



BREEZESUITE™ 8.6 REV D

Release & Installation Notice

BreezeSuite version 8.6 Rev D is the latest version of software available for the Medical Graphics' Platinum Elite™ Series, Elite™ Series, Ultima™ Series, and CPFS/D™USB systems.

CAUTIONS & WARNINGS

WARNING: After the installation of BreezeSuite 8.6 Rev D, Service Pack 6 or higher for BreezeSuite 8.6 must be installed on Windows 11 operating systems. Failure to install this Service Pack may result in the software not functioning correctly.

► **IMPORTANT SYSTEM INSTALLATION NOTE: Medical Graphics USB Device must be powered on and the USB Device driver must be installed prior to configuring BreezeSuite for first time use. Failure to follow these directions may result in BreezeSuite configuration and diagnostic testing failure.**

► **NOTE:** New Installation of BreezeSuite 8.6 Rev D or upgrade from BreezeSuite 7.2 SP7 requires an access code (CD Key) that must be obtained from Customer Service during the software installation. Customer Service is available Monday – Friday 7a.m. to 6p.m. (Central Time) by calling (1-800-333-4137). International customers should contact their local MGC Diagnostics Business Partner. (see upgrade note below)

► Installing BreezeSuite 8.6 Rev D on a computer with Windows 7, 8/8.1,10 or 11 operating system that is controlling a Platinum Elite with a part number that ends with -001 requires a hardware upgrade to the Platinum Elite. Without the hardware upgrade, the Platinum Elite will not function properly. Contact your local sales representative or Technical Support for information on upgrading the Platinum Elite.

► BreezeSuite 8.6 Rev D **does not** support:

- Elite Series Plethysmographs with model numbers ending in -001 thru -005
- Ultima Series with model numbers ending in -001 thru -005 unless noted with a label indicating system has been upgraded to -006 compatibility
- BreezeLink HL7 (Link Medical interface)
- CPFS/D spirometer with model numbers ending in -001 & -002.

► Upgrading to BreezeSuite 8.6 Rev D is only supported from the following BreezeSuite versions: BreezeSuite 7.2 SP7 and BreezeSuite 8.0 or higher.

WARNINGS: BreezeSuite 8.6 Rev D will not install on a Windows XP computer. BreezeSuite WebReview is no longer supported in BreezeSuite 8.6. At the time of this release, Windows 11 Operating System is not supported for an Ultima Cardio2 (CPET & ECG) system. Check with Technical Support for any updates.

► BreezeSuite 8.x added a higher level of security to help customers comply with HIPAA/HITech security requirements. If upgrading from BreezeSuite v7.2 Sp2, all previously entered passwords will be reset and require the configuration of a new temporary password by your designated security administrator prior to users accessing BreezeSuite 8.6. See the Security Administrators Guide located with the installation instructions on the BreezeSuite 8.6 Flash Drive for additional information.

► GLI 2012 and GLI 2017 are the default predicted authors for spirometry and DLco on all new software installations. Installing BreezeSuite on top of an existing installation will not change the previously selected predicted authors.

► **MGC Diagnostics does not have a “back-door” to the BreezeSuite application security feature. If you create a password and the password is forgotten or lost, access to your patient data will be denied.**

CAUTIONS & WARNINGS continued

► When installing or upgrading to BreezeSuite 8.6 Rev D the folders listed below (and all subfolders) will be moved from 'Program Files' to 'ProgramData'. Further information on this important change, and the permissions/ rights needed for each folder, is available in the BreezeSuite software installation instructions:

-C:\Program Files (x86)\MedGraphics\Breeze to C:\ProgramData\MedGraphics\Breeze

► When installing or upgrading an Ultima™ CardiO2 ® gas exchange analysis system to BreezeSuite 8.6 Rev D, the folders listed below (and all subfolders) will be moved from 'Program Files' to 'ProgramData'. Further information on this important change, and the permissions/ rights needed for each folder, is available in the BreezeSuite software installation instructions:

-C:\Mortara Instrument Inc\XScribeII\COMMAND to C:\ProgramData\MedGraphics\XScribe\COMMAND

-C:\Mortara Instrument Inc\XScribeII\CURRENT to C:\ProgramData\MedGraphics\XScribe\CURRENT

► With the 2017 guidelines on methacholine challenge testing, the ERS has determined that best practice is to look at the PD20 value for interpretation rather than the PC20 value. PD20 is the provocative dose that causes a 20% decrease in FEV1. PC20 is the provocative concentration that causes a 20% decrease in FEV1. To this end it is necessary for the user to understand the specifications of the nebulizer used for delivery of the methacholine. The dose at each stage is a combination of nebulizer and protocol used.

From the ERS guidelines, the nebulizer output in mg/min, the % of droplets less than 5 microns, and nebulizer delivery time must be known. From this information the dose at each stage can be calculated. At the time of this publication, only the specifications for the AeroEclipse BAN II nebulizer were known.

In BreezeSuite 8.5 and prior versions, the protocol editor allowed you to enter the concentration and the number of breaths for each stage. In BreezeSuite 8.6 the protocol editor was changed. The column for Breaths was removed and replaced with Dose. (see examples below) When upgrading from BreezeSuite 8.5 or earlier, the previous protocols were automatically converted to the new format. If you continue using PC20, then no other changes should be necessary; however, these protocols should be verified before patient testing. **If using or changing to the PD20 for testing, you will need to create new protocols and enter the appropriate dose at each stage.** The calculation of each dose and examples of this are outlined in Appendix D & E of the ERS guidelines. Below is an example for BreezeSuite 8.6 Rev C, of a Methacholine protocol using the AeroEclipse BAN II nebulizer for 1 minute at each stage and the quadrupling protocol outlined in the ERS guidelines.

BreezeSuite 8.5

	Stage Label	Concentration	Breaths
1	Pre	0.00000	0
2	Diluent	0.00000	0
3	.063mg/ml	0.06300	5
4	.25mg/ml	0.25000	5
5	1mg/ml	1.00000	5
6	4mg/ml	4.00000	5
7	16mg/ml	16.00000	5
8	Post	0.00000	0

BreezeSuite 8.6

	Stage Label	Concentration	Delivered Dose
1	Pre	0.00000	0.000
2	Diluent	0.00000	0.000
3	0.0156 mg	0.01560	2.000
4	0.0625 mg	0.06250	8.020
5	0.25 mg	0.25000	32.060
6	1.0 mg	1.00000	128.250
7	4.0 mg	4.00000	513.000
8	Post	0.00000	0.000

System Specifications and Prerequisites: For complete listing, see Installation Instructions available on BreezeSuite 8.6 Rev C installation USB Drive.

SYSTEM SPECIFICATIONS FOR WORKSTATION COMPUTER

Operating System	Windows 7 (Pro, Ultimate or Enterprise) Service Pack 1 Windows 8.1 (Pro or Enterprise) Windows 10 (Pro, Enterprise or Enterprise LTSC) Windows 11 (Pro, Enterprise or Enterprise LTSC) Note: The Ultima Cardio2 (CPET & ECG) does not support Windows 11
Supported SQL Versions	SQL Server 2012 (Standard, Enterprise) ▶ Not supported by Windows 11 SQL Server 2014 (Standard, Enterprise) ▶ Not supported by Windows 11 SQL Server 2016 (Standard, Enterprise) ▶ Not supported by Windows 11 SQL Server 2017 (Standard, Enterprise) SQL Server 2019 (Standard, Enterprise)
Processor	Intel Core Duo or Greater Recommended
Hard Disk	80+ GB Recommended
Memory	8+ GB Recommended
Windows Display Properties	1024 x 768 Minimum Resolution
Other Hardware	3+ USB-A Ports if client connecting to diagnostic device 8+ USB-A Ports for Ultima Series Gx Systems
System Type	x86 (32-Bit) and x64 (64-Bit) PC hardware and operating systems are supported.

