CardioChek® Plus

Portable Whole Blood Test System User Guide

For Professional Use

Wilburn Medical USA
146 Furlong Industrial Drive
Kernersville, NC 27284
Toll Free: 1-877-WILBURN (1-877-945-2876)
Toll Free Fax: 1-866-FAXWILBURN (1-866-329-9452)
www.WilburnMedicalUSA.com • wusainfo@WilburnMedical.com

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I. INTRODUCTION

The CardioChek® Plus analyzer from Polymer Technology Systems, Inc. (PTS, Inc.) is intended for in vitro diagnostic use, using whole blood samples. This point-of-care (POC) test system is designed for professional use. The CardioChek Plus test system has an optional printer, software solutions, and wireless communication capability to assist in data reporting.

The CardioChek Plus analyzer is fast, portable, and reliable. This analyzer is a component of a test system that includes PTS Panels® test strips. The PTS Panels test strip box includes 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, Inc. to ensure that you receive product updates and other important information.

For questions or additional assistance with your CardioChek Plus test system, please contact PTS, Inc. (Hours: 8:00 a.m. to 7:00 p.m. USA Eastern Time) using the following contact information:

Polymer Technology Systems, Inc.

7736 Zionsville Road

Indianapolis, IN 46268 USA

+1-317-870-5610 (Direct)

+1-877-870-5610 (Toll-free inside the US)

+1-317-870-5608 (Fax)

Email: inforequest@cardiochek.com

Website: http://www.cardiochek.com/

II. INTRODUCTION TO THE CARDIOCHEK PLUS TEST SYSTEM

The CardioChek Plus Test System

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

The CardioChek Plus Test System and Operating Principle

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, a 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.

II. INTRODUCTION TO THE CARDIOCHEK PLUS TEST SYSTEM, continued

Display (A)

Display shows test results, messages, time, date, and stored results.

Enter Button (B)

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

Reflectance Test Strip Slot (C)

The reflectance test strip slot is positioned in the lower front-center of the analyzer. The reflectance test strip is inserted here with the smooth side facing down.

MEMo Chip Port (D)

The MEMo Chip port is located at the top of the analyzer.

USB Port (E)

A port that allows communication with a CardioChek branded printer.

Next Button (F)

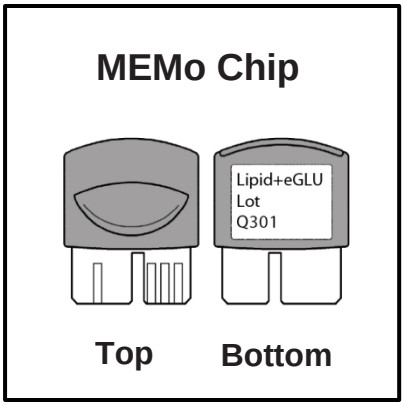
Press this button to turn on the analyzer or to advance to the next menu option.

Electrochemical Test Strip Port (G)

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 color-coded MEMo Chip contains the settings for each test. The top of the MEMo Chip has a finger notch. The bottom has a label with the test name and lot number. Always make sure you insert the MEMo Chip into the port with the finger notch facing up.



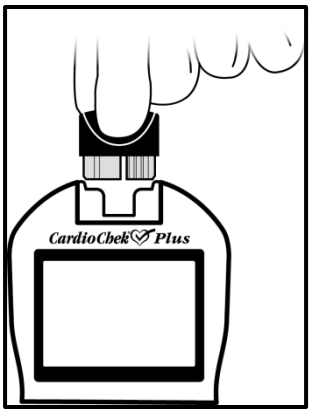
What does the MEMo Chip do?

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

- Reads 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

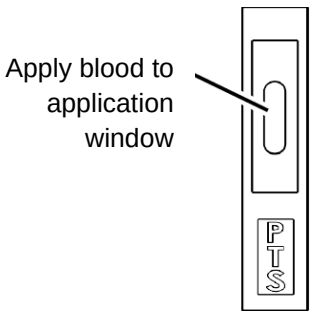
- The MEMo Chip must be inserted to run a test.
- Use only the MEMo Chip that is included with each package of test strips. The lot number code on the test strip vial(s), MEMo Chip, and analyzer display must match.
- If the expiration date in the MEMo Chip has passed, the analyzer will display EXPIRED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



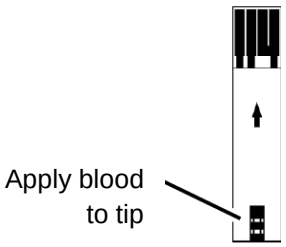
The MEMo Chip port is located at the top center of the analyzer. The MEMo Chip is inserted into this port with the finger notch facing up. Push firmly, but gently, until the MEMo Chip is fully inserted. **Important:** Be careful not to bend the connector.

Test Strip

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. Each PTS Panels test strip box contains a package insert that provides instructions for use and information specific for each test. Please read the instructions completely before testing.



Example of a reflectance test strip



Example of an electrochemical test strip

III. 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 CHANGE BATTERY, 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.

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. Detailed information on the use of each menu follows.

Use the following buttons to navigate the menus:

Enter Button 

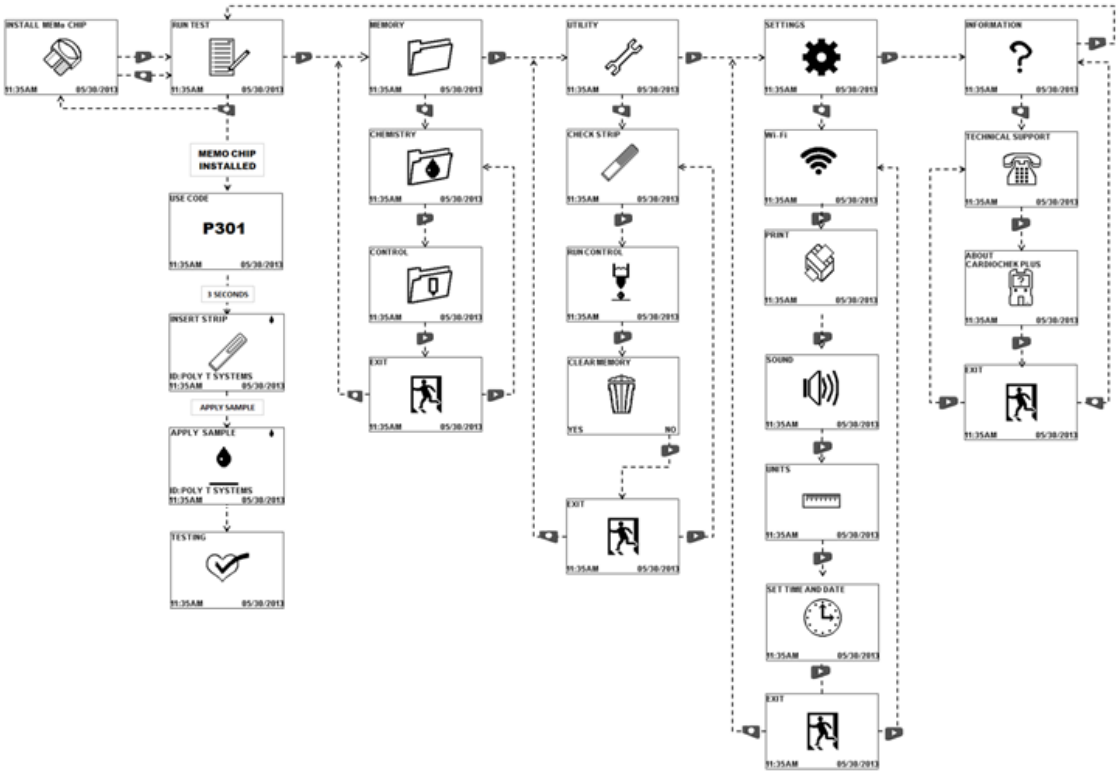
Press this button to turn on the analyzer or to accept the current menu choice.

Next Button 

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

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

CardioChek Plus Analyzer Menus



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

How to Turn Off the Analyzer

To turn off the analyzer, press both buttons (Enter and Next) at the same time for three seconds. After three minutes of idle time (without a test strip or check strip inserted), the analyzer will perform a 6 second count down 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 (PORTUGUÊS), 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. ENGLISH will be displayed. Press Enter if English is desired.
4. For other languages press Next until the desired language is displayed, then press Enter. To set the date and time, proceed to the How to Set the Date and Time section.

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. Press Enter again 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 Date and Time

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read either INSTALL MEMO CHIP (if a current MEMo Chip® is not installed) or INSERT STRIP (if a current MEMo Chip is installed).

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Enter. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter, then press Next until SET TIME is displayed.
5. Press Enter to display the date and the time, which is formatted as YYYY/MM/DD and HH:MM.
6. The display will then highlight the year. Press Enter to accept the highlighted year, or press Next to advance the year. Press Enter to select.
7. The display will then highlight the month. Press Enter to accept the displayed month, or press Next to advance the month. Press Enter to select.
8. The display will then highlight the day. Press Enter to accept the displayed day, or press Next to advance the day. Then press Enter to select.

How to Set the Date and Time, continued

9. The display will then highlight the hour. Press Enter to accept the displayed hour, or press Next to advance the hour. Press Enter to select.
10. The display will then highlight the minutes. Press Enter to accept the displayed minutes, or press Next to advance the minutes. Press Enter to select.
11. The display will then highlight AM or PM. Press Enter to accept the AM/PM 12-hour clock format, or press Next to switch to the 24-hour clock format.
12. Once the clock format has been selected, the SET TIME menu will display. Press Next until EXIT is displayed and press Enter to return to SETTINGS.

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:

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Enter. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter, then press Next 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.
5. 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 screen and then press Enter to select.
6. The display will then read UNITS. Press Next until EXIT is displayed.
7. Press Enter to return to SETTINGS.
8. Press Next to return to RUN TEST.

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 display to read INSTALL MEMO CHIP or INSERT STRIP.

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Next. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter, then Next until SOUND is displayed.
5. Press Enter. The display will highlight (on) .
6. Press Enter to select sound or press Next to highlight (off).
7. Press Enter to accept the sound choice highlighted.
8. Press Next until EXIT is displayed.
9. Press Enter to return to SETTINGS.
10. Press Next to return to RUN TEST.

How to Set the Wi-Fi On or Off

The CardioChek Plus analyzer Wi-Fi communication has been preset to off. To turn the Wi-Fi to 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 display to read INSTALL MEMO CHIP or INSERT STRIP.

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Next. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter. Wi-Fi is displayed.
5. Press Enter. The display will highlight (Wi-Fi on).
6. Press Enter to select Wi-Fi on or press Next to highlight (Wi-Fi off).
7. Press Enter to accept the Wi-Fi choice highlighted.
8. Press Next until EXIT is displayed.
9. Press Enter to return to SETTINGS.
10. Press Next to return to RUN TEST.

Note: See the Wi-Fi Statement section for additional information regarding Wi-Fi compatibility.

How to Set Up the CardioChek Plus Analyzer for Printing

The CardioChek Plus analyzer supports printing on CardioChek branded printers.

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Next. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter, then Next until PRINT is displayed.
5. Press Enter. PRINT MEDIA is displayed.
6. Press Enter.  (Paper) and  (Label) will display.
7. Press Enter to select the highlighted icon or press Next to highlight the desired print media.
8. Press Enter to accept and return to PRINT MEDIA.
9. Press Next to display PRINT COPIES.
10. Press Enter to display icons for one, two, or three copies.
11. Press Enter to select or Next to highlight the desired option.
12. Press Enter to accept and return to PRINT COPIES.
13. Press Next to display OUTPUT SELECT.
14. Press Enter to display  (Printer) and  (PC).
15. Press Enter to select or Next to select the desired icon.
16. Press Enter to accept and return to OUTPUT SELECT.

Testing the Printer

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Next. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter, then Next until PRINTER is displayed.
5. Press Enter, then Next until TEST PRINTER is displayed.
6. Press Enter and a sample printout will be generated.

How to Print Results From Memory

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

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Next. The display will read RUN TEST.
3. Press Next until MEMORY is displayed, then press Enter.
4. Press Enter to select CHEM or press Next, then Enter to select CONTROL.
5. Press Next to highlight the test name, then press Enter to select (LIPIDS for example).
6. Press Next to highlight the date/time of the test result you want to print.
7. Press Enter to print the selected results.

How to Set Up the CardioChek Plus Analyzer for Wired PC Communication

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Next. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter, then Next until PRINT is displayed.
5. Press Enter, then Next until OUTPUT SELECT is displayed.
6. Press Enter, then Next until the  is highlighted.
7. Press Enter to accept and return display to OUTPUT SELECT.
8. Press Next until EXIT is displayed.
9. Press Enter, then Next to return to RUN TEST.

How to Get Help and Information Regarding Your CardioChek Plus Analyzer

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.

   Note: If RUN TEST is displayed, go to Step 3.
2. Press Next. The display will read RUN TEST.
3. Press Next until INFORMATION is displayed.
4. Press Enter, then TECHNICAL SUPPORT is displayed.
5. Press Enter to display contact information.
6. Press Enter, then Next for ABOUT CardioChek Plus display.
7. Press Enter to display serial number (SN) and software version information.
8. Press Next to display wireless IP address and SSID (if applicable).
9. Press Enter to return to ABOUT CardioChek Plus display.
10. Press Next until EXIT, then press Enter.
11. Press Next to return to RUN TEST.

IV. CHECKING THE SYSTEM

Analyzer Check Strips

A quality control of the analyzer operation can be performed using the gray check strip. The check strip (included in the analyzer carrying case) verifies that the CardioChek® Plus analyzer's electronic and optical systems are functioning properly. Each gray check strip is calibrated to read a specific reflectance. 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 acceptable range. 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

How to Use the Analyzer Check Strip

1. Turn on the analyzer by pressing either button.
2. When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
3. Press Enter when CHECK STRIP is displayed.
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 the display reads FAILED, see the note at the end of this section.) Remove the check strip and store it in the analyzer carrying case.
6. Press Next until EXIT is displayed. Press Enter.
7. Press Next until RUN TEST is displayed.
8. Press Enter. The analyzer is ready to run tests.

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 IX. 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 X. Troubleshooting in this user guide.

ChekMate Quality Control

The ChekMate™ quality control kit is an additional quantitative control check strip. ChekMate verifies the CardioChek Plus analyzer functions including:

- Optics
- Power
- MEMo Chip® functionality
- Endpoint algorithm processing

CardioChek ChekMate is to be used in conjunction with liquid PTS Panels® quality control materials. It is recommended that ChekMate quality control strips be run once each day that an analyzer is used.

How to Use the ChekMate Quality Control Test Strips

1. Insert the ChekMate quality control MEMo Chip.
2. Press either button to turn on the analyzer. USE CODE 0001 will display on the analyzer.
3. Insert the LEVEL 1 ChekMate quality control strip into the CardioChek Plus analyzer, and wait for results to be displayed.
4. Record results on the ChekMate Quality Control Results sheet.
5. Compare the results to the LEVEL 1 acceptable ranges printed on the ChekMate Quality Control Results sheet or visit http://www.cardiocheck.com to get a list of the LEVEL 1 acceptable ranges.
6. Remove Level 1 ChekMate quality control strip and press Enter.
7. Repeat Steps 3 – 6 with the ChekMate LEVEL 2 quality control strip and LEVEL 2 acceptable ranges.

Note: Results are displayed as the following readings: C1 RED, C2 RED, C3 RED, and C1 GREEN. These correspond to each chemistry test "window." All results for the ChekMate quality control strips should be within the ranges specified on the ChekMate Quality Control Results sheet or listed at http://www.cardiochek.com/.

If test results are outside the specified range, re-test with a new ChekMate control strip. If the results remain outside of the specified ranges, contact PTS, Inc. Customer Service.

V. 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, Inc. or commercially available quality control materials.

Refer to the Range Card provided with the controls or visit http://www.cardiochek.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 whenever a new lot of PTS Panels test strips are received.

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

1. Install the correct MEMo Chip for the lot of test strips that you are using.
2. Press either button to turn on the analyzer.
3. Press Next until the display reads UTILITY. Press Enter.
4. Press Next until RUN CONTROL is displayed. Press Enter.
5. Insert the reflectance test strip into the analyzer. The CardioChek Plus analyzer will display APPLY SAMPLE. This indicates the system is ready for a sample (control) to be applied. Immediately replace the vial cap, making sure the test strip vial is closed tightly.
6. Remove cap from the quality control material and turn bottle upside down.
7. Hold bottle directly over and perpendicular to the blood application window on the test strip.
8. Squeeze bottle so that a large drop of control solution is formed.
9. Allow the drop of control solution to fall onto the application window of the test strip. Do not allow the tip of the bottle to touch the test strip.
10. Replace the cap on the quality control material.
11. During testing, CONTROL is displayed. Results will be displayed within about one to two minutes.
12. Compare the control results to the values on the Quality Control Range Card included with control materials. The control result(s) will also be stored in the analyzer's memory.
13. To exit the control testing menu, press Next until EXIT is displayed. Press Enter.
14. Press Next until RUN TEST is displayed.

If Quality Control Results Are Not in 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.

V. QUALITY CONTROL TESTING, continued

How To Run a Quality Control Test on Electrochemical Test Strips

1. Install the correct MEMo Chip for the lot of test strips that you are using.
2. Press either button to turn on the analyzer.
3. Press Next until the display reads UTILITY. Press Enter.
4. Press Next until RUN CONTROL is displayed. Press Enter.
5. Insert the electrochemical test strip into the analyzer. The CardioChek Plus analyzer will display APPLY SAMPLE. This indicates the system is ready for a sample (control) to be applied.
6. Remove the cap from the quality control material and turn bottle upside down.
7. Hold bottle near the tip of the test strip.
8. Squeeze the bottle so a drop of control solution is formed.
9. Allow the drop of control solution to touch the tip of the electrochemical test strip. Do not allow the tip of the bottle to touch the test strip.
10. Replace the cap on the quality control material.
11. Results will be displayed in about 10 seconds.
12. Compare control results to the values on the Quality Control Range Card included with control materials.
13. The control result(s) will also be stored in the analyzer's memory.
14. To exit the control testing menu, press Next until EXIT is displayed. Press Enter.
15. Press Next until RUN TEST is displayed.

If Quality Control Results Are Not in 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.

VI. RUNNING A TEST

Blood Testing

A package insert is included with each box of 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
- PTS Panels test strips
- Lot-specific MEMo Chip®
- Sterile lancet
- Pipet or capillary blood collector
- Gauze or cotton balls
- Alcohol wipe (optional)

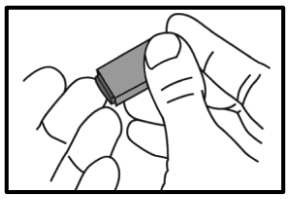
This analyzer requires whole blood for testing. Do not operate the analyzer in direct light. Reference the Section IX Care and Cleaning section for more information.

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.
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 finger tips.

How to Obtain a Blood Sample

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 the following 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.
   - 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, and collect a blood sample for the reflectance test.
   - If only running a reflectance test, lance the finger, 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.
7. Use the test strip and lancet one time only. Dispose of properly.

Precaution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

How to Run a Reflectance Test

1. Insert correct MEMo Chip for the lot of strips in use.
2. Insert MEMo Chip with finger notch (top) side up, lot number code facing down.
3. Press either button to turn on the analyzer.
4. When INSERT STRIP is displayed, insert the test strip into the analyzer as far as it will go.
5. Obtain a blood drop following the correct technique.
6. When APPLY SAMPLE is displayed, apply blood to the test strip. Refer to each specific test strip package insert for sample volume and sample application instructions.
7. Within one to two minutes, the results will be displayed.
8. Remove test strip and discard.
9. The analyzer automatically shuts down after three minutes of idle time with no test strip inserted.

How to Run an Electrochemical Test

1. Insert the MEMo Chip that matches the lot number on the test strip vial.
2. Press either button to turn on the analyzer.
3. Remove a single electrochemical test strip from the test strip vial and immediately replace the cap.
4. Insert the electrochemical test strip into the designated electrochemical test strip port.
5. APPLY SAMPLE icon appears on the display.
6. Obtain a blood drop following the correct technique.
7. 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.
8. Blood will be drawn into the strip automatically by capillary action.
9. TESTING will appear until the result is displayed.

How to Run an Electrochemical Test with a Reflectance Test

1. Insert the MEMo Chip that matches the lot number on both the electrochemical AND the reflectance test strip vials.
2. Press either button to turn on the analyzer.
3. Remove a single electrochemical test strip from the test strip vial and immediately replace the cap.
4. Insert the electrochemical test strip into the designated electrochemical test strip port.
5. Remove a single reflectance test strip from test strip vial and immediately replace cap.
6. Insert the reflectance test strip into the designated test strip slot.
7. The reflectance icon and electrochemical icon will display together.
8. For the electrochemical test:
    a. Obtain a drop of blood using a lancet per the correct technique.
    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 of the reflectance test results.

9. 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 fingertip to accumulate a large drop of blood.
    c. Excessive squeezing of the finger may alter test results.
    d. Use a pipet or capillary blood collector to apply whole blood to the test strip blood application window.
    e. In about 2 minutes, the results will appear on the display. Remove and discard test strips.

DO NOT add more blood to any test strip that has been used.

VII. MEMORY

Test results are automatically stored in the CardioChek® Plus analyzer's memory. The analyzer can store up to 50 results of each chemistry and 10 results for control tests. 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

1. Press either button to turn on the analyzer. If the display reads INSTALL MEMO CHIP, go to Step 2. If the display reads INSERT STRIP, press Enter.
2. Press Next until MEMORY is displayed.
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. To recall Control results, press Next until EXIT is displayed. Press Enter. Press Next until CONTROL is displayed.
    b. Press Enter when the desired Control test is displayed.
    c. For example, to review Lipid Panel results, from the CHEM display, press Next until LIPIDS is displayed, then Enter. The time and date will be displayed. Press Enter when the desired test time and date is displayed. Press Next to scroll through results.
6. To exit, press Next until the display reads EXIT, then press Enter. Repeat this step until you return to RUN TEST.

How to Clear Results Stored in Memory

1. Press either button to turn on the analyzer. Wait for the display to read either INSTALL MEMO CHIP or INSERT STRIP.
2. Press Enter, then press Next until UTILITY is displayed. Press Enter.
3. Press Next until CLEAR MEMORY is displayed. Press Enter.
4. Press Next until the display reads CLEAR YES. Press Enter. The display will read ERASE, CLEARED, and then CLEAR MEMORY.
5. To exit, press Next until the display reads EXIT, then press Enter. Press Next until you return to RUN TEST.

VIII. Wi-Fi

Wi-Fi Statement

This equipment has been tested and found to comply with the limits for a Class B digital device pursuant to part 1 of the FCC Rules. These limits are designed to provide reasonable protections against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures.

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Wi-Fi Compatibility

- See Section III. Setup for instructions on turning Wi-Fi on and off.
- Connecting to Wi-Fi requires a CardioChek Developers Kit. Contact PTS Customer Service or your local authorized CardioChek dealer for more information.

IX. 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 64-95º F (18-35º C) and 20-80% Relative Humidity (RH). **Do not freeze**. If storage temperature is below 64º F (18º C), allow the analyzer to warm up to room temperature 68º F (20º C) before using. If the analyzer has been stored under excessive conditions, allow at least 30 minutes at room temperature for the analyzer 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 Instructions

1. Locate the optical glass within the reflectance test strip slot.
2. Open an alcohol wipe/prep pad.
3. Fold the wipe and carefully wipe the optical glass and test strip guides clean. If the area is especially dirty, this may require additional wipes.
4. Immediately dry the optical glass completely with gauze. Make sure the glass is clean, dry, and completely free from any fingerprints, dust, or smudges. The glass must look clean when held at different angles.

If the exterior of the analyzer needs cleaning, wipe with a damp (not wet) alcohol wipe or dampen cloth with water or medical grade disinfectant and wipe surfaces and the display area very carefully. Be careful not to get the test strip port or slot (where the test strip is inserted) wet. **Do not use bleach, window cleaner, or hydrogen peroxide.**

X. TROUBLESHOOTING

MESSAGE or ISSUE	PROBABLE CAUSE	WHAT TO DO
Desired language is not displayed.	Language has been set incorrectly.	Turn analyzer off. See Section III. Setup – How to Reset the Language.
The wrong date and/or time is displayed.	Date and time have not been set correctly.	See Section III. Setup – How To Set the Date and Time.
FAILED is displayed during a check strip test.	Analyzer needs to be cleaned. Check strip is dirty or damaged.	Wipe the test strip slot with a clean, damp, and lint-free cloth. Use spare check strip. If check strip still fails, call Customer Service.
TOO MUCH LIGHT	Test is being performed in direct light or outside.	Test inside, away from windows, and away from direct lamp light.
MEMO CHIP ERROR	MEMo Chip® is defective.	Use another MEMo Chip from the same lot.
TEST ERROR	Insufficient sample has been added to test strip.	Test again with a new test strip and make sure the correct volume of sample is used.
LANGUAGE	Analyzer is new or language option has not been set.	Follow user guide instructions to set 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.
HI TEMP	Analyzer is above acceptable operating temperature.	Move to acceptable environment and test after analyzer reaches proper temperature.

X. TROUBLESHOOTING. continued

MESSAGE or ISSUE	PROBABLE CAUSE	WHAT TO DO
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 III., Setup – How To Set the Date and Time.
CHANGE BATTERY	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.	Test again with a new test strip.
PRINT ERROR	Print function has been interrupted.	Print result in MEMORY or test again.
Results will not print.	Communication Cable was improperly connected. Printer cover is not closed properly. (Printer indicator light is red.) Labels/paper were not loaded in the printer.	Check all connections. Reprint test results stored in memory. Close printer cover correctly, ensuring that the printer indicator light is green. Reprint test results stored in memory. See Printer System Setup/Operating System Instruction Sheet packaged with the printer.
STRIP ERROR	MEMo Chip is defective.	Use another MEMo Chip from the same lot.
INSUFFICIENT SAMPLE	Sample size was not large enough to complete testing and get result(s).	Repeat test(s) using proper sample amount(s).
STRIP REMOVED	Test strips were removed during testing.	Repeat test(s) without removing test strip(s) until results are displayed.

XI. 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.	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.	Repeat the test. Run controls and confirm that controls are in range.
Display reads "_ _ _ _" or N/A.	Result is not available due to a missing value from a calculation, or a value is outside the measuring range.	Repeat the test. Run controls and confirm that controls are in range.
TRIGS TOO HIGH LDL N/A	Lipid Panel triglycerides test result was 400 mg/dL (4.52 mmol/L) or greater.	No action needed. LDL will not be calculated on samples with triglycerides of 400 mg/dL (4.52 mmol/L) or greater.

XII. CLIA INFORMATION

General CLIA Information (US Only)

(Please read before testing)

1. CLIA-waived. Each laboratory or testing site using the PTS Panels® test strips MUST have a CLIA Certificate of Waiver (or other CLIA operating license) before testing. To obtain a Certificate of Waiver or any other type of laboratory license, call your state health department or PTS, Inc. at +1-877-870-5610 (Toll-free) or +1-317-870-5610 for an application (form CMS 116).
2. Before you start testing, carefully read all instructions, including quality control. Failure to follow instructions, including quality control instructions, will result in high complexity rating and subject the facility to all applicable CLIA requirements for high complexity testing. For complete information including performance, please refer to the product specific package insert and user guide.
3. CLIA-waived for whole blood (fingerstick and venous EDTA or heparin) testing only.

XIII. SPECIFICATIONS

CardioChek® Plus Analyzer

Calibration Curve: Input from MEMo Chip® per test strip lot

Batteries: (4) AA 1.5 volt alkaline

The analyzer storage conditions and optimal operating range are as follows:

Storage Conditions	Optimal Operating Conditions
20 – 30° C **68 – 86° F**	**20 – 27° C** **68 – 80° F**

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)

PTS Panels® Test Strips

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

Optional CardioChek Printer/Power Supply

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

XIV. CONTACT INFORMATION

Help

For assistance with the CardioChek Plus test system, please contact PTS Customer Service or your local authorized CardioChek dealer.

Polymer Technology Systems, Inc.

7736 Zionsville Road

Indianapolis, IN 46268 USA

+1-317-870-5610 (Direct)

+1-877-870-5610 (Toll-free inside the US)

+1-317-870-5608 (Fax)

Email: inforequest@cardiochek.com

Website: http://www.cardiochek.com/

XV. WARRANTY

CardioChek Plus Analyzer Limited Two-Year Warranty

PTS, Inc. 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, Inc. If the analyzer becomes inoperative during this time, PTS, Inc. 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.

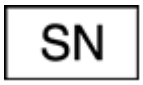
XVI. EXPLANATION OF SYMBOLS

CardioChek Plus Test System Symbols

Consult Instructions for Use

Temperature Limitation

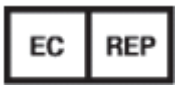
In vitro diagnostic medical device



Serial Number

Manufacturer

Catalog Number



Authorized Representative in the European Community

This product fulfills the requirements of the European Directive 98/79 EC for in vitro diagnostic medical devices.

Product requires separate collection for electrical and electronic equipment per the WEEE Directive

Federal Communications Commission

XVII. INDEX

The CardioChek® brand analyzers and associated test strips may be covered by one or more of the following patents:

U.S. Patent Nos. 7,435,577, 7,625,721, 7,087,397, 7,214,504, 7,374,719, 7,494,818, 5,597,532, and D534444

Australian Patent No. 2002364609

Eurasian Patent No. 010414

Mexican Patent No. 267323

South African Patent Nos. 2004/4929 and 2006/06561

EP Patent No. 0750739 (DE, FR, GB, IT)

Other patents pending.

Polymer Technology Systems, Inc.

7736 Zionsville Road

Indianapolis, IN 46268 USA

+1-877-870-5610 (Toll-free inside USA)

+1-317-870-5610 (Direct)

+1-317-870-5608 (Fax)

E-mail: inforequest@cardiochek.com

Website: http://www.cardiochek.com/

EC REP

MDSS GmbH

Schiffgraben 41

30175 Hannover

Germany

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