Coag-Sense®

Patient Self-Testing User Manual

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

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

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The Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing is intended to be used by a single person and should not be shared.

℞ Only

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

1. Introduction

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

Intended Use

For self-test users, 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.

The device is intended for use by properly selected and suitably trained patients or their caregivers on the order of the treating physician to monitor patients who are on anticoagulation therapy. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self- testing. The device is not intended to be used for screening purposes.

Importance of (PT)/INR Monitoring

Blood-Clotting Time:

The rate at which blood clots is measured in units 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, cancer and venous thromboembolism.

Important Information Regarding This Manual

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

The Coag-Sense® System should only be used with a doctor's prescription. Do not adjust your medication without talking to your doctor or health care professional. Patients should be stabilized 90 days prior to self-testing on warfarin-type (coumarin) anticoagulation therapy.

You must complete proper training on the Coag-Sense (PT)/INR System before you begin using the system. Refer to Package Insert. 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

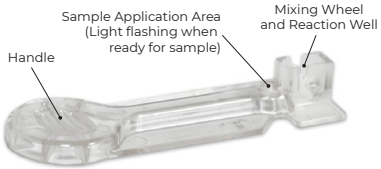
The Meter has a TFT color LCD **Touch Screen** that shows results, information, icons and results recalled from memory. To select an option, gently click on the display button. There are three touch buttons, **Cancel or Previous Screen Button, Home Screen Button and View Menu Button Screen** for the 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 or other Coag-Sense® System 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 pulls 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 detected by a beam of light until a clot forms and interrupts the beam of light. The PT result 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 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 two (2) Low and two (2) 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) analyzer's ability to detect a clot.

Each lot of reagent has an ISI and MNPT value assignment that is traceable to the current World Health Organization (WHO) International Reference Preparation Material (IRP) WHO gold standard. The lot calibration is performed at an external reference laboratory using the WHO gold standard using the tilt tube method. The assay is traceable to NIBSC Code rTF-16. Control testing confirms the performance of the system and should be completed immediately for each new Lot of Test Strips received. Refer to Coag-Sense PT/INR Monitoring System Package Insert, P/N 300554.

NFC Tag

Near Field Communication (NFC) Tag is a micro data tag with antenna that contains the required 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 Patient Self-Test 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 on 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, a 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 Patient Self-Test System **(Catalog #03P70-01)** is supplied with the following items:

Item Description	QTY
Coag-Sense® (PT)/INR Meter	1
Coag-Sense® (PT)/INR System Self-Test User's Manual	1
Coag-Sense® (PT)/INR System Self-Test Quick Reference Guide	1
A/C Micro USB Power Supply	1
Sample Transfer Tubes	1 pk
Single-Use, 21G Auto Safety Lancets	1 pk
Carrying Case	1
Stylus Pen	1

If you participate in a testing service, your service provider will provide you with all the necessary testing components. If you run out of testing supplies, please contact the service provider that gave you your Meter for more supplies and Control Test Strip Kit **(Catalog #03P69-10)**. If you purchased a Coag-Sense® Test Strip Kit **(Catalog #03P57-50)** out-of-pocket, it will include the following items necessary to perform a test:

Item Description	**QTY**
Patient Test Strips	50
Low Control Strips	2
High Control Strips	2
Control Strip Activation Solution	1
Sample Transfer Tubes	1 pk
NFC Tag	1
Package Insert	1

Following are standard medical supplies that are required with each use and may be supplied by your testing service provider:

21G Auto Safety Lancets, single use.

NOTE: *These materials are not provided with the (PT)/INR system. The Coag-Sense® Test Strip Kit- 50 may be ordered from your Meter distributor or home testing service provider separately.*

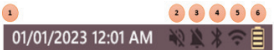
The Coag-Sense Prothrombin Test (PT)/INR Monitoring Meter System and test strip kits components are available by prescription from your Physician.

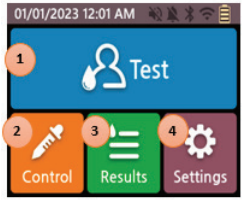
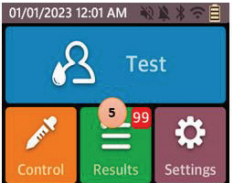
℞ Only **Caution: Federal law restricts this device to sale by or on the order of a physician.**

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 description are provided in “Troubleshooting” section.

