PROFESSIONAL USER´S MANUAL

COAG-SENSE®
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® 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 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 TFT color LCD **Touch screen** that shows results, information, icons and results recalled from memory. To select an option, gently click on display button. There are three touch buttons, **Cancel or Previous Screen Button, Home Screen Button and View Button Screen** for the Guided User Interface (GUI) operation. The **Power ON/OFF** button is located on the 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/Power Adapter port** is a micro USB port used to plug to the power adapter. Multipurpose **USB port** can be used to connect the meter to a) portable printer, b) computer, c) barcode scanner or other Coag-Sense approved accessories. **Ethernet Port** is used to connect the Ethernet cable for a wired connection, this port is provided with a port cover. **Reset button (enclosed within the ethernet port cover)** is used to reset the meter in case of software or power-cycle issues.

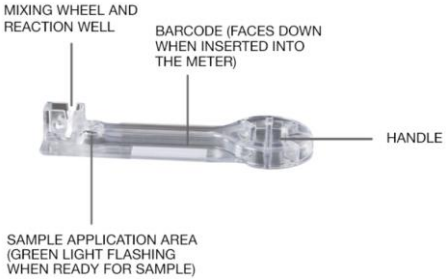
The meter performs a self-check when it is first powered ON and every time a test strip is inserted. If there are any problems detected during self-check, an error message is displayed on the touchscreen. Refer to the "Troubleshooting" section of this manual or contact Technical Support for assistance.

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. The NFC Tag is located on the bottom right front corner of the test strip kit and is touched or brought in close proximity of the NFC scanner built into 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.

In the absence of NFC Tag, the user may manually enter the lot and Barcode number present on the strip packaging using the keypad on the touch screen. A stylus with a rubber capacitive tip may be used to facilitate typing.

Power Supply and Battery:

Coag-Sense PT/INR Professional System can be operated only with the power adapter provided. The power adapter also serves as a charger. It charges the built-in Lithium Polymer Battery.

Note: *The battery is not user replaceable.*

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

Coag-Sense PT/INR Professional System **(Catalog # 03P70-02)** is supplied with the following items**;**

Catalog Name	Qty
Coag-Sense PT/INR Meter	1
Coag-Sense PT/INR System Professional User's Manual	1
Coag-Sense PT/INR System Professional Quick Reference Guide	1
A/C Micro USB Power Supply	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 (Bottom Right Corner of Box)	1
Sample Transfer Tubes w/ plungers	54
Package Insert	1

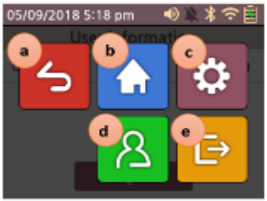
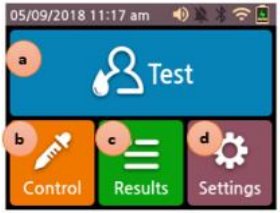
- Following are standard medical supplies that are required with each use:
  - Gauze
  - Isopropyl alcohol or alcohol wipes,
  - Single-Use- 21g Auto Safety Lancets,
  - Puncture-resistant bio-hazard (SHARPS) container

Note: *These materials are not provided with the PT/INR system. The Coag-Sense Professional 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 the its description are provided in 'Troubleshooting' section.

Buttons/Icons	Meaning
	Power ON/OFF To power ON the meter, press and hold Power Button. To Enter/Exit Sleep Mode press the button once quickly and press the button again and hold for few seconds.
	Cancel or return to previous screen
	Go to the home screen
	View additional menu
	Common Keypad input: **a** and **b**) is the input completion button. Returns to previous screen when selected. **c)** Change language button. Enables the user to select keyboard language.
	The Status bar: **a)** Date and Time **b)** Sound ON/OFF status **c)** Alarm Status **d)** Bluetooth ON/OFF status **e)** Wi-Fi ON/OFF status **f)** Battery level

Buttons/Icons	Meaning
	Icons on the touchscreen: **a)** Back Icon- Directs to the previous screen b) Home Icon- Directs to the home screen **c)** Settings Icon- Directs to the setting screen **d)** User Information Icon- Directs to the User Information screen **e)** Log-out Icon- Directs to the logout pop up screen.
	Home Screen: **a)** Test Icon- Directs User to Test Strip information screen and subsequently to testing screen **b)** Control Icon- Allows User to select between High and low control tests. Then directs User to Test Strip information screen and subsequently to control screen. **c)** Results- Allows User to view Patient and Control test results. Refer to Reviewing the memory section for detailed information **d)** Settings- Directs User to the Settings menu.

