PO#2B0767A　TMB-1018-BT(LS-921 Blue)　说明书（A0）

印色：单黑

材质：80g书写纸

尺寸：105*142 mm

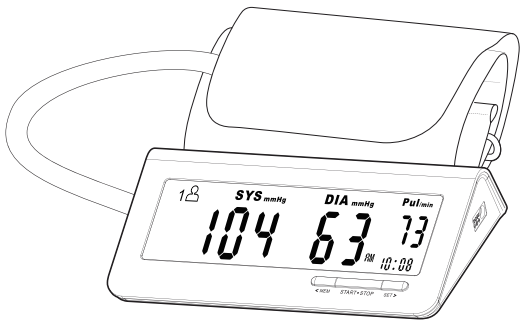
Version:1.1

LIFESMART

User Manual

Blood Pressure Monitor
LS-921

Arm Type



- Thank you very much for selecting the LifeSmart Blood Pressure Monitor LS-921.
- Please do read the user manual carefully and thoroughtly so as to ensure the safe usage of this product, and keep the manual well for further reference in case you have problems.

CE 0123 Bluetooth ENABLED

Manufactured For: GENESIS BIOTECH PTY LTD
Address: Level 1, 16 McDougall Street, MILTON QLD 4064
www.mylifesmart.net.au
CONTACT US
For Australia & New Zealand customers
support@mylifesmart.net.au
Australian customers 1300 110 155

GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO.,LTD
Address: 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

Table of Contents

♥ General Description

Thank you for selecting LifeSmart arm type blood pressure Monitor (LS-921). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service. Reading taken by the LS-921 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 instruction for using the product.

Read the manual thoroughly before using the product.

Features:

- 140mm x 36mm Blue LCD display with white backlight
- Up to 60 pieces of record stored for each user
- Measure-during-inflating Technology
- Bluetooth data transmitting function

♥ Indications For Use

1.The LifeSmart Blood Pressure Monitor is digital monitor intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from about 22cm to 42 cm (about 8¾″-16½″).

2.The monitor detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

3.It is intended for adult use in the home/domestic setting only.

♥ 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 arm 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.The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval then calculates standard deviation.The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals over.

♥ Safety Information

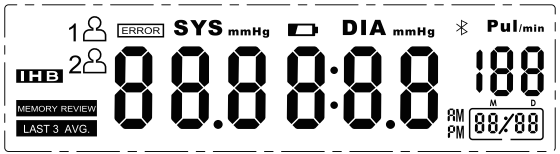
The below signs might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
CE 0123	Symbol for “COMPLIES WITH MDD93/42/EEC REQUIREMENTS”		Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please follow local guidelines.”
	Symbol for “MANUFACTURER”		
SN	Symbol for “SERIAL NUMBER”	⎓	Symbol for “DIRECT CURRENT”
Bluetooth ENABLED	The Bluetooth Combination Mark	EC REP	Symbol for “Authorised Representative in the European Community”
	Symbol for “MANUFACTURE DATE”	⚠	Caution: These notes must be observed to prevent any damage to the device

⚠ CAUTION

·This device is intended for adult use only.
·This device is intended for no-invasive measuring and monitoring of arterial blood pressure.
·It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
·Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment without asking a physician for treatment advice.
·If you are taking medication,consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
·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.
·If the cuff pressure exceeds 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures exceeds 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
·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.
·The operator shall not touch output of batteries and the user simultaneously.
·To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
·The user must check that the equipment functions safely and see that it is in proper working condition before being used.
·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.
·Manufacturer will make available on request circuit diagrams, component parts list etc.
·This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the user’s arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
·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.
·During use, the user 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.
·Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
·The device doesn’t need to be calibrated within the two years of reliable service.
· Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
·If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Lifesmart. Don’t open or repair the device by yourself.
·Please report to Lifesmart if any unexpected operation or events occur.
·Please use the soft cloth to clean the whole unit. Don’t use any abrasive or volatile cleaners.

