
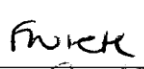


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	STANDARD OPERATING PROCEDURE	
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Reading Copy	X

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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.

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- 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.

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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.

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- 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.

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- 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

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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.


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5.5. Troubleshooting

Error	Cause/s	Solution/s
[error] test strip symbol flashing	<ul style="list-style-type: none"> - Test strip was already inserted when device was switched on - Test strip is unusable or not of the correct brand 	<ul style="list-style-type: none"> - Remove test strip - Remove test strip and repeat test with a new or correct one
[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.

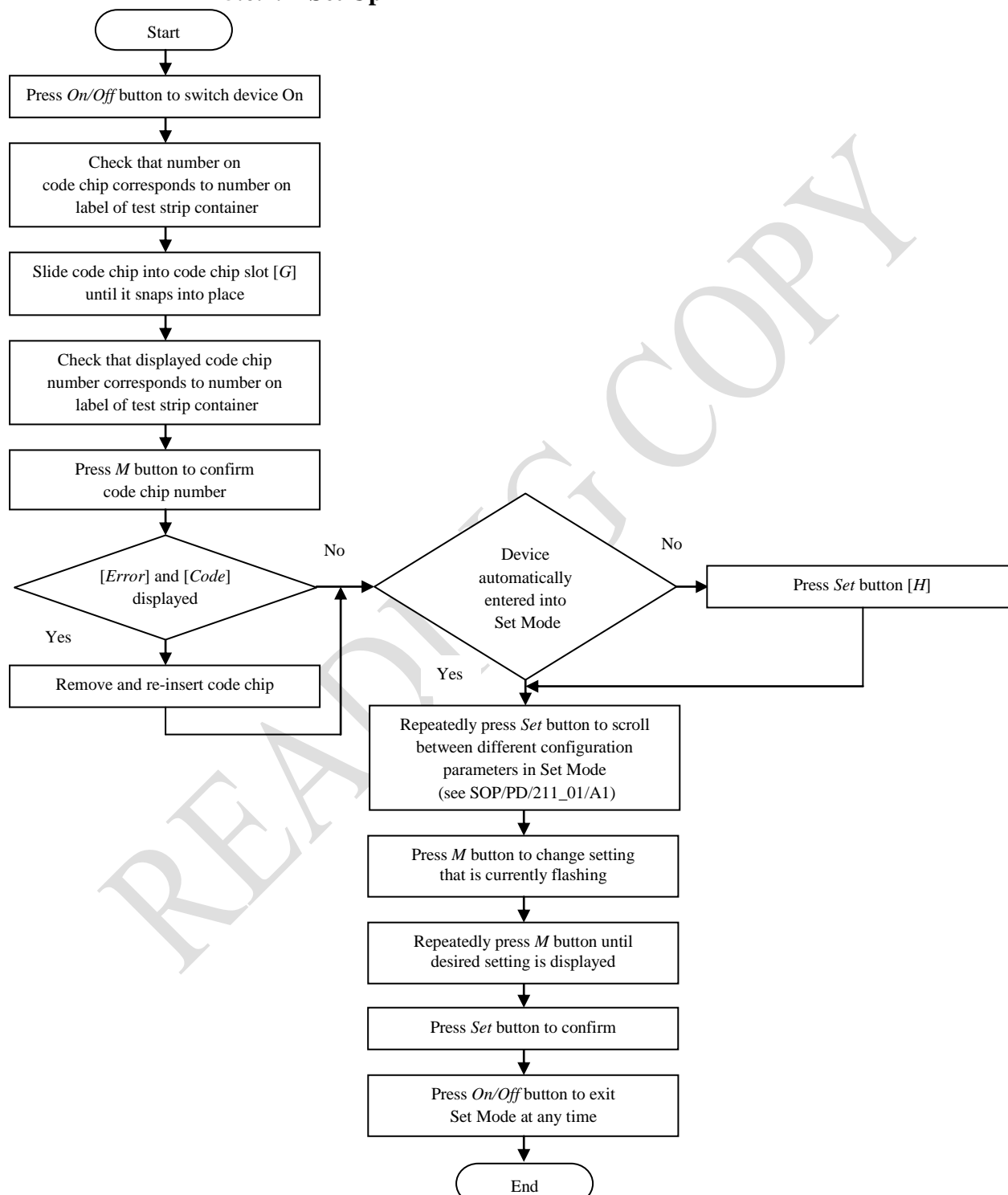
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Error	Cause/s	Solution/s
[error] [5] displayed	Blood not correctly applied to test strip	Repeat test with a new test strip and follow the steps on correctly applying blood sample more carefully
[error] [6] displayed	Measurement error	Switch device off and repeat test with a new test strip. Do not touch or remove test strip when a test is in progress.
[error] [7] displayed	Measurement error resulting from blood sample	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.
[error] [8] displayed	Error during internal diagnostic test	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
[error] [9] displayed	Error during internal diagnostic test	Switch device off and wait for at least 2 minutes. Repeat test and if error message re-appears, contact supplier.

