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Reading Copy ......................... X
1. **Scope**

This Standard Operating Procedure (SOP) applies to the staff and students using the Tensoval® Comfort 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, calibration, maintenance and troubleshooting of the Tensoval® Comfort.

3. **Definitions**

3.1. **Diastolic Blood Pressure:** The minimum pressure in the arteries when the heart is at rest.

3.2. **M1 / M2 Buttons:** Allows the device to save separate readings for 2 different patients or circumstances.

3.3. **Memory Mode:** Allows the user to save the last 30 readings obtained together with their average value. When more than 30 readings are saved, the oldest values are deleted sequentially to allow new readings to be saved. Memory mode is divided into 2 sections i.e. M1 and M2 which can be separately accessed via the M1 and the M2 buttons respectively.

3.4. **Pulse Rate:** The number of pulsations noted in a peripheral artery per unit of time.

3.5. **Systolic Blood Pressure:** The maximum pressure being exerted when the heart is contracting.

3.6. **Tensoval® Comfort:** A non-invasive oscillometric blood pressure measuring device. The measuring ranges for systolic pressure, diastolic pressure and pulse rate are 50-250 mmHg, 40-180 mmHg and 40-160 beats/minute respectively.

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 Tensoval® Comfort

5.2. Set Up

5.2.1. Open the battery compartment lid and insert 4 AA/LR06 batteries, if using the device in battery mode.
5.2.2. Insert the plug of the mains adapter into the socket on the rear side of the device, plug the mains adapter into an electricity socket and switch it On, if using the device with electricity.
5.2.3. Wait for the year to flash in the display.
5.2.4. Use the M1 (+) button or the M2 (-) button to change the year.
5.2.5. Press the START/STOP button to save the year.
5.2.6. Repeat steps 5.2.4. and 5.2.5. to set the month, day, hour and minutes respectively.
5.3. Operation

5.3.1. Fitting the cuff

5.3.1.1. Bare the patient’s upper arm.
5.3.1.2. Thread the end of the cuff through the metal hoop so as to form a loop.
5.3.1.3. Fit the cuff around the bare upper arm.
5.3.1.4. Take the free end of the cuff and wrap it firmly around the arm, securing it with the Velcro fastener.
5.3.1.5. Check that the air tube of the cuff is lying in the centre of the angle of the elbow, pointing towards the hand.
5.3.1.6. Check that the white arrow is pointing towards the bend of the elbow.
5.3.1.7. Check that the lower edge of the cuff is approximately 2.5cm from the bend of the elbow.
5.3.1.8. Check that 2 fingers can still be inserted between the arm and the cuff.
5.3.1.9. Attach the air tube to the cuff socket on the left side of the device.
5.3.1.10. Instruct the patient to lay his or her arm on a table with palm turned upwards and to keep still during the measurement.

5.3.2. Measuring blood pressure

5.3.2.1. Press the START/STOP button.
5.3.2.2. Wait until all display segments followed by a flashing arrow pointing downwards are displayed to indicate that the device is automatically checking itself.
5.3.2.3. Wait for automatic inflation to begin at approximately 190 mmHg.
5.3.2.4. Press the START/STOP button again shortly after inflation starts until the desired cuff pressure is reached, if a higher inflation pressure is required.
5.3.2.5. Press the START/STOP button if measurement process needs to be interrupted.
5.3.2.6. Wait until a beep is heard to indicate that the measurement is complete.
5.3.2.7. Observe the systolic and diastolic readings and pulse rate on the display. Readings are automatically saved.
5.3.2.8. Press the START/STOP button to switch Off the device.
5.3.3. Recalling Memory

5.3.3.1. Press the M1 or the M2 button whilst the device is switched Off to access Memory Mode.

5.3.3.2. Observe the average value displayed with an ‘A’ adjacent to it and the number of readings from which it was calculated, at the top right hand corner.

5.3.3.3. Repeatedly press the M1 or the M2 button (according to what was pressed in step 5.3.3.1.) to scroll through the saved readings in chronological order.

5.3.3.4. Press the START/STOP button to exit Memory Mode.

5.3.4. Deleting Memory

5.3.4.1. Repeat steps 5.3.3.1. and 5.3.3.2.

5.3.4.2. Press and hold the M1 or M2 button (according to what was pressed in step 5.3.3.1.) until the display starts flashing and for an additional 8 seconds until only [M1] or [M2] is displayed.

5.3.4.3. Repeat step 5.3.3.4.

5.4. Calibration

5.4.1. Remove the batteries from the battery compartment.

5.4.2. Press and hold the START/STOP button.

5.4.3. Re-insert the batteries whilst still keeping the START/STOP button pressed.

5.4.4. Release the START/STOP button.

5.4.5. Wait for two zeros to be displayed on top of each other.

5.5. Maintenance

5.5.1. Replace batteries with a new set if the battery symbol is displayed.

5.5.2. Use a soft moistened cloth to clean the outside surface of the device.

5.5.3. Use a moist cloth and a mild cleaning agent to clean the cuff.
5.6. Troubleshooting

<table>
<thead>
<tr>
<th>Error</th>
<th>Possible Cause/s or Solution/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device does not switch On</td>
<td>No batteries inserted or inserted incorrectly or need to be changed</td>
</tr>
<tr>
<td></td>
<td>Check that mains adapter is connected correctly if powering the device with</td>
</tr>
<tr>
<td></td>
<td>electricity</td>
</tr>
<tr>
<td><img src="image1" alt="Error Icon" /></td>
<td>Patient was moving or speaking during measurement</td>
</tr>
<tr>
<td><img src="image2" alt="Error Icon" /></td>
<td>Cuff was incorrectly or loosely applied</td>
</tr>
<tr>
<td><img src="image3" alt="Error Icon" /></td>
<td>Reading needs to be repeated</td>
</tr>
<tr>
<td><img src="image4" alt="Error Icon" /></td>
<td>Pressure in cuff exceeded 330 mmHg leading to automatic release of pressure</td>
</tr>
<tr>
<td><img src="image5" alt="Error Icon" /></td>
<td>Battery life is almost finished and only a few more measurements can be taken</td>
</tr>
<tr>
<td></td>
<td>until new batteries are used</td>
</tr>
<tr>
<td><img src="image6" alt="Error Icon" /></td>
<td>Insert new batteries</td>
</tr>
<tr>
<td>Cuff does not inflate</td>
<td>Cuff connection is incorrectly positioned in device</td>
</tr>
<tr>
<td>Implausible reading displayed</td>
<td>- Incorrect cuff size</td>
</tr>
<tr>
<td></td>
<td>- Cuff placed on top of clothing</td>
</tr>
<tr>
<td></td>
<td>- Rolled up clothing impeding circulation</td>
</tr>
<tr>
<td></td>
<td>- Moving or talking during measurement.</td>
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<tr>
<td></td>
<td>- Deep breathing during measurement</td>
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<tr>
<td></td>
<td>- Lack of relaxation before measurement</td>
</tr>
<tr>
<td></td>
<td>- Stimulants taken just before measurement</td>
</tr>
</tbody>
</table>
5.7. Flow Charts

5.7.1. Set Up

Flow Chart:

- Start
  - Using device in battery mode
    - Open battery compartment lid and insert 4 AA/LR06 batteries
    - Wait for the year to flash in display
    - Use M1 (+) or M2 (-) button to change the year
      - Press START/STOP button to save the year
    - Use M1 (+) or M2 (-) button to change the month
      - Press START/STOP button to save the month
    - Use M1 (+) or M2 (-) button to change the day
      - Press START/STOP button to save the day
    - Use M1 (+) or M2 (-) button to change the hour
      - Press START/STOP button to save the hour
    - Use M1 (+) or M2 (-) button to change the minutes
      - Press START/STOP button to save the minutes
    - End

- Insert plug of mains adapter into socket on rear side of device, plug mains adapter into electricity and switch On

