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Signature/Date: MM/dd/yyyy

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1. Scope

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

2. Objective

To describe the procedure for the configuration, operation, quality control check, data transfer, maintenance and troubleshooting of the ACCU-CHEK® Active.

3. Definitions

3.1. ACCU-CHEK® Active: A blood glucose device used to quantitatively measure blood glucose levels using capillary blood.

3.2. Battery Compartment: The area in which one CR2032 battery is to be inserted to operate the device.

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

3.4. Code Key Slot: The area in which the code key is inserted.

3.5. Control Solution: A solution used to perform a quality control check. There are 2 different control solutions available i.e. for low level testing (with a blue cap) and for high level testing (with a red cap).

3.6. Control Window: Located on the back of the test strip. The colour of the control window changes upon adding a drop of blood or control solution. This can be used as a further verification of the result displayed on the display by comparing the colour attained to the colour scale printed on the test strip container.

3.7. Display Test: Checks that all the display parameters are being shown accordingly.

3.8. Infrared Window: To be pointed towards the infrared window of an infrared port of a computer whenever data is to be downloaded from the device to a computer that has the appropriate software installed.
3.9. **M Button**: To enter or exit Memory mode or to change configuration parameters in Set Mode.

3.10. **Measurement Optics**: The part of the device which uses light to quantitatively measure the glucose concentration in the blood.

3.11. **Memory Mode**: A function that allows the storage of up to 200 different test results together with their relevant time and date. When this memory is full, the device will start to automatically overwrite the oldest entries consecutively.

3.12. **Quality Control Check**: Performed to ensure that both the device and the test strips are functioning appropriately and providing reliable results. This test should be carried out before the first use of the device, when starting a new box of test strips, when inserting a new battery, after a cleaning procedure, after accidentally dropping the device and when test results do not coincide with the clinical symptoms present.

3.13. **S Button**: To enter Set mode, to move between fields in Set mode and to recall stored test results in Memory mode.

3.14. **Set Mode**: Allows the device to be set according to the user’s preferences.

3.15. **Test Strip Guide**: The area covering the measurement optics.

3.16. **Test Strip Slot**: 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 ACCU-CHEK® Active

5.2. Configuration

5.2.1. Insert battery into the battery compartment.
5.2.2. Press the S button while device is still switched Off to enter Set Mode.
5.2.3. Press the M button to choose between a 12h or a 24hr time format.
5.2.4. Press the S button and wait for the hour to flash.
5.2.5. Repeatedly press the M button to change the hour.
5.2.6. Repeat 5.2.4. and 5.2.5. to set-up the minutes, year, month, day and beep tone activation.
5.2.7. Press the S button twice to complete set-up and to turn the device Off.
5.2.8. Insert the code key of the test strips to be used into the code key slot.

5.3. Operation

5.3.1. Remove a test strip from its storage container and replace the container cap tightly.
5.3.2. Check that the colour of the control window on the back of the test strip matches to the colour that corresponds to 0mg/dL or 0 mmol/L on the test strip container.

5.3.3. Insert the test strip into the test strip slot with the orange pad facing upwards and the arrowheads pointing forward.

5.3.4. Gently keep pushing the test strip inwards until the arrowheads are almost no longer visible.

5.3.5. Wait for the device to switch On automatically.

5.3.6. Wait for the display test to take place, lasting approximately 2 seconds.

5.3.7. Check that the displayed code corresponds to the code that is printed on the test strip container.

5.3.8. Wait for the flashing blood drop symbol to be displayed. *(A blood drop must now be applied to the test strip within two minutes).*

5.3.9. Apply the blood drop by touching it to the centre of the square orange pad of the test strip.

5.3.10. Move the finger away from the test strip when an hourglass symbol is displayed.

5.3.11. Wait for the test result to be displayed. This will be automatically saved in memory.

5.3.12. Remove the test strip. The device will switch Off automatically.

5.3.13. Confirm the test result by comparing the colour of the control window on the back of the test strip to the colour range on the test strip container.

5.3.14. Discard the test strip in a suitable sharps container.

5.3.15. Accessing Memory

5.3.15.1. Press the \( M \) button for less than 3 seconds while the device is switched Off to enter Memory Mode.

5.3.15.2. Wait for the most recent test result to be displayed together with its time and date.

5.3.15.3. Press and hold the \( S \) button to scroll quickly through the memory results in chronological order.

5.3.15.4. Press the \( M \) button to switch the device Off.

5.3.15.5. Press the \( M \) button and then press the \( M \) and \( S \) buttons simultaneously to display the average value for the last 7 days.

