

Manual of Procedures for DLCO

ARIC Exam 5



ARIC MOP version 3, date: February 9, 2012

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Section 1: Brief Overview

The diffusing capacity of the lungs for carbon monoxide (DLco) component involves testing two different parameters – the slow vital capacity (SVC) and the DLco itself. The value for the SVC is used by the machine to calculate predicted values for DLco so it must be obtained first.

The machine that we are using is the EasyOne Pro (ndd Medical Technologies, Zurich, Switzerland). The machine requires a tank of gas to be attached in order to measure the DLco. The gas mixture is:

- 10% Helium (He)
- 0.3% Carbon Monoxide (CO)
- 20.9% Oxygen (O₂) (18 – 25%, consult ndd Medical Technologies)
- Remainder Nitrogen (N₂)

Note - There is no hazard to breathing this gas.

Gas tanks come in small and larger size. We are using the larger sized tanks. These need to be secured to the wall.

These are the steps needed for a testing session:

1. Turn on the gas.
2. Turn on the machine
3. Enter subject information
4. Measure the SVC
5. Measure the DLco
6. After each subject – “send” test to machine database to ensure correct format for later download to coordinating center.

At the end of the day:

7. Turn off gas
8. Turn off device

Once per month:

Download data from the machine to a USB drive and then upload to the coordinating center.

Section 2: Turning on the DLco gas

Open the main valve of the gas cylinder completely. – see picture below for more detail.
To open the tank - turn the SILVER gas knob, which is on the right in the picture below.

There are two gauges pictured. The left gauge shows the amount of gas that is being delivered to the patient. **This should always read between 60 and 80 PSI (4-5 bar)** (“PSI” are the units for the outer ring of numbers, bar are the units for the inner ring of numbers), the black dial will allow for adjustments – decrease or increase. The right gauge shows the amount of gas in the tank. A full tank should be around 2000 PSI (units for outer ring of numbers) and once you get to 500 PSI make sure you have another tank ordered and ready to go. **Once 250 PSI is reached there is not enough gas to perform the test.**

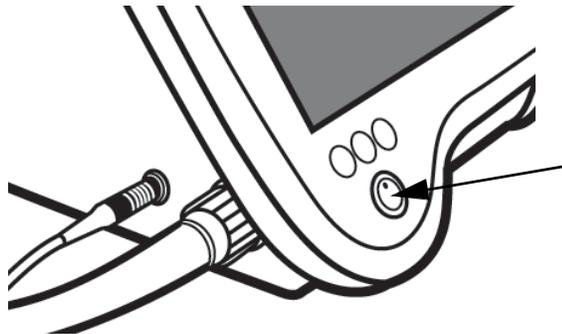
Each site needs an adjustable (monkey) wrench to change the tanks.



Section 3: Turning on the machine

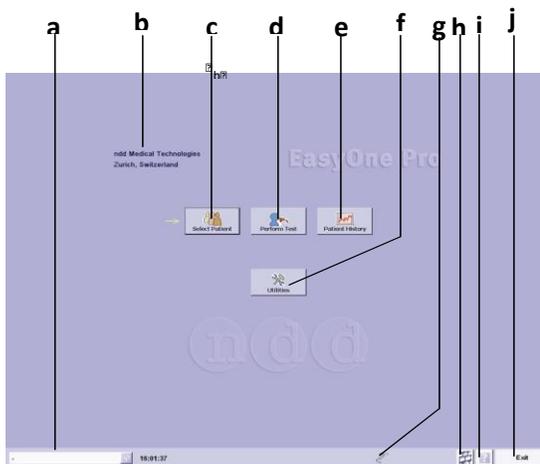
Turn on the main power switch on the rear panel of the device.

Turn on the device with the power button: the green indicator is illuminated.



After a short start-up phase, the initial screen will be displayed.

Note: If the initial screen appears and no error messages are displayed, the device is in good operating condition.

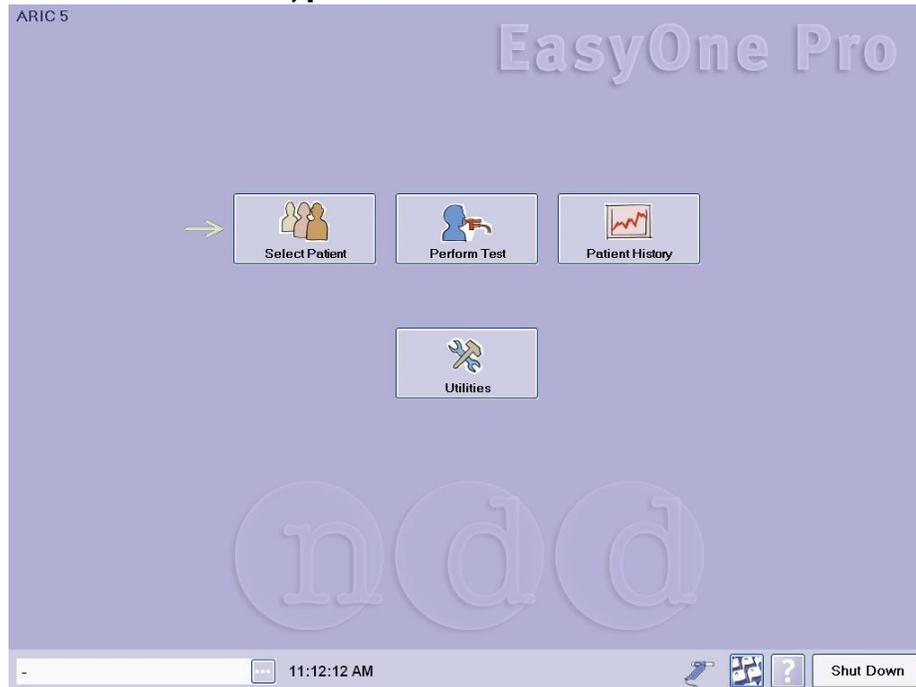


MAIN SCREEN OVERVIEW – This is a touch screen

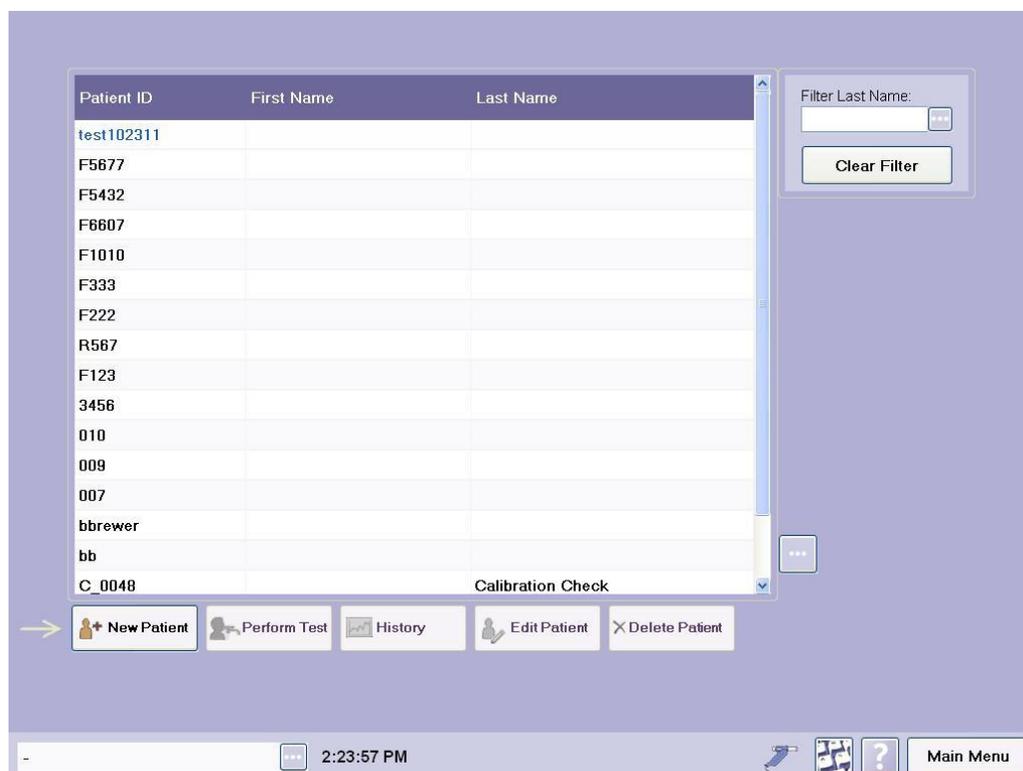
- a Selected subject
- b Practice, office, hospital – it says Aric 5 for us.
- c Click to select a patient or add a new patient
- d Click to perform a test
- e Click to review the results from previous tests
- f Click to view the setup screen
- g Sensor status (sensor icon, if sensor is connected)
- h Click to display the keypad
- i Help button
- j Click to quit the program

Section 4: Entering subject information

From the MAIN MENU, press “Select Patient”



On the next screen, press “New Patient”



The screen below will come up next. Enter ONLY the fields marked by asterisk *. These fields are: Patient ID, Gender, Date of Birth, Height in inches, and Ethnic.

After entering them, press "OK".

The screenshot shows a patient information form with two tabs: "General" and "Comment". The "General" tab is active. The form contains the following fields:

- Patient ID: # *
- Last Name:
- First Name:
- Gender: *
- Date of Birth: / / m/d/yyyy *
- Age: *
- Height: in *
- Weight: lb
- Ethnic: *
- Smoker:
- Asthma:
- COPD:

Buttons: "Update Existing Tests", "Cancel", "Ok". A legend indicates "* Required".

Footer: 11:14:40 AM, Menu

Press "Perform Test" below and then follow directions on the next page to get ready to do the SVC test:

The screenshot shows a patient list table with the following data:

Patient ID	First Name	Last Name
3333		
#0051		Andover QC
C_0048		Calibration Check
Q_0050		Quick Test
457u	Chris	Shannon
PSM-11213	Peter	Smith

Buttons: "New Patient", "Perform Test", "History", "Edit Patient", "Delete Patient".

Footer: / 3333, 11:19:12 AM, Main Menu

Section 5: Measuring the SVC (slow vital capacity)

Before the DLco, you need to measure the SVC. SVC is needed for the machine to provide a predicted DLco value.

The sensor is stored on the unit connected to the white motor block – both are needed for the DLCO test. But just the purple hand sensor is needed for the SVC. So remove the purple hand sensor by pressing on the silver button – marked by a red oval in the picture below.



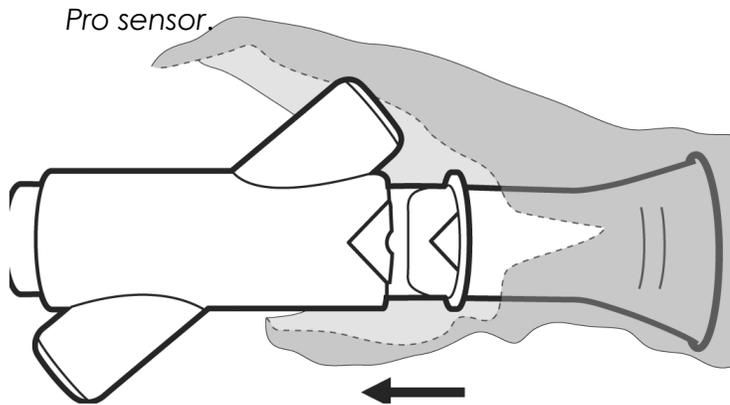
The picture below shows the purple hand sensor after you have removed the white motor block



For each subject you need to insert a fresh spirette into the hand sensor.

Tear open the plastic bag containing the *spirette* and fold the bag back so that you can insert the *spirette* in the *EasyOne Pro* sensor without touching the *spirette* itself. Try to ensure that the plastic bag protects the mouthpiece of the *spirette* until you hand the *EasyOne Pro* sensor over to the patient. This approach not only ensures perfectly hygienic conditions, it also keeps the *spirette* closed for subsequent setting of the baseline.

Insert the *spirette* - as shown in the illustration - into the *EasyOne Pro* sensor as far as possible. When doing this, please ensure that the arrow on the *spirette* is lined up with the arrow on the *EasyOne*

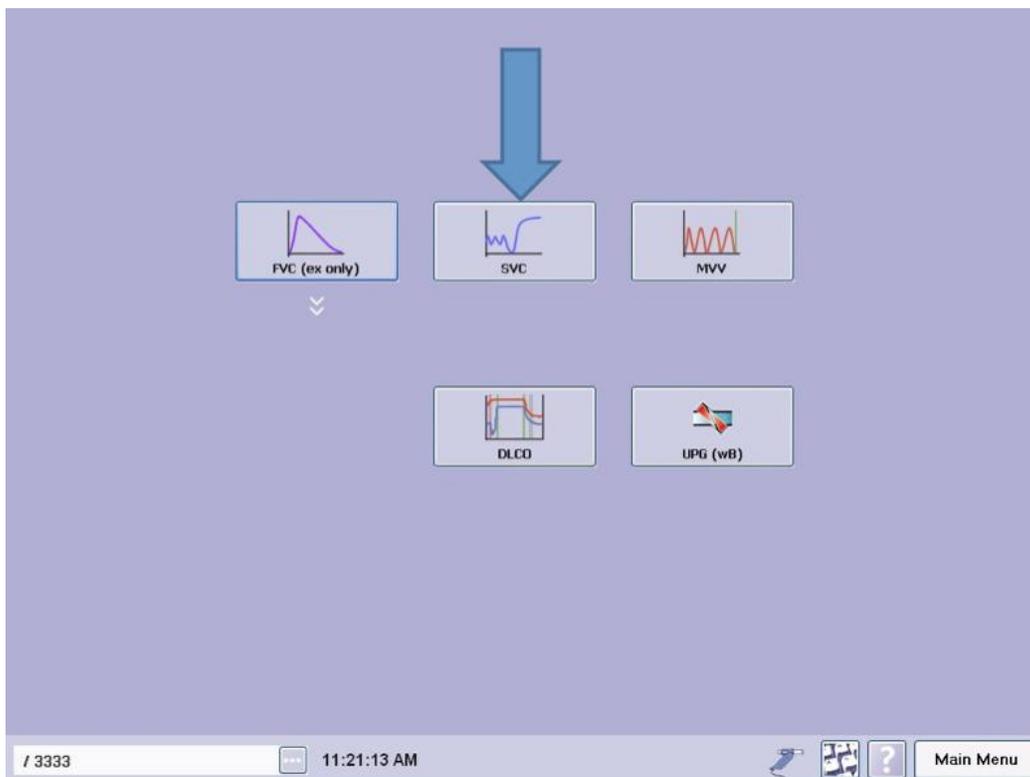


Purple sensor with spirette inserted

Before starting, please have a cup of water handy for the subject. Dry mouth or throat sometimes makes a subject feel like coughing. Ask the subject to take a sip just before the test.

