GEM Premier 5000 Reference Guide

GEM family

DRC-317 Ver 1.0

Werfen
Diagnostic Solutions for Life

Contents

Introduction

This guide has been prepared to facilitate training and use of the GEM Premier 5000 system with Intelligent Quality Management 2 (iQM2). Each section provides instructions for operating the analyser, including routine use, quality management and feature configurations.

The GEM Premier 5000 with iQM2 system provides fast, accurate, quantitative measurements of heparinised whole blood pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct, tBili and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb, sO_2).

NOTE: Despite the recommendations made herein, each facility should establish appropriate protocols according to local, federal, regulatory requirements for specimen management, quality control, patient preparation and patient ranges.

Preparing a sample

Devices and containers

- Syringes
- Capillary tube
- Ampoules
- Tubes

Sample source types

- Arterial
- Capillary
- Mixed venous
- Venous
- Arterial-mixed venous pairs
- Other*

Illuminated universal sampling area
Analyser accepts tubes, syringes or capillaries

Sample collection and processing

- Treat all samples as a potential biohazard.
- Universal precautions should be observed when sampling and using the analyser.
- It is recommended that syringes not be iced; analyse within 30 minutes
- Always thoroughly mix samples immediately after draw and before analysis to optimize Hct, tHb and Total Bilirubin results (where applicable)

*Configurable. May require additional validation to comply with local regulatory requirements.

Sample collection and processing (cont'd)

- Each facility should have written policies in place to ensure that accurate results are obtained by maintaining positive patient identification and specimen integrity from the time of specimen collection to reporting of results.
- Arterial blood gases should be collected using a 1-3 ml plastic, disposable blood-gas syringe, pre-filled with the appropriate concentration of heparin.
- IL recommends lyophilised lithium heparin devices intended for the measurements being obtained.

  CAUTION: Use of citrate, EDTA, oxalate or sodium fluoride anticoagulant may adversely affect sensor performance.
- Due to the permeable nature of plastic syringes and tubes, it is recommended that such devices be kept at room temperature when analyzed within 30 minutes of collection.
- See "Sampling" chapter of GEM Premier 5000 system with iQM2 *Operators Manual* for complete list of sample device and preparation recommendations.

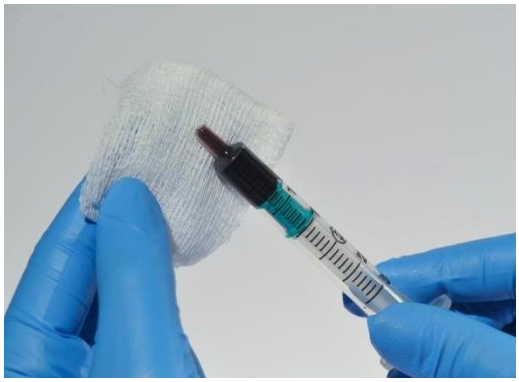
Always mix samples thoroughly after draw and right before analysis to ensure homogeneity and avoid clotting

Syringe

- After sampling from the patient, immediately expel air using a gauze or tissue and then cap the sampler.
- Immediately mix for >30 seconds using quick inversions (1-2 inversions/second).

  Vigorous shaking can cause falsely elevated K+ results.

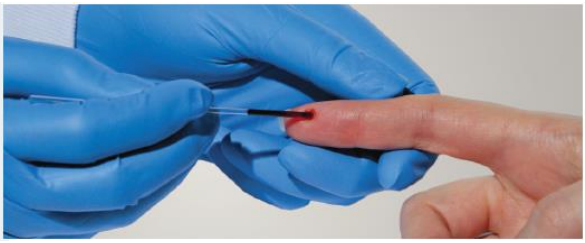
  Mix samples for >30 seconds prior to analysis. Insufficient mixing can cause erroneous Hct/tHb/tBili results.
- Prior to analysis expel a few drops of sample into a gauze pad or tissue to remove any cellular material or clots from the syringe tip.
- Sample should be analysed within 30 minutes of draw to optimise results.



