B21HT英文成册，
材质：封面光面128g铜版纸，内页普通80g书写纸，
尺寸：100×140mm

Manufactured for Ease Healthcare (www.ease.healthcare) by:

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ease HEALTHCARE

Blood Pressure Monitor

Model Number: B21HT

USER'S MANUAL

CONTENTS

1 Introduction and Intended Use

The device is a fully automatic digital blood pressure measuring device using an oscillometric technique to measure systolic and diastolic blood pressure as well as the pulse for adults that aged 12 years or older by wrapping the cuff around the upper arm with cuff circumference ranging from 22 cm to 42 cm. The device can be used in medical facilities or at home, and only for indoor use.

Counterirritation: The device is not used for patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids.

The device is provide accurate blood pressure measurement values that are effective and suitable for clinical and home use.

Before using, please read this instruction manual carefully and then keep it in a safe place.

1.1 Remember...

- Only a health-care professional is qualified to interpret blood pressure measurements.
- This device is NOT intended to replace regular medical checkups.
- The device is intended for use by adults only and not intended for use on children or pregnant patients. The effectiveness has not been established in pregnant (including pre-eclamptic) patients.
- In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with a physician.
- The products, including accessories, shall be processed in accordance with local regulations after reaching the life cycle.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.2 Warnings and cautions ⚠

Do not use the AC adapter if the unit or the power cord is damaged. Turn off the power and unplug the power cord immediately.
The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
If the patient is an intended operator, the functions of monitoring blood pressure and pulse rate can be safely used by patient. Cleaning and changing of the batteries can be performed by the patient.
The device provides a DC input port connected to external AC adapter. It is recommended that to use the adapter specified by the manufacturer. The adapter should meet the following conditions: class II equipment, output voltage: DC 5V, current: ≥1A, and comply with IEC 60950, IEC 60601-1 or IEC 62368-1, provide at least two MOOP insulation between ac input and dc output. The external adapter connected to medical electrical equipment through the DC input port must comply with the respective IEC or ISO standards (e.g. IEC 60950 or IEC 62368-1 for data processing equipment). Further more all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, 60601-1-2, respectively). Anybody connecting the external adapter to medical electrical equipment configurations a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.
Too frequent measurements can cause injury to the patient due to blood flow interference.
Don't 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.
Regularly check the operation of the blood pressure monitor to ensure that it does not cause long-term damage to the patient's blood circulation.
Applying the cuff and its pressurization on the side of the patient's mastectomy or lymph node removal can cause injury.
To avoid any possibility of accidental strangulation, keep this device away from children and do not drape tubing around your neck.
The user must check that the equipment functions safely and see that it is in proper working condition before being used.

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.
The device is intended to monitor, not to diagnose. Unusual values should always be discussed with a physician. Under any circumstance, you should not alter the dosages of any drugs prescribed by a physician.
The device cannot be used to substitute the professional ECG monitor device for monitoring the frequency of heart beat.
This device can not be used together with HF surgical equipment.

Note:
- To obtain the greatest accuracy from your blood pressure monitor, it is recommended that the instrument be used within the specified temperature and the relative humidity, please see the technical specifications.
- The device can not be used in an MRI environment.
- The cuff is defined as the applied part. The user should contact the manufacturer for assistance, if needed, replacing, or maintaining the device.
- 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 the local distributor or the manufacturer.

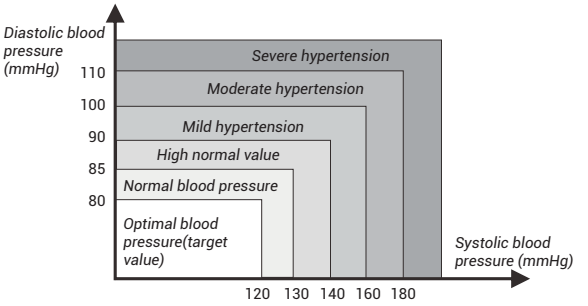
2 Important Information on Blood Pressure and its Measurement

2.1 How does high or low blood pressure rise?

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.
The 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).

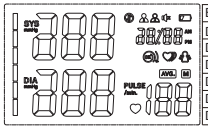
2.2 Which values are normal?

