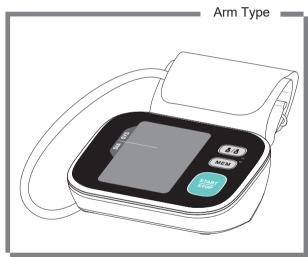
TRANSTEK

User Manual

Blood Pressure Monitor TMB-1776-B



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor TMB-1776-B.
- Please 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.



- FCC ID:OU9TMB1776B2
- **Guangdong Transtek Medical Electronics Co., Ltd.** Zone A, No.105 ,Dongli Road, Torch Development District, 528437 Zhongshan,Guangdong,China

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♥ General Description

Thank you for selecting TRANSTEK arm type blood pressure monitor (TMB-1776-B). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.

Readings taken by the TMB-1776-B 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.

Features:

- *80mm×58.5mm Digital LCD display
- · Maximum 60 records
- · 3rd technonoly: Measuring during inflation

▼ Indications for Use

The Transtek Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 42cm(about 8¾-16½). It is intended for adult indoor use only.

Contraindications

- 1.The device should not be used by any person who may be suspected of,or is pregnant. 2.The device is not suitable for use on patients with implanted,electrical devices,
- such as cardiac pacemakers, defibrillators.

▼ Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the atmopheric 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.

♥ Safety Information

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

③	Refer to instruction manual/booklet To signify that the instruction manual/booklet must be read.
†	Symbol for "Type BF applied part"
À	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
Z	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
88	Symbol for "Recycle"
SN	Symbol for "Serial Number"
===	Symbol for "Direct Current"
<u></u>	Symbol for "Manufacturer"
<u>~</u>	Symbol for "Date and Country of manufacture"
	For indoor use only
	Symbol for "Class II Equipment"

INTRODUCTION

— CAUTION

- * This device is intended for indoor, home use.
- * This device is not intended for public use.
- * This device is portable, but it is not intended for use during patient transport.
- * This device is not suitable for continuous monitoring during medical emergencies or operations.
- *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 any purpose other than obtaining a blood pressure measurement.
- * This device is for adults. Do not use this device on neonates or infants. Do not use it on children unless otherwise instructed by a medical professional.
- * Do not use on the women in pregnant, including pre-eclamptic, patients.
- * The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.
- * The effectiveness of this device has not been established for use:
- -on users with common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation,
- -on users with peripheral arterial disease,
- -on users undergoing intravascular therapy, or with arteriovenous (AV) shunt.
- Consult a medical professional before use.
- Do not use this device for diagnosis or treatment of any health problem or disease. Contact your physician if you have or suspect any medical problem. Do not change your medications without the advice of your physician or health care professional.
- * If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
- * This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
- * Report any unexpected operation or events to the manufacturer.
- * Do not apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
- * Warning: Do not kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result injury.
- * Warning: Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
- * Warning: Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
- * Warning: Do not place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.
- * Do not place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). it is recommended to take measurements on the unaffected side.
- Do not wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
- * Please check that the operation of the device do not result in prolonged impairment of patient blood circulation.
- * Warning: On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
- * Warning: Do not use this device with high-frequency (HF) surgical equipment at the same time.

- * Warning: This device is not AP/APG equipment. Do not use the device where flammable anesthetic are present, or in environments mixture with air of with oxygen or nitrous oxide.
- * The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
- * Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
- * You can use this device to take your own measurement, no third-party operator is required.
- * Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
- * The device may require up to 30 minutes to warm up / cool down from the minimum / maximum storage temperature before it is ready for use.
- * Warning: Excessive cuff tube lengths could cause strangulation if you don't manage them properly.
- * Warning: Do not touch output of the batteries/adapter and the user simultaneously.
- Adapter is specified as a part of ME EQUIPMENT.
- * Warning: The power cord is considered the disconnect device for isolating this equipment from supply mains. Do not position the equipment so that it is difficult to reach or disconnect.
- * The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment.
- * Warning: Do not use this device if you are allergic to polyester, nylon, or plastic.
- * Warning: Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
- * Warning: If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
- No calibration is required within two years of reliable service.
- * Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized service centers.
- * At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
- * It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHq and 200 mmHq).
- * Warning: Do not use the device while under maintenance, or being serviced.
- * Store your device, cuff and adapter in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
- * Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
- * Warning: Keep the device, cuff, and batteries away from children as they may pose a risk of choking or strangulation if used improperly.
- * Clean both device and cuff with a soft, dry cloth. If necessary use a dampened cloth and natural detergent. Do not use alcohol, benzene, or other harsh chemicals.
- * Do not wash the cuff in a washing machine or dishwasher!
- * The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
- * Dispose of accessories, detachable parts, and the device according to the local guidelines.

