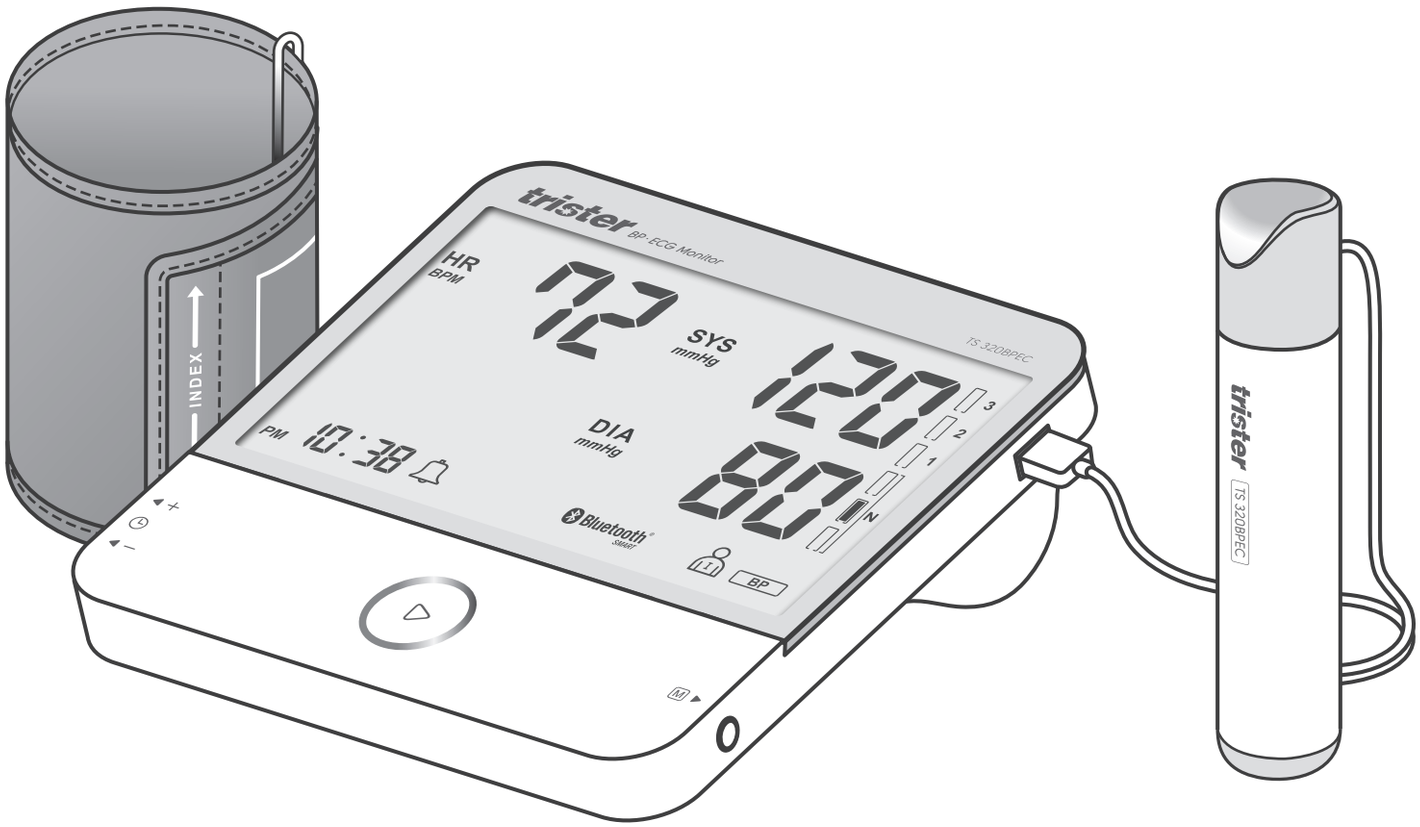
trister™

ADVANCED
BLOOD PRESSURE MONITOR WITH ECG

Model: **TS 320BPEC**



Please read this instruction manual thoroughly before using the device.
Kindly keep this for future reference.

TABLE OF CONTENTS

General Notes 1

Signs and Symbols 2

Important Safety Notes 3

Product Description
- Main Features 5
- Package Contents 7
- Hardware Description 8
- LCD Display 10

Preparation Before Taking Measurement
- Battery Installation 12
- Battery Life and Replacement 13
- Date and Time Setting 14
- Alarm Setting 18
- Selecting User Account 20

Taking Blood Pressure Measurement
- Cautions before Taking Measurement 21
- Applying the Arm Cuff 22
- Operation Procedure 24
- WHO Classification Indicator 26
- Reviewing & Deleting Previous Results 27

Taking ECG Measurement
- Cautions before Taking Measurement 28
- Operation Procedure 29
- Common Wrong Operations 32
- Results Display 33
- Reviewing & Deleting Previous Results 34

