

# **Coag-Sense<sup>®</sup>**

## **Prothrombin Time (PT)/INR**

### **Monitoring System**

*Self-Test User's Manual*



Caution: Federal law restricts this device to sale by or on the order of a physician.

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## Coag-Sense® PT/INR Monitoring System

The Coag-Sense PT/INR Monitoring System is a medical device for quantitative Prothrombin Time (PT) and International Normalized Ratio (INR) testing using Coag-Sense Test Strips.

The Coag-Sense system can be used for self-testing of clotting times by patients at home. However, results obtained should not be used to adjust your medication without talking with your doctor or health care professional.

### Contacting CoaguSense

If you have any questions or concerns with the Coag-Sense system, please contact CoaguSense Technical Support at:

**CoaguSense, Inc.**  
**48377 Fremont Blvd., STE 113**  
**Fremont, CA 94538**  
**Toll Free: 1-866-903-0890**

E-Mail: [techsupport@coagusense.com](mailto:techsupport@coagusense.com)



**WARNING:** Contact your health care provider if you have any questions about your test results and any actions you should take.

**Note** ■: *The Coag-Sense PT/INR Monitoring System meter is packaged in a special box. Do not discard this box. Re-use the package to transport the meter or, if directed by Customer Service to return it for testing.*

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## 1. About This Manual


The purpose of the Coag-Sense PT/INR Monitoring System User's Manual is to help you understand your Coag-Sense system, its parts, and its intended function. It provides you with the information you need to perform PT/INR testing with the Coag-Sense system.

It is important to read this entire User Manual and inserts that came with the disposable Coag-Sense test strips. You must complete proper training on the Coag-Sense system and practice the test with a health care provider before attempting to use this device. The Coag-Sense system should only be used with a doctor's prescription.

This User Manual has different formats and symbols to distinguish warnings, notes, and meter buttons.



**WARNING:** This indicates a warning or precaution. Please read and understand all warnings and precautions. They tell you about potential safety hazards and situations that may cause injury. If you have any questions, please ask your doctor or contact Technical Support (USA) at **1-866-903-0890**.

**Note** : Notes provide additional information that is useful or important. All notes are italicized. Words in **BOLD ALL-CAPITALS** refer to buttons on the Coag-Sense meter.

## 2. System Description

The Coag-Sense Self-Test PT/INR Monitoring System is used for measurement of Prothrombin Time (PT) in fresh, capillary whole blood. The Coag-Sense system is intended for use outside the body by people taking warfarin or other oral anticoagulant (blood thinning) therapy who need to monitor clotting time.

The meter performs a self-test when it is first turned on. If there are any problems with the meter, an error message is shown on the display. Refer to the “Troubleshooting” section of this manual or contact Tech Support. A test strip is inserted and heated in the meter prior to sample application.

The strip contains a tiny wheel with spokes that pull the sample into the reaction well. The spokes quickly and completely mix the sample with the clot initiating component of the test strip.

The PT time is determined from when (a) the sample is drawn into the reaction well of the test strip and detected by a beam of light until (b) a clot forms and interrupts a beam of light. The PT result is converted to an INR (International Normalized Ratio) using the calibration data stored in the meter. INR is a mathematical correction of the PT result that adjusts for sensitivity differences among different PT systems.

The meter continues to check every feature of its operation through a system of self-checks.

Your Coag-Sense Self-Test PT/INR Monitoring System (Catalog number 03P50-01) comes supplied with:

- Coag-Sense PT/INR Meter
- Coag-Sense Self-Test User's Manual
- Coag-Sense Self-Test Quick Reference Guide
- Sample Transfer Tubes
- Sample package of Single-use, Auto Sterile Lancets
- Four AA 1.5 V Alkaline Batteries (not installed)

You will also need:

- Coag-Sense Test Strip (catalog number 03P56-50), which includes:
  - 50 Patient Test Strips
  - 2 Low Control Strips
  - 2 High Control Strips
  - 1 Control Strip Activation Solution
- Gauze or cotton balls
- Lancets, 21 gauge

An optional AC Power Adapter can be ordered (catalog number 03P64-01).

### The Coag-Sense Meter: Top View



### The Coag-Sense Meter: Bottom View

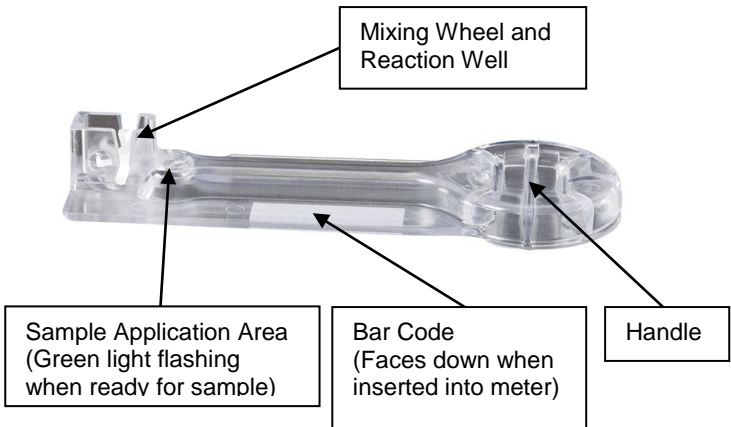




## The Coag-Sense Meter: Rear View



## The Coag-Sense Test Strip



### 3. Reordering Information

Product	Catalog #
Coag-Sense Self-Test PT/INR System	03P50-01
Test Strip Kit (Qty 50)	03P56-50
Sample Transfer Tubes (Pack of 54)	03P53-54
Lancets (Box of 100)	03P58-02
AC Power Adapter (optional item)	03P64-01
Control Strip Kit -4	03P72-04

