Sunbeam

Upper Arm Blood Pressure Monitor

with Comfort Inflate Technology

Instruction Manual

Model: TMB-1583-S
Item: 16985
Manual Version: V1.0
Issue Date: 2021-07-12

General Description

This device measures blood pressure and pulse rate and saves the results in Memory. With proper use, the readings taken by this blood pressure 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, and provides step by step instructions for using this blood pressure monitor.

Read the manual thoroughly before using this product.

Features:

- 2.3" x 3.3" (73 mm x 84 mm) Digital LCD display
- Maximum storage of 60 records per user
- Advanced measuring-during-inflation technology

Indications for Use

This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 8¾" - 16½" (about 22 cm to 42 cm).

It is intended for indoor, adult use only.

Contraindications

1. The device is not suitable for use on 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 or defibrillators.

Measurement Principle

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

SAFETY INFORMATION

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

Note: Not all symbols may appear in this INSTRUCTION MANUAL

	Symbol for “Read and follow the INSTRUCTION MANUAL”		Symbol for “TYPE BF APPLIED PARTS”
	Symbol for “Consult accompanying documents”		Symbol for “Do not dispose with household garbage. Remove the old batteries from the device and follow local recycling guidelines”
	Symbol for “SERIAL NUMBER”		Symbol for “Recycle”
	Symbol for “DIRECT CURRENT”		Symbol for indoor use only
	Symbol for “Class II Equipment”		

⚠ WARNING

- **This device is intended for adult use in homes only.**
- **This 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 any medical conditions.**
- **This device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.**
- **This device is not intended for patient transport outside a healthcare facility.**
- **The device is not intended for public use.**
- **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 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 was 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.**
- **Don’t kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury.**
- **When using this device, please pay attention to the following situations which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.**
- **Warning: Do not apply the cuff over a wound, otherwise it can cause further injury.**
- **Do not inflate the cuff on the same limb of which other monitoring equipment is applied as this could cause temporary loss of function of those simultaneously-used monitoring 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 arm may lead to an ecchymosis.**

⚠ WARNING

- Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
- The device cannot be used with HF surgical equipment at the same time.
- 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 device is not suitable for continuous monitoring during medical emergencies or operations.
- When not in use, store the device with the adapter in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the device.
- This device may be used only for the purpose described in this INSTRUCTION MANUAL. 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 INSTRUCTION MANUAL.
- The equipment is not an AP/APG equipment and is not suitable for use in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.
- Warning: DO NOT service or perform maintenance while the device is in use.
- The patient is the intended operator.
- The patient can measure, change batteries under normal circumstances and maintain the device and its accessories according to the INSTRUCTION MANUAL.
- To avoid measurement errors, please avoid strong electromagnetic field adiated interference signals or electrical fast transient/burst signals.
- The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please do not 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. The device is not known to cause any potential irritation.
- If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
- If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
- Before use, make sure the device functions safely and is in proper working condition. 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 cleaning, skin condition, and storage state. The typical service life is 10000 uses.

⚠ WARNING

- It is recommended that the performance should be checked every two 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 dispose of accessories, detachable parts, and the device according to the local guidelines.
- The plug / adapter plug pins insulate the device from the main supply. Do not position the device where it is difficult to disconnect from the main power supply to safely terminate operation of the device.
- The operator shall not touch output of batteries /adapter and the patient simultaneously.
- This 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 customer service. Do not open or repair the device by yourself in the event of malfunctions. This device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
- Keep this device out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
- DO NOT wrap cuff or tube around the neck.
- Allow 30 minutes for the device to adjust to the temperature in the room when taking it out of storage. Follow the temperature guidelines in the SPECIFICATIONS section of this INSTRUCTION MANUAL.
- This equipment needs to be installed and put into service in accordance with the information provided in this INSTRUCTION MANUAL.
- 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 away from the equipment.
- Please use accessories and detachable parts specified/authorized by the manufacturer. Otherwise, it may cause damage to this device or danger.
- Please use this device under the environment which are provided in this INSTRUCTION MANUAL. Otherwise, the performance and lifetime of the device will be impacted and reduced.