APP Download 35

Cleaning and Maintenance 36

Messages 37

Trouble Shooting 40

Warranty Information 42

Technical Specifications 44

EMC Information 47

General Notes

1. This Instruction for Use is for TS 320BPEC.
2. Please read the Instruction for Use before use and follow the instructions to operate the device.
3. This is a Blood Pressure and Electrocardiogram (ECG) monitoring device provides referential data that could be taken into consideration by medical professionals and enables self-health monitoring.
4. Self diagnosis or treatment is dangerous behavior. Please do not use the blood pressure and electrocardiogram data generated by this device to diagnose yourself. Consult with medical professionals if you notice any change in your condition, regardless of the measurement results.
5. The measurement results produced by this device only reflect the measurement taken at the moment.
6. The electrocardiogram cannot show all variations and symptoms of heart diseases, please consult with medical professionals when feeling discomfort with your heart.
7. People with severe blood flow problems, or blood disorders, should consult a doctor before using this device. Cuff inflation can cause internal bleeding.
8. Please dispose waste batteries according to applicable local regulations.

Signs and Symbols

Following signs and symbols are used in the Instruction for Use, on the packaging and label of the device and accessories :

	Type BF applied part	EC REP	EU Representative
	Type CF applied part		The product is with Bluetooth function
	ATTENTION, should read the Instruction for Use	IP22	Protection against solid foreign objects of 12.5 mm Ø and greater and against vertically falling water drops when enclosure tilted up to 15°
CE 0120	CE Mark (made in compliance with Directive 93/42/EEC on Class IIa medical devices)		
	Consult Instruction for Use		This way up
	Manufacturer		Fragile
	Date of manufacture		Keep dry
REF	Reference number		Keep away from sunlight
SN	Serial number	Operating	Permissible operating temperature and humidity
LOT	Batch number	Storage / Transport	Permissible storage/transport temperature and humidity

Important Safety Notes

- Do not leave this device unattended with infants or persons who cannot express their consent.
- Do not use this device for children weighing less than 10 kgs.
- It is not recommended to use the ECG Pen of this device with a cardiac pacemaker or other implanted devices. Be sure to follow your doctor's instruction if necessary.
- Do not use this device with a defibrillator.
- Do not use this device during an MRI scan.
- Do not submerge (or immerse) this device in water or liquid. Do not clean this device with acetone, or other volatile solution.
- Do not put this device in autoclaves, or gas sterilization devices.
- Avoid hitting, dropping, stamping, shaking of this device.
- Do not disassemble this device that may result in damage, malfunction, or abnormal operation.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not strongly bend the arm cuff or air tube.
- Do not inflate the arm cuff over 299 mmHg.

- Do not splash water on the arm cuff or immerse it in water.
- Do not use this device on people with sensitive skin or allergies.
- Do not operate this device in a moving vehicle (car, airplane).
- Do not use mobile phones, or other devices that emit electromagnetic fields near this device which may result in incorrect operation of the device.
- The electrodes of ECG Pen of this device should not come in contact with other electrically conductive parts, including earth ground.
- Do not store/expose this device in the following environments:
  Locations exposed to direct sunshine, high temperature or humidity, heavy dirt, near water or fire, and under high electromagnetic influence.
- Remove batteries if won't be using this device for some time, to prevent battery to expand, leak and possibly destroy the device.
- Store the device in safe place to avoid small parts swallowed by children in any circumstances.
- Under the environment temperature of 40°C, the temperature of applied part (cuff and ECG electrodes) will reach 42°C highest.

* *Static electricity may cause damage to the electronic components. To prevent electrostatic damage to the device, ensure your body is free of static electricity before using the device. Contact with earthed objects or devices, increase humidity, and moisturize skin can effectively reduce the cause of electrostatic damage.*

Product Description

Main Features

TS 320BPEC is intended to be used in measuring pulse, systolic and diastolic blood pressure and recording personal electrocardiogram (ECG) for approximately 30 seconds.

- **Optimum Monitoring on Blood Pressure and Heart Rhythm**
  The leading design of integrating blood pressure and ECG measurements in one device provides a more comprehensive monitoring solution on personal cardiovascular health.

- **Instant Feedback after Measurement**
  This device provides referential results analyzed from the recorded 30 seconds ECG data, and the corresponding WHO classification of blood pressure readings.

- **Handheld ECG Measurement**
  The handheld ECG design provides great convenience for home use. This patented ergonomic design not only makes detection easier, but also enables signals to be acquired with better resolution and be more conducive for analysis.

- **128 Records Storage Capacity**
  To facilitate long-term monitoring and enable two users' operation, this device supports two user accounts for separated 64 records storage.

- **Alarm Function**
  Reminder of regularly monitoring on blood pressure and heart conditions so as to provide long-term measurement records for doctors' diagnosis.

- **Multifunctional APP**
  The APP can assist you to :
  - Download measurement records.
  - Configure TS 320BPEC device.
  - Review measurement records in chronicle order.
  - Display ECG waveforms to doctors for reference.
  - Provide trend, statistic and distribution analysis of blood pressure readings.

- **Bluetooth 4.0**
  With Bluetooth 4.0 technology, this device ideally provides real-time display of your measurement on Smartphones/Tablets for a great portability of reviewing your records anytime, anywhere.

