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1. Scope

This Standard Operating Procedure (SOP) applies to the staff and students using the CoaguChek® XS in the Pharmacy Practice Resource Unit (PPRU) at the Pharmacy Department, University of Malta.

2. Objective

To describe the procedure for the configuration, operation, maintenance and troubleshooting of the CoaguChek® XS.

3. Definitions

3.1. Battery Compartment \([F]\): The area in which four 1.5V alkali-manganese batteries type AAA are inserted in.

3.2. CoaguChek® XS: A point-of-care testing device used to quantitatively determine prothrombin time using capillary blood from a fingertip or untreated venous whole blood.

3.3. CoaguChek® XS PT Test Strips: Have a lyophilised reagent containing thromboplastin and a peptide substrate. When a blood sample is applied to the test strip, the thromboplastin activates coagulation leading to the formation of thrombin which goes on to cleave the peptide substrate, generating an electrochemical signal. The valid measuring ranges for the strips are 0.8-8.0 for INR, 120-5 for \%Q (quick percentage value) and 9.6-96 for Sec (seconds).

3.4. Code Chip: Provides the device with important information about the test method, the lot number and the expiry date of the test strips being used. Each pack of test strips comes with a new code chip that should be inserted into the device when the new pack of strips is to be used.

3.5. Code Chip Slot \([G]\): The area in which the code chip is inserted.

3.6. Display Screen \([A]\): Displays the results and the information symbols.

3.7. Infrared Window \([I]\): Used to transfer data stored in the device via an infrared interface.
3.8. **M Button** [B]: The memory button used to recall results from memory and to change device settings. Also used to confirm the code number displayed before each test.

3.9. **Memory**: Saves the latest 100-value readings in chronological order, with the latest result first, together with the relevant time and date.

3.10. **On/Off Button** [C]: To turn the device On or Off.

3.11. **Set Button** [H]: To set the various monitor configuration parameters.

3.12. **Set Mode**: Allows the device to be set according to the user’s preferences (see SOP/PD/211_01/A1).

3.13. **Test Strip Guide** [E]: The area in which the test strip is inserted.

3.14. **Test Strip Guide Cover** [D]: To be removed whenever the test strip guide requires cleaning.

### 4. Responsibility

4.1. The members of the Department of Pharmacy (staff and students) are responsible for following this SOP.

4.2. The designated Laboratory Officer or Laboratory Assistant is responsible for ensuring that this SOP is followed.
5. Procedure

5.1. Diagram of CoaguChek® XS

5.2. Configuration

5.2.1. Insert the batteries accordingly into the battery compartment [F].
5.2.2. Press the On/Off button to switch the device On.
5.2.3. Check that the number on the code chip to be inserted into the device corresponds to the number on the label of the test strip container.
5.2.4. Slide the code chip into the code chip slot [G] until it snaps into place.
5.2.5. Check that the displayed code chip number corresponds to the number on the label of the test strip container.
5.2.6. Press the M button to confirm code chip number.
5.2.7. If [Error] and [Code] are displayed, the code chip is incorrectly inserted.
5.2.8. Press the Set button [H] if the device does not automatically enter into Set Mode.
5.2.9. Repeatedly press the Set button to scroll between the different configuration parameters available in the Set Mode (see SOP/PD/211_01/A1).

5.2.10. Press the M button to change the setting that is currently flashing.

5.2.11. Repeatedly press the M button until the desired setting is displayed.

5.2.12. Press the Set button to confirm the selected setting.

5.2.13. Press the On/Off button to exit Set Mode at any time.

5.3. Operation

5.3.1. Place the device on a level stable surface or hold it in such a way as to be roughly in a horizontal position.

5.3.2. Press the On/Off button to switch the device On.

5.3.3. Check that all of the display symbols are displayed properly since results may be misread if a segment of the display is missing.

5.3.4. Wait until a flashing test strip symbol is displayed.

5.3.5. Insert a test strip into the test strip guide [E] with the lettering “CoaguChek XS PT” facing upwards.

5.3.6. Wait until a beep tone is heard to indicate that the device has detected the test strip.

5.3.7. Check that the displayed code chip number corresponds to the code number printed on the label of the test strip container.