NOTE: Ultima™ Cardio2 X-Scribe 3.x gas exchange analysis systems DO NOT support x 64 (64-bit) operating systems.

Installation Instructions:

Place the USB Drive into the computer. Using Windows Explorer, browse to the USB Drive and run (double click on) the “Launch.exe” file. Select **Install Software**, then **Installation Instructions**. The Installation Instructions can be printed from the USB Drive. **NOTE:** The installation instructions are in PDF format. If Adobe Reader is not installed on the computer, select Install Software, then Adobe Reader to install Adobe.

After the software has been installed, follow the Computer Configuration Instructions: Run the “Launch.exe” file, select Install Software, then Computer Configuration .

NOTE: After the installation of BreezeSuite 8.6 Rev C, Service Pack 6 for BreezeSuite 8.6 must be installed on Windows 11 operating systems. Failure to install this Service Pack may result in the software not functioning correctly. Service Pack 6 also has the translation files for 8.6 Rev C.

Highlighted Changes from BreezeSuite 8.0 to BreezeSuite 8.4

To review all of the changes between BreezeSuite 8.0 and 8.4, please see BreezeSuite Release Notice Part Number 147941-004.

Highlighted Changes from BreezeSuite 8.4 to BreezeSuite 8.5

- Added the Lung Volume bar graph to Physician Review
- Changed the Acceptability and Repeatability criteria for DLco testing to match the ATS/ERS 2017 Guidelines.
- Added the 2017 ATS/ERS DLco Guidelines Test Quality Grading available in the DLco Test Screen & Final Report.
- Added new controls in the F5 Options dialog (General Tab) to change font size for the data tables in the test screens and Breeze Review, as well as the font size for the printed report.
- Added the ability to reselect Race entry when you open a patient visit, rather than having to go to Edit.
- To improve database performance, changed BreezeSuite multi-user to only copy modified resources and patients to the local database when logging in or out of BreezeSuite or switching to local mode.
- Allow the user to remove or cancel multiple orders at one time.
- Added a Z-Score graph to the Final Report and Breeze Review.
- In the Final Report, added the ability to shade every other line to make the rows easier to read. This option is turned on in F5 Options – PF Pages Tab.
- Added the ability to have ratios such as FEV1/FVC as either a decimal fraction or a whole number. This option is configured in the F5 Options Units Tab.
- Added a column for Volume Change from Pre-Bronchodilator to either Challenge or Post-Bronchodilator stages. This option is available in the report column headers of PF Pages Tab.
- Added Spirometry Test Quality Grading according to NLHEP and Spirxpert – user selectable in the F5 Options Menu – FVC Tab.
- Added the ability to lock and unlock roles in Security.
- Added the ability to Export/Import PF and Gx Predicted Sets in DBTools.
- Created an Order Status Display filter for Open Patient list. This allows BreezeConnect users to restrict the patient list to those patients that have orders with a specified status.
- Added a “Technician Select Reports” role in Security Roles. This role determines if the user has the ability to select a specific report for export in the Post test Comments dialog.
- Corrected an intermittent issue where the ECG Only flag was getting set incorrectly on Gx tests.
- Allow the user to expand the Post Test Comment dialog box.
- Added the ability to view Billing Modifiers, Hospital Charge Code (CDM Code), Procedure Codes (Professional CPT Code) and Diagnosis Codes (ICD-10 Codes) in Breeze Review.
- The exported data file (SUM file) has been updated to include the above.
- Corrected an issue with the legacy Ultima to allow face tent testing with the legacy fan assembly.
- Corrected an issue with a blank page being inserted into the ExFVL report when only the graphs were selected to be printed.
- Added support for the Tab 004 CPFS/D spirometer.
- Added an additional 80 Aux Data fields, which brings the total Aux Data fields to 100. Only the first 20 Aux Data Fields are checked to display by default. Additional fields can be activated in F5 Options - Visit Tab.