You are now ready to do the SVC test.

Select "SVC" on the "test selection screen" pictured below:



If this is the first test that is being done after the machine has just been turned on (or after the machine has been on for a while so conditions might have changed), the machine will measure the ambient temperature, humidity and pressure and these values will populate the screen. Press "Confirm":



Have the subject perform the SVC:

Explain the test maneuvers to the participant. Tell them that they will do 2-4 short breath tests (This includes the 1-2 SVC tests and the 2 DLCO tests). You can tell them the following:

1. I will ask you to put on nose clip
2. I will hand you the spirette and ask you to put it in your mouth
3. When the machine is ready, I will ask you to take a very big breath in and then immediately start to breath it out (exhale) in a relaxed manner
4. If this test is acceptable we will move on the next text. If not, I will ask you to do one more before moving to the next.

In response to the prompt on the screen below “Block spirette until prompted to Blast Out”, you should keep the spirette with the plastic over the front of the mouth piece. (If you have accidentally discarded the plastic or it has gotten too ripped up, place your hand over the BACK of the spirette to block flow from going through the tube and keep it still)

Then press “OK” in the box pictured below.

4/18/2011 SVC (VC) / Best Value Predicted Ref: NHANES III
Session Quality: Pre -
System Interpretation:
Interval Message: -
Comment: Last Reviewer:

Block spirette until prompted to Blast Out

OK Cancel

Please wait...

Cancel

/ 3333 11:21:57 AM Main Menu

Comment: Last Review:

Test Parameters	Pred	LLN	Best
Trial Rank			
Time			
VC [L]	3.48	2.78	
VCex [L]	--	--	
VCin [L]	3.48	2.78	
IRV [L]	--	--	
IC [L]	--	--	
VT [L]	--	--	

Add Trial ←

Print Preview

Print

History

New Test

Patients

Main Menu

/ f00009 1:22:02 PM

11/6/08 11:56:08 SVC (VC) / Best Value Predicted (at 11:56:08)

Session Quality: Pin

System: Pin

Interpretation: Pin

Interval Message: Pin

Comment: Last Review:

Test Parameters	Pred	LLN	Best
Trial Rank			
Time			
VC [L]	3.48	2.78	
VCex [L]	--	--	
VCin [L]	3.48	2.78	
IRV [L]	--	--	
IC [L]	--	--	
VT [L]	--	--	

Add Trial ←

Print Preview

Print

History

New Test

Patients

Main Menu

/ f00008 1:22:02 PM

Have subject put on nose clips.

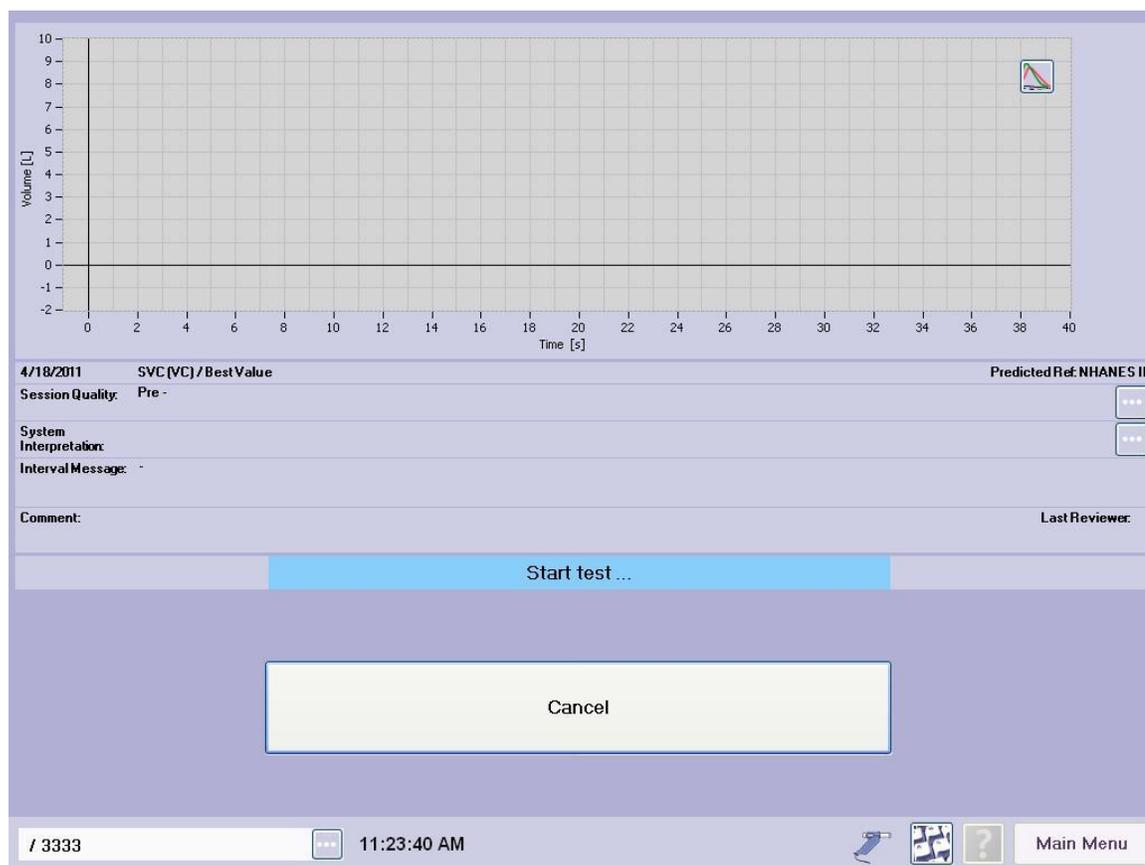
Screen will say “Setting baseline avoid flow”. Keep the sensor still to avoid flow.

Screen will say “Start test” in blue box – see below.

Hand purple sensor to subject without touching the spirette. Have subject place spirette in mouth. (Make sure the mouth is completely around the mouthpiece to get good seal. A tiny bit of pressure makes a good seal but tell them not to bite on it or to block the opening with their tongue.)

Immediately tell subject to take very big breath in and then slowly exhale (in a relaxed way)

The screen will say “keep going” during the exhalation and then will say “analyzing data”. At that point, subject should stop exhaling. Some subjects with lung disease do not empty lungs quickly and thus the screen will keep saying “keep going”. Have subject stop after 12 seconds to avoid tiring them – this will stop the test.

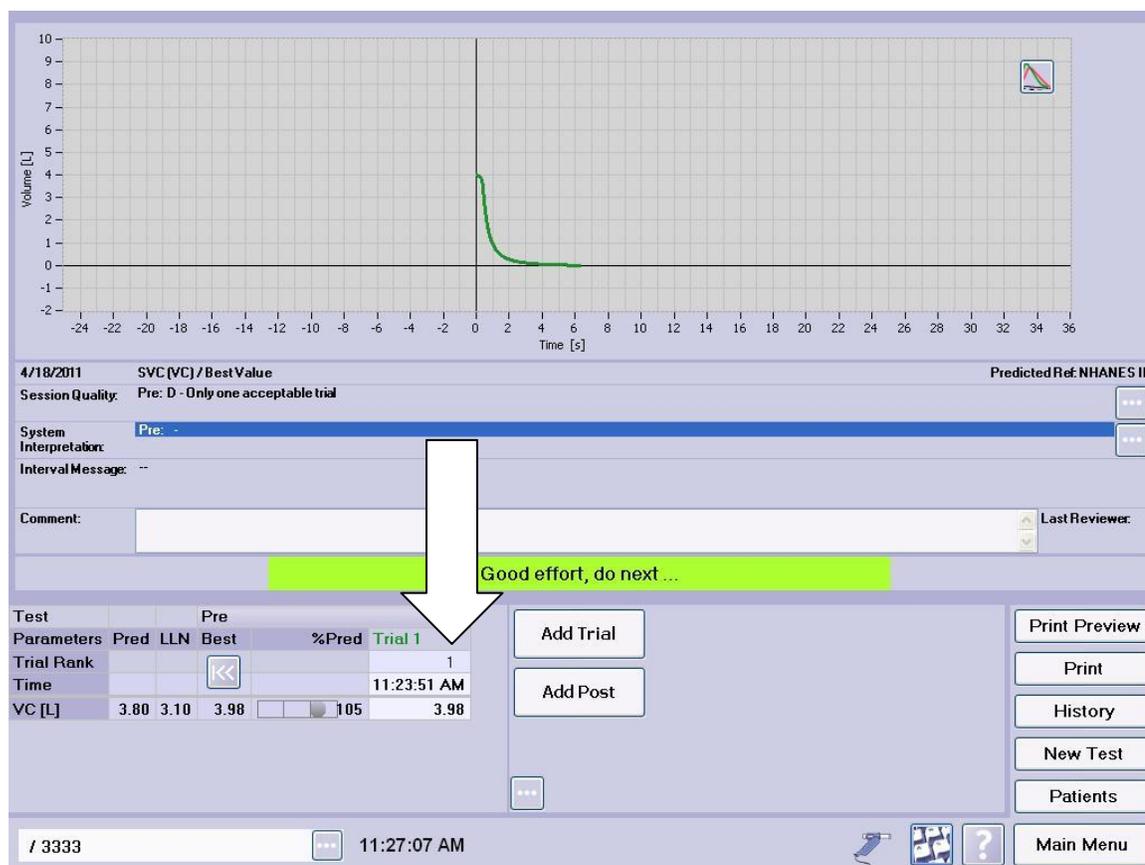


If first trial is acceptable you will do only one. You can tell if a trial acceptable because there be no line through the number “1” under the column Trial 1 on the row marked “Trial Rank”. (See end of this document for an example of a trial number with a line through it indicating a bad test – this was actually a second test). The test below was acceptable so there is no line through the number “1” under “Trial 1”. If you got an acceptable first trial, press “New Test” button on the lower right. This will take you to the “test selection screen”– this is the screen pictured at the beginning of this SVC section. Do not press DLCO yet – you need to get the equipment ready first.

If the first test was NOT acceptable, repeat one more time – press “Add Trial” button. Once you have done the second trial then hit “new test” to go to the “test selection screen”. Do not press DLCO yet – you need to get the equipment ready first.

Have the subject remove the nose clips while you get the equipment ready for the DLCO test.

The graph below shows an acceptable SVC test.



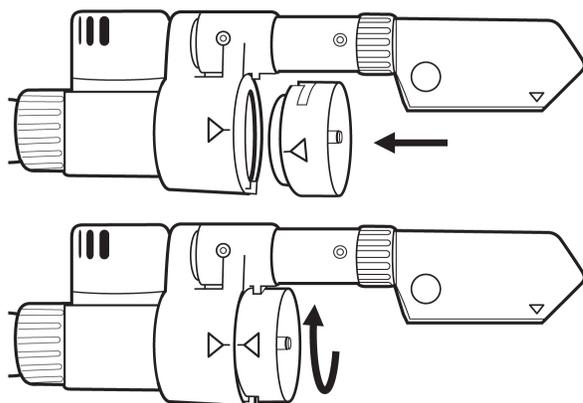
Section 6: Measuring the DLco

Before pressing the button to go to the DLCO test, you need to prepare the equipment. The DLCO test uses the purple hand sensor attached to the white motor block.

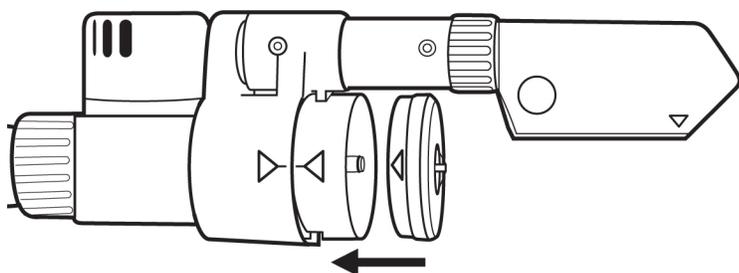
For each subject you need to insert a fresh *barriette*TM into the “one-way valve” on the white motor block

Usually the one way valve is attached already (arrow below points to the one-way valve). But if the one-way valve is not attached (sometimes it gets removed when you pull off a used *barriette*TM- check for this when you remove a used *barriette* so that you do not discard the one way valve), then do as follows:

Attach the one-way valve to the valve unit (aligning the arrows) as shown below. Turn it clockwise as far as possible.



Insert the *barriette*TM in the one-way valve (aligning the arrows) as shown below. Check that it sits tight.



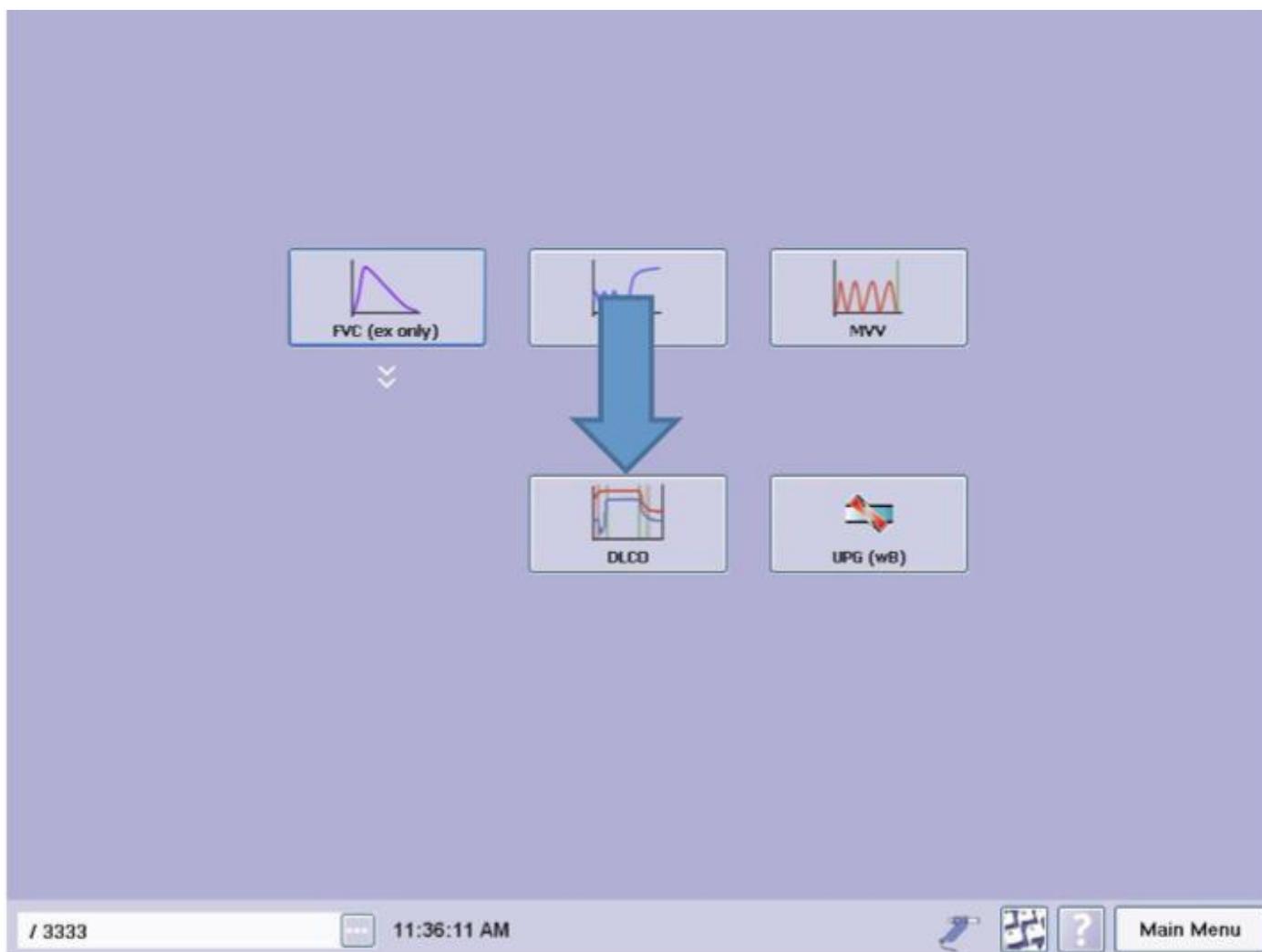
This is a picture of the *barriette*TM from another angle.

Connect DLco white motor block to purple hand sensor. The two gold prongs on white motor block go into the two holes on the grey part of the purple hand sensor. Make sure that you hear a “click” which tells you that it is inserted properly.

The picture below shows the hand unit ready to give to the subject to perform the DLCO test:



SELECT THE "DLCO" BUTTON (arrow below):



If you had not already inserted the barriette and connected the white motor block to the purple sensor before you have pressed “DLCO” you may get the error message below. If so, just make sure everything is attached correctly and press “OK”. You will also get this message if the white motor block is not properly connected to the purple sensor. In that case, remount and press “OK”.

The screenshot displays a software interface for a DLCO test. On the left, there are two graphs: the top one shows Volume [L] on the y-axis (ranging from -1 to 10) and time on the x-axis (ranging from 0 to 22); the bottom one shows CO [ppm] on the y-axis (ranging from 0 to 3000) and time on the x-axis (ranging from 0 to 22). A central error dialog box is overlaid, featuring a green checkmark icon and the text: "DLCO Valve Unit NOT mounted on handle sensor! Mount DLCO Valve Unit and repeat procedure." Below the text is an "OK" button. At the bottom of the dialog is a yellow "Please wait..." box. To the right of the dialog is a red "Stop" button. The top right corner of the interface shows the date "6/22/2011", the test name "DLCO", "Predicted Ref: Miller", and "Session Quality: -". The bottom status bar shows "/ 3456", a time of "9:35:06 AM", and a "Main Menu" button.

Now you are ready to start the DLCO test.

Explain the procedure to the subject. Tell them that they will wear nose clips. You will hand them the sensor, tell them when to put the spirette in the mouth, they will take a few normal breaths and then you will tell them to take a big breath in and then you will tell them to exhale. You will coach them to keep breathing out until you tell them to take a big breath in and hold for a few seconds. When you tell them to, they will then do a relaxed exhale. They will keep the spirette in their mouth until you tell them to remove it.

Make sure subject is sitting upright.

Have the subject take a sip of water. This can prevent cough during the test.

Place the nose clip on the subject's nose. Make sure that it fits properly.

Select START from the screen. You will hear the device flushing the gas for 20-30 seconds.

After the flushing stops, give the sensor to the patient. Instruct the patient to hold the sensor straight (not at an angle) in front of the mouth without taking the spirette™ into the mouth yet.

When you see “START TIDAL BREATHING” across the screen, have subject insert spirette™ in mouth. They should have a good seal. (If subject has dentures and they cannot get a good seal, have them remove the dentures. Bad seal can also be due to nose clip not fitting correctly.)

Have patient breath normally (called tidal breathing) until three tidal breaths show up on the screen. For some reason the first breath taken with the spirette in the mouth does not show up on the screen. After those three breaths on the screen, have them take a big breath in for the fourth breath (Unfortunately the screen says “FULLY EXHALE” during this phase – IGNORE).

After the big breath in, tell subject to exhale completely. As soon as you see that the subject has started to exhale press the “ACTIVATE” button. Tell subject to keep exhaling (say “keep going, keep going...” which the screen will also say). It is important to instruct to keep exhaling because once they see you hit “ACTIVATE”, some subjects instinctively stop which will give a bad test.

The device detects when patient has exhaled completely (low plateau on graph on next page) and then you will hear the valve shut. Screen will then prompt to “fully inhale” and then you will instruct patient to take a quick but deep breath in. You will then hear the gas come through to subject. Keep telling subject to inhale until they cross the dotted horizontal blue line on the screen. Once line has been crossed, the subject should hold the breath - clock will appear. (Note that if subject does not inhale deeply enough to cross the line, test will be unacceptable – so next time have them take a bigger breath in).

Once the clock appears you will hear a ticking sound -- subject should hold the breath until the clock stops. (Screen will say “Hold Your Breath”). When clock stops you will hear a valve open. At that point tell the subject to exhale quickly but completely in a relaxed manner -- screen will say “fully exhale relaxed”. Subject should exhale for about 5 seconds. At this point on the lower graph box on the screen the green and purple lines will start to separate – see next page. Then tell them to take a small breath in with spirette™ still in their mouth – this will stop the test. Device will take a sample (green vertical line). When test stops, screen will briefly say “Analyzing Data”. The first DLco measurement is now complete.

Note: It is important to tell the subject to take the small breath in to stop the test. Otherwise they will exhale for too long which gives a bad test and is also tiring. (see screen shot #2 in Appendix for visual detail). They should also keep the spirette™ in the mouth for that small breath in – the instinct is to remove it before taking the breath in which will spoil the test.

Have subject wait for at least 4 minutes and then repeat the DLco measurement.

Because the maneuver can dry throat, ask subject to take another sip of water before the second DLCO test to avoid coughing.

You and the subject can do other study tasks during the four minutes between tests. This is a good time to fill in the DLCO management form.

Enter the date on which the participant was seen in the clinic.

Enter the staff ID for the person who completed this form.

Record YES if this set of tests (SVC and DLCO – collectively called Diffusing capacity on this form) was started. If YES, go on to question 3.

If NO, Record the reason why the diffusion capacity was not measured.

Record whether SVC was measured.

Record whether DLCO was measured.

Get a total of two DLCO measurements. Do not repeat a third time even if the machine gives the session a poor grade for reproducibility because of time issues.

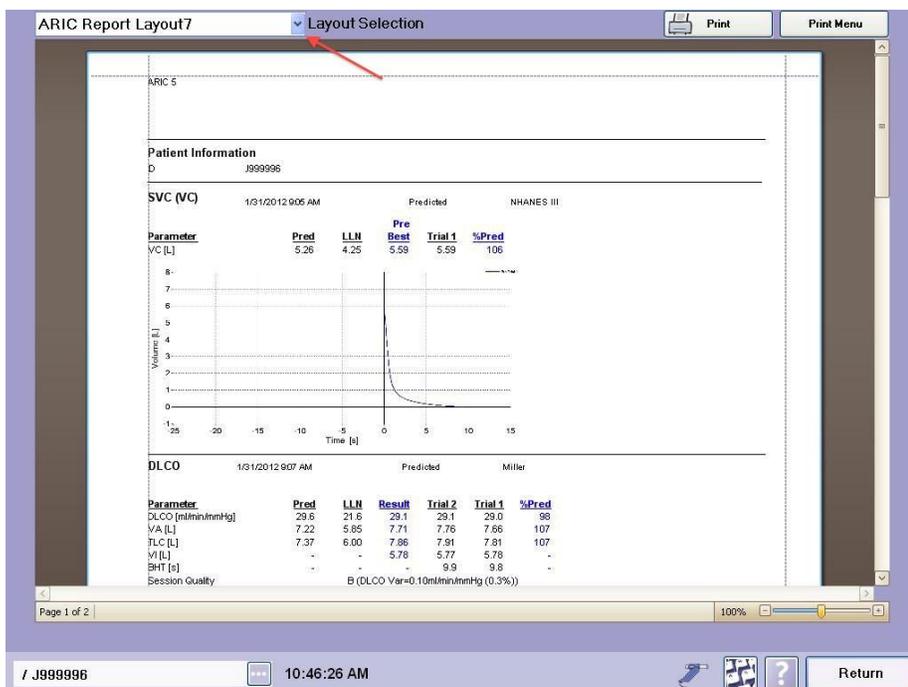
The screen below shows a completed DLCO test session with two trials. The tracing shows the second trial. Both trials were acceptable.



(Note that we are not putting names into the screen so you will never see a name in the box on the bottom left. Peter Smith is a quality control record inserted by ndd Medical Technologies.)

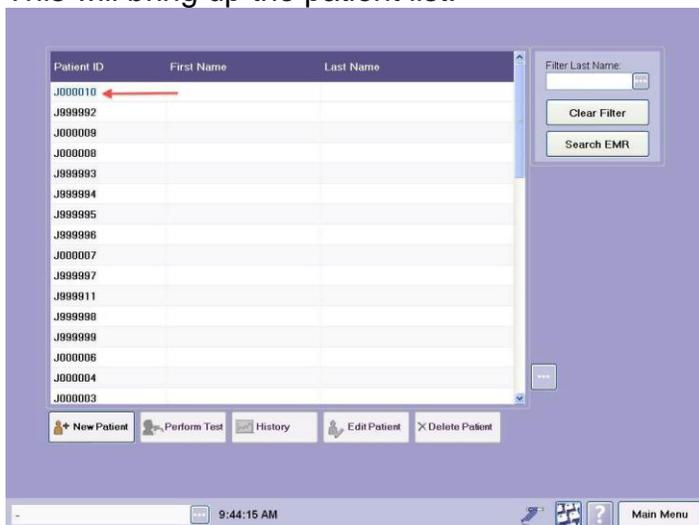
Now that you have finished testing the subject, you need to follow the procedure below to “send” the test to the machine database in the correct format for periodic download to the coordinating center. This is an important step that needs to be done after each subject. It ensures that the file uploaded to the coordinating center does not contain the date of birth and is in the correct format for QC and processing. Steps below:

Press the “Print Preview” button in the picture above which will bring up the report for that test – see picture below. The first time you do “Print Preview” after turning on the machine it will take about 20 seconds for the hourglass to disappear – with subsequent tests done later the same day (assuming machine has been left on) it will take only about 5 seconds. Verify that the “Layout selection” is set to “ARIC REPORT Layout7” – see red arrow below. This is important as the setting can revert to the default setting, such as “DLCO”. If not set to “ARIC REPORT Layout7” toggle to “ARIC REPORT Layout7”. (To toggle touch the small blue box with the down caret next to the words “Layout Selection”). Making sure that the “ARIC REPORT Layout7” format is selected will ensure that dates of birth are removed from the files before download.



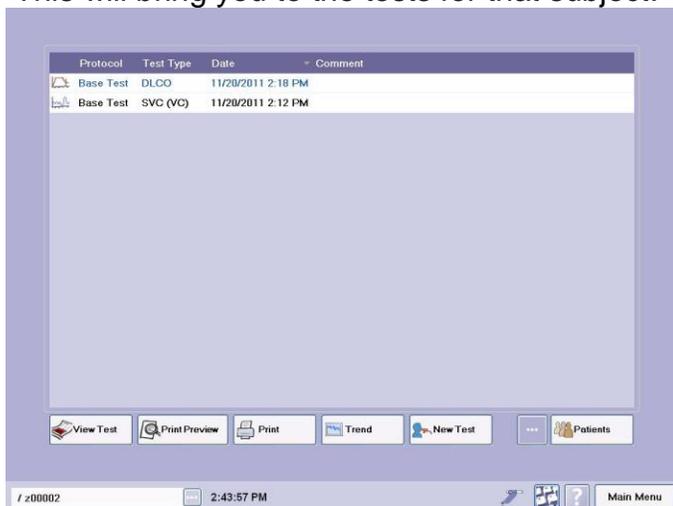
Then press the “Return” button at the bottom right corner of the screen above. This will bring you back to the DLCO test screen on the previous page.

