CardioChek™ P•A Analyzer

Portable Whole Blood Test System



User Guide

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I. INTRODUCTION

Thank you for selecting the CardioChek™ P•A Analyzer from Polymer Technology Systems, Inc. (PTS).

The CardioChek P•A is a fast, portable and accurate whole blood test system. The CardioChek P•A test system includes an analyzer, MEMo Chip and test strips. This system is intended for *in vitro* diagnostic use to test whole blood. Using this system, a health care professional can quickly measure various blood components with a small sample size. The CardioChek P•A test system is capable of monitoring for diabetes and other disease states and lipid screening.

The CardioChek P•A uses reflectance photometry for testing. It reads color changes that occur on a test strip after blood is placed on the test strip.

Before you begin testing, please read this entire User Guide and the test strip package insert completely. This provides the necessary information for the use of this system**.** Please remember to return the enclosed warranty card to ensure you receive product updates.

Polymer Technology Systems, Inc.
Indianapolis, IN 46268 USA
(317) 870-5610
www.ptspanels.com

For questions or assistance with the CardioChek P•A, call:

Customer Service:
1-877-870-5610 (toll free inside USA)
1-317-870-5610
Fax: 1-317-870-5608
E-mail: inforequest@ptspanels.com

II. HOW TO USE THE USER GUIDE

This guide includes all the information you need to test properly. For additional information and specific information for each individual chemistry test, please make sure you read the test strip package insert included with the test strips. This guide is arranged in the order a new user would need the information. Each section can be used separately, after you have read the entire guide.

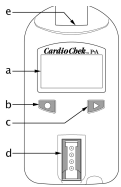
If you have questions about this system, please contact our Customer Service department. Customer Service assistance is available during the hours of 8:00 AM- 5:00 PM Eastern Standard Time, Monday through Friday. If the patient has questions about his/her results, and you are not the healthcare provider, advise them to contact his/her health care provider.

Customer Service:
Hours: 8:00 AM - 5:00 PM Eastern Standard Time
Monday - Friday
1-877-870-5610 (toll free inside USA)
1-317-870-5610
Fax: 1-317-870-5608
E-mail: inforequest@ptspanels.com

III. INTRODUCTION TO THE CARDIOCHEK P•A

The CardioChek P•A Test System:

The CardioChek P•A test system consists of three main parts. These include the analyzer, test strips and a MEMo Chip. When a blood sample is applied to the test strip, a chemical reaction occurs producing a color change on the test strip. This color is measured and compared to a calibration curve stored in the MEMo Chip. The analyzer converts this color reading into a test result. The test result appears on the display screen.



Display (a)
Display shows test results, messages, time, date, and stored results.

ENTER Button (b)
Press this button to turn the analyzer ON or to accept the current menu choice.

NEXT Button (c)
Press this button to turn the analyzer ON or to advance to the next menu option.

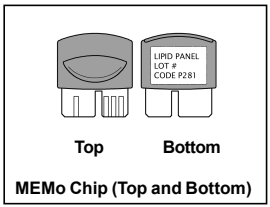
Test Strip Insert Opening (d)
The Test Strip Insert Opening is positioned in the lower front of the analyzer. The strip is inserted here with the raised lines facing up.

MEMo Chip Port (e)
The MEMo Chip Port is on the top of the analyzer. The MEMo Chip is inserted into this port with the finger notch (top) facing up. This port can also be used for the printer communication cable.

III. INTRODUCTION TO THE CARDIOCHEK P•A

The MEMo Chip

Each package of test strips contains a small color-coded plastic rectangle with a connector. This is called the MEMo Chip.



MEMo Chip (Top and Bottom)

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.

What does the MEMo Chip do?

When inserted with the finger notch (top) facing up in your CardioChek P•A, the MEMo Chip does the following:

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

The MEMo Chip ensures you have the proper settings for the test strip you are using.

Guidelines for using the MEMo Chip:

- The MEMo Chip must be in place while running a test.
- Use only the MEMo Chip that is included with each package of strips. The lot number code on the test strip vial, MEMo Chip, and analyzer display must match.
- If the expiration date in the MEMo Chip has expired, the analyzer will display ***EXPIRED LOT***.
- If your MEMo Chip is lost or missing, please call Customer Service for a replacement.

III. INTRODUCTION TO THE CARDIOCHEK P•A

Inserting the MEMo Chip into the MEMo Chip Port.



Using the MEMo Chip (continued):

The MEMo Chip Port is on 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. Be careful not to bend the connector.

Test Strip

To test blood on the CardioChek P•A, use test strips specific for each test. The test strip is inserted into the analyzer, then blood is applied to the test strip. The analyzer reads the color produced on the test strip and displays a test result. Each test strip box contains a package insert that provides instructions for use. The package insert provides information specific for each test. Please read the instructions completely before testing.

IV. SET UP

Battery Use and Replacement

The CardioChek P•A requires two (2) AAA 1.5 volt 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 P•A by pressing and sliding it in the direction of the arrow (toward the MEMo Chip port).
2. Remove old batteries from the compartment and safely discard.
3. Insert the new batteries into the battery compartment with the positive (+) terminal facing to the left on the top battery, and to the right on the bottom battery as marked on the inside compartment.
4. Replace the battery door. To make sure the batteries were installed correctly, push either one of the two buttons on the front of the analyzer to turn the CardioChek P•A ON.

WARNING! Dispose of the old batteries properly.

How to Turn the Analyzer OFF:

The batteries will have a longer life due to the analyzer's automatic shut down feature. The analyzer will perform a 10 second count down and turn OFF after three minutes of idle time (without a test strip inserted). To stop shut down press either button (◀ or ▶). You can turn the analyzer OFF manually by holding down both buttons (◀ and ▶) at the same time for three seconds at any of the following Main Menu headings: RUN TEST, MEMORY, UTILITY, and USER SET. You can also remove the batteries to turn the analyzer OFF.

IV. SET UP

The first time the analyzer is turned on you will be required to set the language, date, and time.

Setting Language

The language menu consists of the following choices: English, German (Deutsch), Italian (Italiano), French (Francais), Spanish (Espanol), and Portuguese (Portugse).

How to Set the Language:

1. Turn the analyzer ON by pressing either button (◀ or ▶).
2. The display will read LANGUAGE. Press ◀.
3. ENGLISH will be displayed. Press ◀ if English is your choice.
4. For other languages press ▶ until the desired language is displayed, then press ◀. To set the time proceed to step 2-How to Set the Time.

How to Reset the Language:

1. Allow the analyzer to automatically turn OFF or remove the batteries and replace them.
2. Press and hold ◀ down for approximately 5 seconds, during the analyzer power-up stage until LANGUAGE is displayed.
3. Press ◀. Press ▶ to scroll through the language choices.
4. Press ◀ to select the language that is displayed. SET TIME will be displayed.

How to Set the Time:

1. If the analyzer is OFF, press either button (◀ or ▶) to turn the analyzer ON (If RUN TEST is displayed, go to step 3). 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). Press ▶. The display will read RUN TEST.
2. Press ▶ until USER SET is displayed.
3. Press ◀. Press ▶ until SET TIME is displayed.
4. Press ◀ and the clock format is displayed: 12/24 HR.

IV. SET UP

How to Set the Time Continued:

5. Press ▶ to alternately display the 12 hour am/pm clock or the 24-hour clock. Press ◀ to accept the displayed clock format. The display will read HOUR and the numerical hour.
6. Press ▶ to increment the hour. Note AM/PM in the upper right hand corner of the display.
7. Press ◀ to accept the displayed hour. The display will read MINUTE and the numerical minute.
8. Press ▶ to increment the minutes.
9. Press ◀ to accept the displayed minute. The display will read SET TIME. To set the date, proceed to step 4-How to Set the Date.
10. To exit, press ▶ until EXIT is displayed. Press ◀.
11. Press ▶ to return the display to RUN TEST.

How to Set the Date:

1. If RUN TEST is displayed, go to step 3. If the analyzer is OFF, press either button (◀ or ▶) to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press ▶. The display will read RUN TEST.
3. Press ▶ until USER SET is displayed. Press ◀.
4. Press ▶ until SET DATE is displayed.
5. Press ◀ and the numerical month is displayed.
6. Press ▶ to increment the month.
7. Press ◀ to accept the displayed month. The display will read DAY and the numerical day of the month.
8. Press ▶ to increment the day.
9. Press ◀ to accept the displayed day. The display will read YEAR and the numerical set year.
10. Press ▶ to increment the year.
11. Press ◀ to accept the displayed year. The display will read SET DATE. To set the units, proceed to step 5-How to Set the Units.
12. Press ▶ until EXIT is displayed. Press ◀.
13. Press ▶ to return the display to RUN TEST.

IV. SET UP

How to Set the Units:

The CardioChek P•A has been preset to US units (i.e. mg/dL). To change the units to INTL (International Standard Units) (i.e. mmol/L) follow the steps listed below:

1. If RUN TEST is displayed, go to step 3. If the analyzer is OFF, press either button (◀ or ▶) to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press ▶. The display will read RUN TEST.
3. Press ▶ until USER SET is displayed.
4. Press ◀. The display will read PRINT.
5. Press ▶ until UNITS is displayed.
6. Press ◀. The display will read US. If INTL units are desired press ▶ to display INTL.
7. Press ◀ to select the units. Display will read UNITS.
8. Press ▶ until EXIT is displayed.
9. Press ◀ to return display to USER SET.
10. Press ▶ to return to RUN TEST.

How to Set the Sound:

The CardioChek P•A sound has been preset to BEEP ON. To turn the sound on or off please follow the steps listed below:

1. If RUN TEST is displayed, go to step 3. If the analyzer is OFF, press either button (◀ or ▶) to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press ▶. The display will read RUN TEST.
3. Press ▶ until USER SET is displayed.
4. Press ▶ until SOUND is displayed.
5. Press ◀. The display will read BEEP ON or BEEP OFF.
6. Press ▶ to select either BEEP OFF or BEEP ON.
7. Press ◀ to accept the sound choice displayed.
8. Press ▶ until EXIT is displayed.
9. Press ◀ to return display to USER SET.
10. Press ▶ to return to RUN TEST.

IV. SET UP

Introduction to the CardioChek P•A and Printer System

The CardioChek P•A analyzer (with software version 2.20 and higher) supports printing in two formats, label or paper, on the CardioChek P•A Thermal Printer or Portable Printer. To verify CardioChek P•A system software, turn the analyzer ON by pressing either button (◀ or ▶). The software version will appear on the display.

How to Set Up the CardioChek P•A for Printing:

For complete details, refer to each printer's User Guides and Set Up / Operating Instruction Sheets.

1. Turn the CardioChek P•A ON by pressing either button (◀ or ▶).
2. Press ◀ until RUN TEST is displayed.
3. Press ▶ until USER SET is displayed. Press ◀.
4. PRINT will be displayed. Press ◀. MEDIA will be displayed.
5. Press ◀ to select the type of print material (MEDIA). Select L for LABEL or P for PAPER. MEDIA will be displayed. Note: Default is set to labels (L).
6. Press ▶. COPIES will be displayed. Note: Default is set to one copy.
7. Press ◀ to select COPIES, press ▶ to scroll to the number of copies of the test results to be printed. 1, 2, or 3.
8. Press ◀ to select the number of copies to be printed. COPIES will be displayed.
9. Press ▶ until EXIT is displayed. Press ◀.
10. Repeat this step until you return to RUN TEST. Make sure the printer power switch is turned OFF.
11. Connect the instrument to the CardioChek P•A Thermal Printer via the Communication Cable. Insert the 9-pin end of the Communication Cable into the printer. Insert the other end of the cable into the analyzer MEMo Chip port.
12. Install the MEMo Chip into the top end of the Communication Cable connected to the analyzer.
13. The Portable Printer is connected in the same way except the Communication Cable connects to a 9-Pin Printer Cable that then connects to the Portable Printer.

IV. SET UP

How to Print Test Results:
At the completion of testing on the CardioChek P•A, the selected number of copies of results will automatically be printed.

How to Print Results From Memory:
(Up to 30 test results per chemistry; up to 10 Control results)

1. Turn the CardioChek P•A ON by pressing either button (◀ or ▶).
2. From the RUN TEST menu press ▶.
3. Press ◀ until RUN TEST is displayed.
4. MEMORY will be displayed. Press ◀.
5. Press ◀ to select CHEM.
6. Press ▶ to select the type of test, LIPIDS for example.
7. Press ▶ to select the date/time of the test result you want to print.
8. Press ◀ to print the selected number of copies of results.
9. Control results can be printed by selecting CONTROL instead of CHEM and then selecting the type of result as above.

V. CHECKING THE SYSTEM

Check Strip

A gray Check Strip is included in the analyzer carrying case to verify the CardioChek P•A's basic functionality of the electronic and optic systems. The gray Check Strip provides a permanent color standard to be read by the analyzer. When the Check Strip is not in use, please store it in the analyzer carrying case.

It is recommended to check the analyzer when:

- It is first received.
- The analyzer is dropped.
- An unexpected result is obtained.

How to Use the Check Strip:

1. Turn the analyzer ON by pressing either button (◀ or ▶).
2. When INSTALL MEMO CHIP or RUN TEST is displayed, press ▶ until UTILITY is displayed. Press ◀.
3. Press ◀ when CK STRIP is displayed.
4. Insert the Check Strip, ribbed side up, into the Test Strip Insert Opening.
5. The analyzer should display PASSED (If the display reads FAILED, see the NOTE at end of this section). Remove the Check Strip and store it in the analyzer carrying case.
7. Press ▶ until EXIT is displayed. Press ◀.
8. Press ▶ until RUN TEST is displayed.
9. Press ◀. The analyzer is ready to run tests.

Note: If the analyzer displays FAILED:

1. Clean the CardioChek P•A Test Strip Insert Opening (where the strip is inserted into the analyzer) with a soft, lint-free, damp cloth. See the Care and Cleaning section.
2. Inspect the Check Strip to make sure it is not dirty or damaged. Use the spare Check Strip and repeat.
3. See the Troubleshooting section.

V. CHECKING THE SYSTEM

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 verify the performance of your entire test system: CardioChek P•A analyzer, MEMo Chip and test strips. Use quality control materials provided by PTS.

PTS PANELS HDL Controls REF/Cat. No. 0722
PTS PANELS Multi-Chemistry Controls REF/Cat. No. 0721
Refer to control package insert for control specifications.

Health care professionals testing with this system should follow their facility's guidelines and policies regarding the use of quality control materials.

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

For running a control, see the section on Running a Test.

To perform a control test the following is needed:

- CardioChek P•A Analyzer
- PTS PANELS™ Test Strips
- Quality Control Materials
- Quality Control Instructions
- Quality Control Range Card for specific test strip lots.

VI. RUNNING A TEST

Control Testing

Control testing, also known as quality control testing, is used to ensure all the parts of the test system are working properly together and the test results are accurate and reliable within the limits of the system. A quality control material, or control, is a liquid containing an analyte that is known to be within a certain range. This range is supplied with the Quality Control Material. Health care professionals should follow their facility's policies on when controls should be tested.

How To Run a Quality Control Test:

1. Install correct MEMo Chip for the lot of strips that you are using.
2. Press either button (◀ or ▶) to turn the analyzer ON.
3. Press ▶ until the display reads UTILITY.
4. Press ◀. Press ▶ until RUN CONTROL is displayed. Press ◀.
5. Insert the test strip into the analyzer. The CardioChek P•A will display APPLY SAMPLE. This indicates the system is ready for a sample (control) to be applied.
    a. Immediately replace the vial cap, making sure the strip vial is closed tightly.
6. Remove control cap and turn bottle upside down.
    a. CONTROL MUST BE APPLIED TO TEST STRIP WITHIN 2 MINUTES OF REMOVING THE STRIP FROM THE VIAL.
7. Hold bottle directly over and perpendicular to the white reaction area on the test strip.
8. Squeeze bottle so that a small drop of control solution is formed.
9. Allow the drop of control solution to fall onto the test strip. Do not allow the tip of the bottle to touch the test strip.
10. Replace control cap.
11. Results will be displayed within about one to two minutes (for most tests).
12. Remove and discard test strip.

VI. RUNNING A TEST

How To Run a Quality Control Test (continued):

13. Compare control results to the values on the Quality Control Range Card included with control solutions. Make sure to match the correct test strip lot number(s) and levels depending on the control solution used.
14. To exit the control testing menu press twice. RUN CONTROL will be displayed.
15. Press until EXIT is displayed. Press .
16. Press until RUN TEST is displayed.

If you have questions or the control range is not listed on the Quality Control Range Card for the lot of test strips you have, please contact Customer Service at:
1-877-870-5610 (toll free inside the USA)
1-317-870-5610
Fax:1-317-870-5608
E-mail: inforequest@ptspanels.com

If Quality Control Results are not in Range:

1. Make sure you have the correct Quality Control Range Card by matching the lot numbers and levels with the controls and test strips you are using.
2. Make sure neither the test strips nor the controls are past the expiration date printed on the label.
3. Repeat the test again using fresh materials.
4. Call Customer Service for assistance.

VI. RUNNING A TEST

Blood Testing
A test strip package insert is included with each box of test strips. Please read the test strip instructions along with this section of the User Guide completely and carefully before testing.

Testing Supplies
To perform a blood test, the following is needed:

- CardioChek P•A Analyzer
- PTS PANELS™ Test Strips
- Matching MEMo Chip
- Lancing device
- Sterile lancet
- Capillary blood collector or pipet
- Gauze or cotton balls
- Soap/water and alcohol

This analyzer requires whole blood for testing. Do not operate the analyzer in direct light. See the Care and Cleaning section.

Helpful Hints on Getting a Good Drop of Blood:
1. Warm the fingers to increase blood flow.
2. Let the arm hang down at the person's side briefly to allow blood flow to the finger tips.
3. Instruct the patient to wash hands in warm, soapy water. Rinse well and dry completely. If an alcohol wipe is used, let the finger air dry before testing.
4. Prepare lancing device according to manufacturer's instructions.

How to Obtain a Blood Sample:
To perform a fingerstick:
1. Wipe the finger with an alcohol wipe. Be sure the finger is dry.
2. Use a new sterile, disposable lancet to puncture the skin.

VI. RUNNING A TEST

3. Stick the finger on the side of the fingertip, instead of the center. See picture below.
   CORRECT WAY TO STICK THE FINGER



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. 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 capillary blood collector or pipet.
5. Follow the specific instructions found in the test strip package insert for each test for sample application and volume ranges. Capillary blood collectors (pipets) are available to ensure the correct 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 Insert Opening.
7. Use the test strip and lancet one time. Discard the used lancet in a closed puncture resistant container, such as a sharps container. Use a new lancet every time you test. Do not share or reuse lancets.

Health Care Professionals: If the analyzer is used for testing several people, be sure to follow the proper infection control procedures for your facility.

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

VI. RUNNING A TEST

How to Run a 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. Turn CardioChek P•A ON by pressing either button (◀ or ▶).
4. When INSERT STRIP is displayed, insert the strip into the Test Strip Insert Opening 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 two minutes, the results will be displayed (for most tests).
8. Due to the analyzer's internal rounding of results, displayed calculated results may not be the same as a manual calculation.
9. The analyzer automatically shuts down after three minutes of idle time with no test strip inserted.

Note: Do not leave a used test strip in the analyzer Test Strip Opening. This will prevent the automatic shut down feature and will shorten battery life.

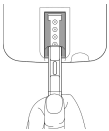
VI. RUNNING A TEST

Quick Reference Testing Guide

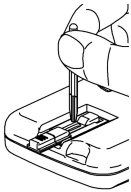
1. *Insert the MEMo Chip with lot number that matches the test strip vial. Press either button (◀ or ▶) to turn the CardioChek P•A ON. Analyzer will display code.*



2. *When INSERT STRIP is displayed, insert strip into the analyzer as far as it will go.*



3. *When APPLY SAMPLE is displayed, apply whole blood* with a capillary blood collector or pipet to the white reaction area on the test strip.*



4. *Within two minutes the result will appear on the display. Remove and discard strip. DO NOT add more blood to a test strip that has been used.*



* *Refer to each specific test strip package insert for sample volume and sample application instructions.*

VII. MEMORY

Test results are automatically stored in the analyzer's memory. CardioChek P•A memory can store up to 30 results of each chemistry and 10 results of each control test. 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 (◀ or ▶) to turn the analyzer ON. Wait for the display to read either INSTALL MEMO CHIP or INSERT STRIP.
2. Press ▶ until MEMORY is displayed.
3. Press ◀. CHEM is displayed.
4. Press ◀, then ▶ to select the desired chemistry (until the chemistry has been run at least once, the test name is not displayed).
5. Press ◀ to view the test result including time and date.
   a. For example, to review Lipid Panel results, from the CHEM display, press ▶ until LIPIDS is displayed, then ◀. The time and date will be displayed. Press ◀ when the desired test time and date is displayed. Press ▶ to scroll through results.
   b. To recall Control results, press ▶ until EXIT is displayed. Press ◀. Press ▶ until CONTROL is displayed.
   c. Press ◀ when the desired Control test is displayed.
6. To exit, press ▶ until the display reads EXIT, then press ◀. Repeat this step until you return to RUN TEST.

How to Clear Results Stored in Memory:

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

VIII. CARE AND CLEANING

Storage and Handling

- The CardioChek P•A is a sensitive electronic device; handle with care. The analyzer should not be dropped.
- Do not store or operate the analyzer in direct light, such as sunlight, spotlight, under a lamp or by a window. Direct light may adversely affect test results.
- Do not expose the analyzer or any of the supplies or accessories to high humidity, extreme heat, cold, dust or dirt. Store the analyzer at room temperature (68-86°F, 20-30°C) and 20-80% Relative Humidity (RH). **Do not freeze.**
- Please read the test strip package insert for storage and handling information that applies to each test strip.
- If the exterior of the analyzer needs cleaning, dampen a cloth with water and wipe the surfaces and the display area carefully. Be careful not to get the Test Strip Insert Opening (where strip is inserted) wet. A number of disinfectants are available to clean/disinfect your analyzer. Do not use bleach, window cleaner or hydrogen peroxide.
- Carefully wipe the Test Strip Insert Opening with a clean, damp (not wet), lint-free tissue or cloth. Make sure the glass is very clean with no dust or fingerprints. The glass must be completely dry before running a test.
- Handle the gray Check Strip by the base of the plastic strip. Be careful not to scratch or damage the surface. Store the gray Check Strip in the analyzer carrying case when not in use.
- **Removing screws from the back of the analyzer voids all warranties. There are no user serviceable parts inside the case.**

IX. TROUBLESHOOTING

Troubleshooting Table

PROBLEM	PROBABLE CAUSE	SOLUTION
Desired language is not displayed.	Language has been set wrong.	Turn analyzer OFF. See Section IV, Set Up How to Reset the Language.
The wrong date and/or time is displayed.	Date and time have not been set correctly.	See Section IV, Set Up to set the correct date and time.
CHANGE BATTERY or no message is displayed.	Batteries are too low to run the analyzer.	Batteries MUST be replaced before the analyzer will function properly.
FAILED is displayed during a Check Strip test.	Analyzer needs to be cleaned. Check Strip is dirty or damaged.	Wipe the Test Strip Insert Opening with a clean damp, lint-free cloth. Use the spare Check Strip. If Check Strip still fails, call Customer Service.
Display reads ***HIGH TEMP*** or ***LOW TEMP***.	The analyzer is outside operating temperature range: 50-104°F 10-40°C and 20-80% RH. Memo Chip is defective.	Move the analyzer to a location that is inside the specified operating range. Run test again. Use a different MEMo Chip of same lot number.
Display reads ***EXPIRED LOT*** and the test strips have not expired.	Date and time have not been set correctly on the analyzer.	See Section IV, Set Up to learn how to set the correct date and time.
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 Section IV, Set Up for instructions on how to load labels/paper into the printer.

IX. TROUBLESHOOTING

High or low results that are incorrect may have serious medical consequences. If the result reads HIGH, > (greater than) or LOW , < (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:

PROBLEM	PROBABLE CAUSE	SOLUTION
Results are not as expected.	Strips have been stored improperly.	Run test again, using a different vial of strips. Run controls and confirm that controls are in range.
	Batteries are defective.	Change batteries.
	The analyzer has been stored improperly.	Make sure that the analyzer was not exposed to high temperatures or humidity and run test again.
	Test Strip Insert Opening is dirty.	Clean the Test Strip Insert Opening.
	MEMo Chip and the test strip are not of the same lot number.	Use MEMo Chip and test strips with the same lot number.
Display reads ***LOW or < (less than)***.	Result is below the measuring range of the test.	If your patient has symptoms, refer them to their health care professional immediately. Repeat the test. Run controls and confirm that controls are in range.
Display reads ***HIGH or > (greater than)***.	Result is above the measuring range of the test.	If your patient has symptoms, refer them to their health care professional immediately. Run test again. 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 of the measuring range.	Run test again, Run controls and confirm that controls are in range.

X. SPECIFICATIONS

CardioChek P•A Specifications:
CardioChek P•A Analyzer REF/Cat. No. 1708

Calibration Curve: Input from MEMo Chip per strip lot
Battery: 2 AAA 1.5 -volt alkaline, life approximately 300 tests
Operating Temperature Range: 50-104°F (10-40°C)
Humidity Range: Between 20 and 80% RH
Dimensions:
Width 3.0 inches (7.62 cm)
Length 5.5 inches (13.97 cm)
Height 1.0 inches (2.54 cm)
Weight (without batteries): 4.3 oz. (121.9 g)

PTS PANELS Test Strips Specifications:
Please read the instructions (package insert) packaged with the test strips for current product specifications and limitations.

CardioChek P•A Printer Specifications:
CardioChek P•A Thermal Printer REF/Cat. No. 0777
Portable Printer REF/Cat. No. 0788

Thermal Printer Dimensions / Power Supply:
Width 3.5 in (8.89 cm) Input 100-240VAC, 47-63Hz, 1.5A
Length 7.0 in (17.78 cm) Output + 20VDC, 2.5A
Height 5.5 in (13.97 cm)
Weight 2.0 lbs. (972 g)

Portable Printer Dimensions / Power Supply:
Width 3.7 in (9.4 cm) Rechargeable NiMH battery pack
Depth 2.6 in (6.6 cm)
Height 6.6 in (16.8 cm)
Weight 1.15 lbs. (500 g)

XI. CONTACT INFORMATION

Help

For assistance with the CardioChek P•A test system, please contact Polymer Technology Systems, Inc. toll-free at 1-877-870-5610 (toll free inside the USA) or 1-317-870-5610; Fax: 1-317-870-5608, E-mail: inforequest@ptspanels.com; Web site: www.ptspanels.com

Catalog Numbers

PTS PANELS Test Strip:

Description	REF/Cat. No.
Glucose (25 tests)	1713
Ketone (6 tests)	1719
Ketone (25 tests)	1718
Cholesterol (6 tests)	1712
Cholesterol (25 tests)	1711
HDL (6 tests)	1715
HDL (25 tests)	1714
Triglyceride (6 tests)	1717
Triglyceride (25 tests)	1716
Lipid Panel (15 tests)	1710
PTS PANELS Controls:	
Multi -Chemistry Controls (Levels 1 & 2)	0721
HDL Cholesterol Controls (Levels 1 & 2)	0722

CardioChek P•A, Printers, and Supplies:

CardioChek P•A Analyzer	1708
CardioChek P•A Thermal Printer	0777
Portable Printer	0788
Communication Cable	0772
Roll of Thermal Labels (500/roll)	0776
Roll of Thermal Paper	0775
Roll of Portable Printer Labels (100/roll)	0790
Roll of Portable Printer Thermal Paper	0789

XII. WARRANTY

CardioChek PA and Printer Limited One Year Warranty:

PTS warrants to the original purchaser only, that the analyzer and printer (excluding print heads)* shall be free of any defects in materials or workmanship for a period of one year from the date of original purchase. Activation of this warranty shall be conditioned upon completion and return of the warranty registration card to PTS. If the equipment becomes inoperative during this time, PTS will replace the equipment with equivalent equipment, at its option, at no cost to the purchaser. The warranty becomes void if the equipment 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.

* Print heads- Since print head wear is part of normal operation, the original print head is covered by a limited warranty period of 6 months from the date of original purchase.

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

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XIV. EXPLANATION OF SYMBOLS

Symbols on the Analyzer and Analyzer Box:

 See accompanying information

 Storage temperature



For *in vitro* diagnostic use

 Attention consult accompanying documents

SN Serial Number

 Manufactured by



Catalog Number

The CardioChek™ P•A system is covered
by one or more patents:
US Patent 5, 597, 532 and EP 0, 750, 739
(DE, FR, GB, IT)
Other Patents Pending.

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