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I. INTRODUCTION

Thank you for selecting the CardioChek[™] Analyzer from Polymer Technology Systems, Inc. (PTS).

The CardioChek is a fast, portable and accurate whole blood analyzer. The CardioChek test system includes an analyzer and separately available PTS PANELS test strips/MEMo Chip. This system is intended for *in vitro* diagnostic use to test whole blood. Using this system, you can quickly measure various blood components from a small sample size. The CardioChek test system is capable of monitoring for diabetes and other disease states and lipid screening.

The CardioChek 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, 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 This guide includes all the information you need to test properly using the CardioChek[™] Analyzer. 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 you need help interpreting your test results, please make sure that you contact your 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 ANALYZER

The CardioChek Test System:

The CardioChek 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. The analyzer measures the color reaction and compares the information to the calibration curve stored in the MEMo Chip. The analyzer converts this color reading into a test result, that is displayed on the 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 D 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. A lot specific MEMo Chip is inserted into this port.

III. INTRODUCTION TO THE CARDIOCHEK ANALYZER

The MEMo Chip

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



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 facing up in your CardioChek, 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.

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 to run 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 ANALYZER



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, use test strips specific for each test. The test strip is inserted into the analyzer, then blood is applied to the test strip. A chemical reaction occurs producing a color change. The analyzer measures the color reaction and compares the information to the calibration curve stored in the MEMo Chip. The analyzer converts this color reading into a test result, that is displayed on the screen. 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.

Battery Use and Replacement

The CardioChek 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:

- Open the battery door on the back of the CardioChek 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 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 (\P or P). You can turn the analyzer OFF manually by holding down both buttons (\P and P) 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.

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, (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 (\Box or \mathbf{P}).
- 2. The display will read LANGUAGE. Press Q.)
- 3. ENGLISH will be displayed. Press Gif English is desired.
- 4. For other languages press **▶** until the desired language is displayed, then press **■**. To set the time proceed to **How to Set the Time** Step 2.

How to Reset the Language:

- 1. Allow the analyzer to automatically turn OFF or remove the batteries and replace them.
- 2. Press and hold **4** down for approximately 5 seconds, during the analyzer power-up stage until LANGUAGE is displayed.
- 3. Press **Q**. Press **D** to scroll through the language choices.
- 4. Press **C** 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.
- 4. Press and the clock format is displayed: 12/24 HR.

How to Set the Time continued:

- 5. Press to alternately display the 12 hour am/pm clock or the 24hour 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.
- Press to accept the displayed minute. The display will read SET TIME. To set the date, proceed to How to Set the Date -Step 4.
- 10. To exit, press D until EXIT is displayed. Press Q
- 11. Press ▶ to return the display to RUN TEST.

How to Set the Date:

- If RUN TEST is displayed, go to step 3. If the analyzer is OFF, press either button (or P) 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 **q** and the numerical month is displayed.
- 6. Press ▶ to increment the month.
- 7. Press **t** 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.
- Press to accept the displayed year. The display will read SET DATE. To set the units, proceed to How to Set the Units -Step 5.
- 12. Press ▶ until EXIT is displayed. Press ♥.
- 13. Press
 to return the display to RUN TEST.

How to Set the Units:

The CardioChek has been preset to US units (i.e. mg/dL). To change your 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 **Q**. The display will read PRINT.
- 5. Press ▶ until UNITS is displayed.
- 7. Press to select the units. Display will read UNITS.
- 8. Press ▶ until EXIT is displayed.
- 9. Press T 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:

- 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.
- 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 **C** to accept the sound choice displayed.
- 8. Press **▶** until EXIT is displayed.
- 9. Press **T** to return display to USER SET.
- 10. Press
 to return to RUN TEST.

V. CHECKING THE SYSTEM

Instrument Check Strip

A gray Instrument Check Strip (included in the analyzer carrying case) can be used to verify proper functioning of the CardioChek's electronic and optical systems. The Instrument 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 that you check your analyzer with the Instrument Check Strip when:

- · You first receive it.
- You drop the analyzer.
- You get a result that is not expected.

How to Use the Instrument Check Strip:

- 1. Turn the analyzer ON by pressing either button (\bigcirc or \triangleright).
- 2. When INSTALL MEMO CHIP or RUN TEST is displayed, press ▶ until UTILITY is displayed. Press **q**.
- 3. Press when CK STRIP is displayed.
- 4. Insert the Check Strip, ribbed side up, into the Test Strip Insert Opening when INSERT STRIP is displayed.
- 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 **Q**. The analyzer is ready to run tests.

Note: If the analyzer displays FAILED:

- Clean the CardioChek 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 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.
 Ref

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 performing a quality control test, see Section VI. RUNNING A TEST.

To perform a control test you need:

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

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 (\bigcirc or \triangleright) to turn the analyzer ON.
- 3. Press ▶ until the display reads UTILITY. Press ♥.
- 4. Press ▶ until RUN CONTROL is displayed. Press ♥.
- Insert the test strip into the analyzer. The CardioChek 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 cap from the Control Material 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 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 cap on the Control Material.
- 11. Results will be displayed within about one to two minutes (for most tests).
- 12. Remove and discard test strip.

How To Run a Quality Control Test (continued):

- 13. Compare control results to the values on the Quality Control Range Card included with control materials. Make sure to match the correct test strip lot number(s) and levels depending on the control material used.
- 14. The control result will also be stored in the analyzer's Memory.
- To exit the control testing menu press Ttwice. RUN CON-TROL will be displayed.
- 16. Press **▶** until EXIT is displayed. Press **■**.
- 17. 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:

- 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. Make sure MeMo Chip matches strip lot.
- 4. Repeat the test again using fresh materials.
- 5. Call Customer Service for assistance.

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 you need:

- CardioChek Analyzer
- PTS PANELS[™] Test Strips
- Lot specific MEMo Chip
- Lancing device and/or
- Sterile lancet
- · Capillary blood collector or pipet
- Gauze or cotton balls
- Alcohol wipe

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.
- 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.

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 to apply directly to the test strip.
- Follow the specific instructions found in the test strip package insert for each test for sample application and volume ranges. Capillary blood collectors (pipets) ensure the correct volume of blood has been applied to the test strip.
- Make sure the test strip is inserted all the way into the Test Strip Insert Opening.
- 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.

How to Run a Test:

- 1. Insert correct MEMo Chip for the lot of strips in use.
- Insert MEMo Chip with finger notch (top) side up, lot number code facing down.
- 3. Turn CardioChek ON by pressing either button (or D).
- 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.
- 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.
- Within one to two minutes, the results will be displayed (for most tests).
- 8. Remove test strip and discard.
- 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 prevents the analyzer from automatically shutting down and shortens battery life.

Quick Reference Testing Guide

- Insert MEMo Chip with lot number that matches test strip vial lot number. Press either button (Q or P) to turn the CardioChek ON. Analyzer will display lot code.
- When INSERT STRIP is displayed, insert strip into the analyzer as far as it will go.

 When APPLY SAMPLE is displayed, apply whole blood* sample with a capillary blood collectoror pipet to white reaction area.

 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 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:

- Press either button (or P) 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 **Q**. 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 **q** to view the test result including time and date.
 - a. To recall Control results, press ▶ until EXIT is displayed. Press
 ♥. Press ▶ until CONTROL is displayed.
 - b. Press 🗨 when the desired Control test is displayed.
- 6. To exit, press **₽** until the display reads EXIT, then press **٩**. 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.
- 3. Press ▶ until CLEAR MEMORY is displayed. Press ♥.
- 4. Press Duntil the display reads CLR YES. Press D. The display will read ERASE, CLEARED and then CLEAR MEMORY.
- 5. To exit, press **D** until the display reads EXIT, then press **D** until you return to RUN TEST.

VIII. CARE AND CLEANING

Storage and Handling

- The CardioChek 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 effect 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 the test 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 Instrument Check Strip by the base of the plastic strip. Be careful not to scratch or damage the surface. Store the Instrument 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.
Display reads TEST ABORTED.	Test strip was removed during testing mode.	Use a new unused test strip and run test again without removing the test strip from the analyzer before the result is displayed.
TEST NOT ALLOWED is displayed.	Analyzer is not able to test with the inserted MEMo Chip and test strip.	Use a test strip and MEMo Chip that are compatible with the CardioChek analyzer.

IX. TROUBLESHOOTING, continued

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 improperly stored.	Repeat test, using a different vial of strips. Run controls, confirm that results are in range.
	Batteries are defective.	Change batteries.
	The analyzer was improperly stored.	Make sure analyzer was not exposed to high temperatures or humidity and repeat test.
	Test Strip Insert Opening is dirty.	Clean the Test Strip Insert Opening.
	MEMo Chip and test strips are not the same lot number.	Use MEMo Chip and test strips with the same lot number.
A displayed result reads <i>LOW</i> or < (less than) a value.	Result is below the measuring range of the test.	If you or your patient has symptoms, refer them to their health care professional immediately. Repeat the test. Run controls and confirm that controls are in range.
A displayed result reads <i>HIGH or</i> > (greater than) a value.	Result is above the measur- ing range of the test.	If you or your patient has symptoms, refer them to their health care professional immediately. Run test again. Run controls and confirm that controls are in range.

X. SPECIFICATIONS

CardioChek:

CardioChek Analyzer REF/Cat. No. 0744 (U.S.)/1709 (Int'l)

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 :

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

XI. CONTACT INFORMATION

Help

For assistance with the CardioChek 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:	U.S.	Int'l
Description	REF/Cat. No.	REF/Cat. No.
Glucose (25 tests)	0579	1713
Ketone (6 tests)	0583	1719
Ketone (25 tests)	0576	1718
Cholesterol (6 tests)	0584	1712
Cholesterol (25tests)	0580	1711
HDL (6 tests)	0585	1715
HDL (25 tests)	0581	1714
Triglycerides (6 tests)	0572	1717
Triglycerides (25 tests)	0578	1716
PTS PANELS Controls:		
Multi -Chemistry Controls (Levels 1	& 2)	0721
HDL Cholesterol Controls (Levels 1	& 2)	0722
Analyzer		
CardioChek	0744	1709

XII. WARRANTY

CardioChek Limited One Year Warranty:

PTS warrants to the original purchaser only, that the analyzer 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.

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

XIII. 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



Self-Testing

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The CardioChek[™] 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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