Mission®

PT/INR Monitoring System
User's Manual

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Section 1 Introduction

Intended Use

The *Mission*® PT/INR Monitoring System is intended for self-testing and professional use for the monitoring of oral anticoagulant therapy by quantitative prothrombin time (PT) testing. The *Mission*® PT/INR Test Strips work with fresh capillary or non-anticoagulated venous whole blood specimens from patients on Coumarin-type (e.g. Warfarin) anticoagulation therapy. The device is not intended to be used for screening purposes.

The easy-to-operate system consists of a portable meter and individual test strips that analyze the clotting time. A programmed code chip with strip parameters is provided with each box of strips to ensure proper coding of the meter. The *Mission*® PT/INR Monitoring System provides results as International Normalized Ratio (INR) or INR+PT values in about 2 minutes and requires only a single drop of whole blood.

The meter can store up to 200 results and can be operated by 4 AA (1.5V) batteries or the included AC adapter.

Note: It is required that the healthcare professional follows the *Mission*® PT/INR Monitoring System Training Manual to train the self-testing patient before the patient uses the *Mission*® PT/INR Monitoring System at home. The self-testing patient must complete the training and practice running a test on the meter with a health care professional. To review these training files, visit *ACON* website at www.aconlabs.com. Click on International Clinical Chemistry, select PT/INR Coagulation, and then click on Download.

To ensure accurate results:

- Read the instructions in the User's Manual and complete any necessary training before use.
- Use the code chip that is included in each box of test strips.
- Only use *Mission*® PT/INR Test Strips with the *Mission*® PT/INR Meter.
- For *in vitro* diagnostic use only.
- For self-testing and professional use.
- Test with fresh fingertip capillary or venous whole blood specimens.
- Verify the testing results using clinical laboratory methods before making any adjustments to your medication, diet, or exercise routines.
- Do not use accessories that are not supplied or recommended by the

manufacturer.

- Use the equipment only for the purpose described in the instructions for use.
- Keep out of reach of children.

Note: Buttons on the meter are represented in this manual by text in ***bold italics***. Other display items on the screen are listed in **bold**.

About Prothrombin Time (PT) Testing

PT testing is the standard method of monitoring patients on oral anticoagulants. The *Mission*® PT/INR Monitoring System is designed to monitor patients on oral Coumarin-type anticoagulants, such as Warfarin (Coumadin® or Marevan®), Phenprocoumon (Marcumar®) or Acenocoumarol (Sintrom®). These anticoagulants require regular monitoring, as many things can interfere with or enhance their effects. These can include:

- Small changes in patient dosing
- Diet
- Exercise
- Alcohol consumption
- Other medications

The *Mission*® PT/INR Monitoring System can report results as INR or INR+PT values in just a few minutes by simply taking a specimen of blood from a fingertip. This information can then be used to adjust the anticoagulant dosage or to determine if further testing is needed.

About International Normalized Ratio (INR) Values

INR values reflect a method of converting PT test results into a common scale that has been adopted internationally. This practice allows medical practitioners throughout the world to report Prothrombin Time test results in a consistent manner. The *Mission*® PT/INR Monitoring System displays results as INR or INR+PT values.

Test Principle

When used as directed, the *Mission*® PT/INR Monitoring System will accurately and reliably measure blood INR levels. Specimens used for testing can either be fingertip capillary or venous whole blood and are applied directly to the test strip.

It is a simple procedure to perform the test. Insert the code chip, which is

provided with each box of test strips, into the slot on the meter. This provides lot specific calibration data to the meter. Then insert a test strip into the meter detection area under the strip holder. After a brief warm-up time, the specimen can be added to the test strip specimen application area. When the specimen is added, the meter detects the specimen application and initiates the test. During the test, a reaction initiating clot formation begins.

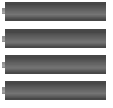
Section 2 System Components

The figures below are labeled to identify the major components of the *Mission*® PT/INR Monitoring System.

PT/INR Meter

Code Chip

Test Strip

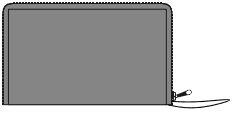


AA Batteries

Plastic Clamp

Control Solution

Capillary Transfer Tube



Carrying Case

AC Adapter

Plug

Safety Lancet

Component Descriptions:

PT/INR Meter: Reads the test strips and displays PT and INR values.

Test Strip: Single use strip with a sample application well where blood samples or control solutions are applied. These are inserted into the meter to measure PT and INR values.

Code Chip: Provided in each box of test strips. This provides lot specific calibration data to the meter when inserted into the meter.

Safety Lancet: Used to draw blood specimens for testing. Discard after use.

Capillary Transfer Tube: Collects capillary blood from fingertip blood testing for accurate results. Ensures the collection of 15 µL of specimen.

Control Solution: Two levels of predetermined ranges: Level 1 (Normal) and Level 2 (High). They are intended for use as a quality control check to verify that the PT/INR Monitoring System is working properly.

Plastic Clamp: Provided in each box of control solutions. Used to break the glass ampoule inside the plastic control solution vial to release the water.

AA Batteries: Provides power for the meter.

AC Adapter: For prolonged or continuous use, an AC adapter may be used, instead of batteries, to power the meter.

Carrying Case: Provides portability for testing and meter protection.

User's Manual: Provides detailed instructions on using the PT/INR Monitoring System.

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

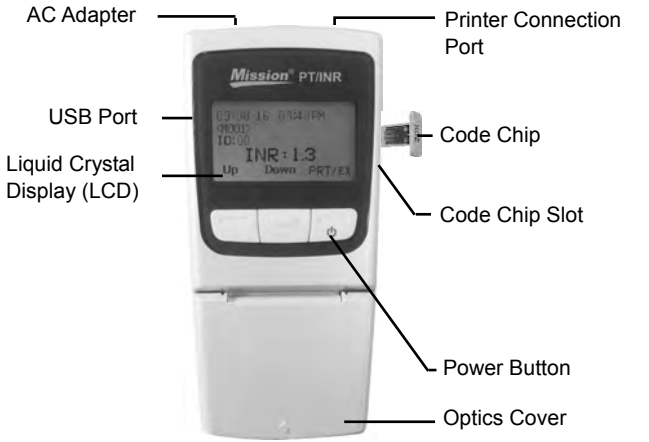
Test Strips Package Insert: Provides detailed instructions on using the *Mission*® PT/INR Test Strips.

Control Solution Package Insert: Provides detailed instructions on using the *Mission*® PT/INR Control Solutions.

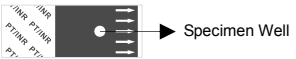
Warranty Card: Card included in the package, which should be completed and returned to the distributor to qualify for the 2-year meter warranty.

