1.0 POLICY

This standard operating procedure (SOP) describes the correct procedures when using the Connex® Spot Monitors for clinical research, including clinical trials, in the W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR). The spot monitors are intended to be used by qualified and trained users of the WJHCPOR for monitoring non-invasive blood pressure (NIBP), pulse rate, non-invasive functional oxygen saturation of arteriolar hemoglobin (SpO₂), and body temperature in normal and axillary modes of neonatal, pediatric and adult research participants.

2.0 PURPOSE

All users of the WJHCPOR should familiarize themselves with this SOP to ensure correct procedures when taking blood pressure, temperature, pulse oximetry, and pulse rate measurements when using the spot monitors.

3.0 RESPONSIBILITY

Users are responsible for:

- Attending orientation and training on the proper use of the spot monitors.
- Following the procedures listed in this SOP. **NOTE:** If at any time users are unsure how to operate the spot monitors safely, please refer to the instructional manual and/or ask the designated KGHRI staff member for assistance.
- Reporting any damage to the spot monitors (or accessories) to the designated KGHRI staff member immediately so equipment repairs can be made.
- Cleaning the spot monitors after each use and between research participants.
KGHRI is responsible for:

- Ensuring all spot monitors are in good repair and labelled with appropriate contact information for maintenance and repair.
- Training new users in safe usage and maintenance of the spot monitors, documenting the training of all users, and supervising use when necessary.
- Ensuring instructional manuals (see Appendix A) and quick guides (see Appendix B) are readily available to all users, if required.
- Ensuring that all the regular and periodic maintenance required for the spot monitors is carried out and recorded in the Maintenance Log. The designated KGHRI staff member will contact Kingston Health Sciences Centre (KHSC) Clinical Engineering Department when regular maintenance inspection and repairs are required.
- Ensuring the records of repair are kept and available for inspection.
- Providing appropriate cleaning supplies to users of the WJHCPOR.

4.0 PROCEDURE

Turning on/off the Spot Monitor

- Locate the power button on the left side of the spot monitor. Push and hold the power button to turn on the spot monitor. The spot monitor will beep when it turns on. The touch display will be visible when the spot monitor is on and ready for use.
- When the spot monitor is not plugged into an electrical wall power outlet, it will display “device is operating in battery mode” when the spot monitor is on. The top right hand corner displays the approximate battery operating time remaining until the spot monitor needs to be plugged in. The spot monitor does not need to be plugged into an electrical wall power outlet to be operating as long as the internal battery is charged.
- When not in use, the touch display will go into sleep mode. Touch the display screen anywhere to awake the spot monitor.
- To turn the spot monitor off, push the power button. The touch display will ask you if you want to power down the spot monitor. Touch the “power down” icon to turn the spot monitor off.
Non-Invasive Blood Pressure (NIBP) Measurement

- Select the appropriate NIBP cuff size to use from the spot monitor basket. Sizes available include child, small adult, adult, and large adult. To determine the correct cuff size, wrap the cuff around the arm of the research participant. The index line at the end of the cuff should fall within the range marked by the white range markers on the cuff.

- Connect the correct NIBP cuff to the spot monitor using the NIBP hose that is connected to the spot monitor.

- Wrap the cuff around the research participant’s arm. The research participant should be sitting and rested for five (5) minutes before the NIBP measurement is taken.

- To take a single NIBP measurement, locate the START icon under the NIBP section of the touch display to begin a single measurement. The START icon shows a person with a blood pressure cuff on their arm and can be found in the middle of the touch display. The cuff will begin to inflate on the research participant.

- The START icon becomes an orange STOP icon when the NIBP is in use. If you need to cancel a NIBP measurement once it begins, touch the STOP icon.

- The NIBP always displays the current inflation rate. When complete, the NIBP will display the completed NIBP measurement.

- The measurement will continue to be displayed until you save it (touch SAVE icon) or you start another NIBP measurement.

- NIBP measurements can be taken as single measurements or interval measurements. When the spot monitor is set up for interval measurements, a timer icon will be displayed next to the START icon under the NIBP section of the touch display. The timer icon visually counts down to the next automatic measurement.

- To take automatic NIBP measurements the spot monitor needs to be set to the “Interval” profile. To change the profile from single measurements (“Spot” profile) to automatic measurements (“Intervals” profile), touch the “Settings” icon and then touch the “Intervals” icon. Touch the “Home” icon when done to go back to main display screen and to obtain automatic NIBP measurements. To switch back to single NIBP measurements, touch the “Settings” icon, then touch the “Profiles” icon and then touch the “Spot” icon. Touch the “Home” icon when done to obtain single NIBP measurements. The default is set to single NIBP measurements.

- While users are in the Intervals profile, touch the START icon under the NIBP section of the touch display to begin an automatic NIBP measurement. The default timer is set for a measurement every 15 minutes. Users can adjust this interval as needed by touching the timer icon (next to NIBP START icon) and adjusting the time (1 to 240 minutes) between NIBP measurements. The START icon becomes an orange STOP icon when the NIBP is in use. If you need to cancel an automatic NIBP measurement once it begins, touch the STOP icon. To stop all automatic measurements, touch the timer icon and then touch “Stop Intervals”.

