SALTER

AUTOMATIC WRIST BLOOD PRESSURE MONITOR

Instructions and Guarantee

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BPW-9101-GB

INTRODUCTION

General Description

Thank you for selecting Salter wrist blood pressure monitor BPW-9101-GB. The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service. Readings taken by the BPW-9101-GB are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product. Read the manual thoroughly before using the product.

Features:

- Systolic blood pressure
- Diastolic blood pressure
- Pulse rate
- 60 records for one user

Indications for Use

The Salter Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with wrist circumference ranging from 13.5cm to 21.5 cm (about 5⅓″-8½″). It is intended for adult indoor use only.

Contraindications

1. The device is not suitable for use on pregnant women or women who think they may be pregnant.
2. The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.

Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the air pressure. Then it starts inflating the cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

Safety Information

The below signs might be in the user manual, labeling or other components. They are the requirement of standard and using.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
CE 0123	Symbol for “COMPLIES WITH MDD 93/42/EEC REQUIREMENTS”		Symbol for “ENVIRONMENT PROTECTION - Wast electrical products should not be disposed of with household waste. Please follow local guidelines.
	Symbol for “MANUFACTURER”		
SN	Symbol for “SERIAL NUMBER”	EC REP	Authorized Representative in the European Community
	Symbol for “DIRECT CURRENT”		Symbol for “Recycle”
	Symbol for “MANUFACTURE DATE”		The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods.
	Caution: These notes must be observed to prevent any damage to the device		

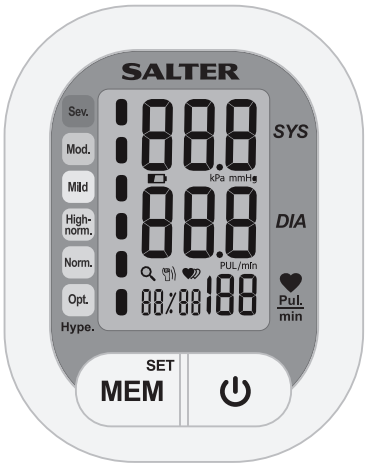
CAUTION

* 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 professional 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 wrist 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 prescribed 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.
* 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 wrist 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 wrist 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 wrist 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 maximum temperature that the applied part can be achieved is 42.5°C while the environmental temperature is 40°C.
* 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 sensization or irritation reaction.
* If you experience discomfort during a measurement, such as pain in the wrist or other

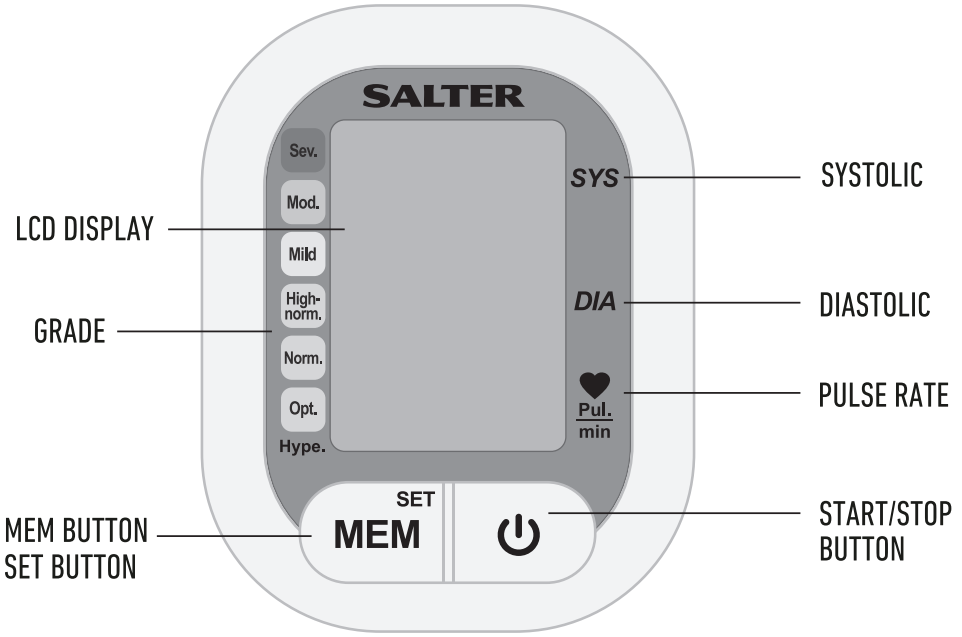
complaints, press the START/STOP button to release the air immediately from the cuff.
Loosen the cuff and remove it from your wrist.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the wrist 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 Salter. 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.
* Please report to Salter if any unexpected operation or events occur.
* 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 parts specified/ authorised by MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no luer lock connectors used in the construction of tubing, there is no 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.

LCD DISPLAY SIGNAL



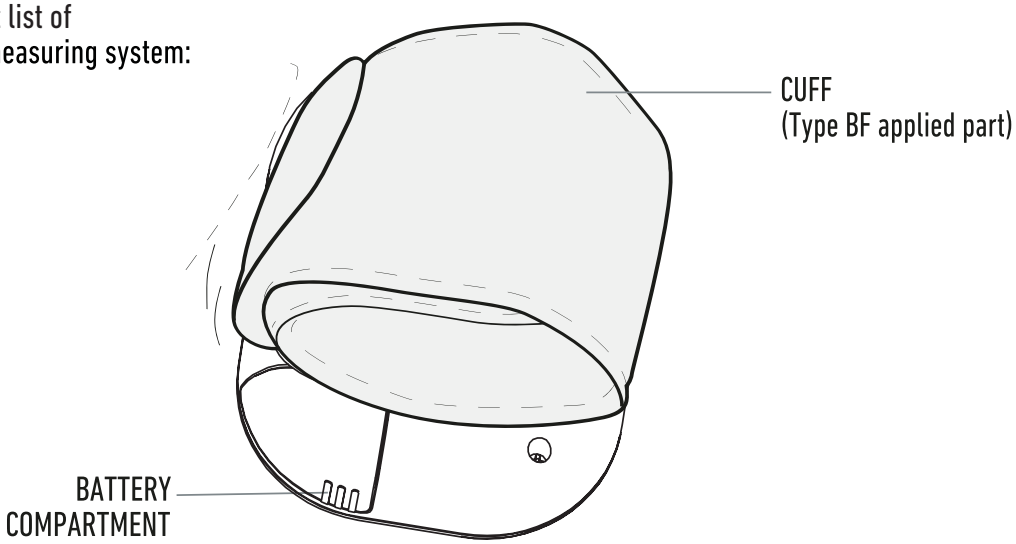
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High blood pressure
DIA	Diastolic blood pressure	Low blood pressure
Pul. min.	Pulse display	Pulse in beats per minute
	Motion indicator	Motion may result in an inaccurate measurement.
+Lo	Low battery	Batteries are low and need to be replaced
kPa	kPa	Measurement unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement unit the blood pressure (1mmHg=0.133kPa)
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
88/88	Current time	Month/Day/Year,Hour : Minute
	Blood pressure level indicator	Indicate the blood pressure level
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	Memory Query	Indicate it is in the memory mode and which group of memory it is.

MONITOR COMPONENTS



Component list of
pressure measuring system:

1. PCBA;
2. Air Pipe;
3. Pump;
4. Valve;
5. Cuff.

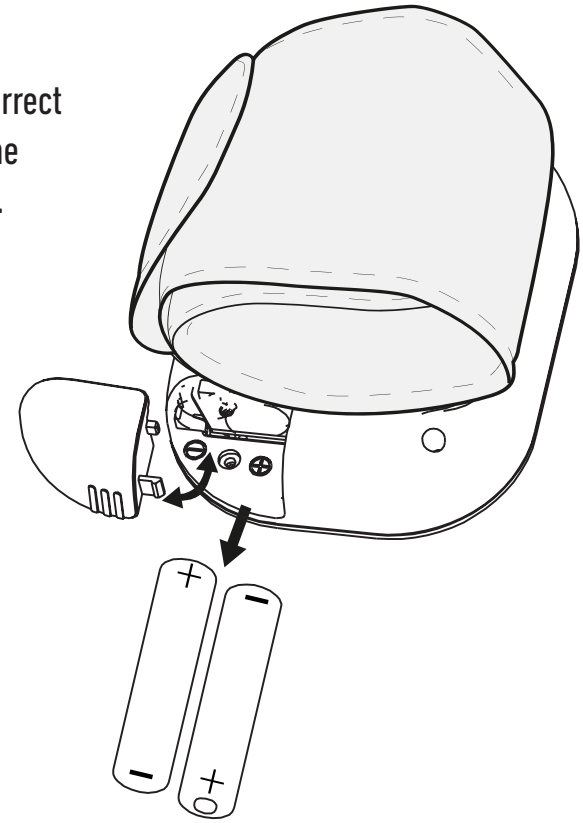


List

1) Automatic Wrist Blood Pressure Monitor
2) 2 x AAA batteries
3) User manual

INSTALLING AND REPLACING THE BATTERIES

- Slide off the battery cover.
- Install the batteries by matching the correct polarity, as shown below. Always use the correct battery type (2 x AAA batteries).
- Replace the battery cover.



CAUTION

Replace the batteries under following circumstances:

- +Lo displays on the LCD
- The LCD display dims
- When powering on the monitor, the LCD doesn't light up.

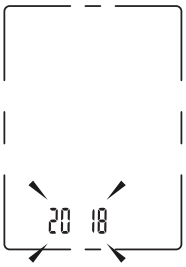
CAUTION

- **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.**

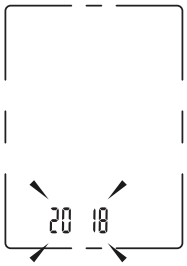
SETTING DATE, TIME AND MEASUREMENT UNIT

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: 2018—2058 time format: 24H)

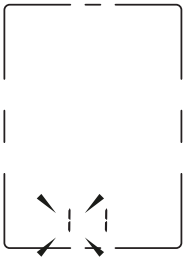
1. When the monitor is off, hold pressing "MEM" button for about 3 seconds to enter into setting mode. The blinking numeral represents [YEAR].



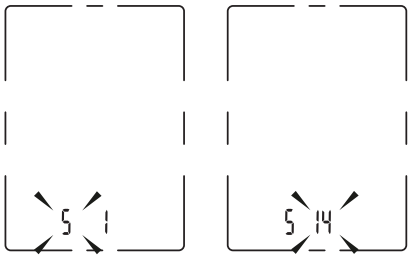
2. Press the "MEM" button to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.



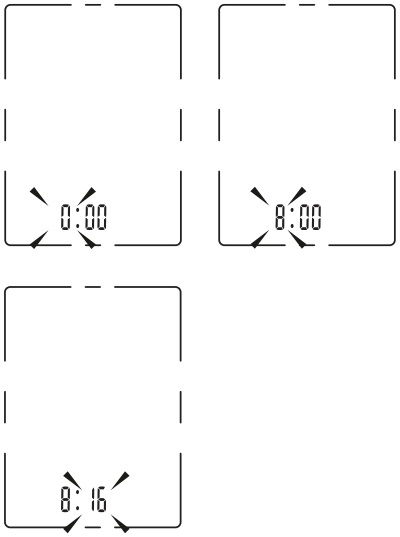
3. When you get the right year, press "START/STOP" button to confirm your selection and it will turn to the next step.



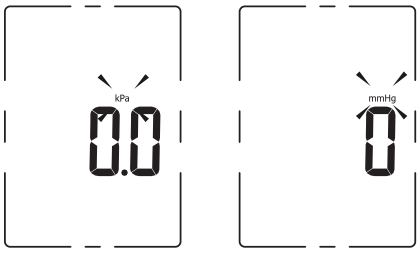
4. Repeat steps 2 and 3 to confirm [MONTH] and [DAY].



