



For Self-Testing Use  
Portable Whole Blood Test System

**CardioChek<sup>®</sup>**

**Analyzer** For Home Use

## Materials Provided

REF 1709 CardioChek® analyzer system (1)

## Materials Needed but Not Provided

PTS Panels® self-test strips

*Product availability will vary per country*

Lot-specific MEMo Chip® included with test strips

*Refer to self-test strip package insert for more information.*

PTS Collect™ capillary tubes, 15 µL, included with test strips

Appropriate sterile, disposable, auto-disabling, single-use lancet included with test strips

Alcohol wipes

Gauze pads or cotton balls

Bandages

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# 1 Introduction

## CardioChek Test System *Intended Use*

Thank you for selecting a CardioChek analyzer from Polymer Technology Systems, Inc. (PTS Diagnostics).

The CardioChek test system (consisting of the CardioChek analyzer and PTS Panels self-test strips) is for the measurement of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in capillary whole blood from the fingertip and is intended for self-testing use. This system should only be used with single-use, auto-disabling lancing devices. This system is for *in vitro* diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The CardioChek analyzer from PTS Diagnostics is intended for *in vitro* diagnostic use to test whole blood.

This user guide includes all the information that you need to run tests using the CardioChek system. Before you begin testing, please read this entire user guide and the package inserts, which are included with the PTS Panels self-test strips.

**CAUTION: Do not take any decision of medical relevance without first consulting your healthcare practitioner.**

**If the device is being used for the monitoring of an existing disease, only adapt the treatment if you have received the appropriate training to do so.**

The CardioChek analyzer is fast, portable, and reliable. This analyzer is a component of a test system that includes PTS Panels self-test strips. The PTS Panels self-test strip box includes a MEMo Chip that contains the assay calibration curve and other important information about the assay. The PTS Panels self-test strip box also includes PTS Collect capillary tubes (15 µL) and auto-disabling, single-use lancets. PTS Panels self-test strips are sold separately and are available as single-analyte self-test strips.

This test system uses reflectance photometry technology. An enzymatic reaction on the test strip produces a color change that is detected by the analyzer after whole blood is applied.

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

For questions or additional assistance with your CardioChek test system, please contact PTS Diagnostics (Hours: 6:00 a.m. to 9:00 p.m. US EST) using the following contact information:

### **PTS Diagnostics**

4600 Anson Boulevard, Whitestown, IN 46075 USA

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

**Fax:** +1-317-870-5608

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

## **Important Safety Instructions**

This is a medical device and needs to be treated with care. In particular there is the risk of disease transmission when using blood glucose monitoring systems and they should be used with caution and care.<sup>1,2</sup>

The analyzer and lancing device are for single patient use. For safety reasons, do not share them with anyone including other family members. Do not use on multiple patients.

All parts of your device come into contact with your blood and are biohazardous. Kit parts can potentially transmit infectious diseases, even after being cleaned and disinfected.

Always wash your hands thoroughly with soap and water and dry well after handling the analyzer, test strips, or your lancing device.

Always consult your diabetes healthcare professional and follow his or her guidance about your blood glucose monitoring routine.

**Blood samples and blood products are potential sources of hepatitis and other infectious diseases. Handle all parts of your device with care. Do not share your analyzer. It is for single-patient use only. Any items that are used to conduct a test such as test strips, lancets, and alcohol swabs, must be disposed of safely to avoid the risk of infection. Please follow your healthcare provider's instructions for proper disposal.**

### **References:**

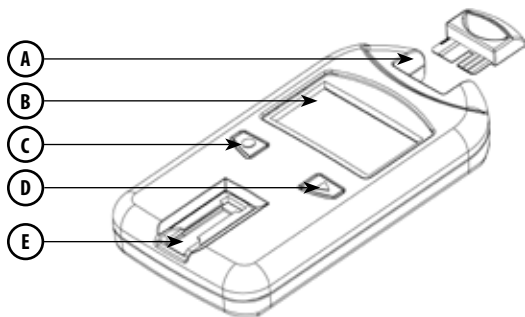
1. "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010). <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
2. "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010). <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>.

## 2 About the CardioChek Test System

### The CardioChek Test System

The CardioChek test system consists of three main parts. These include the analyzer, PTS Panels self-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.



**A MEMo Chip Port**

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

**B Display**

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

**C Enter Button** 

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

**D Next Button** 

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

**E Test Strip Slot**

The test strip slot is positioned in the lower front of the analyzer. The test strip and/or check strip is inserted here with the raised lines facing up.

## The MEMo Chip

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

### What does the MEMo Chip do?

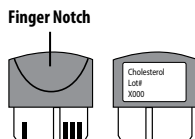
The MEMo Chip contains proper settings for the test strip lot you are using.

### The MEMo Chip:

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

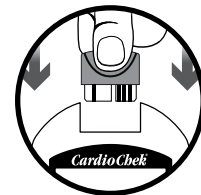
### Guidelines for using the MEMo Chip

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



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

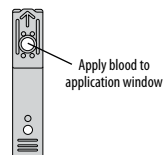
**Important:** Be careful not to bend the connector.



## PTS Panels Self-Test Strips

To test blood on a CardioChek analyzer, use test strips specific for each test. A test strip is inserted into the analyzer, then then blood is applied to the blood application window. A chemical reaction occurs producing a color change, which the analyzer measures and compares the information to the calibration curve stored in the lot-specific MEMo Chip. The analyzer converts this color reading measurement into a test result, displayed on the screen. Each PTS Panels self-test strip box contains a package insert that provides instructions for use and information specific for each test. Please read the instructions completely before testing.

### Example of a reflectance self-test strip



**The CardioChek system has various analyte test strips available for use. Not all test strips are available for use in all countries. Please refer to the package insert of each PTS Panels self-test strip prior to use.**

# 3 Setup

## Battery Use and Replacement

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

When the REPLACE BATTERIES message is displayed, replace the batteries with **2 new AAA alkaline batteries of the same brand.**

Do not use NiCad or rechargeable batteries.

**Caution: Improper installation of batteries can result in decreased battery life or damage to the analyzer.**

## How to Install/Replace the Batteries:

1. Open the battery door on the back of the CardioChek analyzer by pressing and sliding it in the direction of the arrow (toward the MEMo Chip port).
2. Remove old batteries from the compartment and properly discard.
3. Insert the new batteries into the battery compartment with the positive (+) terminals correctly facing as marked on the inside compartment.
4. Replace the battery door. To make sure the batteries were installed correctly, push either of the two buttons on the front of the analyzer to turn on the CardioChek analyzer.

**Warning:** Dispose of the old batteries properly. 

## CardioChek Analyzer Menus



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

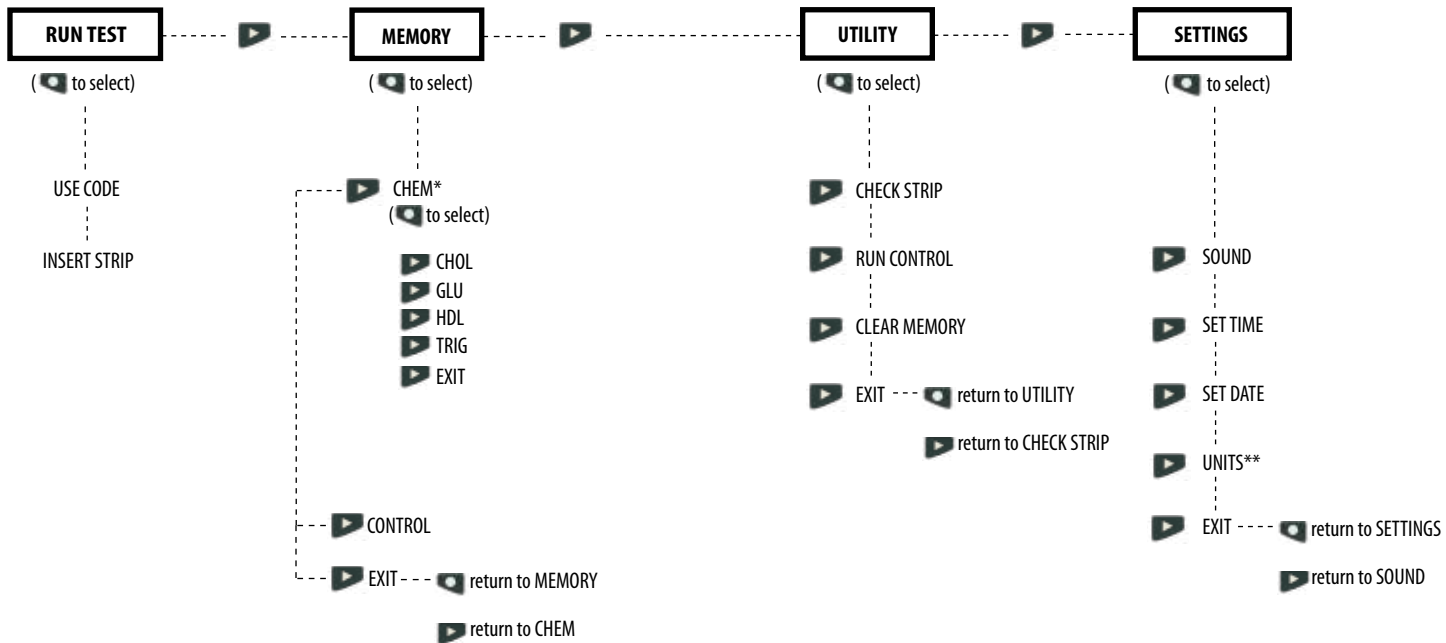
**Enter Button** 

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

**Next Button** 

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

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



\*Memory results will only be shown for chemistries that have been run.

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



## How to Turn Off the Analyzer

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

## Setting Language

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

**Note:** Languages may vary based on analyzer version used.

## How to Set the Language (First-Time Use)

1. Turn on the analyzer by pressing either button (Enter or Next).
2. The display will read LANGUAGE. Press Enter.
3. ENGLISH will be displayed. Press Enter if English is desired.
4. For other languages press Next until the desired language is displayed, then press Enter. To set the date and time, proceed to **How to Set the Time** and **How to Set the Date** sections.

## How to Reset the Language

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

## How to Set the Time

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read either INSTALL MEMO CHIP (if a current MEMO Chip is not installed) or INSERT STRIP (if a current MEMO Chip is installed). Press Enter. The display will read RUN TEST.
2. Press Next until SETTINGS 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. If 12 hour clock was chosen, AM/PM appears in the upper right hand corner of the display.
6. Press Next to increment the hour.
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**.
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 on the analyzer. 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 SETTINGS 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 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 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 analyzer may be shipped with preset units of measure (e.g. mg/dL).

### Note:





- If the SETTINGS menu does not display UNITS the instrument is locked in preset units
- The units cannot be changed if the system has been locked
- To confirm current configuration of the analyzer's units run a check strip in the RUN TEST mode and observe the units that are displayed

### If your analyzer's units have not been preset, follow the steps listed below to change your units to mg/dL, mmol/L, or g/L:

1. If RUN TEST is displayed, go to Step 3. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Enter. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Next until UNITS is displayed. If UNITS is not shown on the display, the units on this analyzer have been locked and cannot be changed. If UNITS appears on the display screen, proceed to the next step.
5. Press Enter. The display will read mg/dL. If mmol/L or g/L is desired, press Next until the desired unit appears on the display screen.
6. Press Enter to select the desired units. The display will then read UNITS.
7. Press Next until EXIT is displayed.
8. Press Enter to return to SETTINGS.
9. Press Next to return to RUN TEST.

## How to Set the Sound

The CardioChek analyzer 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 on the analyzer. 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 SETTINGS is displayed.
4. Press Enter, then Next until SOUND is displayed.
5. Press Enter. The display will read BEEP ON  or BEEP OFF .
6. Press Next to select either BEEP ON  or BEEP OFF .
7. Press Enter to accept the sound choice displayed.
8. Press Next until EXIT is displayed.
9. Press Enter to return display to SETTINGS.
10. Press Next to return to RUN TEST.

## 4 Checking the System

### Analyzer Check Strip

A gray analyzer check strip (included in the analyzer carrying case) can be used to verify proper functioning of the CardioChek analyzer's electronic and optical systems. The 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 check strip when:

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



Check Strip

### How to Use the Analyzer Check Strip:

1. Turn on the analyzer by pressing either button.
2. When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
3. Press Enter when CHECK STRIP is displayed.
4. Hold the check strip at base of strip and insert the check strip, ribbed side up, into the test strip slot when INSERT STRIP is displayed.
5. The analyzer should display PASSED. (If the display reads FAILED, see the note at the end of this section.) Remove the check strip and store it in the analyzer carrying case.
6. Press Next until EXIT is displayed. Press Enter.
7. Press Next until RUN TEST is displayed.
8. Press Enter. The analyzer is ready to run tests.

**Note:** If the analyzer displays FAILED:

1. Clean the CardioChek analyzer test strip slot (where the strip is inserted into the analyzer). See Section 9, **Care and Cleaning**.
2. Inspect the check strip to make sure it is not dirty or damaged. Use the spare check strip and repeat.
3. See Section 10, **Troubleshooting**.

## 5 Quality Control Testing

### Quality Control

Controls (also known as “liquid quality control materials”) are solutions 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. Use quality control materials provided by PTS Diagnostics. Contact Customer Service for ordering information.

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

#### Home users should run quality control materials:

- With each new lot number
- If it has been more than a month since using the lot of test strips
- Or as desired

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

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

#### To perform a control test you need:

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

## How to Run a Quality Control Test

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

### If Quality Control Results Are Not in Range

**IMPORTANT: Tests should not be performed until control results are within range.**

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

# 6 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 self-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. It is very important to keep the analyzer on a flat, stable surface and not move it during testing. See Section 9, **Care and Cleaning** for more information.

### Helpful Hints on Getting a Good Drop of Blood

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

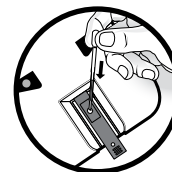
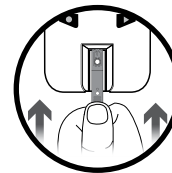
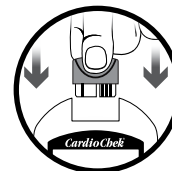
## How to Obtain a Blood Sample from a Fingertick

1. Clean the finger. Be sure the finger is completely dry.
2. Use a new, sterile, disposable lancet to puncture the skin.
3. Stick the finger on the side of the fingertip, instead of the center. See picture.
4. To get a drop of blood, gently apply pressure to the finger starting at the end of the finger closest to the hand and moving towards the tip. (Pressure should be intermittent and it is important not to milk the finger.) Lance the finger, wipe away the first drop of blood with gauze, and use the second blood drop for testing. The blood drop should be hanging down from the finger to make it easier to collect the sample with a pipet or capillary blood collector.
5. Follow the specific instructions found in the test strip package insert for each test for sample application and volume ranges. For reflectance tests, use of a pipet or capillary blood collector ensures a sufficient volume of blood has been applied to the test strip.
6. Make sure the test strip is inserted all the way into the test strip slot immediately before testing.
7. Use the test strip and lancet one time only. Only auto-disabling, single-use lancing devices may be used with this device. **Dispose of properly.**



## Quick Reference - How to Run a Test

1. Press either button to turn the analyzer on.
2. Remove the MEMO Chip from the box of test strips.
3. Insert the MEMO Chip into the port at the top of the analyzer with the finger notch facing up (with the lot code number facing down).
4. When INSERT STRIP is displayed, remove a test strip from the vial and immediately replace the cap.
5. Insert the strip. Ensure that the test strip is inserted fully and the display reads APPLY SAMPLE.
6. Obtain a blood drop following the correct technique. (Immediately collect sample with capillary tube or precision pipet and dispense correct volume\* as specified in test strip instructions for use (package insert) on to the test strip.)
7. Hold the capillary tube by the bulb and position above the blood application window on the test strip. Use care to avoid touching the test strip with the capillary tube. Squeeze the bulb gently to deposit the entire sample on the strip.
8. Once the sample is applied, results will appear on the analyzer display in as little as 45 seconds depending on type of test strip.
9. Remove test strip and **dispose of properly.** Each test strip is for a single test only. Do not reuse the test strips. Use a new test strip each time you test.
10. If the analyzer is idle for more than 3 minutes, it will count down 10 seconds and automatically turn off.



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

## 7 Results

Results for each test are in units of measure specific to each test and your location. The measuring range for each test is listed in the test strip instructions. This is the range that your CardioChek analyzer will display. Results higher or lower than this range will display as > or < followed by a number.

The expected values listed in the instructions are the ranges expected for the majority of healthy persons (persons not diagnosed with any disease).

### Important Test Considerations

1. Make sure that you read and follow the instructions. If you are not sure how to run the test, call PTS Diagnostics Customer Service for assistance before testing.
2. If any result is not as expected, questionable for any reason, above or below the measuring range or expected values range, always repeat the test with a new, unused test strip.
3. Always consult your healthcare provider or medical practitioner and follow their advice.
4. Never make any changes in how you take your medication or make any medical decisions based on the results from this device unless instructed by your healthcare provider.

## 8 Memory

Test results are automatically stored in the CardioChek analyzer's memory. The analyzer can store up to 30 results of each chemistry and at least 10 results for control tests. The analyzer allows review of the results in order from the most recent to the oldest. Each result is displayed with time and date. Results stored in memory are not deleted when the batteries are changed.

### How to Review Results Stored in Memory:

1. Press either button to turn on the analyzer. If the display reads INSTALL MEMO CHIP, go to Step 2. If the display reads INSERT STRIP press Enter.
2. Press Next until MEMORY is displayed.
3. Press Enter. CHEM is displayed.
4. Press Enter, then Next to select the desired chemistry.  
**Note:** Until the chemistry has been run at least once, the test name is not displayed.
5. Press Enter to view the test result including time and date.
  - a. To recall quality control results, press Next until EXIT is displayed. Press Enter. Press Next until CONTROL is displayed.
  - b. Press Enter when the desired quality control test is displayed.
  - c. For example, to review cholesterol results, from the CHEM display, press Next until CHOL is displayed, then Enter. The time and date will be displayed. Press Enter when the desired test time and date is displayed. Press Next to scroll through results.
6. To exit, press Next until the display reads EXIT, then press Enter. Repeat this step until you return to RUN TEST.

## 9 Care and Cleaning

### How to Clear Results Stored in Memory

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

### Storage and Handling

- Handle the CardioChek analyzer with care; do not drop.
- Do not store or operate the analyzer in direct light, such as sunlight, spotlight, under a lamp, or by a window.
- Do not expose the analyzer or any of the supplies or accessories to high humidity, extreme heat, cold, dust, or dirt. The analyzer may be stored at a temperature of 50-104° F (10-40° C) and 20-80% Relative Humidity (RH). **Do not freeze.**
- If storage temperature is below 68° F (20° C) allow the device to warm to room temperature 68° F (20° C) before using. If the analyzer has been stored under excessive conditions or above 86° F (30° C), allow at least 30 minutes at room temperature for the analyzer to equilibrate to these temperatures.
- Do not scratch or damage the surface of the check strip.
- Please read the test strip package insert for storage and handling information that applies to each test strip.

### Cleaning and Disinfection

Cleaning and disinfection of analyzers that come in contact with blood or blood products is critical to avoid transmitting bloodborne pathogens. This analyzer is intended to be used by a single person and should not be shared.

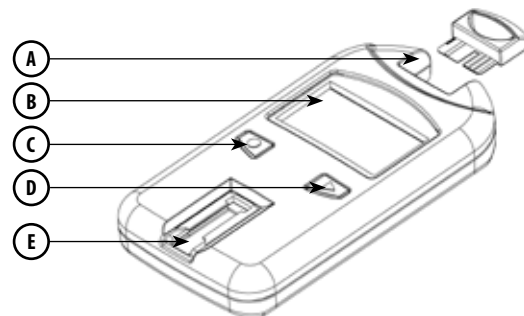
**IMPORTANT SAFETY INSTRUCTIONS: It is critical to properly clean and disinfect analyzers that are used with blood products each time they are used. Additionally, to avoid transmissions of bloodborne pathogens, only use auto-disabling single-use lancing devices. Please see references at the end of this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



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

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

The entire case surface should be cleaned and disinfected.



- A MEMo Chip Port
- B Display
- C Enter Button

- D Next Button
- E Test Strip Slot

## Cleaning Instructions

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

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

## Disinfection Instructions

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

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

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

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



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

After disinfection, user's gloves should be removed and hands should be thoroughly washed with soap and water.

The CardioChek analyzer has been validated for 1,825 cleaning and disinfection cycles. Please obtain a new analyzer after cleaning and disinfecting once the lifetime of the analyzer (5 years) has been reached, whichever comes first. The use of this analyzer beyond its anticipated lifetime is at the user's sole risk and discretion and is not recommended by the manufacturer.

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

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

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

**Fax:** +1-317-870-5608

**Email:** [customerservice@ptsdiagnostics.com](mailto:customerservice@ptsdiagnostics.com) • **Website:** [ptsdiagnostics.com](http://ptsdiagnostics.com)

### References:

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

# 10 Troubleshooting

Message or Issue	Probable Cause	What to Do
Desired language is not displayed.	Language has been set incorrectly.	Turn off analyzer. See Section 3, Setup – How to Reset the Language.
The wrong date and/or time is displayed.	Date and time have not been set correctly.	See Section 3, Setup – How To Set the Date and/or Time.
FAILED is displayed during a check strip test.	Analyzer needs to be cleaned.	Wipe the test strip slot with a clean, damp, and lint-free cloth.
	Check strip is dirty or damaged.	Use spare check strip. If check strip still fails, call Customer Service.
TOO MUCH LIGHT	Test is being performed in direct light or outside.	Test inside, away from windows, and away from direct lamp light.
MEMO CHIP ERROR	MEMo Chip is defective.	Use another MEMo Chip from the same lot.
TEST ERROR	Insufficient sample has been added to test strip.	Test again with a new test strip and make sure the correct volume of sample is used.
LANGUAGE	Analyzer is new or language option has not been set.	See Section 3, Setup - Setting the Language.
TEST NOT ALLOWED	Test selected by MEMo Chip installed cannot be run on your analyzer.	Check MEMo Chip and make sure that the correct MEMo Chip is inserted. Call Customer Service.
LOW TEMP	Analyzer is below acceptable operating temperature.	Move to warmer environment and test after analyzer reaches proper temperature.
HIGH TEMP	Analyzer is above acceptable operating temperature.	Move to acceptable environment and test after analyzer reaches proper temperature.
INSTALL MEMO CHIP	MEMo Chip is not properly inserted or is defective.	Insert same or new MEMo Chip properly.

Message or Issue	Probable Cause	What to Do
EXPIRED LOT	Test strips are expired, wrong MEMo Chip is inserted, or date is not set properly.	Check test strip expiration date and make sure correct MEMo Chip is inserted. Check date setting – see Section 3, Setup – How To Set the Date and/or How to Set the Time.
REPLACE BATTERIES	Batteries need to be replaced.	Replace all 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. Analyzer was moved during testing or not placed on a flat, stable surface.	Test again with a new test strip.
Results are not as expected.	Test strips are improperly stored.	Repeat test, using a different vial of test strips. Run controls, confirm that results are in range.
	Batteries are defective.	Change batteries.
	The analyzer was improperly stored.	Make sure the analyzer was not exposed to high or low temperatures or humidity and repeat test.
	Test strip insert slot is dirty.	Clean the test strip insert slot.
	MEMo Chip and test strips are not the same lot number.	Use MEMo Chip and test strips with the same lot number.

# 11 Unexpected Results

High or low results that are incorrect may have serious medical consequences. If the result reads > (greater than) or < (less than) or results are not as expected, always repeat the test correctly with a new unused test strip. If a test result is displayed that is not expected, consult the following table. Any result which is inconsistent with your medical history should immediately be reported to your physician or healthcare provider.

Message or Issue	Probable Cause	What to do
Results are not as expected.	Test strips improperly stored.	Repeat test, using a different vial of test 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 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 < (less than) a value.	Result is below the measuring range of the test. Analyzer has not been placed on a flat, stable surface while testing or has been moved during testing causing the test strip to slip out of position.	If you have symptoms call a healthcare professional immediately. Repeat the test. Run controls and confirm that controls are in range.
A displayed result reads > (greater than) a value.	Result is above the measuring range of the test. Analyzer has not been placed on a flat, stable surface while testing or has been moved during testing causing the test strip to slip out of position.	If you have symptoms call a healthcare professional immediately. Run test again. Run controls and confirm that controls are in range.

# 12 Specifications

## CardioChek Analyzer

**Calibration Curve:** Input from MEMO Chip per test strip lot

**Battery:** 2 AAA 1.5 volt alkaline

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

**Note:** The analyzer temperature must be within the test strip temperature range to function as a system. See test strip package insert for more details.

**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): 4-6 oz. (113.4 - 170.1 g)

## PTS Panels Self-Test Strips

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

# 13 Contact Information

## Help

For assistance with the CardioChek test system, please contact PTS Diagnostics Customer Service (M-F, 6 a.m.- 9 p.m. US EST) or your local authorized CardioChek dealer.

## PTS Diagnostics

4600 Anson Boulevard, Whitestown, IN 46075 USA

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

**Fax:** +1-317-870-5608

**Email:** [customerservice@ptsdiagnostics.com](mailto:customerservice@ptsdiagnostics.com) • **Website:** [ptsdiagnostics.com](http://ptsdiagnostics.com)

# 14 Warranty

## CardioChek Analyzer Limited One-Year Warranty

PTS Diagnostics warrants to the original purchaser only, that the CardioChek 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 Diagnostics. If the analyzer becomes inoperative during this time, PTS Diagnostics will replace the analyzer with equivalent analyzer, at its option, at no cost to the purchaser. The warranty becomes void if the analyzer is modified, improperly installed or operation not in accordance with the user guide, damaged by accident, or neglect, or if any parts are improperly installed or replaced by the user.


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

# 15 Explanation of Symbols

## Symbols

 Consult instructions for use


 Temperature limitation


 *In vitro* diagnostic medical device

 Serial number

 Manufacturer

 Catalog number

 Authorized representative in the European Community


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

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

 Keep away from sunlight


 Keep dry

 Control

 Humidity limitation

 Batch code

 Use by

 Caution

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CardioChek and associated test strips are covered by one or more patents.  
For details, refer to [www.ptsdiagnostics.com/patents.html](http://www.ptsdiagnostics.com/patents.html).

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