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P/N 650700XXX  
Rev.3/20



# MultiSure GK Link

Blood Glucose and Ketone  
Monitoring System

Model : MTM309

## User's Guide

**APEXBIO**  
Taiwan

For single-patient use

## Dear MultiSure GK Link Owner

Thank you for choosing the MultiSure GK Link Blood Glucose and Ketone Monitoring System to help you easily monitoring your blood glucose and Ketone. We hope it will be of great help in the management of your diabetes. This manual explains how to use your new meter. Before testing, carefully read through this manual and the package inserts that come with: MultiSure GK blood glucose test strip, MultiSure GK blood ketone test strip, Contrex Plus 4 glucose control solution, and KET-1 ketone control solution. Pay particular attention to listed warnings and cautions. Please keep this manual at hand for future reference.

Please call us at 1-877-979-5454 between 8:00 am and 5:00 pm US Central Standard Time, Monday through Friday for questions and inquiries. If you have any questions or need assistance outside the operational days and times, please contact your health care provider.

## **Intended Use**

Your MultiSure GK Link Blood Glucose and Ketone Meter, MultiSure GK blood glucose test strip, and MultiSure GK blood ketone test strip are in vitro diagnostic medical devices to quantitatively measure blood glucose in fresh capillary whole blood drawn from

fingertips, palm, or forearm, and blood ketone in venous whole blood or capillary whole blood from fingertips. Alternative site testing for glucose test should be performed only during steady-state (when glucose is not changing rapidly). They are intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. They are not intended for diagnosis or screening of diabetes and DKA or for neonatal use. Do not alter your treatment on the basis of test results of this meter without previously consulting your doctor or healthcare professional.

### **IMPORTANT:**

- Dehydration – Severe dehydration may lead to inaccurate blood glucose test result. If you suspect you are severely dehydrated, contact your healthcare professional immediately.
- Hematocrit range – A hematocrit range that is higher than 70% or lower than 10% can cause inaccurate blood glucose test results; A hematocrit range that is higher than 60% or lower than 20% can cause inaccurate blood ketone test results.

- Not intended for use on neonates.
- Testing is done outside the body (In Vitro diagnostic use).
- Do not use test strips if expiration date has passed.
- Use MultiSure GK blood glucose test strip within 12 months of opening test strip vial. Use MultiSure GK blood ketone test strip within 3 months of opening test strip vial.

## **Important Safety Instructions**

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

The link of public health notification and standard practice guideline are:

- “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](#)

## **Limitations**

- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with this device.
- No for use on neonates.
- Altitude higher than 10,335 feet may cause inaccurate results.
- A hematocrit range that is higher than 70% or lower than 10% can cause inaccurate blood glucose test results; A hematocrit range that is higher than 60% or lower than 20% can cause inaccurate blood ketone test results.
- Severe dehydration may lead to inaccurate blood glucose/ ketone test result.
- For In vitro diagnostic only.
- For over the counter use.
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).
- For single-patient use only.
- Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).
- Alternative site measurements should never be used for insulin dosing calculations.

- The following drugs do not generally interfere with the MultiSure GK Link system at normal or therapeutic levels. However, higher concentrations (listed below) were found to interfere with glucose measurements.
- Acetaminophen levels above 10 mg/dL may give falsely high test results.
- Tolbutamide levels above 15 mg/dL may cause falsely low test results.
- Ibuprofen levels above 40 mg/dL may cause falsely low test results.
- Acetylsalicylic acid levels above 40 mg/dL may give falsely low test results.
- Tolazamide levels above 23 mg/dL may cause falsely high test results.
- Paralidoxime Iodide (PAM) levels above 50 mg/dL may cause falsely high test results.
- Uric acid levels above 15 mg/dL may give falsely low test results.
- Cholesterol levels above 500 mg/dL may give falsely low test results.
- Triglyceride levels above 1500 mg/dL may give falsely high test results.
- Glutathione levels above 46 mg/dL may give falsely high test results.

# Table of Contents

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## Understanding Your New Blood Glucose and Ketone Monitoring System

The MultiSure GK Link Blood Glucose and Ketone Meter . . . . .	10
The MultiSure GK Link Blood Glucose and Ketone Meter Display Screen . . . . .	12
The MultiSure GK Link Blood Glucose Test Strip . . . . .	16
The MultiSure GK Link Blood Ketone Test Strip . . . . .	17

## Setting Up Your New System

The Setup Screen . . . . .	18
Setting the Clock . . . . .	19
Alarm Setup . . . . .	22
Beeper Setup . . . . .	25
Setting up hypo/hyper warning value . . . . .	26
Ketone test warning setup . . . . .	29

## Before Testing

Caution when using the meter . . . . .	31
Caution when using the test strips . . . . .	32

## Testing Your Blood Glucose

Preparing Your Lancing Device . . . . .	34
Important Information on Alternative Site Testing (AST) . . . . .	36
Performing a Blood Glucose Test . . . . .	38

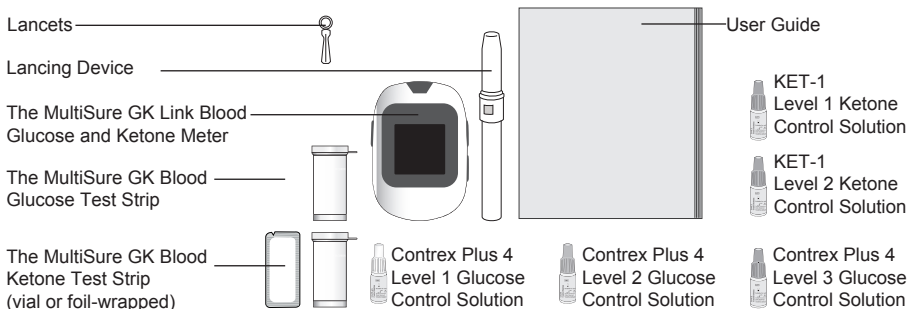
Marking Test Results . . . . .	42
<b>Glucose control Solution Testing</b>	
Performing a Glucose Control Solution Test . . . . .	44
<b>Testing Your Blood Ketone</b>	
Preparing Your Lancing Device . . . . .	48
Performing a Blood Ketone Test . . . . .	49
<b>Ketone Control Solution Testing</b>	
Performing a Ketone Control Solution Test . . . . .	54
<b>Viewing Stored Readings from Memory</b>	
Reviewing glucose past results . . . . .	58
Reviewing ketone past results . . . . .	61
<b>Data transmission</b>	
Upload data via USB . . . . .	63
Upload data via Bluetooth . . . . .	65
<b>Caring for the Meter</b>	
Cleaning and Disinfecting Your Meter and Lancing Device. . . . .	70
Purchase Information for Clorox Healthcare Bleach Germicidal Wipes. . . . .	74



<b>Changing the Batteries</b> .....	<b>75</b>
<b>Storage and Precautions</b> .....	<b>77</b>
<b>Solving Problems</b> .....	<b>78</b>
<b>Understanding Your Blood Glucose Test Results</b> .....	<b>84</b>
<b>Understanding Your Blood Ketone Test Results</b> .....	<b>86</b>
<b>Product Warranty</b> .....	<b>88</b>
<b>Specifications</b> .....	<b>89</b>
<b>FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT</b> ....	<b>92</b>

## Understanding Your New Blood Glucose and Ketone Monitoring System

Each MultiSure GK Link Blood Glucose and Ketone system may include the following items:

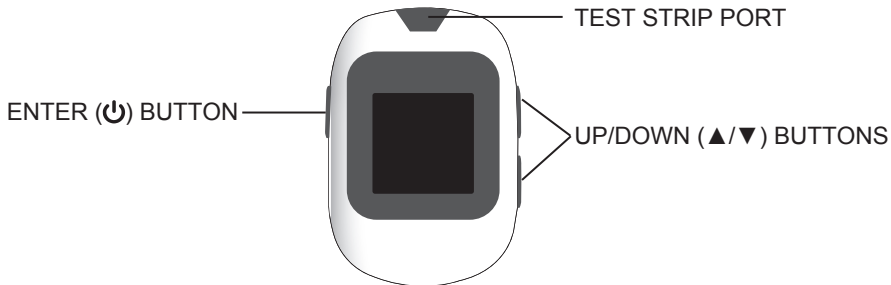


### Note:

- Contents may change without notice.
- Lancets and Lancing Device are optional components.
- MultiSure GK Blood Glucose Test Strip MultiSure GK Blood Ketone Test Strip , Contrex Plus 4 glucose control solution and KET-1 ketone control solution are necessary but sold separately.

Please contact us at 1-877-979-5454 Monday through Friday from 8am to 5pm US Central Standard Time for purchasing information.

