USER's Manual

COAG-SENSE®
PT3 PROTHROMBIN TIME(PT)/INR MONITORING SYSTEM

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
USA
Toll Free: 1-866-903-0890

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

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1. Introduction

The Coag-Sense® PT3 Prothrombin Time (PT)/INR Monitoring System

Intended Use

The Coag-Sense PT3 Prothrombin Time (PT)/INR Monitoring System is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and International Normalized Ratio (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.

Importance of PT/INR Monitoring

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 anticoagulants.

Anticoagulation Medication:

Oral anticoagulation medications, 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.

Important Information Regarding 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.

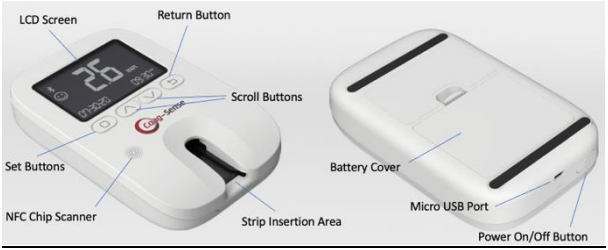
You must complete proper training on the Coag-Sense PT/INR system and configure the meter to your needs before you begin using the system. It is also important to read this entire User Manual and the inserts that come with the disposable Coag-Sense test strips. This User Manual has different formats 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 Technical Support at 1-866-903-0890 (USA).

2. System Description

The Coag-Sense Prothrombin Time (PT)/INR System is used for quantitative measurement of INR (International Normalized Ratio) based on a Prothrombin Time (PT) response to monitor the effect of therapy with vitamin K antagonists like Coumadin® (warfarin). The system uses fresh, capillary whole blood.



Meter:

The meter has a **LCD screen** that shows results, information, icons and results recalled from memory. To select an option, gently click on button below the screen. There are four buttons, **SET, SCROLL UP, SCROLL DOWN and RETURN or Previous Screen Button**. The **Power ON/OFF** button is located on the top right side of the meter. The **NFC (Near Field Communication) Tag scanner** is a built-in scanner that is used to scan the NFC card containing the strip (Control and Test Strip) data. **Strip Insertion Area** guides the test strip into the meter. **Micro USB port** is to update the meter software.

The meter performs a self-check when it is first powered ON and every time a test strip is inserted. If there are any problems detected during self-check, an error message is displayed on the touchscreen. Refer to the "Troubleshooting" section of this manual or contact Technical Support for assistance.

Test Strips:

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 the sample is drawn into the reaction well of the test strip and is detected by a beam of light until a clot forms and interrupts another beam of light. The PT seconds result (a true prothrombin time) is converted to an INR (International Normalized Ratio) using the INR normalization data communicated by the NFC tag and subsequently stored in the meter. INR is a mathematical correction of the PT result that adjusts for sensitivity differences among different PT/INR systems.

Control Strips and Control Activation Solution

Quality control is an important part of PT testing to verify the integrity of the performance characteristics of the testing system. The Coag-Sense Meter has been designed with multiple internal systems to ensure proper system function. When powered ON, the meter runs an extensive self-check protocol to ensure, for example, that operating temperature, timing functions, battery level and optical and mechanical functions are within specification. There are 2 Low Control strips, 2 High Control strips and a control activation solution shipped with each test strip kit. Each control strip contains plasma of known INR. Real plasma allows for a fully functional liquid quality control test of both the a) reagent's ability to generate a clot and b) the analyzer's ability to detect a clot. Control testing confirms the performance of the system and should be completed immediately for each new lot of test strips received

NFC Tag:

Near Field Communication (NFC) Tag is a micro data tag with antenna that contains the required test strip kit information. It allows transmission of the test strip kit information to the meter by placing it the NFC scanner on the meter. The scanner reads the data stored in the NFC Tag and auto populates the relevant test strip kit lot information on the touch screen.

Battery:

Coag-Sense PT3 PT/INR Professional System is powered with 4 AA batteries.

Note: *The battery is user replaceable.*

To save power, the meter automatically powers off by itself if left unattended for a set time (user configurable). When the meter powers off, all results obtained up to that point remain in the memory.

