S4000 Project Update.

To : John Lamb. From : Simon Watmough. Date : 14 / 7 / '00.

Please find attached a copy of a memo given to Steve Nixon last week.

Following our meeting of 13 / 7 / 00 regarding the direction of the S4000 project, I am currently looking into the feasibility of squeezing the internal components of the S4000 into the largest DL type case with handle. The problems discussed in the memo of 5 / 7 / 00 still apply regarding the chassis design.

Questions.

Have we had dealings with a local metal fabrication company who would be capable of manufacturing the chassis design ?

Are we able to retain the transformer in the chassis (see diagram) ?

Can I speak to you regarding the questions above over the coming few days ?

S4000 Project Update.

To : Steve Nixon. From : Simon Watmough. Date : 5 / 7 / '00.

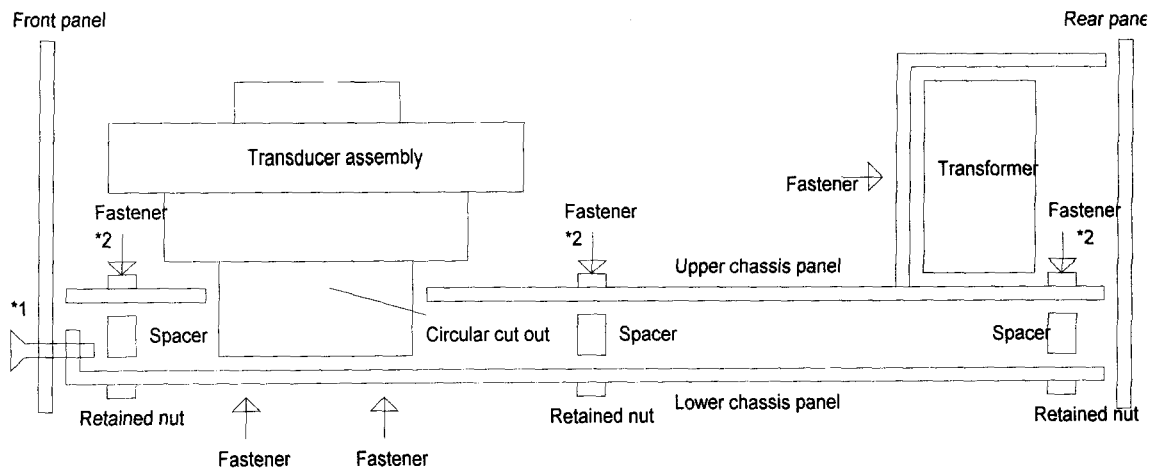
Sample DL-3000 type cases arrived from OKW. Largest one with handle is too small in width, next size up with no handle is equally too big. Have approached OKW for practicality of custom case, dimensionally half way between the above - seems no problem, will advise of cost. If this new case cost is reasonable, I can see no reason why the S4000 cannot be re-cased using the same layout of components as the original, possibly rearranging slightly (to a similar layout of the DL).

The only significant change will be the design of a new chassis, bearing in mind the foreseen problems detailed below :-

1. Lower casing panel is not strong enough to support the transducer assembly, therefore the chassis will have to support this weight, engaging into the lower side extrusion sub-rails. These rails will take approx. 1.5mm thick panels, ideally of aluminium but if this material does not prove strong enough, steel (or similar) will have to be used.

2. Rear panel screws on DL self tap into the side rail extrusions - the resulting threads are poor and degrade with repeated rear panel removal & fit. On new S4000 case, these screws cannot be relied on to retain the weight of the transducer assembly and /or transformer, when the unit is carried upside down by the handle. Chassis will have to retain the transducer assembly & transformer and be attached to the rear of the front facia panel.

Envisaged design of chassis.



Two panels, both inserted into the two slots in the lower sub-rail.

The lower chassis panel is clearance drilled to accept bolts retaining the transducer assembly. The front of this panel is lipped upwards and engages onto bolts passing through the front panel (*1 - top of bolts countersunk into front panel and beneath tactile facia / keyboard). It is clearance drilled to accept the PCB retaining bolts (*2 - 6 fasteners) and 3 fasteners down other side. Retained nuts for PCB retaining bolts are mounted on the lower surface.

The upper chassis panel has a circular cut-out to allow the transducer assembly to pass through it. PCB mounted on insulating spacers and retained using 6 fasteners, passing through this panel, spacers beneath and engaging into retained nuts in the lower panel. 3 similar fasteners in other side of chassis. Boxed area formed at rear, to accept mounting of transformer then flying leads to mains socket etc. on rear panel.

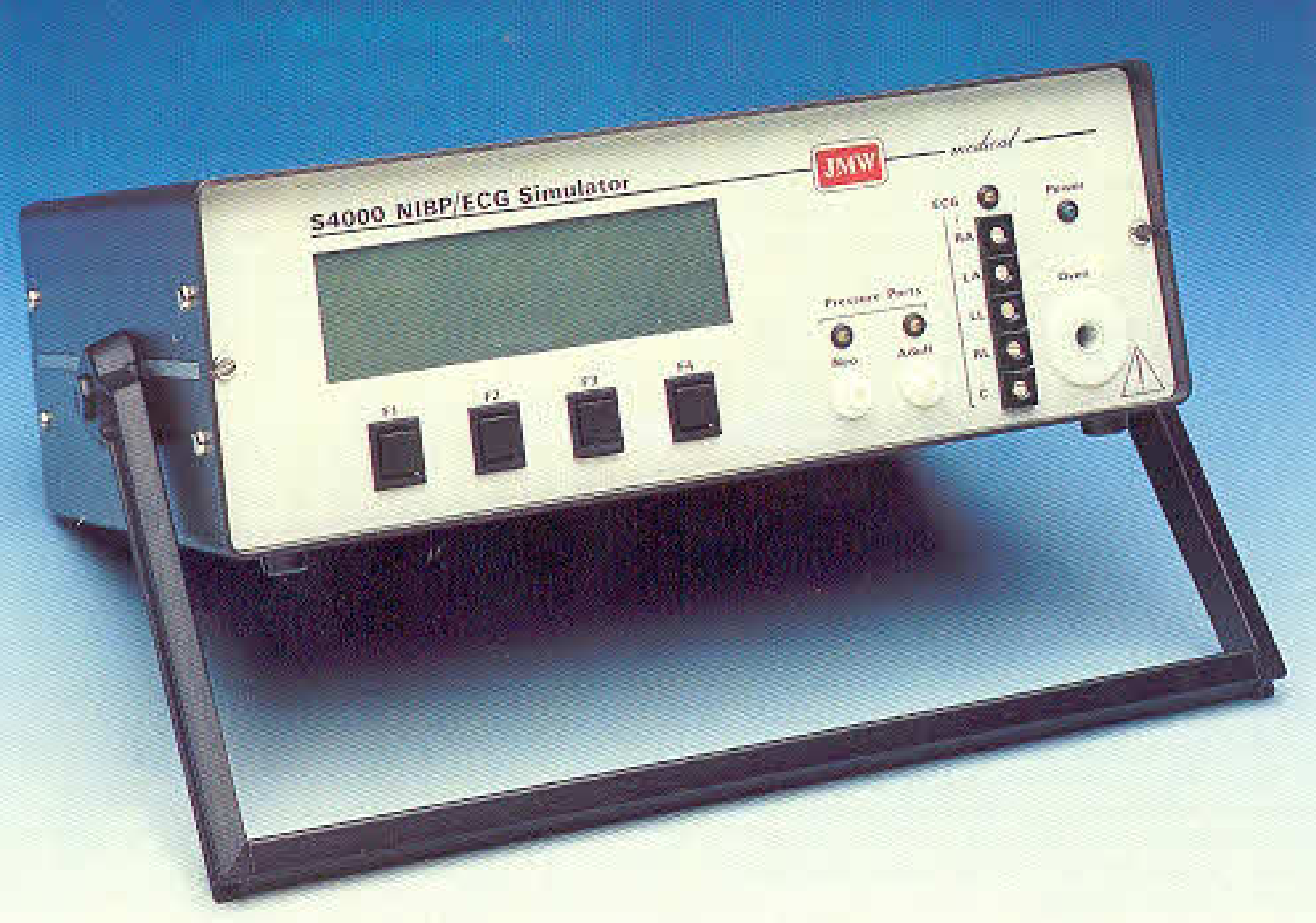
The combination of two panels held together with bolts and spacers should provide a rigid enough combination to support the transducer assembly. Lipped lower panel allows this panel to be inserted first and fastened to front panel. The lower panel then cannot move either forwards or rearwards. Upper panel can then be inserted and PCB / transducer assembly screwed in. This will unfortunately necessitate the removal of the lower enclosure case panel, unless cut-outs are formed in the upper chassis panel to allow the chassis lower panel to be secured whilst the upper is in situ (a similar gap may also have to be present in the chassis front area as access for tactile keyboard cabling).

Front & rear panels retained as per DL-3000 with 4 screws.

Other points which I feel may be benefitial to the final product are the repositioning of the ECG outputs to the rear panel (as the DL-3000 with coloured 4mm sockets), new facia similar to the DL-3000 & removal of ECG LED (?). Are 'keyboard' & 'serial interface' connectors / facilities required ? Does the new unit have to be mains powered (providing a handled case does imply portability) ?

Can you please leave a memo of your views on this, as I will not see you again before you return from your break.

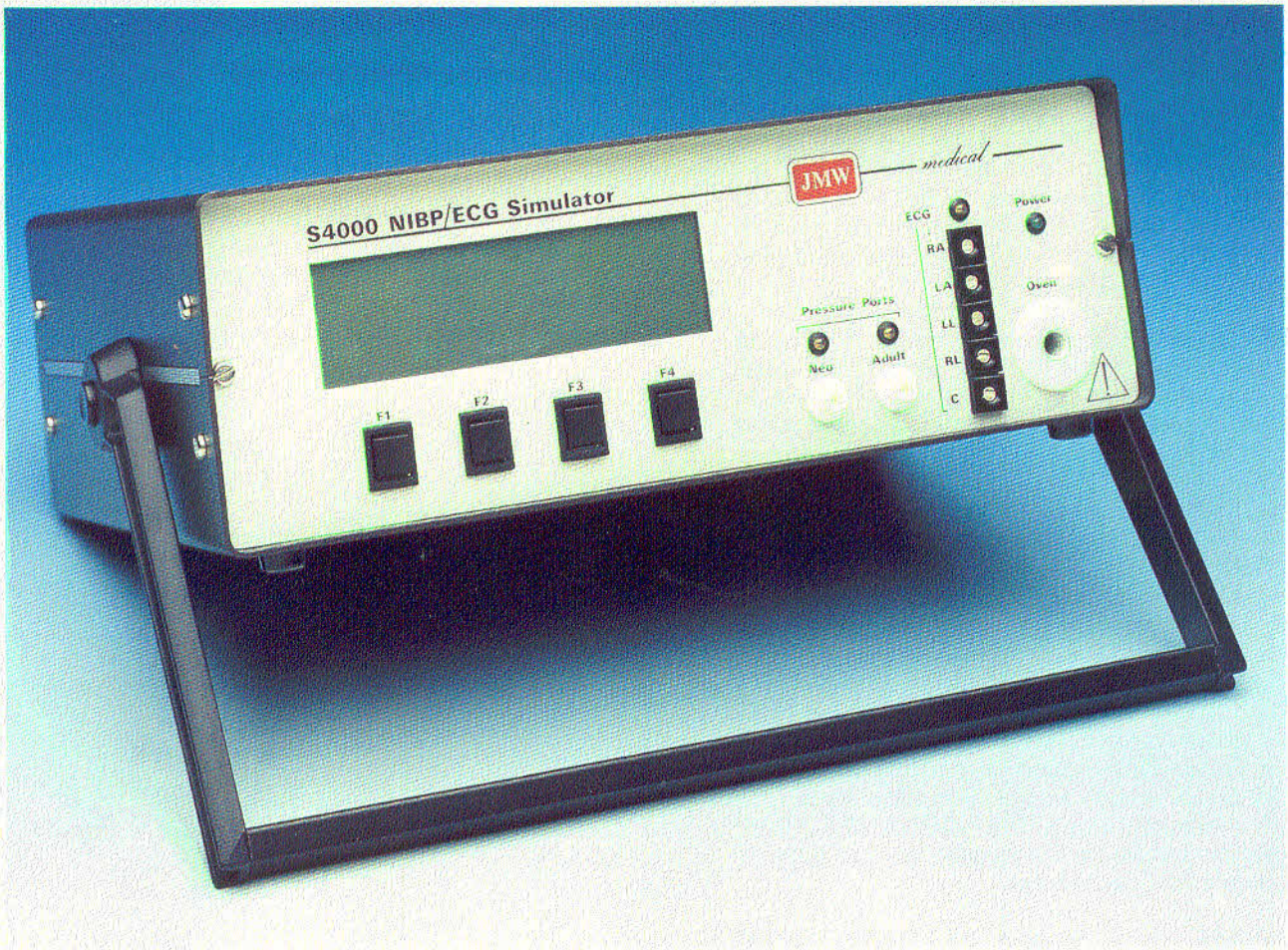
Questions on design procedures which may have been addressed during DL-3000 design phase : Are there laid down criteria which have to adhered to regarding EMC, component locations and fixing techniques (for transformer especially) or others factors for safety (physical or electrical) ?


S4000 NIBP/ECG Simulator
JMW
medical
ECG
RA
LA
LL
RL
C
Power
Pressure Ports
Zero
Adult
F1
F2
F3
F4

JMW systems

NIBP Simulator

NON INVASIVE BLOOD PRESSURE MONITOR TESTER



MAIN FUNCTIONS

* STATIC AND DYNAMIC TESTING OF NIBP/ECG MONITORS
* TESTS MONITORS SENSITIVITY TO WEAK PULSES
* DYNAMICALLY TESTS MONITORS AT PRE-SET BLOOD PRESSURE
* TESTS NEONATAL MONITORS
* INCORPORATES OVEN TO TEST TEMPERATURE PROBES
* PERFORMS TREND, LEAKAGE AND ALARM TESTS

MAIN FEATURES

* USER FRIENDLY MENU FORMAT
* RELIABLE AND ACCURATE MEASUREMENT
* BUILT IN ALGORITHMS FOR TESTING DIFFERENT MAKES OF MONITOR
* MEMORY FOR NAMED CONFIGURATIONS
* SYNCHRONISED ECG
* ON SCREEN WAVE FORM GRAPHS

NON INVASIVE BLOOD PRESSURE MONITOR TESTER

PRODUCT FEATURES

The NIBP SIMULATOR has been designed to test the function of Blood Pressure Monitors. Electrocardiograph (ECG) Monitors and Temperature Probes.

JMW Systems' NIBP SIMULATOR has an easy to use menu driven format with clear and simple functions.

The Trend Testing feature enables automatic checking of NIBP Monitors against a number of preset pressure values. This is an invaluable facility, especially when you are testing monitors with trend displays, as it allows a BP Monitor's ability to follow a changing BP to be observed. This feature is also ideal for Long Term Testing.

The Pulse Amplitude is adjustable via the front panel to test the sensitivity of a NIBP monitor to weak pulses. The amplitude adjusts from 100% down to 10% in 1% decrements with a switch on default value of 50% (0.500).

When selected the Calibration feature will statically test a NIBP Monitor against pressure generated by the NIBP SIMULATOR'S internal pump. Incorporated within the Calibration feature is a Digital Manometer facility used to verify the accuracy of a NIBP Monitor's pressure system.

The NIBP SIMULATOR includes a five lead ECG Output which is synchronised with the Blood Pressure Pulse. This enables the testing of Critical Signs Monitors which do not determine pulse rate from blood pressure alone. The NIBP SIMULATOR has a graphic screen for verification of the shape of the simulated ECG waveform.

Repeatability is a feature of JMW's NIBP SIMULATOR that makes it an essential piece of test equipment. The unit can be set for various Algorithms making it compatible with the different types of NIBP Monitors you will find on the market today. Additional Algorithms will be supplied free of charge as they become available during the first year of purchase. A small charge will be made in subsequent years for annual upgrades.

