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Cardiac Monitors</td></tr>
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1.0   POLICY

All users of the Philips IntelliVue MP5 Patient Monitors ("cardiac monitors") in the W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR) are required to undergo hands-on training prior to using the cardiac monitors. Trained personnel **MUST** be the only staff to use cardiac monitors and be able to respond to alarms and emergencies when working with research participants. Only trained personnel **MUST** interpret ECG findings. Cardiac monitoring as part of any clinical research project or clinical trial is under the medical supervision/oversight of the principal investigator at **ALL** times.

2.0   PURPOSE

To standardize the training required when research participants are undergoing cardiac monitoring in the Clinical Investigation Unit located within the WJHCPOR.

3.0   RESPONSIBILITY

Users are responsible for:

- Completing the Cardiac Monitor course and participating in hands-on training.

- Operating and maintaining all cardiac monitors in accordance with manufacturer's instructions for safe usage and professional best practice procedures.

- Reporting any damage to the cardiac monitors to the designated Kingston General Health Research Institute (KGHRI) staff member **immediately** so equipment repairs can be made.

- Wearing appropriate personal protective equipment when using the cardiac monitors (i.e. disposable gloves when applying electrodes).

- Disposing all regular, biohazardous, sharps and drug waste in the appropriate bins/containers. See Disposal of Biohazardous and Sharps Waste SOP.

KGHRI is responsible for:

- Ensuring all cardiac monitors are in good working condition and labelled with appropriate contact information for maintenance and repair.

- Ensuring default settings for adult, paediatric, and neonate populations are available and adjustable, if needed.

- Ensuring copies of cardiac monitor instructions (see Appendix A) and quick guides (see Appendix B) are readily available to all users.

- Contacting KHSC's Clinical Engineering to arrange for routine inspections and/or repair of all cardiac monitors.

- Ensuring that all routine inspection for regular maintenance is carried out and documented in the Maintenance Log and available for inspection.

- Ensuring all records of repair are kept and available for inspection.

- Providing appropriate personal protective equipment (PPE) for users (i.e. disposable gloves) and other supplies for preparing and monitoring research participants (i.e. razors, gauze, alcohol wipes, electrocardiogram (ECG) electrodes, ECG paper).

- Providing users with the appropriate regular, biohazardous, sharps and drug waste bins/containers in designated areas within WJHCPOR and/or KHSC's Pharmacy Services (Connell 0).

4.0   PROCEDURE

➢ Cardiac monitors **MUST** be mounted onto stands when in use.

➢ Cardiac monitors **MUST** remain in the Clinical Investigation Unit and should not be moved to other areas within the WJHCPOR.

➢ When using the cardiac monitors, whether for daytime and/or overnight stays of research participants, at least two users (one research nurse and one other research team member), possessing the following minimum qualifications, **MUST** be present at all times in the Clinical Investigation Unit in order to monitor research participants' safety:

   ▪ One user must be (a) certified in advanced cardiovascular life support (ACLS), (b) able to activate a KHSC emergency response plan (i.e. CODE 99), and (c) competent in basic first aid.

   ▪ A second user must be (a) certified in basic life support (BLS), and (b) able to activate a KHSC emergency response plan (i.e. CODE 99).

➢ The principal investigator (clinician) **MUST** be accessible (located in KHSC-KGH site) and readily available at all times when a research participant is undergoing cardiac monitoring as part of a clinical research project or clinical trial in the Clinical Investigation Unit within the WJHCPOR. If the principal investigator is not available, arrangements must be made in advance by the principal investigator for a co-investigator (clinician only) to be made available as the delegate for oversight.

➢ **Turning ON/OFF the Cardiac Monitor**

- Locate the power button on the bottom left-hand side of the cardiac monitor. Push the power button for one (1) second to turn on the cardiac monitor. A red LED light appears beside the power button and then the light turns green. The cardiac monitor will beep and the touch display screen will illuminate when the cardiac monitor is on and ready for use.