Coag-Sense PT3 PT/INR System **(Catalog # 03P83-01)** is supplied with the following items**;**

Catalog Name	Qty
Coag-Sense PT3 PT/INR Meter	1
Coag-Sense PT3 PT/INR System User's Manual	1
Coag-Sense PT3 PT/INR System Quick Reference Guide	1
Sample Transfer Tubes	54
Single-Use, 21g Auto Safety Lancets (sample pack)	8
Carrying Case	1

To perform a test, you require the following:

- Coag-Sense Test Strip Kit- 50 **(Catalog # 03P56-50)** is supplied with the following items;

Item Description	Qty
Patient Test Strips	50
Low Control Strips	2
High Control Strips	2
Control Strip Activation Solution	1
Lot Info label w/NFC Tag	1
Sample Transfer Tubes w/ plungers	54
Package Insert	1

- Following are standard medical supplies that are required with each use:
  - Gauze
  - Isopropyl alcohol or alcohol wipes,
  - Single-Use- 21g Auto Safety Lancets,
  - Puncture-resistant bio-hazard (SHARPS) container

Note: *These materials are not provided with the PT/INR system. The Coag-Sense Test Strip Kit- 50 may be ordered from your distributor separately.*

Overview of Buttons and Icons

The buttons and icons that appear during normal operation are shown here, along with their respective meanings. Error message and its description are provided in 'Troubleshooting' section.

Buttons/Icons	Meaning
	Power ON/OFF To power ON the meter, press and hold Power Button
	Cancel or return to previous screen
	Select or confirm
	Scroll Up and Down

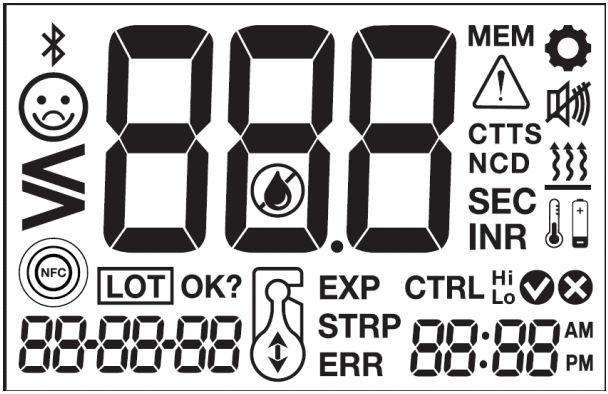


Image	Description
	Settings
	Blue Tooth
	Sound

	**Thermometer**
	**Battery**
	**NFC Tag-Reader**
	**Apply Sample**
	**No Sample Detected**
	**Error**

MEM	Memory
	Insert/Remove Strip
	Control Hi/Low Pass/ Fail
	Result in Range/Out of Range
	Date
	Time

3. Meter Specifications

Operating Temperature	64.4°F to 89.6°F (18°C to 32°C)
Operating Humidity	10% to 90% (without condensation)
Storage Temperature	32°F to 122°F (0°C to 50°C)
Storage Humidity	20% to 80% (without condensation)
Altitude	10.000 ft (3,048 m) above sea level
Memory	Capable of storing up to, ♣ 500 test results with date and time
Battery	4 AA Batteries
Battery Capacity	Minimum 100 tests
Power Output	6.0V, 1.5A
Pollution Degree	2
Overvoltage Category	II
Use Circumstance	Indoor only
Blood Sample Size	10-12 µL
Communication Port	Micro USB
Size in mm (Height X Width X Depth)	152 x 100 x 28.5
Weight in g	334g
Bluetooth	2.402GHz ~ 2.480GHz unlicensed ISM band

NFC	13.56MHz
Equipment Classification	Internally powered when operated with battery. IPX0 rating.

4. 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

5. Warnings and Precautions

This test system is not recommended for patients who have recently taken or are currently taking any type of Heparin anticoagulants. The system should also not be used to monitor patients on direct oral anticoagulants (DOACs) including Factor Xa and Direct Thrombin inhibitors.

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 CoaguSense 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.

- Do not use wipes containing chlorhexidine gluconate, as it may produce 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.

Meter

- 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, contact Technical Support.
- Do not allow any liquids to spill on the meter. If this should occur, contact 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.
- Do not pull the strip out during a test while the wheel is spinning. STOP the test, meter will display “Test Cancelled, Remove Strip' The strip should be removed at this time only.
- 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 are 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.
- 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. The Coag-Sense Prothrombin Time (PT)/INR Monitoring System needs special precautions regarding EMC and needs to be put into service according to the EMC information provided in this manual."
- "Portable and mobile RF communications equipment can affect The Coag-Sense Prothrombin Time (PT)/INR Monitoring System."
- "The use of accessories, transducers and cables other than those specified by CoaguSense, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT."
- "The Coag-Sense Prothrombin Time (PT)/INR Monitoring System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Coag-Sense PT3 Prothrombin Time (PT)/INR Monitoring System should be observed to verify normal operation in the configuration in which it will be used."