5.3.8. Press the M button to confirm that the two values are identical.

5.3.9. Wait until a beep tone is heard to indicate that test strip warm-up time is complete.

5.3.10. Wait until both the blood drop symbol and the symbol for the test strip application test area start flashing to indicate that the device is ready to perform a test. A blood drop must now be applied to the test strip in 180 seconds.

5.3.11. Apply the first drop of blood to the semicircular, transparent sample application area of the test strip or else touch the blood drop against the side of the sample application area to draw the blood via capillary action.

5.3.12. Hold the blood drop to the test strip until the flashing blood drop symbol disappears and a beep tone is heard.

5.3.13. Wait until a tick appears next to [QC] to indicate that the test strip has passed the automatic quality control check of the meter.

5.3.14. Wait until the result is displayed.
5.3.15. Repeatedly press the Set button while the result is being displayed until the desired unit of measurement is displayed, if the current unit is not the desired one. Result is automatically saved in memory.

5.3.16. If result is displayed in INR and an up (too high) or down (too low) arrow is also displayed, this indicates that the value is outside the defined target range.

5.3.17. If [c] is displayed along with the result, this indicates that the haematocrit value was very low or that the blood used was erroneously collected. Repeat the measurement checking that hands are completely dry.

5.3.18. If [>] or [<] is displayed next to the result, this indicates that the result is outside the valid measuring ranges of the test strips.

5.3.19. Remove the test strip from the test strip guide.

5.3.20. Press the On/Off button to switch the device off.

5.3.21. Discard the used test strip in the sharps container.

5.3.22. Accessing Memory

5.3.22.1. Press the M button while the device is switched off.

5.3.22.2. Wait until the display is stabilised and the most recent value is displayed.

5.3.22.3. Repeatedly press the M button to scroll through the saved readings.

5.3.22.4. Repeatedly press the Set button while viewing a result in memory, if the displayed unit is not the desired one, to temporarily change the unit in which the result is being displayed.

5.3.23. Erasing Memory

5.3.23.1. Press and hold the M button while the device is switched off.

5.3.23.2. Press and hold the On/Off button.

5.3.23.3. Keep both buttons pressed for at least 5 seconds.

5.3.23.4. Wait until [mem] and [clr] are displayed together with the number of results in memory on the upper right hand corner of the display.

5.3.23.5. Press the On/Off button to exit the Erase Mode without erasing the results.

5.3.23.6. Press the M button to confirm.

5.3.23.7. Wait until the displayed number of results in memory is set to 0 and [--] are displayed in the
centre of the display to indicate that the entire memory has been erased.