Capillary

- Collect sample with capillary tube and cap ends.
- Mix immediately by rolling capillary tube between finger tips for >30 seconds or by using other CLSI recommended procedures.
    - Vigorous shaking can cause falsely elevated K^+ results. Metal mixing bars can be used to facilitate mixing.
- Remove blood and debris from the outside of the capillary tube prior to placement in the analyser sampling port.
    - If metal mixing bar is used, uncap capillary and remove the bar prior to sample aspiration.
- Sample should be analysed within 5 minutes of draw to optimise results.

- Avoid “milking” the puncture site.
- Wipe away first drop to remove extracellular fluid.



Sample volumes

- Sample volume required to perform analyte measurement on the GEM Premier 5000 system.

Analytes	Sample volume (µl)
pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct, tHb, O_2Hb, COHb, MetHb, HHb, sO_2, tBili or any combination aforementioned analytes.	150
tHb, O_2Hb, COHb, MetHb, HHb, sO_2, tBili	100
pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct	65 (Capillary only)

Analysing a sample

“Ready” state

Smartcolour status bar
Shows analyser and iQM2 status.

Custom quick-start button
Press to run a sample. Displays information on panel name, sample source.

i-button for quick-start
Provides analyte status, sample volume, menu and source.

i-button for iQM2
Real-time info on current analyte status.

Barcode reader in presentation mode
One-hand activation.

Universal sampling
For tubes, syringes or capillaries. LED-illuminated.

- **Sample-analysis process** 

- Ensure analyser is in “Ready” state (status bar is blue or green).
  - Mix, uncap and expel drop of blood from sample onto gauze pad prior to introduction to analyzer for analysis
- Select desired panel from QuickStart screen.
  - Micro-sampling is available only for capillary samples.
- Scan or enter **your** unique user ID
- Sampler will extend to receive syringe, tube or capillary specimen based on panel.
- Present sample and select “Start Aspiration”
- Analyser will provide audible and visual signals when aspiration is complete and the device can be removed.
  - Avoid hitting the plunger of the syringe with sampler probe.
- Discard sampling device in appropriate biohazard container.
- When analysis is completed, the *Required and Optional Information* screen will be displayed for patient demographic entry.
- All required fields must be completed to view results.

- Enter information by using the keypad or barcode scanner.
  - Fields may be pre-populated from the database information system after the patient ID has been entered.
- After patient and sample information have been entered, results may be viewed following analysis period.
- Sample results will print automatically.

Sample-analysis process (cont'd)

- Results flags, if configured, are defined below:

Exception Symbol	Exception Symbol Description
▲	Outside Reference Range - High
▼	Outside Reference Range - Low
⇈	Outside Critical Limit - High
⇊	Outside Critical Limit - Low
>	Outside Reportable Range – Greater Than
<	Outside Reportable Range – Less Than
incalculable	Result Incalculable
A	Absorbance Error
SHb	Sulfhemoglobin Interference Detected
T	High Turbidity Detected
I	Interference Detected
M	Micro Clot Detected
!	Temporary Sensor Error
MHb	High Methemoglobin Warning
SHb MHb	Sulfhemoglobin and High Methemoglobin Warning
SHb	Corrected for Sulfhemoglobin
i	iQM2 IntraSpect

Result Flag explanations:

Flag Results for Interference and Micro Clots

Reporting of patient results will only be displayed after the post-sample sensor check is completed. The GEM Premier 5000 system will flag analytes if an interference or micro clot is detected through the IntraSpect or Sensor Checks, utilising the Pattern Recognition Check to determine error cause. When this option is disabled, patient results will be displayed immediately after completion of measurement, and results will not display flags unless an error is detected by IntraSpect check during sample analysis. However, the operator will be presented with a pop-up dialogue message when an interference or clot is detected in the previous sample by the post-sample sensor and pattern recognition checks. The dialogue pop-up message will be displayed until dismissed by the operator.

Result Incalculable

When the Incalculable flag (Incalc) is presented for measured analytes it indicates that the required measurement criteria were not met during sample analysis. The Incalculable flag is displayed by a derived parameter when a required measured analyte result is not available. A measured parameter with an Incalculable flag or a measured parameter outside of the reportable range is an example of when a measured analyte will not be available for use in a calculation. If an entered value required for the calculation is not supplied Incalculable will also be displayed. In addition, an error detected by IntraSpect will display an Incalc or IntraSpect flag and suppress results of affected analyte(s).

