QUALITY CONTROL SPECIFICATIONS

PURPOSE:

The Syringe Quality Control Specifications have been standardized for all of the systems. The new specifications are detailed below.

SPIROMETRY:

Perform 5-6 FVC efforts.
See Spirometry Quality Control Procedure for instructions on performing testing.
Vary flows: some slow efforts, some medium, some fast (Peak Flow ~0.5 to 12.0 L/sec)
Specification: VC +/-3%
Target = 3.00 +/- 3%
Low Range 2.91
High Range 3.09

NITROGEN WASHOUT:

NOTE: Quality Control for Nitrogen Washout is designed to be performed without a PF filter in line.

See FRC (N2) Quality Control Procedure for instructions on performing testing.
Respiratory rate of ~12-16 bpm
Specification: FRC 10%
Target FRC = Syringe Volume + Syringe Deadspace
Target FRC = Target FRC = 2.60 +/- 10%
Low Range = Target FRC * .90 (2.60*.90=2.34)
High Range = Target FRC * 1.10 (2.60*1.10=2.86)

DIFFUSION:

See DLCO Quality Control Procedure for instructions on performing testing.
DLco Quality Control Test is completed using a 3 Liter syringe, setup so that it contains 1 liter of room air (starting the syringe QC with either the collar or thumb positioned exactly at the 2 liter mark). No tidal breathing will be needed for DLco QC Test.
Test is completed with BTPS correction turned off.
This table is based on a syringe dead space of 100ml.
Target IVC = 2.0 liters +/-5% Target VA = 3.0 liters +/-8% Target DLco = 0 +/-0.5
Measured IVC should be 1.90 to 2.10. To find Target VA, find Measured IVC in second column. Target VA and Min/Max values will be displayed to the right of the Measured IVC.

Syringe Stroke	Measured IVC	Target VA	Minimum VA	Maximum VA
2.0	1.90	2.83	2.60	3.06
2.0	1.91	2.84	2.61	3.07
2.0	1.92	2.86	2.63	3.09
2.0	1.93	2.88	2.65	3.11
2.0	1.94	2.90	2.67	3.13
2.0	1.95	2.91	2.68	3.14
2.0	1.96	2.93	2.70	3.16
2.0	1.97	2.95	2.71	3.19
2.0	1.98	2.97	2.73	3.21
2.0	1.99	2.98	2.74	3.22
2.0	2.00	3.00	2.76	3.24
2.0	2.01	3.02	2.78	3.26
2.0	2.02	3.03	2.79	3.27
2.0	2.03	3.05	2.81	3.29
2.0	2.04	3.07	2.82	3.32
2.0	2.05	3.09	2.84	3.34
2.0	2.06	3.10	2.85	3.35
2.0	2.07	3.12	2.87	3.37
2.0	2.08	3.14	2.89	3.39
2.0	2.09	3.16	2.91	3.41
2.0	2.10	3.17	2.92	3.42

FRC Shapetable for Nitrogen Washout:

NOTE: The FRC Shapetable program should be used only by a qualified Service Engineer or under the direction of MEDGRAPHICS Technical Support. Inappropriate use of this program may potentially mask hardware issues. The FRC Shapetable program should not be used with a filter in line.