3. Meter Specifications

Operating Temperature	65°F to 90°F (18°C to 32°C)
Operating Humidity	10% to 85% (without condensation)
Storage Temperature	32°F to 122°F (0°C to 50°C)
Storage Humidity	20% to 80%
Memory	Capable of storing up to, • 2000 patient test results with date and time • 500 control test results with date and time • 1000 Operator accounts
Lithium Battery	Rechargeable Lithium Polymer Battery (3.7V, 2350mAh)
Battery Capacity	Fully charged (6 hours of charging) can run ~200 tests
Power Input	120V AC Adapter (Use with Coag-Sense Adapter Only)
Power Output	5.0V, 2.0A
Blood Sample Size	10-12 µL
Communication Port	Micro and Standard USB
Size in mm (Height X Width X Depth)	152 x 100 x 29.5
Weight in g	315g
Equipment Classification	Class II with external power supply. Internally powered when operated with battery. IPX0 rating.

WARNING: Use the Coag-Sense meter along with the provided Power Adapter only.

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 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 has a built-in rechargeable lithium polymer battery (3.7V, 2350 mAh).
- Use only the included Coag-Sense Power 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.

- Do not pull the strip out 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.
- In the unlikely event of an electric power surge (i.e., severe static discharge during a thunderstorm), when using the 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. 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 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 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.

6. Hazards and Symbols

	**Warning:** This indicates a warning or precaution, requiring special attention.
	Class II Equipment. The Power Adapter is double insulated.
	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

7. Meter Setup

Operating Conditions

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

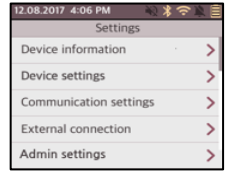
- Be sure that the meter and strips are at room temperature before use. Operating conditions are between 65ºF and 90ºF (18ºC and 32ºC). **The meter will not allow a test to proceed until the meter is at room temperature.**
- Relative humidity should be between 10% and 85%, without condensation, for testing.
- 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.

Power ON/OFF

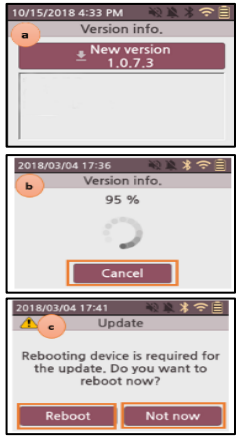
- The Coag-Sense PT/INR Professional System can be operated with the power adapter provided. The power adapter also serves as a charger.
- Place the meter on a flat, stable surface. To turn the meter ON/OFF, **press and hold** the POWER button of the right side of the meter.

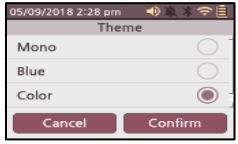
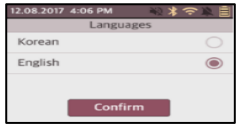
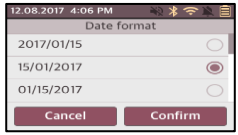
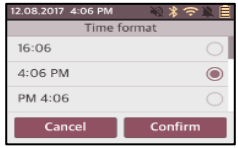
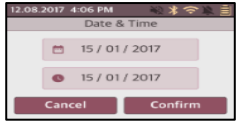
System and User Settings:

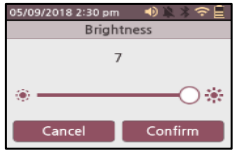
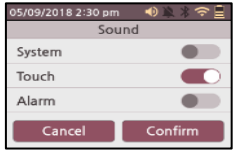
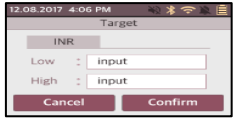
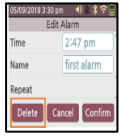
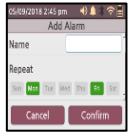
The meter is set to default factory settings, English is the default language and time/time zone is Pacific Standard time (UTC-8:00). User may modify User settings as appropriate. Refer to User Settings section in this manual for the list of settings and their function. These User settings help the User to configure their PT/INR meter. **Note that all Settings options will only be available when logged in as Admin. When logged in as a standard user only Device Information and Device Setting will be displayed.**

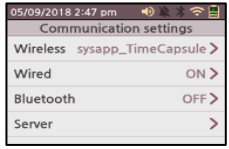
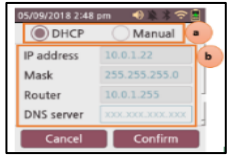


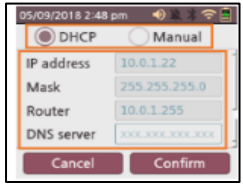
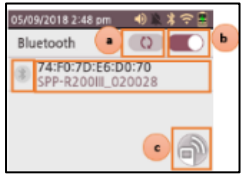
No.	Action	Image guided instruction
Device Information Setting		
1.	Device Information Screen	

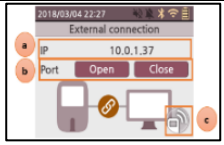
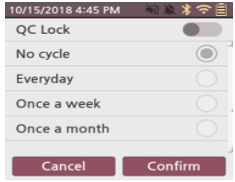
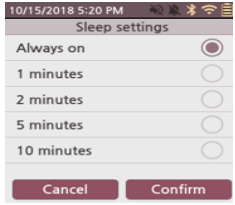
No.	Action	Image guided instruction
2.	Software Version Update **a**) If there is a new software version available, it can be found in this screen **(only if meter is connected to the Internet- Refer to Section 15).** **b**) Clicking the new version will download the version. **c**) User may choose to Reboot the meter after the download or push the reboot to a later time.	
Device Settings		
1.	Device Settings Screen	

