Witness Statement Ref. No. 180/1

NAME OF CHILD: Adam Strain

Name: David Wheeler

Title: Critical Care and Clinical Chemistry Business Manager

Present position and employer/institution:

Business Manager for the Critical Care and Clinical Chemistry Division

Instrumentation Laboratory UK Ltd,

Kelvin Close, Birchwood, Warrington, Cheshire WA3 7PB

Previous position and institution:
Senior Product Specialist for Critical Care Division

Membership of Advisory Panels and Committees:

Previous Statements, Depositions and Reports:

OFFICIAL USE:
List of previous statements, depositions and reports attached:

Ref:	Date:	

IMPORTANT INSTRUCTIONS FOR ANSWERING:
Please identify clearly and provide a copy of any document to which you refer or rely upon for your answer. Please provide your answer directly under the relevant question.

(1) Use of heparin with the IL Blood Gas Analyser machine 1400, serial number 89070125

Please explain the use of heparin in the testing of serum sodium in association with the IL Blood Gas Analyser machine 1400, serial number 89070125 including:

(i) The practice in 1995 and the form/type of heparin used

(ii) The current practice and the form/type of heparin used

(iii) If the current practice is different to that in 1995 then please explain what led to those changes and identify any published material where the reason for and the institution of such changes is addressed

Why and how heparin is used in the testing of serum sodium in association with the Machine, including what form the heparin would have taken in 1995.
Any serum sodium analysis on a blood gas analyser requires the sample to be heparinised. This is to stop the coagulation process.
Heparin acts as an anticoagulant because it catalyses the activation of antithrombin III. Due to heparin's activity as a catalyst, very little is needed, but it must be rapidly dissolved in the blood specimen to inhibit coagulation. Once the coagulation process begins, heparin cannot reverse the process. Therefore, it is essential that the sample be mixed thoroughly immediately after collection.

The recommended heparin in 1995 would have been Lithium heparin at a final concentration of less than 15 I.U. /ml of whole blood or lithium heparin balanced with calcium, potassium and sodium (balanced heparin IL P/N 98326-50) at a final concentration of approximately 20 to 50 I.U. /ml of whole blood are the only acceptable anticoagulants for blood gas, Na+, K+, Ca++ and Hct simultaneous determination.

Care should also be taken to avoid dilution effect caused by the anticoagulant solution. These effects are greater when the syringe is filled with less than the nominal volumes.

The pages from the operator's guide that details the choice of anticoagulant has been included *refer to document 1400 manual heparin.*

(2) Effect of the use of heparin on the operation of the IL Blood Gas Analyser machine 1400, serial number 89070125

Please explain what in 1995 was the likely effect of using sodium heparin on the results produced by the IL Blood Gas Analyser machine 1400, serial number 89070125 for serum sodium levels, including:

(i) The extent to which it affected the accuracy of the reading by comparison with the result from a Laboratory test

(ii) Whether the use of sodium heparin would have had a predictable effect, such as generally increasing or decreasing the value shown

The likely effect of sodium heparin on the results produced by the Machine in 1995 for serum sodium levels.

When blood gas analysis is combined with electrolyte analysis, syringes should provide a final heparin concentration of no more than approximately 20 IU/mL of blood, per the CLSI1 guideline.
IL does not recommend the use of sodium heparin as an anticoagulant, because doing so will increase sodium levels measured by 1 to 3 mmol/L even in the presence of the correct proportion of heparin and blood.

Whether the use of sodium heparin would have a set effect on the sodium result (i.e. always increase or always decrease the level) in 1995.

IL does not recommend the use of sodium heparin as an anticoagulant, because doing so will increase sodium levels measured by 1 to 3 mmol/L even in the presence of the correct proportion of heparin and blood.

(3) Information provided to operators on the use of heparin and the IL Blood Gas Analyser machine 1400, serial number 89070125

Please describe the information to those operating the IL Blood Gas Analyser machine 1400, serial number 89070125, including:

(i) The instructions that would have been provided both in 1995 and currently. Please identify and explain any differences between what was done in 1995 and what is done now

(ii) The training that was recommended in 1995 to properly operate it

(iii) The training that would have been provided both in 1995 and currently especially with regard to:
  (a) How the training was arranged and who was typically invited
  (b) How often the training was provided
  (c) The issues covered in the training and please provide any literature that you can in relation to 1995 training and current training

  Please identify and explain any differences between what was done in 1995 and what is done now

The instructions provided in 1995 to operators of the machine regarding the use of heparin and how those instructions were provided.

The instructions provided are detailed in the document 1400 manual heparin. Guidance to staff maintaining the machine would have been given at IL training seminars in Warrington.

The training that was recommended as in 1995 to properly operate the Machine.