LCD DISPLAY SIGNAL

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.
Lo +	Low battery	Batteries are low and need to be replaced.
Pulse/min	Beats/minute	Measurement Unit of Pulse Rate.
♥	Heartbeat	Heart rate detected during measurement.
IHB	Irregular heartbeat	Irregular heartbeat detected during measurement.
1 2	User ID	1 Appears when the monitor is operated by User 1. 2 Appears when the monitor is operated by User 2.
MEMORY REVIEW	Memory display	Indicates records in memory.
ERROR	Error	Error.
LAST 3 AVG.	Average value	The average value of the latest three records in memory.
D M M D	Current Time	Time and date (year/month/day; hour:minute).
▌	Blood pressure level	Indicates the blood pressure level.
H	Hour	The hour in the clock mode.
M	Minute	The minute in the clock mode.
S	Second	The second in the clock mode.

COMPONENTS

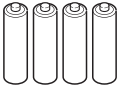
①

BLOOD PRESSURE MONITOR
(TMB-1583-S)

②

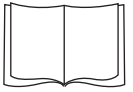
CUFF (TYPE BF APPLIED PART)
8.7″ - 16.5″ (22CM - 42CM)

③



4 X AAA BATTERIES

④



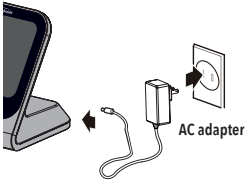
INSTRUCTION MANUAL

⑤

AC ADAPTER

THE POWER SUPPLY OPTIONS

1. Battery-powered mode: DC 6V (4×1.5V AAA batteries) batteries.
2. AC adapter-powered mode: 6V 1A (Please only use the recommended AC adapter).

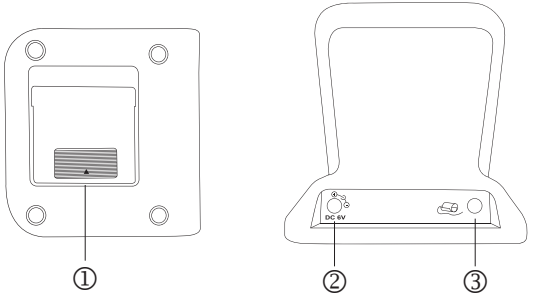


⚠ CAUTION

For best results and to avoid damage to this device, please use this correct batteries.

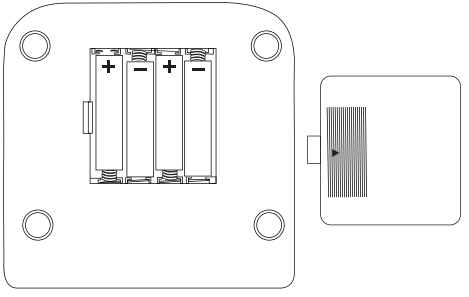
LCD DISPLAY SIGNAL

① LCD DISPLAY
② START/STOP BUTTON
③ SET BUTTON
④ LOCK BUTTON
⑤ MEM BUTTON
⑥ CUFF
⑦ TUBE



① BATTERY COMPARTMENT
② DC POWER SOCKET
③ TUBE CONNECTOR

INSTALLING AND REPLACING THE BATTERIES



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

REPLACE THE BATTERIES WHENEVER THE FOLLOWING HAPPENS:

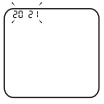
- Lo + shows.
- The display is dim.
- The display does not light up.

⚠ WARNING

- **Do not use new and used batteries together.**
- **Do not use different types of batteries together.**
- **Do not dispose of 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 household garbage.**
- **Remove the old batteries from the device and follow local recycling guidelines.**

SETTING DATE AND TIME

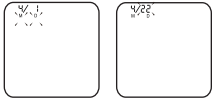
It is important to set the Date and Time before using your blood pressure monitor, so that a time stamp can be assigned to each record stored in the memory.
(The setting range of the year: 2021–2061, Time format: 12/24H)



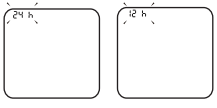
1 When the monitor is off, press and hold "SET" to enter the mode for year setting.

2 Change the [YEAR] by pressing "MEM" button. Each press of "MEM" will increase the number by one in a cycling manner. Note: press and hold the "MEM" button to quickly cycle through the numbers.

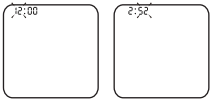
3 When you reach the correct year, press "SET" to confirm the entry.



