PERFORM Centre

PERFORM Operating Document

Use and Cleaning of HIC-4000I Impedance Cardiograph

PC-POD-CP-006-v01

Revision History

Version	Reason for Revision	Date
01	New POD	August/19/2015

Summary

The content of this PERFORM Operating Document (POD) provides guidelines for the safe use and cleaning of the HIC-4000I Impedance Cardiograph as identified as equipment inventory at the PERFORM Centre, Concordia University.

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7. Definition of Terms

PERFORM operating document (POD)	Operating documents that are specific to an instrument or technique that require approval by area managers.
Standard Operating Procedure (SOP)	SOP's at PERFORM are any operating document that require a full review process and approval by the SD.
User	Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.
Supervisors	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

2. Relevant Documents

This POD is governed by the following Concordia University policies, SOPs, and PODs:

- PC-POD-GA-001 "PERFORM Centre Booking System for Facilities and Equipment".
- PC-SOP-GA-002 "Handling of Biological Materials at PERFORM".
- 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-SOP-CP-001 "Cardio-Pulmonary Suite – Access, Use, Safety, and Training of Personnel".
- PC-POD-CP-002 "Use and Cleaning Procedures for Manual and Automatic Aneroid Sphygmomanometers".

3. Introduction

3.1 Background

The HIC-4000I Impedance Cardiograph is a noninvasive instrument for detecting and monitoring bioelectric impedance cardiography (ICG) signals from human subjects. It is a standalone system, which acquires, displays, and produces ICG analog signals. This system is primarily intended for ICG applications involving the assessment of heart rate, stroke volume, cardiac output, basal thoracic impedance (Zo), rate of change of impedance (dZ/dt), pre-ejection period (PEP), delta-Z (dZ), heart sounds, and

respiratory rate (R). A separate unit (SunTech Tango+™) is used in conjunction with the HIC-4000I Impedance Cardiograph to measure blood pressure.

3.2 Purpose

The objectives of the current POD are to 1) outline the procedure of using the HIC-4000I Impedance Cardiograph; 2) provide a set of standard practices for safe operation and training guide for new users of the system at the PERFORM Centre, Concordia University; and 3) outline the procedure for cleaning/disinfecting.

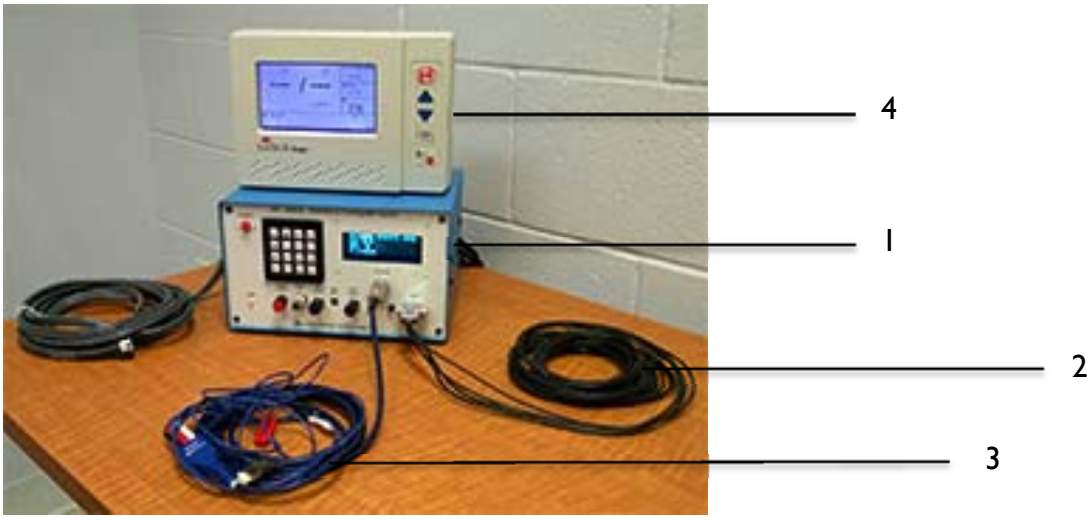
3.3 Scope

This POD applies to all users and supervisors using the HIC-4000I Impedance Cardiograph 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.

4. Main Components



1. HIC-4000I - Impedance Cardiograph System
2. DB-9 connector (black cable) – Four miniature coaxial cables with a 9-pin male connector at the instrument end, and four small alligator clips at participant end. Each cable is numbered 1 through 4.
3. External ECG electrode cable assembly (blue cable) – Separate external 3-electrode ECG cable with 5-pin circular connector.
4. SunTech® Tango+ - Automatic blood pressure system.

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5. Acronyms

5.1 Hardware

- HR = Heart Rate
- dZ/dt = Rate of Change of Impedance
- PEP = Pre-Ejection Period
- RSP = Respiration
- SIM= Simulation Mode
- * = Wildcard
- INT = Initialization Control
- SL = Signal Levels
- OFF = Off Button
- L40 = Low-Pass 40Hz Filter
- N60 = 60Hz Notch Filter
- N50 = 50 Hz Notch Filter
- OP = Operate Mode
- BL = Baseline
- CAL= Calibrate
- dZ = Change in Basal Thoracic Impedance.
- PWR = Power on when light on.
- RESP GAIN = Adjust level of Respiration Signal between 0 and max.
- RESP IN = Inlet for Respiration Transducer.
- HS GAIN = Adjust level of the Heart Sound (HS) signal between 0 and max.
- HS MIC = Inlet for Heart Sounds (HS) Microphone.
- ECG GAIN = Adjust level of the Electrocardiogram signal (ECG) signal between 0 and max.
- INT = "Internal" ECG collected through Impedance Cables.
- EXT = "External" ECG collected through separate ECG Cables.
- ECG-IN = Inlet for the External ECG electrode cable assembly.
- Z-IN = Inlet for the DB-9 connector.

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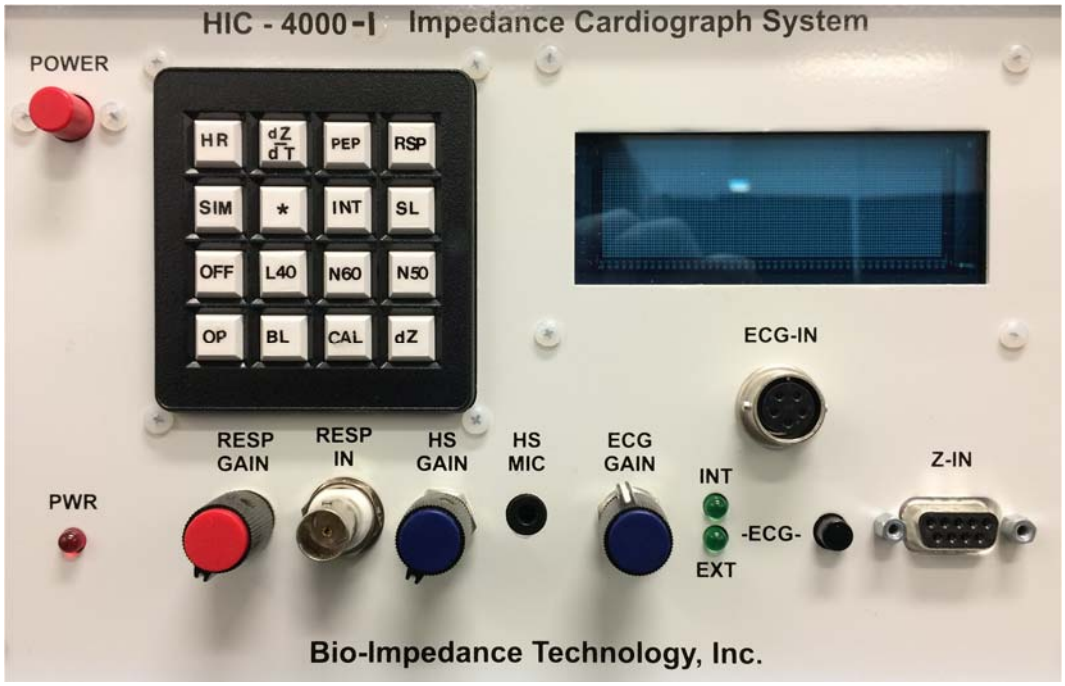

5.2 Software

- CI (Cardiac Index) = CO/ BSA (L/min/m^2)
- SI (Stroke Index) = SV/BSA (ml/beat/m^2)
- VI (Velocity Index) = dZ/dt (peak)/ Avg. Zo * 1000 (Value/1000sec)
- TFC (Total Fluid Content) = 1000/ Avg. Zo (Value/ K Ohm)
- Zo = Basal Thoracic Impedance. This is the base impedance of the thorax, displayed in Ohms in the software.

6. Hardware and Software Setup

6.1 Plug in main cable for HIC-4000I - Impedance Cardiograph to power source. Connect other end of cable to "Connect MED POWER" located on the lower right corner of the rear panel.

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6.2 Plug in main cable for SunTech® Tango+ to power source and connect other end of the cable to the input located on the lower left corner of the rear panel.
6.3 If using electrode tape to measure impedance, connect the DB-9 connector to the electrode input connector labeled Z-IN. Secure the plug by tightening the two screws on either side.
6.4 If using spot electrodes to measure impendence, connect the 3-electrode ECG cable to the electrode input connector labeled ECG-IN.
6.5 Connect appropriately sized blood pressure cuff to the end of the grey cable making sure that both the bladder and the artery are connected.
6.6 Connect the USB cable attached to the "RS-232" input on the left side of the rear panel of the SunTech® Tango+ to SPIRO 1 or SPIRO 2 laptop.
6.7 Connect the USB cable attached to the rear panel of the HIC-4000I Impedance Cardiograph labeled "USB" to the laptop.
6.8 Power on laptop SPIRO 1 or SPIRO 2.
6.9 Turn the HIC-4000I Impedance Cardiograph power on by pressing on the "POWER" button.

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7. Test Setup

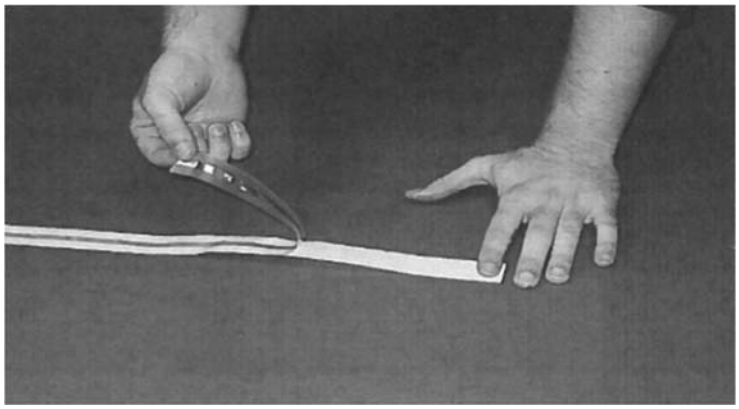
7.1 ECG Setup

7.1.1 OPTION 1 - Attachment of Band Impedance Electrodes

NOTE: Manufacturer recommends the use of band electrodes in ICG applications for research purposes when the best signal quality and parameter accuracy is desired.

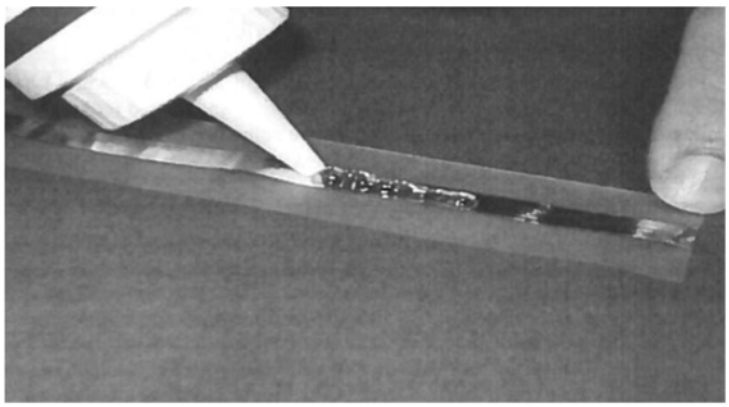
7.1.1.1 Using the electrode tape measure the quantity required by placing it around the upper limit of the participant's neck, leaving an extra 3-4 inches at each end of the electrode tape and cut accordingly.

7.1.1.2 Place the tape on a flat surface with the metallic/colored part facing upward. Strip off the electrode tape insulation backing.



NOTE: You can tape the ends to the table to prevent the tape from twisting.

7.1.1.3 Apply conductive electrode gel to the metallic/colored surface on the sticky side of the tape leaving 3-4 inches at each end not coated.



7.1.1.4 Fold-back the ends of the tape so that the sticky part is not exposed.

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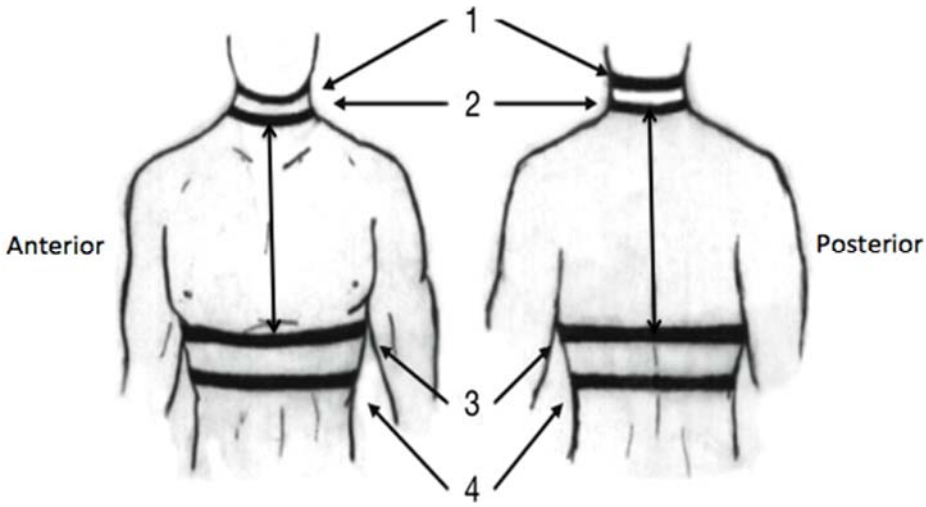
7.1.1.5 Stick the band electrode around the participant at the first attachment location, as shown below, making sure that the folded back ends of the tape are joined on the anterior surface of the participant.

NOTE: Use enough tension so that the band sticks, but not too much to the point that it wrinkles or twists.

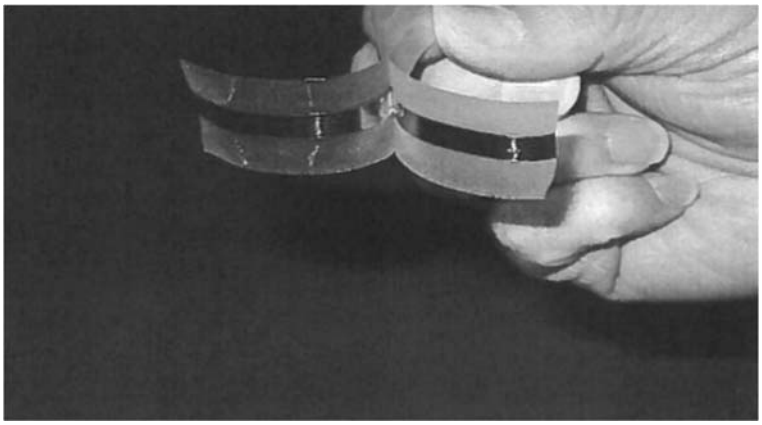


7.1.1.6 Measure at least 3cm from the lower edge of the conductive part of electrode band #1 (metallic/colored band) and mark the location.

7.1.1.7 Using the electrode tape, measure the quantity required by placing the upper edge of the conductive part of the electrode tape on the mark, leaving an extra 3-4 inches at each end of the electrode tape and cut accordingly.

7.1.1.8 Place the tape on a flat surface with the metallic/colored part facing upward.

7.1.1.9 Strip off the electrode tape insulation backing.



7.1.1.10 Apply conductive electrode gel to the metallic/colored surface on the sticky side of the tape leaving 3-4 inches at each end not coated.

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7.1.1.11 Fold-back the ends of the tape so that the sticky part is not exposed.

7.1.1.12 Stick the band electrode tape around the participant's neck so that the mark is aligned with the upper edge of the conductive part of the electrode tape. Make sure that the folded back ends of the tape are joined on the anterior surface of the participant.

7.1.1.13 Place electrode band #3 directly under the breast line (under xyphoid process) following the same procedure as described above.

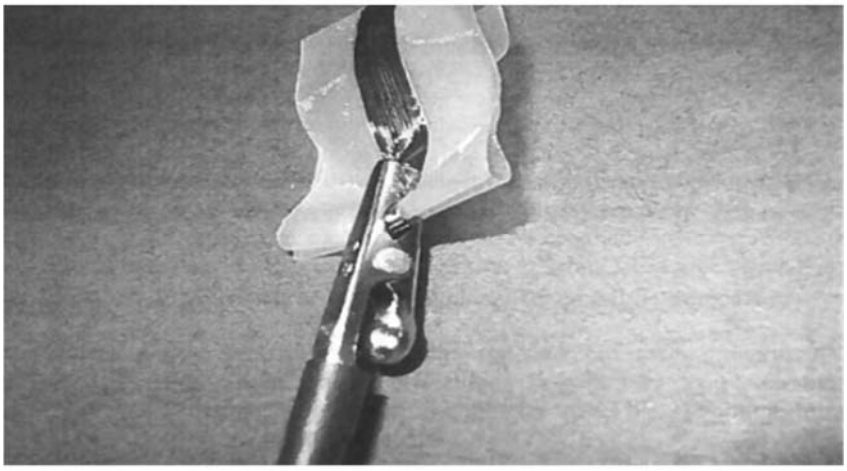
NOTE: For female participants, make sure that the electrode band is not in contact with the participant's bra.

7.1.1.14 Measure at least 3cm from lower edge of the conductive part of electrode band #3 (metallic band) and mark the location.

7.1.1.15 Place electrode band #4 so that the mark is aligned with the upper edge of the conductive part of the electrode tape following the same procedure as described above.

7.1.1.16 Measure the distance in cm between the lower edge of the conductive portion of band #2 and the upper edge of the conductive portion of band #3 in both the anterior and posterior of the participant and take note for future use.

7.1.1.17 Connect the appropriately numbered electrode clip of the DB-9 connector to both folded ends of the folded back ends of the electrode band.



