CE 0123

aspedan

User Manual

Aspedan's Blood Pressure
Model: TMB-2284-B

- Thank you for using Aspedan's Bluetooth Blood Pressure Monitor TMB-2284-B.
- Please read the user manual carefully and thoroughly to ensure the safe usage of this product. Keep the manual for further reference in case you have any problems.

CE 0123 MD

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♥ General Description

Thank you for selecting Aspedan's arm-type blood pressure monitor. This monitor features blood pressure measurement and pulse rate measurement, and then stores the result. These results can then be uploaded to your Aspedan App. The warranty period is two years.

Readings taken by the monitor are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, whilst providing step-by-step instructions for using the product.

Read the manual thoroughly before using this product.

Features include:

- **59x72.5 mm digital LCD display with white backlight**
- **Maximum 199 records per user**
- **3rd technology: Measuring during inflation**

♥ Indications for Use

This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate for arm circumferences ranging from **22cm-32cm (about 8.7ins-12.5ins).** It is intended for people of at least 3 years of age or older, and for indoor use only.

♥ Measurement Principle

This device employs the oscillometric technique for blood pressure measurement. It initially sets a baseline at 'zero pressure,' aligning with the surrounding atmospheric pressure. During the process, as the cuff around the arm is inflated, the device captures fluctuations in pressure. These oscillations are then analysed to ascertain systolic and diastolic blood pressures, along with the pulse rate.

♥ Receiving and Inspecting your Monitor

Check that the device packaging has not been tampered with and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified customer services address.

♥ Safety Information

The signs below are in the user manual, labelling and other components of the blood pressure monitor and its accessories.

	Manufacturer		Type BF applied part
	Date of manufacture		Direct Current
		SN	Serial Number
	Recyclable	MD	Medical Device
	For indoor use only		Class II Equipment
	Refer to instruction manual/booklet To signify that the instruction manual/ booklet must be read. Note: The background colour of the symbol is blue.		
	Caution This symbol indicates that the operator needs to exercise caution by referring to the user manual/safety precautions at this point in the operation of the product, to avoid possible harm.		
	The symbol indicates that the product should not be discarded as unsorted waste and must be sent to separate collection facilities for recovery and recycling.		
	CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health, and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.		
EC REP	Authorised representative in the European Community/ European Union.		

Before Use

- This device is intended for indoor, home use, and is not intended for self-use in public areas.
- 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 non-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 babies or infants.
- Consult with your physician before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats or atrial fibrillation; peripheral arterial disease; pregnancy; preeclampsia; implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt; Parkinson's disease; or mastectomy. Please note that any of these conditions may affect measurement readings, in addition to patient motion, trembling or shivering.
- Do not use this device for diagnosis or treatment of any health problems or diseases. Please consult with your physician first whether the blood pressure or pulse rate readings can be used as an input in determining clinical actions. Please note that clinical actions can only be determined by a physician, otherwise it may lead to delayed treatment or misdiagnosis.
- 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 and the importer shall have no liability for any incidental, consequential, or damages caused by misuse or abuse.
- Please use the device under the environment described and shown in this 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.
- The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment.
- Do not wash the cuff in a washing machine or dishwasher.
- The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field, radiated interference signals or electrical fast transient/burst signals.
- Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies, may cause interference that affects the accuracy of that measurement. A minimum distance of 30cm should be kept from such devices during device operation.
- This blood pressure monitor can be used by medical professionals, lay persons, and patients.

⚠ Caution

- Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorised service centres.
- It is recommended that device 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 50mmHg and 200mmHg). Please contact manufacturer or distributor for authorised service personnel.
- Store your device, cuff, and adaptor 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.
- Dispose of accessories, detachable parts, and the device according to your local guidelines.

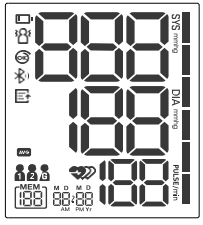
Warning

- Do not apply the cuff on an arm that has an intravenous drip, or a blood transfusion attached.
- 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 in injury.
- Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
- Do not apply cuff to areas on a patient where skin is delicate or damaged. Check cuff site frequently for irritation.
- 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 (for example, by observation of the limb concerned) that the operation of the device does not result in prolonged impairment of patient blood circulation.
- 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 >300mmHg or constant pressure >15mmHg for more than 3 minutes) might lead to bruising and discoloured skin.
- Do not use this device with high-frequency (HF) surgical equipment at the same time.
- This device is not intended to be used in conjunction with oxygen rich environments, not intended for use with flammable anaesthetics, and not intended for use in conjunction with flammable agents.
- Do not touch output of the batteries/adaptor and the user simultaneously.
- The power cord is considered the disconnecting device for isolating this equipment from the mains supply. Do not position the equipment so that it is difficult to reach or disconnect.
- Do not use this device if you are allergic to polyester, nylon, or plastic.
- Only use accessories approved by the manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
- 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.
- Do not use the device while under maintenance or being serviced.
- The air tube poses a risk of strangulation. Furthermore, the small parts of the product and the batteries present a choking hazard if swallowed. They should therefore always be kept away from infants/children.
- Sensor degradation or looseness may reduce device performance or cause other problems.