### 4. Warnings and Precautions



#### General

- Patients taking Warfarin (Coumadin) and other oral blood thinners should consult with their healthcare provider before adjusting their dosage.
- Patients should consult with their doctor for the appropriate INR therapeutic range for them.
- Patients who have recently taken or are currently taking any type of Heparin or Low Molecular Weight Heparin anticoagulant should not use this test system and should consult their doctor.


#### Test Site and Blood Sample

- The quality of the blood sample can become the weakest link in any PT test. A blood sample of poor quality can produce results of poor quality. Read the

section on “Collecting a Fingerstick Sample” for more information.

- Use only fresh fingerstick capillary blood for testing. The blood should only come in contact with the products provided with the Coag-Sense System. Other products may have anti-coagulant agents on their surfaces and result in unreliable test results.
- The Coag-Sense PT/INR System is for in vitro diagnostic use only.
- **Blood samples must be applied to the test strip immediately after collection or the blood begins to clot, causing unreliable results.**
- Squeezing the fingerstick site excessively (milking) releases “tissue layer” fluid and tissue factors that can cause unreliable results.
- The fingerstick site should be washed with warm water and soap, and then completely dried. The site must be clean of all hand oils/lotions and foreign matter, which may cause unreliable results.
- If Alcohol wipes are used, wipe the fingerstick site with a gauze pad and make sure the site is completely dry. If any alcohol remains (or is re-introduced) on the finger, it may cause unreliable results.
- The quality of fingerstick and the sample delivered are important to the test results. **If there is a question about the sample or sample collection, obtain a new strip, repeat the fingerstick on a different finger, and test again.**
- If a test requires a repeat, use a different finger for the fingerstick, since blood may have started to clot on the first finger, which may cause unreliable results.

- If there is a bubble or an air pocket showing in the blood sample in the transfer tube, start the test over. Use a new strip and fingerstick (using a different finger and transfer tube) or results may be unreliable.

**Note** : *If you are unable to get a PT/ INR test result contact Technical Support at 1-866-903-0890, your home testing service provider or your healthcare provider.*

## Meter

- Use only AA 1.5 V alkaline batteries in the Coag-Sense meter. Rechargeable batteries cannot be used because damage to the meter may result. Do not throw used batteries in the trash. Dispose of properly.
- The meter is a delicate instrument, and should be handled with care. Dropping or other mishandling may cause damage to the meter. If this should occur, call Tech Support.
- Do not allow any liquids to spill on the meter. If this should occur, call Tech Support.
- Do not put the meter in liquid. Do not allow liquids to get into any of the connectors or plugs on the meter.
- Only use the method provided in this User's Manual to clean the Coag-Sense meter.
- Do not move or touch the meter while it is running a test. Unreliable results may occur.
- Store and use the Coag-Sense PT/INR Test System following the instructions in this manual.
- Use only the optional Coag-Sense AC power adapter with the meter or damage to the meter may result.











- The Coag-Sense PT/INR Test System is designed for indoor use only.
- This equipment generates, uses, and can radiate radiofrequency (RF) energy. If your meter is not set up and used according to this User Manual, the RF energy may interfere with other devices in the area.
- This equipment is tested to meet the limits for medical devices, which is designed to provide a reasonable protection against harmful interference when the equipment is operated in a home environment. If not installed and used in accordance with these instructions, it may cause harmful interference to other devices in the vicinity. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving device.
  - Increase the separation between the equipment.
  - Connect the equipment to an outlet on a circuit different from that to which the other devices are connected.
- In the unlikely event of an electric power surge (i.e., severe static discharge during a thunderstorm), when using the optional AC power adapter, the display screen may go blank. If this occurs, unplug the power supply from the back of your meter, wait 5 seconds and plug it back in. Normal operation should return, but you may have to reset the time and date.
- **DO NOT OPEN THE METER.** Do not attempt to repair or modify this meter. The Coag-Sense Self-Test PT Meter does not require any periodic maintenance

and there are no user serviceable parts inside. If you have problems, please contact technical support or your health care provider to arrange for service.

### **Test Strips/Control Strips/Control Strip Activating Solution**


- The test strips are designed for single use only. Do not reuse the test strips.
- Discard used strips in a puncture resistant, biohazard waste (SHARPS) container.
- PT Test Strips, Control Strips, and Control Strip Activating Solution are perishable goods with a limited shelf life. Do not use any of these items if the expiration date has passed.
- Refer to the package insert that is supplied with each box of test strips for more information.

