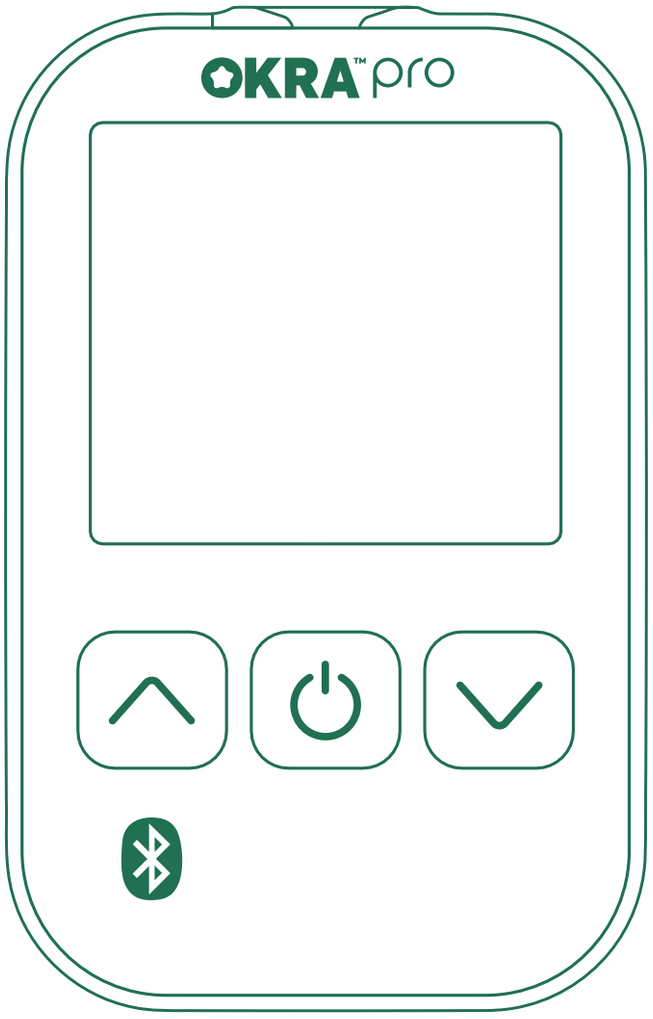
06 User Manual



OKRA™

Blood Glucose
Monitoring System

Instuctions for Use

Dear OKRA Pro Blood Glucose Monitoring System Owner,

Thank you for choosing OKRA Pro Blood Glucose Monitoring System. This manual contains everything you need to know about your new glucose meter and how it works. Please take a moment to read the instructions carefully.

We understand that self-testing of blood glucose level provides a way to control your diabetes and may give you peace of mind by testing regularly. The OKRA Pro Blood Glucose Monitoring System has been developed to provide you with a fast and accurate reading by a convenient and simple process. Our goal with the OKRA Pro is to provide the best quality healthcare products coupled with superior customer service. Always consult with your Healthcare Professional before making any changes to your diabetes management program. The OKRA Pro Blood Glucose Monitoring System is for in vitro diagnostic use only.

OKRA Pro Customer Support is available Monday thru Friday,9 to 5pm Eastern Time.

Please call toll free	(833-977-1339)
Email	support@okra.care
Website	www.okra.care

Intended Use

The OKRA Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The OKRA Pro Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The OKRA Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The OKRA Pro Test Strips are for use with the OKRA Pro Meter to quantitatively measure glucose in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh.

The OKRA Pro Control Solutions are for use with the OKRA Pro Meter and OKRA Pro Test Strips to check that the meter and test strips are working together properly and the test is performing correctly.

Important Information

The OKRA Pro Blood Glucose Monitoring System provides a quick and easy way for patients with diabetes to measure their blood sugar levels.

It should only be used with fresh capillary whole blood samples. It is designed for in-vitro diagnostics use only and should not be used for any purpose other than monitoring blood sugar levels. It should not be used for the diagnosis of diabetes or for the testing of newborns (neonates).

WARNING:
Do not change your medication based on the OKRA Pro meter test results without contacting your Physician or Healthcare Professional.

Important Safety Instructions

The Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) have become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other bloodborne pathogens to people undergoing finger stick procedures for blood sampling. For instance, people with diabetes who require assistance monitoring their blood glucose levels.

Reports of HBV infection outbreaks linked to diabetes care have been increasing. This notice serves as a reminder that finger stick devices should never be used for more than one person.

WARNING:

1. The OKRA Pro meter and the reusable lancing device are for single patient use only. Do not share them with anyone including other family members. Do not use on multiple patients.

2. All parts of the kit are considered bio-hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

3. Always use a new, sterile lancet. Lancets are for single use only.

4. Please refer to page 46 and 51 for cleaning and disinfecting the OKRA Pro Blood Glucose Monitoring System.

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication Update 11/29/2010"

http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm 224025.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

Cautions and Safety Information

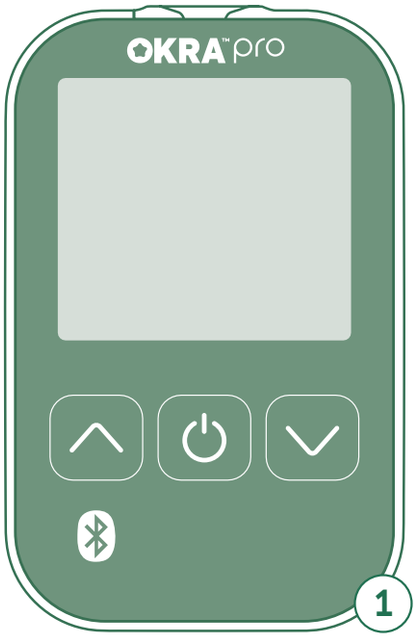
1. For in vitro diagnostic use only.
2. The single-patient use system is for single-patient use only and should not be shared
3. Not for neonatal use.
4. Do not use for diagnosis of or screening for diabetes mellitus.
5. Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients.
6. Alternative site testing (AST) should only be performed during periods of steady-state blood glucose conditions (when glucose is not changing rapidly).
7. AST should not be used to calibrate continuous glucose monitors (CGMs).
8. AST should not be used for insulin dose calculations.
9. Avoid getting hand lotions, oil, dirt or debris in and/or on the lancets, reusable lancing device and test strips.
10. Do not use OKRA Pro glucose meter in a dry environment.
11. Practice using the lancing device and become accustomed with its use.
12. Wash your hands with warm clean water and soap before testing.

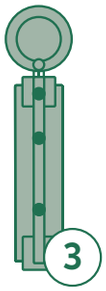
13. Dry your hands completely before testing.
14. Avoid testing in direct sunlight to receive more accurate test results.
15. Store the OKRA Pro test strip vials in a cool, dry place. Keep out of direct sunlight. Do not freeze.
16. Store the test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
17. Immediately replace the vial cap and close tightly after removing any test strips from the vial.
18. Make a note of the discard date, which is three months from the date you first open a new vial of strips. Throw OKRA Pro test strips and vial away after the discard date.
19. Do not use the test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
20. OKRA Pro test strips are for single use only. DO NOT RE-USE.
21. Do not test at temperatures below 50°F(10°C) or above 104°F(40°C).
22. Do not test with humidity below 10% or above 90%.
23. Do not bend, cut, or alter the test strips.
24. Avoid getting dirt, food, and water on the color-coding label (backside of test strip).
25. Refer to additional information in the OKRA Pro test strip package.

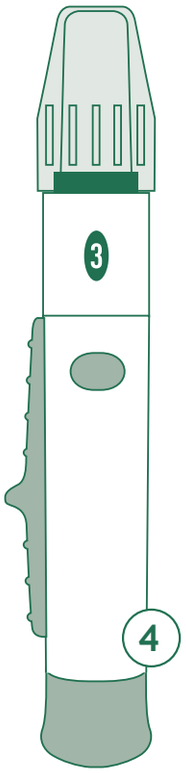
Table of Contents

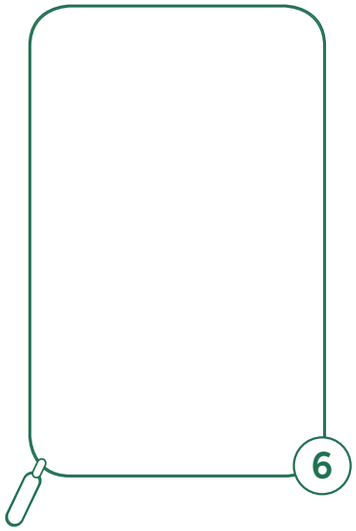
About your New OKRA Pro Blood Glucose Monitoring

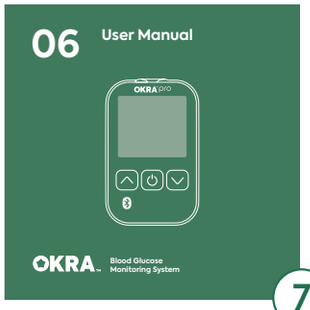
OKRA Pro Starter Kit Contents

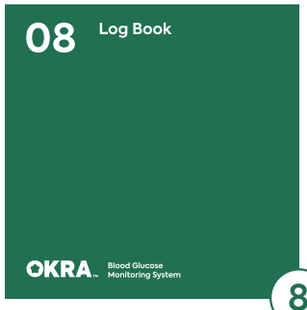


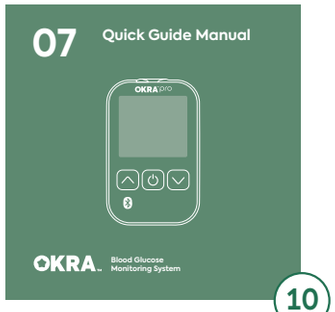










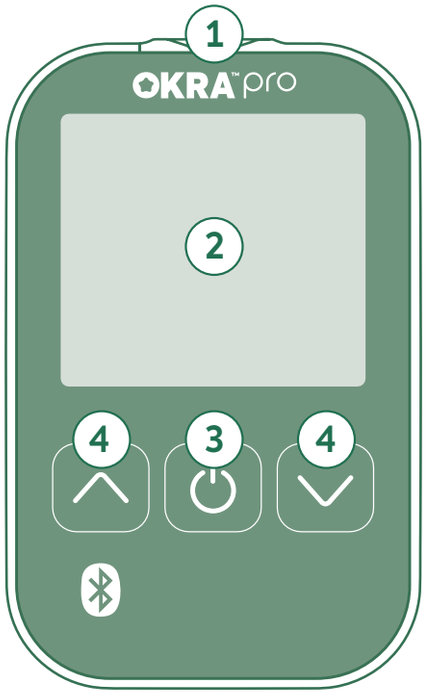


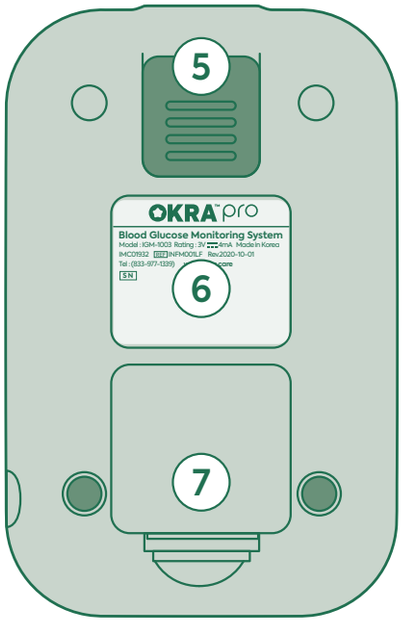
OKRA Pro Starter Kit Contents

1. OKRA Pro Meter
2. 150 OKRA Pro Test Strips
3. 150 Lancets
4. Lancing Device
5. Level 2 OKRA Pro Control Solution
6. Carrying Case
7. User Manual
8. Logbook
9. Batteries Included
10. Quick Guide

There are two additional levels (Level 1 & Level 3) of control solutions that can be purchased separately.
Please call toll free (833-977-1339) or visit www.okra.care for purchase

OKRA Pro Meter





1. Test Strip port

Insert the OKRA Pro Test Strip here.

2. Display Screen

Displays your test results, symbols, and messages.

3. Power/Enter Button

Power the meter on/off, prompts memory data and acts as an enter button during setup and after tests.

4. Up/Down Arrow Buttons

Scroll up or down to adjust settings or to retrieve memory.