Please refer to the diagram below (Picture-01)



Picture-01

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

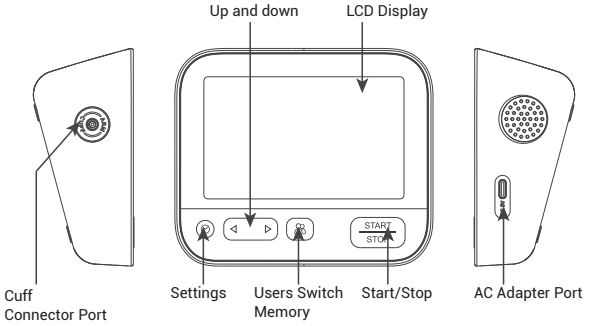


Blood pressure value	WHO grids in device	WHO Classification
DIA<80 & SYS <120	1	Optimal blood pressure
DIA<85 & SYS <130	2	Normal blood pressure
DIA<90 & SYS <140	3	High normal value
DIA<100 & SYS <160	4	Mild hypertension
DIA<110 & SYS <180	5	Moderate hypertension
DIA>=110 or SYS >=180	6	Severe hypertension

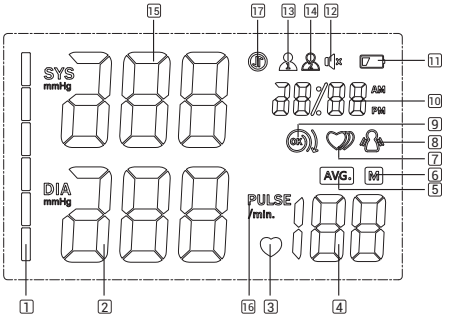
Picture-01-01

3 Components of the B21HT blood pressure monitor

3.1. Measuring unit



Picture-02



Picture-03

3.2 The symbols on the LCD display

1. WHO Function symbol
2. Diastolic blood pressure
3. Heartbeat symbol (Flashes during measurement)
4. Pulse display/ Memory number
5. Average value symbol
6. Memory symbol
7. Irregular heartbeat symbol
8. Movement error symbol
9. Cuff self-checking function
10. Date/Time display
11. Battery low symbol
12. Voice on or mute symbol
13. USER 1
14. USER 2
15. Systolic blood pressure
16. Pulse unit symbol
17. Bluetooth symbol

3.3 Features of Model B21HT

1. Voice function
2. Double users: 2 x 120 sets memory
3. Cuff self-checking function
4. Irregular heartbeat checking
5. Average value function
6. Low battery display
7. WHO function
8. Auto power-off
9. External power adapter support
10. Volume adjustment
11. Date/time display
12. Bluetooth function

4 Using the B21HT Monitor for the First Time

4.1 System settings

After you load the battery or connect power for the monitor

Setting the users

Press the and then you can set the A/B user

Setting the year/month&date/time/volume

Long press the button for more than 3s and then you can start to set.

Setting the year

When the year display is flashing, press the button to adjust, the year will reduce or increase by 1, once the year Setting is OK, press the button to confirm.

Setting month/date

Initial Month/Date is 1/01, when the Month display is flashing, press the button Adjust , the month will reduce or increase by 1, press the button to confirm, and do in the same way to set the date, press the button to confirm.

Setting time

When the hour display is flashing, press the button to increase or reduce the hour by 1. When the time setting is completed, press the button to confirm, Repeat this process to set the minutes.

Setting volume

When the display is flashing "SP", press the button to adjust the volume (1, 2, 3, or OFF). Press the button to confirm.

4.2 Cuff tube connection

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

5 Measurement procedure

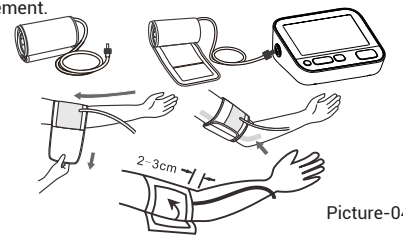
5.1 Before measurement:

- Avoid eating and smoking and all forms of extrusion 10 minutes 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 the upper arm.
- Always measure on the same arm (normally left).
- Always compare measurements taken at the same time of the day because blood pressure can change by as much as 20-40 mmHg during the course of a day.