Now press the “Patients” button – see DLCO test screen on the previous page. This will bring up the patient list.



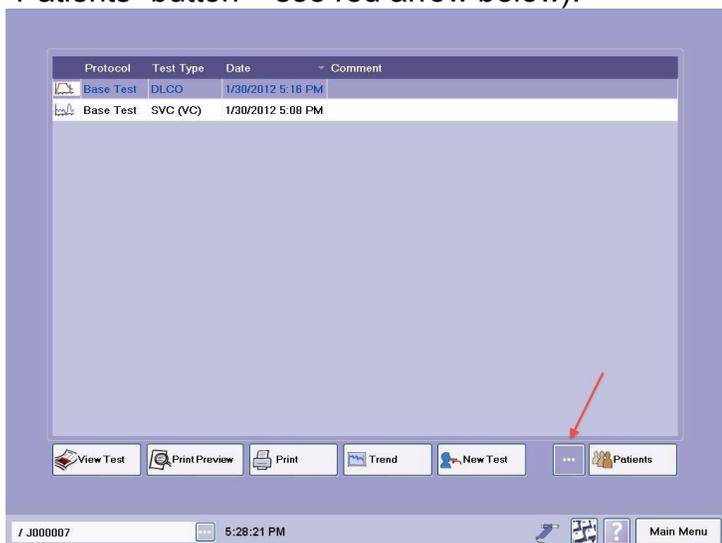
Touch the ID of subject you just did – this will be on top – marked with arrow above – (Note – writer of this manual was not able to get all screen shots for the same ID so ignore the fact that the IDs are different in these pictures)

This will bring you to the tests for that subject:



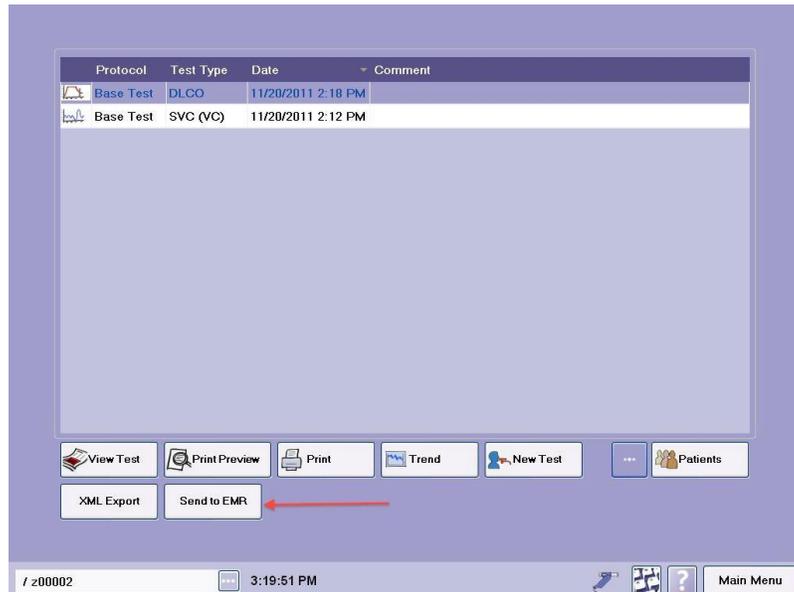
Touch the top test again – it is the DLCO under Test Type above. This will select it and turn it purple again – if it was not already purple. Do NOT select the SVC test.

Press the expand button (the three white dots on purple background which is just to the left of the “Patients” button – see red arrow below).



Pressing that “expand” button will bring up an additional row of buttons including “Send to EMR” (see picture below).

Now press the “Send to EMR” button – see red arrow below:



Sending may take several seconds. If the hourglass comes up, wait for it to go away. Note that what you have just done send both the DLCO and the SVC tests. Do not select the SVC test – this could cause problems.

You are now done with the test session for this subject.

Press “Main Menu”. If you will be testing additional subjects today, you should leave the machine on.

Discard the spirette and barriette that you used for this subject. Hang the hand set back into its cradle as shown in the first picture in the SVC directions.

In the event that you do an SVC test but cannot get any DLCO test, even a failing one, do NOT sent the SVC test. We cannot use the SVC test without the DLCO and sending just the SVC could cause problems. We will know from the DLCO management form that you did just the SVC.

Section 7: Shutting down the gas and the machine

This should be done at the end of the day

- a. Return to the main menu and press “Shut Down” – see arrow below.

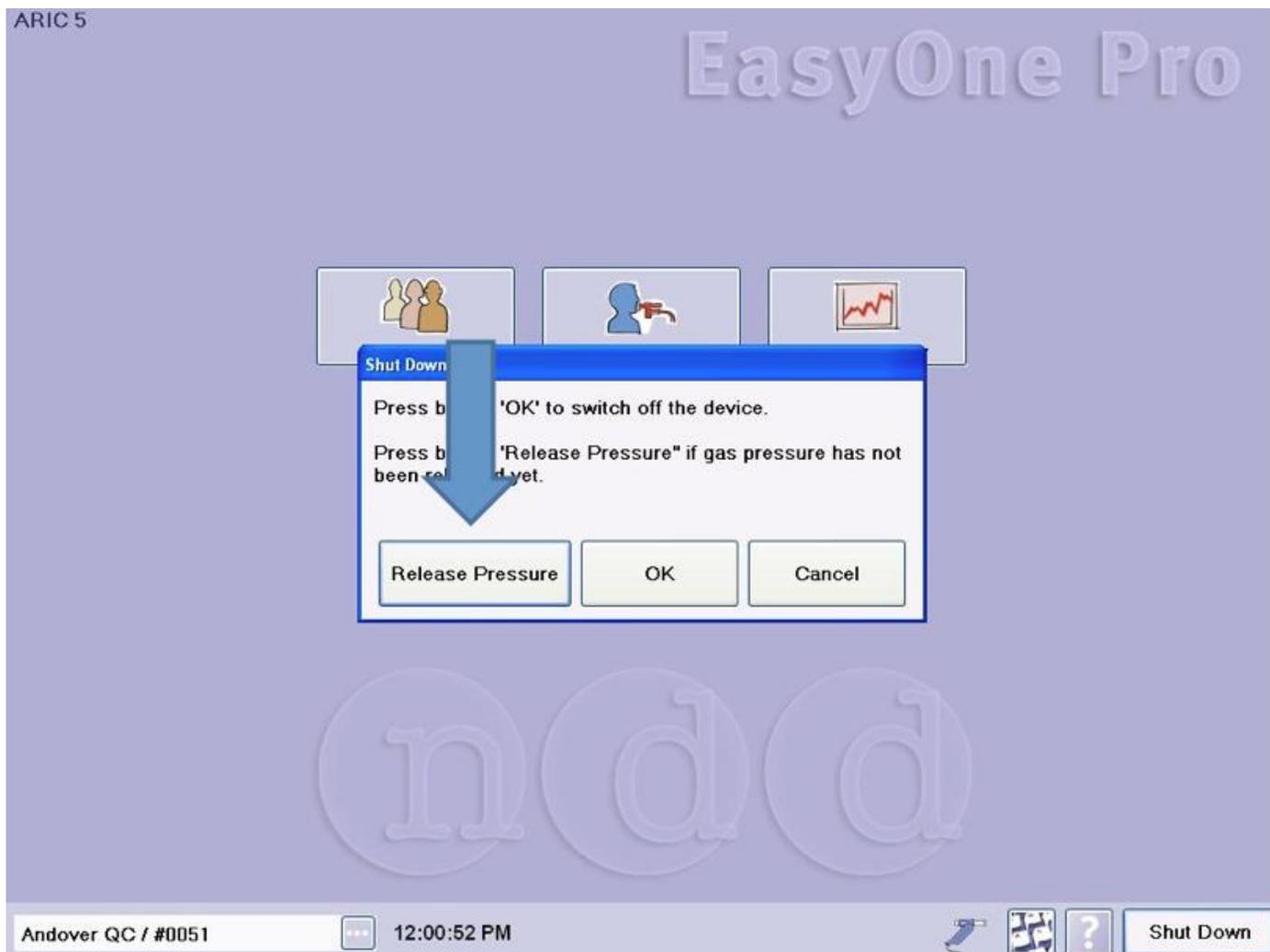


b. Turn off the gas

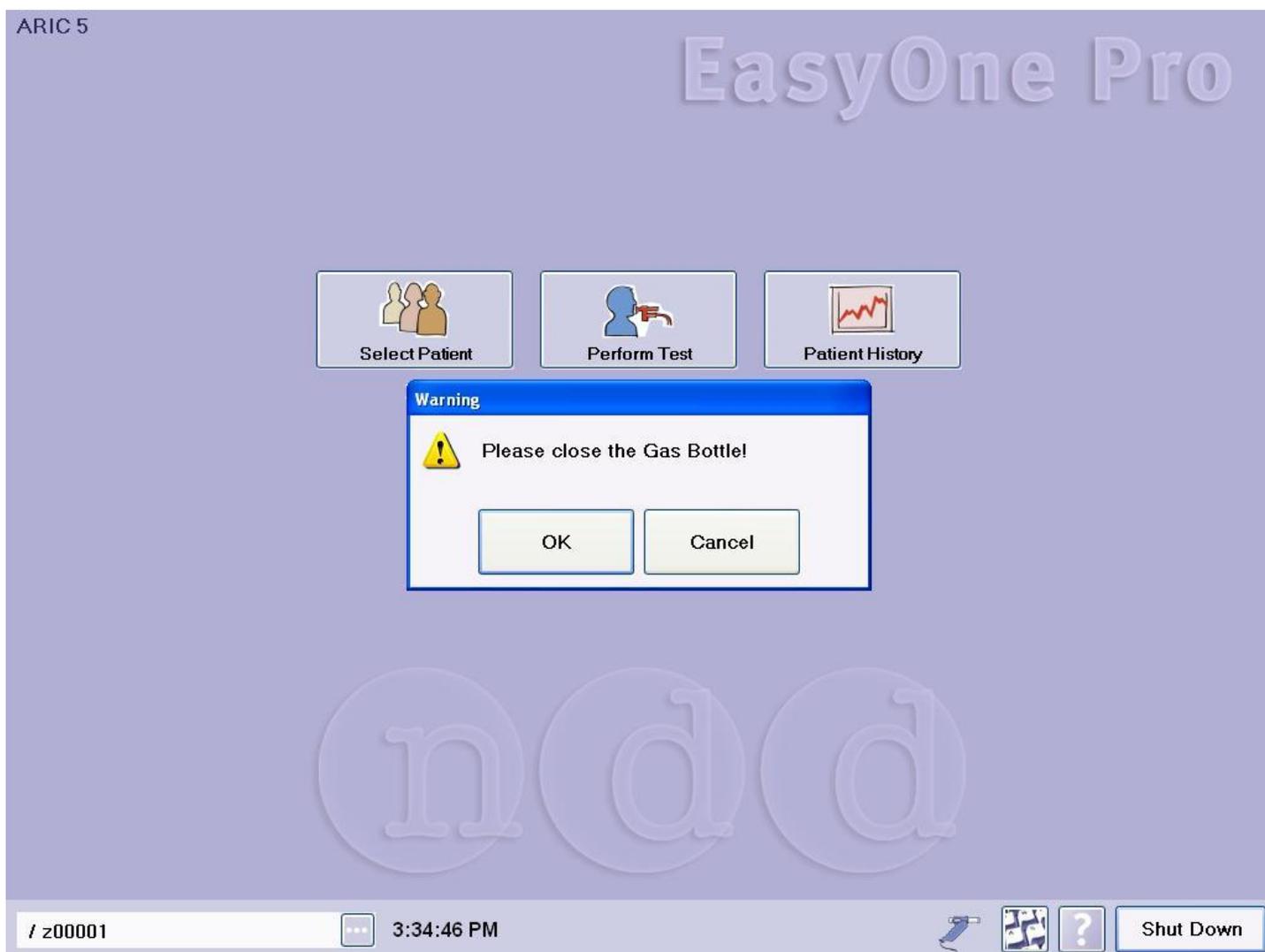
Turn silver gas tank knob to the right to close gas cylinder – see picture below



