iHerz®

INTELLIGENTE PFLEGE

automatic

BLOOD PRESSURE MONITOR

model iCare

DEAR TM iHerz® AUTOMATIC BLOOD PRESSURE MONITOR OWNER

Thank you for choosing Automatic Blood Pressure Monitor **TM iHerz®** model iCare. We are sure that having appraised worthily the high quality and reliability of this device you will become a regular user of the products of Italian Trademark **TM iHerz®**.
Before starting to use this device, please, study the user's manual carefully. The user's manual offers all information you need to measure your blood pressure and pulse correctly. For all questions concerning the device, please, contact your local distributor or **TM iHerz®** service centre in your country.

ATTENTION

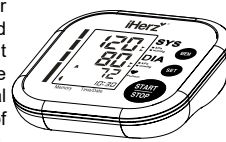
This blood pressure monitor is designed to carry out self-control over blood pressure but NOT to make self-diagnosis of hypertension/hypotension. Please, DO NOT diagnose by yourselves basing on the measurement results obtained with the blood pressure monitor. Please, DO NOT execute self-treatment of high/low blood pressure and DO NOT change the methods prescribed without consulting your doctor.

 Type BF applied part.

 Read the instructions carefully before using this device.

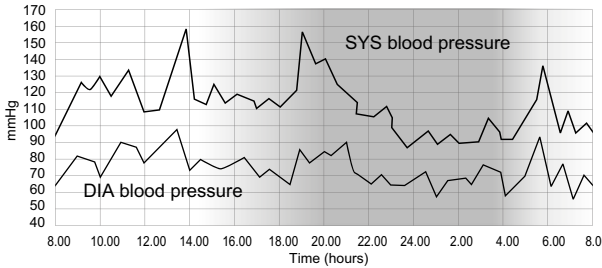
IMPORTANT INFORMATION ON BLOOD PRESSURE AND ITS MEASUREMENT

What Is Blood Pressure?



Blood pressure is the pressure that your blood extends to the vascular walls. Blood pressure is necessary to provide for constant blood flow inside the body. Thanks to it the cells get oxygen that provides for their normal functioning. The heart performs the function of a «pump», sending blood to the blood vessels.
Each heart beat creates a certain level of the blood pressure.
There are 2 kinds of blood pressure: a systolic (upper) one, which corresponds to the heartbeat pushing blood into the arteriae; and a diastolic (lower) one, which means the blood pressure between two heartbeats.
Blood pressure is subject to fluctuations during the day even in healthy people. The fluctuations are influenced by a number of factors - time of day, person's condition, physical or mental activity, environment, etc.

Day-Night Fluctuations of the Blood Pressure



An increase of blood pressure increases the burden onto the heart, affects blood vessels making their walls thick and less elastic.
One of the features of the hypertension is its ability to remain unnoticed for

the patient at its early stages. That's why the self control of the blood pressure is so important. With the illness progressing, headaches and regular dizziness appear, the sight declines, the functioning of vitals (encephalon, heart, kidneys, blood vessels) breaks down. Without special treatment the complications of hypertension might be kidney damages, breast-pang, paralytic stroke, aphasia, dementia, heart attack and stroke.

Which Values are Normal?

The world standard as for the norms of the blood pressure is the Classification* of the World Health Organization (WHO):

Category	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)
Blood pressure too low	< 100	< 60
Blood pressure optimum	100 - 119	60 - 79
Blood pressure normal	120 - 129	80 - 84
Blood pressure slightly high	130 - 139	85 - 89
Blood pressure too high	140 - 159	90 - 99
Blood pressure far too high	160 - 179	100 - 109
Blood pressure dangerously high	≥ 180	≥ 110

* Printed with curtailments.