5.3.15.6. Press the \( M \) and \( S \) buttons simultaneously again to display the average value for the last 14 days.

5.3.15.7. Press the \( M \) button to switch the device Off.
5.3.16. Deleting Memory

5.3.16.1. Press and hold the S button, until [Clr] and [mem] is displayed flashing, while device is switched Off.
5.3.16.2. Press and hold the M and S button until the current result is displayed.
5.3.16.3. Press and hold the M and S button for more than 5 seconds to delete the result. The device will automatically switch Off.

5.4. Quality Control Check

5.4.1. Repeat steps 5.3.1. to 5.3.8.
5.4.2. Press the S button to mark the test as a control.
5.4.3. Check that a control bottle symbol is now also displayed.
5.4.4. Open the desired bottle of control solution and wipe its dropper tip with a clean, dry paper towel to remove any dried-up residues.
5.4.5. Invert the bottle and hold it downwards at an angle.
5.4.6. Squeeze the bottle gently until a small drop is suspended from the tip.
5.4.7. Apply the control solution drop by touching it to the centre of the square orange pad of the test strip.
5.4.8. Wait for the control result to be displayed. This will be automatically saved in memory.
5.4.9. Check that the control result obtained lies within the specified range of the control solution which is printed on the test strip container.
5.4.10. Remove the test strip from the test strip guide. The device will switch Off automatically.
5.4.11. Discard the test strip into a suitable sharps container.

5.5. Data Transfer

5.5.1. Run the appropriate installed software programme in the computer.
5.5.2. Check that the software programme is ready to accept data from the device.
5.5.3. Point the infrared window of the device to the infrared window of the infrared device of the computer.
5.5.4. Press and hold the M button until [PC] starts to flash on the display.
5.5.5. Wait until [End] is displayed to indicate that the information has been successfully transferred to the computer.
5.5.6. Press the M button to switch the device Off.
5.6. Maintenance

5.6.1. Replace the battery with a new one if a battery symbol is being displayed.

5.6.2. Check that the device is switched Off. Press the M and S button simultaneously until the entire display parameters are displayed to periodically check that the display is working accordingly.

5.6.3. Clean the outside of the device and the display with a moist cloth.

5.6.4. Disinfect the outside of the device and the display with a cloth moistened with 70% alcohol.

5.6.5. If blood is present on the test strip guide or the device is displaying an E4 or E5 error message:

5.6.5.1. Remove the test strip guide from the device using the thumb to slide it off.

5.6.5.2. Clean the test strip guide with a soft cloth moistened with cleaning solution.

5.6.5.3. Wipe the measuring window of the test strip guide gently with a lint-free cloth.

5.6.5.4. Wait for the test strip guide to dry thoroughly.

5.6.5.5. Slide the test strip guide back in place.

5.6.5.6. Perform a quality control check (refer to section 5.4.) before commencing with further testing procedures.
## 5.7. Troubleshooting

<table>
<thead>
<tr>
<th>Error</th>
<th>Cause/s</th>
<th>Solution/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>[code] flashing after display test is performed</td>
<td>Code key is missing</td>
<td>Insert appropriate code key</td>
</tr>
<tr>
<td>Therometer symbol displayed</td>
<td>Ambient temperature is above or below the proper range for device to work properly</td>
<td>Slowly acclimatise device at T within permitted range and repeat test with a new strip</td>
</tr>
<tr>
<td>Low battery symbol displayed</td>
<td>Battery strength is low</td>
<td>Replace battery with a new one as soon as possible</td>
</tr>
<tr>
<td>‘Sun’ symbol displayed</td>
<td>Surroundings are too bright to carry out test</td>
<td>Move to another location and repeat test with a new strip</td>
</tr>
<tr>
<td>[LO] displayed</td>
<td>Blood glucose level may be lower than the measuring range of the device or test strip used had been bent</td>
<td>Repeat test and verify result by running a control test</td>
</tr>
<tr>
<td>[HI] displayed</td>
<td>Blood glucose level is higher than the measuring range of the device</td>
<td>Repeat test and verify result by running a control test</td>
</tr>
<tr>
<td>Control test result does not fall within the acceptable range</td>
<td>- Expired test strip or control solution used &lt;br&gt; - Control solution bottle may have not been tightly closed &lt;br&gt; - Check that test was performed with appropriate code key at an appropriate temperature</td>
<td>- Repeat test with new control solution and test strip from a new container &lt;br&gt; - Call supplier if control test result still remains out of range</td>
</tr>
<tr>
<td>[E-1] displayed</td>
<td>Test strip inserted incorrectly or incompletely</td>
<td>Gently insert test strip with orange square pad upwards, in the direction indicated by the arrowheads until it fits accordingly</td>
</tr>
<tr>
<td>[E-2] displayed</td>
<td>Code key inserted incorrectly or wrong code key is inserted</td>
<td>Insert the corresponding code key accordingly</td>
</tr>
<tr>
<td>[E-3] displayed</td>
<td>Device is having trouble reading the code key</td>
<td>Take out code key and re-insert it accordingly</td>
</tr>
<tr>
<td>[E-4] displayed</td>
<td>Problem with reading test strip</td>
<td>- Clean test strip guide &lt;br&gt; - Repeat test ensuring that test strip used is not bent</td>
</tr>
<tr>
<td>Error</td>
<td>Cause/s</td>
<td>Solution/s</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>[E- 5]</td>
<td>Test strip is already used, dirty or expired</td>
<td>- Clean test strip guide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Repeat test with a new test strip</td>
</tr>
<tr>
<td>[E- 7]</td>
<td>Monitor was exposed to a strong electromagnetic field</td>
<td>Move away from source/s of interference and repeat test</td>
</tr>
<tr>
<td>[E- 8]</td>
<td>Code key is defective or was not inserted correctly</td>
<td>Remove code key and re-insert it</td>
</tr>
<tr>
<td>[E- 9]</td>
<td>Test strip was not inserted correctly, was removed during testing, or</td>
<td>Repeat test with a new test strip and check that it is inserted correctly</td>
</tr>
<tr>
<td></td>
<td>blood sample was applied too soon</td>
<td></td>
</tr>
<tr>
<td>[EEE]</td>
<td>Device has a fault</td>
<td>Contact supplier</td>
</tr>
<tr>
<td>[Err]</td>
<td>Too little blood was applied to test strip or the test strip was not</td>
<td>Repeat test with a new test strip and a larger drop of blood</td>
</tr>
<tr>
<td></td>
<td>lying flat and straight in the test strip guide</td>
<td></td>
</tr>
<tr>
<td>[ttt]</td>
<td>Ambient temperature or the temperature of the monitor is outside the</td>
<td>Move device to an area within temperature range, allow it to acclimatise</td>
</tr>
<tr>
<td></td>
<td>permitted range</td>
<td>and repeat test</td>
</tr>
</tbody>
</table>
5.8. Flow Charts

5.8.1. Configuration

Start

Insert battery into battery compartment

Press S button while device is still switched Off to enter Set Mode

Press M button to choose between a 12h or a 24h time format

Press S button and wait for hour to flash

Repeatedly press M button to change hour

Press S button and wait for minutes to flash

Repeatedly press M button to change minutes

Press S button and wait for year to flash

Repeatedly press M button to change year

Press S button and wait for month to flash

Repeatedly press M button to change month

Press S button and wait for day to flash

Repeatedly press M button to change day
1. Press S button to confirm and initiate beep tone setting.

2. Press M button to switch the beep tone [ON] or [OFF].

3. Press S button twice to finish set-up and turn device Off.

4. Insert code key of test strips to be used into code key slot.

End
5.8.2. Operation

Start

Remove test strip from storage container and replace its cap tightly

Check that colour of control window on back of test strip matches to colour that corresponds to 0mg/dL or 0mmol/L on test strip container

Insert test strip into test strip slot with orange pad facing upwards and arrowheads pointing forward

Gently keep pushing test strip inwards until arrowheads are almost no longer visible

Wait for device to switch On automatically

Wait for display test to take place

Check that displayed code corresponds to code printed on test strip container

Wait for flashing blood drop symbol to be displayed

A blood drop must now be applied to test strip within 2 minutes

Apply blood drop by touching it to centre of square orange pad of test strip

Move finger away from test strip when an hourglass symbol is displayed

Wait for test result to be displayed, which will be automatically saved in memory
Confirm test result by comparing colour of control window on back of test strip to colour range on test strip container

Press M button for less than 3 seconds while device is switched Off

Wait for most recent test result to be displayed

Press M button to switch device Off

Press M button and then press M and S buttons simultaneously to display average value for last 7 days

Press M and S buttons again simultaneously to display average value for last 14 days

Press M button to switch device Off

Device will automatically switch Off

End
5.8.3. Quality Control Check

Start

Remove test strip from its container and replace cap tightly

Check that colour of control window on back of test strip matches to colour that corresponds to 0mg/dL or 0mmol/L on test strip container

Insert test strip into test strip slot with orange pad facing upwards and arrowheads pointing forward

Gently keep pushing test strip inwards until arrowheads are almost no longer visible

Wait for device to switch On automatically

Wait for display test to take place

Wait for flashing blood drop symbol to be displayed

A drop of control solution must now be applied to test strip within 2 minutes

Press S button to mark test as control

Check that control bottle symbol is now also displayed

Open desired bottle of control solution and wipe its dropper tip with a clean, dry paper towel to remove any dried-up residues
Invert bottle and hold it at an angle

Squeeze bottle gently until a small drop is suspended from tip

Apply control solution drop by touching it to centre of square orange pad of test strip

Wait for control result to be displayed, which is automatically saved in memory

Check that control result lies within the specified range of control solution which is printed on test strip container

Remove test strip from test strip guide

Discard test strip into sharps container

Device will automatically switch Off

End
5.8.4. Data Transfer

1. Start
2. Run appropriate installed software programme in computer
3. Check that software programme is ready to accept data from device
4. Point infrared window of device to infrared window of infrared device of computer
5. Press and hold M button until [PC] starts to flash on display
6. Wait until [End] is displayed to indicate that data has been successfully transferred to computer
7. Press M button to switch device Off
8. End
5.8.5. Maintenance

Start

Battery symbol displayed

Yes

Replace battery with a new one

No

Check that device is switched Off

Press and hold M and S buttons simultaneously until entire display parameters are displayed to periodically check that display is working accordingly

Outside of device needs cleaning / disinfection

Yes

Clean with moist cloth and disinfect with cloth moistened with 70% alcohol

No

Blood present on test strip guide

Yes

Remove test strip guide from device using thumb to slide it off

Clean test strip guide with soft cloth moistened with cleaning solution

Wipe measuring window of test strip guide gently with a lint-free cloth

Wait for test strip guide to dry thoroughly

Slide test strip guide back in place

Perform a quality control check (see 5.8.3.) before commencing with further testing procedures

No

E4 or E5 message displayed

Yes

End

No
6. Precautions

6.1. The ambient temperature of the area where a test is to be performed must be within the range of +10 to +40°C.
6.2. Operate the device in an environment that has a humidity level less than 85%.
6.3. Do not use the device in close proximity of strong electromagnetic radiation sources.
6.4. Keep the device away from very strong light sources since this may cause error messages to be displayed.
6.5. Always wait for the device to switch Off automatically after each test before commencing with further tests.
6.6. Avoid scratching the measuring window of the test strip guide during its cleaning process since this will impair the measuring function of the device.
6.7. Ensure that no liquid enters the device during the cleaning process.
6.8. Do not spray any type of cleaning solution onto the device.
6.9. Remove the battery from the device whenever it is not going to be used for long periods of time.
6.10. Change the code key each time a new test strip container is to be used.
6.11. When opening a control solution bottle, write down the date of opening and discard it after three months.
6.12. Ensure that the control solution bottle is always tightly closed.
6.13. Do not store test strips in areas of high heat and moisture.
6.14. Do not bend the test strip whilst it is being inserted into the device.
6.15. Do not test blood glucose with expired test strips.
6.16. Do not use a test strip if its control window is green in colour.
6.17. Do not bend or move the test strip during a test since this can lead to an incorrect result.
6.18. Do not leave the test strip container open as this will render the test strips unusable.

7. Reference


8. Appendices

N/A
Revision History

<table>
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<tr>
<th>Version Number</th>
<th>Amendments/ Reasons for change</th>
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<tr>
<td>01</td>
<td>Initial Release</td>
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<tr>
<td>02</td>
<td>Inclusion of subheading titles of Procedure section in Table of Contents</td>
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