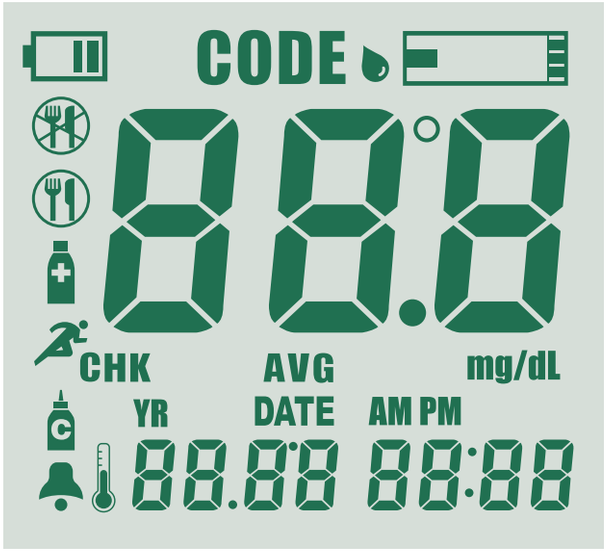
5. Test Strip Ejector

For hands-free disposal of used test strips.

6. Serial Number

7. Battery Cover

OKRA Pro meter display



- Low Battery Warning Symbol
- Alarm Symbol
- **CHK** Caution Symbol
- **AVG** Average Test Result System
- Before Having a Meal
- After Having a Meal
- After Taking Medication
- After Sport Activity
- Control Solution Symbol
- Blood Drop Symbol for Test
- **CODE** Strip Code Symbol
- **mg/dL** Test Result Unit Symbol
- YR DATE Temperature / Date
- AM PM Time / Test Result Amount

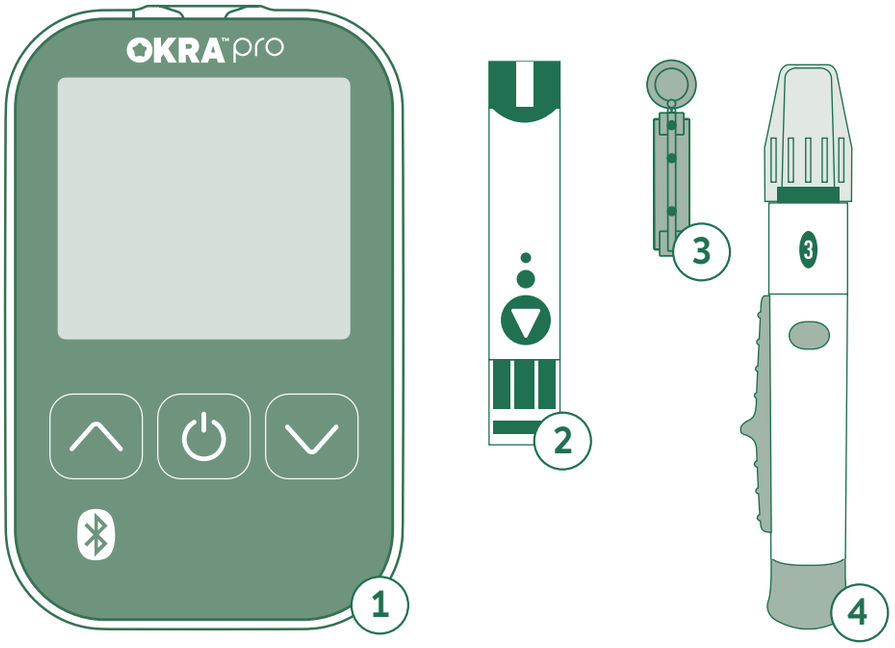
OKRA Pro Test Strip

1. Target to Apply Blood Sample (.5ul)

2. Contact Bar
Insert this End into Test Strip Port

Before Your Test

Make sure to read this section and the test strip package insert found in the test strip box carefully. You will need to have all of the necessary items to begin testing:



Necessary Items

1. OKRA Pro meter
2. OKRA Pro test strip
3. Sterile lancet
4. Lancing device

If the meter is moved from one temperature to another, allow 30 minutes for the meter to adjust to the new temperature before testing.

Make sure that the OKRA Pro meter and test strips have adjusted to the temperature of the location from where you are testing. Do not operate the OKRA Pro system under direct sunlight.

WARNING:
To reduce the chance of infection:

1. The lancing device and sterile lancets should NOT be shared with others.
2. Always use a new sterile lancet and a new blood glucose test strip.
3. Lancets and blood glucose test strips are for single use only.

Comparing your meter and laboratory results

Test results with the OKRA Pro Blood Glucose Monitoring System are plasma-equivalent. This method will help you and your Healthcare Professional compare your meter results with laboratory test results. The OKRA Pro test results and laboratory test results both are expressed in plasma-equivalent units. However, your glucose monitor results may differ from your laboratory results due to normal variation. Your glucose monitor results can be affected by factors and conditions that do not affect laboratory results in the same way.

The following may affect the accuracy of your meter:

1. You are severely dehydrated.
2. You have eaten recently. The blood glucose level from blood obtained from a fingertip can be up to 70mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.1
3. Your hematocrit is above 65% or below 20 %.

[1] Sacks, D.B.: Carbohydrates.: “Carbohydrates.: Burits, C.A. and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959
If you perform a blood sugar test with the system at temperature near the low end of the operating range, it could result in a false high blood sugar.

Repeat the test in warmer environment with a new test strip as soon as possible.

For additional information on possible limitations for accuracy on precision, please refer to your test strip insert.

In order to make the most accurate comparison to your laboratory results, please follow a few basic guidelines:

Before going to the lab

- Do not eat for at least two hours before you test your blood.
- Perform a control solution test to make sure that the meter is working properly.
- Take your meter with you to the lab.

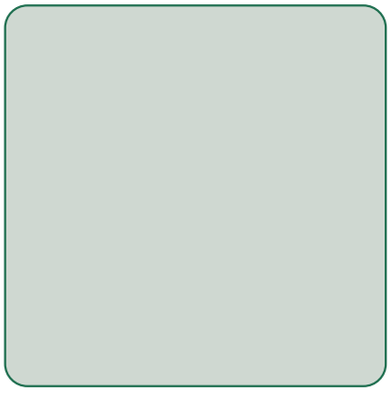
While at the lab

- Follow all instructions in this Instructions for Use for performing a blood sugar test with your meter.
- Conduct your meter test within 30 minutes after lab test.
- Use only fresh capillary whole blood from the fingertip.

You may still experience a difference from the laboratory test results because blood sugars can change very rapidly over a short period of time. This can be for a variety of reasons such as exercise, medication, stress or loss of body fluids.

Setting Your Meter

The OKRA Pro meter has a wide variety of functions. In the setup mode you have the ability to turn activity/meal flags on or off, set the date/time, designate the number of days for your glucose average calculation and set up to five daily alarms.

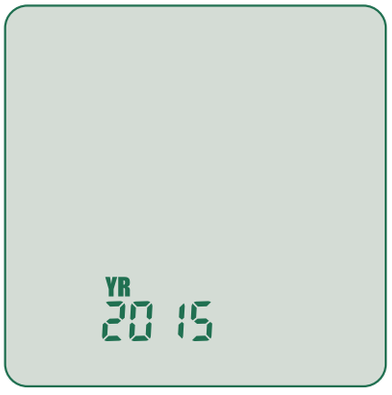


Power On

Press ⏻ for at least 3 seconds.

User Activity Option

After pressing and releasing either the ▲ or ▼ buttons to turn the User Activity Option on/off, confirm by pressing ⏻.

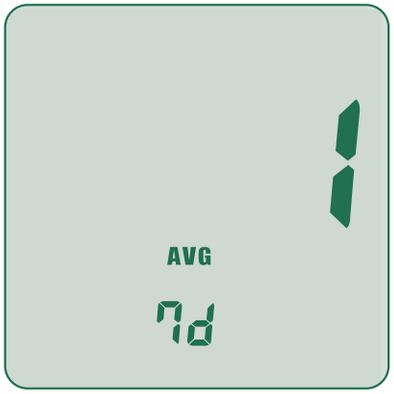


Year

After pressing and releasing either the ▲ or ▼ buttons to set the year, confirm by pressing ⏻.

Date / Time

After pressing and releasing either the ▲ or ▼ buttons to set the date and time, confirm both by pressing ⏻.

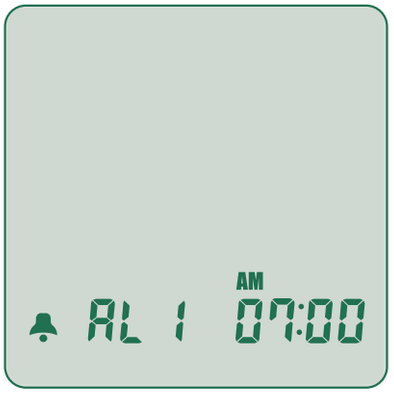


Number of days for average

After pressing and releasing either the ▲ or ▼ buttons to set the number of days (1~99) for average calculation, confirm by pressing ⏻.

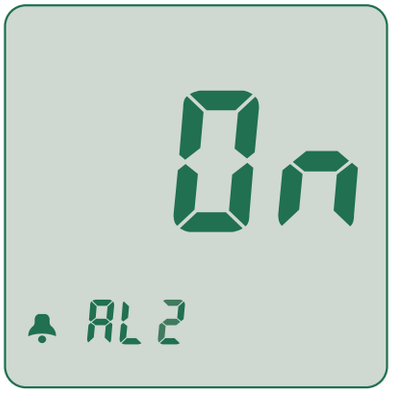
Alarm on/off

After pressing and releasing either the ▲ or ▼ buttons to turn the alarm on/off, confirm by pressing ⏻.



Alarm time

After pressing and releasing either the ▲ or ▼ buttons to set the alarm hour and minute, confirm by pressing ⏻.



Alarm

After programming your desired alarm time (5 alarms are available), confirm by pressing ⏻.

NOTE

1. Year

The year can range from 2015 to 2099.

2. Number of days for average

This will set the number of days that you would like to get your average blood glucose calculation.
The number of days can range from 1 to 99 days.
To increase or decrease the number of days, press the▲ or ▼ arrows.
You have three distinct options to set the number of days
(They are currently defaulted at7, 14, and 21days).

CAUTION

1. VERY IMPORTANT:
   Your OKRA Pro meter testing units arepre-set to mg/dL. If you discover that the meter is not set to mg/dL, please contact us at (833-977-1339) immediately.

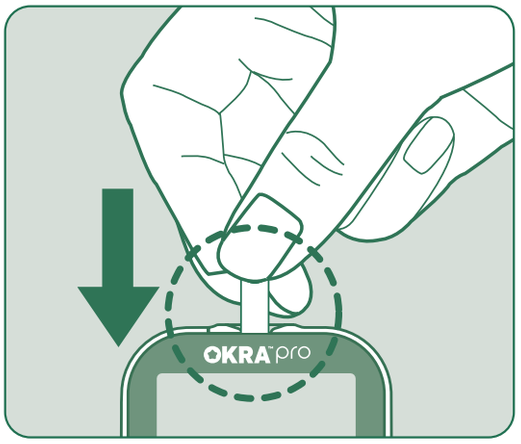
2. The correct units of measure in the U.S. are mg/dL.

3. Without setting the date properly, the average glucose level and the test results in the memory will not show the proper values. It is recommended to set the glucose test meter before you use it and when new batteries are installed.

4. You cannot test your blood glucose while it is in the setting mode.

5. To turn the meter off during the setup, press for at least 3 seconds.

Auto-coding Function



OKRA Pro meter has an automatic code recognition function.

The OKRA Pro meter recognizes the code number automatically. This is a very convenient function preventing the inconvenience of setting the code number on the glucose test meter every time.

CAUTION

1. Do not bend the glucose test strip to prevent automatic code recognition failure.

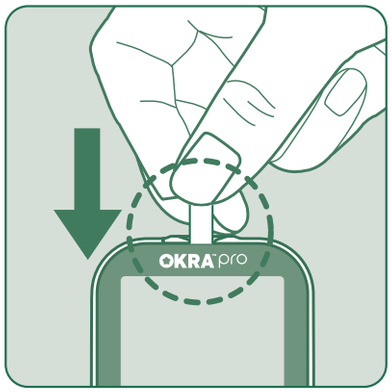
2. If the code recognition label is damaged, the code recognition may fail. Verify that the code number on the LCD window matches the code number on your glucose test strip vial.

Performing a Control Solution Test

The OKRA Pro control solutions contain a known amount of glucose that reacts with the OKRA Pro test strip. By comparing your control solution test results with the expected range printed on the test strip vial, you can verify that the meter and test strips are working properly, and you are performing the test correctly. It is very important that you perform the control solution test routinely to make sure you receive accurate results.

The Glucose control solution should be used:

- Whenever you suspect the blood glucose test meter or blood glucose test strip are not functioning properly.
- If your blood glucose test results are not consistent with your symptoms.
- If you have dropped the blood glucose test meter.
- For quality control in the point of care usage.
- For teaching or learning the system.



