Coag-Sense®
Prothrombin Time (PT)/INR Monitoring System

Professional User's Manual

CoaguSense

© Copyright 2013, CoaguSense, Inc. All rights reserved.

No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system or translated into any language or computer language, in any form or by any means, including, but not limited to, electronic, magnetic, optical, chemical, manual, or otherwise without written permission of CoaguSense.

Coag-Sense is a registered trademark of CoaguSense, Inc.

Contacting CoaguSense

If you have any questions or concerns with the Coag-Sense® Prothrombin Time (PT)/INR Monitoring 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**

Note : *The Coag-Sense Prothrombin Time (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.*

The Coag-Sense PT/INR System may be used for multiple-patient testing in a professional healthcare setting.

The Coag-Sense® Prothrombin Time (PT)/INR Monitoring System

Intended Use

The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professionals at the point of care to monitor patients who are on warfarin-type (coumarin) anticoagulation therapy. The device is not intended to be used for screening purposes.

The Coag-Sense PT/INR System may be used for multiple-patient testing in a professional healthcare setting.

Anticoagulation Medication

Oral anticoagulation medications, also known as blood thinners, are typically prescribed to patients to avoid unwanted clots. The patient's blood clotting time must be monitored to ensure that their dosage is correct.

Oral anti-coagulation medication is prescribed to patients with acute and chronic conditions including, but not limited to: congestive heart failure, atrial fibrillation, prosthetic heart valve, myocardial infarction, joint replacement, deep vein thrombosis, pulmonary embolism, thrombotic stroke, coronary artery disease, venous thromboembolism and cancer.

Blood-clotting Time

The rate at which blood clots is measured in units is called International Normalized Ratio (INR). It is very important for patients to stay within their individual target INR range. If the INR

is too low, the risk of blood clots increases. If the INR is too high, the risk of hemorrhaging increases. The patient's physician will determine the most appropriate INR range for the patient, depending upon the patient's indication and how they respond to the oral anticoagulant.

Table of Contents

1. About This Manual

The purpose of the Coag-Sense Prothrombin Time (PT)/INR Monitoring System User Manual is to help you understand your Coag-Sense PT/INR system, its parts, and its intended function. It provides you with the information you need to perform a PT test with the Coag-Sense PT/INR system.

You must complete proper training on the Coag-Sense PT/INR system before you begin using the system. It is also important to read this entire User Manual and the inserts that come with the disposable Coag-Sense test strips. 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 contact CoaguSense Tech Support at **1-866-903-0890** (USA).

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

2. System Description

The Coag-Sense Prothrombin Time (PT)/INR System is used for quantitative measurement of Prothrombin Time (PT) in fresh, capillary whole blood. The Coag-Sense PT/INR system is intended for use outside the body (in vitro diagnostic use) to test patients taking warfarin-type 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 Technical 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 the 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 series of self-checks.

Your Coag-Sense PT/INR Professional System
(Catalog number 03P60-01) comes supplied with:

- Coag-Sense PT/INR Meter
- Coag-Sense PT/INR System Professional User's Manual
- Coag-Sense PT/INR System Professional Quick Reference Guide
- Four AA 1.5 V Alkaline Batteries (not installed)
- AC Power Supply
- Sample package of Single-use, Auto Sterile Lancets

You will also need:

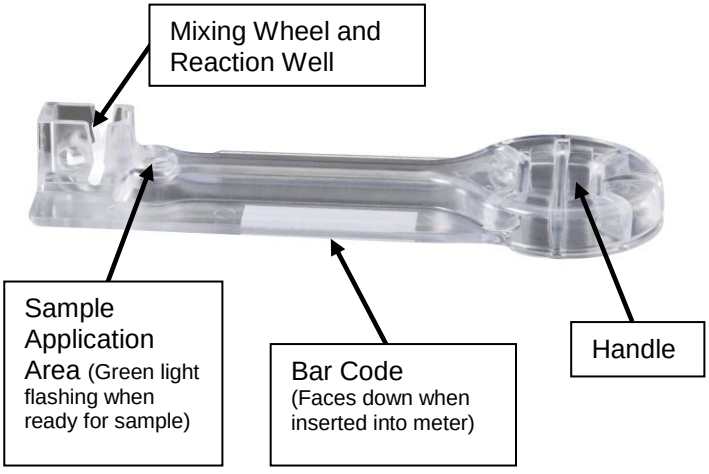
- Coag-Sense Professional Test Strip Kit-50
  (Catalog number 03P56-50), which includes:
  - 50 Patient Test Strips
  - 2 Low Control Strips
  - 2 High Control Strips
  - 1 Control Strip Activation Solution
  - 54 Sample Transfer Tubes
- Isopropyl alcohol or alcohol wipes
- Gauze
- Single-use Auto Lancets, 21 gauge - box of 100
- Puncture-resistant bio-hazard (SHARPS) container

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

For a description of the products listed below, please see the information above.

Product	Catalog #
Coag-Sense PT/INR Professional System	03P60-01
Coag-Sense Test Strip Kit, Box of 50	03P56-50
Coag-Sense Control Strip Kit -10	03P69-10
Sample Transfer Tubes, Pack of 54	03P53-54
Lancets, Normal Depth (Box of 100)	03P58-03
AC Power Adapter	03P64-01

4. Warnings and Precautions

General

- This test system is not recommend for patients who have recently taken or are currently taking any type of Heparin anticoagulant.

Test Site and Blood Sample

- The Coag-Sense PT/INR system is for in vitro diagnostic use only.

- The Coag-Sense meter will not produce a result if the test strip is past its expiration date
- The quality of the blood sample can affect PT test results. A blood sample of poor quality can produce unreliable results. Read the section on “Collecting a Fingerstick Sample” for more information.
- Blood samples must be applied to the test strip **immediately** after collection or the blood begins to clot, causing unreliable results.
- The blood sample transferred to the test strip must be a minimum of 10 µL in volume. Low sample volume may cause an error message.
- Use only fresh fingerstick capillary blood for testing. The blood should only come in contact with the products provided with the Coag-Sense PT/INR system. Other products may have anti-coagulant agents on their surfaces and result in unreliable test results.
- Squeezing the fingerstick site excessively (milking) releases interstitial “tissue layer” fluid that can cause unreliable results.
- The fingerstick site can 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 Isopropyl Alcohol (IPA) 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 delivery technique 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 you need to repeat a test, 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 collection tube, start the test over. Use a new fingerstick (using a different finger and collection tube) or results may be unreliable.
- Refer to the package inserts provided with the Lancets and Sample Transfer Tubes for more information.

Meter

- If using batteries, use only AA 1.5 V alkaline batteries in the Coag-Sense meter. Rechargeable batteries cannot be used as they may damage the meter.
- Use only the included Coag-Sense AC adapter with the meter or damage to the meter may result.
- 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 Technical Support.
- Do not allow any liquids to spill on the meter. If this should occur, call Technical 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 Manual to clean the Coag-Sense PT/INR 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 system following the instructions in this manual.
- 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 clinical or 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.
- Any equipment connected to the data port must be certified to IEC 60601-1. If you connect any equipment that is not recommended by CoaguSense, you are responsible for meeting the requirements of this standard.
- 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 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.
- Patient samples, controls,used strips and lancets are potentially infectious. Discard used materials in a puncture resistant, biohazard waste container using universal precautions.
- 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

	**Warning.** 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
	This product meets the provisions of Council Directive 98/79/EC for In Vitro Diagnostic Devices
	Authorized/European Representative

Directions for Use

Note : *The Coag-Sense PT/INR system 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

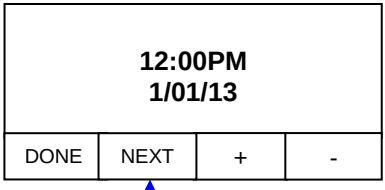
To ensure that your Coag-Sense PT/INR system is working correctly, be sure the following conditions are met:

- Be sure that the meter and strip are at room temperature before use. Room temperature is between 65ºF and 90ºF (18ºC and 32ºC). **The meter will not allow a test to proceed until the meter is at room temperature.**
- 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 AC 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

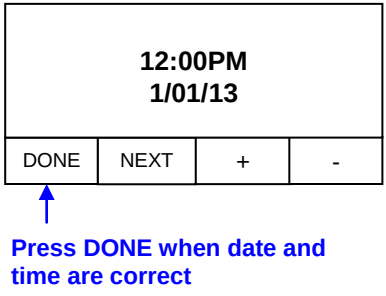
Action	Meter Display
1. If the date and time have not been set before on the meter or the setting has been lost, the display looks like this with blinking characters.	
2. The blinking characters may be changed by pressing + to increase or – to decrease. When correct, press **NEXT** to advance to the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

Action

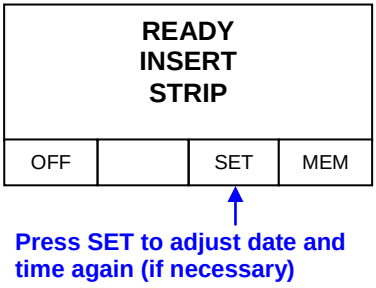
3. Once you have entered the correct date and time, press **DONE** to exit this function.

4. Once the date and time are set, the display looks like this.

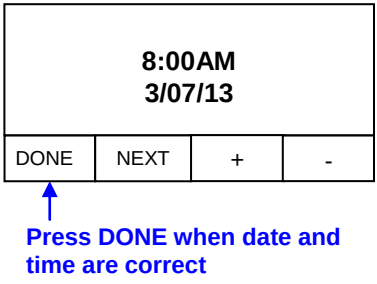
Meter Display



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



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



Note *: The clock time does not adjust for daylight savings time. The date format is mm/dd/yy.*

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. 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.

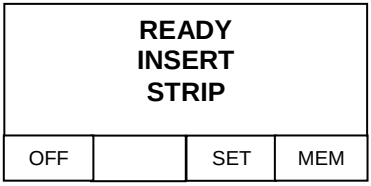
Note : *The following directions are for running a low control strip. When this procedure is complete, run a high control strip. The controls may be run in any order. The meter will display and store the results in PT seconds only. The meter does not use or require results from the control strips prior to running a patient test strip. If multiple boxes of test strips are purchased at the same time and they have the same lot number, only one low and one high control from that lot needs to be tested.*

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.*

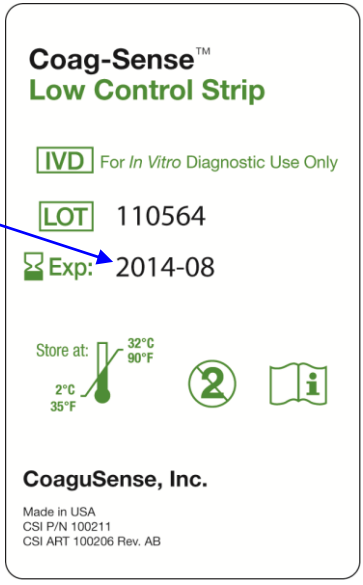
Action	Meter Display

1. Make sure that the power is on by pressing the **POWER** button on the top of the meter and the display looks like this.



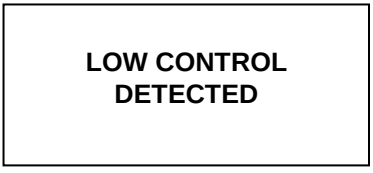
2. Open a low control package, tearing at the notched end. Remove the strip. Set the package aside.

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



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

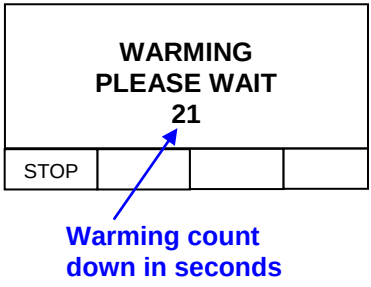
4. When the strip is correctly inserted, the display looks like this.



