

This software is a Service Pack for BreezeSuite™ cardiorespiratory diagnostic software version 8.5 and is intended to be installed on any computer that has BreezeSuite 8.5 already installed.

Minimum System Requirements

- BreezeSuite cardiorespiratory diagnostic software version 8.5.

Important:

- Perform a BreezeSuite database backup prior to installation of Service Pack 8
- For networked multiuser installations, the workstation computer must be connected to the network and BreezeSuite must be in shared database mode during installation of Service Pack 8. Service Pack 8 is applied to all BreezeSuite workstations connected to the networked database.
- After successful installation of Service Pack 8, the software cannot be rolled-back to a previous version of BreezeSuite 8.5. If a software repair is performed, Service Pack 6 must be immediately reinstalled.
- Installing the English version of Service Pack 8 will remove language translation files. Reinstall Service Pack 8 in the correct language.

NOTE: For multiuser installations, Service Pack 8 is applied to all BreezeSuite installations. SP8 is not applied to the BreezeSuite SQL database.

Installation Procedure

NOTE: Download Service Pack 8 from the MGC Diagnostics website, extract/unzip the file prior to starting installation.

1. Close all applications.
2. Browse to the appropriate “BreezeSuite85SP8.exe” file on your installation media (USB flash drive, etc). Each file has the name of the language it is translated into.
3. Right click on the “BreezeSuite85SP8.exe” file and select “Run as Administrator”.
4. Follow the on-screen prompts to complete the installation.
5. After the files have been installed, remove the installation media from the computer if applicable.

LANGUAGE TRANSLATIONS

CAUTIONS

1. The 2017 ATS/ERS DLco Guidelines recommend that the DLco predicted value be corrected for hemoglobin. With a subject visit open in BreezeSuite, go to F5 Options, then the DLco/DLco RTD Tab and verify the hemoglobin correction is set to the desired entry.
2. The 2017 ATS/ERS DLco Guidelines recommend that the DLco actual value be corrected for altitude. With a subject visit open in BreezeSuite, go to F5 Options, then the DLco/DLco RTD Tab and verify the altitude correction box is checked

DLco Hemoglobin Correction

Actual Predicted

Altitude Correction (Actual Value Only)

3. The ATS/ERS guidelines recommend using $1.645 \times$ Standard Deviation to calculate the Lower Limit of Normal (LLN). By default, BreezeSuite sets this multiplier to 2.00 for DLco and Lung Volume variables. To change this multiplier to 1.645, in BreezeSuite go to: Tools>Resources>Variables and open variable DLCOunc. In the “95 Percent” dialog box enter 1.645. Repeat above procedure for DLCOcor, VA, KCO, DL/VA, TLC, FRC and RV

Name: DLCOunc Type: [DLCOData] Unit: ml/min/ml SI Unit: mL/min/kF

Miscellaneous

Reported Name: DLCOunc

Tabular Decimal Places: 2 PD Level 1: 0 Fixed Pred: []

Graphical Decimal Places: 2 PD Level 2: 0 Calculate Predicteds

95 Percent: 1.645

Changes for Service Pack 1

- Corrected the calculation of LLN and Z-Score for GLI 2012 variables.
- Added the 2017 GLI DLco predicted equations.
- Corrected issue where some of the buttons were not displayed in the F5 Options screen – especially on laptop computers with smaller resolution screens.
- Corrected an issue so that values for variables that are ratios (FEV1/FVC or DL/VA) are now displayed properly.
- Corrected issue of variables being displayed in red when they were within normal

ranges.

