CardioChek HRA™ (Health Risk Assessment) User Guide

This software program is compatible with Microsoft® Windows 7, 8, and Vista operating systems

Introduction

CardioChek HRA is a health risk assessment (HRA) software program designed to capture data directly from a CardioChek® analyzer linked to a desktop computer via a USB cable. Data may also be manually entered into the CardioChek HRA software. The captured results are then summarized within a visually informative HRA Report that is easy to understand by health care providers and participants being screened.

In addition, a Cardiac Age calculation is included on the HRA Report if all required parameters are collected. Cardiac Age is based on the Framingham Heart Study which is comprised of gender, biological age, total cholesterol, HDL cholesterol, blood pressure, smoking, and diabetes.

Captured data is available for aggregation by the HRA software program and for export to a spreadsheet program such as Microsoft® Excel.

A computer will only run one copy of the CardioChek HRA software and connects to one CardioChek analyzer. If multiple CardioChek analyzers are connected, only one analyzer will be recognized by the program.

Contents
- The CardioChek HRA kit includes:
    - CardioChek HRA software CD-ROM
    - CardioChek USB cable

- The CardioChek HRA software CD-ROM is also sold separately without the CardioChek USB cable.

Before Installing the CardioChek HRA Software
- Close all other programs.
- Make sure the CardioChek USB cable is <u>not</u> attached to your computer.

Installing the CardioChek HRA Software
- Installation of the CardioChek HRA™ software should start automatically when you insert the CD. If the install does not automatically initiate, click the Windows 'Start' button, click 'My Computer', and then double click 'CardiochekHRA.exe' file from the cd-rom drive letter where you have placed the disk and the install will begin.
- The **CardioChek HRA** screen will display. Click 'OK', and follow the on-screen prompts to continue installation.
- An **Important information** screen will display which contains instructions on installation and information on accessing the program for the first time. Please read carefully and then click 'Next' to continue.

- The next screen is the **License agreement**. If you accept, click 'I agree to these terms and conditions' and then click 'Next' to continue installation. If you do not agree, you will not be able to install the software.
- The **Installation options** screen will display. Click 'Install' to use the default location displayed or click 'Browse' to install in another location. Then click 'Install'.
- Once the CardioChek HRA is installed, the **Installation completed** screen appears.   The 'Start the application' button is selected by default. If you do not wish to immediately start the CardioChek HRA application, click 'Start the application' to un-check the box and then click 'Finish'; otherwise, select 'Finish' and the program will begin.

Accessing the program for the first time

The CardioChek HRA application is password protected. Each time a user opens the program, a **Login** window appears and a 'User Id' and 'Password' must be entered to access the health risk assessment software.

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Important: The first time the software is launched, the following must be entered:

<p style="text-align:center"><strong style="color:red">User Ids and Passwords are case sensitive!</p>

<p style="text-align:center">User Id: admin
Password: masterkey</p>

</div>

Once you have completed the initial login, it is recommended that you change the User Id and Password. To create a unique login, click 'Maintenance', click 'Manage Screeners', and then highlight the 'Admin' account. Once you have highlighted the account, click 'Edit', change the User Id, change the Password, rename the account, and click 'Update' to save your changes.

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Important: CardioChek does not maintain User Id's or Passwords. Store your newly created User Id and Password in a safe place. If you forget your login information, you will be required to reload the software.

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Software Registration

Once the installation of the CardioChek HRA software is complete, a **Software Registration** screen will appear. If the screen does not appear, it can be located by clicking 'Maintenance' and then 'Renew Registration' on the CardioChek HRA toolbar.

The CardioChek HRA program is licensed for download to one (1) computer per HRA software copy.

You must register this product.

On the **Software Registration** screen, a unique software code is displayed and a

registration key will need to be obtained to register your copy of the CardioChek HRA software.

To obtain a registration key, complete all of the identification fields located at the bottom of the form. Begin by entering your unique software serial number (S/N).

> **Important: The software serial number (S/N) is unique to each individual copy of the CardioChek HRA program. The serial number is located on the CardioChek HRA software CD and also on the HRA software packaging.**

In addition to the unique software serial number, complete the contact information fields including Company Name, Address, City, State/Region, Postal Code, Country, Phone, Email, and Website if applicable.

Once all information has been entered, click 'Get Registration Key' located below the 'Registration Key' field and your information will be sent to PTS, Inc. for authentication.

> **Important: Your registration key will be sent to the email address you provide!**
>
> **Please note it may take a business day or two for PTS, Inc to process your registration key request.**
>
> **If you do not have an internet connection or you are unable to register this product online, contact CardioChek Customer Service at + 317.870.5610 or send an email to hra@cardiochek.com.**

After you click 'Get Registration Key', an **Information** window will appear confirming that your request for a registration key has been submitted. Click 'OK' to continue.

> **Important: Click the '10 Day Trial' button to immediately begin using your CardioChek HRA program. The CardioChek HRA program will operate without a completed registration for ten (10) days. At the end of ten (10) days, a registration key and completed registration will be required to continue use of the CardioChek HRA program.**

Once you have received your registration key from PTS, Inc. via email, click on 'Maintenance', click 'Renew Registration', cut and paste or enter your registration key, and then click 'Register'. Your HRA software will now be registered.

If you do not have internet access, contact PTS, Inc. Customer Service at + 1.317.870.5610 (Direct) and a registration key will be generated for you via phone. You may also send an email to hra@cardiochek.com for assistance.

10 Day Trial

By clicking the '10 Day Trial' button located on the **Software Registration** form, you may immediately begin using your copy of the CardioChek HRA program. The HRA program will operate without a completed registration for ten (10) days. At the end of

ten (10) days, a registration key and completed registration will be required to continue using the HRA program.

Important:	**To prevent an interruption in use of the HRA software, it is highly recommended that you submit a request for a registration key at the time of installation and register your copy of the HRA software immediately upon receipt of the registration key.**

Setting Up and Managing Additional Screeners

To manage multiple operators on the same computer, the Administrator can create user ids and passwords for additional screeners.

To create a new screener account, click 'Maintenance', click 'Manage Screeners', and 'New'. Create a User Id and Password along with entering the First and Last Name of the additional screener.

Click the 'Administrator Permission' box if you want the new screener account to have the ability to add and remove screeners. If you do not check the 'Administrator Permission' box, the new screener account will still have all the functionality of the 'Administrator' account with the exception of managing screeners.

Setting Up a Screening Event

To begin a screening, an 'Event Profile' must first be created. Create a new 'Event Profile' by clicking the **Screening Event** tab located on the left toolbar of the CardioChek HRA program. Below the **Screening Event** tab on the left toolbar, click 'Event Profiles' and then click 'New Event' to create a new screening profile. The **Create Event Profile** screen will appear.

> **Event Profile:** Create a 'Profile Name' and then complete the contact and location information for the screening event.

> **Personalized Logo:** A personalized logo may be uploaded to create a customized HRA Report summary that can be printed and provided to screened participants.

Important:	**The logo must be in .jpeg or .bmp format and must not exceed the size limit of 80 pixels high by 360 pixels wide! If the logo exceeds this size limit, it will obscure the final report page!**

> **Preferences:** Complete this section to customize the screening event.
>> **Language:** Select the preferred language for all input and output screens.
>> **Test Strip Type:** Select the appropriate test strip for the screening event. Only one test may be performed at a time per individual screened.

Important:	Total Cholesterol (CHOL) and HDL Cholesterol (HDL) are required components for a Cardiac Age calculation. If one of the individual analyte tests or the CHOL+GLU test is selected, a Cardiac Age will not be calculated.

- *Lipid* – Test for total cholesterol (CHOL), HDL cholesterol (HDL), and Triglycerides (Trig). Also provides a calculated LDL cholesterol (LDL) result and total cholesterol to HDL ratio. The total cholesterol to HDL ratio is saved for aggregate reporting purposes, but will not display on the HRA Report summary provided to screened individuals.
- *Lipid + Enter Glucose Manually* – When information is transmitted directly from a CardioChek PA device to a PC, only one test at a time may be performed per individual screened. This option allows for a lipid panel to be performed with a CardioChek PA meter while allowing a glucose value to be entered manually from a second device.
- **CHOL + HDL + GLU** – Test for total cholesterol, HDL cholesterol, and Glucose (GLU).
- **CHOL + HDL** – Test for total cholesterol and HDL cholesterol.
- **CHOL + GLU** – Test for total cholesterol and glucose.
- **Individual analyte Tests:** Total Cholesterol ● HDL Cholesterol ● Triglycerides ● Direct LDL ● Glucose
- **Lipid + eGLU**

Units of Measurement: Select 'mg/dL', 'mmol/L', or 'g/L'.
- **Height/Weight:** Select 'feet/inches/lbs' or 'cm/kg'.
- **Manual Input – Link to PC not available:** Check this box if a CardioChek PA device will not be directly connected to the PC and all results will be entered manually.
- **Enable Questions:** By default, all questions are enabled. If you do not wish to collect a blood pressure reading, ask about smoking, ask if an individual is diabetic, or whether or not the individual being screened is fasting, then uncheck any parameters for which you do not wish to screen.

Important:	Blood pressure, smoking, and diabetes are required components for a Cardiac Age calculation. If any of these questions are disabled and not asked during the screening event, a Cardiac Age calculation will not be calculated.

Cardiac Age

Cardiac Age is based on the Framingham Heart Study, the most widely acknowledged long term study of coronary heart disease.

Cardiac Age is calculated using risk factors associated with gender, biological age, total cholesterol, HDL cholesterol, blood pressure, smoking, and diabetes.

Answers and inputs to all of these components must be collected for a Cardiac Age to be calculated.

The desired outcome is that your Cardiac Age is the same or younger than your biological age.

Important:	**The health risk assessment readings, including the Cardiac Age calculation, are not to be used to change lifestyle, diet, or medical therapy without the consultation and recommendation of the health care provider for the individual being screened.**

Connecting the CardioChek PA Analyzer to the Computer

The first time you insert the CardioChek USB cable into your computer, wait for Windows to find the new hardware and complete the installation. After your computer states "Your new hardware is installed..." or "Found new hardware", the CardioChek HRA is ready for use with a CardioChek analyzer.

The CardioChek HRA software also provides a connection status update in the lower right-hand corner of the program.

Before testing with the CardioChek analyzer connected to your PC, a MEMo Chip must be inserted into the CardioChek USB cable as pictured below.
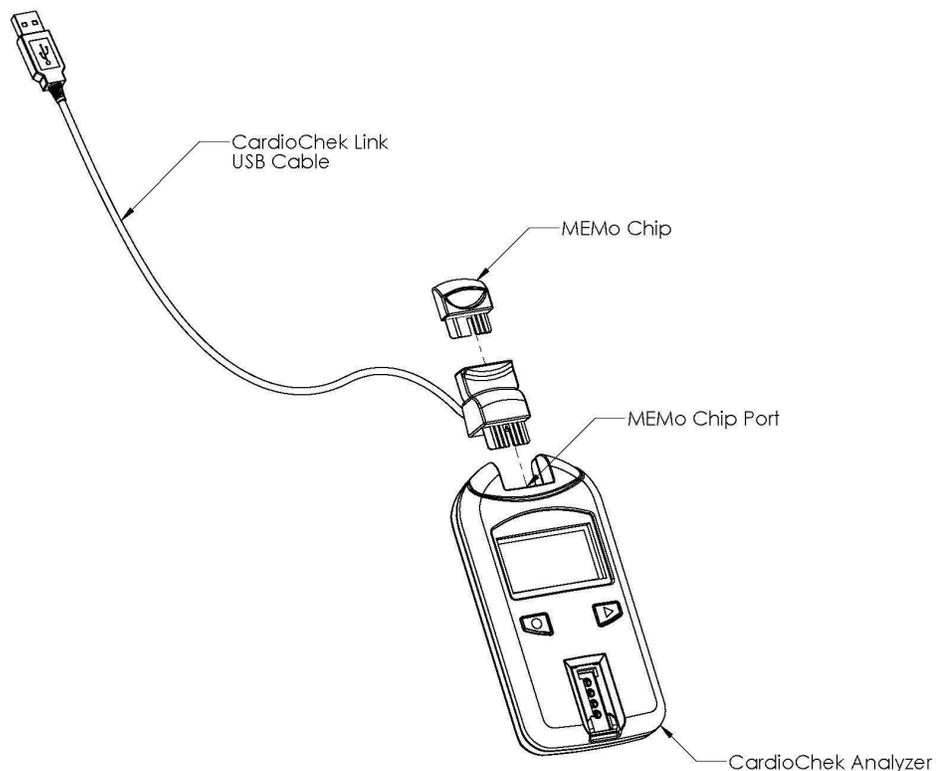
Important:	The CardioChek PA device "Output" must be set to "PC" in order to communicate with your computer and CardioChek HRA software. Turn on the CardioChek PA device and forward to "User Set" or "Settings". Select "User Set" or "Settings", select "Print", and forward to "Output". Select "Output" and then forward to "PC". Select "PC" and exit. See the CardioChek PA User Guide for complete instructions.

Completing a Health Screen Assessment

To begin a health screen, select 'Start Session' and then select the desired screening event from the **Event Profile Selection** window. Next, click 'OK'.

Once a profile is selected, a **Profile** window will be displayed along with a **Scan Status** window which contains a session number (session #). The session # consists of the date and time a screening session is started and provides an additional tracking mechanism for reporting and screener management. The format of the session # is as follows:

2011 09 15 14 30 50
YYYY MM DD HH:MM:SS

After a profile has been selected, click 'New Assessment' and the **Event Profile Review** window displays. Verify the language, units of measure, test strip type, and whether or not data will be directly transmitted from the CardioChek analyzer or manually entered.

If all selections are correct, click 'Continue'. If any of the information is incorrect, click 'Cancel' to edit the event profile.

To edit the event profile, click 'End Session' to close the current scan session. Click 'Event Profiles' in the CardioChek HRA toolbar, click on the event you wish to edit, click 'Edit Event', and make the desired changes. Once the changes have been made, click 'Update' and then 'Done' to return to the main menu. Repeat the instructions for **Completing a Health Screen Assessment**.

Once 'Continue' is chosen from the **Event Profile Review** window, the **CardioChek Wizard** displays and **Participant Information** is ready to be entered for the individual being screened.

- **Participant Information:** Complete this section to obtain the participant's personal information and health history. Only the questions that were enabled during event setup will appear on the form.
    - **First Name** - Enter the participant's first name.
    - **Last Name** - Enter the participant's last name.
    - **Phone** - Phone number is optional and not required to be completed.
    - **Email** - Email address is optional and not required to be completed.
    - **Gender** - From the drop down menu, select 'M' for male or 'F' for female.

- **Date of birth** - From the drop down menus, enter the participant's date of birth in the format of mm/dd/yyyy.
- **Consent for Screening** - Check this box to verify that the participant is aware of the tests to be performed and that they are knowledgeable about how their personal information can and will be used.
- **Do you Smoke?** - Check this box if the participant currently smokes.
- **Did you fast?** - Check this box if the participant has not eaten any food for at least 8 hours.
- **Do you have diabetes?** – Check this box if the participant has been diagnosed with diabetes.

- **Participant Biometrics:** Complete this section to obtain the participant's biometric data. When transmitting data directly from a CardioChek analyzer to the CardioChek HRA program, all parameters requiring manual entry must be entered before clicking 'Receive Test Data'.

> **Important:** **Only the tests that were selected during event setup will appear on the form. Fields that are dark gray such as BMI are automatically calculated. Fields that are light gray are waiting for data to be transmitted directly from the CardioChek analyzer. Fields without shading require manual entry.**

- **Height** - Enter the participant's height in feet and inches or centimeters.
- **Weight** - Enter the participant's weight in pounds or kilograms.
- **BMI** - Body Mass Index will be calculated based on height and weight.
- **Blood Pressure** – Enter the participant's systolic and diastolic blood pressure readings if applicable.
  Cholesterol ● HDL Cholesterol ● Triglycerides ● LDL Cholesterol ● TC/HDL Ratio – If the CardioChek analyzer is connected to a pc, click 'Receive Test Data' and then run the test on the CardioChek analyzer. Results will automatically be transmitted to the CardioChek HRA program. If the CardioChek analyzer is not connected to a pc, run the test and manually enter each result from the CardioChek analyzer.
  Glucose – Click 'Receive Test Data' if connected to a pc or manually
- enter the result from the CardioChek analyzer or glucometer if applicable.

- **Summary** – If a CardioChek analyzer is connected to a pc, a **Summary** window will automatically display when the CardioChek analyzer is done testing. If entering information manually, click 'Continue' once all patient information, patient biometrics, and patient test results are entered. The
- **Summary** window will display.

The summary contains all patient information, health history, biometric information, and test results transmitted by the CardioChek analyzer or manually entered. Units of measure, language, and a unique Patient Id are also displayed within the summary.

The unique Patient Id is generated using a combination of the patient's date of birth (mmddyyyy), gender, and the first (3) letters of the last name.

Example: Jon Deal ● Male ● May 31, 1973	**Unique ID:** 05311973MDEA

Printing the HRA Report

From the **Summary** window, click 'Print Report' to generate a **Report Preview** of the test results**.** Once the **Report Preview** is displayed, click the printer icon in the upper left hand corner and follow your printer's instructions to print the results.

Other options from the Report Preview include:
- **Zoom 100%** - Default preview screen that shows actual size of the report page.
- **Zoom Fit** – Zooms the preview so that the entire report can be seen on your pc screen at one time.
- **Zoom Width** – Zooms the preview to the width of your computer screen.
- **Pdf** – Creates a .pdf file of the report from the preview window.
- **Close** – Closes the report preview and saves the report.

Once a report has been printed, saved as a .pdf file, or closed; a blank **Participant Information** window will display for the next assessment. If there are no more assessments, click 'Close' and then click 'End Session'.

Important: **To disable the print preview, click the 'Preferences' tab on the top toolbar, click 'Report Settings', and uncheck the 'Print Preview' button. Click 'Ok' and start the new test session. Once all data and results have been collected, click 'Print Report' and follow your printer's instructions. No preview will be displayed.**

Reports

Once data has been collected, there are several types of individual and aggregate reports that can be generated. Click the **Reports** tab on the left side toolbar of the CardioChek HRA program. The following reports are available:

- **HRA Report** - This report is used to search for all HRA Reports generated during a specific test session.
    - Click **HRA Report** from the left side toolbar. Select the event profile, click 'Next' and then select the Session number you wish to search.
    - All assessments completed during the session will display and be available for printing.

- **Individual Report** - This report is used to search for individual assessments within an event profile or within multiple profiles by an individual's first or last name.
    - Click **Individual HRA Report** from the left side toolbar, select the

event profile or select 'Search All Profiles'.

- Enter the first name, last name, or both to search for an individual profile.
- The first and last names may be left blank if searching for all assessments within a particular event profile.

- **Aggregate Report** - This report is used to provide aggregate data for one or more event profiles over a specific date range.
  - Click **Aggregate Report** from the left side toolbar and the **Print Aggregate Report** window will display.
  - Check all event profiles that you wish to aggregate.
  - Select a 'Start Date:' and 'End Date:" range that you wish to aggregate.
  - Click 'Print' and the aggregate report will display.
  - The first page of the aggregate report provides the date and time the report was generated and the list of event profiles included in the report.
  - Pages two and three contain the number and percentage of individuals that fall within each risk category for tests completed and each biometric category.

Building Custom Query Reports

Custom queries can be created to further refine aggregate reporting and enhance data mining. The **Custom Query Builder** is comprised of the **Result Fields** and **Conditions** windows. Select the result fields to be analyzed and then set conditions to further refine the analysis. To build a custom query, click **Data Analyzer** and then click **Custom Query Builder** from the left side toolbar. The **Data Analyzer – Custom Query Builder** window will appear.

- **Result Fields** – The **Result Fields** window allows the user to select the fields to be analyzed. The result fields are organized into five main categories with several sub-categories under each. The main categories are: **Assessment**, **Biometrics**, **CardioChek**, **Profiles**, and **Users**.
  - Select the '< Click to add new field >' link.
  - By default, the 'Assessment.Did you fast?' field will appear. Click 'Assessment.Did you fast?' to change to a different field you wish to query.
  - After clicking on "Assessment.Did you fast?", choose the main category, and then select the specific field you wish to analyze. The list of main categories and their associated fields are as follows:

Assessment
Did you fast? • Do you smoke? • Do you have diabetes? • Screener Name • Screening Date • Screening Time
Biometrics

Cardiac age • Height • Weight • BMI Value • Blood Pressure • Diastolic Value • Blood Pressure Systolic Value • Cholesterol • Glucose • HDL • LDL • Triglycerides • TC/HDL Ratio • LDL/HDL Ratio • Non-HDL Ratio • eGLU
CardioChek
Serial Number • Lot Number • Result • Cholesterol • Glucose • HDL • LDL • Triglycerides • TC/HDL Ratio
Profiles
Name • Contact • Address • City • State • Zip Code • Phone • Email • Language • Test Strip Type • Unit of Measurement • Self Reporting – no CardioChek PA device connected • Enable Question - Blood Pressure • Enable Question – Smoking • Enable Question – Fasting • Enable Question – Diabetes
Participants
Patient ID • First Name • Last Name • Gender • Age • DOB • Phone Number • Email

- **Conditions** – The **Conditions** window allows the user to set "Brackets" and "Conditions" to further filter the **Result** data. The "Brackets" and "Conditions" set filters in conjunction with the **Result** fields.
  - **Brackets**:
    - Brackets are used to specify which records should be queried.
    - Brackets include the qualifiers of "all", "any", "none", and "not all".
  - **Conditions:**
    - Conditions are used to specify a specific field to be qualified and the type of condition that needs to be satisfied.
    - Conditions include the following:
      - is equal to
      - is not equal to
      - is less than
      - is less than or equal to
      - is greater than
      - is greater than or equal to
      - is null
      - is in list
      - is not in list
      - starts with
      - does not start with
      - contains
      - does not contain
      - is between
      - is not between

- **Example**: An end user can select 'Cholesterol' in the **Result** window; select the 'Bracket' of '<u>all</u> records'; enter the 'Condition' of 'HDL cholesterol is greater than'; and enter a value such as '60 mg/dL' in the **Conditions** window. This will produce a custom query that returns a 'Total Cholesterol' value and an 'HDL Cholesterol' value for all records where 'HDL Cholesterol' was above '60 mg/dL'.

- **Creating Brackets and Conditions:**
  - To create a Bracket, click on the word '<u>all</u>' within the default sentence of, 'Choose records where <u>all</u> of the following apply' in the **Conditions** window.
  - To create additional Brackets, click the numbered circle to the left of any Bracket or Condition and then select, 'Add Bracket (After Current)'.
  - The numbered circle to the left of any Bracket or Condition can be clicked to also add additional Conditions, delete Brackets or Conditions, and to make Brackets and Conditions inactive.
  - To create a Condition:
    - Click the '<Click here to add new condition>'.
    - Click on the 'Did you fast?' default condition, and then select the field you wish to qualify.
  - Once a field has been selected, the condition defaults to 'is equal to'.
  - To change this condition, click on the 'is equal to' and select the desired qualifier.
  - Once the condition has been chosen, enter the text or value for which you wish to filter.

- **Running, Saving, and Clearing a Query**
  - **Run Query:**
    - After all Result fields, Brackets, and Conditions have been selected, select the 'Run Query' lightning icon on the top toolbar to run the query.
    - Results of the query will be displayed at the bottom of the window.
    - Once a query has been run, it may be modified and the 'Run Query' lightning icon can be clicked again to run the new query.
  - **Save Query:**
    - To save query results, select the 'Save Query' computer disk icon on the top toolbar.
    - Select the location and create a file name.
    - To open a saved query, click the 'Open Query' file folder icon on the top toolbar and select the query file you wish to open.

- **Clear Query:**
  - To clear a query, select the 'Clear Query' pencil with eraser icon on the top toolbar.
  - All previous query Result fields, Brackets, Conditions, and Results will be erased.

Exporting Results to Excel

Once a query has been run, the results can be exported to a spreadsheet such as Excel. To export a query to Excel, perform the following:

- Run the query
  Once the results are displayed, click the 'Export to Excel' icon on the top toolbar.
- A **Save to Excel File** window will appear.
  Select the location to which you wish to save and name the file.
- To open the saved file, go to the save location and click on the file.

Important: When attempting to open a saved query in Excel, a warning may appear.

This warning appears as a result of how the data is stored by the CardioChek HRA program and shared with Excel.

The warning states that the file you are trying to open is in a different format than specified by the file extension.

The warning will also ask to verify that the file is not corrupted and from a trusted source before opening the file. Do you want to open the file now?

If you are sure the file is a query that you or a trusted source created, ignore this warning and click 'Yes' to continue.

CardioChek HRA Toolbar Menu:

The toolbar located at the top of the CardioChek HRA program contains the following items:

- **File**
  - **Exit –** Exits the CardioChek HRA program.
  Preferences
  - **Report Settings –** Toggles whether a "Print Preview" of the HRA Result summary page is shown before printing or if the HRA Result summary page is printed immediately upon receipt of the test results.
- **Maintenance**
  - **Check for Updates –** Click this menu item to initiate a check for updates to the CardioChek HRA software.

- **Re-Index Databases –** Ensures that all collected data is up to date and properly organized with the CardioChek HRA software.
- **Backup Databases –** Creates a backup of all CardioChek HRA databases.
- **Renew Registration –** Enables the end user to register or renew registration of the CardioChek HRA software.
- **Delete HRA Assessment –** Enables the end user to delete an individual HRA assessment.
- **Manage Screener Account –** Enables the Administrator account or screeners with administrative authority to delete and add screeners.
- Only the Administrator account or screeners with administrative authority have the ability to manage screeners.

- **Language**
  - **English -** Available with the initial version of the CardioChek HRA software.

- **Help**
  - **Quick Start –** Provides instruction on how to install and register the CardioChek HRA software.
  - **User Guide –** Provides complete instructions on how to use the CardioChek HRA software.

CardioChek HRA™ is licensed by

Polymer Technology Systems, Inc. Indianapolis, IN 46268

For assistance with CardioChek HRA ™ Call PTS, Inc. Customer Service: +1-317-870-5610 (Direct) +1-317-870-5608 (Fax)

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