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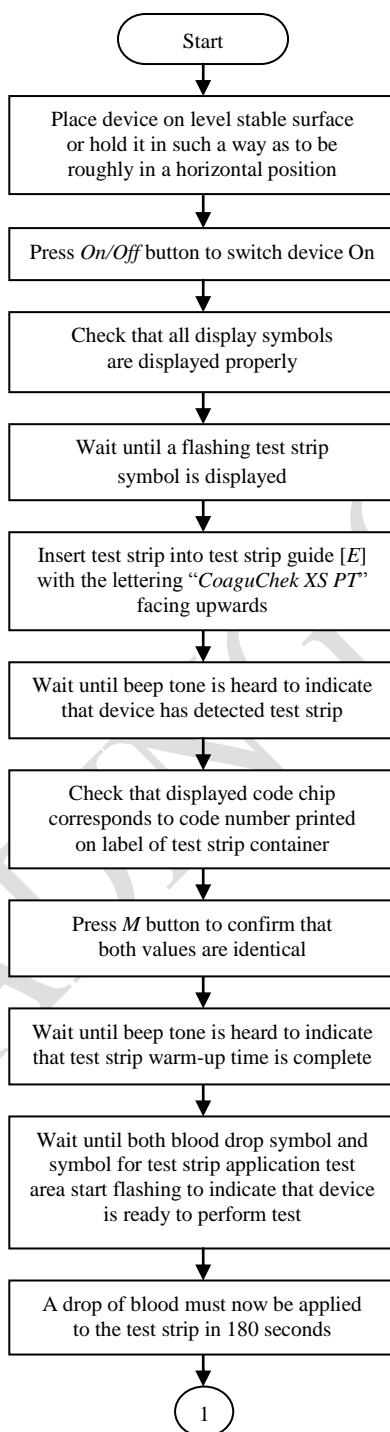
5.6. Flow Charts


