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Reading Copy

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1. **Scope**

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

2. **Objective**

To describe the procedure for set-up, configuration, operation, recording and recalling of results, quality control, maintenance and troubleshooting of the Medisana® Meditouch® Blood Glucose Monitor.

3. **Definitions**

3.1. **Medisana® Meditouch® Blood Glucose Monitor**: Device intended for monitoring a person’s blood glucose at home. It is not suitable for diagnosing diabetes or for testing blood glucose in newborn babies. During a test, electrical current which is caused by the reaction of glucose (glucose oxidase) with the reagent (Aspergillus niger) of the strip is measured. The monitor measures this current and shows the corresponding blood glucose volume. The strength of the current caused by the reaction depends proportionally on the amount of glucose in the blood sample.

3.2. **Control Test**: Control solution is used to check the precision of the monitor and test strips.

3.3. **Memory Function**: A function that allows the storage of up to 360 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.

3.4. **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 Medisana® Meditouch® Blood Glucose Monitor

5.2. Set-Up

5.2.1. Open battery compartment at the back of the device by gently pressing on the panel in the direction of the arrow and insert cell battery (CR2032 lithium battery 3V). The monitor switches on automatically once the battery is inserted.
5.3. Setting Date and Time

5.3.1. The last two digits of the year flash in the display. Press \( \mathbb{D} \) to enter the value for the year and press \( \mathbb{C} \) to confirm.

5.3.2. Repeat Section 5.3.1 to enter the remaining date and time values (the order being month, day, hour and minutes).

5.4. Memory

5.4.1. Set the time and date (section 5.3) to use the memory function.

5.4.2. Switch the monitor On by pressing \( \mathbb{D} \) button for approximately 3 seconds.

5.4.3. Press \( \mathbb{C} \) to access the average value of saved test results from the past 30 days under \( \mathbb{I} \) or \( \mathbb{Q} \).

5.4.4. Press \( \mathbb{D} \) to access all saved test results one after the other in the sequence of 360 to 001 (i.e. the latest entry will be displayed first and the oldest last).

5.4.5. Press \( \mathbb{E} \) for 3 seconds to delete the test results and \( \text{del} \) will appear in the display.

5.4.6. Press \( \mathbb{D} \) to view the next entry saved. If no other button is pressed, the monitor switches off automatically after approximately 2 minutes.

5.4.7. Press \( \mathbb{C} \) to access the average value which was saved with \( \mathbb{I} \), \( \mathbb{Q} \), or \( \mathbb{C} \) test results from the past 30 days.

5.4.8. Press \( \mathbb{D} \) to display the average values of the past 7, 14, 30, 60, 90 days.

5.4.9. Press \( \mathbb{C} \) to return to the \( \mathbb{D} \) display. If no other button is pressed, the monitor switches off automatically after approximately 2 minutes.
5.5. Performing a Control Test

5.5.1. Insert a test strip into the monitor in the direction of the arrow on the test strip. The symbol \( \mathbb{1} \) appears automatically.

5.5.2. Press \( \mathbb{1} \) twice and “CtL” will appear on the display.

5.5.3. Press \( \mathbb{1} \) to confirm.

5.5.4. Place the monitor on a level surface.

5.5.5. Unscrew the cap of the control solution container and wipe the tip with a clean cloth.

5.5.6. Place a drop onto the blood sample area on the end of the test strip. A beep will sound when a sufficient amount of control solution has been absorbed by the test strip. The monitor will begin a 5 second countdown and a test result will appear on the display.

5.5.7. Check whether the result lies within the range indicated on the test strip container (5.8–7.7 mmol/L). See Section 5.7.2.1 if the reading does not lie within range.

5.6. Performing a Blood Glucose Test

5.6.1. Take a test strip from the container and close the container immediately.

5.6.2. Perform the test within 3 minutes of taking the test strip from the container. The monitor will switch on automatically on test strip insertion and the symbol \( \mathbb{1} \) appears automatically.

5.6.3. Press \( \mathbb{1} \) to set \( \mathbb{1} \) (before a meal) or \( \mathbb{2} \) (after a meal) and press \( \mathbb{1} \) to confirm.

5.6.4. Draw a drop of blood (Refer to SOP/PD/207).

5.6.5. Place a drop of blood onto the blood sample area on the test strip once the drop of blood symbol appears \( \mathbb{2} \). When a sufficient amount of blood has been absorbed by the reaction cell on the test strip a beep will sound. The blood glucose test result will appear after approximately 5 seconds.

5.6.6. Dispose the lancet (Refer to SOP/PD/201 and SOP/PD/207).

5.6.7. Remove test strip and monitor will switch off automatically.
5.7. Troubleshooting

5.7.1. General

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Err</td>
<td>Replace with a new test strip</td>
</tr>
<tr>
<td>LP</td>
<td>Low battery</td>
</tr>
<tr>
<td>00:00</td>
<td>Replace the battery, contact supplier if error occurs again</td>
</tr>
<tr>
<td>3.3 mmol/L</td>
<td>Test result is ≥ 33 mmol/L</td>
</tr>
<tr>
<td>1.1-3.3 mmol/L</td>
<td>Test result is between 1.1-3.3 mmol/L; symbol H for hypoglycaemia is shown</td>
</tr>
<tr>
<td>0.0 mmol/L</td>
<td>Test result is &lt;1.1 mmol/L</td>
</tr>
<tr>
<td>0°C-40°C</td>
<td>Temperature is too high or too low</td>
</tr>
</tbody>
</table>
5.7.2. Control Test Result

5.7.2.1. The following options will be displayed to rectify the problem if the control test result does not lie within the range indicated on the test strip container:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Has the test strip been lying around for a long time?</strong></td>
<td>Repeat the test with a test strip that has been correctly stored</td>
</tr>
<tr>
<td><strong>Was the test strip container closed properly?</strong></td>
<td>The test strips are damp; Replace test strip.</td>
</tr>
<tr>
<td><strong>Did the monitor work properly?</strong></td>
<td>Repeat control test. If problems persist, contact the supplier.</td>
</tr>
<tr>
<td><strong>Is the control solution soiled? Or has it exceeded its expiry date?</strong></td>
<td>Use new control solution to check performance of the monitor.</td>
</tr>
</tbody>
</table>

5.7 Care and Maintenance

5.7.1 Ensure that the monitor is switched off and clean the surface of the monitor with a slightly damp cloth or use an alcohol swab.
5.8 Flow Charts

5.8.1 Setting Date and Time

Start

Insert the battery

The last 2 digits of the year flash in the display; press \( \) to enter the value for the year and press \( \) to confirm

Repeat previous step to enter the remaining date and time values (order being month, day, hour and minutes)

End
5.8.2 Memory

Start

Set time and date to use the memory function

Switch the monitor On by pressing button for approximately 3 seconds

Press to access average value of saved test results from the past 30 days under or

Press to access all saved test results in the sequence of 360 to 001 (i.e. the last entry will be displayed first and the oldest last)

Press for 3 seconds to delete the test results and will appear in the display

Press to view the next saved entry; if no other button is pressed, the monitor switches off automatically after approximately 2 minutes

Press to access average value which was saved with , , , or test results from the past 30 days

Press to display the average values of the past 7, 14, 30, 60, 90 days

Press to return to the display; if no other button is pressed, the monitor switches off automatically after approximately 2 minutes

End
5.8.3 Performing a Control Test

Start

Insert test strip to switch device On

Press 🔄 twice, “CtL” appears on display

Press 🔄 to confirm

Place monitor on a level surface

Unscrew cap of the control solution container and wipe tip with a clean cloth

Place a drop onto the blood sample area on the end of the test strip

Reading is within range

No

Refer to Troubleshooting section

Yes

End
5.8.4 Performing a Blood Glucose Test

Start

Take a test strip from the container and close container immediately

Perform test within 3 minutes of taking it out of the container; monitor will switch on automatically on test strip insertion and the symbol 🖼️ appears automatically

Press 🕒 to set ⏰️ (before a meal) or 🕒 (after a meal) and press 📜 to confirm

Draw a drop of blood (Refer to SOP/PD/207)

Apply drop of blood onto the blood sample area on the end of test strip when the drop of blood symbol 🖼️ appears; when a sufficient amount of blood has been absorbed by the reaction cell on the test strip a beep will sound and blood glucose test result will appear after approximately 5 seconds

Dispose of the lancet (Refer to SOP/PD/201 + 207)

Record reading, remove test strip and monitor will switch off automatically

End
6 Precautions

6.1 Use a sterile lancet for each test.

6.2 Dispose of lancets in a sharps container.

6.3 Always use gloves.

6.4 Do not attempt to recharge the device as the battery may explode.

6.5 Do not get any blood on the top of the test strip.

7 References


8 Appendices

SOP/PD/225_01/A1 – List of Symbols

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/225_01/A1 – List of Symbols

- before meals (AC)
- after meals (PC)
- Morning, from 4:00 am to 10:00 am
- Midday, from 10:00 am to 04:00 pm
- Evening, from 04:00 pm to 10:00 pm
- Night, from 10:00 pm to 04:00 am

- Hypoglycemia (low glucose)
  1.1 - 3.3 mmol/L (20 - 60 mg/dL)

- System error
- Button for confirming/selecting
- Button for entering/selecting