4

INTRODUCTION

INTRODUCTION

♥ LCD display signal



SYMBOL	DESCRIPTION	EXPLANATION			
sys	Systolic pressure	High blood pressure			
DIA	Diastolic pressure	Low blood pressure			
PUL/MIN	Pulse display	Pulse in beats per minute			
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)			
s 15	Blood pressure level indicator	Indicate the blood pressure level			
- O + E	Low battery	Batteries are low and need to be replaced			
W	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.			
88 [.] 88	Current Time	Year/Month/Day, Hour : Minute			
•	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.			
AVG	Average value	The average value of blood pressure			
å / å	User A/ User B	Start measurement and save the measuring results for User A/User B			
(88)	Memory	Indicate it is in the memory mode and which group of memory it is.			
	Data pending to transmit	Measurement data stored in the device			
*	Data transmitting	Data transmission succeeds.			

♥ Monitor Components



♥ List

1.Blood Pressure Monitor (TMB-1776-B)



4. 4×AA batteries



2.Cuff (Type BF applied part)

(22cm~42cm)
(Please use TRANSTEK authorized cuff. The size of the actual cuff please refer to the label on the attached cuff.)

5.AC adaptor (BLJ06L060100P-U)

3.User manual





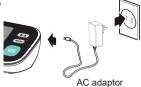
▼ The Choice of Power Supply

- **1**.Battery powered mode: 6VDC 4×AA batteries
- 2 .AC adaptor powered mode:

6V == 1A

(Please only use the recommended AC adaptor model).

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



↑ CAUTION

In order to get the best effect and protect your monitor, please use the right battery and special power adaptor which complies with local safety standard.

▼ Installing and Replacing the Batteries

- · Open the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- Replace the battery cover.



Replace the batteries whenever the below happens

- The to + shows
- •The display is dim
- The display does not light up.

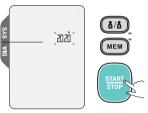
↑CAUTION

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

♥ Setting Date and Time.

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year :2019—2059; Time format:12H)

1. When the monitor is off, hold pressing START/STOP button for 3 seconds to enter the mode for year setting.



 Press MEM or USER button to change the [YEAR]. Each press will increase/decrease the numeral by one in a cycling manner.



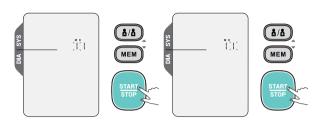
3. Press START/STOP button to confirm [YEAR]. Then the monitor diverts to [MONTH] and [DAY] setting.



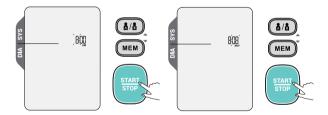




4. Repeat step 2 and 3 to set the [MONTH] and [DAY].



5.Repeat step 2 and 3 to set the [HOUR] and [MINUTE].

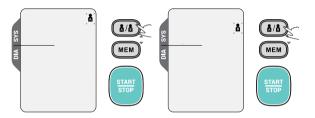


6 After HOUR and MINUTE is set, the LCD will display "donE" and then turn off.

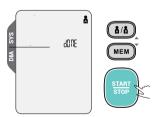


♥ Select the User ID

 Before you start the measurement, please select the desired user ID first. When the blood pressure monitor is off, press USER button the user ID will blink. Then press USER button again to change the user ID between user A and user B.