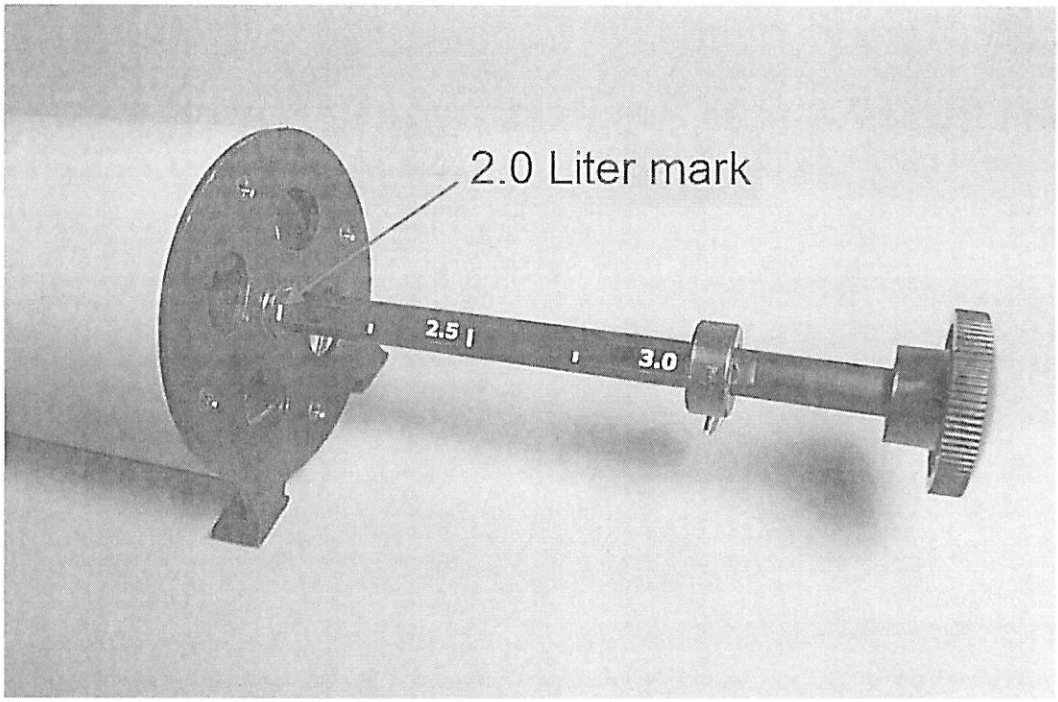
1. The FRC Shapetable program is designed to adjust the calibration factors of Nitrogen Washout in order for the system to be within manufacturers specifications. As the system or analyzers age, changes to the nitrogen washout circuit may occur which need periodic adjustment. The FRC shapetable program is one tool that can be used to make adjustments after all hardware issues have been resolved.
2. When using the FRC Shapetable program, the Human and Syringe Factors in the Workstation Hardware settings in BreezeSuite should be set back to their default values. If you do not know the default values, simply change the hardware type to something other than the current system, change back to the correct hardware type and the default values will automatically be reentered, then save the settings.
3. Calibrate the N2 or O2 analyzer just prior to using the FRC Shapetable program.
4. Upon entering the FRC Shapetable program, enter the Target FRC. This will usually be 2.60 liters if you have a calibration syringe with 100 mls of deadspace.
5. Perform at least two syringe studies or until you have repeatability in the recovered values, then select the efforts you want to use.
6. Save the values, then exit the program.
7. Perform Quality Control testing syringe/biologic without a filter to ensure the system meets manufacturer specifications.

DLCO QUALITY CONTROL PROCEDURE

DLco Quality Control Test is completed using a 3 Liter syringe; setup the syringe to contain 1 liter of room air by starting the syringe QC with the position exactly at the 2.0 liter mark (See Figure 2). No tidal breathing will be needed for DLco QC Test.

Target IVC = 2.0 liters +/-5% Target VA = 3.0 liters +/-8% Target DLco = 0 +/-0.5

Syringe Positioning at 2.0 Liter Mark



Instructions

Note: Do not use flow tube or filter between flow sensor and syringe. If performing Quality Control on a Real-Time DLco (RTD) system, use the white "DLco QC Only" coupler between the syringe and the preVent flow sensor.

1. Click on the DLCO or DLCO RTD tab.
2. Proceed through system calibration routine as prompted.
3. Connect 3 liter calibrating syringe to flow sensor. Ensure that the flow sensor is seated properly into the patient circuit. (See Note above)
4. Start with the syringe plunger pulled out and positioned exactly at the 2.0 liter mark (See figure above).
5. Press the space bar to begin and watch for the flow to be stable.
6. Press the space bar twice.
7. Immediately after pressing the spacebar, completely and quickly withdraw syringe piston to "inhale" 2 liters of diffusion gas.
8. Hold for 20 seconds. When patient circuit valve opens, inject syringe piston until the complete 3 liters is "exhaled."

9. Analysis of exhaled gas is traced on the graph.
10. During this quality control test, ignore any ATS error codes that may occur.
11. See Table below for expected results.