Action **Meter Display**

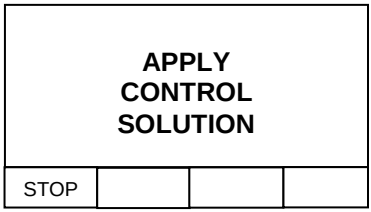
Note : If anything other than this is displayed, refer to the "Troubleshooting" section.

5. 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.*

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



Note : *You now have 2.5 minutes to apply the activation solution to the control strip.*

7. Open the control activation solution and hold at an angle to allow insertion of the transfer tube.

8. Holding the transfer tube below bulb insert into control activation solution.

Note : *DO NOT SQEEZE THE BULB. Be careful to avoid getting bubbles in the transfer tube.*

Action	Meter Display
9. 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.	
10. When the control 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 strip.*

Action	Meter Display
11. When testing is complete, the display shows "OK" and looks similar to this.	**LO CONTL OK** **PT 22.5** **10/18/13 8:01 AM** **REMOVE STRIP**

Action **Meter Display**

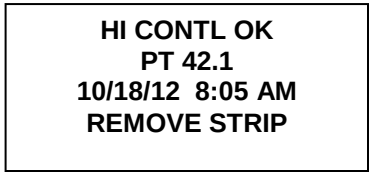
Note : *To avoid confusing control strip INR results with patient test strip INR results, control test results will display in PT seconds only.*

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

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.



13. Once the controls have been successfully tested, remember to throw the control strips into a biohazard container. You can now proceed to testing patient blood samples. If you are not going to test, turn off the meter by pressing the **POWER** button. The opened control activation solution may be used until the expiration date.

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. Wear gloves and follow all applicable hygiene and safety procedures.

Action	Meter Display
1. Make sure that the meter is on by pressing the POWER button on the top of the meter.	READY INSERT STRIP OFF | | SET | MEM
Note : *If an error message appears, refer to the "Troubleshooting" section.*	

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.*

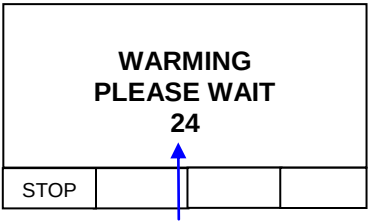
3. Holding the round end, gently push the strip completely into the meter. The strip fits snuggly when pushed all the way toward the back wall of the strip holder.

Action

Meter Display

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

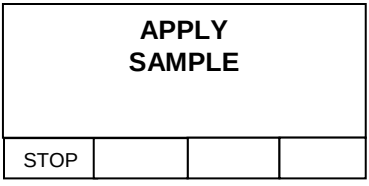
5. The meter warms the strip. The display looks like this. The meter counts down the time remaining during the warm-up cycle.



Note : *Do not apply any sample until the warm-up is complete and the meter tells you 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 is complete, the meter beeps once. The screen looks like this.



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

Action	Meter Display
7. Immediately after collecting the patient sample, place the tip of the sample transfer tube at a 45º 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.	**TESTING** **PLEASE WAIT**

Note : *If this screen is not displayed, either not enough blood sample was applied or the sample had air 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** **10/18/13 8:50 AM** **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 a biohazard collection container.

Note : *Repeat the test if the results seem unusually low or high. If the results still seem unusual after a second test, contact CoaguSense Technical 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 patient's therapeutic target range, or a result that falls inside the target range but is not consistent with the patient's current health status (e.g., patient is experiencing bleeding or bruising).

What can cause unexpected results:

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.

Changes in diet, lifestyle, or taking nutritional supplements such as ginkgo biloba can affect the action of oral blood thinners and the INR value. 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 to confirm whether the patient has any of these conditions before you begin testing, and any time there are changes in health patient 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**. Consider re-testing using an alternative method prior to adjusting the patient's 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 (Single use , auto disabling)
  - Sample Transfer Tubes
  - Sterile alcohol prep pads
  - Gauze square
  - Band-Aids
  - Biohazard waste container (SHARPS)
- For fingerstick blood testing, increasing the flow of blood in the finger will help you capture a good drop of blood. Before you prick the finger, have the patient warm their hand by washing it in warm water, holding it under their armpit, or by using a hand warmer. Ensure that the patient's hand is dry prior to testing.
- Do not use fingers with tight rings, scars, calluses, or other features that prevent getting good access to the blood.
- 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 the patient's fingertip changes to a pinkish shade.
- 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.

