Mission®

Cholesterol Monitoring System

User's Manual

IVD

CE 0123

Mission® Cholesterol Monitoring System

Important Safety Instructions

- **If the meter is powered by AC adapter, unplug the equipment immediately after use.**
- **Misuse of electrical equipment can cause electrocution, burns, fire and other hazards.**
- **Do not place the equipment in liquid, nor put it where it could fall into liquid. If the equipment becomes wet, unplug it before touching it.**
- **If the meter is powered by AC adapter, do not leave the equipment unattended while it is plugged in.**
- **Use the equipment only for the purpose described in the instructions for use.**
- **Do not use accessories which are not supplied or recommended by the manufacturer.**
- **Do not use the equipment if it is not working properly or if it has suffered any damage.**
- **Do not let the equipment or its flexible cord come into contact with surfaces which are too hot to touch.**
- **Do not use the equipment where aerosol sprays are being used or where oxygen is being administered.**
- **Do not use the equipment in direct sun.**
- **Keep these instructions.**

Table of Contents

Section 1 Introduction

The *Mission*® Cholesterol Monitoring System is intended for the quantitative determination of Total Cholesterol (CHOL), High-Density Lipoprotein Cholesterol (HDL), Triglycerides (TRIG), calculated Low-Density Lipoprotein Cholesterol (LDL), and the calculated ratio of CHOL/HDL in capillary and venous human whole blood, plasma, and serum. Professionals can also evaluate a patient's 10-year risk of Coronary Heart Disease with this system. The easy-to-operate system consists of a portable meter that analyzes the intensity and color of light reflected from the reagent area of a test device, ensuring quick and accurate results.

The *Mission*® Cholesterol Monitoring System provides results in less than 2 minutes. The meter can store up to 200 results and records can be transferred to a computer for further analysis using the USB port. The meter can be operated with 4 AAA (1.5V) batteries or an optional AC adapter.

To ensure accurate results:

- Read instructions carefully and complete any necessary training before use.
- Use the code chip that is included in each box of test devices.
- Only use the *Mission*® Cholesterol Test Devices with the *Mission*® Cholesterol Meter.
- For *in vitro* diagnostic use only. Your blood cholesterol monitoring system is only to be used outside the body for testing purposes.
- For self-testing and professional use.
- For professional use: Fresh capillary blood, heparinized or EDTA venous whole blood, serum and heparinized plasma can be tested. For self-testing use: Only test fresh capillary blood from the fingertip.
- For self-testing, consult your physician or healthcare professional before making any adjustments to your medication, diet or activity routines.
- Keep out of reach of children.

Note: Throughout this User's Manual, meter parts or functions will appear in **bold**. Items appearing on displays are identified in ***bold italics***.

Section 2 Getting Started

Before testing, read the instructions carefully and learn about all the components of the *Mission*® Cholesterol Monitoring System. Depending on the package type, some of the components may need to be purchased separately. Please check the list of contents on the outer box for details on which components are included with your purchase. The following items are needed to perform a test:

Cholesterol Meter

Test Device

Control Device

Code Chip

Sterile Lancets

AAA Batteries

Safety Lancet

Control Solution

Capillary Transfer Tube/Dropper

Lancing Device

Carrying Case

Cholesterol Meter: Reads the test devices and displays the concentrations of CHOL, HDL, TRIG, and calculated LDL and CHOL/HDL values.

Test Devices: Part of the system, these are inserted into the meter to measure the concentrations of CHOL, HDL, and TRIG, from which LDL and the CHOL/HDL ratio are calculated.

Code Chip: Automatically calibrates the meter with the code number when inserted into the meter.

Capillary Transfer Tubes/Droppers: Collects capillary blood from fingertip blood testing for accurate results (10μL for an individual test and 35μL for a 3-in-1 test).

Capillary Transfer Tubes Insert: Provides detailed instructions on using the Capillary Transfer Tubes.

AAA Batteries: Provides power for the meter.

Carrying Case: Provides portability for testing.

User's Manual: Provides detailed instructions on using the Cholesterol Monitoring System.

Quick Reference Guide: Provides a brief overview of the Cholesterol Monitoring System and its testing procedures.

Test Devices Package Insert: Provides detailed instructions on using the Cholesterol Test Devices.

Lancing Device: Used with sterile lancets to prick the fingertip for blood specimen collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort. It can also eject the used lancets.

Lancing Device Package Insert: Provides detailed instructions on how to use the lancing device.

Sterile Lancets: Used with the lancing device to draw blood specimens for individual tests. Sterile lancets are inserted into the lancing device for each blood draw and discarded after use.

Safety Lancets: Used to draw blood specimens for the 3-in-1 test and individual tests. Discard after use.

Control Device: Verifies the proper operation of the meter by checking that the meter can detect a pre-calibrated value.

Control Device Package Insert: Provides detailed instructions on how to use the Control Devices.

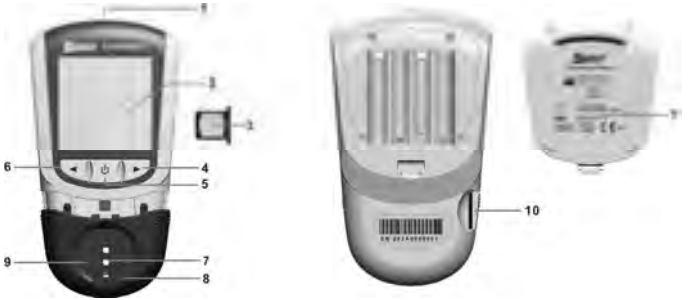
Control Solution: Verifies that the test is being performed correctly and validates that the test device and meter are working together properly.

Warranty Card: Card included in the package, which should be completed and returned to the distributor to qualify for the 2-year meter warranty.

Section 3 Components

The *Mission*® Cholesterol Meter reads the test devices and displays the concentrations of CHOL, HDL, TRIG, the calculated value of LDL and the ratio of CHOL/HDL. Use the below diagram to become familiar with all the parts of the meter.

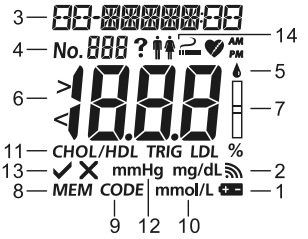
Meter



1	USB Port	**7**	Device Channel
2	Liquid Crystal Display (LCD)	**8**	Test Device Holder
3	Code Chip	**9**	Position Arrows
4	Right Arrow Button ►	**10**	Code Chip Slot
5	On/Off Button ⏻	**11**	Battery Cover
6	Left Arrow Button ◄		

Meter Display

During testing, the *Mission*® Cholesterol Meter will display icons showing the status, options available, and prompts for testing:



1	Battery Icon	**8**	Memory Indicator
2	Sound Icon	**9**	Code
3	Date	**10**	Measurement Units
4	Test Number	**11**	Test Item
5	Blood Drop Symbol	**12**	Systolic Blood Pressure
6	Test Result Area	**13**	Yes/No Option
7	Test Device Symbol	**14**	Options for Gender, Smoker or Non-smoker, and MI

Battery Icon: Appears when the battery should be replaced.

Sound Icon: Appears when the sound is turned on.

Date: Shows the current date or date tested.

Test Number: Indicates the specimen type and assigned test number.

Test Result Area: Displays the test result or menu options.

Memory Indicator (MEM): Appears when a test result is being recalled from memory.

Code: Shows the code number of the test devices.

Measurement Units: Displays the measurement units of the test result.

Test Device and Blood Drop Symbols: Indicate when to insert test device or apply specimen.

Test Item: Shows which item is being tested.

Systolic Blood Pressure: Needed for CHD risk analysis. Calculated CHD is for professional use only.

