

**MBG10-6/0741**  
**Blood Glucose Monitor**



**Instruction Manual**

Please read all instructions carefully and retain for future use

## Table of Contents

Know your Device	3
Principle of Operation	
Intended use of the equipment	
Limitation of Use	
Important Safety Information and precautions	4
Preparation	5
Introduction for Use	
Before Use, Setting the monitor	6
Delete Memory	7
Instruction for Use	8
About Color Bars	10
Physical and Performance Deterioration	11
Alternative Site Testing	
Care and Maintenance	12
Units of Measure	13
Troubleshooting	14
EMC Declaration	16
FCC Compliance	19
Specifications	20
Analysis	21
Additional Glucose Test Strips	22
Warranty Information	

## KNOW YOUR DEVICE

### Principle of Operation

Testing with the Blood Glucose Monitoring is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the strip. The blood glucose monitoring system measures the current and converts it to the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

### Intended use of the equipment

This device is intended to be used for:

- Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh.
- Single person measurement only (it should not be shared)
- Self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

This device should not be used for the diagnosis of or screening for diabetes, or for neonatal use. Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.

The Blood Glucose Test Strips (NGS50-24/0726) are intended for use with the Blood Glucose Monitor (MBG10-6/0741) to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

**MEDICAL DISCLAIMER:** This device and manual are not meant to be a substitute for advice provided by doctors or other medical professionals.

Contact your physician for interpretation of measurements, or if you have or suspect you have a medical issue.

### Limitation of Use

- The Blood Glucose Monitor is not intended for use on neonates.
- The Blood Glucose Monitor is not intended for use on artery blood, serum, plasma and venous blood samples.
- The Blood Glucose Monitor should be only used with the test strips (NGS50-24/0726).
- The Blood Glucose Monitor cannot be used above an altitude of 10744 feet (3275 meters)
- If you are taking acetaminophen containing drugs (Tylenol and other medicines containing acetaminophen, blood concentrations >5 mg/dL) or Vitamin C (ascorbic acid, blood concentrations >4 mg/dL) at doses higher than recommended, these may interfere with your glucose monitor and cause you to get inaccurate results with this system
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not to be used for patients who are dehydrated, hypertensive, hypotensive, or in shock.
- Do not use during or soon after xylose absorption testing.

## Important Safety Information and Precautions

- Misuse of the blood glucose monitoring system can cause electrocution, burns, fire, and other hazards.
- The glucose monitor and lancing device are for single patient use. Do not use either item on multiple patients.
- Do not share the monitor or lancing device with anyone, including other family members.
- Do not place the blood glucose monitoring system in or near liquid.
- Use the blood glucose monitoring system only for the purpose described in the Owner's Manual.
- Use only accessories that are supplied by the manufacturer.
- Do not use the blood glucose monitoring system if it has sustained any damage or is not working properly.
- Do not block test ports or place the blood glucose monitoring system on soft surfaces that may block them. Keep test ports free from lint, hair, debris, etc.
- Do not place anything on top of the blood glucose monitoring system.
- Do not place foreign objects into any opening in the blood glucose monitoring system.
- Do not use the monitor in a manner not specified by the manufacturer.
- All parts of the system are considered biohazards and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Refer to the resources identified below for detailed information:

## FDA Public Health Notification

Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

## CDC Clinical Reminder

Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

## Battery Warning

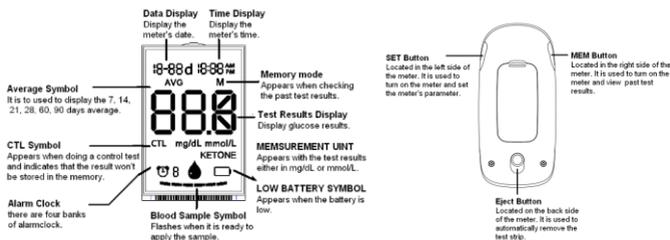
- Do not mix alkaline, stand (carbon-zinc) and rechargeable batteries (nickel hydride).
- Do not mix old and new batteries.
- Non-rechargeable batteries are not to be recharged.
- Rechargeable batteries are to be removed from the unit being charged (if removable).
- Rechargeable batteries are only to be charged under adult supervision (if removable).
- Exhausted batteries are to be removed.
- The supply terminals are not to be short-circuited.
- Only batteries of the same or equivalent type as recommended are to be used.
- Batteries are to be inserted with the correct polarity.