- When the cardiac monitor is not plugged into an electrical wall power outlet, it will operate in "battery mode" when the cardiac monitor is on. When fully charged the cardiac monitor has nine (9) hours of battery life. To determine how much battery life is left when the cardiac monitor is unplugged, click on the "Main Setup" button on the bottom right-hand corner of the display screen. The "Main Setup" window will pop up and be displayed. Scroll down the "Main Set-up" screen to "Battery". When you touch "Battery", the battery status will displays the approximate battery operating time remaining (hours and minutes) until the cardiac monitor needs to be plugged in. The cardiac monitor does not need to be plugged into an electrical wall power outlet to be operating as long as the internal battery is charged.

- To turn the cardiac monitor off, push the power button for one (1) second. The touch display will automatically power down.

➢ **Navigating the Top Bar for General Set Up**

- By clicking on the top bar of the cardiac monitor display panel the monitor "Setup" window will pop up and be displayed. Scroll down the list until you find the setting that you want to review or adjust. When you touch the setting that you want to review, a new window will pop up with information. The settings include the following: Alarm Messages, Alarm Limits, Alarm Volumes, Change Screen, Profiles, Patient Demographics, Equipment, Network, and Date/Time.

- To close down a window, click on the "X" at the top right-hand corner of the window.

➢ **Navigating the Bottom Bar for Shortcuts**

▪ The bottom bar displays a number of shortcut icons. The shortcuts are from left to right on the display screen:

o Silence: to silence an alarm until the next alarm occurs.

o Pause Alarms: to turn off completely all alarms for two (2) minutes. During this time, no alarms will go off when parameters reach outside default or programed limits.

o Start/Stop: to start/stop a non-invasive blood pressure (NBP) measurement.

o Stop All: to stop all automatic measurements.

o Delayed Record: to start a delayed recording.

o Vitals Trend: to review vital signs trend.

o Profiles: to enter the profile menu to choose a default profile setting: research adult setting, research paediatric setting, or research neonatal setting.

o End Case: to discharge a research participant if a research participant's profile data was entered. All research participant data entered into the cardiac monitor is automatically deleted when the unit is turned off.

o Main Setup: allows you to enter into main set-up menu.

o Main Screen: closes all open menus and windows and returns you to the main screen.

➢ **Alarms**

▪ When the alarm is flashing blue, this is an indication of a technical issue (i.e. battery low, wires, sensors, or cuffs not connected). At the top left-hand corner of the display screen a message will be displayed (i.e. "Resp Leads Off", "SpO_2 Sensor Off", "ECG Leads Off").

▪ When the alarm is flashing yellow, this is an indication that parameters are outside the limits (i.e. elevated blood pressure, non-lethal arrhythmias).

▪ When the alarm is flashing red, this is an indication that parameters are significantly elevated outside the limits and intervention is required immediately. The alarm will flash red for the following seven (7) conditions: ventricular fibrillation, ventricular tachycardia, asystole, extreme desaturation, apnea, extreme tachycardia, and extreme bradycardia. When the alarm is flashing red, ECG recordings will automatically print off.

- An alarm message text also appears in the alarm status area at the top of the display screen indicating the source of the alarm. If more than one measurement is in an alarm condition, the message changes every two seconds, and has an arrow (↑) at the side.

- An audible alarm can also be heard. To adjust the alarm volume, touch the "Alarm Volume" icon at the top right-hand of the display screen and select the required volume by scrolling through list.

- To silence an alarm push the "Silence" icon at the bottom left-hand corner. During "Silence" mode, the cardiac monitor is still functioning with alarm sensing capability. An alarm will go off if an outside parameter is detected again when the "Silence" icon is engaged. To return to hearing the alarms, push the "Silence" icon again.

- To pause an alarm(s) push the "Pause Alarms" icon at the bottom left-hand corner. When "Pause Alarms" mode is used, the cardiac monitor will have no alarm capability for 2 minutes. A red light will appear at the top of the cardiac monitor letting you know that the alarm function has been turned off. To return to alarm capability, push the "Pause Alarms" icon again.

> **Admitting and Discharging Research Participants**

- Users are able to enter research participant demographic data into the cardiac monitor prior to use. When you select "New Patient" the display screen is freed up. All settings are automatically reset to defaults and all research participant data and trend data is deleted from the previous participant.   After selecting "New Patient", users can admit their new research participant.