Yes/No Option: Displays answer to yes/no questions during CHD risk analysis. Calculated CHD is for professional use only.

Options for Gender, Smoker or Non-smoker, and MI: Displays answers to questions regarding gender, smoking status and history of heart attack (MI). Calculated CHD is for professional use only.

Meter Use and Precautions

- Do not get water or other liquids on or inside the meter.
- Keep the Device Channel clean.
- Keep the meter dry and avoid exposing it to extreme temperatures and humidity.
- Do not drop the meter or get it wet. If the meter is dropped in water or becomes wet, ensure the meter is working properly by running an Optical Check. Refer to Optical System Check for details.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to Maintenance for details on cleaning the meter.
- Keep the meter and all associated parts out of the reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.

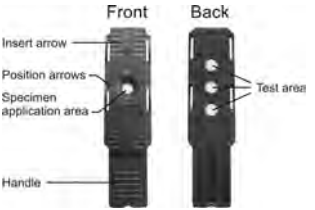
All EMC Preventative Warnings for the Cholesterol Monitoring System

1. This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.
2. This instrument complies with the emission and immunity requirements described in EN 61326-1 and EN 61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the meter.
3. For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

Test Devices

The *Mission*® Cholesterol Test Devices are plastic devices that work with the *Mission*® Cholesterol Meter to measure the lipid concentration in whole blood, plasma and serum.

Test device appears as shown below:



The following test devices are currently available for use with the *Mission*® Cholesterol Meter:

- 3-in-1 Lipid Panel
- Total cholesterol (CHOL) individual test device
- High-Density Lipoprotein (HDL) individual test device
- Triglyceride (TRIG) individual test device

The 3-in-1 Lipid Panel can detect CHOL, HDL and TRIG with one device simultaneously. Calculated LDL and the ratio of CHOL/HDL can also be calculated by the meter at the same time.

Insert Arrow: Located on the front of the test device, the arrows indicate the direction in which the test device should be inserted into the meter.

Specimen Application Area: After the test device is inserted into the Device Channel, apply the correct specimen volume (10µL for individual test devices or 35µL for 3-in-1 test devices) to the region in the center of the test device.

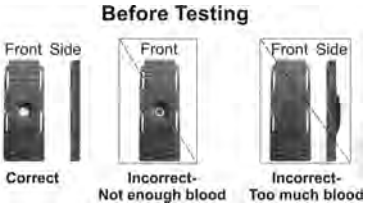
Handle: Located on the end of the test device, the handle is used to insert and remove the test device from the meter.

Test Area: Located on the back of the test device. The meter will detect and read this area to give results of lipid levels.

Position Arrows: Located in the middle of the specimen application area (of the test device). When a test device is inserted, the two arrows should be parallel with the two arrows on the meter holder to make sure the test device is inserted correctly.

Specimen Application

For best results, fill the Specimen Application Area with the correct specimen volume (10μL for individual test devices or 35μL for 3-in-1 test devices). Incorrect results may occur if the specimen is not applied correctly or if the Specimen Application Area is not filled with the correct amount, as shown in the pictures below.



After applying the specimen, ensure that the Specimen Application Area is completely covered. The Specimen Application Area should remain covered throughout the entire test. If the Specimen Application Area is not covered or if there is too much specimen covering the Specimen Application Area, repeat the test with a new test device.

Note: If the specimen applied to the Specimen Application Area is not enough, do not add more specimen to the test device. Instead, retest with a new device. If the E-5 Error or another error appears on the display, please discard the used device and retest with a new device.

Code Number

Printed on each package of test devices is a code number CODE, lot number LOT, unopened expiration date, and test quantity ▽.

Test Device Precautions and Instructions for Use

- Test Devices should be stored in their foil pouch to keep them in working condition.
- Do not store test devices outside of their package. Test devices must be stored in the original package.
- Do not transfer test devices to a new package or any other container.
- For *in vitro* diagnostic use. Test devices are to be used only outside the body for testing purposes.
- Use the test device immediately after removing it from the foil pouch.
- Do not use test devices that are torn, bent, or damaged in anyway. Do not reuse test devices.
- Before performing a test, make sure that the code number on the meter display matches the number shown on the test device foil pouch and on the ink-jet printing on the code chip.

Refer to the test device package insert for more details.

Control Devices

The *Mission*® Cholesterol CTRL Control Devices are gray and black devices, which work with the *Mission*® Cholesterol Meter to ensure the optical system is working properly. After the control device is inserted into the meter, the meter's optical system detects the color intensity of the reference pad in the control device. The meter displays ***YES*** or ***no*** to indicate whether the meter is functioning properly. Refer to Optical System Check for details.

The control device appears as shown below:

Precautions

- Store in the closed canister at room temperature or in the refrigerator within 2-30°C (36 – 86ºF). Avoid exposure to direct sunlight, extreme

temperatures, and humidity.

- Control devices should be stored in their tightly capped canister to keep them in working condition.
- Do not freeze or refrigerate.
- Keep the control devices clean. Do not touch the test area of the device.
- Remove the control device from its canister for immediate use. Put the control device back and close the canister tightly immediately after use. Do not use contaminated, discolored, or damaged control devices.
- Do not use after the expiration date.
- For *in vitro* diagnostic use only.

Storage and Handling

- Store test devices in a cool, dry place. Store away from heat and direct sunlight.
- Transport and store in its closed canister at a temperature between 2-30ºC (36-86ºF) with less than 90% humidity.
- Do not freeze or refrigerate.
- Replace the cap on the devices canister immediately after removing a device. Expired devices may produce incorrect test results.

Note: The expiration date is printed in a Year-Month format.

For example, 2011-01 is January, 2011.

Control Solution

The *Mission*® Cholesterol Control Solution contains stabilizers, preservatives and added chemicals. High-density lipoprotein (HDL) and triglyceride (TRIG) are included in the same control solution. Total Cholesterol (CHOL) is an individual control solution. To confirm that the test device and meter are working together properly and that the test is being performed correctly, the control solution is applied to the specimen well of a *Mission*® Cholesterol test device that has been inserted in the meter. Refer to the *Quality Control* section in the User's Manual for more information.

Note: The *Mission*® Cholesterol Control Solution is intended for validating cholesterol testing while using the *Mission*® Cholesterol Monitoring System. Both levels of control solutions must be tested and fall within the assigned values printed on the bottles.

Refer to the control solution package insert before using the controls. The control solution bottle is labeled with the acceptable range that is specific for that lot of control solution. The system is working properly if the control value displayed by the meter is within the acceptable range printed on the bottle label. If the value does not fall within the range, refer to the Control Solution Package Insert for further instructions.

Precautions

- Set the specimen type to blood (***bL***) before testing with the control solution.
- Make sure the control solution and all the test materials reach operating temperature of 20 - 40°C (68 - 104°F) prior to testing. The control solutions and test materials are only accurate within this temperature range.
- Use the control solution before the expiration date shown on the bottle.
- Discard the control solution if it appears cloudy.
- Use the *Mission*® Cholesterol Control Solution with the *Mission*® Cholesterol meter and test devices.
- Make sure the control solution bottle is tightly closed before use.
- The used device should be discarded according to local regulations after testing.
- Check the code chip before performing a test. Make sure to use the code chip that is included with the box of test devices.

Storage and Handling

- Store the control solution either refrigerated or at room temperature 2 - 30°C (36 - 86°F).
- Do not freeze.
- If the control solution has been refrigerated, allow it to warm up to a temperature of 20 – 40°C (68 - 104ºF) before use.
- Each control solution will expire 4 months after the bottle is opened for the first time. Record this expiration date on the bottle label.

  Note: The expiration date is printed in a Year/Month format.

  For example, 2016-01 is January, 2016.

Section 4 Initial Setup

Before testing, ensure the following procedures are followed.