# Preparation

## PACKAGE CONTENTS

- Blood Glucose Meter
- 10 Test Strips and 10 Lancets
- Storage Case and Log Book
- Lancet Device
- Instruction Manual

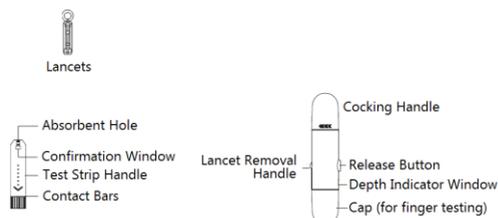
## PARTS OF MONITOR



Date	Display monitor's date
Time	Display monitor's time
Average Range	Display the 7/14/21/28/60/90 days average
Memory	Appears when checking past test result
CTL Symbol	Appears when doing a control test and indicates that the result will not be stored in the memory
Measurement Unit	Appears with the test result either in mg/dL or mmol/L
Low Battery	Appears when battery is low
Alarm Clock	4 Memories for Alarm
Blood Sample	Flashes when it is ready to apply the sample
SET Button	Long press to turn on the monitor and set the parameter
MEM Button	Long press to turn on the monitor and view past test results
Eject Button	Remove the test strip automatically

## PARTS OF TEST STRIPS

Use only the test strips (NGS50-24/0726) with (MBG10-6/0741). Each strip can be used only once.



# Preparation

## Before Use

- Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients who are in shock. Test results that are lower than actual values may occur in individuals who are in a hyperglycemic-hyposmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose monitor.
- If you think your blood glucose results are inconsistent with your feeling or symptoms which you are experiencing, repeat the test first. If you have symptoms or continue to get similar results, follow the treatment advice of your healthcare professional.
- If you are experiencing symptoms that are inconsistent with your blood glucose test, and you have followed all of the instructions provided in this Owner's Manual, contact your healthcare professional immediately.
- Use only fresh whole blood samples to test your blood glucose.
- Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.
- The lancing device is for self-use only. Do not share or re-use lancets. Please refer to the Lancing Device Manual for the detailed procedure.

## Battery Installation

1. Open the battery compartment at the back of device.
2. Insert 2 AAA batteries according to the +/- markings.
3. Re-attach the battery cover back, ensuring it clicks into place.

NOTE: When the low battery symbol appears on screen, turn off this device and follow the instructions above to replace batteries.

**CAUTION:** Never leave any low battery in the battery compartment as it may leak and cause damage to this device.

## Setting the Monitor

Before using this device for the first time or if you change the battery, you should check and update these settings. Make sure you complete the steps below and have your desired settings saved.



When the year flashing, press **M** until the correct **year** appears. Press **S** to confirm.



When the month flashing, press **M** until the correct month appears. Press **S** to confirm.



When the day flashing, Press **M** until the correct day appears. Press **S**.



When the hour flashing, Press **M** until the correct hour appears. Press **S** to confirm.



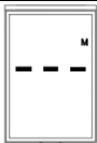
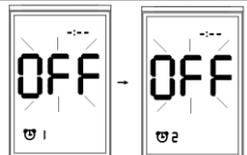
When the minute flashing, Press **M** until the correct minute appears. Press **S** to confirm.



Press **M** to select the unit of measurement. The unit of measurement will be preset to mg/dL before being sold to the U.S.A. Press **S** to confirm.

## Preparation

### Delete Memory

Delete Memory		
		When "dEL" is flashing and a "M" symbol appears on the screen, press <b>M</b> to delete all the memory. " --- " will flash three times and screen will auto off.
Setting of Alarm You may set up any or all of the alarms (1 - 4).		
	When "dEL" is flashing and a "M" symbol appears on the screen, press <b>S</b> to set the alarm.	
		When the "OFF" or "On" and "🕒" symbols appear on the screen, press <b>M</b> to turn on or off the first alarm.  Press <b>M</b> to select on, press <b>S</b> to set the hour.
	When the hour flashing, press <b>M</b> to add one hour. When the correct hour is set, press <b>S</b> to confirm.	
		When the minute flashing, press <b>M</b> to add one minute. Hold <b>M</b> longer to add minutes faster. When the correct minute is set, press <b>S</b> to confirm and go to the next alarm.
		If you do not wish to set an alarm, press <b>S</b> to skip this step. If you wish to turn off an alarm, find the alarm number by pressing <b>S</b> in the setting mode, press <b>M</b> to change from "ON" to "OFF"

At the time of your alarm setting, the monitor will beep and automatically turn on.