Firmly insert the test strip into the meter test port. Insert firmly in the direction of the arrow on the test strip (arrow up). Do not insert the glucose test strip upside down.

Press and release either the ▲ or ▼ button. The control solution bottle
( ) will appear, then press ⏻.

check the expiration date before performing a control solution test. Do not use if expired. Please write down the expiration date on the control solution bottle after first opening.

Gently shake the control solution before use.

Discard the 1st drop of control solution, this will eliminate any residue.

Place a drop of control solution on a clean, dry surface (e.g. the lid of the test strip vial).

Dip the test strip into the control solution.

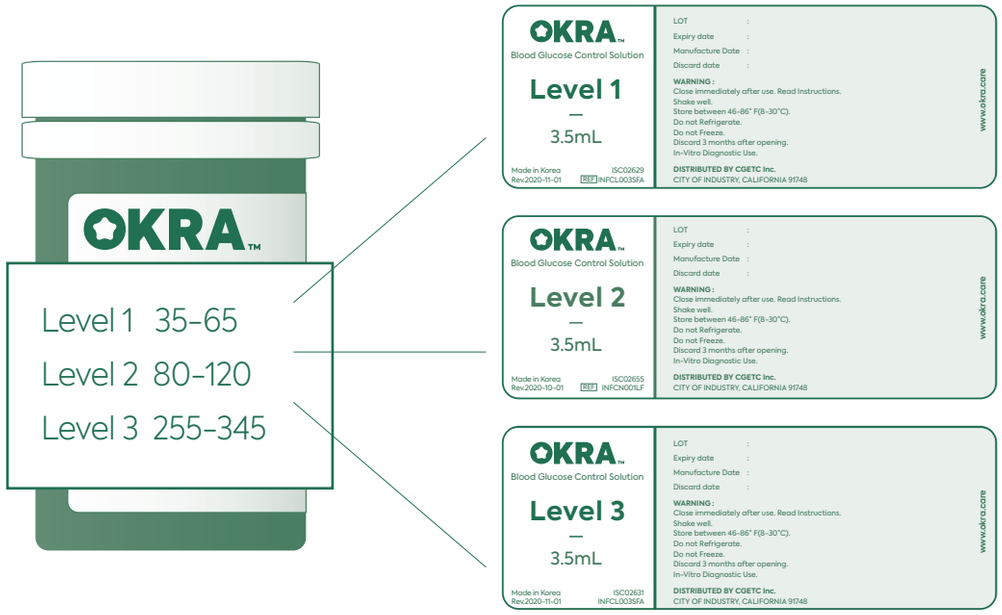
Results will appear in 5 seconds. Compare the result to the range printed on the test strip vial, the result should fall within that range.

CAUTION

The control solution bottle icon (C) contains the letter 'c' so it will not to be confused with the medication bottle icon. This will allow you to differentiate between a control solution test and an actual blood test.

For example only

If you are using the level 2 control solution, according to this particular vial of test strips, your meter should show a number between 80 and 120.



* Caution: The ranges in the picture above are examples only. Please refer to your test strip vial label for the exact ranges.

NOTE

- It is recommended that glucose control solution is stored at 46~86°F(8~30°C) before testing.
- Check the expiration date before performing a glucose control solution test.
- Do not use if expired. Once opened, the control solution expires after 3 months.

If your control solution test falls out of range, please follow the next steps before contacting customer support:

- Check the expiration dates on all the products you are using. Be sure you are using OKRA control solution.

- Try another control solution test
  If this test falls out of range, try another control solution test with a new unopened vial of test strips.

- After following the appropriate steps and the control solution test still falls out of range, do not perform a
  glucose test. Please call customer support toll free:
  (899-977-1339).

Follow-up Action

1. Check your meter and test strips with the glucose control solution.
2. Perform your test again.

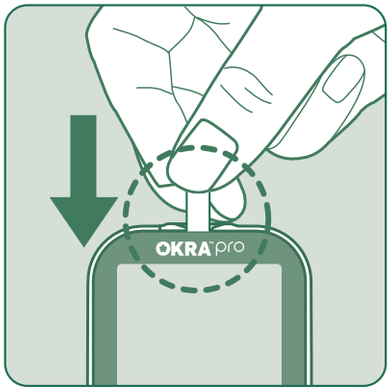
CAUTION

1. If your glucose control solution falls out of range please contact the customer support. ((833-977-1339) or www.okra.care).
2. The glucose control solution range is not the recommended range for your blood glucose level.
3. Discard the used control solution and test strips carefully.
   Contact your Healthcare Provider for instructions on disposal.

Performing Your Test

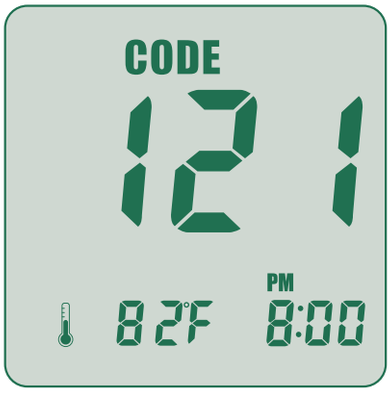
Performing a blood test with your fingertip

Step 1

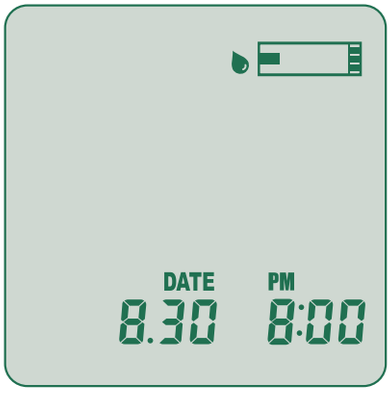


Firmly insert the test strip into the meter test port. Insert down firmly in the direction of the arrow on the test strip (arrow up). Please do not insert the glucose test strip upside down.

When you insert the glucose test strip into the glucose test meter, the power automatically turns on displaying the code and temperature.



Make sure the code number matches the code on your strip vial. The OKRA Pro meter automatically recognizes the test strip code number and adjusts the meter a ccordingly.



A blinking test strip will appear in the top right corner indicating that the meter is ready for testing.

CAUTION

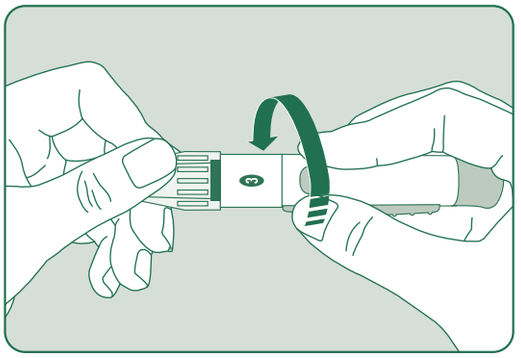
1. If the code is not displayed within a short amount of time, pull the glucose test strip out of the port and re-start the procedure from the beginning.
2. If the code on the LCD display window and the one on the glucose test strip vial do not match, try another new glucose test strip. If the mismatch persists, please contact our customer support.
3. If you apply your blood sample before the blood symbol blinks, an Er5 message will appear on the LCD. Please refer to Page 58.

Step 2

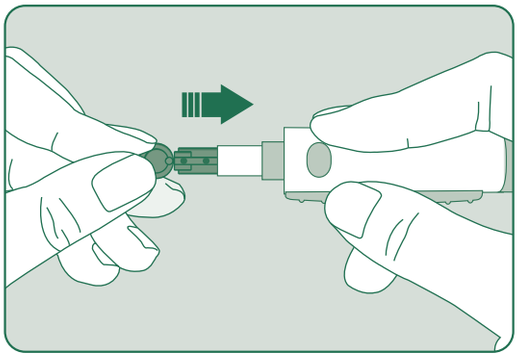
To obtain suitable blood samples

WARNING

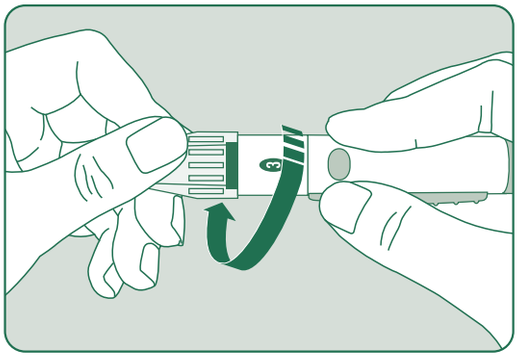
1. OKRA Pro meter and reusable lancing device are for single patient use only. Do not share them with anyone including other family members. Do not use on multiple patients.
2. All parts of the kit are considered to bebio hazardous and can potentially transmit infectious disease, even after you have performed cleaning and disinfection.
3. Please refer to page 46 and 51 for cleaning and disinfecting your OKRA Pro Blood Glucose Monitoring System.
4. Wash your hands thoroughly with soap and clean water after handling the meter, lancing device and/or test strip.



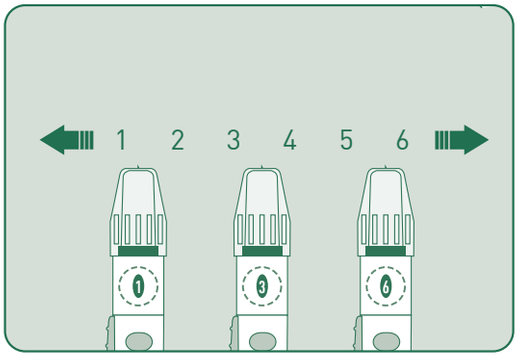
Unscrew the lancing device cap.



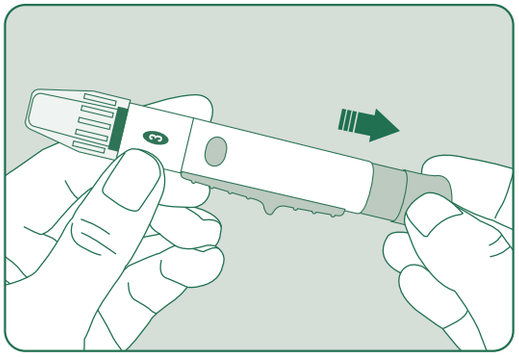
Insert a sterile lancet into the lancing device.



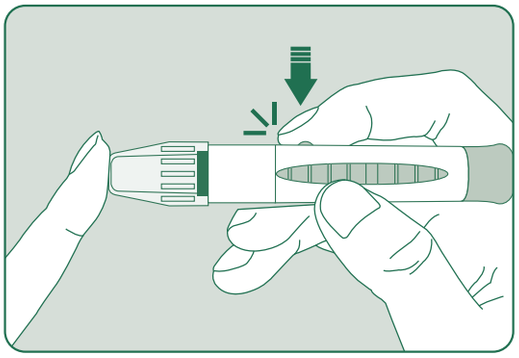
Twist the protective cover off. Do not discard.



Replace the lancing cap by twisting it back on tightly. To adjust the depth setting: Use 1–2 for soft skin, 3–4 for average skin, and 5–6 for thick or calloused skin.



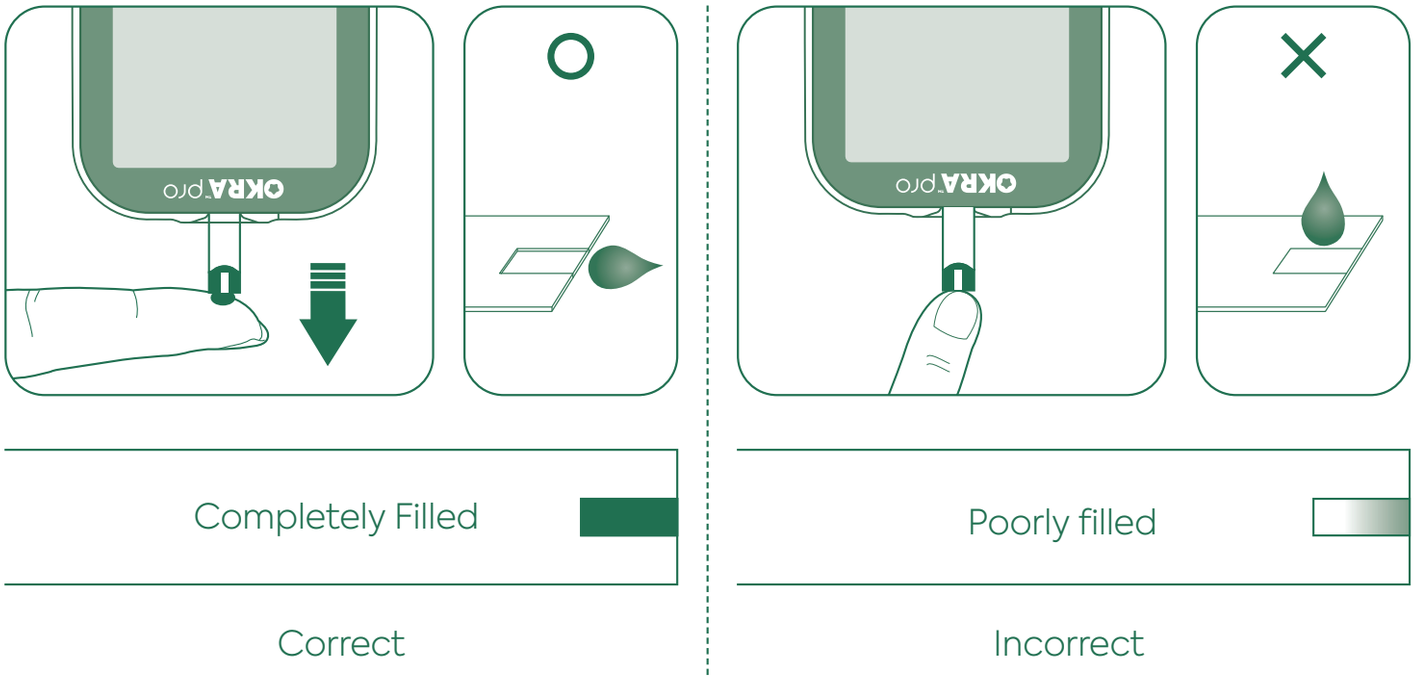
Pull the end of the lancet device back.



