Version:1.0

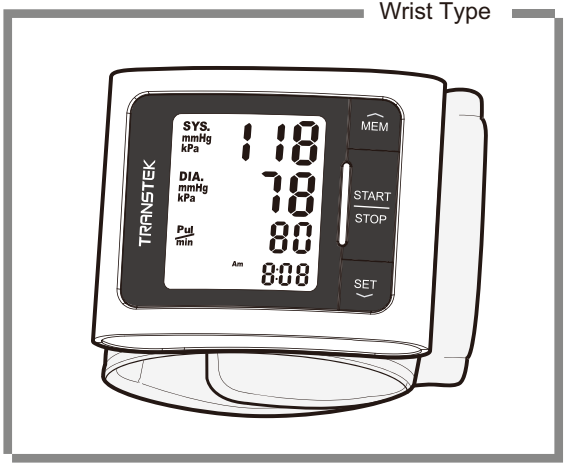
CE 0123

TRANSTEK

User Manual

Blood Pressure Monitor TMB-1014-BT

Wrist Type



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor TMB-1014-BT.
- To use the monitor correctly and safely, please read the manual thoroughly.
- Please well keep this manual in order to reference in future.

Zhongshan Transtek Electronics Co., Ltd
Jin'an Road, Minzhong, Zhongshan 528441, Guangdong, China

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

CE 0123

Thank you for selecting TRANSTEK wrist blood pressure Monitor (TMB-1014-BT). The monitor features blood pressure measurement, pulse rate measurement and auto-save the result. The design provides you with many years of reliable service.

Reading taken by the TMB-1014-BT 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:
- Systolic blood pressure
- Diastolic blood pressure
- Pulse rate
- Historic record of up to 60 measurements

♥ Safety information

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

	Caution:Consult accompanying documents		Type B applied part
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.
	Manufacturer		Direct current
SN	Specifies serial number	EC REP	Authorized Representative in the European Community

⚠ 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 wrist or for functions other than obtaining a blood pressure measurement.

Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment based solely 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.

This unit is not suitable for continuous monitoring during medical emergencies or operations.

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 wrist and press the START/STOP button to stop inflation.

To avoid measurement errors, carefully read this manual before using the product.

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 the battery and the patient simultaneously.

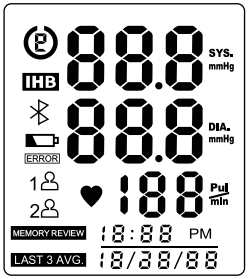
The user must check that the equipment functions safely and see that it is in proper working condition before being used.

The manufacturer does not require such preventive inspections by other persons.

The Max. temperature of apply part can be achieved is 42.5℃ under the environmental temperature of 40℃.

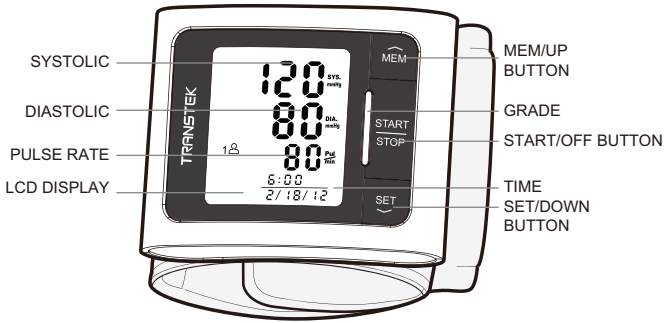
Manufacture will make available on request circuit diagrams, component part list, etc.

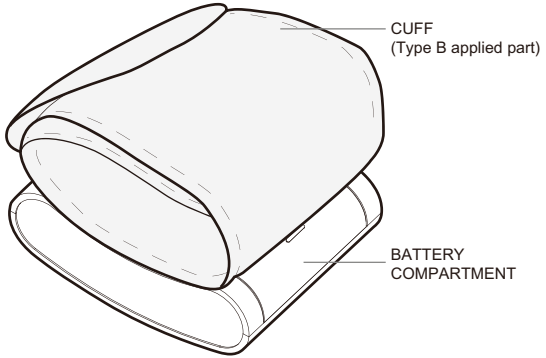
♥ LCD display signal



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pul min	Pulse	Pulse/minute
+Lo	Low battery	Batteries are low and need to be replaced
mmHg	mmHg	Measurement unit the blood pressure
	Grade	The grade of the blood pressure For instructions,refer to Page 13
IHB	Arrhythmia	Arrhythmia is detected
	Bluetooth	Bluetooth is in an open position
ERROR	Error	Blood pressure monitor has detected error
1 2	User	The current selected user
MEMORY REVIEW	Recalling	The erecords will be showed
18:88 PM 18/88/88	Time	Currently time