Absorbance Error

An absorbance error is an indicator of a residual spectrum inaccuracy during the sample analysis. Residual spectrum is estimated by calculating the difference between the measured spectrum and predicted spectrum based on the CO-Oximetry calculation for that sample. The presence of unknown interfering substances, clots or other foreign matter within the blood sample that alters the optical spectrum will result in higher levels of residual spectrum. A sample with an absorbance error should not be reported and the sample should be repeated, as results can be outside specification claims.

Sulfhaemoglobin Interference Detected

This flag is displayed when Sulfhaemoglobin is equal to or greater than 10 percent. Sample results may be outside specification claims.

High Turbidity Detected

A turbidity flag is presented when measured turbidity is equal to or greater than five percent (5%), created by 10% Intralipid fat emulsion with a final concentration of 0.5%, is detected. Sample results may be outside specification claims.

Interference Detected

General spectral interference for CO-Oximetry or total bilirubin, or interference from an interfering chemical and/or drugs. Sample results may be outside specification claims. Please refer to the “Limitations and Interference Testing” provided in the Operators Manual for information on interfering substances.

Temporary Sensor Error

A temporary sensor error reflects when the Process Control solution B post analysis sensor check is outside acceptable ranges. Sample results may be outside specification claims.

High Methaemoglobin Warning
Methaemoglobin detection is equal to or greater than 30 percent. Sample results may be outside claimed specifications.

Sulfhaemoglobin and High Methaemoglobin Warning
The Sulfhaemoglobin detection is equal to or greater than 0.3 percent and the methaemoglobin detection is equal to or greater than 30 percent. Sample results may be outside specification claims.

Corrected for Sulfhaemoglobin
This flag indicates that Sulfhaemoglobin less than 10 percent has been detected in the sample. The appropriate correction algorithm is applied to eliminate the impact of Sulfhaemoglobin on other haemoglobin fractions. The sample results are within the claimed specification.

Limitations

Condition	Result
Room Air Contamination	Samples having a very low or high pO2 content or high HHb levels are especially sensitive to room air contamination. Similarly, pCO2 may be affected and subsequently pH and Ca++ results as well.
Metabolic Changes Due to a Delay in Sampling	Errors can occur due to metabolic changes if there is a delay in the measurement of the samples.
Elevated White Blood Cells or Reticulocyte Counts	Samples will deteriorate more rapidly, even when kept in ice water.
Improper Mixing	Errors will be introduced for measurement of haematocrit, total bilirubin and CO-Ox parameters if the sample is not properly mixed prior to measurement.
Not following Manufacturer's Instructions	Results obtained may be compromised.
Under-Heparinised Sample Due to Using Non-Heparinised Sampling Devices or Inadequate Mixing with Heparinised Devices.	Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinised.
Haemolysis	Haemolysed samples may result in falsely elevated potassium levels.

Limitations (cont'd)

Condition	Result
Over-Heparinised Sample Due to under filling Heparinised Sampling Device or Transferring Heparinised Sample to a Second Heparinised Sampling Device	Over Heparinisation can cause bias in Na+, iCa and Hct results.
Drug/Chemicals	Drugs/Chemicals may change analyte concentration, e.g. Citrate.
Vacutainer tubes with Gel Separator	Gel Separator can significantly elevate COHb levels.

