PixoTest

Instructions for Use

PixoTest® Point of Care Test (POCT) System

The Instruction for Use of PixoTest POCT System on PixoTest A1c & Lipid test strip 1

1. Indication for use 4
2. Test principle 4
3. Before test 4
4. The PixoTest® POCT System includes 5
5. Test strip 5
6. Settings 6
7. Preparing for measurement 6
8. Running test-A1c 7
9. Running test-lipid 9
10. Understanding result 9
11. Record 10
12. Calibration 11
13. Control solution test 11
14. CS test for A1c 12
15. CS test for Lipid 13
16. Control Solution range and meaning 13
17. Shutdown procedure 13
18. Maintenance and troubleshooting 14
19. Clean and disinfection 14
20. Error and Warning message 18
21. Disposal information 20
22. Product information 20
23. Limitation 22
24. Manufacturer 22
25. Symbol 22
26. Servicing 23
27. Limited Warranty 23

Appendix 1: Reference……24

1. Indication for use

The iXensor PixoTest® POCT System is comprised of PixoTest® A1c/Lipid Test Strip, PixoTest® POCT Analyzer, PixoTest® POCT Calibration Card, and the PixoHealth POCT-A1c/Lipid APP as the display component of the system. The iXensor PixoTest® POCT System is intended to be used for the quantitative measurement of HbA1c and Lipids (including Total ciholesterol, Triglycerides, and High-Density Lipoprotein (HDL) cholesterol) in whole blood from both capillary and venous. Estimated values for Low-Density Lipoprotein (LDL) cholesterol are calculated by the PoxoHealth POCT-Lipid APP.

The PixoTest® POCT System is a professional use only product and intended for in vitro diagnostic use and is not intended for use on neonates. Untrained personnel could perform it well

2. Test principle

The iXensor PixoTest® POCT System combines enzymatic methodology and reflectance photometry to measure HbA1c and Lipids. Samples from both capillary and venous whole blood can be used. This whole blood sample is applied to PixoTest® A1c/Lipid Test Strip, and a reaction occurs to produce a color that is read by using reflectance photometry of the reagent area. The level of color produced is proportional to the concentration.

PixoTest® POCT System-A1c uses an anti-HbA1c (%) antibody which is specific for the first few amino acid residues of the glycated N-terminus of the ß-chain of hemoglobin A0. PixoTest® A1c Test Kit contains the PixoTest® A1c Test Strip (nitrocellulose membrane), Spoit with latex-tablet (blue dyed latex micro particles conjugated to specific antibodies) and Buffer solution tube (hemolysis reagent). When whole blood is added to the buffer solution and is mixed with the latex-tablet, the erythrocytes are instantly lysed to release the glycated hemoglobin (hereafter, HbA1c). When the sample mixture is loaded onto the sample port of the test panel, the mixture fluid migrates along the membrane of the test panel by capillary action, and the HbA1c is then immobilized onto the anti-HbA1c antibody coated line. The amount of the blue conjugates on the anti-HbA1c line reflects the amount of HbA1c in the sample, the intensity of hemoglobin color measured from the desired area on the membrane of test panel is measured. Chemical and immune reaction that occurs on the test strip is measured by the optical system in PixoTest® POCT System. This system measures both fractions and an algorithm which converts the result into the percentage HbA1c in the sample.

PixoTest® POCT System-Lipids combines enzymatic methodology and reflectance photometry to measure Total cholesterol, Triglycerides, and HDL cholesterol. When whole blood sample is applied to PixoTest® Lipid Test Strip, the blood reacts to produce color that is read by using reflectance photometry of the reagent area. The level of color produced is proportional to the concentration. All lipid enzymatic reactions can refer to Lipid test strip insert.

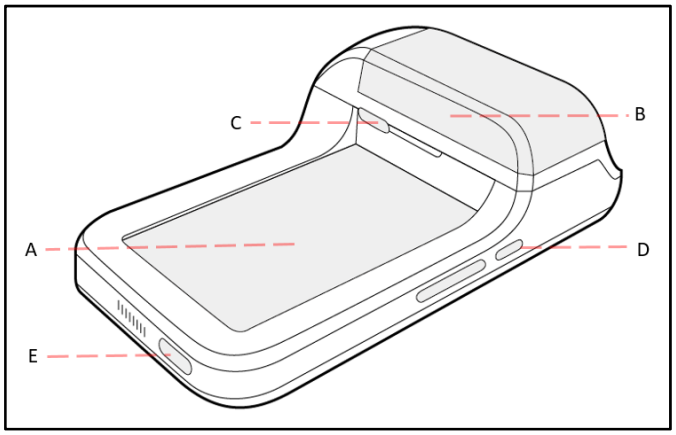
3. Before test

Before using this product to test your A1c and Lipids, carefully read this Instruction for Use. Prior to launching the PixoHealth POCT A1c/Lipids App, use the PixoTest® POCT Calibration Card to verify that the PixoTest® POCT System is working properly. The A1c/Lipids Control Solution is used to verify that the PixoTest® POCT System and PixoTest® A1c/Lipid Test Strip are working properly.

NOTE
The battery life needs to be over 20% before using the PixoTest® POCT System.
Do not charge your PixoTest® POCT System when it is in use.
If the battery is below 20% or charging, an error will appear and the test cannot be started.

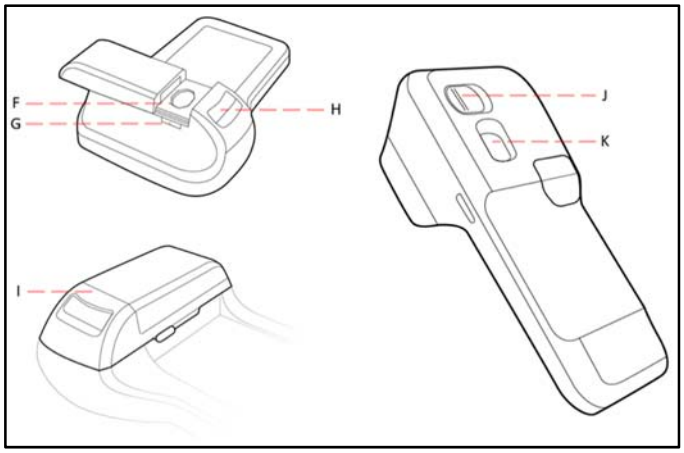
4. **The PixoTest® POCT System includes**
   The PixoTest POCT Analyzer :
   * PixoHealth POCT A1c/Lipid App
   * USB Charger
   * Indications For Use
   * USB Type C Charge Cable
   * Test Strip Insert
   * PixoTest POCT Calibration Card

Fig.1 Front sight of PixoTest® POCT Analyzer (POC-X01)



A	**Display** Shows a test result, messages, and the test results stored in memory.
B	**Sliding Door** Open to apply sample.
C	**Item Selection Key** Select measurement mode.
D	**Power Key** Press to turn analyzer ON or OFF.
E	**USB Charge Port** Charge the analyzer.

