PERFORM Operating Document

Use and Cleaning of Ultima™ CardiO2 Metabolic Systems – Exercise Testing

PC-POD-CP-004-v02

Revision History

Version	Reason for Revision	Date
02	Minor modifications made including update of definitions and update of relevant documents.	August/11/2016

Summary

The content of this POD provides guidelines for the safe use and cleaning of the Ultima™ CardiO$_2$ metabolic systems as identified as equipment inventory at the PERFORM Center, Concordia University.

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1. Definition of Terms

Standard operating procedure (SOP)	SOP's at PERFORM are any operating document that require a full review process and approval by the scientific director.
PERFORM operating document (POD)	Operating documents that are specific to an instrument or technique that require approval by area managers.
Supervisor	Knowledgeable person regarding all or an aspect of a project or program and is familiar with PERFORM's best practices, that is responsible for ensuring that users conduct their activities in a safe manner and within scope of the project.
User	Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.
Exercise Testing	Any clinical method used to evaluate a person's cardiovascular responsiveness (i.e., exercise tolerance)

2. Relevant Documents

This POD is governed by the following Concordia University policies, SOPs, and PODs:
- Ultima^{TM} CardiO2 User Manual.
- PC-SOP-GA-007 "General Access to PERFORM Centre".
- PC-SOP-GA-009 "Emergency Response Procedures at the PERFORM Centre".
- PC-SOP-GA-011 "Guidelines for Management of Incidental Findings at PERFORM".
- PC-POD-GA-001 "PERFORM Centre Booking System for Facilities and Equipment".
- PC-POD-CP-002 "Use and Cleaning Procedures for Manual and Automatic Aneroid Sphygmomanometers".
- PC-POD-CP-001 "Disinfection and Maintenance of Flow Sensor, Mouthpiece, and Patient Circuit".

3. Introduction

3.1 Background

A metabolic cart is a metabolic stress-testing system, which integrates gas-exchange technology (Ultima™ CardiO$_2$), ECG software (Mortara®), a blood pressure machine (SunTech® Tango+), a unit to measure oxygen saturation (Nonin®), as well as a weather station (Vantage VUE™). This system is used to acquire continuous data on a breath-by-breath basis, wireless ECG tracings, and oxygen saturation during rest and exercise. Furthermore, intermittent blood pressure readings can be obtained.

3.2 Purpose

The objectives of the current POD, specific to exercise testing, are to 1) outline the procedure of using the Ultima^{TM} CardiO$_2$ metabolic systems; 2) provide a set of standard practices for the safe operation and training guide for new users of the systems at the PERFORM Centre, Concordia University; and 3) outline the procedure of cleaning/disinfecting of flow sensors and mouthpieces.

3.3 Scope

This POD applies to all users and supervisors using the metabolic carts at the PERFORM Centre, Concordia University. Any other document other than this POD is out of scope for this operating procedure.

3.4 Responsibility

It is the responsibility of all users and supervisors to ensure that this POD is followed.

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4. Main Components of Ultima™ CardiO$_2$ Metabolic System

4.1 **Ultima™ module** – unit which measures breath-by-breath data.

4.2 **SunTech® Tango+** - automatic blood pressure system.

4.3 **Nonin®** - oxygen saturation system.

4.4 **Vantage VUE™** - wireless weather station console.

4.5 **Calibration and Reference Gases** - used for gas calibration.

4.6 **Computer with 2 screens** - used to visualize data.

4.7 **BreezeSuite™ software** – main software used to run metabolic system.

4.8 **Mortara® ECG software** – software used to measure electrical activity of the heart.

5. Opening Metabolic Systems and BreezeSuite™ Software

5.1 Turn on switch behind cart on box called "OneAC".

NOTE: If computer does turn on automatically power on manually by opening door labelled Medgraphics at bottom of cart.

5.2 Wait 30 minutes for system to warm-up. Wait for amber light on Ultima™ to turn green.

5.3 Login to computer using Concordia netname and password.

5.4 Book the station online if not already done prior.
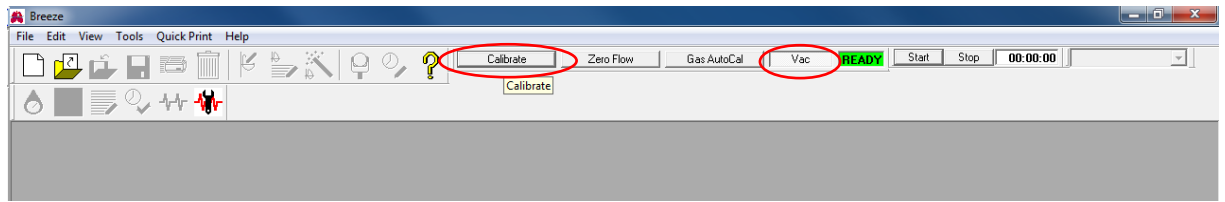
5.5 Click on BreezeSuite™ icon to open software.

NOTE: Please note that screen shots included in this POD are taken from BreezeSuite™ software version 7.1.

6. Calibrations

6.1 *Volume calibration*

6.1.1 The window below will be shown on the screen. Click "Vac" to warm-up vacuum for 2 minutes. Will say "READY" when 2 minutes has elapsed. Then, click "Calibrate".

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Figure 1.

6.1.2 In "Pneumotach" tab, make sure that under "Syringe Volume (L)" it is written 3. If not already written 3 use arrows to adjust. Compare values of "Room Temperature", Barometric Pressure", and "Relative Humidity" found at bottom left of window against values on Davis Weather Station. Adjust if needed.

