Coag-Sense®

Professional User Manual

Coag-Sense®

Prothrombin Time (PT)/INR Monitoring System

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If you have any questions or concerns with the Coag-Sense® Prothrombin Time (PT)/INR Monitoring System, please contact CoaguSense, Inc. Technical Support at:

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1. Introduction

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 a blood clot 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, Inc. Technical Support at 1-866-903-0890.

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:

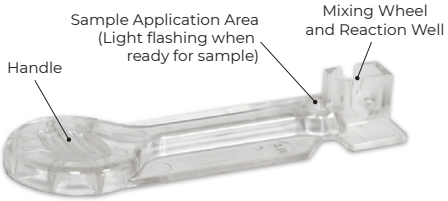
The meter has a TFT color LCD **Touch screen** that shows results, information, icons and results recalled from memory. To select an option, gently click on the display button. There are three touch buttons, **Cancel or Previous Screen Button, Home Screen Button and View Menu Button Screen** for the 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 Tag 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 and High Control Strips, and a Control Activation Solution shipped with each test strip kit. Each control strip contains plasma which is generated from a pool of normal donors where the Vitamin K dependent proteins are removed and added back at different levels to represent the 'Low' and 'High' level ranges. Real plasma allows for a fully functional 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 lot specific test strip kit information. Transfer of the lot specific data to the meter can be accomplished through surface contact of the matching NFC symbols. The NFC Tag communicates the unique data for each lot of strips to the meter. The meter reads the data stored in the NFC Tag and auto populates the relevant test strip information on the 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. The battery life is shown in the top right corner of the meter.

Note: *The battery is not user replaceable.*

To save power, if left unattended for a set time (user configurable), the meter will enter sleep mode. To power meter OFF, manual press and hold of the Power Button is required. The meter retains all results obtained up to that point in its memory.

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

Catalog Name	QTY
Coag-Sense® PT/INR Meter	1
Coag-Sense® Professional User's Manual	1
Coag-Sense® Professional Quick Reference Guide	1
Coag-Sense® Testing Tips Guide	1
A/C Micro USB Power Supply	1
Stylus Pen	1
Carrying Case	1

To perform a test, you require the following:

- Coag-Sense® Professional 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 Activation Solution	1
Lot Info label	1
Sample Transfer Tubes	54
NFC Tag	1
Package Insert	1

Note: *The Coag-Sense® Professional Test Strip Kit-50 may be ordered separately from your distributor.*

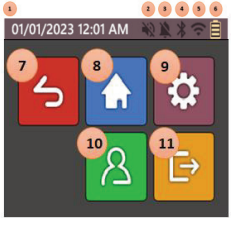
Following are standard medical supplies required for each use that are not provided with the PT/INR System and must be purchased separately:

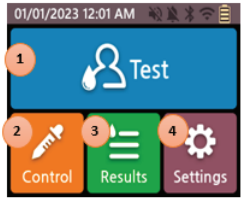
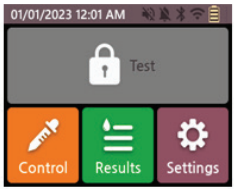
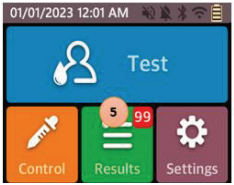
- Gauze
- Isopropyl alcohol or alcohol wipes
- 21g Auto Safety Lancets, single use
- Puncture-resistant bio-hazard (SHARPS) container

Overview of Buttons and Icons

The buttons and icons that appear during normal operation are shown here, along with their respective meanings. Error messages and their descriptions 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** 1. Is the input completion button. Returns to previous screen when selected. 2. Change language button. Enables the user to select keyboard language.

Buttons/Icons	Meaning
	**The Status Bar** 1. Current Date/Time 2. Sound On/Off status 3. Alarm – The presence or absence of set alarm 4. Bluetooth On/Off status 5. Wi-Fi On/Off Status 6. Battery status Icons on the Touchscreen 7. Back Icon - Go to previous screen 8. Home Icon - Go to home screen when touched 9. Settings Icon - Go to settings screen when touched 10. User Information Icon - Go to user Information screen when touched 11. Log-out Icon - Go to log-out pop-up screen when touched.

Buttons/Icons	Meaning
 	**Home Screen** 1. Test Icon - Go forward to test screen when touched. 2. Control Icon - Go forward to control test screen when touched. 3. Results Icon - Go forward to result screen when touched. 4. Settings Icon - Go forward to setup screen when touched. This is a customizable feature. If the control test fails, patient measurements are not possible.
	5. Results Icon - Displays the number of results that have not been synchronized.

