CoaguChek® Pro II Operator Training

Woodlands Health

CoaguChek®

Training Objectives

- Product Overview
- Perform Measurement
  - ✓ Liquid Control Test
  - ✓ Patient Test
- Troubleshooting
- Review Results
- Maintenance and Care

Introduction
Product Overview

- Parameters available:
  - PT (Prothrombin Time)
- Units:
  - PT
    - INR:
    - INR / %Quick
    - INR / SEC

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Introduction

Product Overview

- Sample Types:
  - Capillary blood from fingertip
  - Untreated venous whole blood
- Sample Volume:
  - For each test at least 8µL
- Measurement Time:
  - PT only seconds
- Memory:
  - 2000 patient test results
  - 500 liquid QC tests
  - 60 test strip code chips and 60 control solution code chips

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Introduction

Product Overview

Components

CC Pro II meter

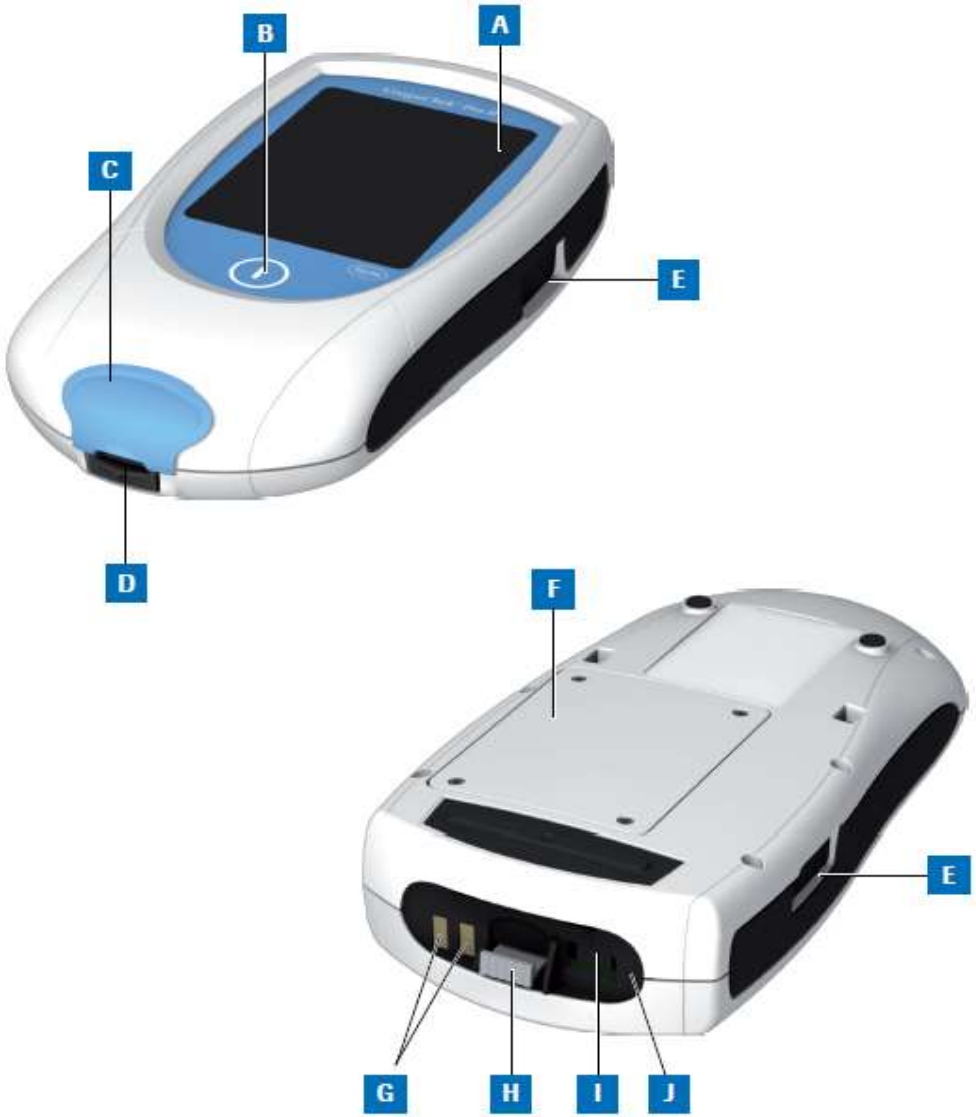
CC Pro II Base Unit

Power Supply

USB cable

Coaguchek Pro II

Meter Overview



A. Touchscreen

B. On/Off Button

C. Test strip guide cover

D. Test strip guide

E. Barcode scanner

F. Battery compartment cover

G. Charging contacts

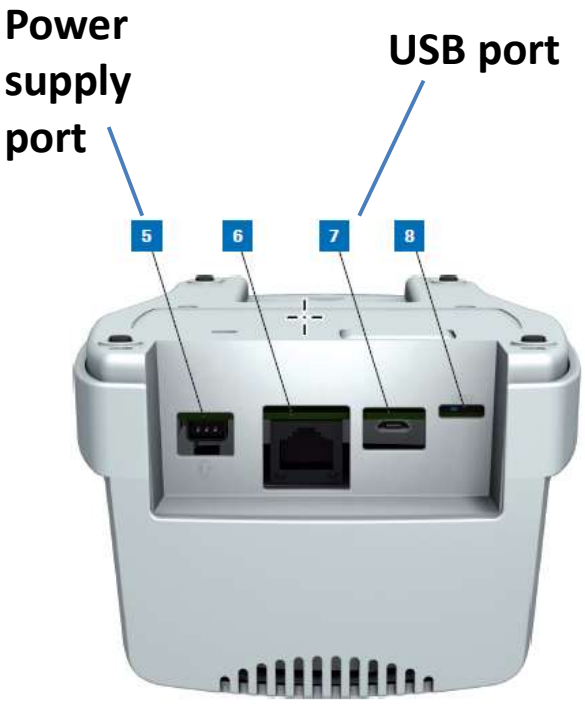
H. Code chip slot

I. Connection socket for power adapter

J. Infrared interface

Coaguchek Pro II

Base Unit Overview