Section 3 Getting Started

Mission® PT/INR Meter



Mission® PT/INR Test Strip



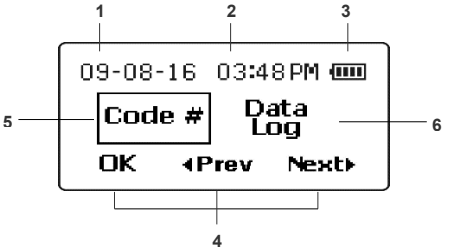
The arrows on the test strip indicate the direction to insert the strip into the meter. The specimen well is the circular target area where the blood specimen is applied.

Code Chip

A **code chip** is provided in each box of test strips. The **code chip** needs to be inserted into the meter **code chip slot** each time a new box of test strips is opened. The code number is printed on the outside of the **code chip**.

Caution: The code chip provided with the box of strips must be used or an incorrect INR measurement may result.

Meter Display



1. **Date:** Shows the current date
2. **Time:** Shows the current time
3. **Battery:** Shows battery status or AC Adapter connection
4. **Function Labels:** Helps navigate between functions and confirm selections
5. **Selection Box:** Indicates which function is selected
6. **Menu Selection:** Lists setup options and functions

During testing, the *Mission*® PT/INR meter will display icons showing the status, options available, and prompts for testing. At the bottom of the display are three function labels representing options which can be selected by pressing one of the three keys directly below each of the display labels (programmable key functions). These three programmable keys are used to move through the meter menus for setting and selecting options for the operation of the meter. Each key represents the function indicated by the label at the bottom of the display, directly above the button.

All display functions are represented by English labels, icons, or numbers. The “Icons” function is an alternative setting from the setup menu showing all display items as icons, with minimal use of English labeling.

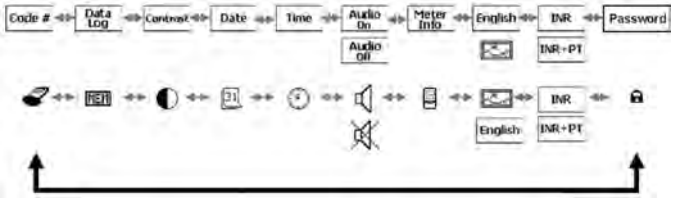
Throughout this User’s Manual, the label shown on the display will be used to indicate the button to press to set or implement a function.

When the meter is turned on by pressing the power button (far-right button), the first screen will show the available setup options. From this screen, all meter settings can be changed, with their functions described below.

Pressing **◄Prev** or **Next►** will move the selection box to the previous or next function, indicating which function is selected. In the example above, **Code #** is selected and the next function is **Data Log**. As **◄Prev** or **Next►** is pressed, the labels will shift to the left or right, revealing additional functions. The selected function will be shown with a box around it.

Pressing **OK** will show the submenu for the function selected.

The available functions are shown in order below.



After the last function is selected, the display will cycle through and return to the first again. The purpose of each function is shown below.

Code # Displays the Code Chip Number

Data Log To review previous test results

Contrast Adjusts the display contrast

Date Sets the meter date

Time Sets the meter time

Audio On/Off Turns the meter sound on or off

Meter Info Displays the meter serial number and software version number

English Displays meter messages in English or as Icons

INR/INR+PT Allows Prothrombin Time to be shown in addition to INR values

Password Password protects patient data in the meter

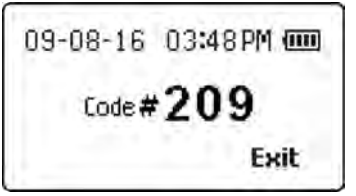
Section 4 Initial Setup

Before turning the meter on, insert the code chip (found inside the box of test strips) into the code chip slot on the right side of the meter. This is shown below. This will transfer the test strip testing parameters into the meter.

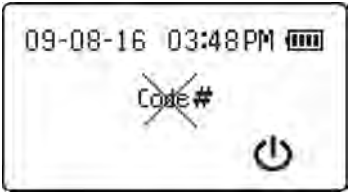
Note: Ensure the code number printed on the code chip is the same as that printed on the test strip box and the same as the number shown on the meter test screen when a test strip is inserted.

Code

Press the ***power button*** (right button) to turn the meter on. The Setup menu will be displayed after the power-on diagnostics test screen. The **Code #** will be highlighted when the meter is turned on. Press **OK** to view the current **Code #** from the code chip. The code chip number is also displayed when a test strip is inserted, after the meter is turned on and patient ID has been entered.



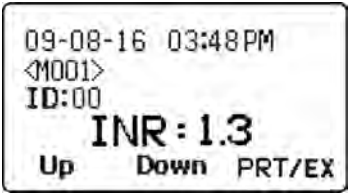
If there is no code chip in the meter when a test strip is inserted or there is a code chip error, the following screen will be shown.



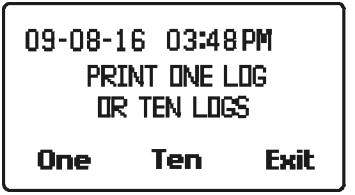
Section 5 Meter Setup and Options

Memory Review

Select **Data Log** and press **OK** to review previous PT/INR Meter test results. The following screen will be shown.



The last test result will be displayed showing the test INR or INR+PT value, date, time, its test number and corresponding patient ID. Pressing **Down** will show the previous result, if any. Pressing **Up** will move to the oldest test in the test result list.

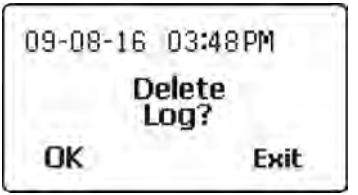


To print the data log(s), connect the printer to the RS232 printer connection port at the top of the meter and press **PRT/EX.** The next screen will show the printing options of one log or ten logs. **One** means printing the current displayed log, while **Ten** means printing 10 consecutive logs starting from the current log. Press **Exit** to quit the print screen and to go back to the Data Log screen. When finished reviewing the test results, press and hold down the **PRT/EX** button until the display returns to the previous menu selection screen.

Deleting Stored Readings

When reviewing stored readings in the section above, all readings can be deleted by momentarily pressing both the **Up** and **Down** buttons at the same time. This will display the Delete Log screen below, with **Delete Log?**

flashing.

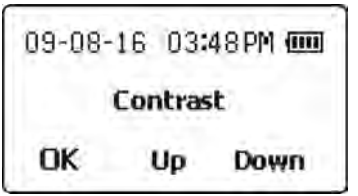


Press **OK** to delete all stored data in the memory or **Exit** to exit without deleting the stored data and return to the previous data screen.

Once all data is deleted, the memory review function will show only dashes for the stored data.

