicted onment due to fixed RF transmitters, an elec- d field strength in the location in which the ove, the device should be observed to verify ional measures may be necessary, such as would be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 $d\!=\!1,2\sqrt{P}$	80 MHz to 800 MHz $d=1, 2\sqrt{P}$	800 MHz to 2.7 GHz $d\!=\!2,3\sqrt{P}$		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by a bsorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

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

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{a)}	Maximum power (w)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse Modulation ^{b)} 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ^{c)} ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800,			0.3	28
870		IDEN 820, CDMA 850, LTE Band 5	Pulse Modulation ^{b)} 18 Hz	2		
930						

1720		GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3 4, 25;UMTS	Pulse Modulation ^{b)} 217 Hz	2	0.3	28
1845	1700 - 1990					
1970						
2450	2400 - 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation ^{b)} 217 Hz	2	0.3	28
5240		WLAN 802.11 Puls a/n		0.2	0.3	9
5500	5100 - 5800		Pulse Modulation ^{b)} 217 Hz			
5785						

and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation. 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Guidance and manufacturer's declaration - electromagnetic immunity

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d} \sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

Customer Support

If you have any questions or concerns about your product, please contact our helpful Customer Support Team.*

- 🗹 Email: info@alcedohealth.com
- **C** Toll-Free: (833)682-8655
- www.AlcedoHealth.com

Support Hours

Monday-Friday 10:00 am - 4:00 pm EST

Distributed by:

Nature Major Inc.

500 7th Ave New York, NY 10018

*Please have your order invoice and order ID ready before contacting Customer Support.