THE STANDARD DEVIATION OF TARGET VALUE OF THE NIBP SIMULATOR IS WITHIN 0.5% OR ±1, WHICHEVER IS THE GREATER. THE PULSE RATE IS ACCURATE TO ±1.

The NIBP SIMULATOR incorporates a Leakage Test which applies a known static pressure to calculate and display the leakage rate of the attached monitor or cuff.

B.P.'s AVAILABLE:
ADULT: 80/40, 100/60, 110/70, 120/80, 130/90, 140/100, 150/110, 160/120.
The Neonatal feature of the NIBP SIMULATOR when used in conjunction with a Neonate Cuff will produce a BP of 55/35 at 120 bpm.

PULSE RATES AVAILABLE:
40 TO 200 IN 5 BPM INCREMENTS.

Due to the unique (patent applied for) design the NIBP SIMULATOR can produce physiologically correct pressure pulses as demonstrated by the charts in figures 1 and 2 below.

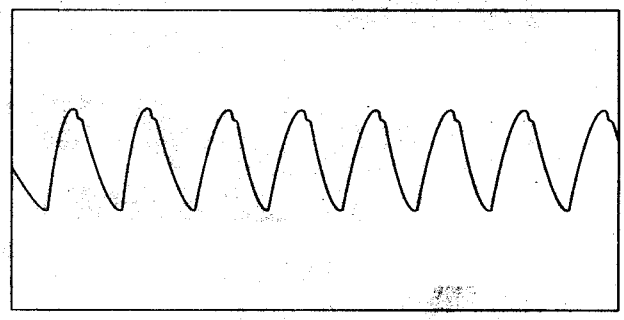


FIGURE 1 - S4000 NIBP Simulator Pulse.

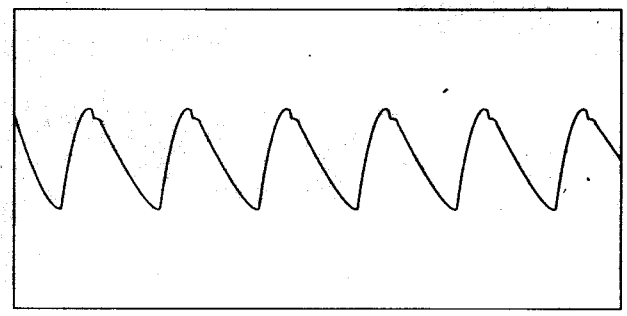


FIGURE 2 - Human Pressure Pulse produced in a Blood Pressure Cuff.

FUTURE DEVELOPMENTS: a further addition to the unit will be a Saturated Oxygen Monitor Simulator (SaO_2/SpO_2) with the ability to accurately test a complete SaO_2 Monitor including the probe. This feature will be available in due course and will allow this test unit to Calibrate and Test various kinds of medical monitors.

WHEN ORDERING PLEASE QUOTE "S4000"

JMW

JMW Systems Ltd.,

Systems House, Pentland Industrial Estate, Loanhead, Midlothian, Scotland. EH20 9QH
Tel: 0131 440 3633 Fax: 0131 440 3637

WHY NIBP SIMULATORS ARE A NECESSITY IN HOSPITALS

(File:WHYNIBP/Disk:NIBP SALES INFO)

Blood-pressure is one of the most important physiological parameters that can be measured in clinical situations and various automatic monitors have been developed to meet this requirement. These monitors use the NON-INVASIVE OSCILLOMETRIC method for determining BLOOD-PRESSURE.

This method involves the inflation of a cuff normally positioned around the patients arm. The pressure of inflation is increased to a value were the patients artery is occluded and no pressure pulses are detected in the measuring system. The pressure is then gradually released either in discrete steps or as a continuous linear bleed off, the monitor then detects and records the height of the small pressure pulsation's induced in the cuff by the patients pulsatile blood flow. The SYSTOLIC, DIASTOLIC and MEAN ARTERIAL blood-pressures are then calculated in conjunction with a mathematical algorithm and displayed on the monitor along with the patients PULSE rate.

Other monitor features available are:-

1. alarm thresholds for the above parameters which can be set by the user, which cause the monitor to issue an alarm condition if the patients BP or PULSE rate fall outside the set limits.

2. Automatic time intervals that can be set by the operator which determine how often a measurement is taken and repeated.

3.Trend recording enabling patient variations to be displayed over a selectable time period.

4. Mode selection to optimise measurement for adult, paediatric or neonatal patients.

These monitors are now used extensively by hospitals and clinics through-out the world for accurately determining patients blood-pressure. They are easy and quick to use and have the added advantage of the elimination of human error as was inherent when using the early mercury sphygmomanometers. Also they do not require doctors or nurses to be constantly at the bedside of the patient therefore enabling these important personnel to attend to other duties.

As can be seen from the above, the **correct operation** of these monitors is paramount, since clinical judgements are made and actioned based on the results obtained from these machines.

VERIFICATION OF MONITOR ACCURACY WITHOUT AN NIBP SIMULATOR

It is the responsibility of the hospital bio-medical technicians to accurately determine if an NIBP monitor is performing within the manufacturers specification, without the NIBP simulator the following tests can be performed:-

1.Leakage Test
The monitor under test is placed in the calibration mode and a known pressure is applied manually via an inflation bulb. This is then timed for one minute and the leakage rate calculated in mmHg/min if this is outside the manufacturers acceptable limits the leak is repaired.
The formula used for this calculation is:-

$$\textbf{LEAKAGE RATE} = \frac{\textbf{START PRESSURE - END PRESSURE}}{60}\ \textbf{(mmhg/min)}$$

2. Static Pressure Calibration
The monitor under test is placed in the calibration test mode and the pressure measurement system is vented to atmosphere, the zero is then checked and if necessary adjusted. Next a calibrated pressure gauge is connected in to the system and a pressure is applied manually via an inflation bulb, the pressure displayed on the monitor is then compared to that displayed on the gauge any differences are trimmed out using the monitors span potentiometer or by software control.

3. Over-pressure Release
All monitors have this built in safety feature, if for some reason the monitor fails and the pressure applied to the patient reaches a dangerously high value the excess pressure is released before any physical damage can be sustained by the patient.
This involves applying a pressure manually using an inflation bulb, in to the measuring system when the monitor is in the calibration mode.The pressure at which this release occurs is then recorded. This is then compared to the manufacturers laid down specification and if necessary adjusted.

4. Dynamic test
The final test to be performed by the technician is the dynamic test, this involves placing the cuff round the arm and taking a blood-pressure measurement.(HOW CAN This be regarded as a reference when the technician does not know what his **REAL BP IS!!!!)**

THE COMPREHENSIVE TEST OF MONITOR ACCURACY USING THE NIBP SIMULATOR

With the NIBP simulator the following comprehensive tests can be performed:-

1. Leakage Test
The monitor is placed in the calibration mode and connected to the NIBP simulator the leakage test facility is then selected on the simulator this causes the monitor measurement system to be automatically inflated by the simulators internal pump to a target pressure of 200mmHg.
On reaching this pressure the simulator begins a count down from 60 seconds, when the count down is finished the simulator calculates and displays the captured leakage rate which can then be compared to the manufacturers acceptable limits and if necessary the leak repaired. The advantage of using the simulator over other manual methods, is that the technician does not have to time the leakage test, or record the start pressure or end pressure. The simulator takes care of the inflation and then calculates and displays the result automatically.

2. Static Pressure Calibration
The BP monitor is placed in the calibration test mode and the pressure measurement system is vented to atmosphere, the zero is then check and if necessary adjusted.
Next the NIBP simulator is connected to the monitors pressure system and the auto-calibration facility is selected. The simulator can then be used to automatically inflate and display known target pressures, these can then be compared to the monitors display and if required adjustments to the monitor can be made.

3. Overpressure Release
This involves placing the monitor under test in to the calibration mode and connecting its pressure system to the simulator. The overpressure facility is then selected on the simulator. The monitor is then inflated automatically to the safety release pressure, this pressure is accurately captured and displayed by the simulator. If necessary adjustments sre made to the NIBP monitor.

4. Dynamic Test
The monitor is connected to the simulator and the simulation facility is selected along with the monitor type. A target BP simulation is then selected and the monitor is placed in the measurement mode, a determination is then started. The BP reading displayed by the monitor is then compared to the target selected, this enables a true physiological accuracy test to be performed.

5. Pulse Sensitivity Test
The parameter adjustment facility is selected on the simulator and a BP measurement is started on the monitor under test. The values displayed by the monitor are then compared to the target BP set on the simulator. The pulse height of the simulator is then gradually decreased down from 100% to the point were the monitor is unable to accurately determine the target BP. This value of percentage pulse height then gives

an indication of the monitors sensitivity relating to weak patient pulses. This is an important test since the monitor may perform accurately on a healthy technician but may fail in the clinical situation due to its lack of sensitivity.

6. BP Monitor Stability Test
A dynamic test is selected as in 4 above and the monitor is run continuously for a long period of time. The start BP is then compared to the end BP displayed by the monitor. If a significant variation between these values is detected, then this is an indication that the monitor under test is unstable when used over a period of time and this should be investigated and rectified. It is not practical for a technician to take multiple measurements of his blood pressure over a long period of time, besides his arm will ache. The BP monitor may give an accurate determination for a single BP measurement, but may be in-accurate when used for multiple determinations in the clinical area over a long period of time.

7. Trend Testing (for monitors with this facility)
For this test the Trend facility is selected on the simulator and the BP monitor is used to make multiple BP determinations over a long period of time. The resulting BP trends are then examined on the BP monitors display to determine if accurate tracking of bloodpressure is occurring. This feature of the BP monitor is used in the clinical area to determine the stability of a patient over a period of time. The only way to accurately check the monitors trend capability is the use of the BP simulator.

8. Alarm Threshold Test
This test is used to determine if a BP monitors alarm thresholds are functioning correctly. The monitors upper and lower alarm limits are set by the technician and target Blood-pressures and pulse rates outside these limits are selected on the simulator. A determination is then started on the monitor and the operation of these alarms is then verified .
Obviously the operation of these alarms in the clinical area is paramount and the only true way to test their operation is by using the simulator.

to be completed.....

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brookline, ma 02446 - usa
(tel) 617-277-6663
(fax) 617-277-2415
(e-mail) sales@morelusa.com

Company Profile

VIAMED

Certificate of Calibration.

Certificate No : 000000 1.	Date of Calibration : 11 / 11 / 99.	Page 1 of 3.

Submitted by :	**Clinical Equipment Management,** **St Bartholomew's Hospital,** **3rd Floor,** **Dominion House,** **West Smithfield,** **London,** **EC1A 7BE.**
Manufacturer :	**JMW Systems.**
Description :	**S4000 NIBP Simulator.**
Serial No :	**495070017.**
Condition prior to calibration :	**Casing dented and heavily marked.** **Right hand handle attachment missing.** **Facia covering marked on LCD window.**
Environmental conditions of test :	**Temperature 19 °C.** **Relative Humidity 53 %.** **Barometric Pressure 1029 mbar.**
Uncertainty of measurement :	**DC voltages : ± 0.025%.** **AC peaks : ± 3%.** **Temperature : ± (0.5% + 2).** **Pressure : ± (0.1% rdg + 1.5),** (Ambient Temp. : 20 to 30°C). **: ± (0.15% rdg + 2.25),** (Ambient Temp. : -10 to 50°C).

This is to certify that the equipment detailed hereon has been calibrated and now conforms to the manufacturer's published specifications and where applicable BS EN 61010, unless otherwise stated above.

All measurements made are traceable to NAMAS. These measurements are recorded and can be obtained by quoting the certificate number.

The Q.A. arrangements for the above are in strict conformity to BS.5750 / ISO 9001.

S Watmough I Eng., B Eng.

Smart
Funding Innovation

RS 28343 FS 28344

Viamed Limited, 15 Station Road, Cross Hills,
Keighley, West Yorkshire BD20 7DT
Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
Email: info@viamed.co.uk www.viamed.co.uk
BS EN ISO 9001 BS EN 46001
Registration No 12917565 in England

Safety Test.

Description :	S4000 NIBP Simulator.
Manufacturer :	JMW.
Serial No :	495070017.
Class :	I.
Type :	B.

Checks.	Limits.	Result.	
Mains supply voltage.		234V.	
Insulation resistance : mains to case.	1Mohm ± 15%.	Infinity.	Pass
Protective earth continuity.	0.1 to 0.2 ohms.	<0.1 ohms	Pass
Earth leakage current.	500µA.		
Normal.		<50.	Pass
Reverse.		<50.	Pass
Earth leakage current : open supply.	1000µA.		
Normal.		0.	Pass
Reverse.		<100.	Pass
Enclosure leakage current - normal.	100µA.		
Normal.		<1.	Pass
Reverse.		<1.	Pass
Enclosure leakage current - open ground.	500µA.		
Normal.		<50.	Pass
Reverse.		<50.	Pass
Enclosure leakage current - open supply.	500µA.		
Normal.		0.	Pass
Reverse.		0.	Pass

Note.

Safety Tester used (Rigel Type 233) is "indication only. Before release of the equipment to the user, please reassess with a calibrated safety tester.

Test Results Sheet : S4000 NIBP Simulator.

Calibration Certificate No.	Unit Serial No.	Engineer.	Date.
0000001	495070017	S Watmough	11 /11/ 99.

Test.	Check 1.	Check 2.	Initials.
Fit / Remove Test EPROM.	-----	-----	SW
Inspection.	-----	-----	SW.
TP1 : +5V ± 0.3V.	+5.054V	—	SW.
TP2 : +12V ± 0.3V.	+12.196V	—	SW.
TP3 : -12V ± 0.3V.	−12.083V	—	SW.
TP5 : +5V ± 0.001V.	+5.015V	5.000V	SW.
TP6 : 0.000V.	−0.027V	0.000V	SW.
TP9 : $10V_{p-p}$ triangular.	±5V	—	SW
TP10 : $10V_{p-p}$ triangular.	±5V	—	SW.
TP8 : $28V_{p-p}$ triangular.	−14.5 → +13.5V	—	SW.
TP7 : 4.00V ± 0.1V.	+4.025V	4.000V	SW.
TP13 : -7.5V ± 0.5V.	−7.792V	—	SW.
Heater : 37.4 ± 0.2°C.	37.75°C	37.4°C	SW.
Pressure : 300 ± 1mmHg.	299/300	—	SW.
Pressure : 200 ± 2mmHg.	199/200	—	SW.
Pressure : 100 ± 2mmHg.	98/101	—	SW.
Leakage at 200mmHg.	4mmHg/min		SW.
Switches & Display Check.	OK	-----	SW
ECG Waveform Functions.	ATTACHED	-----	SW.

30-Jul-99

	Hospital	Serial No	W/O	Invoice	Date	Comments
v	Scrapped	493110001				
	Given to Colin	493110002		None found		
i	MOD RAF Lyneham	494010003	23609	5532	29.09.94	
i	George Elliot	494030004	23484	5535	29.09.94	re cal 16.08.95 25901/6393
i	St John's	494030004(5)	22655	5024	16.03.94	re cal 03.11.95 26548/6662
i	North Devon	494030006	24817	5929	07.03.95	re cal 21.06.95 25364/6231
i	North Devon	494040007	24556	6000	31.03.95	
i	James Paget	494040008	24160	5711	14.12.94	
	Not Made	494060009				
i	Raigmore	494040010	24753	5996	31.03.95	re cal 17.06.95 27924/7231
	Not Made	0011				
	Not Made	0012				
i	Worcester Ri	495030013	24982	5997	31.03.95	
i	St Georges	495030014	24978	5955	23.03.95	
i	Kontron	495070015	25181	6341	25.07.95	
i	Kontron	495070016	25182	6371	30.07.95	
i	St Bartholomew	495070017	25632	6568	12.10.95	re cal 25.01.96 27208
i	Withington	495070018	27007	6960	22.02.96	
i	Broomfield	495070019	2956	7897	26.03.97	
i	Royal London	495070020	25603	6594	17.10.95	
i	Hartlepool	496030021	27641	7060	29.03.96	
i	Beneden	496030022	27399	7061	29.03.96	
i	Thameside	496030023	27836	7187	28.05.96	
v	Scrapped	496030024	356 or 26913			
i	Hull RI	497080026	30054	8266	18.09.97	