- Modified the calculations for % Change and % Predicted Change to be the same in terms of rounding to the next number.
- Resized the FOT graphs so that the data table and graphs are on one page.
- Added the Gutierrez 2004 predicted author for TGV. Previously it was on FRC(N2 Washout) only.
- Changed the “Sensitivity” label on the bottom of the BRP Trend graphs to PD20.
- Added a PD column to the BRP Trend Tab in the data table. This can also be printed in the Final Report. The PC20 and PD20 are separate options in the F5 Options dialog of BRP Trend Tab.
- Added CO Index (Direct Fick) variable.
- Added CO (Direct Fick) VO2 Mean variable called: “CO DF VO2 Mean”.
- BreezeSuite now displays a message recommending to perform a gas calibration immediately prior to starting a gas exchange test. The message will appear if it has been over 5 minutes since the last gas calibration.
- Updated the derived Treadmill Watts equations.
- Added the ability to have User Defined/Selected predicteds for HR Max. This is configured in the Selected Author Tab of the GX Predicted Set.
- Changed the method of determining Exercise Oscillatory Ventilation (EOV). BreezeSuite now uses the average resting VE instead of resting VE amplitude.
- Added the ability to interface with the Zephyr Heart Rate Monitor.
- Added the variable VCO2/Flow
- Added variable and tab for Chronotropic Index.
- When reopening an existing visit and going into a test tab, BreezeSuite will automatically display the graphs of all selected efforts.
- User authentication has been updated to allow for integration with Active Directory in both an automatic and manual method. Users can be authenticated and logged into the BreezeSuite application automatically based upon the Windows credentials of the hosting computer. The BreezeSuite application can also be configured to ask the user for their Windows credentials which are then authenticated via Active Directory. This update allows for all application user accounts to be managed at the domain level.
- Disabled the File/Exit menu button when a patient visit is open in Breeze Review.
- Corrected an issue where communication would drop out (watts & RPM) between the Ergoline ergometer and the Ultima when a blood pressure measurement is taken.
- Corrected an issue where Diagnosis entries could not be deleted.
- Added an option to determine if the patient list should be refreshed every time the patient list is displayed. This option is configured in F5 Options – Patient Tab.
- Enhanced the search option when searching for a physician, technician or site name in the filter drop-down box. Previously only able to type in the first letter. Enhanced to be able to type in multiple letters.
- Updated the installation to install Microsoft SQL Server 2014 Express instead of SQL Server 2008.
- Corrected an issue where audit changes to staff were not being tracked.
- On systems entering new visits via “Orders” only, added the ability to manually enter a new visit for a Syringe Study or Biologic QC Subject by unchecking “Add Visits via Orders Only” checkbox in F5 Options – Orders Tab.
- Added a “Biologic QC Subject” checkbox on the patient dialog screen to designate this subject as a Biological QC test.
- Corrected issue of duplicate Staff entries when merging from Local to Shared database.
- Added Order ID and Order Description to text report headers.
- Added new text report, “Complete Report w/Post Pred”, that includes Post % Predicted.
- Added the ability to make the Physician drop down entries a required field. This is set in F5 Options>Visit

Tab.

- Corrected issue of graph settings when a second page was added to a report with the graphs on the side.
- Added Exercise Consult to the report header options.
- Corrected an issue where Order IDs were not getting deleted and are visible in the Patient Visit Tab.
- Corrected an issue where the calibration factors for TcpCO₂, Sweat and Body Temperature were not being saved.
- Increased the Order ID character length to 30 characters.
- Corrected an issue where Orders were not staying assigned to patients with prior visits when navigating between the previous visits prior to saving the changes.
- Corrected an issue where the physicians name was duplicated on the PF and GX consults.
- Created a “GX Other” Tab in Breeze Review for displaying OUES Slope, VE/VCO₂ Slope, VO₂ Work Slope and Chronotropic Index.

Changes for BreezeSuite 8.5 Rev C

- Added Digital Signature to installation files.

Changes for BreezeSuite 8.5 Rev D

- Added Digital Signature to all all .EXE, .OCX and .DLL files.

Changes for BreezeSuite 8.5 Rev E

- Removed Digital Signatures on USB driver installation executables to correct installation issue on Windows 10 operating systems.

