CE 0123

LEICKE

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User's Manual

LEICKE Sharon Blood Pressure Monitor

with Bluetooth

Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China

EC REP MDSS - Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany

Product number: LH67402

Model:LS810-BS

技术要求:
1、黏合不可露胶
2、保持印刷面板上的清洁
3、注意套印的准确性
4、表面处理不可爆开
5、颜色参考:

广东乐心医疗电子股份有限公司
2019-04-29
受 控 文 件

产品型号	LS810-BS-004	材质	80g书写纸	零件名称	
产品名称	血压计	尺寸	95*135 mm		
对应结构图纸	-	印色	单黑	P0#2B4069-LS810-BS-004-GB-06-EN说明书-A3	
	比例 1:1	表面处理	-	零件图号	
	单位 mm	设计	李秋燕 2019-04-29	LS810-BS-004-GB-06	
Transtek 广东乐心医疗电子股份有限公司		审核	罗佳钰 2019-04-29	共 32 张	第 1 张
		批准	谭文昊 2019-04-29	版 本	A/3

Thank you for purchasing the Blood Pressure Monitor from LEICKE Sharon.

We continuously work on the development of our products, our customer support and innovations. Our products have a long service life, are eco-friendly and high performing. Furthermore, every day we do our very best to satisfy you as our customer. That is why you, no matter if private or business customer, are in the focus of our company's efforts. We take your reviews and proposals seriously and evaluate them continuously. That way, we get to know you and your demands on our products and services better and thus allow for positive enhancements.

To discover more about LEICKE products or if you have any questions about this product visit our website www.leicke.com.

PACKAGE CONTENTS

Before attempting to use this device, please check the packaging and make sure the following items are contained in the package:

Number of Pieces	Name	Note
1	Blood Pressure Monitor (USB interface)	Bluetooth 4.0
1	USB Cable	-
1	User's Manual	-

TECHNICAL DETAILS

Power supply	3.7V 420mAH Built-in rechargeable lithium-ion battery,5V ⎓ 1A USB
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%
Normal working condition	Temperature: 5°C to 40°C A relative humidity range of 15% to 93%, 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
Degree of protection	Type BF applied part
Protection against ingress of water	IP22
Software version	A01
Device classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor charged Mode: Class II ME Equipment
RF Frequency Range	2402 MHz to 2480 MHz
Transmitting Distance	10 m

Weight	108 g
Dimensions	Size: 79.8 mm x 72.5 mm x 13.2 mm

PRODUCT INFORMATION

The device features blood pressure measurement, pulse rate measurement and the result storage. Readings taken by this device 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.
Please do read this user manual carefully and thoroughly before use.

FEATURES:

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Pulse Rate
- Memory: Up to 60 pieces of records

MEASUREMENT PRINCIPLE

This product uses the Oscillometric Measuring Method to detect blood pressure.
Before every measurement, the unit establishes a “zero point” equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as pulse rate.
The device also compares the longest and the shortest intervals of detected pulse wave with the average value, and then calculates the standard deviation.
The monitor will light up a warning symbol when the calculated standard deviation is larger than or equal to 15.

SAFETY INFORMATION

The signs below might be in the user manual, labelling 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 - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “MANUFACTURER”		
SN	Symbol for “SERIAL NUMBER”		Symbol for “DIRECT CURRENT”
	Symbol for “Including RF transmitter”	EC REP	Symbol for “Authorised Representative in the European Community”
	Caution: These notes must be observed to prevent any damage to the device.		Symbol for “MANUFACTURE DATE”

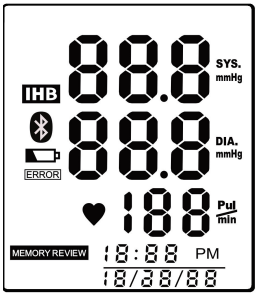
INDICATIONS FOR USE

The LEICKE Sharon Blood Pressure Monitor is a digital monitor intended for measuring blood pressure and heartbeat rate with wrist circumferences ranging from 13.5 cm to 21.5 cm (about 5¼ inches to 8½ inches).
It is intended for adult indoor use only.

