	UNIVERSITY OF MALTA FACULTY OF MEDICINE & SURGERY PHARMACY DEPARTMENT	Ref. No. SOP/PD/222_02
	STANDARD OPERATING PROCEDURE	
	ACCUTREND® PLUS	**Valid for:** 2 years from approval

Table of Contents

		Page
1.	Scope	2
2.	Objective	2
3.	Definitions	2
4.	Responsibility	2
5.	Procedure	3
	5.1. Diagram of Accutrend® Plus	3
	5.2. Configuration	4
	5.3. Operation	4
	5.4. Storing Results	5
	5.5. Quality Control	6
	5.6. Maintenance	6
	5.7. Troubleshooting	8
	5.8. Flow Charts	10
6.	Precautions	19
7.	References	19
8.	Appendices	19
9.	Revision History	19

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1. Scope

This Standard Operating Procedure (SOP) applies to the staff and students using Accutrend® Plus in the laboratories of the Pharmacy Department, University of Malta.

2. Objective

To describe the procedure for the configuration, operation, recording of results, quality control, maintenance and troubleshooting of Accutrend® Plus.

3. Definitions

3.1. **Accutrend® Plus:** used for quantitative measurement of blood glucose and blood cholesterol, such tests are done using reflectance photometric measurements using test strips specific to each of the mentioned parameters.

3.2. **Code Strip:** A code chip supplied with each test strip container, containing an imprinted barcode with lot-specific information which is read and stored by the Accutrend® Plus.

3.3. **Control Solutions:** Solutions used to perform a quality control check. There are 2 different control solutions available i.e. for low level testing and for high level testing.

3.4. **Memory Mode:** A function that allows the storage of up to 100 different test results together with their relevant time and date. Once this memory is full, the device will start to automatically overwrite the oldest entries consecutively.

3.5. **Optical Measurement System:** The part of the device which uses light to quantitatively measure the glucose concentration in the blood. It is located underneath the measurement optics cover.

3.6. **Set Mode:** Allows the device to be set according to the user's preferences.

3.7. **Test Strip**: A strip of sensitised material used in testing of bodily fluids.

3.8. **Test Strip Guide**: The area in which the test strip is inserted.

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 Accutrend® Plus

A: Display
B: M Button (memory):
C: *On/Off* button
D: Measurement chamber flap
E: Test Strip guide
F: Set button.
G: Battery compartment lid
H: Measurement chamber cover

5.2. Configuration

5.2.1 Insert 4 AAA 1.5 alkaline batteries.
5.2.2. Press the *On/Off* button to switch the device On.
5.2.3. Hold the *On/Off* button when the device is switched On to perform a display test. Display test is shown for the time the button is held.
5.2.4. Check that the last stored code is displayed at the end of the display test.
5.2.5. Press the *SET* button to enter SET mode.
5.2.6. Refer to SOP/PD/222_02/A1 to set up each parameter in the set up menu.

5.3. Operation

5.3.1. Inserting code strip

5.3.1.1. Hold the code strip from its white area at the bottom avoiding the printed area.
5.3.1.2. Insert the code strip into the test strip guide.
5.3.1.3. Stop at the end of directional arrows printed on code strip.
5.3.1.4. Withdraw code strip and leave measurement chamber flap closed.
5.3.1.5. Wait for a short beep to be heard to confirm that coding was successful.
5.3.1.6. Wait for the 3-digit code that is printed on the code strip to be displayed.

5.3.2. Performing a measurement

5.3.2.1. Wait for a flashing test strip symbol to be displayed.
5.3.2.2. Remove a test strip from its storage container and replace its cap tightly.
5.3.2.3. Check back of test strip for discolouration. Discard test strip if discoloured.
5.3.2.4. Hold test strip so that application area is facing upwards.
5.3.2.5. Insert test strip into test strip guide. Wait for 2 consecutive beeps to be heard to indicate that the test strip has been positioned correctly.
5.3.2.6. Open the measurement chamber flap.
5.3.2.7. Wait for a flashing drop symbol to be displayed.
5.3.2.8. To perform a glucose reading, immediately apply a drop of blood against the yellow sampling area.

5.3.2.9. To perform a cholesterol reading, wipe the first drop of blood and apply the second drop of blood to the yellow sampling area.

5.3.2.10. Close measurement chamber flap to initiate measurement process.

5.3.2.11. Wait for a test evaluation time of approximately 12 seconds to perform a glucose reading.

5.3.2.12. Wait for a test evaluation time of approximately 180 seconds to perform a cholesterol reading.

5.3.2.13. Wait for a final long beep to indicate completion of measurement.

5.3.2.14. Perform a plausibility test (see 5.3.3) if a glucose measurement is being performed. Displayed reading falls outside the measurement range if a *Hi* or *Lo* symbol is indicated.

5.3.2.15. Refer to 5.3.4 if flagging of result is required.

5.3.2.16. Open the measurement chamber flap and remove test strip.

5.3.2.17. Discard the test strip and lancet in the sharps container.

5.3.2.18. Press *On / Off* button to turn the device Off.

5.3.3. Plausibility check after glucose measurement

5.3.3.1. Remove test strip and compare the reaction area at the bottom of the test strip with the scale present on the label of the test strip container.

5.1.3.2. Perform a quality control test if result is unusually high or low as per 5.5

5.3.4. Flagging a measurement

5.3.4.1. Press the *M* button if measurement is to be labelled as a control.

5.3.4.2. Press *SET* button if measurement is to be labelled as an event.

5.3.4.3. Press *SET b*utton to increase event value from Zero (0) to Nine (9).

5.4. Storing Results

5.4.1. Hold the *M* button to switch on the device in memory mode.

5.4.2. Wait for [*mem*] symbol to be displayed to indicate that the device instrument is in memory mode.

5.4.3. Wait for the last stored value to be displayed.

5.4.4. Press *SET* button to switch between the two test-parameters of each memory area (Glucose or Cholesterol).

5.4.5. Press *M* button to display the next value.

5.4.6. Press and hold the *M* button to cycle through older readings in memory.
5.4.7. If entire memory is empty three dashes will be displayed.
5.4.8. If entire memory area of a test parameter is empty two dashes will be displayed.
5.4.9. If a single measured value is stored incorrectly one dash will be displayed.
5.4.10. Press the *On/Off* button to exit memory mode.

5.5. Quality Control

5.5.1. Remove a test strip from its storage container and replace its cap tightly.
5.5.2. Hold test strip so that application area is facing upwards.
5.5.3. Insert test strip into the test strip guide. Two consecutive beeps are heard if test strip was inserted correctly.
5.5.4. Press the *M* button to flag measurement as a control.
5.5.5. Open measurement chamber flap until it locks into a vertical position.
5.5.6. Apply a drop of either glucose or cholesterol low level control solution.
5.5.7. Close the measurement chamber flap to initiate measurement process.
5.5.8. Wait for a test evaluation time of approximately 12 seconds to perform a glucose reading.
5.5.9. Wait for a test evaluation time of approximately 180 seconds to perform a cholesterol reading.
5.5.10. Wait for a final long beep to indicate completion of measurement.
5.5.11. Check if displayed result falls within the acceptable range found on labels / package insert of test strips or control solution.
5.5.12. Repeat 5.5.4 – 5.5.11 using either glucose or cholesterol high level control solution

5.6. Maintenance

5.6.1. Hold the *On/Off* button to turn On the device to perform a display test.
5.6.2. Check that date and time are correct.
5.6.3. Change batteries if battery symbol is displayed.
5.6.4. Check that the device is switched Off.

5.6.5. Clean the outside of the device with a moist cloth and a mild cleaning agent.

5.6.6. Check that the device is switched Off.

5.6.7. Open the measurement chamber flap.

5.6.8. Remove the test strip guide by simultaneously pushing forward and upwards gently.

5.6.9. Rinse test strip guide and dry using a clean cloth.

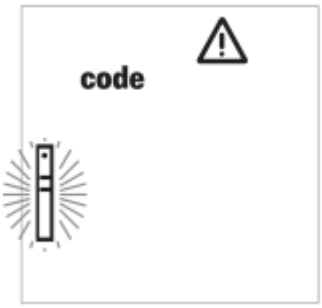
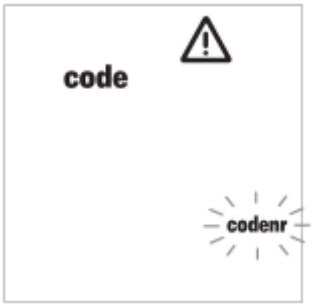
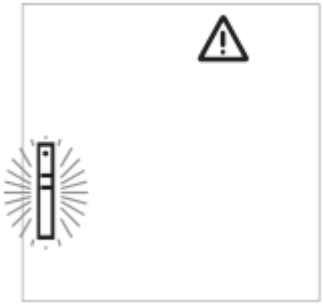
5.6.10. Clean the optical measuring system using a lint free pad or lightly moistened cotton ball and allow drying.

5.6.11. Replace test strip guide by pressing it down slightly until it clicks into place.

5.6.12. Close the measurement chamber flap.

5.6.13. Perform a quality control test (see 5.5)

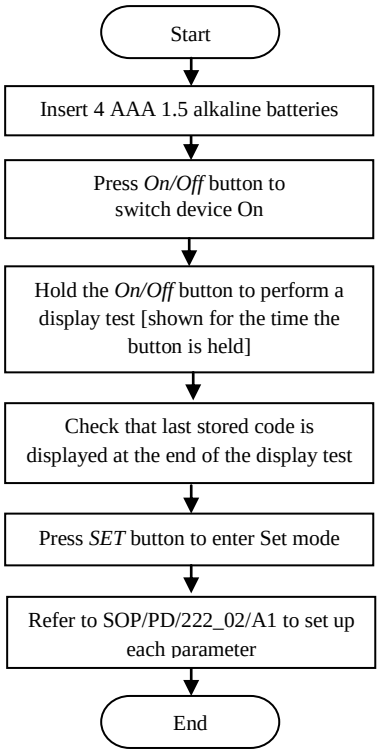
5.7. Troubleshooting

Display Message	Cause/s	Solution/s
	Unknown barcode	Check that barcode is not tainted with dirt Repeat test with new test strip Keep device away from electromagnetic sources
	Test strip code does not match stored code	Repeat using test strip with matching code
	Unusable test-strip	Repeat test using new test strip
	Temperature is not within acceptable limits	Move device to an area with an acceptable temperature range.