- Added the ability to manually enter FOT variables.
- Removed the large blank space between the header and interpretation on an Interp Only report.
- Removed access to the Security menus when in Breeze Review.
- Added the ability to convert Micro Medical/Microlab spirometry data into BreezeSuite from the Microlab PC based database.
- Improved the RS-232 communication with a treadmill protocol.
- Corrected issue of Naughton Treadmill Protocol reported Time.
- Verified that the F4 Function Key displays the Manual Event dialog.
- Corrected issue of “<” missing from sRaw predicted value in Text Report.
- Increased the number of fields that can be added to the Header/History sections of a report.
- Corrected an issue so that the Row ID (first column in the patient list) automatically adjusts the width of the column based on the number of patients.
- Corrected issue with Frontera Reports.
- Verified the Standard Deviations (SD) for FOT are the same on the Resmon FOT and in BreezeSuite.
- Corrected issue where the number of decimal places for height were not displayed on the report.
- Changed the label for “Consult” button in Breeze Review to “Interpretation”.
- Increased the password expiration from 90 to 180 days.
- Corrected issue in the BRP Graph for the BRP Stage markers.
- Verified that manually entered Gx events appear in the appropriate data type, such as Rest, Exercise, etc.
- Created two Text Reports: Metabolic Summary and GX Consult.
- Corrected the identification of VO2 Max which could be off by one breath.
- Added Exp Time, Back Extrap and FEFmax variables to all Text Reports with spirometry.
- Added BHT, IVC and TLC(SB) variables to all Text Reports with DLco.
- Improved the ability to combine patients or staff members.
- Added a Registry Key setting for automatically adding workstations rather than having the user manually create one the first time they run BreezeSuite.
- Increased the number of exercise protocol stages to 200.
- Added the ability to add an electronic signature for a new physician without needing a password by using Active Directory.

Changes for Service Pack 2

- When using an Ergoline cycle with Blood Pressure measurements, corrected an issue where the BP value was being retained from previous test.
- Updated Shunt calculation to use equation from Gregg Ruppel's Manual Of Pulmonary Function Testing when testing with 100% oxygen.
- Added three new reports to mimic the October 2017 ATS Recommendations for a Standardized Pulmonary Function Report. Once SP2 has been installed, these reports can be imported by opening DBTools, then go to: Tools>Import>Reports. Use the Browse button and browse to:

C:\Program Files (x86)\MedGraphics\Breeze\ATS Reports 2017\

Highlight the reports and select Import/Restore.

- Changed Audit Trail to update when making FOT changes.
- Changed the column Header “#SD” to “Z-Score” to comply with the ATS standardized report format.
- Corrected issue of not being able to adjust VO2 Max within the AT Tab.
- Made the following changes to Physician Review:
 - Added the option to trend visits based on First Visit or Prior Visit
 - Allows user to list visits by Ascending or Descending order
 - Added the option to trend the percent change of the percent predicted value (%Change-%Pred-Pre)
 - Added a check box for Pulmonary/Exercise Consult (Interpretation) to run automatically if no interpretation exists
 - Added a Quick Code ID feature which allows the physician to type in the ID of a pre-canned statement rather than selecting that statement from a list
- Added the ability for Custom Consult to comment on data from a previous (First or Prior) visit, such as: “The actual FEV1 changed by x% compared to previous visit.”
- Improved functionality when using the Zephyr Heart Rate monitor.
- Increased (doubled) the size of the Header and History Sections for the Final Report.
- Added the new ATS FVC and FEV1 Quality Grading scores in the Test Screen as well as in the Final Report. Note: This replaced the Spirexpert grading system.
- Modified the DLco Grading System to comply with the October 2017 ATS Recommendations for Standardized Pulmonary Function Report.
- Improved the way Orders are sent to BreezeSuite when running in multi-user mode.
- Added a “Reset All’ button to the HIS dialog to reset a corrupt HIS Table.
- Allow the detection of breaths even if the first breath occurs more than 10 minutes

after selecting Start button.

- Added a new role option where the person going into Physician Review has only access rights to view the patient data, but not make changes to interpretation.
- Updated the Lung Volume Bar Graph to comply with the October 2017 ATS Recommendations for a Standardized Pulmonary Function Report.
- Corrected an issue where the NICO graphs could not be viewed or adjusted.
- Corrected an issue where the BRP Tab in Physician Review was not viewable.
- When the GLI 2012 spirometry reference equations are used AND the SVC predicted value is set to be the same as FVC, SVC will have the same SD, LLN and ULN as FVC.
- Corrected an issue where the P(a-ET)CO₂ was missing from the Summary Page.
- Added support for the Lode Cycle Blood Pressure when using the Lode protocol.
- For Bronchial Provocation:
 - Changed the “Dose” label to “Concentration”
 - Updated the PD calculation to use Dose Units and not CDUs
 - The “Post BD” marker is moved to the right on the graph to separate from other stages
 - Increased the number of breaths allowed in the Protocol column
 - Removed the units from the PD label
- Updated the DLco RTD calibration lower limits as follows:
 - CO Gain = 0.4
 - CH₄ Gain = 0.5
 - CO₂ Gain = 5.0
- Added the updates for the Ohio State Reports.