Figure 2.
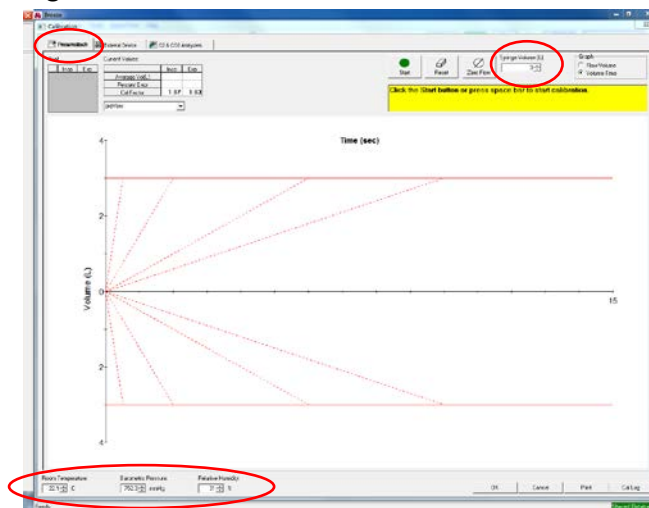
6.1.3 While wearing gloves, place flow sensor in 3L syringe with honeycomb end facing inward. Connect umbilical clip to flow sensor with smooth part of umbilical cable facing honeycomb end of flow sensor and with umbilical cable facing upwards.

Figure 3.

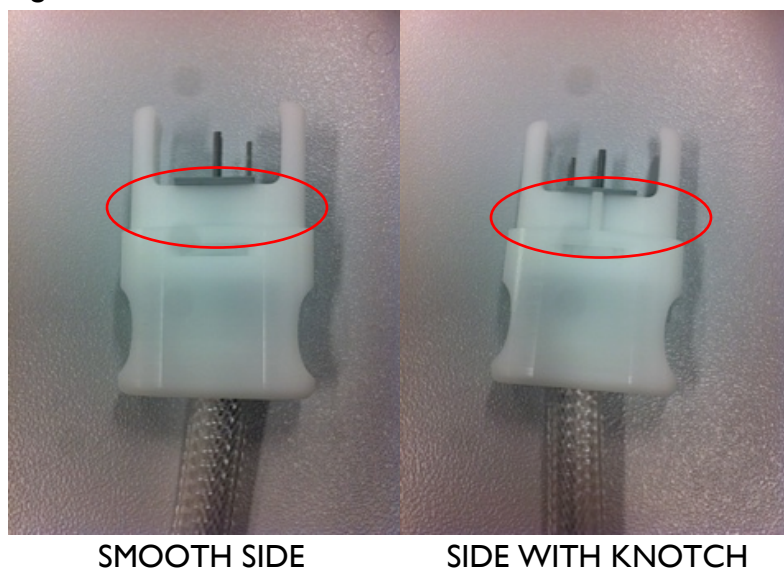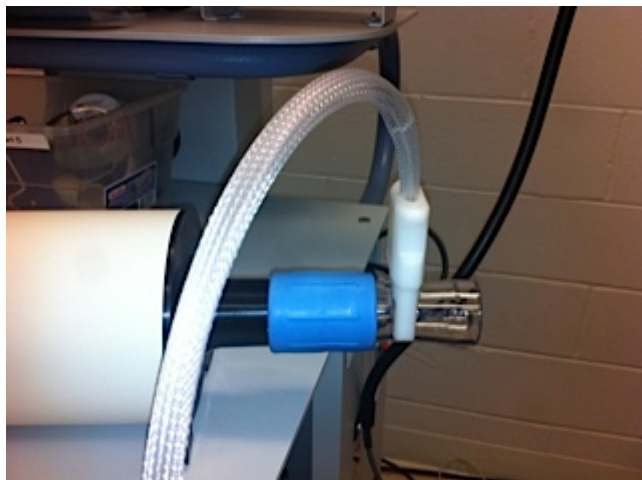SMOOTH SIDE   SIDE WITH KNOTCH

Figure 4.

**6.1.4** Click "Zero Flow". Then, click "Start" or space bar to begin volume calibration. Wait for the message "WITHDRAW" to appear at the bottom of the graph to retract the lever from the 3L syringe. Wait for the message "INJECT" to appear above the graph to push in the lever into the 3L syringe. Use red dotted lines as a guide for flow rates. Try to obtain a spread of different volumes over time.

Figure 5.
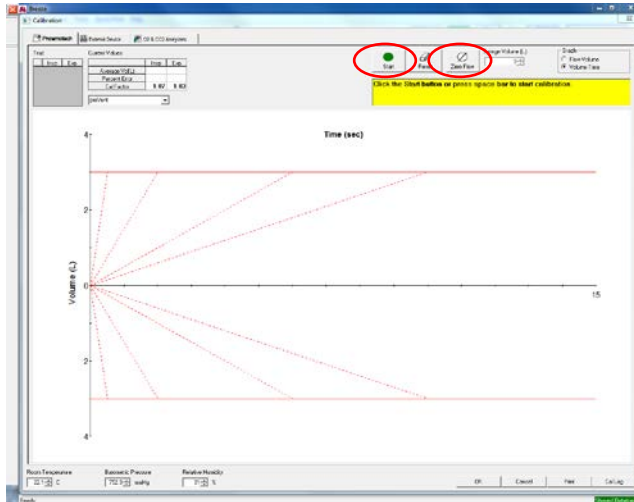
6.1.5 A passed calibration will read "Calibration Successful". Should it read "Calibration Failed", repeat step 5.1.4. If passed, remove umbilical clip from flow sensor and plug back into Ultima™ CardiO$_2$. Remove flow sensor from 3L syringe and re-place 3L syringe in holder at side of cart.
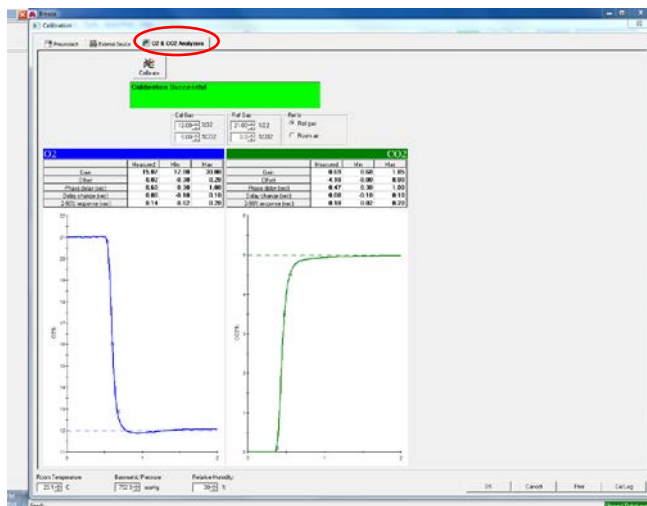
Figure 6.
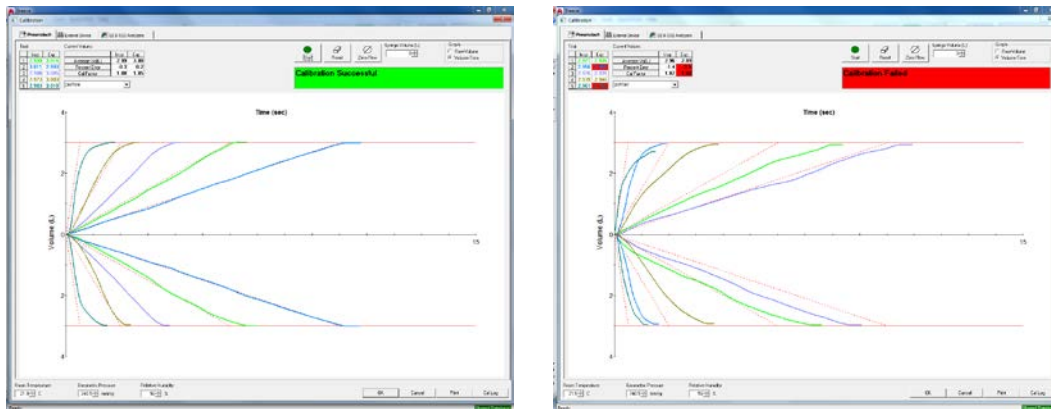
PASSED   **FAILED**

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6.2 ***Gas Calibration***

6.2.1 Click on "O2 & CO2 Analyzers" tab to calibrate reference and calibration gases.

6.2.2 Turn on gas tanks <u>slowly</u> by turning knobs counter clockwise using tank opener.

6.2.3 Click "Calibrate". Should it read "Calibration Successful", click "Ok".

Figure 7.

NOTE: Should it read "Calibration Failed", make sure that the umbilical cord is plugged in to Ultima™ CardiO$_2$ and that your gas tanks are on. If calibration fails, check left gauge on both tanks to verify that the psi is set between 6 and 8 and check right gauge on both tanks to verify that gas tank pressure is > 500 psi. Repeat calibration as necessary.

Figure 8.

6.2.4 Close calibration and reference tanks by turning the knobs clockwise.

NOTE: Make sure to perform at least a gas calibration between participants.
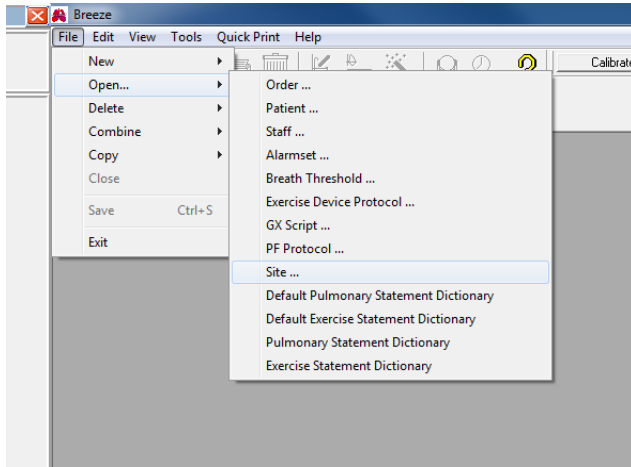
7. Parameter Setup

7.1 *Site Verification*

PURPOSE: To ensure that the desired testing equipment and COM ports are selected at the station.

7.1.1 File → Open… → Site…. → Select "Concordia University" → Click "Open".
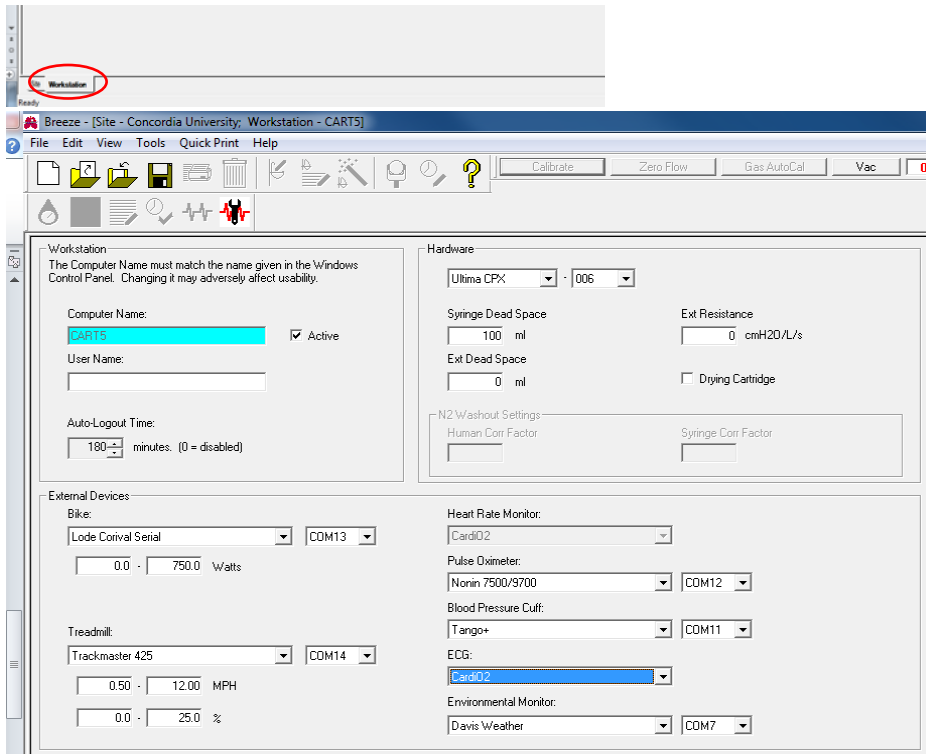
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Figure 11.

