

Mission Lipid Data Management Software User's Guide

V1.0.2 March 2019

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1. Overview

1.1 About the Mission Lipid Data Management Software

This software is designed for patient office visits and community screening events. It enables the user to quickly transfer test data from the meter to a PC, securely create and manage electronic patient records containing current/archived test data and standard health information, and provide patients with a personalized, up-to-date lipid health report at each visit.

The personalized patient report includes the patient's current test results, as they compare to standard reference values, for Total Cholesterol, Triglycerides, HDL, calculated LDL and calculated Total Cholesterol/HDL Ratio. It is a helpful educational tool that automatically calculates the patient's 10-year risk of Coronary Heart Disease, using either the Framingham or PROCAM scoring algorithms. If the Framingham algorithm is selected in the software settings, the report will also calculate an individual's "Heart Age," another predictive indicator of cardiovascular health, based on known risk factors.

Note: A computer will run only one copy of this software program and connect with one meter at a time.

1.2 System Requirements

The following are minimum requirements for Mission Lipid Data Management Software:

Operating System: Win 7 Home Premium – 32 bit

Win 7 Pro – 64 bit Win 8.1 Pro – 64 bit Win 10 Pro – 64 bit

Memory: 1 GB

Hard Disk Space: 500 MB for software installation and patient database expansion

Connection Port: Available USB port

Display: 1024 x 768 or higher

1.3 Materials Required

- Mission Cholesterol Meter –or-- Mission Lipid Panel Meter
- Mission USB cable

2. Administrator Instructions

2.1 Installation

NOTE: During the installation process, please make sure the USB cable is disconnected from your computer. Do not connect it to your computer until the software installation is completely finished.

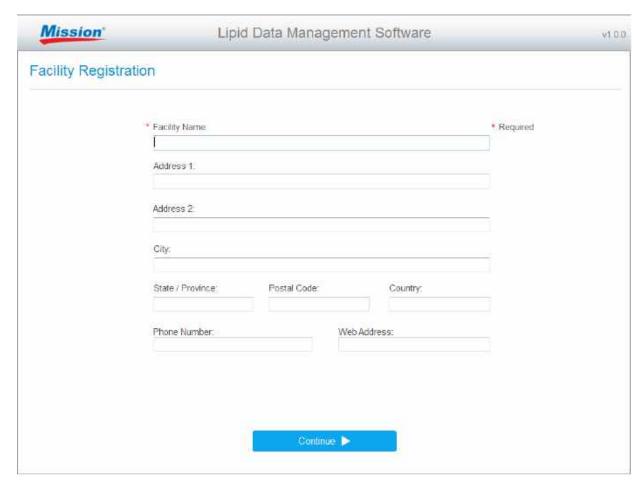
To install, click on the Mission Lipid Data Management Software icon and follow the prompts.

2.2 Setup

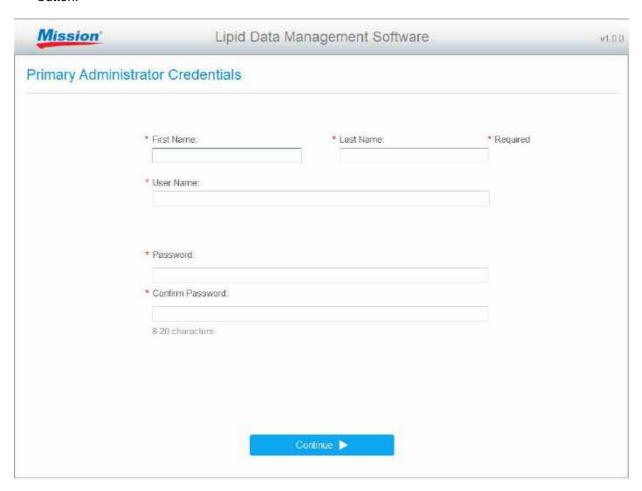
The setup window will automatically appear after installation is finished.

NOTE: If your computer shuts down during setup, the set up process will remain incomplete. To restart the set up process, the software must be reinstalled.

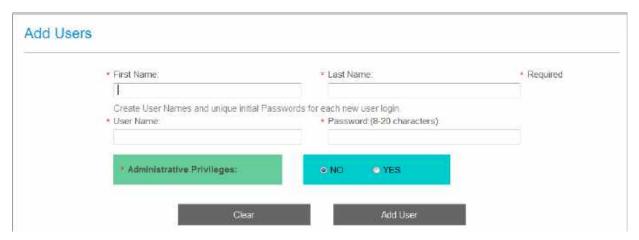
- 1. Setup begins at the "Select Language" screen. Select preferred language from the dropdown menu and click the "Continue" button.
- 2. Fill in the facility information on the "Facility Registration" screen and click the "Continue" button.



3. Fill in your information on the "Primary Administrator Credentials" screen. (For User Name, use company email ID or create a naming system for yourself and other users.) Click the "Continue" button.



4. On "Add Users" screen, enter information for each individual who will be authorized to use the software and access patient information. Enter each user, one at a time, and click the "Add User" button after each entry to save.



When all users have been entered (additional users may be added later), click the "Continue" button.

NOTE: Administrative privileges include:

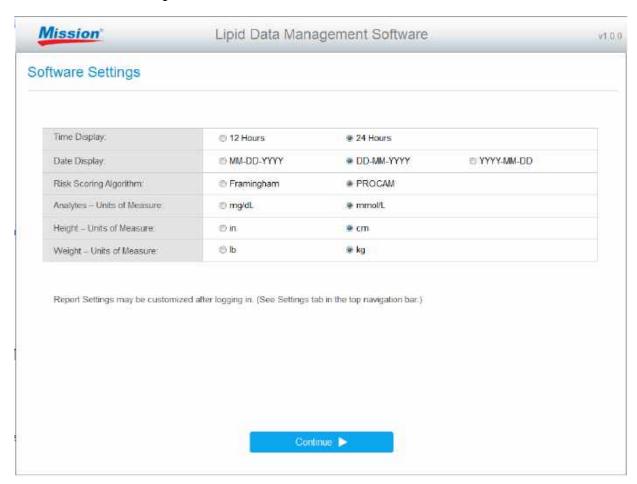
- Adding, editing, deleting user records from the software
- Modifying facility information in the software
- Modifying software settings
- Exporting patient data to CSV text files
- Creating a backup of the patient database
- Accessing the control solution test history
- Uploading company logo for the customized patient report (optional)



NOTE: A user will have a "pending" status until they log in for the first time. Then their status will change to "Active."



5. Select software settings and click the "Continue" button.

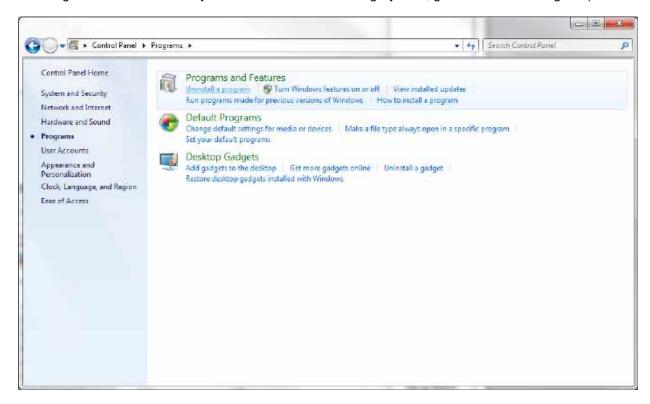


Note: You will have the option of customizing report settings after logging in.