4 Repeat steps 2 and 3 to set the [DATE FORMAT], then set the [MONTH] and [DAY].



5 Repeat steps 2 and 3 to confirm the time format between [12H] and [24H].

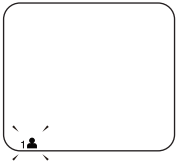


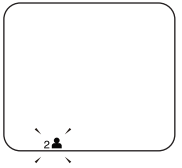
6 Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].

7 After the MINUTE is set, the LCD will display "donE" and will turn off automatically.

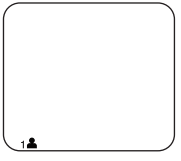
SELECT THE USER ID

1. When the monitor is off, press and hold "MEM". The user ID will show. Press "MEM" to switch the user ID between user 1 and user 2 .



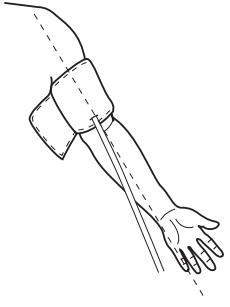


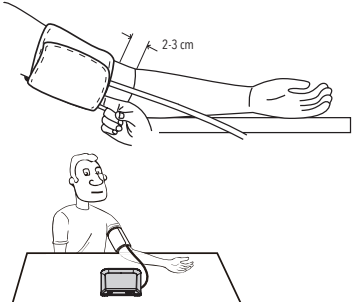
2. Press "SET" to confirm your choice. The display will show User ID and then turn off.



ATTACHING THE CUFF

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

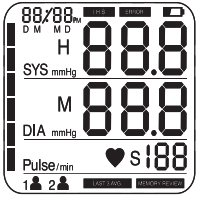




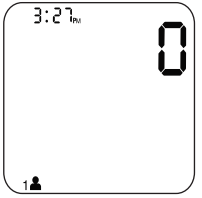
TAKING THE MEASUREMENT

There are two ways to take a measurement:

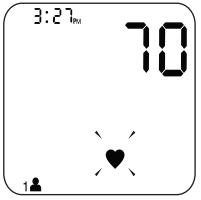
1. Press "START/STOP". The monitor will take the whole measurement automatically and save the data for the selected user. (User 1, for example.)



LCD DISPLAY



INFLATION ABOUT TO BEGIN



INFLATING AND MEASURING

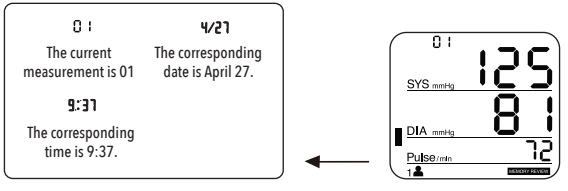
DISPLAYING AND SAVING THE MEASUREMENT RESULTS

2. When the monitor is off, press and hold "MEM".
   The display will illuminate, and the user ID's will flash alternatively.
   Toggle to the User ID you wish to select by pressing "MEM".
   When the desired User ID is flashing, and without pressing "SET" to confirm, press "START/STOP" and the device will take the whole measurement automatically and save the data for the selected user.

To power off the device, press "START/STOP". (Or the monitor will turn off automatically within 1 minute).

RECALL THE RECORDS

1. Press “MEM” to view readings stored in memory. The most recent record will display first when there are less than three measurements. When there are three or more measurements, it will display the average value of the three most recent records first. (User 1 for example).



2. Each additional press of the “MEM” or “SET” button will show the next record. Date, Time will display alternately.

⚠ NOTE

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

DELETING RECORDS

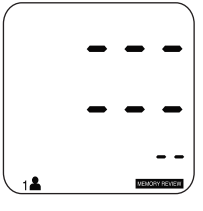
To delete all results for the selected user (User 1, for example.)

1. Press and hold the “MEM” button When the monitor is in memory recall mode, the display will show “dEL ALL” + User ID.

2. Press “SET” to confirm deleting. The LCD will display “dEL do nE” and then turn off.

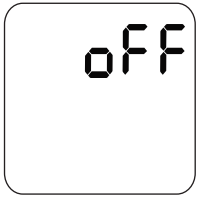
   If you don’t want to delete the records, press “START/STOP” to escape.

   NOTE: If there is no record when you press “MEM”, the display will show a series of dashes.