## The MultiSure GK Link Blood Glucose and Ketone Meter



### **TEST STRIP PORT**

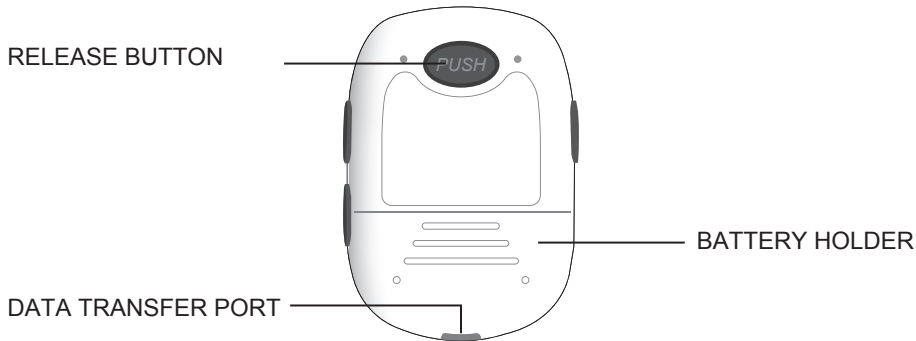
This is where you insert the test strip and the meter will turn on automatically.

### **ENTER (⏻) BUTTON**

Press and hold for 2 seconds to access meter memory or simultaneously press **▲** and **▼** for 2 seconds to enter setup mode while not testing.

### **UP/DOWN (▲/▼) BUTTONS**

Press or hold to scroll through different options and/or values.

**RELEASE BUTTON**

Press this button to remove used test strip.

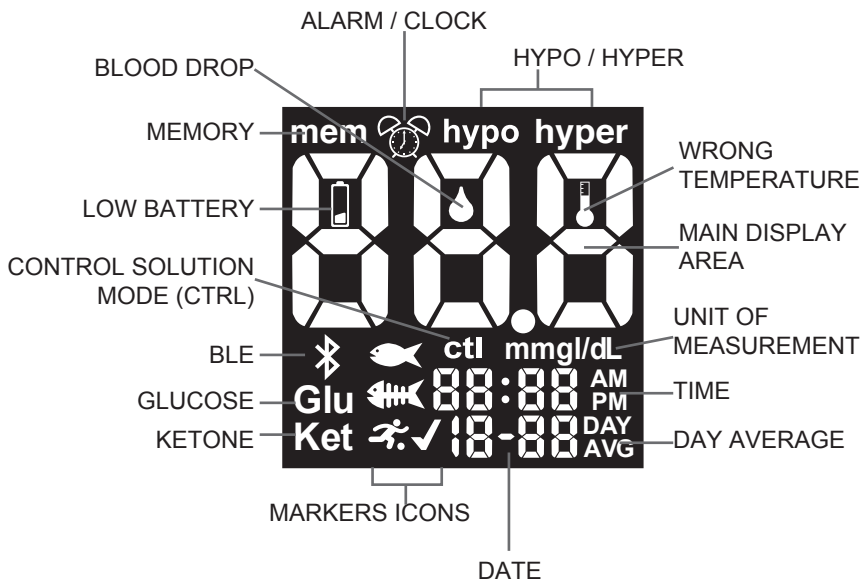
**BATTERY HOLDER**

Houses two CR2032 3V lithium coin cell batteries.





**DATA TRANSFER PORT**




Connection port for PC data cable and Bluetooth device from Apex Biotechnology Corp.

## The MultiSure GK Link Blood Glucose and Ketone Meter Display Screen



MEMORY .....	Indicates that you are using the memory
CLOCK/ALARM.....	“clock” appears while setting the time (see page 19); “alarm” appears while setting the acoustic reminder(s), and will be displayed if any alarm is on (see page 22).
HYPO .....	<ul style="list-style-type: none"> <li>• Setting up your hypoglycemic threshold value (see page 26)</li> <li>• Indicates your glucose test result maybe at or below your hypoglycemic threshold value</li> <li>• Indicates the memorized result maybe at or below your hypoglycemic threshold value</li> </ul>
HYPER .....	<ul style="list-style-type: none"> <li>• Setting up your hyperglycemic threshold value (see page 26)</li> <li>• Indicates your test result maybe at or above your hyperglycemic threshold value</li> <li>• Indicates the memorized result maybe at or above your hyperglycemic threshold value</li> </ul>
DROP .....	This icon will flash to indicate that the meter is ready for blood or control solution testing
MAIN DISPLAY AREA.....	Displays test results, stored test values, result averages and messages.
UNIT OF MEASUREMENT ..	Shows the unit of measurement of your meter (mg/dL for glucose; mmol/L only for ketone).

TIME .....	Shows time (HH:MM, 12H AM/PM or 24H format).
AVERAGE .....	Shows the period related to the displayed average (1, 7, 14, 30, 60 or 90 days –(see page 59)
DATE .....	shows the date (DD-MM format)
GLUCOSE .....	Appears when the value shown in the Main Display Area refers to glucose test results.
KETONE .....	Appears when the value shown in the Main Display Area refers to ketone test results, while setting the ketone test alert threshold or, if blinking and displayed after a glucose test, to indicate that a ketone measurement is suggested (see page 29).
WRONG TEMPERATURE ..	Appears while testing and temperature is outside the allowed temperature range.
LOW BATTERY .....	Appears when the battery needs to be replaced (see page 75).
MARKERS .....	Displayed while marking a test result (see page 42) or reviewing a marked result.
	 Before meal marker
	 After meal marker
	 Exercise marker
	 Check marker

- BLE ICON.....Indicate Bluetooth (BLE) icon
-  Used to indicate the icon is flashing rapidly and meter's BLE is on and waiting for pairing.
  -  Used to indicate the icon is flashing slowly and meter's BLE is transmitting data after pairing
  -  Again, used to indicate the icon is shown without flashing and meter's BLE is waiting instruction from cell-phone after pairing.
- CTL.....Indicates a control solution test (see page 43 & 54)



## The MultiSure GK Blood Glucose Test Strip

### Contact Points

Insert this end to the test strip port on the meter



### Sampling End

Apply blood or control solution here

The MultiSure GK Blood Glucose Test Strip is a glucose specific, biosensor-based test strip that can test glucose in capillary whole blood in as quickly as 5 seconds and requires very little blood sample. The test result is plasma referenced for easy comparison to lab results. The test strip has under-fill detection to alert you when there is not enough blood to perform a test, so you can be assured that every reading you get is an accurate and meaningful result.

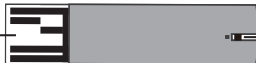
### IMPORTANT:

- The MultiSure GK Blood Glucose Test Strip is sensitive to moisture and light. For vial test strip, it is important to close the vial cap of the test strip bottle tightly after each use. DO NOT leave any test strips outside the bottle while not in use.
- DO NOT reuse test strips. Test strips are for single use only.
- Carefully discard used test strips and lancets in proper waste containers.
- Be sure to use only the MultiSure GK Blood Glucose Test Strip with the MultiSure GK Link Blood Glucose and Ketone Meter. Other brands of test strips will not work with the meter.

## The MultiSure GK Blood Ketone Test Strip

### Contact Points

Insert this end to the test strip port on the meter



### Sampling End

Apply blood or control solution here







The MultiSure GK Blood Ketone Test Strip is ketone specific, biosensor-based test strip that can test blood ketone level in capillary whole blood in as quickly as 8 seconds and requires very little blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be assured that each reading you get is an accurate and meaningful result when the control reading is within the specified range.

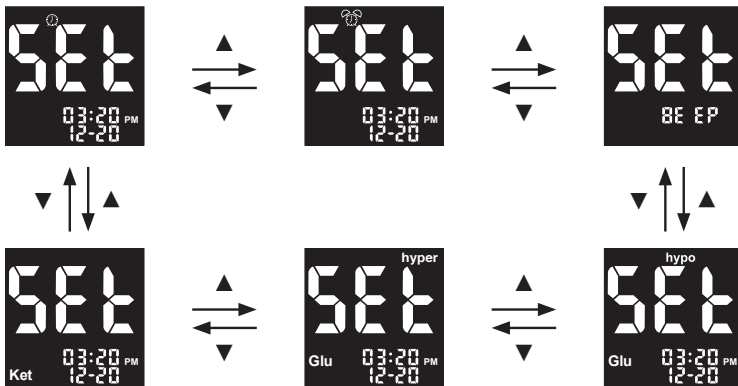
### IMPORTANT:

- The MultiSure GK Blood Ketone Test Strip is sensitive to moisture and light. For vial test strip, it is important to close the vial cap of the test strip bottle tightly after each use. DO NOT leave any test strips outside the bottle while not in use. For foil-wrapped test strip, DO NOT open the foil wrapping until performing tests.
- DO NOT reuse test strips. Test strips are for single use only.
- Carefully discard used test strips and lancets in proper waste containers.
- Be sure to use only the MultiSure GK Blood Ketone Test Strip with the MultiSure GK Link Blood Glucose and Ketone Meter. Other brands of test strips will not work with the meter.

# Setting Up Your New System

## The Setup Screen

1. Make sure the meter is off (to turn the meter off press  for 3 seconds until the screen switches off).
2. Simultaneously press  and  for 2 seconds to enter the setup menu.
3. Press  or  to scroll through the setting menus (see pictures below) and press  to enter each single menu.