Yes

No
5.7.2. **Operation**

1. **Start**
   - Bare patient’s upper arm
   - Thread end of cuff through metal hoop so as to form a loop
   - Fit cuff around bare upper arm
   - Take free end of cuff and wrap it firmly around arm, securing it with the Velcro fastener
   - Check that air tube of cuff is lying in the centre of the angle of the elbow, pointing towards the hand
   - Check that white arrow is pointing towards the bend of the elbow
   - Check that lower edge of cuff is approximately 2.5cm from bend of elbow on the artery
   - Check that 2 fingers can still be inserted between arm and cuff
   - Attach air tube to cuff socket on left side of device
   - Instruct patient to lay his or her arm on table with palm turned upwards and to keep still during measurement
   - Press **START/STOP** button
   - Wait until all display segments followed by a flashing arrow pointing downwards are displayed to indicate that device is automatically checking itself

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1. Wait for automatic inflation to begin at approximately 190mmHg

2. Higher inflation pressure required
   Yes: Press START/STOP button again shortly after inflation starts until desired cuff pressure is reached
   No: Need to interrupt measurement process

3. Wait until beep is heard to indicate that measurement is complete

4. Observe systolic and diastolic readings and pulse rate on the display. Readings are automatically saved

5. Press START/STOP button to switch Off device

6. Need to recall memory
   Yes: Press M1 or M2 button whilst device is switched Off to access Memory Mode
   No: Need to delete memory

7. Observe average value displayed with an 'A' adjacent to it and the number of readings from which it was calculated at top right hand corner

8. Repeatedly press M1 or M2 button (according to what was used to enter Memory Mode) to scroll through saved readings in chronological order

9. Press START/STOP button to exit Memory Mode
Observe average value displayed with an ‘A’ adjacent to it and the number of readings from which it was calculated at top right hand corner

Press and hold M1 or M2 button (according to what was used to enter Memory Mode) until display starts flashing and for an additional 8 seconds until only [M1] or [M2] is displayed

Press START/STOP button to exit Memory Mode

End
5.7.3. Calibration

Start

Remove batteries from battery compartment

Press and hold START/STOP button

Re-insert batteries whilst still keeping START/STOP button pressed

Wait for 2 zeros to be displayed on top of each other

End

5.7.4. Maintenance

Start

Battery symbol displayed

Yes

Replace batteries with a new set

No

Need to clean outside surface of device

Yes

Use a soft moistened cloth

No

Need to clean cuff

Yes

Use moist cloth with mild cleaning agent

No

End
6. Precautions

6.1. Medical Device

6.1.1. Protect the device from temperature fluctuations, humidity, dust and sunlight.
6.1.2. Store the device in its original packaging in a suitable locked cabinet.
6.1.3. Remove any batteries before storing device to prevent any leakages from taking place.
6.1.4. Do not fold or over stretch the cuff.
6.1.5. Do not completely immerse the cuff in water when cleaning it.
6.1.6. Do not allow any fluids to enter into the air tube.
6.1.7. Do not switch on the device before the cuff has been properly fitted to the upper arm since this can be damaged by the resulting excessive pressure.
6.1.8. Check that a measurement function test is being carried out by the authorised supplier every two years.

6.2. Accurate Measurement

6.2.1. Check that the white arrow on the cuff lies within the red marking strip to ensure that the cuff size is correct (normal cuff – for upper arm circumference between 22 and 32cm and larger cuff – for upper arm circumference between 32 and 42cm).
6.2.2. Ensure that the patient is relaxed, still and not speaking when measurement is being taken.
6.2.3. Wait for 5 minutes until the pulse rate returns to normal if the patient had been active before taking measurement.
6.2.4. Ensure that the patient is sitting down and that the cuff is positioned at heart level when taking a measurement.
6.2.5. Ensure that measurements are performed on a bare arm, since circulation could be restricted.
6.2.6. Ensure that the cuff is not too tight or too loose fitting since inaccurate readings may result.
6.2.7. Ensure that the patient’s arm is kept still while wearing the cuff to avoid disruptive impulses.
6.2.8. Allow a period of about 1 minute between successive measurements in order to avoid measurement errors.
7. References

Paul Hartmann AG. Hartmann Tensoval® Comfort Instructions for use. Hartmann: Heidenheim.

8. Appendices

N/A

9. Revision History

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