Setting the Display Contrast

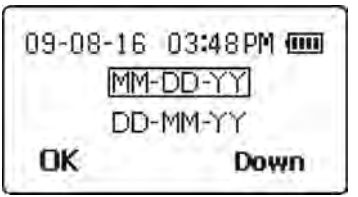
Select **Contrast** as shown in the screen below to adjust the display contrast.



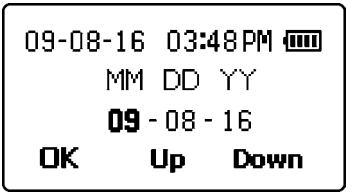
Press the **Up** or **Down** buttons to increase or decrease the display contrast. Press **OK** to save the setting and exit to the previous menu selection screen.

Setting the Date

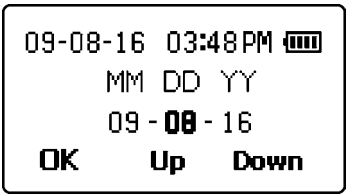
Select **Date** to change the date format. The first screen shows the date format selections. Press **Down** to move the selection box to the desired format, then press **OK** to save the chosen format.



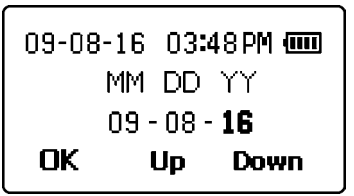
The next screen will show the current date, with the first selection flashing. In the screen below, the month is flashing. If the date format selection is MM-DD-YY, the first number highlighted will be the month. Press **Up** or **Down** to increase or decrease the current setting until the correct month is shown.



Press **OK** to move the highlight to the day. Press **Up** or **Down** to increase or decrease the setting until the correct day is shown.



Press **OK** to move the highlight to the year. Press **Up** or **Down** to increase or decrease the setting until the correct year is shown.



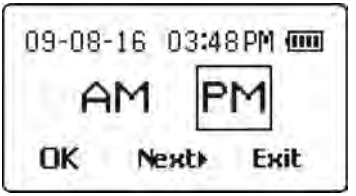
Press **OK** to accept the new date and exit to the previous menu selection screen.

Setting the Time

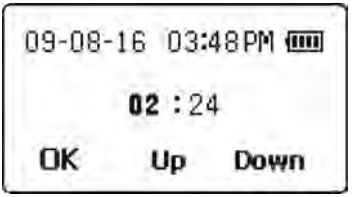
Select **Time** to choose the time format. Press **Next►** to move the selection box between the 12 hour and 24 hour format. You may press **Exit** at any

time to exit the screen and return to the previous menu selection screen without making any time changes.

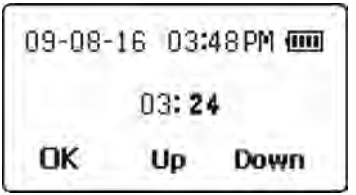
When the correct time format is shown, press **OK** to select the chosen format. If **12H** format is chosen, the screen below will allow the selection of **AM** or **PM**. Press **Next►** to move the selection box between **AM** and **PM** until the time of day is correct.



Press **OK** to select the correct time of day, as in the screen below. The current hour setting will be highlighted. Press **Up** or **Down** to increase or decrease the hour setting until the correct hour is shown.



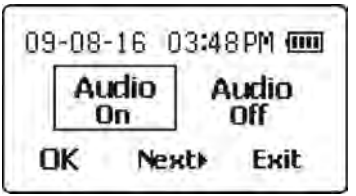
Press **OK** to select the correct hour. The current minutes setting will be highlighted. Press **Up** or **Down** to increase or decrease the minutes setting until the correct minutes are shown.



Press **OK** to save the new time settings and exit to the previous menu selection screen.

Sound

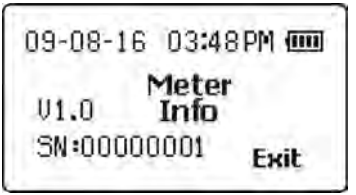
The Audio Menu selection will show the current state of the Audio setting, which is either **Audio On** or **Audio Off**. To change this setting, press **Next►** to move the selection box to the Audio setting and press **OK** to show the display below. The current Audio setting will be selected, which is either **Audio On** or **Audio Off**. Press **Next►** to move the selection box between the **Audio On** and **Audio Off** setting.



When the desired setting is selected, press **OK** to save the sound setting and return to the previous menu selection screen. Press **Exit** to exit this submenu with no changes.

Meter Information

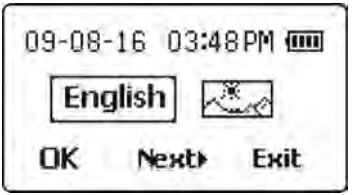
Select **Meter Info** to display the meter information screen, shown below. This screen shows the Meter Serial Number and the installed software version number.



Press **Exit** to return to the previous menu selection screen.

Display Language

Next on the menu selection screen is the **Display Language**, which will be displayed either in **English** or as a landscape picture representing icons shown in the screen below. To change this setting, press **OK** with the item selected. Then press **Next►** to move the selection box to either **English** or the landscape picture selection for icons.

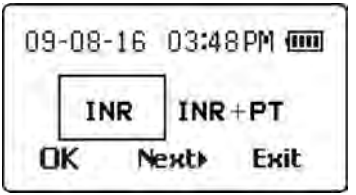


When the desired setting is selected, press **OK** to save the new setting and return to the previous menu selection screen. Press **Exit** to exit this submenu without making any changes.

INR Display

INR is the normal default setting for the results displayed. If the corresponding PT time is also of interest, the PT time can be displayed as well.

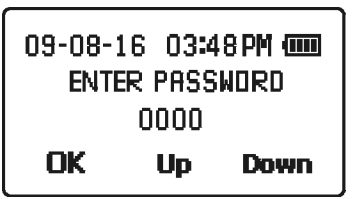
From the selection menu, the current data display format selection showing either **INR** or **INR+PT** will be seen in the selection sequence. To change this setting, press **Next** until this item is selected. The current selection will be shown with a box around it.



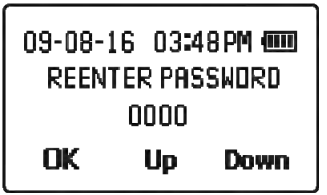
When the desired setting is selected, press **OK** to save the new setting and exit to the previous menu selection screen. Press **Exit** to exit this submenu without making any changes.

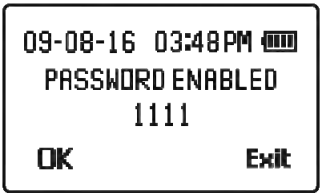
Password

The Password menu provides a method to set and clear a number that will be used to password protect the patient information in the data log. The desired number can be selected using the **Up** or **Down** buttons on each digit to increase or decrease the current flashing digit. The **OK** button will advance the selection to the next digit until all four have been entered. Possible password values range from 0000-9999. The display starts with the value 0000.