- The diagnosis of hypertension requires from the patient to combine medical treatment prescribed by the doctor and mode of life correction.
- People with normal pressure and high normal pressure are recommended to carry out self-control of their tension in order to timely take measures to decrease the blood pressure level down to the optimal one without using any medications.
- For people more than 50 years old high level of systolic blood pressure (higher than 140 mmHg) is more crucial than diastolic pressure.
- Even with blood pressure being normal, people run the bigger risk of hypertension development with advancing age.

ATTENTION
If you have normal results of blood pressure measured under calm conditions but your results are excessively high when measured under the conditions of physical or mental exhaustion, this might be a sign of so called brittle (that is unstable) hypertension. If you suspect that, please, consult your doctor.

When measured correctly, if diastolic blood pressure is more than 120 mmHg, it is necessary to call the doctor immediately.

ADVANTAGES OF AUTOMATIC BLOOD PRESSURE MONITOR MODEL iCare

Blood Pressure Rate Indicator

Blood pressure rate indicator is located along left side of the display. The classification corresponds to 6 ranges described in the table of the section «Which values are normal?». After the measurement there appears the dotted line in the left part of the display opposite the zone to which the result of the measurement corresponds: green zone - optimal blood pressure, yellow - elevated, orange - too high, red - dangerously high. This function helps you to self-orient in the measurement results.

Irregular Heartbeat Detection Technology

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure.During each measurement, the monitor records all the pulse intervals and calculate the average ; if there are two or more pulse intervals ,the difference between each interval and the average is more than the average value of ±25% , or there are four or more pulse intervals ,the difference between each interval and the average is more than the average value of ±15%,the irregular heartbeat symbol appears on the display when the measurement results are appear.

Multiple Users

2 users can make measurements and store data together. Memory allows up to 60 results for each user enabling to display average results, which include quite long period
of time. There is no need to write down and store the results on hard copies every time
after measurement.

GETTING READY FOR MEASUREMENT

⚠ Safety Precautions

* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with
implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor
before using it on older children.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure.
It is not intended for use on extremities other than the arm or for functions other than
obtaining a blood pressure measurement.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment without asking a physician for treatment advice.
* If you are taking medication,consult your physician to determine the most appropriate time to measure your blood pressure. Never change a pre-

scribed medication without consulting your physician.
* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with
deviation. Please consult your physician about the result.
* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
* Warning: Do not apply the cuff over a wound;otherwise it can cause further injury.
*Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
*On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure $>$ 300mmHg or constant pressure > 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER
was clinically investigated according to the requirements of ISO 81060-2:2013.

* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood
circulation and injuries.
* This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
*This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.
* The patient can measure data and change batteries under normal circumstances and
maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic
field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sen-

sization or irritation reaction.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after
maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists,
descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The operator shall not touch output of batteries and the patient simultaneously.
* Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don’t use any abrasive or volatile cleaners.
* The device doesn’t need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Transtek. Don’t open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at

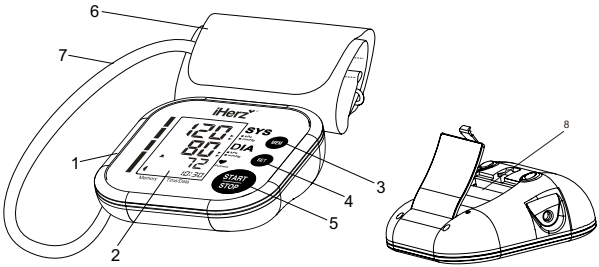
authorized sales/service centers.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is caculated by the MANUFACTURER from the 80MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
* Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

KEEP THIS MANUAL DURING THE WHOLE LIFETIME OF THE DEVICE

Components of Your Blood Pressure Monitor Kit

The blood pressure monitor kit includes Automatic Blood Pressure Monitor model iCare, 22 - 32 cm cuff, 4 batteries 1,5 V (AAA), user's manual, warranty card, kit box.