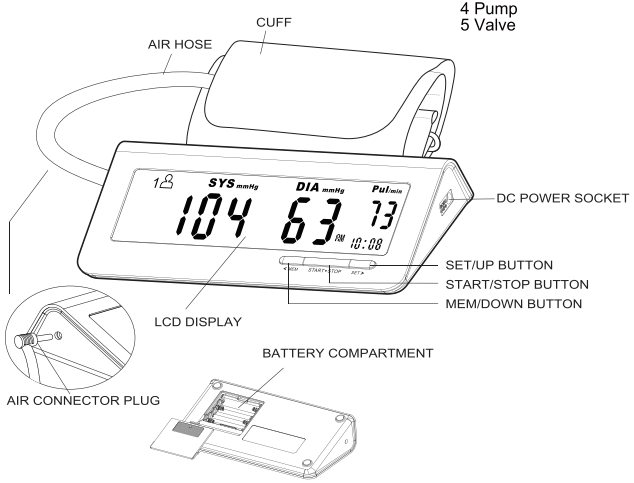
♥ LCD Display Signal



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	High blood pressure
DIA	Diastolic Blood Pressure	Low blood pressure
Pul/min	Pulse	beat/minute
1	User 1	Start measurement for user 1 and transmit the measuring result automatically.
2	User 2	Start measurement for user 2 and transmit the measuring result automatically.
MEMORY REVIEW	Memory Review Mode	the query log, and a few memories
	Successful Bluetooth Connection	Bluetooth is turned on
LAST 3 AVG.	Average Value	Average value of last three measurements.
ERROR	Error	The monitor detects error.
	Low Battery	Low battery and please replace the batteries.
mmHg	Unit	Measurement unit of blood pressure
AM PM M D	Current Time	Month:Day (Hour:Minute)
IHB	Irregular Heartbeat Detector	Detects irregular heart beats.

♥ Monitor Components

Component list of pressure measuring system
1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve



♥ List

1.Blood Pressure Monitor (LS-921)

2.Cuff (Type BF Applied Part) (about 22cm~42cm)
(Please use LifeSmart authorized cuff)

3. 4*AAA alkaline batteries

4. User manual

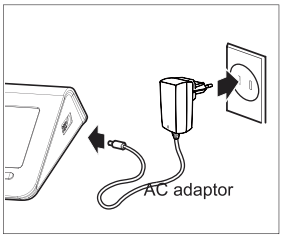
5. Optional - AC Adaptor (UE08WCP-060100SPA)

♥ The Choice of Power Supply

1.Battery powered mode:
6VDC 4*AAA alkaline batteries

2.AC adaptor powered mode:
6V ⎓ 1A
(Can be supplied by AC adaptor model UE08WCP-060100SPA only) (Not Included)

Please unplug the adaptor to depart from the using utility power.

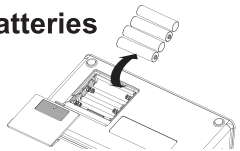


⚠ CAUTION

In order to achieve the best performance and protect your monitor, please use the authorized / specified battery and power adaptor.

♥ Installing and Replacing the Batteries

1. Open the battery door.
2. Insert the batteries according to the polarity indications.
3. Close the battery door.



Battery Life: Approx. 44 days

(Battery capacity: 600 mAH. If measured three times per day, each measurement takes 35s, measuring result display takes 20s and data transmission takes 10s. The current for measurement is 400 mA and that for records display and data transmission is 50 mA and 50 mA separately, while the current when shutdown is 35 uA.

Replace the batteries under following circumstances:

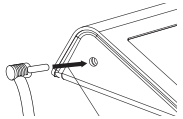
-  displays on the LCD.
- The LCD display dims.
- When powering on the monitor, the LCD doesn't light up.

⚠ CAUTION

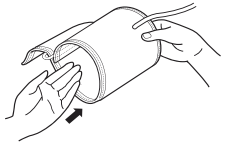
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode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

♥ Apply the Cuff

1.Insert the plug of cuff's air pipe into the interface located on the right side of the monitor.

