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1. **Scope**

This Standard Operating Procedure (SOP) applies to the staff and students using the STAT-Site® M\(^{Hgb}\) in the Pharmacy Practice Resource Unit (PPRU) at the Pharmacy Department, University of Malta.

2. **Objective**

To describe the procedure for the set up, operation, maintenance and troubleshooting of the STAT-Site® M\(^{Hgb}\).

3. **Definitions**

3.1. **CODE Key:** A chip that provides the device with important information about the test method and the lot number of the test cards. Each pack of test cards comes with a new CODE key that should be inserted into the device when a new pack of test cards is to be used.

3.2. **Down Button:** To select options.

3.3. **On/Off Button:** To switch the device on or off.

3.4. **SET Button:** Located under the test card platform and is used to set the desired unit of measurement i.e. mmol/L or g/dL.

3.5. **STAT-Site® M\(^{Hgb}\):** A precision reflectance photometer used for the quantitative determination of haemoglobin in samples of whole blood.

3.6. **Test Card Holder:** The area into which the STAT-Site® M\(^{Hgb}\) Test Cards are inserted.

3.7. **Test Card Platform:** Removed to provide access to the battery, the CODE key and the SET button.

3.8. **Up Button:** To access memory and select options.
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 STAT-Site® M$^{Hgb}$

5.2. Set Up

5.2.1. Press the On/Off button to switch the device on.
5.2.2. Place thumb just under the test card platform tab.
5.2.3. Pull the entire test card platform up and away from the device.
5.2.4. Insert the appropriate CODE Key into the opening marked with an arrow.
5.2.5. Wait until [CODE], the coded test name (i.e. Hgb) and the code number is displayed to indicate that the CODE key has been correctly inserted.
5.2.6. Check that the displayed number corresponds to the number present on the test card container.
5.2.7. Press and hold the blue SET button until [g/dl] starts flashing.
5.2.8. Press the *Up* and *Down* buttons to scroll between the different units of measurements available i.e. mmol/L or g/dL.

5.2.9. Line up the top end of the test card platform with the corresponding edges of the device.

5.2.10. Press down on the test card platform until it snaps firmly into place.

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. Wait until a flashing test card symbol is displayed.

5.3.4. Slide the edges of the test card under the guide tabs of the test card holder.

5.3.5. Push the test card firmly to the back.

5.3.6. Check that the test card is locked firmly in place.

5.3.7. Wait until the test type (i.e. Hgb), a test card symbol and a flashing blood drop symbol are displayed to apply the blood sample.

5.3.8. Wipe the first drop of blood.

5.3.9. Apply the second free-flowing blood drop.

5.3.10. Position the drop of blood directly over the centre of the test card.

5.3.11. Carefully touch the drop of blood to the reagent pad in the central hole of the test card.

5.3.12. Wait until the test result countdown finishes.

5.3.13. Read the result from the display.

5.3.14. Press the *On/Off* button to switch the device on and the *Up* button to retrieve the last result if the device automatically switches off. The device switches off automatically after 2 minutes.

5.4. Maintenance

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

5.4.2. Replace the battery if a battery symbol is displayed on switching on the device.

5.4.2.1. Remove the test card platform.

5.4.2.2. Place a fingernail under the front edge of the battery and pull it upwards and away.

5.4.2.3. Insert a new 3V (CR 2032) lithium battery.

5.4.2.4. Check that the positive side of the battery is the visible side.
5.4.3. Wipe the exterior of the meter with a lint free cloth slightly moistened with 70% ethanol or 10% bleach solution.

5.4.4. Wipe the display screen and the optical area with a lint free cloth slightly moistened with water.

5.5. Troubleshooting

<table>
<thead>
<tr>
<th>Error</th>
<th>Cause/s</th>
<th>Solution/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Lo] displayed</td>
<td>Result is &lt; 6g/dL</td>
<td>Repeat test with a larger blood sample</td>
</tr>
<tr>
<td>[Hi] displayed</td>
<td>Result is &gt; 21g/dL</td>
<td>Repeat test and follow the steps on correctly applying blood samples more carefully</td>
</tr>
<tr>
<td>[E-1] displayed</td>
<td>Temperature Error</td>
<td>Room temperature is outside the operating temperature of the device. Allow device to stabilise at adequate temperature and repeat test.</td>
</tr>
<tr>
<td>[E-2] displayed</td>
<td>Too much sample on test card</td>
<td>Repeat test with a new test card</td>
</tr>
<tr>
<td>[E-3] displayed</td>
<td>Test card not fully inserted</td>
<td>- Insert test card correctly</td>
</tr>
<tr>
<td></td>
<td>Not enough sample present</td>
<td>- Repeat test with a new test card</td>
</tr>
<tr>
<td>[E-4] displayed</td>
<td>Device Error</td>
<td>Clean device and repeat test</td>
</tr>
<tr>
<td>[E-5] displayed</td>
<td>Card Error</td>
<td>Clean device and repeat test. Do not apply sample to test card before this is inserted into device.</td>
</tr>
<tr>
<td>[E-6] displayed</td>
<td>Calibration Error</td>
<td>Contact supplier</td>
</tr>
<tr>
<td>[E-8] displayed</td>
<td>CODE Key Error</td>
<td>Contact supplier</td>
</tr>
</tbody>
</table>
5.6. **Flow Charts**

5.6.1. **Set Up**

![Flow Chart Diagram]

- Start
- Press *On/Off* button to switch device on
- Place thumb just under the test card platform tab
- Pull entire test card platform up and away from device
- Insert appropriate **CODE** Key into the opening marked with an arrow
- Wait until \([\text{CODE}], [\text{Hgb}]\) and code number are displayed to indicate that **CODE** key has been correctly inserted
- Check that displayed number corresponds with number present on test card container
- Press and hold blue **SET** button until \([\text{g/dL}]\) starts flashing
- Press **Up** and **Down** buttons to scroll between the different units of measurements available (mmol/L or g/dL)
- Line up top end of test card platform with the corresponding edges of the device
- Press down on test card platform until it snaps into place
- End
5.6.2. Operation

1. Start

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

2. Press On/Off button to switch device on.

3. Wait until flashing card symbol is displayed.

4. Slide edges of test card under guide tabs of test card holder.

5. Push test card firmly to the back.

6. Check that test card is locked firmly in place.

7. Wait until the $[^{\text{Hgb}}]$ symbol, a test card symbol, and a flashing blood drop symbol are displayed to apply blood sample.

8. Wipe first drop of blood.


10. Position drop of blood directly over centre of test card.

11. Carefully touch drop of blood to reagent pad in the central hole of test card.

12. Wait until test result countdown finishes.

13. Read result from display.
5.6.3. Maintenance

Start

Check that device is switched off before commencing with any maintenance procedures

Battery symbol displayed on switching on device

Yes

Remove test card platform

Place fingernail under front edge of battery and pull it upwards and away

Insert a new 3V (CR 2032) lithium battery

Check that positive side of battery is the visible side

No

Device automatically switched off

Press On/Off button to switch device on

Press Up button to retrieve last result

End

Display screen and/or optical area need/s cleaning

Yes

Wipe with a lint free cloth slightly moistened with water

No

Device exterior needs cleaning

Yes

Wipe with a lint free cloth slightly moistened with 70% ethanol or 10% bleach

No

Yes

End
6. Precautions

6.1. Operate the device in an ambient temperature of +16°C to +35°C.
6.2. Do not store the device in damp and humid conditions.
6.3. Do not clean the device with isopropyl alcohol or products containing isopropyl alcohol.
6.4. Do not use a different CODE key from the one supplied with the test cards.
6.5. Do not touch or reposition the device while a test is being performed since this can compromise the precision and accuracy of the test.
6.6. Be careful not to scratch the test card platform window during cleaning.
6.7. Be careful not to scratch the window of the device when cleaning it whilst the test card platform is removed.
6.8. Stanbio STAT-Site® M-Hgb Haemoglobin External Controls can be used to check that the test cards and the device are working correctly.

7. References


8. Appendices

N/A

9. Revision History

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Amendments/ Reasons for change</th>
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