## Setting the Clock

Material you will need:

- Your MultiSure GK Link Blood Glucose and Ketone Meter


### Begin Set Up

Step 1.

press  and  for 2 seconds to turn on the meter.



Step 2.

Select Clock  and Press  to confirm



### Set Year

Step 3.

The current year will flash. Press “▲” or “▼” to select the correct year.

Press  to confirm your choice and advance to set the month.

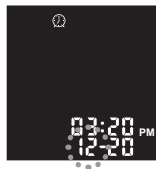


**Set Month**

Step 4.

The current month will flash. Press “▲” or “▼” to select the correct month.

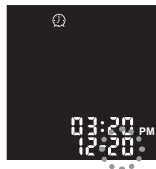
Press “⏻” to confirm your choice and advance to set the day.

**Set Day**

Step 5.

The current day will flash. Press “▲” or “▼” to select the correct day.

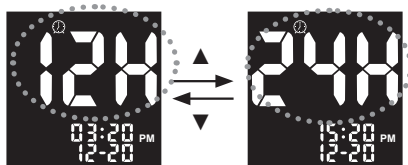
Press “⏻” to confirm your choice and advance to set the 12-hour or 24-hour time format.

**Set 12-hour or 24-hour Time Format**

Step 6.

The current time format will flash. Press ▲ or ▼ to select either 12-hour format or 24-hour format.

Press “⏻” to confirm your choice and advance to set the hour.



## **Set Hour**

### **Step 7.**

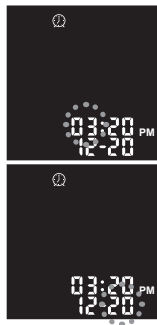
The current hour will flash. Press ▲ or ▼ to select the correct hour. Press “⏻” to confirm your choice and advance to set minutes.

## **Set Minutes**

### **Step 8.**

The current minutes will flash. Press ▲ or ▼ to select the correct minutes.

Press “⏻” to confirm your choice and finish setting the clock. Then return to the setting menus



Begin testing by inserting a MultiSure GK Blood Glucose Test Strip (see Testing Your Blood Glucose on page 34), MultiSure GK Blood Ketone Test Strip (see Testing Your Blood Ketone on page 48) or press and hold ⏻ to turn off the meter, or continue to set up the alarm feature on your meter.

## **NOTE:**

1. If you do not set the date and time on the MultiSure GK Link Blood Glucose and Ketone Meter, the test or control results will not be stored in the meter's memory.
2. Anytime during setup, you can insert a MultiSure GK Test Strip to begin testing. Any changes made so far will be stored.
3. You may need to reset time after changing batteries.

## Alarm Setup

You can set up to six alarms on your MultiSure GK Link Blood Glucose and Ketone Meter: three for glucose test reminders, and three for ketone test reminders. When the alarm reaches the set time, the meter sounds for 30 second. Pressing “⏻” or insert a test strip will silence the alarm.

Materials you need:

- Your MultiSure GK Link Blood Glucose and Ketone Meter

### **CAUTION:**

- Before setting the alarms please check that the time is properly set.

Step 1.

Select Alarm clock  and Press “⏻” to confirm

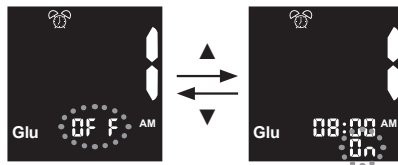


Step 2.

The display will show the alarm clock and the “Glu” icons, both blinking. Press “▲” or “▼” to scroll between glucose (“Glu” icon blinking) and ketone (“Ket” icon blinking) alarm section. Press “⏻” to confirm the selection and move on to the next step. In the following steps either “Glu” or “Ket” icon will be shown, indicating the selected alarm section.

**Step 3.**

The display will show alarm 1 status (the default setting is OFF). You can turn it on by pressing “▲” or “▼”. Press “⏻” to confirm the selection and move on to the next step.

**Step 4.**

Press “▲” or “▼” to select the hour. Press “⏻” to confirm the selection and move on to the next step.

**Step 5.**

Press “▲” or “▼” to select the minutes. Press “⏻” to confirm the selection and move on to the alarm 2 setting.





**Step 6.**

Set alarm 2 and 3 by following steps 4 to 5. After you have finished setting all alarms, press “⏻” to return to the setting menus.

**NOTE:**

- Alarm will not ring during testing.
- Alarm will follow the time format (12-hour or 24-hour) you choose when setting up the clock.
- Alarm settings will not be erased when changing the batteries.

Begin testing by inserting a Test Strip (see Testing Your Blood Glucose on page 34, see Testing Your Blood Ketone on page 48 or Control Solution Testing on page 43 & 54), or press “⏻” to turn off the meter, or continue to set up the Beeper on your meter.

## **Beeper Setup**

The beeper on your MultiSure GK Link Blood Glucose and Ketone Meter is preset to ON. You can adjust the beeper feature as follows.

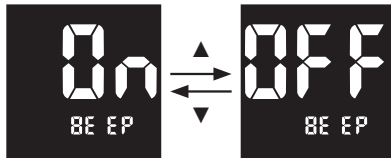
Step 1.

Select BEEP  and Press  to enter beeper setup




Step 2.

Press  or  to turn on/off the tone.



Step 3.

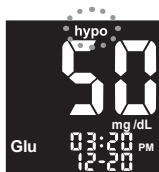
Press  to confirm and return to the setting menus once you have made your selection.

### **IMPORTANT:**

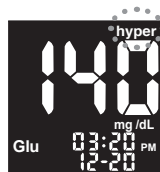
- Turning off the beeper could mean you miss many important cues from your meter, such as confirmation or error messages.

## Setting up hypo/hyper warning value

Your MultiSure GK Link Blood Glucose and Ketone Meter has an alarm feature that allows you to set your high (hyperglycemia) and low (hypoglycemia) blood glucose thresholds. Based on the values set, the screen will show “hypo” or “hyper”, depending on whether your blood glucose test result is below your low glucose or above your high glucose threshold values. Please consult your physician or healthcare provider when setting up the Hypo and Hyper values.



HYPO (hypoglycemia) warning



HYPER (hyperglycemia) warning

### **IMPORTANT:**

- Do not alter or stop your medication based on this feature, always consult your doctor or healthcare provider before altering or stopping medication.

The MultiSure GK Link Blood Glucose and Ketone Meter comes with Hypo/Hyper warning OFF as preset, and the preset threshold value is 180 mg/dL (10 mmol/L) for Hyper and 70 mg/dL (3.9 mmol/L) for Hypo. Follow the steps below to adjust the Hyper and Hypo threshold values.

Material you will need:

- Your MultiSure GK Link Blood Glucose and Ketone Meter

### **Set hypo**

Step 1.

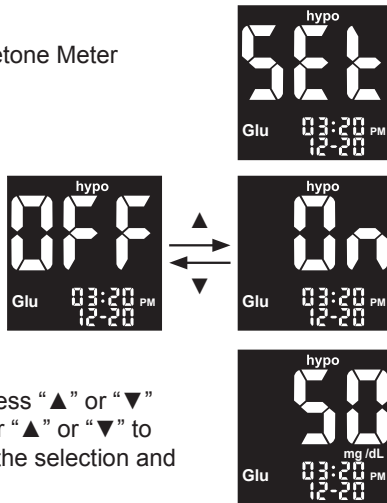
Press “▲” or “▼” until the meter display screen shows “hypo” and Press “⏻” to enter hypo setup

Step 2.

Press “▲” or “▼” to turn ON/OFF hypo warning.

Step 3.

Press “⏻” to set the hypo alarm value (if ON). Press “▲” or “▼” to select the desired value. Press and hold either “▲” or “▼” to accelerate the numbering. Press “⏻” to confirm the selection and return to the setting menus.



**Set hyper**

Step 4.

Press “▲” or “▼” until the meter display screen shows “hyper” and  
Press “⏻” to enter hyper setup.



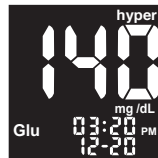
Step 5.

Press “▲” or “▼” to turn the hyper alarm ON/  
OFF.



Step 6.

Press “⏻” to set the hyper alarm value (if ON). Press “▲” or “▼”  
to select the desired value. Press and hold either “▲” or “▼” to  
accelerate the numbering. Press “⏻” to confirm the selection and  
return to the setting menus.



## **Ketone test warning setup**

Your MultiSure GK Link blood glucose and ketone meter has an additional warning feature that allows you to set a blood glucose threshold as a warning for blood ketone testing. When the ketone test warning is turned ON, if your blood glucose is above the set threshold (e.g., 200 mg/dL or higher) the ketone icon “Ket” will start blinking and an intermittent beep will sound, reminding the user that a blood ketone test would be recommended.

