GEM 7000 General Operating Procedure

Purpose

This document provides operating instructions and procedures for use with the Werfen GEM 7000 analyzers in the Chemistry Department. The GEM Premier 7000 with iQM3 is a portable critical care system for use by health care professionals to rapidly analyze lithium heparinized whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory.

The instrument provides quantitative measurements of pH, pCO2, pO2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin, and CO-Oximetry (tHb, O2Hb, COHb, MetHb, HHb, sO2) parameters from arterial, venous, or capillary lithium heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity.[1]

Policy Statements

This procedure is intended for all personnel responsible for the operation of the GEM 7000 analyzer.

Personnel operating the GEM 7000 analyzer must demonstrate competence in its operation and maintenance per laboratory policy.

Principle

The GEM Premier 7000 system makes use of potentiometric sensors to measure pCO2, pH, Na+, K+, Cl-, and Ca++. It uses amperometric sensors to measure pO2, glucose, and lactate concentrations. Blood conductivity is the method used to measure Hct. CO-Oximetry and tBili measurements involve chemically lysing the whole blood sample and then utilizing a broad-spectrum spectrophotometer to evaluate the sample at a variety of wavelengths. Hemolysis detection is performed simultaneous to the measurement process of patient samples, through the isolation of plasma and optical measurement of plasma free hemoglobin.[1]

Materials

GEM Premier 7000 instrument, Product Number 00000015279

- GEM01 SN 25061758 Minneapolis, Asset Tag 043620
- GEM02 SN 25061757 Minneapolis, Asset Tag 043619
- GEM03 SN 25061755 Minneapolis, Asset Tag 043622
- GEM04 SN 25061756 Minneapolis, Asset Tag 043621
- GEM05 SN 25061771 St. Paul, Asset Tag 043111
- GEM06 SN 25061772 St. Paul, Asset Tag 043110
- MCY NICU SN 25061770 Mercy Point of Care NICU, Asset Tag 043109

Product Description	*Product Code*	*Stability*
GEM PAK, 600 Count Blood Gas/ISE/Glucose/Co-Ox	**MFR#** 00077360010 **CHC#** 36080	**Store at:** Room temperature. **Stable 21 days once loaded onto the analyzer.**
GEM PAK, 450 Count Blood Gas/ISE/Glucose/Co-Ox	**MFR#** 00077445010 **CHC#** 36079	**Store at:** Room temperature. **Stable 31 days once loaded onto the analyzer.**

