GEM 5000 BLOOD GAS ANALYSER

LOCATION	Satellite locations across the RD&E Wonford site – AMU/MTU POCT room, Creedy, Culm, ED, ITU, Labour, NNU
APPARATUS	Werfen GEM 5000 blood gas analyser
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CIRCULATION LIST
Laboratory copies must not be photocopied or amended

Copy number	Location
1 Master copy	Q Pulse
2 Laboratory copy	Manual/Bench Section SOP Folder
3 Electronic copies	Exeter Laboratory Website POCT Section [https://www.exeterlabortory.com/point-of-care-testing/policies/]

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GEM 5000 BLOOD GAS ANALYSER STANDARD OPERATING PROCEDURE

1. LABORATORY CONTACTS AND WARD BASED KEY TRAINERS

Laboratory contact details are located on the analyser.
Open up the Menu tab on the LHS of the screen.
Open up the Help tab
Open up the contacts tab.
The contacts tab will provide details of the telephone number and bleep to be used to contact Clinical Chemistry.

The latest list of ward based key trainers can be obtained by e-mailing the Clinical Chemistry MTO team, rde-tr.ChemMTO@nhs.net
The key trainers will be able to provide face-to-face training on the Gem 5000 blood gas analyser. Once training has been completed, a barcode will be issued (if the staff member is not already assigned one for the Blood Track system) and the details e-mailed to the MTO team for an account to be added to the blood gas system. The user details required for the medical devices database are Name, Staff Grade, 7-digit barcode and location where trained.

2. PURPOSE OF THE EXAMINATION

The GEM Premier 5000 system provides fast, accurate, quantitative measurements of whole blood pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, haematocrit, total bilirubin and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb). Clinical utility of each measurement described below:

- pH and pCO_2, along with their derived parameters Base Excess, standard bicarbonate, and TCO_2, define acid-base status.
- Arterial pO_2 indicates adequacy of oxygen exchange.
- Electrolytes in the human body have multiple roles. Nearly all metabolic processes depend on or vary with electrolytes:
  - Sodium (Na^+) is the major cation of extracellular fluid. It is critical for maintenance of water distribution and osmotic pressure in body tissues.
  - Potassium (K^+) is the major intracellular cation. It is critical for maintaining proper neuromuscular irritability including respiratory and myocardial function.
  - Ionised calcium (Ca^{++}) is critical for functions including haemostasis.
  - Chloride (Cl^-) is the major negative ion in the fluid outside the body's cells. Its main function is to maintain electrical neutrality, mostly as a counter-ion to sodium. Changes in the chloride level often accompany sodium losses and excesses.
- Haematocrit (Hct) indicates the red cell fraction of the blood, a vital component in determining its oxygen carrying capacity.
- Glucose (Glu) is the primary energy source, and its blood level is maintained within a fairly narrow range. The most common disorder affecting blood glucose levels is due to diabetes mellitus, which can cause hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose).

- Lactate (Lac) is an intermediary product of carbohydrate metabolism and is derived mainly from muscle cells and erythrocytes. Severe oxygen deprivation of tissues due to shock, cardiac decompensation, haematologic disorders, and pulmonary insufficiency leads to “lactic acidosis” and is associated with a significant increase in blood lactate.
  - Lactate clearance has been utilised as a prognostic marker of global tissue hypoxia in circulatory shock. Liver malfunction may also play an important role in the production of lactate.
  - Hyperlactatemia is an indicator commonly used to detect tissue hyperfusion, particularly in case of sepsis, but also in trauma and surgical settings.
- Bilirubin (tBili) is produced by the degradation of heme groups present in haemoglobin. High levels of bilirubin (hyperbilirubinaemia) lead to jaundice. Severe jaundice (total bilirubin >20 mg/dL) may in turn lead to Kernicterus, a disease that may cause irreversible brain damage to the newborn. The GEM Premier 5000 measures total bilirubin. Total bilirubin is the sum of the concentrations of two typical bilirubin fractions, Unconjugated (Indirect) and Conjugated (Direct) bilirubins, as well as delta bilirubin. Different bilirubin fractions exhibit slightly different spectral properties and the GEM Premier 5000 measures and reports the total bilirubin concentration for neonates.
- CO-Oximetry (tHb, COHb, MetHb, O_2Hb and HHb) evaluates the ability of the blood to carry oxygen by measuring total haemoglobin and determining the percentage of functional and dysfunctional haemoglobin species.
- Carboxyhaemoglobin is a stable complex of carbon monoxide and haemoglobin. Haemoglobin binds to carbon monoxide preferentially compared to oxygen and has a strong affinity that the carbon monoxide is not released therefore reducing the oxygen carrying capacity in the body. Carbon monoxide has a half-life in the blood of 4 to 6 hours, but this can be reduced to 70 minutes with the administration of pure oxygen in cases of suspected carbon monoxide poisoning. This can be further reduced to 35 minutes by using oxygen with 4-5% of CO_2 to cause hyperventilation.
- Methaemoglobin is a form of the oxygen-carrying metalloprotein haemoglobin in which the iron in the heme group is in the ferric (Fe^{3+}) state and not the ferrous (Fe^{2+}) of normal haemoglobin. It is usual to have 1-2% of methaemoglobin in normal circulation; the NADH-dependent enzyme methaemoglobin reductase is responsible for converting methaemoglobin back to haemoglobin.

The GEM Premier 5000 system is also capable of calculating derived parameters for:

- Base excess of blood (*in vitro*). Base excess is a term that approximates the amount of acid or base that would be needed to titrate one liter of blood back to a normal pH of 7.40. This quantity is also called “in-vitro base excess.”
- Ionised calcium normalized to a pH of 7.4.
- Calculated oxygen saturation. Knowing the oxygen saturation is useful for predicting the amount of oxygen available to tissue perfusion.
- Standard bicarbonate, which gives a crude indication of acid-base balance.

Pleural Fluid pH (note: currently the GEM 5000 is not CE marked for fluid analysis)

- Pleural fluid pH is normally about 7.6 because of bicarbonate accumulation in the pleural cavity (compared to blood which has a pH of ~7.4).
- Various conditions affect pleural fluid dynamics resulting in an accumulation of excess fluid in the cavity this is known as a pleural effusion.

LABORATORY PROCEDURE

- Pleural fluid pH is performed on all non-purulent effusions to differentiate between empyemas and parapneumonic effusions.
  - pH <7.20 – indicative of an empyema requiring drainage
  - pH 7.21-7.29 – indicative of a complicated parapneumonic effusion which may require drainage
  - pH >7.29 – indicative of a simple parapneumonic effusion which usually responds to antibiotics

3. PRINCIPLE AND METHOD OF THE PROCEDURE

The GEM Premier 5000 system makes use of potentiometric sensors to measure pCO_2, pH, Na^+, K^+, Cl^-, and Ca^{++}. It uses amperometric sensors to measure pO_2, glucose, and lactate concentrations. CO-Oximetry and total bilirubin measurements involve chemically lysing the whole blood sample and then utilising a broad spectrum spectrometer to evaluate the sample at a variety of wavelengths.

pH and Electrolytes (Na^+, K^+, Cl^- and Ca^{++})

The pH and electrolyte sensors are based on the principle of ion-selective electrodes; in which electrical potential can be established across a membrane resulting from chemical selectivity of the membrane to a specific ion. The potential can be described by this simplified form of the Nernst equation E=E' +(S x Log C), where E is the electrode potential, E' is the standard potential for that membrane, S is the sensitivity (slope), and C is the ion activity. E' and S can be determined by the sensor response to the Process Control Solutions, and the equation can be solved for the activity of the ion of interest. For pH, "log C" is replaced by "pH" and the equation solved accordingly.

The pH and electrolyte sensors are polyvinyl chloride (PVC) based ion selective electrodes, consisting of an internal Ag/AgCl reference electrode and an internal electrolyte layer. Their potentials are measured against the card reference electrode (Ag/Ag^+).

If pH reports with an exception, then results for pCO_2, $sO_{2(c)}$ and any derived parameter dependent on pH will not be reported. If sodium reports with an exception, then a Hematocrit value will not be reported.

***p*CO_2**

The pCO_2 sensor is a patented design which relies on a pH selective polymer as a gas permeable outer membrane. The sensor has an internal Ag/AgCl reference electrode and an internal bicarbonate buffer. The pCO_2 in the internal solution will come to equilibrium with the pCO_2 of a liquid (e.g. blood) in contact with the outer surface of the membrane.

The pH of the internal solution varies with the $_2$ in accordance with the Henderson-Hasselbalch equation:

$H = pKa + \log [HCO_3^-/ pCO_2 \times a]$

Where pKa is equilibrium constant, HCO_3^- is the bicarbonate ion concentration, and "a" is the solubility coefficient of CO_2 in water. The generated potential versus the pH sensor is related to the logarithm of pCO_2 content in the sample.

If *pCO2* reports with an exception, then HCO_3^- and TCO_2 will not be reported.

***p*O_2**

The oxygen sensor is an amperometric electrode consisting of a small platinum electrode poised at a negative potential with respect to the card reference electrode.

A gas permeable membrane protects the platinum from protein contamination, prolonging sensor life.

The current flow between the platinum surface and the ground electrode is proportional to the rate at which oxygen molecules diffuse to the platinum and are electrochemically reduced, which in turn is directly proportional to the pO_2 level in the sample. This relationship is described by the equation I = (S x pO_2) + IZ, where "I" is the electrode current, "S" is the sensitivity, and IZ is the zero current. The values of S and IZ can be calculated from the Process Control Solution data for the sensor. The equation can then be solved for pO_2, where "I" becomes the electrode current produced by the blood sample.

If pO_2 reports with an exception, then results for $sO2_{(c)}$ and any derived parameter dependent on pO_2 will not be reported.

Glucose and Lactate

The glucose and lactate sensors are amperometric biosensors consisting of a platinum electrode poised at a positive potential with respect to the card reference electrode.

Glucose or lactate determination is accomplished by enzymatic reaction of glucose or lactate with oxygen in the presence of glucose oxidase or lactate oxidase and the electrochemical oxidation of the resulting hydrogen peroxide at the platinum electrode. The current flow between the platinum electrode and the ground electrode is proportional to the rate at which hydrogen peroxide molecules diffuse to the platinum and are oxidized, which in turn is directly proportional to the metabolite (glucose or lactate) concentration I = (S x metabolite) + IZ, where "I" is the electrode current, "S" is the sensitivity, and IZ is the zero current. The value of S and IZ can be calculated from the Process Control Solution data for the sensor. The equation can then be solved for the metabolite concentration, where "I" becomes the electrode current produced by the blood sample.

CO-Oximetry (tHb, O2Hb, COHb, MetHb HHb and sO_2)

CO-Oximetry is based on an optical absorbance measurement of the sample. An in-line optical cell is integrated in the flow path of the haemolysed sample to provide a measure of hemoglobin and its derivatives. The optical cell is a flow through channel with two parallel plate optical windows separated by a well-defined path length. The chemical lysing of the sample is implemented to minimize the scattering effect of the blood and to make the spectral measurement more reliable. The optical measurement hardware consisting of a white light-emitting diode (LED) light source, a neon reference and a high resolution spectrometer with a holographic diffraction grating and a charge-coupled device (CCD) array (2048 pixels, 0.15 nm/pixel) are all contained in the analyser. The optical components are connected through optical fibers into a read head. Only the optical cell is located in the disposable cartridge (GEM PAK) and is aligned with the analyser optics for spectral measurements following installation of the GEM PAK.

The sample spectrum is measured simultaneously at about 2000 wavelengths between 480 to 650 nm. Multi-component analysis of the sample spectrum leads to its resolution into hemoglobin derivatives and any other optically absorbing components present in the sample. From the spectral values, absorbance is calculated from AbsS = Log10 [IB / IS], where IB and IS are dark corrected spectra for the PCS B and sample respectively.

Absorbance spectra data are collected and stored. The matrix data processing, using the internally stored coefficients, is used for calculating concentration results for hemoglobin derivatives.

Calculation of Derived Parameters

Standard Bicarbonate

Standard bicarbonate is the bicarbonate concentration from blood that has been equilibrated at 37°C with a pCO_2 of 40 mmHg and a pO_2 to produce full oxygen saturation.

The equation is:

HCO_3^- std = 25 + 0.78 x BE (B) + 0.002 x tHb x (O_2Hb -100) mmol/L

Where:

tHb = Measured total hemoglobin, in g/dL, for current sample, calculated tHb is used if measured tHb is not available

O_2Hb = O_2Hb measured locally for current arterial sample, in %

BE (B) = Base excess approximates the amount of acid or base that would be needed to titrate one liter of blood back to a normal pH of 7.40. This quantity is also called “in-vitro base excess”. The GEM Premier 5000 provides two formulae options to choose from in Configuration. See Base Excess section for more information.

Base Excess of Blood [BE(B)]

The GEM Premier 5000 system provides two formula options to choose from during configuration, which are described next.

CL SI Equation: (this equation is the one used across the RD&E analysers)

BE(B) mmol/L = (1 - 0.014 x tHb) x [HCO_3^- - 24.8 + (1.43 x tHb + 7.7) x (pH - 7.4)]

Where:

tHb = Measured total hemoglobin, in g/dL, for current sample. Calculated tHb is used if measured tHb is not available.

HCO_3^- = Calculated bicarbonate for current sample

pH = pH measured from the current sample

Rolf Zander Equation:

BE(B) in mmol/L = (1- 0.0143 x tHb) x ((0.0304 x pCO_2 x 10(pH -6.1) - 24.26) + (9.5 + 1.63 x tHb) x (pH - 7.4)) - 0.2 x tHb x (100 – SAT)/100

Where:

tHb = Measured total hemoglobin, in g/dL, for current sample. Calculated tHb is used if measured tHb is not available.

HCO_3^- = Calculated bicarbonate for current sample

pH = pH measured from the current sample

pCO_2 = pCO_2 measured from the current sample

pO_2 = pO_2 measured from the current sample

SAT = O2 saturation, in %, measured from the current sample. If the measured sO_2 is not available, then SAT is calculated using the following equation:

SAT = 100 / [1 + (23400 / [pO_2pp + 150 x pO_2pp])] (%) $_3$

pO_2pp = pO_2 x e (C + 0.003 * X - 2.2) x (7.4 - pH) (%)

C = (pO_2 / 26.7) 0.184

X = (1 - 0.014 x tHb) x [HCO_3^- - 24 + (1.63 x tHb + 9:5) x (pH - 7.4)]

Calculated Oxygen Saturation

Oxygen saturation is a ratio, expressed as a percentage of the volume of oxygen carried, to the maximum volume which the blood could carry.

The equation is:

$sO2_{(c)}$ = 100 / [1 + (23400 / (pO_2pp3 + 150 * pO_2pp))] %

Where:

pO_2pp is partial pressure of oxygen in blood at pH of 7.4 and a temperature of 37°C, and is calculated from:

pO_2pp = pO_2 x e (C + 0.003 * BE(B) - 2.2) * (7.4 - pH) (%), where:

e = 2.718 and

C = (pO_2 / 26.7) 0.184
BE(B) is *In vitro* base excess and is calculated from the formula described by Siggaard- Anderson:
BE(B) = (1 - 0.014 x tHb) x [HCO_3^- - 24.8 + (1.43 x tHb + 7.7) x (pH - 7.4)]

Ionised Calcium normalized to a pH of 7.4
Ionised calcium can be normalized and reported as an acid/base value with respect to pH = 7.4.
The equation is:
Ca^{++}(7.4) mmol/L = Ca^{++} x 10 [-0.178 x (7.4 - pH)]
Where:
Ca^{++} = ionised Ca^{++} measured from the current sample
pH = pH measured from the current sample

Temperature Correction
Actual patient temperature (Temp), the default temperature is 37°C. This temperature will be used to calculate pH, pCO2 and pO2 unless a different entry is made by the operator. The measured and corrected temperature results, if applicable, are displayed on the View Results screen and on the printout. Allowable range for patient temperature (Temp) °C is 15.0 to 45.0.

The following equations are used to calculate the temperature corrected parameters pH, pCO_2 and pO_2.
pH(T) = pH + (T - 37) * [-0.0147 + 0.0065 x (7.4 – pH)]
pCO_2(T) = pCO_2 x 10 [0.019 x (T - 37)]
pO_2(T) = pO_2 x 10 [K x (T – 37)]
Where: T = Temperature entered by the operator for the sample
K = Temporary subordinate calculation
Reference: CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

4. PERFORMANCE CHARACTERISTICS

See **Chapter 11: Performance Characteristics** pages 160 – 193. Gem Premier 5000 iQM_2 Operators Manual P/N 00024019203 Rev 00. September 2015.

Validation data for comparison of Werfen Gem 5000 v Gem 3500/4000 and Roche Cobas 8000 can be located on Q-pulse.
Q-pulse reference BS/CT/12 Upgrade to Gem 5000 blood analyser from Gem 3500/4000

Measured Analytes

Measured Analyte	Units	Measuring Range *	Claimed Measuring Range **	Resolution
pH	n/a	6.00 to 8.50	6.80 to 7.92	0.01
pCO2	kPa	0 to 31.9	0.8 to 20.0	0.1
pO_2	kPa	-13.1 to 126.4	0.8 to 100.8	0.1
Na^+	mmol/L	55 to 220	100 to 200	1
K^+	mmol/L	0.0 to 27.5	1.0 to 20.0	0.1

Ca^{++} (ionised)	mmol/L	0.00 to 5.50	0.11 to 5.00	0.01
Cl^{-}	mmol/L	30 to 200	40 to 170	1
Glu	mmol/L	-1.1 to 111.0	0.2 to 41.6	0.1
Lac	mmol/L	-1 to 50	0.3 to 20.0	0.1
tHb	g/L	-50 to 300	30 to 230	1
COHb	%	-10 to 110.0	0.0 to 75.0	0.1
MetHb	%	-10 to 110.0	0.0 to 30.0	0.1

* The Measuring Range for a parameter is the analyser electronics capability range translated into analyte measurement units.

** The Claimed Measuring Range for a parameter is the range where performance claims are verified and validated. Analytes with measured values outside the Claimed Measuring Range and within Measuring Range are reported with a > or < symbol. Analyte with measured values outside the Measuring Range will be reported as Incalculable.

Derived (Calculated) Analytes

Derived Parameter	Unit of Measure	Resolution
BE(B) (*in vitro*)	mmol/L	0.1
$Ca^{++}7.4$ (ionised)	mmol/L	0.01
$sO_{2(c)}$	%	0.1
HCO_3^- std	mmol/L	0.1

5. TYPE OF SAMPLE

Types of patient sample sources accepted by the GEM Premier 5000 system include:

- arterial
- capillary
- mixed venous
- venous
- arterial-mixed venous pairs
- pleural fluid (for pH analysis only)

Types of sampling devices accepted include:

- syringe
- capillary tube
- opened ampoules
- uncapped collection tubes using the syringe or ampoule sampling position
- Lithium Heparin blood tube (for COHb analysis from GP's and COHb/MetHb from those wards without trained staff with access to a GEM 5000 analyser)

Minimum volume of blood 65µl micro-capillary setting, 100µl for co-oximetry analysis only and 150µl for a full profile from a syringe or capillary.