5.4. Maintenance

5.4.1. Check that the device is switched off before performing any maintenance procedures.

5.4.2. Replace all 4 batteries if no bars are left in the battery symbol on the lower left hand corner of the display.

5.4.3. Clean/disinfect the device whenever it becomes contaminated with blood.

5.4.3.1. Wipe the exterior with a piece of cloth moistened in 70% alcohol.

5.4.3.2. Wipe away any residual moisture with a lint-free cloth.

5.4.3.3. Press the front edge of the test strip guide cover upwards to remove it.

5.4.3.4. Wipe the test strip guide cover with a piece of cloth moistened in 70% alcohol.

5.4.3.5. Hold the device upright with the test strip guide facing downwards.

5.4.3.6. Clean the accessible white area with a cotton bud moistened in 70% alcohol.

5.4.3.7. Wipe away any residual moisture with a dry cotton bud.

5.4.3.8. Allow all wiped areas to dry for at least 10 minutes before performing a test.

5.4.3.9. Re-attach the test strip guide cover.
## 5.5. Troubleshooting

<table>
<thead>
<tr>
<th>Error</th>
<th>Cause/s</th>
<th>Solution/s</th>
</tr>
</thead>
</table>
| [error] test strip symbol flashing | - Test strip was already inserted when device was switched on  
- Test strip is unusable or not of the correct brand | - Remove test strip  
- Remove test strip and repeat test with a new or correct one |
<p>| [error] temperature symbol flashing | Device is too cold or too warm to measure correctly | Switch device off and allow to stand for about 30 minutes at room temperature (+15°C to +32°C) |
| [error] battery symbol flashing | Battery level is too low to perform test | Replace batteries with a new set |
| [error] cover symbol flashing | Test strip guide cover is not closed properly | Arrange test strip guide cover accordingly |
| [error] infrared symbol flashing | Error during communication via an infrared interface caused by stray light | Keep away from sources of stray light while using the infrared interface |
| [error] [QC] flashing | Test strip failed internal quality control check | Switch device off and remove test strip. Repeat test with a new test strip |
| [error] [code] flashing | Code chip is missing, not properly inserted or damaged | Insert code chip or remove and re-insert it |
| [error] [000] displayed | Maximum allowed time of 180 seconds for applying blood has been exceeded | Switch device off, remove test strip and start new test using the same test strip |
| [error] [3] displayed | Test strip is beyond its expiry date | First check that date setting is correct. If not, arrange accordingly (see SOP/PD/211_01/A1) and repeat test. If correct, switch device Off, remove code chip and repeat test with a test strip from a new lot together with the new code chip that is supplied with new test strips |
| [error] [4] displayed | Test strip is unusable | Switch device off, remove test strip and re-insert it. If error message re-appears, discard test strip and use a new one. |</p>
<table>
<thead>
<tr>
<th>Error</th>
<th>Cause/s</th>
<th>Solution/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>[error] [5] displayed</td>
<td>Blood not correctly applied to test strip</td>
<td>Repeat test with a new test strip and follow the steps on correctly applying blood sample more carefully</td>
</tr>
<tr>
<td>[error] [6] displayed</td>
<td>Measurement error</td>
<td>Switch device off and repeat test with a new test strip. Do not touch or remove test strip when a test is in progress.</td>
</tr>
<tr>
<td>[error] [7] displayed</td>
<td>Measurement error resulting from blood sample</td>
<td>Switch device off and repeat test with a new test strip and blood taken from a new puncture site at the tip of another finger.</td>
</tr>
<tr>
<td>[error] [8] displayed</td>
<td>Error during internal diagnostic test</td>
<td>Switch device off and remove batteries. Wait for at least 1 minute before re-inserting them and reset the date and time. Repeat test and if error message re-appears, contact supplier</td>
</tr>
<tr>
<td>[error] [9] displayed</td>
<td>Error during internal diagnostic test</td>
<td>Switch device off and wait for at least 2 minutes. Repeat test and if error message re-appears, contact supplier.</td>
</tr>
</tbody>
</table>
5.6. Flow Charts

5.6.1. Set Up

Start

Press On/Off button to switch device On

Check that number on code chip corresponds to number on label of test strip container

Slide code chip into code chip slot [G] until it snaps into place

Check that displayed code chip number corresponds to number on label of test strip container

Press M button to confirm code chip number

[Error] and [Code] displayed

Yes

Remove and re-insert code chip

No

Device automatically entered into Set Mode

Press Set button [H]

Yes

Repeatedly press Set button to scroll between different configuration parameters in Set Mode (see SOP/PD/211_01/A1)

Press M button to change setting that is currently flashing

Repeatedly press M button until desired setting is displayed

Press Set button to confirm

Press On/Off button to exit Set Mode at any time

End

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5.6.2. Operation

1. Start

   Place device on level stable surface or hold it in such a way as to be roughly in a horizontal position

   Press On/Off button to switch device On

   Check that all display symbols are displayed properly

   Wait until a flashing test strip symbol is displayed

   Insert test strip into test strip guide [E] with the lettering “CoaguChek XS PT” facing upwards

   Wait until beep tone is heard to indicate that device has detected test strip

   Check that displayed code chip corresponds to code number printed on label of test strip container

   Press M button to confirm that both values are identical

   Wait until beep tone is heard to indicate that test strip warm-up time is complete

   Wait until both blood drop symbol and symbol for test strip application test area start flashing to indicate that device is ready to perform test

   A drop of blood must now be applied to the test strip in 180 seconds
1. Apply first drop of blood to application test area of strip or else touch blood drop against side of application test area to draw blood via capillary action.

2. Hold blood drop to test strip until flashing blood drop symbol disappears and a beep tone is heard.

3. Wait until a tick appears next to \[QC\] to indicate that test strip has passed automatic quality control check.

4. Wait until result is displayed.

   - Desired unit of measurement displayed:
     - Yes: Result is automatically saved.
     - No: Repeatedly press \[Set\] button until desired unit of measurement is displayed.