5.6.1. Set Up

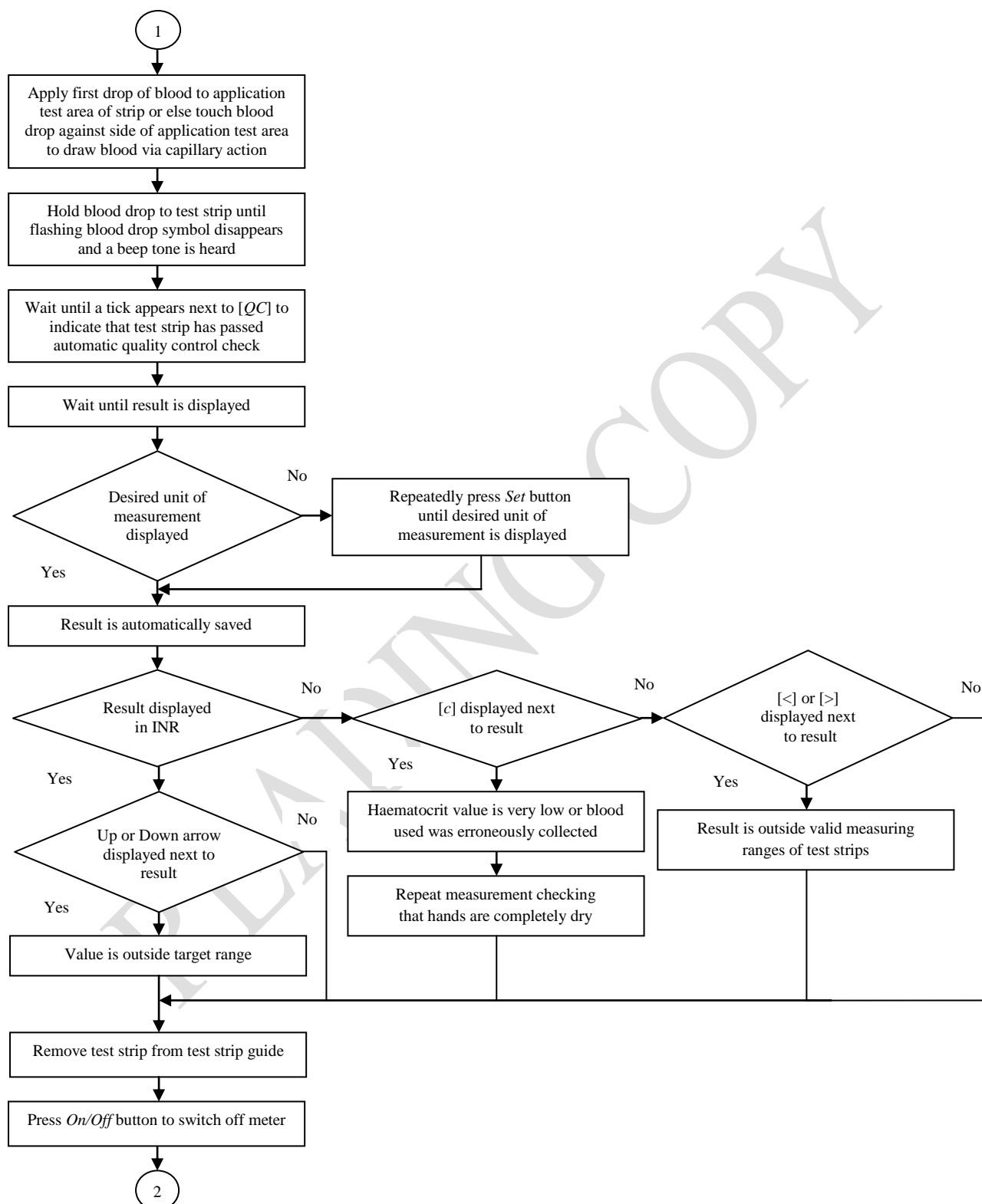



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