Turn on Meter

The meter can be operated using the certified AC Adapter or 4 AAA batteries (1.5V).

To use the meter with batteries, insert 4 AAA batteries (1.5V) into the battery compartment on the back of the meter.

To use the meter with a power adapter, use a USB cable to connect the Mini USB port of the power adapter to the USB port on the top of the meter. Then plug the adapter into a 100-240V ac, 50-60 Hz primary power outlet.

The meter can also be powered from a personal computer with a USB cable.

OR

The meter will automatically turn on after the batteries are inserted. The meter will display the date and time setup screen. Refer to Meter Setup and Options for details. After the date and time have been set, the meter will automatically turn off.

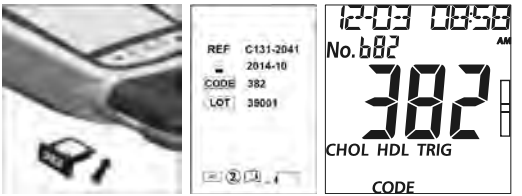
Press ⏻ to turn the meter on. The screen will briefly display all of the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on. There should not be missing icons or elements. After startup, ensure that there are no permanently turned on segments or icons. After the power-on diagnostic check, the Initial Screen will be displayed.

The meter will automatically turn off after 5 minutes of inactivity.

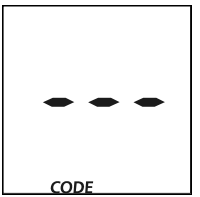
Coding the Meter

Each time a new box of test devices is used, the new **code chip** included in the box must be inserted into the meter. Compare the code number on the

code chip from the box with the code number printed on the test device foil pouch. Results may be inaccurate if the two numbers are not identical. Insert the new **code chip** into the **code chip slot** of the meter. It should easily snap into place. The **code chip** should remain in the meter. Do not take it out until a new box of test devices is needed. The code number will appear on the Initial Screen after startup.



If the **code chip** is not properly inserted into the **code chip slot** or if it is missing, the meter will display ***three dashes*** as shown below.



Section 5 Meter Setup and Options

With the meter turned off, press and hold ⏻ for 4 seconds to enter the **Meter Setup** mode, shown below.

Press ◄ or ► to display several setup sub-modes:

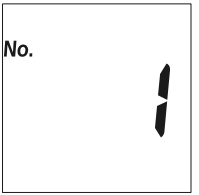
No. SEt	Test number setup. The test number can be set from 1 to 99.
CHE	**Optical Check** mode. Refer to Optical System Check.
SEt	System setup, including date, time, test number reset, units, sound, specimen type and CHD.
PC	**Data Transfer** mode. Refer to Data/Communication.
dEL	**Memory Delete** mode. Refer to Data/Communication.
Elt	Exit setup modes and save changes when ⏻ is pressed. The meter will automatically return to the Initial Screen.

Press ⏻ to enter the mode when the desired sub-mode is displayed.

Test Number Setup

From the ***No. SEt*** screen, press ⏻ to enter **Test Number Setup**.

The test number can be set to any number from 1 to 99.



Press ◄ or ► until the correct test number is displayed. To quickly cycle to the desired test number, press and hold ◄ or ►.

Press ⏻ to save and return to the **Meter Setup** screen.

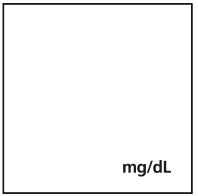
Note: Once the meter reaches test number 99, the next test number will be 1.

System Setup

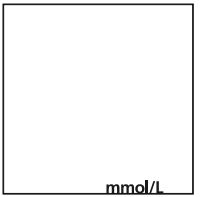
From the ***SEt*** screen, press ⏻ to enter the **System Setup**.

Unit Setup

The first option sets the units to either **mg/dL** or **mmol/L**. Press ◄ or ► to switch between the two settings.



OR



Hour Setup

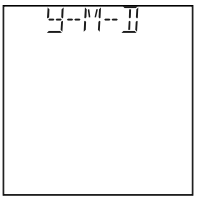
The second option sets the clock to either **12** or **24 hour** mode. Press ◄ or ► to switch between the two settings.

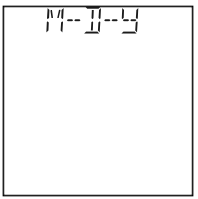
OR

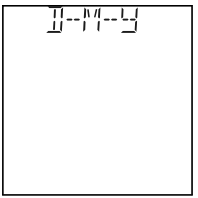
Press ⏻ to save and advance to **Date Setup**.

Date Setup

The third option sets the date to Y-M-D, M-D-Y or D-M-Y mode. Press ◄ or ► to switch between the three settings.





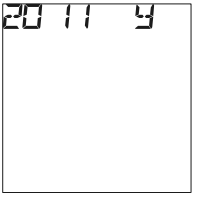


Press ⏻ to save and advance to the **Year Setup**.

Note: The date in the display will be shown in the form of M-D or D-M according to the mode you select. However, the year will not be shown on the display due to limited space. The year will only be shown during data transfer, such as printing or exporting data to computer.

Year Setup

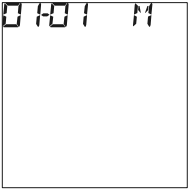
The year will appear at the top of the display with **Y** indicating year setup. Press ◄ or ► until the correct year is displayed.



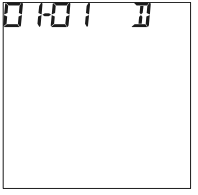
Press ⏻ to save and enter the **Month and Date Setup**.

Month and Date Setup

The month and date will appear at the top of the display separated by a single dash (**-**), with the month flashing. **M** will also appear indicating month setup. Press ◄ or ► until the correct month is displayed.



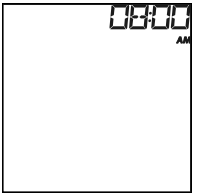
Press ⏻ to save. The day will flash and **D** will appear indicating day setup. Press ◄ or ► until the correct day is displayed.



Press ⏻ to save and proceed to **Time Setup**.

Time Setup

The hour and minutes will appear at the top of the display separated by a colon, with the hour flashing.



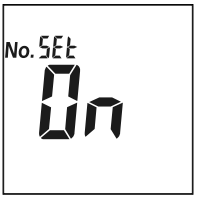
Press ◄ or ► until the correct hour is displayed. Press ⏻ to save and proceed to **Minutes**.

Note: The meter will display ***AM*** or ***PM*** if the 12H time setting is chosen.

Minutes will flash. Press ◄ or ► until the correct **Minutes** are displayed. Press ⏻ to save and proceed to Test Number Reset Setup.

Test Number Reset Setup

Press ◄ or ► to turn the test number reset ***On*** or ***OFF***. The test number will reset to 1 for each new day of testing when the test number reset is turned on.



OR

Press ⏻ to save and proceed to **Sound Setup**.

Sound Setup

Press ◄ or ► to select sound either ***On*** or ***OFF***. The ***Sound Symbol*** will appear on the display when the sound is turned on. Press ⏻ to save and proceed to CHD Setup.

OR

CHD Setup

Press ◄ or ► to set CHD to either ***On*** or ***OFF***. When CHD is set to ***On***, the meter can enter the Coronary Heart Disease risk evaluation. Press ⏻ to save and proceed to Specimen Type Setup.

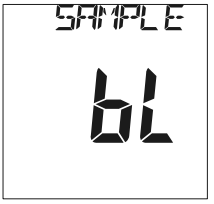
For professional use: Use this function to evaluate the 10-year CHD risk of your patients.

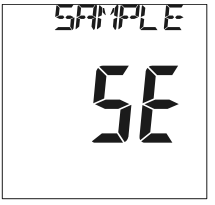
This function is not designed for self-testing use. It can only be used by professionals.