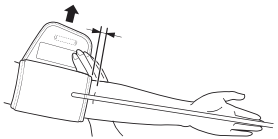


2.As pictured on the right, wear the cuff on your upper arm.



3.Tighten the cuff up. Make sure the cuff is fixed 2 to 3 centimeters above your elbow.

Appropriate to insert one finger when the cuff is tightened around your upper arm.



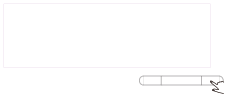
4.Correct Posture:
Bare your arm or wear tights only when starting measurement.
Sit comfortably and relaxed on a proper-size chair.
The central of the cuff should maintain at the same level as your heart.
Legs relaxed with the feet falling outwards.
Palms up.

♥ Settings

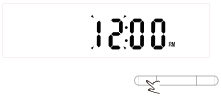
Please proceed to time setting before your initial use so as to ensure each piece of record is labeled with a time stamp. (The range of the year is 2000 to 2050. Time Format: 12 Hours)

NOTE: The monitor will shut off automatically in 60 seconds after last operation when in Setting Interface.

1.When the monitor is OFF, press and hold SET button to enter [HOUR] and [MINUTE] setting.



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



HOUR

3.Press SET button to confirm the [HOUR] and [MINUTE]. Then the monitor diverts to [MONTH] and [DAY] setting automatically.

MINUTE

4.Repeat step 2 and 3 to confirm [MONTH] and [DAY]. Then the monitor diverts to [YEAR] setting automatically.

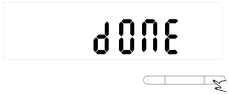
MONTH

DAY

5.Repeat step 2 and 3 to confirm [YEAR].

YEAR

6.After confirming the [YEAR], the LCD will display “dOnE” and the monitor will shut off automatically.



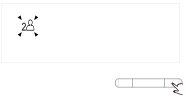
♥ Select User ID

NOTE: The monitor will shut off automatically in 60 seconds after last operation when under User ID selection mode.

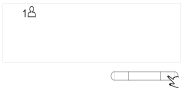
1.When the monitor is OFF, press and hold MEM button to enter User ID selection mode.

2.The current User ID blinks.

3.Press MEM button to switch between User 1 and User 2.



4.Press SET button to confirm the selected User ID.



♥ Pair-up the Blood Pressure Monitor with Your Device

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

2.When the monitor is OFF, press and hold the START button to start pair-up. The symbol ᛒ blinks, indicating pair-up is proceeding.

If SUCCEED, symbols will be shown on the LCD just like the picture on the right.

If FAIL, symbols will be shown on the LCD just like the picture on the right.

3.The monitor will shut off automatically after Pair-up process is complete.

Bluetooth Module No.: AW8001
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: 0 dBm
Supply Voltage: 1.8-3.6 V
Transmitting Distance: 10 meters

♥ Start Measurement

After correctly positioning the cuff and selecting User ID, press START·STOP button to turn on the monitor, and it will complete the measurement process automatically. Take User 1 for example.

1.LCD display

2.Adjust to zero automatically.

3.Inflating and measuring automatically.

4.Display and save the results. And the result will be transmitted to the app. The icon ᛒ blinks.

If the data is successfully transmitted, the LCD will then display “dOnE”

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

5. Press START·STOP button to turn off the monitor. Otherwise, the monitor will shut off within 1 minute after last operation.

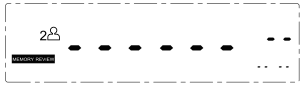
Tips:
Maximum 60 records are both for user 1 and user 2.

♥ Recall the Records

1.When the monitor is OFF, press MEM button to retrieve the memory. The monitor will display the average value of last three measurements.

2.Press MEM button again to rotate the records. Up to 60 records will be stored under each user ID.
The measurement date and time will be displayed alternatively.

3.If you would like to check another user ID's history, please follow the instructions in Select User ID to change to another User ID first.



No Record found for User 2!