### **IMPORTANT:**

- Consult your doctor or healthcare provider when setting the ketone test warning value.
- Do not alter or stop your medication based on this feature, always consult your doctor or healthcare provider before altering or stopping medication.

The ketone test warning on your MultiSure GK Link Blood Glucose and Ketone Meter is preset to OFF. You can set up the ketone test warning threshold value as follows:

Material you will need:

- Your MultiSure GK Link Blood Glucose and Ketone Meter

**Step 1.**

Press “▲” or “▼” until the meter display screen shows “Ket”. and  
Press “⏻” to enter Ket setup

**Step 2.**

Press “▲” or “▼” to turn the ketone test  
warning ON/OFF.

**Step 3.**

Press “⏻” to set the blood glucose threshold value (if Ketone test  
warning is ON). Press “▲” or “▼” to select the desired value. Press  
and hold either “▲” or “▼” to accelerate the numbering. Press “⏻”  
to confirm the selection and return to the setting menus.

**NOTE:**

- With high blood glucose threshold ("hyper") ON, the minimum settable ketone test warning threshold is "hyper" +10 mg/dL (+0.6 mmol/L).

## Before testing

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### Caution when using the meter

#### **CAUTION:**

- For accurate test results, allow the meter to adjust to its surroundings for 30 minutes before testing your blood glucose or ketone levels:

#### Glucose test

- Temperature: 41°F to 113°F;
- Relative Humidity: 20 to 90%RH

#### Ketone test

- Temperature: 50°F to 104 °F;
- Relative Humidity: < 85% RH.

- Do not store or use the meter where:
  - there are sharp temperature fluctuations;
  - humidity is high and causes condensation (bathrooms, drying rooms, kitchen, etc.);
  - there is a strong electromagnetic field (close to a microwave oven, cell phone, etc.).
- Keep the meter out of the reach of children. Coin batteries may represent a choking hazard.



- Do not use the meter after if it has been dropped in a liquid or liquids have entered inside, even if dried afterwards.
- Avoid hand contact with test strip port on the meter. A thermo sensor is housed inside the meter to minimize any errors.
- Do not connect the data cable to the data transfer port during testing. The meter may be damaged, leading to inaccurate test results.
- Do not apply blood directly to the test strip port on the meter.
- Do not share your meter with anyone else to avoid the risk of infection.
- The meter complies with applicable electromagnetic emission requirements (EMC). However, do not perform measurements with this meter near mobile devices or electrical or electronical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter..

## **Caution when using the test strips**

### **CAUTION:**

- For testing with MultiSure GK Link Blood Glucose and Ketone Meter use MultiSure GK blood glucose test strip or MultiSure GK blood ketone test strip only. Do not use other brand test strips, it causes inaccurate test results.
- Do not use test strips after their expiry date. The expiry date is either written on the

test strip vial (glucose sensor) or on the foil pouch (ketone sensor).

- For accurate test results, allow the test strips to adjust to the their surroundings for at least 30 minutes before testing your blood glucose or ketone levels:

Glucose test

- Temperature: 41°F to 113°F;
- Relative Humidity 20 to 90% RH.

Ketone test

- Temperature: 50°F to 104°F;
- Relative Humidity < 85% RH.

- After first opening the vial, do not use the test strips beyond the time limit indicated on the label.
- The test strips are for single-use only. Do not use test strips that have already absorbed blood or control solution.
- Keep all unused test strips in the original vial and after having removed one, immediately close the cap tightly to preserve their quality. Do not transfer them into any other container.

## Testing Your Blood Glucose

---

Material you will need:

- Your MultiSure GK Link Blood Glucose and Ketone Meter
- A new MultiSure GK Blood Glucose Test Strip
- Lancing device with a sterile, unused lancet
- Clear cap for Alternative Site Testing (AST) on palm and forearm

### **Preparing Your Lancing Device**

#### **CAUTION:**

- The lancets are for single use only. Always use a new, sterile lancet each time you perform the test.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets can lead to disease transmission.
- Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets.
- When performing a blood glucose test, use a new sterile lancet every time. If alcohol wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

**Step 1.**

Wash hands with soap and warm water and dry thoroughly. Warm water stimulates blood flow to the fingers making it easier to obtain a sample.

**Step 2.**

Hang the arm down at the side for 10 to 15 seconds massaging through the wrist, palm, and then finger. This can stimulate the blood flow to the finger more quickly.

**Step 3.**

Hold the lancing device or lancet against the side of the finger and lance the finger. Follow manufacturer's instruction for how the lancing device or lancet should be used.

**TIP:**

- To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

## **Important Information on Alternative site testing (AST)**

This meter can test the glucose levels of blood from your fingertip, palm and forearm. However, test results from sites other than the fingertip may differ from fingertip measurements. Consult your doctor or healthcare professional before testing blood from the palm or forearm.



DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since last meal)
- 2 hours or more after taking insulin
- 2 hours or more after exercise

Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs). Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).

Alternative site measurements should never be used for insulin dosing calculations.

**Alternative site Testing SHOULD NOT be used:**

- You have hypoglycemic unawareness (not able to tell if you have low blood sugar).
- You will be operating machinery or driving a car.
- You are sick.
- Within 2 hours of a meal, exercise, or medication.
- When You think your blood glucose is low.
- When Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

Consult with your healthcare professional to decide if AST is right for you.

**NOTE:**

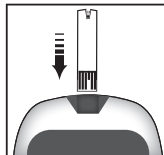
- Rubbing forearm until warm before lancing will help minimize the difference with fingertip test results. The palm (at the base of the thumb) does not require rubbing before testing.
- If results from alternative site testing do not agree with how you feel, use fingertip testing instead.

1. Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differs Among Blood Glucose Monitoring Sites. Diabetes Care 28(3):708–709, 2005

## **Performing a Blood Glucose Test**

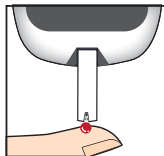
### **Step 1.**

Insert a new MultiSure GK blood glucose test strip (white color) into the test strip port. The drop icon starts blinking on the screen and the glucose icon “Glu” will be shown at the bottom left hand corner of the display. Make sure the test strip contact points are inserted all the way into the meter. The meter will turn on automatically. If nothing appears on the screen, remove the test strip, insert it into the test strip port again and wait for the drop icon to start blinking.



### **Step 2.**

Apply the drop of blood to the tip of the test strip until the meter beeps to indicate the test strip has enough blood to test. The screen will start to count down.



**NOTE:**

- For accurate test results, apply the drop of blood to the tip of the test strip within 20 seconds after puncturing.
- Do not test blood that runs or spreads out from the puncture site.
- Do not smear blood onto the test strip.
- Do not forcefully press the test strip into your puncture site.
- Do not touch the test strip once the meter has started the countdown.

**Step 3.**

Read your test result. You will hear a beep when the test result appears on the screen together with the glucose icon “GLU”.

**CAUTION:**

If LO or HI appears on the screen:

- If you see “HI” or “LO” displayed, your blood glucose level may be above 600 mg/dL (33.3 mmol/L) or below 20 mg/dL (1.1 mmol/L). Test again using fingertip testing, DO NOT test on palm or forearm. If you still receive the same result, call your physician or healthcare professional immediately.
- The “hypo” or “hyper” icons may appear depending on the threshold limit you have set.

Ketone test warning.

- If your own blood glucose is above a given threshold (200 mg/dL or higher, to be



set), the ketone icon “Ket” will start blinking at the bottom left hand corner of the display and an intermittent beep will sound, reminding the user that a blood ketone test would be recommended.

If test results do not match with how you feel:

- Make sure you have performed the test correctly as explained in Page 38. Then, conduct a glucose control test to check that the system is working properly (Page 43). Repeat the test using a blood sample taken from a fingertip (do not use an alternative site). If the test result still does not match how you feel, contact your doctor or healthcare professional.
- Do not ignore test results. Do not alter your blood glucose management or treatment without first consulting your doctor or healthcare professional.

#### Step 4.

Press the release button to remove the test strip or by pulling it out with your hand and throw it into a proper wastebasket and the meter will turn off automatically. The meter will also time-out after 1.5 minutes of inactivity.

#### Step 5.

Remove the used lancet from your lancing device according to instructions and discard into a proper wastebasket according to your healthcare provider's instructions.

**CAUTION:**

- Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Clean and disinfect the meter and lancing device after the test.
- When ejecting the used test strip, point your meter downwards and away from others.
- Disposal of biohazard waste:  
Used lancets and test strips are biohazard materials and can transmit blood-borne disease. Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets and test strips.

## Marking Test Results

After a blood (not control) glucose test is performed with a valid result, you can mark the result as follows:

### Step 1.

With the test result on the display, and the test strip STILL IN THE METER.

Press until the markers icons start blinking. Press ▲ or ▼ to scroll through the icons (backwards or forwards) according to the following sequence:

🐟 ... Before meal marker

🐟 ... After meal marker

🏃 .... Exercise marker

✓ ..... Check marker (General Purpose marker).

..... Blank (Once confirmed it deselects any previously selected marker).



