# TMB-986 英文说明书 (A0)

- 印色: 单黑
- 材质: 80G书纸
- 尺寸: 170\*120mm



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

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#### General Description

Thank you for selecting TRANSTEK arm type blood pressure Monitor (TMB-986). 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 TMB-986 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:

- •128\*50mm Digital LCD display
- ·Touch sensor key
- •Two users for choice
- ·Maximum 60 records per user
- ·Measuring during inflation technology

#### Safety Information

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

6	Symbol for "THE OPERATION GUIDE MUST BE READ"	Ŕ	Symbol for "TYPE BF APPLIED PARTS"
M	Symbol for "MANUFACTURE DATE"		Symbol for "ENVIRONMENT PROTECTION - Wast electrical products should not be disposed of
-	Symbol for "MANUFACTURER"	X	with household waste. Please recycle where facilities exist. Check with your
SN	Symbol for "SERIAL NUMBER"		advice"
	Symbol for "DIRECT CURRENT"	EC REP	Symbol for "Authorised Representative in the European Community
( € 0123	Symbol for "COMPLIES WITH MDD 93/42/EEC REQUIREMENTS"	$\triangle$	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 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.

When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or artrial fibrillation, the best result may occure deviation. Please consult your physician about the result.

If the cuff pressure exceeds 300 mmHg, the unit will automatically deflate. Should the cuff not deflate when pressures exceeds 300 mmHg, detach the cuff from the armand 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 patient 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 provided inaccurate readings, the affects 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 patient'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 been impacted and reduced.

During using, the patient will 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 in 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 with SERVICE PERSONNEL of Transtek. Don't open or repair the device by yourself. Please report to Transtek 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.

#### INTRODUCTION

#### 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		
	Deflating	CUFF air is exhausting of deflating		
ям 8:59	Time (hour:minute)	Currently time		
M 18/60	Memory	If "M" shows, the displayed measurement values is from the memory.		
mmHg	mmHg	Measurement Unit of the blood pressure 1mmHg		
٦ lo	Low battery	Batteries are low and need to be replaced		
Ţ	Shocking remainding	Shocking will result in inaccurate		
AVG	Average	The average of blood pressure		
्	Recalling	The erecords will be showed		
	Irregular heartbeat	Irregular heartbeat		
Å	User A	The User A is chosen		
B	User B	The User B is chosen		
Normal	Grade	The grade of the blood pressure		
××××××××××××××××××××××××××××××××××××××	Date	"M" shows the month, "D" shows the day		
•	Heartbeat	Heartbeat detection during the measureme		

#### Monitor Components



#### ♥ List



4. User manual

3.4 x AAA Batteries



#### Installing and Replacing the Batteries

Battery powered mode: 6VDC 4\*AAA batteries

- 1. Slide off the battery cover.
- 2. Install the batteries by matching the correct polarity, as shown.
- 3. Replace the cover.



Replace the batteries whenever the below happen

•The shows

- •The display dims
- The display does not light up

# 

- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, so please disposal with other daily trash.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.
- In order to achieve the best performance and protect your monitor, please use the authorized / specified battery, which complies with CE safety standard.

#### ♥ 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. (year :2000—2050,time:24 H)

1.When the unit is off, hold pressing "SET" for 3 seconds to enter the mode for year setting.



Press the "MEM" to change the [YEAR].



**3**.When you get the right year, press "SET" to set down and turn to next step.



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 confirming the minute,the LCD will display "dOnE" and the monitor will shut off.



#### MEASUREMENT

🎔 Pul/min 🔊

10:38

#### Tie the Cuff

- **1**. Tie the cuff on your upper arm, the position the tube off-center toward the inner side of arm in line with the little finger.
- 2. The cuff should be sung but not too tight. You should be able to insert one fingers between the cuff and your arm.
- 3.Sit comfortably with your arm resting on a flat surface.
- 4. Correct Posture for Patients with Hypertension, especially for Hypertension patient
- Bare your arm or wear tights only when starting measurement.
- Sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported. The central of the cuff should maintain at the same level as the right atrium of the heart.
- 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 arm, or as directed by a physician.





#### Start the Measurement

1. When the monitor is off, select User A or User B, press the start to turn on



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al Mild Moderate Severe

mmHe

the monitor, and it will finish the whole measurement. 

LCD display

Adjust the zero.

Inflating and measuring.

Display and save the results.



to power off. 2.Press the otherwise it will turn off within 1 minute.



#### Recall the Records

 Please choose the user A or user B when the blood pressure monitor turns off, and press the "MEM" to show the average of the last 3 records.