Highlighted Changes from BreezeSuite 8.5 to BreezeSuite 8.6

- Added the software option for the 6 Minute Walk Test (6MWT). This test is a software option and is activated via a CD Key. When activated, a new test tab is displayed on the bottom of the BreezeSuite screen. A 6MWT Tab was also added to Breeze Physician Review. This test supports the Nonin 3150 WristOx Oximeter. Note: BreezeSuite does not support the **Nonin 3150 BLE** WristOx.
- Two new reports for the 6MWT.
- Changed the label for “Unspecified” race selection to “Other” to conform to the Global Lung Initiative standards.
- Improved the functionality of the Protocol Editor to more easily accommodate the ERS Methacholine guidelines. The Protocol Editor was changed to remove the column for Breaths and replaced it with Dose. The user must enter the “delivered dose” for each stage, rather than multiplying the concentration by the number of breaths. The value for PD₂₀ is calculated on the delivered dose for each stage. Mannitol PD₁₅ is calculated on Cummulative Dose Units. The user must indicate if they want PC_x or PD_x on the report.

NOTE: Previous Methacholine Protocols were converted automatically. Per above, the Breaths column was replaced by a Dose column. The dose was populated based on the concentration for that stage multiplied by the number of breaths.

- For both Methacholine and Mannitol testing, added a message that warns when the patient has had a decrease in their FEV₁ based upon the PD value set in the protocol. Also added a message when the FEV₁ decreases by 10% from the previous dose.
- Added a test summary application (TestSum) to the Start Menu which allows the user to calculate how many PF tests and the type of test that were performed.
- For new installation as well as upgrade from previous versions of BreezeSuite, the software installs or updates to SQL 2014 Express.
- Added the ability to modify Pre and Post Test Comments in the Physician Review Mode.
- Increased the character length for statements in the Statement Dictionary to 1000 characters. Added the ability to label and report ExFVL efforts by stage.

- Added the following variables to Custom Consult and Patient Query: VO₂/Work Slope, OUES, VE/VCO₂ Slope, EO_V (0 or 1 value) and Chronotropic Index.
- Added the ATS grades for FEV₁ and FVC to Custom Consult and Patient Query.
- Added the ability to convert SentrySuite pulmonary data in DBTools.
- Added the ability to make the Reviewing Physician entry required in Breeze Review. Also added the option to have the Reviewing Physician autopopulate in Breeze Review. Both of these are controlled in the F5 Options screen – Review Tab.
- Added the Post Test Comments on “Reason Exercise Stopped” and “Exercise ECG Interpretations” into the Interpretation Section of Exercise Consult.
- Added two new FOT reports: “FOT 5 Hz w/Spiro/SVC/Interp” and “FOT 5-1-19 w/Spiro/SVC/Interp”.
- Increased the max volume limit on the Flow/Volume graph from 10 liters to 20 liters.
- Corrected issue where the Lower Limit of Normal was slightly different for FVC and SVC, even though the predicted values were the same.
- Added a new option in Security>Breeze Review Section, that prevents the user from making changes to the Export Settings in Breeze Review.
- Improved the communication with the Zephyr Heart Rate monitor
- Improved the functionality of the Lung Volume Bar Graph
- Changed BreezeSuite login so that the user’s Password cannot be the same as the user’s Login Name.
- Added the intergration of BioHarness 1-lead ECG.
- Added additional checking for conflicts when importing patients that may have the same ID.
- Corrected an issue where a variable that was using a Fix Predicted Value was not displaying the correct value.
- Added the ability to change the names of the databases during installation.
- Added the ability to report three VE/VCO₂ Slope values including from start of exercise to AT, RC, and the entire exercise window by default. The ability to have a user-defined VE/VCO₂ slope still exists.
- Added the Woodway treadmill protocol.
- Added the Test Grade for DLco efforts to Patient Query as well as Sum, Audit, Text and PDF reports.
- Corrected an issue of the DLco predicted values not calculating when converting SensorMedics patient files. Also corrected issue of corrected Dlco for hemoglobin when hemoglobin is entered as a blood gas variable.
- In Custom Consult, added visit qualifiers for demographic information (Current Visit, First Visit, etc).
- Corrected MFC Application Error when the OUES and EO_V tabs are displayed.
- Corrected issue of Aux Data Fields appearing in red.
- For new networked installations, added the “No Local” database check box. If a No Local installation already exists, it is automatically detected.
- Added the ability for the user to limit the number of patients or visits displayed in the Open Patient or Open Visit screen. The default is On and set to 500.
- Expanded the Aux Data Field window in a report.
- Created a new Ideal Body Weight predicted author: “Peterson, Thomas, Blackburn, Heym”.
- Added new VO₂ variable relative to Ideal Body Weight: VO₂ (mL/kgIBW/min).
- Added Ideal Body Weight to patient demographics.
- Added a new column for “Max Value Exercise” in the CPET Summary Report.
- Corrected issue of the SVC predicted value not being displayed in the test screen.
- Improved the grading of DLco efforts after an effort has been performed and that effort has a larger IVC,