5.2 Fitting the cuff

Please refer to picture-04

1. The cuff is preformed for easier use. Remove tight or bulky clothing from your upper arm.
2. Wrap the cuff around the upper left arm. The rubber tube should be on the inside of your arm extending downward towards your hand. Make certain the cuff lies approximately 2 to 3 cm) above the elbow. Important! The Φ 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 the arm and press the hook and loop closure together.
4. There should be little free space between the arm and the cuff. It should be able to fit 2 fingers between the arm and the cuff. Cuffs that don't fit properly result in false measurement values. Measure the arm circumference if you are not sure of the proper fit.
5. Lay your arm on a table (palm upwards) so the cuff is at the same height as the heart. Make sure the tube is not kinked.
6. Remain seated quietly for at least two minutes before you begin the measurement.



Picture-04

5.3 Measure procedure

Refer to picture 05.The monitor is designed to take measurements and store the measurement values in memory for two people using User ID 1 and User ID 2.

1. Sit comfortably in a chair in front of a table with feet flat on the floor.
2. Select the User ID (1 or 2).Stretch your arm forward on the table 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:

Operate on the device

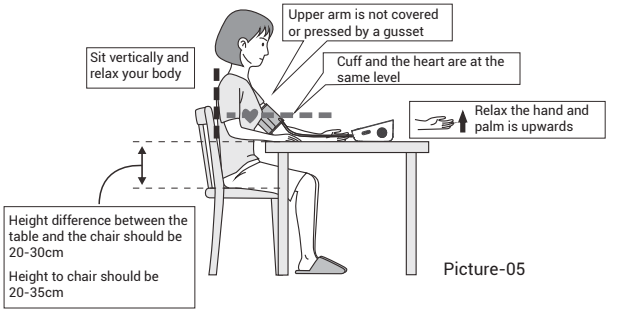
1. Press the Stop/Start button to begin the measurement process, The pump will be begin to inflate the cuff. The increasing cuff pressure will be shown in the display.

Note: If the voice is playing, you can skip the voice by pressing the( ) button before the pump begins to inflate the cuff.

2. After automatically reaching an individual pressure, the pump will stop causing the pressure to slowly decrease. The cuff pressure will be continually displayed during the measurement.
3. When the device has detected your pulse, the heart symbol in the display will begin to blink.
4. When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse will be displayed.
5. The measurement results will be displayed until switch the device off. If no button is pressed for 60S, the device will switch off automatically.
6. Cuff self-checking symbol ( ) will be displayed if the cuff position is correct, otherwise the wrong symbol( ) will be displayed. Check again to see if the cuff displays the wrong symbol( ).
7. Movement error symbol ( ) is displayed if you move your body during the measurement. Remove the cuff, and wait 2-3 minutes. Reapply the cuff and take another measurement.

Recommended Use methods

1. Recommendation that the patient should relax as much as possible and do not talk during the measurement procedure.
2. It is recommended that 10 minutes should elapse before the first reading is taken.
3. Any reading can be affected by the measurement site, the position of the patient, exercise, or the patients' physiologic condition.
4. Performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity, and altitude.
5. To stop the inflation or measurement, push the Start/Stop button. The monitor will stop inflating, start deflating, and will turn off.
6. After the monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed.
7. The monitor will automatically turn off after one minute.



Picture-05

5.4 Irregular heartbeat detector

This symbol indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal basal blood pressure so repeat the measurement. It is recommended to inform a medical professional if there is a frequent appearance of the irregular heartbeat symbol. This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested.
If pulse irregularities occur during measurement, the irregular heartbeat symbol is displayed after the measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend the patient to seek medical advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

5.5 Error indicates

The following symbols will appear on the display when measuring abnormal.

SYMBOL	CAUSE	CORRECTION
No display appears	Weak battery or improper placement	Replace both batteries with new ones. Check the battery installation for proper placement of the battery polarities.
Er 1	Sensor abnormality	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.
Er 2	Monitor could not detect pulse wave or cannot calculate the blood pressure data	Tie the cuff correctly and make the measurement again. If the error is still displayed, please send it to local distributor
Er 3	Measurement results are abnormal or out the measurable range of blood pressure	Keep silent,don't move,and measure again.
Er 4	Too loose cuff or air leakage	Tie the cuff correctly and make sure the air plug is properly inserted in the unit
Er 5	The air tube is crimped	Correct it and make the measurement again
Er 6	The sensor is sensing great fluctuation in the pressure	Keep quiet and don't move
Er 7	The pressure that the sensor sensing is over the limit	Return the unit back to the distributor
Er 8	The demarcation is incorrect or the device has not been demarcated	Send back to the local distributor
HI	The pulse rate exceeds the upper limit (>199 per minute)	Beyond the measurement range, normal reminder
LO	The pulse rate is less than the lower limit (<40 per minute)	Beyond the measurement range, normal reminder