All samples must be, **free of air bubbles, well mixed and free of clots**. All specimens must be mixed immediately after collection and again before analysis by rolling between the palms of the hands (be aware of how hot or cold your hands are, if using this technique) or by gently inversion.

Arterial Samples

Collection of arterial samples is typically obtained by needle puncture or from in-dwelling catheters. Arterial blood gases are measured for the purpose of evaluating the gas exchange function of the lungs as well as for the assessment of metabolic acid base disorders and electrolytes.

Heparinised arterial blood in a syringe; - Seal the syringe with a blind end stop after expulsion of any residual air bubbles**. DO NOT** leave needles attached.

Syringe samples must be mixed thoroughly immediately after sample collection by inverting 10 times. Immediately before sampling, mix again for at least 30 seconds and discard the first few drops of blood from the syringe.

Note: Vigorous shaking can cause falsely elevated K^+ results.

Note: Samples should be mixed for >30 seconds prior to sample analysis. Insufficient mixing can cause erroneous tHb/tBili results.

Capillary or "Arterialized" Capillary Samples

Peripheral capillary samples may be collected in the event that arterial blood cannot be obtained; however, caution is advised when interpreting results as this only approximates blood gas measurement. Other difficulties associated with capillary sampling include adequate sample volume and air bubbles.

Heparinised capillary samples must be mixed thoroughly immediately after collection. This may be accomplished by rolling the capped capillary tube with outstretched palms for 5 seconds. Alternately a metal "flea" may be inserted into one end of the capillary tube and an external magnet may be applied to move the flea along the path of the capillary tube for 5 seconds. Immediately before sampling, mix again, remove the metal flea prior to sample aspiration.

Note: Vigorous shaking can cause falsely elevated K^+ results.

Venous Samples

Venous blood is suitable for analysing pH, pCO2, electrolytes, glucose, lactate, total bilirubin, total haemoglobin, carboxyhaemoglobin and methaemoglobin. Venous blood is not a suitable substitute for arterial blood gas analysis.

Carboxyhaemoglobin is stable >4 months stored as whole blood in a well capped heparinised tube. (see Tietz 3rd edition page 114), the stability of the analyte allows specimens from primary care to be analysed. Post-mortem sample for carboxyhaemoglobin can be analysed on the Gem 5000 but often the sample quality is poor which leads to absorbance errors and an unreportable result; the local coroner's office is aware of the limitation of the analyser for these samples. Methaemoglobin is unstable and needs be analysed as soon as possible after specimen collection and certainly within an hour collection, this analyte is only available for specimens taken on the RD&E(Wonford) site.

Mixed Venous Samples

Mixed venous blood is obtained from the pulmonary artery via a pulmonary artery catheter and is used to measure and evaluate oxygen uptake and cardiac output. It may also be used to assess the degree of intrapulmonary shunting.

Syringe sample for fluid pH analysis

(NOTE: fluid pH is currently not CE marked for use on the Gem 5000 analyser)

Any pleural fluid samples containing particular matter can cause blockages of the analyser and can result in complete cartridge failure. Any fluid samples containing visible particular matter should be sent to Blood Sciences lab for assessment and analysis using a clot catcher.

- Any samples sent to the laboratory **NOT** in a heparinised blood gas syringe will be rejected using the following reporting comment (Code: **NOHEP**)
    - *Although a fluid pH was requested on this specimen, it was not carried out as the sample was sent in a plain universal container. All fluid pH requests should be sent to lab immediately in a heparinised blood gas syringe, and following verbal notification.*
- **Samples received after more than 1hour** from collection will be rejected and reported with the following comment (Code: **LATE**)
    - *Fluid specimen pH not carried out due to delay between collection of sample and receipt in laboratory. Please send specimens for fluid pH immediately to the laboratory, and following verbal notification.*
- **Samples containing an air bubble** may be analysed as long as they arrive in the laboratory immediately after collection, the following reporting comment will be added (Code: **BUB)**
    - *Please note: Syringe for fluid pH contained an air bubble. Please interpret result with caution.*

6. PATIENT PREPARATION

Urgent measurements of blood gases require immediate specimen collection.

To determine the effect of ventilator changes a steady state of ventilation should be achieved before obtaining arterial blood samples. Twenty to thirty minutes of stable ventilatory status is desired for spontaneously breathing patients. Other patients may require more than 30 minutes to equilibrate following ventilatory changes. Less time may elapse for specific applications, such as obtaining confirmation that a change in ventilator settings is having the desired effect, without waiting for complete equilibration.

7. TYPE OF CONTAINER AND ADDITIVES

Anticoagulants
The GEM Premier 5000 system requires the use of properly heparinised syringes. Blood samples that have not been mixed correctly or without anticoagulant will result in clots and fluidic errors. Lyophilised lithium heparin is the anticoagulant of choice for analysing whole blood specimens on the GEM Premier 5000 system. In addition, the type of anticoagulant used must have little to no effect on all the analytes measured. Therefore, Instrumentation Laboratory recommends the use of devices containing low concentrations of lyophilised lithium heparin when electrolytes will be analysed. A final heparin concentration of no more than 20 IU/mL of blood is the recommendation made by CLSI guidelines. Lyophilised anticoagulants eliminate the dilution issue associated with aqueous heparin preparations. However, dried heparin preparations may not dissolve adequately or quickly if the sample is not thoroughly mixed immediately after sample collection. Therefore, Werfen recommends that specimens obtained in syringes or capillary tubes containing lyophilised heparin be thoroughly mixed for >30 seconds by repeatedly inverting and rolling between outstretched palms immediately following collection.
For capillary tubes, cap tube and mix samples immediately by rolling capillary tube between fingers for >30 seconds.
Note: Vigorous shaking can cause falsely elevated K^+ results.
Note: Key for a thorough mixing is the quick and fast inversion of the syringe.

Note: Samples should be mixed for >30 seconds prior to sample analysis. Insufficient mixing can cause erroneous tHb results.

CAUTION: The use of Citrate, EDTA, oxalate or sodium fluoride anticoagulant may adversely affect sensor performance.

8. EQUIPMENT AND REAGENTS

Gem 5000 locations and analyser details

Location	Analyser Serial Number	Panels available	Analytes
AMU/MTU POCT room	16030248	Arterial, Venous, Capillary, Micro, Other (pH), CarboxyMetHb	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb, COHb, MetHb
Creedy	16040272	Arterial, Venous, Capillary, Micro	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb
Culm	16040271	Arterial, Venous, Capillary, Micro, Other (pH), CarboxyMetHb	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb, COHb, MetHb
ED	16030249	Arterial, Venous, Capillary, Micro, CarboxyMetHb	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb, COHb, MetHb
ITU One	16020235	Arterial, Venous, Capillary, Micro	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb
ITU Two	16030250	Arterial, Venous, Capillary, Micro	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb
Labour One	16020236	Arterial, Venous, FBS	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb
Labour Two	16030251	Arterial, Venous, FBS	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb
NNU	16030237	Arterial, Venous, Capillary, Micro	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb

Other equipment

- Every GEM 5000 is connected to the network to allow connectivity to the GemWeb server. The Network Status Button on the top bar on the analyser screen indicates whether the analyser is connected to a network. Selecting this button provides more detailed information about the network connection to GEMweb Plus.
- Every GEM 5000 is connected to the electrical supply via a UPS. The UPS allows a 20-minute back up power supply in times of the Trust requiring to switch to the generator power supply. Every analyser should be plugged into an 'E' (essential) socket to allow the analyser to remain functional in event of switching to the generator power supply.

- The GemWeb server is located in the Blood Sciences laboratory. See SOP CC/SOP/0292 Werfen GEM 5000 GEMWeb plus blood gas server.
- Werfen GEM 5000 trolley, stored in the Blood Sciences laboratory. This trolley can be used to transport an analyser and be used to house an analyser when it is removed from a location during the deep clean process.

Gem cartridge pak sizes and ordering codes

Note: the number of samples run on each analyser is reviewed at regular intervals and assigned pak sizes adjusted to allow for the most efficiency and cost-effective provision of the gas service.

Roche account number: 42100711, using the latest Peninsula Royal and Exeter Order Form. This spreadsheet contains all the current third party ordering code for the products assigned on the Blood Sciences managed service contract. E-mail the completed order form to burgesshill.ivd@roche.com

Cartridge pak size	Werfen product description	Werfen product code	Roche SAP ordering code	Location assigned
75	GEM500 BG/ISE/GL/COOX 75 test cartridge	55407510	07969490001	Creedy Ward
150 full profile	GEM 5000 BG/ISE/GL/Co-ox 150 Test Pak	55415010	08007683001	Labour ward (one analyser) & Culm Ward
150 blood gases and tHb only	GEM 5000 BG/Co-ox 150 Test Pak	55415004	08007462001	Labour ward (one analyser)
300	GEM 5000 BG/ISE/GL/Co-ox 300 Test Pak	55430010	08007691001	NNU
450	GEM 5000 BG/ISE/GL/Co-ox 450 Test Pak	55445010	07969481001	MTU/AMU & ITU (one analyser)
600	GEM 5000 BG/ISE/GL/Co-ox 600 Test Pak	55360010	07969473001	ED & ITU (one analyser)

Consumables

Product	Werfen product code	Roche SAP ordering code
GEM Printer paper (5 rolls per box)	00025000500	05523354001

Consumables (ordered via EROS)
Branch code: D0564D Blood gas consumables
Location: D164 delivery address for Clinical Chemistry

Product	Werfen Code/EROS ordering code
GEM SYSTEM EVALULATOR LEVEL 1	00025000101
GEM SYSTEM EVALULATOR LEVEL 2	00025000102
GEM SYSTEM EVALULATOR LEVEL 3	00025000103

9. ENVIRONMENTAL AND SAFETY CONTROLS

Q-pulse reference for Werfen GEM 5000 pak MSDS: - CC\H&S\COSHH\0530

Use PPE when collection and analysing samples, gloves and aprons are available on the wards.

Transportation and Handling of Samples Effects on Sample
When Exposed to Air Atmospheric air can significantly affect blood gases, in particular pH, pCO_2, O_2Hb, HHb, and pO_2. However, exposure to air can also affect ionised calcium and consequently the pH in the sample (which can also alter magnesium). Therefore, Werfen highly recommends and emphasizes the importance of expelling all air bubbles from sample prior to analysis. Sample Transport Hand carrying a blood gas sample appears to have minimal effect on the blood gas and pH results. Therefore, whenever practical, it is preferable to hand carry blood gas specimens without any vigorous movement to the location where they will be analysed. A blood sample is very rapidly accelerated and decelerated during pneumatic tube transport, which can robustly agitate the blood in a syringe. If even small air bubbles are present in the blood specimen, pneumatic transport can equilibrate these air bubbles with the blood and have a noticeable effect on pO_2. Therefore, it is important to continually emphasize the importance of removing all air bubbles from a blood gas syringe prior to pneumatic transportation. Note: It is recommended to analyse samples within 15 minutes from draw to optimize sample quality. Note: It is recommended that syringes not be iced; they should be kept at room temperature as long as the blood can be analysed within 30 minutes or less. If analysis is delayed by more than 30 minutes, storage in icy slurry may be considered but this may impact gases and electrolyte results (particularly K+). Haemolysis Potassium measurements can be significantly altered through inducing trauma to the sample during the collection (vigorous shaking) and transportation (pneumatic tube) phase. Werfen recommends hand carrying of blood gas samples where possible without any vigorous movement.

Sample disposal
Sample needles and capillaries should be discarded in sharps bins.
Plastic capped syringes may be disposed in yellow clinical waste bags (note not used on all wards) if the needle has been removed**.**

Cartridge disposal
Used cartridges are disposed of in a double yellow clinical waste bag.

10. CALIBRATION PROCEDURES

The setup of the instrument consists of inserting the GEM PAK into the instrument. The instrument will perform an automated PAK warm-up during which the sensors are hydrated and a variety of checks occur, all of which take about 40 minutes. During warmup, the instrument requires no user intervention. After GEM PAK warmup, Auto PAK Validation (APV) process is automatically completed: two completely independent NIST-traceable solutions containing two levels of concentration for each analyte (PC Solution D and E), are run by the analyser to validate the integrity of the PC Solutions and the overall performance of the analytical system (GEM PAK). After successfully performance of APV, iQM2 manages the quality control process, replacing the use of external quality controls.

11. PROCEDURAL STEPS

(Band 2 and above – ward trained staff. Band 5 and above – laboratory trained staff)

Sample Preparation Prior to Analysis

Prior to analysis, it is essential that air bubbles are expelled and the sample be thoroughly mixed. Haematocrit, total haemoglobin, haemoglobin derivatives, total bilirubin and oxygen content are particularly affected when samples are not well mixed. Improper mixing may also produce erroneous results for other analytes. A uniform distribution of red blood cells and plasma prior to sample aspiration is mandatory for reliable results.

Syringe Sampling

1. After taking the sample position the syringe vertically and carefully expel any air. To ensure that the clinical area is not contaminated please place a paper towel adjacent to the tip of the syringe. Seal the syringe with the cap provided.
2. Mix the sample thoroughly by rolling between the palms of your hands or by gentle inversion at least ten times.
3. Prior to sampling push out a few drops of the sample onto a gauze pad or tissue to ensure that there is no clot in the syringe tip. Mix the sample again.
4. The sample should be analysed within 10 minutes to prevent inaccurate results.

Capillary Sampling

Before taking a sample ensure that you are wearing gloves

1. Ensure an adequate volume of sample has been collected (see below) and that there are no air bubbles in the blood sample in the capillary.
2. To ensure the uniformity of the capillary sample mix the sample by rolling the capillary between finger and thumb.
3. The sample should be analysed within 5 minutes to prevent inaccurate results. Sample stability is reduced without the use of caps.
4. If caps are being used remove prior to sampling.

Specimen Volumes

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 of Electrochemical* analytes and CO-Oximetry** and/or tBili	150
tHb, O_2Hb, COHb, MetHb, HHb, sO_2, tBili	100
pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct, (Capillary Device Only)	65 (Capillary Only)

Lithium Heparin Tube

(For laboratory staff only to analyse carboxyhaemoglobin from primary care requestors)

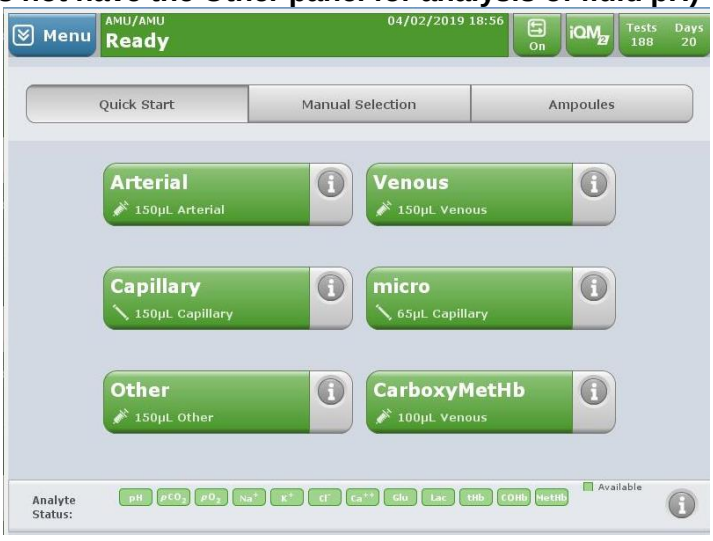
1. The request and specimen will be labelled in the Blood Sciences specimen reception following the department procedures. Once the request form has been scanned, verified and checked in the Pathology system, the labelled sample will be passed to the BMS working on the Manual/Bench section.
2. Before leaving the laboratory the BMS needs check the volume of blood in the lithium heparin tube. The sampling probe on the Gem 5000 cannot reach the bottom of a full sized LiHep tube and a small amount of the whole blood may need to be drawn up into a 2ml syringe (stored in the lab with other blood gas consumables) or transferred to a small tube/Hitachi cup (ensure to take a couple of pastuer pipettes from the lab to carry this out next to the analyser).
3. Carboxyhaemoglobin analysis is only activated on the analyser on Culm ward, AMU (MTU POCT room) and ED.
4. Fully mix the sample before transfer to an appropriate device ready for analysis, once the transfer has been made follow the instruction below for sample analysis.

Analysing a sample

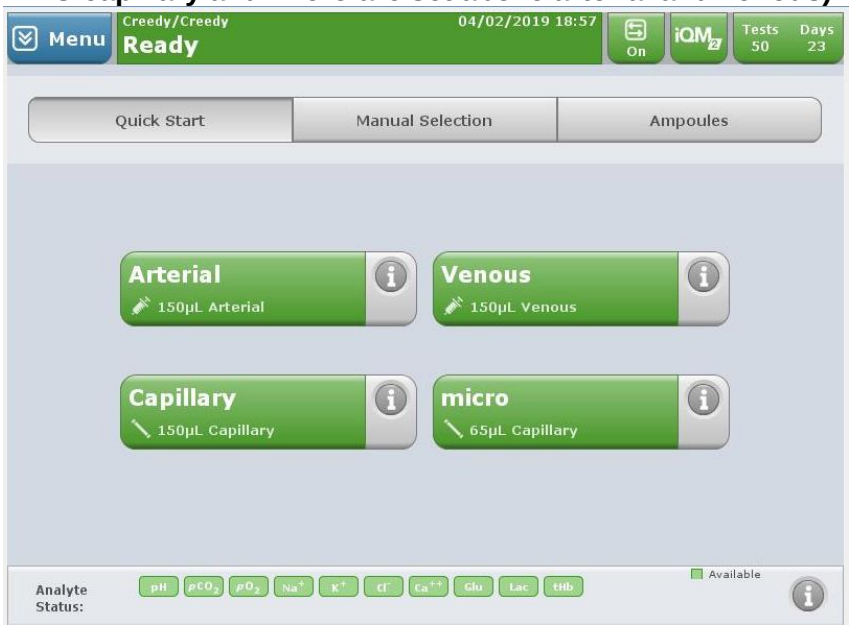
Gem Premier 5000 Screen layout

The illustrations below show the screen of the Gem Premier 5000 when the analyser is in ready mode.