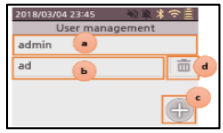
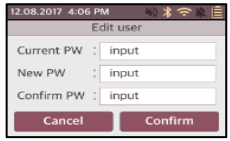
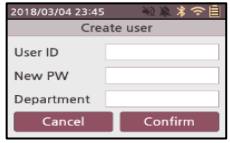
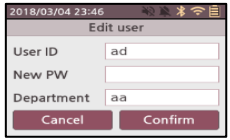
No.	Action	Image guided instruction
2.	**Theme:** User chooses from Mono/Blue/Color	
3.	Language Setup ***Note:*** *The default language is set to English.*	
4.	Date Format Setup	
5.	Time Format Setup	
6.	Date and Time Setup ***Note:*** *The time automatically adjusts for daylight savings time.*	

No.	Action	Image guided instruction
7.	Time Zone Setup	
8.	**Brightness:** User chooses from range of 1-7	
9.	**Sound Setting:** User chooses to Turn sound ON or OFF	
10.	Target Range Setup	
11.	**Alarm:** User can set alarm as a reminder function with Time and set to repeat on selected days of the week. User may edit delete an alarm at any time.	 

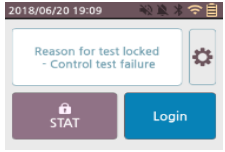
No.	Action	Image guided instruction
Communication Settings		
1.	The screen lists the status of the communication channels. If connected to Wireless (Wi-Fi), the touchscreen displays the name of the Wi-Fi network. The forward button on each type will direct the User to a detailed view.	
2.	**Wireless (Wi-Fi) Setting:** This screen displays icons that **a)** Scans for Wireless networks nearby **b)** Wireless ON/OFF icon Clicking the 'Connect' icon will require User to input passphrase to connect to the network.	
3.	Upon clicking the 'Setup' icon, the touchscreen displays the Wireless Information screen, User may **a)** select a connection method and **b)** input the fields containing network information. Click 'Confirm' to proceed and input the passphrase for connecting to a network. If the desired wireless network cannot be automatically connected via DHCP then it can be configured manually.	

No.	Action	Image guided instruction
4.	**Wired Setting:** Setup wired network connection by inputting the fields displayed in the screen. ***Note:*** *If the connection method is DHCP, the contents are automatically assigned if the network with the DHCP server is plugged in.*	
5.	**Bluetooth Setting:** This screen displays icons that **a)** Scan for Bluetooth enabled devices nearby **b)** Bluetooth ON/OFF icon **c)** Bluetooth broadcast icon This screen displays the list of scanned Bluetooth enabled devices.	
6.	Broadcast Bluetooth will pair the Coag-Sense PT/INR meter to external device. ***Note:*** *Set the external device ready to connect to the Coag-Sense meter.*	
7.	The touchscreen displays a message if the Bluetooth connection fails. ***Note:*** *The screen shot on the right shows the Bluetooth Connectivity icons*.	

No.	Action	Image guided instruction
External Connection		
8.	**a)** Screen lists server IP address for socket communication **b)** Open/Close port for serial communication with external program **c)** Connects PT/INR meter to PC program using Bypass Mode.	
Admin Settings		
9.	**QC Lock Settings:** If a Control test (High Control or Low control) does not produce a result, or if the result is outside of the target value range, the meter can be locked from further patient testing. The frequency for required testing can be set. ***Note:*** *Refer to QC Lockout section below for detailed information.*	
10.	**Sleep Settings:** If left unattended, the meter powers itself off. You manage the time in minutes before going into sleep mode or turn off the sleep function so the meter will always be on until manually powered OFF.	

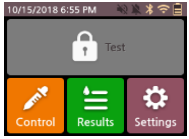
No.	Action	Image guided instruction
11.	**User Management:** User Management screen, **a)** displays the 'Admin' account that was previously set up (Initial Setting Section). Admin User may choose to change the password by clicking this field. **b)** displays the list of User accounts. **c, d)** lets you add and delete user accounts. ***Note:*** *User Management is only visible in the Admin login view.*	 **Edit Administrator Login** 
12.	**Create and Edit User Accounts:** You can Create User accounts or Edit User accounts and enter their department information.	 

QC Lockout (Optional Settings):



When the optional QC Lockout feature is turned On, a control test must be completed successfully before a patient test can be performed. The QC Lockout ensures compliance with facility policy by checking that quality control tests are run on the required (Admin User defined) frequency. In the QC Lock Settings menu, the

Admin User can define the QC Testing time intervals. The time intervals options are; Daily, Weekly, Monthly and No cycle.



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 <u>immediately</u> 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.

If the Control tests (High Control or Low control) do not produce a result, or if the result is outside of the target value range, the meter is locked from further patient testing until a valid QC result is obtained. The Test button will be grayed with a lock symbol indicating that it is in QC lockout mode.

