

Coag-Sense®

Prothrombin Time (PT)/INR Monitoring System

PRO

Quick Reference Guide



Getting Started and Setting Up the Meter

1. One low and one high control strip should be run with each new shipment/lot of strips received. Run controls if this has not been done yet. Controls are not required for calibration.
2. Gather test supplies such as test strips, alcohol pads, lancets and sample transfer tubes.
3. Warm the patient's hands to increase circulation.
4. Wash the patient's hands with warm soapy water or wipe the finger with alcohol. Dry patient's hands completely as alcohol can effect results.

Activity

1. Turn the meter on by pressing and holding the POWER button on the right side of the meter. Enter login credentials (if required by your facility) or scan operator barcode using a barcode scanner. Press **TEST**.
2. Confirm that the Patient Strip Lot # is correct by matching with pouch. If blank or incorrect press **CHANGE** then touch the NFC chip (located on the bottom front right corner of the test strip kit) to the NFC target rings on meter case. If the test strip kit box with NFC chip is not available then manually enter the lot # and Barcode # from the patient test strip pouch and Press **CONTINUE**.
3. Holding the round end, gently push the strip completely into the meter. The meter warms the strip (for 25 seconds) to operating temperature. The display shows a countdown in seconds.
4. Insert the black plastic plunger into the end of the glass capillary tube with the red stripe. Use care to avoid hitting white plug. The meter will beep to let you know it is ready for a sample and display the message **"APPLY SAMPLE"**. You have 2.5 minutes to apply the sample to the strip.

Display/Visual Aid



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

Activity

Display/Visual Aid

4. Remove the cap from the one-time-use 21g lancet, place it against the patient's skin, and push down firmly against the finger to lance the surface of skin.

Note: smaller gauge diabetes lancets should not be used.

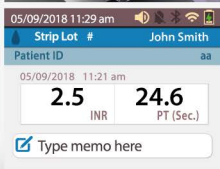
5. The blood should bleed freely. If it doesn't, gently squeeze the finger to get it started. Lower the patient's hand below their heart if necessary. Generate a dome shaped bead of blood.

6. Approach bead of blood with transfer tube horizontal. Touch tip to bead of blood and let capillary action fill until blood flow stops at white plug. Squeeze finger to generate additional blood if required to completely fill to white plug.

7. Insert transfer tube tip into sample application well of test strip, **touching tip down** at flashing green light in front of wheel. Depress black plunger completely to dispense the blood. **You must apply blood to the test strip within 15 seconds of lancing the finger.**

The meter will know that you have added the sample and the display will then read: **"TESTING, PLEASE WAIT"**. Testing time is patient's actual Prothrombin Time (PT).

8. When testing is complete, the meter beeps once and the results (INR and PT seconds) appear on the screen. Record the results. Remove the test strip and properly dispose along with the sample transfer tube and lancet. Turn off the meter.



NOTE: Read Professional User's Manual for complete instructions for use, indications, warnings, precautions and troubleshooting tips. If any error messages are displayed, refer to the "Troubleshooting" section of the User Manual or call CoaguSense Technical Service at 1-866-903-0890

For In Vitro Diagnostic Use



EMERGO EUROPE
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

CSI P/N 200225 Rev. AD

© CoaguSense Inc.
48377 Fremont Blvd., Ste. 113
Fremont, CA 94538 USA
(510) 270-5442 (510) 226-6540 (Fax)
www.coagusense.com