5. Repeat steps 2 and 3 to confirm [HOUR] and [MINUTE].



6. Repeat steps 2 and 3 to confirm the [MEASUREMENT UNIT].



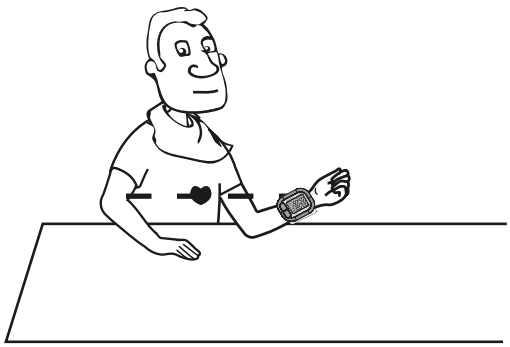
7. After confirming the meausrement unit, the LCD will display all the settings you have done once again and then turn off.

MEASUREMENT

Tie the Cuff

1. Remove all accessories (watch, bracelet,etc) from your wrist. If your physician has diagnosed you with poor circulation in your wrist, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your wrist with your palm facing up.
4. Position the edge of the cuff about 1cm~1.5cm from wrist joints.
5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.
6. Sit comfortably with your tested wrist 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.
7. Patients with Hypertension:

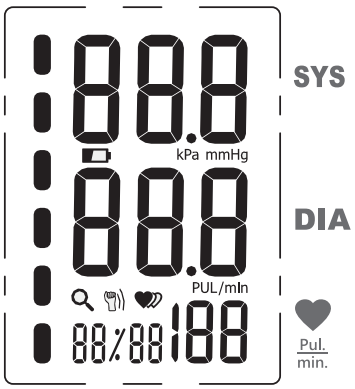
- The middle of the cuff should be at the level of the right atrium of the heart; Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and wrist supported.
- Rest for 5 minutes before measuring.
- Wait at least 3 minutes between measurements. This allows 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.
- Do not cross your legs and keep your feet 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 wrist, or as directed by a physician.



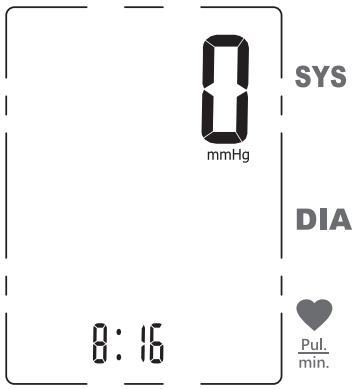
Start the Measurement

1. When the monitor is off, press “START/STOP” button to turn on the monitor, and it will finish the whole measurement.

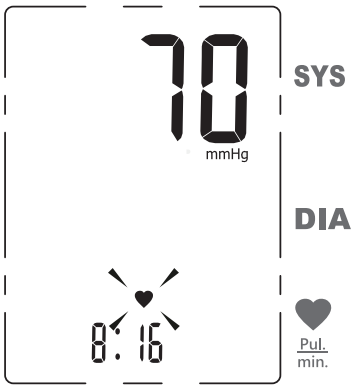
LCD display



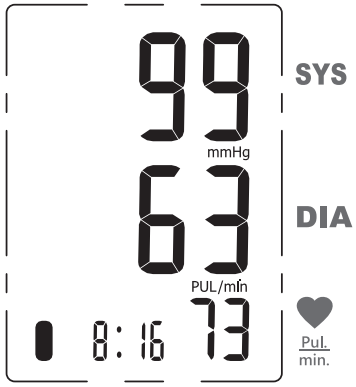
Adjust the zero



Inflating and measuring



Display and save the results

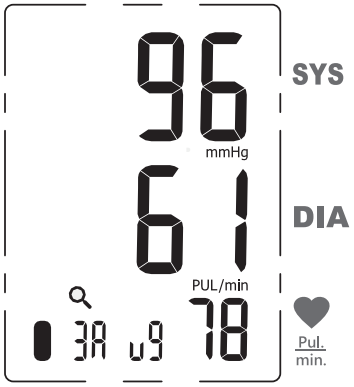


2. Press “START/STOP” button to power off, otherwise it will turn off within 1 minute.

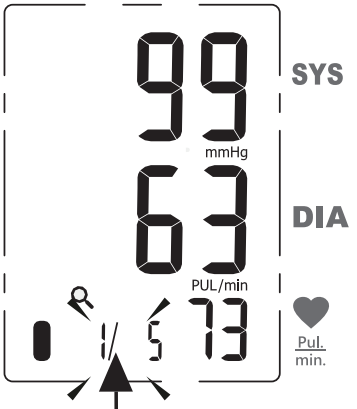
DATA MANAGEMENT

Recall the measurements

1. When the monitor is off, press “MEM” button to show the average value of the latest three measurement records. If the records are less than 3 groups, it will display the latest record instead.