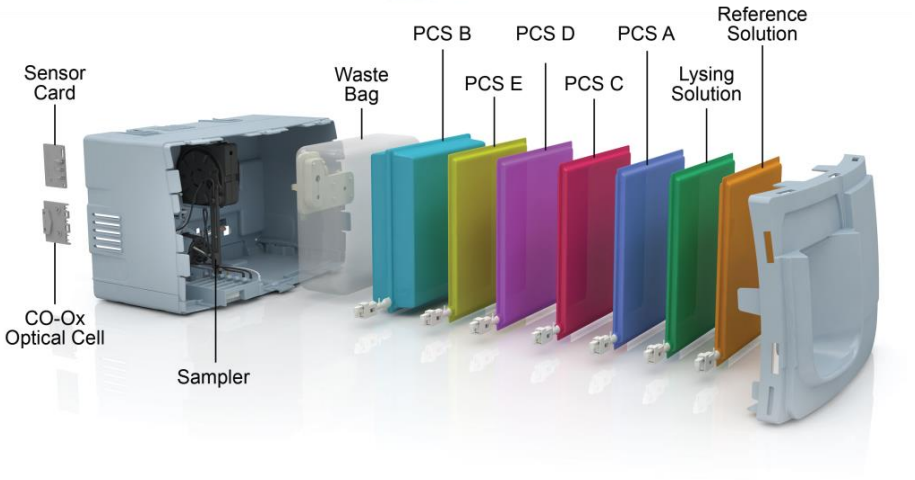
GEM PAK overview

What's inside

GEM Premier 5000 system with iQM2 features two primary components:

1. Analyser
2. All-in-one, multi-use GEM PAK

Each GEM PAK contains reagents, sensors, CO-Ox and tBili optical cell, sampler, and waste bag, to enable analysis of 75-600 samples. Maintenance-free, the GEM PAK requires replacement once every 31 days.*



*600-test PAK use-life is 21 days.

Replacing a GEM PAK

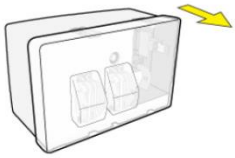
Removing a cartridge

To manually initiate cartridge removal from the analyser:

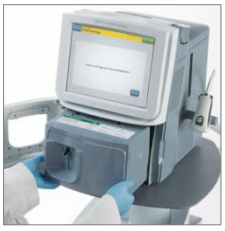
1. Select "**Remove Cartridge**" from Menu.
2. Enter password (if required).
3. Confirm.
4. The door will open slightly, manually pull the door open all the way.
5. Taking hold of the cartridge, pull it forward, removing it from the analyser.
   - Once removed, the cartridge cannot be reused.

- The cartridge contains bio-hazardous waste.
- Discard immediately in an appropriate biohazard container.

Introducing a new cartridge



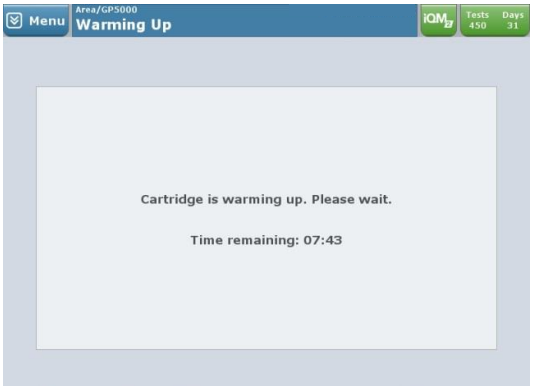
- Unpack the cartridge from its protective wrapper.
  - GEM PAK should be stored at room temperature and not in direct sunlight.
- Remove and discard the protective cover and desiccant from the back of the cartridge.
- If required, press "**Open Door**" on the touchscreen. Manually open the door fully.
- Position the cartridge with the sampling area facing forward.
- Insert the cartridge until resistance is felt.
- Close door until audible click is heard.
- Analyser will begin warm-up.



AutoPAK Validation

Process upon new GEM PAK replacement

- After automated GEM PAK warm-up completes (approximately 40 mins), the analyser will indicate that the cartridge is performing AutoPAK validation (APV).
- APV is an automated validation process that utilises two independent NIST- or CLSI-traceable Process Control Solutions (PCSs) included in the GEM PAK, with known concentrations of all analytes: pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glu, Lac, tBili, Hct, tHb, O_2Hb, COHb, MetHb, and HHb.
- Analysis of APV is automatically performed following insertion and warm-up of a new PAK and before analysis of patient samples is permitted.
- When APV is complete, patient samples can be run.
    - If tBili is required an additional level of validation must be performed using an external ampoule (CVP5).



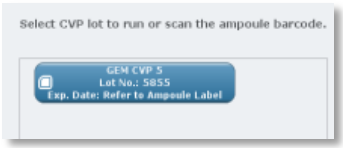
CVP 5 (Total Bilirubin only)

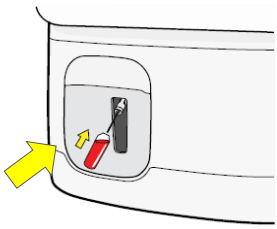
CVP5

- Ensure CVP 5 has been pre-defined and active lot number entered.
- Performance of CVP5 is required for GEM PAKs running tBili analyte.