Buttons/Icons	Meaning
	**Power ON/OFF** To power ON the Meter, press and hold Power Button. To Enter/Exit Sleep Mode press the button once quickly and press the button again and hold for few seconds
	Cancel or return to previous screen
	Go to the home screen
	View additional menu
	**Common Keypad Input** Is the input completion button. Returns to previous screen when selected. 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
	**The Icons on the Touch Screen** 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.
	5. Results Icon – Displays the number of results that have not been synchronized.

3. Meter Specifications

Category	Features
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: • 2,000 patient test results with date and time • 500 control test results with date and time • 1,000 Operator accounts
Lithium Battery	Rechargeable Lithium Polymer Battery (3.7 V, 2350 mAh)
Battery Capacity	Fully charged battery (6 hours of charging) can run ~100 tests
Power Input	120V AC Adapter (Use with Coag-Sense® Adapter Only)
AC Input	100–240 V~, 50–60 Hz, 0.5 A (Mains supply voltage fluctuation: ±10%)
Power Output	5.0 V, 2.0 A
Pollution Degree	2
Overvoltage Category	II
Use Circumstance	Indoor only

Category	Features
Blood Sample Size	10–12 µL, equivalent to one drop of blood
Communication Port	Micro and Standard USB
Size in mm (Height x Width x Depth)	152 × 100 × 29.5
Weight in grams	315 grams
Equipment Classification	Class II with external power supply. Internally powered when operated with battery. IPX0 rating.
Mode of Operation	Automatic

WARNING: Use the Coag-Sense® Meter along with the provided Power Adapter only. Use only AC adapter type UES12lCP-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 results represent a common normal range for an individual 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

- **Patients taking Warfarin (Coumadin®) and other oral blood thinners should consult with their healthcare provider before adjusting their dosage.**
- **Patients should be stabilized 90 days prior to self-testing on Warfarin-type (Coumarin) anticoagulation therapy.**
- **Patients should consult with their doctor for their appropriate INR therapeutic range. INR values above 4.5 (a high INR level) or below 2 (a low INR level) should be verified or repeated by a laboratory method.**
- **Patients who have recently taken or are currently taking any type of Heparin or Low Molecular Weight Heparin anticoagulant should not use this test system and should consult their doctor.**
- **The system should also not be used to monitor patients on direct oral anticoagulants (DOACs) including Factor Xa and Direct Thrombin inhibitors.**

WARNING: The Coag-Sense Prothrombin Test (PT)/INR Monitoring Meter System and test strip kits components are available by prescription from your Physician.

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

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 questionable 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 questionable results.
- The sample drop of blood must be transfered to the Test Strip. Questionable results may occur if sample is too small.
- 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 questionable 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 questionable results.
- **If Isopropyl Alcohol (IPA) wipes are used, wipe the fingerstick site with a gauze pad (not supplied) and make sure the site is completely dry. If any alcohol remains (or is re-introduced) on the finger, it may cause questionable results.**
- Do not use wipes containing chlorhexidine gluconate, as it may produce questionable 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 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.

- 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 questionable results.

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. For cleaning purposes, use hospital grade disinfectant, i.e., 1,000 ppm (parts per million) or use Healthcare Bleach Germicidal Wipes containing Sodium Hypochlorite (Bleach) to clean the exterior meter housing only. DO NOT SPRAY ANY LIQUIDS DIRECTLY ONTO THE METER.
- Do not move or touch the Meter while it is running a test. Questionable results may occur.
- Do not pull the strip out during a test while the wheel is spinning. STOP the test by pressing the cancel or back arrow. The display prompts you to confirm test cancellation. The strip should be removed after confirming test cancellation.
- 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 60601-1-2. 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 that if adjacent or stacked use is necessary, the Coag-Sense Prothrombin Time (PT)/INR Monitoring System should be observed to verify normal operation in the configuration in which it will be used.

Test Strips/Control Strips/Control Strip Activating Solution

- The Test Strips are designed for single use only. Do not reuse the Test Strips.
- Patient samples, controls, used strips, Transfer Tubes and lancets are potentially infectious. Discard used materials in a safe manner using

local government regulations for hazardous medical waste. Use universal precautions will in contact with contaminated strips and control activation solution. Follow governing policies and procedures for proper handling and disposal of potentially infectionus waste.

- 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.

Contraindications

- The PT/INR Monitoring System should be used only for testing outside the body (in vitro diagnostic use only). This system should NOT be used to diagnose diabetes or test newborns.
- The Software does not give clinical judgments.
- The system may not provide accurate measurement results if the ambient temperature is outside the specified range (18 ~ 32 °C).
- Meaningful results cannot be produced without use of Coag-Sense PT/INR strips with the meter as a system.