Notice

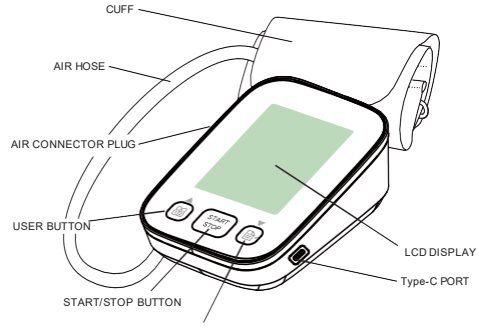
- You can use this device to take your own measurement. No third-party operator is required.
- Adaptor is specified as a part of ME EQUIPMENT.
- At the request of authorised service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
- The expected lifetime of the cuff may vary by the frequency of washing, skin condition, and storage state.
- Please report to the manufacturer and the competent authority of the Member State / the FDA in which you are established about any serious incident that has occurred in relation to this device.

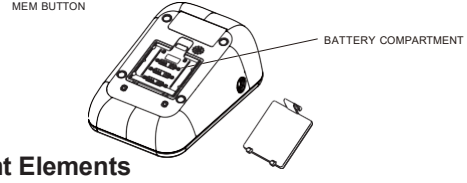
♥ LCD display



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
PULSE/min	Pulse display	Pulse in beats per minute
mmhg	mmHg	Measurement unit of blood pressure
	User ID	User 1/2/Guest
	Current time	Time (year : month : day : hour : minute)
	Pulse rate	Pulse rate detection during measurement
	Hand shaking	Hand shaking is making results inaccurate
	Battery indicator	Indicates the current battery level
	Irregular pulse rate	Irregular pulse rate
	Data transmitting	Data is transmitting
OK	Cuff wearing	The cuff is secured
	Blood pressure level	Indicates blood pressure level
	Bluetooth icon	The Bluetooth icon blinks when Bluetooth is operating
AVG	Average value	The average value of the latest three blood pressure value readings
MEM	Memory query	Indicates the device is in memory mode, and which memory group is being used

♥ Monitoring Device





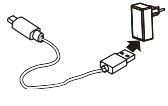
♥ Component Elements

1. Blood Pressure Monitor (TMB-2284-B)

2. Upper Arm Cuff (22-32cm)

3. 4 x AAA batteries (Optional)

4. AC Adaptor (Optional)

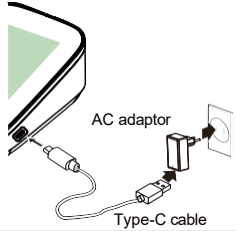


5. User manual

♥ Choice of Power Supply

1. Battery powered mode:
   6VDC 4×AAA batteries (optional)
2. AC adaptor powered mode:
   5V⎓1A (optional)
   (Please use an AC adaptor which is authorised by the manufacturer)

Please unplug the adaptor to remove the device from using utility power.

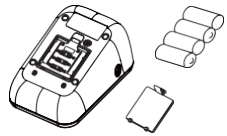


⚠CAUTION

To optimise performance and protect your monitor, please use the correct batteries and a power adaptor which complies with local safety standards.

♥ Installing and Replacing the Batteries

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



Replace the batteries in any of the following circumstances:

- The [+] bAt Lo shows
- The display is dim.
- The display does not light up

⚠CAUTION

- New and used batteries, or batteries of differing types, should not be used together.
- Remove batteries if the device is not likely to be used for some time.
- Do not heat or deform the batteries or dispose of them in a fire.
- Batteries should not be disposed of with household waste.
- Please check with your local authority for battery recycling advice.

♥ Setting the Date and Time

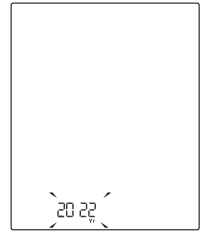
It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. The setting ranges from the years 2022 - 2052, with a 12Hr/24Hr time format.