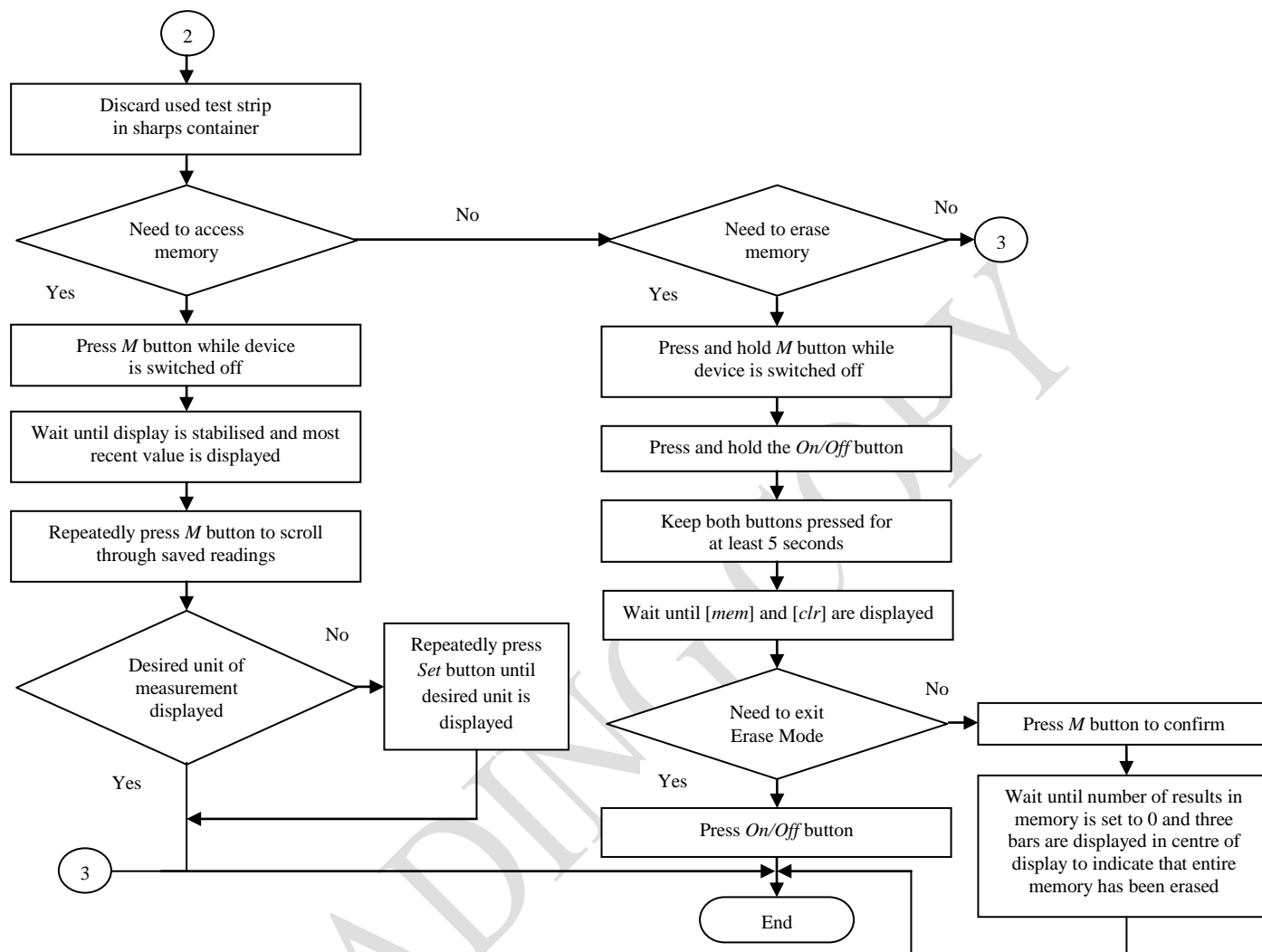
5.6.2. Operation




