Arm Blood Pressure Monitor UserManual



Model: ARM-30H

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Thank you for purchasing the Arm Blood Pressure

Monitor.Themonitorusestheoscillometricmethodofbloodpressuremeas
urement. This means the monitor detects your bloodmovement
through your brachial artery and converts

themovementsintoadigitalreading.

The device can be used in homecare environment, and thepatientisanintendedoperator, and all the functions can be safely used. This monitor complies with the requirements of ISO 81060-2.

1. UnpackingInspection

Before use, please open the package carefully and checkwhetherallthepartsareavailableaccordingtothefollowingpacking list and whether the parts are damaged duringtransportation, and then install and operate in strictaccordancewiththeusermanual.

2. PackingList

No.	Name	Quantity
1	ArmBloodPressureMonitor	1
2	Cuff22~42cm(8.6~16.5inches)	1
3	Type-CChargingCable	1
4	UserManual	1
5	QuickStartGuide	1

3. Symbol Definition

Knowledgeofthewarningsignsandsymbolsiscrucialtothesafe and proper use of this device. Kindly get informed onthe following signs and symbols which you might

encounterwithinthisusermanualoronthelabel:

\triangle	Caution
†	TYPE BF APPLIED PART
¥	Symbol for the marking of electrical and
	electronics devices according to Directive
	2012/19/EU.
③	Refer to instruction manual
*	Keepdry
	Lowvoltageprompt
*	Keepawayfromthesunlight
<u>11</u>	Verticalupward

IP21	2 Protected against solid foreign objects of 12.5 mm Øand greater;		
	1 Protection against vertically falling water drops		
RoHS	RoHSmark		
C € ₀₁₂₃	CEmark		
	Manufacturer		
w	Dateofmanufacture		
SN	Serialnumber		
LOT	Batch code		
EC REP	Authorized representative in the European Community ,		
MD	Medical device		
((<u>~</u>))	Non-ionizing electromagnetic radiation		
	Indicates the entity importing the medical device into the local		
UDI	Unique deviceidentifier		

4. ProductComposition

Thisproductiscomposed of the main body and cuff.

5 IntendedUse/InstructionsforUse

The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.

Intended users

1.Lay person or clinical professionals.

2.can read and understand the user manual.

Clinical benefit

The traditional auscultation method needs to learn to determine the level of blood pressure through the sound, ithas high requirements for the u ser, requiring the user to accurately hear the Kirknoise and make a judgme nt, and this method judges the value by

human vision and hearing, with subjective factors, unless professional doctors, it is difficult for ordinary people to obtain accurate blood pressure values, and it is not very convenient to carry the stethoscope.

However, the arm blood pressure monitorbased on the principle of Non-invasive oscillometric method is easy to operate, and the reading is obvious and intuitive. Patients can monitor systolic pressure, diastolic pressure and pulse rate at home at any time, greatly reducing the number of visits to the hospital, reducing the risk of travel and improving the quality of patient's life.

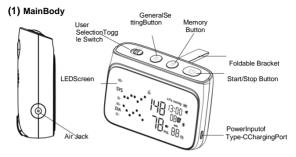
6. Contraindication

Do not use this device if the patient's condition meets the following contraindications, to avoid inaccurate measurements or injuries.

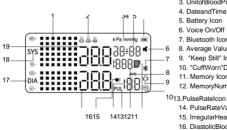
- 1.The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers,
- and defibrillators.
- Avoid taking measurement on the arm on the side of a mastectomy or lymph node clearance.
- 3.The device measures blood pressure using a pressured cuff. If the measuring limb suffers from injuries (for example open wounds) or under conditions or treatments (for example intravenous drip) making it unsuitable for surface contact or pressurization, do not use the device, to avoid worsening of the injuries or conditions.
- 4. Avoid taking measurements of patients with conditions, diseases, and susceptible to environment conditions that lead to incontrollable motions (e.g. trembling or shivering) and inability to communicate clearly (for example children and unconscious patients).
- 5.The device uses oscillometric method to determine blood pressure. The arm being measure should have normal perfusion.

The device is not intended to be used on a limb with restricted or impaired blood circulation. If you suffer with perfusion or blood disorders, consult your doctor before using the device.