To prick your finger, push the center button.

CAUTION
If the blood smears or runs, do not use that sample. Dry the area and gently squeeze another drop or puncture a new site.

Step 3



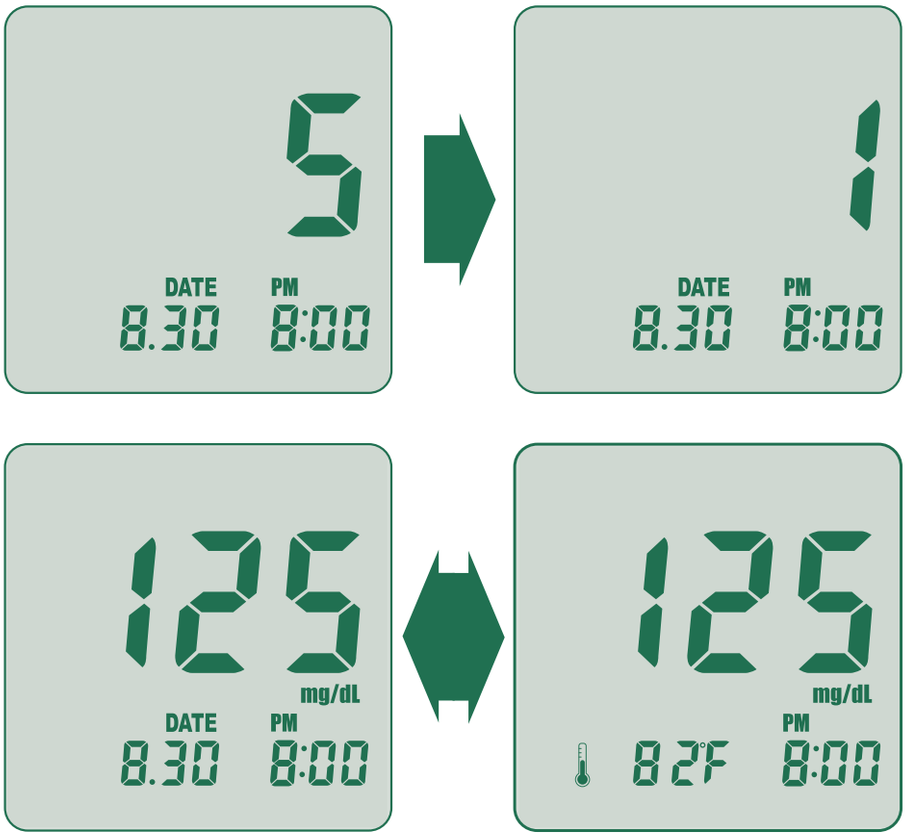
OKRA Pro test meter only requires 0.5 uL sample volume.

- Place the edge of the test strip to the drop of blood.
- The blood will be automatically ‘drawn’ into the test strip channel.
- When your blood sample size is enough, your meter will automatically count down.
- Apply the blood to the glucose test strip and do not take off your finger until you get the completion sound.

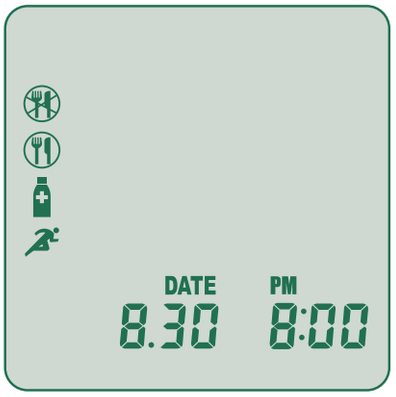
CAUTION

1. If the countdown does not start, do not add more blood to the glucose test strip. Discard the glucose test strip and re-start testing.
2. If you do not conduct the test within 3 minutes, the glucose test meter will automatically power off to save battery life. In this case the test procedure should start again from the beginning.
3. You may get an inaccurate result if the blood sample is not completely filled.

Step 4



- After the beeping sound, the test will start automatically and your test result will appear in 5 seconds. It will begin counting down from 5 to 1 second on the LCD display window. When finished, the LCD window will display the result of your blood glucose level, temperature and time.



If the activity/meal featureis ON in the setup mode (Page 15),

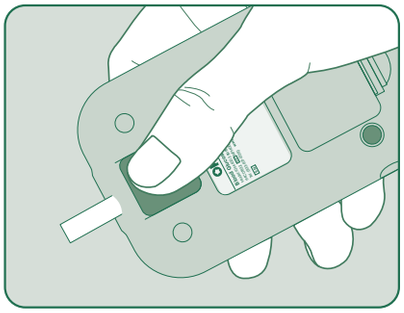
you can choose the activity/meal flags (, , ,) by pressing and releasing the ▲ or ▼ button to select the activity that will correlate with your results. Then press and release the power button ⏻.

- Record the result value in your logbook. When the glucose test strip is removed, the glucose test meter turns off automatically.

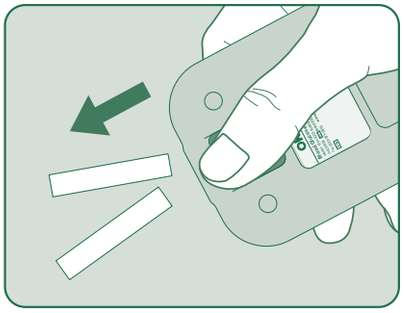
CAUTION

1. If the test result is out of the test range, the HI/Lo message will be shown on the LCD. Please contact your Healthcare Provider immediately when you see a HI/Lo result.
2. Please contact your Healthcare Provider for instructions on disposing of your glucose test strips and lancets.

Removing and Disposing of Used Test Strip

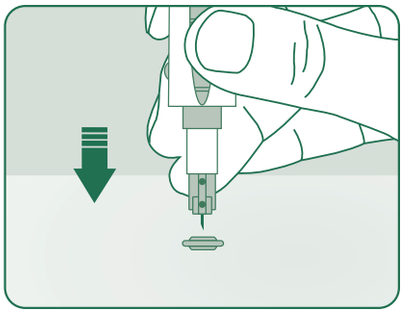


Once the test is complete, push the ejector button forward to remove the test strip from the meter.

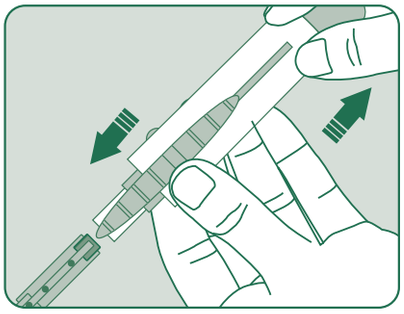


Used test strips may be considered bio hazardous waste in your area. Be sure to contact your Healthcare Provider for instructions on disposing of your test strips.

Disposing of your lancet



Push the needle into the protective cover.



Pull the lancet out.

Be sure to contact your Healthcare Provider for instructions on disposing of your lancets.

Reviewing Your Results

Reviewing your blood sugar

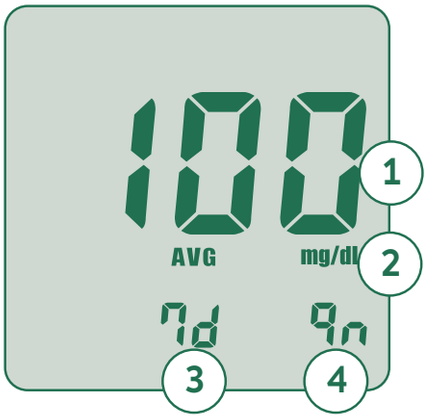
The OKRA Pro meter stores up to 365 test results in its built-in memory, along with the average sugar level for the number of days, which you have preset the glucose test meter to calculate.

The latest | The Second latest | The Third latest

Press and release the (⏻) button. The most recent result appears first. Note the time and day of your blood sugar result.

Press and release the ▼ button and your previous result will appear on the display.

Reviewing your averages



The average from 7 days worth of data from your recent test date.

The average from 14 days worth of data from your recent test date.

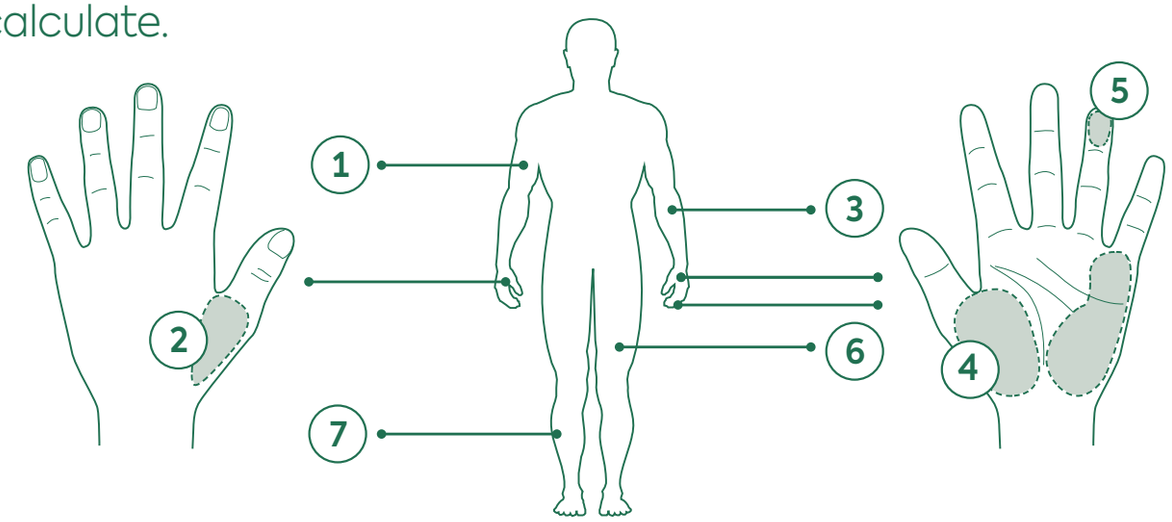
The average from 21 days worth of data from your recent test date.

1. Average Test Result / 2. Test Unit /
3. Average Test Result Days / 4. The Number of Tests

Alternative Site Test

Performing a blood test with an alternative site

The OKRA Pro meter stores up to 365 test results in its built-in memory, along with the average sugar level for the number of days, which you have preset the glucose test meter to calculate.



1. Upper Arm / 2. Dorsal Hand / 3. Forearm / 4. Ventral Palm 5. Fingertips / 6. Thigh / 7. Calf

The OKRA Pro Blood Glucose Monitoring System gives you the ability to obtain a blood sample for testing your sugar from different areas of your body.

The figure shown above displays the areas where you can test using your OKRA Pro meter.

You may test your blood sugar from your forearm, upper arm, palm (ventral palm or dorsal hand, fingertips, thigh, or calf.

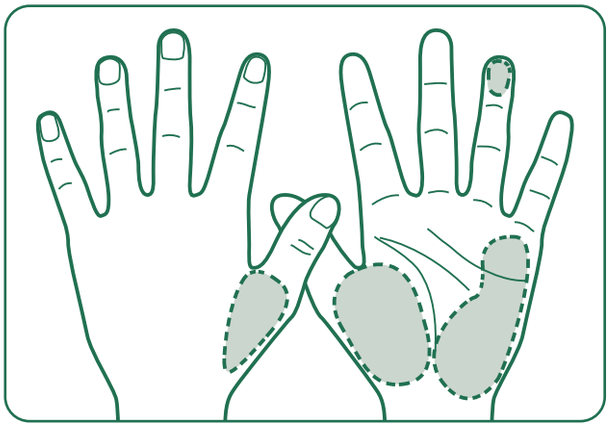
It is recommended that alternative site testing be used when sugars are stable: before meals and before bedtime. However, when sugars are changing, blood from the fingertips may show these changes sooner than blood from other sites.

Lancing and sampling from an alternative site area.

Sampling from your upperarm, forearm, dorsal hand, ventral palm, thigh, or calf allows you to use your fingertips less often.

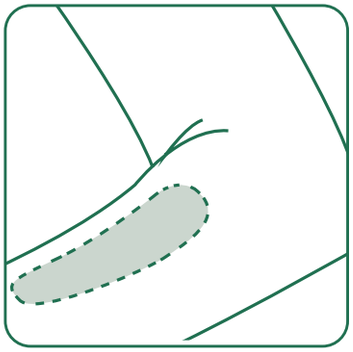
You may find that obtaining a blood sample from an alternative site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertip.

Ventral palm / Dorsal hand

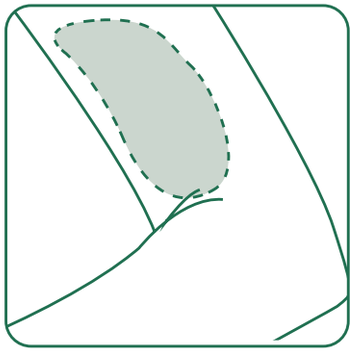


Choose a fleshy area on the palm, below your thumb or pinky finger. Select a spot without any visible veins and away from any deep lines. This may cause your blood sample to smear.

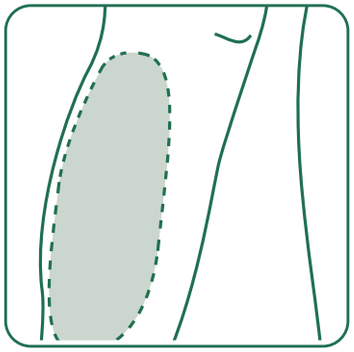
Forearm



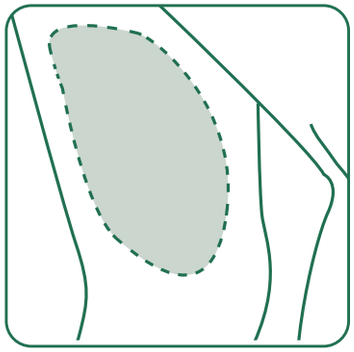
Upper arm



Calf



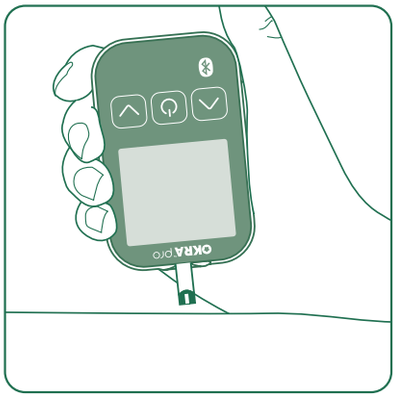
Thigh



Choose a fleshy area of the forearm, upper arm, thigh, or calf away from the bone, visible veins and/or hair. Sometimes there is less blood flow in these areas than the fingertip.

To help you get enough blood, you may gently massage or apply a heating pad to the site to increase the blood flow.

IMPORTANT
We recommend that you test on your fingertips if you are testing for hypoglycemia (low blood glucose) or if you are suffering from hypoglycemia unawareness.

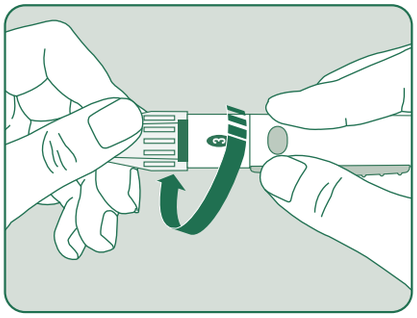


To ensure accurate results when lancing your arm (forearm or upper arm), leg (calf or thigh), or palm (ventral palm or dorsal hand), clean the test site with soap and water.

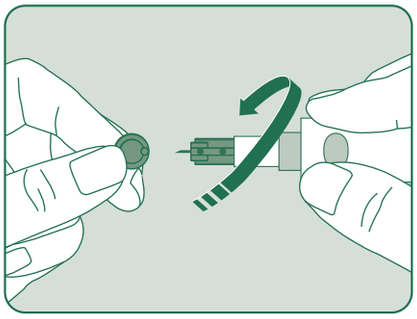
WARNING
To reduce the chances of getting infection: never share a lancet or a reusable lancing device with anyone.

Lancing Using the Clear for an Alternate Site Area

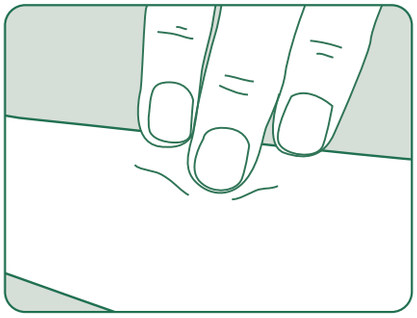
Lance the test site with the lancing device



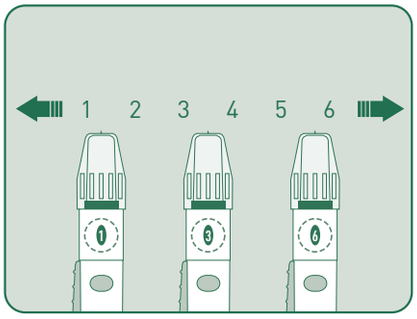
1. Remove the lancing cap by twisting off.



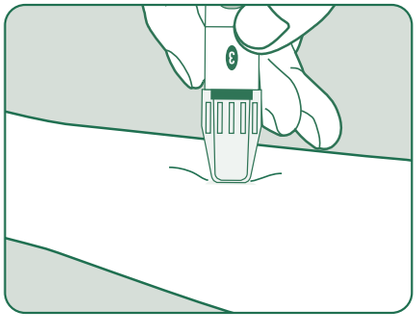
2. Insert a lancet and replace with the clear cap.



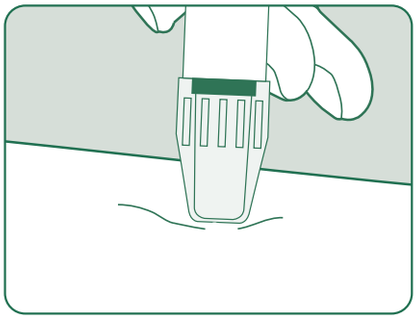
3. To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm. Applying a heating pad may be helpful.



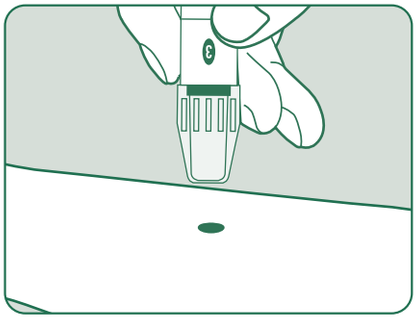
4. Adjust the clear cap to the highest setting (6). Hold the clear cap down against a fleshy area on the alternative site and press the release button. Do not lift up.



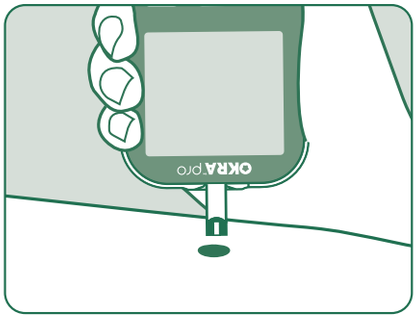
5. Continue to hold the lancing device and gradually increase pressure for several seconds.



6. While holding the lancing device on your test site, look through the clear cap until a round drop of blood appears
(approximately 0.5ul).



7. Lift the lancing device straight up; be careful not to smear the blood on your testing site.



8. Place the edge of the test strip to the drop of blood. The blood will be automatically drawn up.

REMEMBER

1. Consult with your Healthcare Professional before using alternative site testing.
2. Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.
3. If bruising occurs at an alternative site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your Healthcare Professional.
4. Do not share your reusable lancing device with anyone including other family members.

CAUTION

Do not test on your upper arm, forearm, dorsal hand, ventral palm, thigh, or calf when:

1. You think your blood glucose is rapidly falling. For example within two hours of exercise, rapid-action insulin injection, or an insulin pump bolus.
2. Testing with a fingertip sample may identify hypoglycemia or an insulin reaction sooner than testing with a forearm or palm sample.

Caring for your OKRA Pro System

Cleaning and disinfecting your OKRA Pro system

Why should cleaning and disinfecting the meter and the reusable lancing device be performed?

Blood glucose meters and reusable lancing devices are at the high Riskof becoming contaminated with bloodborne pathogens such as Hepatitis B Virus(HBV). Transmission of this virus has been documented due to contaminated blood glucose devices. According to the Centers for Disease Control and Prevention, cleaning and disinfecting meters and lancing devices can prevent the transmission of this virus through indirect contact.

The cleaning is to remove soil and dirt on all surfaces of the devices while the disinfecting is to kill the bloodborne pathogen stated above.

Materials needed

Cleaning and disinfecting can be completed by CaviWipes™ Disinfecting Towelettes.

The CaviWipes™ are pre-moistened towelettes manufactured by Metrex and readily available through major medical distributors and online shopping websites (ex. www.amazon.com/ www.staples.com).

Please refer to the disinfectant labeling for additional instructions on the safe use of this disinfectant.
If you have difficulty getting the CaviWipes™ towelettes,
Please contact us at (833-977-1339).

NOTE

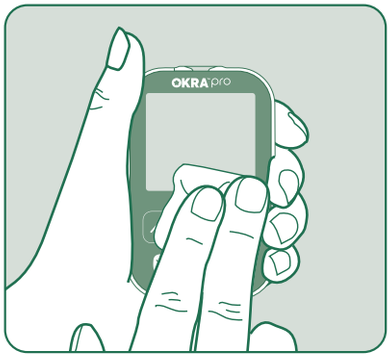
1. For cleaning and disinfectingthe meter/lancing device, use CaviWipes™ which has been shown to be safe for use with this meter and lancing device. Other cleaning agents have not been validated with the meter and reusable lancing device.
2. Please call OKRA Pro Customer Service at (833-977-1339). If you have any questions regarding proper cleaning and disinfecting procedures and purchasing the materials needed.

Cleaning and disinfecting procedures

1. Wash your hands before performing cleaning and disinfecting procedures.

2. Remove the wipe from the container.

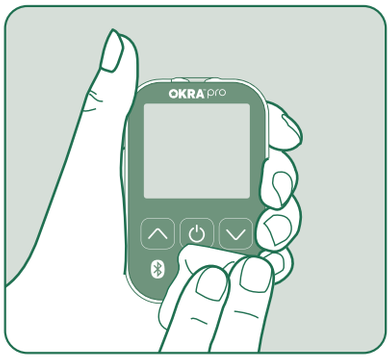
3. Make sure the meter is turned off.



4. Wipe the outside of the meter carefully (3 passes horizontally and 3 passes vertically).

* To clean the meter, wipe it with a CaviWipes™ towelette.

* To disinfect the meter, wipe it with an other CaviWipes™ towelette and leave it wet for 2 minutes.



NOTE

1. The meter should be cleaned prior to each disinfection. (Two CaviWipes™ disinfecting towelettes in total.)

2. To achieve disinfection of the stated efficacy kill claim, the meter should remain visibly wet for 2 minutes right after disinfecting treatment.

CAUTION
Take extreme care that the liquid does not soak into the data ports. Do not use any type of spray.

5. Dispose of the used wipes.

6. Wash your hands thoroughly with soap and water.

The meter must be cleaned and disinfected a minimum of once per week.

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

Reusable lancing device

1. Wash your hands before performing cleaning and disinfecting procedures.

2. Remove the wipe from the container.

3. Make sure the used lancet is removed prior to cleaning.

4. Wipe the outside of the reusable lancing device carefully (3 passes horizontal and 3 passes vertical).

* To clean the reusable lancing device, wipe it with a CaviWipes™ towelette.

CAUTION
To achieve disinfection of the stated efficacy kill claim, the reusable lancing device should remain visibly wet for 2 minutes right after the completion of disinfecting treatment.

5. Dispose of the used wipes.

6. Wash your hands thoroughly with soap and water.

The meter must be cleaned and disinfected a minimum of once per week.

We recommend that you perform the cleaning and disinfecting procedures on it once per week.

Your OKRA Pro Blood Glucose Monitoring System has an expected life of 3 years and should withstand the cleaning and the disinfecting recommended in this Instructions for Use. We tested the meter and the lancing device with CaviWipes™ representing daily cleaning and disinfecting (two separate steps) for three years (1 timeper day(365 days) x 3 years x 1 cleaning/disinfecting steps for a total of 1,095 times for both the meter and reusable lancing device). We did not observe any change in performance, accuracy, or appearance.

The meter can withstand up to 1,095 cleaning and disinfecting cycles which represents cleaning and disinfecting once per day for 3 years. The meter can withstand cleaning and disinfecting 7 times per week over the 3 year life of the device.

NOTE

1. After cleaning and disinfection procedures, verify that the reusable lancing device and the meter work properly.
2. If any of the following physical and functional signs of deterioration appear after cleaning and disinfection of the devices, stop using them and contact OKRA Pro Customer Service at (833-977-1339).

- Cloudy meter display.
- Meter displays broken character or icons.
- Meter will not power on.
- Meter button or strip ejector does not function.
- Control solution test falls out of range.
- Lancing device does not function.

Ex. Lancing device is broken (Crooked spring, Cracked cap, etc.)

WARNING

Do not share your reusable lancing device with anyone including other family members.

Storage of your OKRA Pro System

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

Meter Storage

- Storage condition:36~86°F or 2~30°C (Temperature).
- Always store or transport the meter in its original storage case.
- Avoid dropping the meter.
- Avoid direct sunlight and humidity.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.

Strip Storage

- Storage condition:36~86°F or 2~30°C (Temperature)
- Store your test strips in their original vial only.
  Do not store in other types of containers.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- Record the discard date (It expires 6 months after first opening) on the strip label.
- Do not use if expiry date has passed.
- Touch the test strip with clean and dry hands.

Control Solution Storage

- Storage condition: Store in a cool dry place between 46~86°F or 8~30°C (Temperature).
- After use, close cap tightly.
- Record the discard date (It expires 3 months after first opening) on the control solution bottle.
- Do not use if expiry date has passed.

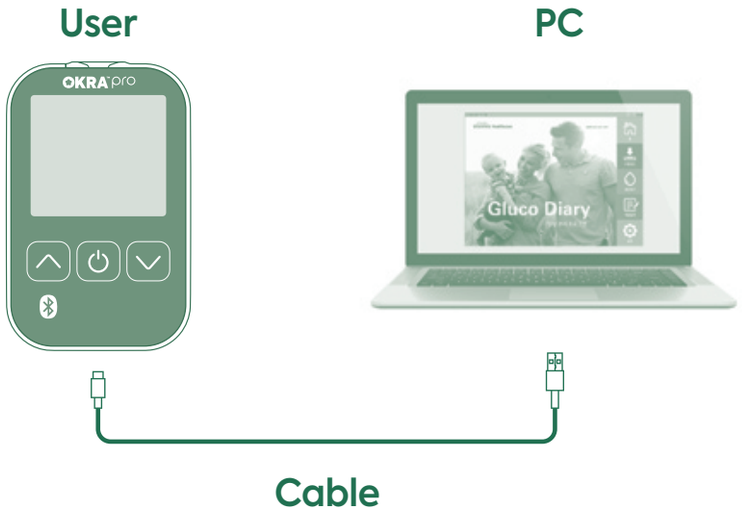
Transferring your results

You can transferyour test results from the OKRA Pro meter to a computer.

You will need to download the software from the following website:

(https://www.okra.care/support-->download)

Purchase the computer cable from our sales reoresentative. The cable is sold separately.



Bluetooth function

OKRA Pro meter stores glucose test result data and can transmit it to wireless device such as a Smart Phone (android or ios) and Tablet PC via Bluetooth wireless technology.

Step 1 Ensure you have completed one or more tests on your OKRA Pro meter and your Bluetooth is switched 'ON' on your mobile device.

Step 2 Go to your app store on your mobile device (you can find your app store at google play or the apple app store), and search for the 'mHealthgate App'. Download and launch the mHealthgate app and fill in all details required.

Step 3 Once your mHealthgate app is ready to use, select 'Connect Device' on the mHealthgate app on your mobile device. From the drop down list shown on you mobile device, select the meter that you are using.

Step 4 Ensure your meter is switched off, then press the left arrow button pointing upwards above the Bluetooth symbol on your meter for 3 seconds until you hear the sound of a beep. A 'bt' for Bluetooth and a flashing 'p' for pairing will appear on your screen. This indicates your meter is transferring Bluetooth signals to your mobile device. When reconnecting to a mobile device that has already been paired, simply press the left arrow button to enter data transfer mode.

Step 5 Press 'OK' to the alert appearing on the mHealthgate app on your mobile device. A flashing 'c' for confirmed will now appear on you meter to show that the pairing between your meter and your mobile device has been successful.

Step 6 Your meter will now transfer all glucose test result data to your mHealthgate app. When this has been completed, your meter will automatically switch to sleep mode.

NOTE

- When ejecting the test strip, this will automatically activate the Bluetooth on your meter. If you wish to transmit your results to your mHealthgate app on your mobile device, open your mHealthgate app and follow the instructions above. If you do not wish to transmit your result to your mHealthgate app at this time, simply press the middle 'OFF' button

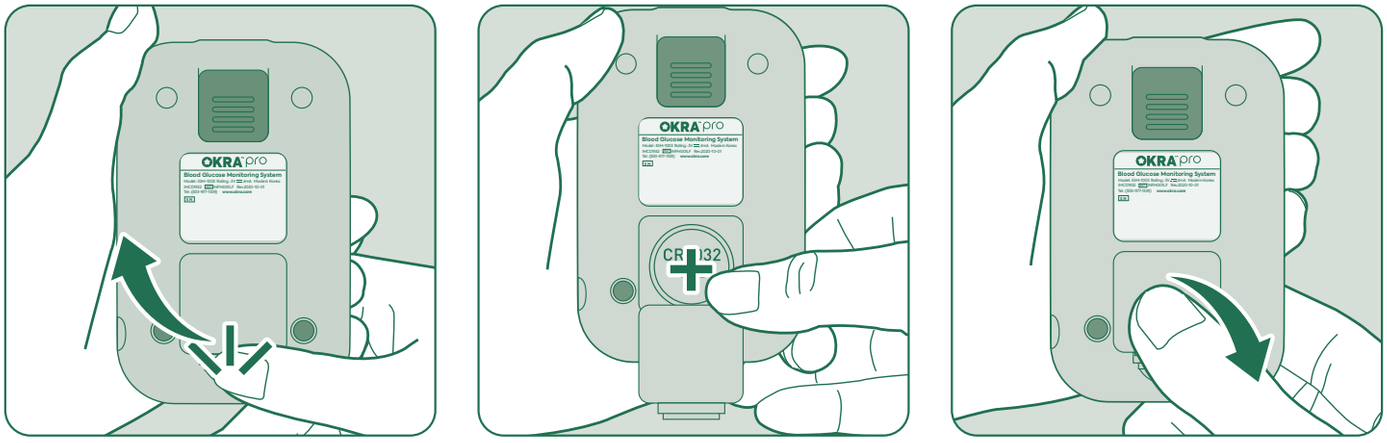
–Your meter will enter sleep mode and your results can be transmitted to your mHealthgate app another time.

- Activate at the Bluetooth function at a close distance.

- Do not turn off the app whilst transmitting data via Bluetooth from your meter

Battery Installation

The low battery icon will appear in the upper left corner of the LCD display to alert you when the battery power is running low, indicating new battery is needed.



Your OKRA Pro meter uses only one 3V coin battery (CR2032), which is included. When replacing the battery, only CR2032 or equivalent coin battery should be used.

After changing the battery, please be sure to recheck your meter settings.

Follow-up Action

1. Check your meter with the glucose control solution.
2. Perform your test again.
3. If you are experiencing wymptoms that are not consistent with your blood glucose test results, call you healthcare professional.

NOTE

Verify the date and time are correct after changing your batteres. Re-set the date and time if necessary.

Troubleshooting

The following chart may help you identify certain problems, but may not solve all the problems that can occur. Contact your authorized representative or contact OKRA Pro Customer Service at (833-977-1339).

Hardware is defective.

Reboot the meter by removing and then replace the battery while no test strip is inserted. Contact customer support if the problem persists.

Test strip may be contaminated or reused.

Please, insert a new glucose test strip and perform your test again.

Insufficient amount of blood sample is placed on the test strip.

Please insert a new glucose test strip and apply the blood sample and confirm the window is completely filled.

Blood glucose test strip is damaged.

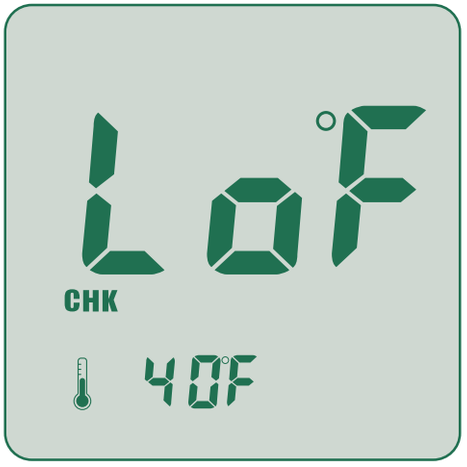
Please insert a new glucose test strip and perform your test again.

Blood sample is placed on the test strip before the symbol for blood blinks.

Wait for the meter to display the blinking blood icon before applying your blood sample.

Color area of the test strip is dirty, defective or there is too much sunlight. Action required.

Please insert a new glucose test strip and perform your test again, or if it blinks with “sun”, avoid direct sunlight and retest. Contact customer support if the problem persists.



The ambient temperature is less than 50°F (10°C).

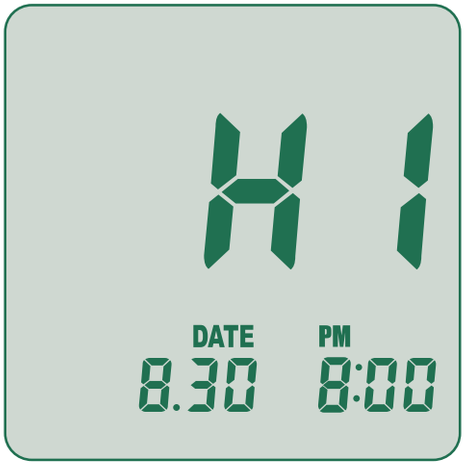
Place the meter at a temperature between 50 ~ 104°F (10 ~ 40°C) for more than 10 minutes and test again.

The ambient temperature is over 104°F (40°C).

Place the meter at a temperature between 50 ~ 104°F (10 ~ 40°C) for more than 10 minutes and test again.

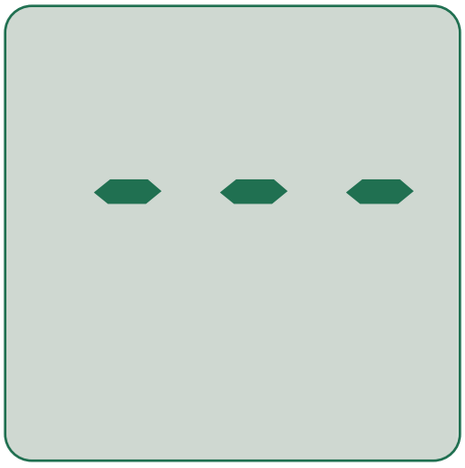
The test result is less than 20mg/dL.

If “Lo” appears on the LCD screen for the Glucose result, the measured concentration is below 20mg/dL. The test should be repeated to ensure that the test procedure was done correctly. If you are certain the meter is functioning correctly and no errors were made during the test procedure and the blood glucose is still consistently measured as “Lo”, the result may indicate severe hypoglycemia (low blood glucose). You should inform your Healthcare Professional immediately.

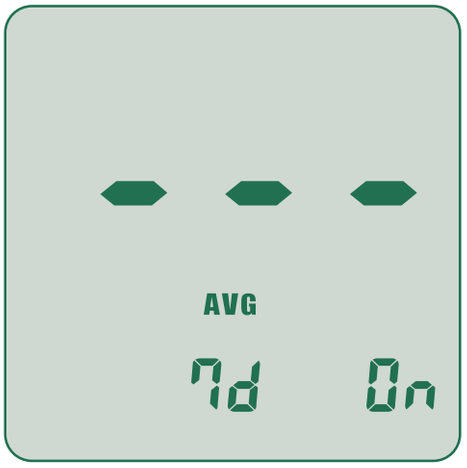


The test result is over 600mg/dL

If “HI” appears on the LCD screen for the Glucose result,the measured concentration is above 600mg/dL. The test should be repeated to ensure that the test procedure was done correctly. If you are certain the meter is functioning correctly and no errors were made during the test procedure and the blood glucose is still consistently measured as “HI”, the result may indicate severe hyperglycemia (high blood glucose). You should inform your Healthcare Professional immediately.



There are no readings stored in the meter.



Not enough readings in the memory to display designated averages.

The glucose test meter does not turn on.

The battery is dead or there is a problem with the meter.

Change the battery and if the problem persists, contact our customer support.

The glucose test meter does not start after applying the blood sample.

Insufficient amount of blood.

Please insert a new test strip and perform your test again.

The results are inconsistent.

There may be a problem with the glucose test strips.

Please insert a new test strip and perform your test again.

Inconsistent or Unexpected Test Results

If you continue to get unexpected test results, check your system with control solution. If you experience symptoms that are not consistent with your glucose results, review and follow all instructions in this Instructions for Use. Never ignore symptoms or make significant changes to your diabetes control program. Inform your Healthcare Professional of symptoms and/or concerns.

CAUTION

1. Low Glucose Results: if your result is lower than 70mg/dL, it may mean hypoglycemia (low blood sugar). This may require immediate treatment according to your Healthcare Professional's recommendations. Although this result could be due to a test error, it is safer to treat first and test after.
2. High Glucose Results: if your test result is higher than 180 mg/dL, it may mean hyperglycemia (high blood sugar). If you are uncertain about your test results, consider testing again. Your Healthcare Professional will help you decide how to take action. If the meter displays HI all the time, please re-check your blood sugar, however if your test result is still high, please contact your Healthcare Professional immediately.

Range of Expected Values

Self-testing may help to monitor your blood glucose levels. Consults with your physician to determine the best range of expected blood glucose values for you.

Expected blood glucose values for non-diabetic adults are as follows: Before eating < 100 mg/dL(5.6 mmol/L)

One to Two hours after meals < 140 mg/dL(7.8 mmol/L) Reference: American Diabetes Association: Clinical Practice Recommendations(2013) Diabetes Care, Vol 36, Supplement 1, p. S1-S100.

Warranty

Manufacturer's Warranty

OKRA Pro offers 2 years warranty to the original purchaser. OKRA Pro will repair or replace the meter if it is found to be defective or fails to perform as designed. Proof of purchase may be required. Please contact OKRA Pro Customer support at (833-977-1339) or visit www.okra.care.

Limitations of Warranty

This warranty is subject to the following exceptions and limitations.

1. OKRA Pro shall not be required to replace any units which are damaged or malfunction due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than OKRA Pro, or failure to operate in accordance with the instructions.
2. OKRA Pro reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured devices.
3. OKRA Pro has no knowledge of the performance of the device when the test strip is altered or modified in any manner.

For Warranty Service

Purchaser must contact OKRA Pro Customer Support by calling toll free (833-977-1339) or visit www.okra.care for assitance.

Service Information

OKRA Pro Customer Service, has trained specialists to help you Monday thru Friday, 9 to 5pm Eastern Time.

IMPORTANT
Confirm with OKRA Pro Customer Service, before returning your meter for any reason. You will be given the information needed to get your problem handled correctly and efficiently as possible. Make sure to have your meter, test strips and control solution nearby when you call.

Specifications

Sample Type	Fresh capillary whole blood
Sample Volume	0.5μℓ
Test Range	20 ~ 600 mg/dL
Reading Time	5 seconds
Calibration	Plasma - equivalent
Hematocrit	20 ~ 65%
Altitude	Up to 10,000 feet (3048 meter)
Operating Temperature	50 ~ 104°F (10 ~ 40°C)
Operating Humidity	10 ~ 90%
Strip Storage Temperature	Store 36~86 °F or 2~30°C and keep out of direct sunlight. Do not Freeze.
Display Type	LCD
Dimension	3.2X 2.0X 0.6 in. (81 X 52 X 16 mm)
Weight	1.51±0.03 oz (43±1g) Including batteries
Power Source	3V (Coin Battery, CR2032 X 1EA)
Battery Life	Running 1,000 times
Bluetooth	Bluetooth Smart (Bluetooth Low Energy)

OKRA Pro Test Strip Manual

OKRA Pro Glucose Test Strip

IMPORTANT
Please read this information and your OKRA Pro Instructions for use before using the OKRA Pro test strips. Customer support is available Monday thru Friday, 9 to 5pm Eastern Time.

Please call toll free: (833-977-1339)

Indications For Use

The OKRA Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. The OKRA Pro Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The OKRA Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening of diabetes and/or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The OKRA Pro test strips are for use with the OKRA Pro meter to quantitatively measure glucose in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

General

OKRA Pro test strips have the new bio-sensor technology, requiring only a tiny drop of blood. OKRA Pro meter can store 365 readings in memory with date & time. All your results are easily downloadable to your computer.

Storage and Handling

- Store the test strip vial in a cool, dry place between 36-86°F (2-30°C). Keep out of direct sunlight. Do not freeze.
- Store test strips in its original vial only. Do not mix the test strips in new vials or in any other container.
- Immediately replace the cap and close tightly after removing a test strip.
- Use test strip immediately after removing it from the vial.
- Do not use test strips after the expiration date. It may cause inaccurate results.
- Make a notation of the discard date when you first open it.
- Discard any remaining test strips after 6 months of first opening.
- Avoid getting dirt, food, and water on the test strip. Do not handle test strips with wet hands.
- Do not bend, cut, or alter test strips in anyway.

Cautions and Safety Information section

- For in vitro diagnostic use only
- The single-patient use system is for single-patient use only and should not be shared.
- Not for neonatal use
- Do not use for diagnosis of or screening for diabetes mellitus.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
- Alternative site testing (AST) should only be performed during periods of steady-state blood glucose conditions (when glucose is not changing rapidly).
- AST should not be used to calibrate continuous glucose monitors (CGMs).
- AST should not be used for insulin dose calculations.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfecting.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotions, oils, dirt or debris in or on the lancets and the reusable landing device.
- Please refer to the Instructions for use for cleaning and disinfecting OKRA Pro glucose monitoring system.
- Make sure to fill the strip with sufficient amount of blood to avoid inaccurate result.
- Verify the meter code matches the code number printed on the test strip vial.

- Do not reuse test strip. Test strip is for single use only.
- If you experience any symptoms that are not consistent with your test results, call your Health-care Professional.
- Do not make significant changes to your diabetes control program without consulting your Healthcare Professional.
- Do not ignore problems without consulting your Healthcare Professional.
- Do not perform tests at temperatures below 50°F(10°C) or above 104°F(40°C).
- Do not perform tests with humidity below 10% or above 90%.
- Avoid getting dirt, food, and water on the color-coded label (back of test strip).

Test Principle

Sugar in the blood sample will react to the electrodes in the test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the meter and displayed as your result.

Note
Different levels of reactions will occur depending on the amount of sugar in the blood sample.

Reagent Composition

Each OKRA Pro Test Strip contains:

Glucose Dehydrogenase (Aspergillus sp.): 7.2%
Mediator (Hexaammineruthenium Chloride): 42.8%

Binder: 2.2%

Stabilizer: 47.8%

The procedure for Blood Glucose Measurement

- Materials provided: OKRA Pro Test strips
- Materials required but not provided: OKRA Pro meter, Instructions for use, control solution Level 2, reusable lancing device and lancets.

Obtaining Blood Sample

The test strips are designed to be used with fresh capillary whole blood. The meter gives you the ability to obtain a blood sample for testing your sugars from different areas of your body. You may obtain a blood drop from either a fingertip or an alternative site (dorsal hand, ventral palm, upper arm, forearm, calf, and thigh).

Caution

- OKRA Pro meter and reusable lancing device are for single patient use only. Do not share them with anyone including other family members! Do not use on multiple users!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Never share a lancet or a reusable lancing device with anyone.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotions, oils, dirt or debris in or on the lancets and the reusable landing device.
- Please refer to page 46-51 in the Instructions for use for cleaning and disinfecting OKRA Pro Blood Glucose Monitoring System.

To test a drop of blood, follow these steps

Step 1 Wash your hands and test site with warm soapy water. Dry thoroughly. You may also use an alcohol wipe to clean. Make sure it is completely dry before testing. (Dirt, oil, lotion, or sweat may affect the test result).

Step 2 Prepare the lancing device. Insert a lancet into the lancing device. The device holds, positions, and controls how deeply the lancet goes into the skin. (Refer to the Instructions for use for more information).

Step 3 Remove a test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other test strips. Insert the test strip into the port of the meter with the “arrow” mark facing up.The meter will automatically turn

on and display the code number. Make sure the code number matches the code number on the test strip vial. If the code numbers do not match, do not use it and contact customer support immediately. Refer to Instructions for use.

Step 4 Poke the test site. Only a small drop of blood is necessary for accurate test results. Touch the top edge of your test strip to the drop of blood and do not remove it until you hear the "beep" sound. The meter will countdown from 5 to 1 and a test result will be displayed.

NOTE
Poking the side of your fingertip is less painful. Do not squeeze or milk the puncture site.

Step 5 The meter will automatically store your results in the memory to be retrieved at anytime. Push the ejector button forward to discard the test strip.

Important Information about Using Alternative Sites Testing

- Alternative sites where you can test are dorsal hand, ventral palm, upper arm, forearm, calf, and thigh.
- Under certain conditions, blood glucose test results obtained using samples taken from your alternative sites may differ significantly from fingertip samples.
- The conditions in which these differences are more likely to occur is when your blood glucose is changing rapidly such as following a meal, insulin dose, or physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternative sites samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood sugar) level sooner than a test with an alternative site sample.
- Use alternative sites samples only for testing prior to or more than two hours after a meal, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise or whenever you feel that your glucose levels may be changing rapidly should be done

from the fingertip.

• You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) particularly if you suffer from hypoglycemic unawareness (lack of symptom to indicate as insulin reaction), as forearm testing may fail to detect hypoglycemia.

Test Results

The results are displayed on the meter as milligrams of glucose per deciliter of blood (mg/dL). The meter displays results between 20~600mg/dL. If the test result is below 20mg/dL, "Lo" will appear on the meter display. Consult with your healthcare professional immediately on how to treat extremely low blood sugar (hypoglycemia). If the test result is above 600mg/dL, "HI" will appear on the meter display. This indicates extremely high blood sugar (hyperglycemia). Seek medical assistance immediately.

IMPORTANT NOTE
Blood sugars may be altered by your food, physical activity, and/or stress.

Range of Expected Values:

Self-testing of blood glucose levels provides a way to control your diabetes. Consult with your healthcare professional to determine the best range of expected blood glucose values for you.

Expected blood glucose values for non-diabetic adults are as follows: Before eating < 100 mg/dL (5.6 mmol/L)
One to two hours after meals < 140 mg/dL(7.8 mmol/L)

Reference: American Diabetes Association, Clinical Practice Recommendations (2013) Diabetes Care, Vol. 36, Supplement 1, p S1 – S100

IMPORTANT

If your blood glucose result is unusually low or high, repeat the test again with a new test strip.

If the results are still inconsistent, please consult your Healthcare Professional.

Quality Control (System Maintenance)

Control Solution is designed to ensure that the meter and the test strips are working together properly.

NOTE
Control Solution Level 2 is included in the system package. Levels 1 and 3 control solutions are also sold separately. Please contact OKRA Pro Customer Service at (833-977-1339) or visit www.okra.care for purchasing.

OKRA Pro glucose control solution can be used with the OKRA Pro meter and OKRA Pro test strips only.

Always perform a control solution test when

- A new vial of test strips is opened.
- Any suspicion that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with your symptoms.
- If you drop the meter.

When the control solution is applied to the top edge of the test strip, you should get results within theexpected range printed on the label of the test strip vial. If the control solution test results fall outside the range, repeat the test. Results that fall outside the range may be caused by:

- Error in performing the test.
- Failure to shake the control solution bottle well (must shake vigorously).
- Failure to discard the first drop of control solution.
- Expired or contaminated control solution.
- Test strip deterioration.
- Meter malfunction.
- Control solution that is too warm or cold.

IMPORTANT NOTE

If the control solution test results continually fall outside the range printed on the vial, the OKRA Pro glucose monitoring system may not be functioning properly. DO NOT use the system to test your blood until you receive a control solution test result that falls within the correct range. If you continue to have problems, contact your local representative immediately.

Limitations of System

The OKRA Pro test strips provide accurate results when the following constraints are observed: Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with this meter.

- Use only the OKRA Pro test strips with the OKRA Pro meter.
- Use fresh capillary whole blood only.
- The test strips are for single use only. Do not reuse.
- Dehydration may cause higher test results.
- Inaccurate results may occur when in shock, hypotensive, hyperglycemic, or hyperosmolar state and with or without ketosis.
- OKRA Pro test strips used above altitudes of 10,000 feet will have an effect on test results.

Please note the following interferences that may affect test results:

OKRA Pro test strip results can be used with hematocrit levels in the range of 20% to 65%. If the hematocrit range is out of the range(20%~65%), then the test results may be lower or higher than the actual value.

- Interferences: Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances

(when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results. Samples containing Bilirubin up to 30.0 mg/dL, Ascorbic acid up to 3.0 mg/dL & Ibuprofen up to 37.5 mg/dL do not significantly affect results.

- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dL do not significantly affect the results. Values beyond these levels should be interpreted with caution.

- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.

- Icodextrin does not interfere with OKRA Pro strips.

Performance Characteristics

The performance of the test strips has been evaluated in clinical trials. Measurement Range: The measurement range of the OKRA Pro glucose monitoring system is 20 to 600 mg/dL.

Accuracy: The accuracy results obtained with the OKRA Pro glucose monitoring system were compared to glucose results obtained with the YSI 2300 Auto analyzer, a laboratory instrument. Glucose levels were measured on 100 fresh capillary specimens at three different clinical centers.

System accuracy results for Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
35/51 (68.6%)	48/51 (94.1%)	51/51 (100.0%)

System accuracy results for Glucose concentration <75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
148/249 (59.4%)	222/249 (89.2%)	248/249 (99.6%)	249/249 (100.0%)

Regressions between OKRA Pro BGMS results and the YSI 2300 for the capillary whole blood samples:

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y= 0.9886x - 0.3843	(0.978, 0.999)	(-2.610, 1.842)	0.9916	300

The study shows that the OKRA Pro glucose monitoring system compares well with the laboratory method.

Precision

Precision Results for venous whole blood samples.

Blood Conc. Level	N	44 mg/dL	83mg/dL	125 mg/dL	208 mg/dL	332mg/dL
grand mean	300	43	81	127	209	332
pooled variance	300	2.4	4.4	11.7	27.9	76.3
pooled SD	300	1.6	2.1	3.4	5.3	78.7
95% CI		(1.57, 1.63)	(2.04, 2.16)	(3.33, 3.47)	(5.18, 5.42)	(8.53, 8.87)
pooled CV (%)	300	3.7	2.6	2.7	2.5	2.6

Precision Results for control solutions.

Control Solution Level	N	45 mg/dL	111 mg/dL	307mg/dL
grand mean	600	51	111	311
pooled variance	600	4.8	7.5	60.2
pooled SD	600	2.2	2.7	7.8
95% CI	600	(2.18, 2.22)	(2.26, 2.73)	(7.67, 7.93)
pooled CV (%)	600	4.3	2.4	2.5

Alternative Site Testing Accuracy

The OKRA Pro glucose monitoring system was evaluated for alternative site testing accuracy by comparing blood glucose results of alternate sitesmeasured by patients and health professionals using OKRA Pro glucose monitoring system, and the results measured by the YSI 2300 Autoanalyzer, a laboratory instrument. Glucose levels were measured on 150 fresh capillary specimens at three different clinical centers.

Table 1. Data analysis at DORSAL HAND

Patient DORSAL HAND vs YSI 2300 Finger

System accuracy results for glucose concentration<75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
2/4 (50%)	4/4 (100%)	4/4 (100%)

System accuracy results for glucose concentration≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
92/146 (63%)	123/146 (84%)	143/146 (98%)	146/146 (100%)

Table 2. Regressions analysis at DORSAL HAND

Patient DORSAL HAND vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9922x + 8.3679	(0.975, 1.009)	(3.616, 13.120)	0.9891	150

Table 3. Data analysis at VENTRAL PALM

Patient VENTRAL PALM vs YSI 2300 Finger

System accuracy results for glucose concentration<75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
2/3 (67%)	3/3 (100%)	3/3 (100%)

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/147 (68%)	130/147 (88%)	144/147 (98%)	147/147 (100%)

Table 4. Regressions analysis at VENTRAL PALM

Patient VENTRAL PALM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9834x + 4.4829	(0.966, 1.001)	(-0.332, 9.298)	0.9885	150

Table 5. Data analysis at UPPER ARM

Patient UPPER ARM vs YSI 2300 Finger

System accuracy results for glucose concentration<75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
3/4 (75%)	4/4 (100%)	4/4 (100%)

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
105/146 (72%)	130/146 (89%)	142/146 (97%)	146/146 (100%)

Table 6. Regressions analysis at UPPER ARM

Patient UPPER ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9819x + 4.7354	(0.967, 0.997)	(0.449, 9.022)	v	150

Table 7. Data analysis at FORE ARM

Patient FORE ARM vs YSI 2300 Finger

System accuracy results for glucose concentration<75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
2/3 (67%)	3/3 (100%)	3/3 (100%)

System accuracy results for glucose concentration≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
102/147 (69%)	125/147 (85%)	144/147 (98%)	147/147 (100%)

Table 8. Regressions analysis at FORE ARM

Patient FORE ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9989x - 0.0575	(0.981, 1.017)	(-5.167, 5.052)	0.9874	150

Table 9. Data analysis at THIGH

Patient THIGH vs YSI 2300 Finger

System accuracy results for glucose concentration<75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
1/4 (25%)	3/4 (75%)	4/4 (100%)

System accuracy results for glucose concentration≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
98/146 (67%)	124/146 (85%)	140/146 (96%)	146/146 (100%)

Table 10. Regressions analysis at THIGH

Patient THIGH vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9827x + 1.3423	(0.965, 1.001)	(-3.693, 6.377)	0.9875	150

Table 11. Data analysis at CALF

Patient CALF vs YSI 2300 Finger

System accuracy results for glucose concentration<75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
3/4 (75%)	4/4 (100%)	4/4 (100%)

System accuracy results for glucose concentration≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
101/146 (69%)	128/146 (88%)	140/146 (96%)	146/146 (100%)

Table 12. Regressions analysis at CALF

Patient CALF vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9907x + 5.6915	(0.974, 1.008)	(0.878, 10.505)	0.9888	150

IMPORTANT

- Before using the OKRA Pro meter and test strips, read all of the operating instructions in the Instructions for use.
- Consult with your Healthcare Professionals on managing your diabetes daily with the OKRA Pro brand glucose monitoring system.
- If you have any questions about using the products, please contact OKRA Pro Customer Service at (833-977-1339) or visit www.okra.care.

Table 11. Data analysis at CALF

We understand that self-testing your blood sugar levels provides a way to control your diabetes. As a result, the OKRA Pro glucose monitoring system was developed to help you manage your diabetes by the most comfortable and convenient way possible. Our goal at OKRA Pro is to provide you the best quality products and superior customer service. If you have any questions or comments, please

contact OKRA Pro Customer Service at (833-977-1339) or visit www.okra.care.

For customer support, please contact toll free:
(833-977-1339) Available Monday thru Friday,
9 to 5 pm Eastern Time.

Control Solution Manual

Intended Use

The OKRA Pro control solutions are for use with OKRA Pro meter and test strips to check that the meter and test strips are working together properly and that the test as a quality control checks to verify the accuracy of blood glucose test results.

Quality Control

Acceptable performance is assured when the control test results falls within the appropriate range listed on the vial of your test strips.

Summary

The control solution contains a known amount of glucose that reacts with the test strip. A test with control solution is similar to that of a blood test. All you do is to use your control solution instead of a drop of blood. The control solution result should fall within the appropriate range printed on the side of the test strip vial.

CAUTION
If the glucose control solution test is not in range, DO NOT continue with a blood glucose test. Please contact customer support toll free at (833-977-1339) Monday thru Friday, 9 to 5pm Eastern Time.

Performing a glucose control solution test

- Before using a new box of strips.
- Whenever you feel that your sugar levels are inaccurate.
- If you feel the meter or test strips have been compromised in anyway.
- When your test results are inconsistent with your symptoms.

Storage and handling

- Make sure the control solution bottle is tightly closed and stored between 46~86°F (8~30°C) and not in direct sunlight. Do not Freeze.
- If the control solution is too warm or cold, do not use until the solution has remained at room temperature for at least 30 minutes.
- Use before the expiration date shown on the bottle.
- Once opened, the control solution expires after 3 months.
- Record the discard date on the control solution bottle. Discard after three months.
- Discard according to local regulations.
- Do not use if the expiration date has passed.

Test Procedure

Accurate results are dependent on following instructions carefully.

1. It is recommended that the meter, control solution, and test strips are at room temperature(68~77°F) before testing.
2. Prior to use, gently shake the bottle.
3. Discard the first drop of control solution.
4. Wipe the tip clean.
5. Make sure the test strip is inserted fully into the test port of the meter.
6. The meter will automatically turn on and display the code number. Make sure the code number matches the code number on the test strip vial.
7. Specify that it's a control solution test and not a regular blood sugar test by pressing the up or down button. A control solution bottle(C)will appear on the bottom of the screen.
8. Place a drop of control solution on a clean, dry surface (For example: the lid of your test strip vial). Pick up the meter and touch the end of the test strip to the drop. Be sure to hold the test strip to the drop until you hear a 'beep' sound.
9. A result will appear in 5 seconds.
10. Compare the result to the range printed on the test strip vial, the result should fall within that range.

Reagents

Each OKRA Pro control solution is provided as a buffered, stabilized, aqueous solution of D-glucose containing a preservative and other non-reactive ingredient.

Level 1 0.04 wt% glucose 99.96 wt% non-reactive ingredients

Level 2 0.12 wt% glucose 99.88 wt% non-reactive ingredients

Level 3 0.20 wt% glucose 99.80 wt% non-reactive ingredients

Precautions

The control solution is for In-Vitro Diagnostic use only. This means that it is only used for testing outside of the body.

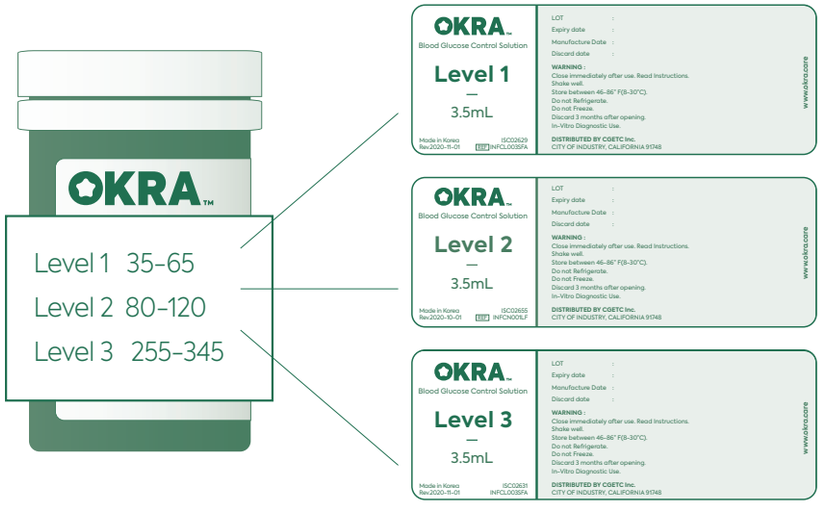
- The control solution is made for the OKRA Pro glucose monitoring system. Do not use any other brand of control solutions.
- Check the expiration date on the bottle. Do not use if expired.
- Do not swallow. Not for human or animal consumption.

Expected Results

At room temperature, control solution test results will fall within the expected range printed on the test strip bottle.

For example only

If you are using the Level 2 control solution, according to this particular vial of strips, your meter should show a number between 80 and 120.



* Caution: The ranges in the picture above are examples only.
Please refer to your test strip vial label for the exact ranges.

If your control solution test falls out of range, please follow the next steps before contacting customer support:

- Check the expiration dates on all the products you are using. Be sure you are using OKRA Pro control solution.
- Try another control solution test.
  If this test falls out of range, try another control solution test with a new unopened vial of strips.
- After following the appropriate steps and the control test still falls out of range, do not perform a glucose test. Please call customer support toll free: (833-977-1339)

Results that fall outside the expected range may indicate:

1. Test performed was not in room temperature.
2. Expired or contaminated control solution.
3. Control solution is too warm or cold.
4. Failure to discard the first drop of control solution and to wipe the bottle tip clean.
5. Failure to shake the control solution adequately.
6. A problem with the meter.
7. An error in the way you are doing the test.

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Quality Guarantee

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