2. Confirming the user ID, press the START/STOP button to confirm ,the LCD will display USER ID+donE and then turn off.



BEFORE YOU START MEASUREMENT

♥ Pair up 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 MEM button to start pair-up. The below picture will be shown on the LCD alternatively indicating pair-up is proceeding.



(3) Then connect with your smartphone on the app to continute the pair-up.

If SUCCEED, the below picture will be shown on the LCD.



If FAIL, the below picture

will be shown on the LCD.



(4) The monitor will shut off after Pair-up process is complete.

Bluetooth Module No.: LS51802

RF Frequency Range: 2402 MHz to 2480 MHz

Output Power Range: -2.41 dBm Supply Voltage: 1.8-3.6 V

▼ Tie the cuff

- 1. Remove all iewelry, such as watches and bracelets from your left arm. Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.
- 2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.
- 3. Hold your arm with your palm facing up and tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger. Or position the artery mark Φ over the main artery (on the inside of your arm). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.
- 4. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.
- 5. Sit comfortably with your tested arm resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.
- 6. Helpful tips for Patients, especially for Patients with Hypertension:
- · Rest for 5 minutes before first measuring
- · Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- Take the measurement in a silent room.
- . The patient must relax as much as possible and do not move and talk during the measurement procedure.
- . The cuff should maintain at the same level as the right atrium of the heart.
- · Please sit comfortably. Do not cross your legs and keep your feet flat on the ground.
- · Keep your back against the backrest of the chair.
- · For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time. on the same arm, or as directed by a physician.



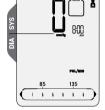
♥ Start the Measurement

1. When the monitor is off, press START/STOP button to turn on the monitor, the user ID will blink ,confirm the User ID, then press "START/STOP" button again and it will finish the whole measurement.
(Take user A for example.)

LCD display







Adjust the zero.

å/å

Inflating and measuring.





STOP

Display and save the measurement result.





If the data transmission fails, the Bluetooth symbol blinks all the time until it turns off.





If the data transmission succeeds, the Bluetooth symbol will not blink and then turn off.



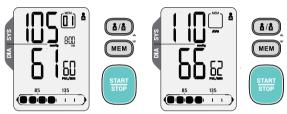


⚠ CAUTION

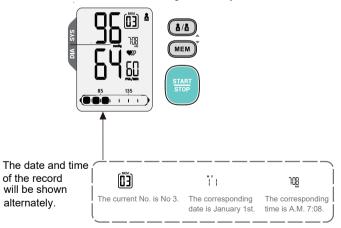
- With TMB-1776-B successfully pair-up with your mobile device, the measurement data will be automatically transmitted to your mobile device via Bluetooth.
- 2.The symbol [will disappear after successful data transmission, and you may check your personal health data stored in your mobile device.
- 3.If the data transmission fails, the symbol will remain. The pending measurement data will be transmitted to your mobile device when next measurement is complete.

♥ Recall the Records

1. When the monitor is off, please press MEM button to confirm the User, then press START/STOP button to show the latest record. Press the MEM button again to show the average value of the latest three records. If the records are less than 3 groups, it will display the latest record instead.



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



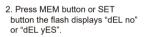
♥ Delete the Records

If you did not get the correct measurement, you can delete the result for the selected user by following steps below.

A: Delete one record

1.Hold pressing MEM button for 3 second when the monitor is in the memory recall mode (except average),the flash display "dEL yES" will show to delete the one group result.













MEM



Tips: Press START/STOP button when it shows "dEL no". it will drop out.

DATA MANAGEMENT

B: Delete all records

1.Hold pressing both USER button and MEM botton for 3 second when the monitor is in the memory recall mode, the flash display "dEL yES + 15 Er" will show to delete all result.



2. Press USER button or MEM button the flash displays "dEL no" or "dEL yES".

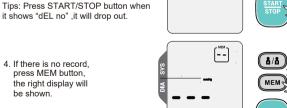


anne

1 1 1 1 1 1

3. Press START/STOP button to confirm deleting when it shows "dELvES".then the monitor with turn off when it shows "User + donE".

Tips: Press START/STOP button when it shows "dEL no" .it will drop out.