WARNING: PATIENT SELF-TEST ONLY

The Coag-Sense Prothrombin Time (PT)/INR Monitoring System for Patient Self-Testing is intended to be used by a single person and should not be shared.

6. Symbols Glossary

Icons	Meaning
	Warning: This indicates a warning or precaution, requiring special attention
	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
EXP	Expiration Date
LOT	Indicates the manufacturer's batch code so that the batch or Lot can be identified
IVD	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Indicates the total number of tests that can be performed with the 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
REF	Indicates the manufacturer's catalog number so that the medical device can be identified
EC REP	Indicates authorized representative in the European Community/ European Union

Icons	Meaning
	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
CE NNNN	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 the entity importing the medical device into the locale
	Near Field Communication (NFC) Tag
N US 61010-1	The system fulfills the U.S. safety requirements (NEMKO listed)
	Consult instructions for use
SN	Indicates the manufacturer's serial number so that specific medical device can be identified
UDI	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
Rx Only	Prescription Use Only

Icons	Meaning
	For self-testing: a lay person can use the device marked with this symbol even without professional medical experience
	Medical device contains lithium batteries or fuel cell. Potential for hazardous situation(s). These situations include fires, explosion, or excessive temperatures, etc. Lithium batteries are considered hazardous goods and should not be thrown in the trash or with regular recycling.
	Lithium-ion battery
	Recycle according to local, state and international laws and regulations
CONTROL	A control material that is intended to verify the performance of another medical device
CONTROL +	Plus indicates a control material that is intended to verify the results in the expected positive range
CONTROL −	Indicates a control material that is intended to verify the results in the expected negative range
 	Contains or incorporates human blood (insert blood drop) or use plasma derivatives
US ONLY	US Distribution Only
INR	International Normalized Ratio
PT	Prothrombin Time

Directions for Use

7. Meter Setup

Operating Conditions

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

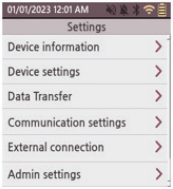
- Be sure that the Meter and strips are at room temperature before use. Operating conditions are between 65 °F and 90 °F (18 °C and 32 °C). **The Meter will not allow a test to proceed unless it is within the operating temperature range.**
- Relative humidity should be between 10% and 90%, without condensation, 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 Patient Self-Test 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.

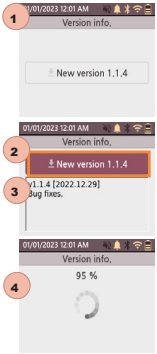
System and User Settings

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.

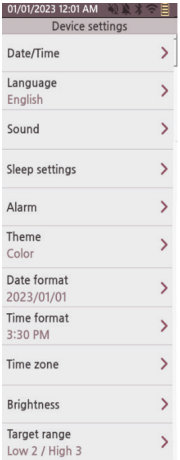
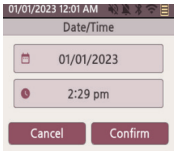


Device Information Setting

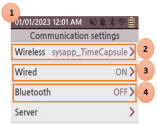
No. Action	Instructions
Device Information Screen	

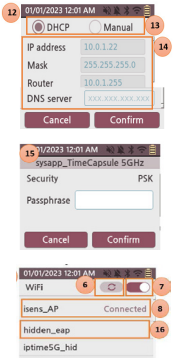
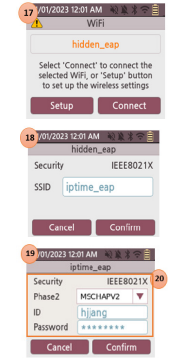
No.	Action	Instructions
1.	Software Version Update. (See Device Information screen for version of software.)	
2.	If there is a new software version: The latest version can be found in this screen. Clicking the ‘New version’ will download the software update.	
3.	A description of the software version 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.	

Device Setup

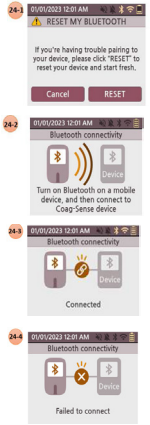
No. Action	Instructions
Device Settings Screen	
Date/Time Settings	

Communication Settings

No. Action	Instructions
Status 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. 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. Clicking 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	Instructions
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	Instructions
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. Bluetooth Select Menu. 23. Connect mobile device. 23-1. Set the external device ready to connect to the Coag-Sense® Meter. 23-2. Bluetooth broadcast success pop-up. 23-3. Bluetooth Broadcast Fail pop-up. Troubleshoot when mobile device has a Bluetooth pairing problem.	

No. Action	Instructions
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.	