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

#### ♥ Delete the Records

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



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#### ♥ Tips for Measurement

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

![](_page_8_Picture_4.jpeg)

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

#### 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.

![](_page_9_Picture_4.jpeg)

#### 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.

110	Grade 3 hypertension(severe)					
100	Grade 2 hypertension(moderate)					
95	Grade	1 hypertension(mild)				
90	Subgroup: borderline High-normal Blood Pressure Normal Blood Pressure					
85						
80						
	Optimal Blood Pressure					
	120 130 140 150 160 180					
	Systolic blood pressure (mmHa)					

Level Blood Pressure (mm Hg)	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 25%, this equipment will light up the IHB symbol on the screen when displaying the measuring result.

#### - $\triangle$ 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.

#### If the result is the same if measuring on the right arm?

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

![](_page_9_Picture_22.jpeg)

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.

![](_page_9_Picture_26.jpeg)

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
Low batteries	Display is dim or shows □+	Batteries are low.	Replace with new batteries
	E 1 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 2 shows	The cuff is very tight	Refasten the cuff and then measure again.
Error message	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E10 or E11 shows	The monitor detected motion while measuring.	Movement can affect the measurement.Relax for a moment and then measure again.
	E20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E21 shows	The treatment of the measurement failed.	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	Battery powered mode: 4*AAA batteries,6V	
Display mode	Digital LCD display, V.A.128mm*50mm	
Measurement mode	Oscillographic testing mode	
Measurement range	Rated cuff pressure: 0mmHg~300mmHg Measurement pressure: 40mmHg-230mmHg pulse value: (40-199) beat/minute	
	Pressure:	
Accuracy	5°C-40°C within±3mmHg	
Normal working condition	Temperature:5°C to 40°C Relative humidity ≤85%RH Atmospheric pressure: 86kPa to 106kPa	
Storage & transportation condition	Temperature:-20 C -60 C Relative Humidity: 10%RH-93%RH Atmospheric Pressure: 50kPa-106 kPa	
Measurement perimeter of the upper arm	About 22cm~42cm	
Net Weight	Approx.320g(Excluding the dry cells)	
External dimensions	Approx.182mm*100mm*39mm	
Attachment	4*AAA batteries,user manual	
Mode of operation	Continuous operation	
Degree of protection	Type BF applied part	
Protection against ingress of water	IP21	
Software Version	V01	

#### 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: 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	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
Labeling	EN 980:2008 Symbols for use in the labelling of medical devices
User manual	EN 1041:2008 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 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	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 ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
Usability	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability EN 62366:2008 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 Medical device software - Software life cycle processes

#### ♥ EMC Guidance

 \* This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
 2) \* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
 3) \* Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

4) \* Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

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

Guidance and manufacturer's declaration – electromagnetic emissions						
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	Emissions test Compliance Electromagnetic environment - guidance					
RF emissions CISPR 11         Group 1         The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.						
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply				
Harmonic emissions IEC 61000-3-2	s Not applicable Not					
Voltage fluctuations/ flicker emissions IEC Not applicable 61000-3-3						

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# 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	MMUNITY test IEC 60601 test level Compliance level Electromagnetic environment - guidance						
Electrostatic discharge (ESD) IEC 61000-4-2 Electrostatic ±8 kV air Electrostatic ±8 kV air							
Electrical fast ±2 kV for power supply lines IEC 61000-4-4 ±1 kV for input/output lines Not applicable network. Not applicable environment.							
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	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     <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle     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.       IEC 61000-4-11     <5% U <sub>T</sub> (>95% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 2 5 cycles     Not applicable     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 (50/60Hz) 3A/m 3A/m A/m Power frequency magnetic characteristic of a typical location in a typical commercial or hospital environment.							
NOTE U <sub>T</sub> is the a.	c. mains voltage prior to a	pplication of the test lev	el.				

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

Guidance and m	anufacturer's declar	ration – electromag	inetic 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		
			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.		
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Recommended separation distance $d = 1, 2\sqrt{P}$		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1, 2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.6 CHz		
a = 2,3 where 1 rating o accordi and d is distance		where <b>P</b> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in metres (m).			
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ashould be less than the compliance level in each frequency range. <sup>b</sup>		
			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.					
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broad-cast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.					

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 80 MHz to 800 MHz 800 MHz to 2.5 GHz					
	$d = 1,2\sqrt{P}$	$d = 1, 2\sqrt{P}$	$d = 2, 3\sqrt{P}$			
0.01	0.12	0.12	0.23			
0.1	0.38	0.38	0.73			
1	1.2	1.2	2.3			
10	3.8	3.8	7.3			
100 12 12 23						
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.						

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency

range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.