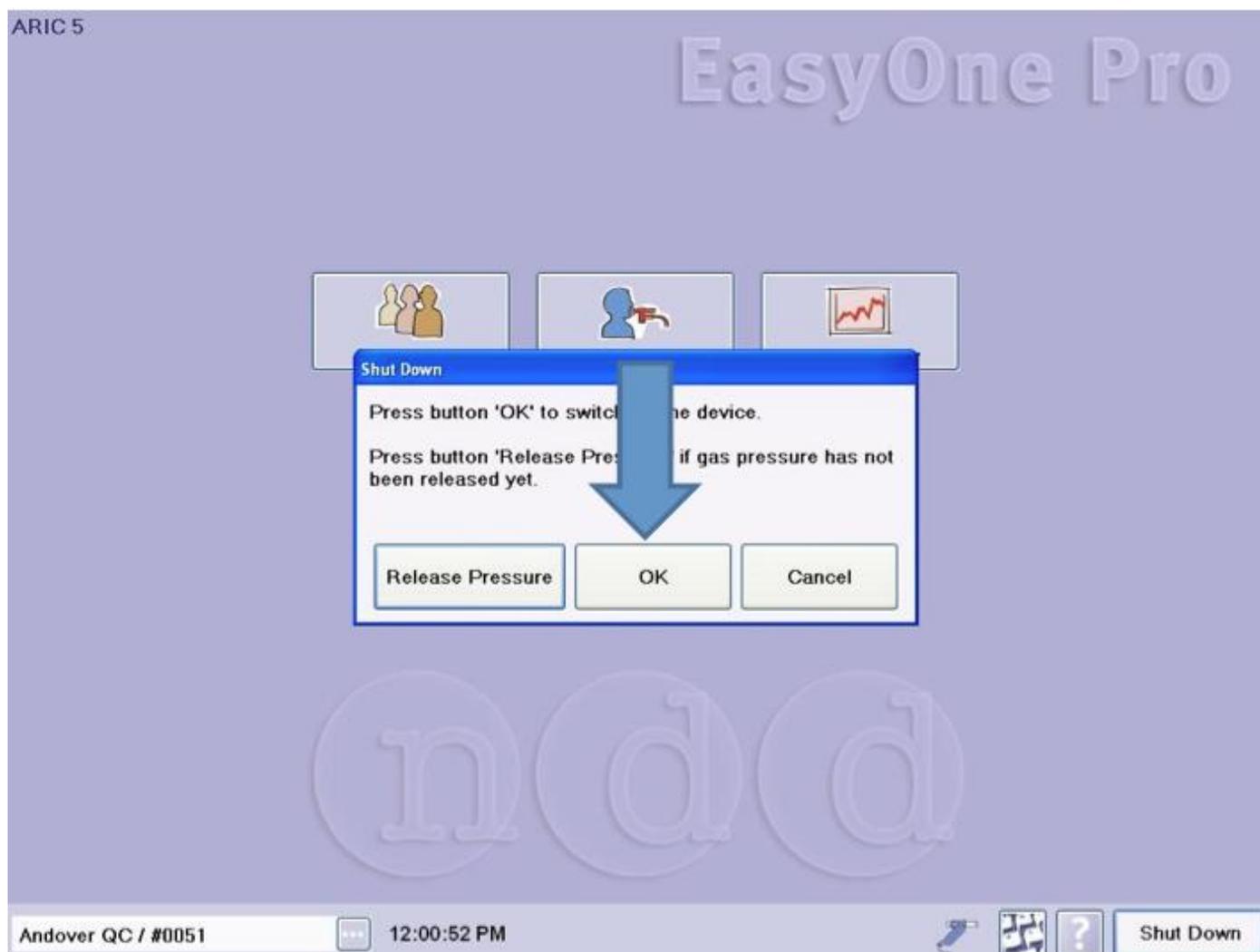
c. After gas cylinder is closed press **"Release Pressure"**:



A safety icon may appear reminding you to “Please close the Gas Bottle!” even though you just did this. Press “OK”.



Then press “OK” again (see below) to continue with releasing the pressure - you will hear the device release the pressure.



The shut down menu will then re-appear – press “OK” again to shut down the device. The green light on the button on the bottom left of the console will go off.

Section 8: Cleaning

After a test session you can wipe the parts that have been touched by the subject with a cloth moistened with alcohol – 70% max. So this would be the purple hand sensor. Do not let liquid enter the parts.

The one-way valve can be cleaned with a cloth moistened with alcohol (50% max). Clean only the side facing the barriette and the housing. Avoid letting liquid center inside the parts or the device.

If display is dirty, use a soft, dry cloth. In case of major contamination, you can use a cloth moistened with alcohol (50% max.). Avoid letting liquid enter the device.

To clean the rear panel and the temperature and humidity sensor (should they get dusty), simply wipe them off with a dry cloth. Do not apply liquid to these.

If needed, the connecting tube to the gas cylinder and the touch stylus can be cleaned with a cloth moistened with alcohol (70% max.). Likewise, if needed the device surface can be cleaned with a cloth moistened with alcohol (70% max.), but avoiding display, the rear panel and the temperature and humidity sensor. Do not let liquid enter the device.

Section 9: Quality Control

A. Biologic QC of DLco

A Biological Standard subject at the testing site (healthy, non-smoker) should perform a set of DLCO tests periodically. A series of 20 tests are needed to establish a baseline. So when the machine is first set up, the Biologic Standard person should make a measurement twice per day until 20 have been done. After that this same person should make a measurement once per week plus when a gas tank is changed. If the Biologic Standard subject leaves, the new person needs to do the series of 20 tests to establish a new baseline. Once the 20 baseline tests have been done, drift in weekly biologic standard values can help to detect machine problems.

- a* Sensor selection
- b* Parameter Values tabs
- c* Deselecting a test (remove check mark)
- d* Click to conduct a new test
- e* Click to select the BioCal Subject
- f* Click to select a parameter
- g* Click to display the graphic trends
- h* Click to add a new BioCal Subject

The screenshot shows a software interface for Biologic QC of DLco. The interface is divided into several sections:

- Device Selection:** A table with columns 'Serial Number' and 'Device Type'. It lists two devices: '11427 EASY_BOX' and '200076 SPIROSON_AS'.
- BioCal Subject Selection:** A table with columns 'Patient ID', 'Last Name', and 'First Name'. It lists one subject: 'BioCal-1 TrueFlow Martin'. There is an 'Add New BioCal Subject' button below this table.
- Parameter Values:** A section with tabs for 'Baseline Values' and 'Control Values'. Below the tabs is a table with columns 'Test Date', 'Parameter Value', and 'Selected'. The table contains five rows of data:

Test Date	Parameter Value	Selected
10.03.2008	4.102	<input checked="" type="checkbox"/>
11.03.2008	3.767	<input checked="" type="checkbox"/>
12.03.2008	3.926	<input checked="" type="checkbox"/>
13.03.2008	3.817	<input checked="" type="checkbox"/>
14.03.2008	3.870	<input checked="" type="checkbox"/>
17.03.2008	3.711	<input checked="" type="checkbox"/>
- Displayed Parameter Selection:** A section with a dropdown menu set to 'FVC'. It shows 'Mean Value: 3.930' and 'CV%: 4.553'. Below this is an 'Analysis' section with 'Based on: 20 Values from 09.03.2008 - 02.04.2008' and 'Analysis status: Valid Analysis'.
- Bio Calibration Check:** A section with 'Result' and 'Bio Calibration Check' sub-sections. It shows 'FVC Grade: BA', 'FEV1 Grade: BA', and 'FEV6 Grade: BA'. There is a 'Bio Calibration Check' section with a green bar and 'BA' text. Below this is an 'FVC FEV1 FEV6' section with a dropdown menu.
- Buttons:** 'Add New Test' and 'Graph' buttons are located below the 'Parameter Values' table.
- Footer:** 'TrueFlow, Martin / BioCal-1' and '21:59:45' are displayed at the bottom left. A 'Main Menu' button is at the bottom right.

Selecting a Test Subject and Performing a DLCO BioQC Check

The bold small case letters below refer to the screen shot on the previous page

From the Main Menu, press the “Utilities” button.

Press “Check Calibration”. Next press “Biological Calibration Control”.

The *Biological Calibration* menu (BioCal-Check main screen) will open.

Select the device according to its serial number (check label on back of device).

Select the BioCal Test Subject **e**. If the subject is not in the list, press “Add New BioCal Subject” **h** and add a new one. This will take you to the usual screen for adding a new subject – select “New Patient” and enter the usual fields marked by the asterisks. Then press “Add Selected Subject” to return to the BioCal-Check main screen.

(Recommendation for IDs: Set the Patient ID to “Bio-1” for the first person who does this. If that person leaves, use “Bio-2”).

Press “Add New Test” **d**.

Select “DLCO”. There is no choice for SVC – it is not needed for this purpose because the calibration does not use predicted values.

Recommendation: Try to blow a QC grade of “A” test. But if not, just do the best you can.

Press “Finish Test”.

Toggle to “DLCO ml/min/mm” under the “Displayed Parameter Selection” **f**

To show the graphic trend for your DLCO values, click the “Graph” button **g**.

The DLCO BioCal quality grades will be displayed once you have the required 20 baseline tests.

The parameter values are divided into two tab sheets **b**: *Baseline Values* (used to calculate warning levels) and *Control Values* (controlled values for BioCal-Check QC grade calculation).

If you did a bad test and want to remove it you can deselect it. To deselect a Test (Baseline and Control Values) remove the check mark **c** of the corresponding test. A deselected test is not used for calculations any more. This means also that by deselecting a baseline value, the first control value is moved to the baseline values, because a minimum number (20) of baseline tests is required for a valid analysis.

The software will establish a baseline mean value (precision range) for each BioCal Subject and sensor from the 20 baseline trials. This baseline will then be used to trend all subsequent BioCal-Check sessions for the BioCal Subject and sensor. Immediate quality feedback will be provided by the software in accordance with the BioCal-Check QC grades alerting the user of quality warning conditions for the parameters collected.

The BioCal-Check data will be plotted against time. The BioCal-Check reference lines will be mean (precision range), upper limit and lower limit. The upper and lower limits are +/- 2 SD (Standard Deviation).

Once you have your 20 tests, if you detect a systematic drift – upwards or downwards in your weekly QC check, contact Stephanie London or Paul Enright. It might help to send a screen shot of your graph. To make a screen shot, put a USB drive in any slot in the back of the machine. Use your finger to swipe along the right edge of the screen and then across in a large backwards “L”. This should bring up the menu to save the file to your USB drive. You can then email that screen shot to Stephanie or Paul.

B. Factory Calibration

Factory calibration will be done once per year at ndd Medical Technologies. This will require shipping machines to ndd Medical Technologies. This should be done at the same time across all sites, ideally during a period when there are few subjects being tested.

Contact for instructions on mailing units for calibration: ndd Medical Technologies Tech Support:
Phone 978-470-0923, option 1 or
email to customerservice@nddmed.com

Contact for reimbursement for shipping expense (forward invoices): Heidi Staub: hstaub@s-3.com
or (919)287-4355 .

Section 10: Changing the gas cylinder

Note: After each exchange of the gas cylinder, check whether the gas concentration in the program corresponds to the specifications on the cylinder. Follow these steps:

Select *Utilities* -> *Configuration* -> *Test* -> *DLCO*.

Compare the displayed values with the data on the gas cylinder.

Close the tab with **OK**.

The screenshot shows a software interface with a top navigation bar containing tabs: General, Device, Test, Report, Environment, Printer, and EMR. The 'Test' tab is selected. Below it, there are sub-tabs: General, FVC/FVL, SVC, MVV, DLCO, and Cal-Check. The 'DLCO' sub-tab is active. The main content area is divided into two columns. The left column is titled 'Gas Concentration Test-Gas' and contains three rows of data: CO with a value of 0,3 and a range of 0.200..0.350; HE with a value of 10,18 and a range of 8.00..22.00; and O2 with a value of 21,18 and a range of 16.00..30.00. The right column is titled 'Volumes' and contains two rows: Anatomic Dead Space with a value of 0,15 and a range of L (0..1); and System Dead Space with a value of 0,05 and a range of L (0..1). Below the 'Volumes' section, there is a checkbox labeled 'Automatic Discard Volume' which is checked. At the bottom left, there is a section titled 'Test Procedure' with a checkbox labeled 'Activate Manual Close' which is unchecked.

Gas	Value	Range
CO	0,3	% mol (0.200..0.350)
HE	10,18	% mol (8.00..22.00)
O2	21,18	% mol (16.00..30.00)

Volume	Value	Range
Anatomic Dead Space	0,15	L (0..1)
System Dead Space	0,05	L (0..1)

Automatic Discard Volume

Activate Manual Close

Section 11: Troubleshooting Tips

When the <i>EasyOne Pro</i> is switched on, you see the following error message on the display	Self-test failed	Quit the program and restart. If you receive the same message again, contact your ndd dealer.
When you start a test, you see the message <i>Check spirette insertion</i> .	The <i>spirette</i> [™] is not correctly positioned.	Ensure that the triangle on the spirometer is lined up with the triangle on the <i>spirette</i>

Should you get a screen freeze, try to restart the machine by holding down the on-off button for 15 seconds. If this does not accomplish anything, turn the machine off using the switch on the back of the machine. Wait 15 seconds and turn it on again.

Note: The most recent information and frequently asked questions can be found on the web site www.ndd.ch. But when in doubt, contact ndd Medical Technologies technical support.

Section 12: Configuration for when a site starts testing

First time that machine is used:

Select “Utilities” button

Then select “Configuration” button

Then select “test” tab

Then select “SVC” tab

Make sure that “tidal breathing” is Unselected. If there is a green check there, uncheck it.

Then press OK.

This should be verified when machines return yearly from nnd Medical Technologies after factory calibration.

Section 13: Questions that may arise

Q. Subject is wearing oxygen – what should I do?

A. The subject needs to remove the oxygen while doing the DLco testing. OK to leave it on for SVC.

Q. Subject has dentures – what should they do?

A. If subject cannot get a good seal because of poorly fitting dentures, ask the subject to remove them.

Q. Subject cannot hold breath long enough – what can I do?

A. If patient is unable to hold breath for 10 seconds, you can change setting on the screen where it says “set breath hold time (t):” to 8 seconds. Default setting is 10 seconds – it will reset automatically for the next subject. This button is to the right of the graphs on the screen.

Q. Subject is concerned about breathing in carbon monoxide.

A. You can tell subjects that the amount that they would get is less than sitting in traffic for one minute.

Section 14: Ordering information

a. Per subject consumables - Barriettes and Spirettes

Before the site starts to run low on spirettes and barriettes, site coordinator should contact Heidi Staub to order more of them and have them sent to the site. Part numbers:

Barriettes, Part # 3050-1 (Package of 50)

Spirettes, Part #2050-1 (Case of 200)

Contact Information for Ordering: Heidi Staub at Social & Scientific Systems, Inc.: (919)287-4355 or hstaub@s-3.com.

b. Gas

Order the gas from your local supplier. Contact Heidi Staub (see above) for reimbursement – forward invoices.