Changes for Service Pack 3

- Corrected an issue in which the computer would not communicate with MGC testing systems after Windows 10 Feature Update, version 1803 was installed.
- Improved the communication between the CPFS/D spirometer and the USB 3.0/3.1 computer ports

Changes for Service Pack 3 Rev B

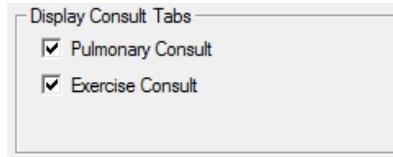
- Added Digital Signature to installation.

Changes for Service Pack 4

- Improved the way BreezeSuite handles new orders from the EMR.
- Added new options under Smoking History: Marijuana, E-Cigarette & Vaping.
- Corrected issue of missing SVC predicted values in the Pleth Tab
- Corrected an issue with Custom Consult displaying an error when the consult

contained rules concerning previous visits.

- Corrected the issue of Auxiliary Data Fields being displayed in red.
- Updated the Altitude correction for DLco.
- In the F5 Options Menu, General Tab, added ability to turn off either the Pulmonary



or Exercise Consult Tabs.

- Improved the importing of physician and technician names and IDs when converting VMax test data into BreezeSuite.
- Improved the importing of DLco predicted values from VMax into BreezeSuite using DBTools and Autoconvert.
- Corrected issue of the SUM file not reporting the Reviewing physician.
- Corrected issue of testing P100s when Nonin 7500 oximeter was connected.
- In Breeze Review, corrected issue of the Volume Change header being listed as Unknown.
- Corrected issue of missing graph for GX when graph was on second page.
- Corrected issue of a blank space in the AuxData Field.
- Added the PF Summary 75 Character report to the Text Report Selection.
- Changed the rounding of age formula when converting VMax patients.
- Changed the flushing of gas routine when exiting the DLco test screen. Flushing of O2 will only occur when going into the FRC or SBN2 test screen.
- Corrected issue of FOT values not trending when patient file is imported.
- Corrected issue of LLN not displaying properly when decimal places is set to one.
- Updated the limits for the mouth pressure gauge that is displayed during lockout of DLco testing. Lower limit was changed from 0 cmH2O to -10 cmH2O.
- Improved the detecting of breaths in the Rest phase after sending supine and standing ECG.
- Added support for TLS 1.1 and 1.2

Changes for Service Pack 5

- Corrected issue of Breeze Review requiring a Reviewing Physician name when changing Review Status to Completed-Posted-Lock
- Corrected issue of wrong patient age being sent to Mortara software
- Corrected issue of SQL Native Client not being installed on a “no local” installation

Changes for Service Pack 6

- Corrected issue of Breeze closing on its own when an error message “Mortara is not responding” and an MFC Application Error is displayed when saving Mortara files.
- Corrected issue with data discrepancies in text reports.
- Corrected issue with Auto-Logout in Breeze Review.
- Corrected issue with age recalculation when sent to BreezeSuite from BreezeConnect Instrument Manager.
- Corrected issue with version update in BreezeSuite Assert Error Log
- Removed ability to copy orders from shared database to local database to improve database and application performance.

Changes for Service Pack 7

- Added O2/CO2 augmentation for the current Ultima Series.
- Enhanced the detection of a slow or bad O2 Cell during calibration.
- Improved CO2 accuracy when a newer board is present.
- Improved the sorting function when the Patient List is displayed.
- Updated CO DF VO2 Mean & CO DF CO2 Mean BSA to use mean VO2 value from resting phase.

Changes for Service Pack 8

- Corrected an issue when Recovery was selected in BreezeSuite and the device did not move to Recovery.