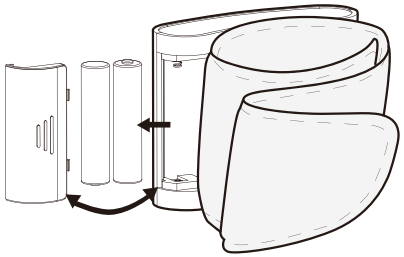
♥ Monitor components





♥ The installment and replacement of battery

1. Slide off the battery cover.
2. Install the batteries by matching the correct polarity, as shown below. Always use the correct battery type (2 alkaline LR03AAA-size).
3. Replace the cover.



Replace the batteries whenever the below happen

- The +Lo shows
- The display dims
- The display does not light up

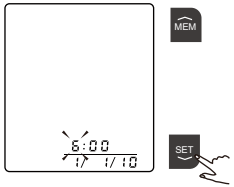
⚠ CAUTION

- Remove batteries if the device is not likely to be used for some time.
- The old battery is harmful to the environment, so please disposal with other daily trash.
- Remove the old battery from the device and follow your local recycling guidelines.

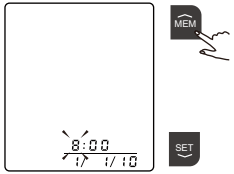
♥ Setting Date, time and measurement unit

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. In sure the "lock" key is glided to the unlock mode.(year :2010—2050; time:24 H))

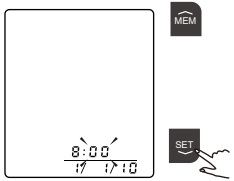
1.Pressing "SET" for 3 seconds to enter the mode for [Hour] setting.



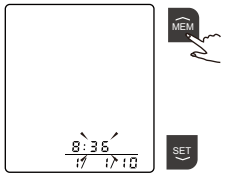
2.Press the "MEM" to change the [Hour].



3.When you get the right [Hour], press "SET" to set down and turn to next step automatically.

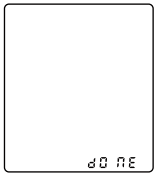


4.Repeat the 2 and 3 to set the [Minute].



5.Repeat the 2 and 3 to set the [YEAR], [MONTH] and [DAY].

7.After the unit is set, the right picture will show, then it turn off automatically.

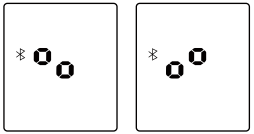


♥ Bluetooth phones' test software

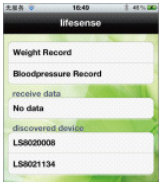
1.Open the Bluetooth 4.0 special test mobile phones after electrify blood pressure monitor.

2.After operating Bluetooth Test program (It is about 8 m from mobile to blood pressure monitor), the "discovered device" column will remind "searching for device"...

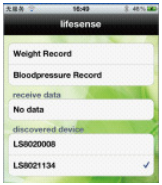
3.Long press the "START" button after power off the blood pressure monitor, it'll show moving "o".



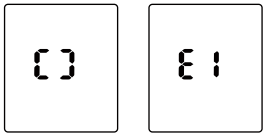
4.At this moment, the "discovered device" column of mobile will display devices list.



5.Choose detected device from the list. (There is "√" on the right.)



6.When the blood pressure monitor show "[ ]", it means matching successfully; When it display"E1", it indicates matching unsuccessfully.



7.If matching successfully, it will show the lately measuring record on the "receive data" column.

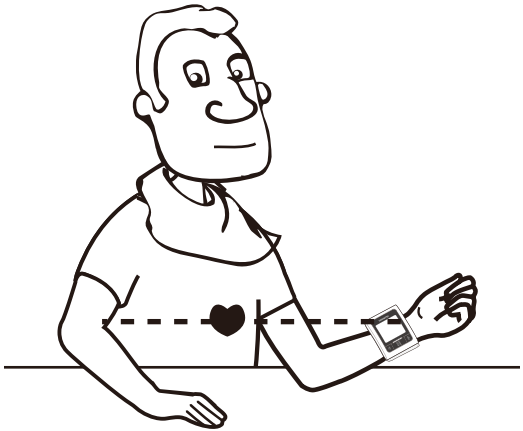
8.Choose "Bloodpressure Record" to view the history record.