2. Press “MEM” button again, it will display the latest measurement result, date and time. Press “MEM” button again, it will display the next record,and so on. During the process of displaying the results, if there is no operation, the blood pressure monitor will turn off in one minute. Or you can press “START/STOP” button to turn it off.



The record number, date and time will display alternately.

1/5	5 14	8:16
It means the total records is 5, the current No. is No. 1.	The corresponding date is May 14.	The corresponding time is A.M. 8:16.

CAUTION

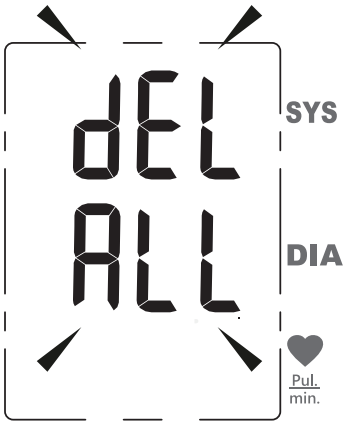
The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (eg 2 becomes 3, and so on), and the last record (60) is dropped.

DATA MANAGEMENT

Delete the Records

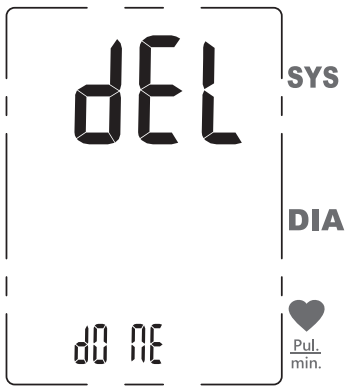
If you did not get the correct measurement, you can delete all results by following steps below.

1. In the memory mode, hold pressing “MEM” button for 3 seconds, the flash display “dEL All” will show.

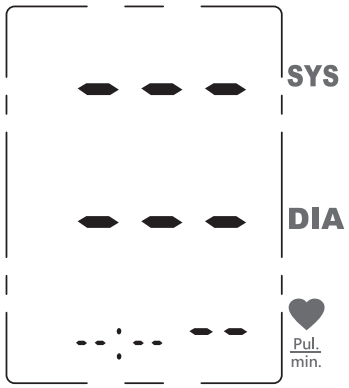


2. Press “MEM” to confirm deleting , the LCD displays “ dEL dOnE” and the monitor will turn off.

Note: To exit out of delete mode without deleting any records, press “START/STOP” button before pressing “MEM” to confirm any delete commands.

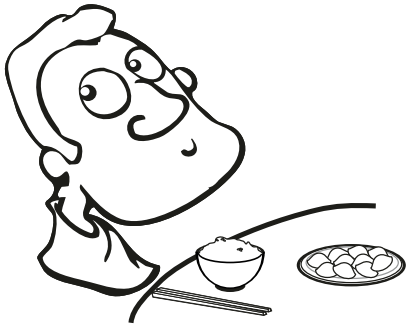


3. If there is no record, the right display will show.



Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.

