

SOFTWARE VERSION 2.1.1 MANDATORY UPGRADE FOR THE GEM[®] PREMIER 4000 ANALYZER AND GEMweb[®] PLUS SERVER

Dear Valued GEM[®] Premier 4000 Customer,

As part of Instrumentation Laboratory's continuous improvement process, we are pleased to announce the release of GEM[®] Premier 4000 software version 2.1.1.

This release includes mandatory updates to address software corrections detailed below.

In addition to the corrections, this version optimizes the performance of your GEM[®] Premier 4000 analysers and provides improvements in system performance for the users of the GEMweb[®] Plus information management system.

Corrections and additional functionality:

- Lowering of the upper slope limit for Ca⁺⁺ from 35 to 34 mV/decade for improved performance
- Introduction of a new iQM check for very low Glucose and Lactate results. If Glucose is less than or equal to 10 mg/dL (0.6 mmol/L), or if the Lactate result is less than 0.2 mmol/L (2 mg/dL) **and** Haematocrit is greater than 10%, then the patient results for those analytes are set to incalculable.
This check has been added to prevent the reporting of results that are not consistent with a patient's clinical picture.
Examples of situations which could cause this phenomenon include poor pre-analytical technique, or failure to follow instructions by using excessive force when applying a capillary tube, causing it to damage the septum.
- Additional integrity checks implemented for total Bilirubin (tBili) reporting to address the issue referenced in the Urgent Product Notification dated June 2010. This software mitigation eliminates the requirement to request total haemoglobin on whole blood samples if requesting total bilirubin analysis.

Analyser / System Improvements:

- Total Bilirubin measurement has been added to the analyte menu.
- A new CVP ampoule, Level 5 has been introduced for use with Total Bilirubin.
- Training Videos can be viewed on the analyser after installing a new training video DVD. After the DVD is loaded in Configuration (see information below in Data Management features), from **Menu**, select **Help** to access the training videos.
 - Please note that the Training Videos DVD for use on a computer (part number 00025000220) cannot be used to install training videos on the analyser.
- An issue is corrected that caused the last sample on a cartridge to be unavailable for testing.
- Format of the internal printing has been modified to make the printout more easily readable.
- New Interface "keep alive" process to minimize the chance of the GEM[®] Premier 4000 or GEMweb[®] Plus losing connectivity with a LIS / HIS.
- O₂ct added as derived parameter.

- Sample volumes can be associated with sample types. This applies to the three default sample types and to any custom sample panels. The order in which sample panels will appear on the READY screen can be specified. See below, **SW v 2.1.1 Sample Panel Changes** for more information.
- Foetal Haemoglobin is now automatically measured and corrected in all samples.
- Cartridge serial number and expiration date have been added to the CVP summary report.
- Analytical Measurement Range (AMR). This feature provides the ability to set analytical reportable ranges.

Information Management enhancements:

- GEMweb[®] Plus 200 information management product, which includes:
 - Automated and customizable operator certification, including exams.
 - Advanced regulatory compliance management.
- GEM[®] Premier 3000, GEM[®] Premier 3500 and Biosite Triage Meterpro can be connected to GEMweb[®] Plus 100 or 200
- Version 2.1.1 introduces new analytical product.
- Wireless connectivity can be enabled via a PCMCIA network card on the analyser.
- A new patient report format has replaced the existing patient report format A, B, and C.
- USB memory devices can be used to backup or transfer data in addition to the existing CD and DVD media. The restriction of copying only one cartridge per disk or USB device remains. A future software release will allow for multiple cartridge files to be copied to a disk or USB device.
- Virtualization of GEMweb[®] Plus server.
- User definable Custom Sample Types.
- Custom Test Panels can have a sample volume associated with the panel. The available volumes are 150 ul, 100ul or 65ul. See below, **SW v 2.1.1 Sample Panel Changes** for more information.
- User definable Operator Security. Once an operator is assigned a Security permission level the individual's permissions can be modified to remove any of the authorized functions within the permission level.
- Default Sample Type within Sample Types Setup. User can select a default sample type selection which will be presented at the top of the sample type frame on the Ready screen.
- A GEMweb[®] Plus client analyser can have a separate independent connection to an external system such as an LIS, clinical monitors or middleware programs.
- The Patient Identification drop down list on the "Enter Information" tab can be disabled so that the user is required to enter a patient identification number each time a sample is run.