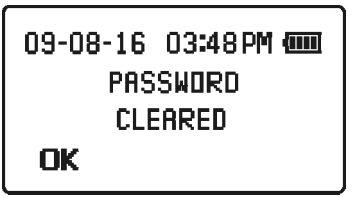


After entering the password, the Reenter Password screen will be shown. Enter the 4 digit password selected previously to confirm and enable the password selection. Once confirmed, the Password Enabled screen with the new password number will be displayed. The data log will now be password protected for subsequent power on cycles.





To clear the password entered or turn off password protection, enter the password saved then reenter the password with **0000** when Reenter Password screen is prompted. The password will be cleared when **OK** is pressed.



Section 6 Testing

The following section explains the steps required to measure the PT and INR results for capillary or venous whole blood.

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

Warning: Only capillary whole blood or venous whole blood can be used with this meter. Do not use any other specimen type or any anticoagulated specimens.

Fingertip Testing (For Professional and Self-Testing Use)

Ensure the meter is set up properly as described in Section 5 Meter Setup and Options.

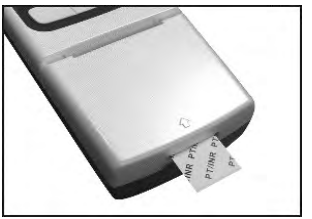
Before turning the meter on, insert the code chip, which is found inside the box of test strips, into the code chip slot on the right side of the meter, as shown below. This will transfer the strip testing parameters into the meter.

Note: Ensure that the code number on the code chip is the same as the number printed on the test strip box, test strip pouch and as the number displayed on the meter test screen when a test strip is inserted.

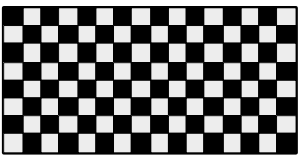
Remove a test strip pouch from the test strip box and note the Code Number on the test strip packaging. Tear the test strip pouch and remove the test strip.

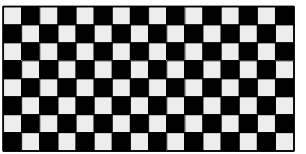
Open the optics cover and ensure that the strip holder is installed properly, as shown below.

Insert the test strip into the optical test area under the strip holder, as shown below.

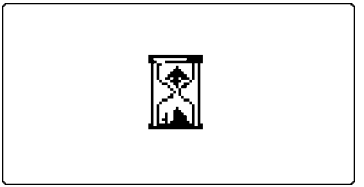


The meter will automatically turn on and beep, if the sound is enabled. Observe the display as the meter is turning on. It will show a checkerboard alternating pattern, as seen in the images below. Make sure the pattern is regular with no missing light or dark areas in the checkerboard.

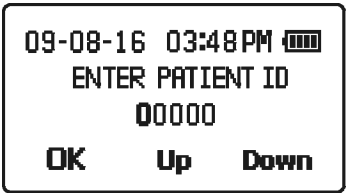




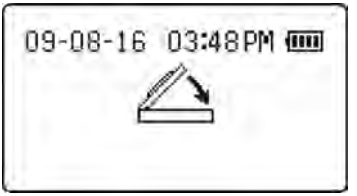
After several seconds, an hourglass symbol will be displayed while the meter runs internal diagnostics to ensure everything is working properly.



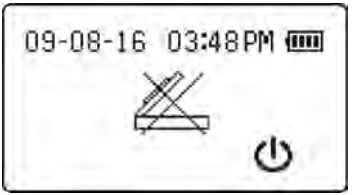
Once the diagnostics are complete, the meter will display the Patient ID screen. There are 5 digits for the patient ID and the accepted range is 00000-65535. Press **Up** or **Down** to increase or decrease each digit and press **OK** to save the current flashing digit and advance to the next one.



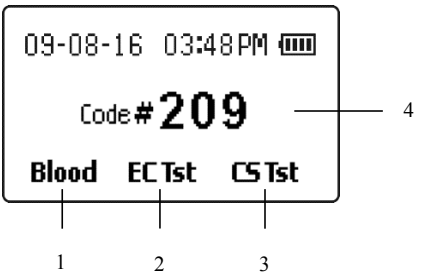
After setting the patient ID, the meter will prompt the user to close the optics cover by displaying the following screen.



If the meter detects that the optics cover is not closed within 6 seconds, the meter will beep if the sound is enabled. About every 4 seconds thereafter, the meter will beep until the meter detects that the optics cover is closed. If the optics cover is not closed within 15 seconds, the following error message will be shown and the test will be terminated.



Once the optics cover is closed within the appropriate amount of time, and after approximately 8 seconds, a screen will display the current Code # from the code chip with buttons indicating testing options which can be initiated from this screen, **Blood**, **EC Tst,** or **CS Tst**. During this display time, check the Code # to make sure it is correct by comparing the displayed code to the code on the test strip pouch. In this example, the Code # is **209**. If this code is incorrect, the code chip is not the correct chip for the test strip – do not continue until the inserted code chip and the Code # displayed on the meter are the same.

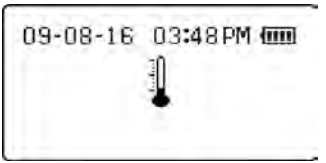


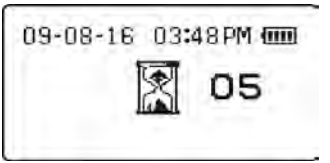
1. Blood test
2. Electronic Calibrator test
3. Control Solution test
4. Code Number

Press the left button under **Blood** to continue with testing a blood specimen. Alternatively, **EC Tst** will run an Electronic Calibrator Test, and **CS Tst** will run a Control Solution Test to ensure the accuracy of the *Mission*® PT/INR Monitoring System. Refer to Section 7 Quality Control for detailed instructions on **EC Tst** and **CS Tst**.

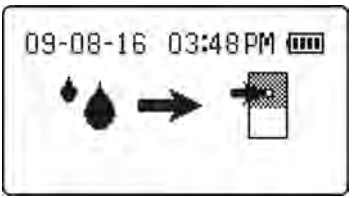
After pressing the left button under **Blood**, the meter will warm up the test strip to its operating temperature (40ºC). The display will indicate the specimen testing status by either showing the warming screen below

followed by the countdown timer screen or will go directly to the countdown timer screen if the time to add specimen is less than 30 seconds away.





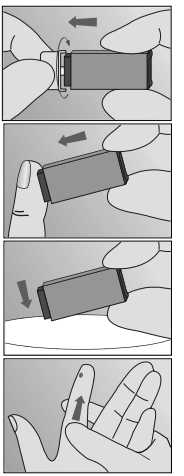
When the screen counts down to zero, the system is ready for specimen application, as indicated by the following screen with a flashing arrow.