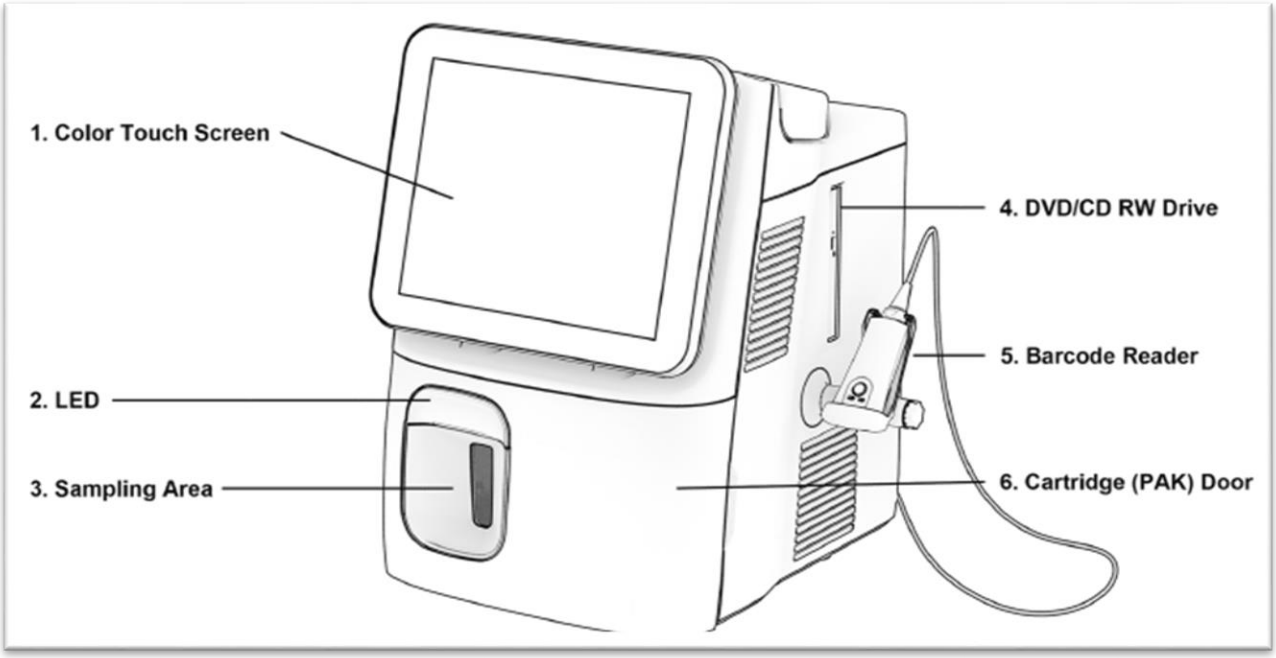
GEM PAK, 75 Count w/tBili Blood Gas/ISE/Glucose/Co-Ox/tBili **Mercy NICU – POC use only**	**MFR#** 00077407511 **CHC# 37464**	**Store at:** Room temperature. **Stable 31 days once loaded onto the analyzer.**
Printer Paper 5 rolls per box	**MFR#** 00025000500 **CHC#** TBD	**Store at:** Room temperature.
PVP (Performance Verification Product) Required for linearity testing. Contains 20 vials, 5 each of 4 levels.	**MFR#** 00024001515 **CHC#** TBD	**Store at**: 2-8C **Unopened:** until expiration date. **Opened:** Use immediately. At room temperature, stable for up to 3 months.
CVP (Calibration Valuation Product) Required for GEM PAKs with tBili only. An external, ampoule-based product prior to measuring samples for tBili.	**MFR#** 00025000145 **CHC#** TBD	**Store at**: 2-8C **Unopened:** until expiration date. **Opened:** Use immediately. At room temperature, stable for up to 3 months.
GEM Mobile Cart	**MFR#** 00024001200 Special Order	**Store at:** Room temperature.
Wand, Bar Code	**MFR#** 00024015859 Special Order	**Store at:** Room temperature.
UPS, Tripp Lite Model SMART1200XLHG, Medical Grade1	**MFR#** 00025002112 Special Order	**Store at:** Room temperature.
Ampoule Breaker, 1 per Box	**MFR#** 00025000450 Special Order	**Store at:** Room temperature.
Shipping Cartridge	**MFR#** 00000015431 Special Order	**Store at:** Room temperature.

Special Safety Precautions

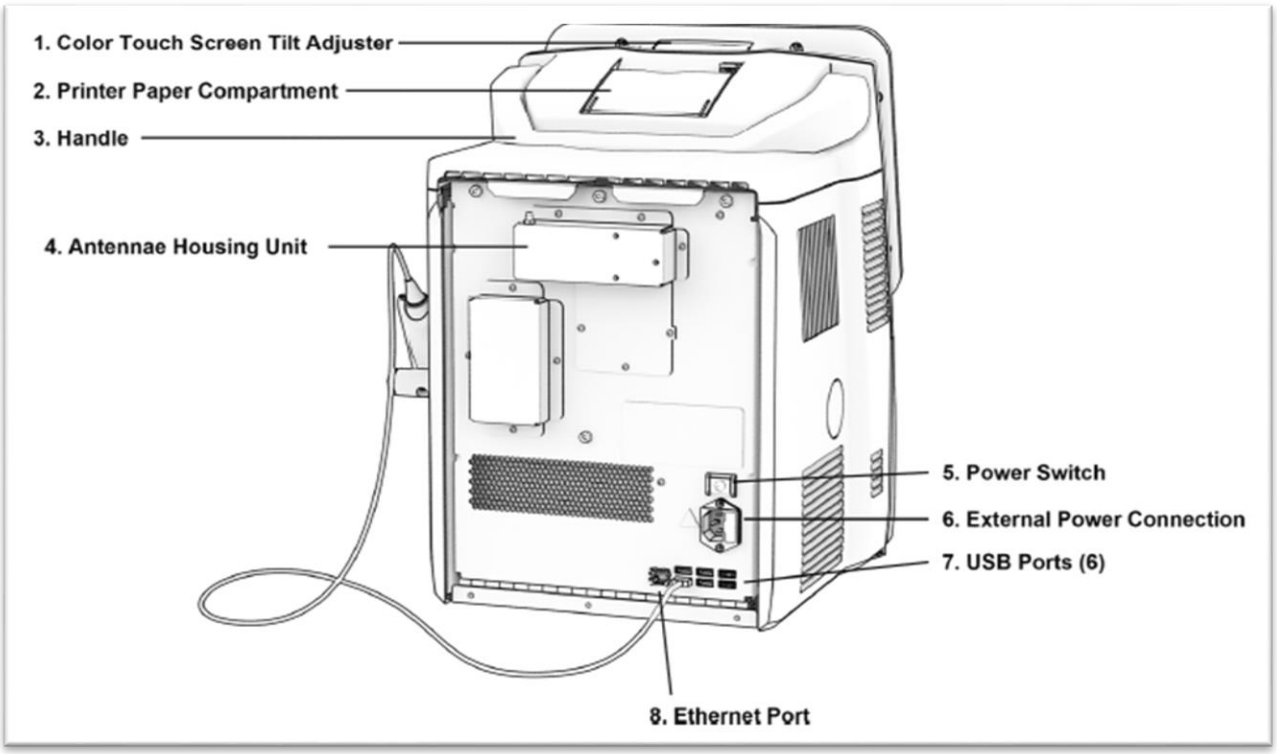
SDS are available via StarNet. Dispose of reagent PAKs and patient samples in biohazardous waste.