7.1.2 Click "Workstation" tab at bottom left of screen. Check site setup for testing equipment that will be used. For exercise testing using ECG use the following setup:
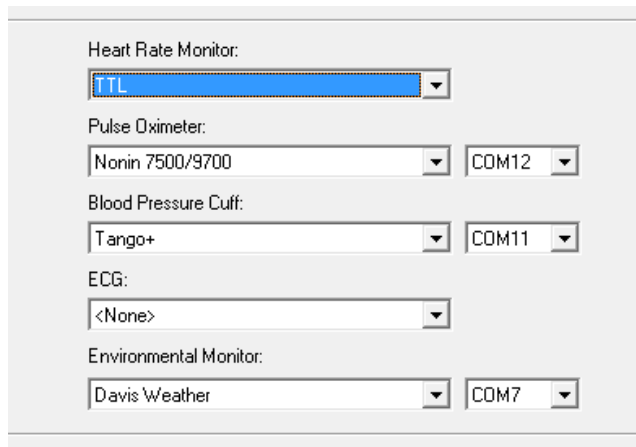
Figure 12.

7.1.3 For exercise testing using polar heart rate monitor use the following setup:

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Figure 13.

7.1.4 Click on save icon .

7.1.5 Click on close icon .

7.2 *Creating a new script*

PURPOSE: To ensure that the desired protocol and testing equipment is selected. A newly created script will be accessible at all stations.

7.2.1 File → New → GXScript…

7.2.2 Fill in mandatory fields in green. Be sure that the appropriate "script type" is chosen according to testing needs (ex. if performing a Bruce protocol make sure you select "Treadmill" from drop down menu).

7.2.3 Choose appropriate "external devices" for testing needs.

7.2.4 Click on .

7.2.5 Click on .

7.3 *Opening/editing an existing script*

7.3.1 File → Open… → GXScript…

7.3.2 Choose desired script.

Figure 14.
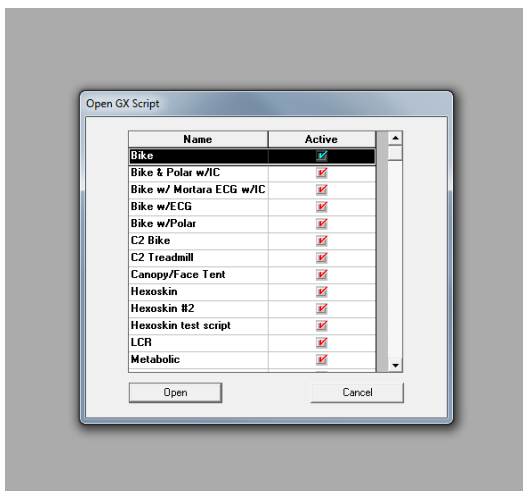
7.3.3 Click "Open".

7.3.4 Edit if desired.

7.3.5 Click on [floppy disk icon].

7.3.6 Click on [open folder icon].

8. Exercise Test Setup

8.1 *Creating a new patient*

8.1.1 File → New → Patient OR click on open patient tab →Click "New"

8.1.2 Fill in mandatory fields in green.

8.1.3 ID = Study ID number; DOB = MM/DD/YYYY.

8.1.4 Click "Add Visit".

NOTE: Unspecified Race - defaults to Caucasian. Unspecified Sex - defaults to male.

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Figure15.
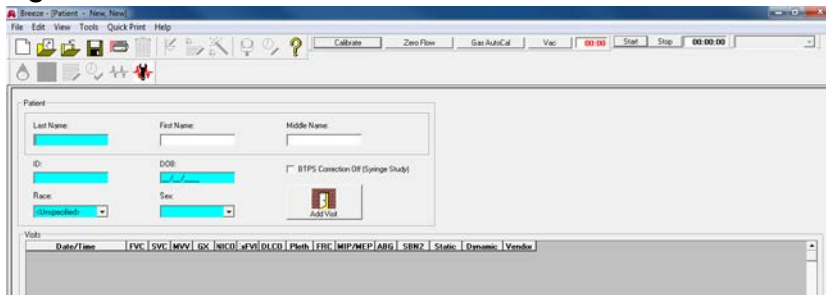
8.1.5 Fill in mandatory fields in green.

8.1.6 Choose Technician from drop-down menu.

8.1.7 Choose Site from drop-down menu.

Figure 16.
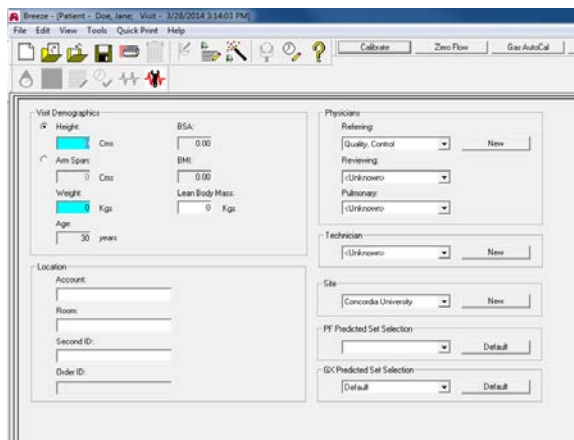
8.1.8 Click on .