Product Description

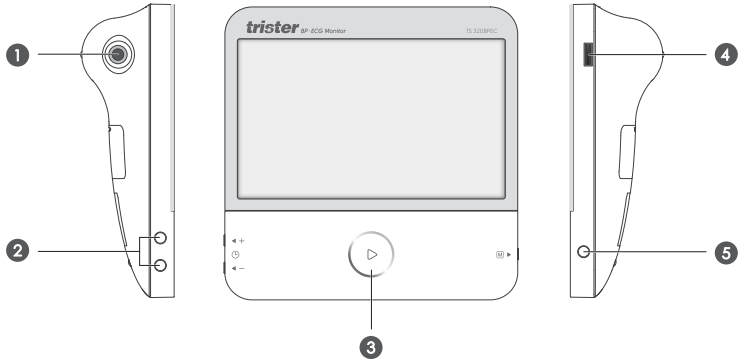
Package Contents

Your package should include the following items.

TS 320BPEC	Main Unit
	ECG Pen
Accessories	Arm Cuff
	Instruction for Use
	4 x AAA batteries (trial use)
	Storage Case

Hardware Description

Main Unit

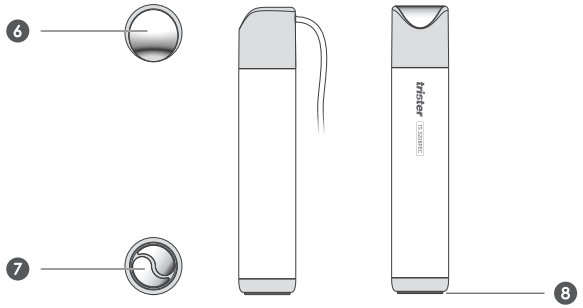


1. **Air Jack :** Connect air tube of arm cuff.
2. **Adjust Button :** Increase/decrease values of time/alarm settings.
3. **Start / Stop Button :** Start the inflation of blood pressure measurement or turn off the device.
4. **ECG Port :** Connect ECG Pen.
5. **Memory Button :** View records, switch user account and apply settings.

Product Description

Hardware Description

ECG Pen

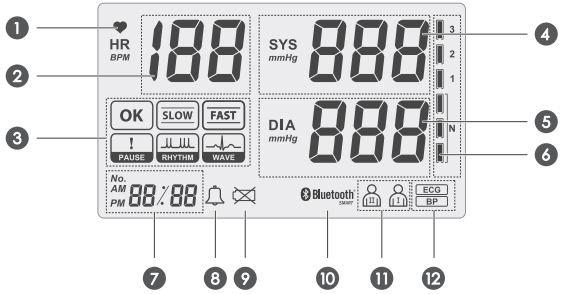


6 Top Electrode

7 Bottom Electrodes

8 Detection Switch

LCD Display



1 Heartbeat Indicator :
Flashes in sync with heartbeats during measurement.

2 Heart Rate :
During recording: Displays the real-time heartbeat.
During reviewing: Displays the average heart rate of each measurement.

3 ECG Result Display : Displays the results of ECG measurements.

4 Systolic Blood Pressure : Displays systolic blood pressure readings.

5 Diastolic Blood Pressure : Displays diastolic blood pressure readings.

Product Description

LCD Display

⑥ **WHO Classification Indicator :**
Displays WHO classification of your blood pressure readings.

⑦ **Digits Display :**
Standby Mode : Displays time.
During ECG Recording : Displays the 30 seconds count down.
During Reviewing : Displays the sequence numbers of stored records and measurement time.

⑧ **Alarm Indicator :** Displays On / Off of the alarm function.

⑨ **Low Battery Indicator :**
Warns users batteries are in low power and need replacement.

⑩ **Bluetooth Connection :** Displays the status of Bluetooth connection.

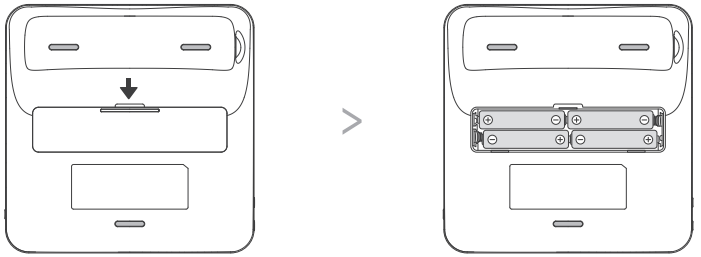
⑪ **User Account :** Displays the user account of present operation.

⑫ **Measurement Type :** Displays the type of present measurement (ECG/BP).

Preparation Before Taking Measurement

Battery Installation

1. Turn the main unit upside down.
2. Slide the battery cover in the direction of arrow while pressing the ribbed part of the cover.
3. Install four “AAA” alkaline batteries by following the + (positive) and - (negative) polarities indicated on the battery compartment.
4. Slide back the battery cover until it clicks into place.

