STATEMENT OF WITNESS

STATEMENT OF: BRIAN FRANCIS McLAUGHLIN

Name *Rank*

AGE OF WITNESS *(If over 18 enter "over 18"):* 3.7.55

To be completed when the statement has been written

I declare that this statement consisting of 3 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 2 day of MAY 2006

William R Cross

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

WILLIAM R CROSS, D/SERGEANT

PRINT NAME IN CAPS

Brian McLaughlin

SIGNATURE OF WITNESS

I am presently Medical Technical Officer 5, which is Chief of Medical Technical Officer in the Anaesthetics, Theatres and Intensive Care Directorate at the Royal Hospitals, Belfast. In 1995 I assisted Mr Jim Wilson in the inspection of equipment. At that time I was Medical Technical Officer 4, in charge of the MTOs for Cardiac, Surgical, Intensive Care and Theatres. Dr Murnaghan requested Mr Wilson to examine the procedures and functions of the anaesthetic based equipment, the anaesthetic, temperature control and monitoring equipment in an RBHSC theatre. I accompanied Mr Wilson in conducting this examination. I recall that we came in on a Saturday and spent from 9.00 am to 11.30 am. The examination was conducted on a Saturday because there is a low usage of theatre on a Saturday. It was 2nd December 1995. I prepared with Mr Wilson a report on our examination. I have been shown a copy of this report by D/Sergeant Cross today, marked WRC70. This was signed by Mr Wilson and I concur with the content of that report. I can explain the following in response to questions by Detective Sergeant Cross. The Lamtec

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Anaesthetic machine delivers anaesthetic gases. The gases are usually oxygen (02) and nitrous oxide (N20), but medical air and carbon dioxide (C02) can also be delivered. The Nuffield Ventilator delivers the volume and the rates of breath to the patient. The Siemens Patient Monitor is a multi-parameter monitor for measuring patient physiology. This allows measurement of electro-cardiogram (ECG), temperature, arterial blood pressure (ABP), and central venous pressure (CVP). The heart rate is measured from the ECG by the Siemens Monitor and respiration rate is also measured. We highlighted in our report that the Siemens monitor (Lone unit0 that was present on 2nd December 1995 in the theatre was functioning within specification. However, we also highlighted that another Siemens monitor was out for repair in relation a new display screen. I would state that I did not know the reason for our examination of the equipment related to an operation on 27th November 1995 and therefore I cannot say with certainty that the Siemens Monitor which we examined was actually the monitor used on 27th November 1995 in an operation on Adam Strain. These monitors are not easily moved and are not routinely replaced unless they are defective. Therefore I would say from my experience it is very likely the monitor which we examined on 2nd December 1995 was the monitor used in theatre on 27th November 1995 unless records show that a monitor was removed from theatre RBHSC after 27th November 1995 and before 2nd December 1995. I can state that the monitor alarms can be set by the manufacturers default, or by department defaults or changed manually by the operator. I cannot state which of these alarm settings was in use during the relevant operation. There are a range of possible alarms which are auditory and visual. The alarms may include disconnect alarms, high and low limit alarms and life threatening

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alarms. The Datex monitor measured End Tidal Carbon dioxide and oxygen. Our examination found the machine to operate within specification. We found that should the pipeline gases have failed, backup cylinders would have been used and they operated correctly. However we were able with some difficulty to interfere with the pin system and cause a gas mismatch. This was a very remote possibility and should it have happened the monitors operated correctly and warned of the gas mismatch, showing an increase of carbon dioxide and a decrease in fraction of inspired oxygen (Fi 02).

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,
Lamtec 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 (FICO2) 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, 7232, and 6992 (Lamtec).

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 Lantec 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.