



MedGraphics[®]

Cardiorespiratory Diagnostic Systems

Breeze Suite Quick Start Operator Manual

An Introduction to Pulmonary Function Testing

The MedGraphics Breeze Suite Quick Start Operator Manual is Part No. 142143-001 Rev A.

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Welcome to Breeze Suite

Breeze Suite is a true multi-tasking software package that allows simultaneous display of pulmonary function and gas exchange graphics, tabular data, and full, 12-lead ECG information. The systems can be used as stand-alone or networked configurations.

Read this manual and the MedGraphics Regulatory Manual (Part No. 142144-001) in their entirety before operating equipment.

Daily Testing Quick Checklist

Step	Description
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- | | |
|----|--|
| 1. | Power up computer. |
| 2. | Check cables, lines, and other connections at the beginning of each day. |
| 3. | Calibrate system at beginning of each day. |
| 4. | Testing Sequence |
| | a. Enter Patient Information |
| | b. Perform Test (s) |
| | c. Evaluate adequacy of efforts |
| | d. Print Test results report |
| | e. Replace Pneumotach |
| 5. | Allow system to remain running or exit Windows and turn off power depending on the amount of time until next test. |

System Calibration

Pneumotach Calibration

1. Allow the system to warm-up for 30 minutes.
2. Install the pneumotach into the clip and connect it to the gray coupler (screen toward coupler).
3. Connect the gray coupler/pneumotach assembly to the calibration syringe.
4. Click the Calibrate button to enter the calibration screen.
5. Enter the appropriate syringe size in liters.
6. Enter the current Temperature, PBar and Humidity at the bottom of the screen.
7. Click Zero Flow to zero the pneumotach. If the calibration is unsuccessful, a message appears stating that Flow Offset is Out of Range. If this happens, repeat the procedure. If the zero continues to fail, try a different pneumotach and verify that the umbilical tubing is not occluded.
8. Click Start or press the spacebar to begin volume calibration.
9. Pull back smoothly on the plunger, being certain to withdraw the complete volume of the syringe. During the withdrawal, the flow should trace downward. If it does not trace downward, the pneumotach or pneumotach umbilical is connected incorrectly.
10. Push in smoothly and evenly on the plunger, being certain to inject the complete volume of the syringe.
11. Repeat steps 9 and 10 until five injections and withdrawals are recorded. The injections should be performed at different flow rates.
12. The sequence stops automatically after five injections and withdrawals.

Pleth Transducer Calibration

1. Close the plethysmograph door and allow for box pressure equilibration (approximately 10 seconds).
2. Click Zero or press the spacebar to automatically zero both pressure transducers.
3. Click Box Cal or press the spacebar to calibrate the box transducer gain. The data table on the left side of the screen is for the box pressure transducer. The measured values should be within the following specifications:

Transducer Gain: 50 - 70
Calibration Pump Frequency 1.2 - 1.5
4. Ensure that the value entered in the Reference Pressure field is the same as the value printed on the sticker on the left side of the Elite.
5. Click Mouth Cal or press the spacebar to calibrate the mouth pressure transducer. The mouth pressure transducer gain should be 5.49 – 8.01.

MIP MEP Calibration

1. Click Calibrate and select the MIP MEP tab.
2. Check that the reference pressure is correct.
3. Click Zero or press the spacebar to zero the transducer.
4. Click Start or press the spacebar to calibrate the transducer.

Calibration Report

To print a report for the latest calibration, click Print at the bottom of the Calibration screen.
To access a database of previous calibrations, click CalLog.

Starting a Visit

Creating a New Patient File

1. From the Open Patient screen, click New.
2. Enter all of the appropriate information.
 - Fields that are *required* are accented with a color.
 - To move from field to field, use the mouse or press the Tab key.
3. Click Add Visit. Enter information in the Visit Demographic screens. Select the Patient History tab to add information such as comments, medications, etc.

If the Open Patient screen is not displayed, you may also enter a new patient by clicking the New Patient icon.

Opening an Existing Patient

To open an existing patient file, highlight the patient's name in the Open Patient screen and click Open. Previous information and visit dates will be displayed.

About Review and Test Modes

Breeze operates in two modes: Test Mode and Review Mode.

Test Mode

To perform a test, Breeze must be in Test Mode. When you create a new visit and start testing, the system is automatically in test mode; the  test mode icon appears in the corner of the test graphs, and the test pad is displayed. Click the  icon at the top of the screen to switch from Review Mode to Test Mode.

Review Mode

Review Mode offers additional analysis options. You can draw graphs, create montages of multiple effort graphs, zoom graphs, show graph labels, etc. If you open an existing visit, the system is automatically in Review Mode. To switch from Test Mode to Review Mode, click the  icon.

Tip: Any time you click a time stamp of an effort to draw it, the system switches to Review Mode. You will need to click the  icon to re-enter Test Mode.

Spirometry

FVC Test Procedure

Caution: FVC testing can cause fatigue and may be dangerous for some patients. Some patients may be at risk for vertigo, arrhythmia or fainting.

Caution: The opening at the end of the pneumotach must not be obstructed. Make sure the patient does not obstruct it with his/her fingers. This will result in erroneously high volume and flow results.

1. Zero the pneumotach by clicking the Zero Flow button.
2. Click the FVC tab. The FVC Data Collection screen appears.
3. Press the spacebar to begin data collection. The patient's breathing efforts are immediately displayed on the screen
4. Instruct the patient to inspire fully.
5. Instruct the patient to exhale as rapidly, forcefully, and completely as possible.
6. Instruct the patient to inspire fully, as rapidly as possible.
7. Press the spacebar or click the Stop button to end the effort.
8. Repeat until consistent, reproducible results are obtained.
9. Place a checkmark in the Select column for all efforts that are to be used in the ATS/Composite row.

SVC Test Procedure

1. Zero the pneumotach by clicking the Zero Flow button.
2. Click the SVC tab. The SVC Data Collection screen is displayed.
3. Press the spacebar to begin data collection. The patient's breathing efforts are displayed immediately on the screen.
4. After obtaining a minimum of four tidal breaths, instruct the patient to inspire slowly and maximally then exhale slowly and maximally.
5. Press the spacebar or click the Stop button to end the test.
6. The software allows performance of either inspiratory or expiratory vital capacities.
7. Place a checkmark in the Select column for all efforts that are to be averaged in the AVG row.

MVV Test Procedure

Caution: *MVV testing can cause fatigue and may be dangerous for some patients. Some patients may be at risk for vertigo, arrhythmia or fainting.*

1. Zero the pneumotach by clicking the Zero Flow button.
2. Click the MVV tab to display the MVV test screen.
3. Press the spacebar and instruct the patient to begin breathing deeply and rapidly through the pneumotach. A Countdown Bar in the upper left part of the screen displays the number of breaths needed before data collection begins.
4. Encourage the patient throughout the entire testing time to breath as deeply and as fast as possible. If the patient is unable to continue the effort through the pre-configured time, stop the test manually by pressing the spacebar or clicking the Stop button.
5. After the pre-configured time, data collection stops automatically. Instruct the patient to resume normal breathing.
6. In the Test Mode column, indicate which effort is to be saved as a Pre or Post effort.

FRC (Nitrogen Washout)

Note: The nitrogen vacuum pump must be turned on at least 30 minutes before attempting to perform a washout test. If the pump is not on, click the N2 Off button at the top of the Patient Tests screen.

Pretesting Procedure

1. Select the FRC N2 Tab. The System begins the pretest calibration.
2. Attach the pneumotach clip to the Profiler or Elite cal port. The system samples room air. If the room air N2 level is not within the system's allowable range (79.6% \pm 2%), flush the system with room air using a calibration syringe and adjust the N2 gain knob. Press the spacebar when N2 gain is within range.
3. The system performs a phase delay measurement. If phase delay measurement fails the first attempt, press the spacebar to repeat the phase delay measurement. If the phase delay continues to fail, adjust the N2 needle valve. A dialog shows the allowable limits and the items that failed. To adjust the N2 needle valve, turn the needle valve clockwise until the N2 reading drops below 50%, and then slowly turn the valve counterclockwise until you obtain the peak N2%. Continue to turn the valve counterclockwise until the reading is reduced by 1%. Press the spacebar to return to the beginning of the calibration routine.
4. If the phase delay measurement passes, the system continues with an N2 zero measurement.
5. If the measurement fails, the system prompts you to adjust the N2 zero knob. The reading turns green when zero offset is within range. When your adjustments are complete, press the spacebar to return to the beginning of the calibration routine.
6. When the N2 zero measurement passes, the system flushes the port with DLCO gas, and then measures the N2 content of that gas. If this fails, check the DLCO gas concentrations on the Options page. If the N2 measurement passes, the system flushes the line with O2, and you may begin testing.
7. Attach the patient circuit to the arm of Profiler Dx or Elite Dx. Connect pneumotach and umbilical clip to patient circuit so umbilical tubing is in a straight up (12 o'clock) position.