### Step 2.

Press ⏻ to confirm the marker you selected. You can select more markers (but only one when setting 🐟 or 🐟) by repeating steps 1 & 2.

## Glucose control Solution Testing

---

The purpose of the control solution testing is to make sure the MultiSure GK Link Blood Glucose and Ketone Meter and the MultiSure GK blood glucose Test Strip is working properly.

You should perform control solution testing when:

- you suspect the meter or MultiSure GK blood glucose test strip are not working properly;
- the meter has been dropped;
- the meter is damaged;
- You leave the test strip bottle cap open for a while;
- your blood glucose test results do not reflect how you feel;
- You want to check the performance of the meter and MultiSure GK blood glucose test strip when you first get them or any time you want to check their performance before a blood glucose test.

### **NOTE:**

- To test your meter and MultiSure GK blood glucose test strip only use the Contrex Plus 4 glucose control solutions (provided separately). Other brands of control solution will produce inaccurate result.
- Do not use the KET-1 ketone control solutions for testing the MultiSure GK blood glucose test strip: erroneous results would be obtained.

**CAUTION:**

- Always check the expiration date. DO NOT use control solutions if they are expired.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution three months after opening.
- For accurate test results, allow the control solution to adjust to its surroundings for at least 30 minutes before running the control test:
  - Temperature: 41 to 113 °F;
  - Relative Humidity: 20 to 90% RH.
- DO NOT FREEZE. Store the control solutions at 39°F - 86°F.
- Do not drink the control solution. It is not intended for human consumption.
- Avoid contact of the solution with the skin and the eyes as this could cause inflammation.
- Discard used control solution bottles according to your local regulation.

**Performing a Glucose Control Solution Test**

You will need:

- Contrex Plus 4 glucose control solution (L1, L2 and L3)
- Your MultiSure GK Link Blood Glucose and Ketone Meter
- A new MultiSure GK Blood Glucose Test Strip

**Step 1.**

Insert a new MultiSure GK blood glucose test strip into the test strip port. The drop icon starts blinking on the screen and the glucose icon “Glu” will be shown at the bottom left hand corner of the display. Make sure the test strip contact points are inserted all the way into the meter. The meter will turn on automatically. If nothing appears on the screen, remove the test strip, insert it into the test strip port again and wait for the drop icon to start blinking.

**Step 2.**

Enable the CTL mode

**WARNING:**

- If the CTL mode has not been enabled before performing the control solution test, the result will be stored as a blood test and used for calculating averages.
- Always enable the CTL mode before conducting a control solution test or the results may fall outside the acceptable range. To enable the CTL mode, simultaneously press the UP/DOWN (▲ / ▼) buttons for two seconds while the drop icon is blinking on the screen.

- Once CTL mode is enabled, CTL mark is displayed together with “ctl” message written in bigger characters on the main screen.

### Step 3.

Gently shake the control solution vial before testing. Discard a drop before use. Squeeze a drop of control solution (Level 1, Level 2 or Level 3) onto a clean, hard, dry nonabsorbent surface. Do not apply control solution to the test strip directly from the bottle. Replace the bottle cap on the control solution bottle immediately after use.

### Step 4.

Hold the meter and touch the control solution to the edge of the sampling end of the test strip. The control solution will be automatically pulled into the reaction area of the test strip. A beeper will sound (if enabled) as the countdown timer starts on the screen.

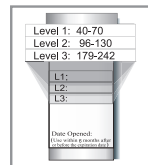


### NOTE:

- The test will not start if you apply your control solution not directly to the edge of the sampling end of the test strip. The test starts when the meter detects the control solution. During the test the meter counts down from 5 to 1.
- Tightly close the control solution vial.
- Do not touch the test strip once the meter has started the countdown.

**Step 5.**

Check that your test result is within the acceptable range indicated on the label of the Your MultiSure GK blood glucose test strip vial. If out of range, make sure that no procedural errors were made, then repeat the control solution test.

**CAUTION:**

- If you still have test results that fall outside the acceptable range, stop using the system, and contact the Apex Biotechnology Corp. customer service.

**Step 6.**

Press the release button to remove the test strip or by pulling it out with your hand and throw it into a proper wastebasket and the meter will turn off automatically. The meter will also time-out after 1.5 minutes of inactivity.

**NOTE:**

- Control solution testing results will be stored into the meter's memory and indicated with "ctl" icon.
- Control solution test results will not be used for calculating averages.
- Replace the bottle cap on the control solution bottle immediately after use.



## Testing Your Blood Ketone

---

You will need:

- Your MultiSure GK Link Blood Glucose and Ketone Meter
- A new MultiSure GK Blood Ketone Test Strip
- Lancing device with a sterile, unused lancet

### **Preparing Your Lancing Device**

For information on how to use the lancing device, read the relevant instructions for use.

#### **CAUTION:**

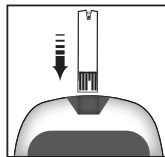
- Wash the puncture site with soap and water and dry the site thoroughly before sampling blood.
- The lancets are for single use only. Always use a new, sterile lancet each time you perform the test.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets can lead to disease transmission.
- Dispose of lancets properly as biohazard waste.
- When performing a blood ketone test, use a new sterile lancet every time. If alcoholic wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

The MultiSure GK blood ketone test strip is not intended for alternative site testing (AST). Use only fresh capillary whole blood from your fingertip for testing.

## **Performing a Blood ketone Test**

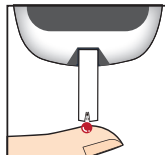
### Step 1.

Insert a new MultiSure GK blood ketone test strip (light purple color) into the test strip port to turn. The drop icon starts blinking on the screen and the ketone icon “Ket” will be shown at the bottom left hand corner of the display. Make sure the test strip contact points are inserted all the way into the meter. The meter will turn on automatically. If nothing appears on the screen, remove the test strip, insert it into the test strip port again and wait for the drop icon to start blinking.



### Step 2.

Apply the drop of blood to the tip of the test strip until the meter beeps to indicate the test strip has enough blood to test. The screen will start to count down.



**NOTE:**

- For accurate test results, apply the drop of blood to the tip of the test strip within 20 seconds after puncturing.
- Do not test blood that runs or spreads out from the puncture site.
- Do not smear blood onto the test strip.
- Do not forcefully press the test strip into your puncture site.
- Do not touch the test strip once the meter has started the countdown.

**Step 3.**

Read your test result. You will hear a beep when the test result appears on the screen together with the ketone icon “Ket”. The test result will blink until meter switches off.

**CAUTION:**

- If HI appears on the screen:  
HI appears if your test result is more than 8.0 mmol/L. Retest your blood ketone immediately using a new sensor. If the reading is still high, contact your doctor or healthcare professional immediately. “0.0” appears if your blood ketone test result is less than 0.1 mmol/L: no action is required.
- If test results do not match with how you feel:  
Make sure you have performed the test correctly. If no procedural errors were made, conduct a ketone control test to check that the system is working properly.

If the system is working properly and your blood test results still do not match with how you feel, contact your doctor or healthcare professional.

- Do not ignore test results. Do not alter your treatment on the basis of the ketone result without previously consulting your doctor or healthcare professional.

#### Step 4.

Press the release button to remove the test strip or by pulling it out with your hand and throw it into a proper wastebasket and the meter will turn off automatically. The meter will also time-out after 1.5 minutes of inactivity.

#### Step 5.

Remove the used lancet from your lancing device according to instructions and discard into a proper wastebasket according to your healthcare provider's instructions

#### **CAUTION:**

- Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Clean and disinfect the meter and lancing device after the test.
- When ejecting the used test strip, point your meter downwards and away from others.
- Disposal of biohazard waste:  
Used lancets and test strips are biohazard materials and can transmit blood-borne

disease. Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets and test strips.

## Ketone control Solution Testing

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The purpose of the ketone control solution testing is to make sure the MultiSure GK Link Blood Glucose and Ketone Meter and the MultiSure GK blood ketone Test Strip is working properly. You should perform control solution testing when:

Conduct a control test if:

- you suspect the meter or MultiSure GK blood ketone test strip are not working properly;
- the meter has been dropped;
- the meter is damaged;
- You want to practice the testing procedure;
- your ketone test results do not match with how you feel;
- you want to check the performance of the meter and MultiSure GK blood ketone test strip when you first get them or any time you want to check their performance before a blood ketone test.

### **NOTE:**

- To test your meter and MultiSure GK blood ketone test strip only use the KET-1 ketone control solutions (provided separately).
- Do not use the Contrex Plus 4 glucose control solutions for testing the MultiSure GK blood ketone test strip: erroneous results would be obtained.

**CAUTION:**

- Do not use control solutions after their expiry date. The expiry date is indicated on the control solution vial.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution three months after opening.
- For accurate test results, allow the control solution to adjust to its surroundings for at least 30 minutes before running the control test:
  - Temperature: 50 to 104 °F;
  - Relative Humidity: < 85% RH.
- DO NOT FREEZE or REFRIGERATE. Store the control solutions at 39°F - 86°F
- Do not drink the control solution. It is not intended for human consumption.
- Avoid contact of the solution with the skin and the eyes as this could cause inflammation.
- Discard used control solution bottles according to your local regulation.