OR

Specimen Type Set Up

Press ◄ or ► to set specimen type to either ***bL*** or ***SE***. When specimen type is set to ***bL***, control solution, fresh capillary blood, EDTA or heparinized venous whole blood can be used. When specimen type is set to ***SE***, serum and heparinized plasma can be used. Press ⏻ to save and return to the setup screen.





Note: ***bL*** means Whole Blood, ***SE*** means Plasma and Serum.
SE is for professional use only.

Press ◄ or ► until ***Elt*** is displayed. Press ⏻ to exit the setup. The screen will briefly go blank and then display the Initial Screen.

Section 6 Testing

Before performing any test, the user should review the *Mission*® Cholesterol Monitoring System's User's Manual for detailed instructions. The following steps show how to use each component to measure lipid concentrations.

Specimen Collection

- For self-testing, use only fresh capillary blood from the fingertip. Please refer to Self-Testing on page 23 for details.
- For professional testing:
  1. Use fresh capillary blood from the fingertip. Please refer to Self-Testing on page 23 for details.
  2. Use heparinized or EDTA venous whole blood, serum and heparinized plasma specimens. Please refer to Professional Testing below.

Note: Before testing, choose a clean, dry work surface. Review the procedure and make sure all of the items needed to obtain a sufficient amount of blood are available.

Professional Testing (Testing with heparinized or EDTA venous whole blood, serum and heparinized plasma)

For heparinized or EDTA venous whole blood, serum and heparinized plasma, mix the specimen well, then collect specimen (10 µL for individual test, 35 µL for 3-in-1 test) into a capillary transfer tube or pipette. Apply it to the center region of the Specimen Application Area of the test device. Do not touch test device with the pipette or tube.

- Specimen must be tested within 8 hours of collection.
- Mix the specimens well before testing in order to ensure the cellular components are evenly distributed.
- Allow the specimen to come to an operating temperature of (15-40°C or 59-104°F) for approximately 15 minutes if the specimen has been refrigerated.
- Anticoagulants other than EDTA and heparin are not recommended.

Note: Refer to NCCLS Documents H3-A6, Collection of Diagnostic Blood Specimens by Venipuncture.

Self-Testing (Testing with fingertip blood)

Wipe away the first drop of blood. Collect capillary blood (10 µL for individual test, 35 µL for 3-in-1 test) using a capillary transfer tube or pipette.

When collecting the blood sample into the capillary tube, it is important not to squeeze the bulb and/or cover the air vent. Holding the tube at a slightly downward angle, touch the tip of the capillary tube to the blood drop. The blood will automatically be drawn to the black fill line and stop.

Note: Never squeeze the capillary transfer tube and/or cover the air vent while collecting the blood sample. Make sure that blood reaches the black line, or it will be difficult to squeeze the blood out of the tube.

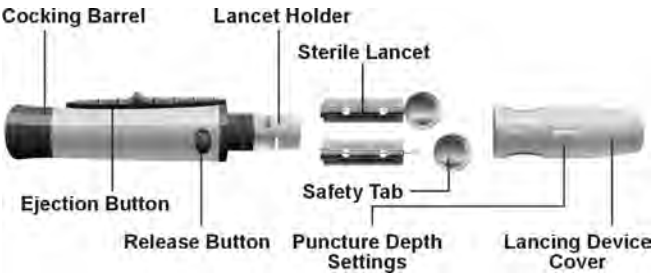
Align the tip of the capillary transfer tube with the sample application area on the test device. Squeeze the bulb and cover the air vent to apply the blood sample to the sample application area (approximately 10 µL for individual test, 35 µL for 3-in-1 test).

Note: Do not touch the test device with the capillary transfer tube or pipette. The capillary blood should be tested immediately after collected. Use of a capillary transfer tube or pipette is recommended for accurate results.

Blood specimens for the 3-in-1 Lipid Panel or the individual tests can be obtained by using a safety lancet. . (For individual tests only, a lancing device may also be used.)

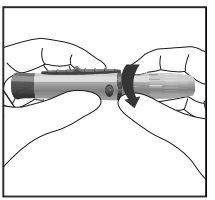
Lancing Device (For individual tests only)

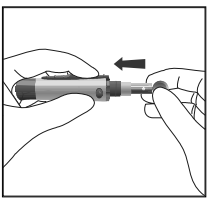
Refer to the instructions below for details.



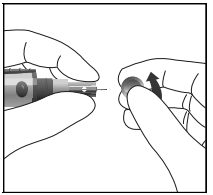
For obtaining a drop of blood from the fingertip, adjust the penetration depth on the lancing device to reduce discomfort.

Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.

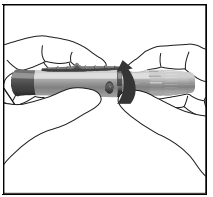




Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens. Then pull the safety tab off the lancet. Save the safety tab for lancet disposal.

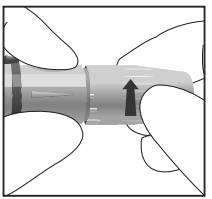


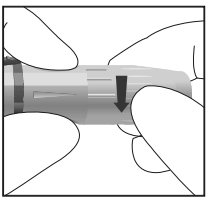
Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully seated on the lancing device.



Adjust the puncture depth by rotating the lancing device cover. There are a total of 6 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.

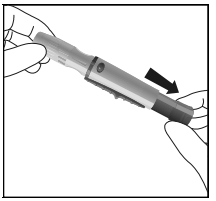
Use settings 1 and 2 for delicate skin, 3 and 4 for normal skin, or 5 and 6 for calloused or thick skin.





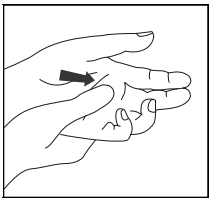
Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

Pull the cocking barrel back to set the lancing device. A click may be heard. The device is now loaded and ready to obtain a drop of blood.

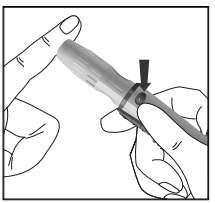


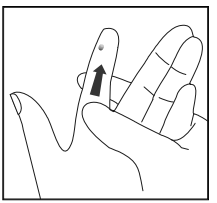
Prior to testing, make sure the patient‘s hand is warm and relaxed before collecting the capillary blood specimen. Use warm water to increase blood flow if necessary. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

Clean the testing site with an alcohol swab or by washing hands with warm soapy water and then dry the testing site thoroughly.



Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick the fingertip. A click should be heard as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood. For the greatest reduction in pain, lance the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make the fingers sore and callused.



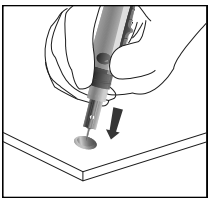


Note: Make sure the patient's hand is warm and relaxed before collecting a capillary blood specimen. Use warm water to increase blood flow if necessary.

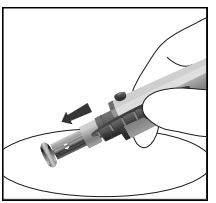
Don't use an infection swab containing iodine. This can give inaccurate results.

Disposal of the Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface. Carefully insert the lancet needle into the safety tab.



Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to eject the used lancet. Place the lancing device cover back on the lancing device.



Note: For professional use, please refer to NCCLS Documents H04-A6, Collection of Diagnostic Capillary Blood Specimens.

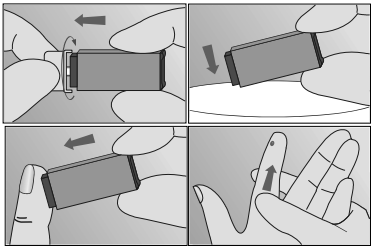
Safety Lancets (For 3-in-1 test and individual tests)

Carefully rotate and pull off the protective cap.