♥ Delete the Records

1.When under data enquiry mode, press and hold both MEM button and SET button for 3 seconds to clear memory. The LCD will display "dEL dOnE", indicating that the memory is cleared.

♥ Data Transmission

Manual Data Transmission

With the advanced Bluetooth 4.0 technology applied, the mobile or portable equipments, which are equipped with Bluetooth function in line with BLE
Technical Specifications as well as BLP Protocol established by global organization Bluetooth SIG, are capable to receive your personal health data.

When both LifeSmart Blood Pressure App and Bluetooth are ON, LS-921 will automatically transmit measurement data to your mobile via Bluetooth.

1.After measurement, the symbol lights up, indicating the measuring result is being automatically transmitted to lifesmart Blood Pressure system.

2.If SUCCEED, the LCD will display "dOnE".

3.If FAIL, the LCD will display "ERROR".

⚠ CAUTION

- Interference may occur in the vicinity of equipment marked with the following symbol . And LS-921 may interfering vicinity electrical equipment.
- Sensitive people, including pregnant women and those who implanted medical electronic instruments, should avoid using the unit whenever possible.
- Keep the monitor at least 20 centimeters away from the human body (especially the head) when the data transmission is proceeding after measurement.
- To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

How to mitigate possible interference?

1. The range between the device and BT end should be reasonably close, from 1 meter to 10 meters. Please ensure no obstacles between the device and BT end so as to obtain quality connection and to lower the RF output range.
2. To avoid interference, other electronic devices (particularly those with wireless transmission / Transmitter) should be kept at least 1 meter away from the monitor.

♥ Tips for Measurement

It can cause inaccuracy if the measurement is taken in the following circumstances.

Within 1 hour
after dinner or drinking

Immediate measurement
after tea, coffe, 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

To obtain the best performance, please follow below instructions.

Put in a dry place and
avoid the sunshine

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

Avoid shaking and collision.

Avoid dusty environment and
unstable temperature surrounding

Use the slightly damp cloth
to remove the dirt.

Avoid washing the cuff

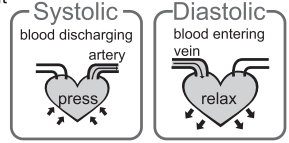
Cleaning: Before Use - Pick out the whole unit of the storage bag. Use the soft cloth to remove the dirt on the monitor and apply some alcohol to disinfect the cuff before tying the cuff.
After Use - Use the soft cloth to wipe the unit and apply some alcohol to disinfect the cuff before putting the whole unit back in the bag.
Please always disinfect the cuff before applying to another patient.

Please follow the instructinos for correct replacement of interchangeable or detachable parts specified by SERVICE PERSONNEL of MANUFACTURER as “replaceable”.

Disposal: Degraded sensors may result in inaccurate measurement while loosened electrodes may cause the monitor’s failure to power on. The expected life of the monitor is two years. Please dispose of ACCESSORIES, detachable parts, and the ME EQUIP-MENT according to the local guidelines.

♥ 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.

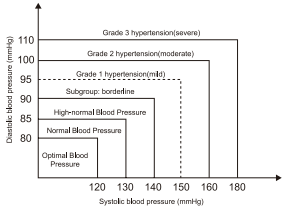


♥ What is the standard blood pressure classification?

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

This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat (IHB) Detector. 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, this equipment will light up the IHB symbol on the screen when displaying the measuring result.

⚠ CAUTION

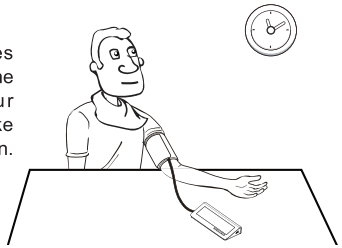
The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace 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 every in one day, it also affected by the way you tie your cuff and the your measurement position, so please take the measurement at the same condition.

2.The varies of the pressure is greater if the person take medicine.

3.Waiting at least 3 minutes for another measurement.



♥ Why the blood pressure I get from the hospital is different from home?

