



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 ring to the target ring 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. For unassembled Transfer Tubes, insert the black plunger into capillary tube from the red stripe end. Use care to avoid hitting white plug. 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

Test

⚠ Patient Strip Lot # Confirmation

Lot #	Barcode #
111111	18119311

If LOT # on pouch matches # above then Continue. If Not then Change

Change Continue

Patient

Please insert a strip

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 finger 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.

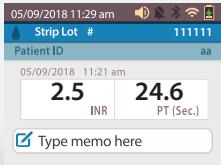
7. Approach bead of blood with transfer tube horizontally. Touch tip to bead of blood and let capillary action fill until blood flow stops at white plug. Squeeze finger to generate additional blood if required to completely fill to white plug.

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, 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



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