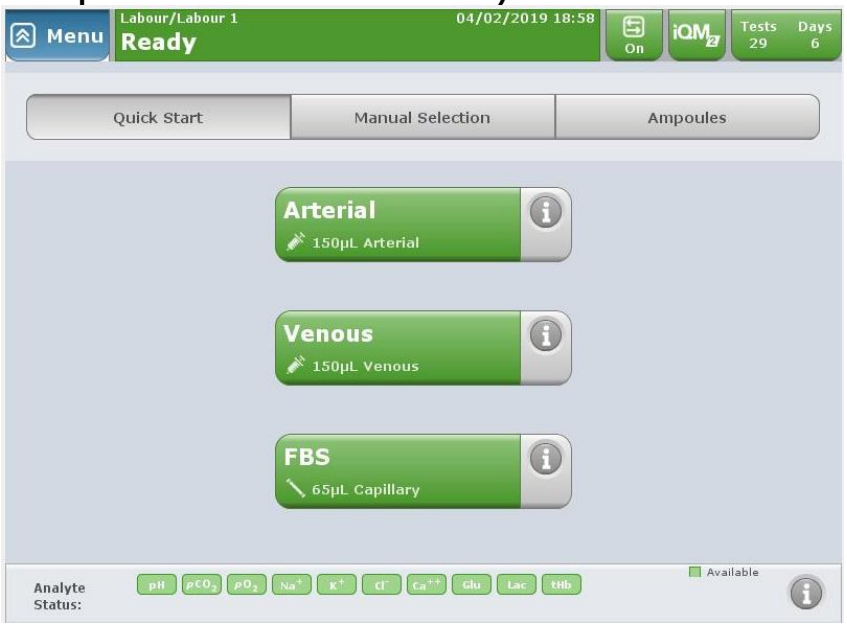
Quick start screen as seen in AMU/MTU, Culm and ED
(Note: ED does not have the Other panel for analysis of fluid pH)



Quick start screen as seen in Creedy, ITU and NNU.
(note: On NNU capillary and micro are set above arterial and venous)



Quick start screen as seen on both analysers in Labour ward
(note: the FBS panel does not contain lactate)



Changes in colour of the Status bar signals different conditions of the GEM Premier 5000 system:

Green	READY
Yellow	User specific action needed
Red	Analyzer is locked
Blue	Analyzer is performing a function

The Tests/Days button on the status bar help the user determine the status of the current GEM PAK inserted and how soon before a new PAK will need to be changed. This information will help you plan PAK changes at a convenient time.

Sample Analysis

Ensure the analyser is in ready mode denoted by the green status bar on the top of the screen. If the analyser is busy the analyser will state that it is "Processing" and the sample option buttons will be grey.

1. Select sampling mode i.e. arterial, venous etc. Micro sampling is applicable to capillary samples only and will not provide any co-oximetry results (note on Labour ward micro mode is called FBS, this panel does not contain lactate or co-oximetry)
2. Scan your operator ID barcode using the barcode scanner, press the W if it does not automatically scan.
   NB. Remember this is your PERSONAL assigned operator ID and is the only ID you should use and should not be shared, especially with untrained operators
   (All location with a GEM 5000 have key trainers, contact Clinical Chemistry for a list of key trainers via e-mail rde-tr.ChemMTO@nhs.net)
3. Present the sample to the probe and press "**OK**" to start sampling.
   - **Syringe sampling –** place the syringe over the end of the probe without touching the bottom of the syringe.
   - **Capillary tube –** Ensure you present the capillary with the sample at the end of the capillary. The probe will extend slightly; place the clean end of the capillary over the probe and ensure contact with the black luer but will minimal pressure. **Excessive pressure on the black luer can result in erroneous results.** Continue to hold the capillary during sample aspiration. **The analyser will discard samples presented with an air gap and/or air bubbles within the sample.**
4. An audio prompt will tell you when to remove the sample. Press "**OK**" to retract the probe. The sampler will automatically retract after 15 seconds if no action is taken.
5. Enter the required patient demographic information by touching the relevant field – an alphanumeric keypad will be displayed.

NB If a hospital number has not been created then leave this field blank and enter known information.

6. Any demographic field marked with a is mandatory and must be completed before the results can be viewed.
7. Press the **View Results** tab to view the patient results once the demographic fields have been completed correctly. These cannot be changed retrospectively by end users.
   If an error has been made in the patient demographics and accepted, contact Clinical Chemistry ext. 2938 with the sample details and ask for the record to be amended, an appropriate comment will be added to the system against this sample record.
8. When the system is finished analysing the sample the results will be displayed on the screen as shown below. The results for any samples run using the arterial mode will display on the screen using a colour key to represent: - normal (green), abnormal (yellow) and critically abnormal (red). For samples run in any other mode the results will all appear grey as no reference ranges are set in the system for these samples types.
9. The results will automatically print.

Sample disposal
Sample needles and capillaries should be discarded in sharps bins.
Plastic capped syringes may be disposed in yellow clinical waste bags (note not used on all wards) if the needle has been removed**.**

Gem Premier 5000 Results screen
(Note: results for samples run in arterial mode will display on the screen with ▲▼and a colour indication, white for results within the reference range, yellow for abnormal results and red for critically abnormal results, grey for any results where there is no set reference range. Results for samples run in all other modes will all appear on the screen with a grey background as there is no reference ranges set for these modes)

NB ANY UNEXPECTED CHANGES TO BLOOD GAS RESULTS WHERE THERE HAS BEEN NO CHANGE IN TREATMENT SHOULD BE CHECKED BEFORE ACTION IS TAKEN AS THESE MAY BE THE RESULT OF A POOR SAMPLE.

Unexpected results **MUST** be confirmed by sending the appropriate sample to Clinical Chemistry.
N.B. Sodium, Potassium, Lactate and Glucose are performed on whole blood on the GEM 5000 whereas the laboratory analyse serum. Please note there may be a difference between the results.

12. QUALITY CONTROL PROCEDURES

Intelligent Quality Management 2 (iQM_2) is used as the quality control and assessment system for the GEM Premier 5000 system. iQM_2 is an active quality process control program designed to provide continuous monitoring of the analytical process before, during and after sample measurement with automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, replacing the use of traditional external quality controls (QC).

iQM_2 performs 5 types of continuous, quality checks to monitor the performance of the GEM PAK, sensors, CO-Ox, and reagents.

These checks include System, Sensor, the NEW IntraSpect, Pattern Recognition and Stability Checks to ensure the delivery of quality patient results every time. iQM_2 utilises the various checks along with pattern recognition software to identify errors, initiate corrective actions, and document all steps in the corrective action process to assure regulatory compliance, while significantly reducing the time and cost required for performing traditional quality control.

Process Control Solution	Frequency	Function
A	Every 4 hours	Measures sensitivity, sensor drift and accuracy at medical decision levels* (MDLs) or clinical reference ranges.
B	Every 30 minutes or after each sample	Measures sensor drift and accuracy at MDLs or clinical reference range. Used as corrective action in high frequency after interference. Remains over sensors and with outputs checked every 30 seconds.
C	Every 24 hours	Measures low level pO_2, pH, pCO_2 for drift. Conditions the interference rejection membrane for glucose/lactate sensor.
D	Every 12 hours	Measures sensor drift and accuracy at MDLs and clinical reference range. Validates calibration (PCS values) and cartridge prior to sample analysis.
E	Every 12 hours	Measures sensor drift and accuracy at MDLs and clinical reference range. Validates calibration (PCS values) and cartridge prior to sample analysis.

Note: PCS values have been established to monitor all analyte-related MDLs. Many hospital protocols and treatment algorithms employ MDLs (e.g, Sepsis Guidelines for Lactate, ARDSnet and ALVEOLI guidelines for pO_2,). PCS MDLs for the GEM Premier 5000 system are based on Clinical Decision Levels for Laboratory Tests, 2nd Edition, Statland, Bernard, 1987.

The sensors are calibrated and monitored with five Process Control Solutions A, B, C, D and E. The Process Control Solutions (PCSs) are pre-tonometered to specific levels of pO_2 and pCO_2, and sealed in gas-impermeable foil laminate. Each PCS contain known quantities of the analytes and dyes tested using NIST traceable standards to establish target values for monitoring medical-decision levels and ensure accuracy of results, where clinical actions are necessary.

PCS target values were established to monitor medical-decision levels, clinical reference ranges, or normal clinical ranges and ensure accuracy of results, where clinical actions are necessary (table below).

Analyte	Units	A	B	C	D	E
pH		6.91	7.40	8.05	7.33	7.17
pCO_2	mmHg	65	33	33	25	75
pO_2	mmHg	120	180	3	43	85
Na^+	mmol/L	105	150	N/A	165	125
K^+	mmol/L	7.1	2.0	N/A	7.5	4.5
Cl^-	mmol/L	49	91	N/A	143	102
Ca^{++}	mmol/L	1.77	0.76	N/A	1.26	0.55
Glu	mg/dL	150	0	N/A	350	72
Lac	mmol/L	3.3	0	N/A	8.2	1.5
Hct	%	28	16	N/A	26	38
tHb	g/dL	14.2	0	N/A	7.3	16.5
O_2Hb	%	94.0	N/A	N/A	80.0	50.9
HHb	%	3.0	N/A	N/A	12.0	30.0
COHb	%	1.5	N/A	N/A	4.0	12.0
MetHb	%	1.5	N/A	N/A	4.0	8.0
tBili	mg/dL	20	0	N/A	10.0	20.0

iQM_2 control or “drift” limits are derived from the Total Allowable Error (TEa) criteria established by Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) for proficiency testing (see table).

