STATEMENT OF WITNESS

STATEMENT OF: JOHN JAMES WILSON

Name *Rank*

AGE OF WITNESS *(If over 18 enter "over 18"):* OVER 18 - 24.8.47

To be completed when the statement has been written

I declare that this statement consisting of 4 pages, each signed by me is true to the best of my knowledge and belief and I make it knowing that, if it is tendered in evidence at a preliminary enquiry or at the trial of any person, I shall be liable to prosecution if I have wilfully stated in it anything which I know to be false or do not believe to be true.

Dated this 24 day of APRIL 2006

William R Cross

SIGNATURE OF MEMBER *by whom statement was recorded or received*

WILLIAM R CROSS, D/SERGEANT

PRINT NAME IN CAPS

John Wilson

SIGNATURE OF WITNESS

I am a Facilities Manager for Baxter Healthcare Ltd. In that role I am responsible for the development and management of renal units across all of Ireland, for Baxter Healthcare and in doing so in Northern Ireland I would work with the hospital trusts. I have been employed since about 1970 in the field of medical physiological measurement and I spent over 30 years in this field within the Health Service based in Intensive Care in the Royal Group of Hospitals. In November 1995 I was the Chief Medical Technical Officer for Anaesthetics, Theatres and Intensive Care for the Royal Group of Hospitals. As such, I was responsible for the development of a technical team, and for providing services to anaesthetists in both theatres and intensive care. I was therefore experienced in the measurement electronically of physiological parameters from about 1972. I have been shown a document by Detective Sergeant Cross marked WRC70. I can confirm that this is my report with my signature attached. Without sight of the report I have no personal recollection of the examination of the equipment, but upon reading it I now recall aspects of that examination and in particular the defective pins on the anaesthetic machine, which I had never encountered before. I can confirm that the Siemens Patient Monitor, which was present in the theatre on the 2 December 1995 was operating to within specifications. Prior to my examination I believe I

STATEMENT OF: JOHN JAMES WILSON

was informed there had been an incident but I was not given any specific details, but requested to test all the equipment in the theatre. I cannot confirm therefore that the Siemens Patient Monitor which I tested was the specific monitor used in any specific operation. I cannot confirm from memory any additional facts of my examination, other than those recorded in my report. I forwarded my report to Dr George Murnaghan as it was he who had requested my examination of the equipment. In response to questions from Detective Sergeant Cross, and from my knowledge and experience of the equipment in use in the operating theatre in November 1995, I can confirm the following. In my experience with adults when a chest x-ray demonstrated that a catheter had routed in the neck or the shoulder that was associated with an abnormally high CVP reading. I did not examine in my experience enough children's cases to be able to comment. I have examined today the trace recording CVP on a sheet marked Adam Strain. I note that the initial recorded CVP at the time the system was switched to the patient is about 17 mm Hg. I am surprised the reading in so high, and that it remained there. I note the calibration is checked within 15 minutes, again at 0900 hours, again at 0915 hours and again at 1000 hours. In the latter two cases, more time was taken in checking the calibration. I note in each case the trace returned to almost its previous reading and between calibrations the nature of the trace is as I would expect to see from a functioning transducer, although the levels which I see is elevated. I also note that the CVP trace rises in correspondence with a rise in the main arterial pressure. I see no evidence from the trace that the transducer was faulty. The procedure in relation to the use of transducers is that they are connected to the Siemens Patient Monitor, then fluid filled to ensure connection to the patient. They were positioned appropriately which is mid chest, then they are zeroed, as per the manufacturer's instructions. The transducer is opened to atmosphere, a button is pressed on the monitor which sets an electronic zone. The transducer is then calibrated, by this I mean the anaesthetist or the technician selected arterial or central venous pressure and a scale of mmHg was selected for display. An electronic calibration was then placed on the

STATEMENT OF: JOHN JAMES WILSON

transducer. These transducers were introduced to the Royal in the 1980s and are still in use today, indicating their reliability. In my experience, once a transducer had successfully zeroed and been calibrated, it was very unlikely to thereafter prove faulty. The other occasional fault I had seen was of an intermittent fault in a transducer which produced intermittent spikes in the trace and such a transducer would often lose its zero. I can see no such spikes on this trace. Once the zeroing and calibration were completed the transducer would then be switched to the patient and an immediate reading would be obtained. If during an operation there arose a doubt about the accuracy of the reading produced by a transducer there are a number of steps which could have been taken. Firstly, if there was a steady arterial pressure so that there were no concerns about the patient, it would be possible to switch the line from the CVP transducer to the monitor with the line from the arterial pressure transducer to the monitor, open both lines to atmosphere to reset zeros in both, then recalibrate both and examine the readings produced. This procedure would take about one minute. Having done this if the new CVP reading was the same as what had been seen previously that would demonstrate that the monitor is functioning properly. If there is a problem with an elevated CVP reading this would confirm that the problem now lies with the transducer or with the patient. As a second step I would remove the suspect transducer and replace it with a new one. The transducer used at that time, and up to the present day, were disposable so this was easily done. When the new transducer is attached, it must be zeroed and calibrated and a new reading is produced. If this reading is comparable to the one previously obtained then you have eliminated the monitor and the transducer as causes of the high reading, and the problem is confirmed to lie within the patient or catheter. To replace the suspect transducer with a new one and have the new one functioning would take about one minute. D/Sergeant Cross has asked me if it would have been possible to swap the two transducers in order to evaluate the readings they were producing. In my opinion that is possible but it is more practical simply to remove the suspect transducer entirely and replace it with a new one. The cost of a new

STATEMENT OF: JOHN JAMES WILSON

transducer is minimal so replacement is the best procedure. Prior to the use of disposable transducers CVP was measured by a manometer. It may also have been possible to check manually the CVP reading, however it is possible that the required manometer may no longer have been available to theatre in 1995.

Certified to be a true copy of an original signed document.

WRC 70.

REPORT ON EQUIPMENT USED DURING UNTOWARD INCIDENTS IN THE OPERATING THEATRES, RBHSC

Mr B. McLaughlin, Medical Technical Officer 4 and Mr J. Wilson, Medical Technical Officer 5 examined the anaesthetic, temperature control and monitoring equipment used in the theatre under investigation.

The investigation was carried out between 0900 hours to 1130 hours on Saturday 2 December 1995.

The equipment examined consisted of the following,
Lantec Anaesthetic Machine, Model 990-905, Serial No. 8704905089
Penlon Nuffield Ventilator, Serial No. 0387-06 fitted with either the NV200 valve, Serial No 33694 or the Paediatric valve, Serial No 432004.

Siemens Patient Monitor, Model 1281, Serial No.
(This monitor is currently out for repair - a new display screen is being fitted and a loan monitor is in use.)
Datex Ultima, Model ULT V-21-01, Serial No 31523.
Hudson Oxygen Analyser.

The Siemens Monitor measures vital signs including ECG, Blood Pressure, Temperature, Heart Rate and Respiration.

The Datex measures End Tidal Carbon Dioxide (ETCO2) and oxygen concentrations (FIO2) in the breathing circuit.

To assist in maintaining the patient's temperature an Aqua-K-Thermia Unit is used. A water blanket in placed below the patient and the circulating water kept at a suitable temperature to maintain body temperature. The patient's temperature in monitored on the Siemens monitor using a reusable general temperature probe.

All service reports pertaining to the equipment were examined and no indication of malfunction found in the documentation. The parts replaced are standard under preventative maintenance and functional checks. The service reports for the period under investigation are Ulster Anaesthetics Job No.DD833 and DD834 (Nuffield) and Anaesthetic Services 7524, 7212, and 6992 (Lantec).

A copy of the service report for the Siemens monitor is expected this week but verbal indications are that nothing untoward was discovered during its overhaul.

The Datex monitor is not on service contract but the calibration was checked and found to be satisfactory.

The Aqua-K-Thermia Unit is not on contract and as it is over 10 tens old does require regular maintenance and must be considered for replacement. It was difficult to assess its performance over a short period, but at the time of the investigation it appeared to work satisfactorily.

All monitor alarms worked and gave no cause for concern.

The Lamtec and Nuffield were set-up and connected to the test lung fitted with a Wright's Respirator and a Hudson Oxygen Analyser. Once a steady state was achieved the patient circuit was disconnected and the low pressure alarm became active within 20 seconds (as specification).

The steady state was again achieved and the oxygen pipeline supply disconnected causing the Alarm Whistle to be activated (as specification).

The standby oxygen cylinder fitted to the Lamtec was opened and the oxygen supply restored (as specification).

All cylinders were removed from the Lamtec, one nitrous oxide (N_2O), two medical air, one Carbon Dioxide (CO_2), one oxygen (O_2). The Pin Index System was checked for security. Five pins were discovered to be loose and could be removed. One on N_2O, both on the CO_2 and both on the O_2. This effectively removes an essential safety feature from the machine and allowed the investigators to fit the CO_2 cylinder in the O_2 yoke and supply CO_2 via the O_2 flowmeter.

At this stage the O_2 supply was still from the hospital pipeline system, that the valve system on the Lamtec should maintain. Instead the supply from the cylinder replaced the pipeline O_2 supply and the percentage oxygen in the breathing circuit fell from 50% to 11%. All anaesthetic machine and ventilator alarms were bypassed. The Datex monitor did function correctly and the high CO_2 and low O_2 alarms were activated.

It must be clearly stated that this could only be achieved by gross misconduct and failure to use the monitoring equipment.

The pins were re-inserted and the Lamtec put back to a safe working condition and again checked by a second person to ensure

correctness of gas delivery. The purity of oxygen was checked and also found to be satisfactory.

Examination of theatre practice would indicate that the cylinders are checked daily by the medical technical officer (MTO) on duty and the cylinders are only changed by the MTO. The Lamtec log book was examined and found to be signed daily prior to the commencement of the days list by the MTO after all safety and function checks were carried out satisfactorily. The Anaesthetist using the machine is also expected to sign the log before commencing the list but this does not happen on most occasions. A reason for this omission should be requested.

The anaesthetic machine is approximately 10 years old and has been regularly serviced by Anaesthetic Services. The last visit was on 12 September 1995. It is difficult to believe that 5 pins have come loose in 3 yokes in such a short time. This must be considered as a major omission on the part of the service company and requires investigation.

It is also essential that all cylinder yokes are replaced or repaired as a matter of urgency. A check of all pin index equipment within the Trust should be carried out forthwith to ensure the safety of such systems. This will include oxygen cylinders in use at ward level.

Finally it must be emphasised that the protocols and monitoring procedures set up within the RBHSC's Theatres, for more than 2 years, would have discovered if a reversal of cylinders had occurred. If these procedures had been ignored the following actions had to occur;

1. MTO did not check the anaesthetic machine
2. Anaesthetist did not check the anaesthetic machine
3. The fresh gas supply was not checked.
4. The Datex monitor was not used.
5. Poor tissue oxygenation was ignored by the Surgeon.
6. The pulse oximeter was not used.

The procedure for constructing arterial lines was examined and found to be satisfactory and in accordance with other areas within the Trust.

In conclusion the equipment was found to be in satisfactory condition. The current practices covering anaesthetic and monitoring equipment are safe and satisfactory.

E J Wh