7.1.1.18 Once placed, tape the alligator clip down to secure, if needed.

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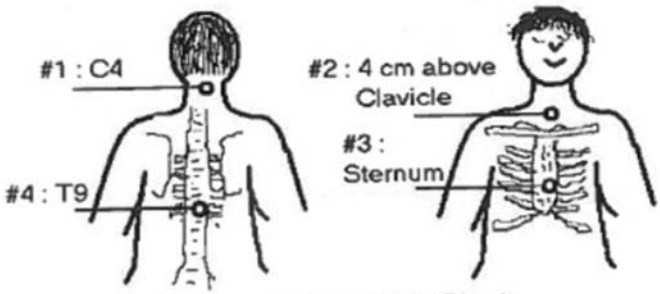
7.1.2 OPTION 2 - Attachment of 4-Lead ECG Electrode Configuration
NOTE: Manufacturer recommends the use of band electrodes in ICG applications for research purposes when the best signal quality and parameter accuracy is desired.

7.1.2.1 Wearing gloves, shave hair from electrode sites, if necessary. Locate electrode sites as shown. Place #1 electrode on C4, #2 electrode 4cm above clavicle, #3 electrode on sternum, #4 electrode on T9.



Rear and Front ICG Single Spot-Electrode Placement

7.1.2.2 Cleanse area with alcohol swab.
7.1.2.3 Using abrasive ECG prep tape, lightly scratch an "X" pattern into the skin, taking care to avoid excess abrading.
7.1.2.4 Dry the skin vigorously with a gauze pad.
7.1.2.5 Place electrodes on the skin.
7.1.2.6 Press the contour of electrode. Avoid pressing the center of the gel area.
7.1.2.7 Attach alligator clips of DB-9 connector to the electrodes at the appropriate locations.

7.1.3 OPTION 3 - Attachment of 3-Lead ECG Electrode Configuration

7.1.3.1 Wearing gloves shave hair from electrode sites, if necessary. Locate electrode sites as shown. The black (+) electrode should be located on the subject's left side, just below the 5th rib, the white (-) electrode near the subject's right shoulder just below the collar bone and the red (common) reference electrode near the subject's left shoulder just below the collar bone.

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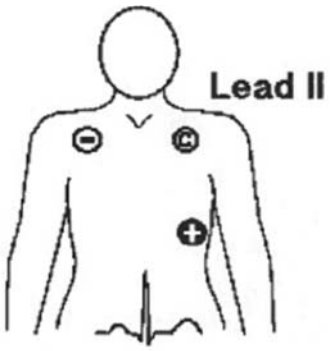

7.1.3.2 Cleanse area with alcohol swab.
7.1.3.3 Using abrasive ECG prep tape, lightly scratch an "X" pattern into the skin, taking care to avoid excess abrading.
7.1.3.4 Dry the skin vigorously with a gauze pad.
7.1.3.5 Place electrodes on the skin.
7.1.3.6 Press the contour of electrode. Avoid pressing the center of the gel area.
7.1.3.7 Attach alligator clips of External ECG electrode cable assembly to the electrodes at the appropriate locations.

7.2 SunTech® Tango+ Blood Pressure Setup

7.2.1 Explain measurement procedure to participant. Instruct participant to relax arm and to not talk during measurements.
7.2.2 Choose the appropriate cuff size.
7.2.2.1 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.
7.2.3 Verify that the microphone and bladder are in the cuff. If not, insert microphone and/or bladder into cuff.
7.2.4 Palpate brachial artery between the bicep and triceps.

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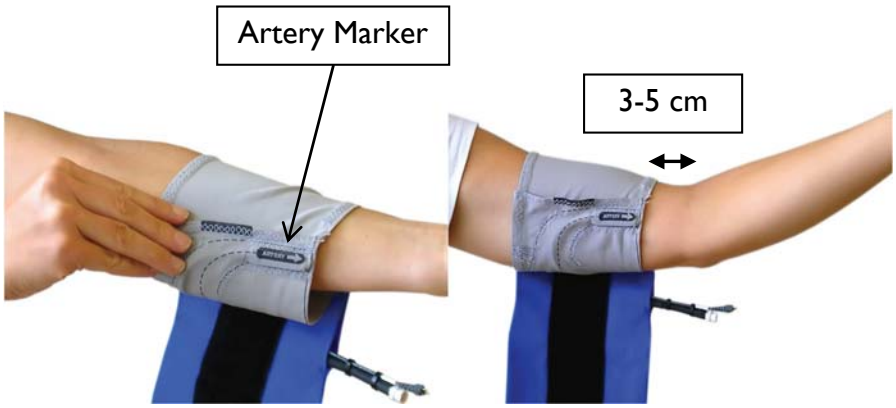
7.2.5 Slide the sanitary sleeve and cuff sleeve up the participant's left arm, ensuring the ARTERY marker points down the arm and is over the participants brachial artery. As well, ensure the lower border of the cuff is placed 3-5 cm above the antecubital fossa.



7.2.6 Wrap the cuff around the arm and secure using Velcro.

7.2.7 If not already done, attach cable to cuff.

7.2.8 Use the Velcro strap to secure the cable to the individual's wrist.

7.2.9 Ask participant to sit down. Wait 5 minutes.

7.2.10 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.

7.3 Software Setup

7.3.1 Creating a New Participant

7.3.1.1 Click on "COPWINHRV" on desktop to open software.

7.3.1.2 Select "File", "New Patient", "New Patient - First Data" to create a new participant file.

7.3.1.3 Select the desired project folder in the dialog box.

7.3.1.4 Enter participant's ID and date in "File Name:" box and click "Save".

NOTE: It is recommended that a project folder be created for each participant.

7.3.1.5 Select "Yes" in the "Patient Folder Creation Option!" window.

7.3.1.6 Enter subject's general information in the top half of the "Patient Information Form" window.

NOTE: "Birth Date" is written as month, day, and year (e.g., Sept 16 1983).

7.3.1.7 In the bottom half of the window, more specifically, in the "Posture" box, select "#1" and assign a posture label (e.g., seated, standing, or reclining). In the red boxes below, enter the electrode distance in centimeters previously noted. Repeat for posture "#2" and "#3", if multiple postures are desired.

7.3.1.8 Click "Save Changes".

7.3.2 Open an Existing Participant

7.3.2.1 Click on "COPWINHRV" on desktop to open software.

7.3.2.2 Select "File", "New Patient", "Previous Patient- New data" to open an existing participant.

7.3.2.3 Select the desired project folder in the dialog box.

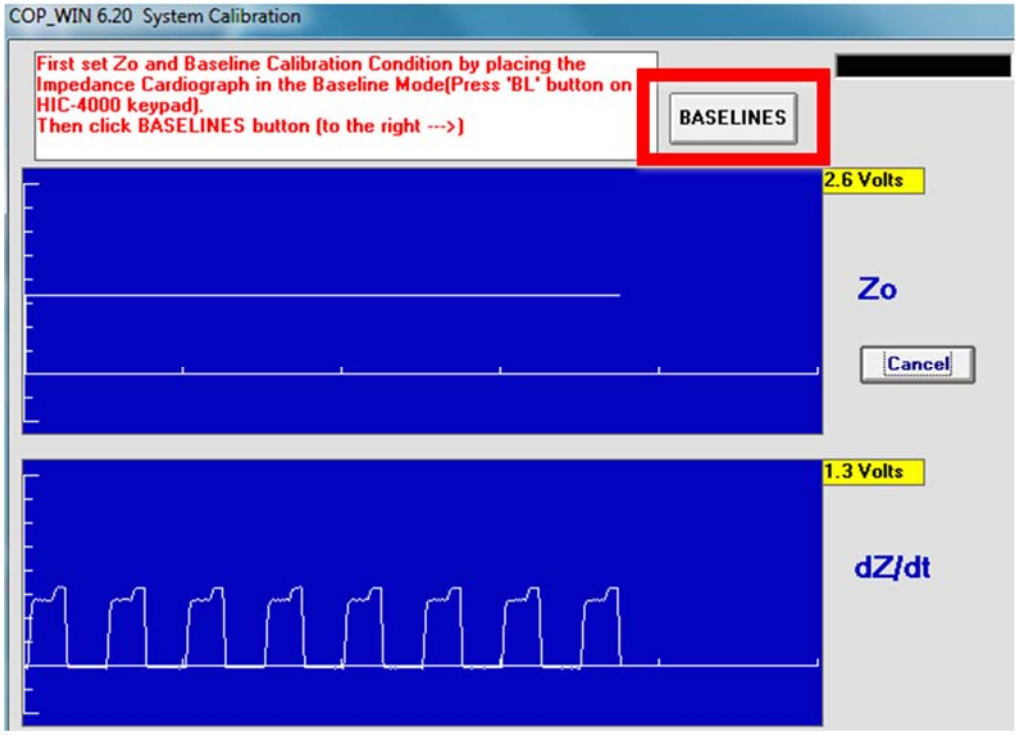
7.3.2.4 Select the patient folder which had previously been created for the participant.

NOTE: Make sure to click on the file ending in ".ifo" and not "(T#)", since "(T#)" represents files with existing data.

7.3.2.5 Click "Open".
7.3.2.6 In the "Program Help Advisory!" window, click "OK".
7.3.2.7 Click "Save".
7.3.2.8 The "Patient (Subject) Information Form" window will appear. In the top half of the window update information, if necessary.
7.3.2.9 In the bottom half of the window, more specifically, in the "Posture" box, select "#1" and assign a posture label (e.g., seated, standing, or reclining). In the red boxes below, enter the electrode distance in centimeters previously noted.
7.3.2.10 Click "Save Changes".

