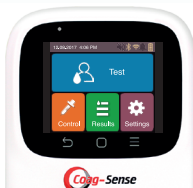


Coag-Sense®

Prothrombin Time (PT)/INR Monitoring System

Quick Reference Guide



PRO

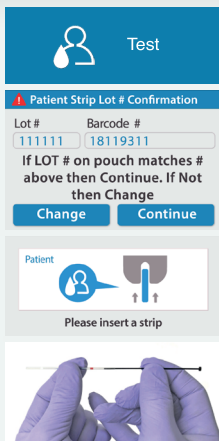
Getting Started and Setting Up the Meter

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 by washing the patient's hands with warm soapy water.
4. Wipe the finger with alcohol. Dry patient's hands completely as alcohol can affect results.

Activity

1. Turn the meter on by pressing and holding the POWER button on the right side of the meter. Enter/Scan login credentials (if required by facility). Press TEST
2. Confirm that the Patient Strip Lot # is correct by matching with pouch. If blank or incorrect press CHANGE then align and touch the NFC Tag rings to the target rings on the meter surface. If the NFC tag 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. At the end of countdown, the meter will beep once and display "APPLY SAMPLE" for 2.5 minutes. Apply the sample to the strip.

Display/Visual Aid

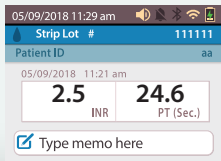


Intended Use- The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professionals at the point 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

5. 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.
6. 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.
7. Approach bead of blood with transfer tube horizontal. Touch tip to bead of blood and let capillary action fill until blood flow stops at the green band. Squeeze finger to generate additional blood if required to completely fill up to green band.
8. Gently touch the tip of the transfer tube to the loading well with the blinking 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).
9. 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 by holding the power button down.

Display/Visual Aid



NOTE: Read Professional User's Manual for complete instructions for use, indications, warnings, symbols, 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

IVD In Vitro Diagnostic Use



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Consult Instructions for Use

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