CardioChek®
Brand Analyzers
Portable Whole Blood Test Systems

(CardioChek and CardioChek P•A)

For Professional and Self-Testing Use

User Guide

TABLE OF CONTENTS

The CardioChek® Analyzer

I. INTRODUCTION

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

The analyzer is available in two models: the CardioChek and the CardioChek P•A. The CardioChek P•A has an optional printer available and will run all PTS PANELS Test Strips, including all multiple Test Strips (e.g. Lipid Panel, CHOL+GLU, etc.).

The CardioChek is a fast, portable and reliable 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 screening lipids (including Cholesterol, HDL Cholesterol and Triglycerides) and monitoring for diabetes and other disease states.

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.

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(317) 870-5610
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II. HOW TO USE THE USER GUIDE

This guide includes all the information you need to properly test using CardioChek Analyzer. For additional information and specific information for each individual chemistry test, please make sure you read the package insert included with the Test Strips. This User 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 PTS Customer Service. Customer Service assistance is available 8:00 AM - 5:00 PM US Eastern Standard Time, Monday through Friday. If you need help interpreting your test results, please contact your healthcare provider.

For questions or assistance with the CardioChek, call:
PTS Customer Service
Hours: 8:00 AM - 5:00 PM US Eastern Standard Time
Monday - Friday
1-877-870-5610 (Toll-free inside US)
**1-317-870-5610**
Fax: 1-317-870-5608
E-mail: inforequest@cardiochek.com

III. INTRODUCTION TO THE CARDIOCHEK ANALYZER

The CardioChek Test System:

The CardioChek test system consists of three main parts. These include the analyzer, PTS Panels 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.
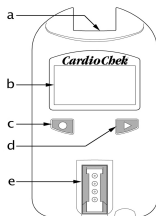
MEMo Chip Port (a)
The MEMo Chip Port is on the top of the analyzer. A lot specific MEMo Chip is inserted into this port.

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

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

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

Test Strip Insert Opening (e)
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.

The MEMo Chip

Each package of PTS Panels Test Strips contains a color-coded MEMo Chip.

Cholesterol
Lot #
C6A1

Top   Bottom
MEMo Chip
(Top and Bottom)
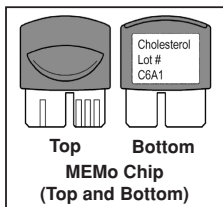
MEMo Chip
The color-coded MEMo Chip contains the settings for each test. The top of the MEMo Chip has a finger notch. The bottom has a label with the test name and lot number.

What does the MEMo Chip do?
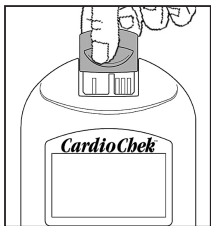When inserted with the finger notch facing up in your CardioChek, the MEMo Chip does the following:
• Reads the Test Strip expiration date.
• Tells the analyzer which test(s) to run.
• Contains the calibration curve and the lot number for the specific Test Strip Lot.
• Controls test sequences and timing.
• Establishes the measuring range for the test.
The MEMo Chip contains proper settings for the Test Strip lot 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 PTS Customer Service for a replacement.

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. **Important:** Be careful not to bend the connector.

Test Strip

To test blood on the CardioChek, use Test Strips specific for each test. A Test Strip is inserted into the analyzer, then blood is applied to the blood application window. 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, 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.

Blood Application Window

PTS Panels Test Strip

IV. SET UP

Battery Use and Replacement
The CardioChek requires two (2) AAA 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 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.

Buttons
ENTER ⬤ Button: Press this button to turn the analyzer ON or to accept the current menu choice.
NEXT ▶ Button: Press this button to turn the analyzer ON or to advance to the next menu option.

How to Turn the Analyzer OFF:
The batteries will have a longer life due to the analyzer's automatic shut down feature. After three minutes of idle time (without a Test Strip or Check Strip inserted) the analyzer will perform a 10 second count down and turn OFF. To stop shutdown press down either button. To turn OFF press both buttons at the same time for three seconds at any of the following Main Menu headings: RUN TEST, MEMORY, UTILITY, or 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 (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 time proceed to **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 Enter down for approximately 5 seconds, during the analyzer power-up stage until LANGUAGE is displayed.
3. Press Enter. Press Next to scroll through the language choices.
4. Press Enter 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 to turn the analyzer ON. 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 Enter. The display will read RUN TEST.
2. Press Next until USER SET is displayed.
3. Press Enter. Press Next until SET TIME is displayed.
4. Press Enter and the clock format is displayed: 12/24 HR.
5. Press Next to alternately display the 12 hour am/pm clock or the 24-hour clock. Press Enter to accept the displayed clock format. The display will read HOUR and the numerical hour.
6. Press Next to increment the hour. Note: AM/PM in the upper right hand corner of the display.
7. Press Enter to accept the displayed hour. The display will read MINUTE and the numerical minute.
8. Press Next to increment the minutes.
9. Press Enter 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 Next until EXIT is displayed. Press Enter.
11. Press Next 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 to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Next. The display will read RUN TEST.
3. Press Next until USER SET is displayed. Press Enter.
4. Press Next until SET DATE is displayed.
5. Press Enter and the numerical month is displayed.
6. Press Next to increment the month.
7. Press Enter to accept the displayed month. The display will read DAY and the numerical day of the month.
8. Press Next to increment the day.
9. Press Enter to accept the displayed day. The display will read YEAR and the numerical set year.
10. Press Next to increment the year.
11. Press Enter to accept the displayed year. The display will read SET DATE. To set the units, proceed to **How to Set the Units**.
12. Press Next until EXIT is displayed. Press Enter.
13. Press Next to return the display to RUN TEST.

How to Set the Units:
The CardioChek has been preset to US units (e.g. 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 to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Enter. The display will read RUN TEST.
3. Press Next until USER SET is displayed.
4. Press Enter. The display will read SOUND.
5. Press Next until UNITS is displayed.

How to Set the Units, continued:
6. Press Enter. The display will read US. If INTL units are desired press Next to display INTL.
7. Press Enter to select the units. Display will read UNITS.
8. Press Next until EXIT is displayed.
9. Press Enter to return display to USER SET.
10. Press Next to return to RUN TEST.

How to Set the Sound:
The CardioChek 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 to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Next. The display will read RUN TEST.
3. Press Next until USER SET is displayed.
4. Press Enter. SOUND will be displayed.
5. Press Enter. The display will read BEEP ON or BEEP OFF.
6. Press Next to select either BEEP OFF or BEEP ON.
7. Press Enter to accept the sound choice displayed.
8. Press Next until EXIT is displayed.
9. Press Enter to return display to USER SET.
10. Press Next to return to RUN TEST.

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. 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.
2. Press Enter until RUN TEST is displayed.
3. Press Next until USER SET is displayed. Press Enter.
4. PRINT will be displayed. Press Enter. MEDIA will be
   displayed.
5. Press Enter 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 Next. COPIES will be displayed. Note: Default is
   set to one copy.
7. Press Enter to select COPIES, press Next to scroll to the
   number of copies of the test results to be printed. 1, 2, or
   3.
8. Press Enter to select the number of copies to be printed.
   COPIES will be displayed.
9. Press Next until EXIT is displayed. Press Enter.
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.

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.
2. From the RUN TEST menu press Next.
3. Press Enter until RUN TEST is displayed.
4. MEMORY will be displayed. Press Enter.
5. Press Enter to select CHEM.
6. Press Next to select the type of test, LIPIDS for example.
7. Press Next to select the date/time of the test result you
    want to print.
8. Press Enter 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

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 color standard 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.
2. When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
3. Press Enter when CK STRIP is displayed.
4. Insert the Check Strip, ribbed side up, into the Test Strip Insert opening when INSERT STRIP is displayed.
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 Next until EXIT is displayed. Press Enter.
8. Press Next until RUN TEST is displayed.
9. Press Enter. The analyzer is ready to run tests.

Note: If the analyzer displays FAILED:
1. 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 check the performance of your test system: CardioChek analyzer, MEMo Chip and Test Strips. Use quality control materials provided by PTS.

PTS PANELS Multi-Chemistry Controls   REF/Cat. No. 721
PTS PANELS HDL Controls   REF/Cat. No. 722
Refer to control package insert for control specifications.

Healthcare 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.

For performing a quality control test, see Section VI.
CONTROL TESTING
To perform a control test you need:
- CardioChek Analyzer
- PTS PANELS Test Strips
- Quality Control Materials
- Quality Control Instructions
- Quality Control Range Insert

VI. CONTROL TESTING

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 known to be within a certain range. This range is supplied with the Quality Control Material or is available online at www.cardiochek.com. Healthcare professionals should follow their facility's policies on when controls should be tested (for example: with each new Test Strip lot; monthly as a continued check on storage conditions; whenever issues (storage, operator, or other) are identified or there are questions about the results).

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 to turn the analyzer ON.
3. Press Next until the display reads UTILITY. Press Enter.
4. Press Next until RUN CONTROL is displayed. Press Enter.
5. 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 10 SECONDS OF REMOVING THE STRIP FROM THE VIAL.
7. Hold bottle directly over and perpendicular to the blood application window on the Test Strip.

How To Run a Quality Control Test (continued):

8. Squeeze bottle, so a small drop of control solution is formed.
9. Allow the drop of control solution to fall onto the application widow of 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.
12. Compare control results to the values on the Quality Control Range Insert 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 Enter twice. RUN CONTROL will be displayed.
15. Press Next until EXIT is displayed. Press Enter.
16. Press Next until RUN TEST is displayed.

If Quality Control Results are not in Range:

1. Ensure Test Strip insert opening 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 MEMo Chip matches strip lot.
4. Repeat the test again using fresh materials.
5. Call Customer Service for assistance.

VII. RUNNING A TEST

Blood Testing
A Test Strip package insert is included with each box of Test Strips. Please read the Test Strip package insert 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
- Sterile lancet
- Capillary blood collector or pipet
- Gauze or cotton balls
- Alcohol wipe (optional)

This analyzer requires whole blood for testing. Do not operate the analyzer in direct light. Reference 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.

How to Obtain a Blood Sample:
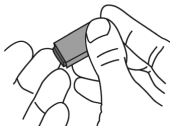To perform a fingerstick:
1. Clean the finger. Be sure the finger is completely dry.
2. Use a new sterile, disposable lancet to puncture the skin.

How to Obtain a Blood Sample, continued:

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 pipet or to apply directly to the Test Strip.

5. Follow the specific instructions found in the Test Strip package insert for each test for sample application and volume ranges. Use of capillary pipet 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 Insert Opening.

7. Use the Test Strip and lancet one time only. Dispose of properly.

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

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.
2. Insert MEMo Chip with finger notch (top) side up, lot number code facing down.
3. Turn CardioChek ON by pressing either button.
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 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.

   Important: Do not leave a used Test Strip or Check Strip in the analyzer Test Strip Opening. This prevents the analyzer from automatically shutting down and shortens battery life.

*As an alternative, the test strip may be inserted into the analyzer within 10 seconds AFTER blood is applied to the strip, when blood is applied to the strip directly from a finger. Touch a drop of blood hanging from the finger to the blood application window of the test strip. The blood drop must fill the entire window. Insert the strip into the analyzer. In about one to two minutes read result.

Quick Reference Testing Guide

1. *Insert MEMo Chip with lot number that matches Test Strip vial lot number. Press either button to turn the CardioChek ON. Analyzer will display lot code.*

2. *When INSERT STRIP is displayed, hold by the raised lines and insert strip into the analyzer as far as it will go.*

3. *When APPLY SAMPLE is displayed, apply whole blood* sample with a capillary pipet to blood application window.*

4. *Within two minutes the result will appear on the display. Remove and <u>discard strip</u>. Do not add more blood to a Test Strip that has been used.*
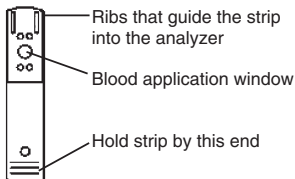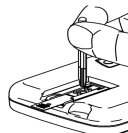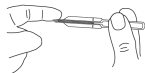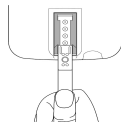
Ribs that guide the strip into the analyzer

Blood application window

Hold strip by this end

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* *Refer to each specific Test Strip package insert for sample volume and sample application instructions.*

VIII. MEMORY

Test results are automatically stored in the analyzer's memory. CardioChek can store up to 30 results of each chemistry and at least 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 to turn the analyzer ON. 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 displa 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 the analyzer ON. 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 CLR YES. Press Enter. The display will read ERASE, CLEARED and then CLEAR MEMORY.
5. To exit, press Enter until the display reads EXIT, then press Enter. Press Next until you return to RUN TEST.

IX. 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 (68-77° F, 20-25°C) and 20-80% Relative Humidity (RH). **Do not freeze.** If room temperature falls below 18°C, allow analyzer to warm up at least 30 minutes - 1 hour before testing.
- 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. <u>Make sure the glass is very clean with no dust or fingerprints. The glass must be completely dry before running a test.</u>
- Handle the gray 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. Do not store in the instrument.
- **Removing screws from the back of the analyzer voids all warranties. There are no user serviceable parts inside the case.**

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 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.
FAILED is displayed during a Check Strip test.	Analyzer needs to be cleaned.	Wipe the Test Strip Insert Opening with a clean, damp and lint-free cloth.
	Check Strip is dirty or damaged.	Use spare Check Strip. If Check Strip still fails, call Customer Service.
TOO MUCH LIGHT	Test is being performed in direct light or outside.	Test inside, away from windows and away from direct lamp light.
MEMO ERR	MEMo Chip is defective.	Use another MEMo Chip from the same lot
TEST ERR	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.
SET TIME AND DATE	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.

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.
MEMO CHIP ERROR	MEMo Chip is defective.	Use another MEMo Chip from same lot of product.
EXPIRED LOT	Test Strips are expired, wrong MEMo Chip is inserted or analyzer Date is not set properly.	Check Test Strip expiration date and make sure correct MEMo Chip is inserted. Check analyzer Date setting – follow User Guide instructions.
CHANGE BATTERY	Batteries need to be replaced.	Replace both batteries with new high quality AAA 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 fresh Test Strip.
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.
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 Section IV, Set Up for instructions on how to load labels/paper into the printer.

High or low results that are incorrect may have serious medical conse-
quences. 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.

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 or low tempera-tures or humidity and repeat test.
	Test Strip Insert Open-ing is dirty.	Clean the Test Strip Insert Open-ing.
	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 < (less than) a value	Result is below the measuring range of the test.	If you or your patient have symptoms call healthcare professional immediately. Re-peat 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.	If you or your patient have symptoms call healthcare profes-sional 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 the measuring range.	Run test again. Run controls and confirm that controls are in range.

XI. CLIA INFORMATION

General CLIA Information (Professionals Only - Please read before testing.)

1. CLIA waived (US only). Each laboratory or testing site using the PTS Panels Test Strips <u>must</u> have a CLIA Certificate of Waiver before testing. To obtain a Certificate of Waiver, call your state health department or PTS at 877-870-5610 (toll-free) or 317-870-5610 for an application (form HCFA-116).
2. Before you start testing, carefully read all instructions. Failure to follow all instructions, including quality control instructions, will result in a high complexity rating and subject the facility to all applicable CLIA requirements for high complexity testing. For complete information including Summary of CLIA Performance, please refer to the specific Test Strip package insert.
3. CLIA waived for whole blood (fingerstick and venous EDTA or heparin) testing only.

XII. SPECIFICATIONS

CardioChek & CardioChek P•A:
Calibration Curve: Input from MEMo Chip per Test Strip lot
Battery: 2 AAA 1.5 volt alkaline,
Operating Temperature Range: 64.4-95°F (18-35°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.

Optional CardioChek P•A Thermal Printer / Power Supply:

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

XIII. 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@cardiochek.com
Web site: www.cardiochek.com

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

XV. EXPLANATION OF SYMBOLS

Symbols on the Analyzer and Analyzer Box:

	Consult Instructions for Use
	Storage Temperature
IVD	For *in vitro* diagnostic use
SN	Serial Number
	Manufactured by
REF	Catalog Number
	Self-Testing

XVI. INDEX

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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