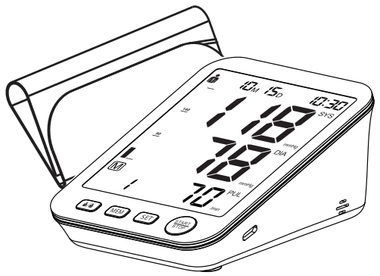
Smilecare

Upper Arm Electronic

Blood Pressure Monitor

Model:U81RH



Instruction Manual

Table of Contents

Introduction

▲ Your new digital blood pressure monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movements into a digital reading. An oscillometric monitor does not need a stethoscope, so the monitor is simple to use.

▲ Intelligent inflation will reduce the uncomfortable feeling by incorrect inflation, and shorten the measurement time, prolong the cuff's usage lifetime.

▲ 2x500sets memory function, each measurement result will be displayed on the screen, and automatically stored .This unit has blood classification index, could easy to check your blood pressure.

Please read the manual carefully before you use the unit, and keep the manual well after using.

INTENDED USE

This automatic blood pressure monitor intends to measure the systolic pressure, diastolic pressure and pulse rate through upper arm. It's expected to be used at home or in the hospital, intended for people over 12 years old.

Contraindication:

This product can't be used in patients who is with severe heart insufficiency to avoid suffocation and death.

This product is not suitable for infants and children.

Safety Information

■ To assure the correct use of the product, basic safety measures should always be followed including the warning and the caution listed in the instruction manual :

Symbol descriptions

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

⚠ WARNING: This alert identifies hazards that may cause serious personal injury or death.

⚠ CAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

Type BF applied part

Manufacturer SN Specifies serial number

EC REP Authorized Representative in the European Community

CE 0123 CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

Direct current

Follow instructions for use

⚠ CAUTION: Consult accompanying documents

Safety Information

⚠ Those who have arrhythmia, diabetes, blood circulation or apoplexy problem, please use under the physician' s instruction.

⚠ Contact your physician for specific information about your blood pressure. Self diagnosis and treatment which use measured results may be dangerous. Follow the instructions of your physician or licensed healthcare provider.

⚠ Please place on a high place where children can' t be touched.

⚠ No modification of this equipment is allowed.

⚠ Do not modify this equipment without authorization of the manufacturer.

⚠ If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

⚠ The cuff hose around neck may cause the suffocation.

⚠ The swallowing of small part like packaging bag, battery, battery cover and so on may cause the suffocation.

⚠ Please don't use a dilution agent, alcohol or petrol to clean the unit. Please don't hit heavily or fall down the product from a high place. Use the right cuff, otherwise it can not work.

⚠ Never leave any low battery in the battery compartment since they may leak and cause damage to the unit.

⚠ Please take off the battery if you won't use in 3 months.

⚠ Replace the new batteries if the unit display a low battery symbol.

Safety Information

⚠ Do not mix the old and new batteries.

⚠ Do not use a cellular phone near the unit. It may result in operational failure.

⚠ Please avoid using in high radiant area in order to make your measuring data correctly.

⚠ Do not use the equipment where flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) are present.

⚠ WARNING:

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact you local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

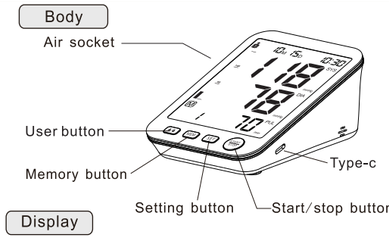
Classification

1. Internally powered equipment;
2. Type BF applied part;
3. Protection against ingress of water or Particulate matter IP21;
4. Not category AP /APG equipment;
5. Mode of operation:Continuous operation.

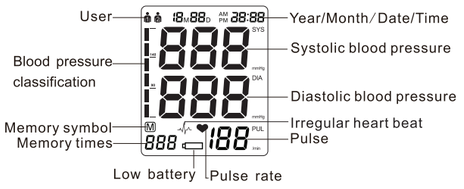
⚠ The user must check that the equipment functions safely and see that it is in proper working condition before being used.