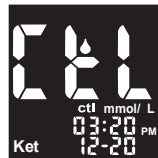
**Performing a Ketone Control Solution Test**

You will need:

- KET-1 ketone control solution (L1 and L2)
- Your MultiSure GK Link Blood Glucose and Ketone Meter
- A new MultiSure GK Blood Ketone Test Strip

**Step 1.**

Insert a new MultiSure GK blood ketone test strip into the test strip port. The drop icon starts blinking on the screen and the ketone icon “Ket” will be shown at the bottom left hand corner of the display. Make sure the test strip contact points are inserted all the way into the meter. The meter will turn on automatically. If nothing appears on the screen, remove the test strip, insert it into the test strip port again and wait for the drop icon to start blinking.

**Step 2.**

Enable the CTL mode

**IMPORTANT:**

- If the CTL mode has not been enabled before performing the control solution test, the result will be stored as a blood ketone test.
- Always enable the CTL mode before conducting a control solution test or the results may fall outside the acceptable range. To enable the CTL mode, simultaneously press the UP/DOWN (▲ / ▼) buttons for two seconds while the drop icon is blinking on the screen.



- Once CTL mode is enabled, CTL mark is displayed together with “ctl” message written in bigger characters on the main screen.

### Step 3.

Gently shake the control solution vial before testing. Discard a drop before use. Squeeze a drop of control solution (Level 1 or Level 2) onto a clean, hard, dry nonabsorbent surface. Do not apply control solution to the test strip directly from the bottle. Replace the bottle cap on the control solution bottle immediately after use.

### Step 4.

Hold the meter and touch the control solution to the edge of the sampling end of the test strip. The control solution will be automatically pulled into the reaction area of the test strip. A beeper will sound (if enabled) as the countdown timer starts on the screen.

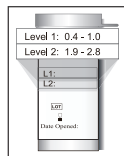


### NOTE:

- The test will not start if you apply your control solution not directly to the edge of the sampling end of the test strip. The test starts when the meter detects the control solution. During the test the meter counts down from 8 to 1.
- Tightly close the control solution vial.
- Do not touch the test strip once the meter has started the countdown.

**Step 5.**

Check that your test result is within the acceptable range indicated on the label of the MultiSure GK blood ketone test strip foil pouch. If out of range, make sure that no procedural errors were made, and then repeat the control solution test.

**CAUTION:**

- If you still have test results that fall outside the acceptable range, stop using the system, and contact the Apex Biotechnology Corp. customer service.

**Step 6.**

Press the release button to remove the test strip or by pulling it out with your hand and throw it into a proper wastebasket and the meter will turn off automatically. The meter will also time-out after 1.5 minutes of inactivity.

## Viewing Stored Readings from Memory


### **WARNING:**

- Please make sure that time and date are correct before the first use, and adjust them if needed. If the time and date settings are not correct the meter will memorize the test results assigning them wrong time and date.


### **Reviewing glucose past results**

You can review past results stored in the memory. Your meter stores up to 730 glucose test results with dates, times and markers. The meter also provides 1, 7, 14, 30, 60, and 90 days averaging to help track your blood glucose trend.

#### Step 1.

Make sure the meter is off (to turn the meter off hold  for 3 seconds until the screen switches off).

#### Step2.

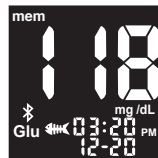
Press  for 2 seconds to turn the meter on and enter the memory recall mode (the “mem” icon appears on the screen and the “Glu” icon will blink).



**Step3.**

Press  to enter in the glucose results memory.

The most recent test result appears on the screen. The screen also shows the “Glu” icon, the date and time of the test, and the corresponding markers.

**Step4.**

Press “▲” or “▼” to scroll through all the stored data.

**Step5.**


Press  for 3 seconds to switch the meter off.

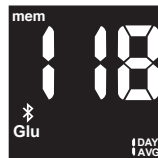
**NOTE:**

- If there are no results in the memory, the screen displays “ooo”.
- At the end of reviewing the individual test results, the screen displays “ooo”.
- Keep “▲” or “▼” pressed to speed up the browsing through the results.

**Viewing glucose results averages****Step6.**

Follow steps 1, 2 and 3.

Press  to enter the average mode (the “avg” icon appears on the screen).



**Step7.**

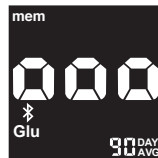
The 1-day average appears on the screen. Press  to scroll through the averages.

**Step8.**

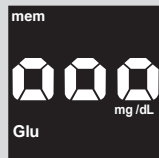
After reviewing the 90-day average, press  to return to the memory recall mode.

**Step9.**

Hold  for 3 seconds to switch the meter off.

**NOTE:**


- If there are less than 2 results in the memory for the averaged period, the screen displays “ooo”. If there are no results, the screen displays “ooo”.
- The averaging function equalizes HI results to 600 mg/dL (33.3 mmol/L) and LO results to 20 mg/dL (1.1 mmol/L).




## Reviewing ketone past results

You can review past results stored in the memory. Your meter stores up to 100 ketone test results with dates, times and markers.

### Step 1.

Make sure the meter is off (to turn the meter off hold  for 3 seconds until the screen switches off).

### Step 2.

Press  for 2 seconds to turn the meter on and enter the memory recall mode (the “mem” icon appears on the screen and the “Ket” icon will blink).



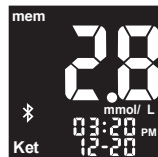
### Step 3.

Press “▲” or “▼” on time to shift to ketone memory section (“Ket” icon blinking on the display).

### Step 4.

Press  to enter in the ketone results memory.

The most recent test result appears on the screen. The screen also shows the “Ket” icon, the date and time of the test, and the corresponding marker (only “ctl” is allowed for ketone measurement).



Step 5.

Press “▲” or “▼” to scroll through all the stored data.

Step 6.

Press  for 3 seconds to switch the meter off.

**NOTE:**

- If there are no results in the memory, the screen displays “ooo”.
- At the end of reviewing the individual test results, the screen displays “ooo”.
- Keep ▲ or ▼ pressed to speed up the browsing through the results.

## Data transmission

Test results stored in the MultiSure GK Link Blood Glucose and Ketone Meter's memory can be transmitted to your personal computer or mobile devices.

### Upload data via USB

Material you will need:

- Your MultiSure GK Link Blood Glucose and Ketone Meter
- A micro USB cable

#### Step 1.

Insert a micro USB cable into the data port to transmit stored readings to Personal Computer. Follow the Data Management System (DMS) instruction manual to upload data. For purchase information of DMS, please contact Apex Biotechnology Corp. customer service.

#### Step 2.

Open APP in PC and execute recognition command. The screen will show "Ent" and "PC" in the meter.






**Step 3.**

Press  to confirm Data transmission.

**Step 4.**

After you finish uploading data, remove the cable and the meter switches off automatically.

**NOTE:**

- The upload feature should be used only with DMS products that specifically identify the MultiSure GK Link as a meter that is compatible with their DMS.
- The Data Management System (DMS) is not included in the meter. If you need this data management function, please contact Apex Biotechnology Corp. customer service.
- The Data Management System (DMS) and dedicated micro USB cable are sold separately, please contact Apex Biotechnology Corp. customer service. for purchase information.
- No button and strip function available during whole USB port transmission procedure, except for button  to confirm Data transmission.
- Function of USB port transmission is not allowed during whole measurement procedure.

- MultiSure GK Link Blood Glucose and Ketone Meter can only transfer memory data, but not accept or upload data.

## **Upload data via Bluetooth**

The process of connecting between the meter and the mobile device is called pairing. You will need an application on your mobile device that can accept the meter's data. You can use this application to wirelessly and selective synchronies your test information between the meter and the mobile device.

Material you will need:

- Your MultiSure GK Link Blood Glucose and Ketone Meter
- A mobile device with Bluetooth

## **For Performing a Glucose / Ketone /Control Solution test Mode**

Step 1.


Follow the step of performing Glucose, Ketone or Control Solution test to get a test result.

Glucose test mode should remove strip.

## Pairing


### Step 2.

To make a Bluetooth transfer, open the app on your mobile device and follow the app instructions to pairing the meter.

The screen will show “Ent” and the “BLE” icon  shall be flashing in the meter.



### Step 3.

Press  to pair with your Mobile Device.



### Step 4.

- As pairing is ok, the BLE icon stop flashing. Then the screen of meter will show “Ent” and “BLE” icon.




- As pairing fails, Er6 is displayed on the screen of the meter. To see page 78 to solve problems.



**BLE transmission**

Step 5.

- Press  to confirm Data transmission. Meter shall start sending data to mobile device.
- When Er7 is displayed on the screen of the meter. To see page 78 to solve problems.