If you do not want to test at this time, press **S** again and again can skip setting alarms and screen will finally off. If you do not press **S**, the monitor will switch off after 2 minutes.

## Instruction For Use

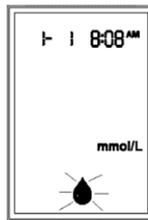
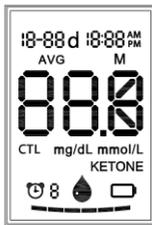
### Before Taking Test for Blood Glucose

To reduce the chance of infection:

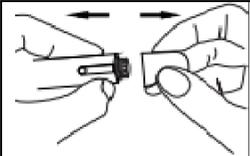
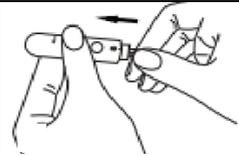
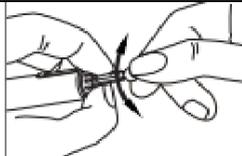
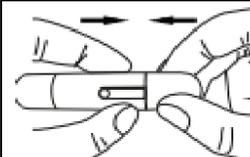
- Choose a clean, dry work surface.
- Never share a lancing device or lancet with other person.
- Always use a new and sterile lancet.
- Always use a new test strip. the test strip is for single use only.
- Avoid getting lotion, oils, dirt, or debris in or on the lancet and lancing device.

### A sample may be obtained from the finger by the following steps:

1. Wash your hands all the time, before the following steps.
2. Insert the test strip into the monitor's strip port with the contact bars facing toward you. The monitor and Blood Sample Symbol will display (see below).



Prepare the lancing device.

		
Snap off the lancing device cap	Insert a new lancet firmly into the lancing holder cup	Twist the lancet cover off
		
Replace the lancing device cap	Set the lancing level	Twist the handle until it clicks

## Instruction For Use

1. Obtain a blood sample

Press the lancing device against the site to be lanced. Press the release button to puncture the site. Squeeze your finger until a drop of blood forms. Wipe away the first blood drop and squeeze until a second small blood drops forms.



2. Apply the blood sample to the test strip

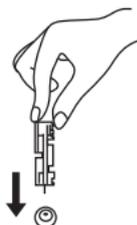
Quickly apply the blood sample to the absorbent hole of the test strip. Make sure the confirmation window of the test strip is completely filled with the blood sample. Quickly remove your finger from the test strip when the countdown (from 5 to 1) begins on the monitor display.

3. Test result will appear on the monitor



*Note: The results obtained from the glucose monitor are plasma-calibrated. This helps you and your physician or other qualified healthcare providers to compare your monitor results with laboratory tests. Refer to the instructions given by your physician or other qualified healthcare providers, do not deviate from these instructions on the basis of the result without first consulting your physician.*

4. Discard the used test strip and lancet. Remove the used test strip from the monitor using a small amount of tissue paper. Discard the used test strip and lancet properly. (Tips: Prior to disposal, stick the lancet into the cover.)



# About Color Bars

## About the Color Bars

On the panel of the Blood Glucose Monitor (MBG10-6/0741), there is a color bar. It is used for indicating blood glucose value range. The Color Bar's image is showing in picture (c) as below.

The flashing black block means the present blood glucose value range which is listed as the following table

Value of Blood Glucose (mg/dL)	Block in Color Bar
<70	Orange Block
70≤N<110	Blue Block
110≤N<126	Purple Block
126≤N<140	
140≤N<200	
≥200	

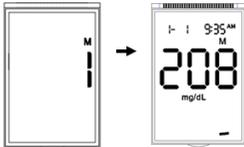


## Reviewing Saved Result on the Monitor



### Day Average Result

1. Long press the MEM button for 3 seconds to view the test results stored in the monitor. The first reading is your recent 7-day average blood glucose result.
2. Press MEM button to review 7-,14-, 21-, 28-, 60- and 90- day average results stored in the monitor.



