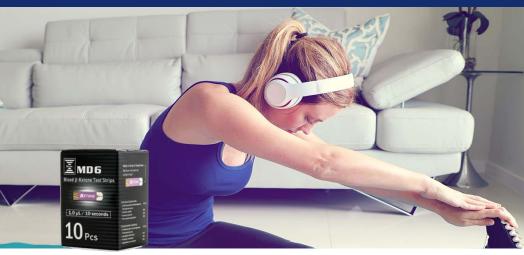
### BRUNO MD<sub>6</sub> QUICK USER GUIDE

Multi-Functional Glucose & β-Ketone Monitoring System



### TESTING BLOOD VERSUS URINE

#### KETONE URINE STRIPS

- will not report the amount of ketones in the blood, but it will limit to show the increased amount of ketones in the urine (acetoacetate), not the presence of D-β-hydroxybutyrate.
- They will not provide accuracy.

#### KETONE BLOOD STRIPS

show an exact and real time microscopic view of the makeup of ketones in your blood. Not only will you know how much acetoacetate is in your system, but you will also discover how much BoHB (also known as D-β-hydroxybutyrate) is in your system. BoHB is the important ketone body that your body converts to fuel muscles and brain.



Extremely important.

#### Dear Bruno MD6 Customer

Thank you for choosing the Bruno MD6 multi-functional monitoring system for glucose and β-ketone testing. Our advanced medical device provides fast, accurate readings of your blood ketone and glucose levels anytime, anywhere. That's right—Bruno MD6 allows you to monitor both with ease! With our patented technology, we are confident that this tool will support your health and dietary goals more effectively than ever before. Whether you're following the Atkins, Paleo, Bulletproof, or Keto diet—or any low-carb, high-fat regimen monitoring both blood ketone and glucose levels is essential. Tracking your glucose helps optimize your diet for maximum weight loss and metabolic efficiency. At Bruno Pharma Innovations, we are passionate about helping you live a healthier life. We believe that a low-carb diet can be a powerful tool for achieving wellness. By adopting a high-fat, low-carb approach, your body efficiently burns fat stores, promoting effective weight loss while maintaining a diet rich in proteins and essential lipids. We are excited to be part of your journey toward better health with the Bruno MD6 monitoring system!

#### Bruno MD6 has:

- EVERYTHING YOU NEED FOR AT HOME TESTING
- PRECISE READINGS EVERY TIME
- CONVENIENT AND FAST RESULTS
- A SAFE AND EFFICIENT WAY TO DIET



#### IMPORTANT SAFETY PRECAUTIONS READ BEFORE USE

• The meter and lancing device are for single use only. Do not share them with anyone including your family members! Do not

use on multiple individuals!

• All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

#### For more information.

#### please visit:

"FDA Public Health Notification: Use of Finger stick Devices on More than One Person Poses Risk for Transmitting Blood borne Pathogens:

Initial Communication" (2010)

http://www.fda.gov/MedicalDevices/Safety/ AlertsandNotices/ ucm22 4025.htm "CDC Clinical Reminder: Use of Finger stick Devices on More than One Person Poses Risk for Transmitting Blood borne Pathogens" (2010) http://www.cdc.gov/injectionsafety/ Fi ngerstick-Devices BG M.htm I

- 1. Use this device ONLY for the intended use described in this manual.2. Do NOT use accessories which are not specified by the manufacturer.3. Do NOT use the device if it is not working properly or if it is damaged.4. Do NOT under any circumstances use the device on newborns or infants.5. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only.
- 6. Before using this device to test blood glucose and B-ketone, read all instructions thoroughly and practice the test.

7. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.

8. 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.

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

10. Proper maintenance is essential to the longevity of your

device.