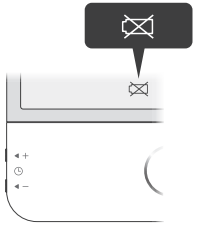


Preparation Before Taking Measurement

Battery Life and Replacement

1. Install or replace the batteries by following the + (positive) and - (negative) polarities indicated on the battery compartment.

2. When the low battery indicator appears on the display, the batteries are nearly running out, please replace new batteries at once.



Note: *Turn the device off before replacing batteries.*

3. Four new “AAA” alkaline batteries will last for approximately 300 measurements.

4. Please use same brand and type of batteries and replace all batteries at the same time. Avoid using used and new batteries together.

5. Do not use rechargeable batteries.

6. Remove batteries if won't be using this device for some time, to prevent the device from being damaged by battery electrolyte.

7. Please dispose waste batteries according to applicable local regulations.

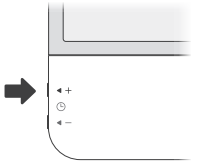
Date and Time Setting

After installing batteries, please set the correct date and time.
This device will automatically store measurement result and its measuring date and time.

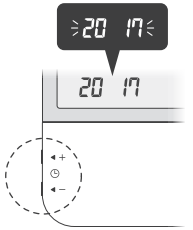
Note: *Removal of the batteries will stop the function of timekeeping, please reset the date and time after replacing new batteries.*

Time setting follow the order of year, month, date, hour and minute.

1. Press and hold the + button on the left side for more than 3 seconds to enter Date/Time setting mode.



2. The year digits will flash on the display. Press + and — buttons to adjust the year.



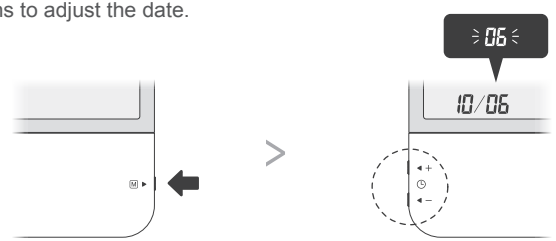
Preparation Before Taking Measurement

Date and Time Setting

3 Press the Ⓜ button on the right side to apply the setting of year.
After completing the setting of year, the month digits will flash on the display.
Press ＋ and － buttons to adjust the month.



4 Press the Ⓜ button to apply the setting of month. After completing the setting of month, the date digits will flash on the display. Press ＋ and － buttons to adjust the date.



Date and Time Setting

5 Press the Ⓜ button to apply the setting of date. After completing the setting of date, the hour digits will flash on the display. Press ＋ and － buttons to adjust the hour.



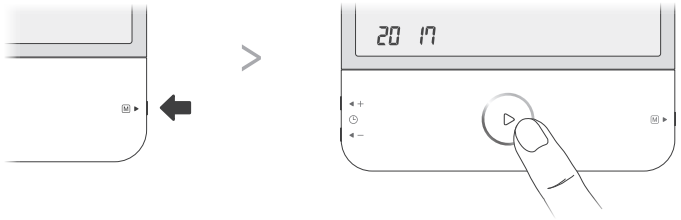
6 Press the Ⓜ button to apply the setting of hour. After completing the setting of hour, the minute digits will flash on the display. Press ＋ and － to adjust the minute.



Preparation Before Taking Measurement

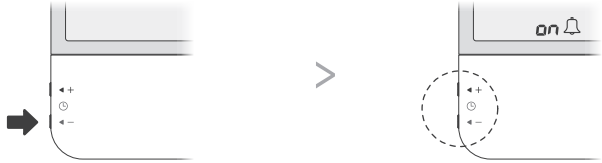
Date and Time Setting

7 Press the Ⓜ button to apply the setting of minute. Setting of year appears again on the display, press the ▷ button to complete the Date and Time Setting.



Alarm Setting

1 Press and hold the — button on the left side for more than 3 seconds to enter Alarm setting mode. The alarm is off if " oFF " flashes on the display; and the alarm is on if " on 🔔 " flashes on the display. Press + and — buttons to switch the alarm function.



2 Press the Ⓜ button to apply the setting. After the alarm function is set on, the hour digits will flash on the display. Press + and — buttons to adjust the hour of your alarm.



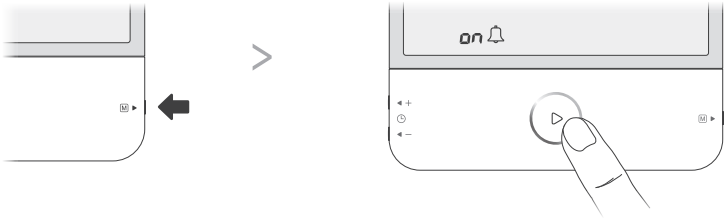
Preparation Before Taking Measurement

Alarm Setting

3 Press the Ⓜ button to apply the setting of hour. After completing the setting of hour, the minute digits will flash on the display. Press ＋ and — buttons to adjust the minute of your alarm.



4 Press the Ⓜ button to apply the setting of minute. Setting of on 🔔 appears again on the display, Press the ▷ button to complete the Alarm Setting.



Selecting User Account

This device provides two user accounts represented by I and II, and each account can store up to 64 measurement records.

If the memory space of the user account has been fulled, the oldest records will be replaced by the most recent one.

Selection Method :

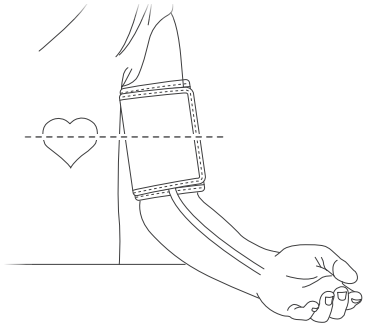
Press the Ⓜ button to see the previous set user account. Then press and hold the Ⓜ button for more than 3 seconds to switch between I and II.

Taking Blood Pressure Measurement

Cautions before Taking Measurement

Please follow the cautions below when using this device for blood pressure measurement:

- Please take the measurement in a quiet place and under appropriate temperature.
- Rest for at least 20 to 30 minutes after exercising, bathing, eating, smoking or drinking alcohol before taking measurement.
- Try to measure your blood pressure at the same time every day.
- You should be in a seated position and relax for 5 to 10 minutes before taking measurement.
- Place your arm on the table and make sure the center of arm cuff is at the same level with your heart.

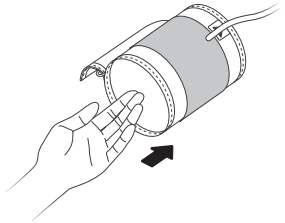


Applying the Arm Cuff

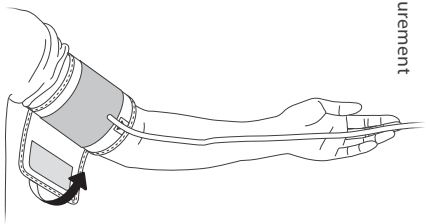
Please make sure the arm cuff is applied correctly in order to obtain correct measurement results.

You can wear light clothing when taking blood pressure measurement, however, the heavy clothing such as sweaters should be taken off.

1. Put your left arm through the cuff loop, and place the cuff on your upper arm.



2. The air tube should run down the inside of your forearm and be in line with your middle finger.

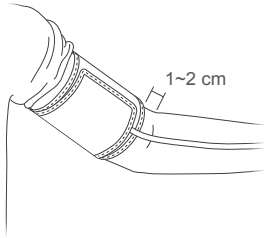


Note : *Be careful not to rest your arm on the air tube to avoid obstructing the airflow into the cuff.*

Taking Blood Pressure Measurement

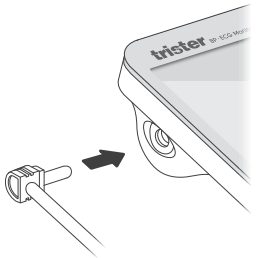
Applying the Arm Cuff

3 Make sure the cuff is 1 to 2 cm above your elbow and attach it firmly around your upper arm.



Note : *Do not over tighten the cuff to avoid affecting the accuracy of blood pressure measurement.*

4 Insert the air plug into the air jack on the left side of the main unit.



Operation Procedure

1 Selecting user account (refer to page 20).

2 Press the ▷ button to start measurement.

3 The BP symbol appears on the display when starting the inflation.

4 During your measurement :

- The digits on the position of systolic pressure increase during the inflation.
- The ♥ symbol flashes in sync as the device detects a pulse.
- You may stop the measurement by pressing the ▷ button at any time.
- The measurement will not be recorded once it is aborted.

5 The measurement result will be displayed after the measurement is completed.



Taking Blood Pressure Measurement

Operation Procedure

6 You may turn off the device by pressing the ▷ button or wait for 2 minutes until the device automatically switches off.

> ***Note :*** *Please wait at least 5 minutes before taking another blood pressure measurement. Waiting between measurements allows the arteries to return to the condition prior to taking the blood pressure measurement.*

WHO Classification Indicator

In accordance to the classification developed by World Health Organization :

Classification		Systolic (mmHg)	Diastolic (mmHg)
3	Stage3 : Severe hypertension	≥ 180	≥ 110
2	Stage2 : Moderate hypertension	160 ~ 179	100 ~ 109
1	Stage1 : Mild hypertension	140 ~ 159	90 ~ 99
	High-Normal pressure	130 ~ 139	85 ~ 89
N	Normal blood pressure	< 130	< 85
	Optimal blood pressure	< 120	< 80

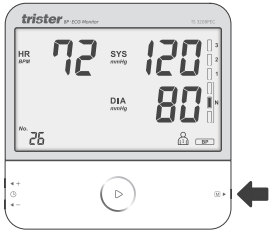
Taking Blood Pressure Measurement

Reviewing & Deleting Previous Results

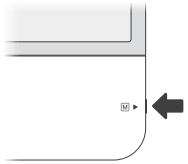
This device will automatically store the measurement result. You may review the records in cyclic order. The latest measurement will replace the oldest one when the memory is full (each account for 64 measurements).

1 When the device is turned off or in standby mode, press the Ⓜ button and you may review the latest record of the selected user account.

> ***Note :*** *To review records in the other user account, please press and hold the Ⓜ button for more than 3 seconds.*



2 You may review the records in cyclic order by repeatedly pressing the Ⓜ button.



3 If you want to delete the entire memory of the respective user account, press and hold the Ⓜ button again, then hold it together with the ▷ button for 5 seconds. All the results in the selected user account will be deleted.

Taking ECG Measurement

Cautions before Taking Measurement

Please read the cautions below to correctly measure your personal ECG :

- Do not attempt to use this ECG Pen over or through clothing.
- If the electrodes are dirty, please use a soft cloth or a cotton swab moistened with disinfectant alcohol to clean dirt from the surface.
- If your skin or hands are dry, moisten them with damp cloth before taking measurement.
- Do not let your right hand in contact with your body during the measurement, and avoid heavily pressing the top and bottom electrodes to influence the accuracy of measuring.
- Do not use the ECG Pen in upside down position.
- Do not move or talk while taking measurement and keep the balance of your body to avoid influencing the accuracy of measurement result.
- Ideally perform the measurement either sitting down or lying down. Do not stand up to take the measurement.

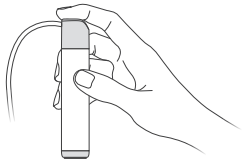
Taking ECG Measurement

Operation Procedure

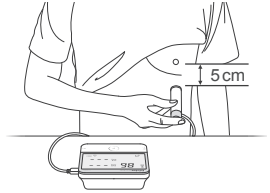
1 Connect the cable connector of ECG Pen to the port on the right side of the device.

2 Selecting user account (refer to page 20).

3 Lay your right index finger on the hollow part of top electrode and hold the ECG Pen in your right hand.



4 Place the bottom electrodes on bare skin about 5 centimeters (2 inches) below your left nipple supported by the ribcage. Press the ECG Pen GENTLY until you hear the click sound.



Note : *The force should be kept constant during the measuring period. Do not press the electrodes hard. Excessive muscle tension might affect the accuracy of measurement result.*

Operation Procedure

5 The measurement will start automatically. The ECG symbol will flash on the display and you will hear “beep” sounds for noticing the initiation of measurement.

6 The Digits Display shows 30 seconds of count down and the ECG symbol will stay on after the ECG measurement start.

7 During ECG measurement :

- Measuring period will count down from 30 seconds.
- The heart rate digits will dynamically show the real-time heartbeat.

Note: *The Averaged Heart Rate will only be displayed once the measurement is completed.*

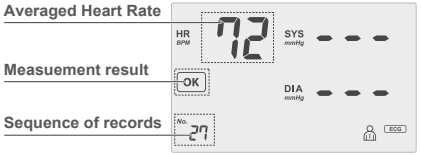
- The ♥ symbol will flash and the sound (if applicable) will beep in sync with your heart beat.

Taking ECG Measurement

Taking ECG Measurement

Operation Procedure

8 Result will be displayed after the measurement is completed.

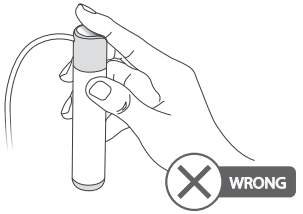


9 You may repeat the above procedure to take ECG measurement or turn off the device by pressing the ▷ button or wait for its automatically switches off after 2 minutes.

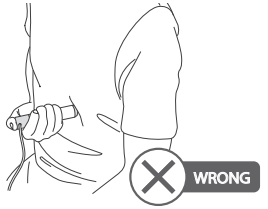
Common Wrong Operations

Please avoid the following operations :

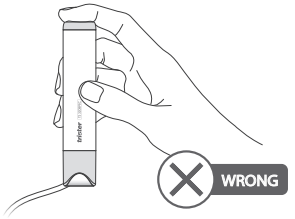
- The right index finger is not in sufficient contact with top electrode.



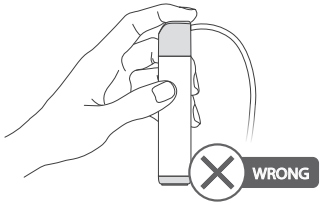
- Measuring over or through clothing.



- Holding ECG Pen in the wrong direction.



- Holding ECG Pen with your left hand.

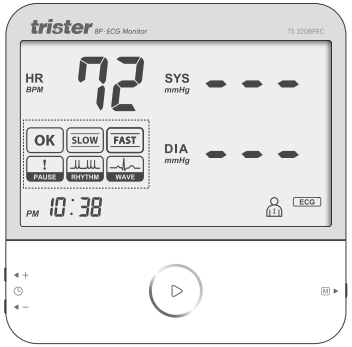


Taking ECG Measurement

Results Display

The ECG measurement result will display as follows :

OK	: Normal Result
SLOW	: Slow Heart Rate (<60 bpm)
FAST	: Fast Heart Rate (>100 bpm)
! PAUSE	: Paused Heartbeat
RHYTHM	: Irregular Rhythm
WAVE	: Abnormal Waveform



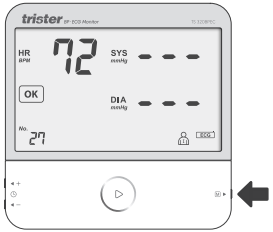
Please retake the measurement if the displayed heart rate is flashing, which indicates ECG signals are unstable or weak.

Reviewing & Deleting Previous Results

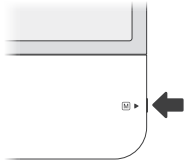
This device will automatically store the measurement result. You may review the records in cyclic order. The latest measurement will replace the oldest one when the memory is full (each account for 64 measurements).

1 When the device is turned off or in standby mode, press the M button and you may review the latest record of the selected user account.

> ***Note :*** *To review records in the other user account, please press and hold the M button for more than 3 seconds.*



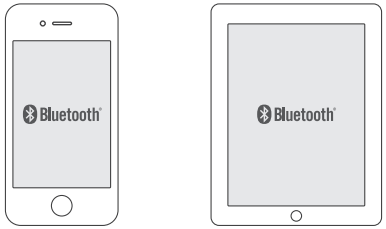
2 You may review the records in cyclic order by repeatedly pressing the M button.



3 If you want to delete the entire memory of the respective user account, press and hold the M button again, then hold it together with the ▷ button for 5 seconds. All the results in the selected user account will be deleted.

APP Download

System Requirements :
Smartphones or Tablets which support Bluetooth4.0 (BLE)

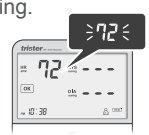
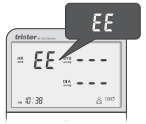


Please scan the QR code to enter APP introduction web page, and follow the instructions to download and use the APP.

Cleaning and Maintenance

- **Main Unit**
  - Please clean the surface of the unit with a soft cloth dampened with water.
  - Please remove all batteries if you expected of not using the unit for a long period of time.
- **ECG Pen**
  - Please clean the surface of the ECG Pen with a soft cloth dampened with water.
  - If the electrodes are dirty, please use a soft cloth or a cotton swab moistened with disinfectant alcohol to clean dirt from the surface.
  - Please unplug the ECG Pen from the main unit when it is not in use.
- **Arm Cuff**
  - Please clean the arm cuff with a soft cloth dampened with water and soap.
  - Please unplug the air plug from the air jack when it is not in use.
  - Please do not bend the air tube excessively when storing the arm cuff.
- **Calibration**
  It is generally recommended to have the device inspected every two years to ensure correct functioning and accuracy. Please consult your authorized provider for the calibration service.

Messages

Message Displayed	Possible Cause	Suggestion
■ The measurement result of averaged heart rate keeps flashing. 	Unstable or weak ECG signals.	Please follow the instructions on page 28~32 to retake the measurement.
■ The ECG measurement result shows EE. 	Failure analysis resulted from insufficient contact, an interruption, or high noise level during measurement.	Please follow the instructions on page 28~32 to retake the measurement.
■ The Blood Pressure measurement result shows EE 0. 	Unable to detect the value of blood pressure.	1. Apply the arm cuff correctly. 2. Take off the heavy clothing which may influence the measurement.

Message Displayed	Possible Cause	Suggestion
■ The Blood Pressure measurement result shows EE 1. 	1. Inflating too slow or cannot inflate normally. 2. Air leakage of cuff.	1. Apply the arm cuff correctly and retake measurement by following the instructions on page 21~25. 2. Replace the arm cuff to a new one.
■ The Blood Pressure measurement result shows EE 2. 	Abnormality found in blood pressure readings.	Please relax and take sufficient rest to take another measurement by following the instructions on page 21~25.
■ The Blood Pressure measurement result shows EE 3. 	Abnormality found in air releasing of arm cuff.	1. Apply the arm cuff correctly and retake measurement by following the instructions on page 21~25. 2. Replace the arm cuff to a new one.

Messages

Message Displayed	Possible Cause	Suggestion
■ The Blood Pressure measurement result shows EE 4. 	Low battery.	Follow the instructions on page 12~13 to replace with new batteries.

Trouble Shooting

Problem	Possible Cause	Suggestion
■ The device cannot be turned on after pressing the start button.	1. Battery power is low. 2. Batteries are installed with wrong direction.	1. Please replace with new batteries. 2. Please ensure the polarities of batteries are matched with the ones indicated on the battery compartment.
■ The pressure of arm cuff does not rise.	1. The air plug might not be inserted into the main unit properly. 2. The arm cuff is leaking.	1. Please ensure the air plug has been inserted into the air jack completely (page 23). 2. Please replace with a new arm cuff.
■ The readings of blood pressure are abnormally high or low.	1. The arm cuff is not applied correctly. 2. Movement or talk during the measurement. 3. Clothes interferes the arm cuff.	1. Please apply the arm cuff correctly (page 22~23). 2. Please remain in fixed position and avoid talking during the measurement (page 21). 3. Please take off the clothes which might interfere the arm cuff.