IL recommended the uptake of training seminars in the recommended use of 1400 blood gas analyser. These training seminars were held in Warrington. This would have included

- Sampling techniques and heparin choice.
- Troubleshooting in the event of analyser breakdown.
- Preventative Maintenance.

Training would have included lecture and practical hands on sessions. Additional manuals and short form user guides would also have been provided.

(4) Results produced by the IL Blood Gas Analyser machine 1400, serial number 89070125

Please explain how and why the serum sodium results from a properly used IL Blood Gas Analyser machine 1400, serial number 89070125 would differ from those produced by Laboratory tests for both 1995 and currently, including:

(i) The speed and ease with which the results are produced from a sample
(ii) The level of accuracy, including whether the trend in any difference was typically in one direction and if so which

The speed with which the machine processed results for serum sodium from a sample in 1995.

Results produced within 60 seconds.

Heparin issue aside, the margin of difference on sodium results in 1995 between the machine and a laboratory test, including whether it was generally in one direction (i.e. producing lower or higher results for sodium than would be produced by a laboratory test)

All Instrumentation Laboratory point of care testing equipment is referenced to laboratory equipment. We would expect minimal margin of difference.
It is not possible to comment on any potential difference between laboratory test and the IL 1400.

(5) Any other points that you wish to make

THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed: D J Wheeler **Dated: 8th September 2011**

SELECTION OF THE SAMPLING SITE

The criteria that should be applied when making selection of the arterial sampling site are:

- presence of collateral blood flow
- vessel accessibility
- insensitivity of periarterial tissues

The radial artery at the wrist is the vessel that best meets these criteria and is usually indicated for drawing the arterial blood.
Other sites utilized in clinical practice are the brachial artery at the elbow and the femoral artery.

Although arterial blood is usually recommended for blood gas studies also capillary blood, if properly collected, is suitable for acid-base, oxygenation and electrolytes study. The capillary beds most frequently used for collection are the heel, the tip of the finger and the earlobe.
Proper procedure for capillary blood collection is reported inside the "Capillary Sampling Kit" (P/N 82590-00).

Venous samples, usually obtained from an anticubital vein, can supply reliable information on pH, pCO_2, electrolyte and hematocrit but should not be considered significant for oxygenation studies.

Mixed venous blood samples can be collected via catheter from the pulmonary artery and are necessary when carrying out the special parameter protocol.
Before sampling the catheter deadspace volume should be cleared of infusion liquid. During actual sampling blood must be withdrawn from the catheter slowly enough to prevent back-mixing of well oxygenated pulmonary capillary blood with the mixed venous one. A flow rate of 1 ml every 5 seconds can be taken as a guideline.

The type of sampling can be specified on the BGE print-out by means of the patient data input frame (see Section 3.2).

In case expired gas samples have to be analyzed a Douglas bag or anesthesia balloon supplied with taps to seal it should be filled with air expired from the patient.
An expired gas sample can be analyzed with the [GAS SAMPLE] key (see Section 3.5).

CHOICE OF THE ANTICOAGULANT

Lithium heparin at a final concentration of less than 15 I.U./ml of whole blood or lithium heparin balanced with calcium, potassium and sodium (balanced heparin IL P/N 98326-50) at a final concentration of approximately 20 to

50 I.U./ml of whole blood are the only acceptable anticoagulants for blood gas, Na^+, K^+, Ca^{++} and Hct simultaneous determination (12).

A slightly higher concentration of balanced heparin (50 to 70 I.U./ml of whole blood) may be used when sampling with capillary tubes.

A lower heparin concentration (less than 15 I.U./ml of whole blood) should be used when working with test tubes (which are only suitable for electrolytes determination).

The sampling process must be carried out properly, avoiding the aspiration of air bubbles that, if present, must be eliminated immediately.

Care should also be taken to avoid dilution effect caused by the anticoagulant solution. These effects are greater when the syringe is filled with less than the nominal volumes.

> CAUTION: Do not use anticoagulant other than lithium heparin or balanced lithium heparin at the proper final concentrations. Anticoagulants such as EDTA, citrate, oxalate may significantly alter pH, ionized calcium and hematocrit.

SAMPLE VOLUME

Minimum sample requirements:

- Normal sample in aspiration mode:	240 µl
- Micro sample in aspiration mode:	120 µl
- Expired gas sample in aspiration mode:	100 ml
- Syringe sample in injection mode:	300 µl

BLOOD COLLECTION WITH GLASS SYRINGES

Glass syringes must have a properly matched barrel and plunger to avoid binding.
The plunger and glass barrel should be lubricated to assure air tightness and reduce friction. Normally, the heparin used to coat the inner barrel surfaces and fill the needle deadspace will provide sufficient lubrication.

Use only enough heparin to wet the internal syringe surfaces and fill the deadspace volume.