5. Result displayed in INR:
   - Yes: Up or Down arrow displayed next to result.
     - Yes: Value is outside target range.
       - Yes: Remove test strip from test strip guide.
       - No: Repeat measurement checking that hands are completely dry.
   - No: [>] or [<] displayed next to result.
     - Yes: Haematocrit value is very low or blood used was erroneously collected.
     - No: Result is outside valid measuring ranges of test strips.

6. Press \[On/Off\] button to switch off meter.
Discard used test strip in sharps container

Need to access memory

- Press M button while device is switched off
- Wait until display is stabilised and most recent value is displayed
- Repeatedly press M button to scroll through saved readings

Desired unit of measurement displayed

Need to erase memory

- Press and hold M button while device is switched off
- Press and hold the On/Off button
- Keep both buttons pressed for at least 5 seconds
- Press M button to confirm

End

Need to exit Erase Mode

- Press On/Off button
- Wait until [mem] and [clr] are displayed
- Repeatly press Set button until desired unit is displayed

Press M button to confirm

Wait until number of results in memory is set to 0 and three bars are displayed in centre of display to indicate that entire memory has been erased
5.6.3. Maintenance

Start

Check that device is switched off before performing any maintenance procedures

Bars left in battery symbol

Replace all 4 batteries

Device contaminated with blood

Wipe exterior with a piece of cloth moistened in 70% alcohol

Wipe away any residual moisture with a lint-free cloth

Press front edge of test strip guide cover upwards to remove it

Wipe test strip guide cover with a piece of cloth moistened in 70% alcohol

Hold device upright with test strip guide facing downwards

Clean accessible white area with a cotton bud moistened in 70% alcohol

Wipe away any residual moisture with a dry cotton bud

Allow all wiped areas to dry for at least 10 minutes before performing a test

Re-attach test strip guide cover

End
6. Precautions

6.1. Operate the device in an ambient temperature of 15°C to 32°C.
6.2. Always close the test strip container as soon as a strip is removed since external influences such as humidity may deteriorate the test strips.
6.3. Do not store the device in damp and humid conditions.
6.4. Do not remove or insert a code chip while the meter is performing a test.
6.5. Do not use a different code chip from the one supplied with the test strips that are being used.
6.6. Always operate the device with the correct set time and date.
6.7. Do not wait for more than 15 seconds after lancing the fingertip before applying the blood to the test strip since longer times would falsify the result as the coagulation process would already have begun.

7. References


8. Appendices

SOP/PD/211_01/A1 – Configuration Parameters Table

9. Revision History

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Amendments/ Reasons for change</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Initial Release</td>
</tr>
</tbody>
</table>
### SOP/PD/211_01/A1 – Configuration Parameters Table

<table>
<thead>
<tr>
<th>Setting</th>
<th>Display Symbol</th>
<th>Function</th>
</tr>
</thead>
</table>
| Date Format                  | [xx-xx-xx]     | To select between:  
  - Day-Month-Year  
  - Month-Day-Year  
  - Year-Month-Day                                                                 |
| Date                         | [xx-xx-xx]     | To enter the date in the following order: Year, Month, Day                                                                            |
| Time Format                  | [24h] or [12hr]| To select between a 24-hour or a 12-hour time format with a.m. and p.m.                                                                 |
| Time                         | [xx:xx]        | To enter the time in the following order: Hours and Minutes                                                                           |
| Unit                         | [INR], [%Q] or [Sec] | To select the desired coagulation unit. If INR is selected, therapeutic target range can also be inputted. |
| Beep Tone                    | [On] or [Off]  | To select between switching On or Off the beep tone signal. Device will beep in the following situations:  
  - When it detects strip  
  - When pre-heating of test strip is complete and sample needs to be applied  
  - When it detects sample  
  - When result is displayed  
  - When an error occurs                        |
| Therapeutic Range (with INR) | [On] or [Off] and [x.x] | To select between switching On or Off the option of displaying whether result is outside therapeutic range.  
  - Set lower limit within the therapeutic range of 1.5-3.5 INR.  
  - Set upper limit within the therapeutic range of 2.5-4.5 INR. |

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