## 5. Hazards and Symbols

	<b>Warning.</b> This indicates a warning or precaution, requiring special attention
	Class II Equipment. The AC Adapter is double insulated
	Biological Risks: Disposable items pose biological risks. The strips and fingerstick materials should be disposed in appropriate biohazard waste containers
	Electronic device. Dispose of unit and batteries properly
	Use by/Expiration Date
	Lot number
	For In vitro diagnostic use
	Storage temperature range
	Manufacturer
	Single Use Only – Do Not Reuse

## Directions for Use

Patients taking Warfarin (Coumadin) and/or other oral blood thinners should consult with their doctor before adjusting their dosage. Consult your doctor for the appropriate PT and INR values for you.

**Note** : *The Coag-Sense PT Test System meter is packaged in a special box. Do not discard this box. Re-use the package to transport the meter or, if directed by Customer Service to return it for testing.*

## 6. Operating Conditions

To ensure that your Coag-Sense System is working correctly, be sure the following conditions are met:

- Be sure that the meter and strip are at room temperature before use. Room temperature is between 65°F and 90°F (18°C and 32°C).
- Relative humidity should be between 10% and 85%, without condensation, for testing.
- Avoid dropping the meter or treating it roughly.
- Use the meter only on a level, stable surface.
- Do not move or touch the meter during testing.
- Do not place the meter in direct sunlight or high intensity light.



## 7. Power On and Off

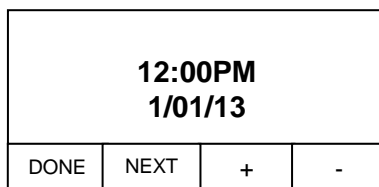
- Install the AA 1.5 V batteries, which are needed to maintain the time and date settings. (See “Replacing the Batteries” for more information). The optional AC power adapter can be connected at this time.
- Place the meter on a flat, stable surface. To turn the meter on. Press the **POWER** button, which is on the topside of the meter, beneath the display. To turn the meter off, press the same **POWER** button again.

## 8. Setting the Time and Date

### Action

1. If the date and time have not been set before on the meter or the setting has been lost, the display looks like this with blinking characters.
2. The blinking characters may be changed by pressing + to increase or – to decrease. When correct, press **NEXT** to advance to the next character.

### Meter Display



↑  
**Press NEXT to advance to next character.**

**Action**

- Once you have entered the correct date and time, press **DONE** to exit this function.
- Once the date and time are set, the display looks like this.

**Meter Display**

<b>12:00PM</b> <b>1/01/013</b>			
DONE	NEXT	+	-

↑  
 Press **DONE** when date and time are correct

- If you need to change the date or time in the future, press **SET**. The meter display shows the set time and date.

<b>READY</b> <b>INSERT</b> <b>STRIP</b>			
OFF		SET	MEM

↑  
 Press **SET** to adjust date and time again (if necessary)

- Adjust the time and date by pressing + to increase or – to decrease. When the time and date are correct, press **DONE** when finished.

<b>8:00AM</b> <b>3/07/13</b>			
DONE	NEXT	+	-


↑  
 Press **DONE** when date and time are correct

**Note** 🚫: The clock time does not adjust for daylight savings time.

## 9. Performing a Control Test


Control testing confirms the performance of both the meter and the test strips and should be completed for each new lot of test strips and any other time as indicated by your testing service provider or doctor. Control testing can also be run whenever the PT results are unexpected to make sure that the system is working properly. There are 2 low control strips, 2 high control strips and a control strip activation solution shipped with each test strip kit. Extra controls may be ordered separately.

Follow these steps to perform a test on a low or high control.

**Note** : *The following directions are for running a low control strip. When this procedure is complete, run a high control strip. The controls may be run in any order. The meter will display and store the results in PT seconds only. The meter does not use or require results from the control strips prior to running a patient test strip.*




**WARNING:** Do not move or touch the meter while it is running a test. Unreliable results may occur.

**Note** : *If an error message appears, consult the “Troubleshooting” section of this manual.*

## Action

1. Make sure that the meter is on by pressing the POWER button on the top of the meter.
2. Open a low control package, tearing at the notched end. Remove the strip. Set the package aside.

**Note** : Make sure that the expiration date has not passed by checking the date on the front of the control package.

## Meter Display



3. Holding the round end, gently push the strip completely into the meter. The strip fits snugly when pushed all the way toward the back wall of the strip holder.
4. When the strip is correctly inserted, the display looks like this.



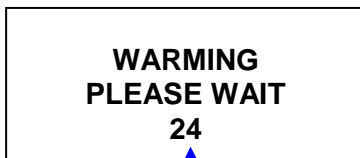
**Note** : If anything other than

## Action

*this is displayed, refer to the “Troubleshooting” section.*

## Meter Display

- The meter warms the strip. The display looks like this. It shows a countdown of the time remaining during the warm-up cycle.



