

User Manual

Blood Pressure Monitor CGTEC TMB-1018

- Thank you very much for selecting cgtec Blood Pressure Monitor TMB-1018.
- To use the monitor correctly and safely, please read the manual thoroughly.
- Please well keep this manual in order to reference in future.

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**Thank you for selecting cgtec arm type blood pressure Monitor (TMB-1018).
The monitor features blood pressure measurement, pulse rate measurement and
auto-save the result. The design provides you with many years of reliable service.**

**Reading taken by the TMB-1018 are equivalent to those obtained by a trained
observer using the cuff and stethoscope auscultation method.**

**This manual contains important safety and care information, and provides step
by step instruction for using the product.**

Read the manual thoroughly before using the product.

INTRODUCTION

Features:

144*39mm Bright LCD display with blue backlight
Maximum 60 records per user
Charging measuring technology

Safety information

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

Caution: Consult accompanying documents

CE Mark: conforms to essential requirements of the Caution: Consult accompanying

Type B applied part

CE Mark: conforms to essential requirements of the
Medical Device Directive 93/42/EEC.

DISPOSAL: Do not dispose this
product as unsorted municipal
waste. Collection of such waste
separately for special treatment is necessary.

Manufacturer

Direct current

Specifies
serial number

Authorized Representative in the European Community

CAUTION

This device is intended for adult use only.

This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the 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 based solely physician for treatment advice. If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.

This unit is not suitable for continuous monitoring during medical emergencies or operations.

If the cuff pressure exceeds 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure exceeds 40 kPa (300 mmHg), detach the cuff from the arm and press the button to stop inflation.

To avoid measurement errors, carefully read this manual before using the product.

The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The operator shall not touch output of AC adapter and the patient simultaneously.

To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal when using the AC adaptor.

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

The manufacturer does not require such preventive inspections by other persons

INTRODUCTION

LCD display signal

SYMBOL DESCRIPTION

Systolic blood pressure High pressure result

Diastolic blood pressure Low pressure result

EXPLANATION

Pulse Pulse/minute

Deflating CUFF air is exhausting of deflating

Time (hour:minute) Currently time

Memory If "M" shows, the displayed measurement values is from the memory.

For instructions, refer to Page 9

mmHg Measurement Unit of the blood pressure

(1mmHg=0.133kPa)

kPa Measurement Unit of the blood pressure

(1kPa=7.5mmHg)

Low battery Batteries are low and need to be replaced

Shocking remaining Shocking will result in inaccurate

Average the average of blood pressure

Recalling the erecords will be showed

Arrhythmia Irregular heartbeat

Grade the grade of the blood pressure.

For instructions, refer to Page 13

Monitor components

- AIR HOSE
- CUFF
- DC POWER SOCKET
- SET/UP BUTTON
- START/OFF BUTTON
- MEM/DOWN BUTTON
- LCD DISPLAY
- AIR CONNECTOR PLUG
- BATTERY COMPARTMENT
- DC POWER SOCKET

1.Blood Pressure Monitor (TMB-1018)

2.Cuff

3. 4*AAA alkaline batteries

4.User manual

Component list of pressure measuring system

1 Cuff

2 Micro Control Unit

3 Amplifier

4 Air pipe

5 Pump

6 Valve

BEFORE YOU START

The Choice of Battery

1.Battery powered mode: 6VDC 4*AAA alkaline batteries

2.AC adaptor powered mode:

100-240V~, 50-60HZ, 400mA (Can be supplied by AC adaptor model UE08WCP-060100SPA

only!) Right picture is the hole in for power adapter.

CAUTION

In order to get the best effect and protect you monitor, please use the right battery and special power adapter.

The installment and replacement of battery

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

Replace the batteries whenever the below happen

The shows

The display dims

The display does not light up

CAUTION

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

The old battery is harmful to the environment, so please disposal with other daily trash.

Remove the old battery from the device and follow your local recycling guidelines.

Setting Date, time and measurement unit

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (year :2000—2050,time:24 H)

1. When the unit is off, hold pressing "SET" for 3 seconds to enter the mode for year setting.
2. Press the "MEM" to change the [YEAR].
3. When you get theright year, press"SET" to set down and turn to next step automatically.
4. Repeat the 2 and 3 to set the [MONTH] and [DAY].
5. Repeat the 2 and 3 to set the [HOUR] and [SECOND].
6. Repeat the 2 and 3 to set the set the [UNIT].
7. After the unit is set, the right picture will show, then it turn off automatically.

MEASUREMENT

Tie the cuff

1. Tie the cuff on your upper arm, the position the tube off-center toward the inner side of arm in line with the little finger.
2. The cuff should be sung but not too tight. You should be able to insert one finger between the cuff and your arm.
3. Sit comfortably with your left arm resting on a flat surface.

Resting for 5 minutes before measuring. Wait at least 3 minutes between measurements. This allows your blood circulation to recover. For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

Start the Measurement

1. Press the "START/STOP" to turn on the monitor, and it will finish the whole measurement automatically.

LCD display

Adjust the zero automatically.
Inflating and measuring automatically.
Display and save the results automatically.

2. Press the "START/STOP" to power off, otherwise it will turn off automatically within 1 minute.

THE OPERATION OF RECALLING RECORDS

Recalling the records

1. Please press the "MEM" to show the average of the record.
The sign of "AVG" will show in the right corner.

2. Press the "MEM" or "SET" to get the record you want.
The order of the record, date, time will display alternately.
It means the total of records is 8,
the current is the No 2. The corresponding date is 10th November.
The corresponding time is 10:38.

CAUTION

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.

THE OPERATION OF RECALLING RECORDS

Deleting a measurement record from memory

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

1. Hold pressing "MEM" for 3 seconds, the flash display will show.
2. Press "SET" to confirm deleting and the monitor will turn off automatically.
3. If you don't want to delete the records, press "START/STOP" to escape.
4. If there is no record the right display will show.

INFORMATION FOR USER

Tips for measurement

It can cause incorrectness if the measurement are taken in the following circumstances.

Wait at least 1 hour after dinner or drinking
Immediate measurement after tea, coffee, smoking
Wait at least 20 minutes after taking a bath
When talking or moving your fingers
In a very cold environment
When you want to discharge urine

INFORMATION

Maintenance

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

Put in a dry place and avoid the sunshine

Avoid touching water, clean it with a dry cloth in case.

Avoid the intense shaking and collision

Avoid the dusty and unstable temperature Environment

Using the wet clothing to remove the dirt

Avoid washing the cuff

ABOUT BLOOD PRESSURE

What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, blood pressure reaches its maximum value, the highest pressure in the cycle is known as systolic pressure. When the heart relaxes between heartbeats, the lowest blood pressure is diastolic pressure.

Systolic

blood discharging artery

Diastolic

blood entering vein

What is the standard blood pressure classification?

Below illustrates the blood pressure classification made by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999.

CAUTION

Only a physician can tell you your normal blood pressure range and the point at which you are at risk. Consult your physician to obtain these values.

If the measurements taken with these products fall outside the range, consult.

Why my blood pressure is variable even in one day?

1. Individual blood pressure varies every in one day, it is also affected by the way you tie your cuff and the measurement position, so please take the measurement at the same condition.
2. The varies of the pressure is greater if the person take medicine.
3. Waiting at least 4-5 minutes for another measurement.

Why the blood pressure I get from the hospital is different from home?

The blood pressure is different even during 24 hours because of the weather, emotion, exercise etc, specially the "white coat" in hospital which makes the results are higher than the ones at home.

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

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

TROUBLESHOOTING

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products is not operating as you think it should, check here before arranging for servicing.

PROBLEM

No power

Low batteries

Error message

SYMPTOM

Display is dim or will not light up.
Show on the display

E 1 shows
E 2 shows
E 3 shows
E 10 or E 11 shows
E 20 or E 21 shows
Eexx,shows on the display.

CHECK THIS

Batteries are exhausted
Batteries are inserted incorrectly.
Batteries are low.
The cuff is not secure
The cuff is very tight
The pressure of the cuff is excess.
The monitor detected motion while measuring
Measure incorrectly
A calibration error occurred.

REMEDY

Replace with new batteries
Insert the batteries correctly
Replace with new batteries
Refasten the cuff and then measure again.
Refasten the cuff and then measure again.
Relax for a moment and then measure again
movement can affect the measurement. Relax for a moment and then measure again.
Relax for a moment and then measure again.
Retake the measurement. If the problem persists contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.

SPECIFICATIONS

Power supply

Battery powered mode: 6VDC 4*AAA alkaline batteries AC adaptor powered mode: 100-240V~, 50-60HZ, 400mA
(Can be supplied by AC adaptor model UE08WCP-060100SPA only!)

Display mode

Digital LCD V.A.144*39mm

Measurement mode

Oscillographic testing mode

Measurement range

Pressure: 0~40kpa(0~300mmHg)
pulse value:(40~199)times/minute

Accuracy

Pressure:
within ± 0.4 kpa(3mmHg)
pulse value: $\pm 5\%$

Normal working condition

Temperature:10℃~40℃ Relative humidity $\leq 80\%$

Storage & transportation condition

Temperature:-20℃~60℃
Relative humidity:10%~93%

Measurement perimeter of the upper arm

About 22cm~42cm

Weight

Approx.345g (Excluding the dry cells)

External dimensions

Approx.180*100*42mm

Attachment

4*AAA alkaline batteries user manual

Mode of operation

Continuous operation

Degree of protection

Type B applied part

Protection against ingress of water

IPX-0

MANUFACTURER

Manufactured by: CGTEC-EUROPE, LDA

Address: PRAÇA MADRE DEUS Nº 107, CANELAS, VILA NOVA DE GAIA, 4410-307 PORTUGAL

Contact: service@cgtec.europe.com

Complied European Standards list

Risk management is the application of medical device

EN/ISO 14971:2007

Graphical symbols for labeling medical devices

EN 980: 2008

Medical equipment manufacturers to provide information

EN 1041: 2008

Medical electrical equipment Part 1-1: General Requirements
for Safety Collateral Standard: Safety requirements for medical
electrical systems

EN 60601-1:1990+A1+A2+A13

Non-invasive blood pressure Part 1: General requirements

EN 1060-1:2001/A1:2002

Non-invasive blood pressure Part 3: Supplementary requirements for
electromechanical blood pressure measuring system

EN 1060-3:1997/A1:2005

Automatic Blood Pressure Monitor overall system Interventional
accuracy of the testing process

EN 1060-4: 2004

Medical electrical equipment Part 1-2: Basic safety and essential
performance of the general requirements Collateral Standard:

Electromagnetic compatibility requirements and tests

EN 60601-1-2:2001+A1 : 2006

Table 1 Guidance and manufacture's declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission

The TMB-1018 is intended for use in the electromagnetic environment specified
below. The customer or the user of the TMB-1018 should assure that it is used in
such an environment.

Emission test

RF emissions

C ISPR 11

RF emission

CISPR 11

Harmonic emissions

IEC 61000-3-2

Voltage fluctuations/
flicker emissions IEC

61000-3-3

Compliance
Group 1
Class B
Not applicable
Not applicable
Electromagnetic environment – guidance

The TMB-1018 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The TMB-1018 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 2 Guidance and manufacture's declaration – electromagnetic immunity – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity
The TMB-1018 is intended for use in the electromagnetic environment specified below. The customer or the user of TMB-1018 should assure that it is used in such an environment.

Immunity test

Electrostatic
discharge (ESD)
IEC 61000-4-2

Electrical fast
transient/burst
IEC 61000-4-4

Surge IEC
61000-4-5

Voltage dips,
short
interruptions and
voltage variations
on power supply
input lines IEC
61000-4-11

Power frequency
(50Hz) magnetic
field IEC
61000-4-8

IEC 60601 test level
±6 kV contact
±8 kV air

±2 kV for
power supply lines

±1 kV line(s)
to line(s)

<5% UT
(>95% dip in UT)
for 0.5 cycle

40% UT
(60% dip in UT)
for 5 cycles

70% UT
(30% dip in UT)
for 25 cycles

<5% UT
(>95% dip in UT)
for 5 sec

3A/m

Compliance level
±6 kV contact
±8 kV air

±2kV for
power supply lines

±1 kV
differential mode

<5% UT
(>95% dip in UT)
for 0.5 cycle

40% UT)
(60% dip in UT)
for 5 cycles

70% UT
(30% dip in UT)
for 25 cycles

<5% UT
(>95% dip in UT)
for 5 sec

3A/m

Electromagnetic
environment – guidance

Floors should be wood,
concrete or ceramic tile. If
floor are covered with
synthetic material, the
relative humidity should be
at least 30%.

Mains power quality should
be that of a typical
commercial or hospital
environment.

Mains power quality should
be that of a typical
commercial or hospital
environment.

Mains power quality
should be that of a typical
commercial or hospital
environment. If the user of
the TMB-1018 requires
continued operation during
power mains interruptions,
it is recommended that the
TMB-1018 be powered
from an uninterruptible
power supply or a battery.

Power frequency magnetic

fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the ac. mains voltage prior to application of the test level.

Table 4 Guidance and manufacture's declaration – electromagnetic immunity – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity
The TMB-1018 is intended for use in the electromagnetic environment specified below.
The customer or the user should assure that it is used in such an environment.

Immunity test

Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3

IEC 60601 test level

3 Vrms
150 kHz to
80 MHz

3 V/m 80 MHz
to 2.5 GHz

Compliance level

3 Vrms
3 V/m

Electromagnetic environment - Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the YS-6100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Portable and mobile RF communications equipment should be used no closer to any part of the including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = 1.167$

$d = 1.167$ 80 MHz to 800 MHz

$d = 2.333$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ELE007839V1 is used exceeds the applicable RF compliance level above, the ELE007839V1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ELE007839V1.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6 Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for ME EQUIPMENT or ME SYSTEM that are not LIFE-SUPPORTING
Recommended separation distances between portable and mobile RF communications equipment and the ELE007839V1 Fitness Equipment.

The TMB-1018 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TMB-1018 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TMB-1018 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output
power of transmitter
W

0,01
0,1
1
10
100

Separation distance according to frequency of transmitter
M

150 kHz to 80 MHz

$d = 1.167$

0.167
0.369
1.167
3.690
11.67

80 MHz to 800 MHz

$d = 1.167$

0.167
0.369
1.167
3.690
11.67

800 MHz to 2,5 GHz

$d = 2.333$

0.233
0.738
2.333
7.388
23.330

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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