8.2 Opening/editing an existing patient

8.2.1 File → Open… → Patient… OR click on open patient tab

8.2.2 Click "Find" → Click "Find" → Click "Cancel" (participant will be highlighted) → Click "Open"
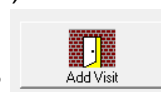
8.2.3 Click "Add Visit" .

8.2.4 Edit information under "Visit Demographics" or "Patient History" tab, if necessary.

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8.2.5 Click on .

8.3 *ECG Preparation and Placement*

PURPOSE: Reduce the potential for myographic noise and baseline wander, ensuring high-quality printouts and displayed data.

8.3.1 Ask participant to remove jewelry (i.e. necklace) and watch, if any.

8.3.2 Wearing gloves, shave hair from electrode sites, if necessary. Refer to Fig. 17 to locate electrode sites.

NOTE: For females, place the precordial electrodes on top of the breast (not underneath the breast tissue).

8.3.3 Cleanse area with alcohol swab.

8.3.4 Using abrasive ECG prep tape, lightly scratch an "X" pattern into the skin, taking care to avoid excess abrading.

8.3.5 Dry the skin vigorously with a gauze pad.

8.3.6 Attach the electrodes to the lead wires before attaching them to participant.

8.3.7 Drape the cable over the right shoulder of participant, with the connector on the bottom end and the RA and LA leads at the top.

8.3.8 Place electrodes as instructed by the manufacturer (as shown in Figure 17). Press the contour of electrode. Avoid pressing the center of the gel area.

NOTE: The placement of electrodes is specific to Mortara® ECG system.

8.3.9 Place foam belt on participant's hip. Avoid contact with electrodes. Connect ECG cable to Mortara T12 Unit. Place battery inside Mortara T12 Unit and close cover. Verify battery strength.

8.3.10 Place Mortara T12 Unit in belt pouch.

Figure 17.
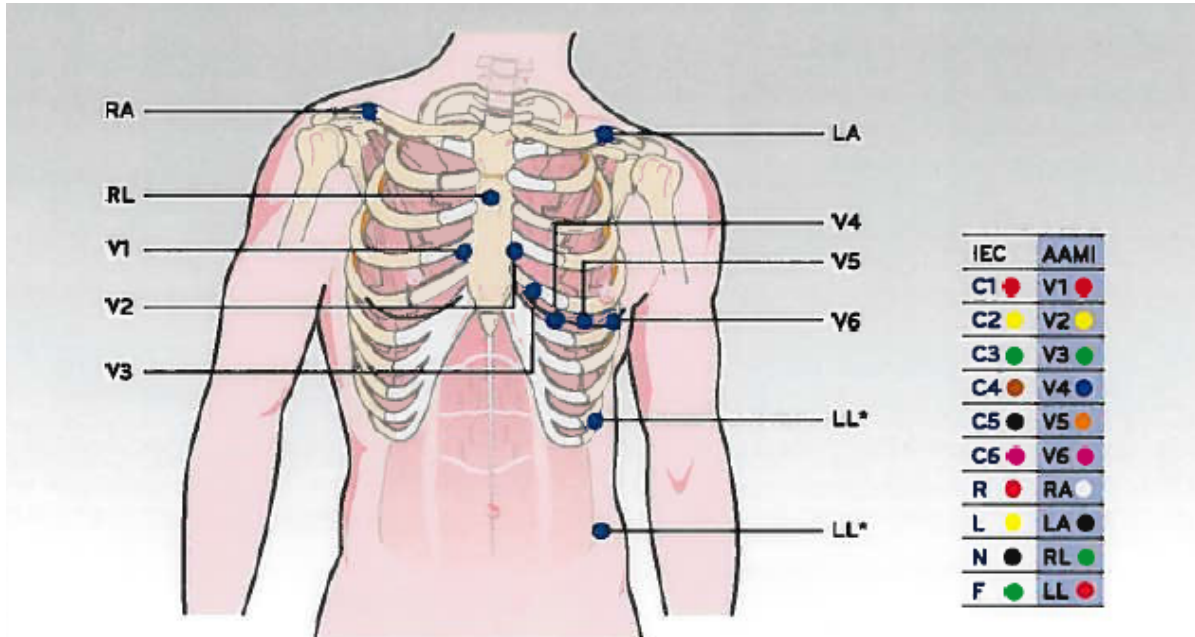
LEAD PLACEMENT

- **V1** – Fourth intercostal space at the right sternal border.
- **V2** – Fourth intercostal space at the left sternal border.
- **V3** – Midway between V2 and V4.
- **V4** – Fifth intercostal space at the left midclavicular line.
- **V5** – Anterior axillary line on same horizontal level as V4.
- **V6** – Mid-axillary line on same horizontal level as V4 and V5.
- **RA** – Right clavicle as shown.
- **LA** – Left clavicle as shown.
- **RL** – Reference or ground lead, placed to maximize patient comfort.
- **LL** – Lower left side of body, as close to hip as possible, on the iliac crest (original Mason-Likar position) **or** lowest rib on the left side of chest (modified Mason-Likar position).

*Note and Caution: Placement of the Left Leg (LL) electrode in the original Mason-Likar position increases the similarity of the acquired ECG with a standard 12-lead ECG and is therefore recommended; however, clothing may interfere with this position and increase the amount of artifact. The modified position may decrease the sensitivity of inferior ECG leads and cause axis shift with respect to the standard 12-lead ECG. Accurate skin preparation and suitable clothing are the most important factors in excessive artifact prevention.

The Right Leg (RL) electrode may be positioned in any location least subject to motion artifact according to clinician preference and specific test requirements.