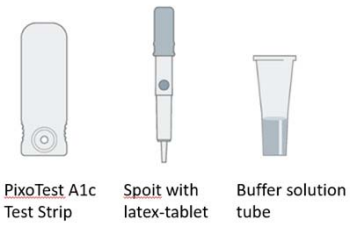
Fig.2 Back sight of PixoTest® POCT Analyzer (POC-X01)



F	**Protection Cover** Remove to clean.
G	**Lipid Test Strip Slot** Insert a lipid test strip here.
H	**A1c Test Strip Slot** Insert A1c test strip here.
I	**Strip Module**
J	**Strip Module Lock Switch** Unlock to change the strip module.
K	**Camera Module** Scan QR code

5. **Test strip**
   PixoTest® POCT System includes PixoTest® POCT A1c Test kit and PixoTest® POCT Lipid Test Strip (both sold separately). The following contents are included:

   PixoTest® POCT A1c Test kit (use with PixoTest® POCT Analyzer):
   - 20 PixoTest® A1c Test Strips (for different package)
   - 20 Spoit with latex-tablet
   - 20 Buffer solution tube
   - 1 package insert



PixoTest® POCT Lipid Test Strip (use with PixoTest® POCT Analyzer):

- 25 PixoTest® Lipid Test Strips (for different package)
- 1 package insert

6. Settings

When using the PixoTest® POCT System for the first time, perform the following steps:

Step 1. Press the Power Key for 2 seconds to turn on the Analyzer.

Step 2. Slide up the screen to unlock the Analyzer.

Step 3. Select "Language" option. The selected language is shown on the 2nd line item.

Step 4. Turn on the Wifi connection, typing in the password if necessary. Connection status is shown at the 2nd line item.

Step 5. Click "Version Check" to verify that the most up-to-date APP version is installed or needs to be updated.

Step 6. Select "Time Zone" option to set the 24-hour Format, and manually select the correct time zone.

Step 7. Press "Next" on the System Activation screen to scan the product key which is provided by the local distributor or the service center to activate the analyzer. Once it is activated, press "Finish" button to complete all settings.

On Home screen, the main screen of the PixoTest® POCT system, press the "Settings" button for the change of the system settings, includes Language, Wifi and Time Zone.

NOTE

After completing all settings, a calibration is required before operating, and must be done daily. Refer to Chapter 13 for the calibration process.

7. Preparing for measurement

The iXensor PixoTest® POCT System

- PixoTest® A1c/Lipid Test Strip
- PixoTest® POCT Analyzer : POC-X01
- PixoHealth POCT-A1c/Lipid APP
- PixoTest® POCT Calibration Card
- A1c/Lipid Control Solution
- Spoit with latex-tablet and Buffer solution tube for A1c test
- 35 µl tube for Lipid test*
- Instructions for use
- Additional required materials:
- Alcohol swabs to clean puncture site
- The EPA-registered disinfectant wipes to disinfect the surface of POCT system
- Lancets for capillary or venous blood collection supplies (vacuum collection tubes, needles and tube holders)
- Gloves
- Biohazard waste containers

NOTE

*: 35 µl tube are not included and can be purchased from a local distributor; collect sample with a suitable tool for 35µL (ex: micropipette or quantitative dropper.)

POC-X01

PixoTest® POCT System is intended to monitor A1c and Lipids using POC-X01 (Fig.1) to conduct the test.
Item selection key: To test A1C, slide the Item Selection key to the "II" indication. To test Lipids, slide the item selection key to the "I" indication.
Sliding door: When testing Lipids, open the sliding door to insert the PixoTest® lipid test strip into the Lipid Test Strip Slot.
A1c Test Strip Slot: To insert the PixoTest® A1c test strip into the A1c test strip slot (Fig.2).
⚠Lipid Test Strip Slot: To insert the PixoTest® lipid test strip into the lipid test strip slot (Fig.2)

CAUTION

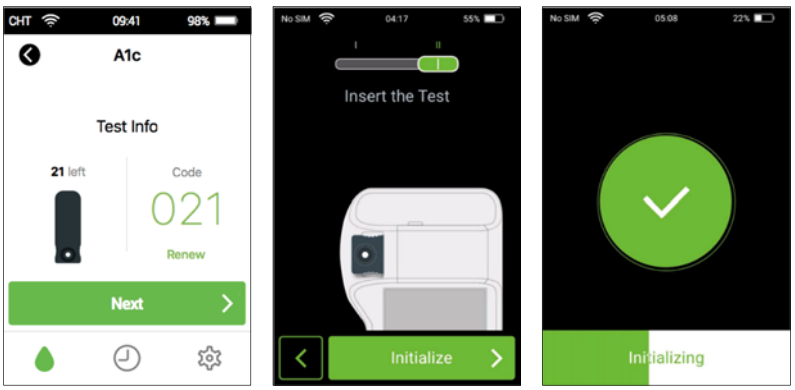
- Keep PixoTest® Lipid Test Strip stored in a dry place between 36 – 90°F(2 – 32°C), and avoid direct sun exposure.
- Keep A1c Test Strip stored in a dry place between 34 – 86°F(1 – 30°C), and avoid direct sun exposure.
- Do Not open the test strip package until ready to perform the test. Use test strip immediately after removal from the package.
- Do Not return the used test strip to the original box after performing the test; dispose of used test strip.
- Do Not re-use a test strip that had blood or control solution applied to it. The strip is for single use only.
- Do Not modify the test strip in any way.
- Do Not use your PixoTest® A1c/Lipid Test Strip if the package is damaged or left open to air.
- Do Not use the device near sources of electromagnetic radiation such as microwaves.
- Do Not carry out the test in direct sunlight. The measurement should be performed in an appropriate light environment.
- Do Not use test strip after the expiration date (printed on the package) or your results may be inaccurate.
- Always keep POC-X01 clean.
- Confirm that the code number is the same as the code on the foil pouch package.
- To conserve power, the Analyzer turns itself off after 10 minutes unless a power button is pressed. When the Analyzer turns itself off, all test results obtained so far remain in the memory.
- When the low battery warning (less than 20%) appears, a test cannot be performed. Charge the Analyzer immediately.
- Measurement results, including the related measurement date and time as well as all other Analyzer settings, remain stored even when there is no power.

8. Running test-A1c

Step 1. Before testing, wash your hands with warm, soapy water. Rinse and dry completely.
Step 2. Tap "Settings" button on the Home screen of PixoTest® POCT System and tap "A1c" button to open the PixoHealth POCT-A1c App.
Step 3. Tap "Renew" to scan the QR code, pasted on the test strip box.
Step 4. Tap "Next" button to start A1c measurement.
Step 5. Please slide the item selection key to the "II" indication. Check the strip code number and insert the test strip in the slot. Press "initialize" button for initialization.