Version 2.0 (May 1, 2019) - 3 - SOP-SM-02
Temperature Measurement

- Remove the temperature probe from the probe well. The spot monitor will sound a tone as it enters the ready state.

- Insert the probe into a new disposable probe cover (place probe directly inside the box of probe covers) and press the probe handle down firmly to connect the probe cover to the probe. The blue button on the top of the probe should pop out when the probe cover is properly attached.

- Touch the “TEMPERATURE” icon on the right-hand side of the touch display to select the measurement site (oral, paediatric axillary or adult axillary). The temperature measurement sites are shown as pictures.

- Hold the temperature probe tip at the measurement site on the research participant. When the measurement is being obtained, the temperature frame displays the process indicator. The monitor will sound a tone (~6-15 seconds) when the final temperature is obtained.

- The temperature frame continues to display the temperature in degrees Fahrenheit and degrees Celsius even after the probe is returned to the probe well.

- Eject the disposable probe cover from the probe by pushing on the blue button on the top of the probe. Toss the used probe cover into the regular waste bin/container.

- Return the probe to the probe well.

SpO₂ and Pulse Rate Measurement

- Clean the application site where the SpO₂ sensor will be placed on the research participant using an alcohol wipe. Remove anything that could interfere with the sensor operation (i.e. nail polish).

- Connect the SpO₂ sensor to the research participant's finger. When taking a SpO₂ measurement and NIBP measurement simultaneously, ensure that the sensor and NIBP cuff are on different limbs.

- The spot monitor will display the SpO₂ and pulse rate within six (6) seconds after connecting the sensor to the research participant.

- While SpO₂ is being measured, the displayed pulse rate is acquired from the sensor. If SpO₂ is not available, the pulse rate is acquired from NIBP.
Cleaning Spot Monitor Accessories

- After each research participant use, users MUST wipe down the spot monitor unit, touch display, NIBP cuffs, SpO₂ sensor and temperature probe with Oxivir®/Accel® INTERVention wipes provided. **DO NOT** use any other cleaning products as it could damage the spot monitor. Ensure the spot monitor is off before cleaning.

- Approved cleaning agents for all Connex® Spot Monitor components include:
  - Accel® INTERVention
  - Accel® TB
  - CaviWipes
  - Clinell® Universal Wipes
  - Oxivir® TB
  - Sani-Cloth® Plus
  - Super Sani-Cloth®
  - 70 percent isopropyl alcohol solution (applied to a clean cloth)

- **DO NOT** use the following cleaning agents on the Connex® Spot Monitor:
  - Cleancide
  - Clorox HealthCare Bleach Germicidal Cleaner
  - Sani-Cloth® Bleach (not approved for cleaning the touch display)
  - Super HDQ® L10 (dilution rate of ½ oz per gallon of water (1:256) applied to a clean cloth
  - Tuffie5 Cleaning Wipes
  - Virex II (256) (dilution rate of ½ oz per gallon of water (1:256) applied to clean cloth
  - 10 percent bleach solution (.5% - 1% sodium hypochlorite) applied to a clean cloth

---

### 5.0 SOP HISTORY

<table>
<thead>
<tr>
<th>SOP Number</th>
<th>Date Issued</th>
<th>Summary of Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOP-SM-01.1</td>
<td>01-FEB-2018</td>
<td>Section added to policy for automatic NBP measurements. Policy currently only lists instructions for single NBP measurements. Spot monitor instruction manual added to policy. New appendix added to policy as “Appendix A”. Spot monitor quick guide added to policy. New appendix added to policy as “Appendix B”.</td>
</tr>
<tr>
<td>SOP-SM-02</td>
<td>01-MAY-2019</td>
<td>Bi-annual review of SOP completed. SOP header format updated. SOP version number updated. SOP effective date updated. Removed “Contacts” section from SOP. Updated section number for “SOP History”. Under Section 4.0, under “Non-Invasive Blood Pressure (NIBP) Measurement”, under bullet 1, a typo correction was made: inserted “.” after first sentence. Under Section 4.0, under “Cleaning Spot Monitor Accessories”, under bullet 1, changed</td>
</tr>
</tbody>
</table>

Version 2.0 (May 1, 2019) - 5 - SOP-SM-02
<table>
<thead>
<tr>
<th>Spot Monitors SOP-SM-02</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Oxivir®&quot; to &quot;Oxivir®/Accel® INTERVention&quot;. Under Section 4.0, under “Cleaning Spot Monitor Accessories”, under bullet 2, under sub-bullet 1 changed “Accel INTERVention” to “Accel® INTERVention”. Under Section 4.0, under “Cleaning Spot Monitor Accessories”, under bullet 2, under sub-bullet 2 changed Accel TB to “Accel® TB”. Under Section 4.0, under “Cleaning Spot Monitor Accessories”, under bullet 2, under sub-bullet 5 changed Oxiver TB to “Oxivir® TB”. Updated “SOP History” section. No updates needed for Appendix A and B.</td>
</tr>
</tbody>
</table>