- On the display screen, select the information line at the top of the display screen (top bar) to open the "Patient Demographics" window. Select "Admit Patient". The "Enter Demographics" window will appear. Enter your research participant data in each field. Fields include: last name (*alternatively you can enter only a participant ID number under this field*), first name, middle name, patient category (adult, paediatric, neonatal), height, weight, date of birth, gender, etc.

- When admission is complete, the research participant's name (or participant ID) appears on the display screen information line at the top of the display screen together with the symbol indicating the patient category. To change a research participant's data at any time, select the information line at the top of the display screen to open the "Patient Demographics" window to make edits.

- Once a research participant has been admitted, research participant data will be continuously recorded and stored for a window up to 48 hours. After 48 hours, the data will start recording over the oldest data so that a 48 hour window will always be recorded and stored.

- Up to 20 profiles can be created and stored at one time.

- To discharge a research participant, select the information line at the top of the display screen to open the "Patient Demographics" window. Select "Discharge Patient" to discharge your research participant without printing any reports or select "End Case" to print any configured end case reports or vital signs recording, to discharge your research participant and to clear the research participant database. Alternatively you can use the "End Case" shortcut icon located in the bottom bar on the display screen. This will also open up the "Patient Demographics" window.

- Discharging a research participant clears the research participant demographics, erases all research participant measurement data (such as trend, event, and calculation data) from the cardiac monitor so that data is not mixed up between research participants, and resets the research participant profile to the default settings.
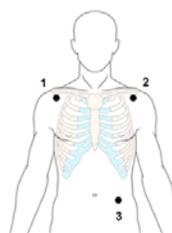
> **Attaching the Research Participant to the Cardiac Monitor**

- ECG Readings:

  o The ECG cable is by default plugged into the ECG connector that is connected to the cardiac monitor in the "ECG Resp" location (left side of cardiac monitor).

  o Users need to perform skin preparation on their research participants wearing PPE. If needed use a razor to shave the area where the ECG electrodes will be applied to the participant's torso. Wipe the skin with an alcohol wipe and let area dry. Attach disposable ECG electrodes in designed location on the research participant's torso depending on the Leads that you want to view. See Figure 1 below.

  o Connect ECG lead cables to the ECG electrodes. They will snap on when secure. Lead cables available include the following: left leg "LL" (red electrode), right leg "RL" (green electrode), left arm "LA" (black electrode), right arm "RA" (white electrode), and V1 (brown electrode).

  o When using 3-lead electrode placement, Leads I, II and III are available to view. When using 5-lead electrode placement, Leads I, II, III, aVR, aVL, aVF, V, MCI and Va are available to view. **PLEASE NOTE:** *the cardiac monitors do not allow for a 10-lead electrode set placement. You will not be able to see or print off a 12-Lead ECG (Leads I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 and V6). Users will have to bring along their own portable ECG machines or use the ECG machines located in the WJHCPOR for 12-lead ECGs, if required for their study.*

  o To review the ECG set up, touch the green "HR" icon on the display screen located in the top right-hand of the screen. It is important to set the paced mode correctly when you start monitoring ECG. Pace pulse rejection must be switched on for paced research participants. Select "Paced Mode" to "On". This means that pacemaker pulses are not counted as extra QRS

complexes. The paced symbol is displayed next to the HR numeric. Pace pulse marks (spikes) are shown on the ECG wave as a small dash.
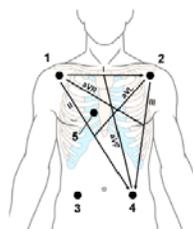
o

o   To review the Lead set-up, touch the green "II" icon on the display screen located in the top left-hand of the screen. The cardiac monitor uses the primary and secondary lead to compute heart rate (HR) and to analyze and detect cardiac arrhythmias. The primary and secondary leads are also available for recordings and for display on the screen.

o   To review the Respiration Rate (wave) set-up, touch the green "Resp" icon on the display screen located in the middle left-hand of the screen. The Resp measurement is displayed on the monitor as a continuous wave and a numeric respiration rate (RR). If the detected respiration rate is close to the HR (pulse rate), this is indicated by the text HR = RR next to the respiration wave if you are in the manual monitoring mode.