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, transfer tubes 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 Activating Solution (CAS) 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.

FCC Statement

Federal Communication Commission Interference Statement
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:
● Reorient or relocate the receiving antenna.
● Increase the separation between the equipment and receiver.
● Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
● Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

IMPORTANT NOTE:

FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

6. Hazards and Symbols

	**Warning:** This indicates a warning or precaution, requiring special attention.
	Class II Equipment.
	Biological Risks: Disposable items pose biological risks. The strips and fingerstick materials should be disposed of in appropriate biohazard waste containers.
	Electronic device. Dispose of unit 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
	Catalog Number
	The system fulfills the U.S safety requirements (NEMKO listed)
	Consult Instructions for Use
	Near Frequency Chip

Directions for Use

7. Meter Setup

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 strips are at room temperature before use. Operating conditions are between 64ºF and 90ºF (18ºC and 32ºC). **The meter will not allow a test to proceed unless it is within the operating temperature range.**
- Relative humidity should be between 10% and 90%, 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.

Power ON/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).
- Place the meter on a flat, stable surface. To turn the meter on. Press the **POWER** button, which is on the top right side of the meter. To turn the meter off, press the same **POWER** button again.

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System and User Settings:

The meter is set to default factory settings, English is the default language and time/time zone is Pacific Standard time (UTC-8:00). User may modify User settings as appropriate. Refer to User Settings section in this manual for the list of settings and their function. These User settings help the User to configure their PT/INR meter.

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.

Use the Settings button and then with the help of Up and Down buttons set the correct Date and Time on the meter.

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

Note: For waived testing performed under a CLIA Certificate of Waiver, quality control checks must be performed by following manufacturer's instructions. Coag-Sense User Instructions recommends testing one set of Controls (High and Low) per new Lot# of Patient Test Strip Kits immediately upon receipt of shipment. All boxes with the same lot # from that shipment are then qualified and "QC Done" can be written on the top of all the boxes. Some States and Accrediting Agencies may have additional requirements or regulations for waived QC testing frequency. The meter does not require the running of controls for any calibration.

8. Performing a Control Test

There are 2 Low Control strips, 2 High Control strips and a control strip activation solution shipped with each test strip kit. Controls should be tested immediately upon receipt of each new lot number. Extra controls may be ordered separately if more frequent QC testing is required.

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.*

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

WARNING: DO NOT move or touch the meter while it is running a test. Unreliable results may occur.

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

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

3. **Scan** the NFC tag against the NFC Tag scanner on the meter, the Lot # (six-digit number) will auto populate.

4. 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.

5. When the strip is correctly inserted, meter starts warm-up cycle and the display shows a countdown of the time remaining.

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

7. Open the control activation solution bottle and hold at an angle to allow insertion of the transfer tube. Insert transfer tube into control activation solution. Let capillary action fill until solution flow stops at plug.

8. Insert transfer tube tip into sample application well of test strip, touching tip down at flashing green light in front of wheel. Depress black plunger completely to dispense the activation solution.

9. When testing is complete, the Pass/Fail results are displayed in PT units.

10. Repeat Steps 2-10 for 'High control strip.'

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: If control test fails, repeat the test with a new strip*. If the control test continues to FAIL, please contact your POC testing administrator or Coag-Sense Technical Support for assistance.*

9. Collecting a Fingerstick Sample

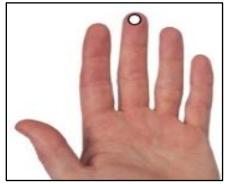
Tips for a Successful Fingerstick

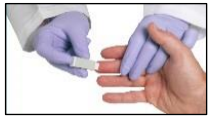
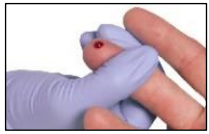
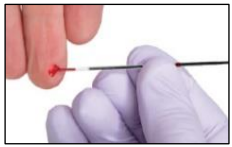
- Make sure that you have all the supplies needed before you start.
  - 21g Lancet device (Single use, auto disabling)
  - Sample Transfer Tubes
  - Sterile alcohol prep pads
  - Gauze square and Band-Aids
  - Biohazard waste container (SHARPS)
- For fingerstick blood testing, increasing the flow of blood in the finger will help you capture a good drop of blood. Before you perform the fingerstick, 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 sample.
- 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 1.8–2.4 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. **If necessary, squeeze the finger from the sides to open the wound for proper blood flow to produce a 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 there is any delay in sample collection or application, 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, transfer tubes and lancets are potentially infectious. Dispose the strips and collection devices using universal precautions.

No.	Action	Image guided instruction
1.	Wash hands with soap and warm water. Dry completely. **If using an alcohol wipe, the finger must be wiped dry with sterile gauze (air drying is insufficient to remove residual alcohol in time)** ***Note: Residual alcohol or water will affect results. Be certain that finger is completely dry.***	
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.*	

No.	Action	Image guided instruction
3.	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 the skin. **Do not lance finger until meter displays "APPLY SAMPLE."** A minimum of 10µl of collected blood sample is required. ***Note:*** *The blood should flow 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 cause unreliable results.	
4.	When ready to collect the drop of blood, hold the Sample Transfer Tube horizontal. Touch tip to bead of blood and let capillary action fill until blood flow stops at plug. Squeeze finger to generate additional blood if required to completely fill to white plug.	
5.	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 present in the blood sample in the transfer tube, start the test over with a fresh fingerstick on a different finger.

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 the test. Unreliable results may occur. Wear gloves and follow all applicable hygiene and safety procedures.

Follow the below steps to perform a patient test:

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

11. Make sure that the meter is on by pressing the POWER button on the top right side of the meter.

12. Open a Patient 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 by checking the date on the front of the control package*

13. Otherwise, **scan** the NFC tag against the NFC Tag scanner on the meter, the Lot # (six-digit number) will auto populate.

14. 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.

15. When the strip is correctly inserted, meter starts warm-up cycle and the display shows a countdown of the time remaining.

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

16. The meter beeps once when it is ready for the sample.

17. **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 in front of the wheel where you see the flashing green light. Gently touch the tip down onto the sample well. Depress the plunger completely to dispense blood sample.

18. When testing is complete, the results are displayed in INR units.

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, antihistamines) 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 patient 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**. Consider re-testing using an alternative method prior to adjusting the patient's dose of anticoagulant medication, or any other corrective actions.

11. Reviewing the Memory

The Coag-Sense meter stores up to 500 test results, along with the respective date and time of the test performed. When the memory has reached maximum storage capacity, the oldest result is automatically deleted and gets replaced with the most recent result.

12. Meter Software Update

If a critical update is available, the meter may require the installation of an update prior to proceeding with testing. Make sure to check if the battery is charged enough before performing an update. If the battery's charge is not enough and then the meter is abruptly turned off during update, an error may occur on the meter. Software can be updated connecting meter to a laptop using a USB Cable.

13. Battery

Turn the meter upside down.

Remove the battery door by pressing on the battery door release.

Remove the old batteries and replace with 4 new standard 1.5V AA alkaline batteries.

Replace the battery door.

Properly dispose of old batteries.

Note: *The Battery is User replaceable.*

When the battery is running low the status bar on the touchscreen of the meter displays a red indicator in the 'Battery status' icon. The touchscreen displays a 'Low Battery' warning.

14. Cleaning and Disinfecting the Meter

No maintenance is required other than routine cleaning and/or disinfecting.

When the power is off and the USB cable is not connected, the meter housing can be cleaned and disinfected. Wipe all exposed surfaces with Healthcare Bleach Germicidal Wipes containing Sodium Hypochlorite (EPA No. 67619-12) for a contact time of 1 minute to pre-clean blood and other body fluids. Caution should be taken to not get fluids inside the meter through the test strip port, data transmission port or battery compartment. Dispose of the used towelette. The meter should be allowed to air dry before use.

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.

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.