Gas mixture specifications: (2% accuracy, medical grade gas only).

- 10% Helium (He)
- 0.3% Carbon Monoxide (CO)
- 20.9% Oxygen (O₂) *
- Rest Nitrogen (N₂)

Bottle pressure is usually 150...300 bar (2175...4351psi) when full.

Handle gas bottle with care (high pressure). Follow the general safety rules for gas/pressure handling.

Large tanks need to be secured. You can either have them secured to a wall-mounted bracket or order a cart. Contact Heidi Staub for reimbursement for either expense.

* Acceptable range for O₂ is 18-25 – contact ndd Medical Technologies if your supplier does not have mixture with O₂ that rounds to 21%.

c. Parts that need replacement annually

Replace the gas supply tube each year. Contact Heidi Staub for reimbursement.

Replace the one-way valve each year. These come from ndd Medical Technologies so site coordinator should contact Heidi Staub to have them ordered and sent to the site. The ndd Medical Technologies part number is 3000-50.9.

Section 15: Contact information

All questions about the equipment – contact ndd Medical Technologies technical support:
Phone 978-470-0923, option 1 or email customerservice@nddmed.com

All questions about the protocol or data issues contact:

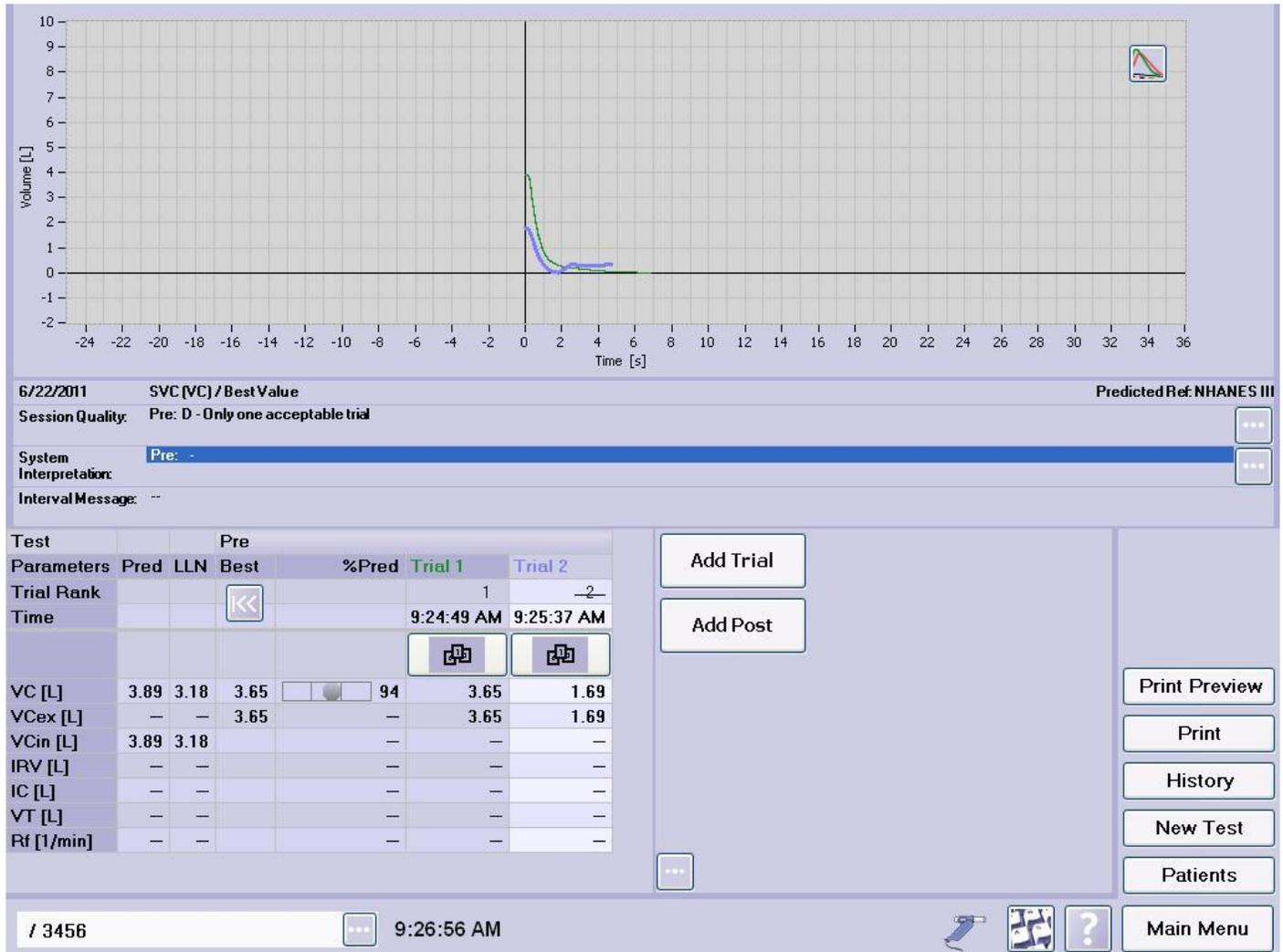
Stephanie London, MD, DrPH. London2@niehs.nih.gov

All questions about reimbursement for supplies: Heidi Staub: hstaub@s-3.com

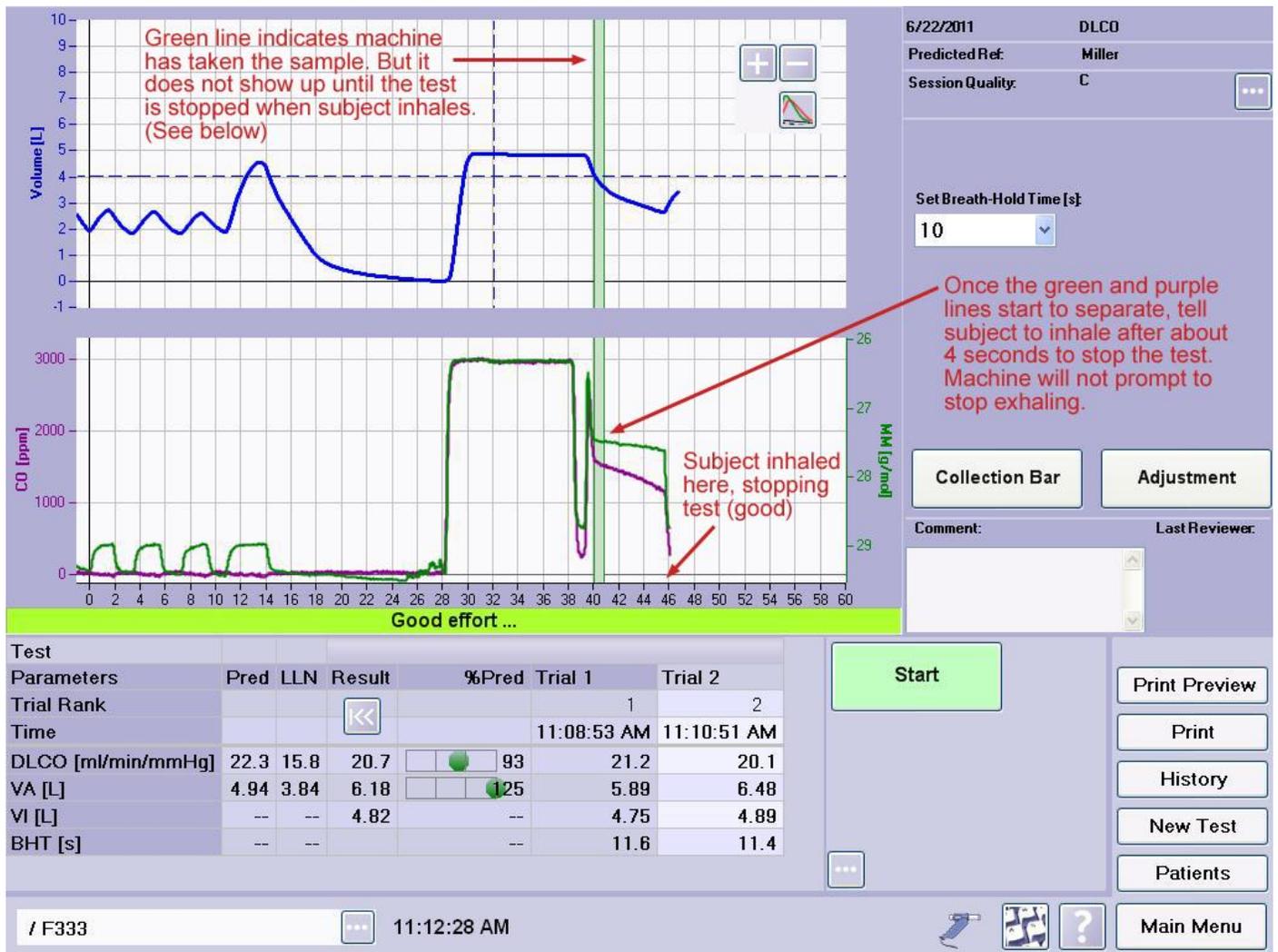
Section 16: Screen shots showing of problems that can occur

Screen shot #1 – BAD SVC TEST

There is a line through the number 2 in the table line Trial Rank – this indicates unacceptable test. On the graph Trial 1 (acceptable) is green and Trial 2 (unacceptable) is in purple. Note that normally you would not do Trial 2 if Trial 1 were acceptable.



Screen shot #2 – Clarifying the need for subject to take a breath to stop the DLco test



Screen shot #3 – Bad DLco test because patient did not inhale deeply enough at start

The blue dotted line below is set by the machine based on the SVC maneuver that the subject just did. So the subject can definitely inhale deeply enough to cross that line. This is needed to get an acceptable test.



Screen shot #4. Error message you will get if you press "SVC" before you have the purple hand sensor ready for the test. If you get this, follow the directions to get the equipment ready – just the purple hand sensor with new spirette inserted and press "OK".

The screenshot displays a software interface for a medical procedure. At the top, there is a graph with a grid. The vertical axis is labeled "Volume [L]" and ranges from -2 to 10. The horizontal axis ranges from -24 to 36. Below the graph, there are several data fields: "1/25/2012 SVC (VC) / Best Value", "Session Quality: Pre -", "System Interpretation:", "Interval Message: -", and "Comment:". On the right side, there are fields for "Predicted Ref: NHANES III" and "Last Reviewer:". A central dialog box with a blue border contains an illustration of a purple hand sensor and a silver spirette. A green arrow points from the spirette to the sensor. The text in the dialog box reads: "DLCO Valve Unit mounted on handle sensor! Remove DLCO Valve Unit and repeat procedure!". Below the text are two buttons: "OK" and "Cancel". At the bottom of the screen, there is a status bar with the text "/ J999911", a menu icon, the time "12:07:02 PM", a printer icon, a help icon, and a "Main Menu" button.

Volume [L]

1/25/2012 SVC (VC) / Best Value

Session Quality: Pre -

System Interpretation:

Interval Message: -

Comment:

Predicted Ref: NHANES III

Last Reviewer:

DLCO Valve Unit mounted on handle sensor!
Remove DLCO Valve Unit and repeat procedure!

OK

Cancel

/ J999911 12:07:02 PM Main Menu

Screen shot #5 – An error message that occurs if the white DLco motor block (called valve unit below) is not mounted or is not properly connected for the DLCO test

If the equipment is not properly assembled for the DLCO test before you press to start the DLCO test, you will get the error message below. In that case you need to follow directions for connecting the purple hand sensor to the white motor block with the barriette inserted. Make sure you hear the click when you connect the motor block. Once properly connected, press OK on the error message box below.

6/22/2011 DLCO
Predicted Ref: Miller
Session Quality: -

Volume [L]

CO [ppm]

DLCO Valve Unit NOT mounted on handle sensor!
Mount DLCO Valve Unit and repeat procedure.

OK

Please wait...

Stop

/ 3456 9:35:06 AM Main Menu

Section 17: Training and certification

TRAINING VIDEO

A simple training video was made on June 22 2011 at one of the ARIC visit 5 sites using a hand-held camera. The voice you hear is Daron Fitzpatrick from ndd Medical Technologies. The video has put place on Youtube and can be viewed at the URL:

<http://www.youtube.com/watch?v=MMHi2JqhrDA>

INITIAL TRAINING AND RECERTIFICATION

Examiners should be trained and certified by the chief trainer. The chief trainer is ideally someone who was present when the ndd Medical Technologies trainer Daron Fitzpatrick visited the site – if there is no one in this category, the ARIC Quality Control Committee will chose a chief trainer. Certification requires familiarity with the protocol and equipment, and successful performance of the two components of the examination (SVC and DLco) on three volunteers, inclusive of data transfer, witnessed by the trainer. After these three volunteer tests, the chief trainer should email Drs. London (london2@niehs.nih.gov) with the pilot ARIC IDs used and the ID number of the technician so that they can review these tests. After initial training and certification, continued education is based on performance indicators monitored by the ARIC Quality Control Committee. Re-training / re-certification may be required at the request of this committee.

RECOMMENDED TRAINING STEPS:

Watch the YouTube video at <http://www.youtube.com/watch?v=MMHi2JqhrDA>.

Read the manual.

Chief trainer explains the procedures to you.

Chief trainer tests you – SVC and two DLCO trials.

If you do not get an acceptable test session, the chief trainer should point out which steps are causing the problem.

Have the trainer test you again at least 30 minutes later – even if you had a good tests.

Watch the video again and read the relevant sections of the manual again. They will mean more to you once you have tried to do the test a couple of times.