7 ProductParts







- 1 RP Indicator
- 2. Userlcon
- UnitofBloodPressure
- 4 DateandTime
- 5. Battery Icon
- 6. Voice On/Off Icon
- 7. Bluetooth Icon
- 8. Average Value Icon
- 9. "Keep Still" Indication
- 10 "CuffWorn"Detection
- 11. Memory Icon
- 12. MemoryNumber
- 14 PulseRateValue
- 15. IrregularHeartbeatIcon
- 16 DiastolicBloodPressureValue
- 17. DiastolicBloodPressureIcon
- 18. Systolic Blood Pressure Icon
- 19. Systolic Blood Pressure Value

8. BloodPressureIndicator

(1) AVGBPGraphofTheLast7MeasurementDays



(2) BloodPressureIndicator



CyataliaBlandDra	Diastolic	ColorDi	Hierarchical
SystolicBloodPre	Diasione	COIOIDI	nierarchicai
ssure(mmHg)	BloodPressure(m	splay	Relationship
	mHg)		
≥160	≥100	red	and(or)
140-159	90-99	yellow	and(or)
90-139	60-89	green	and(or)
<90	<60	yellow	and(or)

Warning: When the blood pressure indicator is red, it means you are hypertension.

Please consult your physician immediately.

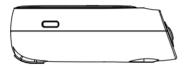
9. PowerConnection

Pleasecheckwhetherthepowerofthedeviceissufficientbeforeusing.

When you find the battery runs out, please use themanufacturerprovidedType-Cchargingcabletorechargethedeviceuntilthe" (indicator stops flashing. (TheType-

Cchargingcableisincludedinthepackage.)

Note: DONOTuse the device while charging because it doesn't work during charging. Please use it after the battery is fully charged or when you stop charging.



NOTE:

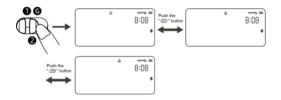
- The Type-C connector is intended to be used as a charging port for the device only.
- The adapter used should comply with the requirement of IEC 60601-1 standard, and the specifications must meet the requirements: input: AC 100-240V 50/60 Hz, output: DC 5V 1.0A. Other AC adapter may vary in output voltage and polarities and may represent a risk on your life and damaging the device.
- After fully charging the battery, if the working time of battery is shorter than before and you want to replace, do not try to replace the rechargeable battery by yourself. Please contact the manufacturer for replacement. Self-disassembly and replacement the battery may cause damage to the main unit and battery.

 When the product is not used for a long time, the battery will discharge slowly. In order to avoid battery damage due to low voltage for a long time, please charge the device for every three months.

10. FunctionSetting

(1) UserMode

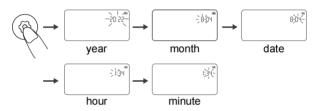
Inthepower-offmode, usethe "buttontoswitchand selectthedesiredusergroup(theleftsideisuser1, and the middleisuser2a ndtherightsideisguestmode). Pressthe "buttonafters digital tingtheuserg roup.



(2) DateAndTimeSetting

In the power-off mode, press the "\overline{\Omega}" button for about 3 seconds to enter the date setting interface, and the "year" will flash. Press the "\verline{\Omega}" button to adjust the year, and then press the "\overline{\Omega}" button to confirm the selection. When

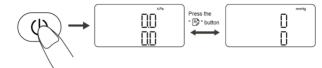
theyearisset,itwillautomaticallyenterthemonthsetting.Pressthe ""b" button to adjust the month. Follow the same stepstoadjustthedate/hour/minute.



(3)UnitDisplaySetting

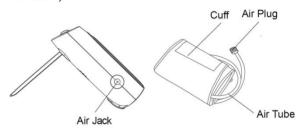
Therearetwokindsofunitsofbloodpressuredisplay,mmHgandkPa.The defaultunitismmHq.

Inthepower-offmode,keeppressingthe "U" buttonfor about 5 seconds to enter the unit selection. Press the "B" buttontoswitchbetweenmmHgandkPa,andthenpressthe "U" buttontoconfirmtheselection.

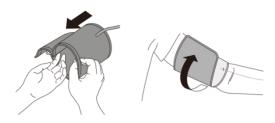


11. HowToApplyTheArmCuff

(1) Connectthearmcufftothemonitorbyinsertingtheairplugintotheairj acksecurely.



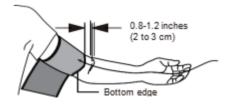
(2) Placeyourhandthroughthecuffloop.Pullthecuffuntilitreachesyourup perarm.