- 6. Once setup has been completed, an account activation screen will be displayed. Enter your new user name and password to activate your account.
- 7. You will now be prompted to restart your computer.
- 8. Provide User Names and (temporary) Passwords to all new authorized users for their first-time login.

2.3 Uninstall Instructions

1. Open the Windows installed software menu or Control Panel. (When in the Control Panel, go to Programs and Features. If your Control Panel is in Category view, go to Uninstall a Program.)



2. Find the Mission Lipid Data Management Software icon.



3. Follow the standard Windows procedure for uninstalling the program.



2.4 Running the Mission Lipid Data Management Software (Administrators Only)

After installation, the software icon will be visible in your computer Start menu. If you created a shortcut during installation, it will be visible on your desktop also. Double-click the icon shown below to launch the program.

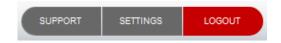


2.4.1 Forgotten Password (Administrators Only)

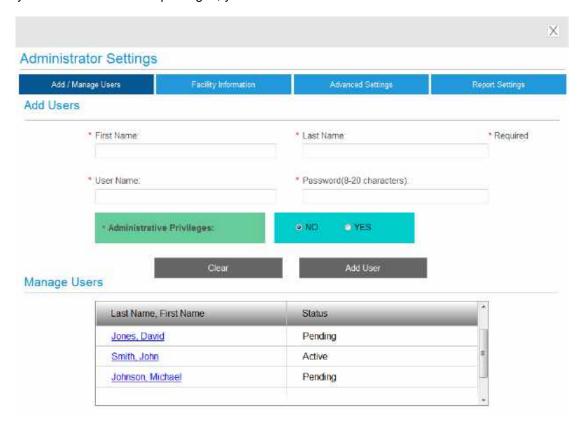
If you forget your password and you are the only user with administrative privileges in your organization, contact ACON Laboratories' Technical Support (techsupport@aconlabs.com). If additional users within your organization have administrative privileges, they also have the ability to view and change all passwords (both Administrators and standard users) in the "Add / Manage Users Tab" (located in "Settings" in the top navigation bar).

2.4.2 Administrator Settings

The Settings button is located in the top navigation bar.



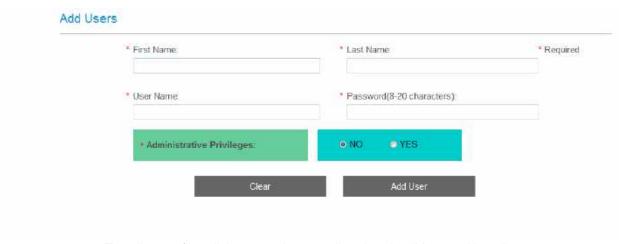
If you have administrative privileges, you will see the screen below:



If the screen above does not come up when the Settings button is clicked, please contact the Primary Administrator of this software at your facility.

2.4.2.1 Add / Manage Users Tab

• To add new users, fill in fields under "Add Users" and click "Add User" button.



 To edit user file, click on user's name listed under "Manage Users" to open user file for editing. Make changes and click "Save" button.

Manage Users

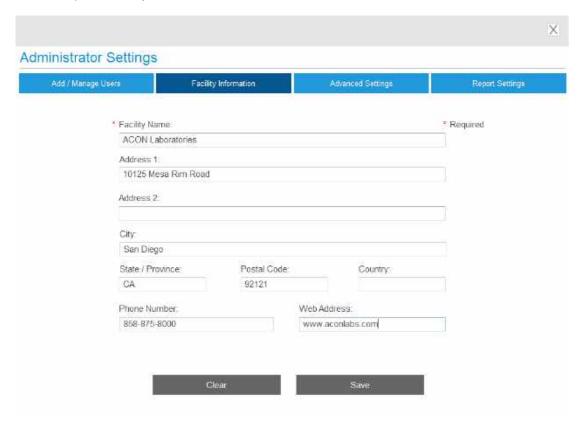


X Edit User * First Name * Last Name David Jones * User Name Password(8-20 characters) djones 123456789 Administrative Privileges: @ YES Clear Delete User Save

 To delete a user file, click on user's name listed under "Manage Users" to open user file. Click "Delete User" button. (Shown above.)

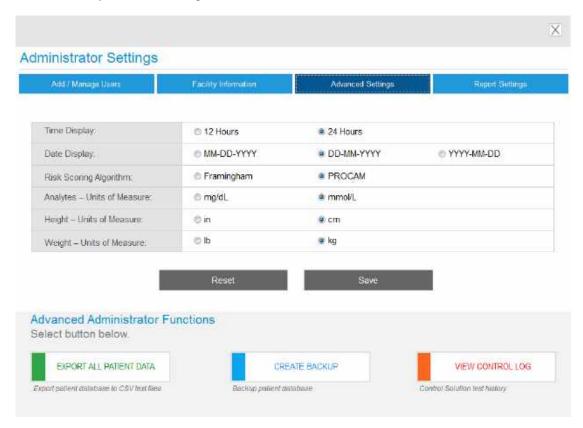
2.4.2.2 Facility Information Tab

Update facility information and click "Save" button.



2.4.2.3 Advanced Settings Tab

Modify software settings if desired and click the "Save" button.

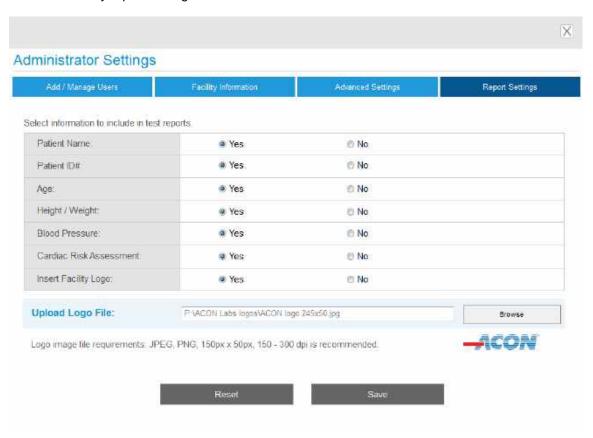


For advanced administrator functions, click the appropriate button.

- Export patient database to a CSV text file.
- Create a backup of the patient database. (For assistance in restoring files, contact ACON Laboratories' Technical Support at techsupport@aconlabs.com).
- View control solution test history.

2.4.2.4 Report Settings Tab

Modify report settings if desired and click the "Save" button.



See Sections 4-9 for additional information on how to use this software.

3. General Instructions

3.1 Running the Software

Double-click the Mission Lipid Data Management Software icon shown below. It is located in the Windows Start menu. It may also be visible on the computer desktop if a shortcut has been created.