### Reviewing Test Result

3. After review 90-day average results, keep to press MEM button again, and the first reading you see is the last blood glucose result along with date, time.
4. Press M to recall the test results stored in the monitor each time you press.

*Note: When the memory is full, the oldest result is dropped and the newest result is added.*



### Exit the Memory Mode

When reaching the last test result. "End" will display, and the monitor will turn off automatically.

## PHYSICAL AND PERFORMANCE DETERIORATION

If you start experience one of the following, Stop using and contact local customer services or the place of purchase for assistance.

1. The device does not work.
2. Discoloration of the monitor casing or lancing device; for example, it is difficult to read the labeling information.
3. Corrosion, crazing (fine cracks), embrittlement, and/or cracking of the monitor casing or lancing device.

## ALTERNATIVE SITE TESTING (AST)

### *What Is Alternate Site Testing?*

Alternative site testing (AST) is the use of parts of the body, other than the fingertips, to check blood glucose levels. The Glucose Monitoring System allows you to test on the palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing when used at appropriate times.

There are limitations for doing AST. Please consult your healthcare professional before you conduct AST. The Glucose Monitoring System should only be used for AST under steady-state blood glucose conditions.

### *What Is the Advantage of Alternative Site Testing?*

Pain is felt more readily on the fingertips because they are full of nerve endings (receptors). At other body sites where nerve endings are not so condensed, pain is not felt as acutely.

### *When Should You Use Alternative Site Testing?*

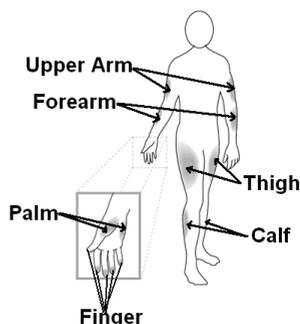
Food, medication, illness, stress, and exercise can affect blood glucose levels. Capillary blood from the fingertips reflects these changes faster than capillary blood from other sites. Therefore, when testing blood glucose levels during or immediately after meals exercise, or when another of the above-noted conditions applies, take a blood sample from your fingertips only. AST should be used only during steady-state times when glucose levels is not changing rapidly.

Blood glucose results from the forearm, upper arm, hand, thigh and calf are not always the same as results from fingertips. Alternative Site Testing is suitable in the following instances:

- In a pre-meal or fasting state (two hours or more after the last meal)
- Two hours or more after taking insulin
- Two hours or more after exercising

**Caution:** Do not use sites other than fingertips for testing when blood glucose is rapidly rising or falling, within 2 hours of eating, after taking insulin, immediately after exercise, or when you are ill or under stress. Alternative Site Testing should not be used to calibrate continuous glucose monitoring systems (CGMs). Results from Alternative Site Testing should not be used in insulin dose calculations. Do not use AST if:

- You think your blood glucose is low
- You are unaware that you might have hypoglycemia
- You are testing for hyperglycemia
- Your AST results do not match the way you feel
- Your routine glucose results fluctuate often



### Compare Glucose Monitor Test Result with Laboratory Results

The results obtained from the glucose monitor are plasma-calibrated. The result you obtain from your glucose monitor may differ somewhat from your laboratory results due to normal variation. Monitor results can be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between monitor and laboratory results, follow the guidelines below.

#### ***Before the Lab Test***

- If possible, fast at least eight hours before conducting a comparison test.
- Take your monitor to the lab.

#### ***While at the Lab***

Make sure that samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your glucose monitor with blood samples collected in a test tube.
- Use fresh capillary blood only.