Product structure

Body



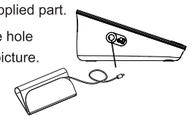
Display



Cuff size and connection

The accessories cuff is L size,for upper-arm circumference 22- 42cm use.The cuff is treated as the applied part.

Insert the connector with cuff tube into the hole which is on the left side of the device as picture. (Only provided cuff can be used, can not change to any other branded cuff.)



Battery installation

Adapter usage (option)

1. When optional AC adapter should comply with the requirement of IEC 60601-1:2005. Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

2.This device is double insulated and protected against short circuit and overload by a primary thermal fuse. Make sure to take the batteries out of the compartment before using the mains part. Equipment class 2.

3. When using AC power, to avoid possible damage to the monitor, use only the exclusive AC adapter that can be purchased from authorized dealers. Other adapters may vary in output voltage and polarities.

4. Insert the adapter plug into the hole on the backside of the unit as picture.

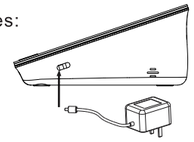
5. Insert the other side of the adapter into the outlet with 100-240V.

6. To remove the AC adapter, disconnect the adapter plug from the outlet first and then disconnect the cord from the unit's socket.

Adapter technical features:

Output voltage: type-c 5V

Output current: At least 600 mA



Setting mode

Note:

・When use AC adapter, the power of battery won't be consumed.

・When suddenly stop during measurement(like the plug off from the outlet by carelessness), it must be reinserted the plug into the unit, and restart the measurement.

How to set

1. User setting:

Press button SET when power off , the screen will display 👤1 or 👤2 , press button MEM ,it will be changed between 👤1 and 👤2 , press button SET when you confirm the user, then it will enter into the year setting mode.

You can also switch users directly by pressing 👤1/👤2 button when power off.

2. Year setting:

Continue to above step, the screen will display and flash 20XX, the last digit of the year will increase 1 when press button MEM each time, you could choose from 2020 to 2099. Press button SET when you confirm the year, then it will enter into the month and date setting mode.

Year setting

Setting mode

3. Month and date setting

Continue to above step, the screen will display xxMxxD and xxxx, and keep flashing on month , the digit will increase 1 when press button MEM each time, you could choose from 1 to 12. Press button SET when you confirm the month, then it will set the date. Same as the month setting , each time you press button MEM , the digit will keep changing from 01 to 31. Press button SET when you confirm the date, then it will enter into the time setting mode.

Month setting

Date setting

4. Time setting:

Continue to above step, the screen will display xxMxxD and xx:xx, and keep flashing on the digits of hour, the digit will increase 1 when press button MEM each time, you could choose from 0 to 23. Press button SET when you confirm the hour, then the digits of minute start to flash , same as the hour setting , each time you press button MEM the digits will keep changing from 00 to 59. Press button SET when you confirm the minute, then the total setting mode is completed.

hour setting

minute setting

Safety Information

⚠ Consecutive blood pressure measurements should be repeated after 1 minute pause or after the arm has been held up in order to allow the accumulated blood to flow away.

⚠ If the arm circumference size is beyond the measuring range of CUFF ,it can't be measured and used ,then it will cause the blood flowing unsmooth and wrong measurement data

⚠ 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.

⚠ Too frequent measurements can cause injury to the PATIENT due to blood flow interference.

⚠ Don't apply CUFF over a wound, it can cause further injury to the PATIENT.

⚠ 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.

⚠ 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 :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。

⚠ 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.

⚠ Please check that operation of the device does not result in prolonged impairment of patient blood circulation.

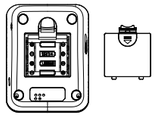
Battery installation

Battery installation

Remove the battery cover from the battery compartment, insert the battery.

a) Remove the battery cover as picture showed.

b) Insert 4 AAA powerful batteries into the compartment and ensure each battery is in the proper direction.