Performing CVP5 for GEM PAKs with tBili

- GEM PAKs with tBili must pass CVP5 within acceptable ranges prior to activating the analyte.
  1. From the Home Screen, select the “ampoules” tab and “CVP” button.
  2. Select lot number* from screen or scan barcode from ampoule.
  3. Mix and remove cap from ready-to-use CVP5 ampoule.
  4. Introduce tip of opened ampoule to analyser probe.
     - *Do not allow the sampler to hit the bottom of the ampoule.*





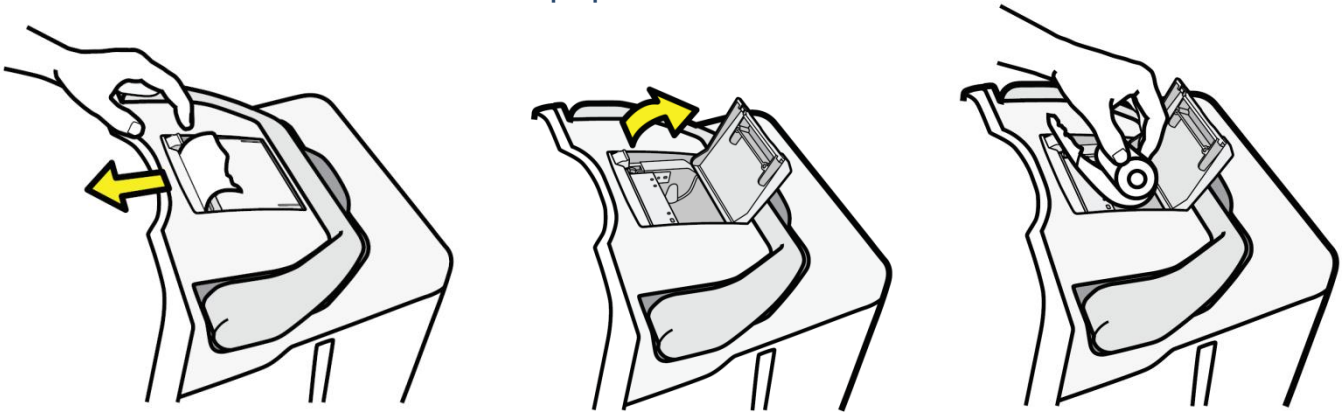
* All new lots of CVP5 must be configured prior to use:
  - Enter “CVP Materials” display in “Configuration” menu. Select “add materials.”
  - Use 2D barcode in package insert to scan lot-specific values.
  - Data fields will reflect the values provided on the barcode. Press OK when complete.

Replacing Printer Paper

Installation

To install the printer paper on top of the system:

1. Press the tab at the top of the GEM Premier 5000 system to release the door.
2. Open the door and extend paper guide if desired.
3. Place the roll of paper in the compartment so the paper uncurls from the bottom.
4. Press the door firmly closed – two clicks!
5. Tear off the excess paper.



Reference ranges

Parameter	Critical Low	Reference Range	Critical High	Unit
pH	7.20	7.35 - 7.45	7.60	pH
pCO_2	2.6	4.6 – 6.4 Venous blood (right atrium) 0.8-0.93 kPa higher than arterial pCO2	9.3	kPa
pO_2	6	11.0 – 14.4	-	kPa
Na^+	120	136 - 145	160	mmol/L
K^+	2.8	3.5 - 5.1	7.8	mmol/L
Cl^-	80	98 - 107	120	mmol/L
Ca^{++}	0.75	1.15 - 1.33 1.16 - 1.32 (venous)	1.60	mmol/L
Hct	18	40-54 (male) and 37-47 (female)	60	%
Gluc	2.2	3.5 – 5.3	25.0	mmol/L
Lac	-	0.4 - 0.8 (at rest) 0.56 - 1.39 (venous)	3.4	mmol/L
tHb	70	12 6-174 (male) and 117-161 (female)	200	g/L
HCO_3-	10.0	21 - 28 22 - 29 (venous)	40.0	mmol/L
tBili (neonate)	-	<137 (premature infant 0-1 day) <205 (premature infant 1-2 days) <274(premature infant 3-5 days) 24-149 (full-term infant 0-1 day) 58-197(full-term infant 1-2 days) 26-205 (full-term infant 3-5 days) 5-21 (>5 days to <60 years)	256	umol/L

