

Coag-Sense[®]




Prothrombin Time (PT)/INR Monitoring System

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.
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.
5. Place the meter on a flat, non-vibrating surface. Turn the meter on by pressing the POWER button on the top left side of the meter.

Performing a ProThrombin Time Test

Activity	Display Screen/Visual Aid
<ol style="list-style-type: none"> 1. After turning on the meter, you will know it is ready when the display reads: "READY INSERT STRIP". Open a PT test strip pouch, tearing at the notched end. Remove the strip and set the package aside. 	
<ol style="list-style-type: none"> 2. Holding the round end, gently push the strip completely into the meter. The meter will display "PAT STRIP DETECTED" and begin the strip warming process changing the display to: "WARMING PLEASE WAIT". The time for completion of the warming process will be displayed in seconds. 	
<ol style="list-style-type: none"> 3. The meter will beep to let you know it is ready for patient sample and display the message "APPLY SAMPLE". The sample application area will flash green indicating where the sample should be applied. You have two minutes thirty seconds to apply the sample to the strip. 	

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.

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 lancets should not be used.



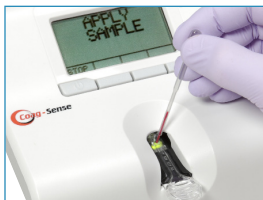
5. The blood should bleed freely. If it doesn't, gently squeeze the finger to get it started. Lower the patient's hand below their heart if necessary. Generate a dome shaped bead of blood. A minimum of 10µl of collected blood sample is required.



6. Hold sample transfer tube below bulb. DO NOT SQUEEZE BULB. With tube horizontal touch tip to bead of blood. Let capillary action fill glass portion of tube until blood flow stops. Squeeze finger to generate additional blood if required to completely fill glass portion of sample transfer tube.



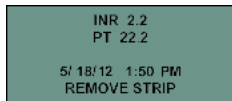
7. Move fingers to flat sides of bulb being sure to **cover** air hole. Rest hand on meter. Insert tip into sample application well of test strip, touching tip down on strip at flashing green light. Gently squeeze bulb until blood leaves tube (do not produce air bubbles). Keep pressure on bulb and pull away from test strip (avoids back suction). **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 clotting time.

8. When testing is complete, the meter beeps once and the results (**INR** and Prothrombin Time (**PT**) in 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 100225 Rev. AJ

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