8. Calibration

8.1 In the main menu, select "Calibration".
8.2 Click on "Calibrate COP_WIN System".
8.3 The "System Calibration" window will open.
8.4 On the ICG machine, press the "BL" key on the keypad.
8.5 In the software, click the "BASELINES" button in the "System Calibration" window.



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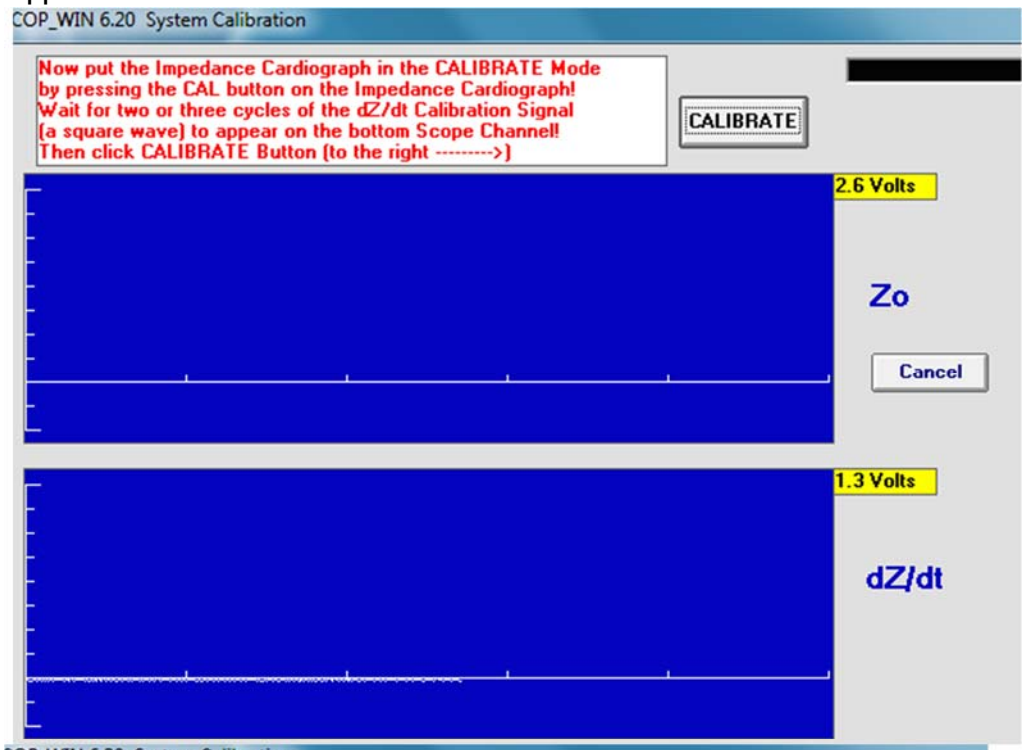
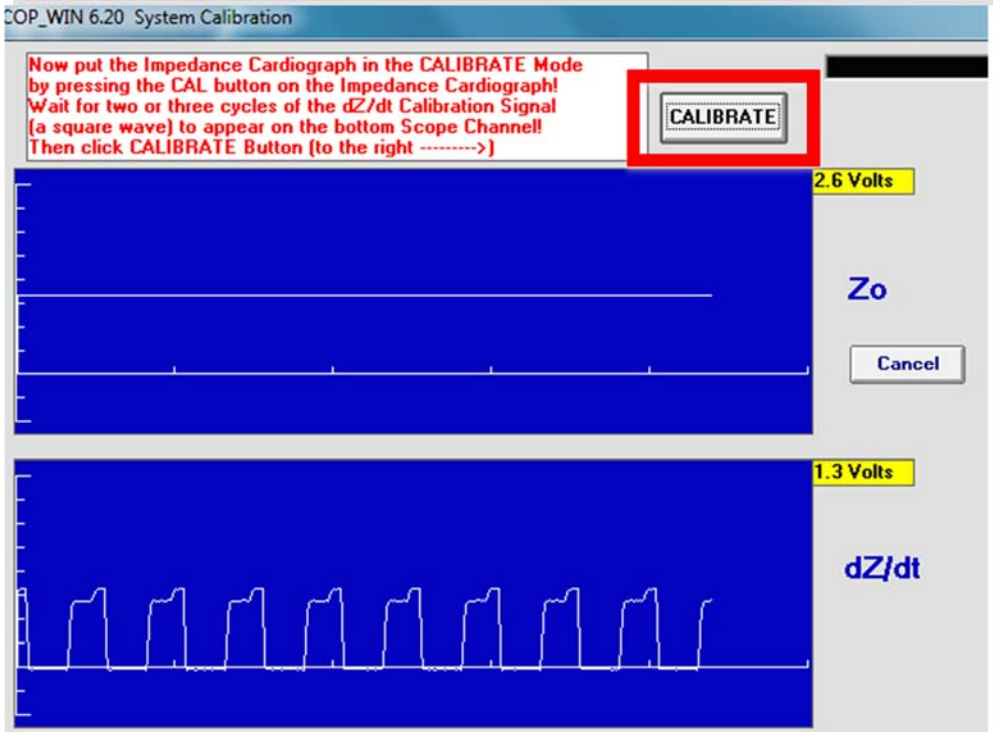
8.6 On the ICG machine, press the "CAL" key on the keypad.

8.7 Wait two or three cycles of the dZ/Dt calibration signal (a square wave) to appear then click the "CALIBRATE" button.





8.8 Click "OK" on the calibration screen to save and exit the calibration screen.

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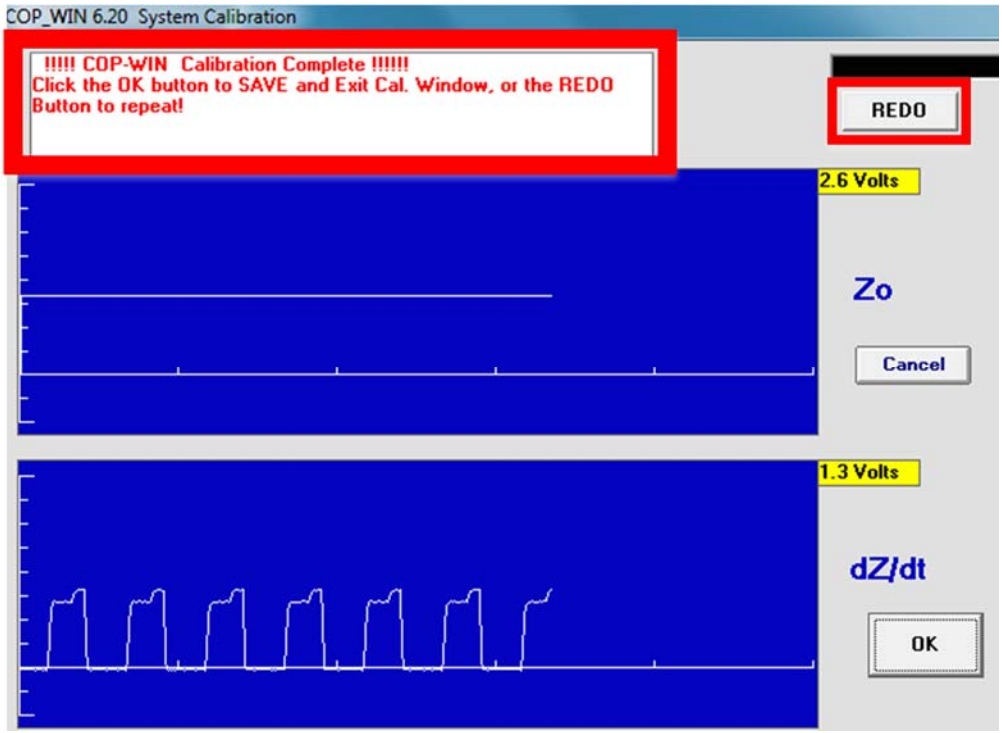
8.9 If calibration is successful, window will show statement "COP-WIN Calibration Complete" as shown below. If calibration is unsuccessful, click "REDO".



8.10 Click "OK".

8.11 The "Calibration Information" window will appear.

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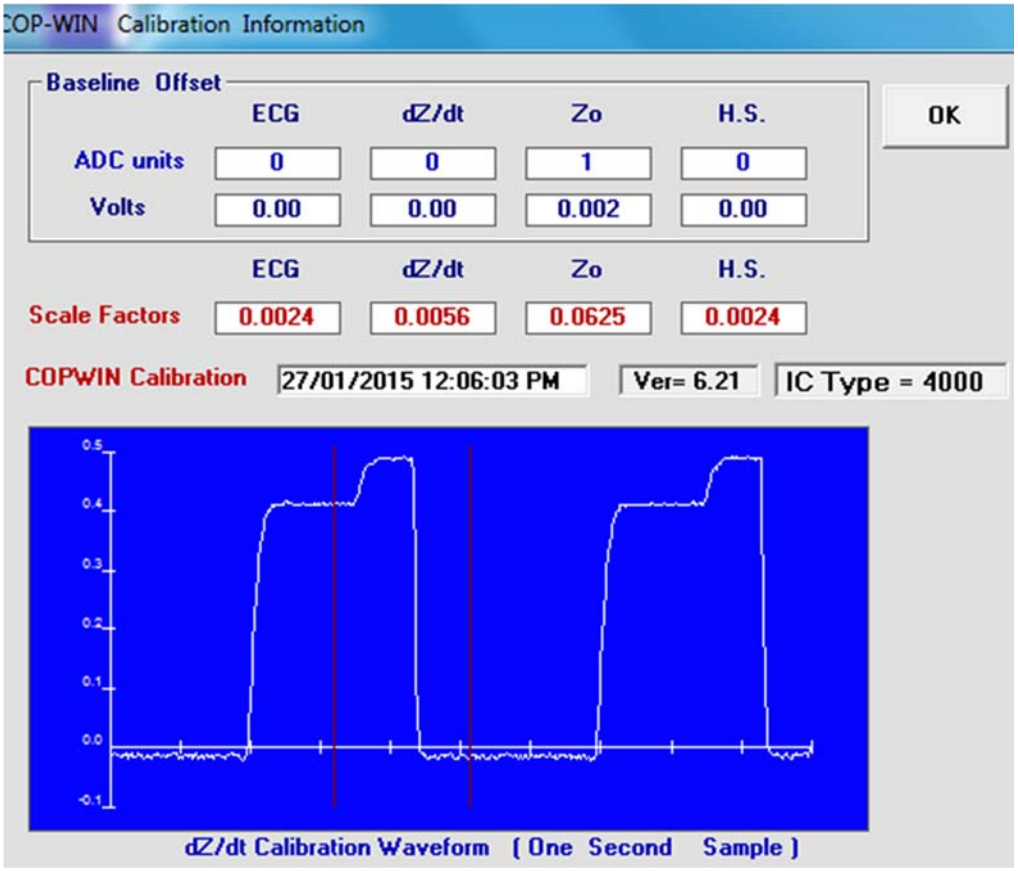