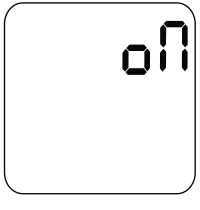


KEY LOCK BUTTON

To help conserve batteries and electricity, you may lock the keys between use. This prevents the monitor from turning on if any key is pressed unintentionally.



1. To Lock the keys:
   Press and hold the Lock button until the LCD displays "OFF." This confirms the touch keys (such as MEM, START/STOP, SET) are inactive.



2. To unlock the keys:
   Press and hold the Lock button until the LCD displays "ON." This confirms the touch keys are active.

TIPS FOR MEASUREMENT

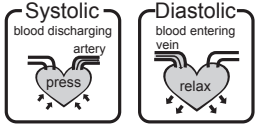
Measurements may be inaccurate if taken in the following circumstances:

- Within 1 hour of eating or drinking.
- Immediately after tea, coffee or smoking.
- Within 20 minutes of bathing.
- While talking or moving your hands/fingers.
- In a cold environment.
- When you feel the urge to urinate.

MAINTENANCE

- Store in a dry place away from sunlight.
- Avoid contact with moisture. Wipe with a soft, dry cloth if necessary.
- Avoid dropping, intense shaking or other impact.
- Avoid dusty conditions and unstable temperature environments.
- Use a lightly damp cloth to remove dirt if necessary.
- Do not clean the reusable cuff with water or other liquid. Never immerse the cuff in water.

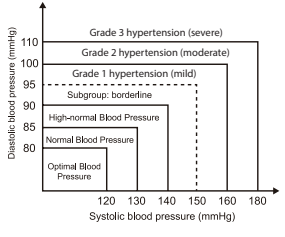
WHAT IS SYSTOLIC PRESSURE AND DIASTOLIC PRESSURE?



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

WHAT IS THE STANDARD BLOOD PRESSURE CLASSIFICATION?

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) is as follows:



⚠ CAUTION

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

LEVEL / BLOOD PRESSURE (mmHg)	OPTIMAL	NORMAL	HIGH NORMAL	MILD	MODERATE	SEVERE
SYS	<120	120 - 129	130 - 139	140 - 159	160 - 179	≥180
DIA	<80	80 - 84	85 - 89	90 - 99	100 - 109	≥110

IRREGULAR HEARTBEAT INDICATOR

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 of the pulse intervals and calculates 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 if 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 displayed.

⚠ CAUTION

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

WHY DOES MY BLOOD PRESSURE FLUCTUATE THROUGHOUT THE DAY?

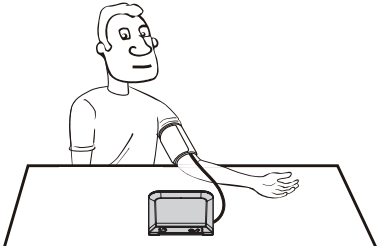
1. Individual blood pressure varies naturally throughout the day.
2. Cuff placement and body position can also affect readings, so try to take the measurement under the same conditions.
3. Certain medications may cause blood pressure to vary.
4. For comparison, wait at least 3 minutes between measurements.

WHY ARE MY BLOOD PRESSURE READINGS AT HOME DIFFERENT FROM AT THE HOSPITAL?

1. A variety of factors may cause blood pressure to fluctuate throughout the day, such as emotions, exercise, or the weather.
2. The "white coat effect" may also affect blood pressure if you feel nervous or anxious in a clinical setting.
3. When taking blood pressure at home, make sure:
   - The cuff is placed on the upper arm and positioned correctly.
   - The cuff is not too tight or too loose.
   - You relax for five minutes before measuring and take 5-6 deep, calming breaths.

WILL THE RESULTS BE THE SAME IF MEASURING ON THE RIGHT ARM?

It is ok to measure on either arm, but results may vary. We suggest you measure the same arm everytime.



PROBLEM	DISPLAY	CAUSE	SOLUTION
NO POWER	Display will not light up.	Batteries are exhausted.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
		AC adapter is inserted incorrectly.	Insert the AC adapter.
LOW BATTERIES	Display is dim or show Lo+	Batteries are low.	Replace with new batteries.
ERROR MESSAGE	E 1	The cuff is not secure.	Refasten the cuff and measure again.
	E 2	The cuff is very tight.	Refasten the cuff and measure again.
	E 3	The pressure of the cuff is excessive.	Relax for a moment and measure again.
	E 10 or E 11	The monitor detected motion, or a weak pulse during measurement	Relax for a moment and measure again.
	E 20	The measurement process does not detect the pulse signal.	Loosen clothing on the arm and measure again.
	E 21	The treatment of the measurement failed.	Relax for a moment and measure again.
	EExx	A calibration error occurred.	Retake the measurement. If the problem persists, contact our customer service department for further assistance. Refer to the warranty for contact information and return instructions.
WARNING MESSAGE	Out	Out of measurement range.	Relax for a moment. Refasten the cuff and measure again. If the problem persists, contact your physician.

LIMITED WARRANTY

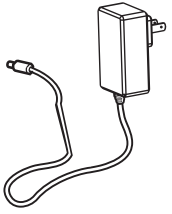
This product has a limited warranty of 3 year(s) on the blood pressure monitor, 2 year warranty on the cuff and accessories (except batteries) from the original date of purchase against workmanship and defects in material. If under normal use, your product fails to operate, please contact our customer service department at info@stareliteinc.com. A refund or replacement will be provided to you with proof of purchase. Star Elite Inc. may deny claims of damage caused by misuse or modifications of this product.

Power supply	Battery powered mode: DC 6V (4 × 1.5V AAA batteries) AC adapter powered mode: 6V 1A (Please only use the recommended AC adapter).
Display mode	Digital LCD Display V.A. 3.3" x 2.8" (8.4 cm × 7.3 cm)
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kPa - 39.9kPa (0mmHg - 299mmHg); Measurement pressure: SYS 8.0kPa - 30.7kPa (60mmHg - 230mmHg); DIA: 5.3kPa - 17.3kPa (40mmHg - 130mmHg); Pulse Value: 40 - 199 beats/minute
Accuracy	Pressure: 41°F - 104°F (5°C - 40°C) within ±3 mmHg (0.4 kPa) Pulse value: ±5%
Normal working condition	A temperature range of: 41°F - 104°F (5°C - 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: -4°F - 140°F (-20°C - 60°C) A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50 hPa
Measurement perimeter of the upper arm	8¾'' - 16½'' (about 22 cm to 42 cm)
Weight	Approx. 8.8oz (250g) (Excluding the batteries and cuff)
Main Unit Dimensions	4.2" x 4.1" x 4.6" (10.7 cm x 10.3 cm x 11.8 cm)
Accessories	4× AAA batteries, instruction manual, AC adapter, and cuff
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 means the device could be protected against solid foreign objects of 0.5" (12.5 mm) and greater, and there is no special protection for water or moisture.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adapter Powered Mode: Class II ME Equipment
Software Version	A01

WARNING: No modification of this equipment is allowed.

AUTHORIZED COMPONENT

Please use the authorized adapter.



Adapter
Model: BLJ06L060100P-U
Input: AC 100-240V
50/60Hz 0.2A Max
Output: 6V 1A

FCC STATEMENT

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.

COMPLIED STANDARDS LIST

Risk Management	EN ISO 14971:2019 / ISO 14971:2019 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User Manual	EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013+A12:2014 / IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic Compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance Requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type IEC80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical Investigation	EN ISO 81060-2:2019/ISO 81060-2:2018, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EMC GUIDANCE

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

⚠ 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.**
- **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.**
- **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.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment TMB-1583-S including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

Technical description:

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

Table 1

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

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2kV,±4kV,±8kV, ±15kV air	±8 kV contact ±2kV,±4kV,±8kV, ±15kV 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% 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	3V 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	3V 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							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communicati-ons equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modula-tion (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5k Hz deviation 1 kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217 Hz	2	0.3	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
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

Sunbeam

If you have any problems, please do not contact the store.
Contact our customer service at 1-877-383-6399
(8:30 am - 5:00 pm EST) Monday - Friday
or contact us at
info@stareliteinc.com
Our customer service will be happy to assist you.

Distributed by Star Elite Inc., 1175 Place du Frère André, Montreal, QC,
Canada H3B 3X9
SE005-071321

Upper Arm Blood Pressure Monitor
Model: TMB-1583-S
Printed in China