### TABLE OF CONTENTS

BEFORE YOU BEGIN	
Important Information	5
Intended Use	5
Test Principle	6
Content of System	6
Meter Overview	7
Meter Display	7
Test Strip	8
Setting the Meter	9-10
MEASURING MODES	
Three Measuring Modes for Blood Glucose Testing	11
BEFORE TESTING YOUR KETONES	
Calibrating for Ketones - To Begin Calibrate	12-13
TESTING WITH BLOOD SAMPLE	
Preparing the Lancing Device for Blood Testing	14
Setting Up the Lancing Device	15
Preparing the Puncture Site	16
Performing a Blood Glucose or Ketone Test	17-18
METER MEMORY	
Reviewing Test Results	19
Reviewing Day Average Results	20

#### DOWNLOADING RESULTS Data Transmission Via Bluetooth 21 22 Bluetooth Indicator on the Meter 23 BRUNO MD6 APP - Features **MAINTENANCE Battery** 24 **25-26** Caring for Your Meter & Disinfecting Procedures Cleaning & Disinfecting Your Lancing Device 27 Caring for Your Test Strip 27 SYSTEM TROUBLESHOOTING **Result Readings** 28 29 **Error Messages** 30 Troubleshooting **DETAILED INFORMATION** Reference Values for Keto Diet Followers only 31 Reference Values for Blood Glucose Level for 32 Keto Diet Reference Values for Diabetic only 33 Comparing Meter and Laboratory results 34 Federal Communications Commission (FCC) 35-36 Statement-Specifications

### BEFORE YOU BEGIN

#### IMPORTANT INFORMATION

• Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.

• If your blood glucose or  $\beta$ -ketone results are lower or higher than usual, and you do not have symptoms of illness, repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare

professional.

• Use only fresh whole blood samples to test your blood glucose and β-ketone. Using other substances will lead to inaccurate results.

• If you are experiencing symptoms that are inconsistent with your blood glucose or  $\beta$ -ketone test results and you have followed all the instructions given in this e-quick user guide, contact your healthcare professional.

• We do not recommend using this product on severely hypotensive individuals or patients who are in shock. Readings which are lower than actual values may occur for individuals in a hyperglycemia-

hyperbola state, with or without ketosis.

Please consult your healthcare professional before use.

• Limitation:

The device should not be used on individuals in hyperglycemiahyperosmolar state, with or without ketosis; not for neonatal use; not for use on critically ill patients.

#### INTENDED USE

The BRUNO MD6 Multi-Functional Monitoring System is intended for use in the quantitative measurement of glucose and  $\beta$ -ketone (beta-hydroxybutyrate) in fresh capillary whole blood from

the finger.

It is intended as an aid in monitoring the effectiveness of diabetes control program and ketogenic diets. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended to be used by a single person and should not be shared.

#### TEST PRINCIPLE

Your system measures the amount of sugar (glucose & ketone) in whole blood. The glucose and ketone testing are based on the measurement of electrical current generated by the reaction of glucose and - ketone with the reagent of the strip. The meter measures the current, calculates the blood glucose and - ketone level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose and ketone in the blood sample.

#### **CONTENTS OF SYSTEM**

The Bruno MD6 system kit includes:



1. Multi-Functional Monitoring System



2. Quick User Guides



3. Traveling Kit & 2 AAA Alkaline Batteries



4. Free Vial of Glucose Test Strips (10ct.)





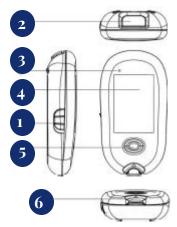
5. Lancets (50ct.) & Lancing Device

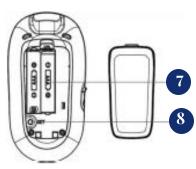


6. Ketone Test Strips(10ct.) & Lancing Code Test Strip

If any of the items from your kit are missing, or opened prior to use, please contact us by emailing at customercare@brunopharma.com, or by calling at 866-816-3400.

#### METER OVERVIEW



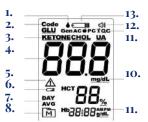


- Bluetooth Switch.
  Activate the Bluetooth function.
- Test Strip Ejector.
  Eject used strip by pushing the bottom.
- Bluetooth Indicator.

  Download test results with Bluetooth connection.
- **4** Display Screen.

- Main Button.
  Enter meter memory and silence a reminder alarm.
- Test Slot with Strip Indication Light.
  Insert test strip to turn meter on for testing.
- Battery Compartment.
- Set Button.
  Enter & confirm meter setting.

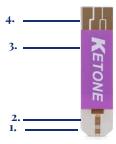
#### METER DISPLAY



- 1. Blood Drop Symbol
- 2. Code
- 3. Ketone Warning
- 4. Test Result
- 5. Error Message
- 6. Low Battery Symbol
- 7. Day Average
- 8. Memory Symbol
- 9. Date / Time

- 10.Measurement Unit
- 11. Measurement Mode
- 12. Volume Symbol 13. Test Strip Symbol

### TEST STRIP



1. Absorbent Hole

Apply a drop of blood here. The blood will be automatically absorbed.2. Confirmation Window

This is where you confirm if enough blood has been applied to the absorbent hole in the strip.3. Test Strip Handle

Hold this part to insert the test strip into the meter slot.4. Contact Bars

Insert this end of the test strip into the meter. Push it in firmly until it stops.

Note: The front side of test strip should face up when inserting test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.

The BRUNO MD6 Multi-Functional Monitoring System should only be used with BRUNO MD6 Test Strips. Using other test strips with this monitoring system can produce inaccurate results.





#### SETTING THE METER

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



#### **Entering the Setting Mode**

- 1. Start with the meter OFF and no test strip inserted.
- 2. Then press SET.







#### **Setting the date**

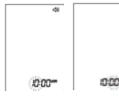
- 1. With the year flashing, press Main button until the correct year appears.
- 2. Then press SET.
- 3. With the month flashing, press Main button until the correct month appears. 4. Then press SET.
- 5. With the day flashing, press Main button until the correct day appears.
- 6. Then press SET.





#### **Setting the time format**

- 1. Press Main button to select the desired time format ---12h or 24h.
- 2. Then press SET.



#### Setting the time

- 1. With the hour flashing, press Main button until the correct hour appears.
- 2. Then press SET.
- 3. With the minute flashing, press Main button until the correct minute appears.
- 4. Then press SET.







#### Setting the buzzer

- 1. With the buzzer displays, press Main to select "universal tone" or "buzzer beep On/Off".
- 2. Then press SET.

**Deleting the memory** 

- 1. With "dEL" and "m" on the display, press Main button and select "no" to keep the results in memory.
- 2. Then press SET to skip. 3. To delete all the results, press Main button and "yes"
- " are displayed on the meter.
- 4. Then press SET to delete the memory.















- 1. Press Main button to select the autosend On or OFF.
- 2. Then press SET. This function is referring to the Bluetooth data transmission. If "On" is selected, your result will be transmitted automatically right after the test.
- 3. After the set-up is complete, press the SET button to turn "OFF" the meter. "OFF" will be displayed before shut down.

#### Congratulations! You have completed all settings!

#### NOTE:

These parameters can ONLY be changed in the setting mode. If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

### MEAUSURING MODES

# Three Measuring Modes for Blood Glucose Testing

The meter provides you with three modes for blood glucose testing: General, AC, and PC.

MODES	USE WHEN
GENERAL TESTS (GEN)	Any time of day without regard to time since last meal
AC (Ante Cibum-Before Meal)	No food intake for at least 8 hours
PC (Post Cibum-After Meal)	2 hours after a meal

You can switch between each mode by:

- 1. Start with the meter switched OFF.
- 2. Insert a code test strip to turn on the meter.
- 3. The screen will display "🍆" and "GEN".









1. Press Main button to switch between General, AC, and PC modes.

Note. For Blood Glucose Testing, calibration process is not required. Therefore control solution is not necessary.

# • BEFORE TESTING YOUR KETONE

### **CALIBRATING FOR KETONES**

You must calibrate the meter every time you begin to use a new box of  $\beta$ -Ketone test strips. The code test strip can only be used with the code test strip (coding key) found within each individual box of ketone strips (See code test strip in the picture below). When you finish a box of ketone strips you must discard the code test strip and re-calibrate the monitor using the code test strip included in the new box. Each code test strip is unique to each individual box.



Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on the strip box.



#### TO BEGIN CALIBRATE



1. Insert the code test strip in the device.



2. If inserted correctly, you should hear a "beep". The symbol CH will appear on the display for few seconds.



3. The display will reveal a number.





4. Ensure both numbers on key and on box match.

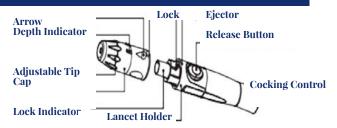
Congratulations! Your device is now calibrated, and ready for use. 5. You can remove the code test strip, and start using your device.





