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The impact of calibration on medical devices performance and patient safety.

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Abstract

Hospitals and health care providers are striving to reduce health care cost without compromising the quality of health care and appropriate medical diagnosis. They are becoming more aware of the importance of medical devices calibration in their health care facilities, and the impact it has on both the quality of health services provided to the patients, and patient's safety. Healthcare providers are beginning to realize that the maintenance of medical devices alone, without assuring proper calibration, may not be sufficient enough to ensure proper function, adequate and reliable measurements. Accurate and reliable measurements are crucial for appropriate medical decisions. On the contrary, un-calibrated medical devices may lead to imprecise measurements. These measurements will have a significant negative impact on the quality of the healthcare provided to patients and might increase the healthcare cost by subjecting patients to excessive medical treatment. The study was conducted on a representative sample of 20.5% from total asset (1034) of high risk medical devices representing 6 devices categories. The objective of this study is to examine the impact of calibration of medical devices on performance and patient's safety by investigating devices performance against international standard reference or manufacturer recommendations. 34% of the sample failed the visual test, 5% failed the safety test, and 58% failed the performance test. However, it is important to note that there was no death or serious incidents associated with these devices. In conclusion, these devices do not meet the international standard and continued use of such devices can compromise patient's safety.

Keywords: Patient's safety, Performance, Calibration, Medical devices accuracies.

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Introduction

The medical devices industry has grown rapidly and incessantly over the past century. The sophistication and complexity of the designed instrumentation is nowadays rising and, with it has also increased the need to develop some better, more effective and efficient maintenance processes, as part of the safety and performance requirements [1]. For the health industry, be it hospitals or manufacturers of medical devices, nothing counts more than the safety of a patient [2]. Therefore all quality conscious hospitals consider the periodic testing and calibration of devices, a permanent feature in their quality control regimen that they strictly adhere to. It is a significant mark to their dedication and commitment to quality and continuous improvement. Testing and calibration of devices ensures accuracy, effectiveness in diagnosis and treatment and long life of devices, which ultimately enables one to achieve the highest degree of quality control and patient safety. Medical errors are a recognized cause of harm in the health care system, but clinical measurement errors are seldom, if ever, identified as causes of adverse events [3]. In recent years, a growing number of patients have suffered from adverse events due to medical devices malfunction [4]. In addition to knowledge and experience of medical doctors, correct diagnosis and appropriate patient treatment largely depend on accuracy and functionality of medical devices. In a large number of serious medical situations, devices proper functionality of medical devices is crucial for patients. Therefore it is necessary to carry out as strict and independent testing of functionalities of medical devices as possible and to obtain the most accurate and reliable diagnosis and patient treatment [5]. The objective of this paper is to examine the impact of calibration on medical devices performance and patient's safety by investigating the performance of selected sample of medical devices against international standard reference or manufacturer recommendations.

Methodology

This research is designed to determine the clinical significant of un-calibrated medical devices in health care facilities. Further, the research will investigate and evaluate the activities

of medical devices function against standard reference. Due to the impact of medical devices bad performance on patient's safety and the quality of health services provided to patients, the main target here is patient safety and medical devices performance. The test is performed on site in different clinical departments of a major hospital in Saudi Arabia. The department and devices were selected randomly as per their availability. The concept of research project design and methodology are shown in Figure 1.

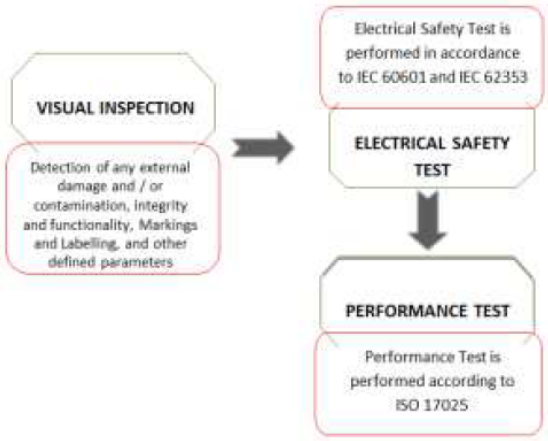

Figure 1. *Research design flowchart.*

The study was conducted on a representative sample of 21% from total asset (1034) of high risk medical devices representing 6 devices categories. The devices are infant incubators, transport incubators, warmers, defibrillators, electrocardiogram (ECG) and vital signs monitor. Each of the devices under test (DUT) was subjected to a sequence of tests in accordance to IEC60601, IEC 62353, and ISO 17025 [6-8]. The sequence of test cycle include: visual inspection, electrical safety testing and performance test. The process of visual inspection is not clearly defined by IEC 60601, however it is a relatively easy procedure to make sure that the medical devices in use still conforms to the specifications as released by the manufacturer and has not suffered from any external damage and/or contamination [9]. These can include the following inspections: housing enclosure, contamination, cabling, fuse rating (check correct values after replacement), markings and labelling, and Integrity of mechanical parts.