8.4 *Polar Heart Rate Monitor Setup*

8.4.1 Moisten the electrodes on the polar heart rate monitor.

8.4.2 Place monitor on torso, as shown below, with strap flat and snug against the skin with Polar logo right side up.

Figure 18.
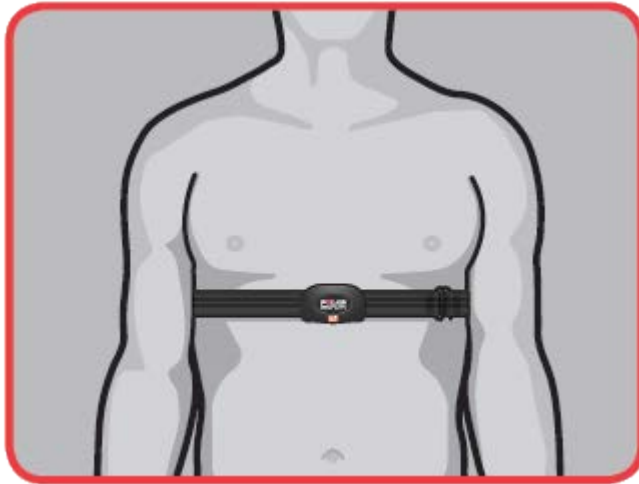
8.4.3 The computer must be within one meter (three feet) from the transmitter.

8.5 *Script Setup*

8.5.1 Click on GX tab at the bottom of the screen.

8.5.2 Choose desired script under "Script Name:".

NOTE: When selecting a script the settings will change according to how the script was setup in the GX Script window.

8.5.3 You can change settings of script in this window, if needed.

NOTE: When performing VO_2 test with ECG, keep "Heart Rate Monitor" checked under external devices since "Heart Rate Monitor" represents the monitoring of heart rate and not the actual use of a heart rate monitor.

8.5.4 Insert appropriate dead space values for external and mechanical dead space. See table below for dead space values for each testing modality:

| Testing Modality	Distal to Sample Line (External Dead Space)	Proximal to Sample Line (Mechanical Dead Space)
Mouthpiece with saliva trap	20	45
Mouthpiece without saliva trap	20	45
Medgraphics PreVent® Mask (all sizes)	20	45

8.5.5 Click on .

8.5.6 Click on "Test" tab.

8.5.7 Click on or to switch to test mode.

8.5.8 Select at the top left of screen to begin ECG observation phase. This phase is observational only and no ECG or gas exchange data is being recorded. Once observation phase is complete, the Start icon will turn green.

Figure 19
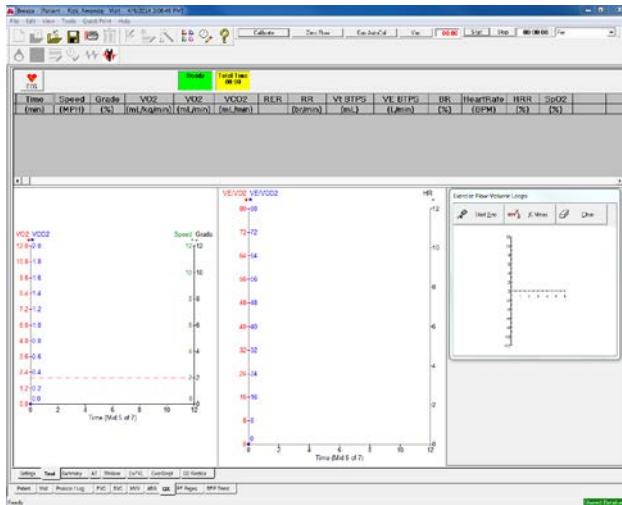
NOTE: If a lead fails, square waves will appear.

9. SunTech® Tango+ Setup and Measurement During Rest

9.1 Explain measurement procedure to participant. Instruct participant to relax arm and to not talk during measurements.[2,3] NOTE: The Tango+ requires an ECG signal to take a measurement.

9.2 Choose the appropriate cuff size.

9.2.1 Without using the sleeve of the cuff, wrap the cuff around the participant's upper arm. Make sure the arm circumference falls within the cuff's RANGE arrow (located on the inside if the cuff). If it does not, use a different cuff size. Remove cuff.

9.3 Verify that the microphone and bladder are in the cuff. If not, insert microphone and/or bladder into cuff.

9.4 Palpate brachial artery between the bicep and tricep.
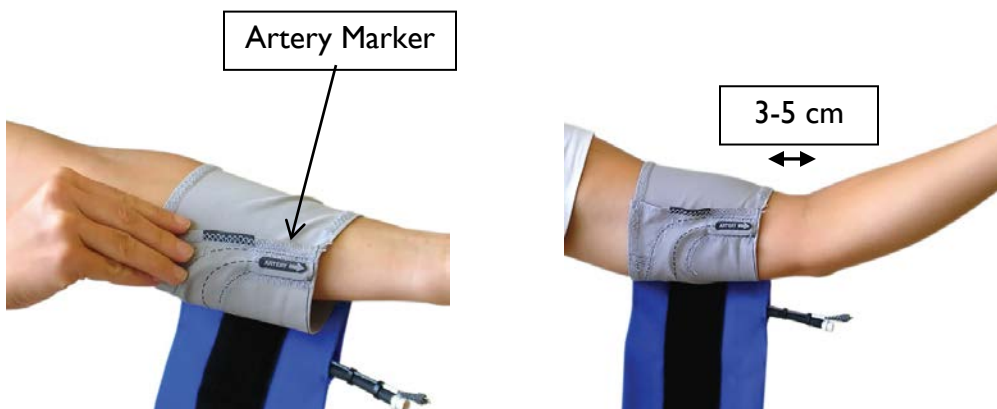
Figure 20.

9.5 Slide the sanitary sleeve and cuff sleeve up the participant's left arm, ensuring the ARTERY marker points down the arm and is over the participants brachial artery. As well, ensure the lower border of the cuff is placed <u>3-5 cm</u> above the antecubital fossa.

Figure 21.

Artery Marker

3-5 cm

9.6 Wrap the cuff around the arm and secure using velcro.

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Figure 22.