If you can test yourself reliably, it will be easier to test others. So the next day, try to test yourself. If you do not get an acceptable session, see if you can figure out why by watching the video again and re-reading the relevant sections of the manual to troubleshoot. Then test yourself again. If you do not get an acceptable test watch the video again, read the manual sections again and ask the trainer to test you again. Then keep going back to the video and manual and the trainer until you can get a good test on yourself. Do not do more than four test sessions on yourself in a day– and wait at least 30 minutes before you attempt a new test session on yourself.

Once you have been able to get two good sessions on yourself, test the three volunteers, witnessed by the trainer as described above.

Section 18: Downloading data

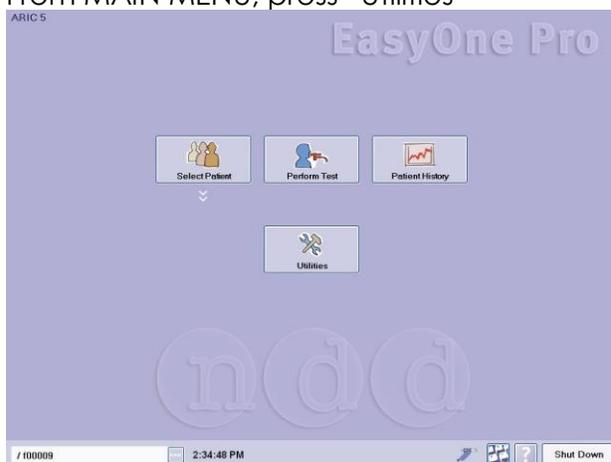
Once per month, you need to copy the data that is on the machine to a flash drive and then upload that to the coordinating center. Then delete the directory from the flash drive. Detailed directions follow.

Before you start you need a flash drive. Create an empty directory on the flash drive that is named using the scheme “DLC download SITENAME mmddy”. Now Insert the flash drive into any of the USB ports on the back of the machine. A thin red arrow points to my flash drive inserted into one of the USB ports.

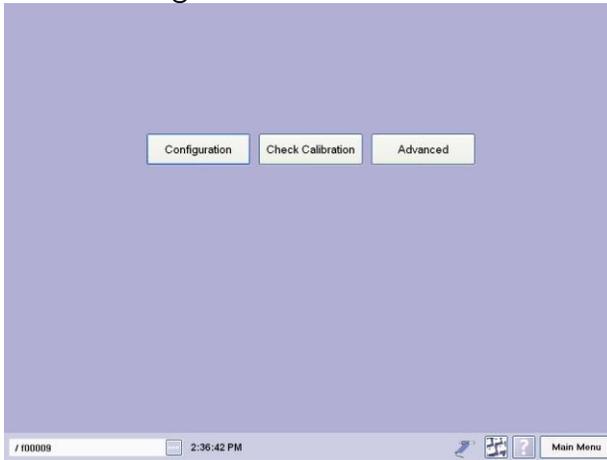


Now you can start the copy procedure:

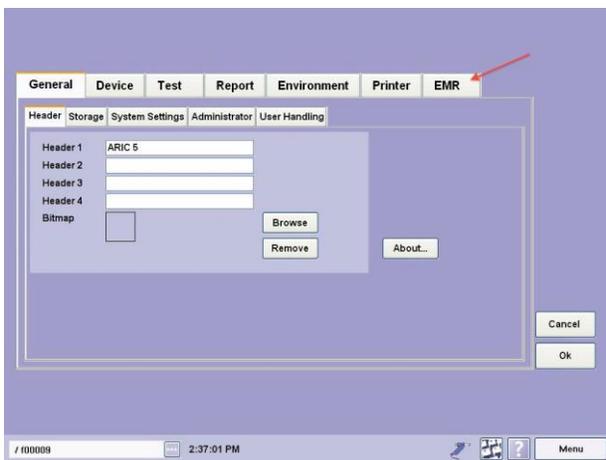
1. From MAIN MENU, press “Utilities”



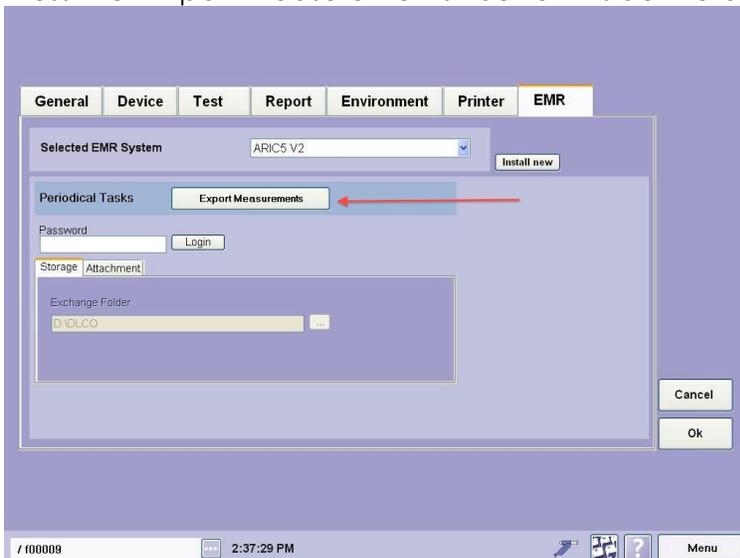
2. Press "Configuration".



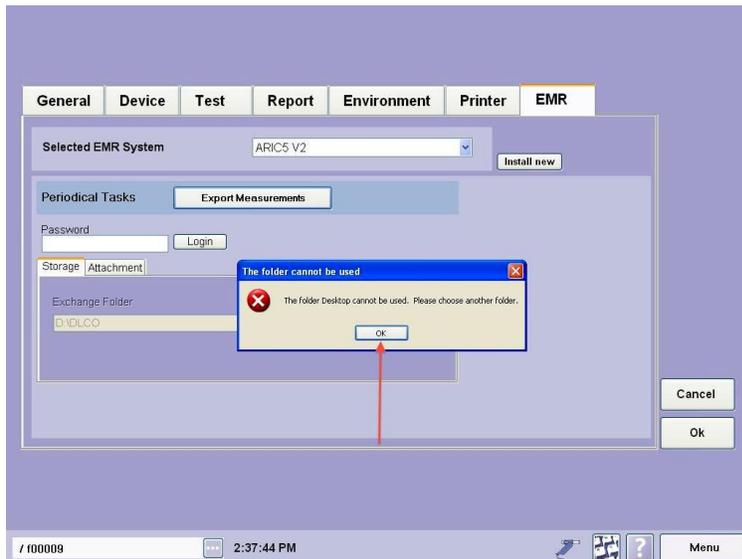
3. Press the "EMR" tab (top right) – see red arrow:



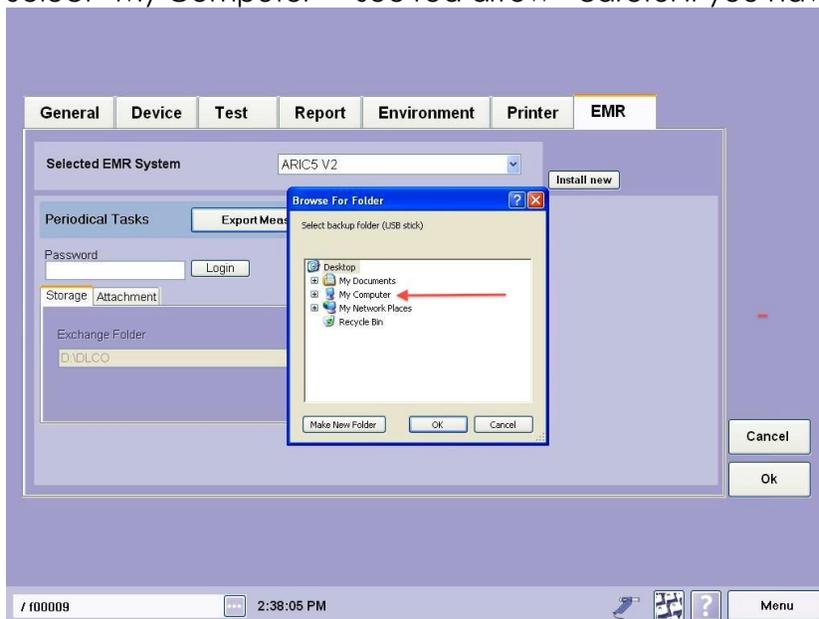
4. Press the "Export Measurements" button inside the blue rectangle – see red arrow:



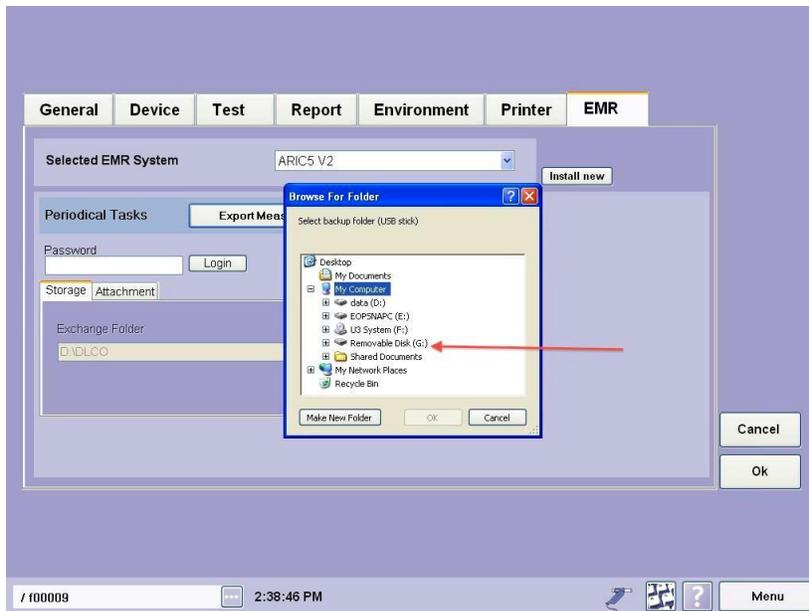
Unfortunately after you press Export Measurements you will probably get the error message below but just click OK in that small error window (see red arrow) and you will be able to continue with the next steps.



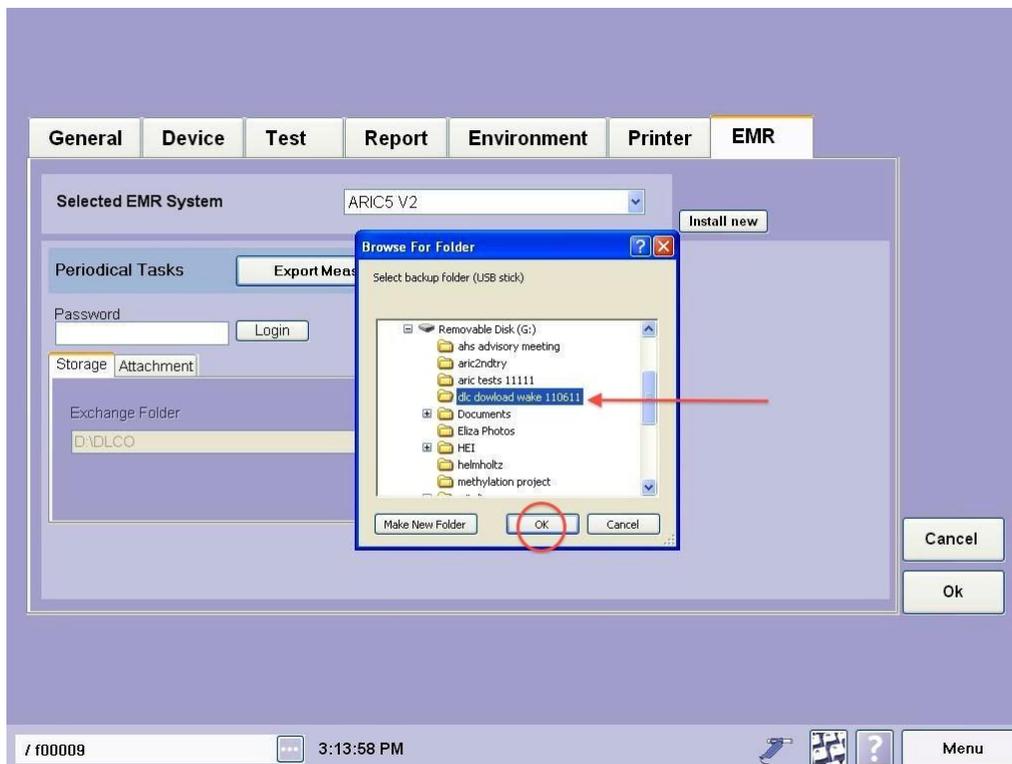
5. The next few screens guide you to selecting the destination folder on your flash drive – these are in the “Browse for Folder” Microsoft Windows screens. Select “My Computer” – see red arrow - careful if you have big fingers.