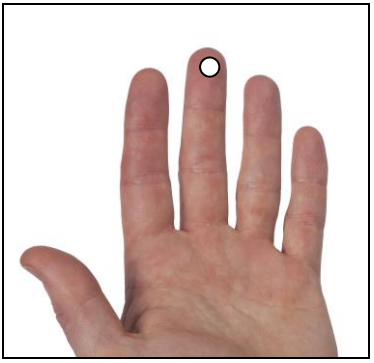
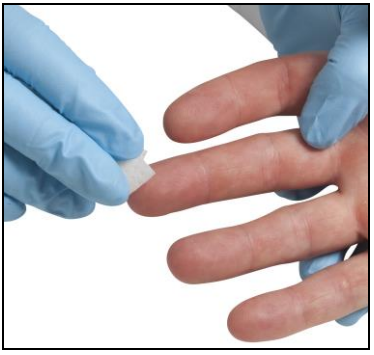
- Lance the fleshy part of the fingertip just slightly left or right of the center. **Press lancet firmly against finger.**
- For better blood flow, you may have the patient hold their hand below their heart. **Squeeze the finger from the sides to open up the wound for proper blood flow if necessary to produce pea sized drop.**

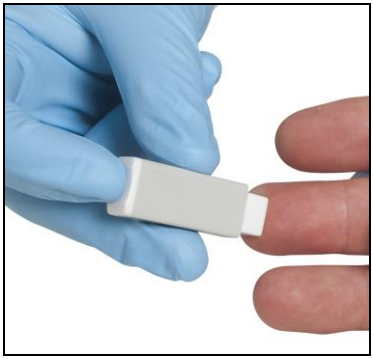
The best test sample is when:

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

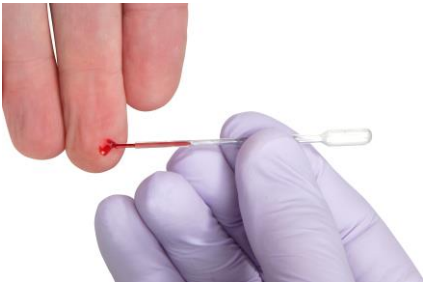
WARNING: Patient samples, controls, used test strips and lancets are potentially infectious. Dispose of strips and collection devices using universal precautions.

Action	Meter Display

Action	Meter Display
1. Have patient wash hands with soap and warm water. Dry completely.	
2. Choose a site near the top of one of the middle fingers to lance.	
Note : *Avoid the more sensitive area in the center. Avoid any calluses or scars.*	
3. 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.	
5. Place the patient's on solid surface with the palm of the hand facing up.	
Note : *Residual alcohol will affect results. Be certain that finger is completely dry.*	

Action	Meter Display
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. **Do not lance finger until meter displays "APPLY SAMPLE".** A minimum of 10µl of collected blood sample is required.	
Note : *The blood should bleed freely. If it doesn't, gently squeeze the finger to get it started. Lowering the patient's hand and arm so that the fingertip is below the heart helps the blood drop form.*	

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

Action	Meter Display
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 glass portion of tube until blood flow stops. Squeeze finger to produce additional blood if require to completely fill glass 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**.	

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

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.

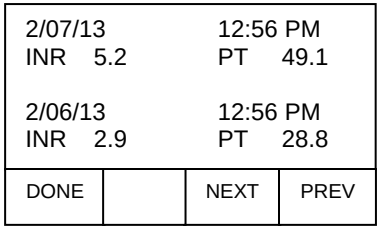
Action

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

1. Press **MEM**. The meter displays the last two records.
2. 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:



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

13. Printing

With the optional portable printer and cable results from the Coag-Sense meter memory can be printed on either thermal paper or other media such as thermal labels for applying to patient charts.

What you'll need:

- Coag-Sense meter running software version 3.87 or greater
- Citizen Pocket Printer PD-22 thermal portable printer
- Citizen RS232C Cable Model PD79901
- Serial Cable Null Modem Adapter (available from CoaguSense at no charge)
- Citizen Thermal Paper PD99906-OM or 2" wide thermal labels

RS-232C Cable (9-pin D-sub type connector)

Printing Test Results:

1. Attach the Null Modem Adapter to the data port on the back of the Coag-Sense Meter. Connect the large DB9 end of the Citizen printer cable to the Null Modem Adapter. Insert the small cable connector into the side of the Citizen printer.

2. Press and hold the green power button on the left side of the Citizen printer until the power light comes on.

3. Turn on the Coag-Sense meter.

4. Press MEM. The two most recent results in memory will be shown. If you wish to go further back into the meter's memory to print a result press NEXT. Continue to press NEXT until the desired result(s) are visible in the display. Press PREV if you need to scroll back to more recent results.

5. Once you have the result(s) you wish to print displayed, press PRINT. To print the top result in the display window press PRN1. To print the bottom result in the display window press PRN2.

If the results fail to print, confirm that the printer is on as it automatically turns off after a few minutes. If the printer turns off after pressing the PRN1 or PRN2 then the batteries in the printer are be too weak and should be replaced.

For assistance with the printing function call Technical Support at 1-866-903-0890.

14. Control Strips

Quality control is an important part of PT time testing. Using the high and low control strips ensures you are performing the steps of the test correctly. It also ensures that your Coag-Sense System is working properly and that reagent in the test strips is working as expected.

Your Coag-Sense test strip includes true control strips containing the same thromboplastin reagent as the test strip along with plasma of known INR. One high and one low control should be tested before using a new PT test strip lot. Controls should also be tested if you have unexpected results. There are 2 low control strips, 2 high control strips and one control activation solution vial shipped with each new box of test strips. Additional controls may be ordered separately. See "Performing a Control Test" in this manual.

15. 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 reset 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 will last for approximately 300 tests if the meter is operating only on batteries. The batteries may 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 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 releases.

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.

16. Cleaning and Disinfecting the Meter

No maintenance is required other than routine cleaning and/or disinfecting. To clean the outside of the meter use a clean damp non-abrasive cloth.

If instructions for use are properly followed, patients should not come in direct contact with the Coag-Sense meter thereby reducing the possible transmission of bloodborne pathogens between patients. Sample should always be transferred from the patient to the meter using a new disposable sample transfer tube or disposable pipette tip.

The meter housing can be disinfected using a 10% bleach solution (EPA reg. No. 5813-50). Apply the disinfecting product to a lint-free cloth and wipe the meter or MiniPipette for a minimum contact time of 2 minutes.

The test strip is designed to contain the patient sample, preventing it from entering the meter. Do not clean/disinfect inside the meter where the test strip is inserted, cleaning this area should be avoided. Please call Technical Support at 1-866-903-0890 if this area requires cleaning/disinfecting.

After disinfecting the meter, gloves should be removed and hands washed before proceeding to the next patient.

Please call technical support at 1-866-903-0890 with any cleaning or disinfecting questions.

WARNING: Do not put the meter in liquid. Do not allow liquids to get inside the meter or into any of the connectors or plugs on the meter. If you suspect any physical damage or deterioration of the meter (such as cracking or gross distortion), or if the meter does not turn on after cleaning, call Technical Support.

Always refer to local, state and federal disinfecting guidelines. More information on bloodborne pathogen safety and proper disinfecting techniques can be found at:

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)
http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.htm

17. Troubleshooting

You may see the following error messages while using the Coag-Sense 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 Technical Support at **866-903-0890** or email **techsupport@coagusense.com**.

Meter Display	Possible Cause	Solution
REMOVE STRIP	Meter turned off with used strip in it. If no strip present possible shipment damage.	Remove the strip and begin again. Call Tech Support
NO SAMPLE DETECTED	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. • Apply the sample within 2 1/2 minutes after display of the “Apply Sample” message. • Ensure that the transfer tube touches the sample well before dispensing sample.

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

Meter Display	Possible Cause	Solution
NO CLOT DETECTED	The sample clotting time was very long and out of testing range. 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.	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. Release pressure on the transfer tube bulb only after removing transfer tube from sample application well. Confirm that the patient has not recently taken heparin or other contraindicated drugs listed on the test strip package insert. Repeat the entire procedure (including fingerstick) with a new strip. If the same message displays, use an alternative testing method and contact Tech Support.
TEST STRIP EXPIRED SEE MANUAL	The lot of strips has expired. Date is incorrect.	Use a different lot of strips that has not expired. Verify the date setting on the meter is current.

Meter Display	Possible Cause	Solution
CONTROL OUT OF RANGE	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.
ROOM TEMP INCORRECT SEE MANUAL	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 (55ºF to 95ºF, 13ºC to 35ºC) and allow meter time to adjust to correct temperature. Repeat testing.
WHEEL PROBLEM	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
BAR CODE READ FAILURE	The strip was inserted at an incorrect angle or speed. There may be a problem with the bar code on the strip or with the meter. The meter is in direct sunlight or near a high-intensity light source.	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. Move the meter indoors into room lighting or away from light source. If error persists try again with another strip. If the message displays again, contact Tech Support.
HEATER PROBLEM	The meter is too warm or too cold, or there may be a problem with the meter.	Move the meter to a place that is within the operating temperature range of the meter (55ºF to 95ºF, 13ºC to 35ºC) and allow meter time to adjust to correct temperature. Repeat testing. Turn meter off then on again. Try again with another strip. If the display persists contact Tech Support.

Meter Display	Possible Cause	Solution
DETECT PROBLEM	There may be a problem with the strip or with the meter.	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. Try again with another strip. If the message persists contact Technical Support.
LIQUID PROBLEM	There may be a problem with the strip or with the meter.	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. Try again with another strip. If the message persists contact Technical Support.

Meter Display	Possible Cause	Solution
MOTOR PROBLEM	There may be a problem with the strip or with the meter.	Turn the meter off then back on. Try again with another strip. If the message persists contact Technical Support.
BATTERY LOW	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.
BATTERY TOO LOW	The meter batteries must be replaced.	Replace batteries to continue with testing.

18. Performance Characteristics

Expected Values: Results are reported in INR units equivalent to the plasma reference method. For PT testing, variations in the source of thromboplastin may cause some differences in results between methods. It is recommended that the same method be used to monitor the anticoagulation therapy over time.

Measuring Range: INR 0.8 to 8.0

Normal Range: The following example represents a common normal range for the Coag-Sense PT/INR system.

INR: 0.7 to 1.2
PT: 8.0 to 15.0

19. 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	120V AC (Use with Coag-Sense Adapter Only)
Power Output	6.0V, 2.0A
Blood Sample Size	10-12 µL
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: 1.8 lb. (658 g)
Equipment Classification	Class II with external power supply. Internally powered when operated with batteries. IPXO rating.

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

20. Warranty

Limited One (1) Year Warranty

Use of the Coag-Sense PT/INR System

The Coag-Sense PT/INR 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 Technical Support at 1-866-903-0890 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, CONSEQUENTIAL (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 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 10% bleach solution as described in the “Cleaning and Disinfecting the Meter” section. The original packaging may be required for this purpose. If this is not available, a cushioned shipping box may be required.

21. Index

R

S

T

U

W

Technical Support

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

E-Mail: **techsupport@coagusense.com**

CoaguSense, Inc.
48377 Fremont Blvd, STE 113
Fremont, CA 94538 USA
Tel: (510) 270-5442
Fax: (510-226-6540

EC REP

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

Product Made in U.S.A.

REF Part No. 100220
CSI P/N 100220 Rev AF