3. Meter Specifications

Operating Temperature	65°F to 90°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: • 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 battery (6 hours of charging) can run ~100 tests
Power Input	120V AC Adapter (Use with Co-ag-Sense® Adapter Only)
AC Input	100-240V~, 50-60Hz, 0.5A (Mains supply voltage fluctuation: ±10%
Power Output	5.0V, 2.0A
Pollution Degree	2
Overvoltage Category	II
Use Circumstance	Indoor only
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 grams	315 grams
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. Use only AC adapter type UES12ICP-050200SPA (Manufacturer: Dongguan Shilong Fuhua Electronics).

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 units

Normal Range: The following example represents a common normal range for a person in good health using the Coag-Sense® PT/INR Monitoring System.

INR: 0.8 to 1.2 units
PT: 11.6 to 14.5 seconds

5. Warnings and Precautions

WARNING: 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 Sample Transfer Tubes 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 should be washed with warm water and soap, and then completely dried. The site must be clean of all hand oils/lotions and foreign matter, which may cause unreliable results.

- I**f 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 (3.7 V, 2350 mAh).
- Use only the power adapter included with the Coag-Sense® System or damage to the meter may result.
- The meter shall be in the position that it is easy to disconnect power.
- 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 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, Inc., 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, Inc., 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 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 Activation 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

	Caution is necessary when operating the device
	Class II Equipment. The Power Adapter is double insulated
	Biological risks: The strips and fingerstick materials should be disposed of in appropriate biohazard waste containers
	Indicates the date after which the medical device is not to be used
	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Indicates the temperature limits to which the medical device can be safely exposed
	Indicates the medical device manufacturer
	Indicates a medical device that is intended for one single use only
	Indicates the manufacturer's catalog number so that the medical device can be identified
	This device must be used by a trained professional in a near-patient setting.

	EU WEEE 2012/19 rules on treating electrical and electronic equipment waste, to contribute to sustainable production and consumption; follow local governmental regulation for recovery and recycling
	Indicates the entity importing the medical device into the locale.
	The system fulfills the U.S. safety requirements (NEMKO listed)
	Consult instructions for use
	Near Field Communication (NFC) Tag
	Indicates the manufacturer's serial number so that specific medical device can be identified
	Indicates a carrier that contains unique identifier information
	Bluetooth Connectivity, BLE Enabled Devices
	Wireless (Wi-Fi) Network
	To identify the country of manufacture of products
	Indicates the entity distributing the medical device into the locale
	Class 2 Equipment
	Indicates the total number of tests that can be performed with the medical device
	Prescription Use Only
	The CE mark followed by a four-digit number stands for the notified body (regulatory body) which reviewed or approved the medical device against all relevant requirements before the CE mark can be affixed on the product as proof that the medical device meets certain EU requirements
	Indicates authorized representative in the European Community/ European Union

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 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 the meter during testing.

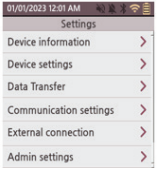
Power ON/OFF

- 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 on the right side of the meter at least 5 to 7 seconds until screen goes dark.

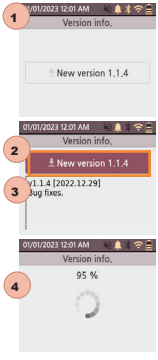
System and User Settings:

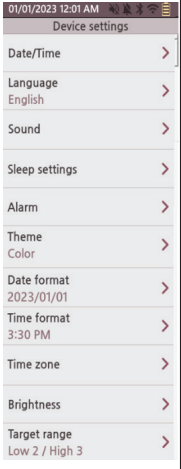
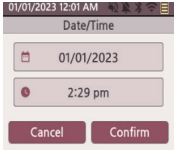
The meter is set to default factory settings, English is the default language and time/time zone is Pacific Standard time (UTC-8:00). User may modify User settings as appropriate. Refer to User Settings section in this manual for the list of settings and their functions. These User Settings help the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

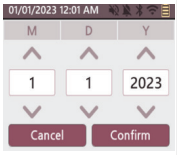
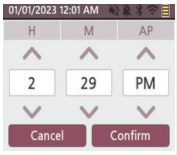
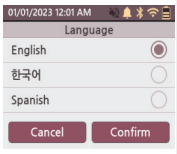
Note: *all Settings options will only be available when logged in as an Admin. If logged in as a standard user, only Device Information and Device Settings will be displayed.*

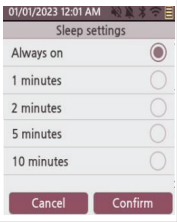
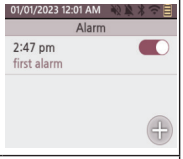
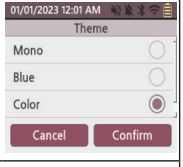
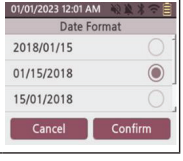