Electrical safety test is performed in accordance to IEC 60601 and IEC 62353. Performance Test is performed according to international standards or manufacturer recommendations by using the suitable calibrated and traceable standard reference(s) or test devices [10,11]. Both the safety and performance of the DUT will be subjected to assessment based on technical comparisons against international standards or manufacturer recommendations, which sets the limit for pass and fail acceptance criteria [12-21]. The limit used to decide the DUT pass/fail criteria is shown in Table 1. The test is performed by ISO 17025 certified biomedical engineers, who are also certified by Fluke biomedical advantage training on the use of test equipment. The test equipment used is calibrated and is shown in Table 2. These test equipment were found to meet Fluke biomedical manufacturing specifications as per the test equipment calibration certificate.

Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibrations standards are measured against in-house performance standards using accepted test procedures. The results obtained from the test equipment are recorded in a hardcopy checklist and at the same time, a copy of the electrical safety automatic test sequence is saved in the analyzer and later printed and attached to the hard copy reports to guarantee the data traceability with electronic archival system.

Table 1. *Pass/fail criteria.*

Measurements	Standard	Limit	
Incubator IEC60601-2-19/60601-2-20		**Baby**	**Transport**
Sound level	201.9.6.2.1.101	≤ 60 dB	≤ 60 dB
Stability of temp	201.12.1.101	± 0.5°C	± 1.0°C
Uniformity of temp	201.12.1.102	± 0.8°C	1.5°C
Skin temp	201.12.1.103	± 0.3°C	± 0.3°C
Accuracy of indicator	201.12.1.105	± 0.8°C	± 1.5°C
Temp control accuracy	201.12.1.106	± 1.5°C	± 1.5°C
Overshoot	201.12.1.108	≤ 2°C	≤ 2°C
RH accuracy	201.12.1.109	± 10%	± 15%
Air flow	201.12.1.111	≤ 0.35 m/s	≤ 0.35 m/s
Radiant warmers			
Distribution accuracy	201.9.6.2.1.102		± 2°C

Operating accuracy	201.12.1.103	± 0.5°C
Skin sensor accuracy	201.9.6.2.1.101	± 0.3°C
Vital signs		
ECG rate	Fluke biomedical	± 5%
Respiration rate	Fluke biomedical	± 5%
NIBP	IEC 80601-1-2-30	± 10 mmHg
SpO_2	ISO 80601-2-61:2011	± 3%
Defibrillator		
Paddle continuity test	Fluke biomedical	≤ 0.15 Ω
Heart rate accuracy	Fluke biomedical	± 5%
Recorder speed	Fluke biomedical	± 4%
Testing energy	Fluke biomedical	± 15%
Energy after 60 s of full charge	Fluke biomedical	≥ 85%
Synchronization test	Fluke biomedical	≤ 60 ms
Battery test@360 J	Fluke biomedical	± 15%
Charge time	Fluke biomedical	≤ 15 s
ECG		
Lead alarm	Fluke biomedical	Observe
Heart rate accuracy	IEC 60601-2-27	± 5%
Paper speed	Fluke biomedical	± 4%
Frequency test	Fluke biomedical	Observe
ECG artefact	Fluke biomedical	Observe
Overshoot	Fluke biomedical	± 1 mm
Damping	Fluke biomedical	± 1 mm
Alarm test	IEC 60601-2-27	10 s
Electrical safety test		
Voltage live to neutral	IEC EN 62353	± 10% (V)
Voltage neutral to earth	IEC EN 62353	± 10% (V)
Voltage live to earth	IEC EN 62353	± 10% (V)
Protective earth resistance	IEC EN 62353	<0.3 (Ω)
Insulation resistance	IEC EN 62353	<2 M (Ω)
Enclosure leakage current closed earth	IEC EN 62353	<1000 μA class I, <500 μA class II
Applied part leakage current	IEC EN 62353	<500 μA class II, <50 μA CF

Table 2. *Test equipment.*

Measured quantity	Range	Accuracy
Measurement of electrical safety parameters		
Voltage	0 to 300 V ac rms	± (2%+0.2 V)

