Dear BioCoach Owner

Thank you for choosing the BioCoach Blood Glucose and Ketone Monitoring System to help you easily monitor your blood glucose levels and ketone levels. This manual explains how to use your new meter. Before testing, carefully read through this manual and the package inserts that come with: BioCoach Blood Glucose Test Strips, BioCoach Blood Ketone Test Strips, BioCoach Glucose Control Solutions and BioCoach Ketone Control Solutions. Pay particular attention to listed warnings and cautions. Please keep this manual at hand for future reference.

Please visit www.biocoach.io for support. We can be reached via our online support page at anytime or call1-800-587-5496 between 8:00 am and 5:00 pm US Central Standard Time, Monday through Friday.

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Intended Use

The BioCoach Blood Glucose and Ketone Monitoring System is intended to quantitatively measure blood glucose or blood ketone in fresh capillary whole blood drawn from fingertips. The system is intended for at home 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; it should only be used by a single patient and should not be shared. It is not intended for diagnosis or screening of diabetes or for neonatal use.

IMPORTANT:

- Dehydration – Severe dehydration may lead to inaccurate blood glucose test results. If you suspect you are severely dehydrated, contact your healthcare professional immediately.
- Hematocrit range – A hematocrit range that is higher than 60% or lower than 20% can cause inaccurate 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 BioCoach blood glucose test strip within 6 months of opening test strip vial.
- Use BioCoach 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

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Limitations

- Inaccurate results may occur in:
  - Severely hypotensive individuals
  - Patients in shock
  - In a hyperglycemic-hyperosmolar state with or without ketosis
- Do not use on critically ill patients.
- Do not use on neonates
- Do not use the system above 10,335 feet (3,150 meters) in altitude.
- Do not use if hematocrit exceeds the acceptable range between 20% to 60% when testing.
- Severe dehydration (excessive water loss) may cause inaccurate results.
- For in vitro diagnostic use only.
- For over-the-counter use only
- For single-patient use only.

Warning:

• "This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens."

The following drugs do not interfere with the BioCoach system at normal or therapeutic levels. However, higher concentrations listed below were found to interfere with glucose/ketone measurements.

- If you are taking acetaminophen or acetaminophen containing drugs (for example Tylenol; at blood concentrations > 10 mg/dL) you may get inaccurate results with this system.
- If you are taking Tolbutamide at blood concentrations > 15 mg/dL, you may get inaccurate results with this system
- If you are taking Ibuprofen or Ibuprofen containing drugs as Advil at blood concentrations > 40 mg/dL, you may get inaccurate results with this system
- If you are taking Paralidoxime Iodide (PAM) or Paralidoxime Iodide (PAM) containing drugs at blood concentrations > 50 mg/dL, you may get inaccurate results with this system
- If you have a disease or condition in which uric acid levels in your blood may be elevated (>15 mg/dL), such as gout, you may get inaccurate results with this system.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate glucose results. Ask your doctor how long to wait before performing a glucose test.

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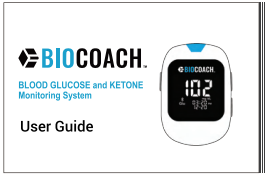
Table of Contents

Understanding Your New Blood Glucose and Ketone Monitoring System

Each BioCoach Blood Glucose and Ketone system includes the following:

Lancets

BioCoach Blood Glucose and Ketone Meter



Lancing Device

BioCoach Blood Glucose Test Strips (foil-wrapped)

BioCoach Blood Ketone Test Strips (foil-wrapped)

NOTE:

- BioCoach Blood Glucose Test Strip, BioCoach Blood Ketone Test Strip, BioCoach Glucose Control Solution, BioCoach Ketone Control Solution or sterile lancets may not be included in the kit (please check the contents on your product box or see page 87). They can be purchased separately.
- Please contact us at 1-800-587-5496 Monday through Friday from 8am to 5pm EST for purchasing information.

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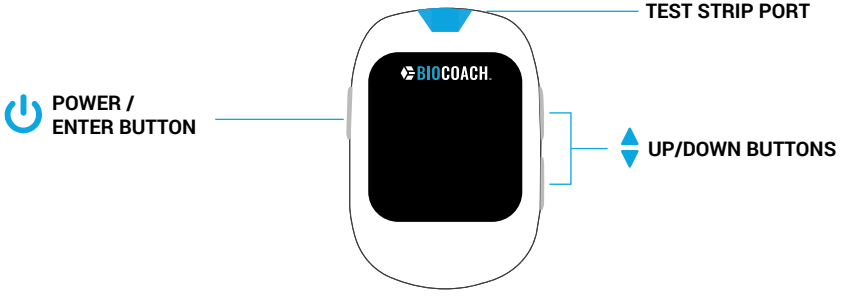
BioCoach Blood Glucose and Ketone Meter



TEST STRIP PORT

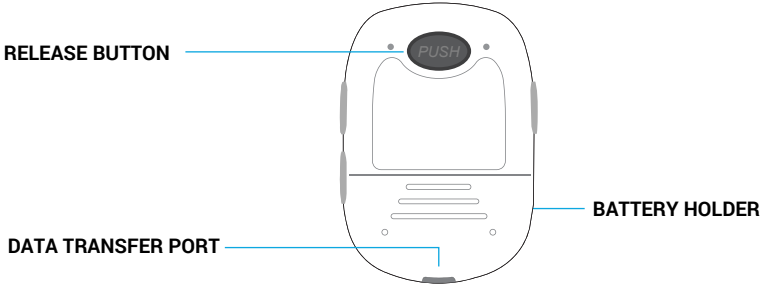
Insert the test strip here and the meter will automatically turn on.

ENTER BUTTON ⏻

To access meter memory press and hold for 2 seconds once the meter is on. To enter set up mode when not testing simultaneously press ⏻ and ▲ for 2 seconds.

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

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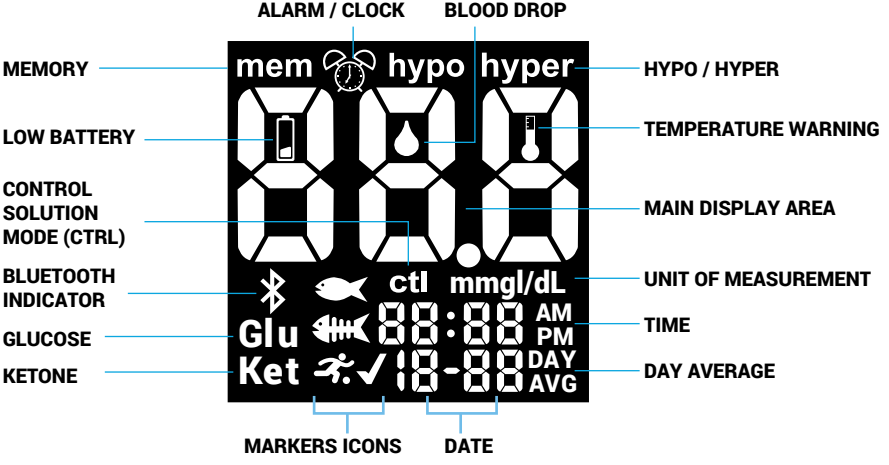
BioCoach Blood Glucose and Ketone Meter Display Screen



MEMORY
Indicates that you are using the memory.

CLOCK
Appears when setting date and time (see page 18).

ALARM
Appears when setting the alarm function (see page 21).

HYPO
- Setting up your hypoglycemic threshold value (see page 25).
- Indicates your glucose test result maybe at or below your hypoglycemic threshold value.
- Indicates the memorized result maybe at or below your hypoglycemic threshold value.

HYPER
- Setting up your hyperglycemic threshold value (see page 27).
- Indicates your test result maybe at or above your hyperglycemic threshold value.
- Indicates the memorized result maybe at or above your hyperglycemic threshold value.

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 56).

DATE
Shows the date (MM-DD format).

GLUCOSE
Appears when the value shown in the Main display area refers to glucose test results.

KETONE

- indicates value shown in the main display area refers to ketone test results
- Indicates meter is setting ketone test alert threshold.
- If blinking and displayed after glucose test, indicates a ketone measurement is suggested (see page 29).

TEMPERATURE WARNING

Indicates temperature is outside the allowed temperature range when testing.

LOW BATTERY

Appears when the battery needs to be replaced (see page 79).

CTL

Indicates meter is in control solution test mode (see pages 41 & 52).

MARKERS

Marking a test result (see page 40).


Before meal marker


After meal marker


Exercise marker


Check marker

BLUETOOTH INDICATOR

Bluetooth (BLE) icon.


Rapidly flashing icon indicates the meter's Bluetooth is on and waiting to pair.


Slowly flashing icon indicates the meter is transmitting data after pairing.


Non-flashing icon indicates the meter is waiting for instruction from mobile device after pairing.

BioCoach Blood Glucose Test Strip

CONTACT POINTS

Insert this end to the test strip port on the meter.

SAMPLING END

Apply blood or control solution.

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 be assured that every reading is an accurate and meaningful result.

IMPORTANT:

- The BioCoach Glucose Test Strip is sensitive to moisture and light.
- 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 BioCoach Glucose Test Strip with the BioCoach Blood Glucose and Ketone Meter. Other brands of test strips will not work with the meter.

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BioCoach Blood Ketone Test Strip

CONTACT POINTS

Insert this end to the test strip port on the meter.

SAMPLING END

Apply blood or control solution.

BioCoach 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 be assured that every reading is an accurate and meaningful result.

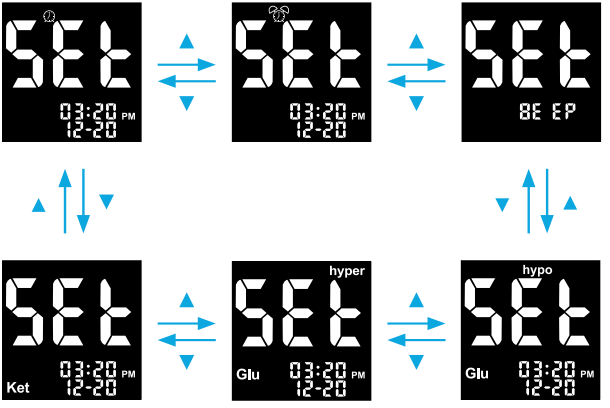
IMPORTANT:

- The BioCoach Blood Ketone Test Strip is sensitive to moisture and light
- 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 BioCoach Blood Ketone Test Strip with the BioCoach 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.



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Setting The Clock

Material you will need:
Your BioCoach Blood Glucose and Ketone Meter

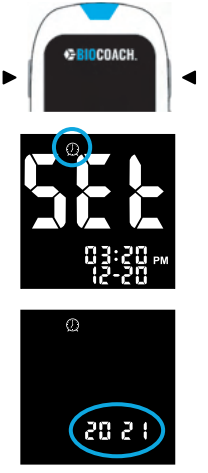
BEGIN SET UP

STEP 1:
With the meter off pres ⏻ and ▲ similtaneously 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.

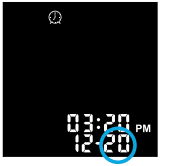


SET MONTH

STEP 4:
The current hour will flash. Press ▲ or ▼ to select the correct month.
Press ⏻ to confirm your choice and advance to set the day.

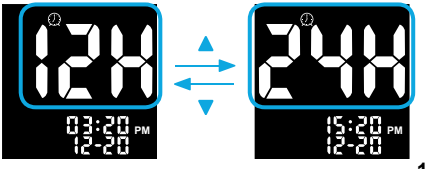
SET DAY

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.



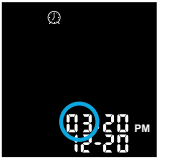
SET 12-HOUR OR 24-HOUR TIME FORMAT

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. The meter will then return to the settings menu.

Begin testing by inserting a BioCoach Blood Glucose Test Strip (see Testing Your Blood Glucose on page 33), BioCoach Blood Ketone Test Strip (see Testing Your Blood Ketone on page 46), press and hold to turn off the meter, or continue to set up the alarm feature on your meter.

IMPORTANT:

1. If you do not set the date and time on the BioCoach 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 BioCoach 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 BioCoach 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 inserting a test strip will silence the alarm.

Material you will need:
Your BioCoach Blood Glucose and Ketone Meter.

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

STEP 1:
In the settings menu 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.

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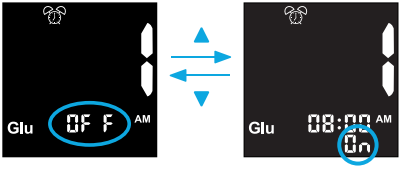
STEP 3:
The display will show alarm 1 status (the default setting is OFF). You can turn it on by pressing ▲ or ▼ Press ⏻ to confirm the selection and move on to the next step.



STEP 4:
Press ▲ or ▼ to select the hour. Press ⏻ to confirm the selection.

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 33, see Testing Your Blood Ketone on page 47 or Control Solution Testing on page 42 & 51), press and hold ⏻ to turn off the meter, or continue to set up the beeper on your meter.

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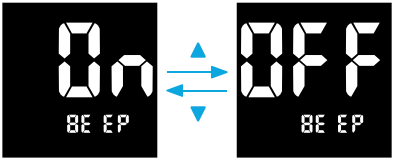
BEEPER SETUP

The beeper on your BioCoach Ketone Glucose Meter is preset to ON. You can adjust the beeper feature as follows.

STEP 1:
Select BEEP BE EP and Press ⏻ to enter beeper setup.



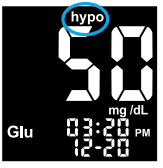
STEP 2:
Press ▲ or ▼ to turn on/off the tone.

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 BioCoach 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.



(Example)

HYPO (hypoglycemia) warning

(Example)

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.

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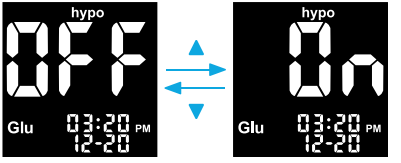
The BioCoach Blood Glucose and Ketone Meter comes with hypo/hyper warning OFF as preset, and the preset threshold value is 200 mg/dL (11.1 mmol/L) for hyper and 70 mg/dL (3.9 mmol/L) for hypo.
Follow the steps below to adjust the hyper and hypo threshold values.

Material you will need:
Your BioCoach Blood Glucose and Ketone Meter

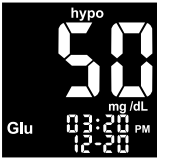
SET HYPO

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.



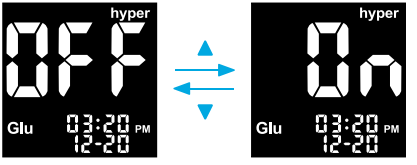
NOTE:

- Default blood glucose threshold value setting and setting ranges are described below:
  Hypoglycemia warning
  Factory Default: 70mg/dL
  Setting Range: 20~190mg/dL

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.

NOTE:

- Default blood glucose threshold value setting and setting ranges are described below:
  Hyperglycemia warning
  Factory Default: 200mg/dL
  Setting Range: 80~590mg/dL

Ketone Flag setup

Your BioCoach Blood Glucose and Ketone Meter has an additional feature that allows you to set a blood glucose threshold as a reminder for blood ketone testing. When the Ketone Flag 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 flag 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 BioCoach Blood Glucose and Ketone Meter is preset to OFF.
You can set up the Ketone Flag threshold value as follows:

Material you will need:
Your BioCoach Blood Glucose and Ketone Meter

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STEP 1:
Press ▲ or ▼ until the meter display screen shows “Ket” and Press ⏻ to enter Ketone Flag setup.

STEP 2:
Press ▲ or ▼ to turn the Ketone Flag ON/ OFF.

STEP 3:
Press ⏻ to set the blood glucose threshold value (if Ketone Flag 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:

Default blood glucose threshold value setting and setting ranges are described below:

Ketone Flag

The glucose value for this Ketone Flag is pre-set at 250 mg/dL as a default but can be set within the range of 210 - 600 mg/dL when you select to turn off hyper glucose warning (please refer to page 28 on how to turn on/off and setup hyper warning). If you select to turn on hyper glucose warning, the glucose range that you can set will be automatically adjusted by the meter software.

For example, you set your meter to give a hyper glucose warning for glucose test results higher than 250 mg/dL, then you can select a glucose level between 260 – 600 mg/dL to trigger a reminder to test your blood ketone. If you set the hyper glucose threshold at 300 mg/dL according to the instructions on page 28, you can only select a trigger threshold between 310 and 600 mg/dL.

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Before Testing

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.

  Temperature: 50°F to 104°F
  Relative Humidity: 20 to 90%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.);
- Keep the meter out of the reach of children. Coin batteries may represent a choking hazard. Consult a physician immediately if coin battery is swallowed.
- 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 thermosensor is housed inside the meter to minimize any errors.
- 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.
- This meter must not be co-located or operating in conjunction with any other antenna or transmitter.

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CAUTION WHEN USING THE TEST STRIPS

CAUTION:

- For testing with BioCoach Blood Glucose and Ketone Meter use BioCoach Blood Glucose Test Strip or BioCoach Blood Ketone Test Strip only. Do not use other brand test strips, it causes inaccurate test results.
- Do not use test strips after their expiration date. The expiry date is either written on the test strip vial or on the foil pouch.
- 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 / Ketone test
  Temperature: 50°F to 104°F;
  Relative Humidity 20 to 90% 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 BioCoach Blood Glucose and Ketone Meter
- A new BioCoach Blood Glucose Test Strip
- Lancing device with a sterile, unused lancet

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.
Soap is important because it removes oils on your hands that inhibit the formation of a blood drop bubble.

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.

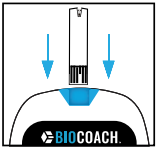
TIP:
To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

PERFORMING A BLOOD GLUCOSE TEST

Visit www.biocoach.io for a video tutorial

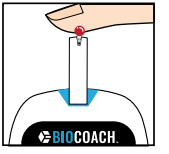
STEP 1:

Insert a new BioCoach 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 (33.3mmol/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 Flag

- 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 37. Then, conduct a glucose control test to check that the system is working properly (page 41). 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'srecommendation 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 ⏻ 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 BioCoach Blood Glucose and Ketone Meter and the BioCoach Blood Glucose Test Strip is working properly.

You should perform control solution testing when:

- You suspect the meter or BioCoach Blood Glucose Test Strips 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 BioCoach Blood Glucose Test Strips 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 BioCoach blood glucose test strip only use the BioCoach Glucose Control Solutions (provided separately). Other brands of control solution will produce inaccurate result.
- Do not use the BioCoach Ketone Control Solutions for testing the BioCoach Blood Glucose Test Strip: erroneous results would be obtained. If the control reading is not within the acceptable

range on the glucose test strip vial, please retesting with a new glucose test strip using the BioCoach glucose control solution.

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: 50 to 104 °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.

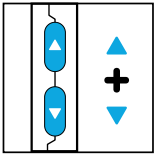
PERFORMING A GLUCOSE CONTROL SOLUTION TEST

You will need:

- BioCoach glucose control solution (L1 and L2)
- Your BioCoach Blood Glucose and Ketone Meter
- A new BioCoach Blood Glucose Test Strip

STEP 1:
Insert a new BioCoach 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 for the drop icon to start blinking.

STEP 2:
Enable the CTL mode by pressing the up and down (▲/▼) buttons simultaneously.



IMPORTANT:

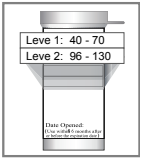
- If the CTL mode has not been enabled before performing the control solution test, the result will be stored as a blood test and used for calculating averages.
- Always enable the CTL mode before conducting a control solution test for accurate control test results. To enable the CTL mode, simultaneously press the UP/DOWN (▲ /▼) buttons for two seconds when 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 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 BioCoach Blood Glucose Test Strip box or the BioCoach Blood Glucose Ketone Meter kit box. Make sure you compare the range from the box the strip came in. 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 BioCoach customer service.

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.

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.

BIOCOACH™

Testing Your Blood Ketone Level

You will need:
- Your BioCoach Blood Glucose and Ketone Meter
- A new BioCoach Blood Ketone Test Strip
- Lancing device with a sterile, unused lancet

PREPARING YOUR LANCING DEVICE

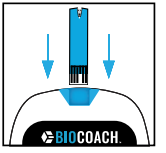
For information on how to use the lancing device, read the relevant instructions for use.

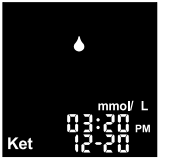
CAUTION:
- Wash the puncture site with soap and water and dry the site thoroughly before sampling blood.
- The lancets are for single use only. Always use a new, sterile lancet each time you perform the test.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets 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 BioCoach Blood Ketone Test Strip is not intended for alternative site testing (AST). Use only fresh capillary whole blood from your fingertip for testing.

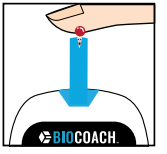
PERFORMING A BLOOD KETONE TEST

Visit www.biocoach.io for a video tutorial





STEP 1:
Insert a new BioCoach Blood Ketone Test Strip (light blue color) into the test strip port to turn the meter on. 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.

CAUTION:

- 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 strip. If the reading is still high, contact your doctor or healthcare professional immediately. LO 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.

BIOCOACH™

Ketone Control Solution Testing

The purpose of the ketone control solution testing is to make sure the BioCoach Blood Glucose and Ketone Meter and the BioCoach Blood Ketone Test Strip is working properly.

Conduct a control test if:

- You suspect the meter or BioCoach 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
- Anytime you want to check the performance before a blood ketone test

NOTE:

- To test your meter and BioCoach Blood Ketone Test Strip only use the BioCoach Ketone Control Solutions (provided separately).
- Do not use the BioCoach Glucose Control Solutions for testing the BioCoach Blood Ketone Test Strip: erroneous results would be obtained. If the control reading is not within the acceptable range on the ketone test strip foil pouch, please retesting with a new ketone test strip using the BioCoach Ketone Control Solution.

CAUTION:

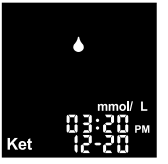
- Do not use control solutions after their expiration date. The expiration date is indicated on the control solution vial.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution three months after opening.
- For accurate test results, allow the control solution to adjust to its surroundings for at least 30 minutes before running the control test:
  Temperature: 50 to 104 °F;
  Relative Humidity: 20-90% 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.

BIOCOACH™

PERFORMING A KETONE CONTROL SOLUTION TEST

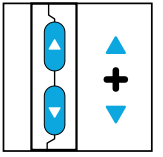
You will need:
- BioCoach Ketone Control Solution (L1 and L2)
- Your BioCoach Blood Glucose and Ketone Meter
- A new BioCoach Blood Ketone Test Strip

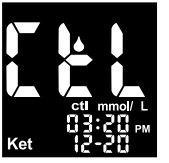
STEP 1:
Insert a new BioCoach Blood Ketone Test Strip (light blue color) into the test strip port to turn the meter on. The drop icon will blink on the screen and the ketone icon "Ket" will be shown at the bottom left hand corner of the display. Make sure the test strip contact points are inserted all 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.



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

STEP 2:
Enable the CTL mode by simultaneously pressing the UP/DOWN (▲/▼) buttons for two seconds when the drop icon is blinking on the screen.



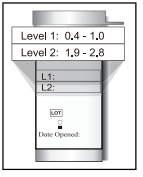


STEP 3:
Gently shake the control solution vial before testing. Discard a drop before use. Squeeze a drop of control solution (Level 1 or Level 2) onto a clean, hard, dry nonabsorbent surface. Do not apply control solution to the test strip directly from the bottle. Replace the bottle cap on the control 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 BioCoach 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 BioCoach 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.If the time and date settings are not correct the meter will memorize the test results assigning them wrong time and date.

REVIEWING PAST GLUCOSE 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).

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 “Glu” icon will blink).

STEP 3:
Press ⏻ to enter 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.

STEP 4:
Press ▲ or ▼ to scroll through all the stored data.

STEP 5:
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 RESULT AVERAGES

STEP 6:
Follow steps 1, 2 and 3.
Press ⏻ to enter the average mode (the “avg” icon appears on the screen).

STEP 7:
The 1-day average appears on the screen. Press ⏻ to scroll through the averages.

STEP 8:
After reviewing the 90-day average, press ⏻ to return to the memory recall mode.

STEP 9:
Hold ⏻ for 3 seconds to switch the meter off.

NOTE:

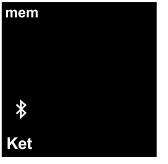
- If there are less than 2 results in the memory for the averaged period, the screen displays “ooo“. If there are no results, the screen displays “ooo“.
- The averaging function equalizes HI results to 600 mg/dL (33.3 mmol/L) and LO results to 20 mg/dL (1.1 mmol/L).

REVIEWING PAST KETONE 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

BIOCOACH™

Data transmission

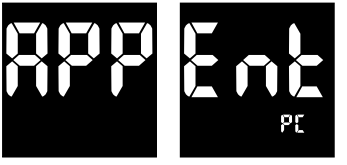
Test results stored in the BioCoach Blood Glucose and Ketone Meter's memory can be transmitted to your personal computer or mobile devices.

UPLOAD DATA VIA USB

Material you will need:
- Your BioCoach Blood Glucose and Ketone Meter
- Micro USB cable (not included)
- Data Management System (DMS) from BioCoach

STEP 1:
Insert a micro USB cable into the data port to transmit stored readings to computer. Follow the Data Management System (DMS) instruction manual to upload data. For purchase information of DMS, please contact BioCoach customer service.

STEP 2:
Open APP in computer 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 only be used with DMS products that specifically identify the BioCoach 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 BioCoach customer service.
- The Data Management System (DMS) and dedicated micro USB cable are sold separately, please contact BioCoach customer service for purchase information.
- No button and strip functions are 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.
- BioCoach Blood Glucose and Ketone Meter can only transfer memory data, it will 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 the BioCoach app on your mobile device in order to transfer the meter's data. You can use this application to wirelessly and selectively syncronize your test information between the meter and the mobile device.

Material you will need:
- Your BioCoach Blood Glucose and Ketone Meter
- A mobile device with Bluetooth
- The BioCoach app from the App Store or Google Play

FOR UPLOADING A GLUCOSE / KETONE / CONTROL SOLUTION TEST

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

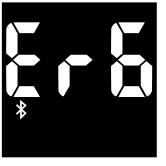
STEP 2:
To make a Bluetooth transfer, open the app on your mobile device and follow the app instructions to pair the meter. The screen will show "Ent" and the Bluetooth icon will flash.

STEP 3:
Press ⏻ to pair with your mobile device.

STEP 4:

- When pairing is complete, the Bluetooth icon will stop flashing. Then the meter's screen will show "Ent" and Bluetooth icon.

- If pairing fails, Er6 is displayed on the screen of the meter. See page 75 to solve problems .



BLE transmission

STEP 5:

- Press ⏻ to confirm data transmission. Meter will start sending data to mobile device.
- If data transmission via Bluetooth fails, Er7 is displayed on the screen of the meter
  See page 75 to solve problems.

STEP 6:

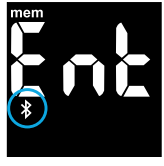
After the data transfer is complete, turn off the meter or it will automatically turn off after 1.5 min of inactivity.

UPLOADING READINGS FROM THE MEMORY (GLUCOSE/KETONE)

STEP 1:

Follow the steps beginning on page 55 to view stored readings in the memory.

PAIRING



STEP 2:

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

The screen will show “Ent” and the Bluetooth icon shall be flashing on the meter.

STEP 3:
Press ⏻ to pair with your mobile device.

STEP 4:
- When pairing is complete, the Bluetooth icon will stop flashing. Then the meter's screen will show "Ent" and Bluetooth icon.

- If pairing fails, Er6 is displayed on the screen of the meter. See page 75 to solve problems.

BLE TRANSMISSION

STEP 5:
- Press ⏻ to confirm data transmission. Meter will start sending data to mobile device.
- If data transmission via Bluetooth fails, Er7 is displayed on the screen of the meter. See page 75 to solve problems.

NOTE:
- You need to install the BioCoach app to transfer data via Bluetooth to 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 32ft.
- BioCoach Blood Glucose and Ketone Meter can only transfer memory data, it will not accept or upload data.
- If the Bluetooth transmission function fails, the screen will display Er5, please contact BioCoach customer service.

WARNING:
- Data transmission via Bluetooth may decrease battery life.
- DO NOT pair another person's meter with your mobile device. To pair the mobile device with your meter, following the steps of Upload data via Bluetooth.

Quality of service for the wireless connectivity for data downloading

Acceptable latency: 4 seconds
Max throughput: low speed; 21kbps
Acceptable level of probability for loss of information within the network: probability is 0%
Accessibility / signal priorities of the network: only Bluetooth is available
Data integrity: check sum function for transmitting and receiving packets

Caring for the Meter

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

NOTE:

- Do not get water inside the BioCoach 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 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 the devices.

A cleaning process using a Clorox Healthcare Bleach Germicidal wipe must be performed before each disinfection step. Disinfection is the removal of bloodborne pathogens as a way to reduce your exposure to disease.

Your meter and lancing device are validated to withstand cleaning and disinfection cycle of once per day for an average period of five years (260 cleaning cycles and 260 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 are available through major retailers online, please refer to page 71 need to check page number for purchase information.

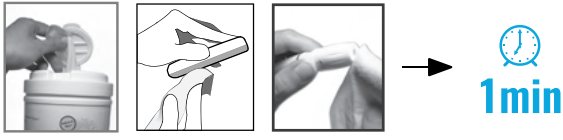
We recommend cleaning and disinfecting the meter and lancing device once per week.

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.

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 miute at room temperature, wipe all external surface with a fresh Clorox Healthcare Bleach Germicidal Wipe.

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.



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 1-800-587-5496 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 questions about cleaning and disinfecting the meter, please contact customer service at 1-800-587-5496 Monday through Friday from 8am to 5pm US Central Standard Time.

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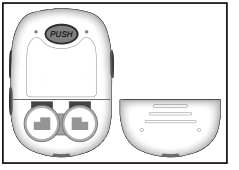
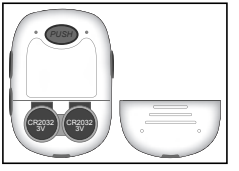
Changing the Batteries

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 BioCoach 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.

WARNING:

- 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.

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Storage and Precautions

- 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/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.
- There are no risk or electromagnetic disturbance to operate the meter around the common RF emitters (e.g. electromagnetic anti-theft systems or metal detectors) in the home environment.
- 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

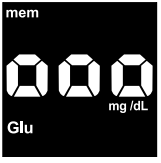
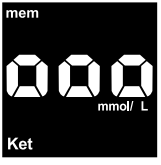
This section details the display screen messages and error codes you may encounter when using your BioCoach Blood Glucose and Ketone Meter and BioCoach Blood Glucose Test Strips or BioCoach Blood Ketone Test Strips.

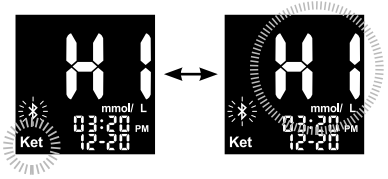
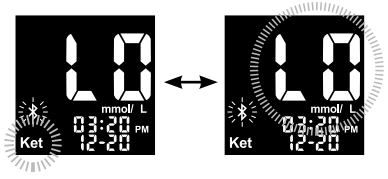
Message	What It Means	What You Should Do
	Damaged meter electronic or test strip	• Replace the batteries and turn on the meter again. • Remove the test strip and insert a new test strip again. • If problem persists, call us at 1-800-587- 5496 Monday through Friday from 8am to 5pm US Central Standard Time.
	Used or contaminated test strip	• 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. * Note: You cannot add more blood to a test strip if you did not get enough on the first try.

Message	What It Means	What You Should Do
	Not enough sample on the test strip to start	• Remove the test strip and repeat the test with a new test strip. See Testing Your Blood Glucose (page 34) or Testing your Blood Ketone Levels (page 48). • See quick start guide for tips on how to get a larger blood sample. • See getting started video on YouTube to see blood collection procedure.
	Removed test strip during countdown	• Turn off the meter and repeat the test with a new test strip.
	Meter fails in Bluetooth status check	• Replace the batteries and turn on the meter again. • If problem persists, call us at 1-800-587- 5496 Monday through Friday from 8am to 5pm US Central Standard Time.

Message	What It Means	What You Should Do
	Bluetooth pairing failed	• Check Bluetooth device is working well and repeat attempt to pair device.
	Data transmission via Bluetooth failed	• Remove USB cable from data transmission port.
	Bluetooth disconnection between meter and mobile device occured during transmission procedure.	• Check Bluetooth device is working well and repeat confirm to pairing and data transmission.

Message	What It Means	What You Should Do
	Temperature out of range	• Move the meter into an area that is within recommended range, and allow 30 minutes for it to reach the new temperature.
	Glucose test result higher than 600 mg/ dL(33.3 mmol/L)	• 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.
	Glucose test result lower than 20 mg/dL (1.1 mmol/ L)	• 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.

Message	What It Means	What You Should Do
	Low battery	• Change the batteries by following the instructions on page 72.
 	No memorized results in the meter	• Check if the date and time on your meter is set up. See Setting Up Your New System on page 17. • Start testing your blood glucose, see Testing Your Blood Glucose on page 33. • Start testing your blood ketone, see Testing Your Blood Ketone on page 46.

Message	What It Means	What You Should Do
	The flashing Ket icon and “HI” reading alternately mean Ketone test result is higher than 8 mmol/L	• 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.
	The flashing Ket icon and “LO” reading alternately icon mean Ketone test result is lower than 0.1 mmol/L	• Wash and dry your hands and repeat the test on your fingertip with a new ketone test strip. If the result is still “LO”, contact your physician or healthcare professional immediately.

Understanding Your Blood Glucose Test Results

Blood glucose values vary due to 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 41.
- 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
  - Patients in shock
  - In a hyperglycemic -hyperosmolar state with or without ketosis
- Do not use on critically ill patients.

American Diabetes Association, Standard of Medical Care in Diabetes 2020, Vol. 43 (Suppl.1).

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Understanding Your Blood Ketone Test Results

Ketones are made when not enough insulin is available to use glucose for energy and the body begins to use fat for energy instead. It is a warning sign that your diabetes is out of control or that you are getting sick[1].

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

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 oss, 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 50.
- 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 severe hypotension, severe dehydration, shock, or a hyperglycemic-hyperosmolar state.

1. Tietz Clinical Guide to Laboratory Tests 4th Edition

BIOCOACH™

Product Warranty

AmVentureX. Inc. warrants the BioCoach 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 BioCoach is limited to repair or replacement and in no event shall BioCoach 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 BioCoach's authorized dealer responsible for the sale of the system. The warranty applies only to the original purchaser of the system.

Specifications

Test Strips:	BioCoach Blood Glucose Test Strip BioCoach 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:	20~60% for glucose / 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 700 tests.
Operating Temperature:.....10˚C~40˚C (50 to 104°F) for glucose / ketone test
Operating Relative Humidity:.....20~90% for Glucose and 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 or error messages Err2, Err3, Err4, HI and LO.
- After 5 seconds for Error messages Err1, Temperature icon and Battery icon.

Test strip Storage Conditions for Glucose and Ketone:
- Temperature:4 to 30°C (39 to 86°F)
  Relative Humidity: 10 to 85%

Meter Storage and Transport Conditions
- Temperature: -20 to 50°C (-4 to 122°F);
  Relative Humidity: 20 to 90%.
  Radio Frequency Technology: Bluetooth 5
  Radio Frequency Band: 2.4 GHz–2.483 GHz
  Maximum Radio Transmitter Power: 4 dBm
  Security Encryption: 128-bit AES (Advanced Encryption Standard) CCM, ECB,AAR
  Electromagnetic Compatibility (EMC):
  The BioCoach Blood Glucose and Ketone meter complies with the electromagnetic requirements specified in IEC 60601-1-2 Edition 4.0. Electromagnetic emissions are low and unlikely to interfere with

other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the BioCoach meter.

For additional information, refer to the BioCoach Blood Glucose Test Strip insert and BioCoach Blood Ketone Test Strip insert.

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BioCoach Blood Glucose and Ketone Monitoring System Contents

Confirm that the system contains the following items:

Product Type	Meter	Lancing	Lancet Device	Blood Glucose Strips	Blood Ketone Strips
Kit	V	V	V	V	V

Suggested Representation of Accuracy for Home Use by Lay-Users

The BioCoach Blood Glucose and Ketone Meter result may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology. **The chart below shows the results of a study where 350 typical users used the BioCoach Blood Glucose and Ketone Meter to test their blood glucose level. The following accuracy results were obtained.**

Difference range in between the true blood glucose **level and BioCoach Blood Glucose and Ketone meter**	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Number (and percent) of fingertip samples within specified range	153 / 350 (43.7%)	317 / 350 (90.6%)	350 / 350 (100%)	350 / 350 (100%)

The BioCoach Blood Glucose and Ketone Meter result may vary slightly from your actual blood ketone value. This may be due to slight differences in technique and the natural variation in the test technology. **The chart below shows the results of a study where 100 typical users used the BioCoach Blood Glucose and Ketone Meter to test their blood ketone level. The following accuracy results were obtained.**

Table 1: System Accuracy Results for Ketone concentration <1.5 mmol/L

Difference range in between the true blood ketone level **and BioCoach Blood Glucose and Ketone meter**	**Within ± 0.15 mmol/L**	**Within ± 0.225 mmol/L**	**Within ± 0.30 mmol/L**
Number (and percent) of fingertip samples within specified range	**76/90 (84.4%)**	**87/90 (96.7%)**	**90/90 (100%)**

Table 2: System Accuracy Results for Ketone concentration >1.5 mmol/L

Difference range in between the true blood ketone **level and BioCoach Blood Glucose and Ketone meter**	**Within ± 10%**	**Within ± 15%**	**Within ± 20%**
Number (and percent) of fingertip samples within specified range	**8/10 (80%)**	**9/10 (90%)**	**10/10 (100%)**

BIOCOACH™

Federal Communications Commission Interference Statement

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.

RF exposure warning

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment. The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.

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.

The meter meets the electromagnetic compatibility requiremwnts as Per IEC 60601- 1-2:2014

Guidance and manufacturer's declaration - electromagnetic emissions		
Test	**compliance**	**Electromagnetic Environment - Guidance**
Conducted and Radiated emission EN 55011	Group 1 Class B	The BioCoach Blood Glucose and Ketone meter must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2	Class A	The BioCoach Blood Glucose and Ketone meter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The BioCoach meter is internally powered by a lithium coin cell CR2032.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15kV air	±8 kV contact ±2, ±4, ±8, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
RF Radiated susceptibility IEC 61000-4-3	10 V/m at frequencies up to 80~2700MHz, 80% AM	10 V/m at frequencies up to 80~2700MHz, 80% AM	The BioCoach with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2:2014, for residential, commercial and light industry environments. Portable and mobile RF communications equipment should be used no closer to any part of the machine, including cables, than the recommended 10 cm separation distance. The BioCoach has been designed to meet EMC standards. However, should you suspect that the machine performance (eg, pressure or flow) is affected by other equipment, move the machine away from the possible cause of interference. The BioCoach complies with Part 15 of the FCC Rules.
RF Conducted susceptibility IEC61000-4-6	3 Vrms 6 Vrms for ISM bands 0.150 MHz to 80 MHz	3 Vrms 6 Vrms for ISM bands 0.150 MHz to 80 MHz	

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
			FCC ID: 2A3RYS84102. Operation is subject to the following two conditions: This machine may not cause harmful interference,and this machine must accept any interference received, including interference that may cause undesired operation. Recommended separation distance: d = 1.17 √P d = 1.17 √P 80 MHz to 800 MHz d = 2.33 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strenghts from RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: a 

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
			Field strengths from fixed transmitted, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in the location due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BioCoach is used exceeds the applicable RF compliance level above, the geko™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the geko™ b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
Electrical fast transient/burst IEC 61000-4-4	±2 kV for input/ output lines	±2 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.