LED Red : Booting-up
LED Flashing "Red": Error
LED Green : Ready

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PT test strip

→ Barcode

→ Dosing area

→ Test & quality control chamber

- 24 strips per bottle (2x24's/box)
- 1 code chip per bottle
- Lot-specific info (S_lot number) such as expiration date and calibration data, test method in code chip

Measuring Range

INR: 0.8 – 8.0

%Qck: 120 – 5

Sec: 9.6 - 96

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Liquid Control

- 2 Levels of control available
- Controls are range-specific (only viewable on the meter or ciPOC)
- 1 box contains:
  - 4 x Level 1
  - 4 x Level 2
  - 8 x diluent bulbs
  - 1 x code chip (labelled C_lot number)
  - Store at 2-8 degrees
- QC requires reconstitution
  - Diluent comes in ready-to-use bulbs
  - Reconstituted QC is stable for 30 mins

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Quality Control – Preparation PT and aPTT

Let the bottle **sit closed for 5 minutes** in order to reconstitute

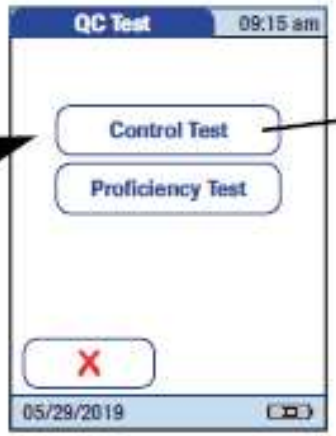
Mix **carefully** by swirling the bottle using a **circular motion**, avoid foam formation

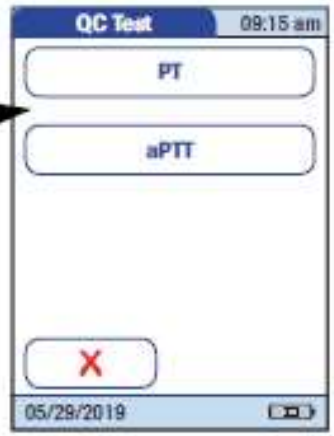
Do not shake the vial or turn it on its side!

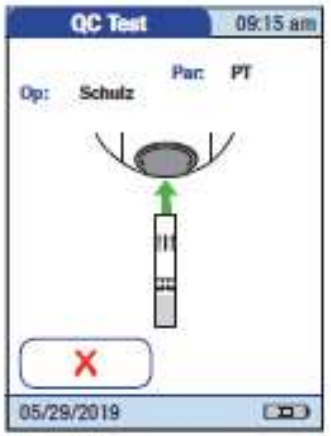
The reconstituted control material is stable for 30 minutes.

Perform Measurement

Liquid Control Test







1. Press ⏻ to turn the meter ON. Scan Operator ID.

2. Select **Control Test.**

3. Select PT.

4. Insert the test strip into the test strip guide in the direction indicated by the arrows.

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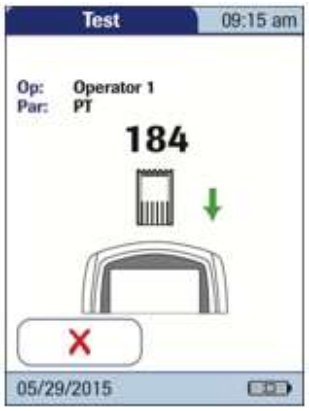
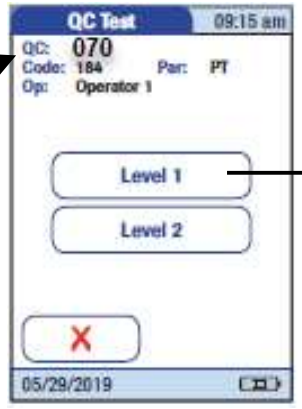
Perform Measurement

Liquid Control Test (code stored on current lot)

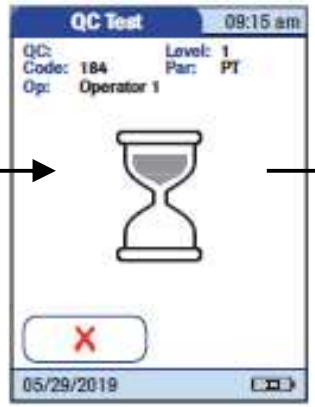


5. If new test strip lot is used, insert the test strip code chip.

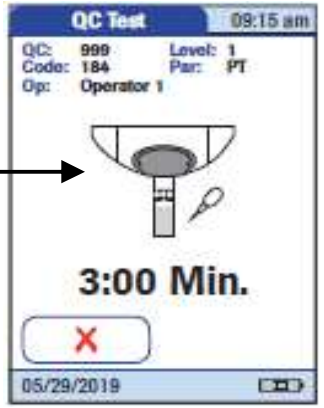
6. Select the code stored for your current control Solution.



7. Select the level for the measurement.



8. The test strip is warming Up.



9. Apply control solution when dropper icon flashes. *(within 3 min)*

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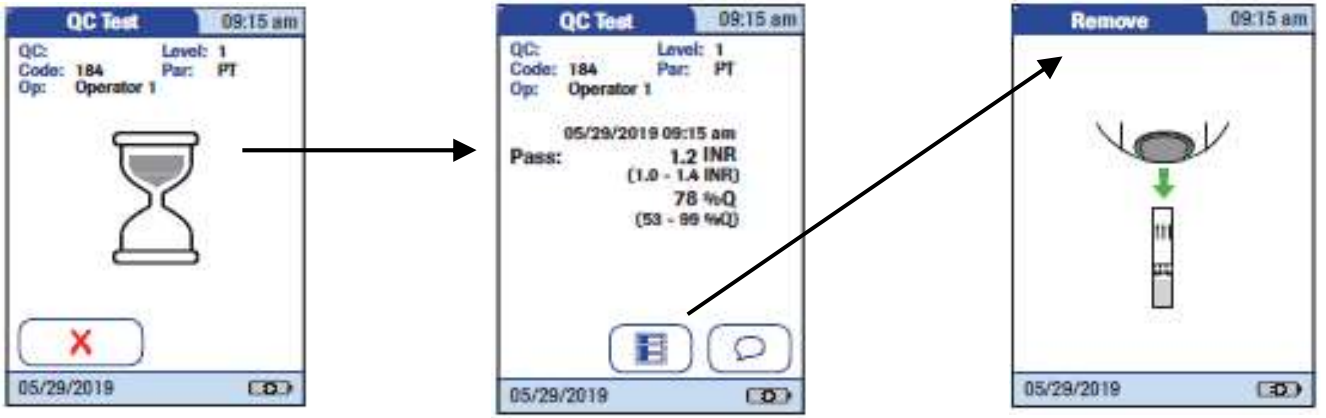
Perform Measurement

Liquid Control Test (code stored on current lot)



10. The dropper icon disappears and the test starts.

11. Ensure QC results are **Pass** and within acceptable range.

12. Select  to remove test strip from meter.

Perform Measurement

Liquid Control Test (new QC lot)

5. Select **New Code** to use new lot of control solution.

6. Remove the strip code chip from the meter and insert the control code chip. (*Capital C in front of lot*)

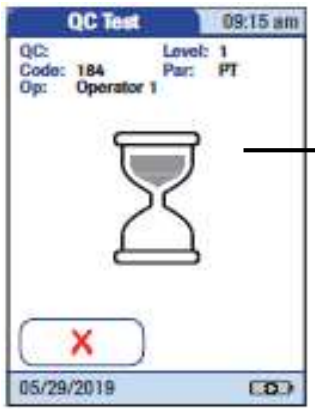
7. Select the level for the measurement.