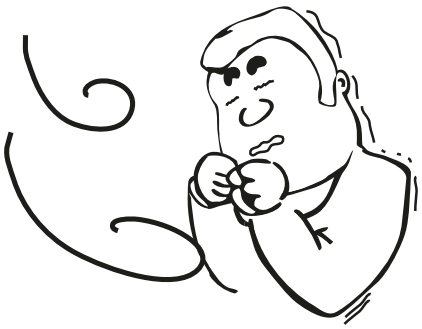


Within 1 hour
after dinner or drinking

Immediate measurement
after tea, coffee, smoking

Within 20 minutes
after taking a bath

When talking or moving your fingers

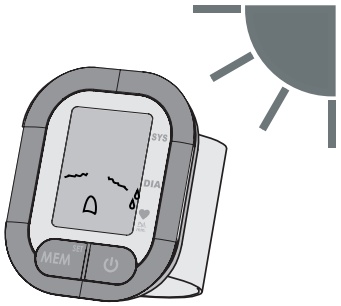


In a very cold environment

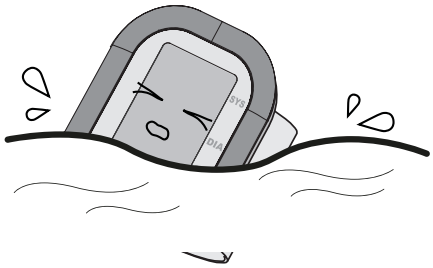
When you want to discharge urine

Maintenance

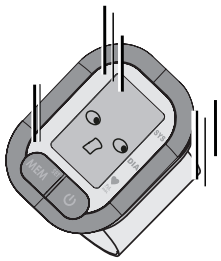
In order to get the best performance, please follow the instructions below.



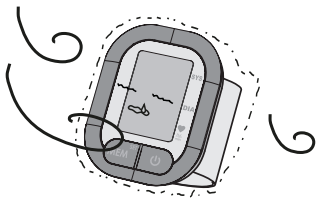
Put in a dry place and avoid the sunshine



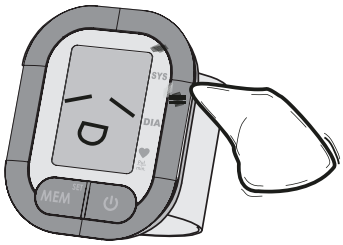
Avoid touching water, clean it with a dry cloth in case.



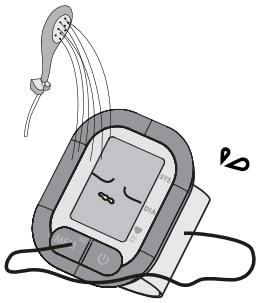
Avoid intense shaking and collisions



Avoid dusty and unstable-temperature environment



Using wet cloths to remove dirt

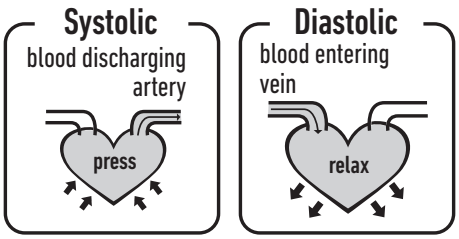


Avoid washing the cuff

ABOUT BLOOD PRESSURE

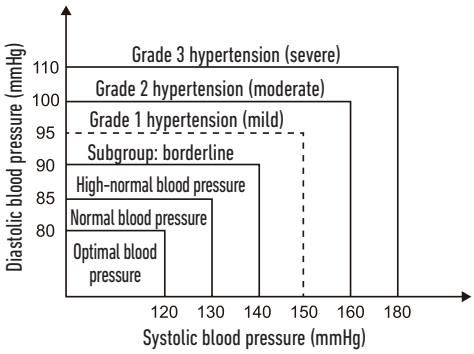
What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



What is the standard blood pressure classification?

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:



CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Kindly note that only a physician could tell whether your blood pressure value has reached a dangerous point.

Blood pressure (mm Hg) \ Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120–129	130–139	140–159	160–179	≥180
DIA	<80	80–84	85–89	90–99	100–109	≥110

Irregular Heartbeat Detector

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 have appeared.

CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.
2. If the person takes medicine, the pressure will vary more.
3. Wait at least 3 minutes for another measurement.

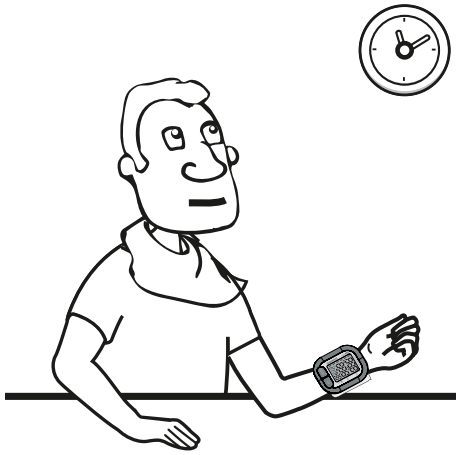
Why do I get a different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise etc, Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

Is the result the same if measuring on the right wrist?