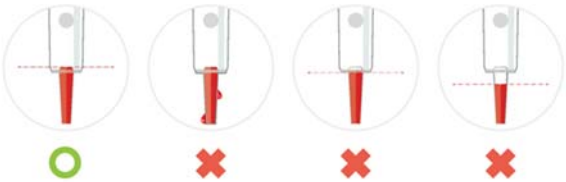
NOTE

1. Please make sure the POC-X01 is placed on a flat surface.
2. The system shows the number of the remaining test. Please open a new strip box and scan its QR code to reset the counting when the remaining tests reaches zero.

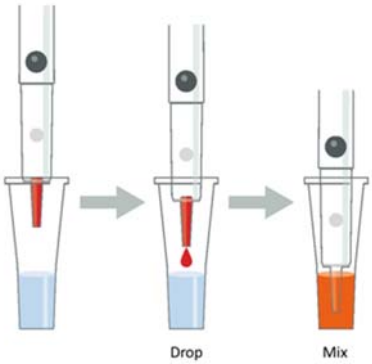


Step 6. Obtain a blood sample using the lancet and lancing device. (If you use the venous blood, check the collection date and the anticoagulant.)

Step 7. Collect the 5 µl blood sample and put it in the buffer solution tube.



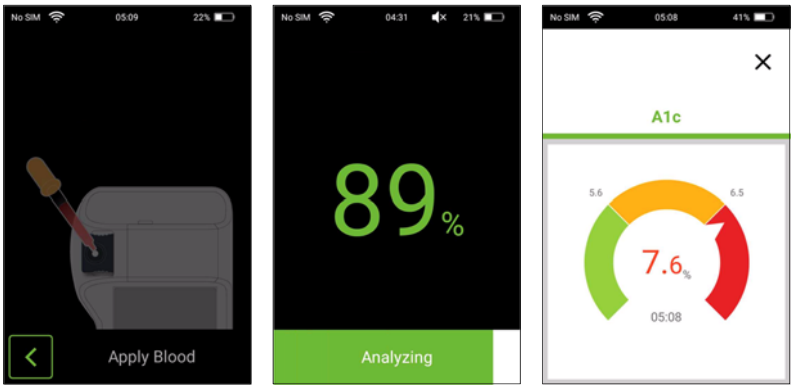
Step 8. Mix the buffer solution and blood sample by gently squeezing the rubber top of the spot 6-8 times.



NOTE

1. Block the hole on the stop of the spot while mixing.
2. Avoid bubbles while mixing.

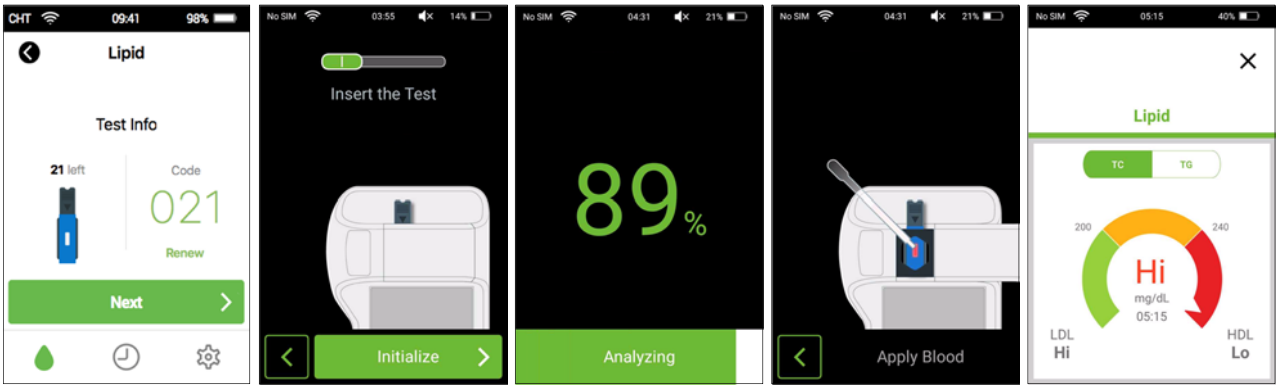
Step 9. Collect all the reaction mixture from the buffer solution tube. Once the “Apply Blood” animation on the screen, the blood sample can be applied on the test strip. The A1c test result will appear after 3 minutes.



9. Running test-lipid

Step 1. Before testing, wash your hands with warm, soapy water. Rinse and dry completely.
Step 2. Tap “Settings” button on Home screen of PixoTest® POCT System and tap “Lipid” button to open the PixoHealth® POCT-Lipid App.
Step 3. Tap “Renew” to scan the QR code pasted on the test strip box.
Step 4. Tap “Next” button to start the lipid measurement.
Step 5. Please slide the item selection key to the “I” indication. Check the strip code number and insert the test strip in the slot. Press “initialize” button for initialization.
Step 6. Obtain a drop of blood sample using the lancet and lancing device.
Step 7. Collect a 35 µl blood sample using the tube. Place the blood sample into the application hole of the test strip. Then, close the sliding door.
Step 8. Lipid test result will appear after 3 minutes.

NOTE
The system shows the number of the remaining test. Please open a new strip box and scan its QR code to reset the counting when the remaining tests reaches zero.



10. Understanding result

Measuring Range
Test strips can measure numerical results in the following ranges:

- HbA1c: 4-15% (68.1 – 383.8 mg/dL, 3.77 – 21.26 mmol/L)
- Total Cholesterol: 100 – 450 mg/dL (2.59 – 11.64 mmol/L)
- Triglycerides: 45 – 650 mg/dL (0.51 – 7.34 mmol/L)
- HDL cholesterol: 25 – 95 mg/dL (0.65 – 2.46 mmol/L)
- LDL calculated range: 66-225 mg/dL (1.71~5.82 mmol/L)

If the result is outside the measuring range, the system will display “Hi” when the results are above the measuring range, and display “Lo” when the results are below the measuring range.

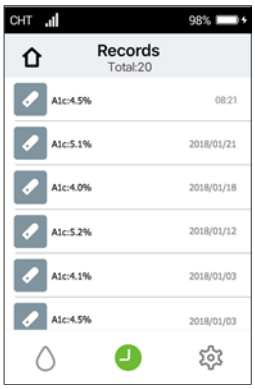
⚠ **CAUTION**
If there is a “Lo/Hi” or an unexpected result for any test, test again with a new test strip.

11. Record

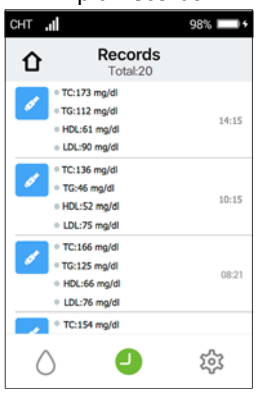
Reviewing Past Results

Open up the PixoHealth POCT-A1c/Lipid App. Three function buttons will appear on the screen. Tap the “Records” icon to review each past result by date and time.