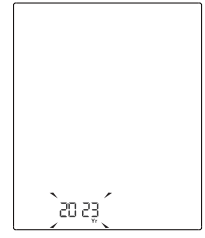
1. When the monitor is off, press and hold the “START/STOP” button. The Bluetooth symbol will display first.

If there is no operation within 60 seconds, or if the “START/STOP” button is pressed again, Bluetooth pairing will skip and the device will enter the [Year] setting.

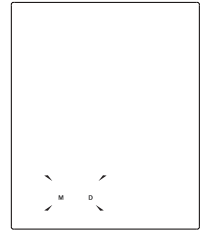
Press the “USER” or “MEM” button to change the year.

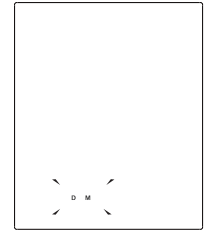
Press and hold the “USER” button to quickly advance year selection.
Press and hold the “MEM” button to quickly go backwards through year selection.



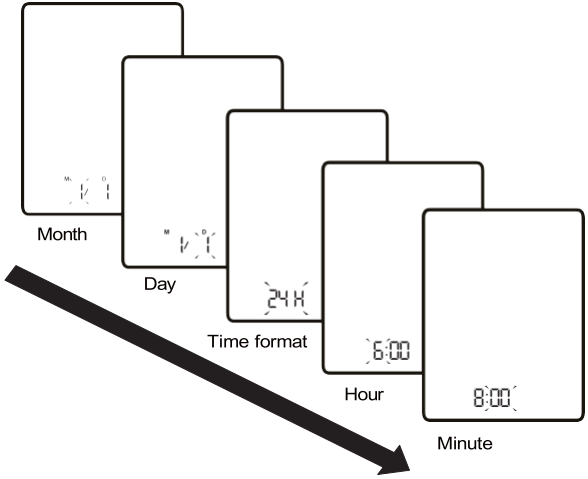


1. Press the “START/STOP” button to confirm the year, then the [date format] will flash. Press the “USER” or “MEM” button to switch the date format between [month/day] and [day/month].

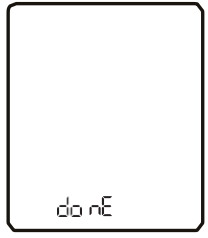




2. Press the “START/STOP” button to confirm the date format, then the month will flash. Repeat the same steps to set the month, day, time format, hour and minute.



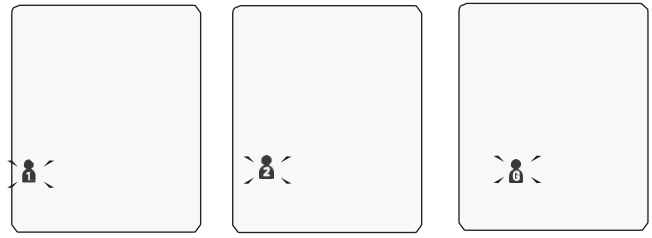
3. After the minute is set, the LCD will display “donE” and then turn off after several seconds.



♥ Setting a user ID

There are 3 user IDs 1 2 0 available. User 1 and 2, each with 199 memory spaces, are designed for 2 different people to save their measured values separately. The user 0, with no memory space, is reserved for a guest.

1. When the monitor is off, press the “USER” button to display the current user, which will flash on the display. Press the “USER” button to switch the user ID between the user 1, 2 and 0.



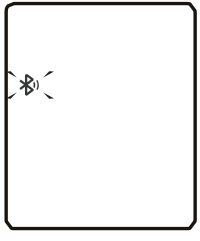
2. Press the “START/STOP” button to confirm the selected user ID, the monitor will then enter the measurement automatically.

♥ Pair your monitor with the Aspedan App

You are the intended operator of this blood pressure monitor. You can measure your blood pressure and then save and send measurement data to the Aspedan app (available on Apple iOS and Google/Android stores) using Bluetooth wireless connectivity.

1. **Turn on Bluetooth on your smart device, and open the Aspedan app.**
   Make sure both are ON when pairing the monitor with your smart device.
   You can download the Aspedan app from Apple App Store or Google Play Store onto a smart device running either iOS or Android.

2. **Follow the instructions displayed on the Aspedan app to pair your blood pressure monitor.** When the monitor is off, press and hold the "MEM" button to start pair-up. The Bluetooth symbol will flash.



3. **If pairing is successful**, the Bluetooth symbol will not flash any more. The monitor will automatically shut off after several seconds.