Insulation resistance	0.5 MΩ to 20 MΩ	± (2% of reading+0.2 MΩ)
Current consumption	0 to 20 A	± (5% of reading+(2 counts or 0.2 A, whichever is greater))
Protective earth resistance	0.000 to 2.999 Ω	± (2% of reading+0.015 Ω)
Fluke biomedical, Vital signs simulator, ProSim8		
NIBP simulations	Adult: 60/30 (40), 80/50 (60); 100/65 (77); 120/80 (93); 150/100 (117); and 200/150 (167) and 255/195 (215)	Repeatability within ± 2 MMHG (At maximal pulse size independent of device under test)
Leakage rate	0 to 200 mmHg/min	<2 mmHg/min into 500 ml rigid volume
Pressure relief	100 to 400 mmHg	± (0.5+0.5 mmHg)
Heart rate	30-240 BPM	±1 % of setting
Oxygen (%)	35-100% with oximeter manufacturer's R-curve	
	Saturation within UUT specific range	± (1 count+specified accuracy of the UUT)
	Saturation outside UUT specific range	monotonic with unspecified accuracy
	With fluke biomedical R-curves 91 to 100%	± (3 counts+specified accuracy of the UUT)
	81 to 90%	± (5 counts+specified accuracy of the UUT)
	71 to 80%	± (7 counts+specified accuracy of the UUT)
	Below 71 %	monotonic with unspecified accuracy
Puls rate	30-250 BPM	± 1% of setting
ECG rate	10 BPM to 360 BPM	± 1% of setting
Pulse wave	30, 60 BPM, with 60 ms pulse width	± 1% of setting
Square wave	0.125, 2.0, 2.5 Hz	± 1% of setting
Triangle wave	0.125, 2.0, 2.5 Hz	± 1% of setting
Sine wave	0.05, 0.5, 1, 2, 5, 10, 25, 30, 40, 50, 60, 100 and 150 Hz	± 1% of setting
Width	8 to 20 ms	± (1%+1 ms)
Respiration rate	10 to 150 BrPM	± 5%
Fluke biomedical, Defibrillator/Transcutaneous pacer analyzer, Impulse 7000DP		
Delivered energy	0.1-600 Joule	± (1%+0.1 J)
Synchronization	-120 to +380 ms	± 1 ms
Charge time	0.1 s to 100 s	± 0.05 s
Calibration of infant incubators and radiant warmer		
Temperature	5 to 70°C	+0.5°C+1 LSB
Relative humidity	0-100% RH	± 5.3% RH
Sound level	30-80 DB	+ 5 dbA
Air flow	0.1 to 0.7 m/s	± 0.1 m/s

Results

Test results are analyzed and validated according to relative international standard and the manufacture specification. The medical devices under test with all valid test results are assigned to, which contains all the DUTs that passed visual, safety and performance test, while the DUT that failed to pass any of the tests will be assigned to as shown in Table 3. The errors of each type of medical device were investigated. The percentage of errors is shown in Table 4. Thus, it is possible to see which error occurs in which ratio. Figures 2 to 7 show the results of each type of selected devices.

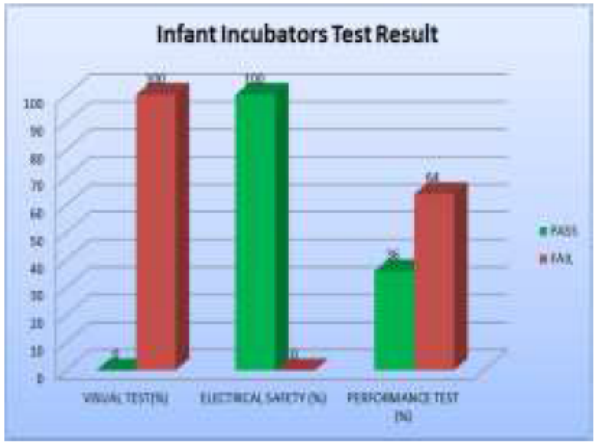

Figure 2. Results of infant incubators.

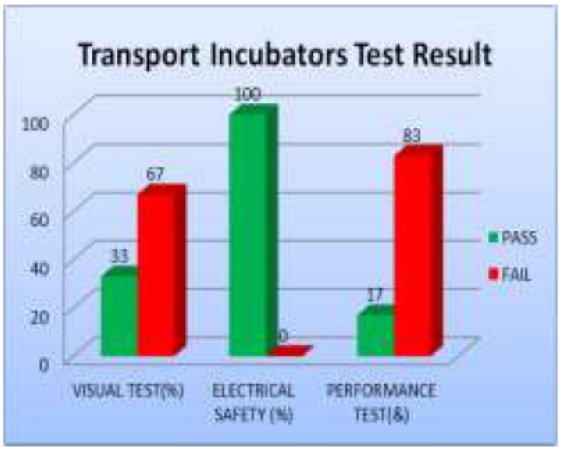

Figure 3. Results of transport incubators.

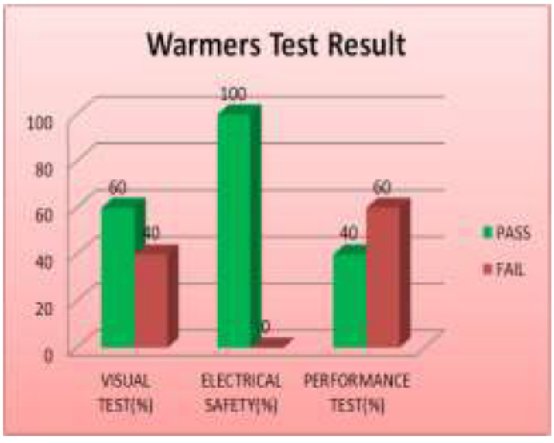

Figure 4. Results of warmers.

In examine the efficiency of medical devices to ensure their performance in accordance with international standards and to determine deviations in measurement. The study showed that there is a difference in the results of visual test, safety test and performance test. 22% of the total assets of infant incubators were tested and 100% of them failed the visual test, 0 % of them failed safety test and 64% of them failed the performance test as showed in Figure 2.

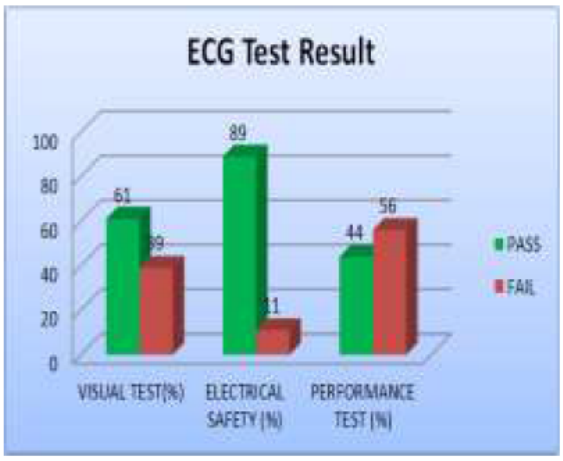

Figure 5. Results of ECG.

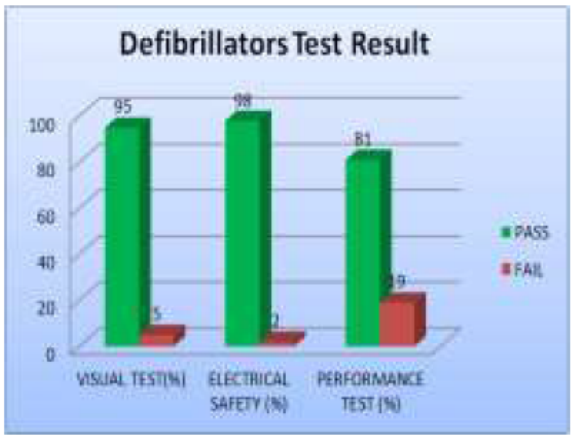

Figure 6. Results of defibrillators.

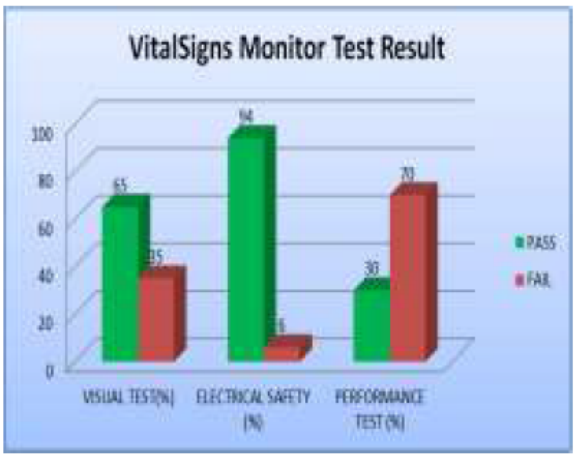

Figure 7. Results of vital signs monitor.

