The Performance of Non-Invasive Blood Pressure Vital Signs Monitor

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Abstract
Health care providers are beginning to realize that maintenance of medical equipment alone without assuring proper calibration of these equipment may not be sufficient enough to ensure proper function, adequate and reliable measurements. Un-calibrated medical equipment may lead to imprecise measurements that will have a significant negative impact on the quality of health care and increase health care cost by subjecting patients to excessive medical treatment. The objective of this study is to measure the performance of Non Invasive Blood Pressure for Vital Signs Monitor by using Fluke Biomedical ProSim™ 8 Vital Signs Simulators. The Study refers to the technical standard BS ISO 81060-2 states for systolic and diastolic blood pressures, the mean value of the differences of the determinations shall be within or equal to ± 5 mmHg for the criteria of deciding the PASS/FAIL. The performance tests of 125 vital signs monitor were performed at site in different medical department of hospital. The selection of the department and the equipment were random as per the availability, the test is performed by teams of qualified engineers. The sequence of test cycle includes: Visual inspection, Electrical Safety Testing and Performance Test. In our Results, most of the equipment failed in Visual inspection because of minor defects, the failing equipment represent 35% of the total 125 vital signs monitors, the percentage of the equipment's failed in Electrical Safety test is 6% and the equipment that did not meet the criteria of standard and failed in performance test is 71%.

Keyword -Non Invasive Blood Pressure; Vital Signs Monitor; quality control chart ;Performance Test.

El rendimiento del monitor de signos vitales no invasivos de presión arterial

Resumen
Los proveedores de atención médica están comenzando a darse cuenta de que el mantenimiento del equipo médico solo sin garantizar la calibración adecuada de este equipo puede no ser suficiente para garantizar el funcionamiento adecuado, las mediciones adecuadas y confiables. El equipo médico no calibrado puede llevar a mediciones imprecisas que tendrán un impacto negativo significativo en la calidad de la atención médica y aumentarán el costo de la atención médica al someter a los pacientes a un tratamiento médico excesivo. El objetivo de este estudio es medir el rendimiento de la presión arterial no invasiva para el monitor de signos vitales mediante el uso de los simuladores de signos vitales Fluke Biomedical ProSim ™ 8. El estudio se refiere a la norma técnica BS ISO 81060-2 para presión arterial sistólica y diastólica, el valor medio de las diferencias de las determinaciones debe ser dentro o igual a ± 5 mmHg para los criterios de decisión del PASS / FAIL. Las pruebas de rendimiento del monitor de 125 signos vitales se realizaron en el sitio en diferentes departamentos médicos del hospital. La selección del departamento y el equipo fueron aleatorios según la disponibilidad, la prueba la realizan equipos de ingenieros calificados. La secuencia del ciclo de prueba incluye: inspección visual, prueba de seguridad eléctrica y prueba de rendimiento. En nuestros resultados, la mayoría de los equipos fallaron en la inspección visual debido a defectos menores, los equipos defectuosos representan el 35% del total de 125 monitores de signos vitales, el porcentaje de fallas en la prueba de seguridad eléctrica del equipo es del 6% y el equipo que no Cumplir con los criterios de estándar y fallido en la prueba de rendimiento es del 71%.

Palabra clave - presión arterial no invasiva; Monitor de signos vitales; tabla de control de calidad; prueba de rendimiento.
1. Introduction

Blood pressure (BP) measurements are used for diagnosis, determination of prognosis and for initiating, evaluating and several medical treatments. As the use of non-invasive blood pressure (NIBP) monitors becomes more widespread, so an adequate training of all the personnel and the standardization of the involved equipment is necessary to minimize the major sources of uncertainty that contribute to variations in BP measurement, and may adversely influence clinical treatment decisions. The standardization should include: selection of BP measuring equipment, proper maintenance, calibration, instruction and accreditation of the measurement techniques of all personnel directly involved in BP measurement [1]. The auscultator and oscillometric procedures are well known non-invasive methods. The mainstream of non-invasive automated BP measuring devices now are implemented on the Oscillometric techniques, which registers the oscillations in the cuff pressure during the cuff deflation and thus systolic, diastolic, MAP (Mean Arterial pressure) and pulse are determined using a mathematical algorithm. This means that algorithms used by different manufacturers can produce different results from device to device [2]. NIBP simulators are used in clinical environment for quick checks of blood pressure monitors as a part of technical maintenance and health-care quality assurance system. They are also included in various tests within the procedures for testing NIBP monitors [3]. This study is intended to test the Performance of Non-Invasive Automated Blood Pressure Measuring Devices. Specifically, this study will address the blood pressure measurement differences between the various commercially available vital signs monitor and The Fluke Biomedical ProSim™ 8 Vital Signs Simulators. By comparing the obtained results produced by the Vital Signs Monitor to settings on NIBP simulators and its compliance with the set requirements and regulations according to the technical standard BS ISO 81060-2 states for systolic and diastolic blood pressures, the mean value of the differences of the determinations shall be within or equal to ± 5 mm Hg (± 0.67 kPa), with a standard deviation not greater than 8 mm Hg (1.07 kPa). This applies to the results from a clinical trial protocol when evaluating the accuracy of the blood pressure algorithm in a population of subjects [4]. Nevertheless, we used these criteria to define the upper and lower control limit to build quality control chart. A control chart is a useful tool for monitoring process variation. Monitoring the performance of equipment with control charts help us catch conformance-related problems relating to the measurement in a proactive way before the problem really becomes a problem. It also provides assistance in quantifying drift when used with other statistical tools, and provides guidelines on determining calibration intervals [5].

2. Method

The method used to test Non-Invasive blood pressure by applying Non-Invasive Blood Pressure Simulators according to The Fluke Biomedical ProSim™ 8 Vital Signs Simulators Operation Manual and The Inspection and Preventive Maintenance System (IPM) procedures which were developed by Emergency Care Research Institute (ECRI) [6, 7]. The performance tests of total 125 vital signs monitor were performed at site in different medical department of hospital. The selection of the department and the equipment were random as per the availability, the test is performed by teams of qualified engineers who visited selected departments in the hospital and performed the test for the randomly selected equipments. The sequence of test cycle might include: Visual inspection, Electrical Safety Testing and Performance Test. The process of visual inspection is to ensure that the medical equipment in use still conforms to the specifications as released by the manufacturer and has not suffered from any external damage and / or contamination. The electrical safety tests assuring that equipment is safe and functional delivers the expected performance within specified parameters. Therefore, recurrent electrical safety test is to verify that current flows only where it is designed to flow, and leakage current with in permissible range. The test equipment (ProSim 8) that we used, have number of Physiological simulations can be used to set all the simulation functions at one time. We use the normal, hypertensive, hypotensive to test the Performance of NIBP Vital Sign Monitor for this study so as to cover all the parameter range.

2.1 Data collection

To perform the test, connect a hose and cuff to the NIBP monitor. Place the cuff around a piece of PVC pipe or other sturdy cylindrical object to simulate placement on a limb. Connect a piece of tubing to the pressure port on the ProSim™ 8. Connect a tee to this tubing and attach tubing and connectors. Connect the two legs of the tee between the hose and the cuff of the NIBP monitor as shown in Figure 1.
- Check the physical condition of the device to make sure device is clean and decontaminated and no physical damage to case, display, mounts, cart or components etc.
- Check the electrical safety of the equipment, Measure ground wire resistance, chassis leakage and current leakage to patient leads if applicable.
- Obtain Readings. Place the NIBP monitor into the normal operating mode.
- From the home screen select the predefined simulation sequence for Hypertensive Simulation on ProSim™ 8.
- Start an NIBP pressure cycle on the monitor. Refer to the monitor manual as necessary.
- After you start the blood pressure measurement cycle: The blood pressure cuff inflates around the mandrel and simulator starts the peripheral pulse simulation when the pressure is 10 mmHg.
- Heart beat simulation starts when the pressure equals the diastolic pressure set into the simulator.
- The NIBP monitor interprets and shows the measured blood pressure values and heart rate when the test stops.
- Record the reading value for all parameter, Compare the NIBP monitor values with the target values.
- Repeat the steps for Normal and Hypotensive simulation.

3. Results
The analysis of the results obtained by the ProSim™ 8 fluke biomedical equipment is presented. The results are related to the perform testing of the NIBP Monitor. The Study refer to the technical standard BS ISO 81060-2 states for systolic and diastolic blood pressures, the mean value of the differences of the determinations shall be within or equal to ± 5 mm Hg for the criteria of deciding the PASS/FAIL. In our analysis, most of the equipment failed in Visual inspection because of minor defects, the failing equipment represent 35% of the total 125 vital signs monitor like leak in BP Cuff, damaged/worn insulation SPO₂ sensor cable, Defective SPO₂ sensor/BP Cuff etc. These items are replaced by another one to complete the test sequence. The percentage of the equipment’s failed in Electrical Safety Test is 6% and was due to defective power cords or high protective earth resistance. These power cords were replaced by another one prior to completing the test sequence (Performance Test). The Major defect if verified are noted and handed over to the concerned for necessary repair and documented in the report and the test was aborted thereafter. The equipment that did not meet the criteria of standard and failed in performance test is 71%. The results were summarized in Table 1.

<table>
<thead>
<tr>
<th>Number of Total Vital Sign Monitors</th>
<th>Sampling Size</th>
<th>(%)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>625</td>
<td>125</td>
<td>Test</td>
</tr>
<tr>
<td>Visual Inspection</td>
<td>65</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>Electrical Safety</td>
<td>94</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Performance</td>
<td>29</td>
<td>71</td>
<td></td>
</tr>
</tbody>
</table>

When closely analyzing the results of the Performance Verification, it is understood that majority of vital sign monitors have failed due to inaccuracy in the NIBP measurements. And most of the time the measured values have increased to a higher degree more than the allowed tolerance (>10 mmHg).The analysis results obtained were given in graphics as control chart (Figures 2-4).

Fig. 2 shows the systolic pressure (120 mmHg) performance test result, by setting control limits (CL) is 120 mmHg, lower control limits (LCL) is 115 mmHg.
5mmHg) and upper control Limits (UCL) is 125mmHg (+5mmHg) to accept the result of performance test.

Fig. 3 shows the diastolic pressure (80 mmHg) performance test result, by setting diastolic control limits (DCL) is 80 mmHg, diastolic lower control limits (DLCL) is 75 mmHg (-5mmHg) and diastolic upper control Limits (DUCL) is 85 mmHg (+5mmHg) to accept the result of performance test.

Fig. 4 shows the mean arterial pressure (93 mmHg) performance test result, by setting control limits (CL) is 93 mmHg, lower control limits (LCL) is 88 mmHg (-5mmHg) and upper control Limits (UCL) is 98 mmHg (+5mmHg) to accept the result of performance test.

4. Discussion

The performance test of NIBP monitors are required to be evaluated or tested in accordance with the manufacturer’s instructions and international standard. The ProSim™ 8 is designed to mimic the dynamic nature of patient NIBP and produce a stable live subject response to the cuff during the measurement cycle; therefore it is possible to use a simulator to determine the repeatability and agreement of these monitors. It is assumed that if the NIBP measured and displayed on the patient monitor matches the simulated Pulse Rate, Systolic/Diastolic, and MAP numeric, and if these fall within the accuracy range specified by the manufacturer and technical standard BS ISO 81060-2, then the performance must be acceptable. For this reason more than one group of simulator settings, including both healthy and disease state affected simulations, are included in the performance testing. By analyzing results obtained, we found that the algorithms used by some manufactures have acceptable results compared to the test equipment, so it is always within the criteria limit. And other results differ significantly compared to the test equipment. But for the errors resulting from the air leakages, plastic broken inside the hose connector and cuff damaged can be solved through preventive maintenance schedule and corrective maintenance. Based on the results obtained and the interpretations derived to ensure that performance testing is necessary for patient care, accuracy of results and economic feasibility, we can stress on the need to standardize the measurement methods used in testing blood pressure, and its urgency to avoid controversy over the accuracy of the results obtained.

The results obtained comparing with others results.

A study performed by Sezdi (Sept. 2013), to investigate the performance of the medical devices by analyzing the problems of the medical devices that do not meet the international standards. The data used in this study were obtained by interpreting of the performance test results of medical devices. The performance tests of total 542 medical devices were performed and the measurement results were interpreted according to the Inspection and Preventive Maintenance System (IPM) procedures which were developed by Emergency Care Research Institute (ECRI). This study showed that the controlling of the performance of the medical devices especially the high risk group medical devices in the hospital will be helpful in quality assurance studies. As a result of this, a preventive maintenance program was created. Thus, predicting the problems before they happen and stocking required spare parts were made possible. Additionally, the analysis of the medical devices according to the manufacturer helped decide the during the purchasing of the new devices [9].

A study performed by MHRA(Dec 2013) concluded that all blood pressure measuring equipment should be regularly checked and calibrated in accordance with the manufacturer’s instructions. These maintenance recommendations vary depending on the type, frequency and location of use. Excessive air leakage from damaged cuffs, hoses and tubing connectors may reduce the accuracy of the readings. Particular concern over the lack of maintenance of blood pressure measurement.
devices, both in the community and acute hospital settings, has been highlighted. Faulty cuffs, hoses, aneroid gauges and mercury manometers can all lead to erroneous blood pressure measurements, with significant effects on patient care. Healthcare organizations have a responsibility to ensure that adequate maintenance arrangements are available \[10\]. CAS Medical Systems Inc. (May, 2013). Non-invasive blood pressure simulators are excellent tools for verifying a host of safety and performance requirements that NIBP monitors approved for clinical use must meet. In the area of blood pressure simulation, it is not the absolute agreement between the oscillometric blood pressure monitor and an NIBP simulator that matters, but how repeatable the results produced by the monitor under test are when using the simulator. With each manufacturer using different criteria to calculate the systolic and diastolic pressure values, it is unreasonable to expect a single NIBP simulator to achieve universal agreement with all clinically approved oscillometric blood pressure monitors \[11\]. D Prakash (June 2015) indicated that it is not mandatory to inflate higher cuff pressure to adult patients because it can be best decided by diagnoses based on health condition and totally a medical concern. However if the target cuff pressure is less than the systolic pressure, the super STAT algorithm is capable of inflating the cuff pressure over the systolic and produce NIBP automatically. Eventually this paper defines that selecting a suitable cuff pressure will produce more accurate readings \[12\].

5. Conclusion

We studied the Performance of Non-Invasive Automated Blood Pressure in vital signs devices through apply The Fluke Biomedical ProSim™ 8 Vital Signs Simulators and procedures used in test is designed from the Simulators Operation Manual and IPM procedures which were developed by ECRI. Results were analyzed according to technical standard BS ISO 81060-2 and control chart for monitoring process variation. Been reached that devices that are compatible with the simulators algorithm results are often acceptable and the devices that are not compatible with the simulator results are unacceptable. And that based on the results obtained in 27% of devices were acceptable and 71% were rejected their results. Therefore, we recommend that further studies in order to obtain standardized method of measuring blood pressure test and avoid the issue with results accuracy of the test consequence difference in methods used by each manufacture.

References


When Compared Against Various Commercially Available NIBP Simulators.