o   To review the numeric Respiration Rate (numeric number) set-up, touch the green "RR" icon on the display screen located in the middle left-hand of the screen.

o   To review the ST Analysis set-up, touch the green "ST-II" icon on the display screen located in the middle right-hand of the screen.

o   For all settings above, a window will pop up with the default settings where you can scroll up/down through the settings and make temporary adjustments to any of the settings. Once you turn off the cardiac monitor, the default settings return the next time you turn on the cardiac monitor.

o   To see the default ECG, Lead, Respiration Rate (wave), Respiration Rate (numeric number), and ST Analysis settings programmed for adult, paediatric, and neonatal research participants, please see Appendix C.

Figure 1: ECG Lead Placement

- o To close down a window when viewing any of the settings, click on the "X" at the top right-hand corner of the window.

- ▪ SpO₂ Reading

  - o The SpO₂ sensor is by default plugged into the SpO₂ connector that is connected to the cardiac monitor in the "SpO₂" location (left side of cardiac monitor). The cardiac monitor has two (2) SpO₂ sensors: adult and paediatric/infant. Please ensure that the correct SpO₂ sensor is connected prior to use. The paediatric/infant SpO₂ sensor also has adhesive sensor wraps to use with the paediatric/infant SpO₂ sensor. These accessories are stored in the cardiac monitor stand's basket.

  - o 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).

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

  - o The cardiac monitor will display the SpO₂, plethysmograph (wave), and pulse rate within 5-10 seconds after connecting the sensor to the research participant, if connected properly.

  - o 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 NBP and will be displayed next to NBP reading.

  - o To review the SpO₂ set up, touch the blue "SpO₂" icon on the display screen located in the middle right-hand of the screen.

  - o To review the pulse (SpO₂) set up, touch the blue "Pulse" icon on the display screen located in the top right-hand of the screen.

  - o To review the Wave (Plethysmograph) set up, touch the blue "Pleth" icon on the display screen located in the middle left-hand of the screen.

  - o For all settings above, a window will pop up with the default settings where you can scroll up/down through the settings and make temporary adjustments to any of the settings. Once you turn off the cardiac monitor, the default settings return the next time you turn on the cardiac monitor.

  - o To see default SpO₂, Wave, and Pulse (SpO₂) settings for adult, paediatric, and neonatal research participants, please see Appendix C.

  - o To close down a window when viewing any of the settings, click on the "X" at the top right-hand corner of the window.

- NBP Reading

  o The NBP connector cable is by default connected to the cardiac monitor in the "NBP" location (left side of cardiac monitor).

  o Select the appropriate NBP cuff size to use from the cardiac monitor basket. Sizes available include infant (10.0-15.0 cm), paediatric (14.0-21.5 cm), small adult (20.5-28.0 cm), adult (27.0-35.0 cm), large adult (34.0-43.0 cm), and thigh (42.0-54.0 cm).

  o To determine the correct cuff size for an arm NBP reading, 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.

  o Connect the correct NBP cuff to the cardiac monitor by attaching the NBP hose attached to the NBP cuff to the NBP connector cable. To remove the NBP cuff, release the NBP connector cable from the NBP hose. All NBP cuffs should be placed back into the cardiac monitor basket when not in use.

  o Locate the "Start/Stop" icon on the bottom bar of the cardiac monitor display monitor. Touch the Start/Stop icon to begin a single measurement. The Start/Stop icon shows a person with a blood pressure cuff on their arm. The cuff will begin to inflate on the research participant.

  o If you need to cancel a NBP measurement once it begins, touch the Start/Stop icon or the "Stop All" icon.

  o The measurement will continue to be displayed until starting another NBP measurement. The measurement will display systolic blood pressure (SBP) over diastolic blood pressure (DBP) and will provide a respiratory (pulse) rate.

  o To review the NBP set up, touch the "NBP" icon on the display screen located in the bottom left-hand of the screen.

  o For all settings above, a window will pop up with the default settings where you can scroll up/down through the settings and make temporary adjustments to any of the settings.

  o To see default NBP settings for adult, paediatric, and neonatal research participants, please see Appendix C.