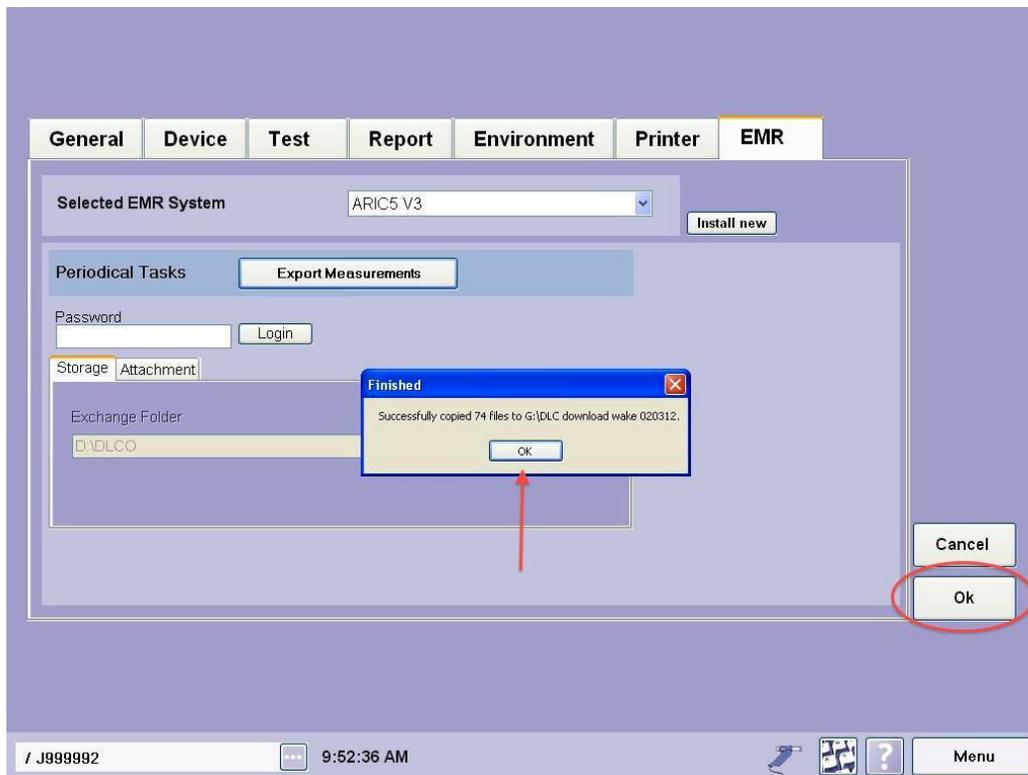
Under My Computer, select “Removable Disk” – see red arrow:



Under “Removable Disk” select the destination directory by touching it – see red ARROW. In the picture below it is “DLC download wake 110611”. The directory is called this because I was using the Wake machine and did this download on 11/06/2011. After you have selected the destination directory, click OK in that same “Browse for Folder” window (not the OK button to on the right of the screen) – see red CIRCLE below.



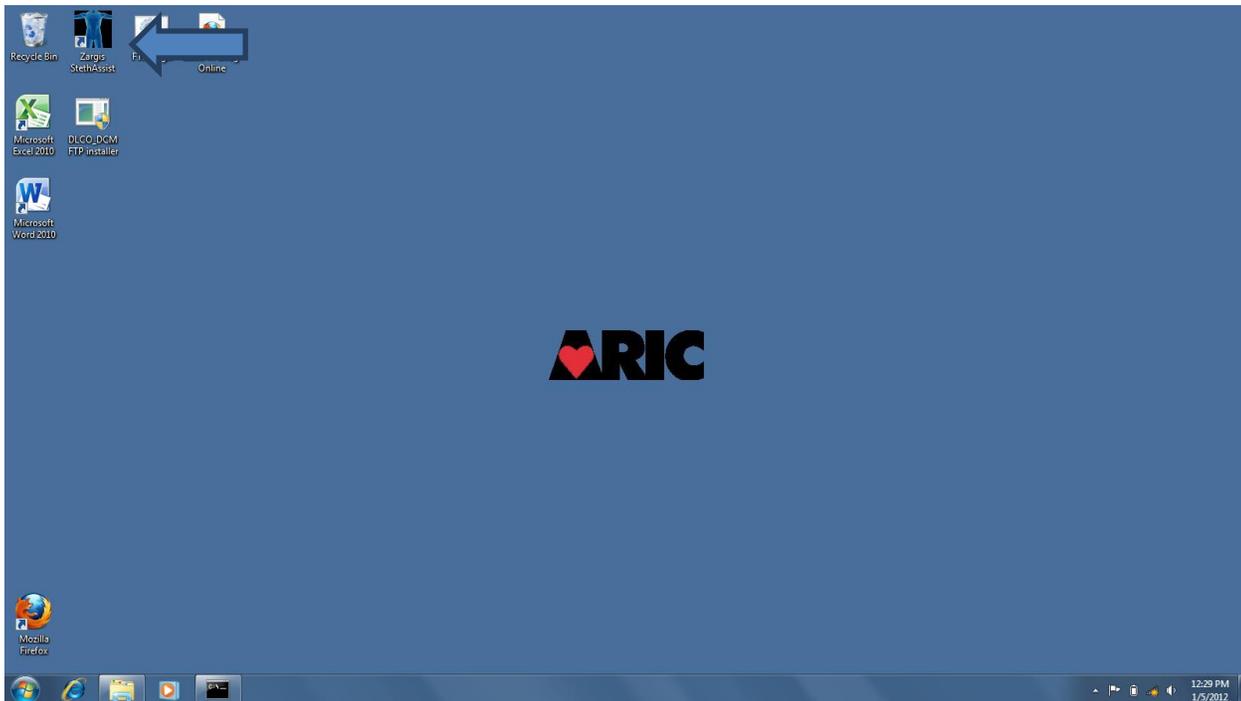
After the files have copied you will see the message below that tell you how many files have been copied to the flash drive. Each time to send to EMR you are resending files that have already been sent along with new tests done since the last download so this number will continue to get bigger with each download. Click “OK” in the windows box (red arrow). Then click the “Ok” button on the lower right (red oval).



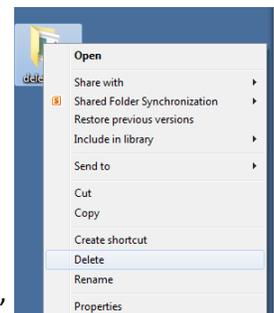
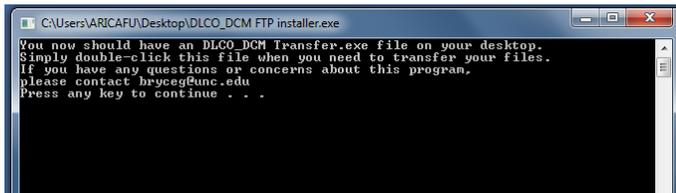
- Remove your flash drive from the EasyOne Pro. There is no eject procedure on this machine – just pull it out.
- Put the flash drive in a computer that is hooked up to the internet that you will use to upload to the coordinating center. Look at your destination directory. For each ID there will be pairs of files that all have the same root name but one is a .pdf file and the other is a .csv file. Sort by date to verify that the most recent tests are there. In the unlikely event that this did not happen, delete this directory from your flash drive, make a new one and repeat the procedure.
- Follow directions from the CC for uploading data. –directions start on the next page.
- Once you have uploaded the data to the CC delete the entire directory on your flash drive.

Appendix 1: INSTALLING PROGRAM TO FTP DLCO-DCM DATA TO ARIC COORDINATING CENTER

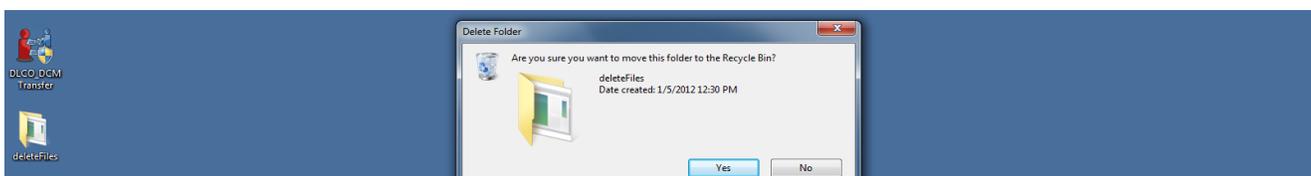
Download installer *DLCO-DCM FTP Installer.exe* from ARIC download area on website (same place Island Mode downloads are located) to desktop of computer to be used for transfer.



Double-click on icon “DLCO-DCM FTP installer”. When asked whether you trust this application, choose “Yes”. When you get the message below, press any key to close the application.



Then, delete desktop folder “deleteFiles” by right clicking over the file and select “delete”.



When prompted, select Yes, it's okay to delete the folder.

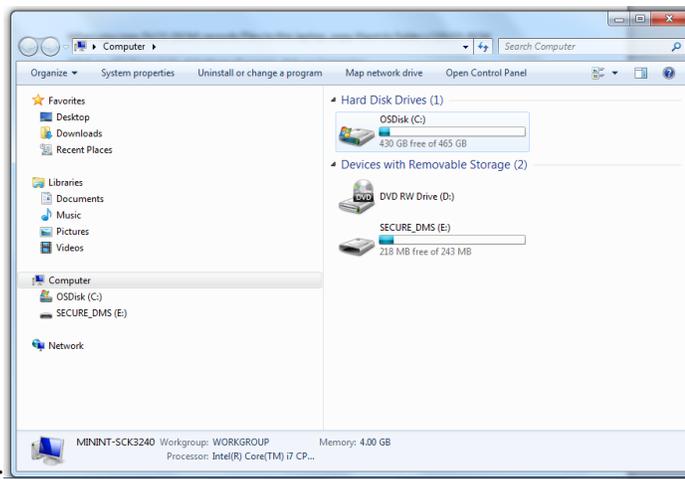
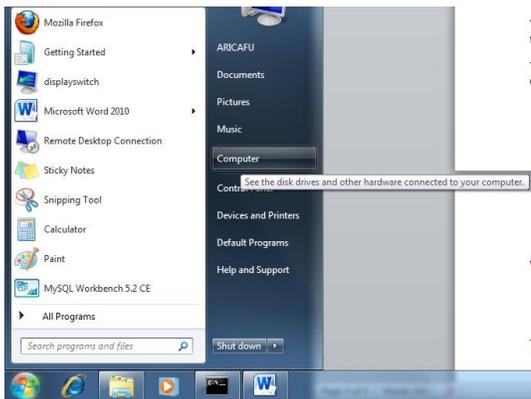
You will have installed “DLCO-DCM Transfer”, whose icon you will click to transfer files after you have copied (DLCO-) DCM files to the c:\DLCO-DCM folder.

HOW TO FTP ARIC DCM-DLCO FILES TO THE ARIC COORDINATING CENTER:

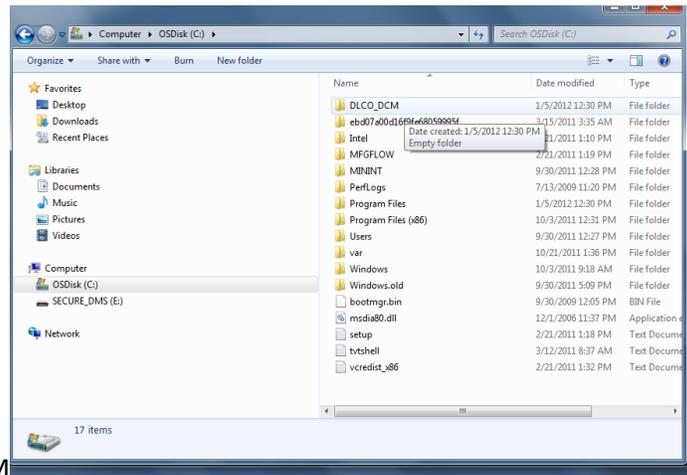
The transfer program will archive the file(s) you’re transferring, as well as FTP the files to the ARIC Coordinating Center.

When you copy DLCO (DCM) records/files to this laptop, copy them to folder c:\DLCO-DCM

(Click on Windows circle at bottom left corner of screen, then click on Computer:

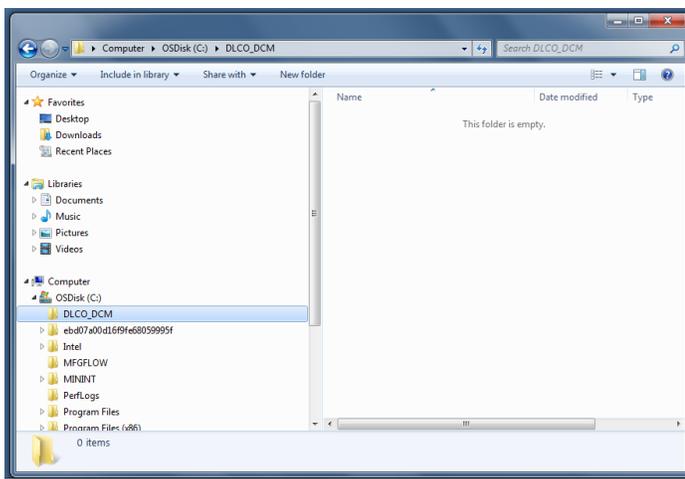


Click on OSDisk C:

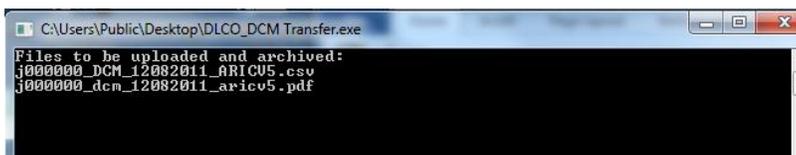


Click on folder C:\DLCO-DCM

Copy the files from your flash drive to the c:\DLCO-DCM folder.

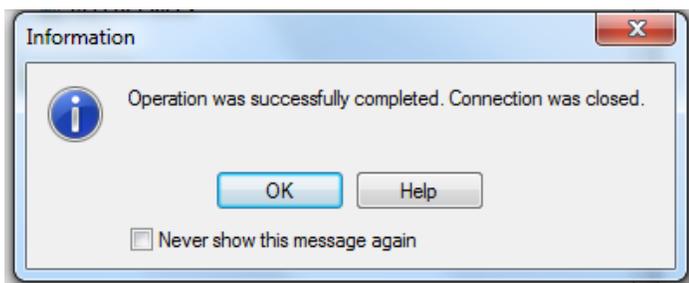


To transfer the files to the Coordinating Center, make sure you have an internet connection, then click icon “DLCO-DCM Transfer”. You'll see some progress messages, such as the following:



There will also be a message telling you to wait. Please do!

Shortly, you will see a message about successful completion, as follows:



We would suggest that you allow the message to show, so that you'll know that the data transfer was successful.

Now you should delete the directory from your flash drive. This will prevent problems the next time you do a download.

That's it!