Analyzer Overview

Analyzer descriptions:



1. The color touch screen provides the User Interface and drives operation of the analyzer. 2. The LED lights the sampling area during use. 3. Sampling area. 4 DVD/CD RW Drive. 5. Barcode Reader reads 2D and 3D barcodes including patient labels and badge IDs. 6. Cartridge PAK Door contains the PAK during use.

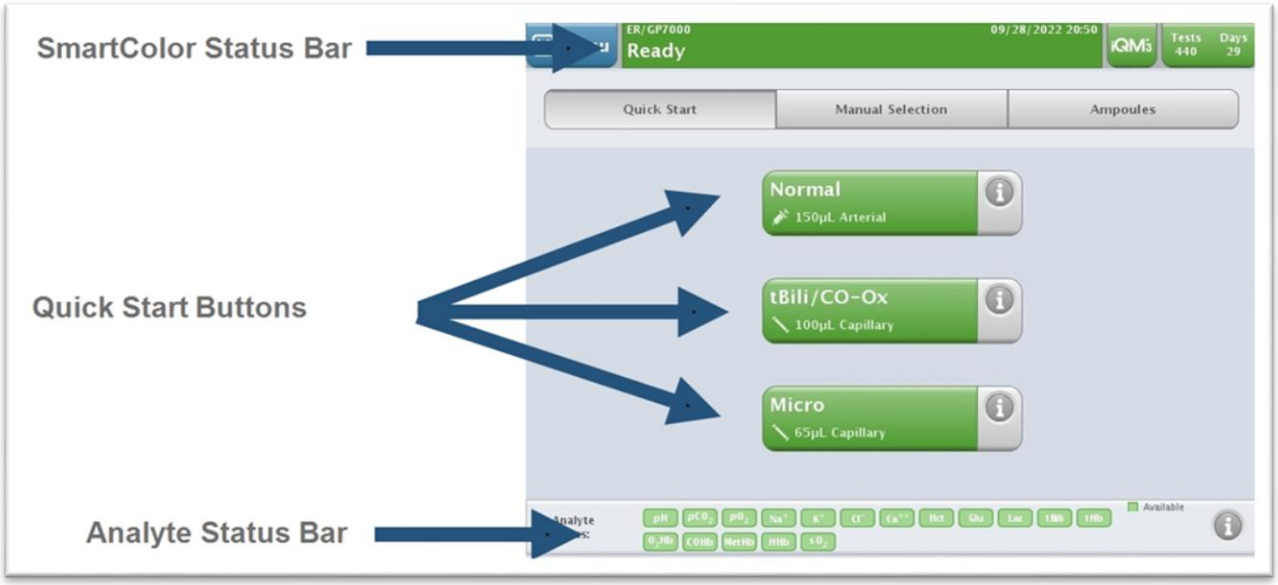


1. Color Touch Screen Tilt Adjuster 2. Printer Paper Compartment. 3. Handle. 4. Antennae Housing Unit provides wireless connectivity. 5. Power Switch turns on the analyzer or provides emergency shutoff. 6. External Power Connection. 7. USB Ports. 8. Ethernet Port provides wired connectivity.

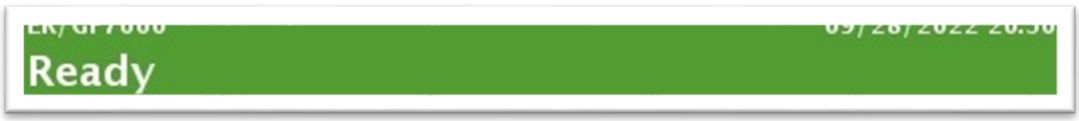
Emergency Shutoff – Utilize the power switch for emergency shutoff.