The specimen must be applied within two minutes to prevent auto-shutdown.

Specimen Collection

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.



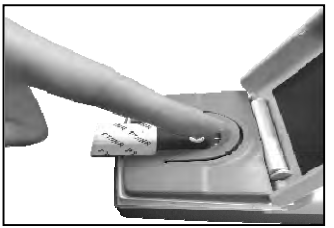
Clean the testing site with an alcohol swab or by washing the hands with warm soapy water and then dry the testing site thoroughly.

Carefully rotate and pull off the protective cap. 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.

Apply the specimen to the specimen well on the test

strip as shown in the picture. The required specimen volume is 15 µL or one hanging drop from a capillary blood specimen, as indicated in the figure below. The finger should be held in line with the strip instead of across at an angle. The blood drop should cover the bottom of the specimen well entirely. The specimen must be applied within 15 seconds after using the lancet.



Correct application

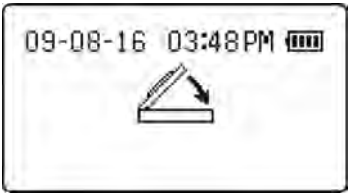
Incorrect application

Caution: Do not touch the test strip, move the meter, or add more blood during testing.

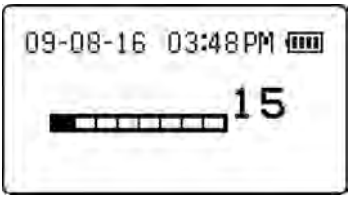
The specimen should cover the entire specimen well. A new test with a new test strip should be run if an insufficient specimen is applied.

Warning: For a fingertip whole blood specimen, if the test needs to be repeated, do not use the same puncture or puncture site. A new puncture must be made for each test to avoid incorrect readings due to the presence of partially clotted blood.

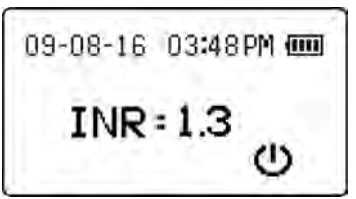
As soon as the meter detects the specimen has been applied, it will beep if the sound is enabled and will display the following screen for about 8 seconds. This screen indicates that the specimen compartment optics cover needs to be closed. If an insufficient specimen size is applied, the meter will indicate that there is an insufficient specimen by displaying the **E5** error code after 15 seconds. Do not open the optics cover until the test is completed.



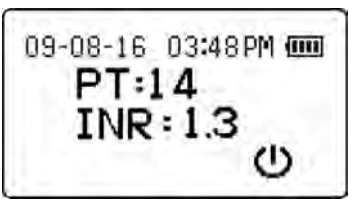
The meter display will change to the screen shown below. This is indicating that the test is in progress and will count up until the test is complete.



When the test is complete, the results will be displayed in International Normalized Ratio units (INR) if the **INR** option was previously selected.



If the selected option is **INR+PT**, the results will be displayed as both INR and Prothrombin Time (PT) as shown below:



The meter can be turned off by removing the used test strip, pressing ⏻, or

waiting for the meter to turn itself off after several minutes. The result is stored in the memory, which can be recalled anytime. Refer to Section 5 Meter Setup and Options.

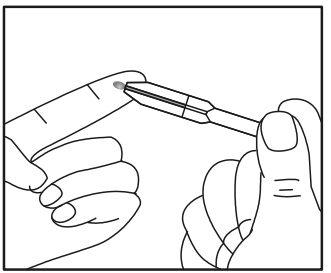
Optional Testing Methods

A Capillary Transfer Tube or pipette may be used to collect blood from a fingertip and to apply the specimen to the test strip.

Caution: Do not use capillary tubes that contain anticoagulants.

The following steps are optional for the fingertip blood specimen instructions above.

For use with the Capillary Transfer Tube, hold the tube slightly downward and touch the tip of the Capillary Transfer Tube to the blood specimen. Capillary action will automatically draw the specimen to the fill line and stop.



Note: The Capillary Transfer Tube will fill automatically. Never squeeze the Capillary Transfer Tube while sampling.

Wipe away the first drop of blood and then align the tip of the capillary transfer tube with the specimen application area of the test strip to apply the next drop of blood (approximately 15 µL).

Note: Do not touch the test strip with the Capillary Transfer Tube or pipette. The capillary blood should be tested immediately after it is collected. Use of a capillary transfer tube or pipette helps to ensure the correct specimen volume is applied. Discard Capillary Transfer Tube or pipette after use.

Venous Blood Testing (For Professional Use Only)

For fresh whole venous blood specimens, insert a new test strip into the meter and allow it to proceed to the specimen application icon on the display. Collect the venous blood using a butterfly collection set into a 3 ml syringe with no anticoagulants. Remove the syringe from the butterfly tubing and allow 4 drops to fall onto a clean gauze pad to be discarded. Apply a small hanging drop (15 µL) from the syringe tip to the specimen application area of the test strip. The blood drop should cover the bottom of the specimen well entirely. Specimens must be run within 15 seconds after collection to obtain an accurate INR reading.

Section 7 Quality Control

To ensure the accuracy of test results, the *Mission*® PT/INR Monitoring System can run an internal Level 1 or Level 2 electro-optical calibration check when a strip is inserted and **EC Tst** is selected. The internal Electronic Calibrator independently simulates the optical signal produced by a specimen applied to a test strip and produces an INR reading, which is the same as applying a blood specimen. The inserted test strip is not affected or consumed and can then be run in the normal sequence with a normal blood specimen if used within 10 minutes from when the test strip was first removed from the pouch.

Control solutions (Level 1 and Level 2) are provided as a second method to confirm the test strips and meter are working together properly and to ensure the test is being performed correctly. The labels on the control solution bottles are printed with the acceptable range for the control INR results.

To ensure continued accuracy of results, control solutions should be run when any of the following events occur:

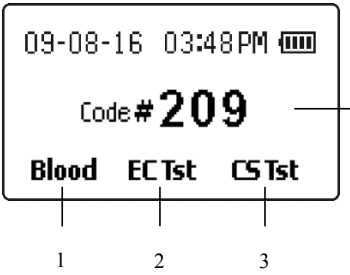
- INR values are unusually high or low
- A meter malfunction is suspected
- A new box or lot of test strips is opened
- Each new day of testing (professional use)
- A new operator uses the meter (professional use)
- After performing maintenance or service on the meter

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

- Ensure the test strips are not expired.
- Ensure the controls are not expired.
- Repeat the test to ensure no errors were made during the testing.

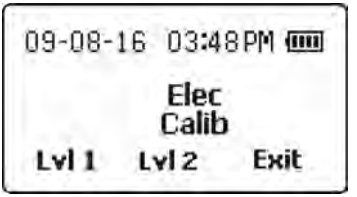
Electronic Calibrator

To initiate the Electronic Calibrator subsystem, insert a test strip to turn the meter on. After the checkerboard test, hour glass, patient ID entry and close optics cover screens are shown, the following screen will be shown.