After cleaning the skin, hold the lancet firmly against the puncture site.

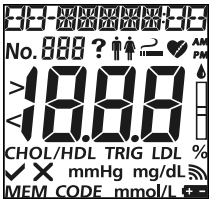
Press the lancet against the puncture site tightly to lance the skin. Discard the lancet in an appropriate sharps container.

Gently massage the surrounding area toward the puncture site to collect the required blood volume.



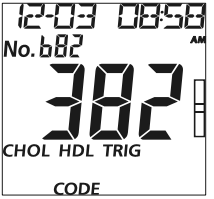
Test Processing

Ensure the meter is set up properly, as described in previous sections. Turn the meter on. The screen will briefly display all of the LCD symbols. Observe the LCD at startup to ensure all segments and display elements are turned on. There should be no missing icons or elements. The meter will briefly show a blank display. Ensure that there are no segments or icons permanently turned on.



After startup, the Initial Screen will be displayed. Ensure the code chip is inserted. Compare the number showed in the display with the code number printed on the foil pouch. Refer to Initial Setup. The ***test device symbol*** will flash when the meter is ready for the device to be inserted.

Check that the specimen type displayed on the meter LCD is the same as the specimen type being tested. If not, set the correct specimen type. Refer to Section 5 Specimen Type Set Up.

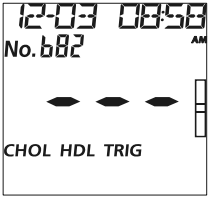


Testing

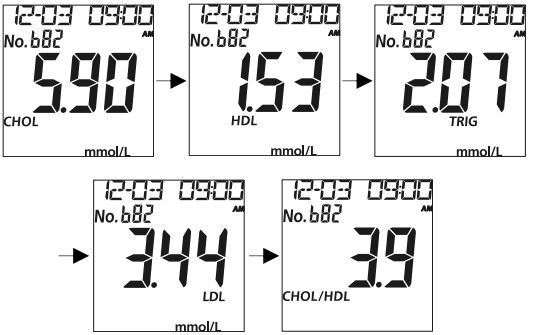
Insert a test device into the Device Channel of the meter in the same direction as the arrow on the test device. Ensure that the test device is inserted all the way to the end of the Device Channel, until the position arrows on the test device are parallel with the two arrows on the Device Holder.

The ***blood drop symbol*** will flash when the meter is ready for the specimen to be applied. Apply the blood specimen (10 µL for individual test, 35 µL for 3-in-1 test) to the center region of the Specimen Application Area of the test device.

The meter will begin testing automatically with ***three dashes*** in a line flashing on the display indicating the test is in progress.



Results will be displayed within 2 minutes. Press ► to view the results.



Note: The date in the display will be shown in the form of M-D or D-M according to the mode you previously selected.

Remove the used test device. The meter will return to the Initial Screen and is ready for another test device to be inserted so a new test can be performed.

Note: Discard all blood specimens, used test devices, and materials carefully. Treat all blood specimens as if they were infectious material. Follow proper precautions and obey all local regulations when discarding blood specimens and materials.

Perform daily cleaning when testing is completed for the day. Refer to the Maintenance section.

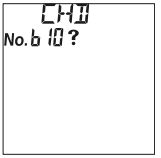
The meter will automatically turn off after 5 minutes of inactivity or when ⏻ is pressed. If the meter is powered with an AC adapter, turn off the meter before removing it from the power outlet. Remove the batteries if the meter will not be used for an extended period of time.

Section 7 Coronary Heart Disease (CHD) Risk Evaluation

Note: This function is for professional use only. This function is not for self-testing use.

If CHD is set to ***On*** during setup, the *Mission*® Cholesterol Monitoring System will automatically evaluate a patient's 10-year risk of Coronary Heart Disease, based on the results of their 3-in-1 Lipid Panel test.

In the results screen for LDL, press ► to enter the CHD risk evaluation screen.



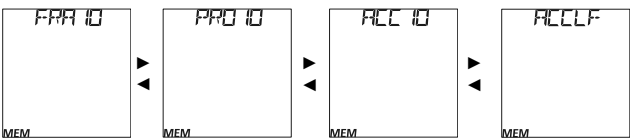
Press ⏻ to enter the evaluation method. There are four methods to choose from: FRA10, PRO10, ACC10 and ACCLF.

FRA10 (CHD 10-year risk estimation based on Framingham Heart Study) is popular in the United States and is suitable for both men and women ages 20-79 years old.

PRO10 (CHD 10-year risk estimation based on Procam method) is popular in Europe and is suitable for men ages 35-65 years old.

ACC10 (CHD 10-year risk estimation by ACC/AHA) is a sex-specific and race-specific modification based on FRA method, suitable for men and women ages 40-79 years old.[1]

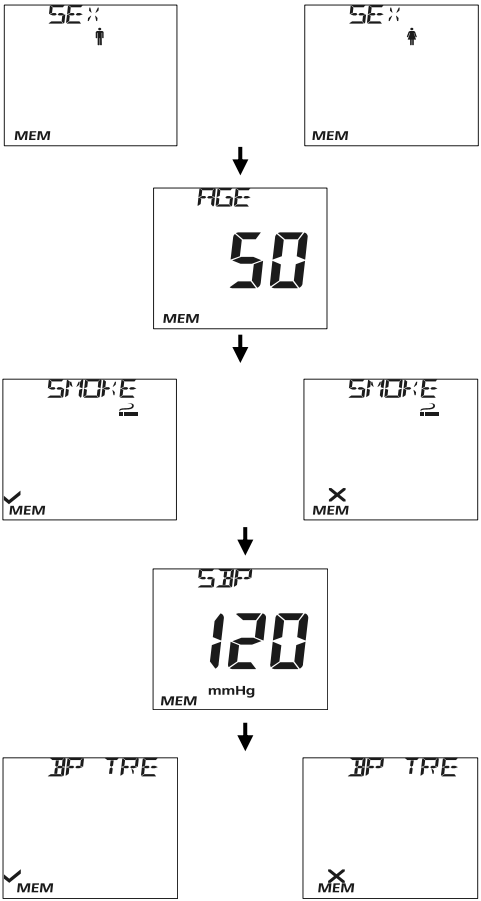
ACCLF (CHD lifetime risk estimation by ACC/AHA) is suitable for men and women ages 20-59 years old who are free from CHD and not at high short-term risk.[1]



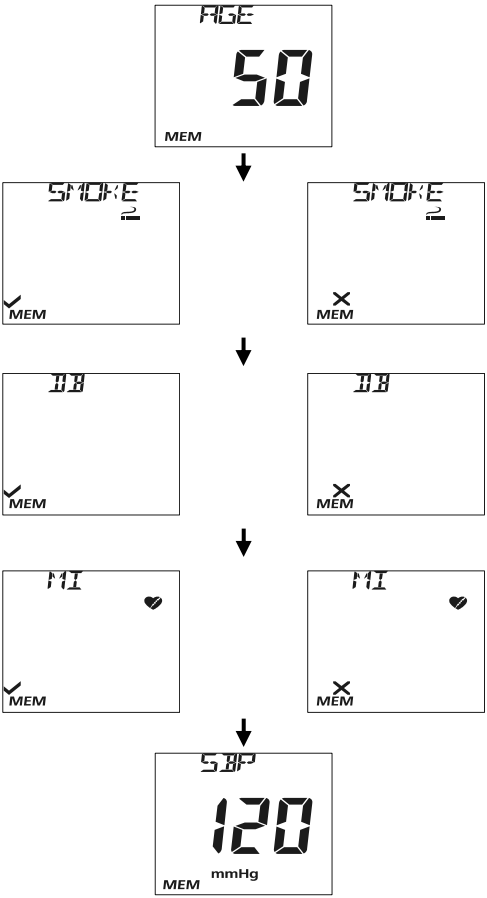
Press ⏻ to choose the method.