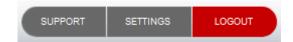
3.2 First-time Login / Forgotten Password

The primary Administrator will provide you with a User Name and initial (temporary) password. During the first-time login process, your account will be activated and you will have the opportunity to change your password.

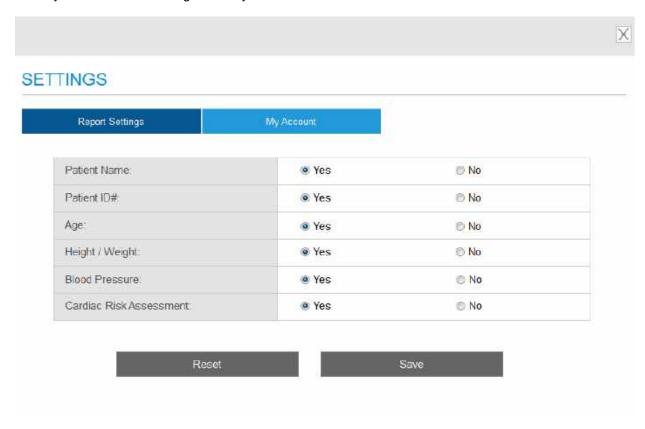
Note: If you forget your password, contact your Administrator.

3.3 Standard Settings

The Settings button is located in the top navigation bar.



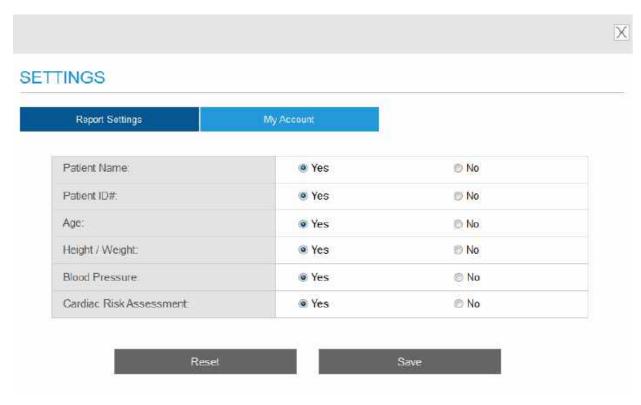
When you click on the Settings button you should see the screen below:



If this screen does not come up when the Settings button is clicked, please contact the Primary Administrator of this software at your facility.

3.3.1 Report Settings Tab

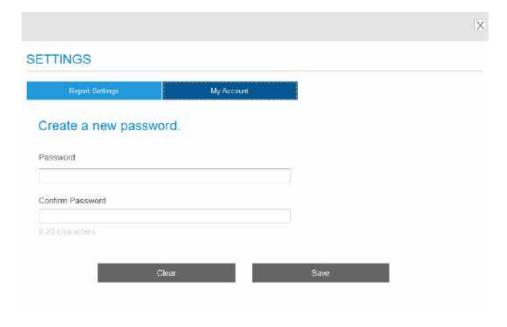
Modify report settings if desired and click the "Save" button.



3.3.2 My Account Tab / Change Password

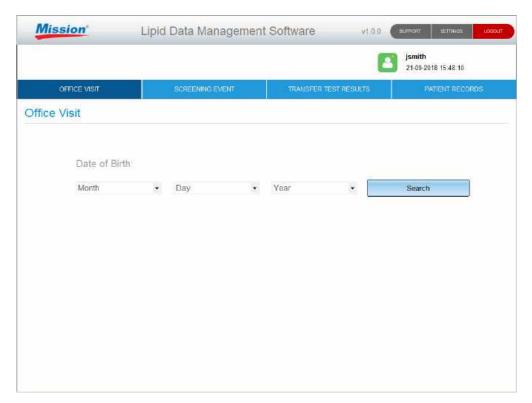
Change password if desired and click the "Save" button.

It is recommended that you change your password on a regular basis.



4. Home Screen

The Home screen is the first screen of the Office Visit tab. It appears as the screen below.



5. Office Visit

The Office Visit mode (Home Screen) is for use in a physician office setting during a patient appointment. The workflow consists of the following:

- 1) Clear meter memory at the start of the day (optional, but recommended)
- 2) Ask the patient some questions
- 3) Perform lipid testing; remove used test device/cartridge from meter
- 4) Transfer test data from the meter to the computer
- 5) Generate a patient report

5.1 Clear the Meter Memory

To optimize data transfer speed, it is recommended that the meter memory be cleared daily or a few times per week (depending on lipid test volume). For instructions on how to clear the meter memory, click on the link called "How do I clear the meter memory?" This link navigates directly to the Support page, which can also be opened from the Support button in the top navigation bar.

Optimize Data Transfer

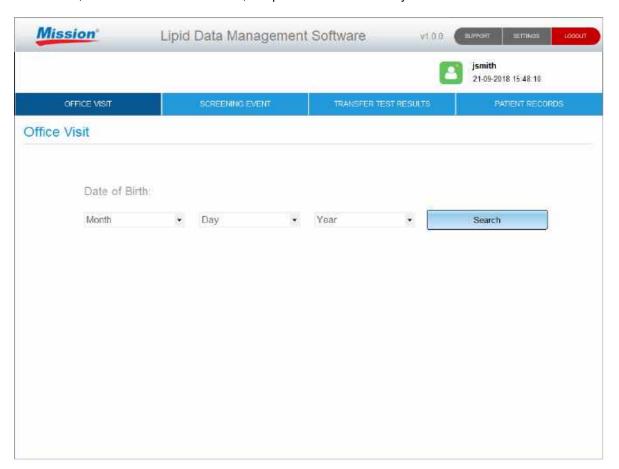


How Do I Clear the Meter Memory - PDF

Requires Adobe Acrobat Reader

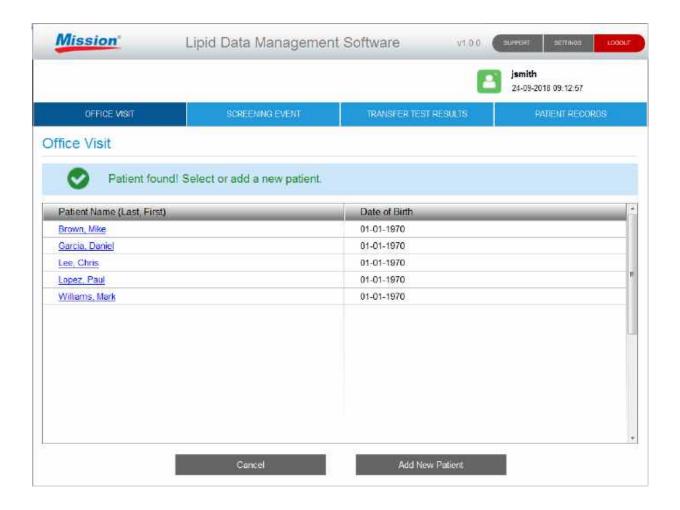
5.2 Enter Date of Birth

Click on the Office Visit button (if you are not already on the Home screen). Enter the patient's date of birth to locate, or confirm the existence of, the patient record in the system.



5.2.1 Patient Record Found

All patient records associated with the entered date of birth will be listed. Select the correct patient from the list by clicking on the patient name. The patient record will open. Update the patient's vital information. Confirm answers to health questions and update if necessary. Click "Save."