8.12 Click "OK".

8.13 On ICG machine, press "OP" key to switch back to operate mode, which allows data to be collected.

9. Data Acquisition

9.1 Opening Acquisition Window

9.1.1 From the main menu select "Acquisition" then "Data Acquisition and Setup". This window will allow for operational parameters to be specified.

9.1.2 Under "Acquisition Mode" select the desired mode of data acquisition. Options are the following:

9.2 OPTION 1 – Collect data intermittently using inter-sample pauses

9.2.1 For acquisition of impedance data intermittently at preset time intervals select "Continuous Time Intervals (Auto)" under Acquisition Mode. Enter the desired "Inter-Sample Interval Time" in either minutes (blue) or seconds (red).

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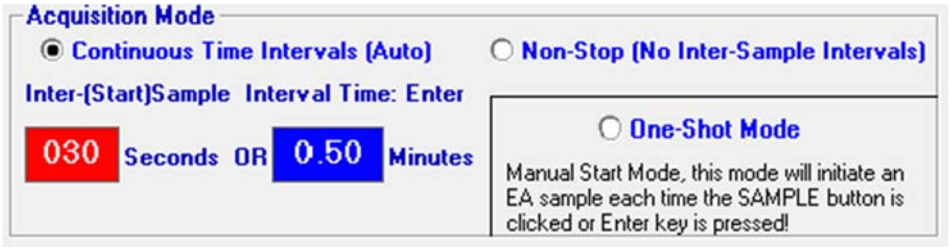

9.2.2 Change the "Ensemble Average DURATION" accordingly to make sure that it is at least one second less than the Inter-Sample Interval Time. For example, if you want the total duration of your test to be 30 seconds, yet would like to acquire data for 20 seconds then have a 10 second break of no data acquisition, then type 30 in the red box and 20 in the "Ensemble Time (sec)" box as shown.

9.2.3 Click the "Apply" button that appears.

9.2.4 If you like to manually start and stop data acquisition, under the "Total Run Time For Continuous/ Non-Stop EA Acquisition Mode" select "No limit".

9.2.5 If you want to set it to a pre-determine time interval, under the "Total Run Time For Continuous/ Non-Stop EA Acquisition Mode" select "Limit to" and choose the total time under "Hours" and "Minutes".

9.2.5.1 The "Continuous Time Intervals" mode offer a Block Mode option that permits the user to acquire and label data samples with an ID Code. To turn this option on, select "Limit to", then check "BLOCK MODE" under "Block Run Time For Continuous/ Non-Stop EA Acquisition Mode".

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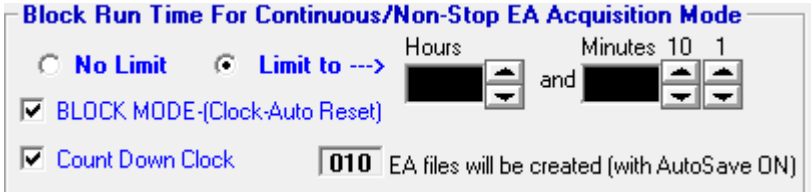
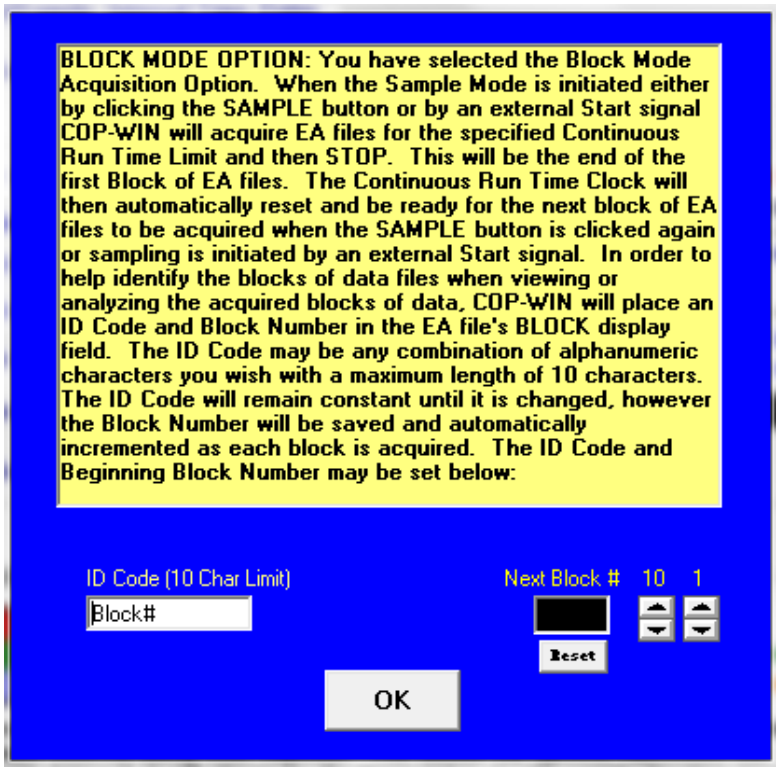


When this option is selected and the "OK" button is pressed, a screen will appear allowing for the selection of a specific ID Code.



NOTE: If there are any parameters left to change in the prior screen, do so prior to clicking "OK" as data acquisition will begin as soon as "OK" is selected.

9.2.5.2 Under the "Ensemble Average MODE" select the mode by which data is to be collected. "Cardiac Cycles" mode is recommended when using blocks.

9.2.6 Under "Input-Digital-Filter-Setting", select filter.

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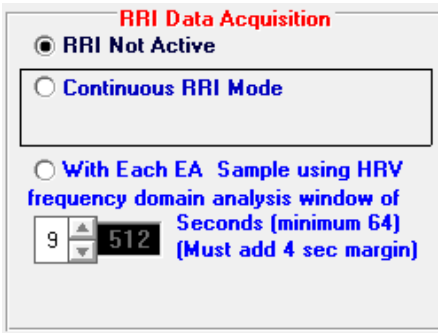
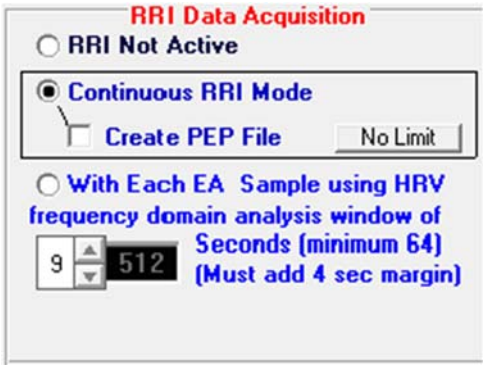
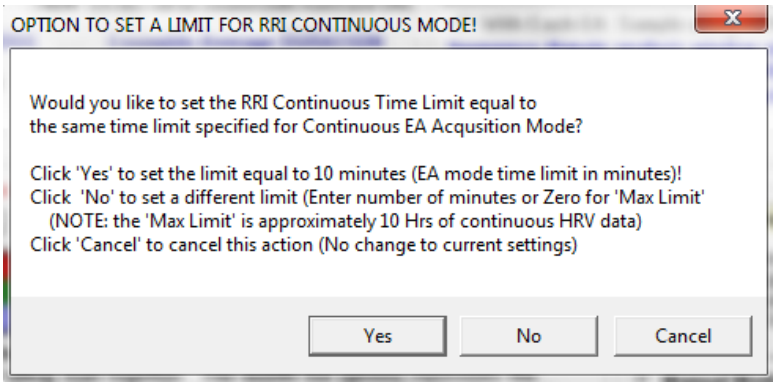
9.2.7 RRI options are used to calculate heart rate variability by measuring the distances between the R peaks in the QRS complex. Under "RRI Data Acquisition" (RRI = R-R Interval) select "RRI Not Active" to disable RRI data acquisition OR select "Continuous RRI Mode" to enable RRI data acquisition during pre-selected time intervals OR select "With Each EA Sample using HRV frequency…". Note that the latter option can only be selected if the inter-sample interval time is > 1.2 minutes.