Diffusion Specifications

Measured IVC should be 1.90 to 2.10. To find Target VA, find Measured IVC in second column. Target VA and Min/Max values will be displayed to the right of the Measured IVC.

Syringe Stroke	Measured IVC	Target VA	Minimum VA	Maximum VA
2.0	1.90	2.83	2.60	3.06
2.0	1.91	2.84	2.61	3.07
2.0	1.92	2.86	2.63	3.09
2.0	1.93	2.88	2.65	3.11
2.0	1.94	2.90	2.67	3.13
2.0	1.95	2.91	2.68	3.14
2.0	1.96	2.93	2.70	3.16
2.0	1.97	2.95	2.71	3.19
2.0	1.98	2.97	2.73	3.21
2.0	1.99	2.98	2.74	3.22
2.0	2.00	3.00	2.76	3.24
2.0	2.01	3.02	2.78	3.26
2.0	2.02	3.03	2.79	3.27
2.0	2.03	3.05	2.81	3.29
2.0	2.04	3.07	2.82	3.32
2.0	2.05	3.09	2.84	3.34
2.0	2.06	3.10	2.85	3.35
2.0	2.07	3.12	2.87	3.37
2.0	2.08	3.14	2.89	3.39
2.0	2.09	3.16	2.91	3.41
2.0	2.10	3.17	2.92	3.42

Indication of Leaks

If the measured VA is not within 8% of the target, a leak is indicated. Inspect the diffusion circuit and secure all connections. Repeat the DLCO QC Test.

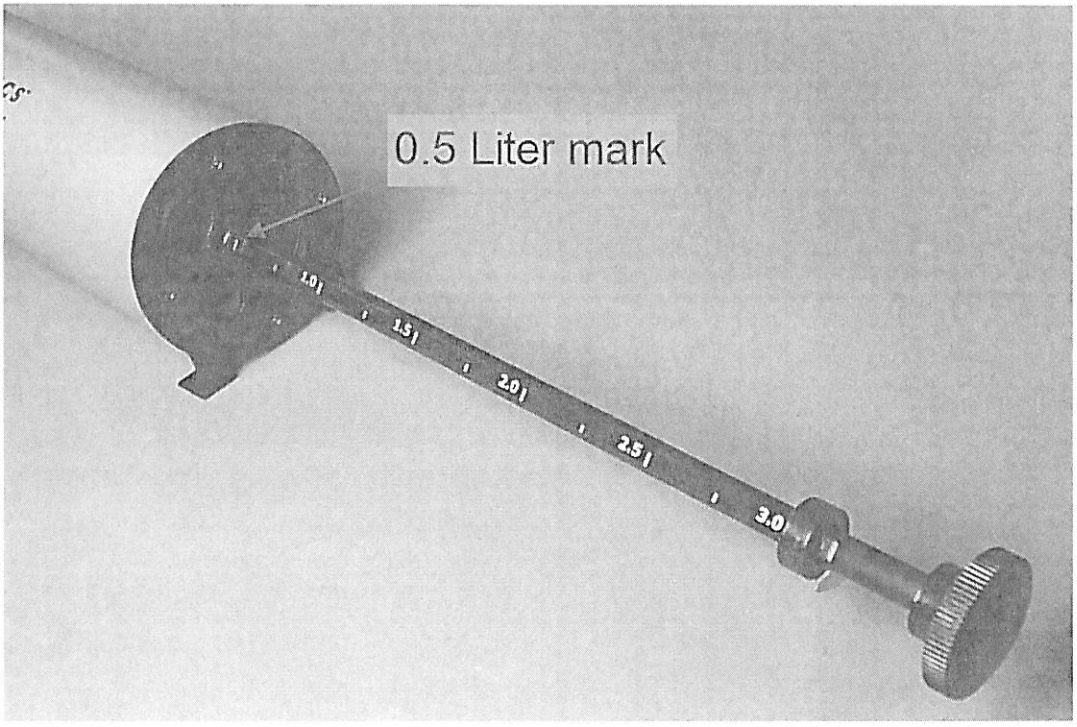
FRC N2 QUALITY CONTROL PROCEDURE

Note: Quality Control for Nitrogen Washout is designed to be performed without a PF filter in line.