If none of the patients listed are the correct patient, click "Add New Patient" and a new record will open. Complete all fields and click "Save."

5.2.2 Patient Record Not Found (Creating a Patient Record)

If no patient records associated with the entered date of birth are found, a new record will open. Complete all fields and click "Save."

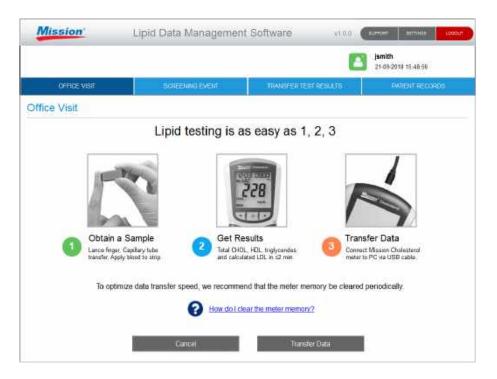
5.3 Perform Test Using Mission Meter

Perform lipid testing with your Mission brand meter. See the meter user manual and/or quick reference guide for more details on how to perform a test using the Mission meter. Results may be viewed on the meter screen within 2 minutes. Remove used test device/cartridge after results are displayed on meter.

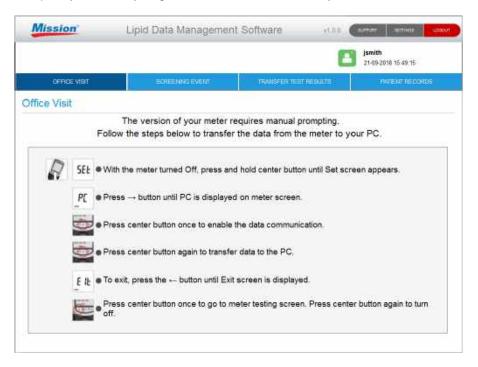
5.4 Transfer Test Data

Make sure the Mission meter is connected to your computer using a USB to mini-USB cable. Click the "Transfer Data" button.

Note: Never click the "Transfer Data" button before removing the used test device/cartridge and connecting the meter to your computer.



If your meter is an earlier model (uni-directional), you will see special instructions on the screen explaining how to quickly and easily begin the data transfer manually.



5.5 Patient Report

After the test data transfer, a personalized patient report will be generated automatically, and will appear like the one shown on the next page. If the personalized patient report does not appear on the screen, make sure the used test device/cartridge has been removed from the meter. To print the report, click the

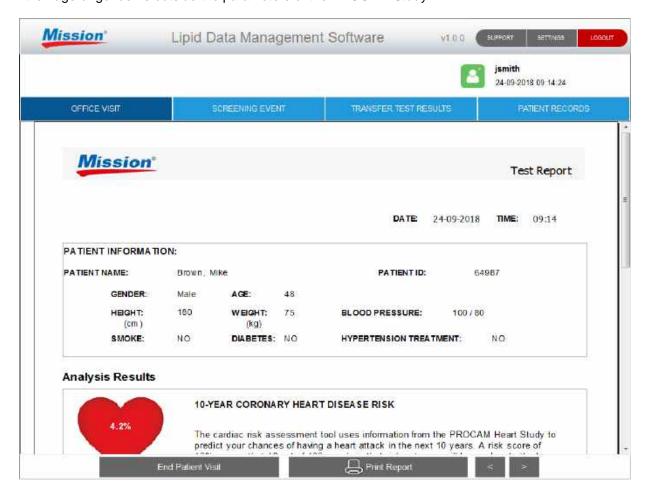
"Print Report" button. Otherwise, click the "End Patient Visit" button to return to the Home screen without printing a report.

The patient report contains general health information, 10-year coronary heart disease risk, "heart age" (only if the Framingham scoring method is selected in the software settings), test results, and any historical lipid test results. The value of providing patients with a personalized report is that it can serve as an education tool and a motivator for patients to make lifestyle changes. The patient report may be printed using a local or networked printer; however, use a local/non-networked printer to print in color.

Note: This software utilizes the most up-to-date CHD risk algorithms available. Since earlier versions of the meter may not have the updated algorithms, some differences may be observed between the CHD risk stated on the report and the CHD risk generated by the meter individually.

Note: When "Framingham" has been selected in the software settings, the 10-year risk and heart age calculators in the report is based on data from the Framingham Study and are meant for individuals 30-74 years old who have no history of cardiovascular disease (heart attack, stroke, peripheral artery disease or heart failure). A patient's CHD risk may be overestimated or under estimated by these calculators if their age is outside this reference age range.

Note: When "PROCAM" has been selected in the software settings, the 10-year risk calculator in the report is based on data from the PROCAM Study and is used for estimating overall CHD risk in men 35-65 years old who have no history of cardiovascular disease (heart attack, stroke, peripheral artery disease or heart failure). A patient's CHD risk may be overestimated or underestimated by this calculator if their age or gender is outside the parameters of the PROCAM Study.



6. Screening Event

The Screening Event mode is for use in a screening event setting, such as a pharmacy or health fair. The workflow is very similar to the Office Visit workflow and consists of the following:

- 1) Name the screening event and provide event date
- 2) Clear meter memory before screening event (optional, but recommended)
- 3) Ask the screening participant some questions
- 4) Perform lipid testing; remove used test device/cartridge from meter
- 5) Transfer test data from the meter to the computer
- 6) Generate a patient report
- 7) End screening event

6.1 Name Screening Event and Enter Event Date

Click on the Screening Event button. Screening events require names and dates to be searchable in the system. Establish a consistent naming convention for events (with consistent spelling as well). This will make it easier to pull up information in organized groupings.

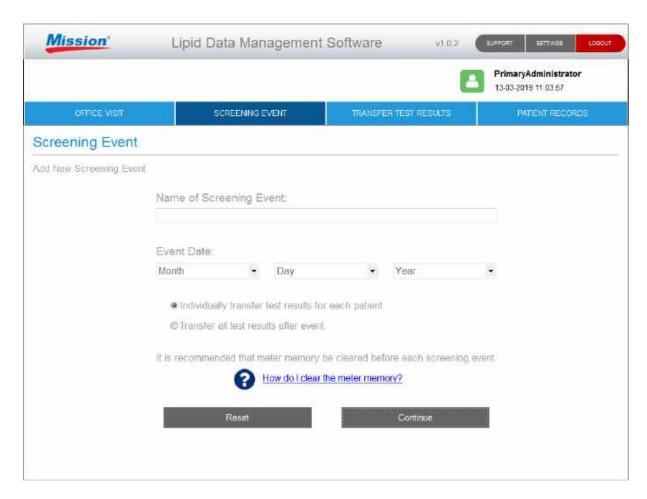
This software provides two options for conducting Screening Events:

Test results are transferred individually

Each participant's height, weight, and blood pressure are taken, the screener asks a few questions to identify the individual and their risk factors, a lipid test is run, test results are transferred from the meter, a patient report is provided to the participant.