Parameter	Critical Low	Reference Range	Critical High	Unit
O_2Hb		90.0 - 95.0		%
COHb		<3.0 (nonsmoker) <10.0 (smokers)		%
MetHb		0 - 1.5		%
HHb		2.0 - 6.0		%
sO_2		94.0 - 98.0		%
TCO_2		19.0 - 24.0 22.0 - 26.0 (Venous)		mmol/L
BE		-2.0 - 3.0		mmol/L
Anion Gap		10 - 20 $(Na^+ + K^+) - (Cl^- + HCO_3)$		mEq/L

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Intelligent Quality Management 2

iQM2 is an active quality process control program designed to provide continuous monitoring of the analytical process before, *during*, and after sample measurement with real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, replacing the use of traditional external quality controls (QC).

All analytical components are monitored with five PCSs. Each PCS contains known quantities of the analytes tested using NIST- or CLSI-traceable standards to establish target values for monitoring medical-decision levels.

Throughout the use-life of the GEM PAK, PCSs continuously perform System, Sensor, PCS Stability, Pattern and NEW IntraSpect checks to ensure quality results regardless of operator, time or location. The operator is automatically alerted of any potential error detected—ensuring patient safety.

Error codes and operator messages

The GEM Premier 5000 system is designed for simple, trouble-free operation. However, should you encounter any system errors or other issues, this information will help you understand the code or message displayed. Should you require any further assistance please contact your local POCT Team.

Error codes associated with System malfunctions

Error Code	Description of error	Operator Message
201	Process control not detected	Process control solution not detected. Preparing for cartridge removal. Please wait.
203	Air slug before sample not detected	Sample not detected. Repeat test
204	Sample not detected	Sample not detected. Repeat test
220	Sample luer did not move into position	Sample probe error. Preparing for cartridge removal. Please wait
222	Air detected in sample during aspiration	Insufficient sample. Repeat test
223	Air detected within sample during post aspiration	Air detected in sample. Repeat test
224	Insufficient sample volume for CO-OX	Insufficient sample for CO-OX. Repeat test.

Error Code	Description of error	Operator Message
230	Block temperature out of valid range	Temperature out of range. Analyser will be shut down. Contact Technical Support.
236	Power supply voltage out of range	Power supply voltage error. Analyser will be shut down. Contact Technical Support.
240	No air detected before a Process Control solution	Process Control solution not detected. Preparing for cartridge removal. Please wait.
241	Rotary valve sensor not found	Rotary valve error. Preparing for cartridge removal. Please wait.
260	Door sensor did not respond	Door failure. Door must be opened manually. Contact Technical Support for assistance.
261	Pump mechanism calibration failure	Cartridge error. Preparing for cartridge removal. Please wait.
264	CO-OX integration time could not be set	CO-OX hardware failure. Analyser will be shut down. Contact Technical Support.
265	Reference voltage out of range	Reference solution not detected. Preparing for cartridge removal. Please wait.

Error Code	Description of error	Operator Message
266	Sensor polarization voltages out of range	Voltages out of range. Analyser will be shut down. Contact Technical Support.
267	Pump mechanism error	Cartridge error. Preparing for cartridge removal. Please wait.
268	Hct circuit gain is out of range	Hct calibration failed. Preparing for cartridge removal. Insert new cartridge.
270	Analytical Component leak	Cartridge error. Preparing for cartridge removal. Please wait
280	Diverter and /or mixing solenoid error	Valve error. Analyser will be shut down. Contact Technical Support
285	CO-OX wavelength calibration failure	CO-OX hardware failure. Analyser will be shut down. Contact Technical Support
287	CO-OX initialisation failure	Analyser will be shut down. Contact Technical Support
288	CO-OX error (due to spectrometer read error, or other types of errors)	CO-OX hardware failure. Analyser will be shut down. Contact Technical Support.