Note:

The bottom edge of the arm cuff should be 0.8-

1.2inches(2to3cm)abovetheinsideelbow.Theairtubeison the inside of your arm and aligned with your middlefinger.



(3) Makesurethattheairtubeispositionedontheinsideof your arm and wrap the cuff securely, so it can not movearoundyourarm.

Note: Repeated measurement will result in blood congestion in the arm, whi chwill affect the measurement result.

Be careful not to rest your arm on the air tube.

Howtoavoidbloodcongestionandensuretherepeatedmeasurementisrig ht?

Youcanraisethelefthandandholdthefistseveraltimes, ortake off the cuff and rest for at least 2-3 minutes beforetakingthemeasurement.

(4) SittingCorrectly

To take a measurement, you need to be relaxed andcomfortablyseatedinaroomwithacomfortabletemperature.

- Sitinacomfortablechairwithyourba ckandarmsupported.
- Keepyourfeetflatandyourlegsuncross ed.
- Thearmcuffshouldbeplacedonyour arm at the same level as yourheart, with the arm restingcomfortablyonatable.



Warning: Do not kink the connecting tubing, as the resulting continuous cuff pressure can cause interference with blood flow and harmful injury to the patient.

12. HowToTakeProperMeasurements

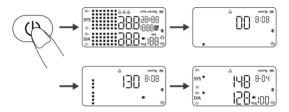
(1) PreparationBeforeMeasurement

- -- Takeofftheclothesonthearm
- --Alwaysmeasureinthesamearm(generallytheleftarm).
- --Remainstillandkeepquietduringmeasurement.
- -- Relax as much as possible and do not talk during measurementPROCEDURE.
- -- Measureyourbloodpressureataboutthesametimeeveryday.
- -- Do not measure the blood pressure immediately afterphysicalexerciseorabath.Restfor20-
- 30minutesbeforetakingthemeasurement.
- --Measurementsundertheconditionslistedbelowmayaffectresults: Withinanhourafterdinner,afterhavingwine,coffee,tea,sports; talking, being nervous, being in unsteady mood,bending forward, moving, room temperature dramaticallychanging during measuring; inside a moving vehicle,repeatedandcontinuousmeasuring.

(2) TakingAMeasurement

- 1) Fasten the arm cuff following the instruction of "How ToApplyTheArmCuff".Startmeasurementafterwearingthecuffcorrect ly.
- 2) Pressthe" button. After allicons are turned on, the monitor will start inflating formeasurement and display"". Pleast to not move or talk during the measurement.

Checkthemeasuredvaluesafterthemeasurementisfinished.



Note: If you feel uncomfortable during the measurement, pressthe "U" buttonimmediatelytostopthemeasurement. Please consult your doctor if unexpected readings are obtained.

(3) MemoryFunction

- Eachmeasuredvalueisstoredautomaticallyundertheappropriate
 "user" group. This device can store up to 110sets of
 measurements for each user. (Note: There is nomemory log for
 "Guest") Once the memory log is full,
 oldvaluesarerefreshedwithnewones.
- 2) TochecktheAVGBPstatusofthelast7measurementdays
 In the power-off mode, press the "" button once, and thesevencolumn blood pressure indicator bar graph on the
 leftsideofthedevicewillbedisplayed.Eachcolumnrepresentstheaverage
 bloodpressureofeachday.
- 3) TocheckdailyBPmemoryofonedayinthelast14measurement days

In the power-off mode, press the "" button and the AVGBP status will display. Then press the "" button, and theleftcolumnoftheBPindicatorbarflashes,indicatingthatthedevicewillen terthememorychecksetting.

Pressthe "O"buttontochoosethedate(onedayinthelast 14 measurement days). The date will be displayed in the "Date and Time" area. Then press the "D" button once toconfirm the date, and the device will display the latestmeasurement value of the day. Press the "D" button

againandtherestmeasurementva@softhedaywillbedisplayedonebyon e.Pressthe" "buttontocheckthelastmemory.

Duringtheprocessofthecheckingthehistoricalmemories, press the "(O)" button for 3 seconds, you could exit thechecking mode and return to the initial page.

(4) DeleteAllMemory

Inthepower-offmode,pushthe

"switchtoselecttheusergroupwhosemeasuredvaluesneedtobedeleted.