8. Performing a Control Test

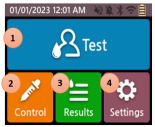
There are two (2) Low Control Strips, two (2) High Control Strips and a Control Strip Activation Solution shipped with each Test Strip Kit. Controls of each new Lot number should be run before performing a patient test. Extra controls may be ordered separately if more frequent QC testing is required. Please note that your home testing service provider may not include Control Strips in your supply shipment.

Note: *The following directions are for running a High Control Strips. When this procedure is complete, run a Low Control Strips. 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.*

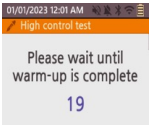
Note: *If an error message appears, consult the "Troubleshooting" section of this manual.*

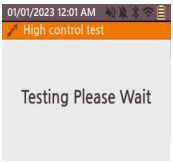
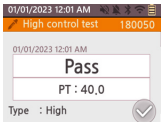
WARNING: DO NOT move or touch the Meter while it is running a test. Questionable results may occur.

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

No. Action	Instructions
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 any errors encountered during self-check.*	
2. Home screen will be displayed. 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.	
3. Press the control icon on the display. Select from the following two options as applicable. Low Control Test or High Control Test. 1. Select High control test.	

No.	Action	Instructions
4.	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. High Control Test Strip Lot confirmation. 3. Change button. Go forward to new strip information Enter screen when touched. 4. Continue button. Continue to the Lot number, the previously entered strip when touched. 5. Otherwise press Change and scan the NFC Tag against the NFC Tag scanner on the Meter, the Lot number (six-digit number) and Barcode # (eight-digit number) will auto populate. If the NFC Tag information is not available, enter the Lot number and Barcode # manually using the keypad on the touchscreen. 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.*	  
5.	Open the packaging of the selected Control Strip by tearing the notched end.	

No.	Action	Instructions
6.	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.	
7.	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'.* 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.*	 
8.	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.	
9.	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	Instructions
10. 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.*	
11. Repeat steps 2–10 for 'Low Control Strips' with new Transfer Tube. DO NOT reuse Transfer Tubes. Please use new Transfer Tube for testing Low and High Controls, as well as blood sample tests.	
12. 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.*	
13. Once the controls have been successfully tested, remember to remove and discard the Control Strips. You can now proceed to testing blood samples. If you are not going to test, turn off the Meter by **pressing and holding** the **POWER** button. The opened Control Activation Solution may be used until the expiration date.	

Note: *If control test fails, repeat the test with a new strip. If the control test continues to FAIL, contact 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
- For fingerstick blood testing, increasing the flow of blood in the finger will help you capture a good drop of blood. Before you lance your finger, warm your hand by washing it in warm water, holding it under your armpit, or by using a hand warmer. **Ensure that your hand is dry prior to testing.**
- Do not use fingers with tight rings, scars, calluses, or other features that prevent getting good access to the blood.
- One of the middle or index fingers on either hand is recommended.
- Gently squeeze or massage the finger to be lanced, near the tip. Good circulation can be seen if the fingertip changes to a pinkish shade.
- Use a **21G 1.8-2.2 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 hold your hand below your heart. **If necessary, squeeze the finger from the sides to open the wound for proper blood flow to produce a pea sized drop.**

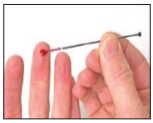
The Best Test Sample is When

- 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: Blood samples, controls, used Test Strips, Transfer Tubes and lancets are potentially infectious. Dispose of strips and collection devices using universal precautions.

No.	Action	Instructions
1.	Wash your hands with soap and warm water. Dry completely. **If cleaning with an alcohol wipe, the finger must be wiped dry with sterile gauze (air drying is insufficient to remove residual alcohol in time).**	
2.	Choose a site just off the center near the top of one of the middle fingers to lance. ***Note:*** *Avoid the more sensitive area in the center. Avoid any calluses or scars.*	
3.	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'.** The sample drop of blood must be transferred to the Test Strip. ***Note:*** *The blood should flow freely. If it doesn't, gently squeeze the finger to get it started. Lowering your 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 questionable results.

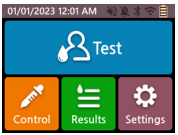
No.	Action	Instructions
4.	When ready to collect the drop of blood, hold the Sample Transfer Tube horizontally. Touch tip to bead of blood and let capillary action fill until blood flow stops at the green band. Squeeze the finger to generate additional blood if required to completely fill to the green band.	
5.	Once you have collected the blood sample, **IMMEDIATELY** put it into the sample well on the Test Strip. See "Performing a PT Test" section of this manual.	

