



SLEEK & SMALL ENCLOSURE



CONNECTING CLINICS & PATIENTS

The most precise point-of-care PT/INR system EVER!

Intelligent design on a proven detection platform



# INTRODUCING: THE NEW COAG-SENSE® PT2 METER



### **ACCESSORIES**





Sample Transfer Tubes w/Plunger



Control Strips & Activation Solution



Portable Printer



# EXPERIENCE THE BENEFITS OF

# SUPERIOR ACCURACY, PRECISION, AND SAFETY

# Proven Methodology

- Micro-mechanical detection process offers superb accuracy and precision
- Not susceptible to changes in Hemoglobin & Hematocrit levels
- Ability to run whole blood, real plasma controls, and plasma calibrants
- Testing time is patient's actual clotting time nothing is faster than that
- The only CLIA-Waived system that produces a true prothrombin time - a simple clot timer
- Linear response even in the high INR range often out performs lab systems!

## A more direct approach to INR

- Only POC system that directly detects clotting endpoint (emulates the WHO Tilt-Tube method)
- · Offers gold standard accuracy and precision (CV 2.5%)
- Determines actual PT time without look-up tables or curve-fitting algorithms
- · Displays PT results in less than 1 minute
- INR range from 0.8 to 8.0

### Simple & accurate sample collection

- Small sample size just one 10 µL drop of blood
- Sample transfer tubes included
- · Allows stable accurate transfer of sample to test strip
- Reduces errors and wasted strips with correct volume delivery
- Supports proper bloodborne-pathogen control compliance

# Self-Testing - more frequent results benefit patients

- · Testing at home is a safe and convenient option
- · Simplicity of design give better confidence in results
- · Offers full point-of-care reportable range up to 8.0 INR
- · Conveniently portable, connected design
- · Sends results to service provider using app

# Extending control through the continuum of care

- Consistency of monitoring from hospital, to clinics, to home; same meter, same test strips, same reportable range
- Safety profile puts both home testers and their clinicians at ease
- Included sample transfer tubes ensures proper blood volume and technique
- · Communicates patient's home testing results to provider
- Improve testing adherence with test frequency monitoring and easy supply fulfillment requesting
- Medicare covers weekly home PT/INR monitoring for patients with a variety of conditions
- Independent Diagnostic Testing Facility (IDTF) supervision ensures compliance
- · Superb IDTF home testing partners

#### Track Patient Results

Quickly plot patient result history to get a complete picture of time in therapeutic range.



# Set Target Ranges & Alarms

Target therapeutic ranges and testing alarms can be set to aid in testing frequency and reviewing test results easily.

# Multiple Connectivity Options

The Coag-Sense® system offers clinics and patients wireless (Wi-Fi and Bluetooth) and wired (USB and Ethernet) connectivity options for sending results data to electronic health records, testing service providers, or data management systems.

# Near Field Communication (NFC)

Test strip lot information is quickly and easily communicated wirelessly to the Coag-Sense® meter via an NFC chip on the test strip kit box.



#### Color Touchscreen

The user friendly color touchscreen makes the Coag-Sense® meter simple to use. The display instructions are easy to read, understand, and follow.

## Data Entry Made Easy

Using an optional wired or wireless bar code scanner, operator, and patient ID can be quickly captured for data management.





# SENSIBLE PT/INR TESTING IN THE PALM OF YOUR HAND

# How to use the Coag-Sense PT/INR Meter



Step 1

Insert a test strip



Step 2

Lance finger and collect a bead of blood with included transfer tube



Step 3

Dispense sample onto test strip



Step 4

Wait for results (testing time is the patient's actual clotting time)

### **Professional User Ordering Information**

03P70-04 COAG-SENSE® STARTER BUNDLE

03P70-02 COAG-SENSE® PRO PT/INR SYSTEM (meter only)

03P56-50 COAG-SENSE® PT/INR TEST STRIP KIT

03P58-04 COAG-SENSE® LANCETS AUTO

SINGLE USE, 21G, 2.2mm depth - BOX OF 100

#### Self-Test User Ordering Information

03P70-01 COAG-SENSE® SELF-TEST PT/INR SYSTEM (meter only)

03P56-50 COAG-SENSE® PT/INR TEST STRIP KIT

03P58-04 COAG-SENSE® LANCETS AUTO

SINGLE USE,21G, 2.2mm depth - BOX OF 100

#### Accessories

03P78-01 BAR CODE SCANNER

 ${\bf 03P76\text{-}01}$  COAG-SENSE® PORTABLE PRINTER, USB, BLUETOOTH AND WI-FI

PD-99906 PORTABLE PRINTER PAPER, 5 ROLLS

**03P58-04** COAG-SENSE® LANCETS AUTO SINGLE USE,21G, 2.2mm depth - BOX OF 100

03P69-10 COAG-SENSE® CONTROL TEST STRIP KIT -10

03P52-54 COAG-SENSE® SAMPLE

TRANSFER TUBES, VIAL OF 54

03P52-55 COAG-SENSE® SAMPLE

TRANSFER TUBES - PRELOADED, VIAL OF 54

03P74-01 POWER SUPPLY

### Current Procedural Test (CPT) codes

Prothrombin time 85610
CLIA-Waived PT test 85610QW

#### CoaguSense Inc.

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PN 200466 Rev AA

Cleared for home use	Yes - Patient self-testing (Prescription required)
Cleared for professional use	Yes - CLIA-Waived
Sample size	1 drop (10 μL) capillary blood minimum
Sampling method	21g lancet; sample transfer tube
Device specifications	Portable
Display	TFT color LCD touchscreen
Size	5.9 in (150 mm) x 3.9 in (100 mm) x 1.2 in (30 mm)
Weight	11.3 ounces (0.32 kg)
Test strips packaging	Individually pouched in boxed quantities
Storage	Non-refrigerated; up to 24-month shelf life
Strip lot communication	Near Field Communication (NFC) chip
Connectivity	Wired: Ethernet, USB   Wireless: Wi-Fi, Bluetooth
Barcode scanning	Yes - Optional USB or Bluetooth scanner
Connectivity interface	POCTIA/HL7 to LIS/HIS/Middleware
Heparin sensitive	Yes - POC devices not recommended for bridging
Hematocrit range	15% - 60%
Clot detection principle	Direct micro-mechanical
INR range	0.8-8.0
Prothrombin time (PT)	8-80 seconds
ISI	~1.0
Analysis time	<1 minute (Patient actual clotting time)
QC	External using control strips containing plasma
QC & operator lockouts	Yes using control strips containing plasma
Memory	2,000 patient test results, 500 QC test results
Printing	Yes with optional Bluetooth, USB, or Wi-Fi printer
Power source	Built-in lithium polymer rechargeable battery
Operating temperature	65° F to 90° F (18° C to 32°)
Warranty	1 year with immediate replacement

Visit **www.coag-sense.com/tech-specs** or scan the QR code on the right with your smart phone for training videos and detailed user information.