⚠ CAUTION:

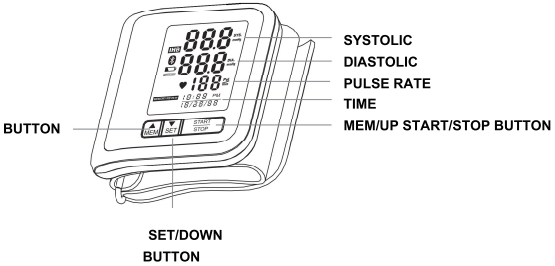
* Intended for adult indoor use only. Pregnant women, neonatal patients, pre-eclamptic patients and patients with severe obesity must not use the device. If in need, please consult a professional doctor.
* Intended for non-invasive measuring and monitoring of arterial blood pressure. Not intended for use on extremities other than wrist or for functions other than obtaining a blood pressure measurement.
* Please use device under user manual specified environment, otherwise accuracy may be influenced.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not start 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 for your measurement. Never change a prescribed medication without your physician's consent.
* If the cuff's pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. If the cuff doesn't deflate when its pressure resaches 40 kPa (300 mmHg), detach cuff from wrist and press the START/STOP button to stop inflation.
* Do not use the monitor under a strong electromagnetic field (e.g. medical RF equipment) that radiates interference signals or electrical fast transient/ burst signals.
* The maximum temperature of the device is 42.5°C the environmental temperature being 40°C.
* The device is not AP/APG equipment. It is not suitable for use in the presence of a flammable anaesthetic mixture with air (or oxygen, nitrous oxide).
* Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.
* Please use ACCESSORIES and detachable parts specified / authorised by MANUFACTURER. Otherwise, it may cause damage to the unit or endanger the user / patient.
* The patient is an intended operator. The patient can measure, transmit data and charge battery under normal circumstances and maintain the device and its accessories according to the user manual.
* The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient's environment. If you are allergic to dacron or plastic, please don't use this device.
* The device is not intended for PATIENT transport outside a healthcare facility.
* This device cannot be used with HF surgical equipment at the same time.
* There is a PTC current limiter in the monitor, whose specification is 8V and 0.5A. When the voltage and current exceed the limiting value, the monitor will stop working.
* The adaptor is specified as a part of ME equipment.
* The device is not suitable for public use.
* The adapter insulates the device from the main supply. Do not position the plug in a position where it is difficult to disconnect from the supply mains.
* Sensitive people, including pregnant women pre-eclamptic patients, patients who implanted medical electronic instruments and have atrial fibrillation (AF), premature ventricular beats and peripheral arterial disease (PAD)., should avoid using the unit whenever possible.
* This unit is not suitable for continuous monitoring during medical emergencies or operations.
* Manufacturer will make available on request circuit diagrams, component parts list etc.

LCD DISPLAY SIGNAL



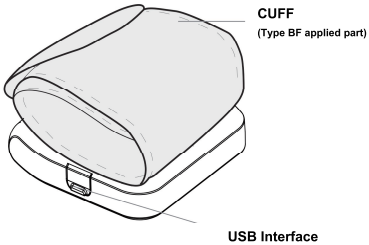
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	High blood pressure
DIA	Diastolic Blood Pressure	High blood pressure
Pul min	Pulse	Beat/minute
+Lo	Low Battery	Low battery - please charge
mmHg	Unit	Measurement unit of blood pressure (1mmHg=0.133kPa)
IHB	IHB Detector	Irregular Heartbeat Detector
	Bluetooth	Successful Bluetooth Connection
ERROR	Error	Error
MEMORY REVIEW	Memory	Recalling the history records
PM	Time	Hour: Minute (Month/Day/Year)
	Heartbeat	Heartbeat detection during the measurement

Monitor Components



Component list of
pressure measuring system:

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



Charging the Device

1. The battery of the monitor is a built-in rechargeable lithium-ion battery, the battery current is 420 mAh.
2. Please use the USB cable to charge the battery, just like the following pictures:

Method 1

Method 2

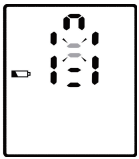
Adaptor(Not included) Input:100-240V, 50-60Hz 0.2A MAX
Type:BLJ06L050100U-V Output: 5V 1000mA

Charging the power under following circumstances:

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

⚠ **CAUTION:**

1. The battery of the monitor is built-in rechargeable lithium-ion battery, please do not disassemble yourself or by unauthorized maintenance personnel.
2. When used normally, it can be charged about 300 times, if the battery cannot be charged normally or the blood pressure monitor cannot be used normally, please contact authorized maintenance personnel. If you measure three times per day, and the battery was fully charged, it can be used for about 20 days.
3. Store and use the blood pressure monitor in a cool, dry and ventilated environment. Avoid fire and heat sources, or the battery may explode.
4. Only use the authorized USB cable (5V⎓1A) to charge power.
5. During the charging process, the blood pressure monitor displays:



When charging is finished, please pull the plug in time.

⚠ **CAUTION:**

6. When charging, do not touch charging connector and patient simultaneously.
7. Do not attempt to replace your blood pressure monitor's battery. It is built-in and not changeable.
8. Only charge the battery in accordance with the user instructions supplied with the blood pressure monitor.
9. Avoid charging your blood pressure monitor in extremely high or low temperatures.
10. Do not use your blood pressure monitor while you are charging it.
11. Do not attempt to disassemble the blood pressure monitor or force open the built-in battery.
12. Do not clean the blood pressure monitor when it is being charged. Always unplug the charger first before cleaning the blood pressure monitor.
13. Do not dispose of your blood pressure monitor in a fire. The battery could explode causing injury or death.
14. Batteries (battery pack or batteries installed) shall not be exposed to excessive heat such as sunshine, fire or the like.

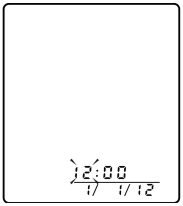
Activate Your Blood Pressure Monitor

Getting the Blood Pressure Monitor, the first thing to do after charging is to activate it. Please press and hold the SET button to activate it and enter setting mode.

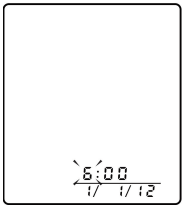
Setting Date and Time

Please proceed to time setting before your initial use so as to ensure each piece of record is labelled with a time stamp. (Year Range: 2012-2052; Time Format: 12 Hours)

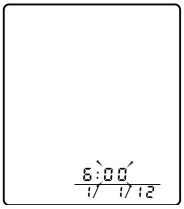
1. When the monitor is OFF, press and hold “SET” button for 3 seconds to enter Time Setting Mode.



2. As pictured in the right, the blinking number represents the [HOUR]. Press “MEM” button to change the number. Each press will increase the number by one in a cycling manner.

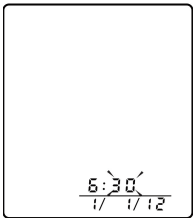


3. Press “SET” button again to confirm [HOUR]. Then the number representing [MINUTE] blinks.

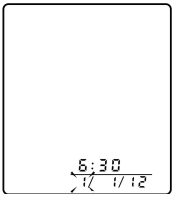


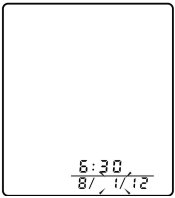
Setting Date and Time

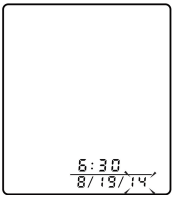
4. Repeat steps 2 and 3 to confirm [MINUTE].



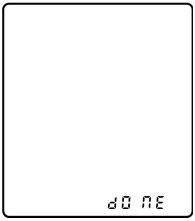
5. Repeat steps 2 and 3 to confirm [MONTH], [DAY] and [YEAR].







6. After confirming [YEAR], the LCD will display “dONE” and then shut off.



Positioning the Cuff

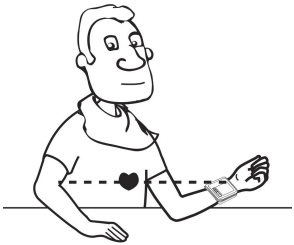
1. Remove all accessories (watch, bracelet, etc.) from your left wrist. If your physician has diagnosed you with poor circulation in your left wrist, use your right wrist.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your left wrist with your palm facing up.
4. Position the edge of the cuff about 1-2 cm below the wrist.
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. 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 arm supported.