[1] Goff DC Jr, et al. 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation, journal of American Heart Association. 2013.

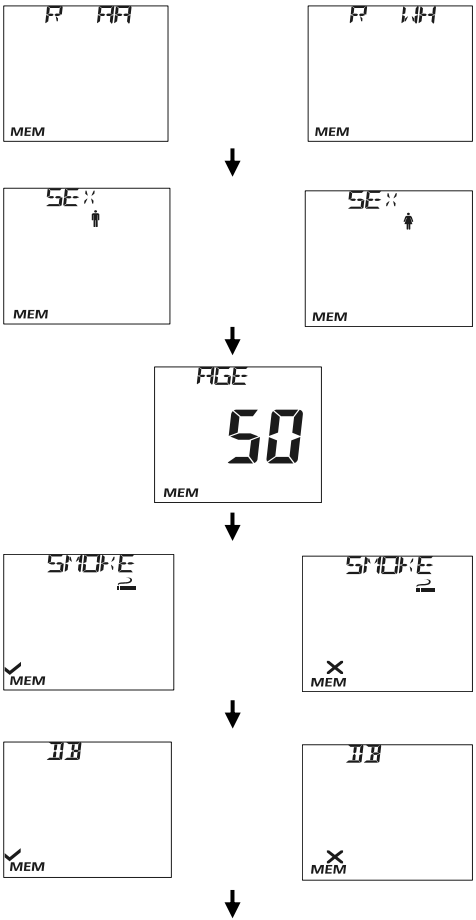
If FRA10 is chosen, Press ⏻ to enter patient information regarding gender, age, smoker or non-smoker, Systolic Blood Pressure (SBP), and blood pressure treatment (BP TRE).

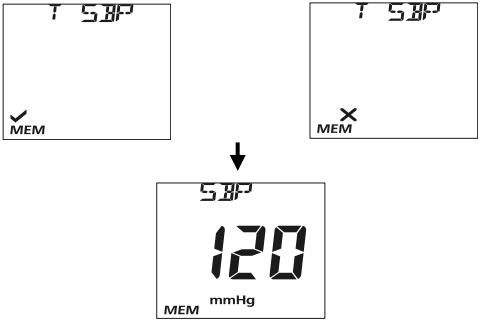


If PRO10 is chosen, Press ⏻ to enter patient information regarding age, smoker or non-smoker, Diabetic (DB), Myocardial Infraction (MI), and Systolic Blood Pressure (SBP).

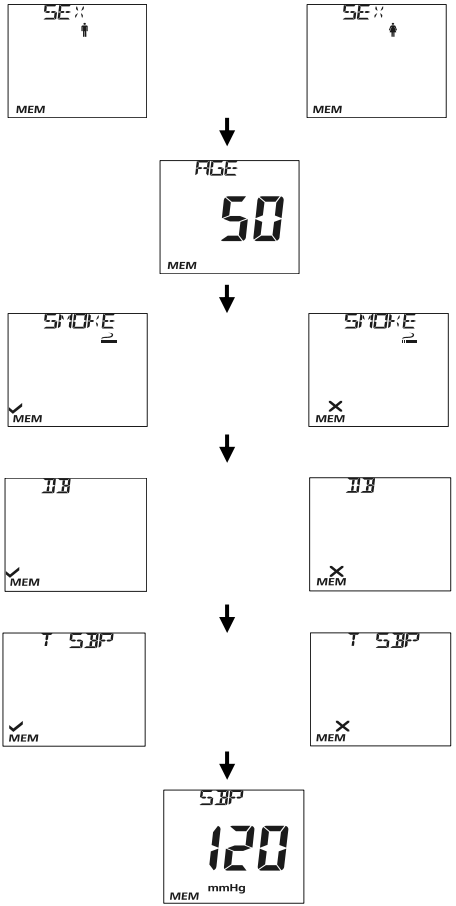


If ACC10 is chosen, Press ⏻ to enter patient information regarding race (AA: African American, WH: White), gender, age, smoker or non-smoker, Diabetic (DB), Treatment for High Blood Pressure (T SBP), and Systolic Blood Pressure (SBP).




SBP
MEM
SBP
MEM
SBP
120
mmHg
MEM

If ACCLF is chosen, Press ⏻ to enter patient information regarding gender, age, smoker or non-smoker, Diabetic (DB), Treatment for High Blood Pressure (T SBP), and Systolic Blood Pressure (SBP).



Press ⏻ to enter all the input. The CHD risk ratio will be displayed on the screen.

Press and hold ⏻ to return to the testing screen.

For the PRO/FRA methods, the 10-year risk is categorized into three levels[1,2]:

CHD≤10%, low risk
10%<CHD≤20%, medium risk
CHD>20%, high risk

According to the ACC/AHA guidelines, individuals who are assessed by the ACC10 method should be under a doctor's care if they have a risk of 7.5% or greater.[3]

In FRA10 and PRO10 mode, results below 1.0% will display "<1.0%" and results above 30.0% will display ">30.0%". When the concentration of calculation factors are out of range, the result will display "- -". Please refer to Table.1 below for details.

Table1. Calculation limits for different methods

	PRO10	ACC10	ACCLF
TC (mg/dL)	100-500	130-320	130-320
HDL (mg/dL)	15-100	20-100	-
TRIG (mg/dL)	45-400	-	-

[1] Mathijs O. Versteylen, et al. Comparison of Framingham, PROCAM, SCORE, and Diamond Forrester to predict coronary atherosclerosis and cardiovascular events. J Nucl Cardiol. 2011 Oct; 18(5): 904–911.

[2] ATP III NCEP Guidelines for CHD Risk. JAMA.2001. 285:2486-2509.

[3] Goff DC Jr, et al. 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation, journal of American Heart Association. 2013.

Section 8 Data/Communication

Data Transmission

Plug the USB cable into the USB port located on the top of the meter and connect the other end of the USB cable to a PC or a printer.

Note: The PC must have compatible software installed to receive and process the data transmitted from the meter.

The printer is sold separately and for professional use only.

To transfer data to a PC, go to the Setup screen, press ◄ or ► until ***PC*** is displayed. Refer to Meter Setup and Options for more details. Press ⏻ to enable the Data Communication mode. ***MEM*** will be displayed.

Press ⏻ to transmit the data to an external certified PC. After data transmission is complete, the meter will return to the Setup Menu.

Data can also be printed using the *Mission*® printer. Results can be printed directly after each test or printed from memory. Refer to the Printer Package Insert for more details.

Note: Up to 200 test records are automatically stored in the memory. After 200 test records are stored, the oldest test record will be replaced by a new record. For example, if 200 records are stored in the memory, the next test result (201) will replace the first result in the memory.

Deleting Data

To delete all data from the meter database, enter the Setup Menu. Refer to Meter Setup and Options for more details. Press ◄ or ► until ***dEL*** is displayed.

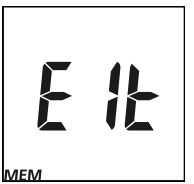
Press ⏻ to enable data deletion, ***MEM*** will be displayed.

Press ⏻ until the meter returns to the Setup Menu.

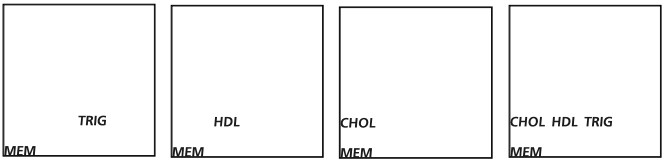
Memory/Database

From the initial test screen, press ◄ or ► to enter the memory/database.