- Reduces the download time when connecting a new client analyser to an existing GEMweb® Plus network.
 - A modification to the software installation wizard on client analysers (new clients or replaced clients) which now only downloads pending HIS/LIS orders from the server. This greatly reduces the time required for replication to bring a client on line when Order download is enabled.
- For instruments connected to GEMweb® PLUS, analyser names can now be reused.
- Batch deletion of Orders.
 - Search by date range, or PID, or patient name, or order number, or sample type.
- Sample counter.
 - Count by accepted and excluded samples, by Area and Analyser.
- Software accommodates ampoule expiration dates. When an ampoule product barcode does not include expiration date, "Refer to Ampoule Label" will be shown instead of the expiration date on the ampoule selection screen after pressing GO!
- The message indicating that an ampoule lot scanned is not yet defined in Configuration has been improved to clearly communicate that the lot is not defined, and that authorization is required to access the Configuration feature.
- A data purge process has been added to remove historical cartridge data solely used to investigate cartridge issues that are more than 183 days old. This greatly reduces the risk of getting a "disk full" condition due to the accumulation of very large unneeded cartridge data files. No iQM® or patient information is deleted with this process. The initial purge occurs during the upgrade process. Subsequent data purging is done automatically as a back ground process requiring no operator action.
- Cartridge "keep alive" feature to preserve the cartridge if upgrade process exceeds 20 minutes.
- **For standalone analysers only:** In the event of a Date/Time change, the operator is warned via a dialog box that the change could result in the rejection of the cartridge. The operator must dismiss the dialog box by pressing the "OK" button.
- Configurable Demographic Fetch applies to standalone and GEMweb® Plus.
- User can define what key field a demographic search will use - i.e. accession number, sample number, order number. Customer may also define their own custom field. Using a field other than Patient Identification (PID) may require a modification of the interface by the LIS depending on the vendor.
- The amount of time before CVP can be sampled if CVP is requested during iQM processing is now displayed.
- Advanced Regulatory Management (Audit Logs)
 - Three logs on a standalone analyser or GEMweb® Plus 100
 - Patient Record Amendments
 - Patient Record Access
 - System Access
 - Five logs on GEMweb® Plus 200
 - Patient Record Amendments
 - Patient Record Access
 - System Access
 - System Configuration Changes
 - Security and Operator Management

- Simple ADT: When looking for patient demographic information the system will always query the LIS/HIS for the latest demographic information. The database in GWP will be updated accordingly so the most current patient information is present in the GWP.
- Under Operator Management, extending operators expiration dates can be performed as a batch process instead of by individual operators.
- In Configuration, the Security Matrix label “Manage Operators” is changed to “Manage Operators/Certification” for GEMweb[®] Plus. The label for a Stand Alone remains as “Manage Operators”.
- New Configuration field named “Other Material Setup”, which is located on Tab 1 for a stand-alone analyser and on the Global Configuration tab for GEMweb[®] Plus analysers. GEM[®] Evaluator lots must be defined in this location.

SW Version 2.1.1 Sample Panel Changes

The addition of the 100 μL sample volume for the tBili/CO-Ox combination necessitated a change to the Sample Panel selection portion of the Start New Sample tab.

It was not possible to design a 3-way toggle button to toggle between normal (150 μL), micro (65 μL) and tBili/CO-Ox (100 μL) options. In order to have a similar structure to that, prior to SW version 2.1.1., it would be necessary to present 3 separate radio buttons, each with one of the three sample volumes labels (150 μL , 100 μL , 65 μL). This would minimize the number of panels that could be displayed on the Start New Sample tab without requiring the *More Panels* to be selected.

Screen layout prior to SW 2.1.1



For investigation purposes only. Performance characteristics have not been established for this product.

Default Screen layout in V2.1.1



If custom panels are configured, after the SW version 2.1.1 upgrade the three default panels will be displayed, followed by the custom panels. Existing custom panels will show a sample volume of 150µL, because prior to 2.1.1 a sample volume could not be associated with a custom panel. Please see the example below.

Screen lay out v 2.1.1 with custom panels shown



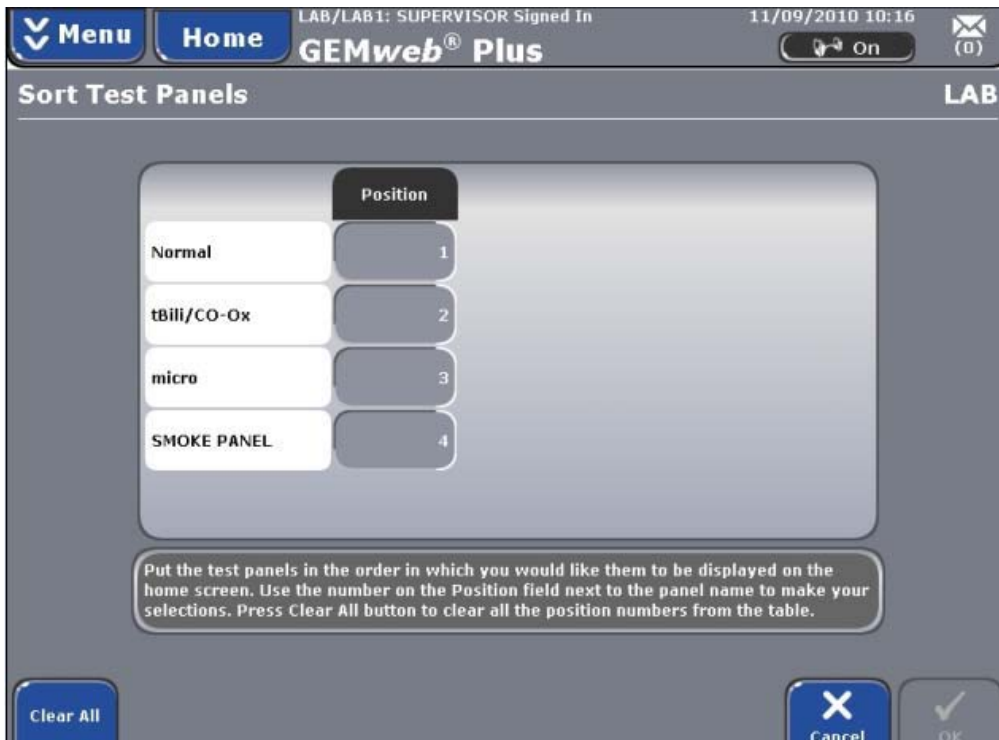
The custom panel can then be edited in Configuration (Area Tab/Tab 2), Test Panel Setup, in order to change the sample volume displayed, name of analytes, depending on the volume selected.

Custom panel names may contain:

- Upper case and lower case alpha characters
- Numeric Values
- The symbols +, -, /, @, _

The order on the screen of custom panels is determined by the first component of the panel name. The order is plus sign (+), hyphen (-), forward slash (/), the 'at' symbol (@), numerical values, underscore symbol (_), uppercase alpha characters and then lower case alpha characters.

When a default panel is modified in configuration the order presented on the screen is determined by the first component of the panel name per the order listed above. Presently, panel order cannot be determined independent of the first character of the panel name. Therefore, careful consideration must be given to sample panel designation prior to making changes to default panels or creating custom panels.



Test Panels after sorting



Display of the sample volume designation can be disabled in Configuration.



Foetal Haemoglobin

With SW version 2.1,1 it is no longer required to manually select foetal haemoglobin detection. Each sample will be evaluated during the optical system measurement for the foetal haemoglobin spectrum. The Foetal Haemoglobin button has been removed from the READY screen as a result. If foetal haemoglobin is detected, applicable CO-Oximetry parameters will automatically be corrected. There is no foetal haemoglobin correction exception flag presented when the correction is applied in software version 2.1.1.

It is expected that these enhancements to the analytical and data management functionality will favourably impact your satisfaction with the GEM® Premier family of analysers and GEMweb® Plus.

Please do not hesitate to contact Abacus ALS at techservices@abacus-als.com with any questions or Free Call AUS 1800 222 287 or NZ 0800 222 170.

Best Regards,

Anthy Hatzilias
Product Specialist
Abacus ALS