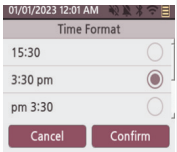
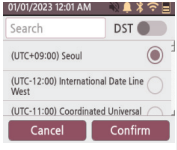
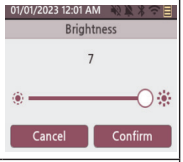
No.	Action	Image Guided Instruction
Device Information Setting		
1.	Device Information Screen	

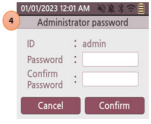
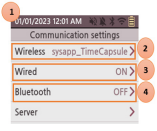
No.	Action	Image Guided Instruction
2.	Software Version Update 1. See Device Information screen for version of software. 2. If there is a new software version. The latest version can be found in this screen. Clicking the 'New version' will download the software update. 3. A description of the software version to bring the system up-to-date or improve characteristics. 4. Progress bar displayed after the download. User may choose to Reboot the meter after the download.	

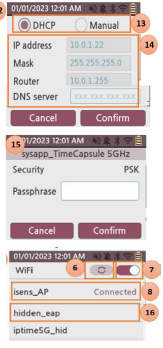
No.	Action	Image Guided Instruction
Device Setup		
1.	Device Settings Screen	
2.	Date/Time Settings	

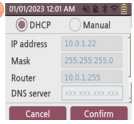
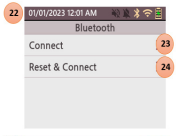
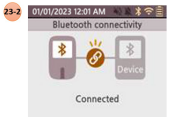
No.	Action	Image Guided Instruction
Device Setup		
3.	Date Settings	
4.	Time Settings	
5.	Language Settings ***Note:*** *The default language is set to English.*	
6.	Sound Settings User chooses to Turn sound ON or OFF	

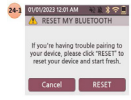
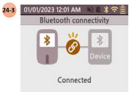
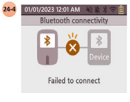
No.	Action	Image Guided Instruction
7.	Sleep Settings	
8.	Alarm Settings	
9.	Theme Settings (User chooses Mono/Blue/Color)	
10.	Date Format Settings	

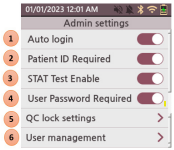
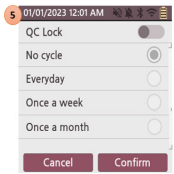
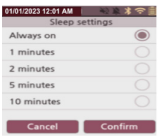
No.	Action	Image Guided Instruction
11.	Time Format Settings	
12.	Time Zone Settings	
13.	Brightness Settings User chooses from range of 1-7 (1 is the darkest, 7 is the brightest).	
14.	Target Range Settings	

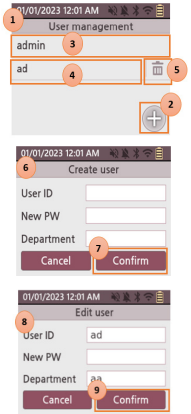
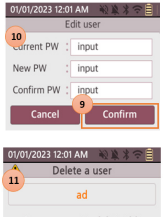
No.	Action	Image Guided Instruction
15.	Administrator Password Setup	
Communication Settings		
The screen lists the status of the communication channels. The forward button on each type will direct the User to a detailed view. 1. Communication settings (Admin or User) 2. If connected to the Wireless, touchscreen displays the name of the Wi-Fi network. 3. Wired ON/OFF 4. Bluetooth ON/OFF		
Wireless (Wi-Fi) Setting: 5. This screen displays icons for Wireless settings. 6. When the button is touched it scans Wireless for networks nearby. 7. Wireless ON/OFF icon. 8. Shows connection if there are connected networks. Go to connect/ disconnect AP screen. 9. Connection pop-up, Click the 'Connect' icon will require User to input password to connect to the network. 10. Wireless setup button. Clicking the 'Setup' icon will display the wireless information screen. 11. To disconnect pop-up files the user selects 'Disconnect' as shown.		

No.	Action	Image Guided Instruction
	Upon clicking the 'Setup' icon. 12. The touchscreen displays the Wireless Information screen. 13. Select a connection method. 14. Input into the fields for the wireless network information, i.e., IP address, Mask, Router and DNS server. 15. Click 'Confirm' to proceed and enter the security password for connecting to a network. Then click 'Confirm'. 16. See Wi-Fi Setting containing the Hidden AP (Enterprise) added when the AP of the hidden attribute is scanned.	
	Connect to Hidden AP Enterprise 17. The hidden AP pop-up (Enterprise). Setup wired network connection by inputting the fields displayed in the screen. 18. Enter the SSID of the hidden attribute pop-up to be connected. 19. Occurs when connecting to enterprise type Wi-Fi. 20. Enter security method, ID, password, etc.	