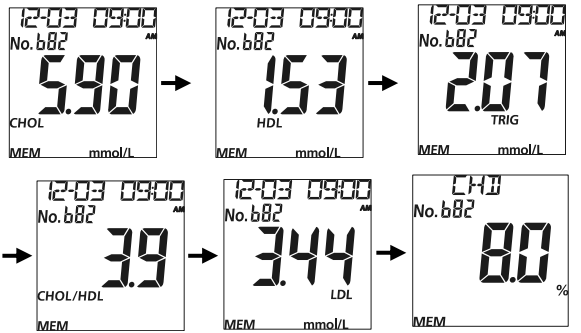
Press ► to enter the EIt screen. Press ⏻ to return to the testing screen.



Press ◄ or ► to view the memory from corresponding tests: both individual and 3-in-1 tests.



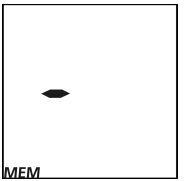
Press ⏻ to enter the selected memory screen. The screen will show the latest results. Press ◄ or ► to choose the No. of results and view each record in the date/time sequence. To view the 3-in-1 test results, press ⏻ to enter to the record. Then press ◄ or ► to view results of CHOL, HDL, TRIG, CHOL/HDL, LDL, and CHD, if the CHD evaluation has been enabled.



Note: The date in the display will be shown in the form of M-D or D-M according to the date mode you select.

Press and hold ⏻ to return to the Initial Screen.

If no data is stored, the meter will display ***one dash*** (**-**) and ***MEM***.



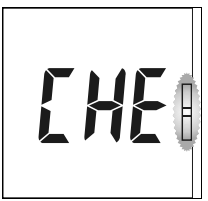
Section 9 Optical System Check

Press ◄ or ► from the Setup Screen to select the Optical Check mode, as shown below.

Note:

- The control device is intended to check the optical system.
- Allow the control devices and the meter to reach operating temperature (15-40°C or 59-104°F) prior to testing.
- The optical check should be performed under normal lab lighting conditions. Do not perform under sunlight or extreme lighting conditions.

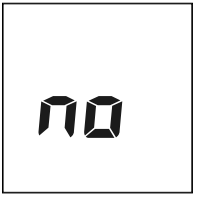
Press ⏻ to enter this mode. The meter will flash the test device symbol, as shown below.



Insert a control device into the Device Channel of the meter. Follow the direction of the arrow indicated on the control device. Ensure that the control device is inserted all the way.

Press ⏻ to start the optical check. If the meter displays ***YES***, the meter is functioning normally. If the meter displays ***no***, the meter is not functioning properly.

OR



If the meter displays ***no***, check the control device for contamination or damage. If there are any visible signs of damage or contamination, discard the control device and retest using a new device.

Press ⏻ to return to the Setup Screen.

Section 10 Quality Control

Each lab should use its own standards and procedures for performance. Test known specimens/controls under the following circumstances in accordance with local, state, and/or federal regulations or accreditation requirements:

- Each new day of testing
- When a new package of test devices is opened
- When a new operator uses the meter
- When test results seem inaccurate
- After performing maintenance or service on the meter

If QC tests do not provide expected results, perform the following checks:

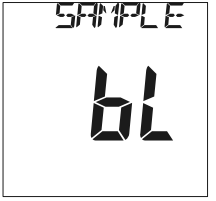
- Ensure that the test devices used are not expired.
- Ensure that the test devices are fresh from a new package.
- Ensure that the controls are not expired.
- Repeat the test to ensure no errors were made during the test.

Control Solution Testing

Cholesterol Control Solution testing is performed in a very similar manner to blood tests. The *Mission*® Cholesterol Control Solution is used instead of blood.

Note: Make sure the control solution and all the test materials reach operating temperatures of 20 - 40°C (68 - 104°F) prior to testing. Tests can only be accurately performed when the control solutions and test materials are within this temperature range.

1. Turn on the meter, and press ◄ or ► from the Setup Screen to confirm the ***bL*** mode is selected, as shown below. Refer to *Specimen Type Set Up* in the User's Manual for more details.



2. Insert the code chip into the meter. Refer to *Coding the Meter* in the User's Manual for details. Make sure the control solution is tightly closed before use.
3. Compare the code number on the code chip with the code number printed on the test device pouch label and ensure the two numbers are identical to avoid inaccurate results.

4. Wait for the meter to flash the test device symbol. Insert a test device completely into the device channel of the meter in the same direction as the arrow printed on the test device until it cannot be inserted any further.

5. When the meter is flashing the blood drop symbol, open the screw cap of the control solution bottle and turn the bottle upside down. Squeeze the control solution bottle gently and discard the first drop. If there are bubbles in the previous drop, squeeze the bottle and discard another drop until there are no bubbles in the drop. Apply the next drop to the specimen well on the test device while keeping the bottle vertically upside down. Use about 35 µL of control solution for the 3-in-1 test device or about 10 µL of control solution for an individual test device. Make sure the control solution is applied directly into the specimen well and that there is no bubble in the solution drop. Because the required sample volume of the 3-in-1 test device is larger than the volume required for the individual test device, there are two kinds of bottles with different dropper tips.

Check the labels on the control solution bottle and kit box to make sure that you are using the correct bottle for each device type, 3-in-1 or individual.

Note:

- Make sure the bottle is completely upside down when applying the solution to the device. The volume will be inconsistent if the bottle is not completely vertical.
- Gently squeeze the bottle so that the solution makes a complete drop on the tip of the bottle and falls freely into the specimen well. Avoid touching the device with the tip of the bottle to finish an incomplete drop.

6. For the 3-in-1 test, two kinds of control solutions need to be tested on two separate test devices. Remember to switch to a new test device after each use.

Interpreting Results

The results should fall within the range(s) printed on the bottle label and are specific for each lot of controls. If the results fall within the specified control range, it indicates the *Mission*® Cholesterol Monitoring System is working correctly and the procedures are being performed properly.

If the results do not fall within the respective range(s), refer to the Control Solution Package Insert for further instructions.

Section 11 Maintenance

Proper maintenance is recommended for best results.

General Cleaning

For best results, the meter should be cleaned after each day of testing.

Meter Surface

A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary.

A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use.

Avoid getting liquids, residue, or control solutions in the meter through the **Device Channel, Code Chip Slot**, or **USB Port**.

Test Device Holder

Remove the **Test Device Holder** by pressing in on the middle of the **Test Device Holder** and sliding it out from the meter. Wipe it down with a damp cloth or a mild detergent. Dry it with a dry, soft cloth. Slide the **Test Device Holder** back into the meter by laying it flat on the meter. Firmly press down on the two sides of the **Test Device Holder** with your thumb and push it in until it clicks into place.

Note: Do not use organic solvents, such as gasoline or paint thinner. This will cause damage to the meter.

Meter Sensor Area

Remove the **Test Device Holder** as described in the previous section. Wipe down the **Meter Sensor Area** with a cotton swab. Do not scratch the transparent window covering the sensors.

Note: Do not use bleach or alcohol to clean the **Meter Sensor Area**. This will cause damage to the meter.

Disinfection Process

The disinfection process should be performed before each test to prevent potential infectious disease transmissions through bloodborne pathogens.

Cleaning Before Disinfection and How to Disinfect

Cleaning and disinfection is a two-step process. To clean the meter, use a disposable, germicidal towelette/wipe that contains Isopropyl alcohol as its active ingredient and meets local government agency guidelines. First, remove all stains/debris with the towelette/wipe. Then disinfect the meter by using another isopropyl alcohol wipe to wipe down the entire surface of the meter.

Be sure to wet the entire outer meter surface thoroughly. The outer meter surface must remain visibly wet for one full minute. After wiping, allow the meter to air dry completely before using the meter again.