8. The test strip is warming up.

9. Apply control solution when dropper icon flashes. *(within 3 min)*

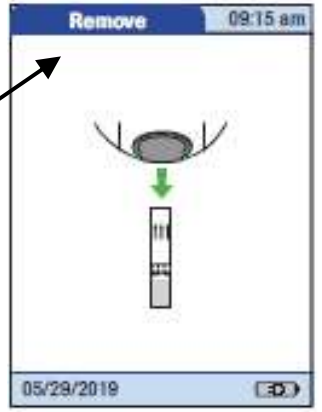
Perform Measurement

Liquid Control Test (new QC lot)



10. The dropper icon disappears and the test starts.

11. Ensure QC results are **Pass** and within acceptable range.



12. Select  to remove test strip from meter.

Perform Measurement

Liquid Control Test

What to do when QC is out of range?

- Check when was the control reconstituted
- Check the integrity of the test strips (blue reagent)
- Ensure that the correct level of control solution (Level 1 or 2) was dosed according to the control level selected on the meter.
- Ensure that the test strip was freshly taken out of the vial.
- Ensure that the controls and test strips were stored appropriately.

Repeat Control test:

1. Using the same vial of strips and controls.
2. Using a new vial of controls.
3. Using a new vial of test strips.

If you are still unsure of the problem, please contact your POCT coordinator.

Perform Measurement

Patient Test

1. Press ⏻ to turn the meter ON. Scan Operator ID.

2. Select **Patient Test** at Main Menu

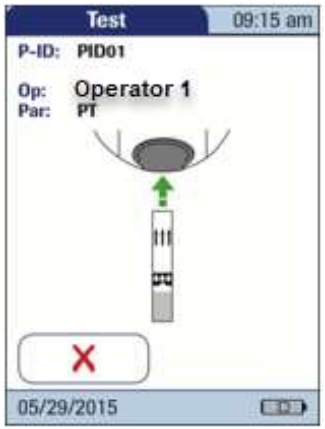
3. Key in Patient ID manually using the keypad.

OR

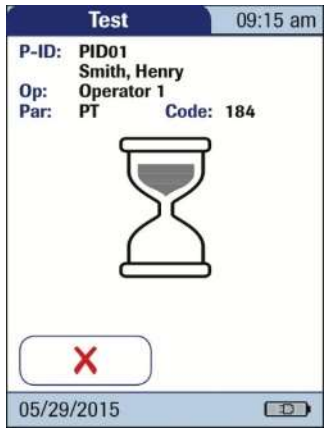
Scan Patient ID using in-build barcode scanner.