TROUBLE REMOVAL

Problem	Check	Cause and solutions
No power	Check the battery power	Replace the batteries
	Check the battery's polarity orientation	Reinstall the batteries in the correct orientation
No inflation	Check if the plug is inserted	Insert plug into the air socket tightly
	Check whether the plug is broken or leak	Change a new cuff
Err and stop working	Check whether the arm moved during the reading	Keep the body peaceful
	Check if the user was talking	Keep quite when measure
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly
	Check whether the cuff is broken	Change a new cuff
⚠ Please contact the distributor if you can't solve the problem, do not disassemble the unit by yourself!		

5.6 Memory

At the end of a measurement, this monitor will automatically store each result with its date and time. Each unit stores 120 sets measurements for each of two users (240 total data sets), totally 240 sets (User 1 and 2). Be certain that you are viewing the measurements for the correct user.

Viewing the stored values

With the unit off, press the ( ) button. The monitor will display User ID and the average value of the last 3 times measurements stored in the unit. (If there are less than 3 sets of measurements, the monitor will display the first set), press the ( ) button to query different measurements.

Delete memory

In average value memory viewing mode, the average value symbol (AVG.) is being displayed, long press the ( ) button for 3 seconds which will delete all measurements for the current user.
In the single set memory viewing mode, long press the ( ) button for 3 seconds to delete the measurement set being displayed.

Note: If you decide to delete a record, please keep the record in another way, in case you need it at a later date. Taking the battery out will not lead to a records being lost.

5.7 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 will then immediately lower the cuff pressure automatically.

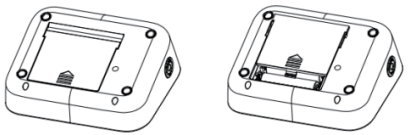
5.8 Battery charge indicator

Batteries discharged– replacement batteries are required

When the batteries are discharged, the battery symbol will flash as soon as the instrument is switched on. You cannot take any further measurements and must replace the batteries.

The battery compartment is located on the back side of the unit

1. Remove the cover from the bottom plate, as illustrated below in picture-06
2. Insert the batteries (3x AA). Always use long life batteries or alkaline 1.5V batteries.
3. After battery replacement, the memory will retain all values, although the date and time must be reset - the year number therefore, flashes automatically after the batteries are replaced.
4. To set the date and time, follow the procedure described in Section 4.2.



Picture-06

Additional information about batteries

Use three new, longlife 1.5V AA batteries. 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.

Using rechargeable batteries

You can also operate this instrument using rechargeable batteries.

- Only use "NiMH" reusable batteries.
- If the battery symbol shows a depleted battery ( ), the batteries must be removed and recharged, They must not remain inside the instrument as they may become damaged through total discharge even when the instrument is switched off. The batteries must NOT be discharged in the blood pressure monitor. If you do not intend to use the instrument for a week or more, always remove the rechargeable batteries!
- Recharge these batteries using an external charger and follow manufacturer's instructions carefully.

5.9 Using the AC adapter

You may also operate this monitor using the AC adapter (output DC 5V 1A with TYPE-C plug).

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

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

(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.

6 Care and maintenance

1. Wash hands after each time measurement.
2. If one device is used by different patients, wash hands before and after each use.
3. Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
4. The cuff contains a sensitive air-tight bladder. Handle this cuff carefully and avoid all types of stress through twisting or buckling.
5. Clean the device with a soft, dry cloth. Do not use, 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.
6. Handle the tube carefully. Do not pull on the tube or allow it to kink or come in contact with sharp edges.
7. Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.
8. Never open the monitor. This invalidates the manufacturer's warranty.
9. Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

6.1 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 refer to the local distributor or the manufacturer.

7 Warranty/service

Your blood pressure monitor is guaranteed for 1 year against manufacturer's defects for the original purchaser only, from the date of purchase. The warranty does not apply to damage caused by improper handling, accidents, unprofessional use, not following the operating instructions, or alterations made to the instrument by third parties.
The warranty applies to the instrument including the cuff, but excludes the TYPE C charging cable.
There are no user serviceable parts inside. Batteries or damage caused by old batteries is not covered by the warranty.
Note: According to international standards, your monitor should be checked for accuracy every year.