Note

1. The date and time on your monitor will automatically be set after pairing with your smart device successfully.
2. The device can also enter the Bluetooth pairing by long pressing the "START/STOP" button.

If pairing is unsuccessful within 60 seconds, it will be judged as a timeout, and the monitor will shut off.

Specifications for Bluetooth Transmission		
Bluetooth	Throughput	2.5K-5K
	Latency	50ms
	PER	< 10%
	Operating Frequency	2402-2480MHz
	Transmission Power	0±2dBm
	Transmission Distance	10m

Note:

1. The necessary Quality of Service (QoS) is fully considered here for wirelessly enabled functions.
2. Interference may occur in the vicinity of equipment marked with the following symbol . And TMB-2284-B may interfere with electrical equipment within its vicinity.
3. Keep the monitor at least 20 centimetres away from the human body (especially the head) when data transmission is proceeding after measurement.
4. To enable the data transmission function, this device should be paired to an appropriate BT mobile terminal.

Warning

About a wireless communication interference

The monitor operates in the unlicensed ISM band at 2.4 GHz. In the event that the monitor is used around other wireless devices, including microwaves and wireless LAN, which operate at the same frequency band as the monitor, there is a possibility that interference will occur between the monitor and these other devices. If such interference occurs, please stop the operation of these other devices, relocate the monitor before using it, or refrain from using it around other wireless devices.

List of compatible devices:

For iOS devices:
The operating system must be iOS 13.0 or more.

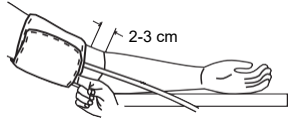
For Android devices:

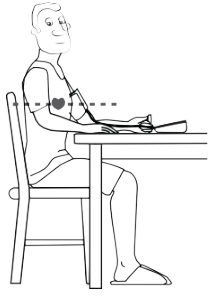
The operating system must be Android 5.0 or more.

♥ How to apply the arm cuff to measure your blood pressure

Only use a cuff that has been approved by the manufacturer for this device model. Before use, please check that the cuff fits around the circumference of your arm.

1. **Remove all jewellery, such as watches and bracelets, from your arms (measure using 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 on your measuring arm. Ensure your sleeve is not too tight.**
3. **Hold your arm with your palm facing up and tie the cuff on your upper arm. Align the artery indicator ϕ with your main artery (on the inside of your arm).**
   Note: Locate your main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your arm. Identify where the pulse can be felt the strongest - this is your main artery.
4. **Make sure the bottom edge of the arm cuff is 2 to 3 cm above the inside of your elbow. Then, wrap the cuff securely.**
   Note: 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 upright in a comfortable chair with your back against the backrest of the chair. Keep your feet flat, and your legs uncrossed. Place your arm resting comfortably on a flat table. The cuff worn on your arm should be placed on the same level as the right atrium of your heart.**
6. **Take 5-6 deep breaths and start measuring.**





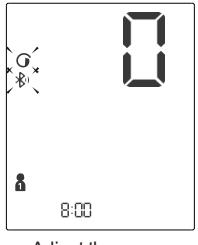
Helpful tips:

- Take the measurement in a silent room.
- Rest for 5 minutes before a measurement.
- Wait at least 3 minutes before taking another measurement. This allows your blood circulation to recover.
- Be relaxed and do not move or talk during the measuring process.
- For a meaningful comparison, try to take all your measurements under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

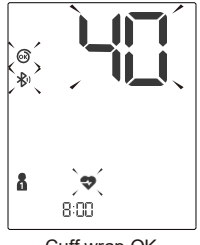
♥ Start the Measurement

You can use your monitor without pairing to the Aspedan App. To pair your monitor with the Aspedan App, please refer to the previous pages in this manual.

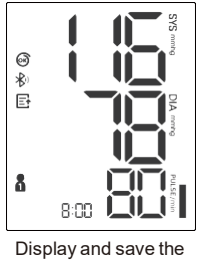
1. **After applying the arm cuff and when the monitor is OFF, press the "START/STOP" button to begin blood pressure measurement. The monitor will complete the whole measurement automatically, save it, and transmit the measurement data for the selected user.**



Adjust the zero.



Cuff wrap OK.
Inflating and measuring.



Display and save the measurement result.

Note

- To stop the measurement at any time, press the “START/STOP” button.
- If you don’t pair with the Aspedan app, or don’t keep the app ON during measurement, the Bluetooth symbol will flash.
- If there is unsent data, the symbol will display during the measurement.