Then press the "(1)" button to power off the device andpress the "

button once to activate the screen. Keeppressingthe buttonforabout3secondstodeletethememoriesoftheselecteduseran dthe control of the control

willappearonthescreen, which means all the memories have been delete d.

(5) "CuffWorn"Detection

The "(0K))" icon is always displayed on the screen when thecuff is worn correctly. When the cuff is worn too loosely, the (0K)) "iconwillflashtoremindyou.

(6) "KeepStill"Indication

The "iconflasheswhenyoumoveyourbodyorshakeyour arm during the measurement, which may causeincorrect measurement results. Please adjust your postureandmeasureagain.

(7) Turn off the unit

Press "(b)tton to turn off the arm blood pressure monitor. The monitor automatically turns off after 1 minutes.

13. Specifications

Model	ARM-30H		
Display	LargeLEDscreen		
Measuring Method	Oscillometric	measurement	
Measuring Part	Upperarm		
PneumaticPressureMe			
asuringRange	0~295mmHg((0~39.3kPa)	
Maximum			
PressureProtection	295mmHg (39	9.3kPa)	
MeasurementRang	Blood	SYS: 57~255	
е	pressurev	mmHg(7.6~34.0 kPa);	
	alue	DIA: 25~195	
		mmHg(3.3~26.0 kPa);	
	Pulse rate	40~199bpm	
Accuracy	Blood	±3 mmHg (±0.4 kPa)	
	pressurev		
	alue		
	Pulse rate	±5%	
LowBattery	When the power is lower than 3.4V±0.1V,		
	thedevicewillbeturnedoff.		
Power Source	3.7Vrechargeablelithiumbattery		

ChargingMethod	Type-C charging
	port;Chargingvoltage:
	d.c.5V/1A
Memory	It can be used for 3 users (user 1, user 2
	andguestmode).
	2users*110memoriesandguestmode
	withoutmemory.
Dimension	128mm(L)x 89.8mm(W) x30.8mm(H)
Screen Size	98.1 mm (L) x 45.3 mm (W)(4.25inches)
CuffSize	22~42cm(8.6~16.5inches)
Weight	About195g
Anti ElectronicShock	Internally powered ME equipment (When
Туре	using only batteries) Class II ME equipment (if equipped with
	AC adapter)
Auto Power-off	1minutewithoutoperation
Degree of protection	Type BF
Operation Mode	Continuousoperation
Protection	IP21
AgainstHarmful Ingress	
ofWater or	
ParticularMatter	
Monitor Servicelife	5 years

Cuff Servicelife	10000 times
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Operating	Temperature	5°C~40°C	If stored
Environment	condition		orused
	Humidity	15%~90%RH	beyondthe
	condition		designatedtem
	Atmospheric	70kPa~106kPa	peratureand
	condition		humidityrange,
			it willnot be
			usedproperly
Transportation and Avoid strong impact, direct impact, exposure or			
Storage Environment	rain during trar	nsportation.	
	Store your monitor and other components in a		
	clean, safe location.		
	Remove the ar	m cuff from the	monitor.
	Gently fold the air tube into the arm cuff.		
	The device shall be stored indoors at the		
	temperature of -20°C~55°C and the relative		
	humidity of 10%~93%.		
	Atmospheric condition: 70kPa~106kPa without		
	corrosive gas and with good ventilation.		

Essential Performance

1.Measurement Range (Blood Pressure):

SYS: 57-255mmHg

DIA: 25-195 mmHg

Pulse rate: 40-199 bpm

2.Accuracy:

Blood Pressure: ±3 mmHg (±0.4 Kpa)

Pulse Rate:±5%

Bluetooth:

Arm blood pressure monitor using Bluetooth 4.2 technology, transmitting and receiving frequencies of 2402-2480MHz, modulation type GFSK, effective radiation power of 2.79dBm.

Note: The specified power supply should meet the following condition:

Output voltage: DC 5V, Output current:1000mA.

Class II

Comply with IEC 60601-1.

Provide at least two MOOP insulation between ac input and dc output,

Comply with US and Canadian deviation requirements.

Statement: "The ARM-30H of Arm Blood Pressure Monitor was tested according to the recommendations of Technical Report IEC TR 60601-4-2:

Medical electrical equipment – Part 4-2: Guidance and interpretation –

Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems."

14. Warnings and Cautions

Warnings

- Nomaintenanceorservicingwhenusing.
- Too frequent measurements can cause injury to the PATIENT due to blood flow interference.
- Consult with your physician before using this monitor on an arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy or lymph node clearance.
- Do not use the monitoring ME EQUIPMENT on the same limb simultaneously. This could temporarily cause loss of function or an inaccurate measurement.
- Please check whether the operation of the Arm blood pressure monitor leads to prolonged impairment of patient's blood circulation by observing the limb concerned.
- Please use component (eg. cuff) provided by manufacturer. Otherwise, the measurement accuracy will be affected.
- No modification of this equipment is allowed.
- To avoid strangulation, please keep the air tube and type-C charging cable away from the infants, toddlers and children.
- Do not leave the small parts where children can reach them. Children may swallow them. If a child accidentally swallows them, battery cover, please contact a doctor immediately

- The cuff complies with the requirements of ISO 10993-5, ISO 10993-10,
 ISO 10993-23. But few sensitive people may have allergies.
- $\bullet \ \mathsf{DONOT} use this monitor on an injure darm or an arm \ under medical treatment.$

Cautions

- Do not perform measurements more frequently than necessary.
 Due to the interference of blood flow, some bruising may occur.
- Maintenanceshouldbedonebythemanufactureras suggested.
- Whentheambienttemperatureislessthan 5°C, please takethedevicetotheplacewheretheambienttemperature isbetween 5°C~40°Catleast 1 hour; Whentheambient temperatureishigherthan 40°C, pleasetakethedeviceto

the placewheretheambienttemperatureisbetween $5\,^{\circ}\text{C}{\sim}40\,^{\circ}\text{Catleast}$ 2 hours

- DONOTusethismonitorforinfants, toddlers, childrenor personswhocannotexpressthemselves.
- DONOTtakemedicinebasedonreadingsfromthe device. Contactyourphysicianforspecificinformationabout yourbloodpressure. Thepatientshouldnotself-diagnoseor selfmedicatepermeasuredresults. Kindlyadheretothe instructionsofyourphysicianorhealthprovider.
- DONOTusethedevicewhileyouareonanintravenous driporbloodtransfusion.
- DONOTusethismonitorinareascontaininghigh frequency(HF) surgicalequipment, magneticresonance imaging (MRI) equipment, computerizedtomography (CT)

scannersThismayresultinincorrectoperationofthe monitorand/ orcauseaninaccuratereading.

- Make sure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular therapy,or anarteriovenous(AV)shunt.
- Consultwithyourphysicianbeforeusingthismonitorifyou havecommonarrhythmiassuchasatrialorventricular prematurebeatsoratrialfibrillation, arterialsclerosis, poor perfusion, diabetes, pregnancy, pre-eclampsiaorrenal disease.
- Stopusingthismonitorandconsultwithyourphysicianifyouexperienceskinirrit ationordiscomfort
- Consultwithyourphysicianbeforeusingthismonitorifyou haveseverebloodflowproblemsorblooddisorders, becausethecuffinflationcancausebruising.
- DONOTusethismonitorforanypurposeotherthanmeasuringbloodpre ssureandoulserate.
- DONOT disassemble or attempt to repair this monitor or other components.
 This mav cause an inaccurate reading.
- DONOTuseinalocationwherethereismoistureorarisk ofwatersplashingthismonitor. Thismaydamagethis monitor.
- DONOTusethismonitorinamovingvehiclesuchasina car.
- DONOTdroporsubjectthismonitortostrongshocksor vibrations.
- •Do not use or store the monitor outside the manufacturer's specified conditions (extremely high or low temperatures and humidity), as this may affect the performance or cause inaccurate measurements.
- When the performance changes (such as: inaccurate measurement or abnormal display), please stop using it immediately and contact the sales service personnel in time.

15. CommonQ&AonBloodPressure

Q1:Whyisthebloodpressurevalueobtainedathomelowerthantha tobtainedatthehospital?

- Thebloodpressuredifferencebetweenhomeandhospitalmeasuremen ts is about 20 mmHg~30 mmHg (2.7 kPa~4.0kPa). This is because individuals tend to be more relaxed athomethanatthehospital.
- If the device is placed at a position over the heart, thebloodpressurevaluetendstobemuchlowerthanitactuallyis. Ensuret hedeviceispositionedrightattheheartlevel.

Q2:Whyisthebloodpressurevalueobtainedathomehigherthanth atobtainedatthehospital?

- Theanti-hypertensivedrugthepatientmightbeusinghas lostitsefficacy.Kindlyadheretoyourdoctor'sinstructions.
- The cuff might not be in the correct position. If the cuff isnotplacedright,noarterialpressurevaluewillbeobtained,and the blood pressure value might be much higher than itis. Therefore, properly position the cuff.
- The cuff is not tight enough. If the cuff is loose, thecompressionforcemightfailtotransmittotheartery,causingthe blood pressure value to be much higher than it is. Therefore, readjustandtightenthecufffurther.
- The patient is not sitting correctly during measurement. Slouching, tilting, bending, and sitting cross-legged are notencouragedwhiletakingbloodpressuremeasurementsdueto increased abdominal pressure or the arm position beingbelowtheheart. Kindlytakereadingsinthecorrectposture.

Q3:Whencanlohtainhettermeasurements?

 Measurementsarebesttakeninthemorningsrightafteryou urinate or when your mind and body are stable. Werecommend taking readings at the same time of the day, everytime.

Q4. Why the blood pressure value measured each time is different?

- 1) When systole each time, the blood pressure will change tosome extent. For example, a person with the pulse of 70beats per minute will have 100,800 blood pressure changes every day. Because the blood pressure is constantly changing, it is difficult to obtain the correct blood pressure value by measurement only once. Please make measurement for 2~3 times. The first measurement will generally be higher due to nervousness or inadequate preparation, and then when the second measurement, the nervous emotion will be slightlyalleviated, so generally, the second measurement will be5mmHg-10mmHg (0.7kPa-1.3kPa) lower than the first time. This will be more obvious for those with higher blood pressure.
 - --When continuous measurement, please note that: There might be extravasated blood because the arm is compressed, resulting that the fingertip blood does not flow smoothly, If you continue the measurement in case of extravasated blood, you cannot obtain the correct measured value. Loosen the arm band, raise your hand over the head and grasp and stretch your left and right palms for 15 times repeatedly. Then the extravasated blood can be dis solved and you can continue the blood pressure measurement.
- Cuff position and twining method. The measured value varies with the cuff size. Particularly, if the cuff is twined

round the elbow, you cannot obtain the correct measured value

--Please use the correct cuff twining method for measurement. The arm circumference range of the enclosedcuff is 22–42 cm (center of the upper arm). If the model isinconsistent, please purchase separately.

16. AbnormalPhenomenaandHandling

If the measurement is abnormal, any of the followingsymbolsmayappear. Kindlyusetherecommended method for measurement.

Errors	Cause/Solution
Er U	The pressure cannot reach 30 mmHg (4 kPa) in
	12seconds.
Er H	Theinflationreaches295mmHg.
Er 1	Thepulserateisnotdetectedcorrectly.
Er 2	Too much disturbance (Move, talk, or
	magneticdisturbanceduringameasurement).
Er 3	Themeasurementresultisabnormal.
Er23	SYSvaluereadslowerthan57mmHg.
Er24	SYSvaluereadshigherthan255mmHg.
Er25	DIAvaluereadslowerthan25mmHg.
Er26	DIAvaluereadshigherthan195mmHg.

*Troubleshooting

Anomaly	Inspection Items	Solution
Failure	Thebatteryisdepleted	Recharge the device
topowero		tillthe " "
n		indicatorstops flashing
Nopressuriz	Whether the air	Insert the air tube
ing	tubeplugisinsertedtig	plugfirmlyintothejack
	htly	
	Whether the air tube	Please contact
	isbrokenorleaked	thedealer to replace
		with anewcuff
Unable	Whether the arm	Keep your arm
tomeasur	ismoved	andbodystill
edueto	whenpressurizatio	
the	n	
displayerro	Whether you talk	Keep quiet
r	duringthe measurement	whilemeasuring the
		bloodpressure
Air	Whether the cuff	Please tighten the cuff
leakageoft	istwinedtooloose	
he cuff	The airbag of the cuff	Please contact
	isripped	thedealer to replace
		with anewcuff
Δ	I .	I .

If the blood pressure still cannot be measured after trying theabove-stated solutions, please contact the dealer. DO NOT attempttodisassemblethe devicebyyourself.

17. CleaningandDisinfection

(1) Cleaning

The device can be cleaned with a small amount of neutral detergent or water.

It is suggested to clean the monitor before and after each use. Complete the cleaning in 3min each time. The number of repeatedcleaning each time shall not exceed 3 times.



Do not use any corrosive cleaning agent. When

cleaning, be careful not to immerse any part of the monitor to avoid liquid flow into the instrument.

(2) Disinfection

RecommendedDisinfectingAgent

75%medicalalcohol Steps:

- Carefully wipe the device with a soft, clean cloth dampenedwithasmallamountoftheabovedisinfectant, and dry immediately with a soft, clean, dry cloth.
- The body of the device can also be cleaned with a soft, cleanclothdampenedwithasmallamountof75%medical alcohol for tion.

Do not disinfect through methods like high-

temperaturesteamorultravioletradiation.Thesemightdamagethe device and reduce its service life

Itissuggestedtodisinfectthemonitorbeforeandafteruse each time. Each time of disinfection shall be completed

within1min.Thenumberofrepeateddisinfectioneachtime shall not exceed 2 times.

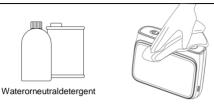
(3) Disposal

Disposeofthemonitor, other components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

Notes

- Donotbendorcreasetheairtubeexcessively.
- Donotstorethemonitororitscomponents:
- if the monitor or its parts is wet.
- in locations with extreme temperatures, humidity, direct sunlight, dust, orcorrosive gases.
- in areas with a high risk of vibrations or shocks.

18. UpkeepandMaintenance



- Alwayskeepthesurfaceofthedevicecleanandtidy,helpfultoprol ongitsservicelife.
- Ifthedeviceisdirty,pleasewipewithadrysoftcloth.Ifthe dirt cannot be eliminated easily, wipe with a softcloth stained with water or neutral detergent, and thendrywithadrycloth.
- We suggest to calibrate the monitor once a year at least. Please contact manufacturer or agent if you need.

Warning:

Donotallowwaterorotherliquidstoflowintothe device.

The arm pressure monitor should not no longer be reused when liquid enter and damage the device and cuff.

19. Appendix1EMCInformation

Guidance and manufacturer's declaration - Electromagneticemission

The Arm Blood Pressure Monitor is intended for use in theelectromagnetic environment specified below. The customer or theuser of the Arm Blood Pressure Monitor should assure that it is used in such an environment.

Emissions	Compliance	Electromagneticenvironme
		nt-guidance
RF	Group 1	The Arm Blood PressureMonitor
emissionsCIS		uses RF energy
PR11		onlyforitsinternalfunction.
		Therefore, its RF emissionsare
		very low and are not likelyto cause
		any interference
		innearbyelectronicequipment.
RF	ClassB	The Arm Blood
emissionsCIS		PressureMonitorissuitableforusein
PR11		all establishments,
		includingdomestic establishments
		andthose directly connected to
		thepublic low-voltage powersupply
		network that suppliesbuildings
		used for domesticpurposes.

Harmonicemi	N.A.	
ssionsIEC610		
00-3-2		
Voltagefluctu	N.A.	
ations/-		
flickeremissio		
nsIEC61000-		
3-3		

Guidance and manufacturer's declaration - Electromagneticimmunity

The Arm Blood Pressure Monitor is intended for use in theelectromagnetic environment specified below. The customer or theuser of the Arm Blood Pressure Monitor should assure that it issuedinsuch anenvironment.

Immunity test	IEC 60601	Compliancelevel
	testlevel	
Electrostaticdisc	±8 kV contact	±8 kV contact
harge	±2 kV, ±4 kV,	±2 kV, ±4 kV,
(ESD)IEC61000	±8kV,±15 kVair	±8kV,±15 kVair
-4-2		
Electrostaticdisc	±8 kV contact	±8 kV contact
harge	±2 kV, ±4 kV,	±2 kV, ±4 kV, ±8 kV,
(ESD)IEC61000	±8kV,±15 kVair	±15kVair
-4-2		
Electrical fast	±1 kV signal	±1 kV signal
transient/burst	input/output	input/output
IEC 61000-4-4	100 kHz repetition	100 kHz repetition
	frequency	frequency
Surge	Notapplicable	Notapplicable
IEC61000		
-4-5		

Voltagedips,short	Notapplicable	Notapplicable			
interruptionsand					
voltagevariations					
onpower					
supplyinput lines					
IEC61000-4-11					
Power	30A/m,50/60Hz	30A/m,50/60Hz			
frequencyMagne					
tic					
fieldIEC61000-4-					
8					
ConductedRF	3V signal	3V signal input/output;			
IEC61000-4-6	input/output;	0,15MHz-80MHz			
	0,15MHz-80MHz	6 V in ISM and amateur			
	6 V in ISM and	radio bands between			
	amateur	0,15 MHz and 80 MHz			
	radio bands	80% AM at 2Hz			
	between				
	0,15 MHz and 80				
	MHz				
	80% AM at 2Hz				
Radiated	10V/m	10V/m			
RFIEC61000-	80 MHz -	80MHz-2.7GHz			
4-3	2.7GHz 80 %	80%AMat2 Hz			
	AM at2 Hz				
NOTE: UT is the a.c. mains voltage prior to application of the					

testlevel

Guidance and manufacturer's declaration - electromagneticImmunity

The Arm Blood Pressure Monitor is intended for use in theelectromagnetic environment specified below. The customer or theuser of the Arm Blood Pressure Monitor should assure that it is used in such an environment.

Radiat	Test	Ban	Service	Modulati	Max.	Dist	IEC6	Com
edRFI	Freq	d(M		on	Pow	anc	0601	plian
EC610	uenc	Hz)			er(W	e(m	-	celev
00-4-3	y(M))	1-2	el(V/
(Testsp	Hz)						Test	m)
ecificati							Lev	
ons							el(V	
forENC							/m)	
LOSUR	385	380-	TETR	Pulsemo	1.8	0.3	27	27
EPORTI		390	A400	dulation				
MMUNI				18Hz				
TY	450	430-	GMR	FM ±5	2	0.3	28	28
to		470	S460	kHz				
RFwirel			,	deviatio				
esscom			FRS46	n1kHzsi				
municati			0	ne				
onsequi	710	704-	LTE	Pulsemo	0.2	0.3	9	9
pment)	745	787	Band13	dulation				

Ι Γ	780		,	217Hz				
			17					
	810	800-	GSM8	Pulsemo	2	0.3	28	28
	870	960	00/900	dulation				
	930		,TETR	18Hz				
			A800,					
			DEN					
			820,CD					
			MA850					
			,					
			LTE					
			Band 5					
	1720	1700	GSM	Pulsemo	2	0.3	28	28
	1845	-	1800	dulation				
	1970	1990	;CD	217Hz				
			MA1					
			900;					
			GSM					
			1900					
			;DEC					
			T;LT					
			E					
			Band1,					
			3, 4,					
			25;U					
			MTS					

2450	2400	Bluetoo	Pulsemo	2	0.3	28	28
	-	th,WLA	dulation				
	2570	N,802.1	217Hz				
		1					
		b/g/					
		n,R					
		FID					
		245					
		0,L					
		TE					
		Band 7					
5240	5100	WLA	Pulsemo	0.2	0.3	9	9
5500	-	N802	dulation				
5785	5800	.11	217Hz				
		a/n					

Guidance and manufacturer's declaration - electromagneticImmunity							
RadiatedRF	Test	Moduation	IEC60601-	Compliance			
IEC61000-4-	Frequency		1-2	level(A/m)			
39			TestLevel				
(Test	Test (A/m)						
specification	30kHz	CW	8	8			

S	134.2kHz	Pulsemo	65	65
for		dulation		
ENCLOSU		2.1kHz		
REPORTI	13.56MHz	Pulsemo	7.5	7.5
MMUNITY		dulation		
to		50kHz		
proxim				
itymag				
neticfi				
elds)				

Warning:

- 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 like antenna cables and external antennas) should be kept at least 30cm (12 inches) from the device and its parts to prevent degradation of the monitor.
- Do not use this device adjacent to or stacked on other equipment to prevent improper functioning. If such use is necessary, all accessories involved must be checked for normal operation.
- Do not use this device within regions of active HF-surgical equipment or RF-shielded room of an ME system for magnetic resonance imaging, where EM disturbances may be high.

Notice:

If users or patients have occurred any serious incident that relation to the device, please report to manufacturer and the competent authority of the Member State in which you are established.



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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, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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 on, 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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.