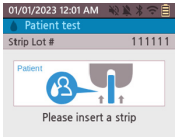
WARNING: If there is a bubble or an air pocket present in the blood sample in the Transfer Tube, start the test over with a fresh fingerstick on a different finger.

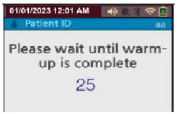
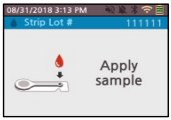
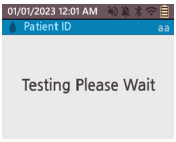
10. Performing a Patient Test

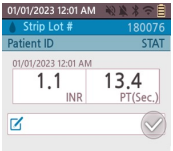
WARNING: Place the Meter on a stationary, level surface for testing. DO NOT move the Meter or allow it to vibrate during the test. Questionable results may occur.

Follow the below steps to perform a patient test:

No.	Action	Instructions
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.	Home screen will be displayed. Press the 'Test' icon on the display screen.	

No. Action	Instructions
3. Patient Strip Lot confirmation screen displays the Lot information of the strip that was last recorded. Proceed with testing if the Test Strip is from the same Lot. Otherwise, scan the NFC Tag against the NFC Tag scanner on the Meter, the Lot number (six-digit numeric identifier) and Barcode # (eight-digit numeric identifier) will auto populate. If the NFC Tag information is not available, you may manually enter the Lot number 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 supplier when you need additional strips.*	  
4. Open the packaging of the Test Strip by tearing the notched end.	
5. 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	Instructions
6.	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.* 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 minutes and 30 seconds to perform a fingerstick and apply the sample to the Test Strip.*	 
7.	**IMMEDIATELY** after collecting your blood 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:*** *Depress black plunger completely to dispense the blood.*	
8.	When the sample is detected, the Meter displays a 'Testing Please Wait' message. ***Note:*** *If this screen is not displayed within 8 seconds not enough blood sample was applied. DO NOT attempt to add more sample. Stop the test and retest with a new strip and fingerstick.*	

No.	Action	Instructions
9.	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 you to make notes such as medication or diet change 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, such as: "**CLOT TIME TOO SHORT" or "NO CLOT DETECTED".***	
10.	Remove the Test Strip and properly dispose. ***Note: Repeat the test if the results seem unusually low or high.** The Coag-Sense Test Strips provide test results in the INR value between 0.8 and 8.0. Normal value is between 0.8 and 1.2 INR units. If the results still seem unusual after a second test, contact Technical Support.*	
11.	You may print the results if you purchased the optional portable printer. Refer to the "Printing" section in this manual. ***Note:** The Meter stores 2,000 patient test results in memory with the time and date stamp. Refer to "Reviewing the Memory" in this manual for more information.*	
12.	Turn the Meter OFF by pressing and holding the **POWER** button when you are finished testing. If left unattended for a set time (User preferred Setting), the Meter powers itself OFF.	

WARNING: An questionable 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 questionable 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.**

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

What to do when you get an unexpected result:

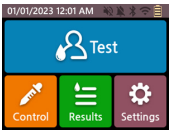
Follow instructions for re-testing on the Coag-Sense® (PT)/INR Meter.

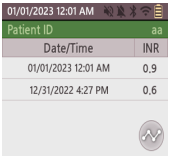
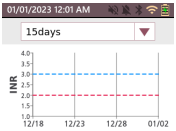
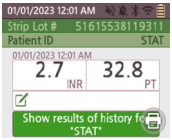
For questionable results, contact Technical Support at +1-866-903-0890. Always follow your doctor's instructions for adjusting your dose of anticoagulant medication, or any other corrective action.

11. Reviewing the Memory

The Coag-Sense® Meter stores up to 2,000 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, and control tests. Memory is not lost if there is a break in power for any length of time. Test results stored in the Memory cannot be manually erased by the user.

Follow the steps below to review results in memory:

No.	Action	Instructions
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.	Home screen is displayed. Press Results on the Home screen.	
3.	The 'Results' screen lists Patient test results and Control test results.	

No.	Action	Instructions
4.	User can select an individual result from the list of results stored in memory to view its details or select the graph icon in the lower right corner to plot the results over a time period. ***Note:*** *The results shown here are for representation only.*	
5.	Clicking the chart icon displays test results for the selected time interval. ***Note:*** *The target range lines are set in "Settings>Device Settings>Target range".* ***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.*	
6.	When an individual result is viewed, a memo can be added or changed, and the result can be printed to an optional portable printer.	