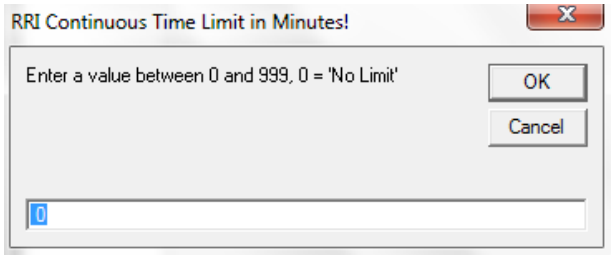
9.2.8 If the "Continuous RRI Mode" is selected and the "No Limit" button appears, acquisition will be continuous from the time the user starts data acquisition, until the user stops the acquisition.



9.2.9 In order to set a time limit, click the "No Limit" button and a Dialogue Box will appear.



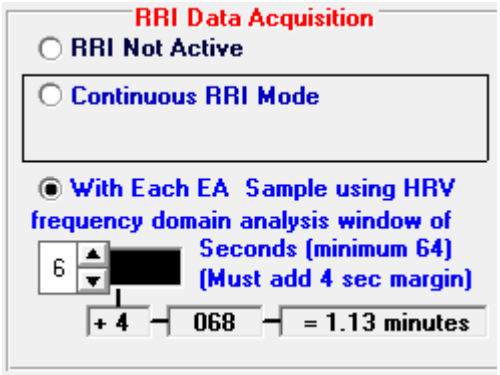
9.2.10 Select "Yes" to set the time limit for RRI data acquisition as equal to the time limit specified for Continuous EA (Ensemble Averaged) acquisition Mode earlier. Select "Cancel" to make no change to the current settings. Select "No" and another Dialogue Box will appear.



9.2.11 Enter a time limit in minutes in the blank area.

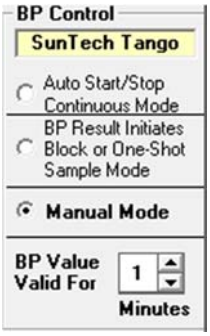
9.2.12 Select "OK".

9.2.12.1 If "With Each EA Sample using HRV frequency…" is selected, set the number of seconds to be used for the RRI sample by using the spin control. The options for the number of seconds for these samples are limited to resultants obtained from raising 2 to the power of 7, 8, 9, or 10.



NOTE: The minimum time is 128 seconds and the maximum possible time is 1024 seconds.

9.2.13 Under BP Control make sure "SunTech Tango" appears.

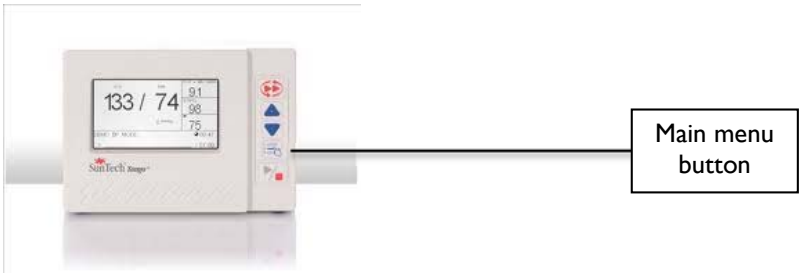


9.2.14 Select "Auto Start/Stop Continuous Mode" when it is important that EA data samples be acquired at preset intervals over a finite length of time.

9.2.15 Select "BP Result Initiates Block or One-Shot Mode" to be able to control output data acquisition through the BP monitor's interval times and/or clicking the "READ" BP control button.

9.2.16 Select "Manual Mode" in order to collect COP/HRV data and BP data that is independent of each other.

NOTE: If "Manual Mode" is selected, make sure to program the SunTech® Tango. To do so, press on the main menu button → select "Measurement Setup" → select "Interval" → using up and down arrows select interval desired. This may or may not be the same interval for EA samples.



NOTE: In this mode BP will only be collected when the "READ" button is clicked in the "Acquisition Window" or when another reading is initiated by the monitor's internal timer.

9.2.17 Under "BP Value Valid For", set the length of time that BP values are to be considered valid.

NOTE: When acquiring cardiac output data, bear in mind that the BP values are only retrieved from the BP frame at the very end of the EA period.

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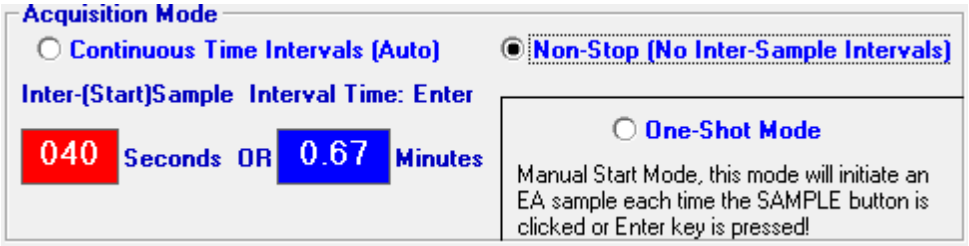
9.2.18 Check the "Automatically save EA Data to Disk" to have acquired data saved.
9.2.19 Check the "Use PEP value from PEP Detector (B-wave cursor placement)" to be able to compute systolic time interval values.

9.2.20 Click OK to store and retain the options selected. These will be retained through all subsequent executions of the software until changed by the user.
9.2.21 The "Data Acquisition Window" will appear.

9.3 OPTION 2 – Collect data continuously

9.3.1 For acquisition of impedance data intermittently at preset time intervals select "Non-Stop…" under Acquisition Mode.

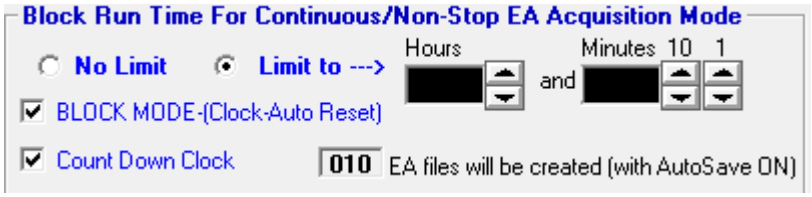


9.3.2 Under "Ensemble Average DURATION", specify desired EA.

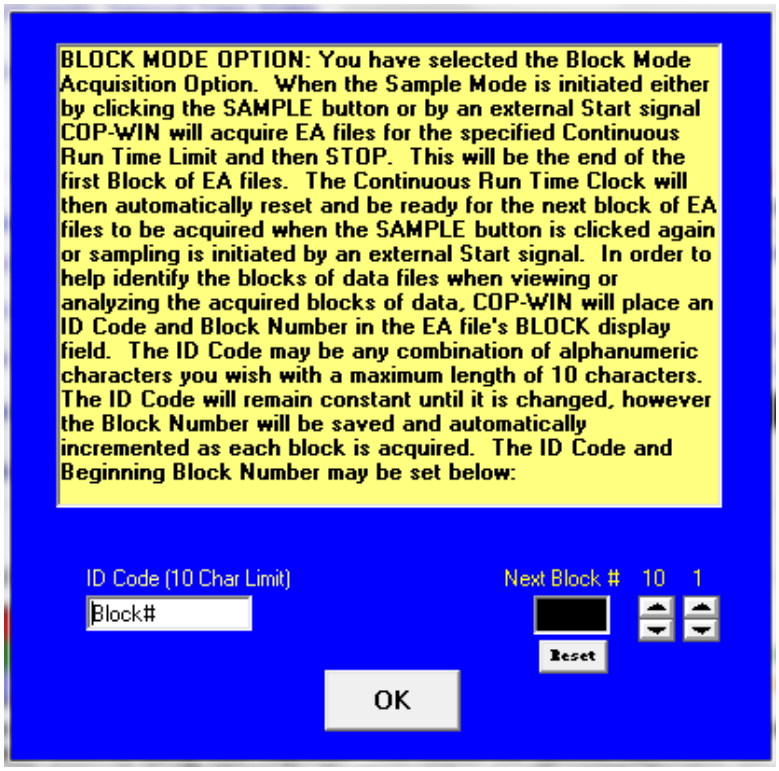
9.3.3 If you like to manually start and stop data acquisition, under the "Total Run Time For Continuous/ Non-Stop EA Acquisition Mode" select "No limit".

9.3.4 If you want to set it to a pre-determine time interval, under the "Total Run Time For Continuous/ Non-Stop EA Acquisition Mode" select "Limit to" and choose the total time under "Hours" and "Minutes".

9.3.4.1 The "Continuous Time Intervals" mode offer a Block Mode option that permits the user to acquire and label data samples with an ID Code. To turn this option on, select "Limit to", then check "BLOCK MODE" under "Block Run Time For Continuous/ Non-Stop EA Acquisition Mode".



When this option is selected and the "OK" button is pressed, a screen will appear allowing for the selection of a specific ID Code.



NOTE: If there are any parameters left to change in the prior screen, do so prior to clicking "OK" as data acquisition will begin as soon as "OK" is selected.

9.3.4.2 Under the "Ensemble Average MODE" select the mode by which data is to be collected.

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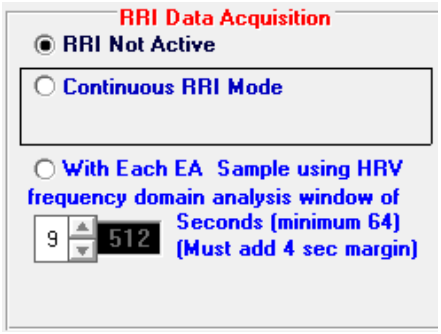
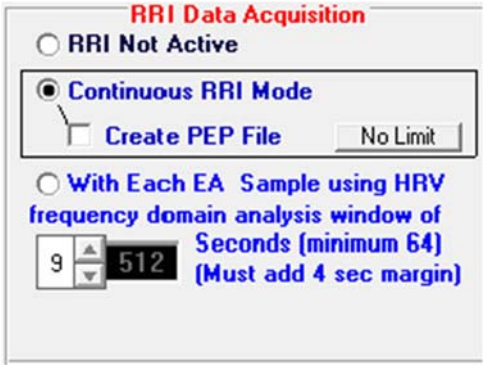
9.3.5 Under "Input-Digital-Filter-Setting", select filter.