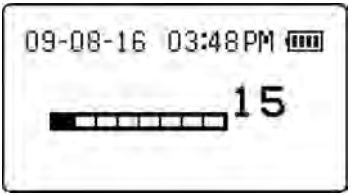
1. Blood test
2. Electronic Calibrator test
3. Control Solution test
4. Code Number

Within 10 seconds, press **EC Tst** to initiate the Electronic Calibration test process. The next screen will allow selection of Level 1 (Normal) or Level 2 calibration values. Press **Lvl 1** for Level 1 test, **Lvl 2** for Level 2 test, or **Exit** to return to the specimen testing screen.

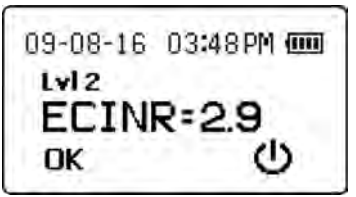


If **Lvl 1** or **Lvl 2** were selected, an hourglass figure will be displayed while the meter performs internal tests.

After performing internal tests, a timer will be displayed indicating that the test has begun.



After a time appropriate for the level selected, an icon showing the related level will be displayed along with the Electronic Calibrator INR value. The EC Test passes when an ECINR result is displayed without any error messages, as shown below.



Press **OK** to exit the test function and run a blood specimen, control solution, or another EC test. Remove the test strip to return to the menu selection screen or press ⏻ to turn the meter off.

Liquid Control Test

The *Mission*® PT/INR Control Solutions contain non-human plasma specimens with predetermined acceptable ranges and are packaged as Level 1 (Normal) and Level 2 (High) values. If the *Mission*® PT/INR Monitoring System is working properly, the INR value will be within the range of accepted values printed on the control solution pouch label.

Liquid control tests are performed in a very similar manner to blood tests, using the *Mission*® PT/INR Control Solutions instead of blood. Read the Control Solution Package Insert before using the controls. Refer to the control solution pouch label for acceptable ranges for the control solution lot. The system is working properly if the control value displayed by the meter is within the acceptable range printed on the pouch label. If the value is outside of the acceptable range, repeat the test. If the results are still out of range in the second test, refer to the troubleshooting section of the Control Solution Package Insert.

Preparing the Control Solution

Check the expiration date on the foil pouch or the box. Do not use if the expiration date has passed.

Tear open the foil pouch and remove the control solution vial.

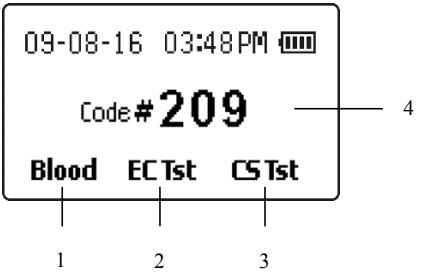
Hold the vial upright (vertically). Squeeze the vial firmly using the Plastic Clamp packaged with the control solution until the glass ampoule inside the plastic vial breaks to release the water.

Caution: Excessive squeezing or bending of the vial may force glass shards through the plastic vial wall.

Tap the vial firmly 5-10 times so that the water dissolves the powder. After tapping the vial, set the vial down for later use.

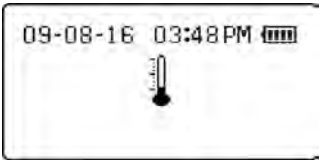
Caution: Liquid control solutions are made from animal plasma. Although they are safe to use, wash your hands after use.

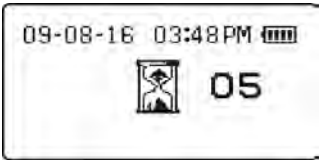
Remove a test strip from its pouch and insert it into the meter, which will turn the meter on. After the checkerboard test, hourglass, patient ID entry and close optics cover screens are shown, the following screen will be displayed. Check that the Code # shown on the display is the same as the Code # on the test strip packaging. If the Code # is correct, press **CS Tst** to run a liquid control test.



1. Blood test
2. Electronic Calibrator test
3. Control Solution test
4. Code Number

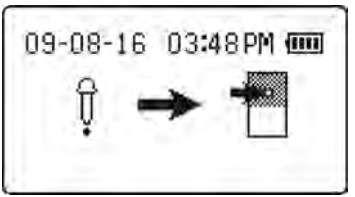
After selecting **CS Tst**, the meter will indicate the test strip is warming up to its operating temperature (40ºC). This is done either by showing the warming screen below or the countdown timer screen, also shown below, if the time to add control solution is less than 30 seconds away.





Applying the Control Solution

When the displayed countdown reaches zero, the meter will indicate that the control solution can now be applied to the test strip.



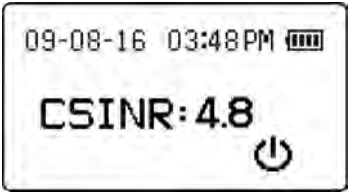
Holding the prepared control solution vial with the tip down, gently shake or tap the bottom of the vial to make the solution move down to the dropper.

Then squeeze one large, hanging drop of solution onto the test strip specimen well, as shown below. The meter will beep when it detects that the control solution has been added if the sound is enabled.

Close the optics cover when prompted by the meter. The meter will continue to display the prompt for a few seconds after the optics cover has been closed. Then the test timer screen will be displayed, to show how long the test has been processing. Do not open the optics cover until the test is finished.

Interpreting Results

When the test is complete, the results screen will be displayed, indicating the result is a Control Solution Test result.



If the result is within the range printed on the *Mission*® PT/INR Control Solution label, the meter and test strips are performing properly.

If the INR value is outside of the range printed on the control solution label or if the meter is displaying an error message, see the Control Solution Package Insert or contact your local distributor for further instructions.

Note: Discard the control solution vial after use. The control solution is only good for 30 minutes after mixing the components.

Section 8 Maintenance

It is recommended that the meter be stored in the carrying case after each use. Avoid getting liquids, residue, or control solution inside the meter. The only required periodic maintenance is the following:

Check that the code number on the code chip matches the code number on the test strip pouch label for each new lot of test strips (See Section 4).

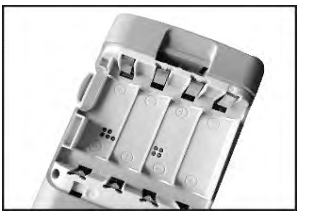
Set the meter's internal clock with the correct date and time, if necessary (e.g. daylight savings time. See Section 5).

Change the batteries when necessary.