No.	Action	Image Guided Instruction
Wired Settings 21.	If the connection method is DCHP, the contents are filled when the network with the DHCP server is plugged in.	
Bluetooth 22. 23. 23-1. 23-2.	Bluetooth Select Menu Connect cell. Set the external device ready to connect to the Coag-Sense® Meter. Bluetooth broadcast success pop-up.	  
23-3.	Bluetooth Broadcast Fail pop-up. Troubleshoot when phone has a bluetooth pairing problem.	

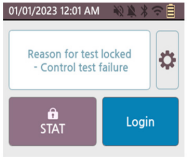
No.	Action	Image Guided Instruction
Reset Bluetooth Paired Devices. 24-1. Reset and connect cell. Reset Bluetooth paired devices pop-up Broadcast Bluetooth will pair the Coag-Sense® PT/INR Meter to an external device. Set the external device ready to connect to the PT/INR meter. 24-2. Broadcast bluetooth		 
24-3. Broadcast bluetooth connection success pop-up. 24-4. Broadcast bluetooth Fail pop-up		 
External Connection Screen to connect with external program. 1. Server IP address for socket communication is used for socket communication with external program. 2. Open/Close button is used for serial communication with external program.		

No.	Action	Image Guided Instruction
Admin Settings		
Admin settings 1. Automatic login settings. 2. Set whether enter Patient ID is required. 3. Set STAT test enable. 4. Set the need for a User Password (password is optional to login). 5. QC Lock settings (Control Test Fail, period). 6. Go to the User Management screen when touched.		
QC Lock Settings Control Test Fail, period. 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.*		
Sleep Settings If left unattended for a set of time (user configurable), the meter will enter sleep mode. To power meter OFF, manual press and hold of the Power Button is required.		

No.	Action	Image Guided Instruction
User Management 1. User Management screen displays the user 'Admin' account that was previously set up (Initial Setting Section) is on the top. 2. Create user button (touchscreen). 3. Edit the administration screen. 4. Edit team. 5. Delete user account button, confirm deletion when pop-up appears for selection of user to delete when touched. 6. Create and Edit User Accounts 7. Go forward to create user screen. The User ID, Password, Department can be created using this screen. 8. Add save button. Creates user information you entered when Confirm is touched. 9. User information and department information can be edited. ***Note:*** *User Management is only visible in the Admin login view.*		
10. Reset password to add new password. 11. Using the Edit User can also delete a user. ***Note:*** *User Management is only visible in the Admin login view.*		

QC Lockout (Optional Settings):

When the optional QC Lockout feature is turned on, a control test must be completed before a patient test can be performed. The QC Lockout ensures compliance with facility policy by checking that quality control tests are run at 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: No cycle, Everyday, Once a week and Once a month.



Note: *For waived testing performed under a CLIA Certificate of Waiver, quality control checks must be performed by following manufacturer's instructions. Coag-Sense® PT/INR System 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.*

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

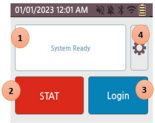
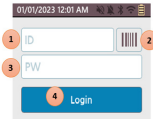
There are 2 Low Control Strips, 2 High Control Strips and a Control Activation Solution shipped with each test strip kit. Controls should be tested immediately upon receipt of each new lot number. Extra Controls may be ordered separately if more frequent QC testing is required.

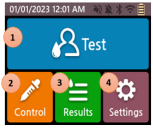
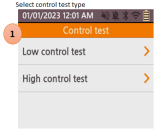
Note: *The following directions are for running a Low Control Strip. When this procedure is complete, run a High Control Strip. The controls may be run in any order. The meter will display and store the results in PT seconds only. The meter does not use or require results from the control strips prior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

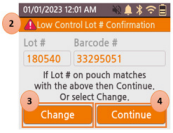
Note: *If an error message appears, consult the "Troubleshooting" section of this manual.*

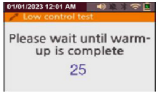
WARNING: DO NOT move or touch the meter while it is running a test. Unreliable results may occur.

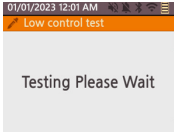
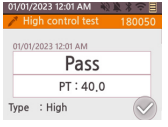
Follow these steps to perform a test on a Low or High Control.