Backup Analyzer – Each analyzer will be the backup for the other analyzers at that location. Blood gas samples do not have the required stability for transport between locations. In the event of recall or all blood gas analyzers are not operational, iSTAT may be used as a backup analyzer by qualified operators.

Analyzer Display

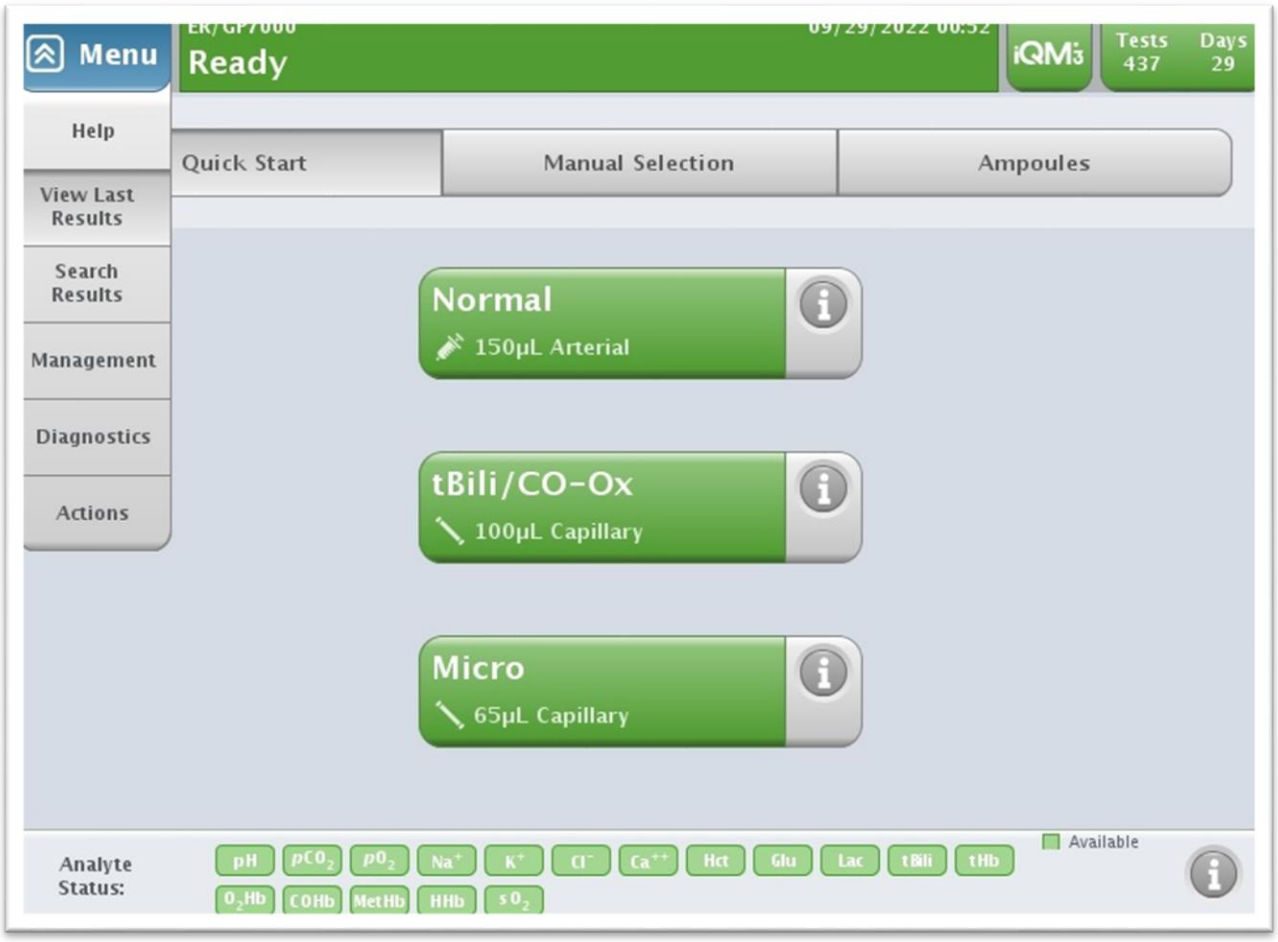


The quick start main screen shows analyzer status, and offers quick start standardized panels.



The System status bar shows analyzer status & indicates analyzer overall readiness.

