Performance Analysis for Medical Devices

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***Abstract*- The objective of this study is 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 study includes high risk group medical devices used at the departments of operation room and intensive care in Cerrahpasa Faculty of Medicine in Istanbul University. 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). The obtained data were analyzed and the results were given in graphics. 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, tracing 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 us to decide the right during the purchasing of the new devices.**

Keywords- Performance Test; Preventive Maintenance; Quality Management; Risk Analysis

I. INTRODUCTION

In health organizations, the quality assurance programs need a qualified medical technology management. Hospitals must create a safe environment for patients, relatives and employees. To achieve this goal, like the management of the physical environment and human resources, management of the medical devices is very important. Here, the main target is the patient safety because of the potential hazards that may be caused by the bad performance of the medical devices. High-tech medical devices that are used for both diagnosis and treatment are the most important determining factors for patient safety.

The management of the performance control of medical devices is becoming more prominent as the number of medical devices increases. Because of this, specific activities are needed to manage the performance tests for the medical device safety.

Performance test is the measurement of the accuracy of the medical device or the medical system by using the standard measurement system whose accuracy is known, and is the determination and the record of the deviations [1-2]. In short, by the performance measurements, it is established whether the medical devices meet the international standards or not, and the problems are also determined if the device is not adequate to the international standards.

The determination and the analysis of the problems of medical devices are essential in the quality assurance applications. