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Meraw Aspen

Wrist Blood Pressure Monitor

Global Customer Service

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V1.0

Meraw Aspen

Table of Contents

01

Device Overview

Indication for use

Contraindications

Safety information

Monitor components

LCD display

Indications for Use

This Blood Pressure Monitor Meraw aspen is a digital monitor intended for use in measuring blood pressure and heartbeat rate with wrist circumference ranging from 5 1/3″-8½″(13.5 cm to 21.5 cm) . It is intended for indoor, adult use only.

Contraindications

1. The device is not suitable for use on the women who are or may be pregnant.

2. The device is not suitable for use on patients with implanted electrical devices, such as cardiac pacemakers, defibrillators.

Safety Information

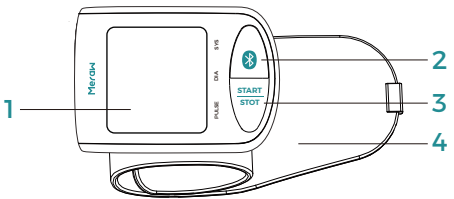
The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Refer to instruction manual/booklet To signify that the instruction manual/ booklet must be read.		Symbol for "TYPE BF APPLIED PART"
	Date and Country of manufacture		The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
	Symbol for "MANUFACTURER"		
SN	Symbol for "SERIAL NUMBER"		
	Symbol for "RECYCLE"		
	Symbol for "DIRECT CURRENT"		Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

Measurement Principle

This product uses the Oscillometric Measuring Method to detect blood pressure. Before every measurement, the unit establishes a "zero point" equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as pulse rate.

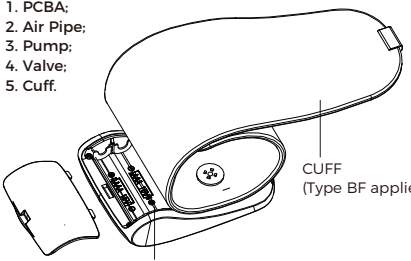
Monitor Components



1. LCD DISPLAY
2. BLUETOOTH BUTTON
3. START/STOP BUTTON
4. CUFF

Component list of pressure measuring system:

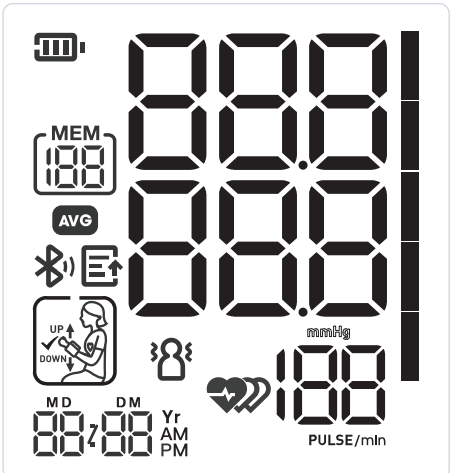
1. PCBA;
2. Air Pipe;
3. Pump;
4. Valve;
5. Cuff.



List

1. Blood Pressure Monitor TMB-2085-K
2. 2× AAA Batteries
3. User manual

LCD Display



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	The high pressure measured.
DIA	Diastolic blood pressure	The low pressure measured.
mmhg	mmHg	Measurement Unit of the blood pressure
PULSE /min	Pulse display	Pulse in beats per minute.
AVG	Average value	Displays average of last 3 readings.
	Heartbeat	Heartbeat dectetion during measurement.
	Irregular heartbeat	Irregular heartbeat detected during measurement.
	Wrist Positioning Guide	Guide for you to make the wrist in ideal position.

SYMBOL	DESCRIPTION	EXPLANATION
	Bluetooth transfer icon	The bluetooth transfer icon blinks when the bluetooth is working.
	Battery indicator	Indicate the current battery.
	Excessive Body Motion Detector	Appears when talking, moving, or hand shaking is detectedduring the measurement. NOTE: The measured blood pressure reading may not beaccurate if the icon is displayed.
	Memory display	Indicate it is in the memory mode and which group of memory it is.
	Current time	Time and date (year/month/day; hour:minute)
	Blood pressure level	Indicates the blood pressure level, See page 24 for more information.
	Data pending to transmit	Appears in next measurement, when the data transmission fails.

02

Device Set Up

Power supply

Installing Batteries

Setting date and time

Power Supply

Battery powered mode: 3V DC 2× AAA batteries

CAUTION

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

Installing Batteries

- 1.Slide off the battery cover.
- 2.Install or replace 2× AAA size batteries as indicated in the battery compartment. The display will light up and show the icon  . Press “START/ STOP” button to turn off, otherwise it will power off automatically after 10 seconds. Any time the battery is low, it will display the icon“ bAt Lo” &  . It will power off automatically after 5 seconds.
- 3.Close the battery cover.

  Replace the batteries if:

  • The low battery symbol appears on the display.

  • When any button is pressed and nothing is displayed on the screen.

CAUTION

Do not use new and used batteries together.

Do not use different types of batteries together.

Do not dispose the batteries in fire. Batteries may explode or leak.

Remove batteries if the device is not likely to be used for some time.

Worn batteries are harmful to the environment. Do not dispose with daily garbage.

Remove the old batteries from the device following your local recycling guidelines.

Setting Date and Time

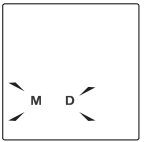
It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory.

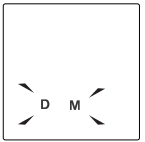
Auto Setting

Once connected to smartphone App via Bluetooth, date and time will be syned to BPM automatically.

Manual Setting

1. When the monitor is off, press and hold the “START/ STOP ” button to display the date format. Press the “Bluetooth” button to switch the date format between [month/day] and [day/month].

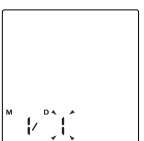




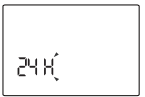
2. Press the “START/ STOP ” button to confirm the date format, then the year will flash. Press the “Bluetooth”button to change the year.

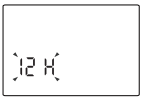
3.When you get the right year, press the “START / STOP” button to confirm the year. The screen will then show a blinking number representing the [MONTH].

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

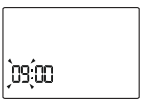


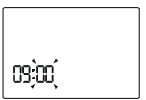
5.Repeat steps 2 and 3 to set the time format.





6.Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].





7.Repeat steps 2 and 3 to confirm [Wrist Positioning Guide] on or off.

Note: When the Wrist Positioning Guide is OFF, the instruction will not appear at the start of the measurement.

8.After confirming the [Wrist Positioning Guide],the LCD will display"donE"and then the monitor will turn off.

WRIST POSITIONING GUIDE

When using wrist blood pressure monitor, it is important to take the measurement while relaxing your wrist at heart level. This will help ensure an accurate reading will be taken. Because it is difficult to find the ideal location for a wrist measurement, we have included an optional Wrist Positioning Sensor that will assist in directing your wrist to the ideal location for a blood pressure measurement.
Each time you take a measurement, the display will illuminate with different icons that are designed to help you move your wrist. Once the ideal location is found, the wrist symbol ✓ will flash and after several seconds, measurement will begin. Keep your arm still until measurement is completed.

Move your wrist up.

Move your wrist down.

Wrist in ideal position, the symbol ✓ flash.

Do not move, Measurement start.

Note: Due to differences in individual sizes and physique, this feature may not be helpful in all cases and you may wish to turn this feature OFF. If you feel the suggested wrist position does not match your heart level, please turn this feature OFF and follow your judgment.

03

Measurement

Put on device

Sit correctly

Start the measurement

Measurement tips

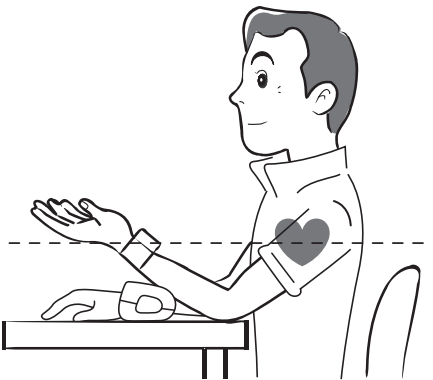
Put on device

- Remove all accessories (watch, bracelet,etc) from your wrist. If your physician has diagnosed you with poor circulation in your wrist, use the other one.
- Roll or push up your sleeve to expose the skin.
- Apply the cuff to your wrist with your palm facing up.
- Position the edge of the cuff about 1cm~2cm from wrist joints.
- Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.
- Sit comfortably with your tested wrist resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.

Sit Correctly

To take a measurement, you need to be relaxed and comfortably seated, under comfortable room temperature. Avoid bathing, drinking alcohol or caffeine, smoking, exercising or eating 30 minutes before taking a measurement.

- Keep palm relaxed during measurement
- Sit in a chair with your legs uncrossed and feet flat on the floor.
- Sit with your back and arm supported.



Start The Measurement

Notes:
-To stop the measurement, press the START/STOP button once to defalte the arm cuff.
-Remain still and quiet while taking a measurement.

Press the START/STOP button.

-The arm cuff will start to inflate automatically.

-The whole measurement takes around 35 seconds.

▼START ▼INFLATING ▼COMPLETED

Measurement Tips

Patients with Hypertension:
The middle of the cuff should be at the level of the right atrium of the heart; Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and wrist supported.Rest for 5 minutes before measuring.Wait at least 3 minutes between measurements. This allows your blood circulation to recover.The patient must relax as much as possible and do not move and talk during the measurement procedure.For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist, or as directed by a physician.Take the measurement in a silent room.The cuff should maintain at the same level as the right atrium of the heart.Do not cross your legs and keep your feet on the ground.
Keep your back against the backrest of the chair.

CAUTION

- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.

04

Bluetooth & App

Download App

Add My device

View data

Track trends

Download App

Meraw Health app is available both on Google play and App Store, search and download.

Make sure your phone has enough storage and meet lowest system version requirement before downloading.

Scan above QR code to download App and get App instruction.

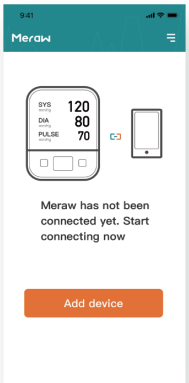
GET IT ON Google Play

Android system:
Android 9.0 or above

GET IT ON App Store

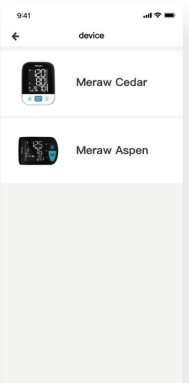
iOS system:
iOS 10.0 or above

Add My Device



Step 1. Add device

After opening Meraw App for the first time, it will guide you to add new device.

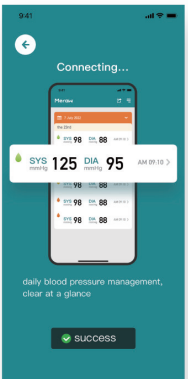


Step 2. Choose device

Choose Meraw Aspen and continue.

Step 3. Start Connection

Follow the instruction and start connection.



Step 4. Connection successfuly

The connection process will complete automatically.

View Data

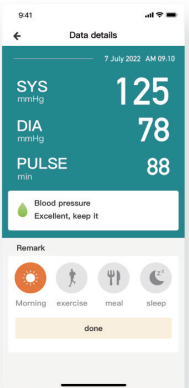
All synced data will be listed by month, and show brief information including:

-Blood pressure level

-SYS

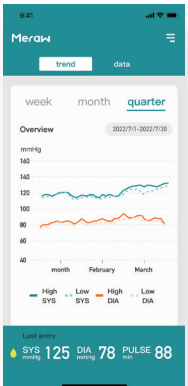
-DIA

-measured time



Some factors may influence the accuracy of measure-ment,click a data and add remark on it.

Track Trends



View your blood pressure in trend, clear at a glance

05

Data Management

Recall the records

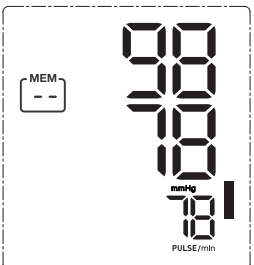
Sync the records

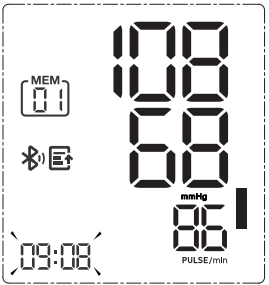
Delete the records

Recall the records

1.When the monitor is off, press"Bluetooth" button, the display will show the average value of the latest three records first.

2.When the memory record is less than three groups, the display will show the latest record(memory record 01)



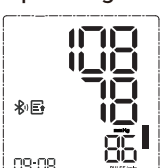


2. Press “Bluetooth” button to get the record you want.
Each press “Bluetooth” butooth will increase the memory record by one in a cycling manner (AVG-01-02...).

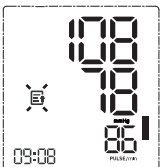
Sync the records

1.Turn on Bluetooth and open App on your smartphone before you sync the records.

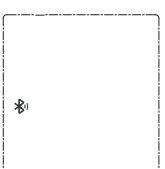
2. Each time you complete a measurement, data will be synced to App automatically, will blink during uploading and turn solid on after uploading successful.



3. If you data is not synced to App, will show in data page, indicating the record is not uploaded to App.



4. You could press 'Bluetooth' button when the blood pressure monitor is off to sync data that are not uploaded.



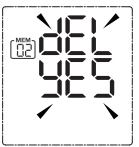
Delete the records

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

A: To delete a single measurement:

1. Enter the memory recall mode as described in section [Recall the Records]. Press “Bluetooth” button to get the measurement you would like to erase.
2. Press and hold “Bluetooth” button for 3 seconds, and the display will show a blinking “dEL yES” along with the memory number of the reading.
3. Use the “Start/Stop” or “Bluetooth” button to toggle between “dEL yES” and “dEL no”, Press “START/STOP” to confirm the selection.

If “dEL yES” is selected, the unit will delete the record and display “dEL do nE” along with the memory number of the reading. After then it will return to last memory record and All the records are pushed forward one digit (e.g., 03 becomes 02, and so on)
If “dEL no” is selected, it will stop the deletion.



“DEL YES” blinks

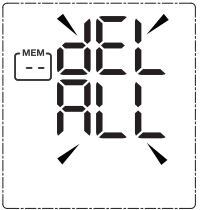
“DEL no” blinks

Deletion is done

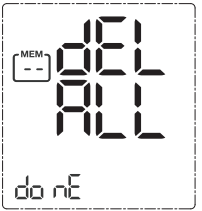
B: To delete all measurements:

1. Enter the memory recall mode as described in section [Recall the Records].
2. Press and hold “BLUETOOTH” and “RECORD” button for 5 seconds, and the display will show a blinking “dEL ALL” along with the user ID.
3. Use the “BLUETOOTH” or “RECORD” button to toggle between “dEL ALL” and “dEL no”, Press “START/STOP” to confirm the selection.

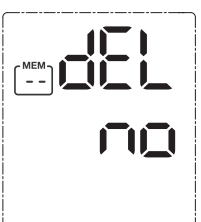
If “dEL ALL” is selected, the unit will display “dEL ALL do nE” + User ID and delete all the record of the current user. Several seconds later, it will display “---”. If “dEL no” is selected, it will stop the deletion.



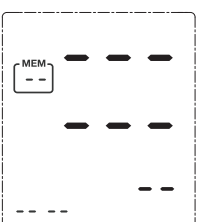
“DEL ALL” blinks



“DEL no” blinks



Deletion is done



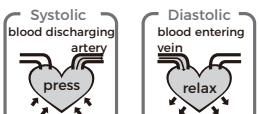
No record

06

ABOUT BLOOD PRESSURE

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.



CAUTION

Only a physician can tell your normal BP range.Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Standard blood pressure classification

The blood pressure classification published by AAC/AHA in 2017 is as follows:

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)	and/or	DIASTOLIC mm Hg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120 - 129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130 - 139	or	80-89
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120

Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records all the pulse intervals and calculate the average; if there are two or more pulse intervals, the difference between each interval and the average is more than the average value of ±25%, or there are four or more pulse intervals, the difference between each interval and the average is more than the average value of ±15%, the irregular heartbeat symbol appears on the display when the measurement results are appeared.

CAUTION

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

Blood pressure fluctuate throughout the day

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

Different blood pressure at home compared to the hospital

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

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

If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.
Taking 2-3 deep breaths before beginning will be better for measuring.
Advice: Relax yourself for 4-5 minutes until you calm down.

Measuring on the right arm

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

07

Information

Trouble Shooting

Specification

Product Maintainance

Trouble Shooting

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

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power		Batteries are exhausted.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
Low batteries	bAt Lo & shows	Batteries are low.	Please replace batteries.
Warning message	"out" shows	Out of measure-ment range	Relax for a moment. Refastenthe cuff and vthen measure again. If the problem persists, contact your physician.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
Error message	E 01 shows	The cuff is not secure	Refasten the cuff and then measure again.
	E 02 shows	The monitor detected motion, talking, or the pulse is too poor while measuring.	Relax for 5 minutes. and then keep still, measure again.
	E 03 shows	Pulse is not detected during measuring.	Loosen the clothing on the wrist and then measure again.
	E 04 shows	The measurement failed.	Relax for 5 minutes and measure again.
	EEx shows	Hardware error (X 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 or our customer service

NOTE: If the product still does not work, contact Meraw Customer Service. Under no circumstance should you disassemble or attempt to repair the unit by yourself.

Specifications

Power supply	Battery powered mode: 2x AAA batteries 3V ⎓
Display mode	Digital LCD V.A.43 mm x 46 mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0 mmHg ~ 299 mmHg Measurement pressure: SYS: 60 mmHg ~ 230 mmHg DIA: 40 mmHg ~ 130 mmHg Pulse value: (40-199) beat/minute
Accuracy	Pressure: 5˚C-40˚C within ±3 mmHg Pulse value: ±5%
Working condition	A temperature range of : +5˚C to +40˚C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of: 700 hPa to 1060 hPa
Storage & transportation condition	Temperature: -20˚C to +60˚C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the wrist	About 13.5-21.5 cm
Weight	Approx.103 g (Excluding the batteries)
External dimensions	Approx. 85.7 mm × 60.8 mm × 24.7 mm (Excluding the cuff)
Attachment **Mode of operation**	2x AAA batteries, user manual Continuous operation
Degree of protection	Type BF applied part
Device Classification	Internally Powered ME Equipment
IP Classification	IP22: The first number 2: Protected against solid foreign objects of 12.5mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure titled up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15° on either side of the vertical.
Software Version	A01

Product Maintainance

CAUTION

* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure .Do not begin or end medical treatment without asking a 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.
* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* When the device is used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
* Warning: Do not apply the cuff over a wound;otherwise it can cause further injury.
*Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
*On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure ＞ 300mmHg or constant pressure ＞ 15mmHg for more than 3 minutes) applied to the wrist may lead to an ecchymosis.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.

CAUTION

* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2018.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's wrist and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
*This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
* The maximum temperature that the applied part can be achieved is 42.5℃ while the environmental temperature is 40℃.
* 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.
* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.
* The patient can measure data and change batteries under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* During use, the patient will be in 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.
* If you experience discomfort during a measurement, such as pain in the wrist or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your wrist.

CAUTION

* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. Thetypical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
*Please dipose of any accessories, detachable parts, and the ME equipment according to the local guidelines
*Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The operator shall not touch output of batteries and the patient simultaneously.
* Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
* The device doesn't need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Transtek. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
* Please report to Transtek if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.

CAUTION

* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided
in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014 as appropriate.
* Please use ACCESSORIES and detachable parts specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

08

Complaince

FCC Statement

EMC guidance

FCC Statement

FCC ID: OU9TMB2085-K

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

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

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

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

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

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

ECC Radiation Exposure Statement:
This equipment complies with Fcc radiation exposure limits set forth for an uncontrolled environment.This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.
Warning:Don't be near the active He 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 emissionsor decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:Portable RE communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches)to any part of the equipment.

TMB-2084 including cables specified by the manufacturer. Otherwise.degradation of the performance of this equipment could result.

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

Table 1

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

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	+2 kV for power supply lines +1 kV signal input/output 100 kHz repetition frequency	+2 kV for power supply lines Not Applicable 100 kHz repetition frequency
Surge IEC61000-4-5	10.5 kV,1 kV differential mode ±0.5kV,±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% UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase: at 0°. 0% UT; 250 / 300 cycle	0% UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase: at 0°. 0% UT; 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 UT is the a.c.mains voltage prior to application of the test level.

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity

	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communicati- ons equipment)	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
	710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	1720 1845 1970	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
	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 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9