The Admin User when logged in, can override the QC Lockout function either by disabling the QC lock feature or by changing the QC testing time interval. This will allow patient testing to proceed and the Test button will turn blue again. Standard Users cannot change the QC Lock Setting, only the Admin user can change the settings.

8. Performing a Control Test

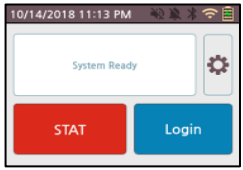
There are 2 low control strips, 2 high control strips and a control strip activation solution shipped with each test strip kit. Controls should be tested immediately upon receipt of each new lot number. Extra controls may be ordered separately if more frequent QC testing is required.

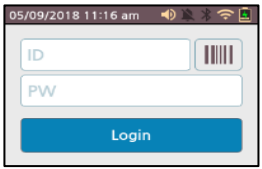
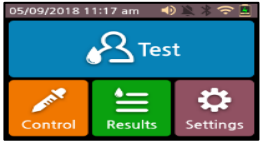
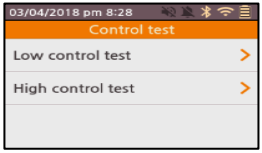
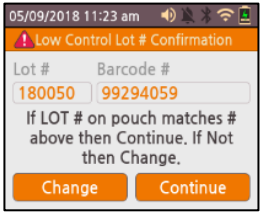
Note: *The following directions are for running a low control strip. When this procedure is complete, run a high control strip. The controls may be run in any order. The meter will display and store the results in PT seconds only. The meter does not use or require results from the control strips prior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

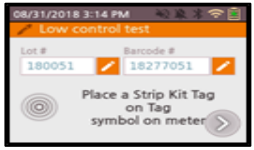
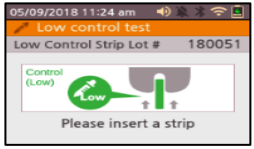
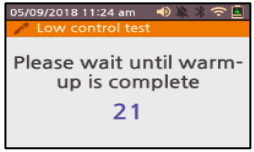
Note: *If an error message appears, consult the 'Troubleshooting' section of this manual.*

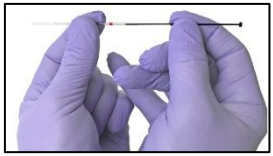
WARNING: DO NOT move or touch the meter while it is running a test. Unreliable results may occur.

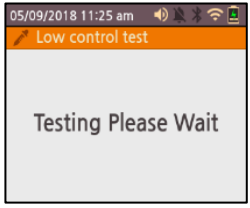
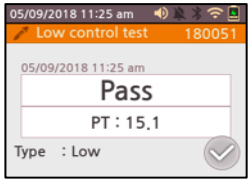
Follow these steps to perform a test on a low or high control.

No.	Action	Image guided instruction
1.	Turn the meter ON by press and holding the ⏻ (**POWER)** button on the right side of the meter. ***Note:*** *The message field on the first screen will display errors encountered during self-check if any.*	

No.	Action	Image guided instruction
2.	Press the Login icon. User is now directed to enter login credentials or scan operator barcode using a standard barcode scanner. ***Note:*** *To configure your meter for Auto login please contact technical support.*	
3.	Successful login directs the user to the Home screen. Press the Control icon on display icon.	
4.	Select from the following two options as applicable; Low Control Test or High Control Test.	
5.	Strip lot confirmation screen displays the Lot information of the strip that was last recorded. Proceed with testing if the control strip is from the same lot. Otherwise, press Change and **scan** the NFC tag (located on the bottom right corner of test strip kit box) against the NFC Tag scanner on the meter, the Lot # (six-digit number) and	Representative example only 

No.	Action	Image guided instruction
	Barcode # (eight-digit number) will auto populate. If box with NFC tag information is not available, you may manually enter the Lot # and Barcode # using the keypad on the touchscreen into the respective fields. Press the forward button. ***Note:*** *Ensure the strip expiration date on the strip packaging has not passed. Contact your Coag-Sense distributor for help with reordering.*	 
6.	Open the packaging of the selected control strip by tearing the notched end.	
7.	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 insertion area.	
8.	The meter warms the strip (for 25 seconds) to operating temperature, the display shows a countdown in seconds. ***Note:*** *Do not apply the control activation solution until the warm-up is complete and the meter display shows 'Apply Control Solution'.*	

No.	Action	Image guided instruction
9.	Insert the black plastic plunger into the end of the glass capillary tube with the red stripe. Use care to avoid hitting white plug. (Preloaded tubes are also available).	
10.	Open the control activation solution 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 white plug.	
11.	The meter beeps once and displays "Apply Control Solution" when it is ready for the control strip activation solution. ***Note:*** *You now have up to 2 ½ minutes to apply the activation solution to the control strip.* Rest hand on the meter or counter top to steady. 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.	