2. Press the “START/STOP” button to turn off the monitor. The monitor will automatically shut off after about 1 minute.

3. If your monitor is already paired with the Aspedan app, and both Bluetooth and the app are ON, when the is measurement completed it will start transmitting to the app (only user 1 and user 2 available).

If successful, the symbol “ ” will disappear first, and after several seconds “ ” will also disappear. The monitor will then turn off automatically.

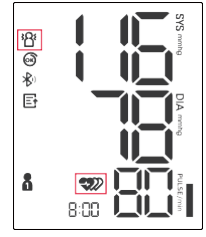
If unsuccessful within 60 seconds, this will be judged as a timeout and the monitor will shut off. In the case of a data transmission failure, up to 199 measurements are saved on the device for user 1 and 2. The data from this measurement will be sent to the Aspedan app once a successful connection is achieved.

4. Information regarding irregular pulse rates and excessive body motion during blood pressure measurements.

- If an irregular pulse rate is detected during a measurement, the symbol will display in the measurement result. See page 24 for more information.
- If excessive body motion is detected during a measurement, especially from the arm on which the cuff is being worn, the symbol will flash for about 5 seconds, whilst the monitor continues to scan for excessive movement. If excessive motion is no longer detected, the symbol will disappear; however, if it is still detected, the symbol will display in the final measurement result.

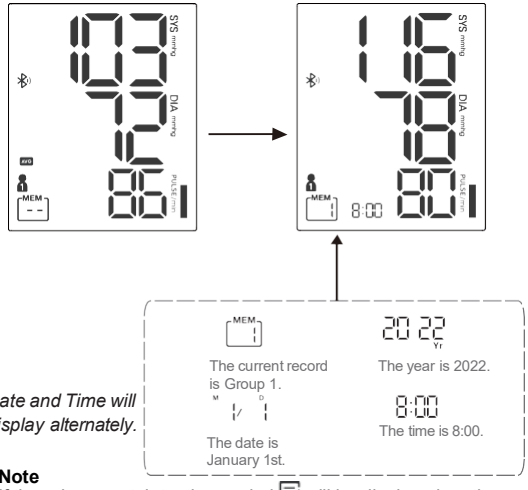
Note

The measured blood pressure reading may not be accurate if this symbol is displayed.



♥ Recall Measurement Records

1. **When the monitor is off, press the "MEM" button. The user ID symbol will blink.**
2. **Press the "USER" or "MEM" button to switch the user ID between user 1 and 2. Press the "START/STOP" button to confirm the selected user ID.**
3. **The LCD will then display the average value of the last 3 readings for the selected user. When there are fewer than three groups of records, the device will display the most recent record. (See example below for User 1.)**
4. **Press the "USER" or "MEM" button to display the next record.**



Date and Time will display alternately.

Note

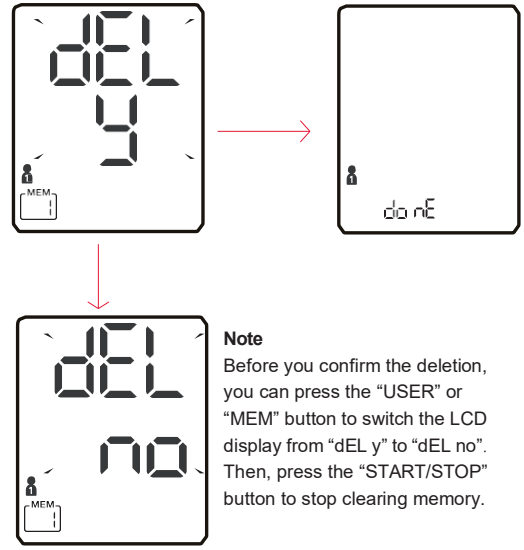
- If there is unsent data, the symbol will be displayed on the record.
- The latest record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one (e.g. 2 becomes 3, and so on). The last record (199) will be dropped from the list.

♥ Delete Measurement Records

Delete your recorded measurements by following the steps detailed below.

A: Delete one record (example shown below for User 1).