No.	Action	Image Guided Instruction
1.	Power the meter ON by pressing and holding the **(POWER)** button on the right side of the meter. 1. Message display cell 2. STAT Button 3. Login Button 4. Setup Button ***Note:*** *The message field on the first screen will display any errors encountered during self-check.*	 
2.	Press the 'Login' icon. User is now directed to enter login credentials or scan operator barcode using a standard barcode scanner. 1. User ID. Go forward to keyboard Enter screen when touched. 2. ID Barcode. Go forward to barcode Enter screen when touched. 3. Password. Go forward to keyboard Enter screen when touched. 4. Login. Go forward to Home screen when touched. ***Note:*** *To configure your meter for Auto login please contact technical support.*	

No.	Action	Image Guided Instruction
3.	Successful login directs the user to the Home screen. Press the Control icon on the display. 1. Test. Go forward to Test screen when touched. 2. Control Test. Go forward to Control test screen when touched. 3. Results. Go to forward to Results screen when touched. 4. Settings. Go forward to Settings screen when touched.	
4.	Select from the following two options as applicable. Low Control Test or High Control Test. 1. Select control test type.	

No.	Action	Image Guided Instruction
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. 2. Low Control Test Strip lot confirmation. 3. If the Lot information does not match, press Change and 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 the NFC Tag information is not available, you may manually enter the Lot # and Barcode # using the keypad on the touchscreen. 4. Continue using the Lot # identified. Press the “Forward arrow.” ***Note:*** *Ensure the strip expiration date on the strip packaging has not passed. Contact your Coag-Sense® System distributor for help with reordering.*	 
6.	Open the packaging of the selected Control 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 snugly 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'.*	 
9.	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 green band.	
10.	The meter beeps once and displays 'Apply Control Solution' when it is ready for the Control Activation Solution. ***Note:*** *You now have up to 2 ½ minutes to apply the Control Activation Solution to the control strip.* Insert transfer tube tip into sample application well of test strip, touching tip down at flashing green light in front of wheel. Depress plunger completely to dispense the Control Activation Solution.	

No.	Action	Image Guided Instruction
11.	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 control solution was applied. Remove the strip. Retest with a new control strip. DO NOT attempt to add more control activation solution to the strip.*	
12.	Repeat steps 3-11 for 'High Control Strip'.	
13.	When testing is complete, the Pass/ Fail results are displayed in PT units. Date and Time are also displayed. Remove and discard the Control Strips. ***Note:*** *Control test results only display PT seconds, this is to avoid confusing control strip INR results with patient test strip INR results.*	
14.	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 the 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, 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.**

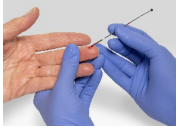
The best test sample is when:

- 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 of the strips and collection devices using universal precautions.

No.	Action	Image Guided Instruction
1.	Have patient wash their 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 the finger is completely dry. Do not use antiseptic wipes.*	
2.	Choose a site near the top fleshy part of the fingertip just slightly left or right of the center. Any one of the middle fingers can be used to lance. ***Note:*** *Avoid the more sensitive area in the center. Avoid any calluses or scars.*	
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 causes unreliable results.

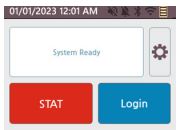
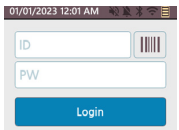
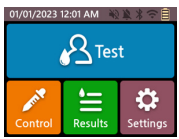
No.	Action	Image Guided Instruction
4.	When ready to collect the drop of blood, hold the Sample Transfer Tube horizontally. Touch tip to bead of blood and let capillary action fill until blood flow stops at green band. Squeeze finger to generate additional blood if required to completely fill to green band.	
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.	

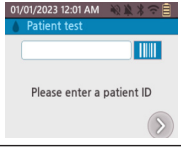
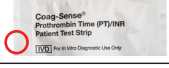
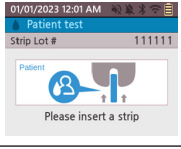
WARNING: If there is a bubble or an air pocket present in the blood sample in the transfer tube, start the test over with a fresh fingerstick on a different finger.

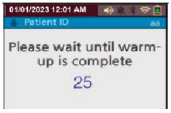
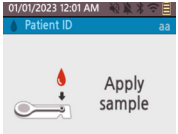
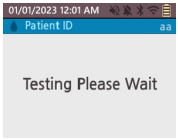
10. Performing a PT Test

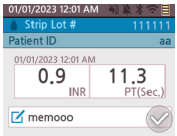
WARNING: Place the meter on a stationary, level surface for testing. DO NOT move the meter or allow it to vibrate during the test. Unreliable results may occur. Wear gloves and follow all applicable hygiene and safety procedures.

Follow the below steps to perform a patient test:

No.	Action	Image Guided Instruction
1.	Power 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 the display screen. ***Note:*** *When the QC Lockout is ON, if the control test fails, then the patient test feature will be disabled, please contact your Admin 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, press Change and 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 the NFC Tag information is not available, you may manually enter the Lot # and Barcode # using the keypad on the touchscreen. Press the forward arrow. ***Note:*** *Make sure the expiration date on the strip packaging has not passed. Contact your Coag-Sense® System distributor for help with reordering.*	 
5.	If Patient ID feature is enabled, then Patient ID information must be scanned using the optional barcode scanner or manually entered in the field. Press the forward arrow.	
6.	Open the packaging of the test strip by tearing the notched end.	
7.	Holding the round end, gently push the strip completely into the meter. The strip fits snugly when pushed all the way toward the back wall of the strip insertion area.	

No.	Action	Image Guided Instruction
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. Perform the Fingerstick. ***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 45° 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.*	
11.	When the 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.*	

No.	Action	Image Guided Instruction
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 of it 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 "Printing" section in this manual. ***Note:** The meter stores 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.	

WARNING: 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 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.

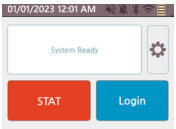
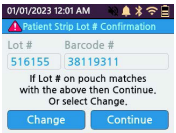
What to do when you get an unexpected result:
Follow instructions for re-testing on the Coag-Sense® PT/INR Meter. For unexpected results, contact **CoaguSense, Inc. Technical Support at 1-866-903-0890.** Consider re-testing using an alternative method prior to adjusting the patient's dose of anticoagulant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

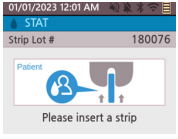
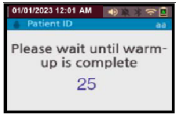
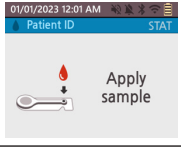
11. Performing a STAT Test

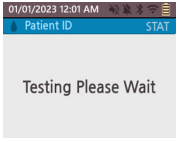
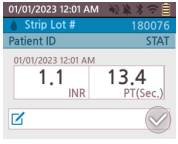
A STAT Test allows the user to perform and obtain results of a patient test without logging in a User account or entering a Patient ID. STAT test results are saved in the memory of the meter with Patient ID as STAT, along with patient result it also records the date and time the test was performed.

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

Follow the steps below to perform a STAT test:

No.	Action	Image Guided Instruction
1.	Power 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 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 respective fields. Press the forward button.	 

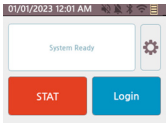
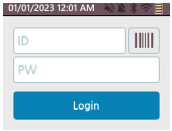
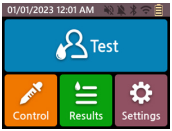
No.	Action	Image Guided Instruction
	Note: *Make sure the expiration date on the strip packaging has not passed. Contact your Coag-Sense® System distributor for help with reordering.*	
3.	Open the packaging of the test strip by tearing the notched end.	
4.	Holding the round end, gently push the strip completely into the meter. The strip fits snugly 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 the sound is turned ON) and the screen displays 'Apply sample' message. Perform fingerstick now. ***Note:*** *You now have up to 2 ½ minutes to perform a fingerstick and apply the sample to the test strip.*	

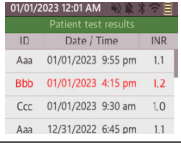
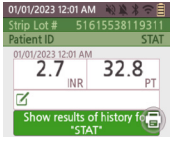
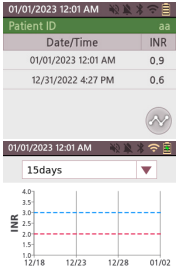
No.	Action	Image Guided Instruction
8.	IMMEDIATELY after collecting the patient sample, place the tip of the sample transfer tube at a 45º angle into the sample well on the test strip in front of the wheel where you see the flashing green light. Gently touch the tip down onto the sample well. Depress 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 the 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:* ***CLOT TIME TOO SHORT or NO CLOT DETECTED.***	
15.	Remove the test strip and dispose of it 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 using POCT1-A protocol. Memory is not lost if there is a break in power for any length of time.

Follow the steps below to review results in memory:

No.	Action	Image Guided Instruction
1.	Power 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.	
3.	Successful login directs the user to the Home screen. Press Results on the display screen.	

No.	Action	Image Guided Instruction
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 'STAT'.*	
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 more than one month.*	

13. Printing

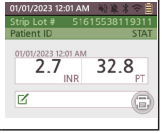
With the portable printer (optional accessory) available from CoaguSense, Inc., results from the Coag-Sense® Meter memory can be printed on either thermal paper or other media such as thermal labels for applying to patient charts.

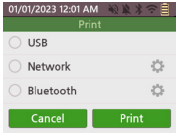
Note: *Contact your Coag-Sense® System distributor to order accessories such as the printer and paper.*
Note: Refer to the User Manual provided with the printer for its general operation.

What you'll need:

- Coag-Sense® Meter
- Optional Portable Printer, Catalog # 03P76-01
- 2" Thermal Paper, Catalog # PD99906

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 the manufacturer. The meter cannot print directly to your computer printer. The printer can be connected via Bluetooth connectivity. Refer to the Printer Guide, CSI P/N 200464.

For assistance contact CoaguSense, Inc. Technical Support at techsupport@coag-sense.com or call 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. We offer WPA2-Enterprise level of security to log into hidden Wi-Fi if required. 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 to 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 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.

Report any malfunction or security risks such as unauthorized access, modification, interference, or vulnerabilities that occur related to Coag-Sense® PT/INR Monitoring System to Technical Support at techsupport@coagusense.com or call 1-866-903-0890.

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 fully charged before performing an update. If the battery's charge is not enough and 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 100 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 of the 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 contact Technical Support at techsupport@coag-sense.com or call 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
(https://www.federalregister.gov/documents/2010/11/29/2010-29795/guidance-for-industry-and-food-and-drug-administration-staff-blood-lancet-labeling-availability#:~:text=On%20August%2026%2C%202010%2C%20the%20FDA%20and%20Centers,patient%20poses%20a%20risk%20of%20transmitting%20bloodborne%20pathogens.)

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

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 CoaguSense, Inc. Technical Support at techsupport@coag-sense.com or call 1-866-903-0890.

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.

Meter Display	Possible Cause(s)	Solution
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 for at least 10-15 mins before powering it back on. Try again with another strip. If the display persists, contact Technical Support.
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 green band and touches the sample well before dispensing sample.

Meter Display	Possible Cause(s)	Solution
STRIP ERROR	The strip was inserted incorrectly. There may be a problem with the strip or meter. The strip was being pulled out without stopping the test, resulting in motor coupler and spline of wheel not disengaging properly. The strip might be missing the wheel.	**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 fully using a quick smooth motion. This will help the strip and motor alignment.** **Do not pull the strip out until the test has been completed.** **Verify that the strip is not missing a wheel.** **Insert another strip, which has the wheel on it and if error persists, call 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.

Meter Display	Possible Cause(s)	Solution
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 a meter malfunction.**
CONTROL FAIL-CLOT TIME TOO SHORT	The clotting time was very short and out of testing range (<8 seconds). An air bubble was detected in the control activation solution sample. The sample transfer tube was not filled with the control activation solution to the green band. Applying the control activation solution to the test strip before ¨Apply Control Solution¨ displayed on screen.	Repeat the entire procedure with a new control strip. Visually confirm that no air bubbles are in the control activation solution sample before applying to test strip. Ensure that the tube is filled to the green band. Depress black plunger completely to dispense the control activation solution sample. 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.

Meter Display	Possible Cause(s)	Solution
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.**
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 to use a 21g lancet for good flow of blood).	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.

BATTERY LOW/ DISPLAY IS BLANK	The meter battery is low.	**Connect power adapter into the wall socket at least for 30 minutes to use it for testing. The meter will take 6 hours to charge fully.** **Verify that the battery is getting charged by checking the charging indications (green lightning bolt on the left top corner of meter display and the red dot on the right side of the meter). The meter will be charging despite being in sleep mode or powered off.** **After completing the test, make sure to turn off the meter completely by pressing and holding the Power button until the screen goes dark after every use to save battery. Inform users that manually powering off will ensure that meter battery will not drain due to sleep mode**

General Troubleshooting

Meter Display	Possible Cause(s)	Solution
Meter does not power ON	Insufficient Battery to Power ON. Power Adapter is 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.

Meter Display	Possible Cause(s)	Solution
Cannot insert strip completely	Accumulation of dirt, dust, control activation solution, or blood in the strip insertion area. Wheel is not seated properly in 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 the wall socket. Change 'Brightness' User setting in the 'Device Settings' menu of the meter.
Touch screen not responding	Prolonged exposure to direct sunlight. Dropping or subjecting the meter to strong shocks.	Avoid prolonged exposure to direct sunlight, as it may reduce life expectancy and functionality of the display. Contact Technical Support.
Touch screen scratched or cracked	Dropping or subjecting the meter to strong shocks. Using pointed or sharp-edged objects other than the recommended 'finger' or rubber stylus to touch the screen elements.	Contact Technical Support.
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 If issue persists, press Reset button to restore factory settings. If issue still exists, contact Technical Support.