9.7 If not already done, attach cable to cuff.

9.8 Use the velcro strap to secure the cable to the individual's wrist.

9.9 Ask participant to sit down. Wait 5 minutes.

9.10 Ensure a stable heart rate is displayed on the monitor.

NOTE: A stable heart rate must be displayed on the monitor for Tango+ to be able to obtain an accurate reading.

9.11 Press the START/STOP key (see Figure 23) to take the BP measurement.

9.12 At least three measurements should be taken in the left arm with the participant in the same position.[2] The first reading should be discarded and latter two averaged.[2] Leaving the cuff partially inflated for too long will fill the venous system and make the sounds difficult to hear. To avoid venous congestion, it is recommended that at least one minute should elapse between readings.[1,2,3]

9.13 Repeat on right arm.

9.14 Blood pressure should be measured in both arms on at least one visit and if one arm has a consistently higher pressure, that arm should be subsequently used for BP measurement and interpretation.[1,2]

10. Nonin Oximetry Setup and Measurement

10.1 Insert a finger (preferably the index, middle, or ring finger but not thumb) into the Adult Articulated Finger Clip Sensor until the end of the finger reaches the finger stop. Keep the finger nail facing the sensor top. Ensure that long finger nails do not interfere with proper finger position.

NOTE: Place Nonin sensor on opposite arm of blood pressure cuff, if blood pressure is being measured.

10.2 For the best results when using the sensor for data collection, secure the sensor cable independently from the sensor with medical tape, preferably around the base of the finger. Make sure that the tape securing the cable does not restrict the blood flow.

NOTE: Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in SpO_2 inaccuracies.

NOTE: If participant is wearing nail polish or fake nails this may hinder measurement and accuracy.

11. SunTech® Tango+ Setup and Measurement During Exercise

11.1 Take 1-2 blood pressure measurements with the participant or sitting standing still before starting the exercise test by pressing the START/STOP key (see Figure 23).

11.2 Tango+ has the ability to take blood pressure at desired intervals (ex. every 2 1/2 minutes). Should you want to have blood pressure measured at specific intervals (for example, every 2 ½ minutes) during rest and exercise, configure SunTech® Tango+ as follows:

11.2.1 Press SELECT button twice on SunTech® Tango+.

11.2.2 Use UP or DOWN arrow buttons to highlight "Measurement Setup". Press SELECT button.

11.2.3 Use up or down arrow buttons to highlight "Interval". Press SELECT button.

11.2.4 Use up or down arrow buttons to adjust time. Press SELECT button once desired time interval has been chosen.

11.2.5 Use up or down arrow buttons to highlight "Exit". Press SELECT button twice.

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Figure 23.
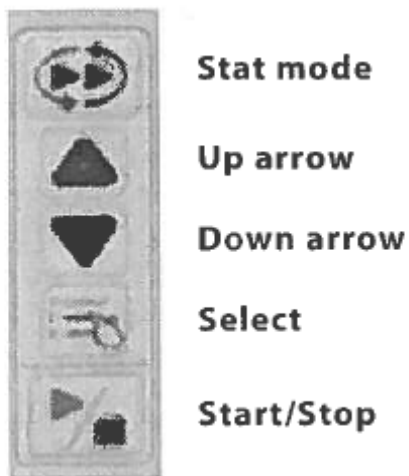
11.3   **OR** when ready to take each measurement, press (preferred method).

11.4   While the measurement is being taken, watch the display for the cuff pressure and waveform display. With the waveform display showing Korotkoff sounds, you should see Korotkoff sounds just as you would hear them if taking a manual blood pressure measurement.

11.5   Once you obtain a reliable measurement, proceed with exercise test.

11.6   During test, remind participant to relax arm during measurement by loosening their grip on the handlebars or asking the participant to turn their hand over so that the palm is facing upward and resting in the treadmill bar. See image below for acceptable and unacceptable arm movement during blood pressure measurement.

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Figure 24.

This is an acceptable arm movement during a BP reading

This is an <u>unacceptable</u> arm movement during a BP reading

12. Conducting an Exercise Test

12.1   Setup participant up on equipment.

12.2   Connect flow sensor to umbilical cable and selected mouthpiece/mask.

12.3   Place mouthpiece/mask on participant.

12.4   Select [Start] to begin VO_2 ECG test. Data is now being recorded.

12.5   Ask participant to stand still.

12.6   Select the [clock/pencil icon] to mark and perform a resting ECG. Record resting data for desired time (usually 3 minutes).

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12.7   Use [icon] to manually enter blood pressure values, [icon] to manually enter rate of perceived exertion (can choose from dyspnea, leg fatigue, RPE, etc),

and [icon] to associate a specific time point to a specific event (for example system will automatically mark the time point by clicking on the icon and you mark the event associated with that point in time (BP, chest pain, dyspnea, leg fatigue, etc.). These options can be used at any time during a test.

12.8   Click on the [Exercise] icon to begin the exercise protocol.

NOTE: During the test a snapshot of the ECG (at that moment in time) can be printed by selecting [ECG] icon.

12.9   Should you need to divert from the protocol, click [Manual].

NOTE: Once you select manual you cannot go back to pre-programmed protocol.

12.10   Should you need to hold a stage click [Hold Stg]. Should you need to go to the next stage click [Next Stg].

12.11   Click on [Recovery] to begin cool-down phase (this will not stop equipment).

12.12   Inform participant that you will stop equipment and that it will stop abruptly.

12.13   Click on [Stop] when it is no longer necessary to collect gas exchange data.

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12.14   Click on when recovery ECG monitoring is no longer necessary.

12.15   Click on "Save Report" (on left screen).

12.16   Click on (on left screen).

12.17   Remove equipment from participant (mouthpiece/mask first) and then ask participant to get off equipment.

12.18   Provide the option of sitting and drinking some water to the participant.
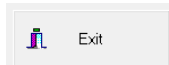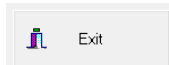
12.19   Remove all ECG electrodes from the participant and clean each ECG electrode site with an alcohol swab.