Step 6.

After the data transfer is completed, turn off the meter or the meter switches off automatically.

**For Memory recall Mode (Glucose / Ketone)**


Step 1.

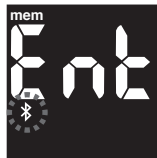
Follow the step of Viewing Stored Readings from Memory

**Pairing**


Step 2.

To make a Bluetooth transfer, open the app on your mobile device and follow the app instructions to pairing the meter.

The screen will show “Ent” and the “BLE” icon  shall be flashing in the meter.




**Step 3.**

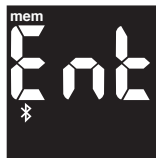
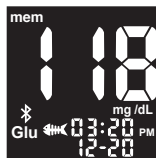
Press  to pair with your Mobile Device.

**Step 4.**

- As pairing is ok, the BLE icon stop flashing. Then the screen of meter will show “Ent” and “BLE” icon.
- As pairing fails, Er6 is displayed on the screen of the meter. To see page 78 to solve problems.

**BLE transmission****Step 5.**

- Press  to confirm Data transmission. Meter shall start sending data to mobile device.
- When Er7 is displayed on the screen of the meter. To see page 78 to solve problems.



**NOTE:**

- You need to install an app that accepts meter data on your mobile device.
- As long as the mobile device has an application that can accept meter data, the meter does not need to be paired.
- When the meter is in transfer mode, testing is not possible.
- The distance between the meter and the mobile device can be transmitted within a range of 10 m/m.
- MultiSure GK Link Blood Glucose and Ketone Meter can only transfer memory data, but not accept or upload data
- If the Bluetooth transmission function fails, the screen will display Err5, please contact Apex Biotechnology Corp. customer service.

**WARNING:**

- Data transmission via Bluetooth may decrease battery life.

## Caring for the Meter

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Caring for your MultiSure GK Link Blood Glucose and Ketone Meter is easy. Follow these simple guidelines to keep your MultiSure GK Link Blood Glucose and Ketone Meter working properly.

### **NOTE:**

- Do not get water inside the MultiSure GK Link Blood Glucose and Ketone Meter. Never immerse the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Do not try to clean the test strip holder.
- Do not contaminate the strip holder with blood or control solution.
- Handle the meter with care; severe shock, such as dropping the meter, could damage the electronics.

## **Cleaning and Disinfecting Your Meter and Lancing Device**

Cleaning and disinfecting your meter and lancing device are very important in the prevention of infectious disease. Cleaning is the removal of dust and dirt from the meter and lancing device surface so no dust or dirt gets inside. A cleaning step using a Clorox Healthcare Bleach Germicidal wipe must be performed before each disinfection step. Disinfection is the removal of bloodborne pathogens that is the way

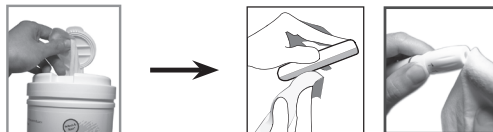
to reduce your exposure to disease.

Your meter and lancing device is validated to withstand cleaning and disinfection cycle of once per day for an average period of five years (1825 cleaning cycles and 1825 disinfection cycles over the 5 year use life of the meter) using Clorox Healthcare Bleach Germicidal Wipes (EPA Registration Number: 67619-12). Clorox Healthcare Bleach Germicidal Wipes is available through major retailers online, please refer to page 74 for purchase information.

We recommend the frequency for cleaning and disinfection is once per week.

1. Wash hands with soap and water and dry thoroughly.
2. Inspect for blood, debris, dust, or lint anywhere on the meter or lancing device.
3. To clean the meter or lancing device, use Clorox Healthcare Bleach Germicidal Wipe.

Wipe all external areas of the meter or lancing device including both front and back surfaces until visibly clean at a minimum wipe all surfaces with 3 vertical and 3 horizontal wipes. Discard used towel in a sealed container where it will not be touched by others.





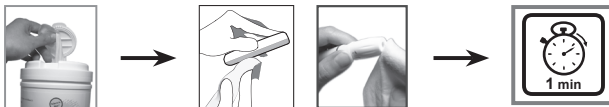
**NOTE:**

- If towelettes seem very dry, invert the canister once or twice to distribute the disinfectant on the towelettes. If the towelettes are excessively wet or dripping, squeeze the excess (dripping) liquid out before using them on the meter.
- Do not get water or other liquids inside the meter or immerse the meter or lancing device in water or any other liquids.
- Do not use glass, household cleaners, or ammonia on the meter or lancing device. Use only Clorox HealthCare Bleach Germicidal Wipes.
- The cleaning step should be performed prior to the disinfection step.

4. To disinfect your meter or lancing device, wipe all external surfaces with a fresh Clorox Healthcare Bleach Germicidal Wipes. Allow the surface of meter or lancing device to remain wet for at least 1 minute at room temperature, wipe all external surface with a fresh Clorox Healthcare Bleach Germicidal Wipe.

**NOTE:**

- Avoid wetting the meter data port and test strip holder.



5. Discard used towelettes in a sealed container where it will not be touched by others.
6. Allow to air dry.
7. Wash hands with soap and water and dry thoroughly.

**NOTE:**

- If the meter or lancing device is being operated by a second person who is providing testing assistance to the user, the meter or lancing device should be cleaned and disinfected prior to use by the second person.
- Keep Clorox Healthcare Bleach Germicidal Wipes out of reach of children and stored according to its instruction.
- Do not flush towels down toilet.

**IMPORTANT:**

If you notice any of the below signs after cleaning and disinfecting your meter or lancing device; stop using the device and call customer service immediately at 1-877-979-5454 Monday through Friday from 8am to 5pm US Central Standard Time:

- Control solution out of range.
- Clouding meter LCD display.
- Corrosion or erosion of plastic housing or buttons.
- Cracking of plastic housing.
- Malfunction of any meter button.

## **Purchase Information for Clorox Healthcare Bleach Germicidal Wipes**

Clorox is the product of Clorox, the catalog number is 30577 (150 count) or 35309 (70 count).

Follow the website below to find your nearest Clorox Sales Representative.

<https://www.cloroxpro.com/products/clorox-healthcare/bleach-germicidal-disinfectants/>

To find a local distributor in your area, call Customer Service at 800.234.7700, Mon - Fri 8:30am - 5:00pm EST.

You can also purchase on <http://www.amazon.com> or in the retail store Walmart or Target.

If you need assistance or have question about cleaning and disinfection for the meter, please contact customer service at 1-877-979-5454 Monday through Friday from 8am to 5pm US Central Standard Time

## Changing the Batteries

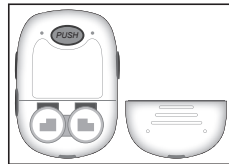
When the low battery icon appears on the screen, the batteries are getting low. Before using your meter, change the batteries.

Materials you will need:

- Two CR 2032 3V Lithium coin cell batteries
- Your MultiSure GK Link Blood Glucose and Ketone Meter

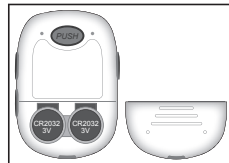
### Step 1.

Turn meter off. Remove the battery cover on the back of the meter by pushing the tab and pulling the door up. Remove the old batteries



### Step 2.

Fit the new batteries into the battery holder with the “+” pole facing upwards. Put the battery door back in the place.



**WARNING:**

- If the batteries are inserted upside down, the meter will not operate.
- The meter clock may stop if you touch the metal parts inside the meter with your hands or metal.
- The date and stored results will not be erased when the batteries are being changed.
- If batteries replacement takes longer than 2 minutes and you do not reset time and date, all subsequent test results will be stored with the incorrect date and time.
- Dispose of old batteries according to local environmental regulations.

**CAUTION:**

To obtain accurate test results:

- Improper use may cause explosion or leakage of flammable liquid.
- Do not expose the batteries to extremely high temperatures.
- Do not expose the batteries to extremely low air pressure.



## Storage and Precautions




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- Handle the meter with care; severe shock, such as dropping the meter, could damage the electronics.
- The meter and the test strips are designed to be used within the temperature ranges between 5°C ~45°C (41°F ~113°F) and relative humidity between 20% ~ 90% for glucose test; the temperature ranges between 10°C ~40°C (50°F ~104°F) and relative humidity less 85% for ketone test
- Avoid leaving the meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the meter or test strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Do not take the meter apart. Doing so will void the warranty.
- Do not use this meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
- Do not use this meter near cellular or cordless telephones, walkie-talkies, garage door openers, radio transmitters, or other electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
- Dispose of the meter according to your local regulations for correct disposal.
- Discard used lancet and test strip according to your local regulations.




## Solving Problems




This section details the significant display screen messages and error codes you will encounter when using your MultiSure GK Link Blood Glucose and Ketone Meter and MultiSure GK blood glucose test strips or MultiSure GK blood ketone test strips.



