	Title:	**Pulse Rate and Blood Pressure Measurement**	
	Version Date:	2017-FEB-15	**Document Number:** SOP_DCS_0008
	Effective Date:	2017-MAY-15	
Data Collection Site (DCS)	**Version:**	2.4	**Number of Pages:** 5

1.0 Purpose:
The purpose of this document is to describe the standardized procedure for taking the blood pressure and pulse rate of a participant.

2.0 Scope:
This document is to be used by the DCS staff when measuring pulse rate and blood pressure of a study participant.

3.0 Responsibilities:
It is the responsibility of the DCS staff to perform the procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:
- **SOP_DCS_0039** – BpTRU Machine SOP – Calibration and Maintenance

5.0 Definitions:
Not applicable

6.0 Equipment:
- VSM BpTRU blood pressure machine; and,

- Blood pressure cuff(s).

7.0 Supplies:
Not applicable

8.0 Procedure Steps:
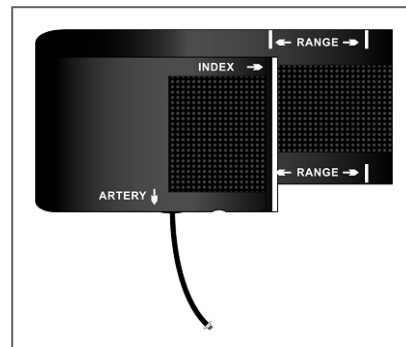**Contraindications:**
The following conditions in both arms:
- Blood pressure cuff too large or too small (to be noted);

- Cast (Contraindications questionnaire);

- Amputation (surgery) (Contraindications questionnaire);

- Open sores or wounds (Contraindications questionnaire);

- Anteriovenous shunt (surgery) (Contraindications questionnaire); and,

- Surgery of the arm, chest or breast in the last 3 months (Contraindications questionnaire).

NOTE: The default is to conduct this measurement on the *left* arm, unless the left arm is affected by one or more of the contraindications listed above (if so, then use the right arm unless it is affected by at least one contraindication as well).

Ensure that the workstation is free of excessive noise or distraction.

Step 1: At the *Interview Tab* in Onyx, look for Blood Pressure in the list of stages. Then select **Start** in that row.

Step 2: The "Blood Pressure: Start" window will pop up.

Step 3: Scan or enter the Interview ID barcode, then click on **Continue**.

Step 4: Make sure the participant is seated upright in the chair (not slouched) with both feet resting flat on the floor and legs and ankles uncrossed. The forearms should be resting flat on the armrests of the chair or a table.

Step 5: Explain to the participant what to expect. The following script is suggested:
"I'm going to record your blood pressure and resting pulse rate. I would like you to sit with both feet on the floor and your arms resting on the armrests of the chair or on the table. The instrument will measure your blood pressure 6 times in a row, and then provide a pulse rate. Once it starts, it will take about 8 minutes to finish all of the measurements. It is important for you to try to stay quiet, relaxed and still throughout the entire procedure."

Step 6: Ask the participant to remove any excess layers of clothing s/he is wearing. Ask the participant to roll up his/her sleeve to expose the arm. If the sleeve is too tight, take the measurement over one layer of clothing.

Step 7: Ensure the participant's arm is comfortably supported at a 10-45° angle from the torso.

Step 8: Select "Arm to be used for measurement" (Left or Right). The default will be the **Left** arm. Select an appropriate size of cuff, and indicate which "Armband size used" from the drop-down menu in Onyx. Click **Next**.
- Small adult 18-26 cm

- Medium (Regular) adult 26-34 cm

- Large adult 32-43 cm

- Extra-large adult 41-52 cm

Step 9: Align the artery indicator on the cuff over the brachial artery of the participant's arm (lower edge of the cuff 2 – 3 cm above the natural crease of the elbow). Wrap the cuff around the arm and check that the white index marking on the edge of the cuff falls within the white range markings on the inside surface of the cuff. If the index does not fall within the range markers, replace the cuff with a smaller or larger cuff, as indicated.

Step 10: Do not wrap the cuff too tightly around the arm. You should be able to insert two finger(s) between the cuff and the arm. If more than one/two finger(s) can be inserted, remove the cuff and reapply. The cuff should be snug but not tight.
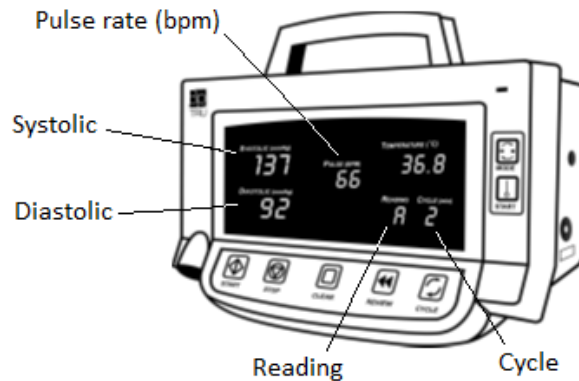
Step 11: Press **Next** and then press **Start** in the Instrument application launch to open the VSM BpTRU pop-up window. (See picture below step 16)

> **NOTE:** If the **VSM BpTRU pop-up** window doesn't appear in Onyx, unplug the internet cord from the VSM BpTRU and plug it back in

Check VSM BpTRU pop-up window: State=Ready, Firmware=1.90 and Cycle=1
Step 12: Press the **Clear** button on the VSM BpTRU to ensure that any previous measurements are cleared from the memory.