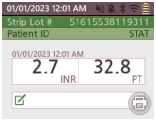
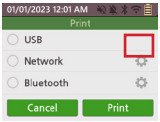
12. Printing

With the portable printer (optional accessory) available from CoaguSense, Inc. results from the Coag-Sense® Meter memory can be printed on thermal paper.

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	Instructions
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 in the lower-right hand corner of the screen to print the result.	
3. You may choose from three different printer connection modes. Network and Bluetooth® modes will require configuration using the setup icon prior to printing. Press Print to print the result.	

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

For assistance with the printing function contact CoaguSense, Inc. Technical Support at techsupport@coag-sense.com or call +1-866-903-0890.

13. Network Connectivity and Security

The Coag-Sense® Meter offers the ability to send test results to electronic medical records or laboratory information systems using middleware in the hospital setting. 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 WiFi if required.

Connecting the device to a local WiFi network is only required when the user is upgrading the software to the latest version. 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.

The PST Meter does not include a user authentication feature (i.e., login). Software updates can occur without user authentication. Customers are responsible for the security of their Local Area Network, especially in protecting it against malicious software and attacks. This protection might include standard security measures, i.e., unique PIN, password, or firewall from malicious attacks and/or intrusion. Ensure that the Meter is protected against unauthorized physical access and theft and that the tamper event label is intact on delivery. Do not share user or operator accounts on Meter nor network. Whether working in a wired or wireless environment, use a strong alpha and numeric password for user account on the Meter and network. Please 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 support@coagusense.com or call Technical Support at +1-866-903-0890.

Minimum IT Requirements

The server requirements primarily follow the middleware specifications required for integration with the PT2 device. Additionally, the general PC specifications recommended for smooth data transmission and reception are as follow:

RAM – 4GB, CPU – Intel Core i3 or AMD Ryzen 3 or higher.

14. Bluetooth® App Security

For security reasons, it is recommended that you only connect your Coag-Sense® Meter to Bluetooth apps that have been provided to you by your home testing service provider. CoaguSense, Inc., does not offer Apps at this time. Ensure that the device is protected against unauthorized physical access and theft. Do not share your user account Meter information. Use a strong password account.

Minimum Bluetooth Requirements

The Coag-Sense PT/IN Monitoring System supports Android 5.0 or later (Samsung Galaxy S5 or later) and iOS 8 (Apple iPhone 4S/5/6/7/8) or later operating systems through Bluetooth enabled applications compatible with Coag-Sense software.

Please 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 support@coagusense.com or call Technical Support at +1-866-903-0890.

15. Meter Software Update

When connected to the Internet the Coag-Sense® Meter will 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.

Meter with Lithium Battery safety tips:

- Once the battery is fully charged remove from the power supply.
- Do not open the Meter to remove the lithium battery.
- Do not throw the Meter in the trash.
- Do not incinerate.
- Put in a separate plastic bag.

17. Cleaning, Disinfecting and Disposal of (PT)/INR System

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. When the power is off and the USB cable is not connected, the Meter housing can be cleaned with a damp non abrasive cloth. For disinfecting wipe all exposed surfaces with Healthcare Bleach Germicidal Wipes containing Sodium Hypochlorite. Wipe all exposed surfaces with Healthcare Bleach Germicidal Wipes containing Sodium Hypochlorite (EPA No. 67619-12) or using a 10% Sodium Hypochloride Bleach Solution 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.

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.

For biosafety, the disposal of blood or other potentially infectious materials; all waste must comply with OSHA's Bloodborne Pathogen Standard, 29 CFR 1910.1030. In general, regulated wastes, other than contaminated sharps, must be placed in containers which are: closable, constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping. For additional information contact OSHA website at http://www.osha.gov.

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

https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/healthcare-equipment.html

Blood Lancet Labeling - Guidance for Industry and Food and Drug Administration Staff

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-lancet-labeling-guidance-industry-and-food-and-drug-administration-staff

To comply with United States, European Union WEEE and other waste management regulations the Meter with batteries must be disposed and/or recycled for sustainability. Rechargeable lithium batteries must be properly disposed at a recycling location by a specialized recycler or retailers that participate in take back services or contact your solid waste or household waste program for options. The Meter must be decontaminate using a 10% bleach or sodium hypochloride solution per the cleaning and disinfectant instructions. Any Coag-Sense (PT)/INR devices that come in contact with blood or contaminated products are potentially biohazardous.

Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Any object that can pierce the skin, such as the lancets, immediately or as soon as possible after uses shall be placed in an appropriate container such as puncture resistant sharps or closed biohazard container. All materials that came in contact with human blood or tissue, such as the Test Strips and Sample Transfer Tube should be placed in biohazard container. All materials should be disposed per local and state government regulations.