All test results are transferred after the event

Participants complete a questionnaire. Their height, weight and blood pressure are taken, and lipid tests are run. After the event, test data is transferred and patient reports are sent out.



6.2 Clear the Meter Memory

To optimize data transfer speed during screening events, it is recommended that the meter memory be cleared prior to the event. For instructions on how to clear the meter memory, click on the link called "How do I clear the meter memory?" This link navigates directly to the Support page, which can also be opened from the Support button in the top navigation bar.

Optimize Data Transfer

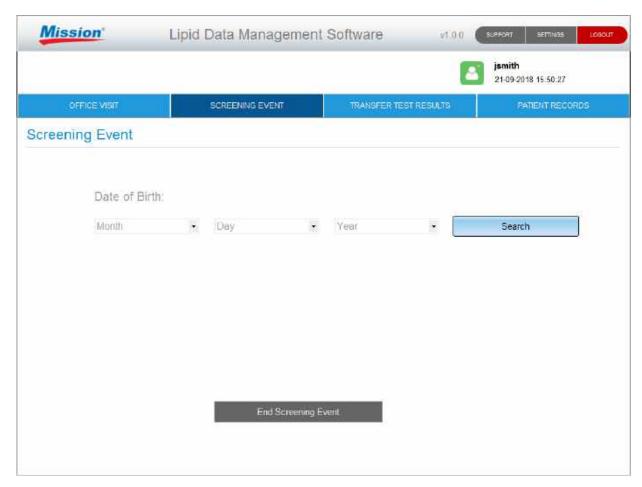


How Do I Clear the Meter Memory - PDF

Requires Adobe Acrobat Reader

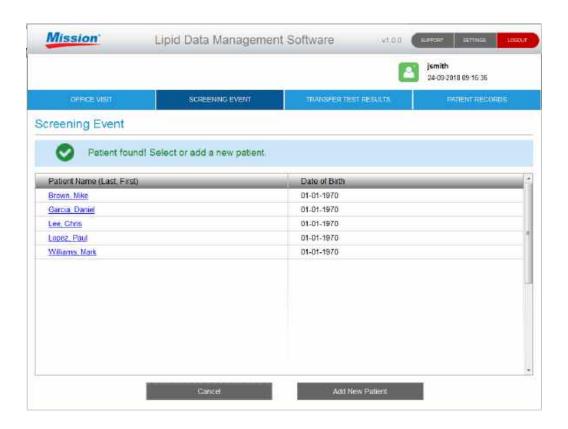
6.3 Enter Date of Birth

Enter the screening participant's date of birth to locate, or confirm the existence of, their record in the system.

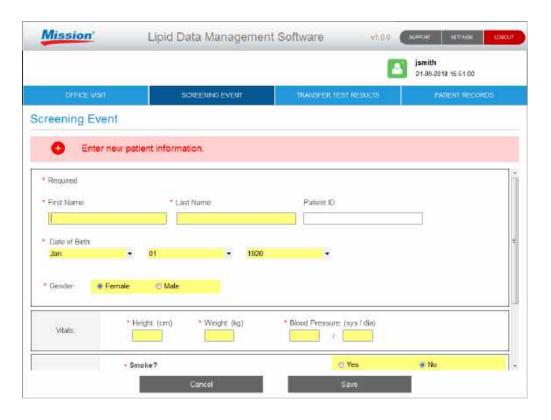


6.3.1 Patient Record Found

All screening participant records associated with the entered date of birth will be listed. Select the correct name from the list by clicking on the participant's name. The record will open. Update the participant's vital information. Confirm answers to health questions and update if necessary. Click "Save."



If none of the names listed are the correct participant, click "Add New Patient" and a new record will open. Complete all fields and click "Save."



6.3.2 Patient Record Not Found (Creating a Patient Record)

If no records associated with the entered date of birth are found, a new record will open. Complete all fields and click "Save."

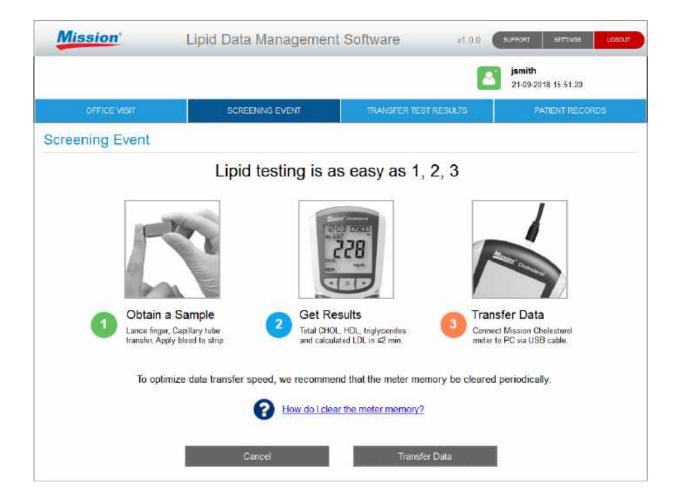
6.4 Perform Test Using Mission Meter

Perform lipid testing with your Mission brand meter. See the meter user manual and/or quick reference guide for more details on how to perform a test using the Mission meter. Results may be viewed on the meter screen within 2 minutes. Remove used test device/cartridge after results are displayed on meter.

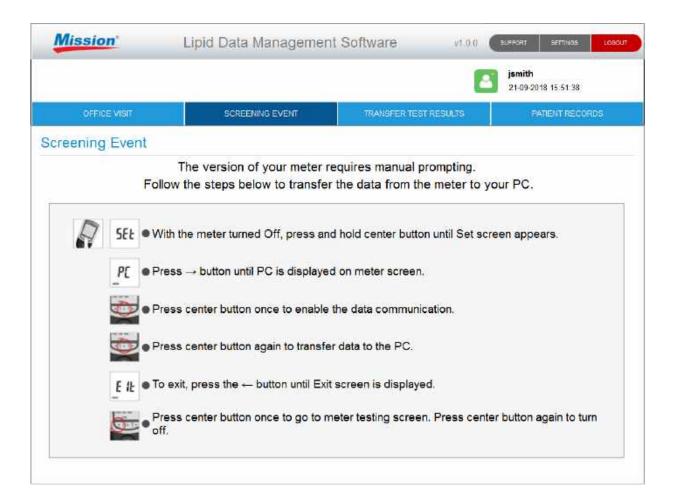
6.5 Transfer Test Data

Make sure the Mission meter is connected to your computer using a USB to mini-USB cable. Click the "Transfer Data" button.

Note: Never click the "Transfer Data" button before removing the used test device/cartridge and connecting the meter to your computer.

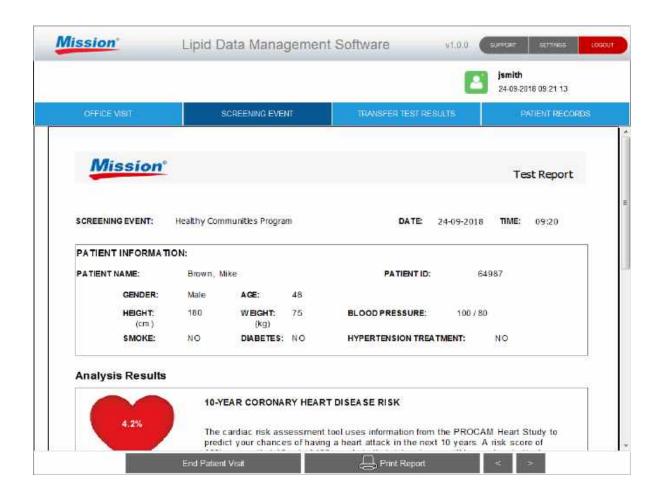


If your meter is an earlier model (uni-directional), you will see special instructions on the screen explaining how to quickly and easily begin the data transfer manually.



6.6 Patient Report

After the test data transfer, a personalized report will be generated automatically, and will appear like the one shown below. If the personalized patient report does not appear on the screen, make sure the used test device/cartridge has been removed from the meter. To print the report, click the "Print Report" button. Otherwise, click the "End Patient Visit" button to screen the next screening participant.



The report contains general health information, 10-year coronary heart disease risk, "heart age" (only if the Framingham scoring method is selected in the software settings), test results, and any historical lipid test results. The value of providing participants with a personalized report is that it can serve as an education tool and a motivator for individuals to make lifestyle changes. The patient report may be printed using a local or networked printer; however, use a local/non-networked printer to print in color.

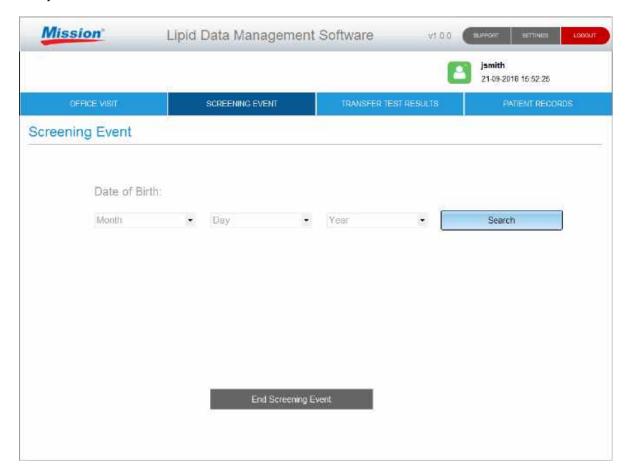
Note: This software utilizes the most up-to-date CHD risk algorithms available. Since earlier versions of the meter may not have the updated algorithms, some differences may be observed between the CHD risk stated on the report and the CHD risk generated by the meter individually.

Note: When "Framingham" has been selected in the software settings, the 10-year risk and heart age calculators in the report is based on data from the Framingham Study and are meant for individuals 30-74 years old who have no history of cardiovascular disease (heart attack, stroke, peripheral artery disease or heart failure). A patient's CHD risk may be overestimated or underestimated by these calculators if their age is outside this reference age range.

Note: When "PROCAM" has been selected in the software settings, the 10-year risk calculator in the report is based on data from the PROCAM Study and is used for estimating overall CHD risk in men 35-65 years old who have no history of cardiovascular disease (heart attack, stroke, peripheral artery disease or heart failure). A patient's CHD risk may be overestimated or underestimated by this calculator if their age or gender is outside the parameters of the PROCAM Study.

6.7 End Screening Event

When the last screening participant has been screened and the report generated, click the "Print Report" button to print the patient report. Otherwise, click the "End Patient Visit" button to go back to the Screening Event Date of Birth Screen. Then click the "End Screening Event" button to close the event for that day.



7. Transfer Test Results

Use the "Transfer Test Results" mode to transfer all data records in your meter at the same time (instead of individually). Typically, this is done at the end of the day, when patients are no longer present.

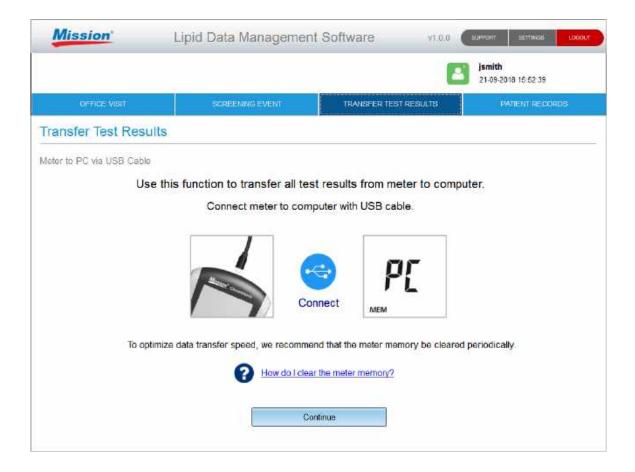
Note: If you plan to use this feature, you must record each person's name, date of birth and gender in the order in which they are tested. To utilize the report risk calculator, you will need to include the following additional information:

- Height
- Weight
- Blood pressure
 - -AND-
- Whether they smoke, have diabetes, are receiving hypertension treatment, or have a family history of premature heart attack (< 45 years old)

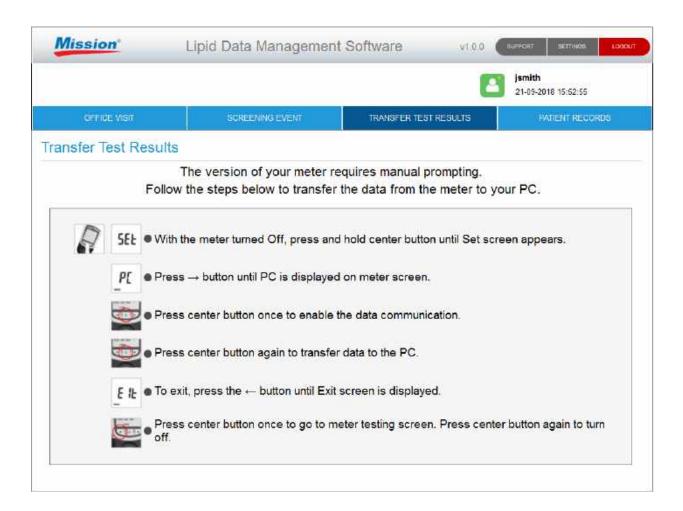
(Users outside the US should also record control tests in the order in which they are run.) You will need to refer to this list when assigning test data to the correct patient or control record in the database.

7.1 Perform Bulk Data Transfer

- 1. Click on the Transfer Test Results button
- 2. Connect meter to PC (with a USB to mini-USB cable)
- 3. Click Continue button to start data transmission

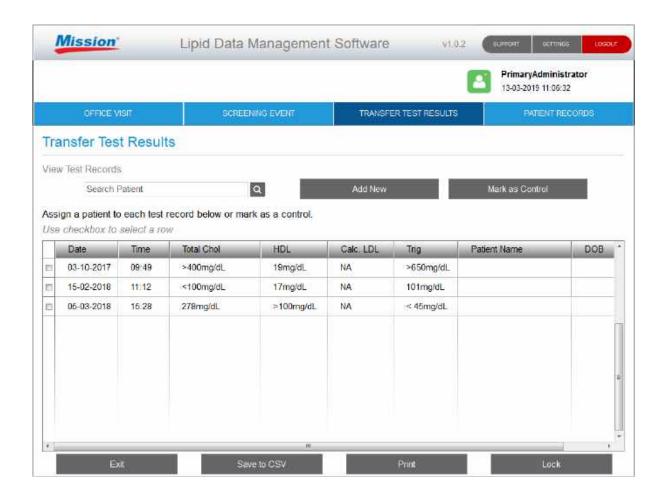


Note: Earlier meter versions require manual data transmission. If your meter requires manual transmission, a list of easy instructions will be displayed on your monitor screen after you click the Continue button.



7.2 Assign Test Data to Patient Records

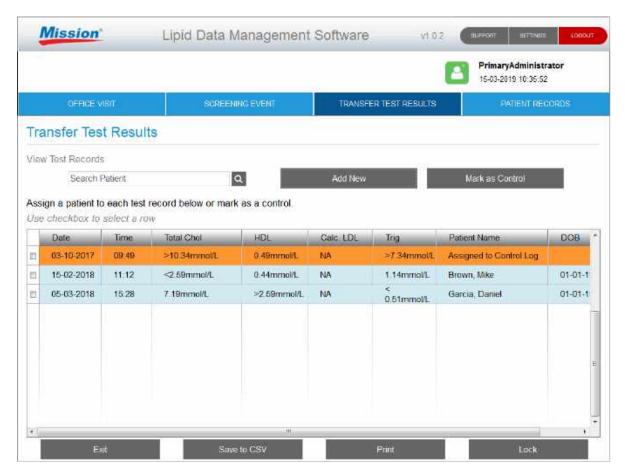
 Before moving to the next step, open the patient list that was created as each individual/control was being tested. (It **must** be in the same order as the order in which each patient/control was tested.) Use this list as a guide to determine which test record belongs to which patient.



- 2. Once the data transfer has been completed, each row of test data will be displayed according to date and time, with oldest first, as shown above. Select the <u>first</u> row by using the checkbox and choose from the following three functions listed below.
 - Search Patient: To search for an existing patient record in the patient database, type the patient's name (last, first) into the search box and select the appropriate patient from the drop-down menu. The patient record will open. To assign the highlighted row of test data to the open patient record, click "Save" or "Save and Print Report."
 - Add New: If a patient is definitely not in the patient database, click the "Add New" button. A new patient record will open. Complete fields with as much information as is available. To assign the highlighted row of test data to the open patient record, click "Save" or "Save and Print Report."
 - Mark as Control: If the test data belongs to a liquid control, click the "Mark as Control" button, which will send the test data to the control solution log. (If you are using a US meter, the controls will be recognized by the software and sent to the control solution log automatically.)

3. Each time one of these three functions is performed, the rows of test data will be displayed, along with the name of the patient to which the data has been assigned (or if it has been assigned to the Control Solution Log). Continue assigning rows of test data (from bottom to top) until they have all been assigned.

Note: If the user finds it necessary to step away from the computer while assigning test data to patient records, the session may be locked for security purposes by pressing the "Lock" button at the bottom of the screen. However, if another user logs in while the screen is locked, all unsaved test data will be lost. If this is a possibility, print or save the screen to a CSV file prior to locking the screen. The test data can be re-transferred later.



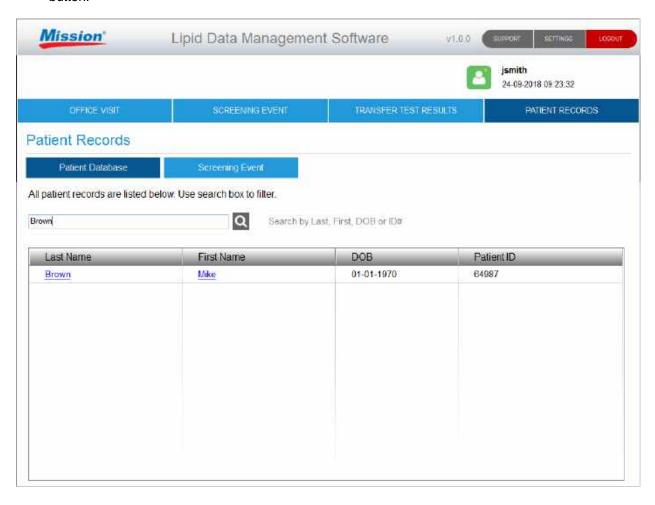
8. Patient Records

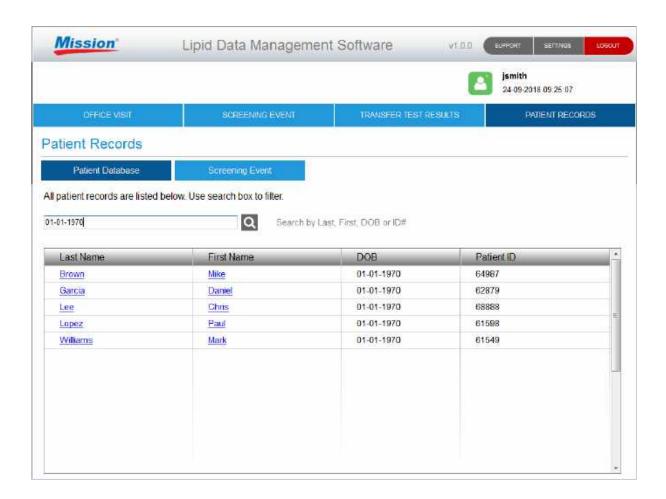
The Patient Records mode provides a quick way to access existing patient records and review past screening events.

8.1 Access Existing Patient Records

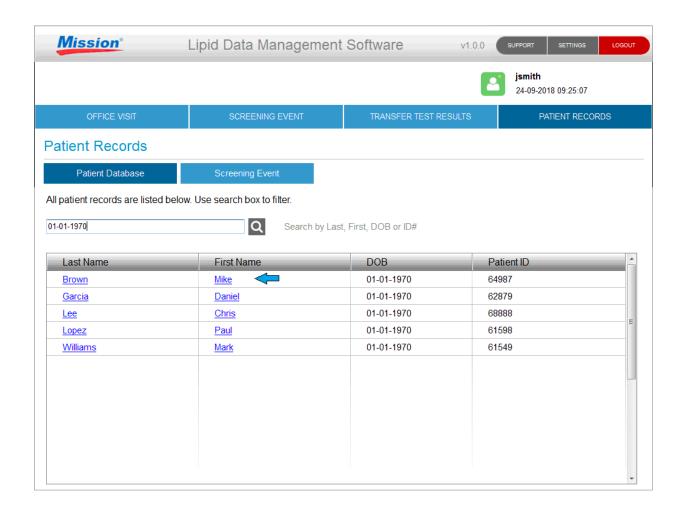
Click on the Patient Records button. This will automatically open to the Patient Database tab. To search for a patient record:

1. Enter the patient's last name, first name, Date of Birth or ID # in the search box. Click the search button.

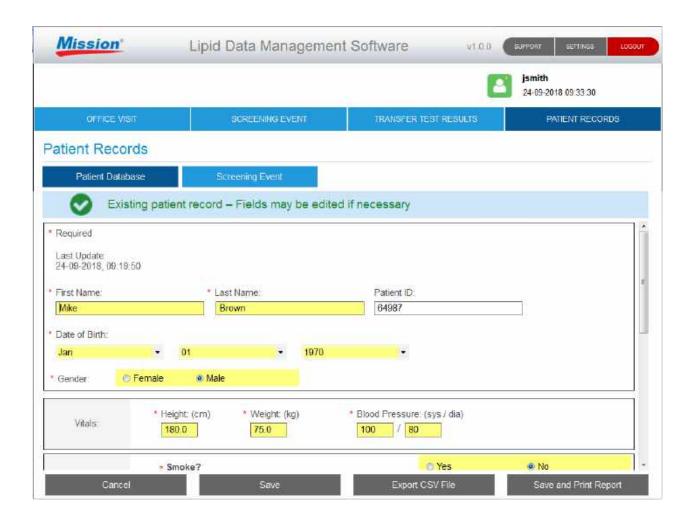




2. Identify the correct patient in the displayed listing and click on the corresponding row of patient information to open the patient record.



3. The displayed patient record may be Exported to a CSV file, Saved, or Saved/Printed. Any of these three functions will exit back to the Patient Records, Patient Database tab.

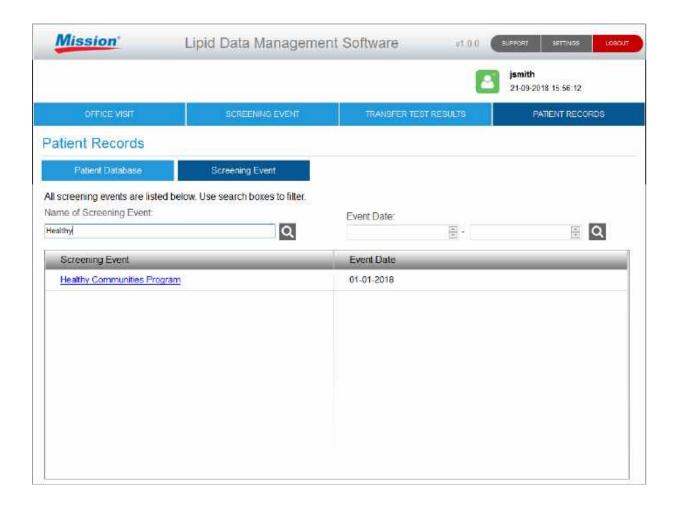


- 4. To see a list of all patient records in the database, clear text from the search box and click the search button.
- 5. To exit the Patient Records mode, simply click on any of the tabs in the sub-navigation bar: Office Visit, Screening Event or Transfer Test Results.

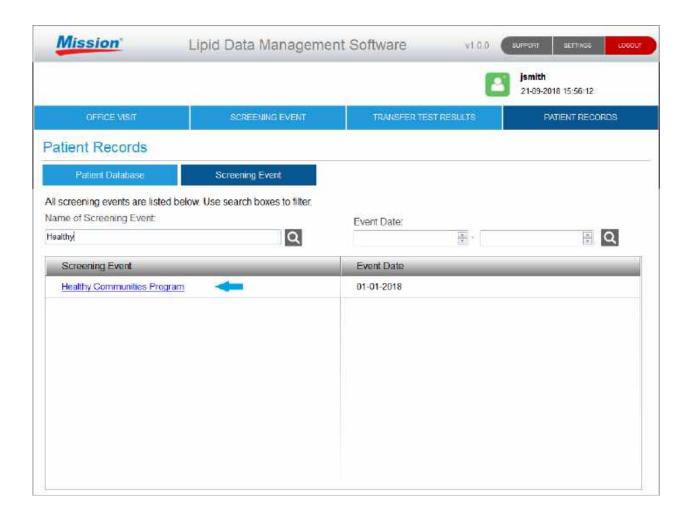
8.2 Access Past Screening Events

In the Patient Records mode, click on the Screening Event tab. To search for a past Screening Event:

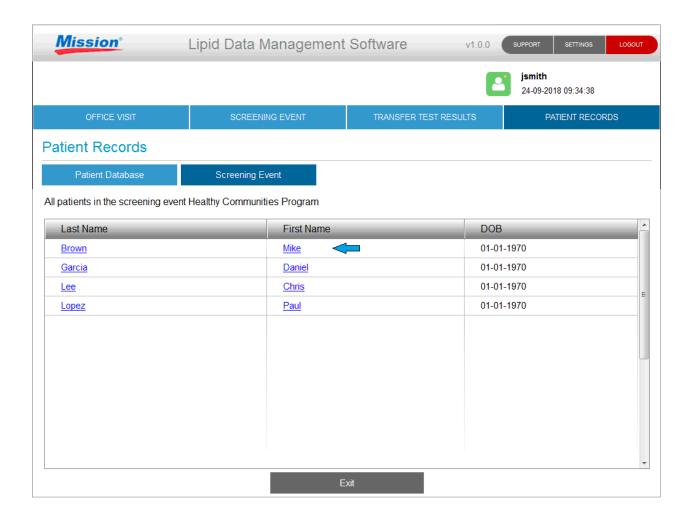
1. Use Screening Event name and/or Event Date range to search for the desired Screening Event.



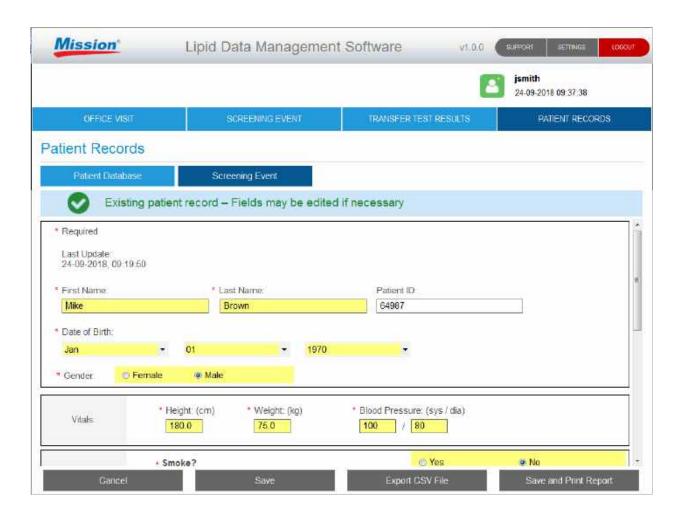
2. Identify the correct Screening Event in the displayed listing and click on the corresponding event name.



3. A listing of the event attendees will be displayed in the search window. Each attendee's patient record may be accessed by clicking on the attendee's name.



4. The displayed patient record may be Exported to a CSV file, Saved or Saved/Printed. Any of these three functions will exit back to the list of attendees for that event.



5. To exit the Patient Records mode, simply click on any of the tabs in the sub-navigation bar: Office Visit, Screening Event or Transfer Test Results.

9. Computer Security

For the security of your patient data, the Mission Lipid Data Management Software provides the following features:

- Encrypted stored patient data
- Automatic time-out after 20-minutes of inactivity
- Password-protected login