Message	What It Means	What You Should Do
	Damaged meter electronic or test strip	<ul style="list-style-type: none"> <li>• Replace the batteries and turn on the meter again.</li> <li>• Remove the test strip and insert a new test strip again.</li> <li>• If problem persists, call us at 1-877-979-5454 Monday through Friday from 8am to 5pm US Central Standard Time.</li> </ul>
	Used or contaminated test strip	<ul style="list-style-type: none"> <li>• Remove the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop icon before you add blood or control solution sample.</li> </ul>


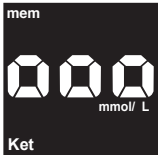
Message	What It Means	What You Should Do
	Not enough sample on the test strip to start	<ul style="list-style-type: none"><li>• Remove the test strip and repeat the test with a new test strip. See Testing Your Blood Glucose on page 34.</li><li>• Remove the test strip and repeat the test with a new test strip. See Testing Your Blood Ketone on page 48.</li></ul>
	Remove test strip during countdown	<ul style="list-style-type: none"><li>• Turn off the meter and repeat the test with a new test strip.</li></ul>
	Meter fails in BLE status check	<ul style="list-style-type: none"><li>• Replace the batteries and turn on the meter again.</li><li>• If problem persists, call us at 1-877-979-5454 Monday through Friday from 8am to 5pm US Central Standard Time.</li></ul>



Message	What It Means	What You Should Do
	BLE pairing is fail	<ul style="list-style-type: none"><li>• Check Bluetooth device is working well and repeat confirm to pairing.</li></ul>
	Data transmission via BLE is fail.	<ul style="list-style-type: none"><li>• Remove USB cable from Data transmission port.</li></ul>
	Low battery	<ul style="list-style-type: none"><li>• Change the batteries according to instruction for Changing the Batteries on page 75</li></ul>

Message	What It Means	What You Should Do
	Temperature out of range	<ul style="list-style-type: none"><li>Move the meter into an area that is within recommended range, and allow 30 minutes for it to reach the new temperature.</li></ul>
	Glucose test result higher than 600 mg/dL (33.3 mmol/L)	<ul style="list-style-type: none"><li>Wash and dry your hands and repeat the test on your fingertip with a new glucose test strip. If the result is still "HI", contact your physician or healthcare professional immediately.</li></ul>
	Glucose test result lower than 20 mg/dL (1.1 mmol/L)	<ul style="list-style-type: none"><li>Wash and dry your hands and repeat the test on your fingertip with a new glucose test strip. If the result is still "LO", contact your physician or healthcare professional immediately.</li></ul>

Message	What It Means	What You Should Do
	The blinking HI icon mean Ketone test result is higher than 8 mmol/L	<ul style="list-style-type: none"><li>Wash and dry your hands and repeat the test on your fingertip with a new ketone test strip. If the result is still “HI”, contact your physician or healthcare professional immediately</li></ul>
	The blinking 0.0 icon mean Ketone test result is lower than 0.1 mmol/L	<ul style="list-style-type: none"><li>Wash and dry your hands and repeat the test on your fingertip with a new ketone test strip. If the result is still “0.0”, contact your physician or healthcare professional immediately</li></ul>

Message	What It Means	What You Should Do
	No memorized results in the meter	<ul style="list-style-type: none"><li>• Check if the date and time on your meter is set up. See Setting Up Your New System on page 18.</li><li>• Start testing your blood glucose, see Testing Your Blood Glucose on page 34.</li><li>• Start testing your blood ketone, see Testing Your Blood Glucose on page 48.</li></ul>
		

## Understanding Your Blood Glucose Test Results

Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are

- less than 100 mg/dL (5.6 mmol/L) before meals.
- less than 140 mg/dL (7.8 mmol/L) two hours after meals.

It is important to consult with your physician or healthcare professional to determine an appropriate target range for you

### **What to Do If You Get a High or Low Reading**

If the meter displays results that are “HI” or “LO”, or you get a result that is more than your high or low blood glucose threshold value AND you feel ill:

- Treat your diabetes according to the instruction from your doctor and/or consult your healthcare provider.
- Test your meter with a glucose control solution, refer to Control Solution Testing on page 43.
- Test again using fingertip with a new test strip.

If you still get a high or low reading, contact your healthcare professional immediately

**NOTE:**

- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with this device.

American Diabetes Association, Standards of Medical Care in Diabetes—2017. Diabetes Care, Vol.40, Supplement 1, p. S14, Table 2.4.

## Understanding Your Blood Ketone Test Results

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For result interpretation for non-diabetic patients refer to the quick start guide. Ketones are made when the body is using fat for energy instead of using glucose because not enough insulin is available to use glucose for energy. It is a warning sign that your diabetes is out of control or that you are getting sick <sup>(1)</sup>.

If your blood glucose is higher than 250 mg/dL (13.9 mmol/L) and your blood ketone result is <sup>(2)</sup>:

- Below 0.6 mmol/L .....a normal blood ketone level
- 0.6 to 1.5 mmol/L .....a moderate level of ketones and probably indicates fat metabolism and weight loss, but not a deficiency of insulin, test again later and contact your healthcare professional for advice
- 1.6 to 3.0 mmol/L .....a high level of ketones and under a risk of diabetes ketoacidosis (DKA), contact your healthcare professional immediately
- Above 3.0 mmol/L .....a serious metabolic condition and emergency medical care is necessary

## **What to Do If You Get a High Reading**

If the meter displays results that are “HI”:

- Treat your diabetes according to the instructions from your doctor and/or consult with your healthcare provider.
- Test your meter with a ketone control solution, refer to Ketone Control Solution Testing on page 54.
- Test again with a new test strip. If you still get a high reading, contact your healthcare professional immediately.

### **IMPORTANT:**

- Inaccurate results may occur for individuals experiencing severely hypotensive, severely dehydrated, in shock, or in a hyperglycemic-hyperosmolar state.

1. DKA (Ketoacidosis) & Ketones, <http://www.diabetes.org/living-with-diabetes/complications/ketoacidosisdka.html>, March 18, 2015
2. A. Rewers, Current Controversies in Treatment and Prevention of Diabetic Ketoacidosis, *Advances in Pediatrics* 57 (2010) 247–267.



## Product Warranty

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Apex Biotechnology Corporation warrants the MultiSure GK Link Blood Glucose and Ketone Meter to be free of defects in workmanship and materials under normal use for a period of five (5) years from the date of purchase to the consumer.

The liability of Apex Biotechnology Corporation is limited to repair or replacement and in no event shall Apex Biotechnology Corporation be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables.

All warranty claims must be directed to the Apex Biotechnology Corporation's authorized dealer responsible for the sale of the system. The warranty applies only to the original purchaser of the system.

## Specifications

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Test Strips:	MultiSure GK Link Blood Glucose Test Strip MultiSure GK Link Blood Ketone Test Strip
Test Range:	20~600 mg/dL (1.1~33.3 mmol/L) for glucose test 0.1~8.0 mmol/L for ketone test
Calibration:	Plasma
Test Time:	5 seconds for glucose test 8 seconds for ketone test
Blood Sample Size:	≥ 0.5 µL for glucose test ≥ 0.8 µL for ketone test
Hematocrit Range:	10~70% for glucose test, 20~60% for ketone test
Display Type:	LCD screen with back lighting
Alarms:	3 for glucose test 3 for ketone test
Data management:	Before/after meals, exercise, check markers available
Memory:	730 test results with date and time for glucose test 100 test results with date and time for ketone test
Result Averaging:	Over 1, 7, 14, 30, 60, 90 days (for glucose results only).
Data transfer:	Via micro USB cable or a Bluetooth device.
Dimensions:	88 mm(L) x 60 mm(W) x 16.5 mm(H)
Weight:	54 g (without battery)

Battery: Two 3.0 V lithium batteries (CR2032).  
Battery Life: A minimum of 900 tests or about 1 year (2-3 tests/day).  
Operating Temperature: 5°C~45°C (41 to 113°F) for glucose test  
10°C~40°C (50 to 104°F) for ketone test  
Operating Relative Humidity: 20~90% for glucose test  
<85% for ketone test

Automatic Power-off:

- After 90 seconds of inactivity before the test (sensor strip inserted into the meter, drop icon flashing).
- After 60 seconds of inactivity after the test and Error messages Err2, Err3, Err4, HI and LO.
- After 5 seconds for Error messages Err1, Temperature icon and Battery icon.

Test strip Storage Conditions:

- Glucose : Temperature: 4 to 30°C (39.2 to 86°F)  
Relative Humidity: 20 to 90% (both for unopened vial and after opening).
- Ketone : Temperature: 4 to 30°C (39.2 to 86 °F).

Meter storage/transport conditions:

- Temperature: -20 to 50°C (-4 to 122°F); Relative Humidity: 20 to 90%.

For additional information, refer to the MultiSure GK blood Glucose Test Strip insert and MultiSure GK blood Ketone Test Strip insert.

## Federal Communications Commission Interference Statement

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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 with 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 into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

**CAUTION:**

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

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.