No.	Action	Image guided instruction
12.	When the control activation solution is properly applied and detected, the flashing green light will turn off, and the meter displays 'Testing Please Wait'. ***Note:*** *If this screen is not displayed within 8 seconds not enough solution was applied. Remove the strip. Retest with a new control strip. DO NOT attempt to add more solution to the strip.*	
13.	When testing is complete, the Pass/Fail results are displayed in PT units. Date and Time are also displayed. ***Note:*** *Control test results only display PT seconds, this is to avoid confusing control strip INR results with patient test strip INR results.*	
14.	Repeat Steps 3-13 for 'High control strip.'	
15.	Once the controls have been successfully tested, remember to remove and discard the control strips. You can now proceed to testing patient blood samples. If you are not going to test, turn off the meter by pressing and holding the **POWER** button. The opened control activation solution may be used until the expiration date.	

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

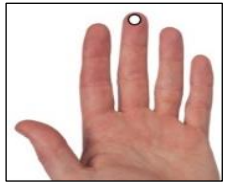
Tips for a Successful Fingerstick

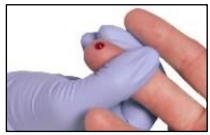
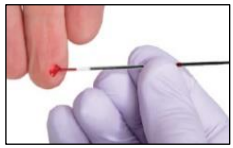
- Make sure that you have all the supplies needed before you start.
  - 21g Lancet device (Single use, auto disabling)
  - Sample Transfer Tubes
  - Sterile alcohol prep pads
  - Gauze square and Band-Aids
  - Biohazard waste container (SHARPS)
- For fingerstick blood testing, increasing the flow of blood in the finger will help you capture a good drop of blood. Before you 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 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 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.

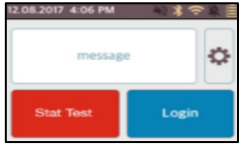
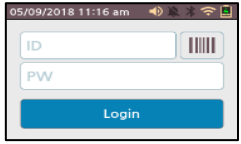
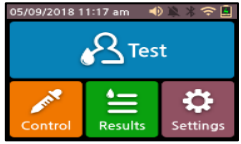
No.	Action	Image guided instruction
1.	Have patient wash hands with soap and warm water. Dry completely. **If using an alcohol wipe, the finger must be wiped dry with sterile gauze (air drying is insufficient to remove residual alcohol in time)** ***Note: Residual alcohol or water will affect results.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

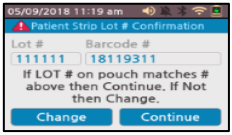
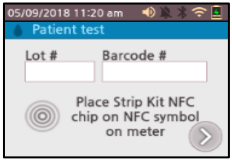
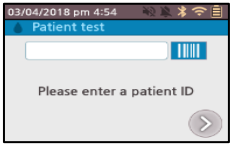
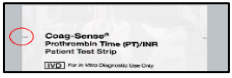
No.	Action	Image guided instruction
3.	Remove the cap from the single use lancet. Place it against the skin. Holding the body of the lancet, push down firmly against the finger to lance the surface of the skin. **Do not lance finger until meter displays "APPLY SAMPLE."** A minimum of 10µl of collected 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 white 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.	

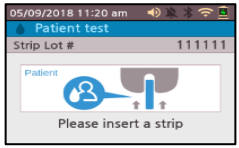
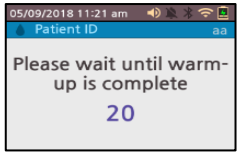
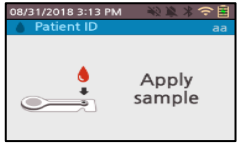
10. Performing a PT Test

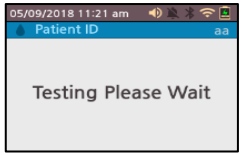
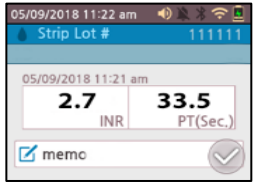
WARNING: Place the meter on a stationary, level surface for testing. DO NOT move the meter or allow it to vibrate during the test. Unreliable results may occur. Wear gloves and follow all applicable hygiene and safety procedures.

Follow the below steps to perform a patient test:

No.	Action	Image guided instruction
1.	Turn the meter ON by **pressing and holding** the ⏻ (POWER**)** button on the right side of the meter. ***Note:*** *The message field on the first screen will display errors encountered during self-check if any.*	
2.	Press the Login icon. Operator is now directed to enter login credentials or scan operator barcode using optional barcode scanner.	
3.	Successful login directs the user to the Home screen. Press the Test icon on display screen. ***Note:*** *If the control test fails, patient test feature will be disabled, please contact CoaguSense technical support for assistance.*	

No.	Action	Image guided instruction
4.	Patient Strip lot confirmation screen displays the Lot information of the strip that was last recorded. Proceed with testing if the test strip is from the same lot. Otherwise, **scan** the NFC tag against the NFC tag scanner on the meter, the Lot # (six-digit number) and Barcode # (eight-digit number) will auto populate. If NFC tag information is not available, you may manually enter the Lot # and Barcode # using the keypad on the touchscreen into the respective fields. Press the forward button. ***Note:*** *Make sure the expiration date on the strip packaging has not passed. Contact your Coag-Sense distributor for help with reordering.*	  
5.	Patient ID information must be scanned using the optional barcode scanner or manually entered in the field. Press the forward button.	
6.	Open the packaging of the test strip by tearing the notched end.	

No.	Action	Image guided instruction
7.	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 insertion area.	
8.	The meter warms the strip (for 25 seconds) to operating temperature. The display shows a countdown in seconds. ***Note: Do not apply test sample until the warm-up is complete and the meter display shows 'Apply sample.'***	
While the meter is warming up, get ready to perform a fingerstick. See "**Collecting a Fingerstick Sample**" section in this manual.		
9.	When the warm-up is complete, the meter beeps (if sound is turned ON) the screen displays a 'Apply Sample' message. ***Note:*** *You now have up to* ***2 ½ minutes*** *to perform a fingerstick and apply the sample to the test strip.*	
10.	**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. *Note: Discard the sample transfer tube in a biohazard container.*	

No.	Action	Image guided instruction
11.	When the sample is detected, the meter displays a 'Testing Please Wait' message. ***Note:*** *If this screen is not displayed within 8 seconds not enough blood sample was applied. DO NOT attempt to add more sample. Stop the test and retest with a new strip and fingerstick.*	
12.	When testing is complete, the meter beeps (if sound is turned ON). The results (INR and PT seconds) are displayed on the screen along with the date and time of the test. ***Note:*** *Memo field allows user to make notes along with the results.* *Upon clicking the Check mark icon, the main screen is displayed.* ***Note:*** *Refer to the* ***"Troubleshooting"*** *section of this manual if the meter displays messaging, like for example:* ***CLOT TIME TOO SHORT or NO CLOT DETECTED.***	
13.	Remove the test strip and dispose 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 Technical Support.*	
14.	User may export recorded results into the electronic medical record system by connecting to a computer or middleware system. User may also print the results as well, refer to the	

No.	Action	Image guided instruction
	"Printing" section in this manual. ***Note:*** *The meter stores about 2000 patient test results in memory with the time and date stamp. Refer to "Reviewing the Memory" in this manual for more information.*	
15.	Turn the meter OFF by **pressing and holding** the ⏻ POWER button when you are finished testing. If left unattended for a set time, (User preferred Setting) the meter powers itself OFF.	

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 patient health status or medications after you have begun testing.

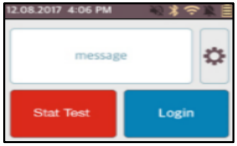
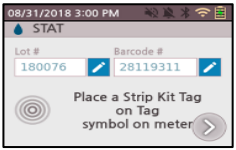
What to do when you get an unexpected result:
Follow instructions for re-testing on the Coag-Sense PT/INR meter. For unexpected results, contact **Technical Support at 1-866-903-0890**. Consider re-testing using an alternative method prior to adjusting the patient's dose of anticoagulant medication, or any other corrective actions.

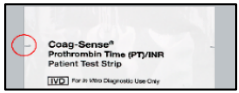
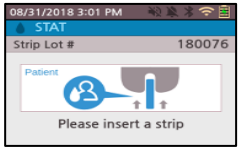
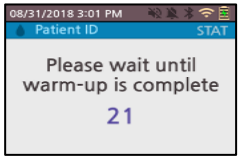
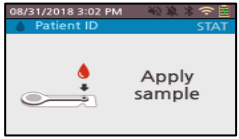
11. Performing a Stat Test

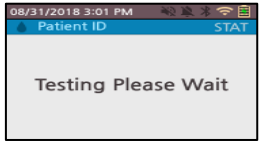
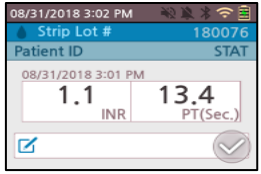
A Stat Test allows the user to perform and obtain results of a patient test without logging in a user account or entering a Patient ID. Stat test results are saved in the memory of the meter with Patient ID as Stat, along with patient result it also records the date and time the test was performed.

***Note**: The memory does not store patient ID or operator ID for any Stat test performed.*

Follow the steps below to perform an Stat test:

No.	Action	Image guided instruction
1.	Turn the meter ON by **pressing and holding** the ⏻ (POWER**)** button on the right side of the meter. ***Note:** The message field on the first screen will display errors encountered during self-check if any.*	
2.	Press the Stat Test icon. User is now directed to the strip lot confirmation screen. The screen displays the Lot information of the strip that was last recorded. Proceed with testing if the test strip is from the same lot as displayed. Otherwise, **scan** the NFC Tag against the NFC Tag scanner on the meter, the Lot # (six-digit number) and Barcode # (eight-digit number) will auto populate If NFC Tag information is not available, you can manually enter the Lot # and Barcode # using the keypad on the touchscreen into the	 

No.	Action	Image guided instruction
	respective fields. Press the forward button. ***Note:*** *Make sure the expiration date on the strip packaging has not passed. Contact your Coag-Sense distributor for help with reordering.*	
3.	Open the packaging of the test strip by tearing the notched end.	
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 insertion area.	
5.	The meter warms the strip (for 25 seconds) to operating temperature. The display shows a countdown in seconds. ***Note:*** *Do not apply test sample until the warm-up is complete and the meter display shows 'Apply Sample'.*	
6.	While the meter is warming up, get ready to perform a fingerstick. See "Collecting a Fingerstick Sample" in this manual.	
7.	When the warm-up is complete, the meter beeps (if sound is turned ON) and the screen displays a 'Apply Sample' message. ***Note:*** *You now have up to 2 ½ minutes to perform a fingerstick and apply the sample to the test strip.*	

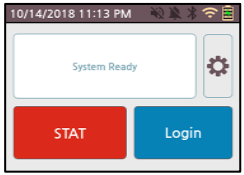
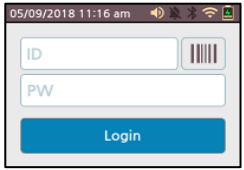
No.	Action	Image guided instruction
8.	**I**MMEDIATELY after collecting the patient sample, place the tip of the sample transfer tube at a 45º angle into the sample well on the test strip in front of the wheel where you see the flashing green light. Gently touch the tip down onto the sample well. Depress plunger completely to apply blood sample. Discard the sample transfer tube in a biohazard waste container.	
9.	When the blood sample is detected, the meter displays a 'Testing Please Wait' message. ***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 and fresh fingerstick.*	
10.	When testing is complete, the meter beeps (if sound is turned ON). The results (INR and PT in seconds) are displayed on the screen along with date and time of the test. ***Note:*** *Memo field allows user to make notes along with the results.* *Upon clicking the Check mark icon, the main screen is displayed.* ***Note:*** *Refer to the* ***"Troubleshooting"*** *section of this manual if the meter displays messaging, like for example:* ***CLOT TIME TOO SHORT or NO CLOT DETECTED.***	

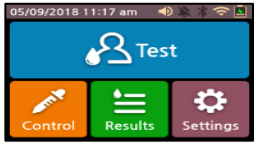
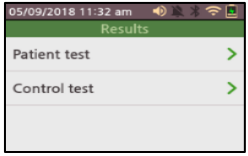
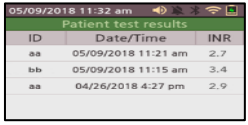
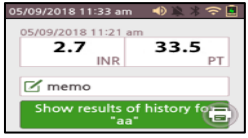
No.	Action	Image guided instruction
11.	Remove the test strip and dispose in a biohazard collection container. ***Note:*** *Repeat the test if the results seem unusually low or high. If the results still seem unusual after a second test, contact Technical Support.*	

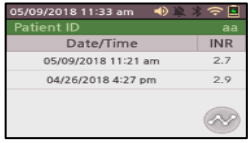
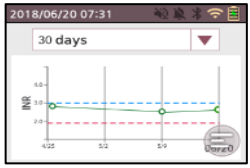
12. Reviewing the Memory

The Coag-Sense meter stores up to 2000 patient test results and 500 control 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. This meter records all test results, i.e. patient tests, control and Stat tests. To avoid the loss of stored test results, the User may export recorded results to an electronic medical record system by connecting to middleware software or directly to a LIS or EHR system using POCT1-A protocol. Memory is not lost if there is a break in power for any length of time. Test results stored in the Memory can only be erased by CoaguSense technical support.

Follow the steps below to review results in memory:

No.	Action	Image guided instruction
1.	Turn the meter ON by pressing and holding the ⏻ (**POWER)** button on the right side of the meter. ***Note:*** *The message field on the first screen will display errors encountered during self-check if any.*	
2.	Press the Login icon. Operator is now directed to enter login credentials or scan operator barcode using any standard barcode scanner.	

No.	Action	Image guided instruction
3.	Successful login directs the user to the Home screen. Press the Results on display screen.	
4.	The 'Results' screen lists Patient test results and Control test results.	
5.	User can select from the various results stored in memory to view details of that results.	
6.	User can filter and view test results for a specific Patient Identifier by clicking on the Show Results of History button. ***Note:*** *User may choose to list result history for a patient by selecting Patient ID. This example displays results for Patient ID 'aa'.*	

No.	Action	Image guided instruction
7.	Clicking the chart icon displays the test result for the selected patient in a chart/list output. ***Note:*** *The unit of the x-axis value of the chart depends on the period selected. The User may choose to view up to one month.*	 

13. Printing

With the portable printer (optional accessory) available from Coag- Sense, 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.

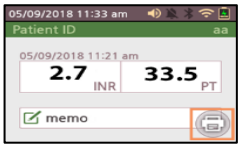
Note: *Contact your Coag-Sense distributor for help with ordering.*

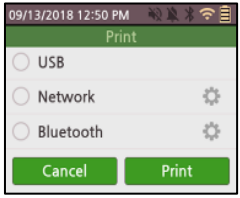
Note: *Refer to the User Manual provided with the printer for its general operation.*

What you'll need:

- Coag-Sense meter
- Optional Portable Printer, Catalog # 03P52-55
- 2" Thermal Paper, Catalog # PD99906-OM

Follow the steps below for printing results.

No.	Action	Image guided instruction
1.	Plug the USB cable from the portable printer into the USB port of the meter.	
2.	From the individual result display click the printer icon on the lower-right hand corner of the screen to print the test results.	

No.	Action	Image guided instruction
3.	User may choose from three different printer connection modes. Network and Bluetooth connection modes will require configuration using the setup icon prior to printing. Press Print to print the result.	

If the results fail to print, confirm that the printer is ON and charged as it automatically turns OFF after a few minutes. Note that the meter can only print to specific printers qualified and supplied by CoaguSense. The meter cannot print directly to your computer printer.

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

14. Network Connectivity and Security

The Coag-Sense meter offers the ability to send patient test results to electronic medical records or laboratory information systems. The Coag-Sense meter can be connected to a Local Area Network (LAN) via either a direct Ethernet connection or wirelessly using Wi-Fi. If this meter is connected to a local area network, the network must be protected against unauthorized access. It must not be linked directly to any other network or the Internet. Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall to separate the device from uncontrolled networks and intrusion detection that ensure that the connected network is free of malicious code including intrusion detection.

If you use commercial middleware or a customized data management system solution, ensure that sensitive patient identifiable data transmitted via the POCT1-A interface is protected by appropriate security measures.

Ensure that the instrument is protected against unauthorized physical access and theft and that the tamper event label has was intact on delivery.

Do not use shared user or operator accounts on meter and network.

Whether working in a wired or wireless environment, use a strong alpha and numeric password for user or operator accounts on the meter and network. Observe your own facility guidelines on password management where available.

15. Meter Software Update

When connected to the Internet, the Coag-Sense meter can check for the availability of meter software updates which can be downloaded. **If the meter is not continuously connected to the Internet, you should make it a practice to periodically connect the meter to the Internet to check for software updates**. 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.

16. Battery

The Coag- Sense meter has a factory installed Rechargeable Lithium Polymer Battery, that charges when the power adapter (provided with the meter) is plugged into the wall socket. A charged battery (6 hours to fully charge) can run approximately 200 tests. Please be aware that battery life may be affected by many factors such as operating conditions (e.g. ambient temperature), frequency of use, and test duration.

Note: *The Battery is not 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. The battery begins charging as soon as the power adapter is connected to the power supply.

WARNING: Lithium Polymer batteries may explode or combust if mishandled. Do not subject the meter to prolonged exposure to sunlight or place the meter on or in heating appliances such as microwave, conventional oven or radiator. Only charge battery using the power adapter provided along with the Coag-Sense meter. Use of other power cables may result in damage to the meter. Do not disassemble or dispose battery in fire. Do not charge/discharge battery out of recommended temperature range.

17. 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

18. 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 (65ºF 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 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 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 ¨Apply Sample¨ 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. The meter connected to the power

Meter Display	Possible Cause(s)	Solution
		adapter should be plugged into the wall socket.

General Troubleshooting

Issue	Possible Causes	Solution
Meter does not power ON	Insufficient Battery to Power ON. Power Adapter not connected properly for charging the battery. Not **pressing and holding** Power button when turning meter on.	Check if the power adapter (provided with the meter) is connected to the port in the Meter and the wall socket. If issue persists, or if the power adapter is faulty, 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.
Touch screen display issues	Insufficient/Low Battery Display Faint or low brightness	Connect the power adapter to wall socket. Change 'Brightness' User setting in the 'Device Settings' menu of the meter.

Issue	Possible Causes	Solution
Touch screen not responding	Prolonged exposure to direct sunlight.	Avoid prolonged exposure to direct sunlight, as it may reduce life expectancy and functionality of the display.
	Dropping or subjecting the meter to strong shocks.	Contact Technical Support.
Touch screen scratched or cracked	Dropping or subjecting the meter to strong shocks	Contact Technical Support.
	Using pointed or sharp-edged objects other than the recommended 'finger' or rubber stylus to touch the screen elements.	
Power Adapter Not working	Faulty Adapter (Bent power cord, Bent power pin in the meter)	Check adapter functionality by plugging the power adapter to a different wall socket. 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 strip kit from the same kit lot, use the NFC tag from that box(es).

Issue	Possible Causes	Solution
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 # and Barcode # 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 or scanner. If the issue persists, contact Technical Support.

19. 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, 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.

20. Reordering Information

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

Product	Catalog #
Coag-Sense PT/INR Professional System	03P70-02
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
AC Power Adapter – U.S.	03P74-01
Optional portable Printer	03P76-01
Thermal Printer Paper, 2”	PD-99906
Replacement Carrying Case	03P75-01

21. Index

Technical Support
CoaguSense, Inc.
48377 Fremont Blvd., STE 113
Fremont, CA 94538
USA
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

EMERGO EUROPE
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Manufactured in South Korea

CSI P/N 200220 Rev AD