9.Click "back" to return main interface of testing software and go on testing next blood pressure monitor.

♥ Positioning the wrist 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 1-1.5cm.
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.

• Resting for 5 minutes before measuring.
• Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
• For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist, or as directed by a physician.



♥ Start the Measurement

Please press the SET to choose the user 1 or user 2 when the blood pressure monitor turn off

1.Press the START/STOP, it will finish the whole measurement automatically.

Adjust the zero automatically.

Inflating and measuring automatically.

Display and save the results automatically.

2.After measuring, it'll display the moving "o" and send data at the same time.

3.If data is sent successfully, go back to display the interface of measuring results.

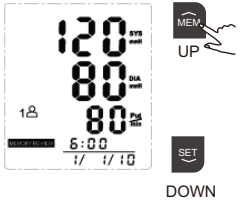
If the data failed to send, go back to display the interface of measuring results after display "E9".

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

♥ Recalling the records

1.Press the “MEM” to show the last 3 average of the record.

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



⚠ CAUTION

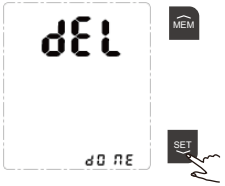
The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

♥ Deleting a measurement record from memory

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

1.Hold pressing “MEM” for 3 seconds, when the memory is shown.

2.When flash “Delete all”, press the “SET” to delete the memory.

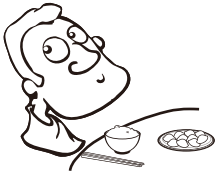


3.If you don’t want to delete the records, press “START/STOP” to escape.

4.If there is no record. the right display will show.

♥ Tips for measurement

It can cause incorrectness if the measurement are taken in the following circumstances.



Wait at least 1 hour
after dinner or drinking

Immediate measurement
after tea, coffee, smoking

Wait at least 20 minutes
after taking a bath

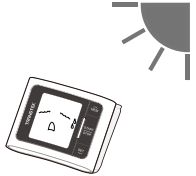
When talking or moving your fingers

In a very cold enviroment

When you want to discharge urine

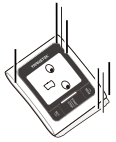
♥ Maintenance

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



Put in a dry place and avoid the sunshine

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



Avoid the intense shaking
and collision

Avoid the dusty and unstable-
temperature environment

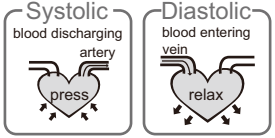
Using the wet clothing to remove the dirt

Avoid washing the cuff

Clean the cuff with a soft dry cloth. Do not use any abrasive or volatile cleaners.
In order to reduce the pollution of the environment, please return to the manufacture when the product is close to the end of life.
Instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL.
Please calibrate the blood pressure monitor in specific institute once every two years to ensure the precise measurement。 In order to get the best performance, please follow the below instructions for storage.

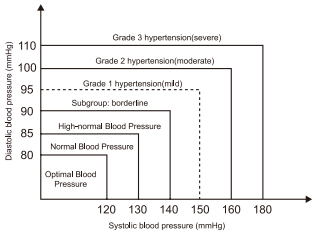
♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, blood pressure reaches its maximum value, the highest pressure in the cycle is known as systolic pressure. When the heart relaxes between heartbeats, the lowest blood pressure is diastolic pressure.



♥ What is the standard blood pressure classification?

Below illustrates the blood pressure classification mode by World Health Organization (WHO) and International Society of Hypertension(ISH) in 1999.



Blood Pressure (mmHg) \ Level	green light			yellow light	red light	
SYS	<120	120~129	130~139	140~159	160~179	⩾180
DIA	<80	80~84	85~89	90~99	100~109	⩾110

⚠ CAUTION

Only a physician can tell you your normal blood pressure range and the point at which you are at risk. Consult your physician to obtain these values.

If the measurements taken with these products fall outside the range, consulty.

♥ Why my blood pressure is varies even in one 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 4-5 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 you 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.

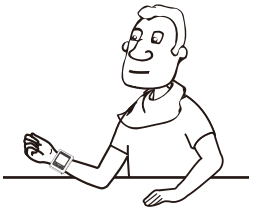
If you feel anxious pressured.

You had better take deep breath 2-3 times before beginning.

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

♥ If the result is the same if measuring on the right wrist?

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



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

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display is dim or will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
Low batteries	+Lo Show on the display	Batteries are low.	Replace with new batteries
Error massage	E 1 shows	Data communication has failed	Make sure that phone's Bluetooth is on or within the distance range
	E 2 shows	The cuff is very tight	Refasten the cuff and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E 9 shows	Product has not been activated.	Reactivated
	E 10 or E 11 shows	The monitor detected motion while measuring.	movement can affect the measurement.Relax for a moment and then measure again.
	E 20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 21 shows	Measure incorrectly.	Relax for a moment and then measure again.
	EExx,shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.

Power supply	2*AAA alkaline batteries
Display moder	Digital LCD V.A.36x41mm
Measurement mode	Oscillographic testing mode
Measurement range	Pressure: 0kpa-40kpa（0mmHg-300mmHg） pulse value:(40-199)times/minute
Accuracy	Pressure: 15℃-25℃within±0.4kpa(3mmHg) 10℃-40℃(out of 15℃-25℃) vithin±0.8kpa(6mmHg) pulse value:±5%
Normal working condition	Temperature:5℃ to 40℃ Relative humidity ≤80% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃ to 60℃ Relative humidity:10% to 93%
Measurement perimeter of the wrist	About 13.5cm-19.5cm
Weight	Approx.120g(Excluding the dry cells)
External dimensions	Approx.80×65×22mm
Attachment	2*AAA alkaline batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type B applied part
Protection against ingress of water	IPXO
Software version	V01
Device classification	Internally Powered ME Equipment

WARNING: No modification of this equipment is allowed.

♥ Contact Information

For more information about our products, please visit www.transtek.cn.you can get customer service, usual problems and customer download, transtek will serve you anytime.

Manufactured by: ZHONGSHAN TRANSTEK ELECTRONICES CO.,LTD
Conpany: ZHONGSHAN TRANSTEK ELECTRONICES CO.,LTD
Address: Jin'an Road, Minzhong, Zhongshan,528441,Guangdong, China

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

♥ Complied European Standards list

Risk management	EN/ISO 14971:2007
Labelling	EN 980: 2008
User manual	EN 1041: 2008
General requirements for safety	EN 60601-1:1990+A1+A2+A13
Non-invasive sphygmomanometers General requirements	EN 1060-1:2001/A1:2002 EN 1060-3:1997/A1:2005 EN 1060-4: 2004
Electromagnetic compatibility	EN 60601-1-2:2001+A1：2006

1) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
2) 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
3) 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.
4) The guidelines for avoiding or identifying and resolving adverse electromagnetic effects on other equipment that may result from operation of the ME EQUIPMENT or ME SYSTEM.
5) Each frequency or frequency band of reception; the preferred frequency or frequency band, if applicable, and the bandwidth of the receiving section of the ME EQUIPMENT or ME SYSTEM in those bands;
6) Warning: the TMB-1014-BT may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.
7) Each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER.

Table 1 Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The TMB-1014-BT is intended for use in the electromagnetic environment specified below. The customer of the user of the TMB-1014-BT should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The TMB-1014-BT 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 emission CISPR 11	Class B	The TMB-1014-BT is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 Guidance and manufacture's declaration – electromagnetic immunity – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The TMB-1014-BT is intended for use in the electromagnetic environment specified below. The customer or the user of TMB-1014-BT 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 floor 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	±2kV 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)	±1 kV differential mode	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	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TMB-1014-BT requires continued operation during power mains interruptions, it is recommended that the TMB-1014-BT be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T) (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/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 manufacture's declaration – electromagnetic immunity – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The TMB-1014-BT is intended for use in the electromagnetic environment specified below. The customer or the user 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 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the YS-6100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Portable and mobile RF communications equipment should be used no closer to any part of the including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 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. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 ELE007839V1 is used exceeds the applicable RF compliance level above, the ELE007839V1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ELE007839V1.

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 EQUIPMENT or SYSTEM – for ME EQUIPMENT or ME SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the ELE007839V1 Fitness Equipment.			
The TMB-1014-BT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TMB-1014-BT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TMB-1014-BT 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	0.167	0.167	0.233
0,1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.690	3.690	7.388
100	11.67	11.67	23.330
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.			

This device complies with Part 15 and Part 18 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 and Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC and IC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.