



CardioChek[®] Plus[®] Test System

For Near-Patient Testing
Portable Whole Blood Test System

This user guide is intended for CardioChek Plus analyzers v1.12 or after.

Materials Provided

REF 3107 CardioChek® Plus near-patient testing analyzer v.1.12 or after (1)

Materials Needed but not Provided

Appropriate sterile, disposable, auto-disabling, single-use lancet

PTS Panels® test strips are available in single- and multi-analyte tests

Product availability will vary per country

Lot-specific MEMo Chip® included with test strips

PTS Collect™ capillary tubes, laboratory pipet, or capillary blood collector—

appropriate volume specific to PTS Panels test strip.

Refer to test strip package insert for required sample size.

Alcohol wipes

Gauze pads or cotton balls

Bandages

Optional

The CardioChek Plus test system may be used with optional PTS Connect™ solutions, which include: printer, and other optional software solutions.

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1 Introduction

CardioChek Plus System *Intended Use*

The CardioChek Plus analyzer is a small, portable analyzer for healthcare professionals to perform near patient testing. The analyzer is intended for multiple patient use and is for *in vitro* diagnostic use only.

The CardioChek Plus analyzer uses both light reflectance and electrochemical biosensor technology to measure an enzymatic chemical reaction. When blood is applied to a reflectance test strip, a chemical reaction causes color change on the test strip. When blood is applied to an electrochemical test strip, an electrical current is produced. The color or current is measured and compared to a calibration curve, which is stored in the lot specific MEMo Chip. The CardioChek Plus analyzer converts this color or current reading into a test result and displays the result on the screen.

The CardioChek Plus analyzer, together with the appropriate test strips, are intended for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol, and triglycerides in venous whole blood and capillary whole blood from the fingertip. The CardioChek Plus analyzer calculates a Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol.

- Cholesterol measurements may be used to screen for and monitor excess cholesterol in the blood, and to aid in the diagnosis of lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements may be used to screen for, monitor or aid in the diagnosis of lipid disorders.
- Triglyceride measurements may be used to screen for, monitor or aid in the diagnosis of lipid metabolism or various endocrine disorders.
- Glucose measurements may be used to monitor, screen for or as an aid in the diagnosis of carbohydrate metabolism disorders.

When used together with a MEMo Chip, the CardioChek Plus analyzer is an automated system. This user guide is for healthcare professionals performing near-patient testing.

The CardioChek Plus test system may be used with an optional printer or optional software solutions. Equipment is not to be used in a manner not specified in this user guide.

This analyzer is a component of a test system that includes PTS Panels® eGLU test strips, PTS Panels glucose test strips and PTS Panels lipid panel test strips. The PTS Panels test strips include a lot-specific MEMo Chip that contains the assay calibration curve and other important information about the assay. PTS Panels test strips are sold separately, and are available as single- and multiple-analyte test strips.

The test system uses reflectance photometry and electrochemical biosensor technology. Reflectance test strips utilize an enzymatic reaction to produce a color change that is detected by the analyzer after whole blood is applied. Electrochemical test strips measure an electrical current when whole blood is applied.

This user guide includes all the information that you need to run point-of-care assays using the CardioChek Plus test system. Before you begin testing, please read this entire user guide and the package inserts (instructions for use), which are included with the PTS Panels test strips.

Please remember to return the enclosed warranty card to PTS Diagnostics to ensure that you receive product updates and other important information.

The CardioChek Plus test system has many different analyte test strips available for use. The test strips outlined in this section are only an example of the available test strips. Not all test strips are available for use in all countries. Please refer to the package insert of each PTS Panels test strip prior to use.

For questions or additional assistance with your CardioChek Plus test system, please contact PTS Diagnostics (Hours: M-F, 8:00 a.m. to 8:00 p.m. USA Eastern Time) using the following contact information:

PTS Diagnostics

4600 Anson Boulevard, Whitestown, IN 46075 USA

Direct: +1-317-870-5610 • **Toll-free inside the US:** 1-877-870-5610

Fax: +1-317-870-5608

Email: customerservice@ptsdiagnostics.com • **Website:** ptsdiagnostics.com

Important Safety Instructions

Users should adhere to standard precautions when handling or using this analyzer. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.

The analyzer should be cleaned and disinfected after use on each patient. This system may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.

Only auto-disabling, single-use lancing devices should be used with this analyzer.

IMPORTANT: Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.



2 About the CardioChek Plus Test System

The CardioChek Plus Test System and Operating Principle

The CardioChek Plus test system consists of three main parts. These include the CardioChek Plus analyzer, PTS Panels test strips, and a lot-specific MEMo Chip.

The analyzer employs both light reflectance and electrochemical biosensor technology to measure an enzymatic chemical reaction. When a blood sample is applied to a reflectance test strip, a chemical reaction occurs that produces a color change on the test strip. When blood is applied to an electrochemical test strip, an electrical current is produced. This color or current is measured and compared to a calibration curve stored in the lot-specific MEMo Chip. The analyzer converts this color or current reading into a test result (the darker the color or greater the electrical current, the higher the analyte concentration). The test result appears on the display screen.



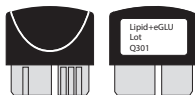
- A Display**
Display shows test results, messages, time, date, and stored results.
- B Enter Button** 
Press this button to turn on the analyzer or to accept the current menu choice.
- C Reflectance Test Strip Slot**
The reflectance test strip slot is positioned in the lower front-center of the analyzer. The reflectance test strip and/or check strip is inserted here with the smooth side facing down.
- D MEMo Chip Port**
The MEMo Chip port is located at the top of the analyzer.
- E USB Port**
A port that allows communication with a CardioChek/PTS Connect printer only.
- F Next Button** 
Press this button to turn on the analyzer or to advance to the next menu option.
- G Electrochemical Test Strip Port**
The electrochemical test strip port is positioned just to the right of the reflectance test strip slot. The electrochemical test strip is inserted here with the arrow facing up and pointing toward the analyzer.

The MEMo Chip

Each package of PTS Panels test strips contains a color-coded lot-specific MEMo Chip. The MEMo Chip contains the settings for each test. The bottom has a label with the test name and lot number. Always make sure you insert the MEMo Chip into the port at the top of the analyzer with the finger notch facing up (with the lot code number facing down).

What does the MEMo Chip do?

The MEMo Chip contains proper settings for the test strip lot you are using.

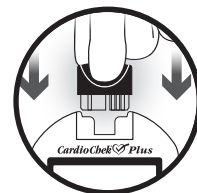


The MEMo Chip:

- Stores the test strip expiration date
- Tells the analyzer which test(s) to run
- Contains the calibration curve and the lot number for the specific test strip lot
- Controls test sequences and timing
- Provides the measuring range for the test

Guidelines for using the MEMo Chip

- The MEMo Chip must be inserted to run a test.
- Use only the MEMo Chip that is included with each package of test strips. The lot number code on the test strip vial(s), MEMo Chip, and analyzer display must match.
- If the expiration date in the MEMo Chip has passed, the analyzer will display EXPIRED LOT.
- If your MEMo Chip is lost or misplaced, please call PTS Diagnostics Customer Service for a replacement or use another MEMo Chip from another vial of the same lot number.



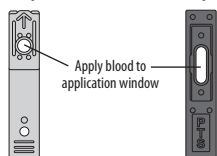
The MEMo Chip port is located at the top center of the analyzer. The MEMo Chip is inserted into this port with the finger notch facing up (with the lot number facing down). Push firmly, but gently, until the MEMo Chip is fully inserted.

Important: Be careful not to bend the connector.

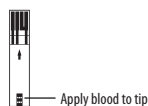
PTS Panels® Test Strips

PTS Panels test strips are designed for specific analytes. A test strip is inserted into the analyzer, then blood is applied to the blood application window for reflectance tests or the tip of the test strip for electrochemical tests. As previously described, the ensuing chemical reaction produces a color change or an electrical current, which the analyzer measures and compares to the calibration curve stored in the lot-specific MEMo Chip. The analyzer converts this color reading or electrical current measurement into a test result, displayed on the screen. All PTS Panels test strips include a package insert that provides instructions for use and information specific for each test. Please read the instructions completely before testing.

Examples of reflectance test strips



Example of an electrochemical test strip



The CardioChek Plus test system has many different analyte test strips available for use. The test strips outlined in this section are only an example of the available test strips. Not all test strips are available for use in all countries. Please refer to the package insert of each PTS Panels test strip prior to use.

Limitations

PTS Panels eGLU Test Strips – Limitations of the Procedure

IMPORTANT: This product has not been tested using neonatal or arterial blood.

Do not use this test system with these samples.

1. The analyzer should not be used to test critically ill patients.
2. Blood samples from patients in shock, patients with severe dehydration, or patients in a hyperosmolar state (with or without ketosis) have not been tested. It is not recommended to test those samples with this system.
3. **PRESERVATIVES:** Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system.
4. **VENOUS SAMPLES:** To minimize glycolysis, venous whole blood samples must be tested within 20 minutes of the draw. Grossly lipemic samples may interfere with some methodologies. Critically ill patients should not be tested by this method, or should be tested with extreme caution.
5. Acetaminophen (Tylenol) and dopamine may interfere causing the test result to be higher than the actual glucose. Not every drug was tested.
6. **METABOLITES:** This test system is specific for glucose. Other sugars and other reducing substances such as ascorbic acid (Vitamin C) at normal blood concentrations have no significant effect on test results.
7. **HEMATOCRIT:** Hematocrit values above 55% or lower than 30% may incorrectly lower the glucose result.
8. **ALTITUDE:** Testing at altitudes from sea level up to 10,000 feet (700-1060 hPa) has no effect on results.
9. **DEHYDRATION:** Severe dehydration and excessive water loss may produce falsely low results.

PTS Panels Glucose Test Strips – Limitations of the Procedure

IMPORTANT: This product has not been tested using neonatal or arterial blood.

Do not use this test system with these samples.

1. The analyzer should not be used to test critically ill patients.
2. Blood samples from patients in shock, patients with severe dehydration, or patients in a hyperosmolar state (with or without ketosis) have not been tested. It is not recommended to test those samples with this system.
3. Not for use on patients who are severely hypotensive.
4. **PRESERVATIVES:** Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system.
5. Acetaminophen (Tylenol) and dopamine may interfere causing the test result to be higher than the actual glucose. Not every drug was tested.
6. **METABOLITES:** This test system is specific for glucose. Other sugars and other reducing substances such as ascorbic acid (Vitamin C) at normal blood concentrations have no significant effect on test results.
7. **HEMATOCRIT:** Hematocrit values above 55% or lower than 30% may incorrectly lower the glucose result.
8. **ALTITUDE:** Testing at altitudes from sea level up to 10,000 feet (700-1060 hPa) has no effect on results.
9. **DEHYDRATION:** Severe dehydration and excessive water loss may produce falsely low results.

PTS Panels Lipid Panel Test Strips – Limitations of the Procedure

IMPORTANT: This product has not been tested using neonatal or arterial blood.

Do not use this test system with these samples.

Studies were performed to test for substances that may interfere with these tests. The results are below.

1. **PRESERVATIVES:** EDTA and heparin in venous blood collection tubes had no effect on the results of the test strip.
2. **DRUGS:** Dopamine and methyl dopa decreased the results of all the lipids.
3. **METABOLITES:** Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the lipids.
4. **HEMATOCRIT:** No hematocrit effect was observed for samples between 30 and 45% HCT.
5. **HAND LOTIONS/COSMETICS:** Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.
6. Displayed results are rounded.

Each test strip is for a single test only. Do not reuse the strips. Use a new test strip each time you test. Use only fresh capillary whole blood from the finger or venous whole blood (EDTA or heparin). Performance testing was done using EDTA and heparin preserved venous whole blood. Do not use serum or plasma unless specified in the package insert. Each test strip has a package insert which contains instructions for use specific to that test strip.

Only auto-disabling, single-use lancing devices should be used with this analyzer.

3 Setup

Battery Use and Replacement

The CardioChek Plus analyzer requires four (4) AA 1.5 volt high-quality alkaline batteries.

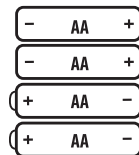
When to Replace the Batteries

The analyzer will give you an indication on the display that the batteries need to be changed. When the display reads REPLACE BATTERIES, no more tests can be run until the batteries are changed. Always replace the batteries with high-quality alkaline batteries. It is recommended to keep a spare set of batteries on hand. To extend battery life, remove the test strip as soon as a result is displayed. The time/date and results stored in memory will not be erased when the batteries are changed.

When the REPLACE BATTERIES message is displayed, replace the batteries with **4 new AA alkaline batteries of the same brand**. Extensive and complete testing has not been done with other types of batteries. Therefore, do not use other types of batteries. e.g., NiCad or rechargeable batteries. **Caution: Improper installation of batteries can result in decreased battery life or damage to the analyzer.**

How to Install/Replace the Batteries

1. Open the battery door on the back of the CardioChek Plus analyzer by releasing the latch and pulling the door away from the back of the analyzer.
2. Remove old batteries from the compartment and properly discard.
3. Insert the new batteries into the battery compartment with the positive (+) terminals correctly facing as marked on the inside compartment.
4. Replace the battery door. To make sure the batteries were installed correctly, push either of the two buttons on the front of the analyzer to turn on the CardioChek Plus analyzer.



Warning: Dispose of the old batteries properly.



CardioChek Plus Analyzer Menus

The following diagram provides a layout of the menus within the CardioChek Plus analyzer v1.12 or later. Detailed information on the use of each menu follows. Use the following buttons to navigate the menus:


Enter Button

Press this button to turn on the analyzer or to accept the current menu choice.

Next Button

Press this button to turn on the analyzer or to advance to the next menu option.

Shut Down

Hold  and  down at the same time for three seconds to turn off the analyzer.

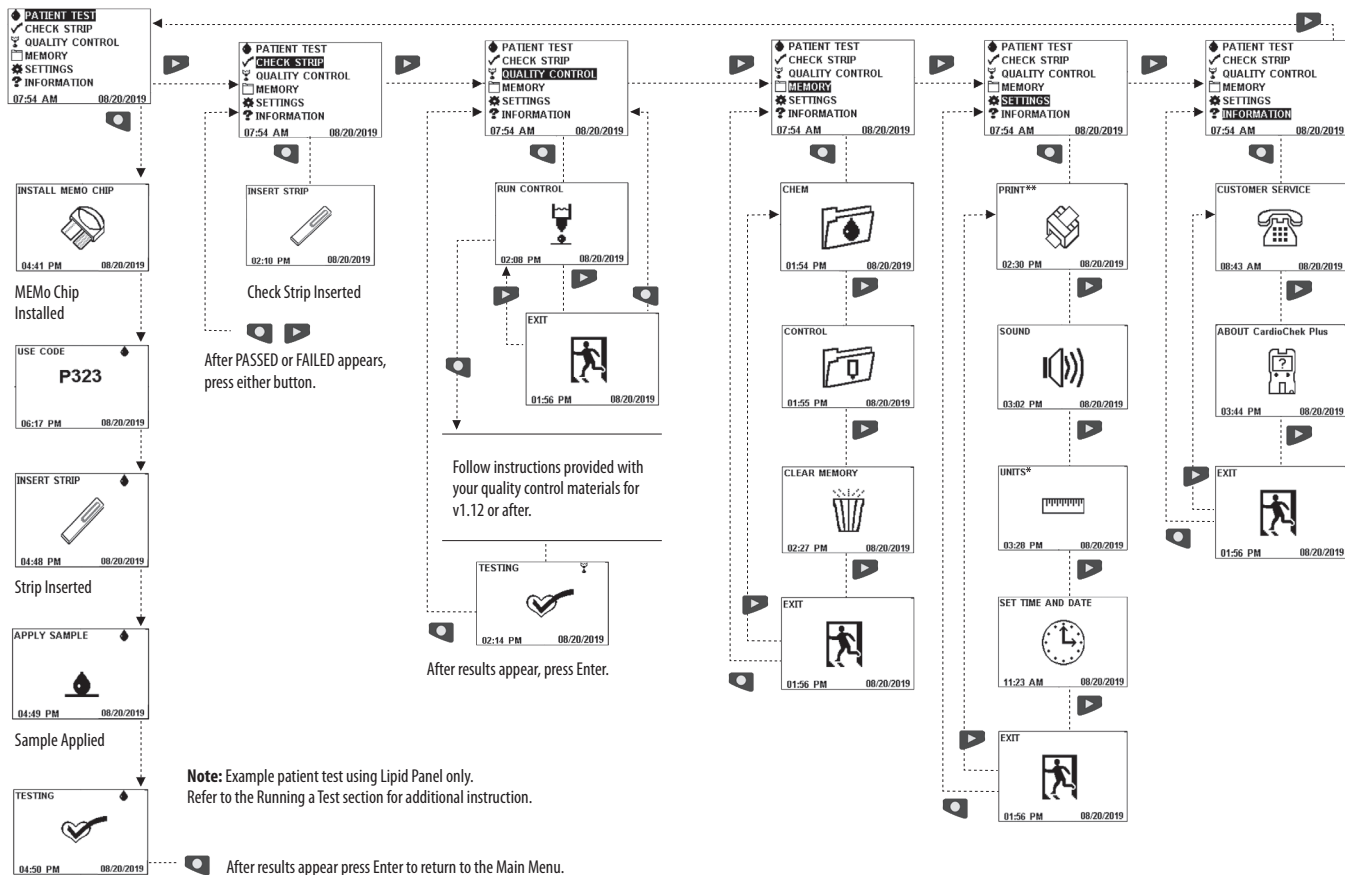
CardioChek Plus Menu Map v1.12 or after

Press either button to turn on the analyzer. The Main Menu will appear.

* If the units are locked, the UNITS screen does not appear.

** The printer may not be available in all countries.

Main Menu



How to Turn Off the Analyzer

To turn off the analyzer, press both buttons (Enter and Next) at the same time and hold for three seconds. After three minutes of idle time (without a test strip or check strip inserted), the analyzer will perform a 10-second countdown and turn off. To stop shutdown, press either button. You can also remove the batteries to turn off the analyzer.

Setting Language

The first time the analyzer is turned on, you will be required to set the language, date, and time. The language menu consists of the following choices: English (ENGLISH), Spanish (ESPAÑOL), Italian (ITALIANO), German (DEUTSCH), French (FRANÇAIS), Portuguese (PORTUGUES), Dutch (NEDERLANDS), Chinese (中文), and Russian (РУССКИЙ).

How to Set the Language (First-Time Use)

1. Turn on the analyzer by pressing either button (Enter or Next).
2. The display will read LANGUAGE. Press Enter.
3. Press Enter to select to select ENGLISH or press Next to scroll through the language choices.
4. Press Enter to select the desired language that is displayed.

How to Reset the Language

1. Turn off the analyzer.
2. Press and hold down Enter for approximately 5 seconds during the analyzer power-up stage until LANGUAGE is displayed.
3. Press Enter to select English or press Next to scroll through the language choices.
4. Press Enter to select the desired language that is displayed.

How to Set the Time and Date

1. Press either button to turn analyzer on. The Main Menu will appear.
2. Press Next to scroll until SETTINGS is highlighted. Press Enter.
3. Press Next to scroll until SET TIME AND DATE is displayed.
Press Enter to display date and time, which are formatted as YYYY/MM/DD and HH:MM.
4. Press Enter to select the highlighted year, or press Next to advance the year.
Press Enter to select.
5. The display will then highlight the month. Press Enter to select the highlighted month, or press Next to advance the month. Press Enter to select.
6. The display will then highlight the day. Press Enter to select the highlighted month, or press Next to advance the day. Press Enter to select.
7. The display default will then highlight 12H. Press Next to advance to 24H. Press Enter to select either 12H or 24H when highlighted.
8. The display will then highlight the hour. Press Next to advance the hour. The default setting is AM. To change AM to PM press Next to advance the hour setting until AM switches to PM. Press Enter to accept. Now press Next to advance the minutes. Press Enter to accept.
9. Once the clock format has been selected, the SET TIME AND DATE symbol is displayed. Press Next to display the EXIT screen. Press Enter to return to the Main Menu.

Note: If you advance the time or date settings too far in steps 4-8 above, press and release the Enter and Next buttons at the same time to return to the SET TIME AND DATE screen. Press Enter and the original settings will be restored.

How to Set the Units




The CardioChek Plus analyzer may be shipped with preset units. If the SETTINGS menu does not display UNITS, the analyzer is locked in preset units. The units cannot be changed if the system has been locked. If your analyzer's units have not been preset, follow the steps listed below to change your units to mg/dL, mmol/L, or g/L (e.g., in the US, the correct units for glucose are mg/dL and the units are preset to mg/dL).

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the Main Menu to appear.
2. Press Next to scroll until SETTINGS is highlighted. Press Enter.
3. Press Next to scroll until UNITS is displayed. If UNITS is not shown on the display, the units on this analyzer have been locked and cannot be changed. If UNITS appears on the display screen, proceed to the next step.
4. Press Enter. The display will highlight mg/dL. If mmol/L or g/L is desired, press Next until the desired units are highlighted on the display. Press Enter to select.
5. The screen will display the UNITS symbol. Press Next until the EXIT screen is displayed. Press Enter to return to the Main Menu.

How to Set the Sound

The CardioChek Plus analyzer sound has been preset to on.

To turn the sound on or off, follow the steps listed below:

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the Main Menu to appear.
2. Press Next to scroll until SETTINGS is highlighted. Press Enter.
3. Press Next to scroll until SOUND  is displayed.
4. Press Enter. SOUND is displayed with  (on) highlighted.
5. Press Enter to select or press Next to highlight  (off).
6. Press Enter to accept the sound choice highlighted.
7. Press Next until EXIT is displayed.
8. Press Enter to return to the Main Menu.

How to Set Up the CardioChek Plus Analyzer for Printing

For complete details, refer to each printer's user guide.

Testing the Printer

1. Press either button to turn analyzer on. The Main Menu will appear.
2. Press Next to scroll until SETTINGS is highlighted. Press Enter.
3. PRINT is displayed. Press Enter.
4. Press Next to scroll until TEST PRINTER is displayed.
5. Press Enter and a sample printout will be generated.
6. Press Next to scroll until EXIT is displayed.
7. Press Enter to return to PRINT screen.
8. Press Next to scroll until EXIT is displayed.
9. Press Enter to return to Main Menu.

How to Print Results from Memory

Note: Up to 50 test results per chemistry and 10 control test results can be stored.

1. If analyzer is off, press either button to turn analyzer on. The Main Menu will appear.
2. Press Next to scroll until MEMORY is highlighted. Press Enter.
3. CHEM is displayed. Press Enter to select or press Next to display CONTROL. Press Enter to select.
4. Press Next to display the test name, then press Enter to select (LIPIDS for example).
5. Press Next to display the time/date of the test result you want to print.
6. Press Enter to print the selected result.
7. Control results can be printed by selecting CONTROL instead of CHEM and then selecting the type of result as stated above.
8. Press Next to scroll until EXIT is displayed.
9. Press Enter to return to Main Menu.

Note: Ensure the printer is not connected to any other device in addition to the CardioChek Plus analyzer.

How to Get Help and Information Regarding Your CardioChek Plus Analyzer

Customer Service

1. Press either button to turn analyzer on. The Main Menu will appear.
2. Press Next to scroll until INFORMATION is highlighted. Press Enter.
3. CUSTOMER SERVICE is displayed.
4. Press Enter to display Customer Service contact information.
5. Press Enter to return to the CUSTOMER SERVICE screen. Press Next to scroll until EXIT is displayed.
6. Press Enter to return to Main Menu.

About the CardioChek Plus Analyzer

1. From the Main Menu. Press Next to scroll until INFORMATION is highlighted. Press Enter.
2. CUSTOMER SERVICE is displayed.
3. Press Next to display ABOUT CardioChek Plus. Press Enter to display Serial Number (SN), version of software, and 5-digit completed test counter.
4. Press Enter to return to the ABOUT CardioChek Plus screen.
5. Press Next. Exit is displayed.
6. Press Enter to return to Main Menu.



4 Checking the System

Analyzer Check Strips

A check of the analyzer operation and optics can be performed using one of the two gray check strips. Two are included in the analyzer carrying case. The check strip verifies that the CardioChek Plus analyzer's electronic and optical systems are functioning properly. To perform this verification, insert the check strip into the analyzer. The analyzer will read the reflectance of the gray check strip and indicate if the reading is within the specified acceptable range by displaying PASSED. When the check strip is not in use, store it in the analyzer carrying case. It is recommended that the check strip verification be performed:

- Daily
- If the analyzer has been dropped
- When a result is not consistent with expected results

Check Strip



How to Use the Analyzer Check Strip

1. Press either button to turn the analyzer on.
2. Main Menu will appear.
3. Press Next button until CHECK STRIP is highlighted. Press Enter.
4. Hold the check strip at the base and insert the check strip, ribbed side up, into the reflectance test strip slot when INSERT STRIP is displayed.
5. The analyzer should display PASSED, along with a checkmark icon.
If PASSED appears, the analyzer is ready to run tests.
If the display reads FAILED, see the note at the end of this section.
6. Remove the check strip and store it in the analyzer carrying case.
7. Press either button to return to the Main Menu.

Note: If the analyzer displays FAILED:

1. Clean the CardioChek Plus analyzer test strip slot (where the check strip is inserted into the analyzer). See Section 8, **Care and Cleaning**.
2. Inspect the check strip to make sure it is not dirty or damaged. Use the spare check strip and repeat.
3. See Section 9, **Troubleshooting** in this user guide.

5 Quality Control Testing

Quality Control

Controls (also known as “quality control materials”) are solutions for which an expected analyte concentration range has been established. Controls are tested to check the performance of your test system: CardioChek Plus analyzer, MEMo Chip, and PTS Panels test strips. Use quality control materials provided by PTS Diagnostics.

Refer to the range card provided with the controls or visit <http://www.ptsdiagnostics.com> for control specifications.

Healthcare professionals should follow their facility’s guidelines and policies regarding quality assurance and the use of quality control materials.

Quality control materials should be run:

- With each new shipment
- With each new lot number
- According to state, local, and federal regulations

Important: Check the expiration date printed on the control bottles. Do not use control solutions that have expired.

For performing a quality control test, see the instructions below.

To perform a control test you need:

- CardioChek Plus analyzer
- PTS Panels test strips
- Quality control materials
- Quality control instructions
- Quality control range card

How to Run a Quality Control Test on Reflectance Test Strips

Refer to the instructions for use provided with your quality control materials.

If Quality Control Results Are Not in Range

IMPORTANT: Patient tests should not be performed until control results are within range.

1. Ensure test strip slot area is clean.
2. Make sure neither the test strips nor the controls are past the expiration date printed on the label.
3. Make sure the MEMo Chip matches the test strip lot.
4. Repeat the test again using fresh materials.
5. Call Customer Service for assistance.

How to Run a Quality Control Test on Electrochemical Test Strips

Refer to the instructions for use provided with your quality control materials.

If Quality Control Results Are Not in Range

IMPORTANT: Patient tests should not be performed until control results are within range.

1. Ensure test strip port area is clean.
2. Make sure neither the test strips nor the controls are past the expiration date printed on the label.
3. Make sure the MEMo Chip matches the test strip lot.
4. Repeat the test again using fresh materials.
5. Call Customer Service for assistance.

6 Running a Patient Test

Blood Testing

A package insert is included with all PTS Panels test strips. Please read the test strip package insert and this section of the user guide completely and carefully before testing.

Testing Supplies

To perform a blood test you need:

- CardioChek Plus analyzer v1.12 or after
- PTS Panels test strips
- Lot-specific MEMo Chip
- Sterile lancet (auto-disabling, single-use)
- Pipet or capillary blood collector
- Gauze or cotton balls
- Alcohol wipe
- Bandages

This analyzer requires whole blood for testing. Do not operate the analyzer in direct light. It is very important to keep the analyzer on a flat, stable surface and not move it during testing. See Section 8, **Care and Cleaning** for more information.

Helpful Hints on Getting a Good Drop of Blood

1. Instruct the patient to wash hands in warm, soapy water.
2. Rinse well and dry completely. If an alcohol wipe is used, let the finger air dry before testing. Clean gauze may be used to dry alcohol.
3. Warm the fingers to increase blood flow.
4. Let the arm hang down at the patient's side briefly to allow blood flow to the fingertips.

How to Obtain a Blood Sample from a Fingertick

A new pair of clean gloves should be worn by the user before testing each patient.

1. Clean the finger. Be sure the finger is completely dry.
2. Use a new, sterile, disposable lancet to puncture the skin.
3. Stick the finger on the side of the fingertip, instead of the center. See picture.
4. To get a drop of blood, gently apply pressure to the finger starting at the end of the finger closest to the hand and moving towards the tip. (Pressure should be intermittent and it is important not to milk the finger.)

If running an electrochemical test with a reflectance test:

Apply a blood sample to the tip of the electrochemical test strip, wipe away any remaining blood with gauze from the fingertip, and collect a second blood sample for the reflectance test.

If only running a reflectance test: Wipe away the first drop of blood with gauze, and use the second blood drop for testing. The blood drop should be hanging down from the finger to make it easier to collect the sample with a pipet or capillary blood collector.

5. Follow the specific instructions found in the test strip package insert for each test for sample application and volume ranges. For reflectance tests, use of a pipet or capillary blood collector ensures a sufficient volume of blood has been applied to the test strip.
6. Make sure the test strip is inserted all the way into the test strip slot immediately before testing.
7. Use the test strip and lancet one time only. Only auto-disabling, single-use lancing devices may be used with this device. Dispose of properly.



Precaution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines. All parts of the system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals.

It is recommended that users refer to the following practice guidelines:

Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at <http://www.cdc.gov/biosafety/publications/bmbl5/>.

“Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition” Clinical and Laboratory Standards Institute (CLSI) M29-A3.

How to Run a Reflectance Test

1. Press either button to turn the analyzer on.
2. Main Menu will appear.
3. Press Next button until PATIENT TEST is highlighted. Press Enter.
4. Display will read INSTALL MEMO CHIP, if not already installed.
5. Insert the MEMO Chip in the port at the top of the analyzer with the finger notch facing up (with the lot code number facing down).
6. Once inserted, a lot number will appear on the display, followed by INSERT STRIP.
7. Remove a single test strip from the vial and immediately replace the desiccant cap.
8. Insert the strip into the designated reflectance test strip slot. Ensure that the test strip is inserted fully and the display reads APPLY SAMPLE.
9. Obtain a drop following the correct technique. (If venous blood is used, collect in an EDTA or heparin tube. Invert gently 5-7 times to mix completely. Immediately collect the sample with capillary tube or precision pipet and dispense correct volume as specified in test strip instructions for use (package insert) on to test strip.)
10. Hold capillary tube by the bulb and position above the blood application window on the test strip. Use care to avoid touching the test strip with the capillary tube. Squeeze the bulb gently to deposit the entire sample on the strip.
11. Once the sample is applied, results will appear on the display in about 90 seconds, depending on the type of test strip.
12. Remove the test strip and dispose of in a biohazardous waste container.
13. If the analyzer is idle for more than 3 minutes, it will count down 10 seconds and automatically turn off.

How to Run an Electrochemical Test

1. Press either button to turn the analyzer on.
2. Main Menu will appear.
3. Press Next button until PATIENT TEST is highlighted. Press Enter.
4. Display will read INSTALL MEMO CHIP, if not already installed.
5. Insert the MEMO Chip in the port at the top of the analyzer with the finger notch facing up (with the lot code number facing down).
6. Once inserted, a lot number will appear on the display, followed by INSERT STRIP.
7. Remove a single electrochemical test strip from the vial and immediately replace the cap.
8. Insert the electrochemical test strip into the designated electrochemical test strip port.
9. APPLY SAMPLE icon appears on the display.
10. Obtain a drop following the correct technique. (If venous blood is used, collect in an EDTA or heparin tube. Invert gently 5-7 times to mix completely. Immediately collect the sample with capillary tube or precision pipet and touch to the end of the test strip.)
11. Gently hold finger to the tip of the electrochemical test strip to apply a drop of blood. Do not place blood on top of the test strip. Do not press the test strip into the finger.
12. Blood will be drawn into the strip automatically by capillary action.
13. TESTING will appear until result is displayed.
14. Remove and discard test strip in a biohazardous waste container.

How to Run an Electrochemical Test with a Reflectance Test

1. Press either button to turn the analyzer on.
2. Main Menu will appear.
3. Press Next button until PATIENT TEST is highlighted. Press Enter.
4. Display will read INSTALL MEMO CHIP, if not already installed.
5. Insert the MEMO Chip in the port at the top of the analyzer with the finger notch facing up (with the lot code number facing down) that matches the lot number on both the electrochemical AND the reflectance test strip vials.
6. Once inserted, a lot number will appear on the display, followed by INSERT STRIP.
7. Remove a single electrochemical test strip from the vial and immediately replace the cap.
8. Insert the electrochemical test strip into the designated electrochemical test strip port.
9. Remove a single reflectance test strip from the vial and immediately replace the desiccant cap.
10. Insert the reflectance test strip into the designated test strip slot.
11. Ensure that the test strips are inserted fully and the display reads APPLY SAMPLE.

12. For the electrochemical test:

- a. Obtain a drop following the correct technique. (If venous blood is used, collect in an EDTA or heparin tube. Invert gently 5-7 times to mix completely. Immediately collect the sample with capillary tube or precision pipet and touch to the end of the test strip.)
- b. Gently hold finger to the tip of the electrochemical test strip to apply a drop of blood. Do not place blood on top of the test strip. Do not press the test strip into the finger.
- c. Blood will be drawn into the strip automatically by capillary action.
- d. Test result will display upon completion with the reflectance test results.

To skip the Lipid Panel test, following the instructions above, insert the eGLU test strip only. Apply sample to the eGLU strip. Skip steps 9-10. When TESTING disappears, hold down the Next button until eGLU result is displayed.

13. For the reflectance test:

- a. After applying blood to the electrochemical test strip, wipe the finger to remove any blood with a clean piece of gauze.
- b. Gently, without force, apply pressure to the end of the finger closest to the hand moving towards the tip to accumulate a large drop of blood. (Pressure should be intermittent and it is important not to milk the finger.) (If venous blood is used, collect in an EDTA or heparin tube. Invert gently 5-7 times to mix completely. Immediately collect the sample with capillary tube or precision pipet and apply to test strip.) **Note:** Excessive squeezing of the finger may alter test result.
- c. Use a pipet or capillary blood collector to apply whole blood to test strip blood application window.
- d. Hold capillary tube by the bulb and position above the blood application window on the test strip. Use care to avoid touching the test strip with the capillary tube. Squeeze the bulb gently to deposit the entire sample on the strip.
- e. In about 90 seconds, the results will appear on the display. Discard test strips in a biohazardous waste container. DO NOT add more blood to any test strip that has been used.
- f. If the analyzer is idle for more than 3 minutes, it will count down 10 seconds and automatically turn off.

To skip the eGLU test, when INSERT STRIP appears, press and hold the Next button until the “no” symbol appears to the right of the reflectance strip icon.

7 Memory

Test results are automatically stored in the CardioChek Plus analyzer's memory. The analyzer can store up to 50 results of each chemistry (CHEM) and 10 results for control tests (CONTROL). The analyzer allows review of the results in order from the most recent to the oldest. Each result is displayed with time and date. Results stored in memory are not deleted when the batteries are changed.

How to Review Results Stored in Memory

To Review CHEM Results

1. Press either button to turn analyzer on. The Main Menu will appear.
2. Press Next until MEMORY is highlighted.
3. Press Enter. CHEM is displayed.
4. Press Enter, then Next to select the desired chemistry.
Note: Until the chemistry has been run at least once, the test name is not displayed.
5. Press Enter to view the test result including time and date.
 - a. For example, to review lipid panel results, from the CHEM display, press Next until LIPIDS is displayed, then press Enter. The time and date will be displayed. Press Next to scroll through results. The most recent results are displayed first.
 - b. Any result can be printed by pressing Enter if a printer is connected.
6. Press Enter. CHEM is displayed. Press Next until EXIT is displayed.
7. Press Enter to return to the Main Menu.

Note: Press and release the Enter and Next buttons at the same time to return to selected chemistry screen (LIPIDS for example).

To Review CONTROL Results

1. From the Main Menu, press Next until MEMORY is highlighted.
2. Press Enter. CHEM is displayed. Press Next until CONTROL is displayed.
3. Press Enter, then Next to select the desired chemistry.
Note: Until the chemistry has been run at least once, the test name is not displayed.
4. Press Enter to view control result including time and date.
 - a. For example, to review lipid panel results, from the CONTROL screen, press Next until LIPIDS is displayed, then press Enter. The time and date will be displayed. Press Next to scroll through results. The most recent results are displayed first.
 - b. Any result can be printed by pressing Enter if a printer is connected.
5. Press both buttons down simultaneously for one second to return to selected chemistry screen. Press Next until Exit is displayed.
6. Press Enter. CONTROL is displayed. Press Next until EXIT is displayed.
7. Press Enter to return to the Main Menu.

How to Clear Results Stored in Memory

1. From the Main Menu, press Next until MEMORY is highlighted. Press Enter.
2. Press Next until CLEAR MEMORY is displayed. Press Enter.
3. [CLEAR, NO] is highlighted. **If you do NOT want to clear memory**, press Enter, then press Next and Exit screen is displayed. Press Enter to return to Main Menu.
4. **If you do want to clear memory**, press Next. [CLEAR, YES] is highlighted. Press Enter to clear.
5. When memory has been cleared, EXIT is displayed.
6. Press Enter to return to the Main Menu.

8 Care and Cleaning

Storage and Handling

- Handle the CardioChek Plus analyzer with care; do not drop.
- Do not store or operate the analyzer in direct light, such as sunlight, spotlight, under a lamp, or by a window.
- Do not expose the analyzer or any of the supplies or accessories to high humidity, extreme heat, cold, dust, or dirt. The analyzer may be stored at a temperature of 50-104°F (10-40°C) and 20-80% Relative Humidity (RH). **Do not freeze.**
- If storage temperature is below 68°F (20°C) allow the device to warm to room temperature 68°F (20°C) before using. It is recommended if the device has been stored under excessive conditions, allow at least 30 minutes at room temperature for the device to equilibrate to these temperatures.
- Do not scratch or damage the surface of the check strip.
- Please read the test strip package insert for storage and handling information that applies to each test strip.

Cleaning and Disinfection

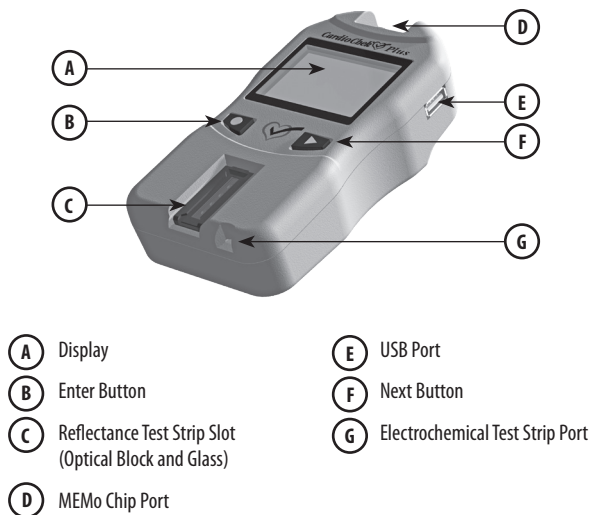
Cleaning and disinfection of analyzers that come in contact with blood or blood products is critical to avoid transmitting bloodborne pathogens between patients and healthcare professionals.

IMPORTANT SAFETY INSTRUCTIONS: It is critical to properly clean and disinfect analyzers that are used with blood products each time they are used, between each patient. Additionally, to avoid transmissions of bloodborne pathogens, only use auto-disabling, single-use lancing devices. Please see references at the end of this section for further information.

Frequency: Always clean after each use. Always clean and disinfect before storing and between each patient test. Please read the disinfectant manufacturer's product label.

Recommended Disinfectant: Super Sani-Cloth® wipes or any disinfectant with the same EPA Reg. No. (EPA Reg. No. 9480-4, Professional Disposables International, Inc. (PDI), Orangeburg, NY), concentration of active ingredients (0.25%) and with a contact time of 2 minutes. The active ingredients in this disinfectant are n-Alkyl dimethyl ethylbenzyl ammonium chlorides. Super Sani-Cloth was tested and found to be effective per recommended guidelines when used with this system. Please only use this disinfectant. **Use of other disinfectants may cause damage to your analyzer. Do not use bleach, peroxide, or window cleaners on this analyzer.** If you have any questions or need to know where to purchase the disinfectant wipes, call PTS Diagnostics Customer Service at 1-877-870-5610 (US) or +1-317-870-5610. There are a large number of distributors of this disinfectant. If you cannot obtain from the distributor who supplies your other supplies, please contact us for assistance.

The entire case surface should be cleaned and disinfected.



Cleaning Instructions

Cleaning removes visible soil, organic material, and most importantly, blood products. Always clean **before** disinfecting.

1. Please see picture above. Clean and disinfect all surfaces of this analyzer.
2. Obtain recommended wipes.
3. Using a fresh wipe, wring out excess liquid and carefully wipe to clean.
4. Allow to air dry or dry with cotton gauze.

Disinfection Instructions

After cleaning, the next step is to disinfect. Always both clean and disinfect.

1. Using a fresh wipe, wring the wipe to remove excess liquid and wipe all areas thoroughly.
2. Keep area wet for 2 minutes to ensure disinfectant remains in contact for a sufficient time to kill all bloodborne pathogens.
3. Allow to air dry completely.
Note: It is important that the analyzer be thoroughly dry before using.
4. The optical glass should be carefully wiped clean with an alcohol wipe and dried with gauze to remove any residue from the disinfectant.
5. Inspect the glass and ensure it is clean when held at different angles. If it is not, repeat Step 4.

Following cleaning and disinfection, inspect the analyzer for the following signs of deterioration. These include:

- Scratches on optical glass
- Etching on optical glass
- Liquid under optical glass
 - liquid intrusion, or
 - condensation
- Loss of adhesion on optical glass
- Liquid under display lens
- Loss of adhesion on display lens
- Deterioration of painted surfaces (polymer crazing, cracking, swelling, softening, peeling, etc.)
- Any loose parts



IMPORTANT: Keep area wet with disinfectant for two minutes. **DO NOT** soak, saturate, or immerse the analyzer or allow liquid to collect on any surface. Always make sure the analyzer is dry before use.

After disinfection, user's gloves should be removed and hands should be thoroughly washed with soap and water before proceeding to the next patient.

The CardioChek Plus has been validated for 11,001 cleaning and disinfection cycles. For example, if you test 10 patients/day for 365 days/year for 3 years, you will have tested 10,950 patient samples. Please check your analyzer counter to see how many samples you have tested (See Section 3, **About the CardioChek Plus Analyzer**) and obtain a new analyzer after cleaning and disinfecting 11,001 times. The use of this analyzer beyond its anticipated lifetime is at the user's sole risk and discretion and is not recommended by the manufacturer.

Stop using the analyzer and contact Customer Service for a replacement analyzer immediately if you notice any signs of deterioration.

If you have any questions, call PTS Diagnostics Customer Service.

Direct: +1-317-870-5610 • **Toll-free inside the US:** 1-877-870-5610

Fax: +1-317-870-5608

Email: customerservice@ptsdiagnostics.com • **Website:** ptsdiagnostics.com

References:

1. "FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
2. "CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) <http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>
3. Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at <http://www.cdc.gov/biosafety/publications/bmbl5/> "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.

9 Troubleshooting

Message or Issue	Probable Cause	What to Do
Desired language is not displayed.	Language has been set incorrectly.	Turn analyzer off. See Section 3, Setup – How to Reset the Language.
The wrong date and/or time is displayed.	Date and time have not been set correctly.	See Section 3, Setup – How To Set the Time and Date.
FAILED is displayed during a check strip test.	Analyzer needs to be cleaned.	Wipe the test strip slot with a clean, damp, and lint-free cloth.
	Check strip is dirty or damaged.	Use spare check strip. If check strip still fails, call Customer Service.
MEMO CHIP ERROR	MEMo Chip is defective.	Use another MEMo Chip from the same lot.
LANGUAGE	Analyzer is new or language option has not been set.	See Section 3, Setup – Setting Language.
TEST NOT ALLOWED	Test selected by MEMo Chip installed cannot be run on your analyzer.	Check MEMo Chip and make sure that the correct MEMo Chip is inserted. Call Customer Service.
LOW TEMP	Analyzer is below acceptable operating temperature.	Move to warmer environment and test after analyzer reaches proper temperature.
HIGH TEMP	Analyzer is above acceptable operating temperature.	Move to acceptable environment and test after analyzer reaches proper temperature.
INSTALL MEMO CHIP	MEMo Chip is not properly inserted or is defective.	Insert same or new MEMo Chip properly.
EXPIRED LOT	Test strips are expired, wrong MEMo Chip is inserted, or date is not set properly.	Check test strip expiration date and make sure correct MEMo Chip is inserted. Check date setting – see Section 3, Setup – How To Set the Time and Date.
REPLACE BATTERIES	Batteries need to be replaced.	Replace all batteries with new high-quality AA batteries. (The analyzer will not run tests until batteries are replaced.)
TEST ABORTED	Test strip was not properly inserted or was removed before test was complete. Analyzer was moved during testing or not placed on a flat, stable surface.	Repeat test(s) with new test strip(s). Do not remove test strip(s) until results are displayed.

Message or Issue	Probable Cause	What to Do
Results will not print.	Communication cable was improperly connected.	Check all connections. Reprint test results stored in memory.
	Printer cover is not closed properly. (Printer indicator light is red.)	Close printer cover correctly, ensuring that the printer indicator light is green. Reprint test results stored in memory.
	Labels/paper were not loaded in the printer.	See Printer System Setup/Operating System Instruction Sheet packaged with the printer.
TEST ERROR	Insufficient sample has been added to reflectance test strip.	Test again with a new test strip and make sure the correct volume of sample is used.
	Battery voltage or temperature are not within operating range of the test.	Test again with new batteries and within operating temperature.
	An error occurred during eGLU testing.	Test again with a new eGLU test strip.
	Reflectance test strip removed before test has completed.	Test again with a new test strip and make sure that the test strip remains inserted until test finishes.
TOO MUCH LIGHT	Test is being performed in direct light or outside.	Test inside, away from windows, and away from direct lamp light.
E1: STRIP ERROR	eGLU test strip damaged, defective, or test strip and MEMo Chip lot numbers differ.	Test again with a new test strip and make sure test strip and MEMo Chip are the same lot number.
E4: USED STRIP	eGLU test strip has been used.	Test again with a new test strip.
Blank display screen	Software anomaly: after error message such as EXPIRED LOT or MEMO CHIP ERROR	Press the Enter button twice to clear the error and restore the display.

10 Interpreting Results

All test results must be assessed by a qualified medical professional. Depending on the analyte being assessed, high or low results may have medical consequences.

If the result reads > (greater than) or < (less than) or results are not as expected, always repeat the test correctly with a new unused test strip. If a test result is displayed that is not expected, consult the following table.

Message or Issue	Probable Cause	What to do
A displayed result reads < (less than) a value.*	Result is below the measuring range of the test. Analyzer has not been placed on a flat, stable surface while testing or has been moved during testing causing the test strip to slip out of position.	Repeat the test. Run controls and confirm that controls are in range.
A displayed result reads > (greater than) a value.*	Result is above the measuring range of the test. Analyzer has not been placed on a flat, stable surface while testing or has been moved during testing causing the test strip to slip out of position.	Repeat the test. Run controls and confirm that controls are in range.
Display reads "----".	Result is not available due to a missing value from a calculation, or a value is outside the measuring range.	Repeat the test using a new, unused test strip. Run controls and confirm that controls are in range.

* See Measuring Range section of each test strip package insert for the measuring range for that specific test strip.

11 Specifications

CardioChek Plus Analyzer

Calibration Curve: Input from MEMo Chip per test strip lot

Batteries: (4) AA 1.5 volt alkaline

Operating Temperature Range: 50-104°F (10-40°C)

Note: The analyzer temperature must be within the test strip temperature specifications to function as a system.

Humidity Range: Between 20 and 80% RH

Dimensions:

Width: 3.2 in (8.13 cm)

Length: 6.0 in (15.24 cm)

Height: 1.5 in (3.8 cm)

Weight (without batteries): ~5.5 oz. (~156 g)

Enclosure: Type BF 

Indoor Use Only*

Pollution Degree 2F

PTS Panels Test Strips

Please read the instructions (package insert) included with the test strips for information specific to each chemistry.

Optional CardioChek/PTS Connect™ Printer/Power Supply

For complete details, refer to each printer's user guide.

* When operating at 40°C affected parts may reach 42.2°C, contact time for these parts is less than 10 minutes.
This statement is provided in compliance with IEC 60601-1.

12 Contact Information

Help

For assistance with the CardioChek Plus test system, please contact PTS Diagnostics Customer Service (M-F, 8:00 a.m. to 8:00 p.m. USA Eastern Time) or your local authorized CardioChek dealer.

PTS Diagnostics

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Email: customerservice@ptsdiagnostics.com • **Website:** ptsdiagnostics.com

13 Warranty

















CardioChek Plus Analyzer Limited Two-Year Warranty

PTS Diagnostics warrants to the original purchaser only, that the CardioChek Plus analyzer shall be free of any defects in materials or workmanship for a period of two years from the date of original purchase. Activation of this warranty shall be conditioned upon completion and return of the warranty registration card to PTS Diagnostics. If the analyzer becomes inoperative during this time, PTS Diagnostics will replace the analyzer with equivalent analyzer, at its option, at no cost to the purchaser. The warranty becomes void if the analyzer is modified, improperly installed or operation not in accordance with the user guide, damaged by accident, or neglect, or if any parts are improperly installed or replaced by the user.

Note: Removing or loosening screws from the back of the analyzer voids all warranties. There are no user serviceable parts inside the case.

14 Explanation of Symbols

Symbols

	Consult instructions for use		Product requires separate collection for electrical and electronic equipment per the WEEE Directive
	Temperature limitation		Keep away from sunlight
IVD	<i>In vitro</i> diagnostic medical device		Keep dry
SN	Serial number	CONTROL	Control
	Manufacturer		Humidity limitation
REF	Catalog number	LOT	Batch code
UDI	Unique device identifier		Use by
	Date of manufacture		Caution
	Do not use if package is damaged and consult instructions for use		Distributor
EC REP	Authorized representative in the European Community		Importer
CE	This product fulfills the requirements of European Regulation 2017/746 on <i>in vitro</i> diagnostic medical devices.		Type BF applied part
	For near-patient testing		Not for self-testing

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The CardioChek® Plus test system is covered by one or more patents.
For details, refer to www.ptsdiagnostics.com/patents.html.

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