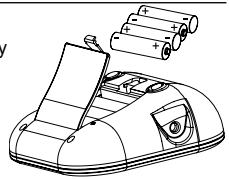
Description of the Blood Pressure Monitor



1. AIR CONNECTOR PLUG
2. LCD DISPLAY
3. MEM BUTTON
4. SET BUTTON
5. START/STOP BUTTON
6. CUFF
7. AIR HOSE
8. BATTERY COMPARTMENT

Installing and Replacing the Batteries

• Open the battery cover.
• Install the batteries as indicated in the battery compartment.
(Always select the authorized / specified battery: Four AAA-size batteries).
• Replace the battery cover.

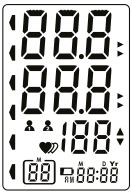


Replace the batteries whenever the below happen

- **The LO + ▭ shows**
- **The display is dim**
- **The display does not light up**

- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.

LCD display signal



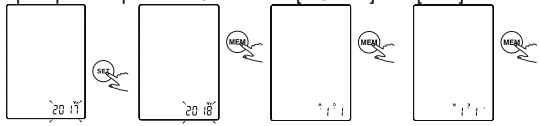
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High blood pressure
DIA	Diastolic blood pressure	Low blood pressure
Pul/min	Pulse display	Pulse in beats per minute
▼	Deflation symbol	The cuff is deflating.
	Memory	Indicate it is in the memory mode and which group of memory it is.
kPa	kPa	Measurement Unit of the blood pressure

mmHg	mmHg	Measurement Unit of the blood pressure
Lo +	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
	Blood pressure level indicator	Indicate the blood pressure level
M D Yr AM 88:88	Current Time	Year/Month/Day, Hour/Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
1 2	User 1, User 2	Start measurement for User 1, User 2

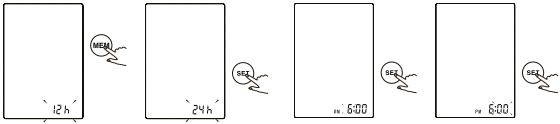
Setting the Date and Time

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year :2014—2054 time format:12 H/24H)

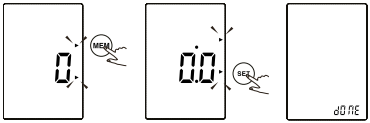
1. When the monitor is off, hold pressing “SET” for 3 seconds to enter the mode for year setting. Or when the monitor is off, press “SET” button shortly, it will display the time. Then hold pressing “SET” button to enter the mode for year setting.
2. Press the “MEM” to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.
3. When you get the right year, press “SET” to set down and turn to next step.Repeat steps 2 and 3 to set the [MONTH] and [DAY].



4. Repeat steps 2 and 3 to confirm the time format [12H] and [24h].
5. Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



6. Repeat steps 2 and 3 to set the [UNIT].
7. After the unit is set,the LCD will display “donE”first,then display all the settings you have done and then it will turn off.



MEASUREMENT PROCEDURE

ATTENTION

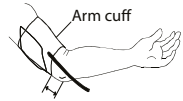
- Find time to relax by sitting in a quiet atmosphere for some time before measurement.
- Be seated with your feet flat on the floor, and don’t cross your legs. Place palm upside in front of you on a flat surface such as desk or table. The middle of the cuff should be at the level of the right atrium of the heart.
- Efforts by the patient to support the arm can increase the blood pressure. Make sure you are in a comfortable, relaxed position and do not activate any muscles in the arm during measurement.
- Always measure on the same arm (normally left).
- Remove any garment that fits closely to your upper arm. Do not roll the sleeve since it can squeeze your hand and this can lead to false results.
- Use only clinically approved original cuff.
- If you want to follow the results of your blood pressure measurements, always perform measurements at the same time of day, since blood pressure changes during the course of the day.
- Measurements should be done after a 5 minute rest to ensure accuracy.

Fitting the Cuff

Select a pressure cuff size that corresponds to the circumference of your shoulder (measured with a tight fit in the middle of the shoulder). The size M (22-32 cm) is a size fitting the majority of people.

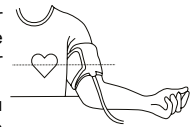
1. Remove all jewelry, such as watches and bracelets from your left arm.Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.

2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.



3. Hold your arm with your palm facing up and tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger. Or position the artery mark ϕ over the main artery (on the inside of your arm).

Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.



4. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.

5. Sit comfortably with your tested arm resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.

6. Helpful tips for Patients, especially for Patients with Hypertension:

- Rest for 5 minutes before first measuring.
- Wait at least 3 minutes between measurements.
- This allows your blood circulation to recover.
- Take the measurement in a silent room.
- The patient must relax as much as possible and do not move and talk during the measurement procedure.
- The cuff should maintain at the same level as the right atrium of the heart.
- Please sit comfortably. Do not cross your legs and keep your feet flat on the ground.

- Keep your back against the backrest of the chair.
- For a meaningful comparison, try to measure under similar conditions.

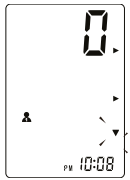
For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

Measuring Procedure

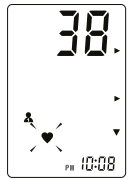
When the monitor is off, press the “START/STOP” to turn on the monitor, and it will finish the whole measurement .(Take User 1 for example)

LCD display

Adjust the zero



Inflating and measuring



Display and save the results

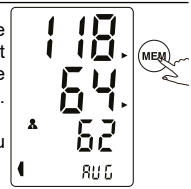
Press the “START/STOP” to power off, otherwise it will turn off within 1 minute.

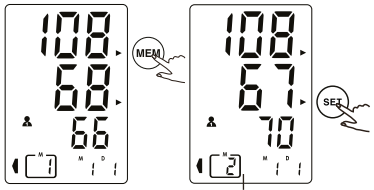
MEMORY FUNCTION

Reading Measurement Results

1. When the monitor is off, please press the “MEM” to show the average value of the latest three records.If the records are less than three groups,it will display the latest record first.

2. Press the “MEM” or “SET” to get the record you want.





The date and time of the record will be shown alternately.

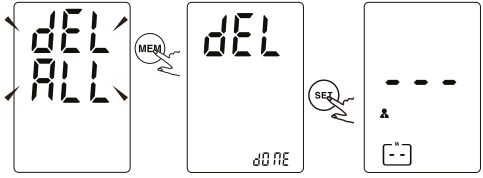
CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped

Delete Memories

If you did not get the correct measurement, you can delete all results by following steps below.

1. Hold pressing “MEM+SET” for 3 seconds when the monitor is in the memory recall mode ,the flash display will show.



2. Press “SET” to confirm deleting and the monitor will turn off.
3. If you don’t want to delete the records, press “START/ STOP” to escape.
4. If there is no record, the right display will show.

ERROR MESSAGES/ TROUBLESHOOTING

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
Low batteries	Display is dim or show LO+	Batteries are low.	Replace with new batteries
Error message	E 1 shows	The cuff is too tight or too loose.	Readjust the cuff ,not too loose or too tight and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E 10 or E 11 shows	The monitor detected motion while measuring.	Movement can affect the measurement. Relax for a moment and then measure again.
	E 20 shows	The measurement processdoes not detect the pulse signal.	Loosen the clothing on the wrist and then measure again.
	E 21 shows	Measure incorrectly.	Relax for a moment and then measure again.
	EExx,shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return

Warning message	“out ” shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

The functionality of this device may be disturbed by the use of strong electromagnetic fields such as mobile phones or radio stations at close range, so we recommend that these devices be kept at least 1 m away. In cases where this is inevitable, please make sure that the device is working properly before use. If you are suffering from a heartbeat disorder (arrhythmia), evaluation of measurement results of the device can be given only after consultation with a physician.

CARE AND MAINTENANCE

In order to get the best performance, please follow the instructions below.

Put in a dry place and avoid the sunshine	
Avoid touching water, clean it with a dry cloth in case.	
Avoid intense shaking and collisions	
Avoid dusty and unstable temperature environment	

Using wet cloths to remove dirt	
Do not attempt to clean the reusable cuff with water and never immerse the cuff in water.	

Disinfection: If required (for example, in a hospital setting), disinfection of the pressure cuff twice per week is recommended.
Disinfect the interior of the pressure cuff (the surfaces that come into contact with the patient's skin) with the use of a soft cloth soaked in ethyl alcohol (75-90%) and wait for the pressure cuff to dry up.
Cleaning of the pressure cuff after 200 uses is recommended.

Periodic calibration of device: the accuracy of measurement instruments must be verified from time to time. For this reason, verification of the indication of statistical pressure periodically (once a year) and after technical maintenance and repair is recommended. More information can be obtained from the service center.

SYMBOL INFORMATION

SYMBOL	REFERENT
	Consult instruction for use
	Manufacturer
	Manufacturing date

SN	Serial number
⎓	Direct current
	Caution, consult accompanying documents
	Dispose of in accordance with the requirements of your country
	The cuff is type BF applied part
EC REP	European representative
CE 0123	CE mark
	Recycle
	The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods.

TECHNICAL SPECIFICATIONS

Power supply	Battery powered mode: 6VDC 4*AAA batteries
Display mode	Blue LCD with white backlight V.A.60mm×40.5mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute

Accuracy	Pressure: 5°C-40°Cwithin±0.4kPa(3mmHg) Pulse value: ±5%
Normal working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	About 22cm~32cm
Net Weight	Approx.168g(Excluding the dry cells)
External dimensions	Approx.110mm×110mm×41mm
Attachment	4×AAA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertcally falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment

WARNING: No modification of this equipment is allowed.

Conformance to standards: DSTU EN 1060-1:2015 “Non-Invasive Sphygmomanometer.” General Requirements. Paragraph 9.2. DSTU EN 1060-3:2015 “Non-Invasive Sphygmomanometer.” Part 3. Paragraph 9.2.

WARRANTY

Your Automatic Blood Pressure Monitor Model iCare is warranted for 5 years from date of purchase. Warranty for the cuff is 1 year from the date of purchase. The warranty does not apply to batteries

and damage caused by improper handling, accidents, not following the operating instructions or self-maintained alterations made to the device. The warranty is only valid upon presentation of the warranty card with purchase date and stamp of trade organization.

COMPLIED STANDARDS LIST

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices -Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems IEC 80601-2-30:2009+A1:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2:Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EMC Guidance

1) 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.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
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.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

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.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	power supply lines: ±2 kV input/output lines: ±1 kV	power supply lines: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC61000-4-5	line(s) to line(s): ±1 kV line(s) to earth: ±2 kV 100 kHz repetition frequency	line(s) to line(s): ±1 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°,270° and 315° 0%UT ; 1 cycle and 70%UT ; 25/30 cycles Single phase: at 0° 0% UT ; 300 cycle	0% UT ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°,270° and 315° 0% UT ; 1 cycle and 70% UT ; 25/30 cycles Single phase: at 0° 0% UT ;300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Table 3

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.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

Conducted RF IEC 61000-4-6	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d=0.35\sqrt{P}$; $d=1.2\sqrt{P}$	
Radiated RF IEC 61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	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) according to the transmitter manufacturer, d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

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 (transmittters) 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 $d = 3.5\sqrt{P}$	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	0.37	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 absorption and reflection from structures, objects and people.

Table 5

Recommended separation distances between portable and mobile RF communications equipment and the device.							
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.							
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 b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	380-390	GMRS 460, FRS 460	FRS 460 FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						

	1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	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 5240 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9

NOTE 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, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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.