Coag-Sense
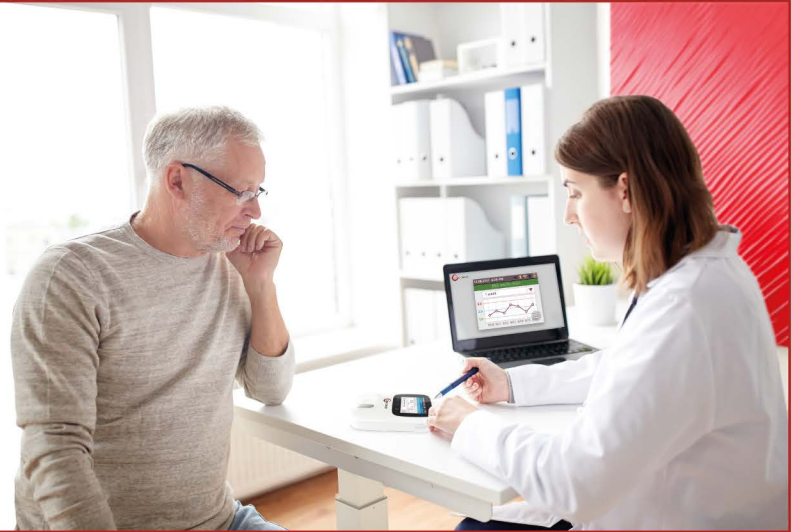
A masterpiece of intelligence on a proven detection platform.

COAG-SENSE® METER
The most precise POC PT/INR system ever.

COAG-SENSE®

PT/INR Monitoring System

Touchscreen

Home Screen
Button

Cancel or Previous
Screen Button

On/Off Button

NFC Chip
Scanner

View
Menu Button

Strip Insertion Area

Micro USB/
Power Adapter

Ethernet Port
(With Cover)

Reset Button
(Enclosed Inside)

USB Port

ACCESSORIES

Patient Test Strips

**Sample Transfer
Tubes w/Plunger**

**Control Strips &
Activation Solution**

Portable Printer

Coag-Sense® PT/INR System Offers:
Superior Accuracy, Precision & Safety

Coag-Sense

A Breakthrough in PT/INR Testing

- 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
- Stellar safety record after almost a decade on the market

A more direct approach to INR testing

- 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 testing benefits patients

- Testing at home is a safe and convenient option
- Simplicity of design give better confidence in results
- Only home testing system with INR range up to 8.0 INR
- Convenient portable, connected design
- Send results to service provider using Bluetooth app
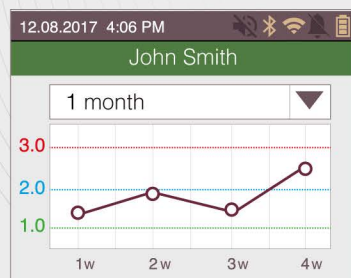
Extending control from physician office to home

- Consistency of monitoring between office POC testing and patient's home
- Safety profile puts both home testers and their clinicians at ease
- Included sample transfer tubes insure 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 insures compliance
- Ask us about our superb IDTF home testing partners

For in vitro diagnostic use

CLIA-Waived

Track Patient Results
Quickly plots patient result history to get a complete picture of time in therapeutic range.

12.08.2017 4:06 PM
John Smith
1 month
3.0
2.0
1.0
1w   2w   3w   4w

Set Target Ranges and Alarms
Target therapeutic ranges and testing alarms can be set to aid in testing frequency and reviewing test result 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.
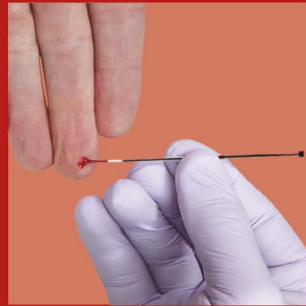
How to use the Coag-Sense®PT/INR

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 actual clotting time

Professional User Ordering Information:

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
03P76-01 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

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 minimun
Sampling method	21g lancet; sample transfer tube
Device specifications	Portable
Display	TFT color LCD touch screen
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	Yes, Wired: Ethernet, USB Wireless: Wi-Fi, Bluetooth
Barcode scanning	Yes, Using optional USB or Bluetooth scanner
Connectivity Interface	POCT1A/HL7 to LIS/HIS/Middelware
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 (Patients actual clotting time)
QC	External using control strips containing plasma
QC and operator lockouts	Yes
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	65º F to 90º F (18º C to 32º)
Warranty	1 year with immediate replacement