   • Rest for 5 minutes before measuring.

   • Wait at least 3 minutes between measurements. This allows your blood circulation to recover.

   • For a useful 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.

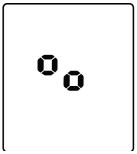


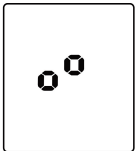
PAIRING THE BLOOD PRESSURE MONITOR WITH YOUR MOBILE DEVICE

Download and install the MedM Health APP to your mobile device which supports Bluetooth 4.0 technology from the APP Store or Google Play.

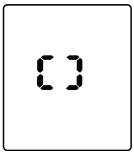
1. Turn on Bluetooth and the app. Make sure both are ON when pairing is proceeding.

2. When the monitor is OFF, press and hold the START/STOP button to start pairing. These symbols will be shown on the LCD alternatively, indicating pairing is proceeding.





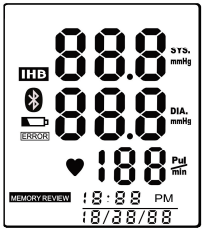
- **If SUCCEED**, this symbol will be shown on the LCD.



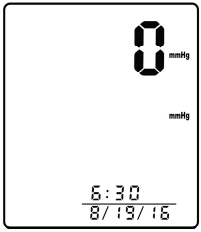
- **If FAIL**, than this symbol (Bluetooth ERROR) will be shown on the LCD**.**

3. The monitor will shut off after pairing process is complete.

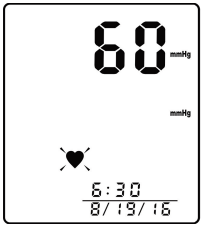
1. After correctly positioning the cuff, press START/STOP button to turn on the monitor, and it will complete the measurement process.



Adjust to zero.



Inflating and measuring.

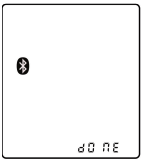


Display and save the measuring result.

2. This device will proceed to data transmission after measurement.

The Bluetooth symbol blinking on the LCD indicates data transmission.

3. If the data is successfully transmitted, the LCD will display “dONE”.



If data transmission fails, the LCD will display “**BLUETOOTH ERROR**” instead.

4. Press START/STOP button to turn off the monitor. Otherwise if there is no operation, it will switch off within 1 minute.

Recall the Records

1. Press “MEM” button to access the memory when the monitor is off. The monitor will display the calculated value of the latest readings first.

2. Press “MEM/UP” button or “SET/DOWN” button to rotate the history records.

   “MEM/UP” to go forward;

   “SET/DOWN” to go backward.

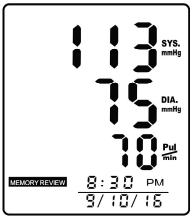
⚠ **CAUTION:**

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 from the list.

Delete the Records

When you did not obtain the accurate measurement, you can clear all the measuring results by following the steps below.

1. Under Memory Recalling Mode, press and hold both the “MEM” button and the “SET” button for 3 seconds.



2. The LCD will display “dEL dONE”, indicating that memory clearing is complete. And then it will shut down.

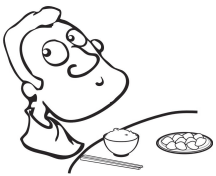
⚠ **CAUTION:**

Under Memory Recalling Mode, if you wish to give up clearing, press “START/STOP” to turn off the monitor.

3. When there is no memory in the monitor, if you press the “MEM” button to look up history, the LCD will display as pictured to the right.

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

When you need to pee urgently

In a very cold environment

Maintenance

To obtain the best performance, please follow the instructions below.

Put in a dry place and avoid sunshine.

Avoid immersing it in water. Clean it with a dry cloth in case.

Avoid shaking and collisions.

Avoid dusty environment and unstable temperature surrounding.

Use a slightly damp cloth to remove dirt.

Avoid washing the cuff.