Step 13: Verify that the Cycle display shows "1"; if not, press the **Cycle** button until the Cycle time shows "1".
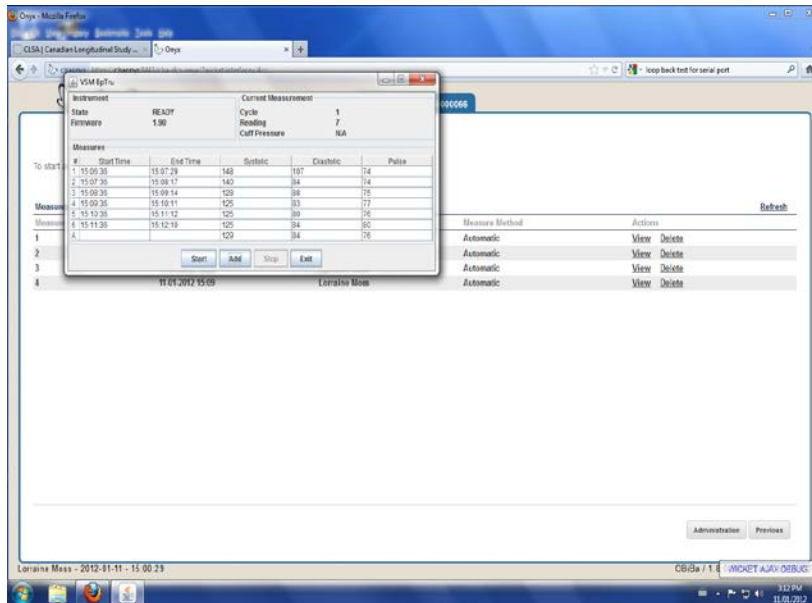

Step 14: Remind the participant to remain still during the readings, while the interviewer is out of the room. Do not speak to the participant while the cuff is inflating or deflating. Initiate the series of measurements by pressing the **Start** button in the VSM BpTRU pop-up window. Staff may leave the room and close the door once they have started the measurements. Turn off the computer monitor or shift the monitor so that the participant cannot see the blood pressure values. Staff should return approximately 6-8 minutes later.

Measurements are shown in Onyx as they are recorded by VSM BpTRU.

Step 15: If the participant's average blood pressure is above 200/120, they are contraindicated for the Spirometry measurement, and it should not be performed.

Step 16: The VSM BpTRU performs the following actions at the end of six measurements:
- The results of the last measurement are displayed for five seconds, while the Reading display shows '6'.

- After five seconds, the average of the last five Systolic, Diastolic and Pulse (pulse rate) measurements is shown in the respective display, while the Reading display shows 'A' (for average).

- If an error code is displayed for any measurement, that measurement is not included in the average.

- When complete the machine will beep.

NOTE:

- The VSM BpTRU will only send valid readings to Onyx. If you need to take additional readings, you have to click on the button in the interface on the Desktop and then perform the steps on that interface (Steps 7-16, modified). This will take an additional reading and send it to Onyx if it is valid.

- If you need to skip the remaining measurements (due to participant request or because you have enough after the previous step), then you close the desktop interface and activate the checkbox in Onyx and comment on why you are skipping the remaining measures. Then simply proceed as you normally would.

- Sometimes the VSM BpTRU connection may fail and cause a trial to list as failed, or the participant may cough, also causing a mistrial. If you need to, you can click the **Add** button on the popup applet that runs the VSM BpTRU device to make the device execute another measurement for the applet to capture.

Step 17: Remove the cuff from the participant's arm.

Step 18: Exit the VSM BpTRU pop-up window by pressing **Exit.** This will open a window showing the results from the second to fifth measurements and the average in Onyx. Click **Refresh** if 5 measurements do not appear in Onyx. Then Click on **Next.**

Step 19: The conclusion screen will appear indicating that you have completed the measurements; first systolic, first diastolic and then measurement 1 to 5 etc.

Step 20: Click **Finish**. The "Blood Pressure: Finish" window will pop up.

Step 21: Indicate in the comment field in Onyx if there was anything that may have affected or influenced the measurement. Ensure that comments do not contain any personally identifying information.

Step 22: Click **Continue** to return to the status page.

9.0 Documentation and Forms:

- **CRF_DCS_0008** - Pulse Rate & Blood Pressure CRF

10.0 References:

- BpTRU Operator's Manual. Manual revision 6.1. BpTRU Medical Devices: a Division of 0764509 B.C. Ltd.; 2007.

F1 Revision History:

New Version #	Revision Date	Revision Author	Content Approval
2.4	2017-FEB-15	Lorraine Moss	Mark Oremus
Summary of Revisions			
Updated formatting.			
New Version #	Revision Date	Revision Author	Content Approval
2.3	2016-APR-13	Lorraine Moss	Mark Oremus
Summary of Revisions			
'Heart rate' changed to 'pulse rate' throughout document.			