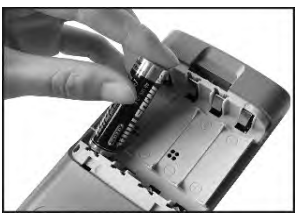
Keep the meter clean.

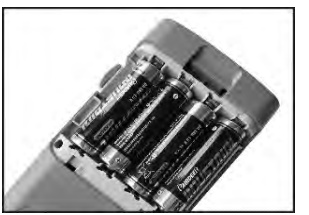
Replacing the Batteries

Remove the included AA batteries from their protective packaging.



Turn the meter over and locate the battery cover on the back of the meter. Open the cover by pressing the cover release tab with an arrow. Press the tab towards the bottom of the meter to release the cover and reveal the battery compartment.





Install the 4 AA batteries into the battery compartment, as shown, alternating orientation up and down as indicated in the bottom of the battery compartment.

Reinstall the battery compartment cover and ensure it locks in place.

Disinfection Process

Reason to Disinfect

The disinfection process is to prevent potential spreading of infectious diseases through blood borne pathogens. It is important to remove any stains/debris for a more effective disinfection of the meter.

Wash your hands thoroughly with soap and water after handling the meter and test strips.

Disinfection and Pre-Cleaning before the Disinfection Process

First use DisCide Ultra Disinfecting wipes (EPA Registration No. 10492-4) to wipe clean the entire meter surface and remove any stains/debris. This pre-cleaning is to prepare the meter surface for a disinfection process.

Next use another fresh DisCide Ultra Disinfecting wipe to wipe the entire meter surface. Make sure the meter surface is thoroughly damp. The meter surface must remain visibly wet for one full minute to effectively disinfect. After disinfection, please allow the meter to air dry completely before using it again. When disinfecting, avoid inserting the DisCide Ultra Disinfecting wipe into the communication ports and the power supply input port.

When cleaning the optical window area, the meter may turn on when the electrodes are wet. After cleaning, the meter may be turned off or it will turn off automatically after two minutes.

Disinfection Wipes

The suggested wipes for your *Mission*® PT/INR meter pre-cleaning and disinfection are DisCide Ultra Disinfecting Wipes (EPA Registration No. 10492-4). The active ingredients include: Isopropyl alcohol 63.25%, n-alkyl dimethyl benzyl ammonium chloride 0.12% and n-alkyl dimethyl ethyl benzyl ammonium chloride 0.12%.

Disinfection and Pre-Cleaning Frequency

Be sure to disinfect the meter after each use. This is important to prevent the potential transmitting of infectious diseases.

Avoid getting liquids, dirt, blood, or control solution into the meter's power or data ports.

It is recommended that the meter is stored in its carrying case after each use. The *Mission*® PT/INR meter is a precision electronic instrument. Please handle it with care.

Always check to ensure all display segments appear when the meter is turned on. This ensures the meter is working properly.

Note: All parts of the kit are considered biohazardous after first use and can potentially transmit infectious diseases, even after cleaning and disinfection. Please follow proper precautions when handling the meter.

General Maintenance

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

Replacing the Optics Cover

Examine the underside of the optics cover. It should be clean and free of blood or other debris. If necessary, clean the underside of the optics cover using the DisCide Ultra Disinfecting wipes as previously outlined.

The meter optics cover can easily be removed if it becomes contaminated or damaged. The optics cover is designed to be removed without damaging the meter.

Hold the meter in one hand. Firmly grasp the optics cover with the other hand with the thumb located on the underside of the optics cover.

Place sideways pressure on the optics cover, bending one arm attaching the optics cover to the meter and moving the other arm with its mounting tab away from its seat. Rotate the free optics cover mounting arm up away from its seat. Once the free arm is away from its seat, the second arm can be disengaged, freeing the optics cover from the meter.

Attach a new optics cover by grasping the optics cover and meter, as explained above, and locate one mounting arm tab into its seat.

Rotate the optics cover down until the second mounting arm snaps into its seat. The optics cover should move freely once it is snapped into place. Once the optics cover is attached, replace the strip holder.

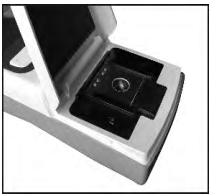
Strip Holder Installation

The strip holder comes already installed on the meter. After cleaning the strip holder, it should be re-installed on the meter.

To remove the strip holder, push the strip holder away from the optics cover, sliding it off the strip holder grooves towards the bottom of the meter. If blood or debris is present, clean the strip holder using the DisCide Ultra Disinfecting wipes as previously outlined.

To install the strip holder, make sure it is aligned with the strip holder grooves, as shown below. Slide the strip holder in until it snaps into place.

The meter is now ready for testing.



Caution: To avoid the transmission of infectious diseases between multiple patients using the same meter, be sure to replace or clean the strip holder as previously described.

Meter Strip/Specimen Application Area

The optical window should be clean and free of lint, blood, and other debris.

Using the DisCide Ultra Disinfecting wipes, remove the strip holder and clean the meter strip and specimen application area and the four metal pins including the optical window area as previously outlined in the Disinfection Process section.

Section 9 Precautions

Observe the precautions listed below to ensure accurate results and proper operation of the analyzer.

- The protection provided by the equipment may be impaired if used in a manner not defined in this instruction manual.
- Read the instructions in the User's Manual and complete any necessary training before use.
- For professional use, wear gloves to avoid contact with potentially hazardous biological specimens during testing.
- Keep the unit clean, as instructed in Section 8 Maintenance.
- Do not use accessories that are not supplied or recommended by the manufacturer.
- Follow all local regulations when discarding the unit and its' accessories.
- Do not use the unit or the test strips outside of the specified operating temperature range.
- Compare your result with the desired target range set by a healthcare professional at specified intervals in order to verify your self-testing performance. An interval of six months or less is recommended and more frequent intervals may be necessary for the new self-testers, e.g. monthly.
- Don't put the equipment in the place where it is difficult to unplug from the power source.

Meter Use and Precautions

- Do not get water or other liquids inside the meter.
- The optics area must be kept clean and free of specimens or other contaminants. Refer to Section 8 Maintenance.
- Make sure the Code Numbers displayed on the meter, printed on the code chip, and printed on the test strip pouch label are the same number.
- Keep the meter dry and avoid exposing it to extreme temperatures or humidity.
- Do not drop the meter or get it wet. If either has occurred, ensure the meter is working properly by running a calibration check.

- Do not take the meter apart. This will void the warranty.
- Only clean with recommended materials to avoid any damage to the meter.
- Keep the meter and all associated parts out of reach of children.
- Avoid storing or operating the meter in direct sunlight, excessive temperatures, or high humidity. Refer to Appendix 1 Meter Specifications for environmental operating requirements.
- This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2.
- 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.

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

Test Strip Use and Precautions

- Do not store test strips outside their pouch. Test strips must be stored in their original strip pouch.
- Once the pouch is opened, use the test strip within 10 minutes.
- For *in vitro* diagnostic use. Test strips are only to be used outside of the body for testing purposes.
- Only use *Mission*® PT/INR Test Strips with the *Mission*® PT /INR Meter.
- Use the code chip that is included in each box of test strips.
- Do not use test strips that are torn, bent, or damaged in anyway. Do not attempt to reuse test strips.
- Before performing an INR test, make sure that the Code Number on the meter display matches the Code Number shown on the test strip pouch.
- Store test strips in a cool, dry place. Store away from heat and direct sunlight.
- Transport and store test strips in their pouches within 2-30 ºC (36-86 ºF) with less than 85% humidity, until the expiration date printed on the strip pouch.

Note: The expiration date is printed in a Year-Month format. For example, 2017-01 is January, 2017.

Section 10 Troubleshooting

Error Codes	Causes	Solutions
E0	Power-on diagnostic failed	Turn the meter off and then on. If error persists, contact your local distributor.
E1	Electronic Calibration test failed	A problem was encountered with the Electronic Calibrator check process or results. Remove and inspect the test strip. Replace, if necessary. Turn the meter off and restart the calibration process.
E3	Specimen applied too soon	Replace the test strip and perform the test again. Wait until display indicates the meter is ready for specimen application.
E4	Contaminated or dirty strip	Check the test strip to ensure it is not used or contaminated. Replace the test strip with a new one and test again.
E5	Insufficient specimen	Applied specimen volume was insufficient to obtain a result. Replace the test strip and run the test again with a fresh specimen.
E7	Heater Failure	A test strip heater failure was detected during operation. Turn the meter off and perform the test again. If it repeats, contact your local distributor.
E8	System Failure	Turn the meter off and then on to see if the error clears. If it repeats, contact your local distributor.
E9	Indeterminate Specimen	The meter is unable to determine an accurate INR reading. Replace the test strip and repeat the test with a fresh specimen.

E10	Communication Error	Turn the meter off, check the cables to the computer, then turn the meter back on. If error persists, contact your local distributor.
E11	Ambient Temperature out of range	Ambient temperature is too high or too low to maintain a controlled test strip temperature. Re-locate the meter into the proper temperature environment.
Warning and Error Icons		
	Flashing ¼ full icon. Batteries are discharged and need to be replaced soon	Test results will still be accurate, but replace the batteries as soon as possible.
	Strip removed during test	Insert a new test strip. Make sure to wait until prompted to remove the strip.
	Low battery	Replace the batteries before the next test is performed.
	INR reading is >7.0	Repeat the test to ensure consistency of readings. Run Electronic Calibrator checks. Run liquid calibrator checks.
	INR reading is <0.7	Repeat the test to ensure consistency of readings. Run Electronic Calibrator checks. Run liquid calibrator checks.
	Code Chip problem	Missing or faulty code chip. Insert the code chip found within the box of test strips and/or remove and replace the code chip.
	Lid Left Open	Close the optics cover and restart the test.

Appendix 1 Meter Specifications

Feature	Specifications
Methodology	Optical Fluorescence
Test Time	About 2 minutes
Measurement Range	0.7 to 7.0 INR (International Normalized Ratio)
Specimen	Capillary whole blood Venous whole blood
Specimen Volume	15 µL
Power Source	4 - AA (LR6) Alkaline Batteries AC Adapter Input: 100-240V~ 50-60Hz, 400mA Output: 6.0V DC 0.85A
Battery Life	> 100 tests
Units of Measurement	INR, PT (seconds)
Memory	200 records
Automatic Shut Off	2 minutes after last operation
Meter Size	152 mm × 72 mm × 38mm
Display Size	53 mm × 29 mm
Weight	170 g (without batteries)
Meter Storage Conditions	0 - 50ºC (32 - 122ºF); ≤ 95% RH
Operating Conditions	15 - 35ºC (59 - 95ºF); ≤ 90% RH
Meter Connectors	RS232 port for printer connection, mini USB port for data transfer, and power adapter port

Appendix 2 Index of Symbols

	Attention, see instructions for use		Use by
	Manufacturer	CODE	Code Number
IVD	For *in vitro* diagnostic use only	REF	Catalog #
	Store between 2-30°C	LOT	Lot Number
	Tests per Kit	SN	Serial Number
	Do not discard along with household waste		This Side Up
	Fragile, handle with care		Keep Dry
	Keep away from sunlight and heat		Do not reuse
EC REP	Authorized Representative		No Code Chip
	Power On/Off		Next
INR ↑	High INR Reading	INR ↓	Low INR Reading
	Battery Status		Optics Cover Left Open

In addition to the standard symbols above, the user interface may be set to display icons or English text. The following list shows the equivalent of the Iconic interface and the English text interface, including the definitions.

Code Chip			No code chip inserted or there is a code chip error
Memory		Data Log	Represents the meter data log memory to review the previous INR readings in chronological order
Delete Log		Delete Log?	Deletes the meter data stored in memory
LCD Contrast Adjustment		Contrast	Sets the contrast of the LCD screen for better viewing
Date Setup		Date	Sets the current date
Time Setup		Time	Sets the current time
Audio On		Audio On	Sets the audio warnings to ON
Audio Off		Audio Off	Sets the audio warnings to OFF
PT Meter Information		Meter Info	Displays the meter serial number and current software version

Icon	 English	Once in the Language sub-menu, displays the choice to display Icons or English text
Password	 Password	Password protects patient data in the meter
Down	 Down	Key to move down
Up	 Up	Key to move up
Exit	 Exit	Key to Exit the menu
Level 1	 Lvl 1	Level 1 EC Test
Level 2	 Lvl 2	Level 2 EC Test
Control Solution Test	 CS Tst	Control Solution Test
Electronic Calibrator	 Elec Calib	Electronic Calibrator
OK	 OK	Key to accept the current setting
Strip Removed	 No Strip	Strip removed during test
Print Log(s) or Exit	 PRT/EX	Press to display print screen, hold the button to exit back to the previous screen

One/Ten	 One Ten	Print one or ten data logs
Enter Password	 ENTER PASSWORD	Enter the password
Incorrect Password Entered	 INCORRECT PASSWORD ENTERED	Entered password does not match the saved password
Reenter Password	REENTER PASSWORD	Reenter the password
Passwords do not match	PASSWORD REENTER DOES NOT MATCH	Password reentered does not match the previous password
Password Cleared	 PASSWORD CLEARED	Password is cleared, meter is not password protected
Password Enabled	 PASSWORD ENABLED	Password is enabled, meter is password protected

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.

For your records, write the purchase date of your meter 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 dates of original purchase or installation (except as noted below). During the stated two years 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 strips other than strips 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 express 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.

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