Error Code	Description of error	Operator Message
289	*p*O2 mV is outside threshold when measured during Process Control solution C measurement during cartridge start-up	iQM2 error for *p*O2. Preparing for cartridge removal. Please wait.
300	The SBC board and CPU temperature is monitored. If the temperature rises to 70ºC, a warning is issued. The operator should check the analyser environment blocked ventilation, excessive ambient temperature, etc.	Temperature out of range. Check ambient.
301	The SBC board and CPU temperature is monitored. If the temperature rises to 90ºC, the analyser is shut down.	Analyser temperature too high. Analyser will be shut down. Contact Technical Support.
302	Hard drive showing excessive amount of errors indicating it may fail soon. Operator should perform backup and contact Technical Support.	Hard drive showing excessive errors and may fail soon. Perform backup. Contact Technical Support.
303	One of the LCD backlights failed	LCD backlight failed. Contact Technical Support.
304	One of the 4 USB ports on the back panel failed (overload detected)	Disconnect USB device and then reconnect.

Error Code	Description of error	Operator Message
305	Overload detected on the CO-Ox USB port	CO-Ox port failure. Analyser will be reset.
306	Memory error detected	Memory error. Analyser will be reset.
2010	iQM2 solution stability check failed	Process control solutions stability failure. Preparing for cartridge removal. Please wait.
2012	Reference sensor voltage is saturated or out of range	Reference voltage error. Preparing for cartridge removal. Please wait.
2014	An error occurred while reading or writing to the cartridge EEPROM	Cartridge ID error. Preparing for cartridge removal. Please wait.
2016	Ground voltage is saturated or out of range	Ground voltage error. Preparing for cartridge removal. Please wait.
2017	Special rinse failed leading to cartridge removal	Micro clot caused solution detect error after sample. Preparing for cartridge removal. Please wait.

Error codes associated with Software malfunctions

Error Code	Error location	Cause of Error	Operator Message
3001	Analyser	The file system check, performed during start-up, failed and could not self correct.	File system check error. System will be reset.
3002	Analyser	The instrument software could not communicate to the FPGA (hardware).	FPGA communication error. System will be reset.
3004	Analyser	FPGA (hardware) failed to initialize or rese.	FPGA error. System will be reset.
3006	Analyser	The DM (Data Management Module) and AM (Analytical Module) could not communicate, or went out of synch.	Internal communications error. System will be reset.
3007	Analyser /Server	An error during a database operation.	DB error. System will be reset.
3008	Analyser /Server	An error during a file I/O operation.	File I/O error. System will be reset.
3009	Analyser /Server	User interface to Data Management Module communication error.	Internal communications error. System will be reset.

Error Code	Error location	Cause of error	Operator Message
3010	Analyser	UI to DM communication error. This occurs on remote GWP only.	Server in unreachable. GEMweb Plus connection will be closed.
3012	Analyser	An illegal script command or an illegal command argument. The script cannot be executed by the script engine.	Script error. System will be reset.
3013	Analyser	More than 3 analyser resets occurred.	Too many resets. Shutting down. Contact Technical Support.
3203	Analyser	Problem accessing GEMweb Plus server.	This operation failed. Retry after server is available.
3205	Analyser /Server	The system cannot perform the requested operation.	The system cannot perform the requested operation.
3206	Analyser /Server	DM (Data Management) software error.	Internal DM software error. System will be reset.
3207	Analyser	Problem accessing GWP server during installation setup of the client analyser.	Cannot access server. System will be reset.

Error Code	Error location	Cause of error	Operator Message
3208	Analyser	Problem accessing GWP server when performing any operation on Remote GWP.	Operation failed. GEMweb Plus session will be closed.
3302	Analyser	State timed out in GEMweb.	Operation failed. Please re-launch the application.

Site Specific Information

Please ensure you refer to your institutions specific requirements pertaining to the following:

- Analyser Access:
    - Log on
    - Barcode
    - Password
    - Recertification
- Patient Demographic requirements:
    - Use of Patient Identifier(PID)
    - PID Query
    - Procedure when PID not available
- Results:
    - Procedure for checking erroneous results: