BeneCheck™

Supreme
Blood Multi-Monitoring System
(Glucose/Uric Acid/Total Cholesterol/β-Ketone)
Supreme among multiples

User's Manual

BX-M100,BX-M10D

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Model:BX-M100,BX-M10D

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EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

IVD CE 0197

For self-testing or near-patient testing

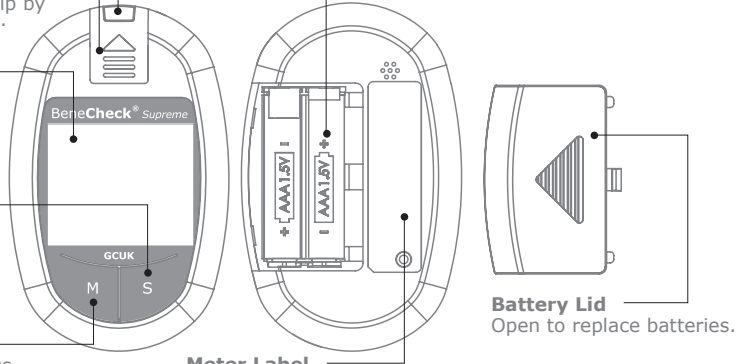
Doc.#:FIG-540BNKXXXXX-D Nov, 2023

手冊封面: 80P雪銅，上水性光，四色印刷
手冊內頁: 50-60P道林，單色印刷
裝訂: 騎馬釘

C5 K45
C100 M45
C60 M40 Y20
M30 Y90
K100
C100 M70 K30
C65 Y100 K40

圖號	料號	料品名稱	
FIG-540BNK		手冊,Supreme,BX-M10D,4國	290 x 100mm

BeneCheck Meter Kit Meter (Front Side & Back Side)



Test Port
Insert the test strip here to turn the meter on.

Ejection Button
Eject the used test strip by pushing up the button.

LCD Screen
Shows test results, messages, and test results stored in memory.

Right "S" Button
Press to accept a selection. Press and hold to enter the setting mode.

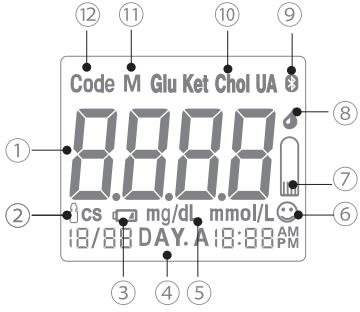
Left "M" Button
Press to adjust settings. Press and hold to enter the memory mode / to turn the meter off.

Battery compartment
Remove the plastic tab under the batteries before first use.

Meter Label

Battery Lid
Open to replace batteries.

LCD Screen Display: Information and test result display

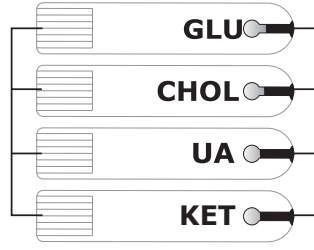


1. Result Area
2. Control Solution
3. Low Battery
4. Average (GLU)
5. Unit Icon
6. System Check, Data upload successful
7. Strip Loading Icon
8. Blood Loading Icon
9. Bluetooth on
10. Test Mode Icon
11. Memory Mode Icon
12. Code Number Icon

Alert Tones:
- Normal Alert: a short "beep"
- Warning Alert: 3 short "beeps"
- Turning On/ Off: a long "beep"

Test Strip:
GLU (GDH-FAD)- Glucose
CHOL- Total Cholesterol
UA- Uric Acid
KET- Ketone

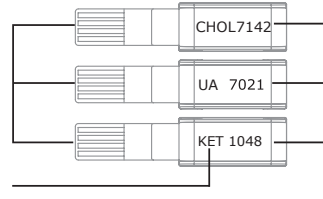
Electronic Contact Bars
Insert this end into the meter.



Sample Inlet
Touch blood drop or control solution here.

Code Strip:

Contact Bar
Insert this end into the meter.



Code

Test Mode

Labelling and Information

• Use-by date

• Manufacturer

• Do not re-use

• Keep dry

• Consult instructions for use

• *In-vitro* diagnostic medical device

• Batch code

• Date of Manufacture

• Serial number

• Keep away from sunlight

• Caution

• Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste

• Temperature limit

• Period-after-opening

• Humidity limitation

REF • Catalogue number

CE 0197 • CE Marking of Conformity

EC REP • Authorized representative in the European Community

EN

Chapter 1 Introduction

Introduction

Please read carefully before using meter kit, and consult healthcare professional before making any important medical decision. Please contact your local customer service for further assistance with the product.

Intended Use

- *In vitro* diagnostic use only.
- Measuring blood glucose in fresh capillary whole blood from fingertip, palm, or forearm/ venous blood.
- Measuring total cholesterol/ uric acid / β-Ketone in fresh capillary whole blood from fingertip.
- The meter can be used by laypersons or healthcare professionals.

Principles of the Examination Method

- Electrochemical biosensor technology.

The meter is plasma-calibrated by reference instruments, which are traceable to the following standard reference materials and methods.

Test	Standard	Method
Glucose	NIST SRM 917	Glucose Dehydrogenase
Total Cholesterol	NIST SRM 911	Abell / Kendall
Uric Acid	NIST SRM 913	Uricase / UV
β-Ketone	internal master calibrator	UV

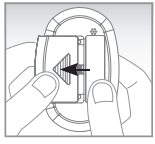
Chapter 2 Setting the Meter

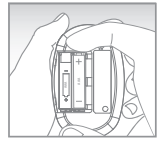
2.1 Installing/ Replacing the Batteries

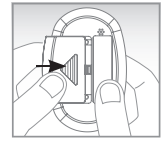
This meter uses two 1.5 V AAA batteries. This type of battery can be found in many stores. Please remove the plastic tab under the batteries before first use.

Note:

- Always have a spare set of batteries.
- Meter data is not lost when you replace the batteries.
- Remove the batteries if the meter will not be used for a long period of time.
- Dispose the batteries according to your local environmental regulations.

1 

2 

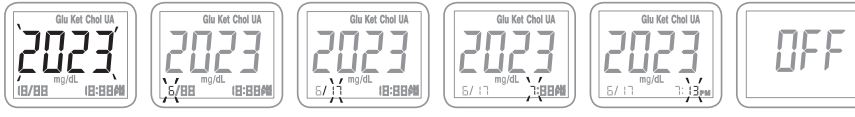
3 

2.2 Set the Date and Time

Press "S" Button (3 secs) → One "Beep" Sound → Setting Mode → Turn Off Automatically after Setting

- Setting order: Year/ Month/ Date/ Hour/ Minute
- Press "M" button to advance one unit, "S" button to enter next setting.

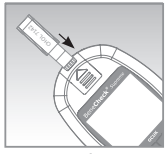
Note: Correct setting is important while managing your health records.



2.3 Code the Meter (Uric Acid/ Total Cholesterol/ β-Ketone)

- Code your meter when you first use it or open a new retail box of strips.
- Make sure the meter is off before you insert the code strip.
- Make sure the codes on screen, code strip, and strip vial label or the foil pack are the same.

1



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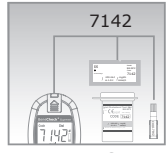
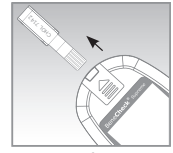


3



Note: With Auto Strip Recognition function, once you code your meter, the meter will switch to the test mode automatically when you insert a strip.

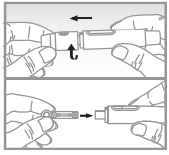
Chapter 3 How to Perform the Test

Materials you need to perform the test:
BeneCheck Meter/ BeneCheck Test Strip/ Lancing Device/ Lancets/ Tissue or Cotton Ball with 75% Ethanol or Disinfection Wipes

3.1 Perform the Test

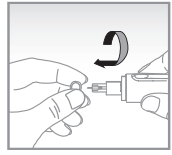
- Wash and clean your hands with disinfection wipes, and make sure your hands are dry before testing.

1



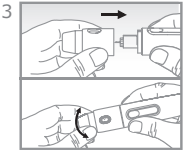
Insert lancet firmly.

2



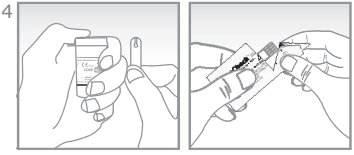
Remove and save the protective cap.

3



Recap lancing device and adjust penetration depth.

4



Take a strip and close the vial immediately.

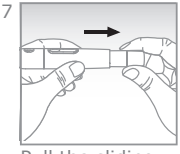
5

Insert the strip.

6

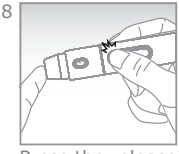
Make sure the code number is correct.

7



Pull the sliding barrel till it clicks.

8

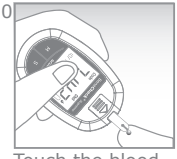


Press the release button to sample.

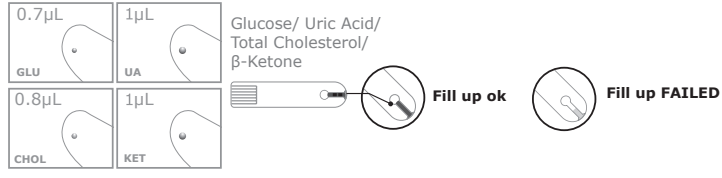
9

Wipe off first drop of blood and start sampling.

10



Touch the blood sample with strip.



Note: Insufficient fill up of blood sample could lead to inaccurate or failed test result. Do not refill the test strip.

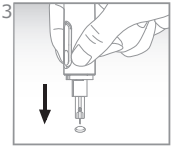
11

Result will show after countdown. Then eject the used strip to biohazard container.

12

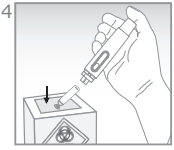
The meter will turn off automatically.

13



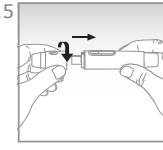
Pierce used lancet into protective cap.

14



Discard used lancet to biohazard container.

15



Recap lancing device and storage.

Note: Please refer to Lancing Device Instructions for detail procedure.

Note:

- Use only BeneCheck Supreme Glucose Test Strips, BeneCheck Supreme Total Cholesterol Test Strips, BeneCheck Supreme Uric Acid Test Strips, and BeneCheck β-Ketone Test Strips.
- Close the test strip vial tightly immediately after removing a test strip. Moisture can damage the test strips and produce incorrect results.
- Store the unused test strips in their original vial with the cap tightly closed.
- Discard the test strips if they are past the Use By date printed on the test strip vial/foil pack. If the Use By date is missing or cannot be read, do not use the test strips. contact your local distributor for service.
- Use the system for blood glucose/uric acid/total cholesterol testing at temperatures between 10–40°C and between 10–90% relative humidity. Use the system for blood β-ketone testing at temperatures between 15–40°C and between 10–90% relative humidity. Whenever the system is moved from one location to another, allow approximately 20 minutes for the system to adjust to the temperature of the new location before performing a test.

- The discard date is 6 months after you first open a BeneCheck Supreme Glucose Test Strip vial. When you first open a vial of test strips, record the discard date on the vial.
- The discard date is 3 months after you first open a BeneCheck Supreme Uric Acid Test Strip vial, a BeneCheck Supreme Total Cholesterol Test Strip vial, or a BeneCheck β-Ketone Test Strip vial. When you first open a vial of test strips, record the discard date on the vial.
- Please finish the test within 3 minutes or the meter will turn off automatically.
- The meter will not turn on if you insert the wrong end or wrong side of strip.
- Dropping, bumping or other violent impact will damage the meter or cause malfunction.
- Do not use the meter in an environment with possible magnetic, electromagnetic, and radioactive interferences.
- Do not inhale or swallow.
- Consult your healthcare professional to determine if it is appropriate for your adolescent to be taught how to use the meter system or any other medical products.
- The electromagnetic environment should be evaluated prior to operation of the device.

Warning:

- Please follow local regulations to discard used test strips and lancets.
- Used test strips, lancets and any other material that has been in contact with blood should be treated as potential biohazards.
- If user has infectious disease, the used test materials could be sources of infection.
- Lancets cannot be reused.
- Always use certified lancets to ensure safety.
- Keep the system away from children and pets.

3.2 Alternate Site Testing (AST)

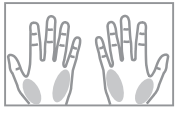
You can test your glucose from fingertip, palm or forearm. Taking blood from palm or forearm could reduce the pain, but the glucose level changes faster. These differences may cause wrong medical decision.

Note: Please consult healthcare professional before AST sampling. AST is the method only for blood glucose tests.

Suitable timing to acquire blood sample from alternate sites:
- Routinely before meal.
- Prior or 2 hours after meal/ short-acting or rapid-acting insulin analogue/ exercise.

DO NOT test from alternate sites:
- During or less than 2 hours after meal/ short-acting or rapid-acting insulin analogue/ exercise.
- When you think your glucose level is low or unaware of your low blood glucose condition.
- When you are examined for hypoglycemia or hyperglycemia.
- Your AST test result does not match your health condition.
- When you are ill, or you are operating machinery or driving a car.

Palm sampling
- No visible veins.
- Away from deep palm prints.



Forearm sampling
- Away from bones, visible veins and hair.

Sampling from an Alternative Site:

1.Repeat the steps 1-7 in Chapter 3.1.(Replace the lancing device tip with adjustable AST tip.)
2.Hold the lancing device against sampling site, and press the release button.
Keep holding the lancing device against sampling site until sufficient sample formed.
3.Then repeat steps 10-15 in Chapter 3.1.

Note:
- Sampling from fingertip if your AST test result does not match your health condition.

- Repeat puncturing the same spot may cause soreness and calluses.
- Do not squeeze the site excessively. It may take longer for sufficient blood sample to form.
- Do not use smeared blood sample, please acquire new blood sample.
- If you continue failing in getting enough blood samples, please try to get lancets in lower gauge or sample from fingertip instead.

Expected Test Result Values

Warning:
Do not change any therapy without first talking to a healthcare professional.

- The normal fasting glucose level for a non-diabetic adult is below 100 mg/dL. The normal glucose level for a non-diabetic adult 2 hours after meals is less than 140 mg/dL.
  For people with diabetes: Consult your healthcare professional for the blood glucose range appropriate for you. You should treat your low or high blood glucose as recommended by your healthcare professional.
- The normal uric acid level for a healthy male is between 3.4–7.0 mg/dL. The normal uric acid level for a healthy female is between 2.4–6.0 mg/dL.
  Consult your healthcare professional for the uric acid range appropriate for you.
- The normal total cholesterol level for a healthy adult is below 200 mg/dL.
  Consult your healthcare professional for the total cholesterol range appropriate for you.
- The normal β-ketone level for a non-diabetic adult is below 0.6 mmol/L.
  For people with diabetes: Consult your healthcare professional for the blood β-ketone range appropriate for you, and when and how you should test for β-ketone.

3.3 Sample collection and preparation by healthcare professionals

- Always follow the recognized procedures for handling objects that are potentially contaminated with human material. Practice the hygiene and safety policy of your laboratory or institution.
- Venous whole blood samples containing heparin sodium anticoagulants or preservatives are acceptable.
- To minimize the effect of glycolysis, venous whole blood glucose test need to be performed within 15 minutes of obtaining the blood samples.

Warning:
Users need to adhere to standard precautions when handling or using this device. All parts of the system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)" https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

- Wear gloves. Change gloves between patients.
- If used for testing multiple patients, the meter and lancing device must be properly cleaned and disinfected after every patient following the instructions provided in this User's Manual (see the Meter and Lancing Device Cleaning and Disinfecting section in Chapter 7.2).
- The gloves worn during cleaning and disinfection should be removed and hands washed thoroughly with soap and water before performing the next patient test.
- Dispose of used lancets and test strips in line with the disposal policy of your laboratory or institution.

Chapter 4 Meter Memory Function

- Glucose - 800 results, capable in counting 7-, 14-, 21- and 28- days average
- Total Cholesterol - 50 results
- Uric Acid - 50 results
- β-Ketone - 200 results

The latest test result will replace the oldest when the records exceed maximum memory capacity. The memories start record from M1 to M800 or M1 to M50 or M1 to M200, include test results and control solution test results.

Note: The control results are not included in the average.

Directions for Checking Memories:

No Test Strip in the Meter → Press "M" Button (3 secs) → Full Display on Screen → A Short "Beep" → Enter the Memory Mode → Press "M" Button to Switch Mode (Glu/ Ket/ Chol/ UA/) → Press "S" Button to Confirm → Press "S" Button for Next Test Record/ Press "M" Button for Previous Record → Press "M" Button (3 secs) to Turn Off

- In Glu memory mode, it will display 7-, 14-, 21-, 28- days average first.
- Once you enter one memory mode, you cannot switch. You need to turn off the meter (Press "M" button for 3 seconds) and enter the memory mode again.

Memory Records are shown as follows:

7-, 14-, 21-, 28-days average

Test Record

Control Record

Chapter 5 Control Solution Test

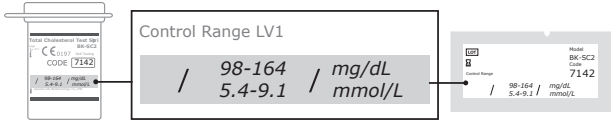
Control solution is used to check the performance of the kit.

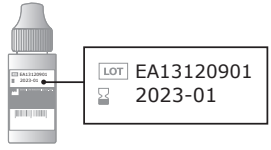
The meter kit should be check:

- When the meter and strip do not work properly.
- When the test result is unusual or inconsistent.

Control solution range is shown as follow:

Please check your strip vial label or the foil pack for exact range.





Perform a Control Test:

Insert an Unused Strip → Make Sure the Code Number is Correct (Uric Acid/ Total Cholesterol/ β-Ketone) → Press "M" Button (3 secs) → Enter Control Solution Mode (Shown cs on Screen) → Shake the Control Solution Well → Discard First Three Drops → Put One Drop onto a Clean Surface → Touch the Control Solution with Strip Sample Inlet → Test Result Display after Count Down → Compare the Result with the Range Listed on Test Strip Vial or the Foil Pack

Note:

- Use the BeneCheck III Glucose Control Solution Level 0, 1, or 2, BeneCheck Uric Acid Control Solution Level 0, 1, or 2, BeneCheck II Total Cholesterol Control Solution Level 1 or 2, and BeneCheck β-Ketone Control Solution Level 0, 1, or 2.
- Perform the control solution test at temperatures between 10–40°C and between 10–90% relative humidity.

- The discard date is 3 months after you first open a control solution vial. When you first open a vial of control solution, record the discard date on the vial.
- Do not use control solution past the Use By date or the discard date, whichever comes first.
- Do not reuse the test strip.
- Do not use the meter if the control test is out of range.
- If the control test keeps result wrongly, please contact an authorized distributor.
- Control solutions may not be included in your kit. Please contact an authorized distributor for purchasing.

Chapter 6 Transmission Function for BX-M10D

Overview

The process of creating a connection between the meter and the mobile device is called pairing. You will need an application on your mobile device that can accept the meter data. You can use this application to wirelessly receive the test results from your meter via Bluetooth. Download and install the application before pairing your meter and the compatible mobile device.

Transferring Your Single (Current) Test Result Wirelessly

1. On your mobile device: Ensure Bluetooth wireless technology is on and open the app. Follow the instructions to pair your mobile device with the meter.
2. On your meter: Locate the last 4 characters of the meter serial number on the meter label. Performing a blood glucose/uric acid/total cholesterol/β-ketone test (see the Perform the Test section in Chapter 3). When the test result appears on the display after countdown, the Bluetooth Icon appears and flashes on the display.

Note: The meter times out and stop pairing after 30 seconds once the Bluetooth Icon appears and flashes on the display.

3. On your mobile device: Within the app, look for "BeneCheck" and the last 4 characters of the meter serial number on the mobile device display to correctly identify your meter. Follow the instructions within the app to match the meter serial number. Wait for your mobile device to indicate that it is paired with your meter.
4. On your meter: After successfully pairing your meter to the mobile device, the solid Bluetooth Icon will appear on the display. Your single (current) test result will be automatically sent to the paired mobile device.

Transferring Your History Test Results Wirelessly

1. On your mobile device: Ensure Bluetooth wireless technology is on and open the app. Follow the instructions to pair your mobile device with the meter.
2. On your meter: Locate the last 4 characters of the meter serial number on the meter label. With the meter off, press and hold "M" button for 3 seconds until you hear one long beep. The meter turns on and enters the memory mode (the Memory Mode Icon will appear on the display).
3. On your meter: Press "M" button to switch Bluetooth mode (the Bluetooth Icon and "Conn" flash on the display), then press "S" button to confirm.

Note: The meter times out and stop pairing after 60 seconds once you press "S" button.

4. On your mobile device: Within the app, look for "BeneCheck" and the last 4 characters of the meter serial number on the mobile device display to correctly identify your meter. Follow the instructions within the app to match the meter serial number. Wait for your mobile device to indicate that it is paired with your meter.
5. On your meter: After successfully pairing your meter to the mobile device, the solid Bluetooth Icon will appear on the display. Your history test results will be automatically sent to the paired mobile device.

Note:

- Always check that your meter test results are the same as displayed on the paired mobile device.
- Your meter can only pair with 1 mobile device at a time.
- The meter and the mobile device to be paired should be within 5 meters of each other.

Chapter 7 Care and Maintenance

7.1 Storing Your Meter and Strip

Meter:

- Once opened, store your meter in your carrying bag whenever possible.
- Keep in a cool, dry place between 0–60°C and between 10–90% relative humidity.
- Keep away from direct sunlight and heat.
- Avoid bump or violent behavior.
- Do not disassemble the meter for any reason.

Test strip:

- Store the test strip vial/foil pack at temperatures between 4–30°C. Do not freeze. Do not store the test strip vial/foil pack in rooms where the air is humid such as the kitchen, laundry room, or bathroom.
- Store the test strip vial/foil pack between 10–90% relative humidity.
- Keep away from direct sunlight and heat.
- Do not bend, cut or fold the strips.

Control solution:

- Store the control solution vial at temperature between 10–30°C. Do not freeze.
- Keep away from direct sunlight and heat.

If you have problems with the meter, drop the meter, or think the results are not accurate, perform a control solution test with an unexpired test strip and control solution. If the control result is not within the acceptable range, contact your local distributor for service.

7.2 Meter and Lancing Device Cleaning and Disinfecting

How to Clean and Disinfect the Meter

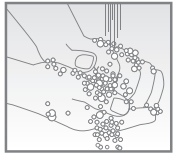
Warning: Failure to follow these instructions will damage the meter and stop it from working properly.

- Do not clean or disinfect the meter while performing a blood or control solution test.
- Do not get any moisture in test port or openings.
- Do not spray anything onto the meter.
- Do not immerse the meter in liquid.
- Always use the same product for both cleaning and disinfecting.

Supplies needed for cleaning and disinfecting:

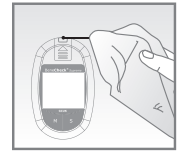
- Super Sani-Cloth® Germicidal Disposable Wipe
- Paper towels

1



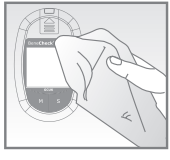
Wash hands with soap and water and dry thoroughly.

2



Turn the meter off and wipe the entire meter surface with a Super Sani-Cloth. Carefully wipe around the test port and other openings. Make sure that no liquid enters the test port or openings.

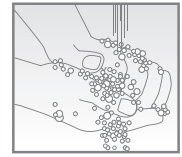
3



Dry as necessary with a clean paper towel.

4 A separate Super Sani-Cloth should be used for cleaning and disinfection. For disinfecting the meter, get a new Super Sani-Cloth and repeat step 2, making sure the surface stays wet for 2 minutes. Make sure that no solution is seen in the test port or openings.

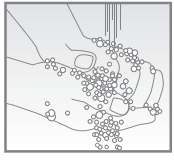
5 Dry all meter surface and test port using a clean paper towel if needed.

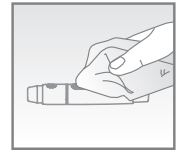
6  Wash hands with soap and water and dry thoroughly.

Note:
If you notice any of the following signs of deterioration after cleaning and disinfecting your meter, stop using your meter and contact your local distributor for service: cracked housing or lens, clouding of display, button malfunction, illegible labels, or out-of-range control results.

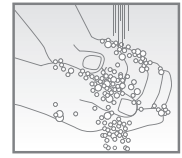
How to Clean and Disinfect the Lancing Device

Warning:
Failure to follow these instructions may damage the lancing device and stop it from working properly.
- Do not get any moisture into any openings.
- Always use the same product for both cleaning and disinfecting.

1  Wash hands with soap and water and dry thoroughly.

2  Wipe the entire surface of the lancing device and the inside of the cap with a Super Sani-Cloth.

3 A separate Super Sani-Cloth should be used for cleaning and disinfection. For disinfecting the lancing device, use a new cloth and repeat step 2, making sure the surface stays wet for 2 minutes.

4 

Wash hands with soap and water and dry thoroughly.

Note:

- Do not allow any other wet cloth or liquid.
- Make sure the meter is completely dry before use.
- Protection impairment if used in a manner not specified by the manufacturer.

Chapter 8 Error Message and Trouble Shooting

Message	Cause	Solution
	• Problem with code strip. • Problem with test strip. • Insert strip improperly.	Repeat the coding procedure (Chapter 2.3) and insert the strip again. If the problem persists, please contact local distributor for service.
	• Low battery.	Replace with new battery.
	• Problem with code strip or meter. • Insert code strip improperly.	Repeat the coding procedure (Chapter 2.3). If the problem persists, please contact local distributor for service.
	• Incorrect meter operating temperature.	Repeat the test after meter return to operating temperature. If the problem persists, please contact local distributor for service.
	• Used strip. • Damped strip.	Follow Chapter 3.1 and repeat the test with a new strip. If the problem persists, please contact local distributor for service.

	• Test incomplete due to removing the strip during measuring.	Follow Chapter 3.1 and repeat the test with a new strip. Do not remove the strip before the test is completed.
	• Improper code strip.	Repeat the coding procedure (Chapter 2.3). If the problem persists, please contact local distributor for service.
	• Sample volume not enough.	Repeat the test with a new strip, and make sure the sample volume is enough. If the problem persists, please contact local distributor for service.
	• Test result is higher than the range listed on Chapter 9.	Follow Chapter 3.1 and repeat the test with a new strip. If the problem persists, please contact local distributor for service.
	• Test result is lower than the range listed on Chapter 9.	Follow Chapter 3.1 and repeat the test with a new strip. If the problem persists, please contact local distributor for service.

Chapter 9 Specification

Test Sample	GLU: Fresh Capillary Whole Blood from fingertip, palm, or forearm/ venous blood UA/ CHOL/ β-Ketone: Fresh Capillary Whole Blood from fingertip
Measuring Time	GLU: 5 seconds; CHOL: 26 seconds; UA: 15 seconds ; β-Ketone: 10 seconds
Measuring Range	GLU: 20-600 mg/dL (1.1-33.3 mmol/L); CHOL: 100-400 mg/dL (2.59-10.35 mmol/L); UA: 3-20 mg/dL (0.18-1.19 mmol/L); β-Ketone: 0.1 - 8 mmol/L
Sample Volume	GLU: 0.7 μL; UA: 1 μL; CHOL: 0.8μL; β-Ketone : 1 μL
Storage & Transportation Condition	Meter :0-60°C(32-140°F); Strip :4-30°C(39-86°F)
Operation Temperature	Meter/GLU/UA/CHOL: 10 - 40ºC (50-104°F) KET: 15 - 40ºC (59-104°F)
Storage & Transportation Relative Humidity	10-90%
Open Vial Relative Humidity	10-90%
Memory	1,100 Test Results (GLU: 800; CHOL: 50 ; UA: 50; KET:200)
Battery Type	1.5V AAA battery * 2
Battery Life	Approximately 1,000 tests
Dimensions	95*60*20 mm
Weight	71 g (with battery)

Altitude	10,000 feet (3048 m) (700~1013 hpa)
Expected Service Life	5 years (Approximately 10,000 times)
Radio frequency connectivity (only for BX-M10D)	Bluetooth low energy technology operating in the frequency band of 2.4 GHz (2.402 GHz to 2.480 GHz) with a maximum transmitted power of 3.79 dBm (2.39 mW); Modulation: GFSK; 40 channels with 2 MHz spacing.

Note: Please refer to the strip insert for accuracy, precision, limitation, and other important information.

Bluetooth Wireless Technology (Only for BX-M10D)

The meter uses Bluetooth low energy wireless technology to communicate and transfer information. Bluetooth wireless technology is a form of radio frequency (RF) technology that operates in the unlicensed industrial, scientific, and medical band at 2.4 to 2.4835 GHz.

Electromagnetic Compatibility

Warning:

- Use of this meter in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging electrostatic discharges that may cause erroneous results.
- To avoid radio frequency interference, do not use the meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
- This equipment is designed for use in HOME HEALTHCARE ENVIRONMENT and PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- Use of this meter adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this meter and the other equipment should be observed to verify that they are operating normally.
- Use of accessories other than those specified or provided by the manufacturer of this meter could result in increased electromagnetic emissions or decreased electromagnetic immunity of this meter and result in improper operation.

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

The meter meets the electromagnetic emissions requirements as IEC 60601-1-2 and IEC 61326-2-6. Its electromagnetic emission is thus low. Interference from the meter to other electrically-driven equipment is not anticipated. In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device.

The device is intended for use in the electromagnetic environment for home and professional healthcare specified below. The customer or the user of the device should ensure that it is used in such an environment.

Manufacturer's declaration - electromagnetic emission

Emission test	Emission limits	Compliance
Radiated RF emissions CISPR 11	Group 1, Class B	Group 1, Class B

Manufacturer's declaration - electromagnetic immunity

Immunity test	Immunity test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV

Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
Radiated RF electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz

Manufacturer's declaration - electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Immunity test	Immunity test level	Compliance level
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Test frequency: 385 MHz Modulation: pulse modulation 18 Hz, 50% duty cycle Immunity test level: 27 V/m	Test frequency: 385 MHz Modulation: pulse modulation 18 Hz, 50% duty cycle Immunity test level: 27 V/m
	Test frequency: 450 MHz Modulation: FM ± 5 kHz deviation, 1 kHz sine Immunity test level: 28 V/m	Test frequency: 450 MHz Modulation: FM ± 5 kHz deviation, 1 kHz sine Immunity test level: 28 V/m
	Test frequency: 810 MHz, 870MHz, 930 MHz Modulation: pulse modulation 18 Hz, 50% duty cycle Immunity test level: 28 V/m	Test frequency: 810 MHz, 870MHz, 930 MHz Modulation: pulse modulation 18 Hz, 50% duty cycle Immunity test level: 28 V/m

	Test frequency: 710 MHz, 745MHz, 780 MHz, 5240 MHz, 5500 MHz, 5785MHz Modulation: pulse modulation 217 Hz, 50% duty cycle Immunity test level: 9 V/m	Test frequency: 710 MHz, 745MHz, 780 MHz, 5240 MHz, 5500 MHz, 5785MHz Modulation: pulse modulation 217 Hz, 50% duty cycle Immunity test level: 9 V/m
	Test frequency: 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz Modulation: pulse modulation 217 Hz, 50% duty cycle Immunity test level: 28 V/m	Test frequency: 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz Modulation: pulse modulation 217 Hz, 50% duty cycle Immunity test level: 28 V/m

Manufacturer's declaration - electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Immunity test	Immunity test level	Compliance level
Proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz IEC 61000-4-39	Test frequency: 30 kHz Modulation: CW Immunity test level: 8 A/m Dwell time: 3 s	Test frequency: 30 kHz Modulation: CW Immunity test level: 8 A/m Dwell time: 3 s

	Test frequency: 134.2 kHz Modulation: Pulse modulation 2.1 kHz Immunity test level: 65 A/m Dwell time: 3 s	Test frequency: 134.2 kHz Modulation: Pulse modulation 2.1 kHz Immunity test level: 65 A/m Dwell time: 3 s
	Test frequency: 13.56 MHz Modulation: Pulse modulation 50 kHz Immunity test level: 7.5 A/m Dwell time: 3 s	Test frequency: 13.56 MHz Modulation: Pulse modulation 50 kHz Immunity test level: 7.5 A/m Dwell time: 3 s

Federal Communications Commission (FCC) Statement (Only for BX-M10D)

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.

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.

FCC RF radiation exposure statement: (1) This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. (2) For portable operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

You are cautioned that changes or modifications not expressly approved by the party responsible for compliance (i.e., the manufacturer) could void the user's authority to operate the equipment.

Performance Analysis
Refer to the test strip package insert.

Product Safety Information

Warning:
- No modification of this meter is allowed.
- This meter meets IEC 60601-1, IEC 60601-1-11, and IEC 61010-2-101 safety standards.
- Protection impairment if used in a manner not specified by the manufacturer.
- Household electronic devices such as humidifiers, heaters, microwaves, and so on may be susceptible to cause interference with the device.

- Protection class: Internally powered device
- Meter type: Continuous operation, indoor or outdoor use
- Overvoltage category: II
- Pollution degree: 2
- IP classification: IP22
- The phone jack port on the meter is for maintenance use only.

Discarding the Meter and Batteries

Warning:
- Any product coming in contact with blood should be treated as potential biohazards.
- During normal testing, any meter may come in contact with blood.

Comply with any laws or ordinances relating to the disposal of contaminated products.
Be sure to follow your healthcare professional's recommendations or local regulations for proper disposal.
Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. Disinfect the meter before discarding. Dispose of batteries according to your local environmental regulations.

Contents of the Kit (refer to your meter outer box for exact details)

- BeneCheck Supreme Blood Multi-Monitoring Meter (GCUK) (BX-M100 and BX-M10D) (two 1.5 V AAA batteries included)
- User's Manual
- Quick Guide
- Carrying Bag
- Lancing Device
  (refer to the package insert for the outsourced supplier's manufacturer information)
- BeneCheck Supreme Glucose Test Strip* (BK-SG1)
- BeneCheck Supreme Total Cholesterol Test Strip* (BK-SC2)
- BeneCheck Supreme Uric Acid Test Strip* (BK-SU1)
- BeneCheck β-Ketone Test Strip* (BK-SK1)
- BeneCheck III Glucose Control Solution*
- BeneCheck II Total Cholesterol Control Solution*
- BeneCheck Uric Acid Control Solution*
- BeneCheck β-Ketone Control Solution*
- Lancets*
  (refer to the package insert for the outsourced supplier's manufacturer information)

* Some items may not be included in the kit but need to be purchased separately in order to use the system. Please contact your local distributor for ordering.

Note: Examine the product for missing, damaged, or broken parts after purchasing. If the

contents are damaged, please contact your local distributor immediately.

- You can contact your local distributor for warranty information.
- Hereby, General Life Biotechnology Co., Ltd. declares that the radio equipment type BX-M10D is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: http://www.glbiotech.com.tw/faq.php
- Summary of Safety and Performance (SSP) is available in the European database on medical devices (Eudamed). Please use the Basic UDI-DI "XXXXXXXXXXXXXXXXX" to search and find the intended SSP.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.