It is ok for both arms, but there will be some different results for different people.

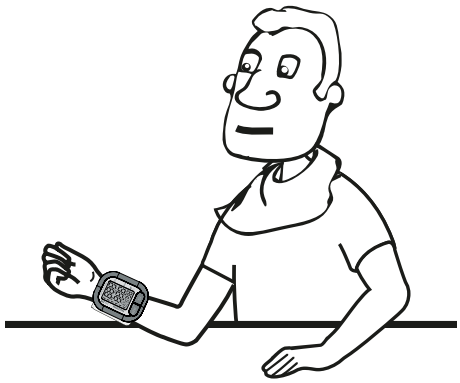
We suggest you measure the same wrist every time.



What you need to pay attention to when you measure your blood pressure at home:

- **If the cuff is tied properly.**
- **If the cuff is too tight or too loose.**
- **If the cuff is tied on the wrist.**
- **If you feel anxious.**
  Taking 2–3 deep breaths before beginning will be better for measuring.

Advice: Relax yourself for 4–5 minutes until you calm down.



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 is 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 not secure.	Refasten the cuff and then measure again.
	E 2 shows	The cuff is too tight.	Refasten the cuff 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 E11 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 process does 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 instructions.
Warning message	“out ” shows	Out of measurement range	the measurement result is out of the measurement range (SYS:60mmHg to 230mmHg; or DIA: 40mmHg to 130mmHg;or Pulse: 40-199 pulse/minute)

SPECIFICATIONS

Power supply	Battery powered mode: 2*AAA batteries (3V DC)
Display mode	Digital LCD V.A.32mm×45mm
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°C within±3mmHg(0.4kPa) Pulse value:±5%
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 13.5cm-21.5cm
Net Weight	Approx.104g(Excluding the batteries)
External dimensions	Approx.85mmx67mmx23mm (Exclude the cuff)
Attachment	2*AAA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Device Classification	Internally Powered ME Equipment
IP Classification	IP22: The first number 2: Protected against solid foreign objects of 12,5mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure titled up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15° on either side of the vertical.
Software version	A01

WARNING: No modification of this equipment is allowed.

CONTACT INFORMATION

For more information about our products, please visit www.salterhousewares.co.uk
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Customer Support: +44(0) 1732 360783
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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

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 2

Guidance and manufacture's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of 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	±15 kV air ±8 kV contact	±15 kV air ±8 kV contact	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	input/output lines: ±1 kV power supply lines: ±2 kV	power supply lines: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	100 kHz repetition frequency line(s) to earth: ±2 kV line(s) to line(s): ±1 kV	100 kHz repetition frequency line(s) to line(s): ±1 kV	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 U_T 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 applicable to the frequency of the transmitter. Recommended separation distance: $d = 0.35\sqrt{P}$ $d = 1.2\sqrt{P}$	
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 manufacture and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] 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 re-orienting 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 determined using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, 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

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.							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communica-tions 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	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	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
	5240						
	5785						

Table 5 (cont)

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.

2 YEAR GUARANTEE

FKA Brands Ltd guarantees this product from defect in material and workmanship for a period of 2 years from the date of purchase, except as noted below. This FKA Brands Ltd product guarantee does not cover damage caused by misuse or abuse; accident; the attachment of any unauthorised accessory; alteration to the product; or any other conditions whatsoever that are beyond the control of FKA Brands Ltd. This guarantee is effective only if the product is purchased and operated in the UK / EU. A product that requires modification or adaptation to enable it to operate in any country other than the country for which it was designed, manufactured, approved and / or authorised, or repair of products damaged by these modifications is not covered under this guarantee. FKA Brands Ltd shall not be responsible for any type of incidental, consequential or special damages.

To obtain guarantee service on your product, return the product post-paid to your local service centre along with your dated sales receipt (as proof of purchase). Upon receipt, FKA Brands Ltd will repair or replace, as appropriate, your product and return it to you, post-paid. Guarantee is solely through Salter Service Centre. Service of this product by anyone other than the Salter Service Centre voids the guarantee.

This guarantee does not affect your statutory rights.

For your local Salter Service Centre, go to **www.salterhousewares.co.uk/servicecentres**

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