1. **Enter the memory recall mode as described in the previous section "Recall Measurement Records". Identify the record you want to delete.**
2. **Press and hold the "MEM" button for about 3 seconds. The LCD will display "dEL y" and blink.**
3. **Press the "START/STOP" button to confirm the deletion. The LCD will display "donE". The previous record will now be displayed.**

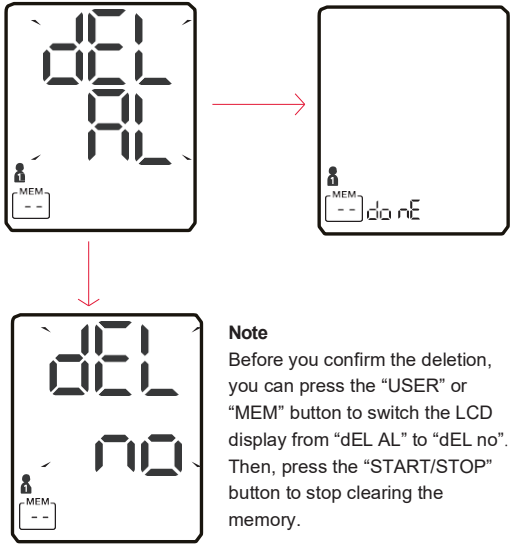


Note

Before you confirm the deletion, you can press the "USER" or "MEM" button to switch the LCD display from "dEL y" to "dEL no". Then, press the "START/STOP" button to stop clearing memory.

B: Delete all records (example shown below for User 1).

1. **Enter the memory recall mode as described in the previous section "Recall Measurement Records**
2. **Press and hold the "USER" and "MEM" button for about 3 seconds, the LCD will display "dEL AL" and blink.**
3. **Press the "START/STOP" button to confirm the deletion, the LCD will display "done".**

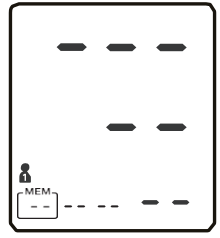


Note

Before you confirm the deletion, you can press the "USER" or "MEM" button to switch the LCD display from "dEL AL" to "dEL no". Then, press the "START/STOP" button to stop clearing the memory.

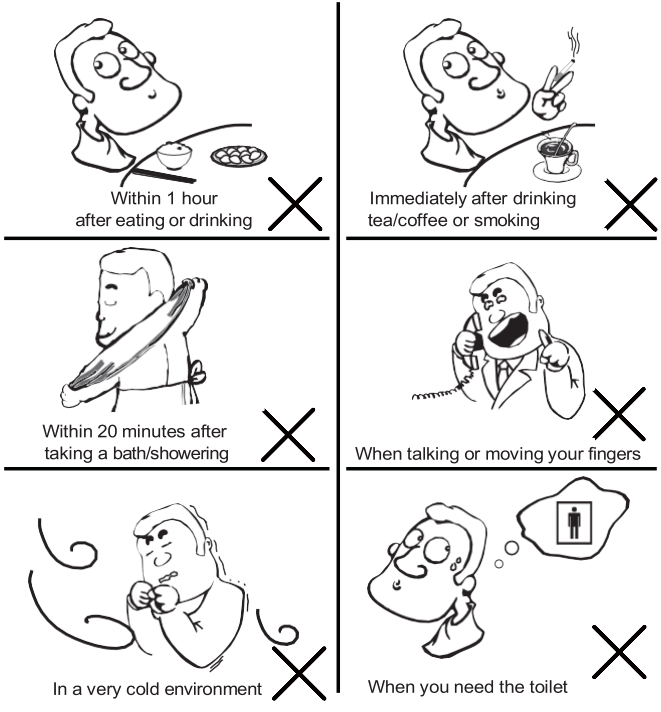
4. Once deleted, your readings cannot be restored. The LCD will display "--", as shown in the diagram below.

Press the "START/STOP" button to turn off the monitor. The monitor will power off automatically after about 1 minute.



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances:



♥ Maintenance

In order to optimise the performance of your blood pressure monitor, please follow the instructions below.

1. Cleaning Process

Step 1: Ensure to switch off and unplug the device prior to cleaning.
Step 2: Use a soft cloth, dampened with soapy water, to clean the cuff first. Then, use a soft cloth dampened with clear water to remove residual soap from the cuff until there are no visible residual soap suds. Attention should be paid to ensure you avoid getting any water into the cuff.
Step 3: Use a dry soft cloth to wipe the cuff, in order to remove residual moisture.
Step 4: Dry the cuff in a well-ventilated place after cleaning.

2. Disinfection Process

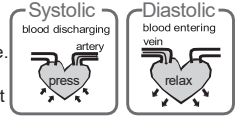
Step 1: Ensure to switch off and unplug the device prior to disinfection.
Step 2: Use a soft cloth dampened with disinfectant (use 70% isopropanol to adhere to manufacturer guarantee) to disinfect the cuff for about 3 minutes. Attention should be paid to ensure you avoid getting any disinfectant into the cuff.
Step 3: Use a clean, dry cloth or towel to wipe off the disinfectant until there is no visible residue.
Step 4: Dry the cuff in a well-ventilated place after disinfection.

Suggestion Frequency of Cleaning and Disinfection:

- For single patient multiple use, it is recommended to clean the device surface at least once a month, or whenever deemed necessary.
- For multiple patient multiple use, it is recommended to clean the device every time the device is used, both before and after usage. Maintenance procedures should be taken as per instruction above.

♥What is systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, blood pressure reaches its maximum value in the heart-beat cycle, which is called systolic pressure. When the ventricles of the heart relax, the blood pressure reaches its minimum value in the heart-beat cycle, which is called diastolic pressure.



♥ Standard blood pressure classifications

Blood pressure classifications published by the World Health Organization (WHO) and International Society of Hypertension (ISH) in 2020 are as follows:

Level / Blood Pressure	Optimal	Elevated-Normal	High Blood Pressure (Hypertension) Stage 1	High Blood Pressure (Hypertension) Stage 2	Hypertensive Crisis (consult your doctor immediately)
Systolic mmHg	Less than 120	120-129	130-139	140 or higher	Higher than 180
Diastolic mmHg	Less than 80	Less than 80	80-89	90 or higher	Higher than 120

CAUTION

Only a physician can formally measure your blood pressure and diagnose hypertension. Please contact a physician if your blood pressure readings fall outside of the normal range, and always if your systolic pressure is higher than 180 mmHg and/or your diastolic pressure is higher than 120 mmHg. Please note that only a physician can formally diagnose high or low blood pressure.

♥Irregular pulse rate detector

An irregular pulse rate (IPR) will be detected if there is an irregular pulse rhythm while measuring systolic and diastolic blood pressure. When measurements are taken, the monitor will record all pulse intervals and calculate the average. If two or more pulse intervals were recorded, and the difference between each interval and the average is larger than ±25% of the average, OR if four or more pulse intervals were recorded, and the difference between each interval and the average is larger than ±15% of the average value, the irregular pulse symbol will be displayed along with measurement results.

CAUTION

The appearance of the IPR icon indicates that a pulse irregularity consistent with an irregular pulse rate 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 irregular pulse rate detector results cannot be used directly for clinical judgement. Please seek medical advice from professionals before making any medical decisions.

♥Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure readings vary throughout the day. Blood pressure readings are also affected by the way you wrap the cuff around your arm during measurements, so ensure to take measurements under the same conditions.
2. If the user takes medicine, there may also be variations in blood pressure readings.
3. Ensure to wait at least 3 minutes between measurements.

♥Why do I get different blood pressure readings at home compared to at a hospital/the doctors?

Blood pressure will vary for everyone throughout the day due to a very wide range of factors, including the weather, emotions, exercise etc. There is a phenomenon known as the 'white coat' effect, whereby blood pressure readings are often higher when a person is in a clinical/medical setting.

♥Things to pay attention to whilst taking your blood pressure

- Ensure the cuff is wrapped around your arm properly.
- Ensure the cuff is not too tight or too loose around your arm.
- Ensure the cuff is fixed above your elbow, on the upper arm.
- If you feel anxious/stressed, take 2-3 deep breaths before beginning the measurement.
- We advise you relax for 4-5 minutes prior to taking a measurement for accuracy.

♥Will my blood pressure results be the same if I measure on different arms?

It is acceptable to take your blood pressure from both your right and left arms, however some people will see different results between their arms. We recommend you measure using the same arm every time.

If any abnormality arises during use, please check the following points:

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display does not light up.	Batteries are depleted.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
		Adaptor is inserted incorrectly.	Insert the AC adaptor correctly.
High Battery	bAt H shows	The battery is too high.	Replace with new batteries.
Low Battery	bAt Lo & shows	The battery is too low.	Replace with new batteries.
Error message	E 1 shows	The cuff is not wrapped or wrapped incorrectly, or the cuff air plug is loose.	Refasten the cuff and insert air tube plug correctly, then measure again.
	E 2 or shows	Excessive body motion (such as shaking of the arm with the cuff on) or weak pulse is detected.	Relax for 5 minutes. Ensuring you are keeping still measure again.
	E 3 shows	Pulse is not detected during measuring.	Loosen any clothing on your arm and measure again.
	E 4 shows	The measurement has failed	Relax for 5 minutes, then measure again.
	EExx shows	Hardware error (XX can be some digital symbol, such as 1, 2, etc)	Turn off monitor and measure again. If EEx still appears on the display, please contact the retailer.
	USb Err shows	The voltage of the blood pressure monitor is high or low.	Replace with the authorised adaptor.
Warning message	out shows	Out of measurement range	Relax for a moment, then measure again. If the problem persists, contact your physician.