9.3.6 RRI options are used to calculate heart rate variability by measuring the distances between the R peaks in the QRS complex. Under "RRI Data Acquisition" (RRI = R-R Interval) select "RRI Not Active" to disable RRI data acquisition OR select "Continuous RRI Mode" to enable RRI data acquisition during pre-selected time intervals OR select "With Each EA Sample using HRV frequency…". Note that the latter option can only be selected if the inter-sample interval time is > 1.2 minutes.

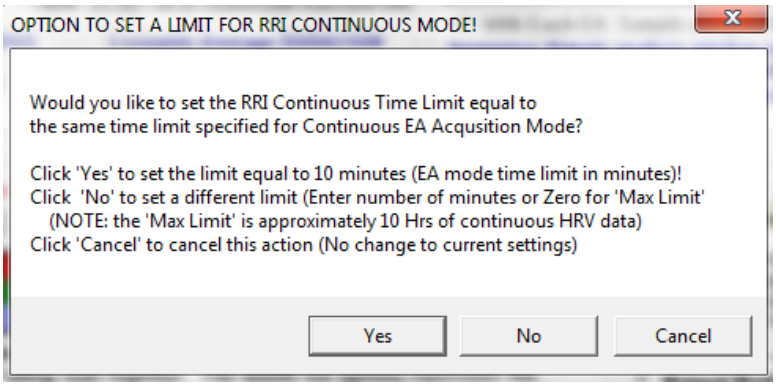


9.3.7 If the "Continuous RRI Mode" is selected and the "No Limit" button appears, acquisition will be continuous from the time the user starts data acquisition, until the user stops the acquisition.

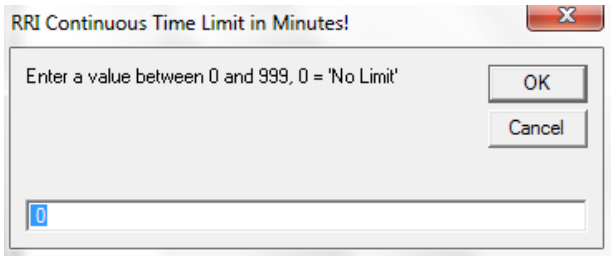


9.3.8 In order to set a time limit, click the "No Limit" button and a Dialogue Box will appear.

PERFORM Centre



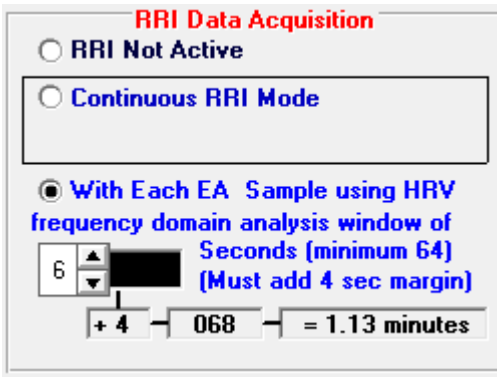
9.3.9 Select "Yes" to set the time limit for RRI data acquisition as equal to the time limit specified for Continuous EA acquisition Mode earlier. Select "Cancel" to make no change to the current settings. Select "No" and another Dialogue Box will appear.



9.3.10 Enter a time limit in minutes in the blank area.

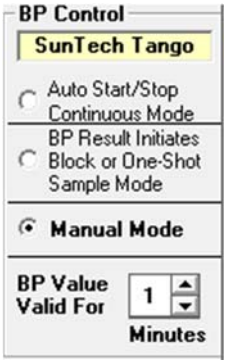
9.3.11 Select "OK".

9.3.11.1 If "With Each EA Sample using HRV frequency…" is selected, set the number of seconds to be used for the RRI sample by using the spin control. The options for the number of seconds for these samples are limited to resultants obtained from raising 2 to the power of 7, 8, 9, or 10.



NOTE: The minimum time is 128 seconds and the maximum possible time is 1024 seconds.

9.3.12 Under BP Control make sure "SunTech® Tango" appears.

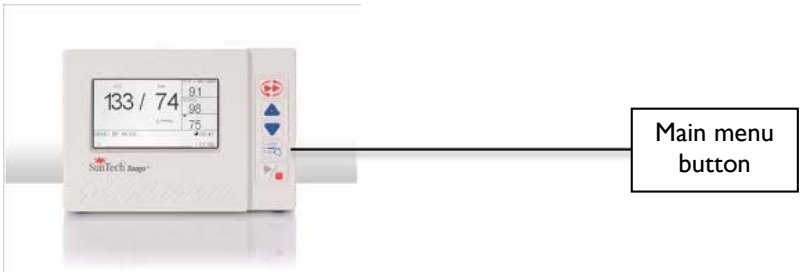


9.3.13 Select "Auto Start/Stop Continuous Mode" when it is important that EA data samples be acquired at preset intervals over a finite length of time.

9.3.14 Select "BP Result Initiates Block or One-Shot Mode" to be able to control output data acquisition through the BP monitor's interval times and/or clicking the "READ" BP control button.

9.3.15 Select "Manual Mode" in order to collect COP/HRV data and BP data that is independent of each other.

NOTE: If "Manual Mode" is selected, make sure to program the SunTech® Tango. To do so, press on the main menu button → select "Measurement Setup" → select "Interval" → using up and down arrows select interval desired. This may or may not be the same interval for EA samples.



NOTE: In this mode BP will only be collected when the "READ" button is clicked in the "Acquisition Window" or when another reading is initiated by the monitor's internal timer.

9.3.16 Under "BP Value Valid For", set the length of time that BP values are to be considered valid.

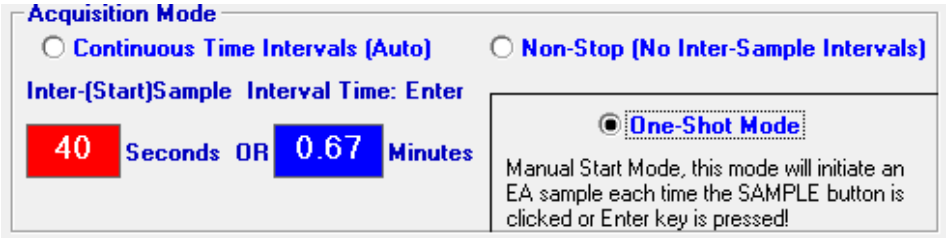
NOTE: When acquiring cardiac output data, bear in mind that the BP values are only retrieved from the BP frame at the very end of the EA period.

9.3.17 Check the "Automatically save EA Data to Disk" to have acquired data saved.
9.3.18 Check the "Use PEP value from PEP Detector (B-wave cursor placement)" to be able to compute systolic time interval values.

9.3.19 Click OK to store and retain the options selected. These will be retained through all subsequent executions of the software until changed by the user.
9.3.20 The "Data Acquisition Window" will appear.

9.4 OPTION 3 – Collect a single sample at a time

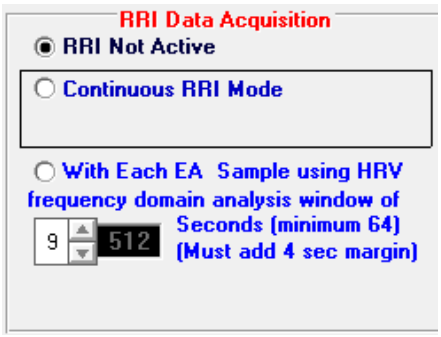
9.4.1 For acquisition of impedance data upon user command according to specifications on the "Acquisition Setup Form" select "One-shot Mode" under "Acquisition Mode".



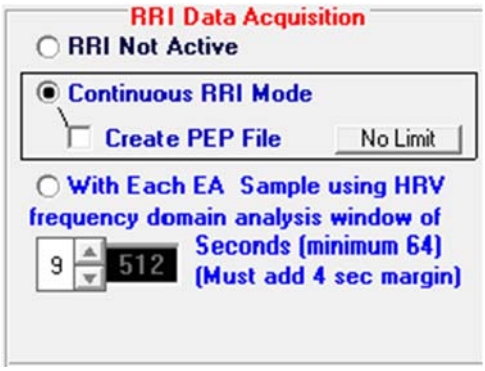
9.4.2 Under the "Ensemble Average MODE" select the mode by which data is to be collected.

9.4.3 Under "Input-Digital-Filter-Setting", select filter.
9.4.4 RRI options are used to calculate heart rate variability by measuring the distances between the R peaks in the QRS complex. Under "RRI Data Acquisition" select "RRI Not Active" to disable RRI data acquisition OR select "Continuous RRI Mode" to enable RRI data acquisition during pre-selected time intervals OR select "With Each EA Sample using HRV frequency…".