Trouble Shooting

Problem	Possible Cause	Suggestion
■ Measurement records disappear from the device storage.	Old records are overwritten by new ones due to storage overload.	Download data periodically to your smartphones/tablets for records keeping.
■ The measurement does not start after the electrodes touching skin.	Press too lightly.	Make sure to press the bottom electrodes with sufficient force.

If the above mentioned problems cannot be solved, please contact with the authorized representatives, distributors or agents of Trister. you purchased devices from.

Warranty Information

Trister warrants your Blood Pressure ECG Monitor TS 320BPEC to be free from defects in workmanship and materials within 3 (three) year from the date of the purchase receipt under normal usage according to the Instruction for Use. This warranty is not transferable.

This warranty covers repair or replace without charge, at our option, upon examination. Repair or replacement is our only responsibility and your only remedy under the above warranties.

The warranty does not cover :

- If the warranty sticker was changed or damaged.
- Accidental fall or collision during usage or transport.
- Damage caused by heavy fall, damp, liquids immersion, foreign objects or materials intrusion, or voltage abnormality.
- Damage caused by lack of reasonable maintenance or personal negligence on the part of the customer.
- Damage caused by improper operations, storage or transport without following the Instruction for Use.
- If the device has been opened by unauthorized repair shops or workshops.
- Wearing parts.
- Damage caused by force majeure, such as natural disaster.

Warranty Information

Trister shall not be liable for loss of use or any other incidental, consequential or indirect costs, expenses or damages in any way linked with the device or use of the device.

To obtain warranty service, the purchaser must notify the authorized distributors, agents or representatives of Trister concerning suspected defects to get the address of the repair location, pack the device carefully to avoid damage in transit, and then ship the device to the designated address.

Technical Specifications

TS 320BPEC - Main Unit	
Measurement Range	Blood Pressure：30 ~ 280 mmHg Pulse：40 ~ 199 beats/min
Measurement Method	Oscillometric method
Display	LCD digital display
Accuracy	Blood Pressure：＜±3mmHg or 2% of reading displayed Pulse：＜±5% of reading displayed
Inflation	Automatic by electric pump
Deflation	Automatic pressure release valve
Memory	2 x 64 memory spaces
Operation Temperature/Humidity	+10°C ~ +40°C，30 ~ 85% RH
Storage/Transport Temperature/Humidity	- 20°C ~ +50°C，15 ~ 85% RH
Power Source	4 AAA Alkaline Batteries
Battery Life	Approximately 300 measurements with 4 new alkaline batteries

Technical Specifications

Dimensions	L128 x W128 x H40 mm
Weight	Approximately 300g without batteries

TS 320BPEC - ECG Pen	
Induction System	Single channel, Bipolar
Heart Rate Range	5 ~ 199 beats/min
Bandwidth	0.05 ~ 40 Hz
Sampling Rate	256 Hz
Operation Temperature/Humidity	+10°C ~ +40°C，30 ~ 85% RH
Storage/Transport Temperature/Humidity	- 20°C ~ +50°C，15 ~ 85% RH
Dimensions	D25 x H125 mm
Cable Length	600 mm
Weight	Approximately 40g

Arm Cuff	
Arm Circumference	22 ~ 42 cm
Dimensions	Approximately L570 x W140 mm
Weight	Approximately 130g

1. Technical information is subject to change without notification to allow for updates.
2. Patent No. : TWM474484, TWI511704, TWM508304, TWI307273, TWM460636, CN102631193A, CN203539335U, CN103519805B, CN100546539C CN101953686B, US9782098, US20130345575, EP2676599, JP3206102U
3. This device complies with European Standard EN60601-1-2 and is subject to special precautionary measures regarding electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit. More details can be found at the end of the Instruction for Use.
4. This device complies with the EU Medical Device Directive 93/42/EEC and the council Radio Equipment Directive 2014/53/EU.
5. The safety class of the blood pressure monitor is BF, and safety class of the ECG Pen is CF.

EMC Information

Guidance and manufacturer's declaration - electromagnetic emissions		
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.		
Emissions	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This 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	This device is suitable for use in all establishments, including domestic establishments 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	Class A	
Voltage fluctuations/ flicker emissions	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
IMMUNITY test	**EN 60601** TEST LEVEL	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	3 A/m	Not applicable	Not applicable

Note : *U_T s the a.c. mains voltage prior to application of the test level.*

Guidance and manufacturer's declaration - electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

IMMUNITY test	EN 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			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).

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 this device is used exceeds the applicable RF compliance level above, This device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this device.*

Recommended separation distances between portable and mobile RF communications equipment and this device

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 KHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2{,}3\sqrt{P}$
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

EMC Information

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.*

trister

www.trister.com

Catalog No.: TS 320BPEC EIM 19/01

For any further information, comments or suggestions you can write to us at **info@trister.com**

or visit **www.trister.com**