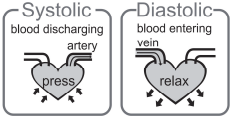
⚠ **CAUTION:**

1. Please make sure the unit functions safely and it is in proper working conditions before use. Don't service or maintain while the device is in use.
2. If you have any problems with this device, such as setting up, maintaining or using, please contact the customer service. Don't open or repair the device by yourself.
3. Please report to LEICKE if any unexpected operation or events occur.
4. Cleaning: Dust environment may affect the performance of the unit. Please use a soft cloth to remove dirt from the device and cuff before and after use.
5. Calibration: The manufacturer does not require such preventive inspections or calibration by other persons and will make available on request circuit diagrams, component part list, etc.
6. Disposal: Degraded sensors may result in inaccurate measurement while loosened electrodes may cause the monitor's failure to power on. Please dispose of ACCESSORIES, detachable parts, and ME EQUIPMENT according to local guidelines.

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.



About Blood Pressure

Irregular Heartbeat Detector:

An irregular heartbeat is detected when the heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, the irregular heartbeat symbol appears when the measurement results are displayed.

⚠ **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?

Individual blood pressure varies multiple times every day. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

1. If the person takes medicine, the pressure will vary more.
2. Wait at least 3 minutes for another measurement.

About Blood Pressure

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.

What do 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.

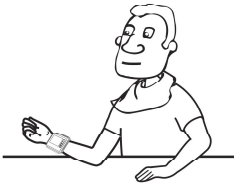
If you feel anxious.

Taking 2-3 deep breaths before beginning will be better for measuring.

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

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

It is ok for both wrists, but there will be some different results for different people. We suggest you measure the same wrist every time.



FAQ

Problem Description	Symptom	Possible Cause/Possible Solution
No Power	Display is dim or will not light up.	• Power is exhausted. Please charge.
Low Batteries	 Shows on the display	• Battery is low. Please charge.
Error Message	 Shows	• Data communication has failed • Make sure that phone's Bluetooth is switched on or within the distance range
	ERROR 1 shows	• Inflation is slow or the cuff is not secure • Refasten the cuff and then measure again.
	ERROR 3 shows	• Refasten the cuff and then measure again. • The pressure of the cuff is too high.
	ERROR 10 or 11 shows	• Relax for a moment and then measure again. • The monitor detected motion, talking or the pulse is too poor while measuring.
	ERROR 20 shows	• The device does not detect the pulse signal. • Loosen the clothing on the

FAQ

Problem Description	Symptom	Possible Cause/ Possible Solution
Error Message	ERROR 21 shows	• Relax for a moment and then measure again. • The treatment of the measurement failed.
Error message	• 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.
"out" shows	Out of measurement Range	Relax for a moment and the measure again

Complied European Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labelling	EN ISO 15223-1:2016 / ISO 15223-1:2016Medical 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/ 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 80601-2-30:2013 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/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability EN 62366-1:2015/ IEC 62366-1:2015Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304:2006 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- for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
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
Harmonic emissions IEC 61000-3-2	Class A	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complines	supplies buildings used for domestic purposes.

EMC Guidance

Table 2 Guidance and MANUFACTURER's declaration – ELECTROMAGNETIC IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth 100 kHz repetition frequency	±1 kV line(s) to line(s) 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%U_T ;0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°,270° and 315° 0%U_T ;1 cycle and 70%U_T ; 25/30 cycles Single phase: at 0° 0% U_T ;300 cycl	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°,270° and 315° 0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0° 0% U_T ;300 cycle	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60Hz) 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.

EMC Guidance

Table 4 Guidance and MANUFACTURER's declaration – ELECTROMAGNETIC IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

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: $d=0.35 \quad P$ $d=1.2 \quad p$ 80 MHz to 800 MHz $d=1.2 \quad P$ 800 MHz to 2.7 GHz $d=2.3 \quad P$ where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer 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:
Radiated RF IEC 61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	

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.

EMC Guidance

Table 6 Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM –

- for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

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 (transmitters) 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 $d = 3.5 \quad P$	80 MHz to 800 MHz $d = 1.2 \quad P$	800 MHz to 2.57GHz $d = 2.3 \quad P$
0.01	0.12	0.12	0.23
0.1	0.38	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 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.			

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 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	430-470	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
	5500						
	5785						

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.

DISPOSAL

This device contains materials that must not be disposed of as household waste. Please check local laws concerning the applicable disposal regulations. Protect the environment by participating in recycling programs.

CONTACT

If you have any questions, please feel free to contact us.

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