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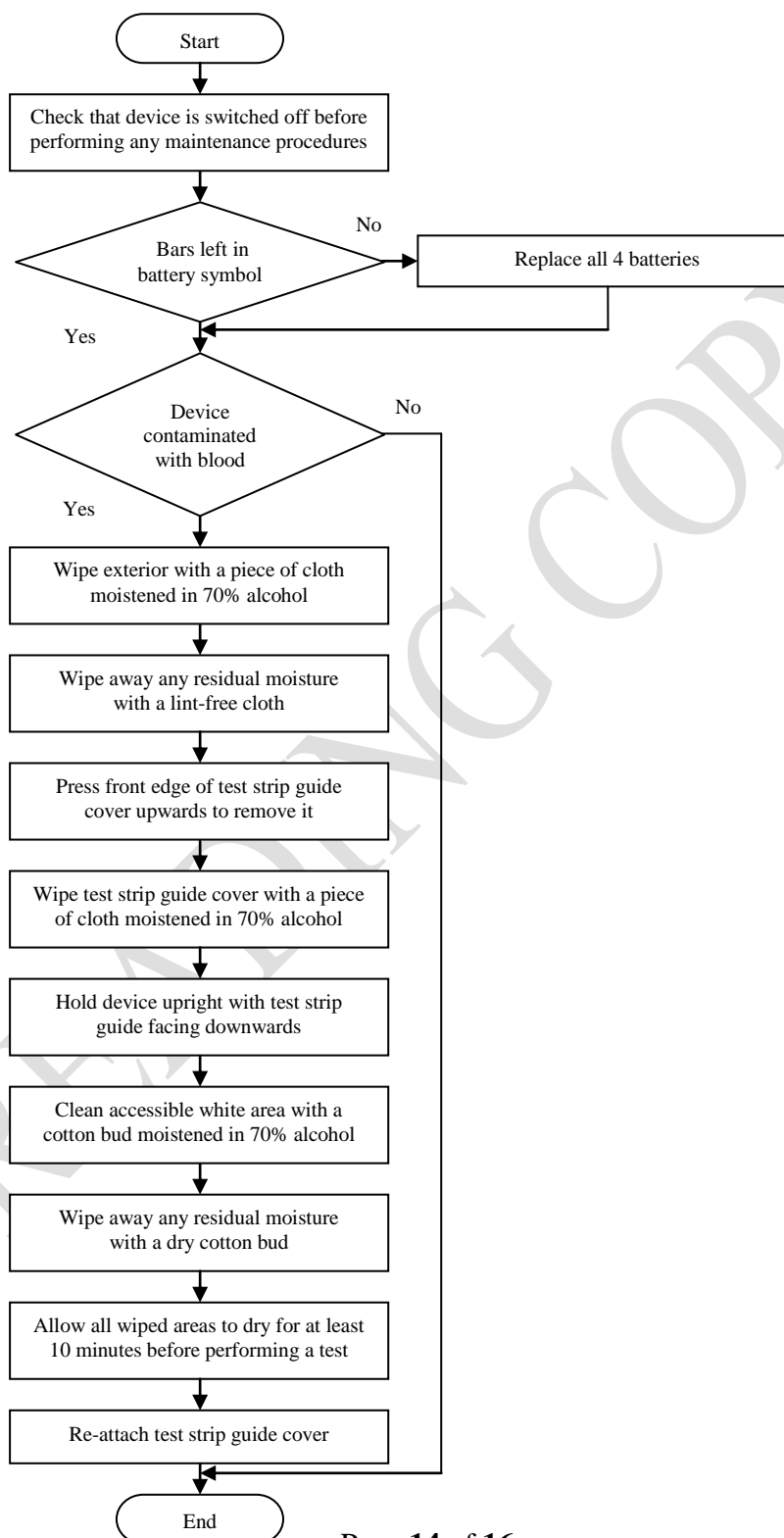



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5.6.3. Maintenance



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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


Roche Diagnostics. CoaguChek® XS User's Manual. Mannheim: Roche Diagnostics GmbH; 2010.

8. Appendices

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

9. Revision History

Version Number	Amendments/ Reasons for change
01	Initial Release

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

Setting	Display Symbol	Function
Date Format	<i>[xx-xx-xx]</i>	To select between: Day-Month-Year Month-Day-Year Year-Month-Day
Date	<i>[xx-xx-xx]</i>	To enter the date in the following order: Year, Month, Day
Time Format	<i>[24h] or [12hr]</i>	To select between a 24-hour or a 12-hour time format with a.m. and p.m.
Time	<i>[xx:xx]</i>	To enter the time in the following order: Hours and Minutes
Unit	<i>[INR], [%Q] or [Sec]</i>	To select the desired coagulation unit. If INR is selected, therapeutic target range can also be inputted.
Beep Tone	<i>[On] or [Off]</i>	To select between switching On or Off the beep tone signal. Device will beep in the following situations: <ul style="list-style-type: none"> - 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)	<i>[On] or [Off] and [x.x]</i>	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.