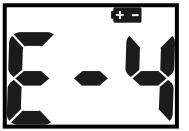
Note: Avoid inserting the towelette/wipe into the inside of the **Code Chip Slot** and the **USB Port** when performing cleaning before and during disinfection.

Disinfection Frequency

The meter disinfection process should be performed throughout the entire life of the meter. Check normal meter electronic operations regularly. Do this by ensuring the LCD display shows all segments once the meter is turned on before testing.

Replacing the Batteries

When the battery icon is flashing, the batteries are low and should be replaced as soon as possible. An ***E-4*** error message will appear if the batteries are too low to perform any more tests. The meter will not function until the batteries are replaced.



Make sure the meter is off before removing the batteries. Turn the meter over to locate the battery cover. Press the battery cover tab on the top and lift the cover to open it. Remove and discard the old batteries. Insert four new AAA batteries into the battery compartment, alternating orientation up and down as indicated on the bottom of the battery compartment.

Close the battery cover and make sure that it snaps shut. Recheck and reset the clock setting if necessary, after replacing the batteries to ensure that the time is correctly set. Refer to Initial Setup.

Note: Do not discard batteries with household waste. Follow local regulations for disposal.

Section 12 Precautions

Follow the precautions listed below to ensure accurate results and proper operation of the meter.

- The protection provided by the equipment may be impaired if used in a manner not defined in this instruction manual.
- Wear gloves to avoid contact with potentially hazardous biological specimens during testing.
- Avoid storing or operating the meter in direct sunlight, excessive temperatures, or high humidity. Refer to Appendix 1 Meter Specifications for operating condition requirements.
- Keep the unit clean. Wipe it frequently with a soft, clean, and dry cloth. Use a damp cloth when needed.
- Do not clean the unit with substances, such as gasoline, paint thinner or other organic solvents to avoid any damage to the meter.
- Do not clean the LCD or sensor area with water. Lightly wipe with a soft, clean, dry cloth.
- The device channel must be kept clean. Lightly wipe with a soft, clean, dry cloth each day. Use a damp cloth as needed. Refer to the Maintenance section.
- Follow all local regulations when discarding the unit or its accessories.
- Do not use the unit or the devices outside of the operating temperature ranges: 15-40°C (59-104°F); ≤ 90％ RH.

Section 13 Troubleshooting

Display	Causes	Solution
E-1	The sensor area is damaged, dirty, or blocked when turned on, such as a used test device left in the meter.	Ensure the sensor area is clean and that there are no objects covering the sensor area. Refer to Maintenance. Restart the meter. Contact your local distributor if the sensor area window is broken.
E-2	Test device was removed during the test.	Repeat the test and ensure the test device remains in place.
E-3	Specimen was applied to the test device too soon.	Repeat the test and apply specimen after blood drop symbol appears.
	Batteries are discharged but have enough power to run 20 more tests.	Test results will still be accurate, but replace the batteries as soon as possible.
E-4	Batteries are low and meter will not allow more tests until the batteries are replaced.	Replace the batteries, or connect the meter to the AC Adapter, then repeat the test.
E-5	Insufficient specimen.	Repeat the test. Apply enough specimen. Use around 10 µL (for individual tests) and 35 µL (for 3-in-1 test) of specimen.
E-6	Expired test device or incorrect date entered.	Ensure the test devices are within the expiration date printed on the package label. If the test devices are still within the expiration date, check to see if the date was entered correctly.
E-7	Code chip was removed during testing.	Insert proper code chip. Confirm the code chip matches the test device code and repeat the test.
E-8	The test device type does not match the code chip.	Use the proper device type that matches the code chip.
HIt	The environment temperature is higher than 40 ºC (104ºF).	Get the meter in a proper environment where the temperature is between 15 - 40ºC (59 -104ºF).
LOt	The environment temperature is lower than 15 ºC (59ºF).	
--- CODE	No code chip in the meter. Code chip is damaged or inserted incorrectly.	Insert the code chip that accompanied the package of test devices. If the code chip is damaged, use a new code chip with the correct code number. If the code chip is inserted incorrectly, remove the code chip and insert it into the code chip slot.

Display	Causes	Solution
No blood drop symbol 	No blood drop symbol flashing after inserting the test device into meter. The Meter Sensor is dirty or contaminated.	Clean the Meter Sensor: remove Test Strip Holder, then wipe front and back side of holder, as well as Meter Sensor Area, finally, slide Test Device Holder back into the meter and repeat the test. Please refer to Section 11 Maintenance for more information. Contact your local distributor, if the blood symbol is still missing, after cleaning meter sensor.

Appendix 1 Meter Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Test Time	≤ 2 min
Measurement Range	CHOL: 100-500 mg/dL (2.59-12.93 mmol/L,1 mmol/L=38.66 mg/dL) HDL: 15-100 mg/dL (0.39-2.59 mmol/L, 1 mmol/L=38.66 mg/dL) TRIG: 45-650 mg/dL (0.51-7.34 mmol/L, 1 mmol/L=88.6 mg/dL)
Specimen	Whole blood, plasma, and serum
Specimen Volume	10 µL for individual test; 35 µL for 3-in1 test
Power Source	4 AAA batteries (1.5V)
	AC Adapter (Mini USB, 5V dc, 50 mA)
Battery Life	85 hours or 1,000 tests
Units of Measurement	mg/dL, mmol/L
Memory	200 records
HCT	30 – 50%
Automatic Shut Off	5 minutes after last use
Meter Size	137 mm × 79 mm × 26 mm (5.4” × 3.11” ×1.02”)
Display Size	50 mm × 50 mm (1.97” ×1.97”)
Weight	145g (without batteries)
Meter Storage Conditions	0 - 50ºC (32 -122ºF); ≤ 90% RH
Operating Conditions	15 - 40ºC (59 -104ºF); ≤ 90% RH
Meter Connectors	USB cable for Data Transfer or Power (optional)

Appendix 2 Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only
REF	Catalog #	SN	Serial Number
	Manufacturer	EC REP	Authorized Representative
LOT	Lot Number		Use by
	Contains sufficient for <*n*> tests		Store between 2 - 30°C (36 - 86°F)
STERILE R	Sterilized using irradiation	CODE	Code Number
	Do not discard along with household waste		USB Port
	Fragile, handle with care		This Side Up
	Keep away from sunlight and heat		Keep Dry
	Do not reuse	MODEL	Model number

Appendix 3 Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within 30 days of purchase.

For your records, write the purchase date of your starter kit here:

Note: This warranty applies only to the meter in the original purchase. It does not apply to the other materials included with the meter.

ACON Laboratories, Inc. warrants to the original purchaser that this meter will be free from defects in materials and workmanship for a period of two years (24 months). The two years starts from the later of the date of original purchase or installation, except as noted below. During the stated two year period, ***ACON*** shall replace the meter under warranty with a reconditioned meter or, at its option, repair at no charge a meter that is found to be defective. ***ACON*** shall not be responsible for shipping charges incurred in the repair of a meter.

This Warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. ***ACON*** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the meter in accordance with the user's manual, or maintenance by anyone other than ***ACON***. Furthermore, ***ACON*** assumes no liability from malfunction or damage to meters caused by the use of devices other than devices manufactured by ***ACON***. ***ACON*** reserves the right to make changes in the design of this meter without obligation to incorporate such changes into previously manufactured meters.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties expressed or implied (either in fact or by operation of law), including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by ***ACON***.

Limitations of Liability

In no event shall ***ACON*** be liable for indirect, special or consequential damages, even if ***ACON*** has been advised of the possibility of such damages.

For warranty service, please contact your local distributor.

***ACON* Laboratories, Inc.**
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Number: 1150687807
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