      ❖ NBP readings are set as a default to be taken manually.

      ❖ To change the setting temporarily to record NBP measurements continuously, touch the "NBP" icon on the display screen located in the bottom left-hand of the screen. A window will pop up with the default setting where you can scroll up/down through the settings. Scroll down the list until you find "Mode". When you touch "Mode",

another window will pop up with three settings: manual, auto and sequence.

❖ When you choose "Manual" setting, NBP measurements are only taken once. Each time you require a NBP measurement from a research participant, you will need to touch "Start/Stop" icon within the bottom bar.

❖ When you choose "Auto", NBP measurements are taken at defined frequencies (i.e. every 10 minutes). In the "Auto" setting you can change the frequency of NBP measurements. Once you have chosen "Auto" as your setting, scroll up/down in the NBP set-up to find "Repeat Time" icon. When you touch "Repeat Time", you can choose a frequency (range includes every 1 minute up to every 24 hours). NBP measurements are taken continuously at the frequency you have selected indefinitely.

❖ In the "Sequence" setting you can define the frequency of NBP measurements and the number of measurements (i.e. NBP measurement taken every 5 minutes for four (4) times). In this example, continuous NBP measurements are taken every 5 minutes and the NBP measurement will stop after the fourth NBP measurement has occurred.

o To close down a window when viewing any of the settings, click on the "X" at the top right-hand corner of the window.

➢ **Printing off Recordings**

▪ To print off a recording observed, select the "Delayed Record" shortcut icon in the bottom bar of the cardiac monitor. The default setting for recording data captures data from 10 seconds prior to hitting the shortcut icon to 20 seconds after hitting the shortcut icon.

▪ When the alarm is flashing red, ECG recordings will automatically print off. The default setting for recording data for red alarms captures data from 15 seconds prior to hitting the shortcut icon to 20 seconds after hitting the shortcut icon.

➢ **Reloading ECG Paper**

▪ Press the latch on the right side of the recorder door to open the door.

▪ Remove the empty core.

▪ Insert a new roll and secure it in place on the paper holder. The paper feeds from the bottom of the roll and over the top of the recorder door.

▪ With at least one inch of paper extending beyond the edge of the door, swing the recorder door up and push it firmly closed. See Figure 2 below.
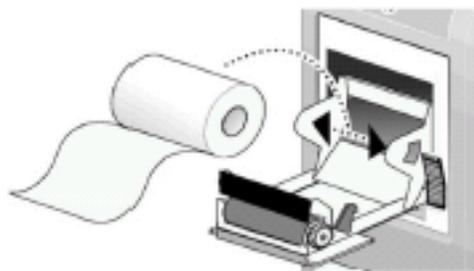
Figure 2: Replacing Paper

➤ **Cleaning Cardiac Monitor Accessories**

▪ After each research participant use, users **MUST** wipe down the cardiac monitor, touch display, NBP cuffs, SpO_2 sensor(s) and ECG cables with Oxivir®/Accel® INTERVention wipes provided. **DO NOT** use any other cleaning products as it could damage the cardiac monitor. Ensure the cardiac monitor is off before cleaning.

5.0   SOP HISTORY

SOP Number	Date Issued	Summary of Revisions
SOP-CM-01	01-FEB-2018	Original version.
SOP-CM-02	01-MAY-2019	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". Added "gauze" to Section 3.0, under "KGHRI Responsibilities", under bullet 7. Under Section 4.0 added new sentence "If the principal investigator is not available, arrangements must be made in advance by the principal investigator for a co-investigator (clinician only) to be made available as the delegate for oversight" to bullet 4 at the end of the last sentence. Added "or use the ECG machines located in the WJHCPOR" to Section 4.0, under "Attaching the Research Participant to the Cardiac Monitor", under "ECG Readings", under bullet 4. Under Section 4.0, under "Cleaning Cardiac Monitor Accessories", under bullet 1, replaced "*Oxivir®*" with "*Oxivir®/Accel® INTERVention*". Updated "SOP History" section. No updates needed to Appendix A, B or C.