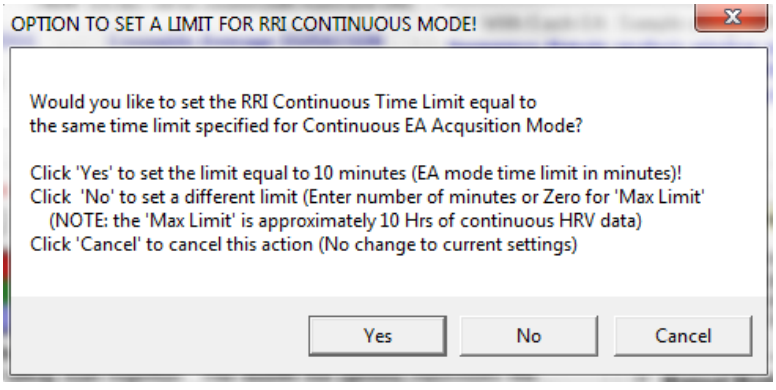
Note that the latter option can only be selected if the inter-sample interval time is > 1.2 minutes.



9.4.5 If the "Continuous RRI Mode" is selected and the "No Limit" button appears, acquisition will be continuous from the time the user starts data acquisition, until the user stops the acquisition.



9.4.6 In order to set a time limit, click the "No Limit" button and a Dialogue Box will appear.



9.4.7 Select "Yes" to set the time limit for RRI data acquisition as equal to the time limit specified for Continuous EA acquisition Mode earlier. Select "Cancel" to make no change to the current settings. Select "No" and another Dialogue Box will appear.

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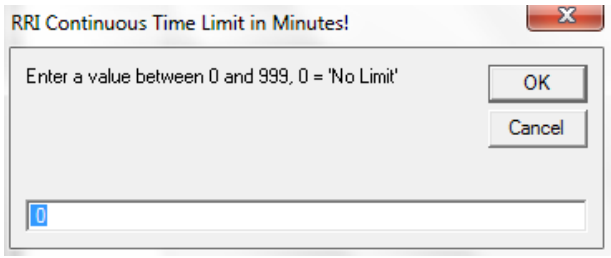
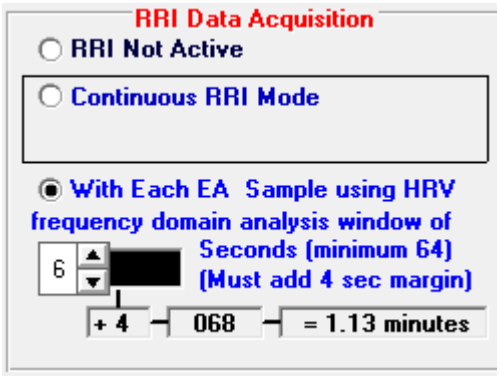


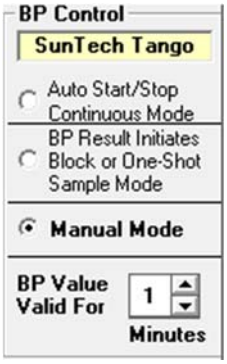
9.4.8 Enter a time limit in minutes in the blank area.
9.4.9 Select "OK".

9.4.9.1 If "With Each EA Sample using HRV frequency…" is selected, set the number of seconds to be used for the RRI sample by using the spin control. The options for the number of seconds for these samples are limited to resultants obtained from raising 2 to the power of 7, 8, 9, or 10.



NOTE: The minimum time is 128 seconds and the maximum possible time is 1024 seconds.

9.4.10 Under BP Control make sure "SunTech Tango" appears.



9.4.11 Select "Auto Start/Stop Continuous Mode" when it is important that EA data samples be acquired at preset intervals over a finite length of time.

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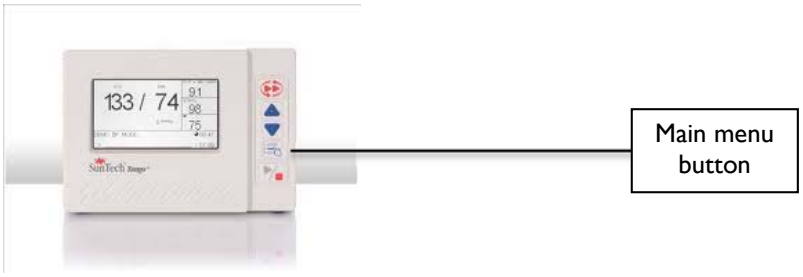
9.4.12 Select "BP Result Initiates Block or One-Shot Mode" to be able to control output data acquisition through the BP monitor's interval times and/or clicking the "READ" BP control button.

9.4.13 Select "Manual Mode" in order to collect COP/HRV data and BP data that is independent of each other.

NOTE: If "Manual Mode" is selected, make sure to program the SunTech® Tango. To do so, press on the main menu button → select "Measurement Setup" → select "Interval" → using up and down arrows select interval desired. This may or may not be the same interval for EA samples.



NOTE: In this mode BP will only be collected when the "READ" button is clicked in the "Acquisition Window" or when another reading is initiated by the monitor's internal timer.

9.4.14 Under "BP Value Valid For", set the length of time that BP values are to be considered valid.

NOTE: When acquiring cardiac output data, bear in mind that the BP values are only retrieved from the BP frame at the very end of the EA period.

9.4.15 Check the "Automatically save EA Data to Disk" to have acquired data saved.

9.4.16 Check the "Use PEP value from PEP Detector (B-wave cursor placement)" to be able to compute systolic time interval values.

9.4.17 Click 

to store and retain the options selected. These will be retained through all subsequent executions of the software until changed by the user.

9.4.18 The "Data Acquisition Window" will appear.

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9.5 Data Acquisition Window

9.5.1 The options in the "Acquisition Setup Window" need to be verified before the software allows access to the "Data Acquisition Window".

9.5.2 Verify that the mode of acquisition under Acquire Mode is correct. This option allows the changing the mode of data acquisition without having to go back to the Acquisition set-up window.

9.5.3 Select "One-shot" mode if a single EA sample is required. This option can be used for doing a trial run by selecting "One-Shot" and deselecting the "Auto Save" option. When ready to save data "Auto Save" should be re-selected.

9.5.4 Select "Continuous" mode if continuous data is required until the pre-set time limit is reached.

9.5.5 Select "Auto Save" if you want data collected to be saved automatically.

9.5.6 Under the Posture frame, ensure that the correct posture is selected (either "Seated" or "Standing" and that the number under "Electrode Distance is accurate". If the subject has changed posture, then adjust the selections accordingly.

9.5.7 Click SAMPLE button to begin data acquisition.

9.5.8 Click the "Stop" button to stop EA data acquisition.

9.5.9 In order to edit the last acquired data file, click the "COP Edit Mode" button.

9.5.10 Click the "Quit" button once data acquisition is complete and you are ready to exit the Acquisition Window.

NOTE: Before selecting "Stop" or "Quit" verify the status of the EA acquisition time under "Status" to make sure that acquisition isn't stopped in the middle of an EA sample, which would end up void.

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9.6 Data Acquisition Window with RRI Data

9.6.1 Controls

The RRI Mode Control Frame displays the current RRI Mode, Session Time, and Event Control.

NOTE: FOR RRI DATA ACQUISITION, THERE MUST BE AN ECG SIGNAL PRESENT.

9.6.1.1 RRI Mode Control → Displays the current RRI mode and mode status. This control allows the user to activate and deactivate the RRI mode.
9.6.1.2 Session Timer → Supplies a time reference for the RRI data acquisition event marks. This timer is automatically activated when any RRI data acquisition is set to "Active". The timer may also be started by the user
9.6.1.3 Event Control → Allows the user to create and display event marks that are to be used for HRV analysis.

9.6.2 RRI Data Acquisition

9.6.2.1 If the RRI acquisition mode is Continuous with "No Time Limit":
- 9.6.2.1.1 To start RRI data acquisition, click "Start RRI Acquisition".
- 9.6.2.1.2 To stop RRI data acquisition, click "Stop RRI Acquisition".

9.6.2.2 If the RRI acquisition mode is Continuous "With Time Limit":
- 9.6.2.2.1 To start RRI data acquisition, click "Start RRI Acquisition".
- 9.6.2.2.2 To stop RRI data acquisition, click "Stop RRI Acquisition" or data acquisition will stop when the time limit is reached.

9.6.2.3 If the RRI acquisition mode is "With Each EA":
- 9.6.2.3.1 To activate RRI data acquisition, click "Start RRI Acquisition". In this mode the session timer will not start and RRI data will not be acquired until the first EA sample.

9.6.2.4 To manually terminate RRI data acquisition:
- 9.6.2.4.1 Click the "ACTIVE-click here to Stop" button under "RRI Mode" to stop data acquisition. In this mode, the "Stop RRI Acquisition" button is disabled.

NOTE: RRI acquisition can be aborted at any point, without saving the data, by double clicking on the "ACQUIRING" indicator in the "RRI Data Acquisition" box.

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10. Reporting

10.1 To create a report click on "Reports" → select option desired from drop down menu.

10.2 Should "Select Parameters for Printing" be selected, a wide range of parameters could be selected for printing.

11. Cleaning/Disinfecting

11.1 Clean blood pressure cuff according to POD entitled "Use and Cleaning Procedures for Manual and Automatic Aneroid Sphygmomanometers".

11.2 Wipe the cables with a soft, slightly moistened cloth.

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APPENDIX I

POD Training Record Form

PERFORM Centre

POD Title

Use and Cleaning of HIC4000I Impedance Cardiograph

SOP Code

Ownership	Document type	Area	SOP Number	Version
PC	POD	CP	006	V01

Training Record

Full Name	
Institution	
Contact (email or phone number)	

Signature

Sign here

Date