FRC Test Procedure

1. Click Zero Flow to zero the pneumotach. There must be no flow through the pneumotach during this procedure.
2. Place nose clip on patient and instruct patient to breathe normally on the mouthpiece. Press the spacebar to begin testing.
3. After four stable tidal breaths, press the spacebar or click Next during an exhalation to begin the washout process. At the end of that exhalation, the computer automatically switches the patient to 100% oxygen.
4. Instruct the patient to continue tidal breathing throughout the test. Have the patient occasionally take a deep breath to ensure complete nitrogen washout. Ensure that the patient's lips remain tightly closed around the mouthpiece. If

there are any leaks, the values from the washout test will be invalid and the study must be repeated.

5. When nitrogen concentration is reduced to 1.7%, the program prompts you to sigh the patient (inspire deeply and exhale maximally). The test stops automatically when the program senses three consecutive breaths with nitrogen concentrations of 1.7% or less.
6. Place a checkmark in the Select column for each effort you wish to average in the AVG row.

Repeating FRC N2 Washout Efforts

If the procedure needs to be repeated, allow sufficient time for the patient to washout excess oxygen in the lungs before attempting the next effort.

Before retesting the patient, flush the circuit with a syringe and re-zero the pneumotach.

MIP/MEP

Note: *Inspiratory and expiratory pressure measurements must be performed in separate maneuvers.*

1. Autozero the pneumotach.
2. Ensure that the pneumotach is attached to the pneumotach clip and umbilical, and that this unit is attached to the patient circuit in the arm of the Profiler or Elite.
3. Place nose clips on the patient and instruct the patient to breathe normally through the mouthpiece.
4. Press the spacebar or click Next to begin testing. After a minimum of three tidal breaths, a MIP or a MEP pressure measurement can be obtained with one of the following steps:
5. MIP:
 - a. Instruct patient to exhale slowly to residual volume (RV).
 - b. When the patient appears to be at RV, press the spacebar or click Next. The occlusion piston will immediately close.
 - c. When the piston closes, have the patient inhale as hard as possible to produce maximal negative pressure. The occlusion piston reopens in four seconds, ending the test. To open the piston prior to this time, press the spacebar or click Next as soon as pressure measurement is made.

OR

6. MEP:
 - a. Instruct the patient to inhale slowly to total lung capacity (TLC).
 - b. When the patient appears to be at TLC, press the spacebar or click Next. The occlusion piston will immediately close.
 - c. When the piston closes, have the patient exhale as hard as possible to produce a maximal positive pressure.
 - d. The occlusion piston reopens in four seconds, ending the test. To open the piston prior to this time, press the spacebar or click Next as soon as the pressure measurement is made.
7. Repeat Steps 3 through 5 until all inspiratory and expiratory test efforts have been made.

Note: *Pressure measurements can be obtained at any lung volume. Measurements do not have to be taken at RV or TLC.*

8. Place a checkmark in the Select column for each effort that is to be used in the Composite row.

Plethysmography

Instructing the Patient

When the patient is comfortable, you may close the door, which will seal automatically, if the Inflate/Deflate switch on the left side of the Elite is in the Inflate mode.

During testing, instruct the patient to breathe through the mouthpiece, put on nose clips, and place palms of hands against the cheeks for support. Supporting the cheeks prevents pressure fluctuations due to cheek flexing. The patient should be sitting fully erect.

Test Procedure

1. Zero the pneumotach by clicking the Zero Flow button. There must be no flow through the pneumotach during this procedure.
2. After the door has been closed for 1 minute, have the patient breathe normally on the mouthpiece. Click Start or press the spacebar to begin testing. Collect at least four stable tidal breaths, and then press the spacebar or Next button. At the end of the next tidal breath, instruct the patient to pant. Panting frequency, which should be approximately 60 to 90 breaths per minute, is displayed on the test pad. If frequency is too high or too low, the breath frequency indicator turns red.
3. After the minimum number of panting efforts is displayed on the graph, click Next or press the spacebar to collect closed-shutter data. The computer goes through the following routine:
 - Closes the shutter.
 - Collects the loops performed during closed-shutter panting.
 - Opens the shutter.
4. When the shutter reopens, have the patient perform an SVC maneuver, then press the spacebar or Stop button.
5. Repeat the above steps until the required efforts have been obtained.

Quiet Breathing Option

As an alternative to the Raw panting test procedure, Breeze Suite allows you to collect Raw data by using the quiet breathing technique (30-50 breaths per minute). Select Quiet Breathing from the F5 Pleth Options menu.

While the patient is breathing on the system, a tracing is displayed on the Flow/Pressure graph. This tracing should always maintain a clockwise rotation and should be as tight as possible without crossing over itself. You can compensate a tracing with the left and right arrow keys on the keyboard while the patient is performing open shutter breathing.

Adjusting Angles and Selecting Efforts

Prior to saving any effort, check the line of best fit on all efforts. If you disagree with the slope of the line that the computer has calculated for either tracing, you can adjust the effort manually.

Double click the effort's time to plot the effort, and then double click the plot to bring up the Pleth Zoom window, which includes the angle adjustment controls. Select which line to adjust, and use the Angle Adjust and Position Adjust controls to manipulate the line. Click Reset to return to the last saved line. Click OK when your changes are complete.

Place a checkmark in the Raw and/or TGV columns for the efforts that are to be averaged in the AVG row.

DLCO

DLCO testing is performed using the preVent pneumotach and a mouthpiece connected to the pneumotach umbilical. The pneumotach must also be connected to the patient circuit in the arm of the Profiler or Elite.

Pretesting Procedure

1. Before testing, He gas must be on for twelve minutes. Warm up time is displayed on the associated timer at the top of the screen.
2. Select the DLCO test tab.
3. Click the Analyze button to begin gas analysis. The program flushes the patient circuit with diffusion gas from your source tank. After analyzing the diffusion gas, the sample chamber is evacuated and a pre-analysis graph is displayed.

Test Procedure

1. Click Zero Flow to zero the pneumotach.
2. Place nose clips on patient and instruct the patient to begin tidal breathing through the mouthpiece. Press the spacebar to begin data collection.
3. Instruct the patient to exhale slowly and maximally to residual volume (RV). While the patient is exhaling, or at the end of this exhalation, click Next or press the spacebar.
4. After the valving system is activated, instruct the patient to rapidly inhale maximally to total lung capacity. The valve will close automatically when zero inspiratory flow is sensed.
5. When the valve system closes, the patient is locked out for the time specified in the Setup menu. Instruct the patient to relax against the closed valve for this period.
6. At the end of lock-out, the valve opens. Instruct the patient to exhale rapidly until the sample is collected.
7. The test ends automatically. At the end of each effort, a gas sample is collected automatically into the chromatograph for analysis.
8. Repeat Steps above until sufficient efforts have been performed.
9. Place a checkmark in the Select column for each effort you wish to average in the AVG row.

About the Bronchial Provocation Option

The optional Bronchial Provocation package provides a set of pre-configured protocols for a variety of challenge agents and a protocol editor which gives you the flexibility of modifying existing protocols or creating new protocols for use with bronchial provocation testing.

To select a test protocol	Click the Protocol/Log tab and choose a test protocol from the Protocol pull down menu. Pre/Post is the default protocol for all new visits.
To modify an existing protocol	Choose Open from the File menu and select PF Protocol. Double click the protocol you wish to open. If an existing protocol has already been used for testing a patient, that protocol cannot be edited.
To insert a protocol stage	<ol style="list-style-type: none"> 1. Place your cursor below where you want the new protocol stage to appear. Protocol stages are always entered above the highlighted line. 2. Click the Insert Stage button. 3. Edit the Protocol Stage fields as necessary. <p>Note: A protocol can have no more than twenty stages.</p>
To create a new protocol	<ol style="list-style-type: none"> 1. Choose New from the File menu and select PF Protocol. 2. Type a protocol name in the Protocol Name box. 3. Select a challenge agent from the Challenge Agent menu. <p>Note: You cannot edit the challenge agent field. New challenge agents must be entered in Microsoft Access.</p>
To delete a protocol stage	<ol style="list-style-type: none"> 1. Place your cursor in the stage you want to delete. 2. Click the Delete Stage button.
To save any change	Select Save from the File menu.

Performing a Challenge Test

1. After entering patient information, click on the Protocol Log tab.
2. In the Protocol dialog box, click on the drop down menu and select the protocol you wish to use.
3. Click on the tab of the first test you wish to test (FVC, Pleth, etc.).
4. Perform all of the testing for each stage before proceeding to the next stage. After testing is complete in one stage, click on the Protocol Stage drop down menu and select the next stage.

5. Stages can be skipped if on this particular patient you do not wish to test in that stage.
6. After all the testing is complete, verify that each stage has at least one effort selected (red checkmark in the Select or Raw column).
7. Also verify that there is a Pre/Baseline, Challenge and Post marker in the Test Mode column of the FVC and Pleth screens if both tests were performed.
8. The Dose Units, Cumulative Doses and PC20 are automatically calculated.
9. Click on Reports in the Menu bar and go to the Report Switchboard. Print the appropriate Bronchial Provocation (BRP) report.

Printing Reports

When testing is complete, select the Reports menu. You may choose from a list of the most recently generated report formats, or you may select Report Switchboard to select from all reports available on your system.