	Measurement chamber flap not properly closed after device has been switched On.	Close measurement chamber flap appropriately.
	Measurement chamber flap not properly closed during measurement.	Close measurement chamber flap appropriately.
	Measurement chamber flap not properly closed after blood application.	Remove test strip and repeat test using a new test strip
	Internal error *(example: Error 142)*	Switch device Off Switch device On Clean device as described in 5.6 If error persists contact supplier

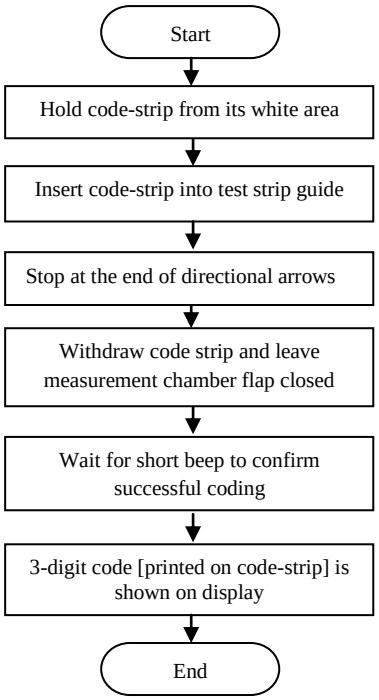
5.8. Flow Charts

5.8.1. Configuration

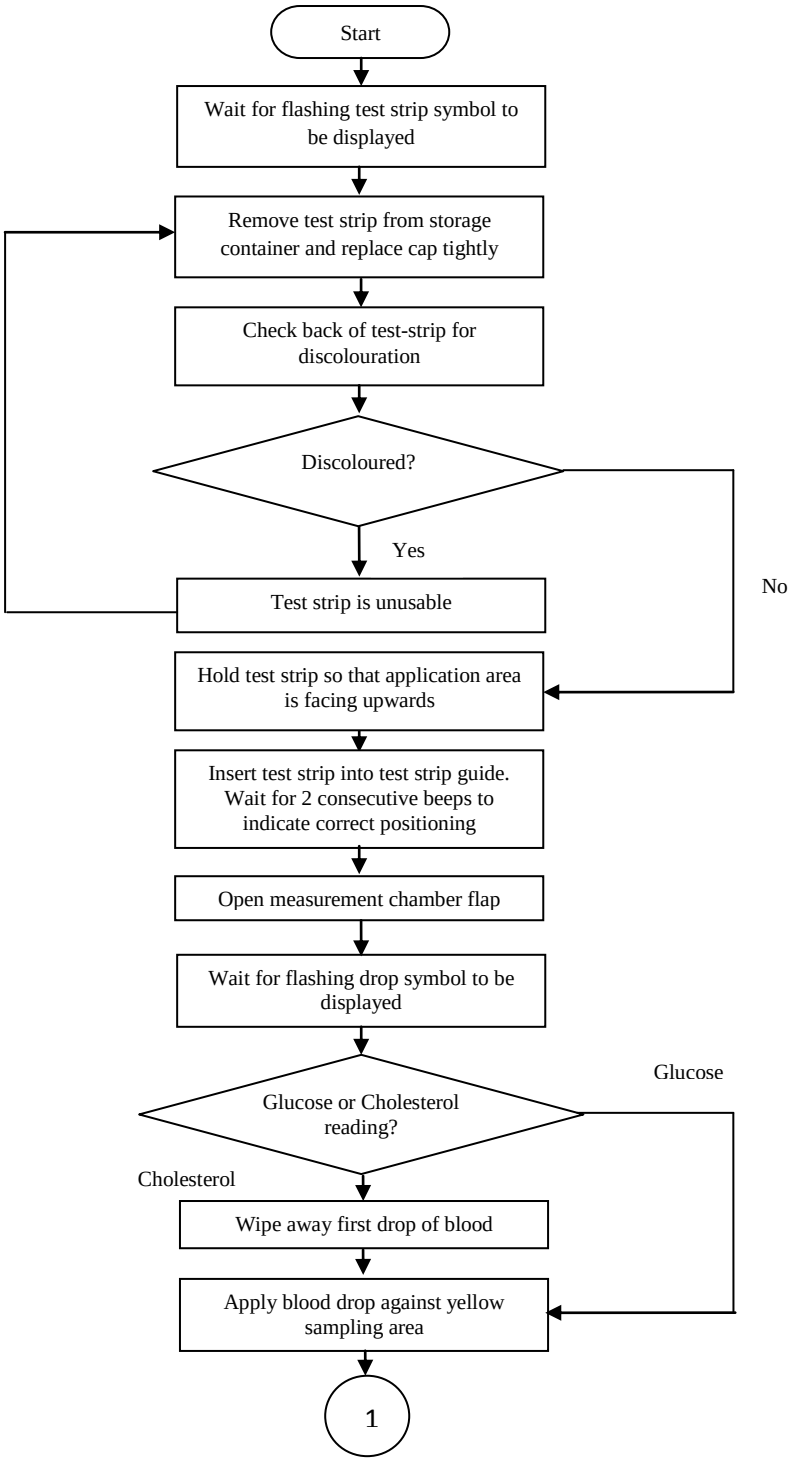


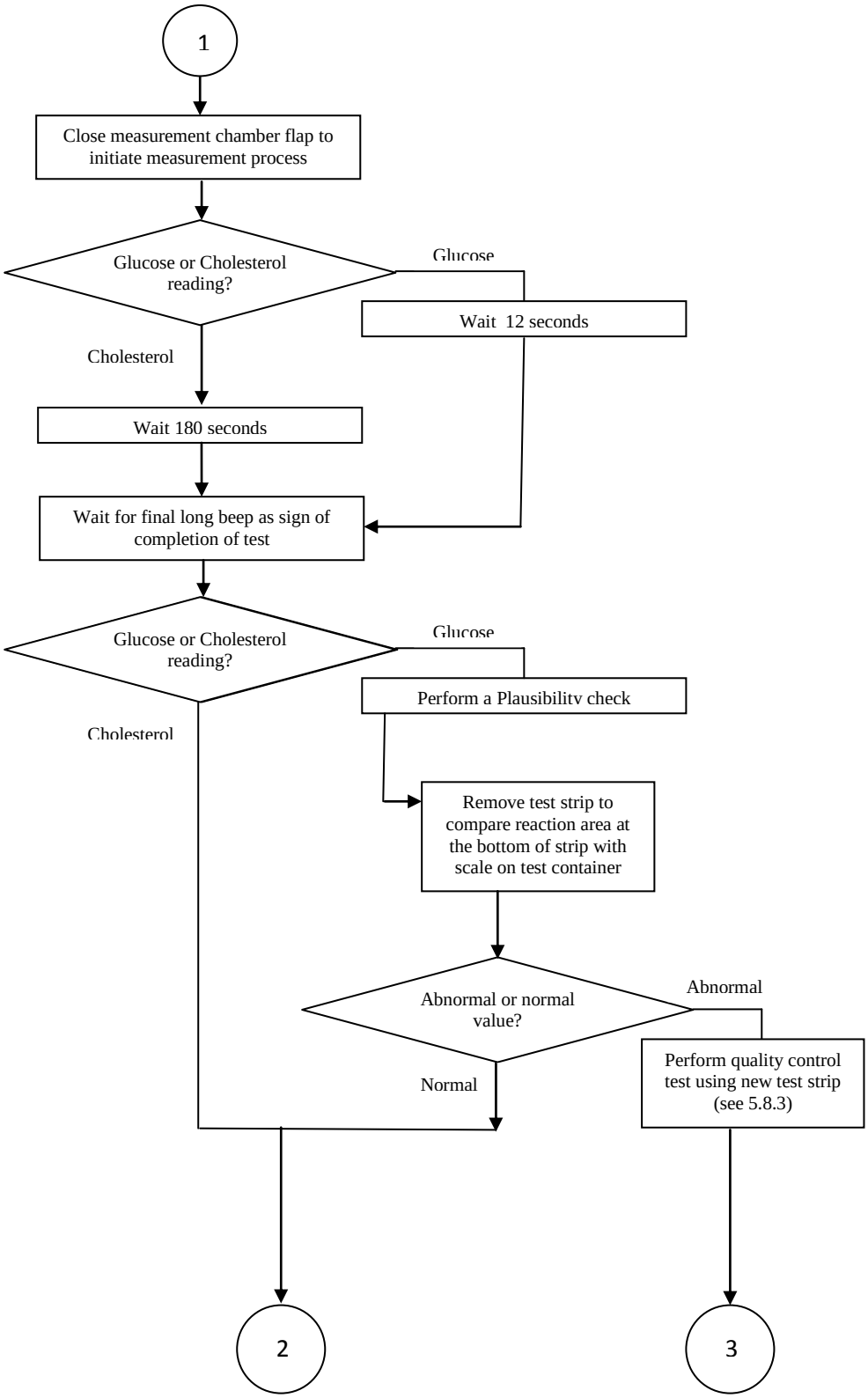
5.8.2. Operation

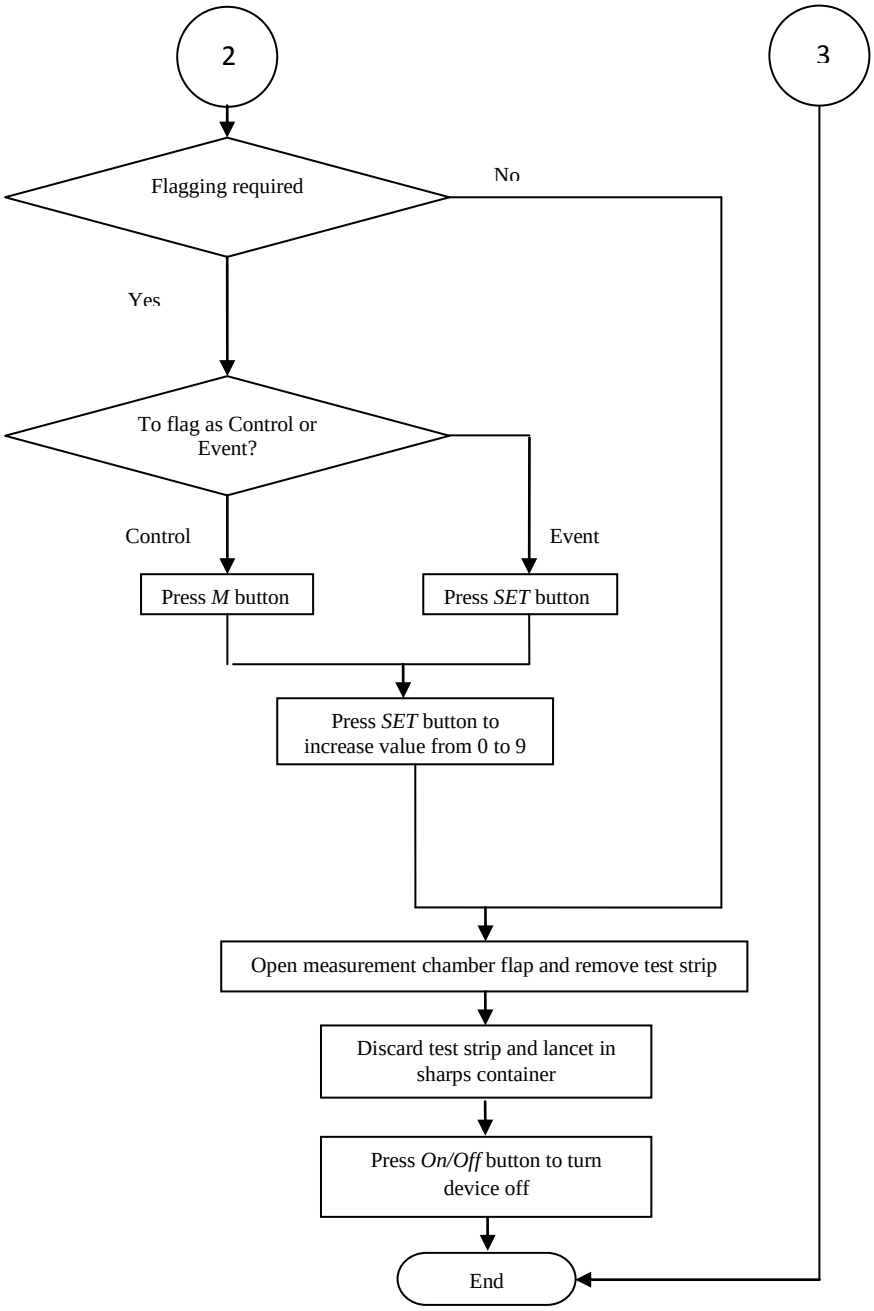
5.8.2.1. Inserting code strip



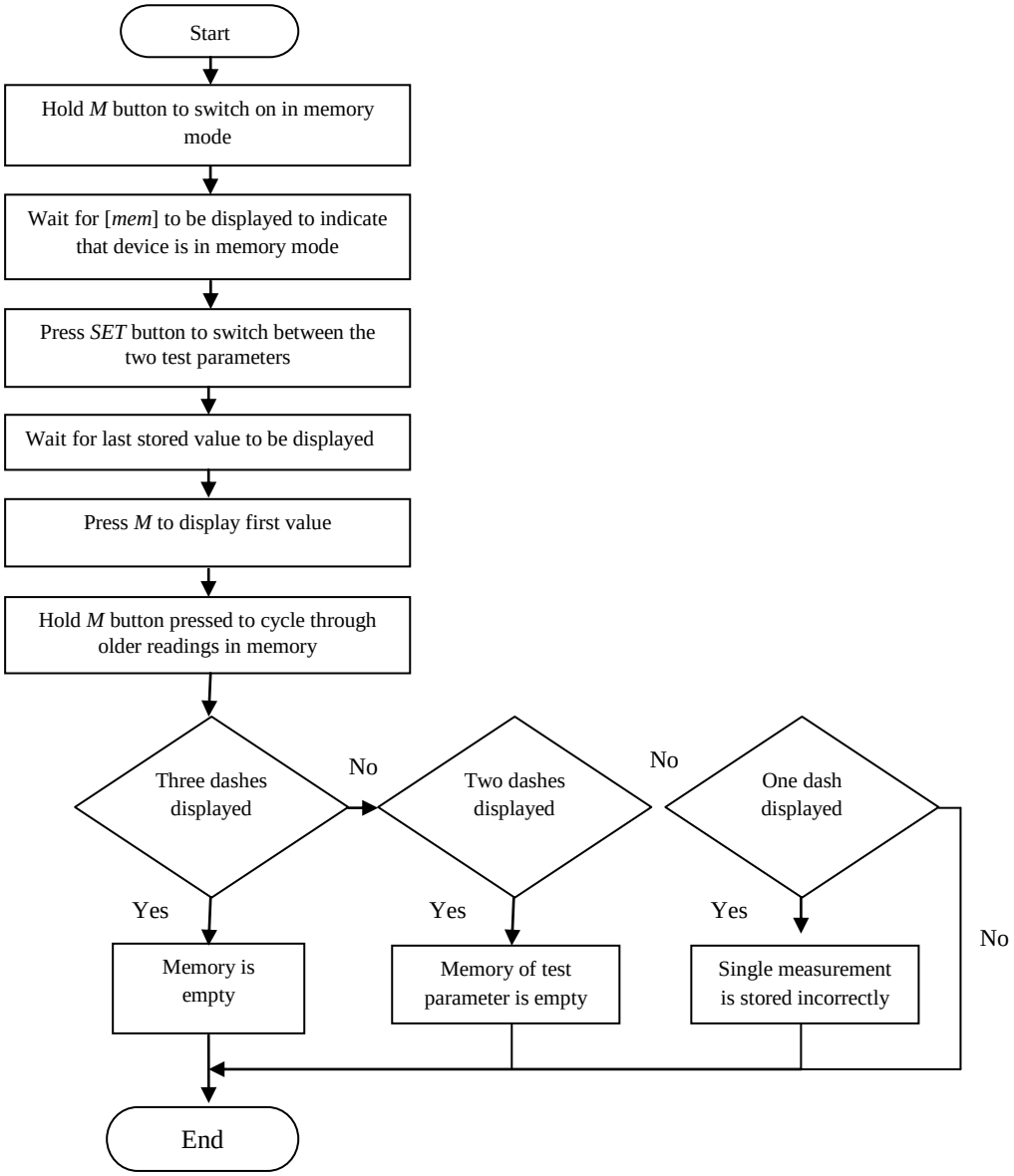
5.8.2.2. Performing a measurement



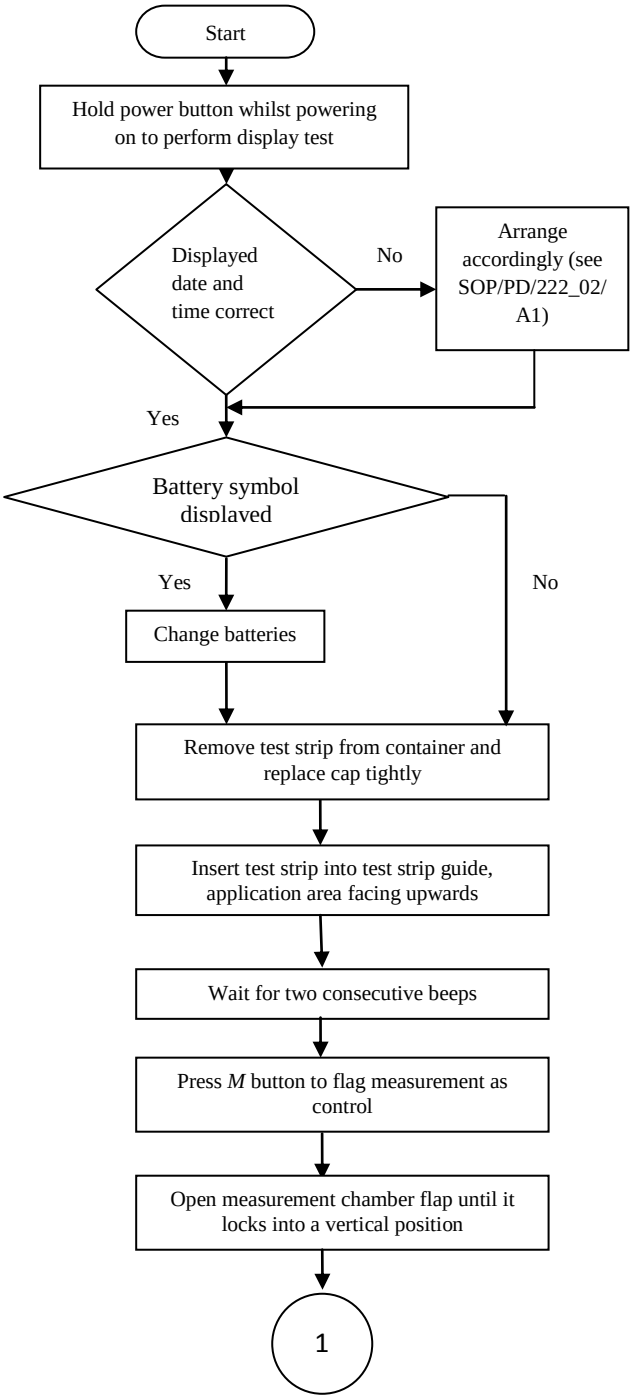

1
Close measurement chamber flap to initiate measurement process
Glucose or Cholesterol reading?
Glucose
Wait 12 seconds
Cholesterol
Wait 180 seconds
Wait for final long beep as sign of completion of test
Glucose or Cholesterol reading?
Glucose
Perform a Plausibility check
Cholesterol
Remove test strip to compare reaction area at the bottom of strip with scale on test container
Abnormal or normal value?
Abnormal
Perform quality control test using new test strip (see 5.8.3)
Normal
2
3

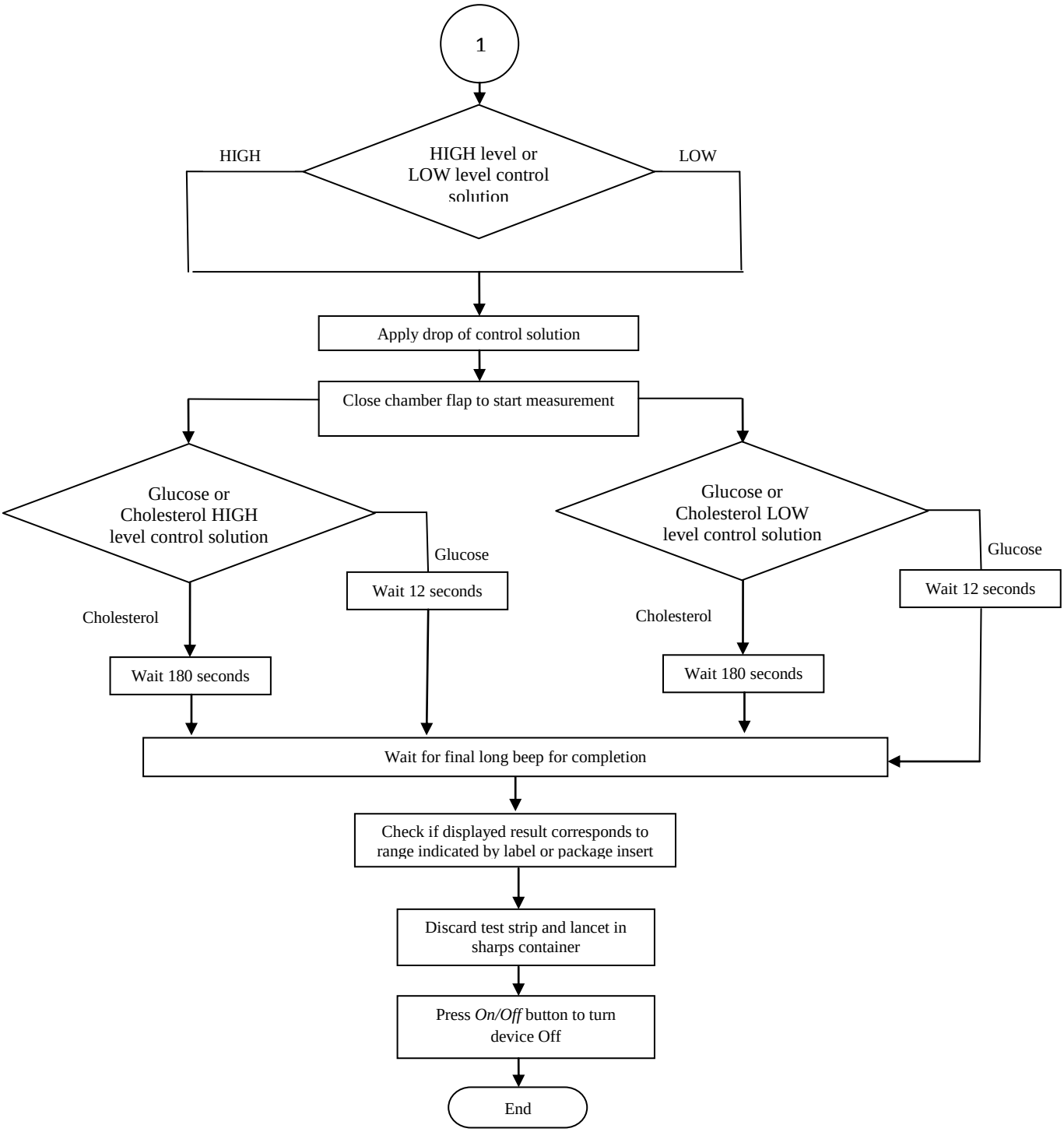

2
3
Flagging required
No
Yes
To flag as Control or Event?
Control
Event
Press *M* button
Press *SET* button
Press *SET* button to increase value from 0 to 9
Open measurement chamber flap and remove test strip
Discard test strip and lancet in sharps container
Press *On/Off* button to turn device off
End

5.8.2.3. Storing Results

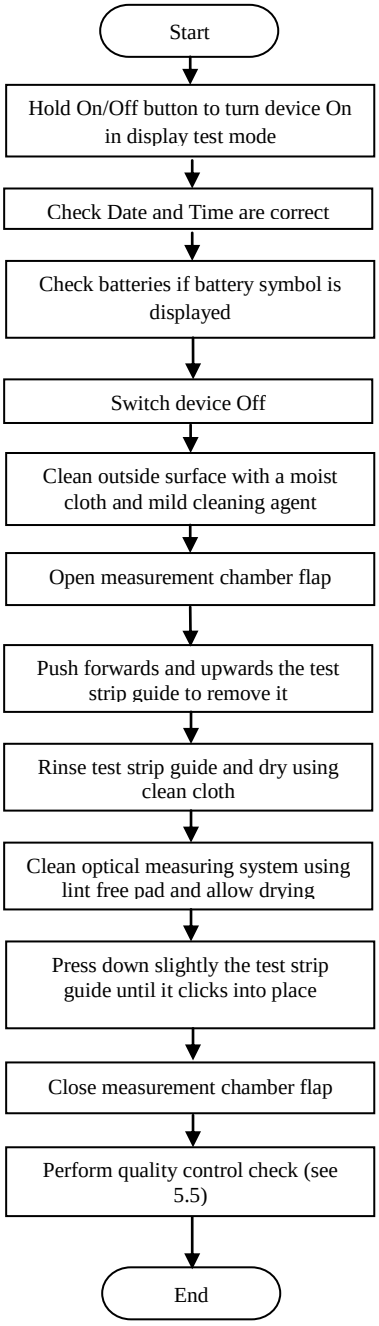


5.8.3. Quality Control




1
HIGH level or LOW level control solution
HIGH
LOW
Apply drop of control solution
Close chamber flap to start measurement
Glucose or Cholesterol HIGH level control solution
Glucose
Wait 12 seconds
Cholesterol
Wait 180 seconds
Glucose or Cholesterol LOW level control solution
Glucose
Wait 12 seconds
Cholesterol
Wait 180 seconds
Wait for final long beep for completion
Check if displayed result corresponds to range indicated by label or package insert
Discard test strip and lancet in sharps container
Press *On/Off* button to turn device Off
End

5.8.4. Maintenance



6. Precautions

6.1. Operate the device under the following test-specific temperatures
- **6.1.1.** Cholesterol : 18-30^{o}C
- **6.1.2.** Glucose 18-32^{o}C

6.2. Keep the device clean at all times (see 5.6).

6.3. Close the test strip container immediately after opening to maintain their shelf life.

6.4. Do not touch or remove test strip during measurement process.

6.5. Store test strip container together with the code strip in their appropriate external packaging.

6.6. If performing measurement for more than one patient refer to SOP 'Health and Safety POCT (SOP/PD/201_01)'
- **6.6.1.** Use gloves. (Gloves are to be used always, even when performing test for one person)
- **6.6.2.** Apply blood outside device using capillary pipettes.
- **6.6.3.** Dispose of used capillary pipettes and test strips in a sharps container.

6.7. Wash hands and rinse with plenty of clean water as creams and soaps contain fat which can yield an incorrect **triglyceride** result if present on test strip.

6.8. For **cholesterol** or **triglycerides** tests, wipe the first drop of blood using a cellulose pad and use the second drop of blood.

7. References

Roche Diagnostics. Accutrend® Plus GmbH, blood glucose, cholesterol, triglycerides and lactate meter monitor user's manual. Mannheim: Roche Diagnostics; 2007.

8. Appendices

SOP/PD/222_02/A1 – Configuration Parameters Table

9. Revision History

Version Number	Amendments/ Reasons for change
01	Initial Release
02	Inclusion of subheading titles of Procedure section in Table of Contents

SOP/PD/222_02/A1 – Configuration Parameters Table

Configuration parameter	Display Symbol	Set Up
Date and Time format	xx.xx.xx*	– Press *SET* button to power on in SET mode – Press *SET* button again to make changes in SET mode – Press *M* button to change between date formats – Press *SET* button to save format and set date – Press *M* button to set the year – Press *SET* button to save displayed year – Press *M* button to set the month – Press *SET* button to save displayed month – Press *M* button to set the day – Press *SET* button to save displayed day and SET time format. – Press *M* button to change time format. – Press *SET* button to save time format and SET time. – Press *M* button to set the hour – Press *SET* button to set minutes – Press *SET* button to save displayed time and SET Beeper
Beeper		– Press *M* button to switch between off and On [default] – Press SET button to save the selected setting.

*x denotes any number