8 Certifications

Device standard:
This device is manufactured to meet the 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
The device was clinicallly investigated and the safety and efficacy is meet the requirements of ISO 81060-2. If you need to acquire a copy of the summary of the Clinical Investigation, please contact the manufacturer.

9 Technical specifications

Model	B21HT
Weight	296g (excluding batteries and AC adapter)
Display	105×69mm (4.13"×2.72") LCD digital display
Size	105 (W)×129(L)×56(H)mm(4.13"×5.08"×2.20")
Accessories	Wide range rigid cuff 8.7" – 16.5" (22 - 42 cm)
Operating Conditions	Temperature: 5℃ to 40℃
	Humidity: 15% to 90% RH
Storage And Shipping Conditions	Temperature: -20℃ to 60℃
	Humidity:10%RH~93%RH;
Atmospheric pressure range	70kPa~106kPa
Measuring method	Oscillometric
Pressure sensor	Resistive
Measuring range	DIA: 40-220mmHg; SYS: 60-260mmHg
	Pulse: 40 to 199 per minute
Cuff pressure display range	0-295mmHg
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	3 × AA batteries, 4.5V AC adapter input: AC 100-240V 50/60HZ Output: DC 5V 1A
Users	Adult (12 years or older)
Automatically power off	60 seconds
IP classification	IP21
Packaging list:1 × main device, 1 × cuff & 1 × user manual,	
Expected service life of the device: 5 years	
Technical alterations reserved	

10 FCC statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference.
(2) This device must accept any interference received, including interference that may cause undesired operation.
This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and back on again, the user is encouraged to try to correct the interference by one or more of the following measures:
• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
• Consult the dealer or an experienced radio/TV technician for help.
Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
• This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
• This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
• The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

11 EMC declaration

The ME equipment or ME system is suitable for home healthcare environments and so on.
• Do not operate near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
• Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
• Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
• Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the blood pressure monitor (B21HT), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any: any list of all cables and maximum lengths of cables (if applicable), transducers and other acessories that are replaceable by the responsible organization and that are likely to affect compliance of the ME equipment or ME system with the requirements of Clause 7 (emissions) and Clause 8 (immunity). Accessories may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by the manufacturer and equipmentor type reference).

If any: the performance of the ME equipment or ME system that was determined to be essential performance and a description of what the OPERATOR can expect if the essential performance is lost or degraded due to EM disturbances (the defined term “essential performance" need not be used).

Technical description

1. All necessary instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration - electromagnetic emissions and immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Applied

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity		
Test frequency	**Modulation**	**IMMUNITY TEST LEVEL (A/m)**
30 kHz	CW	8
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	75 [c]

a) This test is applicable only to ME equipment and ME systems intended for use in the home healthcare environment.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) R.M.S., before modulation is applied.

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
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
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV 100 kHz repetition frequency	Power supply lines: ±2 kV
Surge IEC 61000-4-5	line(s) to line(s): ±0.5 kV line(s) to earth: ±2 kV line(s) to lines(s): ±1 kV	line(s) to line(s): ±0.5 kV line(s) to line(s): ±1 kV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (ISM and amateur radio bands) 80% Am at 1kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m
NOTE 1: U_T is the AC mians voltage prior to application of the test level.		

Table 4

Guidance and manufacturer's declaration - electromagnetic immunity					
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [a]	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	27
	450	430-470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	28
	710	704-787	LTE Band 13, 17	Pulse Modulation [b] 217 Hz	9
	745				
	780				
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	28
	870				
	930				
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	28
	1845				
	1970				
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b] 217 Hz	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	9
	5500				
	5785				
If necessary to achieve the immunity test level, the distance between the transmitting antenna 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, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the Digital Blood Pressure Monitor B21HT, or on it's accessories. Some of the symbols represent standards and compliances associated with the Digital Blood Pressure Monitor B21HT and its use.

	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
IP21	The degree of avoid ingress of water or particulate matter into ME equipment.
	MR unsafe
	Date of manufacture
	Manufacturer
	Specifies batch number
	Type BF applied part
	Direct current
	Follow instructions for use
	Medical device
	This side up
	Fragile
	Afraid of the rain
	Fear of the sun
	Handle gently
	Temperature range
No Sterilize requirement	
Not category AP/APG equipment	
Mode of operation: continuous	