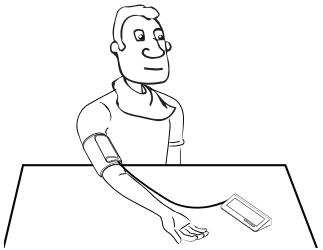
The blood pressure is different even during 24 hour because of the weather,emotion, exercise etc, specially the “white coat” in hospital which makes the results are higher than the ones at home.

The attention need to pay 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 upper arm.
If you feel anxious pressured.
You had better take deep breath 2-3 times before beginning.
Advice:adjust yourself for 4-5 minutes until you calm down.

♥ Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different arm, so suggest you measure the same arm every time.



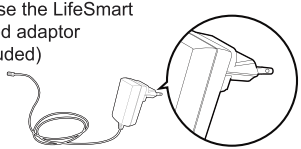
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or display	Batteries are low.	Replace with new batteries
Error message	shows	Data communication has failed	Check if the APP is on or not, try data transmission again.
	Error 1 shows	Inflation is slow or the cuff is not secure.	Refasten the cuff and then measure again.
	Error 2 shows	The cuff is very tight	Readjust the cuff ,not too loose or too tight and then measure again.
	Error 3 shows	The pressure of the cuff is excess.	Refasten the cuff and then measure again.
	Error 5 or Error 6 shows	System 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.
	Error 10 or Error 11 shows	The monitor detected motion,talking or the pluse is too poor while measuring.	Relax for a moment and then measure again.
	Error 20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	Error 21shows on the display.	The treatment of the measurement failed.	Relax for a moment and then measure again.

Power supply	Battery Powered Mode: 6V (4 x AAA-size alkaline-battery) AC Adaptor Powered Mode: 6V ⎓ 1A (Can be supplied by AC adaptor model UE08WCP-060100SPA only!)(Not Included)
Display mode	Blue LCD with White Backlight V.A. = 140mm(L) x 36mm(W)
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kPa - 40kPa (0mmHg~300mmHg) Measurement pressure: 5.3kPa-30.7kPa (40mmHg-230mmHg) pulse value: (40-199) beat/minute
Accuracy	Pressure: 5℃-40℃within±0.4kPa(3mmHg) pulse value:±5%
Working condition	Temperature:5℃-40℃ Relative Humidity: ≤85% Atmospheric Pressure: 80-106 kPa
Storage & transportation condition	Temperature:-20℃-60℃ Relative Humidity 10%-93%RH Atmospheric Pressure: 50-106 kPa
Measurement perimeter of the upper arm	About 22cm to 42 cm
Net Weight	Approx.300g(Excluding the dry cells)
External dimensions	Approx.180*100*40mm
Attachment	4*AAA alkaline batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
IP Classification	IP22
Software Version	V01

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

1. Please use the LifeSmart authorized adaptor (Not Included)



Adaptor
Type: UE08WCP-060100SPA
Input: 100-240V，50-60Hz,400mA
Output: 6V ⎓ 1A
(Conforms to UL Certification)

♥ Contact Information

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Model：TMB-1018-BT
Ref.No.: LS-921
Manufactured For: GENESIS BIOTECH PTY LTD
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Manufactured by: GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD
Company: GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD
Address: Address: Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China

Authorized European Representative:
Company: MDSS - Medical Device Safety Service GmbH
Address: Schiffgraben 41, 30175 Hannover, Germany

♥ Complied European Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	EN 60601-1: 2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC/EN 60601-1-11: 2010 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	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements	EN 1060-1:1995+A2:2009 Non-invasive blood pressure Part 1: General requirements EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	IEC/EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ EMC Guidance

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 2	The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	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	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	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** $d = 1.167\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2,5 GHz 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: 

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 3 V/m.

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 $d = 1{,}167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}167\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}333\sqrt{P}$
0,01	0,117	0,117	0,233
0,1	0,369	0,369	0,738
1	1,167	1,167	2,333
10	3,690	3,690	7,378
100	11,67	11,67	23,33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			