Please use precautions when handling Meters, batteries, electronic equipment, Test Strips, sharp objects, and e-waste, etc. Please follow laws and ordinances of local health and governmental policies, procedures and regulations for proper handling and disposal of potentially infectious waste.

Take to a collection point. Lithium batteries should be taken to a separate recycling or household hazardous waste collection point.

Contact Technical Support at +1-866-903-0890

18. Troubleshooting

The Coag-Sense® Meter continually checks its systems for unexpected conditions. These may arise because of defective components or consumables, environmental factors or due to User handling and procedure errors. This section details how to resolve most problems that you might encounter. If you have any questions or problems during the troubleshooting process, note the display wording and contact Technical Support at **+1-866-903-0890** or email techsupport@coag-sense.com.

Meter Display	Possible Cause(s)	Solution
ROOM TEMP INCORRECT SEE MANUAL	The temperature of the room is either below or above the operating temperature range of the Meter. Battery was depleted and then plugged into AC adapter while repeated testing continued. The charging of the battery can generate enough heat to raise the internal temperature of the Meter outside the operating range.	Move the Meter to a place that is within the operating temperature range of the Meter (65 °F to 90 °F, 18 °C to 32 °C) 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.
STRIP ERROR	The Test Strip was not inserted fully or may have been inserted at an incorrect angle or incorrect speed. There may be a problem with the wheel on the strip or with the Meter.	Reinsert the strip holding the back of the Meter steady with one hand while inserting the strip completely using a quick smooth motion with the other hand. If display persists, try again with another new strip. If the message displays again contact Technical Support.

Meter Display	Possible Cause(s)	Solution
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.
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 (65°F to 90°F, 18°C to 32°C) and allow Meter time to adjust to correct temperature. Repeat testing. Turn Meter off then on again after 5-7 minutes. Try again with another strip. If the display persists, contact Technical Support.
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 minutes and 30 seconds 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 minutes and 30 seconds 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
BATTERY LOW/ DISPLAY IS BLANK	The Meter battery is low.	The Meter can complete the current test. The Meter connected to the power adapter should be plugged into the wall socket
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 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 the error message persists, contact your service provider. This does not indicate a Meter malfunction.
CONTROL FAIL-OUT OF RANGE	The Control Strip result is outside of its acceptable range (FAIL-out of range). This may be due to a problem with the shipment/storage of the Control Strips or the Control Activation Solution. Plasma on Control Strips has a limited shelf life and the clotting time will change when exposed to temperatures outside the storage range.	Repeat test with another Control Strip. If the second test is out of range, contact Technical Support. Control Strips should be tested immediately upon receipt of your shipment of new Test Strips as they have a limited shelf life. This does not indicate a Meter malfunction.

Meter Display	Possible Cause(s)	Solution
CLOT TIME TOO SHORT	The clotting time was very short and out of testing range (<8 seconds). An air bubble was detected in the sample. Lancing the finger before 'Apply sample' displayed on screen. Taking too long to collect the sample in Transfer Tube (make sure to use a 21G lancet for a 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.	You should not use this test if you are also taking 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.
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.
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. If issue persists, Contact Technical Support.

General Troubleshooting

Meter Display	Possible Cause(s)	Solution
TOUCH SCREEN DISPLAY ISSUES	Insufficient/Low Battery. Display Faint or Low brightness. Display Screen Flickers.	Connect the power adapter to the wall socket. Change 'Brightness' User setting in the 'Device Settings' menu of the Meter. Check Battery level and if issue persists, contact Technical Support
TOUCH SCREEN NOT RESPONDING	Dropping or subjecting the Meter to strong shocks.	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.
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.
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.

Meter Display	Possible Cause(s)	Solution
NFC TAG ISSUES: • **NFC Tag not working** • **Scanned information does not match the information on the strip packaging**	Improper scanning of the NFC Tag. Faulty NFC Tag scanner in the Meter.	Touch or bring the NFC Tag 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 number 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.

Attention User(s): If any serious incident has occurred in relation to the device shall be reported to CoaguSense, Inc. Technical Support at +1-866-903-0890 or email: support@coagusense.com. In addition, the competent authority of the Member State in which the user and/or the patient is established must be notified also.

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.

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, Disinfecting and Disposal of the (PT)/INR System" 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 Patient Self-Test System	03P70-01
Coag-Sense® Test Strip Kit – 50 count, Controls included	03P57-50
Coag-Sense® Lancets Auto Single Use, 21G, 2.2 mm depth – Box of 100	03P58-04
AC Power Adapter – Switching Adaper	03P74-01
PT2 Carrying Case	03P75-01
Sample Transfer Tubes, 54 count	03P52-57

WARNING: The Coag-Sense Prothrombin Test (PT)/INR Monitoring Meter System and test strip kits components are available by prescription from your Physician.

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

21. EMC Tables

The following tables contain the Manufacturer's declaration and additional information required by IEC 60601-1-2:2020, Ed. 4.1.

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 contact8kV 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	

Test Name	Ref. Standard	Ports to Test	AC Mains Voltage	Test Level Required	Notes
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°
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. Precision Performance Study

Principle of Assessment

The intended use or technological characteristics for the current 2nd generation device do not change from those of the cleared 1st generation Coag-Sense® Prothrombin Time (PT)/INR Monitoring System. In addition, this device uses an identical Test Strip and method of detection as those used with the 1st generation device. The thromboplastin reagent and calibration approach also remain unchanged in form, fit or function since introduced into commercial distribution in April 2010 (K050243 and K093243).

Assessment Performance

The precision study was conducted, including the precision of duplicates for capillary whole blood results calculated for both trained subject users and Health Care Professionals (HCPs). The study allowed the determination of precision based on duplicate INR runs on the same subject obtained by the same operator within a short period of time. For each subject, duplicate testing was performed by the HCP at clinic and by the subject at home. The following results were obtained:

	User Results	Professional Results
N	226	225
Ave. CV(%)	3.44	2.53
95% CI	2.79–4.10	2.12–2.94

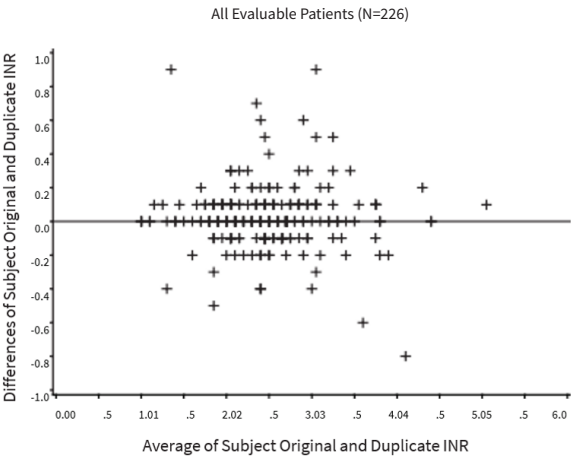
Method Comparison

Bland-Altman bias plots (or difference plot) are useful in analyzing the agreement between duplicate results from trained subject users. Below is a Bland-Altman plot that compares the difference of the trained subject user's original INR and the duplicate INR to the average of the original and duplicate INR.

Summary of Performance

This study demonstrated that trained users obtain results that are comparable to those obtained by healthcare professionals.

Bland-Altman Plot of Subject Duplicate INR vs Subject Original INR



Coag-Sense® Prothrombin Time (PT)/INR Monitoring System Package Insert, PN 300554 is shipped with ever Coag-Sense Prothrombin Time (PT)/INR Test Strip Kit, which provides the performance characteristics for accuracy and precision.

CoaguSense publishes a Summary of Safety and Performance Report. The report is made available to public in Eudamed's database and updated accordingly. In addition, any information regarding Periodic Safety User Reporting is included. Contact Technical Support for additional information.

References

1. EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
2. EP15-A3E: User Verification of Precision and Estimation of Bias; Approved Guidelines – Third Edition
3. EP09c: Measurement Procedure Comparison and Bias Estimation Using Patient Samples – Third Edition
4. ISO 17593:2007: Clinical Laboratory Testing and In-vitro Monitoring Systems for Self-testing of Oral Anticoagulant Therapy
5. Coag-Sense Prothrombin Time (PT)/INR Monitoring System Package insert, P/N 300554.

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Technical Support

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48377 Fremont Blvd., Ste 113
Fremont, CA 94538 U.S.A.

Made in Korea

Additional Information

Any adverse event/serious incident (patient or user safety) experienced with the use of this product and/or quality problems, please use interactive FDA Form 3500. FDA encourages online reporting because it is the quickest and most direct route.

- Phone: Call +1-800-FDA-1088 Monday–Friday between 8:00am and 4:30pm EST
- Web: www.FDA.gov/safety/medwatch.

In the EU, the competent authority of the Member State in which the user and/or the patient is established must be notified also.

CE 2797

IVD *In vitro* diagnostic medical device

61010-1

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

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