▼ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



INFORMATION FOR USER

▼ Maintenance

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



Put in a dry place and avoid the sunshine



Avoid intense shaking and collisions



Using wet cloths to remove dirt



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



Avoid dusty and unstable temperature environment



Do not attempt to clean the reusable cuff with water and never immerse the cuff in water.

♥ 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 chart on the right is the standard blood pressure classification published by American Heart Association (AHA).

This chart reflects blood pressure categories defined by American Heart Association.						
Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)			
Normal	less than 120	and	less than 80			
Elevated	120-129	and	less than 80			
High Blood Pressure (Hypertension) Stage 1	130-139	ог	80-89			
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher			
Hypertensive Crisis (Consult your doctor immediately)	Higher than 180	and/or	Higher than 120			

⚠ CAUTION-

Please consult a physician if your measuring result falls outside the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

▼ Irregular Heartbeat Detector

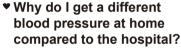
An irregular heartbeat is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them. If there are two or more pulse intervals , the difference between each interval and the average is more than the average value of ±25% , or there are four or more pulse intervals , the difference between each interval and the average is more than the average value of ±15%, then the irregular heartbeat symbol will appear on the display with the measurement result.

⚠ CAUTION

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

Why does my blood pressure fluctuate throughout the day?

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



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

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

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



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

If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
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.



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		
	Display will not	Batteries are exhausted.	Replace with new batteries		
No power	light up.	Batteries are inserted incorrectly.	Insert the batteries correctly.		
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly.		
Low batteries	Display is dim or show P+ 0	Batteries are low.	Replace with new batteries		
	E 1 shows	The cuff is too tight or too loose.	Refasten the cuff and then measure again.		
	E 2 shows	The monitor detected motion while measuring.	Movement can affect the measurement.Relax for a moment and then measure again.		
Error message	E 3 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.		
	E 4 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.		
	EExx,shows on the display.	A calibration error occurred. (XX can be some digital symbol, such as 01, 02,etc., if this similar situation appear, all belong to calibration error.)	Retake the measurement If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.		
Warning message	out shows	Out of measurement range Relax for a moment. Refasten the cuff an measure again. If th problem persists, co your physician.			

Power supply Display mode	Battery powered mode: 6VDC 4×AA batteries AC adaptor powered mode: 6V1A (Please only use the recommended AC adaptor model). Digital LCD display V.A.80mm×58.5mm
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	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	About 22cm~42cm
Weight	Approx.283g(Excluding the dry cells and cuff)
External dimensions	Approx.140.4mm×110.4mm×64.8mm
Attachment	4×AA batteries,user manual,AC adaptor ,carry bag
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Software Version	A04

▼ Authorized Components

1. please use the TRANSTEK authorized adapter.



Adaptor

Type: BLJ06L060100P-U

Input: 100-240V,50-60Hz,0.2Amax

Output: 6V === 1000mA

♥ Contact Information

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

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

▼ FCC Statement

FCC ID:OU9TMB1776B2

This device complies with Part 15 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 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 quarantee that interference will

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.

not occur in a particular installation.

- -- 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. FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

▼ EMC Guidance

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

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

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

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment TMB-1776-B including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

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

Table 1

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

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity					
Immunity Test	IEC 60601-1-2 Test level	Compliance level			
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air			
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not Applicable 100 kHz repetition frequency			
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not Applicable			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Uτ; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% Uτ; 1 cycle and 70% Uτ; 25/30 cycles; Single phase: at 0°. 0% Uτ; 250 / 300 cycle	0% Uτ; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% Uτ; 1 cycle and 70% Uτ; 25/30 cycles; Single phase: at 0°. 0% Uτ; 250 / 300 cycle			
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz			
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz			
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz			
NOTE U_T is the a.c. mains voltage prior to application of the test level.					

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
for ENCLOSURE PORT	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
IMMUNITY to RF wireless communicati-	450	430-470	GMRS 460, FRS 460	FM ± 5k Hz deviation 1 kHz sine	2	0.3	28	28
ons equipment)	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
l ' ' '	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5		2	0.3	28	28
	870							
	930							
	1720	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							