### TESTING WITH BLOOD SAMPLE

# Preparing the Lancing Device for Blood Testing



Please follow the instructions in the lancing device insert for collecting a blood sample. Lancing device insert can be found inside the MD6 kit. A video tutorial on how to use the lancing device can be also found on www.brunomd.com, and on our BRUNO MD6 Amazon store page.

The important features on the lancing device are:



1. The adjustable tip offers you 6 depths of skin penetration.



2. The locking mechanism in the down position will allow you to remove the cap to insert the lancet.



3. The release button will turn orange when the locking mechanism is completely engaged.

#### Note

To reduce the chance of infection:

• Never share a lancet or the lancing device • Always use a new, sterile lancet. Lancets are for single use only • Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device. • Wash and dry your hands thoroughly after handling the meter, please refer to the MAINTENANCE section on page 25–26.

• If the meter is being operated by a second person who is providing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

### Setting up the Lancing Device for Blood Testing



1. Twist the cap in a downward direction to remove it.



2. Insert a lancet into the device. You do not need to push down very hard. It will be safely secured when you put the cap back on.



Twist the protective disk.



4. Gently remove the blue cap from the lancets by twisting. You may want to save this cap for proper disposal.



5. Place the cap back onto your device and gently twist up until you hear a locking sound.



6. Select the depth you would like for penetration.



7. To engage the device you will want to pull back on the cocking mechanism until you hear a click.



8. The window in the release button will turn orange. The device if fully engaged and ready to take a sample.

# Preparing the Puncture Site

• Wash and dry your hands before starting.• Select the puncture site on fingertips.• Rub the puncture site for about 20 seconds before penetration.• Clean the puncture site using cotton moistened with 70% and let it air dry.

Stimulating blood perfusion by rubbing the puncture site before blood extraction significantly reduces variations between measurements.

Please follow the suggestions below before obtaining a drop of blood:



1. Press the lancing device against your finger. Through trial and error, you will discover a preferred area for penetration. Some people prefer to use the side of the finger, but the finger tip is always the easiest to begin.



2. Press the lancing device against your finger and engage the release button.



4. You do not need much for a good sample, about the equivalent of the head on a sewing pin. If you did not draw enough, you may need to penetrate a second time. Be careful to not smear your sample.



3. You will feel a slight pinch in your finger. It is always best to wipe off the first drop of blood for more accurate results.

#### Note:

Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses. It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

### Performing a Blood Glucose or Ketone Test



1. Every kit comes with a vial of complimentary glucose and ketone strips.



2. Pick up your device and wake it up by hitting the M button.



3. Place your finger against the bottom of the device. The device will drink up the sample. Ensure that the sample is drawn all the way into the chamber.



4. If a large enough sample is not collected you may get an error message.



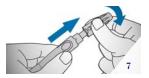
The device will display your blood glucose or ketone level.



6. When you have finished testing, you can safely dispose the strips by holding it over the trash and hitting the eject button. The device will automatically power down after 10 seconds of non use, so you do not worry about turning it off.

#### Note:

Do not press the punctured site against the test strip or try to smear the blood. If you do not apply a blood sample within 3 minutes, the meter will automatically turn off. You must remove the test strip and insert it back into the meter to restart a new test. The confirmation window should be filled with blood before the meter begins to count down. NEVER try to add more blood to the test strip after the drop of blood has moved away. Discard the used test strip and retest with a new one.



7. You can always dispose of the lancet by twisting off the cap.



8 If you saved the lancet top, you may want to stick it back on there for safety reasons. There is no wrong way to do it since it will be discarded.



9. The lancet can be removed as well by clocking the device and ejecting into the trash.

#### Note:

The used lancet and test strip may be bio-hazardous. Please discard them properly. Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the MAINTENANCE section on page 24. A video tutorial can also be found on www.brunomd.com., and on our BRUNO MD6Amazon store page.



The Best Way to Measure Results with Extreme Accuracy at the Best Value

### • METER MEMORY

### **Reviewing Test Results**

Your meter stores the 1000 most recent test results with date and time in its memory. To enter the meter memory, start with the meter switched OFF. Follow the same steps for reviewing glucose and  $\beta$ - ketone test results.



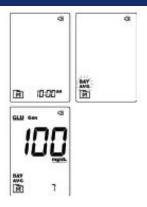
1. Press and release Main button " " will appear on the display. Press Main button again, and the first reading you see is the last testing result along with date, time and the measurement mode.



2. Press the Main button to recall the test results stored in the meter each time you press. After the last test result, press Main button again and the meter will be turned off.



### REVIEWING DAY AVERAGE RESULTS



- 1. Press and release Main button. When "m" appears on the display, keep pressing Main button for 3 seconds until the flashing "DAY AVG" appears. Release Main button and then your 7-day average result measured in general mode will appear on the display.
- 2. Press Main button to review 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode.
- 3. Exit the meter memory. Keep pressing the Main button and the meter will turn off after displaying the last test result.

Note:

Any time you wish to exit the memory, hold the Main button for 5 seconds or leave the meter idle for 3 minutes. The meter will turn off automatically. If there are no records in memory, "---" displays when you recall the test results or review the average results.



### DOWNLOADING RESULTS

### Data Transmission via Bluetooth

You can transmit your data from the meter to your devices via Bluetooth. Please note that you must pair your meter to your device before transmitting data. You have to set an account after having downloaded your Bruno MD6 APP. Please note meter must be OFF the entire time while setting the APP Bruno MD6 and opening an account. See instructions below:

• Go to Apple Store or Google Play and search for Bruno MD6.

• Tap the icon and download App.

• Tap the "OPEN" button.

• Tap Create New (Account).

• Type in your account ID (Example: jmiller).

Type in your account PW. Confirm PW.

Type in your email address. Type in your Birthday .

- Check Male or Female Option. Type in your first name. Type in your last name.
- Select Type 1, 2 or Keto Diet from drop-down menu. Note that if you are on a Keto diet you can choose one of the 2 selections (1 or 2). Your results will not be affected by this selection.

Tap "Register Account".

• With your left thumb pull down the button on the left side of the monitor until the blue light at the top left of the monitor starts flashing.

• Now click on "pair meter" next to the field requesting "Meter" (serial number)

(serial number).

- You will be prompted to "Add" Available Meter. Click on "Add".
- Go back by clicking on the Arrow at the top left of your phone's screen (< Pair Bluetooth Smart Meter).
- Save and leave.

Click on "Yes".

- Click on "Pair Meter" again. Serial number should populate the blank field.
- If prompted go back by clicking on the Arrow at the top left of your phone's screen (< Pair Bluetooth Smart Meter).

• Click on Register Meter.

• The App should start importing all your data at this point (only if you have already measured your Ketones and/or Glucose)y. At the bottom of the screen click on the "Data" icon and check if your Data have been imported. At the bottom of the screen click on the "Analysis" scroll down using your right or left thumb check Blood Glucose and Ketones pie charts + Trends Graphs.

#### Remember:

You are responsible for setting your Health Targets. Click on the "Setting" icon at the bottom of your screen. Click on the "Health Target" button. Set your health Target Goals for Glucose levels before meals (full Carrot) and After Meal (Half Carrot). Set your Health Target Goals for Ketones. Always check for updates listed under your Apple Store or Google Play.

## Bluetooth Indicator on the Meter

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is enabled and waiting for connection
Solid Blue	The Bluetooth connection has been established

#### NOTE:

While the meter is in transmission mode, it will be unable to perform a test. Make sure that your device supporting Bluetooth Smart Technology has turned on Bluetooth before transmitting the data and the meter is within the receiving range.

As soon as finalizing your glucose or ketone blood test your information will be sent wireless via Bluetooth to your mobile device and be stored in your internal memory with a time and date stamp.



#### **BRUNO MD6 APP Features**

Bruno MD6 App is **Available** from **Apple Store** or **Google Play**. The APP is the perfect tool to track your daily blood ketone and glucose readings. With the Bruno MD6 APP, you can see your trends displayed in detailed graphics, record your food intake, dosages, and much more such as:

- DATA RECORD
- RECORD LIST
- LOGBOOK
- TREND GRAPH
- STANDARD DAY
- DIARY

#### and plus it is FREE!





### Maintenance

### **Battery**

Your meter comes with two 1.5V AAA size alkaline batteries.



#### Low Battery Signal.

The meter will display the message below to alert you when the meter power is getting low.

The"**□**"appears with E-band low:

The power is not enough to do a test. Please change the battery immediately.



#### Replacing the Battery.

To replace the battery, make sure that the meter is turned off.

1. Press the edge of the battery cover and lift it up to remove.2. Remove the old battery and replace it with two 1.5V AAA size alkaline batteries.3. Close the battery cover. If the battery is inserted correctly, you will hear a "beep" afterwards.

#### NOTE:

Replacing the batteries does not affect the test results stored in the memory.

As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance. Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more). Properly dispose of the batteries according to your local environmental regulations. After replacing batteries, the meter will enter the setting mode.

# Caring for Your Meter and Disinfecting Procedure

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after use.

What is Cleaning and Disinfection?

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), disinfection is the process of killing germs (e.g. bacteria and viruses).

#### When to clean and disinfect the meter?

Clean the meter when you see any dirt on it. You should disinfect the meter at least once a week to prevent infection.

#### How to clean and disinfect the meter?

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe.

Use a second wipe to disinfect the meter. Do NOT use organic solvents to clean the meter.



Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter. Wipe all meter's exterior surface display and buttons. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get insides. Keep the meter surface wet with disinfection solution for a minimum of 2 minutes. Remove the wipe. Allow the meter surface to dry completely. Discard the used wipes and never reuse them. Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination. Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact customer service by emailing us at customercare@brunopharma.com.

This device has been validated to withstand 10950 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 10 cleaning and disinfection cycle per meter per day for 3 years. the expect life of device. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first. Stop using the meter if you see any signs of deterioration. For example:

• Meter cannot be turned on • LCD display cracks or becomes cloudy • Buttons no longer function • Meter outer casing cracks • Data cannot be transmitted • Color or paint/printing on housing is abnormal • Scratches or abrasions on meter are higher than acceptable. Please contact customer service by emailing us at customercare@brunopharma.com, or by calling us at 1-866-816-3400 for a replacement meter if any of the signs of deterioration are noticed.

#### NOTE:

Do NOT clean and disinfect the meter while performing tests. If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to use by the second person.

Do NOT allow cleaning and disinfecting solution to get in the test slot. If you do get moisture in the test strip slot, wipe it away with a corner of tissue.

Always dry the meter thoroughly before using it.

Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry.

Meter Storage

Storage conditions: -4°F to 140°F (-20°C to 60°C), below 95%

relative humidity.

Always store or transport the meter in its original storage case.

Avoid dropping and heavy impact.

Avoid direct sunlight and high humidity.



# Cleaning and Disinfecting of Your Lancing Device

• For home users, the lancing device is reusable. Please disinfect your lancing device regularly.

• To clean the lancing device, use a disinfecting wipe to clean the

lancing device.

• Disinfect the cap by placing it in 70% alcohol for 10 minutes and then allow it to air dry.

• Do NOT place the device in a dishwasher or use detergents.

### **Caring for Your Test Strips**

• Storage conditions: 35.6°F to 89.6°F (2°C to 32°C) for blood glucose test trips; 35.6°F to 86.0°F (2°C to 30°C) for blood β-Ketone test trips. Both relative humidity are between 10% ~ 85%. Do NOT freeze. Store your test strips in their original vial only. Do not transfer to another container. • Store test strip package in a cool dry place. Keep away from direct sunlight and heat. After removing a test strip from the vial, immediately close the vial cap tightly. Touch the test strip with clean and dry hands. Use each test strip immediately after removing it from the vial. • Write the opening date on the vial label when you first opened it. Discard remaining test strips after 6months. • Do not use test strips beyond the expiration date. This may cause inaccurate results. Do not bend, cut, or alter a test strip in anyway.• Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help. For further information, please refer to the test strip package insert that can be found inside the strip box.

### SYSTEM TROUBLESHOOTING

### **Result Reading**

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, we recommend to re-do your calibration procedure. Go to page 12-13 "Calibrating for Ketones" for further assistance, you will find a step by step procedure on how calibrating the meter. Feel free to email us at customercare@brunopharma.com for any questions. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

#### **B-KETONE TEST**

MESSAGE	WHAT IT MEANS
Lo	Appears when β-Ketone test result is below the lower measurement limit, which is less than 0.1 mmol/L.
Ηı	Appears when β-Ketone test result is higher than the measurement limit, which is higher than 0.8 mmol/L.

#### **GLUCOSE TEST**

MESSAGE	WHAT IT MEANS
Lo	Appears when blood glucose test result is below the lower measurement limit, which is less than 20 mg/dl (0.55 mmol/L).
Hı	Appears when blood glucose test result is higher than the measurement limit, which is higher than 600 mg/dl (33.3 mmol/L).

### **Error Messages**

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, we recommend to re-do your calibration procedure. Go to page 12-13 "Calibrating for Ketones" for further assistance, you will find a step by step procedure on how calibrating the meter. Feel free to email us at customercare@brunopharma.com for any questions. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-B	Battery power is too low to operate meter.Batteries must be replaced	Replace the batteries immediately
E-2	Expired code strip, or calibration process must be re-done	Check the expiration date, if not expired, re- calibrate the meter
E-U	Insert a used test strip, or blood sample is input before the " " symbol for blood blinks	Repeat the test with a new strip. Wait for the " • " symbol to blink, then retest using correct amount of blood
E-E E-O E-A	Problem in operation	Re-calibrate the meter, then repeat the test
E-F	Appears when the test strip is removed while counting down	Repeat the test waiting until the process ends
Е-С	Appears when the wrong code strip is inserted.	Make sure you use Bruno MD6 strips
E-t	Appears when meter or test strip are in an environmental temperature below or above system operating range	System operation range is 10-40C (50- 104F).Repeat testing when temperature is reached

### **Troubleshooting**

1.If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Battery exhausted	Recharge the battery
Test strip inserted upside down or incompletely	Insert the test strip with contact bars end first and facing up
Defective meter or test strips	Repeat calibration process. Follow instructions found on page 12–13 "Calibrating for Ketones"

2. If the test does not start counting down after applying the sample;

POSSIBLE CAUSE	WHAT TO DO
Defective test strip	Repeat calibration process. Follow instructions found on page 12-13 "Calibrating for Ketones"
Sample applied after automatic switch-off (3 minutes after last user action)	Repeat calibration process. Follow instructions found on page 12-13 "Calibrating for Ketones"
Defective meter	Repeat calibration process. Follow instructions found on page 12-13 "Calibrating for Ketones"

### DETAILED INFORMATION

# Reference Values for Keto Diet Followers Only

Blood glucose plus  $\beta$ -ketone monitoring plays an important role in diabetes control and in a ketogenic diet. The optimal ketone levels you'll want to achieve will likely be different depending on whether you're looking to lose weight, get improved mental clarity, or to improve your athletics performance. In addition the numbers may also vary depending on your body's current insulin resistance.

NOTE: the ranges below are general ones, and if yours doesn't fall within the range, it's not a definitive indicator that you're doing something wrong, but it is a helpful guide to ensure you think about tweaking and testing your Keto diet to see if something can be improved.

#### SUGGESTED KETONE LEVELS ON NUTRITIONAL KETOSIS

GOAL	KETONE LEVELS
Weight loss	Above o.5mmol/L
Improved athletic performance	Above o.5mmol/L
Improved mental performance	1.5 - 3 mmol/L



### Reference Values of Blood Glucose level for Keto Diet

### THE IMPORTANCE OF MEASURING YOUR BLOOD GLUCOSE LEVEL WHILE ON A KETO DIET

If you are doing a Keto Diet, knowing the amount of glucose in your blood will help you optimize your eating for maximum weight loss.

#### SUGGESTED BLOOD GLUCOSE LEVEL WHILE ON A KETO DIET

VALUE	WHAT IT MEANS
<60-65 mg/dL	WAY TO LOW. Anything under about 60+65 is a sign that your blood sugar is too low
65 to 90 mg/dL	JUST RIGHT. This is the sweet-spot for a keto based diet. It means your body currently has no real source of glucose available to eat. A person doing a keto based diet should aim to be in this range
90 to 115 mg/dL	TOO HIGH. If you are in this range, it is a sign you've eaten something that your body is reacting negatively too. You are producing insulin in small amounts. (Enough to prevent weight loss on a keto based diet, and enough to knock you out of ketosis)

TIPS: We recommend to always keep glucose strips in your keto-toolbox. Measure your blood glucose level when you wake up, and 1 hour after each meal. Use Bruno MD6 APP to track your results.( time of day, reading, and what you ate). Aim your blood glucose level in the 65 TO 90 mg/dL range.

### DETAILED INFORMATION

# Reference Values for Diabetic Only

Blood glucose plus  $\beta$ -Ketone monitoring plays an important role in diabetes control and in a ketogenic diet. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%1. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

TIME OF DAY	NORMAL PLASMA GLUCOSE RANGE FOR PEOPLE WITHOUT DIABETES (mg/dl)
Fasting and before meal	<100 mg/dl (5.6 mmol/L)
2 hours after meals	<140 mg/dl (7.8 mmol/L)

\*1: American Diabetes Association: Diabetes Care, January 2015, volume 38 (Suppl. 1) S8-S16. The β-Ketone test measures Beta-Hydroxybutyrate (β-OHB), the most important of the three β-Ketone bodies in the blood. Normally, levels of β-OHB are expected to be less than 0.6 mmol/L. β-OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your β-Ketone result is o.o mmol/L, repeat the β-Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication program. If your β-Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your β-Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis(DKA). Please work with your doctor to determine a target range that works best for you.

# Comparing Meter and Laboratory Results

The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results maybe affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below:

Before going to the lab

Fast for at least eight hours before doing comparison tests, if possible. Take your meter with you to the lab.

While staying at the lab

Make sure that the 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 meter with blood that has been collected in a gray-top tube.

Use fresh capillary or venous blood only.

You may still have a variation from the result because blood glucose or  $\beta$ -ketone levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication or experienced stress\*2. In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab est\*3. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a meter result to be different from a laboratory result.

<sup>2:</sup> Surwit, R.S.,and Feinglos, M.N.:Diabetes Forecast (1988), April, 49–51. 3: Sacks,D.B.: "Carbohydrates. " Burtis, C.A.,and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

### FEDERAL COMMUNICATIONS COMMISSION (FCC)STATEMENT

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

# FEDERAL COMMUNICATIONS COMMISSION (FCC)STATEMENT

15.105(b)

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.

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 of the device. FCC RF Radiation Exposure Statement:
- 1) This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.2) This equipment complies with FCCRF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

#### **SPECIFICATIONS**

Model No.: BRUNO MD6

**Dimension:** 110 (L)x57 (W)x25 (H) mm

**Weight:** 71 g (without battery)

Power Source: two 1.5V AAA alkaline batteries

Display:LCD

Memory:1000 measurement results with date and time External

Output:Bluetooth

Automatic detection of electrode insertion Automatic reaction time count-down Temperature warningAuto turn-off after 3 minutes without action

**Operating Condition:** 

50°F to 104°F(10°C to 40°C), 10% to 85% R.H.(non-condensing)

#### Meter Storage/Transportation Conditions:

-4°F to 140°F (-20°C to 60°C), below 95% R.H.

**Glucose Test Strip Storage / Transportation Conditions:** 

35.6°F to 89.6°F (2°C to 32°C), 10% to 85% R.H.(non-condensing), up to 21 months for unopened vial.

Glucose Measurement Units:mg/dL

Glucose Measurement Range:20 to 600 mg/dL (0.55 to 33.3 mmol/L)

**β-Ketone Test Strip Storage / Transportation Conditions:** 

35.6°F to 86.0°F (2°C to 30°C), 10% to 85% R.H.(non-condensing), up to 18 months for unopened vial.

#### **β-Ketone Measurement Units:**

mmol/L

#### **β-Ketone Measurement Range:**

0.1 ~ 8.0 mmol/L

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, EN61326-2-6.





# 

Should you have any questions or require further clarification, feel free to email us at customercare@brunopharma.com