Specification: FRC +/-10%
Target FRC = Syringe Volume + Syringe Dead Space

	100 ml Syringe Dead Space	175 ml Dead Space
Target FRC = 2.5 + Dead Space	2.600	2.675
Low Range = Target FRC * .90	2.34	2.41
High Range = Target FRC * 1.10	2.86	2.94

Syringe Positioning at 0.5 Liter Mark:



Instructions:

Note: Do not use flow tube or filter between flow sensor and syringe.

1. Click the FRC (N2) tab.
2. Proceed through system calibration routine as prompted.
3. Connect 3-liter calibration syringe directly to flow sensor. Ensure flow sensor is seated properly into patient circuit with umbilical tubing in a straight-up (12 o'clock) position. Extend syringe piston and place your thumb exactly at the 0.5 liter mark (See Figure3).
4. Press the spacebar. The system will automatically zero the preVent flow sensor.
5. Perform tidal breathing with syringe, injecting and withdrawing exactly 0.5 liters.
6. The message "Waiting for 4 tidal breaths" is displayed. After four tidal breaths have been collected, press the spacebar again. The system opens automatically to 100% oxygen. Continue to wash out 0.5 liters of the syringe at a respiratory rate of approximately 12 to 16 bpm until the system shuts off.
7. See Table above for expected results.

Indication of Leaks

If the system does not meet the above specifications, inspect the patient circuit and flow sensor assembly for leaks. Repeat the N2 analyzer

calibration and an N2 washout QC test.

FRC Shapetable for Nitrogen Washout (Not available on Real-Time Diffusion systems)

Note: The FRC Shapetable program should be used only by a qualified Service Engineer or under the direction of MEDGRAPHICS Technical Support. Inappropriate use of this program may potentially mask hardware issues. The FRC Shapetable program should not be used with a filter in line.

1. The FRC Shapetable program is designed to adjust the calibration factors of Nitrogen Washout in order for the system to be within manufacturer specifications. As the system or analyzers age, changes to the nitrogen washout circuit may occur which need periodic adjustment. The FRC shapetable program is one tool that can be used to make adjustments after all hardware issues have been resolved.
2. When using the FRC Shapetable program, the Human and Syringe Factors in the Workstation Hardware settings in BreezeSuite should be set back to their default values. If you do not know the default values, simply change the hardware type to something other than the current system, change back to the correct hardware type and the default values will automatically be reentered, then save the settings.
3. Calibrate the N2 or O2 analyzer just prior to using the FRC Shapetable program.
4. Upon entering the FRC Shapetable program, enter the Target FRC. This will usually be 2.60 liters if you have a calibration syringe with 100 mls of deadspace.
5. Perform at least two syringe studies or until you have repeatability in the recovered values, then select the efforts you want to use.
6. Save the values, then exit the program.
7. Perform Quality Control testing syringe/biologic without a filter to ensure the system meets manufacturer specifications.