12.20   Turn off vacuum pump (i.e. Vac).

13.   Reviewing and Printing Exercise Reports

13.1   *Reviewing*

13.1.1 Once the exercise test is complete, the ECG tracings can be reviewed by clicking on the [Review Exam] button on the left screen.

13.2   *Printing a Report*

13.2.1 Click "Quick Print" from the menu bar.

13.2.2 If report has been previously printed it will appear at the bottom of the Quick Print menu.

13.2.3 Selecting a report will automatically send the report to the printer.

13.2.4 If the desired report is not displayed in the Quick Print menu select "Report Switchboard…" to display the entire list of available reports. Here you have the option to print a report or preview it on the screen.

14.   Cleaning/Disinfecting Flow Sensors and Mouthpieces

14.1   The flow sensor and mouthpiece must be cleaned and disinfected after each use according to the manufacturer's guidelines.

14.2   Wear lab coat, safety glasses, and gloves.[4]

14.3   Rinse the flow sensor with warm tap water using a cleaning brush and warm soapy water to loosen and remove any foreign matter.[4]

14.4   Soak items in a solution of 10% household bleach and water for 60 minutes, OR soak in a 2.4% gluteraldehyde solution for 45 minutes.[4]

NOTE: Excess soaking will degrade the flow sensor, mouthpiece and patient circuit materials and reduce accuracy.[4]

14.4.1 Rinse items for 5 minutes using tap water.[4]

14.4.2 Air dry for a minimum of 24 hours.[4]

14.4.3 Using gloves, place items separately in sealed plastic bags. On the plastic bag, write the date items were cleaned and the number of times used.

14.4.4 Clean items will be stored in the cardiopulmonary suite cleaning room (S1.169), more specifically, in their respective bins.

NOTE: Flow sensors may be cleaned and disinfected **10 times** according to the procedures outlined above. Under no circumstances may heat > 120°F/49°C be used to disinfect or to dry the flow sensors.[4]

NOTE: Mouthpieces may be cleaned and disinfected a maximum of **20 times** according to the procedures outlined above. Under no circumstances may heat > 120°F/49°C be used to disinfect or to dry the mouthpieces.[4]

14.4.5 Prior to use always, inspect the flow sensor for cracks, chips, and/or loose screen. If any of these conditions exist replace the flow sensor.

15. Safety and Effectiveness Considerations

Consider the following safety and effectiveness issues prior to using the SunTech® Tango+ monitor:

15.1   **SunTech® Tango+**

15.1.1 Use SunTech® Tango+ only with adult participants.
15.1.2 SunTech® Tango+ device is defibrillator protected.

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15.2   Warnings and Contraindications

For safety reasons working alone should be avoided. Someone should always be within call when a laboratory procedure is being performed.

15.2.1 DO NOT USE THE MONITOR IF it has failed its diagnostic self-test or if it displays a greater than zero pressure with no cuff attached. The values displayed by such a unit may be inaccurate.

15.2.2 DO NOT USE ON NEONATES, CHILDREN, and participants known to be readily susceptible to bruising.

15.2.3 DO NOT ATTACH THE CUFF to a limb being used for IV infusions as the cuff inflation can block the infusion, causing harm to the participant.

15.2.4 DO NOT USE IN THE PRESENCE OF FLAMMABLE anesthetics; this could cause an explosion.

15.2.5 DO NOT IMMERSE the monitor in any fluid, place fluids on top of, or attempt to clean the unit with any liquid detergents or cleaning agents. This may cause an electrical hazard. If any of these situations occur, please contact coordinator of Cardio-Pulmonary Suite.

15.2.6 DO NOT MAKE REPAIRS YOURSELF: No repair should be undertaken or attempted by anyone not having been service trained by SunTech® Medical or having a thorough understanding of the repair and operation of automatic blood pressure equipment.

16. REFERENCES

1. ACSM's Guidelines for exercise testing and prescription / American College of Sports Medicine; senior editor, Linda S. Pescatello; associate editors, Ross Arena, Deborah Riebe, Paul D. Thompson. – 2014. 9th ed. p. 45.

2. The 2014 Canadian Hypertension Education Program (CHEP) Recommendations for Blood Pressure Measurement, Diagnosis, Assessment Risk, Prevention and Treatment of Hypertension. Canadian Journal of Cardiology 2014; Accepted In-Press.

3. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals. *Hypertension*. 2005;45(1):142-61.

4. Medgraphics manufacturer's guidelines. Models: CCM, CPX, $CardiO_2$ and PFX Ultima GX Operator Manual. Section 7-1, pg. 80.

APPENDIX I

POD Training Checklist

UNIVERSITÉ
Concordia
UNIVERSITY

PERFORM Centre

User has read the following sections and was trained accordingly:

Use of Ultima CardiO$_2$
Metabolic Carts: Yes   ☐   No   ☐   Not Applicable   ☐

Cleaning of flow sensors and facemasks:
Yes   ☐   No   ☐   Not Applicable   ☐

Comments:

_____

_____

_____

_____

_____

_____

_____

* Access and use of the C-P Suite equipment: Individual must demonstrate adequate ability to operate the specified equipment independently, at which time the coordinator of C-P Suite signs off on the training record form.

Trainee Name:
_____
Signature   *Date*

Training given by:
_____
Signature   *Date*

APPENDIX II

POD Training Record Form

UNIVERSITÉ Concordia UNIVERSITY

PERFORM Centre

POD Title
Use and Cleaning Procedures for Ultima™ CardiO2 Metabolic Systems - Exercise Testing

SOP Code

Ownership	Document type	Area	SOP Number	Version
PC	POD	CP	004	02

Training Record

Full Name	
Institution	
Contact (email or phone number)	

Signature

_____   _____

Sign here   Date