A1c Records



Lipid Records



Expected Values

A1c:

% HbA1c	Interpretation of results	Display color
<=5.6%	Non Diabetic Range	Green
5.6%-6.5%	ADA (American Diabetes Association) Target	Yellow
>=6.5%	Above Target	Red

Lipid:

The national Heart, Lung and Blood Institute issued the Third Report of National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) in May 2001. The ATPIII report presented the NCEP’s updated clinical guidelines for cholesterol testing and management and described the following classifications for cholesterol and triglyceride testing.

	mg/dL	mmol/L	Classification	Display color
TC (Total Cholesterol)	<200	<5.18	Desirable	Green
	200-239	5.18-6.19	Borderline high	Yellow
	>=240	>=6.22	High	Red
TG (Triglycerides)	<150	<1.69	Normal	Green
	150-199	1.69-2.25	Borderline high	Yellow
	>=200	>=2.26	High	Red
HDL	<40	<1.03	Low	Black
	>=60	>=1.55	High	Black
LDL	<100	<2.59	Optimal	Black
	100-129	2.59-3.34	Near optimal / above optimal	Black
	130-159	3.36-4.11	Borderline high	Black
	160-189	4.14-4.89	High	Black
	>=190	>=4.91	Very high	Black

The ATPIII identified HDL levels below 40 mg/dL (1.03 mmol/L) as associated with increased risk of coronary heart disease (CHD) in men and women. A high HDL level greater than or equal to 60 mg/dL (1.55 mmol/L) is protective and decreases CHD risk.

LDL

LDL can be calculated using the equation below. Calculated LDL is an estimation of LDL, defined by the specification of TC, TG, and HDL.

- LDL (calculated)=Total Cholesterol-HDL-(Triglyceride/5) (mg/dL)
- LDL (calculated)=Total Cholesterol-HDL-(Triglyceride/2.17) (mmol/L)

12. Calibration

The PixotTest® POCT system will automatically alert the User to complete a calibration. The user must to complete the calibration with PixoTest® POCT Calibration Card.

PixoTest ®POCT Calibration Card is used to calibrate the PixoTest® POCT system and to confirm the function of the front camera and PixoHealth POCT-A1c/Lipid App.

The PixoTest® POCT System must be calibrated daily. If this has not been completed, the PixoHealth POCT A1c/Lipid App will not be able to perform tests until calibration has completed.

When to do a Calibration:

- When using a new box of A1c/Lipid Test Strip.
- When there is an unexpected test result.

Where to perform a Calibration:

- The system shows “CALIBRATION” on the Home screen automatically at the first time using the Analyzer every day. Tap the “Calibration” button to start the calibration process.
- To perform a calibration anytime, tap “Settings” button on Home screen of PixoTest® POCT system and tap “Calibration” button to start the calibration process.
- A calibration test can be initialized from the “Settings” of PixoHealth POCT-A1c/Lipid App anytime.

How to Calibrate:

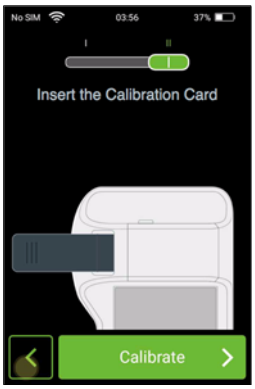
Step 1: Please slide the item selection key to the “II” indication. Insert the Calibration card into the A1c slot and press “Calibrate” button.

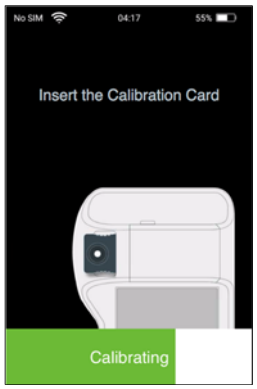
Step 2: The APP will automatically start the calibration. Wait for a few seconds to complete the calibration.

Step 3: When the calibration is complete, tap “Confirm” to continue the testing mode.

NOTE

1. Avoid long exposures to light.
2. Avoid touching finished surface on color block of calibration card.
3. Keep calibration card in black protective sheath when completed calibration.





13. Control solution test

iXensor Co. Ltd. does not provide control solutions, Bio-Rad control solution of A1c and Lipid are

recommended for PixoTest® POCT System:
A1c: Bio-Rad Liquicheck Diabetes Control (level 1, 2), Cat# 171, 172
Lipid: Bio-Rad Liquicheck Lipids Control (level 1, 2), Cat# 641, 642

The Control Solution is used to verify that the PixoTest® POCT System is working properly (A1c/Lipid Control Solution are sold separately). To purchase the control solution, please contact iXensor Co. Ltd. toll free at 1-800-218-0929, Mon-Fri 9AM-5PM (PST).

When to do a A1c/Lipid Control Solution Test

- If the strip, PixoHealth POCT-A1c/Lipid App or POCT-X01 seems to not be working properly.
- If the testing results are unusual or unexpected.
- If the Analyzer has been dropped or damaged.

⚠ **CAUTION**

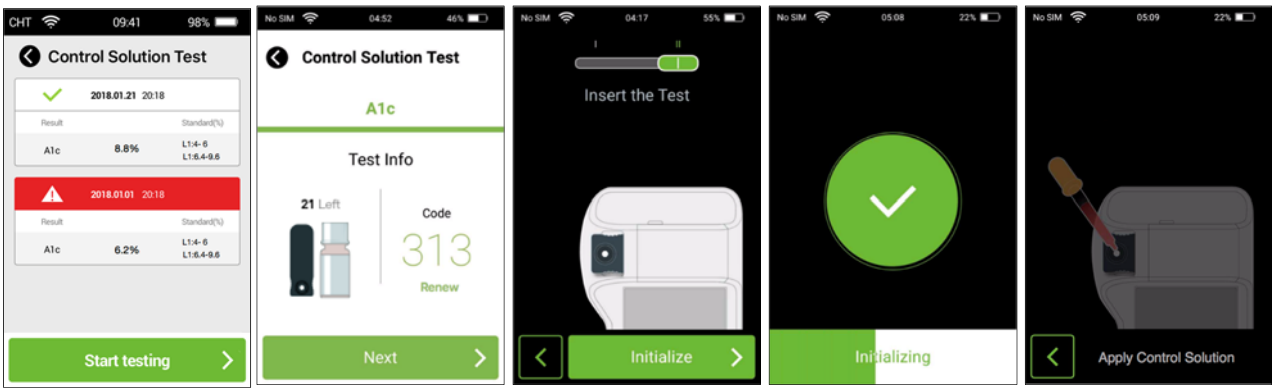
- Use only the BioRad A1c/Lipid control solution to verify that the PixoTest POCT System is working properly. Do not use any other brand of control solution.
- A1c/Lipid Control Solution is for in vitro diagnostic use only. This means that is only used for testing outside of the body.
- Do Not swallow or ingest A1c/Lipid control solution.
- Do Not use A1c/Lipid control solution after the expiration date (printed on control solution bottle, shelf life: 3 year at -20℃ to -70℃) or the discard date (14 days from the date the control solution vial was opened), whichever comes first. Using the solution after the expiration or discard date will cause your results to be inaccurate.

14. CS test for A1c

Step 1: Before testing, wash your hands with warm, soapy water. Rinse and dry completely.
Step 2: Clean and disinfect the Analyzer surface as instructed. Start a control solution test by tapping the icon "Settings" and select "Control Solution Test" option in the PixoHealth POCT-A1c App.
Step 3: The main screen of Control Solution Test lists all test results, tap the "Start testing" button to enter the Test Info screen.
Step 4: Tap "Renew" to scan the code on the test strip box if the code hasn't been scanned. And press "Next" button to start the test.
Step 5: Please slide the item selection key to the "II" indication. Check the strip code number and insert the test strip in the slot. Press "initialize" button for initialization.
Step 6: Once the control solution-applying animation is displayed on the screen, obtain a control solution sample of Level 1 or Level 2 and apply the control solution on the test strip. The test result will appear after 3 minutes.

NOTE

1. Please make sure the Analyzer is placed on a flat surface.
2. The system shows the number of remaining tests. Please open a new strip box and scan its QR code to reset the counting when the remaining tests reaches zero.



15. CS test for Lipid

Step 1: Before testing, wash your hands with warm, soapy water. Rinse and dry completely.

Step 2: Clean and disinfect the Analyzer surface as instructed. Start a control solution test by tapping the icon “Settings” and select “Control Solution Test” in the PixoHealth POCT-Lipid App.

Step 3: The main screen of Control Solution Test lists all test results, tap the “Start testing” button to enter the Test Info screen.

Step 4: Tap “Renew” to scan the code on the test strip box if the code hasn’t been scanned. And press “Next” button to start the test.

Step 5: Please slide the item selection key to the “I” indication. Check the strip code number and insert the test strip in the slot. Press “initialize” button for initialization.

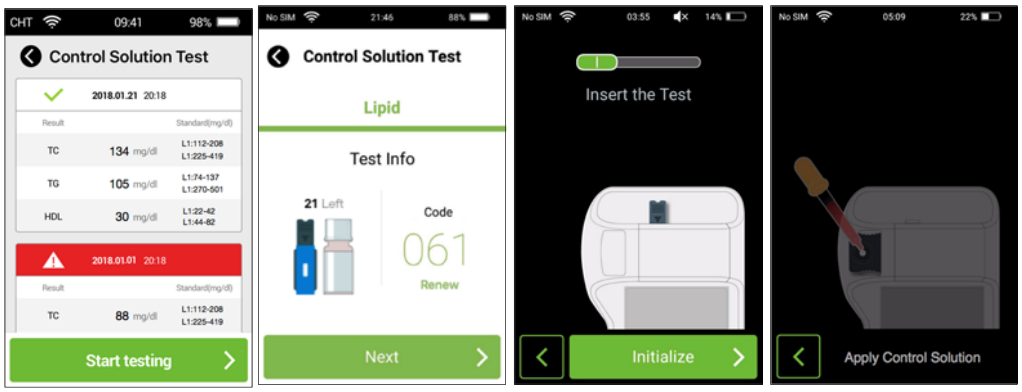
Step 6: Obtain a control solution sample using the 35 µl tube.

Step 7: Collect the 35 µl control solution using the tube and place the control solution sample to the application hole of the test strip, then close the sliding door.

Step 8: Lipid control solution test result will appear after 3 minutes.

NOTE

1. The system shows the number of the remaining tests. Please open a new strip box and scan its QR code to reset the counting when the remaining tests reaches zero.
2. Remove and discard the used test strip. Do not add more blood to a used test strip.



16. Control Solution range and meaning

Out of Range Results

After control solution test, check the result of the control solution value and confirm it is within range. If test results fall outside of the expected range, please repeat the test. Do not continue with your A1c/Lipid test if the control solution test results are continuously out of range. Results that fall outside of the expected range may indicate:

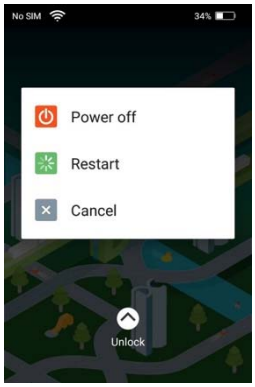
- Test is not performed at room temperature.
- Control solution has expired, is beyond its discard date, or contaminated.
- A technical problem with your PixoTest® POCT System.
- Control solution that is too warm or too cold.
- A problem with the Test Strip (expired or damaged).
- An error calls during the test.

17. Shutdown procedure

When finish using the PixoTest® POCT System, follow the steps to turn the Analyzer off:

Step 1. Press the Power Key for 2 seconds.

Step 2. Tap “Power off” to turn off the Analyzer.



18. Maintenance and troubleshooting

Caring for the PixoTest® POCT System is easy. Simply keep it free of dust. If the system needs cleaning, follow these guidelines carefully to obtain the best performance. To prevent malfunction of the Analyzer, keep the test strip slot free of blood, dirt, or dust. Use a lint-free cloth dampened with water to clean the Analyzer. Ensure the cloth is damp, and not wet. Do not use an abrasive cloth or antiseptic solution, as these may damage the display screen.

A clean optical measuring system is a basic prerequisite for determining precise measured values. Therefore, clean the Analyzer regularly and immediately after it becomes dirty. Always switch off the Analyzer before cleaning it.
Use only the following items for cleaning:

- Ordinary lint-free cotton buds
- Ordinary lint-free tissues
- Ordinary disinfecting tissues
- Do not use any disinfectant sprays or tissues or cotton buds which are dripping wet as the liquid may enter the Analyzer and damage it.

Cleaning the outer Analyzer components

1. Wipe the outside of the Analyzer with a lightly moistened, lint-free cotton cloth.
2. Remove the protection cover.
3. In case of significant dirt, you can rinse the protection cover (separately from the Analyzer) under warm running water.
4. Dry the measurement chamber cover with a fresh cloth.

Cleaning the optical measuring system

1. Remove the strip module.
2. Clean the easily accessible areas of the optical measuring system with a lint-free pad or a moistened cotton swab. Make sure that no liquid enters the Analyzer.
3. Allow the Analyzer to dry thoroughly.
4. Do not fit the strip module into the Analyzer until it is completely dry.
5. Fit the strip module into Analyzer.
6. The Analyzer is now ready for operation again

Maintenance, Testing and Transportation Analyzer

1. Keep the test strip slots free of dust.
2. Protect the internal Analyzer from humidity.
3. There are no effects on product quality in environmental temperatures of -20 – 50°C (-4 – 122°F) during 8 hours and humidity of up to 93% RH, non-condensing during 8hours.

19. Clean and disinfection

Due to the risk of spreading blood born infections, clean and disinfect the POC-X01 after every blood test. Clean the POC-X01 to remove visible dirt, blood or other materials prior to disinfecting. Follow with a second wipe to disinfect the measurement module.

- Clean and disinfect the measurement module at least once per week and when blood is present on the surface of the POC-X01.
- For disinfecting your POC-X01, only use Clorox® Healthcare Bleach Germicidal Wipes (EPA* reg. no. 67619 – 12), containing Sodium Hypochlorite 0.55%. [Can be purchased from Amazon.com, Officedepot.com and Walmart.com].
- Do not use any other cleaning or disinfecting solutions.
- Use of disinfecting products other than Clorox® Healthcare Bleach Germicidal Wipes have not been validated for the PixoTest® POCT System have not been validated. Always use Clorox Healthcare Bleach Germicidal Wipes.

Test process – Lipid
Use two wipes.
Follow the cleaning instruction for the first wipe and the disinfection instruction for the second.

Cleaning:
1. Follow the cleaning instruction first.
2. Put on clean gloves
3. Take one wipe and squeeze out excess moisture from the wipe before use.
4. Follow the Figure 3 to wipe the meter front and meter screen respectively.

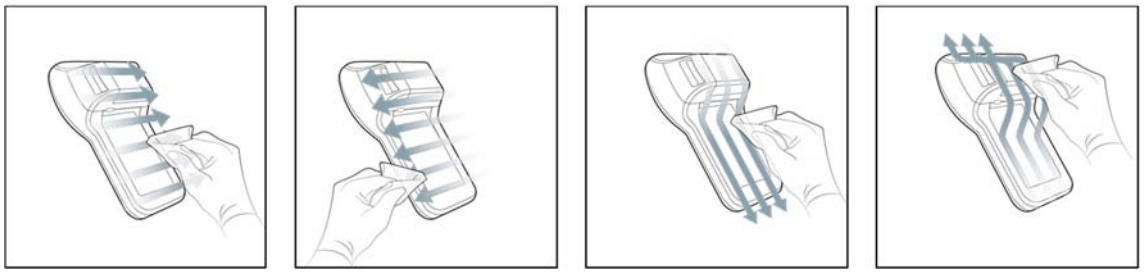


Figure 3. Wipe the meter front and meter screen respectively.

5. Follow the Figure 4 to wipe the meter back.

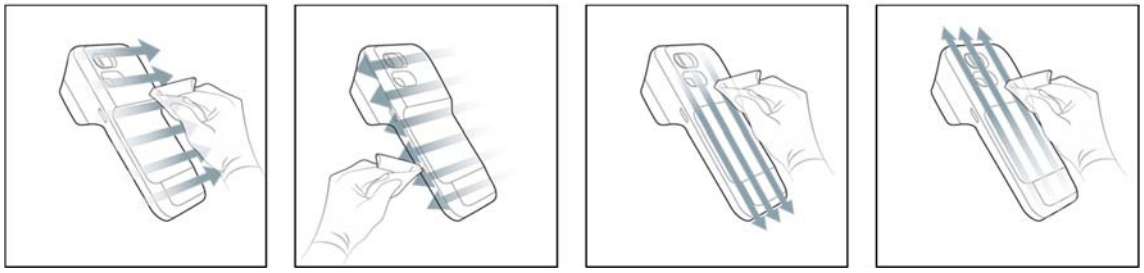


Figure 4. Wipe the meter back

6. Follow the Figure 5 to wipe the insertion area of strip.

Figure 5. Wipe the insertion area of strip

7. Follow the Figure 6 to wipe the item selection key.

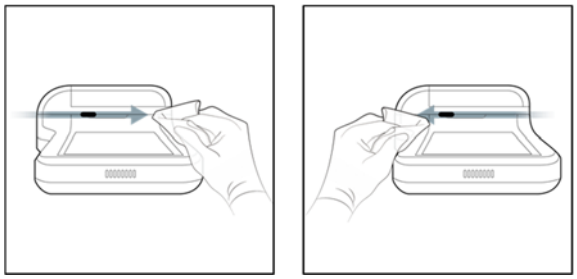


Figure 6. Wipe the item selection key.

8. Follow the Figure 7 to wipe the meter frame.

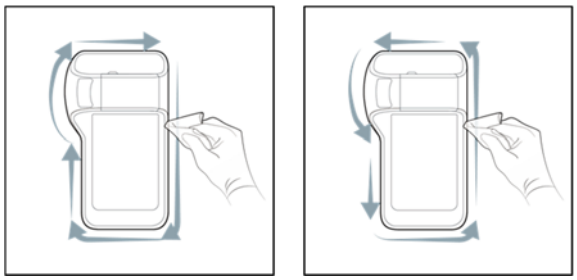


Figure 7. Wipe the meter frame

9. Make sure all the dirt, dust, blood and other body fluids are cleaned from meter using the first wipe.

Disinfection:
1. After cleaning, use a second wipe and thoroughly wet the surfaces of meter.
2. Make sure the treated area remains wet for a minute to effectively kill blood-borne pathogens.
3. Ensure the treated area are thoroughly dry.
4. Discard the wipes and achieve a cleaning/disinfection cycle.

Test process – A1c

Cleaning:
1. Use two wipes.
2. Follow the cleaning instruction for the first wipe and the disinfection instruction for the second.
3. Put on clean gloves
4. Take one wipe and squeeze out excess moisture from the wipe before use.
5. Follow the Figure 8 to wipe the meter front and meter screen respectively.

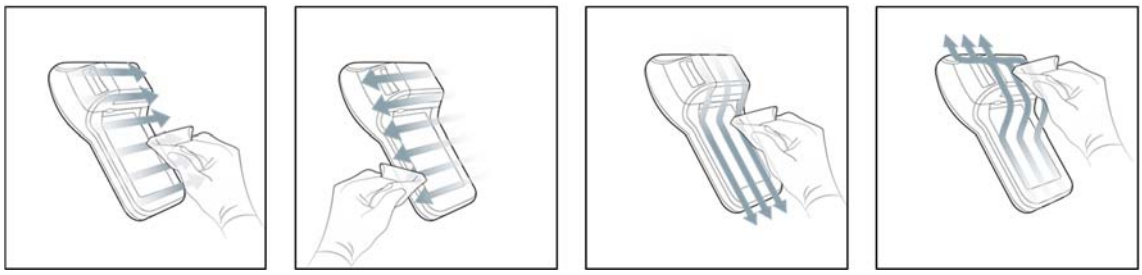


Figure 8. Wipe the meter front and meter screen respectively.

6. Follow the Figure 9 to wipe the meter back.

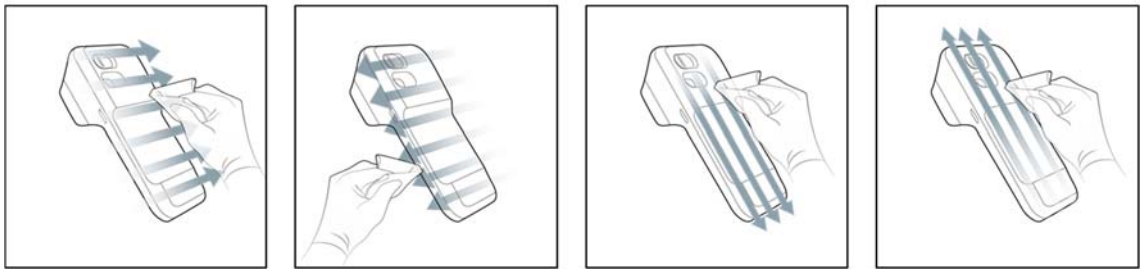


Figure 9. Wipe the meter back

7. Follow the Figure 10 to wipe the item selection key.

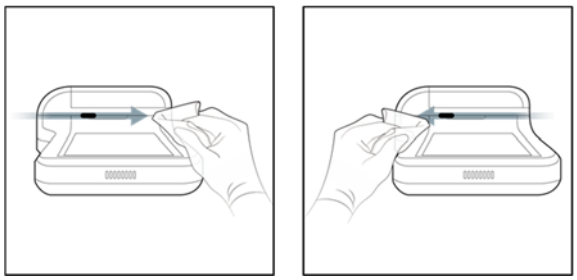


Figure 10. Wipe the item selection key.

8. Follow the Figure 11 to wipe the meter frame.

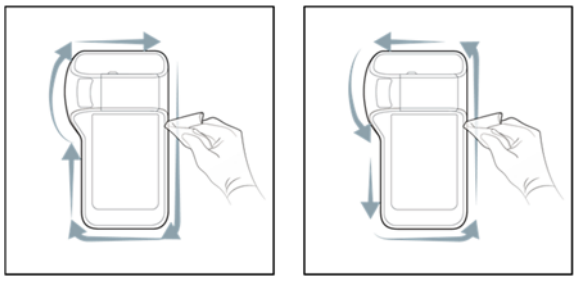


Figure 11. Wipe the meter frame

9. Make sure all the dirt, dust, blood and other body fluids are cleaned from meter using the first wipe.

Disinfection:

1. After cleaning, use a second wipe and thoroughly wet the surfaces of meter.
2. Make sure the treated area remains wet for a minute to effectively kill blood-borne pathogens.
3. Ensure the treated area are thoroughly dry.
4. Discard the wipes and achieve a cleaning/disinfection cycle.

20. Error and Warning message

Error messages and trouble-shooting tips will be displayed on the screen. Please pay attention to the error messages and information to make sure the PixoTest® POCT System is performing accurately.
The following table lists error message and troubleshooting tips, which may appear on the screen during performing the system.

Error message – A1c

Error Number	Error Message	Problem Cause	What to Do
Note 01	Measurement Failure	The measurement is interrupted due to improper operation.	Please keep the test strip stabilized and don't move the test strip during measurement. If this error still happens on blood samples with normal range of total hemoglobin, please contact your system provider.
Note 02	System Tilt	It is detected that the tilts during measurement.	Please keep the POC-X01 flat and stabilized on a table during measurement.
Note 03	Out-of-range Temperature	The ambient temperature is outside the recommended operating temperature range.	Perform a test in an environment with the temperature between 15 - 32°C (59 - 89.6°F). Do not heat or cool your POC-X01.
Note 04	Blood Sample Error	No sample or insufficient sample volume applied on the test strip was detected after the system indicates to apply the blood sample.	Discard this test strip and re-test with a new test kit.
Note 05	Test Strip Error	Invalid test strip or improper installation of the test strip was detected during measurement.	Reinstall a new test kit properly and test again.
Note 06	Calibration Error	Incomplete or incorrect calibration process was detected.	Insert only the Calibration Card provided by the manufacturer and switch the Item selection key to the A1c mode for the calibration. **Do Not** move the Calibration Card during calibration.
Note 07	System Error	Abnormal signals coming from hardware problems were detected	Do the calibration again and if the error still persists, please

		during calibration process.	contact your system provider.

Error message – Lipid

Error Number	Error Message	Problem Cause	What to Do
Note 01	Measurement Failure	The measurement is interrupted due to improper operation.	Please keep the test strip stabilized and don't move the test strip during measurement.
Note 02	Light Signal Error	The measurement is interrupted due to the strong stray light in the strip module.	Please make sure that the strip module is securely attached and the sliding door is closed completely.
Note 03	Out-of-range Temperature	The ambient temperature is outside the recommended operating temperature range.	Perform a test in an environment with the temperature between 18 - 32°C (64.4 - 89.6°F). Do not heat or cool your POC-X01.
Note 04	Blood Sample Error	No sample or insufficient sample volume applied on the test strip was detected after the system indicates to apply the blood sample.	Discard this test strip and re-test with a new test kit.
Note 05	Test Strip Error	Invalid test strip or improper installation of the test strip was detected during measurement.	Reinstall a new test kit properly and test again.
Note 06	Calibration Error	Incomplete or incorrect calibration process was detected.	Insert only the Calibration Card provided by the manufacturer and switch the Item selection key to the A1c mode for the calibration. **Do Not** move the Calibration Card during calibration.
Note 07	System Error	Abnormal signals coming from hardware problems were detected during calibration process.	Do the calibration again and if the error still persists, please contact your system provider.

21. Disposal information

Discard the used test strips carefully. Used test strips may be considered as bio hazardous waste in your area. Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines. Wash your hands with soap and water after handling the test strip.

22. Product information

Specification

POC-X01 Analyzer

Dimension	181 mm (L) x 111 mm (W) x 53mm (H)
Weight	131.3g
Power	5000 mAh battery, non-removable
storage	10000 sets
Operating	Temperature 10℃ ~ 40℃ (50℉ ~ 104℉)
	Humidity 10 % ~ 90% RH
	Operation atmospheric pressure range 760mmHg ~ 526mmHg
Storage & Transportation condition	Temperature 1℃ ~ 40℃ (34℉ ~ 104℉)
	Humidity 10 % ~ 90% RH
Calibration Card	Stored in the package pouch and with 1 years shelf life
others	• Indoor use • Overvoltage category II • Pollution degrees 2

Charger

US version	Manufacture: DONGGUAN AOHAI POWER TECHNOLOGY CO.,LTD. Model : A18A-050100U-US2 Input : 100-240V~ 50/60Hz Max0.2A Output : 5V 1.0A
EN version	Manufacture: DONGGUAN AOHAI POWER TECHNOLOGY CO.,LTD. Model : A824A-120150U-EU1 Input : 100-240V~ 50/60Hz 0.5A Output : 5V 2.0A / 9V 2A /12V 1.5A
UK version	Manufacture: DONGGUAN AOHAI POWER TECHNOLOGY CO.,LTD. Model : A806-050100U-UK1 Input : 100-240V~ 50/60Hz 0.2A Output : 5V 1.0A

Test strip for Lipid

Measuring Range	TC: 100 – 450 mg/dL, (2.59 – 11.64 mmol/L) TG: 45 – 650mg/dL, (0.51 – 7.34 mmol/L) HDL: 25 – 95 mg/dL, (0.65 – 2.46 mmol/L)
Sample	Fresh capillary or venous whole blood
Sample Size	35 µL
Test Time	3 minutes
Hematocrit	TC/TG: 30–55%; HDL: 30–52%
Operating Temperature Range	18 – 32°C (64 – 90°F)
Test Strip Storage Temperature	2 – 32°C (36 – 90°F)
Shelf-life	18 months

*: Test strip may be stored in a refrigerator at 2–8°C (36-46°F), but must be brought to room temperature before use.

Test strip for A1c

Measuring Range	4.0 – 15.0%
Sample	Fresh capillary or venous whole blood
Sample Size	5 µL
Test Time	3minutes
Hematocrit	25 – 65%
Operating Temperature Range	15 – 32°C (59-90°F)
Test Strip Storage Temperature*	1 – 30°C (34 to 86°F)
Shelf-life	18 months

*: Test strip may be stored in a refrigerator at 2–8°C (36-46°F), but must be brought to room temperature before use.

23. Limitations

PixoTest A1c Test Strip

1. The battery life needs to be over 20% before using the PixoTest POCT System.
2. Do not charge your smartphone when you use the PixoText POCT System.
3. PixoTest POCT System can performs in the hemoglobin a range of 7-23 g/dL and a hematocrit range of 25 to 65%.
4. Performance of PixoTest POCT System has not been tested on samples from newborns.
5. Cosmetics such as hand creams or lotions often contain glycerol. Use of these products may cause inaccurate results.
6. For in vitro diagnostic use only.
7. PixoTest A1c Test Strip is for single use.
8. Do not carry out the test in direct sunlight. The measurement should be performed in an appropriate light environment.
9. Strong electromagnetic fields (e.g. microwave ovens) may affect performance.
10. Interferences: The following substances may cause false results at levels of the below.

Substances concentration (mg/dL)	
Acetylsalicylic acid	> 30 mg/dL
Ascorbic acid	> 10 mg/dL
Acetaminophenol	> 30 mg/dL
Billirubin	> 20 mg/dL
Caffeine	> 30 mg/dL
Hydroxyzine Dihydrocholoride	> 30 mg/dL
Triglyceride	> 900 mg/dL
Glyburide	> 20 mg/dL
Ibuprofen	> 20 mg/dL
Dopamine	> 2 mg/dL

PixoTest Lipid Test Strip

1. The battery life needs to be over 20% before using the PixoTest POCT System.
2. Do not charge POC-X01 when you use the PixoText POCT System.
3. Hematocrits of 30 to 55% (TC/TG), 30 to 52% (HDL) for Lipid Test Strip do not affect results.
4. Performance of PixoTest POCT System has not been tested on samples from newborns.
5. Cosmetics such as hand creams or lotions often contain glycerol. Use of these products may cause inaccurate results.
6. For in vitro diagnostic use only.
7. Test strip is for single use.
8. Do not carry out the test in direct sunlight. The measurement should be performed in an appropriate light environment.
9. Strong electromagnetic fields (e.g. microwave ovens) may affect performance.
10. Interferences: The following substances may cause false results at levels of the below.

Substances concentration (mg/dL)			
Hemoglobin	> 300	L-Dopa	> 1.6
Ascorbic acid	> 2.5	Urea	> 700
Fructose	> 30	Creatinine	> 30
Gentisic acid	> 1	Glutathione	> 2
Qxytetracycline	> 10	Lactose	TC, TG > 100/ HDL > 50
Cysteine	> 2.5	Billirubin	TC > 20/ TG, HDL> 10
α-mrthyldopa	> 2	Nicotinic acid	> 30
Dipyrone	> 30	Dopamine	> 2

24. Manufacturer

iXensor Co., Ltd.
6F., No.9, Aly. 2, Ln. 35, Jihu Rd., Neihu Dist., Taipei City, 11492, Taiwan
www.ixensor.com

EC REP

Authorized representative
MDSS GmbH
Schiffgraben 4130175 Hannover, Germany

25. Symbol

REF	Catalogue number	SN	Serial number of the analyzer
	Consult instructions for use	Σ	Contains Sufficient for <n> Tests
EC REP	Authorized representative in the European Community		Temperature limitation
	Manufacturer		Date of Manufacture
LOT	Batch Code	IVD	In-vitro diagnostic Use
	Use by date		Caution, Consult accompanying documents
	Do not reuse		

26. Servicing

The PixoTest POCT Systems is intended to provide safe and reliable operation according to the instructions provided by iXensor Co., Ltd. iXensor Co., Ltd recommends that the PixoTest POCT system can be inspected and serviced by authorized technicians if there is any concern with device function. Otherwise, service and inspection of the devices generally should not be required if used by following the instruction for use.

27. Limited Warranty

iXensor Co., Ltd (hereafter 'iXensor') gives the customer a limited manufacturer warranty on new original iXensor products and relative accessories in accordance with the warranty conditions applicable to the item in question and in accordance with the warranty periods from purchase date, please refer to the list as below. This warranty does not cover damage caused by operator himself, accident, misuse, abuse, alteration and other defects not related to material or workmanship. To exercise your rights under this warranty, please contact your local, authorized distributors or service center.

Item	Warranty period
PixoTest POCT Analyzer	1 year
USB Charger	1 year
PixoTest POCT Calibration Card	1 year
USB Type C Charge Cable	None
Other disposable parts	None

Customer Name :

_____

Customer Address:

_____

Telephone: _____

E-mail address: _____

Date of purchase: _____

Distributor information :

_____

Appendix 1: Reference

1. American Diabetes Association, Clinical Practice Recommendation Guidelines 2003, Diabetes care, Vol. 26. Supplement 1. p.22
2. Stedman, TL. Stedman's Medical Dictionary, 27th Edition, 1999, p. 2082.
3. Ellen T. Chen, James H. Nichols, Show-Hong Duh, Glen Hortin, MD: Diabetes Technology & Therapeutics, Performance Evaluation of Blood Glucose Monitoring Devices, Oct 2003, Vol. 5, No. 5: 749 -768
4. Siedel J, Hagele EO, Ziegenhorm J, Wahlefeld AW. Reagent for the enzymatic determination of serum total cholesterol with improved lipolytic efficiency. Clin Chem 1983; 29: 1075-80.
5. Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults. Executive summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III). JAMA 2001; 285: 2486-97.
6. IDF Clinical Guidelines Task Force. Global guideline for Type 2 diabetes. Brussels; International Diabetes Federation, 2005.
7. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. WHO, Geneva 2006 (ISBN 92 4 159493 4, ISBN 978 98 4 159793 6).
8. D'Orazio et al.: "Approved IFCC Recommendation of Reporting Results for Blood Glucose(Abbreviated);" Clinical Chemistry 51:9 1573-1576-(2005).
9. American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 35:S4-S10, 2012.
10. American Diabetes Association: Clinical Practice Recommendations (2013) Diabetes Care, Vol36, Supplement 1, p. S1-S100

FCC Caution: To assure continued compliance, any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. (Example - use only shielded interface cables when connecting to computer or peripheral devices).

FCC Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

This device complies with Part 15, 22, 24 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.

SAR: 0.73 W/Kg