FLOW SENSOR CALIBRATION

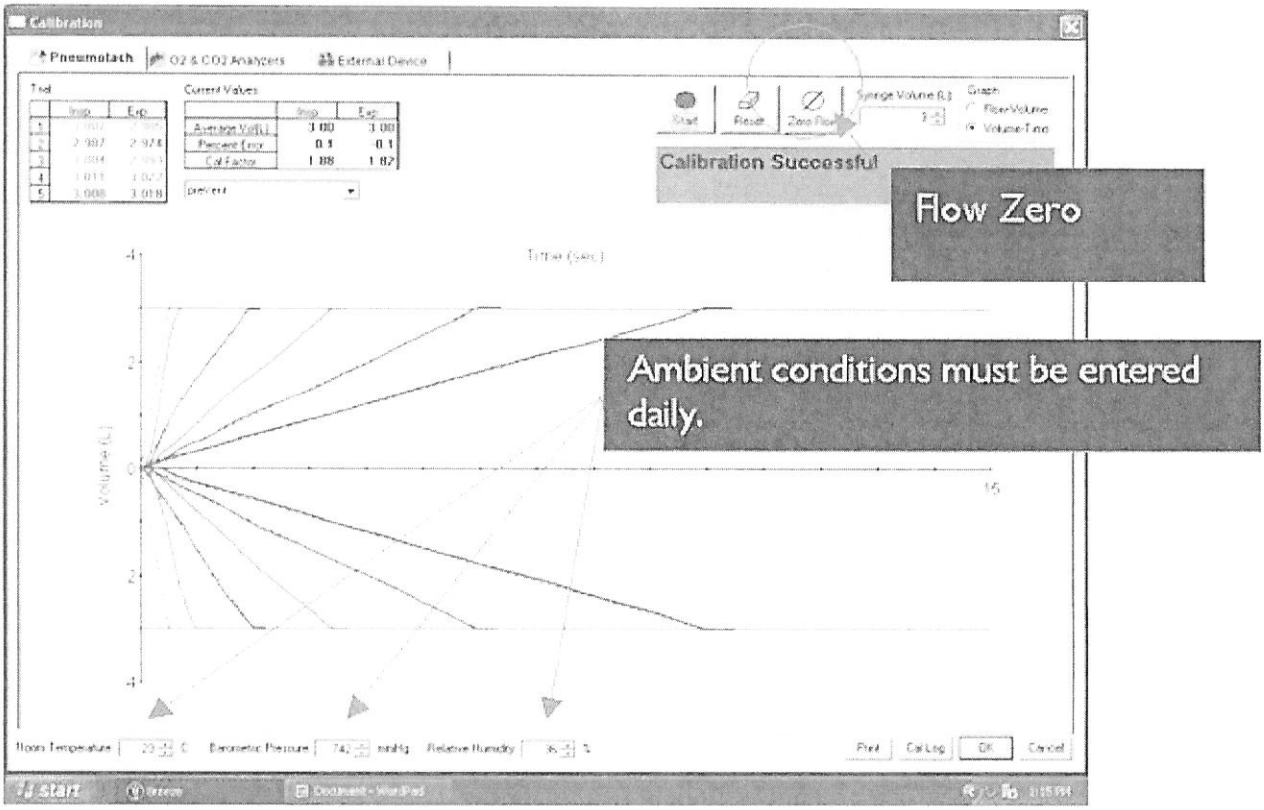
Flow Sensor calibration is a two-step procedure:

1. Set a zero reference to ensure that the system is reading zero flow when no flow is being introduced. The Flow Sensor must be zeroed before each test. It is also zeroed as part of the automatic gas analyzer calibration.
2. Perform a volume calibration to match the volume being introduced with an actual syringe volume. Volume calibration of the Flow Sensor is required only once per day. It does not need to be performed on each new Flow Sensor after the initial daily calibration. The calibration routine consists of introducing a known calibration volume into the Flow Sensor several times at different flow rates from slow to fast. You should perform five injections and withdrawals. These signals are measured by the Flow Sensor system (flow sensor and transducer) and sent to the waveform analyzer. The waveform analyzer converts the analog signal to correlate with flow. Integration of flow relative to time is volume. This volume is then compared to the actual volume to calculate a calibration factor.

Before Flow Sensor Calibration

1. Allow the system to warm-up and stabilize for 30 minutes.
2. Install the Flow Sensor into the clip (see "Assembling the Patient Circuit") and connect it to the rubber coupler (screen toward coupler).
3. Connect the rubber coupler/Flow Sensor assembly to the calibration syringe.
4. Select Calibrate at the top of your screen to enter the calibration screen. Note: You must have the Patient Entry screen closed to select Calibration.
5. The software defaults to 3 liters for the calibration syringe size. If you are utilizing a different volume syringe you must enter this value in place of the default value of 3 liters.
6. Enter the current Temperature, Barometric Pressure, and Humidity at the bottom of the screen. Verify the units of measurement are correct.

Ambient conditions must be entered daily.

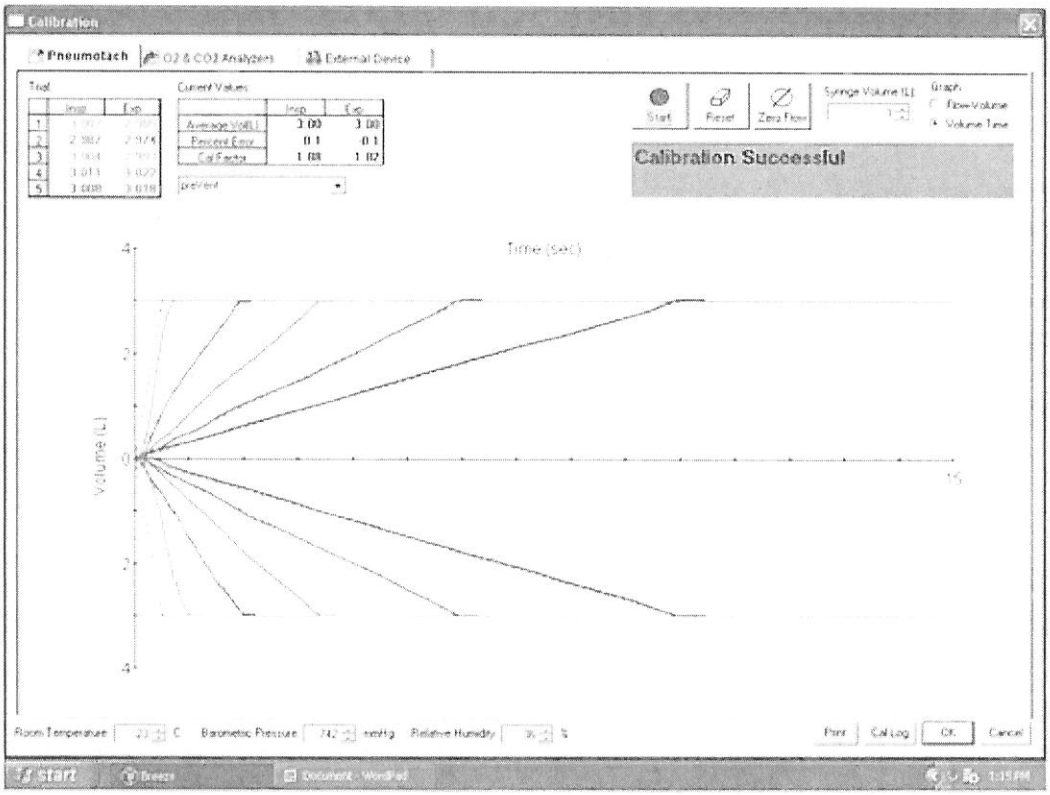


Tip: Set the syringe on a solid surface during calibration to ensure accurate results.

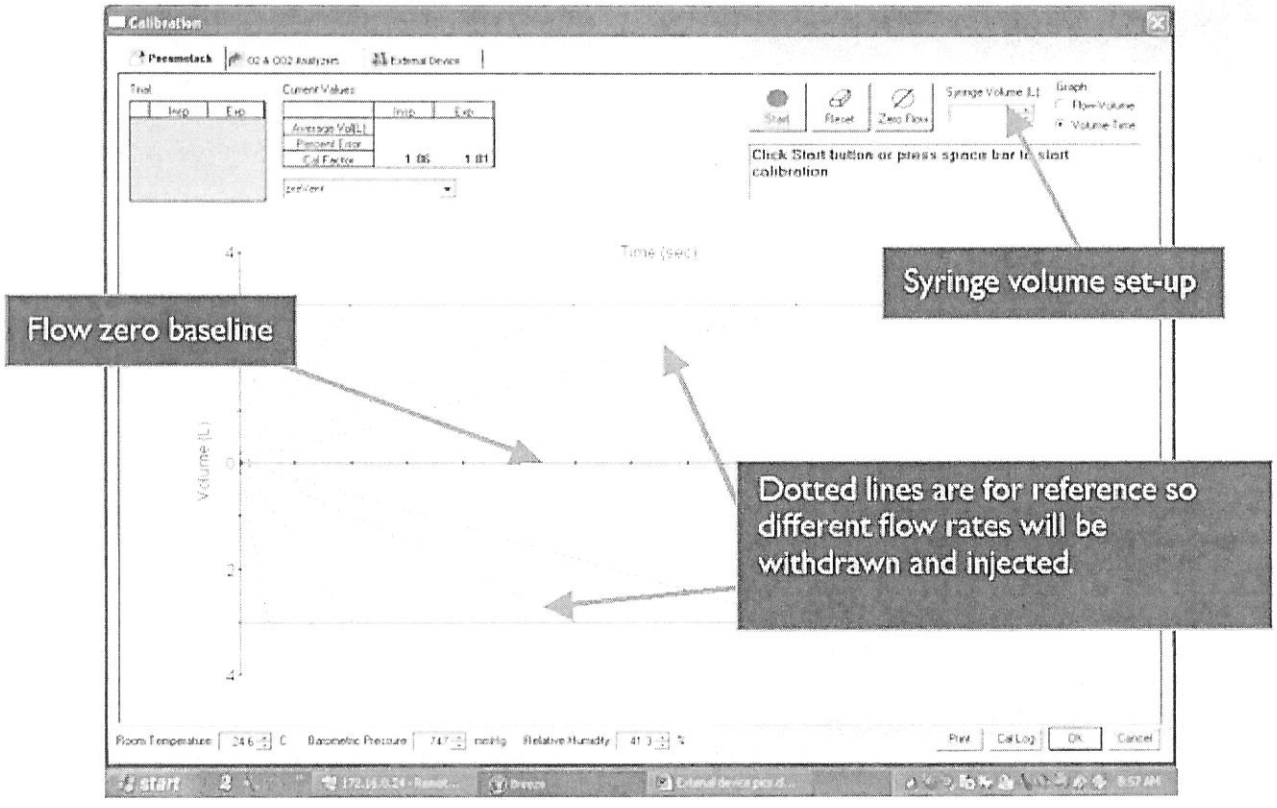
7. Click Zero Flow to zero the Flow Sensor . If the calibration is unsuccessful, a message appears stating that the Flow Offset is out of range. Repeat the procedure. If the zero continues to fail, try a different Flow Sensor and verify that the umbilical tubing is not occluded.
8. Click Start or press the spacebar to begin volume calibration.
9. The software will first prompt you to withdraw the syringe. Withdraw the complete volume of the syringe. Use the guides/markers to assist you with the variance/speed of your withdraws, and injections with your calibration syringe.

Note: Within Flow Sensor calibration the flow should trace downward for all withdraws, and upwards for all injections. If it does not trace downward, the Flow Sensor or Flow Sensor umbilical could be connected incorrectly, or the Flow Sensor may have been inserted in the syringe incorrectly.

10. Push in smoothly and evenly on the plunger. Be certain to inject the complete volume of the syringe.
11. Repeat steps 9 and 10 until five injections and withdrawals are recorded. The withdrawals and injections should be performed at varied rates. The sequence stops automatically after five injections and withdrawals.



Example of Syringe calibration



Different features of the calibration page.

Understanding Flow Sensor Calibration Results

The calibration results are shown in the data tables at the top of the screen.

Average Volume - The average of the sampled volumes in liters.

Percent Error - The percent error of the average measured volume from the actual syringe volume. The calibration will fail if the percent error is ± 2%.

Cal **Factor** - The number by which the measured volume must be multiplied to arrive at the actual volume during the volume calibration of the flow sensor.

What if the Flow Sensor Volume Calibration Fails?

There are two reasons the Flow Sensor might fail:

1. If the mean measured volume for either inspiratory or expiratory differ from the syringe size by more than 2%. You can perform a second volume calibration to have the computer adjust the Cal Factor and accept the Flow Sensor . If the mean measured volume was incorrect because of an incomplete volume excursion, you can reject the excursion by selecting it in the Trial table and pressing the delete key.
2. If the range of recovered volumes is greater than 3% of the syringe size, i.e., 0.09 liters for a 3-liter syringe size. If the mean measured volume was incorrect because of an incomplete volume excursion, you can reject the excursion by selecting it in the Trial table and pressing the delete key.