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://wayback.archive-it.org/7993/20170111013014/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

15. Troubleshooting

The Coag-Sense Meter continually checks its systems for unexpected conditions. These may arise because of defective components or consumables, environmental factors or due to User handling and procedure errors. This section details 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(s)	Solution
ROOM TEMP INCORRECT SEE MANUAL	The temperature of the room is either below or above the operating temperature range of the meter. Battery was depleted and then plugged into AC adapter while repeated testing continued. The charging of the battery can generate enough heat to raise the internal temperature of the meter outside the operating range.	Move the meter to a place that is within the operating temperature range of the meter (64ºF to 90ºF, 18ºC to 32ºC) and allow meter time to adjust to correct temperature. Repeat testing. Remove AC power and allow meter to cool prior to continuing testing or suspend testing until battery has charged and the internal temperature has cooled down sufficiently.
REMOVE STRIP	Meter turned off with used strip in it. If no strip present, possible shipment damage.	Remove the strip and begin again. Call Technical Support.
WHEEL PROBLEM	The test strip was not inserted fully or may have been inserted at an incorrect angle or incorrect speed. There may be a problem with the wheel on the strip or with the meter.	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 new strip. If the message displays again contact Technical Support.

Meter Display	Possible Cause(s)	Solution
DETECT PROBLEM	There may be a problem with the strip insertion or with the motor carriage in 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 optical system of 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.
MOTOR PROBLEM	There may be a problem with the motor function of the meter.	Turn the meter off then back on. Try again with another strip. If the message persists, contact Technical Support.
HEATER PROBLEM	The meter is too warm, 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 (65ºF to 90ºF, 18ºC to 32ºC) and allow meter time to adjust to correct temperature. Repeat testing. Turn meter off then on again after 5-7 minutes Try again with another strip. If the display persists, contact Technical Support.

Meter Display	Possible Cause(s)	Solution
TEST STRIP EXPIRED SEE MANUAL	The lot of strips have expired. Meter date is not set correctly.	Use a different lot of strips that has not expired. Verify the date setting on the meter is current.
NO SAMPLE DETECTED	Either no sample or not enough sample was applied to the strip within 2 1/2 minutes after  icon 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  icon. Ensure that the transfer tube is filled to the white plug and touches the sample well before dispensing sample.
CONTROL FAIL-NO CLOT DETECTED	There was no clot formation; sample clotting time was very long and out of testing range. There was insufficient control activation solution transferred to the test strip. Possible causes include; an air bubble in the sample or not allowing control activation solution to completely fill transfer tube. This may be due to a problem with the shipment/storage of the control strips or the control activation solution. Plasma on control strips is sensitive to exposure to temperatures outside the storage range.	Repeat the entire procedure with a new control strip. If the same message persists and if you have additional inventory of the test strip kit from the same kit lot, use the control strip from that box(es). If you don't have additional inventory OR if the error message persists, contact Technical Support. Control strips should be tested immediately upon receipt of your shipment of new test strips as they have a limited shelf life. **This does not indicate meter malfunction**
CONTROL FAIL-CLOT TIME TOO SHORT	The clotting time was very short and out of testing range (<8 seconds).	Repeat the entire procedure with a new control strip. Visually confirm that no air bubbles are in the control

Meter Display	Possible Cause(s)	Solution
	An air bubble was detected in the control activation solution sample.	activation solution sample before applying to test strip.
	The sample transfer tube was not filled with the control activation solution to the white plug	**Ensure that the tube is filled to the white plug.** Depress black plunger completely to dispense the control activation solution sample.
	Applying the control activation solution to the test strip before ¨Apply Control Solution¨ displayed on screen.	Repeat the entire procedure with a new strip. If the same message persists and if you have additional inventory of the test strip kit from the same kit lot, use the control strip from that box(es). If you don't have additional inventory OR if the error message persists, contact Technical Support.
CONTROL FAIL-OUT OF RANGE	The control strip result is outside of its acceptable range (FAIL- out of 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 has 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 Technical Support. Control strips should be tested immediately upon receipt of your shipment of new test strips as they have a limited shelf life. **This does not indicate a meter malfunction.**

Meter Display	Possible Cause(s)	Solution
CLOT TIME TOO SHORT	The clotting time was very short and out of testing range (<8 seconds). An air bubble was detected in the sample. Lancing the finger before  icon is displayed on screen. Taking too long to collect the sample in transfer tube (make sure of using 21g needle lancet for good flow of blood flow).	Repeat the entire procedure (including fingerstick on a different finger) with a new strip. Visually confirm that no air bubbles are in the sample before applying to test strip. Depress black plunger completely to dispense the sample. If the same message repeats, contact Technical Support.
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 or not allowing sample to completely fill transfer tube.	Confirm that the patient has not recently taken heparin or other contraindicated drugs listed on the test strip package insert. Visually confirm that no air bubbles are in the sample before applying to test strip. Depress black plunger completely to dispense the sample Repeat the entire procedure (including fingerstick) with a new strip. If the same message displays, use an alternative testing method and contact Technical Support.
LOW BATTERY	The meter battery is low	The meter can complete the current test. 4 AA batteries

Meter Display	Possible Cause(s)	Solution
		should be replaced with new one.