Perform Measurement

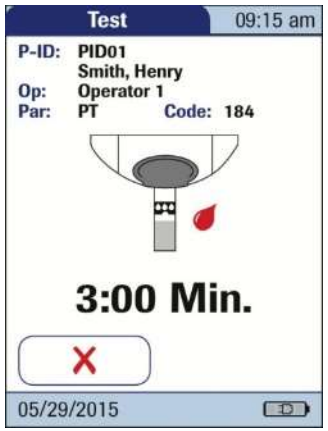
Patient Test



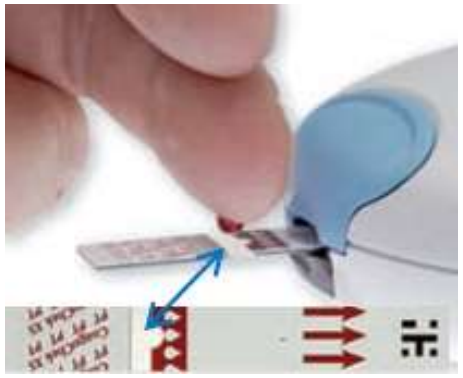
4. Insert test strip when prompted



5. The test strip is warming up



6. A **3 minute** countdown begins. Puncture and apply a drop of blood to the test strip before countdown ends



7. Apply **first drop** of blood from side or top to the application area of the strip

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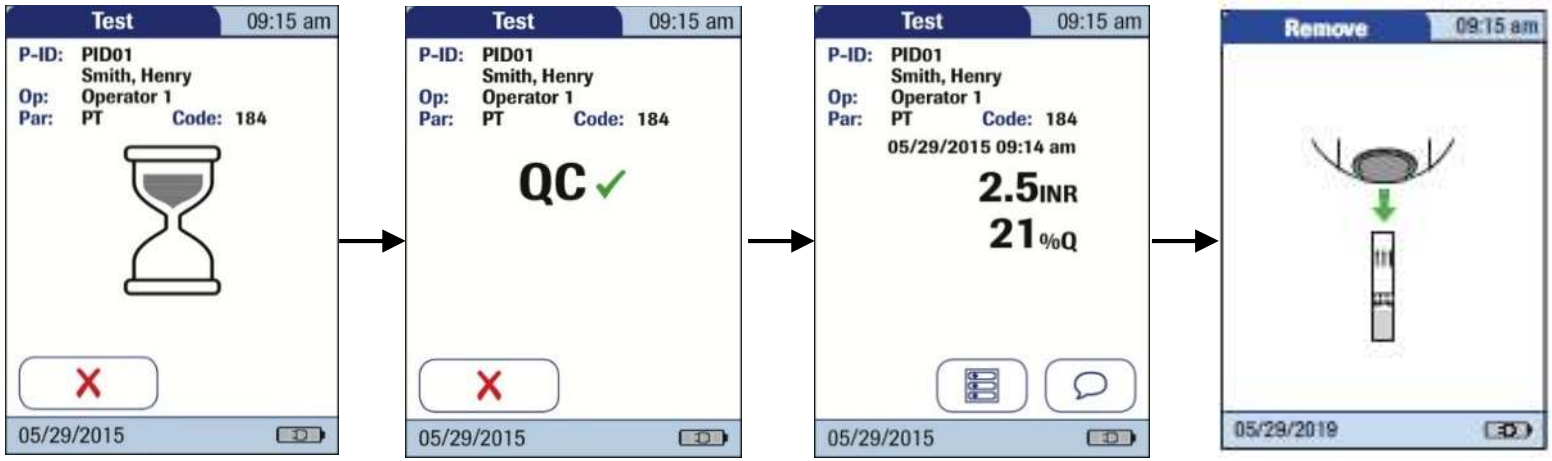
Perform Measurement

Patient Test



8. Beep tone and blood symbol disappear. Test starts.

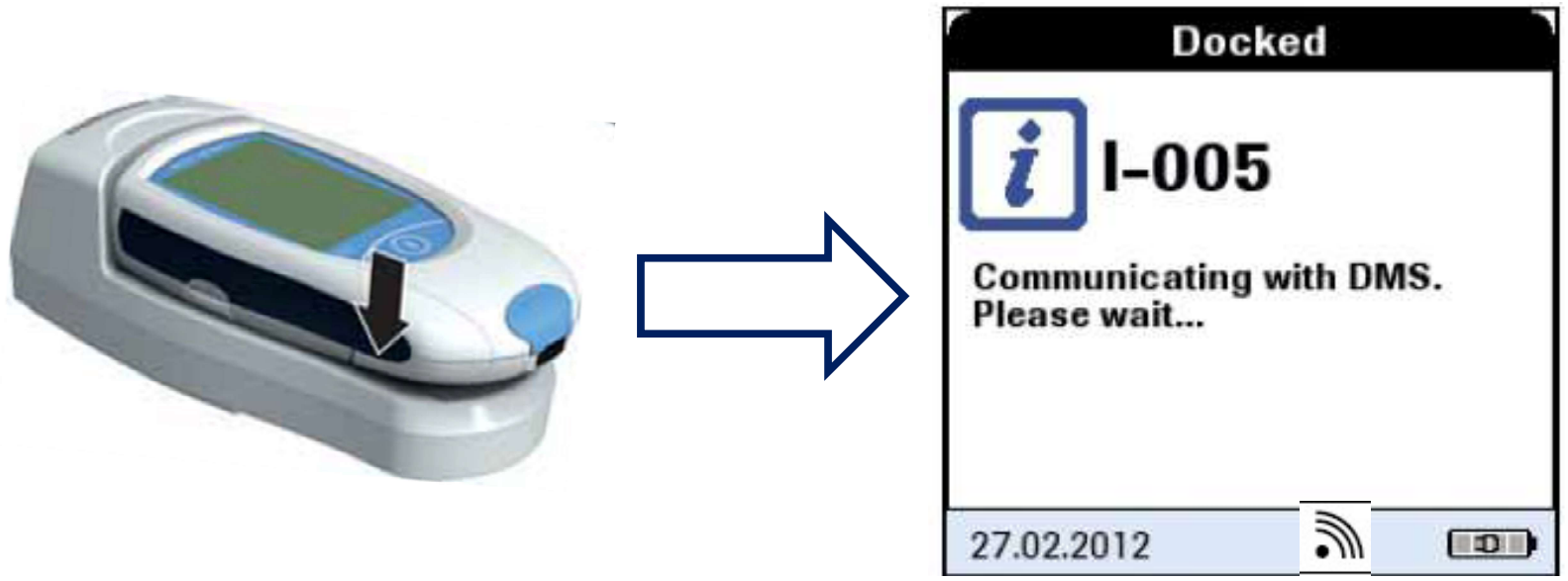
9. Measurement includes a QC of test strip. A successful QC shows √

10. When measurement is finished the result is displayed.

11. Select  to remove test strip from meter

Transmitting Data

Base Unit – docking station to upload and download data



Transmitting Data

Base Unit - Troubleshooting

Base Unit Status Display

- **Red :** Booting-up
- Flashing **"Red":** Error
- **Green :** Ready

What can you do when Base Unit is flashing Red?

1.Check the USB connection to the PC.

2. Power off and on the base unit, wait for green light.

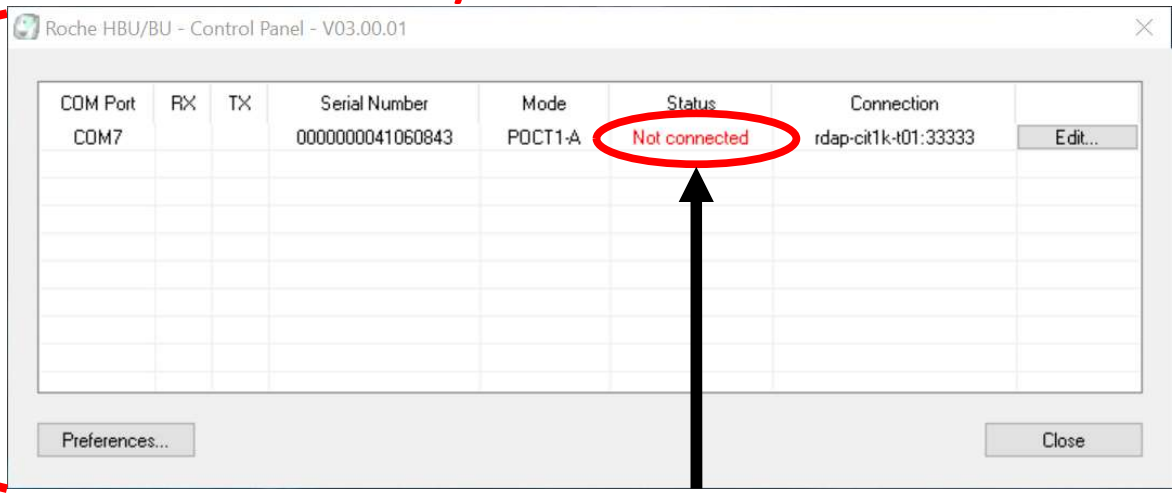
3. Re-dock the meter.

4. If problem still persist, dock the meter in another Base Unit for transmission while reporting the problem.

CC Pro II Base Unit Troubleshooting

Base Unit is blinking Red OR Meter unable to sync.

ROCHE HBU/BU - Control Panel



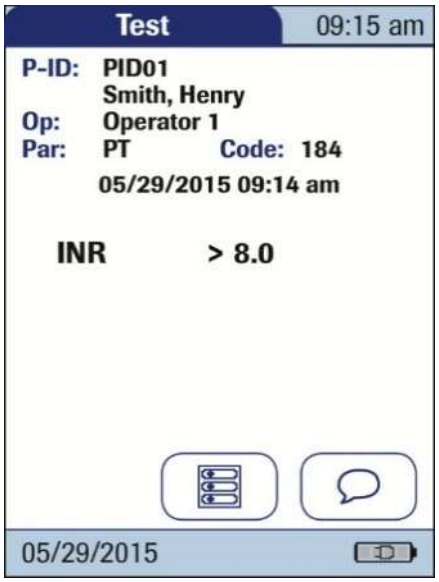
- Ensure that the status shows Connected'.
- Dock the meter.
- If problem persists, dock the meter in another Base Unit while reporting the problem.

Perform Measurement

Patient Test Results

If result is outside measurement range a “<“ smaller than, or “>” greater then sign is displayed

INR	0.8 – 8.0
%Q	120 – 5
Sec	9.6 – 96



Perform Measurement

Patient Test Results

If a **"C"** is displayed along with the result:

- the hematocrit value is very low (<15%)
- Due to erroneous blood collection (e.g., wet hands)

If a **"*"** is displayed along with the result:

- the test result is out of normal range

Troubleshooting

Meter Restart / Reset

If the meter hangs in a screen and the icons on the display doesn´t react,

- Restart the meter.
- Press the power button for only **5 sec**, till Roche logo appear and a single beep sounds.

If this do not work,

- Reset the meter.
- Press and hold the power button of the meter for at least **12 sec** prior release.

Note: Date & time setting will be lost during reset of meter. Re-dock meter to sync data.

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Troubleshooting

E-206: Strip error

Reason:

- Test strip has abrasions on the gold foil, or is defective.
- Test strip was NOT inserted correctly.
- Contaminated plug contacts in the meter

Solution:

- Power the meter off and on. Repeat the test with a new test strip.
- Make sure the strip does not have abrasions/scratch marks on the gold foil.
- Occasionally clean the pad under the test strip port cover.

Troubleshooting

E-403: Dosing error

Possible causes:

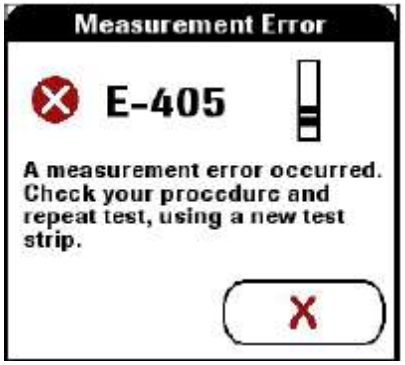
- Insufficient sample volume applied to the test strip OR due to double dosing.
- Sample applied too early
- Test strip wet

Solution:

- Repeat the measurement using a new test strip from the same vial and blood from a new puncture.

Troubleshooting

E-405: Measurement error



Possible causes:

- Test strip was moved during measurement
- Hematocrit too high (>55%)
- Instrument has no proper contact with test strip
- Compromised/wet test strip

Solution:

- Make sure the strip does not have abrasions/scratch marks on the gold foil.
- Repeat the measurement using a new test strip from the same vial and blood from a new puncture.

Troubleshooting

E-406: Sample Error; Unsuitable sample composition

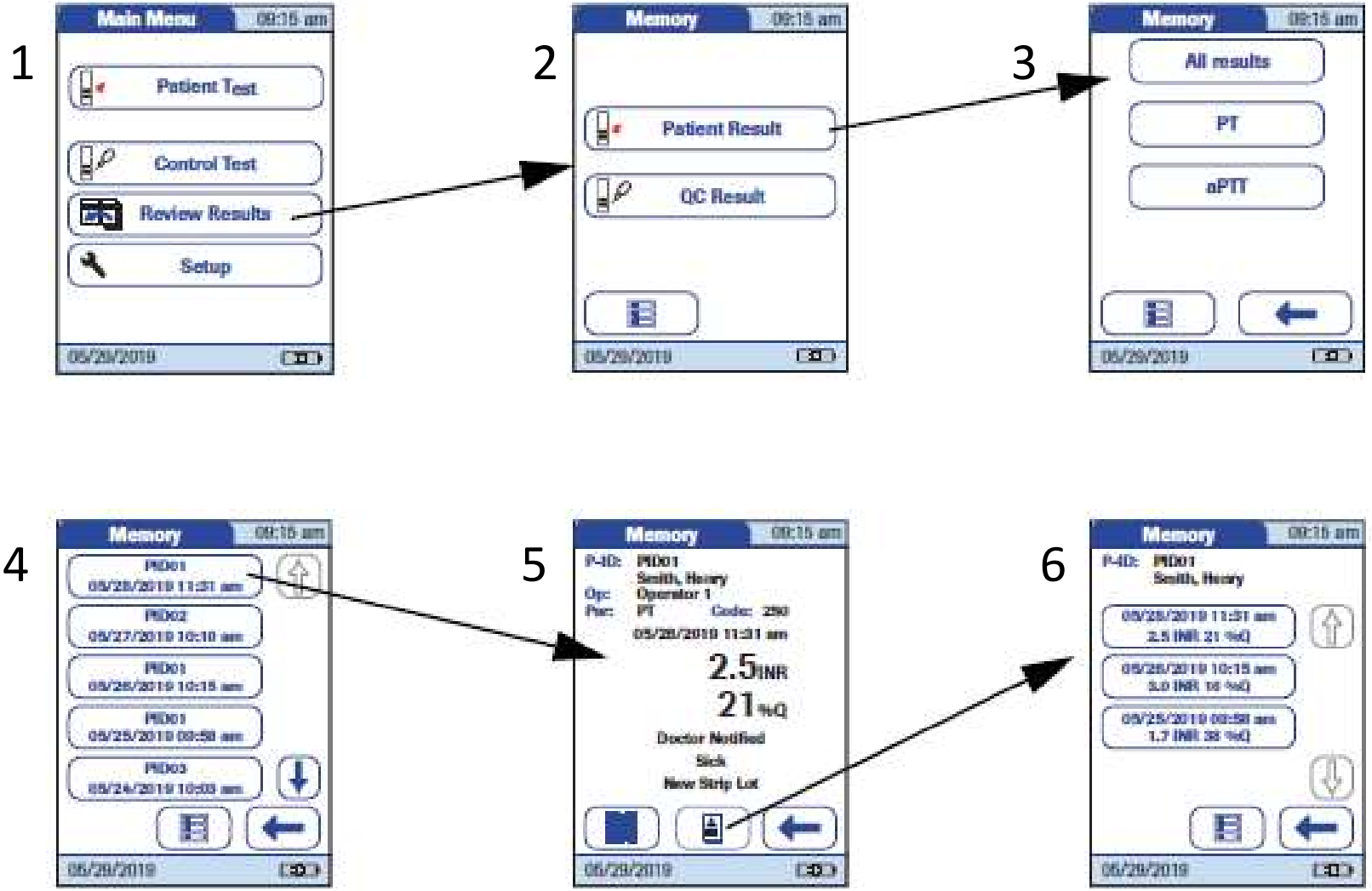
Possible causes:

- Sample is anti-coagulated/usage of heparin or citrate blood
- Blood sample has a very long coagulation time (>8 INR)

Solution:

- Repeat the measurement using a new test strip from the same vial and blood from a new puncture.
- Observe proper pre-analytics, and correct sample type.

Review Results



Maintenance and Care

Do's and Don'ts

- DO NOT get moisture, liquid, blood, or cleaning agents in the test strip port
- DO NOT spray any cleaning agents onto the meter
- DO NOT drop the meter
- DO NOT use sharp objects to press on the touchscreen

Each meter costs $2500

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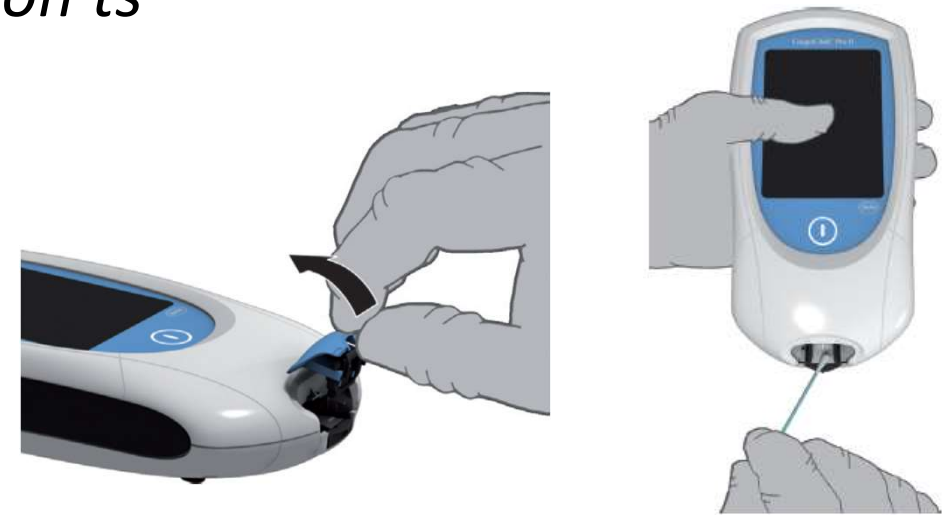
Maintenance and Care

Do's and Don'ts



- DO check the test strip guide regularly for signs of soiling.

If necessary clean this area:

- Power OFF the meter.
- Remove test strip guide cover by pressing upwards from the front.
- Rinse the test strip guide cover with water and dry for 10 minutes.
- Clean the easily accessible white areas with a moistened cotton swab/bud.
- Re-attach the test strip guide cover.

Maintenance and Care

Clean and disinfect the exterior (meter housing)

For cleaning only:

- A soft cloth slightly dampened *(not wet)* with a small amount of liquid soap diluted in water

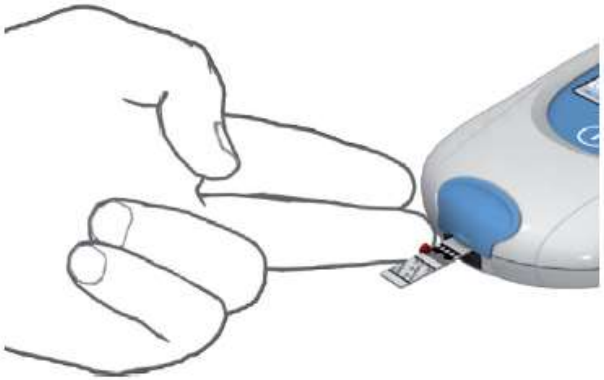
For cleaning and disinfection:

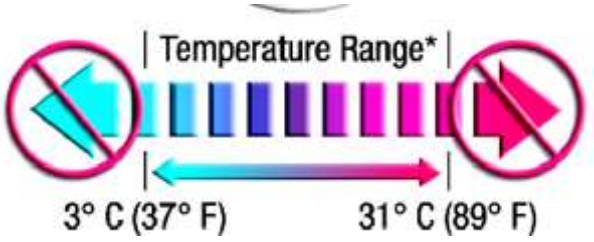
- Rubbing alcohol (70% ethanol or isopropyl alcohol)
- 10% sodium- hypochloride solution
  (1 part bleach to 9 parts de-ionized water)

Maintenance and Care

Reminders:

- Place the meter on a horizontal surface before dosing
- Always keep the test strip vial tightly closed when not in use





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Doing now what patients need next