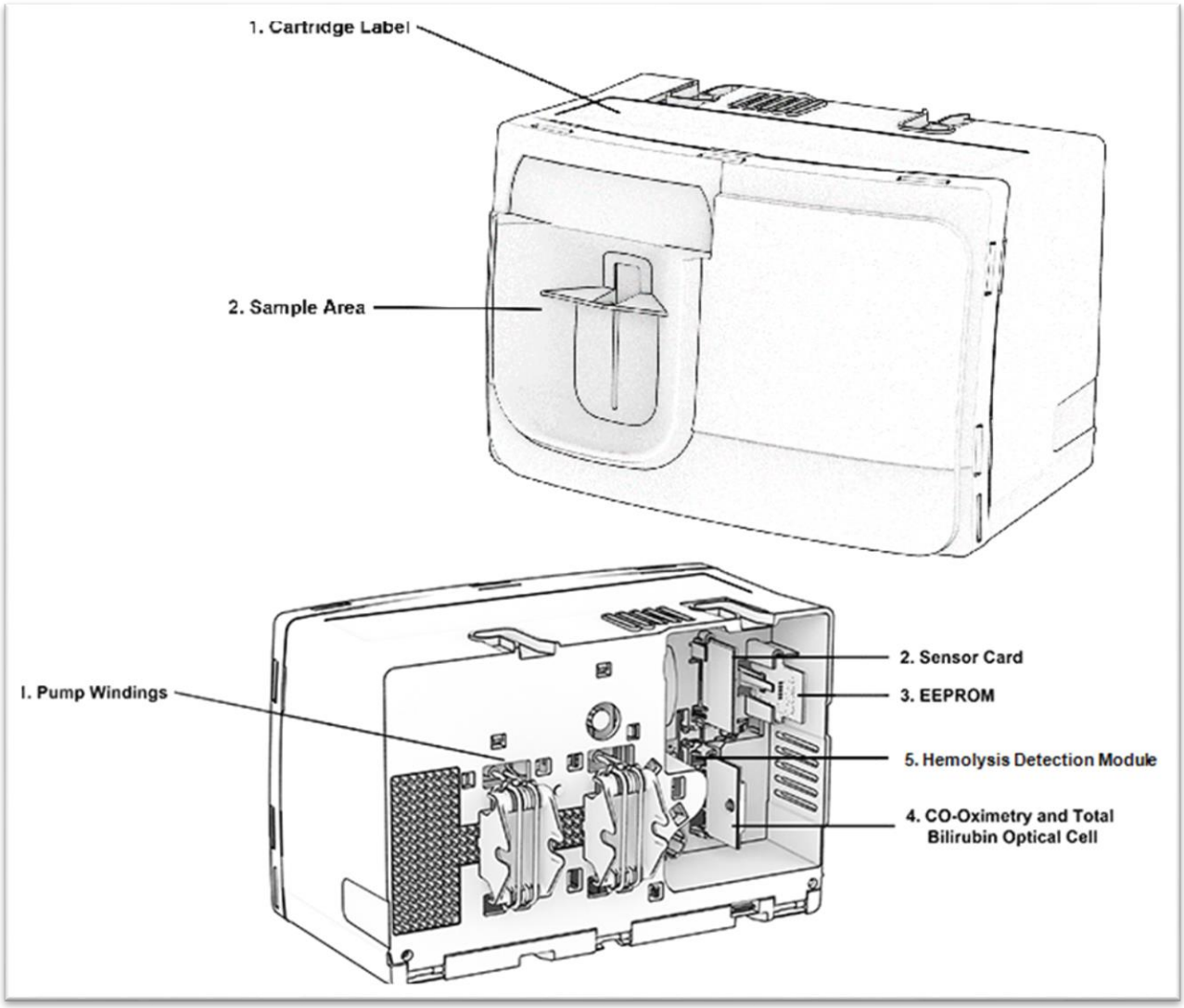
iQM3 Button will turn yellow during iQM3 (QC) processes. Network Status button – select this button for more information on network status. Tests/Days Button shows the remaining test count and onboard stability of the reagent PAK.



Menu Button drop-down functions: Help – provides direct access to topic-based training videos. View Last Results – enables search of last 20 patient results. Search Results – enables search of patient results from the database. Management – provides manager level access. Diagnostics – provides diagnostics options. Action – enables manual removal of the PAK, restart, or shutdown.

Reagent Cartridge Overview

The reagent cartridge (GEM PAK) includes all replaceable and consumable components, except for the printer paper. The reagent cartridge is shipped in an insulated container and in a foil pouch. There is a clear plastic cover protecting the rear of the PAK, which must be removed prior to reagent change.