### CARE AND MAINTENANCE

- For regular maintenance, this device only needs to be wiped gently with a soft, dry cloth. Never immerse this device or any components in water.
- Do not carry out repairs of any kind yourself. If a defect occurs, please contact your local authorized distributor. Use only authorized parts and accessories.
- The cleaning and disinfection is absolutely necessary for the test procedure, because cleaning can insure the monitor works well (for example, display will be clear to see after cleaning); and disinfection can avoid the infection to you or to the other people, and the cross-infection.
- The monitor and lancing device should be cleaned and disinfected following each use.
- The monitor and the lancing device are for single-patient use, if user test 6 times every day, the monitor and lancing device should be cleaned and disinfected 6 times per day which equals to 10950 number of cycles over the 5 year life of the devices. The monitor and lancing device were validated for 11,000 cycles which could support up to 6 cleaning and disinfection cycles per day.
- Below are the steps on how to clean and disinfect the monitor and lancing device.
  1. After a test, clean and wash your hands.
  2. Use wipes carefully to clean the entire external surface of the monitor.
  3. Then wipe the entire external surface of the monitor with another wipe, keep the surface wet for 2min.
  4. Use the same method with the wipes to clean and disinfect the lancing device.
- Note:
  - Wash hands thoroughly with soap and water after handling the monitor, lancing device, or test strips.
  - Only the surface of the monitor can be cleaned and disinfected with the disinfecting towelette. Do not insert the disinfecting towelette into the test strip port and the metal connector, or else the performance of the monitor may be affected.
  - If you have any questions you can call your local customer service.
  - If the monitor is being operated by a second person who is providing testing assistance to the user, the monitor and lancing device should be cleaned and disinfected prior to use by the second person.

# Units of Measure

## INTERNATIONAL BLOOD GLUCOSE UNITS OF MEASURE

Country	Unit of Measure Used	Country	Unit of Measure Used
Algeria	mg/dL	Australia	mmol/L
Argentina	mg/dL	Canada	mmol/L
Austria	mg/dL	China	mmol/L
Bahrain	mg/dL	Czech Republic	mmol/L
Bangladesh	mg/dL	Denmark	mmol/L
Belgium	mg/dL	Finland	mmol/L
Brazil	mg/dL	Germany	mmol/L
Caribbean Countries	mg/dL	Hong Kong	mmol/L
Chile	mg/dL	Ireland	mmol/L
Colombia	mg/dL	Kazakhstan	mmol/L
Ecuador	mg/dL	Malaysia	mmol/L
Egypt	mg/dL	Malta	mmol/L
France	mg/dL	Netherlands	mmol/L
Georgia	mg/dL	New Zealand	mmol/L
Greece	mg/dL	Norway	mmol/L
India	mg/dL	Qatar	mmol/L
Indonesia	mg/dL	Russia	mmol/L
Israel	mg/dL	Singapore	mmol/L
Italy	mg/dL	Slovakia	mmol/L
Japan	mg/dL	South Africa	mmol/L
Jordan	mg/dL	Sub-Saharan Africa	mmol/L
Korea	mg/dL	Sweden	mmol/L
Kuwait	mg/dL	Switzerland	mmol/L
Lebanon	mg/dL	Ukraine	mmol/L
Luxembourg	mg/dL	United Kingdom	mmol/L
Mexico	mg/dL	Vietnam	mmol/L
Oman	mg/dL		
Peru	mg/dL		
Philippines	mg/dL		
Poland	mg/dL		
Portugal	mg/dL		
Saudi Arabia	mg/dL		
Spain	mg/dL		
Syria	mg/dL		
Taiwan	mg/dL		
Thailand	mg/dL		
Tunisia	mg/dL		
Turkey	mg/dL		
United Arab Emirates (UAE)	mg/dL		
United States	mg/dL		
Uruguay	mg/dL		
Venezuela	mg/dL		
Yemen	mg/dL		

Note: The default setting in US is mg/dL. Please contact customer support if your monitor isn't set to mg/dL when purchased.

## Troubleshooting

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair the monitor by yourself and never try to disassemble the monitor under any circumstances.

### Display Messages

Message	What It Means	What To Do
	Blood glucose level is lower than 20mg/dL (1.1mmol/L).	The message indicates very low blood glucose. Consult with your healthcare professional.
	Blood glucose level is higher than 600mg/dL (33.3mmol/L).	The message indicates severe hyperglycemia (high blood glucose). Seek immediate medical assistance.
	The battery in your monitor is low on power.	Please change the battery.
	Problem with the monitor.	Re-test with a new test strip.
	Problems have occurred that are related to test strip use, such as: <ul style="list-style-type: none"> <li>- test strip may be wet or damaged</li> <li>- test strip may be removed too early</li> <li>- you applied more blood after testing began</li> </ul>	Retest using a new test strip.
	The environmental temperature is lower than 50°F (10°C).	The operating temperature is 50°F ~ 104°F (10°C ~ 40°C)
	The environmental temperature is higher than 104°F (40°C) .	The operating temperature is 50°F ~ 104°F (10°C ~ 40°C)

## Troubleshooting

(continued)

Problem	Possible Causes	Solution(s)
Display remains blank after the test strip has been inserted into the monitor.	<ol style="list-style-type: none"> <li>1. Battery power is too low for use.</li> <li>2. Too much time has passed between inserting the test strip and performing the test.</li> <li>3. Test strip has not been fully inserted into the monitor.</li> </ol>	<ol style="list-style-type: none"> <li>1. Please change the battery.</li> <li>2. Reinsert the test strip into the monitor.</li> <li>3. Reinsert the test strip into the monitor, pressing firmly.</li> </ol>
Test results are inconsistent.	<ol style="list-style-type: none"> <li>1. Not enough sample in the test strip.</li> <li>2. Test strip has expired.</li> <li>3. Test strip has been damaged due to heat or humidity so that the sample cannot be applied, or the speed of application is too slow.</li> <li>4. System is not performing due to the environment being above or below room temperature.</li> </ol>	<ol style="list-style-type: none"> <li>1. Re-test with a new test strip and make sure that enough sample has been applied.</li> <li>2. Re-test with a new test strip.</li> <li>3. Replace with new vial of test strips.</li> <li>4. Bring the system to a room-temperature environment and wait approximately 30 minutes before performing a new test.</li> </ol>
The monitor countdown did not start.	Test strip has not been inserted correctly.	Use a new test strip and redo the test.

## ELECTROMAGNETIC COMPATIBILITY INFORMATION

**Table 1 For all ME EQUIPMENT and ME SYSTEMS**

<b>Guidance and manufacturer's declaration - electromagnetic emissions</b>			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>	
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		
<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
<b>Immunity Test</b>	<b>IEC 60601 Test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact	± 6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 8 kV air	± 8 kV air	
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.			

# EMC Declaration

Table 2 For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b>  <math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz  <math>d = 2.3 \sqrt{P}</math> 800 MHz to 2,5 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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.			
<p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this device.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			

**Table 3 For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING**

Recommended separation distances between portable and mobile RF communications equipment and this device			
This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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.			

**NOTE 1** It is the manufacturer’s responsibility to provide equipment electromagnetic compatibility information to the customer or user.

**NOTE 2** It is the user’s responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.

Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

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: Changes or modifications to this device 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 energy and, if not installed and used in accordance to the Instructions, may cause harmful interference to radio communications. However, there is no guarantee 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 to 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.

## Specifications

Model	MBG10-6/0741
Product Size	110mm (L) x 52mm (W) x 20.5mm (D)
Measuring Method	Amperometric technology using glucose dehydrogenase
Result Range	20 mg/dL ~600 mg/dL (1.1 mmol/L ~33.3mmol/L)
Power	DC3V  2 AAA (Not Included)
Storage Condition - Monitor	-4°F ~131° F (-20°C ~55°C); Humidity 10% ~80%RH
Storage Condition – Test Strips	39.2°F ~86°F (4°C ~30°C), Humidity 10% ~ 85%RH
Operating Condition	50°F ~104°F (10°C ~40°C) , 25%RH ~80%RH
Blood Source	Fresh capillary whole blood
Blood Volume	Minimum 0.7 micro liter
Life Span	5 Years

### CALIBRATION AND SERVICE

The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life. It is generally recommended to have this device inspected and calibrated every 2 years to ensure correct functioning and accuracy. Please consult you authorized distributor.

Always use care when handling the Blood Glucose Monitor. Dropping or throwing the monitor may cause damage.

Always wash your hands with soap and water, and rinse and dry them completely before handling the Blood Glucose Monitor and test strips.

# Analysis

If you are taking acetaminophen containing drugs (Tylenol and other medicines containing acetaminophen, blood concentrations >5 mg/dL) or Vitamin C (ascorbic acid, blood concentrations >4 mg/dL) at doses higher than recommended, these may interfere with your glucose meter and cause you to get inaccurate results with this system.

System Accuracy: The System was tested on 350 capillary blood samples, and this is the accuracy in the hands of lay users.

Regression analysis between the meter and YSI reference

	Finger	Palm	Forearm	Upper arm	Calf
Slope (comparison with YSI)	0.9838	0.9964	0.9809	0.9853	0.9856
Y-Intercept (Comparison with YSI)	-1.0011	-2.2901	-0.6385	-0.7838	-0.5727
R <sup>2</sup> (Comparison with YSI)	0.9813	0.9829	0.9844	0.9812	0.985

System accuracy results for glucose concentrations < 75 mg/dL

Anatomical site	Within ± 5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	Within ±20 mg/dL
Finger	31/55 (56.4%)	51/55 (91.1%)	55/55 (100%)	55/55 (100%)
Palm	32/56 (57.1%)	55/56 (98.2%)	56/56 (100%)	56/56 (100%)
Forearm	31/55 (56.3%)	54/55 (98.2%)	55/55 (100%)	55/55 (100%)
Upper Arm	33/55 (60%)	53/55 (96.4%)	55/55 (100%)	55/55 (100%)
Calf	29/53 (54.7%)	50/53 (94.3%)	53/53 (100%)	53/53 (100%)
Thigh	32/55 (58.2%)	53/55 (96.4%)	55/55 (100%)	55/55 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Anatomical site	Within±5%	Within ±10%	Within ±15%	Within ±20%
Finger	124/295 (42%)	242/295 (82%)	292/295 (99%)	295/295 (100%)
Palm	122/294 (41.5%)	232/294 (78.9%)	286/294 (97.3%)	294/294 (100%)
Forearm	136/295 (46.1%)	235/295 (79.7%)	285/295 (96.6%)	295/295 (100%)
Upper Arm	134/295 (45.4%)	237/295 (80.3%)	287/295 (97.3%)	295/295 (100%)
Calf	122/297 (41.1%)	245/297 (82.5%)	288/297 (97%)	297/297 (100%)
Thigh	136/295 (46.1%)	246/295 (83.4%)	286/295 (96.3%)	295/295 (100%)

### **ADDITIONAL GLUCOSE TEST STRIPS**

To buy additional Glucose-Test Strips, please visit [www.nuvomed.us](http://www.nuvomed.us)

**WARRANTY DURATION:** All materials and workmanship are warranted to the original consumer purchaser for a period of ninety (90) days from the original purchase date.

**WARRANTY COVERAGE:** This product is warranted against defective materials or workmanship. This warranty is void if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, commercial use, repairs by unauthorized personnel or other causes not arising out of defects in materials or workmanship. This warranty does not cover the following which may be supplied with product, including but not limited to; LCD Screens, glass parts, lenses, bulbs etc. This warranty is effective only if the product is purchased and operated in USA, and does not extend to any units which have been used in violation of written instructions furnished by manufacturer or to units which have been altered or modified or, to damaged products or parts thereof which have had the serial number removed, altered, defaced or rendered illegible.

**WARRANTY PERFORMANCE:** During the above 90 day warranty period, a product with a defect will be either repaired or replaced with a reconditioned comparable model (at manufacturer's option). The repaired or replacement product will be in warranty for the balance of the 90 day warranty period and an additional one-month period. No charge will be applicable for such repair or replacement.

**SERVICE AND REPAIR:** If service is required for this product, you should first contact Nuvomed Inc. Customer Service at [info@nuvomed.us](mailto:info@nuvomed.us) or by calling Toll-Free Number 1 (866) 815-4714, Monday to Friday 10am to 6pm EST.

**NOTE:** Manufacturer cannot assume responsibility for loss or damage during incoming shipment. As a precautionary measure, carefully package the product for shipment, and insure it with the carrier. Be sure to enclose the following details with the product: your full name, return address and daytime phone number, a note describing the problem you experienced, a copy of your sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.

This manufacturer's product warranty extends to the original consumer purchaser of the product. Neither the retailer nor any other company involved in the sale or promotion of this product is a co-warrantor of this manufacturer warranty.

**WARRANTY DISCLAIMERS:** This warranty is in lieu of all warranties expressed or implied and

## Warranty Information

no representative or person is authorized to assume for manufacturer any other liability in connection with the sale of our products. There shall be no claims for defects or failure under any theory of tort, contractor commercial law including but not limited to, negligence, gross negligence, strict liability, breach of warranty and breach of contract. Under no circumstances will Manufacturer's / Distributor's maximum liability exceed the retail value of the product.

Manufactured by ANDON HEALTH CO., LTD.

Address: No. 3 Jin Ping Street, Ya An Road, Nankai District, Tianjin 300190, China

Made in china.

Rev.11/2018