Analyte	Total Allowable Error (TEa)*
pH	+/- 0.04
pCO_2	+/- 5 mmHg or 8%, whichever is greater
pO_2	+/- 9 mmHg or 10%, whichever is greater
Na^+	+/- 4 mmol/L within clinical range (120-160 mmol/L), 5 mmol/L outside clinical range
K^+	+/- 0.5 mmol/L or 7%, whichever is greater
Cl^-	+/- 4 mmol/L or 5%, whichever is greater
iCa	+/- 0.1 mmol/L or 10%, whichever is greater
Glucose	+/- 6 mg/dL or 10%, whichever is greater
Lactate	+/- 0.4 mmol/L or 15%, whichever is greater
Hct	+/- 4% absolute
tHb	+/- 0.7 g/dL for tHb < 18 g/dL and 1.0 g/dL for tHb >18 g/dL
O_2Hb	+/- 3% absolute
COHb	+/- 2% absolute
MetHb	+/- 2% absolute or 10% relative, whichever is greater
HHb	+/- 3% absolute
tBili	+/- 0.8 mg/dL or 20%, whichever is greater

*Note: TEa is equal to bias + 2 x imprecision.

iQM_2 Process

Upon manufacture at IL/Werfen and before sensor cards are assembled into GEM PAKs, every sensor is functionally tested for seven hours using solutions that are NIST-traceable. Sensors test results are documented by sensor card serial number and sensors that do not meet specifications are discarded. The unique and proprietary design of the sensor architecture allows for multiple hydration and drying stages without effecting sensor performance. This ensures that the quality of all sensors has been confirmed with NISTtraceable solutions prior to PAK manufacturing and clinical use. Every lot of PCS is tested and analyte values assigned, using NIST-traceable standards prior to assembly into GEM PAKs. PCS values are encoded electronically through an EEPROM chip on each PAK. Upon PAK insertion, the GEM Premier 5000 system reads and records all factory-assigned information, including lot number, expiration date, test menu, sample capacity and PCS assigned values and acceptable ranges. With the iQM_2 process the PCSs are exposed to the sensor and CO-Ox along the same fluidic pathway as patient samples, including the full extent of the sampler. iQM_2 is thus able to detect any obstructions or malfunctions originating from the sampler through the entire analytical pathway. After insertion of the GEM PAK into the analyser, PCS A, B and C are calibrated and the slope and intercept of the sensors are compared to factoryassigned values on the EEPROM. After performing PC Solutions A, B and C, the APV (Auto PAK Validation) process is automatically completed: two completely independent NIST-traceable solutions containing two levels of concentration for each analyte (PCS D and E), are run by the analyser to validate the integrity of the PCSs and the overall performance of the analytical system. APV must be acceptable prior to the GEM Premier 5000 system accepting patient samples.

iQM failures

Depending on the serverity of the failure the analyser will block or disable the analyte. If the analyte is block the analyser can be used (when in ready state) for sample analysis but the block analyte will be witheld from the report (note: if this analyte is required to calculate a dervied parameter this will report with a ‘?’ and no numerical result), the analyte will be shown as grey, yellow or red on the analyte status bar at the bottom of the Quick Start tab. In the background the analyser will be attempting to correct the iQM error. If the analyser is able to correct the error the analyte will return to green status and will report on all subsequent samples. The iQM error and resolution will be recorded electronically on the iQM report (this data is exported on a monthly basis by laboratory staff for audit purposes). If the failure is severe the analyte will be disabled and the only way to overcome this situation is to install a new cartridge, again the remaining analyte/s with a green status can continue to be analysed and reported. The decision to change the cartridge should be made by communication between the laboratory and ward staff. Any failed cartridges that are removed before the end of the on-board cartridge life need to be reported to the labrotory to ensure a refund claim is submitted to the supplier for the percentage of the cartridge not used.

13. INTERFERENCES

Flag Results for Interference and Micro Clots

When this option is enabled in Configuration, reporting of patient results will 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 (as set on the analysers across the RD&E)**, 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 flag.

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.

Condition	Result
Room Air Contamination	Samples having a very low or high pO_2 content or high HHb levels are especially sensitive to room air contamination. Similarly, pCO_2 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 hematocrit, total bilirubin and CO-Ox parameters if the sample is not properly mixed prior to measurement.
Not following Manufacturer's Instructions or Method Verification Protocols	Results obtained may be compromised.
Improper Installation	The instrument must be installed per the manufacturer's instructions. Failure to do so invalidates any warranty, explicit or implied.
Under-Heparinized Sample Due to Using Non-Heparinized Sampling Devices or Inadequate Mixing with Heparinized Devices.	Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinized.
Hemolysis	Hemolyzed samples may result in falsely elevated potassium levels.
Over-Heparinized Sample Due to under filling Heparinized Sampling Device or Transferring Heparinized Sample to a Second Heparinized Sampling Device	Over Heparinization can cause bias in Na+, iCa and Hct results.

Interference Testing Results

All Interference testing followed CLSI EP-7A2, "Interference Testing in Clinical Chemistry, Approved Guideline".

Table 1

Substances for which no interference was observed on EC

The substances listed in the Table 1 did not show noticeable interference with electrolyte analytes (Na^+, K^+, Cl^-, iCa) on the GEM Premier 5000 system when tested at the concentrations listed as per CLSI. Interference was tested on three different lots of GEM Premier 5000 GEM PAKs on 3 GEM Premier 5000 instruments.

Substance	Concentration	Tested analytes where interference was not observed
Acetaminophen	1324 µmol/L	Glucose, Lactate
Acetoacetate	2 mmol/L	Glucose, Lactate
Ammonium (Chloride)	107 µmol/L	Sodium, Potassium, Calcium
Aprotinin	50 mg/L	pH, pCO_2, pO_2
Ascorbic acid	342 µmol/L	Glucose, Lactate
Atracurium	50 mg/L	pH, pCO_2, pO_2
Benzalkonium (Chloride)	5 mg/L	Sodium, Potassium, Calcium
(Sodium) Bromide	37.5 mmol/L	Potassium, Calcium
Calcium (Chloride)	2.5 mmol/L	Sodium, Potassium
Chlorpromazine	6.3 µmol/L	Glucose, Lactate
(Sodium) Citrate	12 mmol/L	Potassium, Calcium, Glucose, Lactate
Creatinine	5 mg/dL	Glucose, Lactate
Dobutamine	2 mg/dL	Glucose, Lactate
Dopamine	5.87 µmol/L	Glucose, Lactate
Ethanol	86.8 mmol/L	Sodium, Potassium, Calcium, Chloride, pH, pCO_2, pO_2, Glucose, Lactate
Etomidate	50 mg/L	pH, pCO_2, pO_2
Fentanyl	.02 µg/ml	pH, pCO_2, pO_2
Flaxedil (Gallamine triethiodide)	5 mg/dL	Glucose, Lactate
(Sodium) Fluoride	105 µmol/L	Potassium, Calcium, Chloride, Glucose, Lactate
Fructose	1 mmol/L	Glucose, Lactate
Galactose	0.84 mmol/L	Glucose, Lactate
Glucose	1000 mg/dL	Lactate
Glycolic acid	1 mmol/L	Glucose
Halothane	759 µmol/L	pH, pCO_2, pO_2
Heparin	100,000 U/L	Sodium, Potassium, Calcium, Chloride, Glucose, Lactate
ß-hydroxybutyrate	2 mmol/L	Glucose, Lactate
Ibuprofen	2425 µmol/L	Sodium, Potassium, Calcium, Chloride, Glucose, Lactate
Icodextrin	20 mg/dL	Glucose, Lactate
(Sodium) Iodide	3 mmol/L	Potassium, Calcium
Ipratropium bromide	.08 mg/L	Sodium, Potassium, Calcium, Chloride
Isoniazide	292 µmol/L	Glucose, Lactate

Lactate	6.6 mmol/L	Glucose
Lithium (Chloride)	3.2 mmol/L	Sodium, Potassium, Calcium
Magnesium (Chloride)	15 mmol/L	Sodium, Potassium
Maltose	20 mg/dL	Glucose, Lactate
Mannose	20 mg/dL	Glucose, Lactate
Midazolam	.5 µg/mL	pH, pCO_2, pO_2
N-acetylcysteine	10.2 mmol/L	Glucose, Lactate
(Sodium) Oxalate	500 mg/dL	Potassium, Calcium, Chloride, Glucose, Lactate
(Sodium) Perchlorate	20 mg/dL	Potassium, Chloride, Calcium
pH (with HCl)	6.8	Sodium, Potassium, Calcium
Phenobarbital	431 µmol/L	pH, pCO_2, pO_2
pO_2	30 mmHg	Glucose, Lactate
Pralidoxime iodide	40 µg/mL	Glucose, Lactate
Propofol	0.05 mg/mL	pH, pCO_2, pO_2
Pyruvate	309 µmol/L	Glucose, Lactate
(Sodium) Salicylate	4.34 mmol/L	Potassium, Calcium, Chloride
Sodium (Chloride)	180 mmol/L	Potassium, Calcium
(Sodium) Thiocyanate	6880 µmol/L	Potassium, Calcium, Glucose, Lactate
Thiopental	248 µmol/L	Sodium, Potassium, Calcium, Chloride, pH, pCO_2, pO_2
(Sodium) Thiosulfate	20 mmol/L	Potassium, Calcium, Chloride
Triglycerides (as intralipids)	2%	Sodium, Calcium, Chloride
Urea	42.9 mmol/L	Glucose, Lactate
Uric acid	1.4 mmol/L	Glucose, Lactate
Xylose	20 mg/dL	Glucose, Lactate

Table 2
Interferences observed on Electrochemistry
The substances listed in Table 2 showed an interference with electrolyte analytes (Na^+, K^+, Cl^-, iCa) causing a clinically significant error (TEa). Interference was tested on three different lots of GEM Premier 5000 GEM PAKs on 3 GEM Premier 5000 instruments.

Substance	Analyte	Worst Case Test Concentration	Interfering concentration causing a clinically significant error (TEa)
Ionized Magnesium	Calcium	15 mmol/L	3.128 mmol/L
Triglycerides (Intralipid)	Potassium	2%	0.47%
Bromide	Chloride	37.5 mmol/L	1.346 mmol/L
Thiocyanate	Chloride	6880 µmol/L	388.3 µmol/L
Iodide	Chloride	3 mmol/L	0.700 mmol/L
Citrate	Chloride	12 mmol/L	4.083 mmol/L
Hydroxyurea	Glucose	0.8 mg/dL	0.41 mg/dL
Hydroxyurea	Lactate	0.8 mg/dL	0.37 mg/dL
Glycolic Acid	Lactate	1 mmol/L	0.240 mmol/L
Albumin	Hematocrit	60 g/L	43.92 g/L

* The GEM Premier 5000 system with iQM_2 employs failure pattern recognition checks. These checks include detecting the presence of positively charged lipophilic compounds (e.g., benzalkonium) and negatively lipophilic compounds (e.g., thiopental). The GEM Premier 5000 system offers the facility the ability to enable flagging of patient results if interference patterns for these compounds are detected

by iQM_2 at the time of result reporting. Even if the flagging option is not enabled, following the post analysis check, the operator is informed of the event. The operator must acknowledge the message before it will be removed from the screen.

Table 3

Substances for which no interference was observed on CO-Oximetry, tBili and Hct

The substances listed in Table 3 did not show noticeable interference with Co-Oximetry/ tBili/Hct analytes on the GEM Premier 5000 system when tested at the concentrations listed as per CLSI. Interference was tested on three different lots of GEM Premier 5000 GEM PAKs on 3 GEM Premier 5000 instruments.

Substance	Concentration	Tested analytes where interference was not observed
Bilirubin	20 mg/dL	tHb/Hb fractions
Biliverdin	4 mg/dL	tHb/Hb fractions, tBili
Evans Blue	10 mg/L	tHb/Hb fractions, tBili
Fetal Hemoglobin	75-78%	tHb/Hb fractions, tBili
Hemoglobin	20 g/dL	tBili
Indocyanine Green	10 mg/L	tHb/Hb fractions, tBili
Leukocytes	44.43 x 10^3/µl	Hematocrit
Methylene Blue	20 mg/L	tHb/Hb fractions
Platelets	785.0 x 10^3/µl	Hematocrit
Sulfhemoglobin	10%	tHb/Hb fractions, tBili
Tubidity (Intralipid)	1%	Hematocrit, tHb/Hb fractions

Table 4

Interferences observed on CO-Oximetry and tBili

The substances listed in Table 4 showed an interference with CO-Oximetry/tBili analytes causing a clinically significant error (TEa). Interference was tested on three different lots of GEM Premier 5000 GEM PAKs on 3 GEM Premier 5000 instruments.

Substance	Analyte	Worst Case Test Concentration	Interfering concentration causing a clinically significant error (TEa)*
Cyanocobalamin	tHb/Hb fractions	0.7 g/L	0.45 g/L
	tBili	0.7 g/L	0.26 g/L
Cyanomethemoglobin	tHb/Hb fractions	4%	3.80%
	tBili	4%	0.80%
Hydroxocobalamin	tHb/Hb fractions	1 g/L	0.34 g/L
	tBili	1 g/L	0.18 g/L
Methylene Blue	tBili	20 mg/L	7.1 mg/L
Turbidity	tBili	1%	0.94%

*Note: Results are flagged by IQM2 at the high turbidity, SHb, CNMetHb levels noted.

14. RESULT CALCULATION AND INTERPRETATION

(Band 5 and above – for laboratory staff. For samples analysed by non-laboratory staff – those staff grades able to interpret results to be agreed locally by each area/ward)

Results interpretation

The results produced by the Gem Premier 5000 for arterial samples are subject to reference ranges produced by the Clinical Biochemistry department (see section 13.1 below). In arterial mode, on the analyser screen, abnormal results will be flagged using a colour coded system, on the printout these are denoted by ↑↓ flags and the reference ranges will also appear on the printout. There are no established reference ranges for any other blood gas sample types.

Any result should be interpreted with caution and repeated when an exception flag is present. If the exception flag is present on the repeat analysis, take a fresh sample for analysis. If the exception flag is also present on the repeat freshly taken sample then contact the laboratory for further guidance.

14.1 Biological reference intervals/clinical decision values

Reference ranges for adult arterial blood gases only.
The following arterial ranges have been defined by the Clinical Biochemistry department for use on the Gem Premier 5000 blood gas analyser.

pH	7.35 – 7.45	pH
pCO2	4.6 – 6.4	kPa
pO2	11.0 – 14.4	kPa
Na^+	136 – 145	mmol/L
K^+	3.5 – 5.1	mmol/L
Cl^-	98 – 107	mmol/L
Ca^{++}(ionised)	1.15 – 1.33	mmol/L
$HCO3^-$	21 – 28	mmol/L
Glucose	3.6 – 5.3	mmol/L
Lactate	0.6 - 1.4	mmol/L
tHb	115 – 180	g/L
COHb	0.5 – 6.0	%
MetHb	0.0 – 1.5	%
sO2	95.0 – 98.0	%
Base excess	-2 – 3	mmol/L

14.2 Reportable interval of results

Measured Analyte	Units	Measuring Range *	Claimed Measuring Range **	Resolution
pH	n/a	6.00 to 8.50	6.80 to 7.92	0.01
pCO2	kPa	0 to 31.9	0.8 to 20.0	0.1
pO_2	kPa	-13.1 to 126.4	0.8 to 100.8	0.1
Na^+	mmol/L	55 to 220	100 to 200	1
K^+	mmol/L	0.0 to 27.5	1.0 to 20.0	0.1
Ca^{++} (ionised)	mmol/L	0.00 to 5.50	0.11 to 5.00	0.01
Cl^-	mmol/L	30 to 200	40 to 170	1
Glu	mmol/L	-1.1 to 111.0	0.2 to 41.6	0.1
Lac	mmol/L	-1 to 50	0.3 to 20.0	0.1
tHb	g/L	-50 to 300	30 to 230	1

COHb	%	-10 to 110.0	0.0 to 75.0	0.1
MetHb	%	-10 to 110.0	0.0 to 30.0	0.1

14.3 Determination of quantitative results if result not within measurement interval

Results outside of the measuring range of the analyser will be reported as less than the lower limit (<) or greater than the upper limit (>) of that analyte. Measuring range is shown in the table above under section 14.2 Reportable interval of results.

14.4 Alert/critical values

14.5 Laboratory clinical interpretation of Results

Fluid pH result interpretation

- pH <7.20 – indicative of an empyema requiring drainage
- pH 7.21-7.29 – indicative of a complicated parapneumonic effusion which may require drainage
- pH >7.29 – indicative of a simple parapneumonic effusion which usually responds to antibiotics

Carboxyhaemoglobin result interpretation

COHb%	Patient history/clinical effect
0.5 – 3.0	Non-smokers
Up to 10.0	Smokers
10	Shortness of breath on moderate exercise
20	Shortness of breath on vigorous exercise
30	Decided headache, irritation, fatigue
40-50	Headache, confusion, collapse. Fainting on exertion
60-70	Unconsciousness, respiratory failure > death if not treated
80	Rapidly fatal
>80	Immediately fatal

14.6 Potential sources of variation

- If pH reports with an exception, then results for pCO_2, $sO_{2(c)}$) and any derived parameter dependent on pH will not be reported. If sodium reports with an exception, then a Hematocrit value will not be reported.
- If pO_2 reports with an exception, then results for $sO2_{(c)}$ and any derived parameter dependent on pO_2 will not be reported.
- The standard bicarbonate equation uses the measured total hemoglobin (tHb), in g/dL, for current sample, if a measured tHb is not available then the calculated tHb is used.
- Capillary samples - excessive pressure on the black luer can result in erroneous results.

Factors that may adversely influence results

Room Air	Especially samples having a very low or high pO_2 content. Similarly, pCO_2 may be affected and subsequently pH and Ca^{++} results as well.
Metabolic Changes	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 hematocrit and CO-Ox parameters if the sample is not properly mixed prior to measurement.
Changes to Manufacturer's Instructions or Method Verification Protocols	Results obtained may be compromised.
Improper Installation	The instrument must be installed per the manufacturer's instructions. Failure to do so invalidates any warrant, expicit or implied.
Under-Heparinized Sample	Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinized.

Substances that may interfere

The following substances may show noticeable interference with certain channels on the Gem Premier 5000, causing falsely elevated results.

Substance	Affected Analyte	Substance Concentration Producing Interference
benzalkonium*	Ca^{++}	5 mg/L
bromide	Cl^-	10 mmol/L
Cyanomethemoglobin**	CO-Oximetry	>4%
dopamine	glucose, lactate	5 mg/dL
dobutamine	glucose, lactate	2 mg/dL
fluoride	Cl^-, lactate	500 mg/dL
glycolic acid	lactate	1 mmol/L
Hemoglobin Based Oxygen Carriers (Hemopure®***)	hematocrit	3.2 g/dL
hydroxyurea	glucose, lactate	0.8 mg/dL
iodide	Cl-	3 mmol/L
isoniazide	glucose, lactate	5 mg/dL
oxalate	Cl^-, lactate	500 mg/dL
salicylate	Cl^-	4 mmol/L
Sulfhemoglobin**	CO-Oximetry	>3%
thiopental*	pCO_2, Ca^{++}	30 mg/L
turbidity**	CO-Oximetry	5% based on turbidity created by Intralipid®**** fat emulsion
uric acid	glucose	20 mg/dL

*The Gem Premier 5000 analyser with iQM employs failure pattern recognition checks. These checks include the presence of positively charged lipophilic compounds (e.g. Benzalkonium) and negatively charged lipophilic compounds (e.g. Thiopental). The Gem premier 5000 analyser offers the operator the ability to enable flagging of patient results if interference patterns for these compounds are detected by iQM.

** CO-Oximetry interference is detected and flagged by failure pattern recognition checks.

*** Hemopure® is a registered trademark of Biopure Corp.

****Intralipid® is a registered trademark of Fresenius Kabi AB.

Substance	Affected Analyte	Substance Concentration Producing Interference
oxalate	glucose	1000 mg/dL
fluoride	glucose	500 mg/dL

LABORATORY PROCEDURE

15 REPORTING OF RESULTS
(Band 5 and above)

For results generated by ward based staff, follow local Trust policies on reporting point of care results into the patient notes/chart.

For results generated by laboratory staff that have been requested on the Pathology system need to be reported via Modulab, for both analytes. Phone all of these results to the original requestor or requesting location. Store the Gem 5000 printout in the monthly Manual/Bench results folder.

16 EXTERNAL QUALITY ASSURNACE (EQA)
(Band 3 and above)

Every analyte assayed on the Gem Premier 5000 blood gas analyser **must** be entered in at least one accredited External Quality Assurance (EQA) scheme for all reported analytes.

All blood gas parameters are entered in the RIQAS Blood Gas scheme and all Co-oximetry parameters are entered in the RIQAS Co-oximetry scheme.

- The Clinical Biochemistry Department will analyse the external QC samples once a month.
- There are no 'expected' values for the external QC samples.
- The sample is analysed according to RIQAS instructions, is treated like a patient's sample but analysed using proficiency mode (designed to protect the pO_2 electrode from the aqueous EQA solution used)
- The results will be downloaded via the GemWeb server by the Clinical Chemistry EQA Officer and uploaded to the RIQAS website.
- Any EQA returns graded as a poor performance will be notified to the Clinical Chemistry blood gas senior to investigate.
- Any long term performance issues will be reported to Werfen for guidance and investigation.

17 CHANGING A CARTRIDGE
(Band 2 and above)

Remove a cartridge only when it has reached its maximum use-life or test capacity. Cartridges **cannot** be reused once they have been removed. When a cartridge has reached its maximum use-life or test capacity, the door will open and display a message instructing you to remove the cartridge.

If a cartridge needs removing, due to an analytical failure before it has reached its full use-life, please follow the procedure outlined below.

1. Select "**Remove Cartridge**" from the **Menu** then **Actions** on the touch screen.
2. Enter password
3. Confirm that you want to remove the cartridge. Press **Yes**
4. The door will open slightly. Manually open it fully.

5. Taking hold of the cartridge, pull it towards you, removing it from the analyser.

Cartridge disposal

The cartridge contains bio-hazardous waste; therefore, ensure that it is disposed of in an appropriate manner by placing it inside two clinical waste bags.

Troubleshooting for cartridge removal

If an issue is encountered whereby the door becomes stuck this will result in the analyser becoming stuck in a cycle of attempting to eject the cartridge. To remove the cartridge in this situation the emergency door release catch can be used. To open the door manually use a thin card such as an ID badge and slide along the small but visible gap above the door from the top right hand corner, this will hit the catch to release the door. This problem should be reported to the laboratory so it can then be reported onto Werfen and an engineer visit can be arranged, if required.

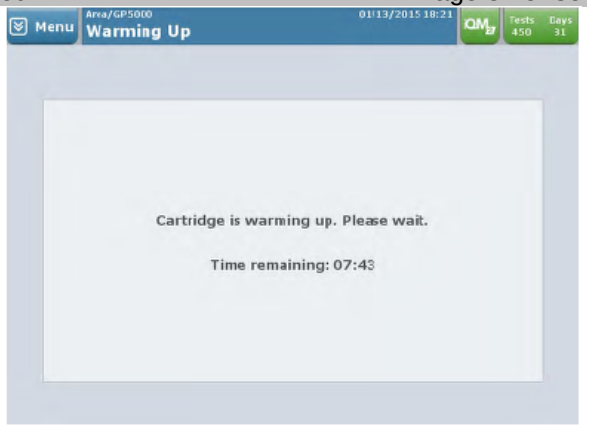
Inserting new cartridge

1. If required, press "**Open Door**" on the touch screen. The door will open slightly and the following screen will be displayed:

2. Manually open the door fully.
3. Remove the cartridge from its protective foil wrapper.
4. At the back of the cartridge remove the cover from the pump winding area.
5. Position the cartridge with the sampling area facing you.
6. Insert the cartridge until you feel resistance. About one inch of the cartridge will extend beyond the front (see following diagram):

7. Gently push the door closed.

In approximately 20 seconds, the analyzer will inform you that the GEM PAK is warming up. The clock will count down for the next 40 minutes as the GEM PAK warms up. During this time, the sensors will hydrate, and the analyzer will perform internal checks and processes.



After the warm up period is complete, the GEM Premier 5000 system will automatically perform calibration validation utilizing two (2) independent NIST-traceable on-board solutions called Auto PAK Validation or APV. Only after the APV process is successful can samples be performed on the selected analytes.

Once the AVP has been assayed and accepted there is no need to run internal quality control material through the Gem Premier 5000 as the system is regulated internally by the intelligent Quality Management (iQM™).

18 MAINTENANCE (changing paper & cleaning touch screen) (Band 2 and above)

Changing the paper

1. Press the tab on the top of the analyser to release the door
2. Remove the previous paper reel from the bottom of the compartment
3. Place the new roll of paper in the compartment so the paper unfurls from the bottom, pull the paper clear of the compartment
4. Press the door firmly closed
5. If no results are printed on the paper, remove the paper and replace in the compartment in the opposite direction (the printer paper is thermal and will only print on one side)

Cleaning the Touch Screen

1. Dampen a soft cleaning cloth with water or a mild cleaning solution.
2. Be sure that the cloth is only moist, not dripping wet.
3. Carefully wipe the face of the touch screen free of fingerprints and other smudges.

Warning - Do NOT use any abrasive cleaners or bleach mixtures as this will damage the screen!

19 DEEP CLEAN

The analysers **cannot** be left in situ during a deep clean. The deep clean process can cause problems with the internal mechanisms of the analyser and damage the cartridge installed at the time. The laboratory has access to the

deep cleaning schedule via the HUB and every effort will be made to contact the ward to arrange relocation of the analyser before the event is due to take place but ultimately it is the responsible of the ward staff to contact laboratory to ensure the require arrangements are in place before the deep clean commences.

Laboratory contacts can be found on the analyser.
From the home screen, press Menu > Help

20 REFERENCES

- Gem Premier 5000 iQM$_2$ Operators Manual P/N 00024019203 Rev 00. September 2015. [Copy available on Q-pulse]
- Tietz Fundamentals of Clinical Chemistry, 3rd Edition.

21 APPENDIX – ANALYSER ERROR CODES

Copy of analyser error codes from user guide, chapter 8, error code and operator messages. [Copy available on Q-pulse]

Error Codes Associated With System Malfunctions

Error Code	Cause of Error	Operator Message
201	Process Control solution 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	Sampler luer did not move into position	Sample probe error. Preparing for cartridge removal. Please wait.
222	Air detected within sample during aspiration	Insufficient sample. Repeat test.
223	Air detected within sample during post aspiration	Air detected within sample. Repeat test.
224	Insufficient sample volume for CO-Ox	Insufficient sample for CO-Ox. Repeat test.
230	Block temperature out of valid range	Temperature out of range. Analyzer will be shut down. Contact Technical Support.
236	Power supply voltage out of valid range	Power supply voltage error. Analyzer 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 failed	Cartridge error. Preparing for cartridge removal. Please wait.
264	CO-Ox integration time could not be set	CO-Ox hardware failure. Analyzer will be shut down. Contact Technical Support.
265	Reference voltage out of range	Reference solution not detected. Preparing for cartridge removal. Please wait.
266	Sensor polarization voltages out of range	Voltages out of range. Analyzer 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.

Error Code	Cause of Error	Operator Message
280	Diverter and/or mixing solenoid error	Valve error. Analyzer will be shut down. Contact Technical Support.
285	CO-Ox neon light calibration failure	CO-Ox hardware failure. Analyzer will be shut down. Contact Technical Support.
287	CO-Ox Initialization failure	Analyzer 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. Analyzer will be shut down. Contact Technical Support.
289	pO_2 mV is outside threshold when measured during Process Control solution C measurement during cartridge warm-up	iQM2 error for pO_2. Preparing for cartridge removal. Please wait.
300	The SBC board and CPU temperature is monitored. If the temperature rises to 70ºC, a warning is isused. The operator should check the analyzer 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 analyzer is shut down.	Analyzer temperature too high. Analyzer 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.
305	Overload detected on the CO-Ox USB port	CO-Ox port failure. Analyzer will be reset.
306	Memory error detected	Memory error. Analyzer 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 Can Occur On: Analyzer, Server or Both	Cause of Error	Operator Message
3001	Analyzer	The file system check, performed during startup, failed and could not self correct.	File system check error. System will be reset.
3002	Analyzer	The instrument software could not communicate to the FPGA (hardware).	FPGA communication error. System will be reset.
3004	Analyzer	FPGA (hardware) failed to initialize or reset.	FPGA error. System will be reset.
3006	Analyzer	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	Both	An error during a database operation.	DB error. System will be reset.
3008	Both	An error during a file I/O operation.	File I/O error. System will be reset.
3009	Both	User interface to Data Management Module communication error.	Internal communications error. System will be reset
3010	Analyzer	UI to DM communication error. This occurs on remote GWP only.	Server in unreachable. GEMweb Plus connection will be closed.
3012	Analyzer	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	Analyzer	More than 3 analyzer resets occurred.	Too many resets. Shutting down. Contact Technical Support.
3203	Analyzer	Problem accessing GEMweb Plus server.	This operation failed. Retry after server is available.
3205	Both	The system cannot perform the requested operation.	The system cannot perform the requested operation.
3206	Both	DM (Data Management) software error.	Internal DM software error. System will be reset.
3207	Analyzer	Problem accessing GWP server during installation setup of the client analyzer.	Cannot access server. System will be reset.
3208	Analyzer	Problem accessing GWP server when performing any operation on Remote GWP.	Operation failed. GEMweb Plus session will be closed.
3302	Analyzer	State timed out in GEMweb.	Operation failed. Please re-launch the application.