Low battery and replacement

When power on, the low battery symbol will display once the unit start to work, and you must replace with new batteries, otherwise the unit can' t work.

Battery type and replacement

Please use 4pcs AAA identical 1.5V alkaline batteries.

Do not use the batteries beyond their expiry date.

Please remove the batteries if you do not need to use for long time.

⚠ WARNING:

Dispose of the battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

Setting mode

Proper use of the unit

Measurement

Pre-measurement

- Relax for about five to ten minutes prior to the measurement Avoid eating, drinking alcohol, smoking, exercising and bathing for 30 minutes before taking a measurement. All these factors will influence the measurement result.
- Remove any garment that fits closely to your upper arm.
- Always measure on the same arm(normally left).
- Take measurement regularly at the same time of every day,as blood pressure changes even during the day.

Common factors of wrong measurement

- All efforts by the patient to support their arm can increase blood pressure.
- Make sure you are in a comfortable, relax position and do not activate any of the muscles in the measurement arm , don't legs uncrossed ,keep the feel flat on floor, back and arm supported during measurement. Use a cushion for support if necessary.
- If the arm artery lies lower or higher than the heart,a false reading will be obtained.

Note:

- Only use clinically approved cuffs!
- A loose cuff or a exposed bladder causes false reading.
- With repeated measurements ,blood accumulates in the arm which can lead to false reading. Consecutive blood pressure measurements should be repeated after 1 minute pause or after the arm has been held up in order to allow the accumulated blood to flow away.

Proper use of the unit

Fitting the cuff

1). Put the cuff on a table flatly with the velcro side down. Pass the end of the cuff through the metal loop so that a circle is formed. The velcro closer will now be facing outwards (ignore this step if the cuff has already been prepared).

2). Push the cuff over the left upper arm so that the tube points in the direction of the lower arm.

3). Wrap the cuff on the arm as illustrated. Make certain that the lower edge of the cuff lies approximately 2 to 3 cm above the elbow and the rubber tube leaves the cuff on the inner side of the arm.

4). Tighten the free end of the cuff and close the cuff by affixing the velcro.

5). The cuff should be snug on your upper arm so That you can fit 2 fingers between the cuff and your upper arm. Any piece of clothing restricts the arm which must be taken off.

6). Secure the cuff with the velcro closer in such a way that it lies comfortably and not too tight. Lay your arm on a table(palm upwards) so that the cuff is at the same height as the heart. Do not bend the tube.

Note:

If it is not possible to fit the cuff to your left arm, it can also be placed on the right. However, all measurements should be made using the same arm.

Proper use of the unit

Measuring procedure:

After the cuff has been appropriately positioned,the measurement can begin:

1).Press the START/STOP button, all symbols appear on the display , then the pump begins to inflate the cuff, the rising pressure in the cuff is shown on the display.

2).After the suitable pressure has been reached,the pump stops and the pressure gradually falls.The cuff pressure is displayed.In case that the inflation is not sufficient,the device automatically re-inflates to a higher pressure.

3).When the device detects the signal, the heart symbol ❤ on the display starts to flash.

4). When the measurement has been completed, the systolic,diastolic and pulse rate will appear on the display.

5). The measurement readings remain on the display until you switch off the device.If no button is pressed for a period of 3 minutes, the device switches off itself in order to save the power.

Note:

The symbol will be displayed along with the reading if the irregular heartbeat is detected during the measurement.

Discontinuing a measurement

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

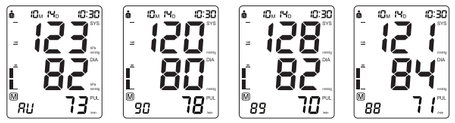
Memory-recall of measurements

This blood pressure monitor automatically stores 2x90 sets measurements value, the oldest record will be replaced by the latest measurement value when more than 90 sets each user.