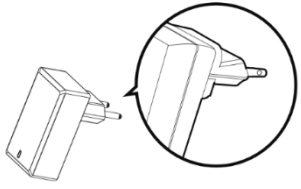
NOTE: If the product still does not work, contact Customer Service. Under n o circumstance should you disassemble or attempt to repair the unit by yourself.

External dimensions	Approx. 100.3 mm x 132.3 mm x 47.1 mm
Display mode	Digital LCD V.A. 59 mm x 72.5 mm
Weight	Approx. 273 g (excluding batteries and cuff)
Measurement mode	Oscillographic testing mode
Mode of operation	Continuous operation
Measurement range	Rated cuff pressure: 0 mmHg ~ 299 mmHg Measurement pressure: SYS: 60 mmHg ~ 230 mm Hg DIA: 40 mmHg ~ 130 mm Hg Pulse value: 40 – 199 beats/minute
Accuracy	Static pressure: 5℃ – 40℃ within ± 3 mmHg Pulse value: ± 5% Clinical validation: Mean difference within ± 5 mmHg Standard deviation ± 8 mmHg
Normal working conditions	Temperature: +5℃ to +40℃ A relative humidity range of 15% to 90%, non-condensing, but not requiring water vapour partial pressure greater than 50 hPa An atmospheric pressure range of 700 hPa to 1060 hPa
Storage and transportation conditions	Temperature: -20℃ to +60℃ A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50 hPa An atmospheric pressure range of 500 hPa to 1060 hPa
Measurement perimeter of the upper arm	22 cm – 32 cm
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 – the device could be protected against solid foreign objects of 12.5 mm Φ and greater, and against vertically falling water drops
Device classification	Battery Powered Mode: Internally powered ME
Expected lifetime	Device: 3 years or 30,000 measurements (may vary based on usage conditions) Cuff: 10,000 times Alkaline battery: About 200-300 times
Types of use/reuse	Multiple patient, multiple use

WARNING: No modification of this equipment is allowed.

♥ Authorised Component

Please use the authorised adaptor.



Adaptor
Type: BLJ06L050100U-V
BLJ06L050100U-S
BLJ06L050100U-B

Input: 100-240V, 50-60Hz, 0.2A max
Output: 5V ⎓ 1000 mA

♥ Contact Information

For more information about our products, please visit www.aspedan.com.

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

Importer: Aspedan Ltd, Unit 4, Capenhurst Technology Park, Capenhurst, Chester, United Kingdom, CH1 6ES

♥ EU Declaration of Conformity

Hereby we
Guangdong TRANSTEK Medical Electronics Co., Ltd. Address: Zone A, No.105 Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China

declare that this DoC is issued under our sole responsibility for the below equipment:

Product Name:	Blood Pressure Monitor
Model name:	TMB-2284-B
Software:	A01
Accessories:	Cuff AC1636-01, AC2232-10, AC2242-17, AC2242-31, AC2245-05

complies with the following directives and regulations:

2014/53/EU (The Radio Equipment Directive)

For the evaluation of the compliance with these Directives and Regulations, the following standards/requirements were applied:

Safety Article3.1(a)	IEC 60601-1:2005+AMD1:2012+AMD2:2020 IEC 60601-1-11:2015+AMD1:2020
EMC Article3.1(b)	EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4
Radio Article3.2	EN 300 328 V2.2.2
Health Article3.1(a)	EN 62479:2010

Person responsible for making this declaration

Print name/Title: Li Sheng Li/Product manager

Guangdong Transtek Medical Electronics Co.,Ltd

♥EMC Guidance

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

Essential performance:
Accuracy of measuring blood pressure and pulse rate

Measurement Range	Systolic pressure: 60-230 mmHg Diastolic pressure: 40-130 mmHg Pulse: 40-199 beats/minute
Rated Cuff Pressure	0-299 mmHg (0-39.9 kPa)
Accuracy	Static Pressure: 5℃-40℃ within ±3mmHg Pulse value: ±5% Clinical validation: Mean difference within ±5mmHg; Standard deviation ≤ 8 mmHg

The Basis Safety of the Blood Pressure Monitor (TMB-2284-B) is as follows:
Deviation from normal operation that poses an unacceptable risk to the patient or operator.

Warning: Do not 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 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 expected lifetime.

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
discharge (ESD) Electrostatic 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% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 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 for ENCLOSURE PORT IMMUNITY to RF wireless communicati-ons equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5k Hz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation 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							