- Note** 📌: *Do not apply the control activation solution until the warm-up is complete and the meter tells you to do so.*

↑  
**Warming count  
down in seconds**

- The meter beeps once when it is ready for the control strip activation solution. The screen looks like this.



- Note** 📌: *You now have 2 minutes to apply the activation solution to the control strip.*

- Open the control activation solution and hold at an angle to allow insertion of the transfer tube
- Holding the transfer tube below bulb insert into control activation solution.



- Note** 📌: *DO NOT SQUEEZE THE BULB. Be careful to avoid getting*

## Action

## Meter Display

*bubbles in the transfer tube.*

- Rest hand on instrument to steady. Move fingers to flat sides of bulb being sure to cover air hole. Insert tip into sample application well of test strip, touching tip down on strip at flashing green light. Squeeze bulb until solution leaves tube.



**Note** 📌: Keep pressure on bulb and pull away from strip (avoids back suction)

- When the control strip activation solution is properly applied and detected the flashing green light will turn off, and the meter display looks like this.


**TESTING  
PLEASE  
WAIT**


**Note** 📌: *If this screen is not displayed, either not enough solution was applied or the solution had bubbles in it. Remove the strip. Retest with a new control strip. Do NOT attempt to add more solution to the control strip.*


- When the low control testing is complete, the display shows “OK” and looks similar to this.


**LO CONTL OK  
PT 12.8  
12/18/13 4:01 PM  
REMOVE STRIP**

**Action****Meter Display**

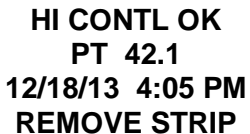
**Note** : To avoid confusing control strip INR results with patient test strip INR results, the high control test will display the control result in PT seconds only.

**Note** : If anything other than this is displayed, refer to the “Troubleshooting” section.


**Note** : The date and time shown in the display are examples only. The date and time shown after actual testing is the current date and time.

**Note** : Remember to repeat this entire procedure with a high control strip.

12. When high control testing is complete, the display shows “OK” and looks similar to this.



**HI CONTL OK  
PT 42.1  
12/18/13 4:05 PM  
REMOVE STRIP**

**Note** : If an error message appears, refer to the “Troubleshooting” section.

13. Once the controls have been successfully tested, remember to throw the control strips into a biohazard (SHARPS) container. You can now proceed to test your blood. If you are not going to test, turn off the meter by pressing the **POWER** button.

## 10. Performing a PT Test



**WARNING:** Place the meter on a stationary, level surface for testing. Do not move the meter or allow it to vibrate during a test. Unreliable results may occur.

### Action

1. Make sure that the meter is on by pressing the **POWER** button on the top of the meter.

**Note** 📌: *If an error message appears, refer to the "Troubleshooting" section.*

### Meter Display

<b>READY INSERT STRIP</b>			
OFF		SET	MEM

2. Open a PT test strip package, tearing at the notched end. Remove the strip. Set the package aside.

**Note** 📌: *Make sure that the expiration date has not passed.*

3. Holding the round end, gently push the strip completely into the meter in one smooth motion. The strip fits snugly when pushed all the way toward the back wall of the strip holder.



**Action**

4. When the test strip is correctly inserted, the display looks like this.

**Meter Display**

<b>PAT. STRIP DETECTED</b>			
OFF		SET	MEM

5. The meter warms the strip. The display looks like this. The meter counts down the time remaining during the warm-up cycle.

<b>WARMING PLEASE WAIT 24</b>			
---------------------------------------	--	--	--

↑  
Warming count down  
in seconds

**Note** 📌: *Do not apply any test sample until the warm-up completes and the meter tells you to do so.*

**While the meter is warming up, get ready to perform a fingerstick. See “Collecting a Fingerstick Sample” in this manual.**

6. When the warm-up completes, the meter beeps once. The screen looks like this.

<b>APPLY SAMPLE</b>			
OFF		SET	MEM

**Note** 📌: *You now have 2 ½ minutes to apply the sample to the test strip.*

## Action

7. Immediately after collecting the patient sample, place the tip of the sample transfer tube at a 45° angle into the sample well on the test strip where you see the flashing green light. Gently touch the tip down onto the sample well.
8. Slowly squeeze the bulb until the blood leaves the tube being careful not to introduce air bubbles into the sample. Keep pressure on bulb while you pull your hand away to avoid back suction of sample.
9. Discard the sample transfer tube in a biohazard waste container.
10. When the sample is detected, the meter display looks like this.

## Meter Display



**TESTING  
PLEASE  
WAIT**

**Note** 🚫: *If this screen is not displayed, either not enough blood sample was applied or the sample had bubbles in it. Remove the strip and retest with a new strip.*

**Action****Meter Display**

11. When testing is complete, the meter beeps once. The results (INR and PT in seconds) are shown on the screen.

**INR 2.2**  
**PT 22.2**  
**1/18/13 5:50 PM**  
**REMOVE STRIP**

**Note** 📌: *If any display other than the one shown is visible (such as **CLOT TIME TOO SHORT** or **NO CLOT DETECTED**), refer to the “Troubleshooting” section.*

12. Record the results. Then remove the test strip. Throw it away in the biohazard container.

**Note** 📌: *Repeat the test if the results seem unusually low or high. If the results still seem unusual after a second test, contact your doctor or CoaguSense Tech Support.*

Turn the meter off by pressing the **POWER** button when you are finished testing. If left unattended, the meter automatically turns off in a few minutes.

The last 100 test results are stored in memory with the time and date. Refer to “Reviewing the Memory” in this manual for more information.



**WARNING:** Unexpected results

An unexpected result may include any result that falls outside the therapeutic target range, or a result that falls inside the target range but is not consistent with your current health status (e.g., you have bleeding or bruising).

What can cause unexpected results:

1. Certain prescription drugs (for example, heparin) and certain over-the-counter medications (for example, antibiotics) can affect the action of oral blood thinners and the INR value.
2. Changes in diet, lifestyle, or taking nutritional supplements such as ginkgo biloba can affect the action of oral blood thinners and the INR value.
3. Liver diseases, congestive heart failure, thyroid dysfunction, Lupus, antiphospholipid antibody syndrome (APS) and other diseases or conditions can affect the action of oral blood thinners and the INR value.

Be sure your doctor is aware of any of these conditions before you begin testing, and any time there are changes in health status or medications after you have begun testing.


**What to do when you get an unexpected result:**

Follow instructions for re-testing on the Coag-Sense PT/INR meter. For unexpected results, contact Technical support at 1-866-903-0890. Always follow your doctor's instructions for adjusting your dose of anticoagulant medication, or any other corrective actions.

## 11. Collecting a Fingerstick Sample

### Tips for a Successful Fingerstick

- Make sure that you have all the supplies needed before you start.
  - Lancet device
  - Sample Transfer Tubes
  - Sterile alcohol prep pad
  - Gauze square or cotton ball
  - Band-Aid (optional)
  - Puncture resistant biohazard container (SHARPS)
- Do not use fingers with tight rings, scars, calluses, or other features that prevent getting good access to the blood.
- Thoroughly clean your hands by washing with soap and warm water first. The warm water also helps blood circulation. Completely dry your hands. Instead, you may use Isopropyl alcohol wipes and then dry the area with gauze.
- For better blood flow, keep your hand below your heart.
- One of the middle or index fingers on either hand is recommended.
- Gently squeeze or massage the finger to be lanced, near the tip. Good circulation can be seen if your fingertip changes to a pinkish shade.
- Gently squeeze or massage the finger to be lanced, near the tip. Good circulation can be seen if your fingertip changes to a pinkish shade.

**Note** : *If the fingertip color is not changing, then warm the fingers carefully by running them under warm water or rubbing them vigorously. Remember to dry them completely or your results may be unreliable.*

- Always use new unused materials (such as lancet, gauze, etc.).
- If you are being helped when getting a test sample, your helper should wash their hands with soap and warm water. They should also put on gloves before doing the fingerstick.
- Use a 21g 1.8 mm depth single-use auto-disabling lancet. Smaller gauge/shallow depth lancets (i.e. diabetes 23g lancets) should not be used. Refer to the Lancet device instructions for more information on use.
- Lance the fleshy part of the fingertip just slightly left or right of the center. **Press lancet firmly against finger.**
- Refer to the package inserts for the Lancet device for more information.

### **The best test sample is when:**

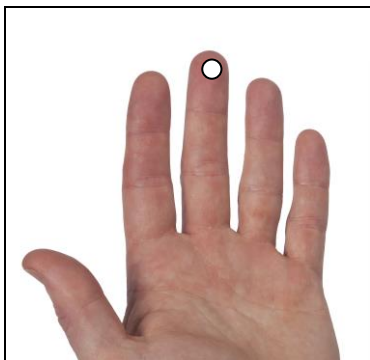
- The blood is collected right after the fingerstick and put into the test strip sample well without delay. If the blood is not collected or tested quickly (within 15 seconds), repeat with a fresh fingerstick and a new strip.
- There are no bubbles or air pockets in the tube or sample.

## Action

1. Wash hands with soap and warm water. Dry completely.
2. Choose a site toward the center of one of the middle fingers to lance.

**Note** 📌: *Avoid the more sensitive area in the center. Stay away from any calluses or scars.*

## Meter Display



3. If desired, clean the fingertip with an alcohol wipe using one side for the first cleaning. Use the second side for a final wipe.
4. Dry the fingertip with gauze to remove any excess alcohol.




- Note** 📌: Residual alcohol will affect results. Be certain that finger is completely dry.
5. Hold the finger tightly between your thumb and index finger, or place hand on a table with the palm facing up. Keep your fingertip from touching anything so that it remains clean and ready.

## Action

6. Remove the cap from the single use lancet. Place it against the skin. Holding the body of the lancet, push down firmly against the finger to lance the surface of skin.

## Meter Display



**Note** : *The blood should flow freely. If it doesn't, gently squeeze the finger to get it started. Lowering your hand and arm to your lap so that the fingertip is below the heart helps the blood drop form.*



### **WARNING:**

Squeezing the fingerstick site excessively (milking) releases "tissue layer" fluid that can cause unreliable results.

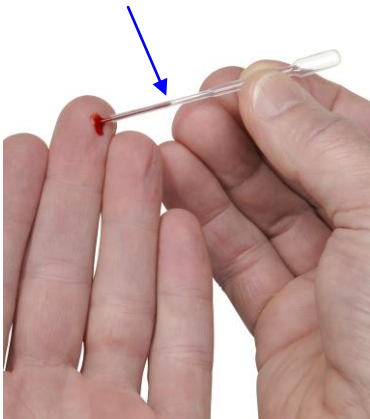


## Action

7. When ready to collect the drop of blood, hold the Sample Transfer Tube between your thumb and forefinger below the bulb, being sure not to cover the air hole in bulb. **DO NOT SQUEEZE THE BULB.**
8. With tube horizontal touch tip to bead of blood. Let capillary action fill capillary portion of tube until blood flow stops. Squeeze finger to produce additional blood if require to completely fill capillary portion of tube.
9. Once you have collected the sample, immediately put it into the sample well on the test strip. See “**Performing a PT Test**” section of this manual.
10. Apply gauze to your fingerstick site with firm pressure until the bleeding stops. Apply a bandage if desired.
11. Throw the lancet and the strip into a biohazard container.

## Meter Display

Capillary portion of tube ends here



**WARNING:** If there is a bubble or an air pocket showing in the blood sample in the sample transfer tube, start the test over with a new fingerstick on a different finger.

**Note** 📌: The minimum amount must be collected before adding it to the test strip. Never add more blood to the test strip.

## 12. Reviewing the Memory

The Coag-Sense meter stores up to 100 results along with the date and time, in its memory. When the 100th result is reached, the first result 1 is replaced (written over) with test results for test number 101. This continues with the oldest result being replaced with the most recent. Memory is not lost if there is a break in power for any length of time. Memory cannot be erased.

### Action


The memory can be accessed from any mode that displays a **MEM** button.

1. Press **MEM**. The meter displays the last two records. Press **PREV** or **NEXT** to scroll through the result records.
3. Press **DONE** when finished.

### Meter Display

Example of display with two most recent records:

2/07/13		12:56 PM	
INR	5.2	PT	49.1
4/07/13		12:56 PM	
INR	2.9	PT	28.8
DONE		NEXT	PREV

**Note** : If any messages are displayed, such as **CLOT TIME TOO SHORT**, or **NO CLOT DETECTED** refer to the “Troubleshooting” section of this manual.

## 13. Control Strips

Quality control is an important part of PT time testing. Using control strips make sure that you are carrying out the steps of the test correctly. It also ensures that your Coag-Sense System is working properly and that test strip integrity has been maintained. Both a high and low control should be tested before running the first PT test strip from a new box. A control can also be tested if you have unexpected results. There are 2 low control strips, 2 high control strips and control activation solution shipped with each box of test strips. Additional controls may be ordered separately. See “Performing a Control Test” in this manual.

## 14. Replacing the Batteries

It is not necessary to install batteries in the meter if the optional AC adapter is plugged into a wall socket. However, if no batteries are installed and the meter is unplugged or there is a power outage, the time and date settings go back to the factory settings.

The meter is designed for AA 1.5 V alkaline batteries only. It does not re-charge these alkaline batteries when connected to AC power.



**WARNING:** Use only AA 1.5 V alkaline batteries in the Coag-Sense meter. Rechargeable batteries should not be used as they can result in damage to the meter.

The AA 1.5 V batteries can last for approximately 300 tests if the meter is operating only on batteries. The batteries can last

through their shelf life if the optional AC power adapter is plugged in.

If the batteries are running low, the meter displays a BATTERY LOW message. The meter can run another one or two additional PT tests, but the batteries should be replaced as soon as possible. You can plug the optional AC power adapter into a wall socket and replace the batteries later.

When the message BATTERY TOO LOW SEE MANUAL appears on the meter display, the meter shuts off after a brief delay. The batteries must be replaced or the meter must be connected to a wall socket with the optional AC power adapter to continue testing. The meter time and date settings are lost and the meter will need to have the date and time reset. See “Setting the Time and Date” in this manual.

### **Complete the following steps to replace the AA 1.5 V alkaline batteries.**

1. Turn the meter upside down.
2. Remove the battery door by pressing on the battery door release.



3. Remove the old batteries and replace with 4 new standard 1.5V AA alkaline batteries. (The proper direction for battery placement is shown on a figure inside the battery compartment).
4. Replace the battery door.
5. Properly dispose of old batteries.



## 15. Cleaning the Meter

No maintenance is required other than routine cleaning.

Clean the outside of the Coag-Sense meter with a clean damp non-abrasive cloth. If required, a mild disinfectant (such as a 10% bleach solution or 70% isopropyl alcohol) may be used. Apply the cleaning solution to the cloth to dampen. Then put cloth on the meter. Alcohol prep pads may also be used.



**WARNING:** Do not put the meter in liquid. Do not allow liquids to get into any of the connectors or plugs on the meter.



**WARNING:** Do not allow any liquids to spill on the meter. If this should occur, unplug the meter (if plugged in) and call Tech Support.

## 16. Troubleshooting

You may see the following error messages while using the CoagSense meter. This section discusses how to resolve most problems that you might encounter. If you have any questions or problems during the troubleshooting process, note the display wording and contact Tech Support at **866-903-0890** or email [support@coagusense.com](mailto:support@coagusense.com).

Meter Display	Possible Cause	Solution
<b>REMOVE STRIP</b>	Meter turned off with used strip in it.	Remove the strip and begin again.
	If no strip present possible shipment damage.	Call Tech Support
<b>NO SAMPLE DETECTED</b>	Either no sample or not enough sample was applied to the strip within 2 1/2 minutes after the “Apply Sample” message was displayed. This can also happen if sample is applied on the strip but outside of the sample application well.	Repeat the entire procedure (including fingerstick on a different finger) with a new strip. <ul style="list-style-type: none"> <li>• Apply the sample within 2 1/2 minutes after display of the “Apply Sample” message.</li> <li>• Ensure that the pipette tip/transfer tube touches the sample well before dispensing sample.</li> </ul>

Meter Display	Possible Cause	Solution
<p><b>CLOT TIME TOO SHORT</b></p>	<p>The clotting time was very short and out of testing range (&lt;8 seconds).</p> <p>An air bubble was detected in the sample.</p>	<p>Repeat the entire procedure (including fingerstick on a different finger) with a new strip.</p> <p>Visually confirm that no air bubbles are in the sample before applying to test strip.</p> <p>Gently squeeze the transfer tube bulb until the blood exits being sure not to introduce air bubbles.</p> <p>If the same message repeats, contact Technical Support.</p>



Meter Display	Possible Cause	Solution
<b>NO CLOT DETECTED</b>	<p>The sample clotting time was very long and out of testing range.</p> <p>There was insufficient sample transferred to the test strip. Possible causes include; improper lancing (21g lancet required), an air bubble in the sample, not allowing sample to completely fill glass portion of transfer tube, or the sample was drawn back into the transfer tube before removing tip from the test strip well..</p>	<p>Visually confirm that no air bubbles are in the sample and that the glass portion of the transfer tube is full before applying to test strip.</p> <p>Release pressure on the transfer tube bulb only after removing transfer tube from sample application well.</p> <p>Repeat the entire procedure (including fingerstick) with a new strip. If the same message displays, use an alternative testing method and contact Tech Support.</p>
<b>TEST STRIP EXPIRED SEE MANUAL</b>	<p>The lot of strips has expired.</p> <p>Date is incorrect.</p>	<p>Use a different lot of strips that has not expired.</p> <p>Verify the date setting on the meter is current.</p>

Meter Display	Possible Cause	Solution
<b>CONTROL OUT OF RANGE</b>	The control strip result is outside of its acceptable range. This may be due to a problem with the shipment/storage of the control strips or the control activation solution. Plasma on control strips have a limited shelf life and the clotting time will change when exposed to temperatures outside the storage range.	Repeat test with another control strip. If the second test is out of range, contact Tech Support.  Control strips should be tested immediately upon receipt of your shipment of new test strips as they have a limited shelf life.
<b>ROOM TEMP INCORRECT SEE MANUAL</b>	The temperature of the room is either below or above the operating temperature range of the meter.	Move the meter to a place that is within the operating temperature range of the meter (55°F to 95°F, 13°C to 35°C) and allow meter time to adjust to correct temperature. Repeat testing.
<b>WHEEL PROBLEM</b>	The test strip was inserted at an incorrect angle or speed.  There may be a problem with the wheel on the strip or with the meter  A used strip was inserted.	Reinsert the strip holding the back of the meter steady with one hand while inserting the strip completely using a quick smooth motion with the other hand. If display persists try again with another strip.  If the message displays again, contact Tech Support.

Meter Display	Possible Cause	Solution
<p><b>BAR CODE READ FAILURE</b></p>	<p>The strip was inserted at an incorrect angle or speed.</p> <p>There may be a problem with the bar code on the strip or with the meter.</p> <p>The meter is in direct sunlight or near a high-intensity light source.</p>	<p>Take the strip out and reinsert holding the back of the instrument steady with one hand while inserting the strip completely with the other hand. Insert the strip using a quick smooth motion.</p> <p>Move the meter indoors into room lighting or away from light source.</p> <p>If error persists try again with another strip. If the message displays again, contact Tech Support.</p>
<p><b>HEATER PROBLEM</b></p>	<p>The meter is too warm or too cold, or there may be a problem with the meter.</p>	<p>Move the meter to a place that is within the operating temperature range of the meter (55°F to 95°F, 13°C to 35°C) and allow meter time to adjust to correct temperature. Repeat testing.</p> <p>Turn meter off then on again.</p> <p>Try again with another strip.</p> <p>If the display persists contact Tech Support.</p>

Meter Display	Possible Cause	Solution
<b>DETECT PROBLEM</b>	There may be a problem with the strip or with the meter.	<p>Take the strip out and reinsert holding the back of the instrument steady with one hand while inserting the strip completely with the other hand. Insert the strip using a quick smooth motion.</p> <p>Try again with another strip.</p> <p>If the message persists contact Technical Support.</p>
<b>LIQUID PROBLEM</b>	There may be a problem with the strip or with the meter.	<p>Take the strip out and reinsert holding the back of the instrument steady with one hand while inserting the strip completely with the other hand. Insert the strip using a quick smooth motion.</p> <p>Try again with another strip.</p> <p>If the message persists contact Technical Support.</p>
<b>MOTOR PROBLEM</b>	There may be a problem with the strip or with the meter.	Try again with another strip or contact Tech Support.

<b>Meter Display</b>	<b>Possible Cause</b>	<b>Solution</b>
<b>BATTERY LOW</b>	The meter batteries need to be replaced.	The meter can complete the current test, as well as one or two more tests. However, the batteries should be replaced as soon as possible.
<b>BATTERY TOO LOW</b>	The meter batteries must be replaced.	Replace batteries to continue with testing.

## 17. Performance Characteristics

**Expected Values:** Fingertick whole blood results are reported in units equivalent to a reference method.

**Measuring Range:** INR 0.8 to 8.0

**Normal Range:** The following example represents a common normal range for the Coag-Sense System.

INR: 0.7 to 1.2

PT: 8.0 to 15.0

## 18. Meter Specifications

Operating Temperature	55°F to 95°F (13°C to 35°C)
Operating Humidity	10% to 85% (without condensation)
Storage Temperature	-4°F to 122°F (-20°C to 50°C)
Storage Humidity	10% to 95% (without condensation)
Memory	Capable of storing 100 tests with time and date
Battery	Quantity 4 of 1.5V (AA) alkaline batteries.
AC Input	120 VAC (Use Coag-Sense Adapter Only)
Power Output	6.0V, 2.0A
Blood Sample Size	10-12 $\mu$ L
Data Port	RS232
Size	3" (7.6 cm) x 6.5" (16.5 cm) x 5.75" (14.5 cm)
Weight	With 4 AA 1.5 V alkaline batteries: 1.2 lb (0.5 kg)
Equipment Classification	Class II with external power supply. Internally powered when operated with batteries. IPXO rating.



**WARNING:** Use only the Coag-Sense AC power adapter or damage to the meter may result.

## 19. Warranty

### Limited One (1) Year Warranty

#### Use of the Coag-Sense PT/INR Monitoring System

The Coag-Sense PT/INR Monitoring System is designed for use in monitoring patients on oral anticoagulant therapy. Proper adherence to the instructions in this User Manual and package insert are critical to proper operation. **WARNING: Failure to comply with the User Manual could lead to inaccurate PT/INR results which could lead to incorrect medication dosing which could lead to injury or death.**

#### Limited Warranty

CoaguSense warrants that the Coag-Sense meter is free from all defects in material and workmanship for a period of one (1) year from date of purchase. When the meter is used for the intended purpose and in the appropriate manner, the remedy is repair or replacement at CoaguSense's option. The warranty does not apply to a meter damaged by misuse, alteration or tampering to either the hardware or software. Contact CoaguSense Tech Support at 886-903-0890 for instructions.

THIS WARRANTY APPLIES ONLY TO THE METER. COAGUSENSE'S ENTIRE LIABILITY IN CONNECTION WITH THE METER, REGARDLES OF THE LEGAL OR EQUITABLE BASIS OF ANY CLAIM, IS LIMITED TO THE PURCHASE PRICE OF THE METER. IN NO EVENT SHALL COAGUSENSE, INC. BE LIABLE TO THE PURCHASER FOR ANY INCIDENTAL, CONSEQUEN-TIAL (INCLUDING BUT NOT LIMITED TO LOSS OF INCOME OR PROFITS) SPECIAL, INDIRECT, OR PUNITIVE DAMAGES ARISING FROM OR IN



ANY WAY CONNECTED WITH THE PURCHASE OR OPERATION OF THE METER OR ITS PARTS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE IS IMPLIED FROM THE SALE OF THE COAG-SENSE PT/INR TEST SYSTEM. NO WARRANTY, EXPRESS OR IMPLIED (IF ANY) SHALL EXTEND FOR A LONGER DURATION THAN THE DURATION OF THE EXPRESS WARRANTY STATED ABOVE.

### **Instructions for Meter or Product Return**

Upon review and agreement with CoaguSense Customer Service, you may be directed to return the unit. Should this occur, clean the outside surface using 5% bleach solution or 70% isopropyl alcohol as described in the Maintenance” section. The original packaging may be required for this purpose. If this is not available, a cushioned shipping box must be used to return the meter.

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## Technical Support

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**Fremont, CA 94538**  
**Toll Free: 1-866-903-0890**

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