General Troubleshooting

Issue	Possible Causes	Solution
Meter does not power ON	Insufficient Battery to Power ON. Not **pressing and holding** Power button when turning meter on.	Install new batteries. If issue persists, contact Technical Support.
Cannot insert strip completely	Accumulation of dirt, dust, control activation solution, or blood in the strip insertion area. Wheel is not seated properly into of test strip.	Contact Technical Support for assistance with cleaning the strip insertion area. Use your thumbnails to push wheel spindles down to snap wheel into place. If issue persists, Contact Technical Support.
Software Issues	Software version update issue	Power cycle and re-install new software version if available (*Settings_Device Information settings_Software Version).* If issue persists, press Reset button to restore factory settings. If issue still exists, contact Technical Support.
Lost NFC Tag	Misplaced NFC Tag	The NFC tag is affixed to each test strip kit box. Otherwise, enter the strip information manually into the touchscreen to perform the current test. Alternately, if you have additional inventory of the test

Issue	Possible Causes	Solution
		strip kit from the same kit lot, use the NFC tag from that box(es).
NFC Tag Issues: • **NFC tag not working** • **Scanned information does not match the information on the strip packaging**	Improper scanning of the NFC tag. Faulty NFC Tag scanner in the meter	Touch or bring the NFC tag to proximity of the NFC Tag scanner. If the issue persists enter the strip information manually into the touchscreen to perform the current test. If you have more than one meter, try scanning the NFC Tag on another meter to narrow down the root cause to either the tag or scanner. If the issue persists, contact Technical Support.
NFC Tag scanner issue	Tag Scanner works intermittently or does not work. Scanned NFC scan did not match the Lot # on the test strip.	Scan the alternate NFC tag provided. Touch or bring the NFC tag to proximity of the NFC Tag scanner. If the issue persists enter the strip information manually into the touchscreen to perform the current test. If you have more than one meter, try scanning an NFC Tag on another meter to narrow down the root cause to either the tag. If the issue persists, contact Technical Support.

16. Warranty

Limited One (1) Year Warranty

Use of the Coag-Sense PT/INR System

The Coag-Sense PT3 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 PT3 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, REGARDLESS 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 Technical Service, you may be directed to return the unit. Should this occur, clean the outside surface as described in the “Cleaning and Disinfecting the Meter” section. The original packaging may be required for this purpose.

17. Reordering Information

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

Product	Catalog #
Coag-Sense PT3 PT/INR Professional System	03P83-01
Coag-Sense Test Strip Kit, Box of 50	03P56-50
Coag-Sense Control Strip Kit -10	03P69-10
Sample Transfer Tubes with Plungers, vial of 54	03P52-54
Sample Transfer Tubes with Preloaded Plungers, vial of 54	03P52-55
Single-Use, 21g 2.2mm depth Auto Safety Lancets - Box of 100	03P58-04
Replacement Carrying Case	03P75-01

18. EMC Tables

The following tables contain the Manufacturer's declaration and additional information required by IEC60601-2:2014 (Fourth Edition).

Test Name	Ref. Standard	Ports to Test	Test Level Required
Radiated disturbance	CISPR 11: 2015 +A1:2016	Enclosure	Group 1, Class B
Electrostatic	IEC 61000-4-2:2008	Enclosure	±8 kV Contact

Discharges (ESD)			±2 kV, ±4 kV, ±8 kV, ±15 kV Air
Radiated RF electromagnetic Fields	IEC 61000-4-3:2006+ A1:2007+A2:2010	Enclosure	10 V/m 80 MHz to 2.7 GHz 80%, 1 kHz AM RF Wireless Comm. (Refer to test report clause 7.4)
Electric Fast Transients and bursts	IEC 61000-4-4:2012	AC Mains	±2 kV AC, 100 kHz PRR
Surges	IEC 61000-4-5:2014	AC Mains	±0.5 kV, ±1 kV L1 to L2 (DM)
Conducted Disturbances, induced by RF fields	IEC 61000-4-6:2013	AC Mains	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz
Power-frequency Magnetic Field	IEC 61000-4-8:2009	Enclosure	30 A/m

19. Index

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