All transport incubators devices were tested and 67% of them failed visual test, 0% of them failed safety test, and 83% of them failed performance test as shown in Figure 3. 19% of total assets of warmers were tested and 40 % of them failed visual test; 0% of them failed safety and 60 % of them failed performance test as shown in Figure 4.

Table 3. Test results of DUT failed.

Medical devices	Visual test %	Safety test %	Performance test %
Infant incubators	100	0	64
Transport incubators	67	0	83
Warmers	40	0	60
ECG	39	11	56
Defibrillator	5	2	19
VitalSigns monitor	35	6	70

In our examination, 19 % of total asset of ECG machine were tested and 39% of them failed visual test; 11% of them failed in safety and 56 % of them failed performance test as shown in Figure 5. 20% of the total assets of defibrillator were tested and 5% of them failed the visual test, 2 % of them were failed safety test and 19% of them failed the performance test as showed in Figure 6. A 20% sample of total asset of vital signs monitors were tested and 35% of them failed visual test, 6% of safety test, and 70% failed performance test as shown in Figure 7.

The study reflects a method that can be used to improve the efficiency of medical devices and ensure the quality of their performance in accordance with international standards. We were also able to identify problems for each devices and lack of suitability to international standards.

Table 4. The errors of failed DUT.

DUT	Total of DUT	Errors	Number of errors (%)
Infant incubators	11	No skin probe	73
		Fan noise	36
		Display	18
		Temp control damage	9
		Water tank	18
		Skin accuracy	9
Transport incubators	6	Skin probe	34
		Windo cover	17
Warmers	10	No skin probe	40
		Heater stop@33°C	10
		Control key damage	10
ECG	18	Lead broken	28
		Power cable	11
		Printer broken	6
Defibrillator	42	Recorder speed need to adjust	17
		Printed ECG Unclear	7
		Protective earth resistance	2
VitalSigns monitor	125	Caring handle broken	2
		NIBP cuff	4
		ECG lead	3
		Power cable	4
		Printer broken	0.8

Discussion

The study shows a large percentage of devices failed the performance test, with the transport incubator having the highest percentage (83.3%) and the defibrillators having the lowest (19%). This is a very high percentage since these devices are high risk and/or life saving devices, which questions their reliability and may compromise patient safety and health.

In comparing the current research with similar studies that have been carried out, among which are Sezdi in Turkey and Almir et al. in Bosnia and Herzegovina.

Table 5. Test results by Sezdi.

Medical devices	Total asset	Number of devices failed the test	Fail %
Infant incubators	34	6	18
Defibrillator	52	9	17
Ventilator	99	12	12
Anesthesia unit	53	23	43
Electrosurgical unit	59	14	24
Physiological monitor	245	51	21
Total	542	115	21%

A study conducted by Sezdi on high risk group medical devices (Table 5) used at the Departments of Operation Room and Intensive Care in Cerrahpasa, Faculty of Medicine in Istanbul University. Results showed 115 medical devices were signed as “Failed” of the total 542 medical devices from different departments which represents 21% [22].

The study by Badnjevic et al. involved 3 clinical centres, 25 hospitals, 63 health centres and 320 private health institutions in Bosnia and Herzegovina over the course of 1 y. The outcome of this study showed 23 of 90 devices (26%) doesn’t meet the error limits requirements (Table 6) [23].

Table 6. Test results by Badnjević et al.

Medical devices	Total asset	Number of devices failed the test	Fail %
ECG Devices	26	6	23
Defibrillator	15	6	40

Anesthesia machine	7	2	29
Incubator	17	4	24
Respirator	7	0	0
Patient monitor	5	1	20
Therapeutic ultrasound	14	6	43%
Total	90	23	26

Conclusions

The objective of this study is to examine the impact of calibration of medical devices performance and patient's safety. The study found 34% of the total selected sample of medical devices under test from major hospital in Saudi Arabia failed in visual test, 5% failed safety test and 58% failed performance test. This is higher than those reported by the previous two studies conducted by Sezdi et al. which reported failure rate of 21% and 26% respectively.

The study reflects a method that can be used to improve the efficiency of medical devices and ensure the quality of their performance in accordance with international standards. We were also able to identify the problems of each device and lack of suitability to international standards. Accordingly, the expansion of the study in the future to cover all medical devices is very important in order to assess the performance of medical devices in all departments of the hospital. It is important to note that the problems related to the performance test of medical devices in this study did not cause serious accidents or resulted in death, but these devices do not meet international standards and use can be dangerous to the patient because of the risk associated with their performance.

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