Front: 1. Cartridge Label provides cartridge serial number, test count and menu, manufacture and expiration date. 2. Sample area – contains the probe. Back: 1. Bump windings – connect to reagent pouches within the PAK, these are operated by peristaltic pumps within the GEM analyzer and direct the fluidics during sample analysis. 2. Sensor card (EC) - measures blood gas and metabolite parameters. 3. EEPROM – communicates with the GEM analyzer. 4. CO-Oximetry Optical Cell – measures CO-Oximetry parameters. 5. Hemolysis Detection Module – measures hemolysis level. Also Note: on the top and bottom of the PAK are grooves which interlock into the door mechanism.

UPS – Battery System

The Tripp Lite UPS System will provide up to 60 minutes of operation to the analyzer when the analyzer is being moved, or when hospital power fails.

System Care and Maintenance

Most activities are internally managed and logged by the analyzer. The operator will only be responsible for a few activities: As-Needed Cleaning, Replacing the printer paper, Replacing reagent cartridges, or As-needed troubleshooting. Always use PPE as per standard laboratory practice.

As-Needed Cleaning:

- For the analyzer sampling area: With a soft cleaning cloth, wipe the analyzer with up to 10% bleach or mild detergent solution. Make sure the cloth is only damp and not dripping wet.
- For the touch screen: With a soft cleaning cloth, wipe the analyzer with water or mild detergent solution. Make sure the cloth is only damp and not dripping wet.

Replacing printer paper: When the paper roll is nearly exhausted, red ink will appear on the printouts. Change the paper at this time. Push the lever on the printer paper compartment. Open the compartment and remove the old paper roll. Place the new paper roll in the compartment with a few inches of paper hanging out and close the cover until there is a click.

Replacing reagent cartridges: When the days or tests on the main screen reach zero, or when the operator manually selects to change the cartridge, the door will automatically unlatch and partially open and the screen prompts the operator to change the cartridge. Open the door fully to release the spent cartridge. While the door is still fully open, place the new cartridge in the opening. Approximately 1 inch of cartridge will be sticking out. Slowly close the door, the internal latching mechanism will guide the PAK into position. The system will automatically condition, calibrate, and assess PAK validity. This process typically takes 45-50 minutes.

Power recovery: After system restart the system will automatically recover. To power the instrument on, use the white power button on the rear of the analyzer. Power recovery process typically takes 7-10 minutes.

> ***NOTE:*** *Reagent PAKs can only be without power for up to 60 minutes. If power is not restored in this time frame, the PAK must be discarded.*

As-Needed Troubleshooting: When prompted by the analyzer, or when assays do not recover after a significant amount of time, contact service. When network connections are down, contact IT service desk. Communicate instrument or assay downtimes by orange SBAR form.

Service Contact Information

Werfen Tech Support Hotline: 800-678-0710

GEM PAK Failure, Replacement, and Credit

In the event that a GEM PAK fails, contact the Werfen Tech Support Hotline. Generate a ticket for replacement or credit of the failed PAK. Fill out the GEM PAK Credits form, and inform the section supervisor or lead of the failure by email.

When the analyzer detects errors with sensors, the associated test(s) will be disabled. Use your best judgement regarding if the GEM PAK is still useful with disabled test(s). Generally, tests such as pH, pO2, pCO2, or tHb being disabled will require replacement and credit. If the GEM PAK has few tests remaining or is near expiration and a lower use test such as electrolytes or glucose is disabled, you may continue to use the PAK until remaining tests have been consumed.

Sample

Only use lithium heparinized whole blood for patient testing. Acceptable sample types include arterial, venous, and capillary. Acceptable sample containers include syringe, capillary tube, or ampoule. See assay procedure for specific sample requirements.

Other acceptable materials include calibration verification products or proficiency testing materials.

The GEM 7000 tests sample volumes as low as 65uL.

Analytes	Sample Volume (µL)	Analysis Pathway
pH, pCO2, pO2, Na+, K+, Cl-, Ca++, Glu, Lac, Hct, tHb, O2Hb, COHb, MetHb, HHb, sO2, tBili or any combination of	150	Electrochemical (EC) analytes and CO-Ox and/or tBili
tHb, O2Hb, COHb, MetHb, HHb, sO2, tBili	100	CO-Ox and/or tBili
pH, pCO2, pO2, Na+, K+, Cl-, Ca++, Glu, Lac, Hct	65 (Capillary only)	Electrochemical (EC)

Test Codes

See Assay procedure for associated test codes.

Calibration

Calibration is fully automated and internally managed within the analyzer. See section 10 of the GEM user manual for additional information.

Calibration verification and linearity assessment is performed at least every 6 months. Use PVP material.

Quality Control

Quality control is fully automated and internally managed within the analyzer. See section 10 of the GEM user manual for additional information.

Process Control Solutions (PCS) are performed after every analyzed sample and at frequencies between 30 minutes to 24 hours. PCSs are internal solutions for the GEM Premier 7000, traceable to NIST primary

standards or other standards. During QC the System Status Bar will turn blue. If the Quick Start menu options remain green, the QC is interruptible by starting the normal sampling process (scan barcode, quick start, or manual test selection.)

Process Control Solution	Frequency	Function
A	Every 4 hours	Measures sensitivity, sensor drift and accuracy across the span of medical decision limits and clinical reference ranges in combination with other PCSs.
B	Every 30 minutes or after each sample	Measures sensor drift and accuracy across the span of MDLs and clinical reference ranges in combination with other PCSs. Used as corrective action in high frequency after interference or clot bust after clot detection. Remains over sensors and with outputs checked every 30 seconds.
C	Every 24 hours	Measures low level pO2, pH, pCO2 for drift. Conditions the interference rejection membrane for glucose/lactate sensor.
D	Every 12 hours	Measures sensor drift and accuracy across the span of MDLs and clinical reference ranges in combination with other PCSs. Validates PCS values and cartridge prior to sample analysis.
E	Every 12 hours	Measures sensor drift and accuracy across the span of MDLs and clinical reference ranges in combination with other PCSs. Validates PCS values and cartridge prior to sample analysis.

iQM3 – Intelligent Quality Management

1) **System Checks:** GEM Premier 7000 system routinely conducts functional checks of vital system components, including mechanical sub-assemblies/electronics, the hemolysis detection module, and PAK fluidics, to check sample integrity and reagent performance before each sample analysis and at various scheduled times throughout PAK use-life.
   When errors are identified during system checks, iQM3 alerts the operator, automatically initiates corrective actions, and documents the actions taken. System Checks include:
   a) a. Mechanical and Electronic Checks
   b) b. Fluidic Checks
2) **Sensor/CO-Ox/Hemolysis Module Checks:** Five PC Solutions are run automatically to continuously verify sensor, CO-Ox, hemolysis detection module, and PAK performance. PC Solutions are measured and compared to expected values (drift). iQM3 automatically evaluates PC Solutions, alerts the operator, and initiates corrective actions, if applicable. Sensor/CO-Ox Checks are performed continuously throughout GEM PAK use-life, significantly exceeding the discrete testing schedule of traditional QC, which is performed approximately every eight hours. PC Solutions are measured utilizing the identical analytical pathway as samples and verify performance of the analytical system from the aspiration point through the sample measurement process. iQM3 automatically analyzes each PC Solution analyte value, based on established acceptable ranges.

3) **IntraSpect Technology:** During the sample measurement period, iQM3 software collects 15 sample mV readings in 15 seconds and evaluates sensor performance by abnormal sensor response pattern through slope shape and coefficient values. IntraSpect Checks provide continuous sample integrity quality checks throughout the entire measurement process to ensure accuracy of patient results.
4) **Pattern Recognition (PR):** Signals from sensors and the CO-Ox generated by samples or PCSs are analyzed by PR software. Patterns (sensor or spectral response) generated by various sample, sensor, CO-Ox and reagent errors can also be recognized. iQM3 initiates intelligent corrective actions based upon the pattern verified, alerts the operator immediately, attempts to automatically correct the problem, then will disable a specific analyte, if recovery is not possible, or reject the GEM PAK, if needed.
5) **PCS Stability Checks:** These checks verify PCS stability during GEM PAK use-life. If the check fails, the GEM PAK is rejected. This check is performed at least every 4 hours using the measured oxygen in PCS A during use-life.
6) **Hemolysis Detection:** Hemolysis detection is based on an optical photometric measurement of whole blood in the sample. The process for hemolysis detection is simultaneous to sample analysis, without added time-to-results for measured parameters in the system. Based on the plasma free hemoglobin level detected in the sample, the corresponding K+ results will be flagged and/or suppressed according to the configuration settings.

Sampling Procedure

1. Receive into the lab. Ensure sample meets sample requirements per assay procedure, checking stability times, sample type, volume, air bubbles, etc.
2. Prepare for analysis.
    a. Syringe: mix thoroughly with quick inversions or gentle rolling. Expel a few drops to check for a clot.
    b. Capillary: mix by rolling between fingers for >30 seconds or >20 rolls.
3. Scan the barcode. The analyzer will query the order from the LIS and determine the appropriate sample type and test orders (venous, arterial, capillary, etc.). A probe will emerge from the PAK.
4. Aspiration:
    a. Syringe: present the uncapped syringe to the extended probe. The probe will be extended at a 30-degree angle. Ensure the end of the probe stays within the sample throughout aspiration, and that the end of the probe is not occluded or pressing onto the stopper of the syringe. On the analyzer, press **Start Aspiration**.
    b. Capillary: present the uncapped syringe to the probe. The probe will be presented at a 90-degree angle, and only partially extended. Fit the capillary tube around the probe. On the analyzer, press **Start Aspiration**.
    c. The analyzer will provide audio and visual prompts when aspiration is complete. Once complete, immediately remove the sample from the probe and recap.
5. Enter required patient information. The patient's demographic information should populate from the LIS. If patient temperature, FIO2, or other information was given, this is the time to enter that information.
6. Resulting and evaluation. See assay procedure for information on each individual parameter resulting and evaluation. Once the analysis is complete, the results will be displayed. If the patient's temperature was modified, some results will list both the value at 37C and the entered patient temperature. The analyzer then automatically enters a quality control (PCS) process.

Downtime Sampling Procedure

1. Receive into the lab. Ensure sample meets sample requirements per assay procedure, checking stability times, sample type, volume, air bubbles, etc. Assign sample a downtime barcode.
2. Prepare for analysis.
    a. Syringe: mix thoroughly with quick inversions or gentle rolling. Expel a few drops to check for the clot.
    b. Capillary: mix by rolling between fingers for >30 seconds or >20 rolls.
3. From the main screen, select the **Manual Selection** tab. Select the volume, analytes, and sample type. Press **Run Test**. A probe will emerge from the PAK.
4. Aspiration:
    a. Syringe: present the uncapped syringe to the extended probe. The probe will be extended at a 30-degree angle. Ensure the end of the probe stays within the sample throughout aspiration, and that the end of the probe is not occluded or pressing onto the stopper of the syringe. On the analyzer, press **Start Aspiration**.
    b. Capillary: present the uncapped syringe to the probe. The probe will be presented at a 90-degree angle, and only partially extended. Fit the capillary tube around the probe. On the analyzer, press **Start Aspiration**.
    c. The analyzer will provide audio and visual prompts when aspiration is complete. Once complete, immediately remove the sample from the probe and recap.
5. Enter required patient information. Enter the downtime barcode and at least two patient identifiers per laboratory SOP. If patient temperature, FIO2, or other information was given, this is the time to enter that information.
6. Resulting and evaluation. See assay procedure for information on each individual parameter resulting and evaluation. Once the analysis is complete, the results will be displayed. If the patient's temperature was modified, some results will list both the value at 37C and the entered patient temperature. The analyzer then automatically enters a quality control (PCS) process.

POC Sampling Procedure

1. Ensure sample meets sample requirements per assay procedure, checking stability times, sample type, volume, air bubbles, etc.
2. Prepare for analysis.
    a. Syringe: mix thoroughly with quick inversions or gentle rolling. Expel a few drops to check for a clot.
    b. Capillary: mix by rolling between fingers for >30 seconds or >20 rolls.
3. From the main screen, select the **Quick Start** tab. Select the desired panel. Badge in or enter user password. A probe will emerge from the PAK.
4. Aspiration:
    a. Syringe: present the uncapped syringe to the extended probe. The probe will be extended at a 30-degree angle. Ensure the end of the probe stays within the sample throughout aspiration, and that the end of the probe is not occluded or pressing onto the stopper of the syringe. On the analyzer, press **Start Aspiration**.
    b. Capillary: present the uncapped syringe to the probe. The probe will be presented at a 90-degree angle, and only partially extended. Fit the capillary tube around the probe. On the analyzer, press **Start Aspiration**.
    c. The analyzer will provide audio and visual prompts when aspiration is complete. Once complete, immediately remove the sample from the probe and recap.

5. Scan the patient MRN into the MRN field. The analyzer will query the patient's demographics from the LIS. Edit patient temperature, FIO2, or other information as necessary.
6. Resulting and evaluation. See assay procedure for information on each individual parameter resulting and evaluation. Once the analysis is complete, the results will be displayed. If the patient's temperature was modified, some results will list both the value at 37C and the entered patient temperature. The analyzer then automatically enters a quality control (PCS) process.

Limitations

The instrument must be installed per the manufacturer's instructions. Failure to do so invalidates any warranty, explicit or implied.

References

1. GEM Premier 7000 with IQM3 Operator's Manual, PN 00000026407 Rev. 00 Aug 2023

Training Plan/Competency Assessment

Use CH 1.20.T1 GEM 7000 Training for initial employee training. StaffReady will be used to perform Competency Assessments after initial training on the GEM 7000 instrumentation.

Historical Record

Version	Author	Effective Date	Summary
1	Matt Johnson	10/28/2025	Initial Version