Meter Display	Possible Cause(s)	Solution
Lost NFC Tag	Misplaced NFC Tag.	**The NFC Tag is provided with 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.
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 in proximity to 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 Tag 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, INC. WARRANTS THAT THE COAG-SENSE® METER ("METER") IS FREE FROM ALL DEFECTS IN MATERIAL AND WORKMANSHIP FOR A PERIOD OF ONE (1) YEAR FROM DATE OF DELIVERY. WHEN THE METER IS USED FOR THE INTENDED PURPOSE AND IN THE APPROPRIATE MANNER, AND AFTER AN ATTEMPT IS MADE BY YOU AND COAGUSENSE, INC. TO FIX THE ISSUE BY TELEPHONE, COAGUSENSE, INC'S REMEDY IS TO REPAIR OR REPLACE THE METER AT THEIR DISCRETION. THE WARRANTY DOES NOT APPLY TO A METER DAMAGED BY MISUSE, ALTERATION OR TAMPERING TO EITHER HARDWARE OR SOFTWARE. CONTACT TECHNICAL SUPPORT AT 1-866-903-0890 FOR INSTRUCTIONS. THIS WARRANTY APPLIES ONLY TO THE METER. COAGUSENSE, INC'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.FITNESS FOR A PARTICULAR

Expected Service Life

The Coag-Sense® PT/INR Monitoring System's expected service life is five (5) years from the manufacturing date when used according to specifications.

Instructions for Meter's Return

If there is an issue with the Meter, you agree to a telephone consultation with CoaguSense, Inc. Technical Service to attempt to remedy the issue. Upon review and agreement, you may be directed to return the PT/INR Meter to CoaguSense, Inc. Should this occur, clean the outside surface, as described in the "Cleaning and Disinfecting the Meter" section before returning the device. 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
Sample Transfer Tubes Bag Evacuated, 54 Count	03P52-57
Professional Control Test Strip Kit, 10 Count	03P69-10
Coag-Sense® Lancets Auto Single Use, 21G 2.2mm depth, Box of 100	03P58-04
AC Power Adapter – International	03P74-01
Coag-Sense® Portable Printer, USB, Bluetooth, and Wi-Fi	03P76-01
Portable Printer Paper, 5 rolls	PD-99906
Replacement Carrying Case	03P75-01
Coag-Sense® Stylus Pen	05P77-01
Bar Code Scanner	03P78-01

21. EMC Tables

The following tables contain the Manufacturer's declaration and additional information required by IEC 60601-2:2014 (Fourth Edition).

Test Name	Ref. Standard	Ports to Test	AC Mains Voltage	Test Level Required	Notes
Mains Terminal Disturbance Voltage	CISPR 11:2015± A1:2016	AC Mains	100V-50Hz 100V-60Hz 220V-60Hz 230V-50Hz	Group I, Class A	
Radiated Disturbance	CISPR 11:2015± A1:2016	Enclosure	100V-50Hz 100V-60Hz 220V-60Hz 230V-50Hz	Group I, Class A	
Harmonic Current Emissions	EC 61000-3-2:2014	AC Mains	230V-50Hz	Class A	
Voltage Fluctuations & Flicker	EC 61000-3-3:2013	AC Mains	230V-50Hz	Pst = 1 Pit = 0.65 Dmax = 4 DC = 3.3%	
Electrostatic Discharges (ESD)	EC 61000-4-2:2008	Enclosure	230V-50Hz	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	1 pulse/ 1sec contact 8kV air 15kV
Radiated RF Electro-Magnetic Fields	EC 61000-4-3:2008± A1-2007± A2.2010	Enclosure	230V-50Hz	10V/m 80MHz to 2.7GHz 80%AM at 2Hz RF Wireless Comm. (Refer to test report clause 1..15)	Dwell time is 3 sec
Electric Fast Transients & Burst	EC 61000-4-2:2012	AC Mains	230V-50Hz	±2kV AC, 100kHz PRR	
		I/O Lines>3m		±1kV AC, 100KHz PRR	
Surges	EC 61000-4-5:2014/ AMD:2017	AC Mains	230V-50Hz	±0.5kV, ±1kV L1 to L2 (DM)	5 pulses at 0° 90° 180° 270°

Test Name	Ref. Standard	Ports to Test	AC Mains Voltage	Test Level Required	Notes
Conducted Disturbances, Induced by RF fields	EC 61000-6:2013	AC Mains & all I/O	230V-50Hz	3Vrms 150kHz to 80MHz 6Vrms in ISM and Amateur radio bands between 0.15MHz & 80MHz	Dwell time is 3 sec
Voltage Dips, Interruptions & Variations	EC 61000-411:2004/ AMD:2017	AC Mains	100V-60Hz 240V-60Hz	0% UT for 0.5 cycle	At 0°, 45° 90° 135° 180° 225° 270° 315°
				0% UT for 1 cycle 60Hz: 70% UT for 30 cycles	At 0°, 180°
				60Hz: 0% UT for 300 cycles	At 0°, 180°
Power Frequency Magnetic Field	EC 61000-8:2009	Enclosure	230V-50Hz	30A/m	

22. Index

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In vitro diagnostic medical device

61010-1

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