thus creating a new target for IVC. The software only takes the largest selected VC for the target, not a non-selected VC.

- Improved the anchoring of tidal breaths with the IC measurements for ExFVL testing.
- Corrected MFC Application Error when DOB is entered as Today's date.
- Improved the reporting of Z-Scores for variables that are ratios, such as FEV1/FVC.
- Corrected issue when combining patients was not updating the patient's date of birth.
- Corrected issue of the FEV1/SVC not being calculated when converting SensorMedics data.
- Improved the functionality of the Override button when using the Customized ECG.
- Removed the comma between state and zip code in PDF and Text reports.
- Verified that PETO2, PETCO2 and Speed are displayed the same in Text and PDF reports.
- Corrected issue of not being able to adjust race when creating a new visit from an Order.
- Added a new variable to calculate Cardiac Index (CI) by using the calculated CO-Direct Fick variable (CO DF-VO2 Mean value).
- Corrected issue of disabling Predicted Sets.
- Changed the frequency at which GX test data is auto-saved during a test from 50 seconds to every 15 seconds.
- On a new install, changed the location of the Mortara XScribe files to: C:\Mortara Instrument Inc\XScribeII\COMMAND and C:\Mortara Instrument Inc\XScribeII\CURRENT. Details are available in the CAUTIONS & WARNINGS section of this document.
- 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.
- Improved the functionality of Auto Logout in Physician Review.
- Improved the graph properties when "All Selected" is chosen.
- The version of SQL installed is now SQL 2014 Express SP3.
- Improved the Flow Calibration graph in calibration when performing a slow stroke that extends beyond 15 seconds.
- Corrected an issue where the Aux Data Field variables were not being included in Delay Export.
- Added a "Config Patient Options" option in User Roles to verify if a user can modify patient options such as Visit List Limit.
- Added the ability to modify, upload and save ECG PDF Summary reports to the BreezeSuite database where the ECG PDF Summary reports are currently stored.
- Added Test Description for Orders to the Header on PDF reports.
- Corrected the calculation of VO2 based on the GX Predicted author "Blackie".

Highlighted Changes from BreezeSuite 8.6 to BreezeSuite 8.6 Rev B

- Corrected an error message that would display during installation
- Added support for items in BreezeSuite 8.6 Service Pack 6
- Changed the installation to install MSOLEDBSQL instead of SQLOLEDB or SLQNCli11
- "MGConnect.exe" was viewed as a cyberthreat by some antivirus software. This file was removed and its' functionality placed in a DLL already in use

Highlighted Changes from BreezeSuite 8.6 Rev B to BreezeSuite 8.6 Rev C

- Updated the version of SQL for local installations to support Windows 11
- Updated the default version of Adobe Reader

Highlighted Changes from BreezeSuite 8.6 Rev C to BreezeSuite 8.6 Rev D

- Updated the digital signature with a more current encryption method (SHA2). No code changes.