Read memory record

Press the button MEM when power off, the latest 3 times average value will be shown, press the button MEM again,the last measurement value will be shown, as well as subsequent measurements can be display one after the other by pressing the button MEM each time.

About blood pressure

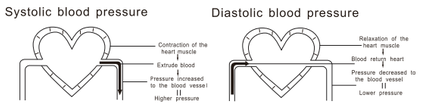


Memory －clear of measurements

If you are sure that you want to permanently remove all stored memories. Press the button SET for 7 times until CL appears when power off, press the START/STOP button ,CL will flash for 3 times to clear all the memories. After this press button MEM, M and “no” will be shown on the display which mean that no memory in store.

About blood pressure

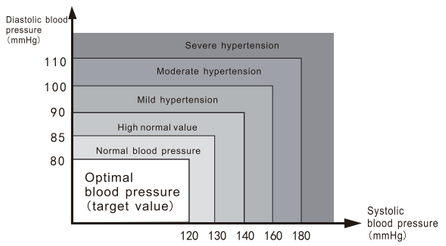
Blood pressure is the pressure exerted the arteries.
The systolic blood pressure value represents the blood pressure produced by contraction of the heart muscle.
The diastolic blood pressure value represents the blood pressure produced by relaxation of the heart muscle.



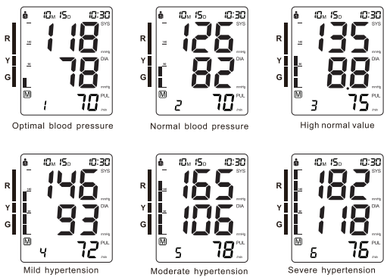
About blood pressure

■According to the blood pressure classification by the WHO/ISH.

■SYS lower than 100mmHg(13.3kPa) is considered as hypotension.



■ Blood pressure type



Exceptional Situation

Error indicators

■The following symbol will appear on the display when measuring abnormal.

Symbol	Cause	Correction
E-1	Weak signal or pressure change suddenly Out of range indicates HI	Wrap the cuff properly. With a correct way.
E-2	External strong disturbance	When near cell phone or other high radiant device , the measurement will be failed. Keep quite and no chatting when measure.
E-3	It appears error during the process of inflating	Wrap the cuff properly. Make sure that the air plug is properly inserted in the unit. Remeasure.
E-5	Abnormal blood pressure	Repeat the measurement after relax for 30 mins , if get unusual readings for 3 times,please contact your doctor.
▭	Low battery	Replace all the worn batteries with new ones.

Trouble removal

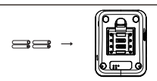
Problem	Check	Cause and solutions
No power	Check the battery power	Replace new one
	Check the polarity position	Installation for proper placement of the batteries polarities
No inflation	Whether the plug insert	Insert into the air socket tightly
	Whether the plug broken or leak	Change a new cuff
Err and stop working	Whether move the arm when inflate	Keep the body peaceful
	Check if chatting when measured	Keep quite when measure
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly
	Whether the cuff broken	Change a new cuff
⚠ Please contact the distributor if you can`t solve the problem, do not disassemble the unit by yourself!		

Care and maintenance

Care for the main unit and blood pressure monitor cuff

● Keep the unit in the storage case when no use. ● Clean the unit with soft dry cloth. Do not use any abrasive or volatile cleaners. ● Never immerse the unit or any component in water.	
● Make sure the monitor is off prior to cleaning. a mixture of distilled water and 10 percent bleach could be used. ● Using a spray bottle, moisten a soft cloth towel with the bleach or detergent mix until it is fully saturated. Squeeze any excess moisture from the cloth to avoid any dripping or potential oversaturation of the cuff. ● Wipe all surfaces of the blood pressure monitor cuff thoroughly, making sure to clean the inside and outside of the cuff. Be cautious not to get any moisture in the main unit. ● Using a dry cloth, gently wipe away any excess moisture that may remain on the blood pressure cuff. Lay the cuff flat in an unrolled position and allow the cuff to air dry.	

Maintenace

● Do not clean the body and cuff with naphtha, thinner or gasoline etc.	● Do not wet the cuff or attempt to clean the cuff with water.
	
● Store the unit in a clean and dry location . Do not subject the unit to extreme hot or cold temperature, humidity and direct sunlight.	● Remove the batteries if the unit will not be used in 3 months or longer.
	
※We won’t be responsible for any quality problem if you don’t care and maintain the product as instructed.	

Specification

Description	Automatic upper arm blood pressure monitor	
Display	LCD digital display	
Measuring principle	Oscillometric method	
Measuring loca ization	Upper arm	
Measurement range	Pressure	0~299 mmHg
	Pulse	40~199 pulses/min
Accuracy	Pressure	±3mmHg
	Pulse	±5% of reading
LCD indication	Pressure	3 digits display of mmHg
	Pulse	3 digits display
	Symbol	Memory/Heartbeat/Low battery
Memory function	2x500sets memory of measurement values	
Power source	4pcs AAA alkaline battery(not included) / type-c 5V	
Automatic power off	In 3 minutes	
Main unit weight	Approx.230g (batteries not included)	
Main unit size	L124mm X W95mm X H52mm	
Main unit lifetime	10,000 times under normal use	
Battery life	Could be used for 300 times for normal condition	
Accessories	Cuff, instruction manual	
Operating environment	Temperature	5~40°C
	Humidity	15% ~ 93%RH
	Air pressure	86kPa ~ 106kPa
Storage environment	Air pressure: 86kPa ~ 106kPa Temperature:-20°C ~ 55°C, Humidity: 10% ~ 93% avoid crash, sun burn or rainduring transportation.	
Expected service life	5 years	
Software Ver	UA1.0	

Warranty information

Statement

- The intended use: the unit is intended to be used by adults at home or medical center to measure blood pressure and pulse rate from the upper arm.
- The unit satisfies the requirements of EN ISO 81060-1 Part 1 Noninvasive sphygmomanometers, EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers, IEC80601-2-30 Part 2 Non-invasive sphygmomanometers.
- Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, manual, electronic, or automated sphygmomanometers.
- The risk of patient and user can be lowered to acceptable level.

Warranty Information

- The unit is guaranteed to be free of defects in workmanship and materials under normal use for a period of Two Years from the date listed on the purchase record.
- For repair under this warranty. Our authorized service agent must be advised of the fault with the period of the warranty. This warranty covers parts and labor only under normal operations. Any defect resulting from natural causes, eg. flood, hurricane etc, is not within this guarantee. This guaranty does not cover damage incurred By use of the unit not in accordance with the instructions, accidental damage, or being tampered with or serviced by unauthorized service agents.
- Monitor subjected to misuse, abuse, and neglect of these manual content , non-instructional purposes; unauthorized repair or modifications will be excluded from this warranty.

⚠ The device requires no calibration.

⚠ The device is not repairable and contains no user serviceable parts.

EMC Declaration

IEC 60601-1-2 2014 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning Don’t near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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.”

Warning Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the blood pressure monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

EMC Declaration

Technical description

1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer’s declaration -electromagnetic emissions and Immunity
Table 1

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

EMC Declaration

Table 2

Guidance and manufacturer’s declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV,±4 kV,±8 kV,±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines ±2 kV 100 kHz repetition frequency	Power supply lines ±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s) ±0.5kV ±1 kV.	line(s) to line(s) ±0.5kV ±1 kV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º 45º, 90º, 135º, 180º, 225º, 270º and 315º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250 cycle 50Hz	0% 0.5 cycle At 0º 45º, 90º, 135º, 180º, 225º, 270º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250 cycle 50Hz
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

EMC Declaration

Table 3

Guidance and manufacturer’s declaration - electromagnetic Immunity							
	Test Frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulation** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430 –470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	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 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						

Smilecare

Upper Arm Electronic Blood Pressure Monitor

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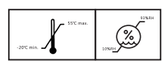

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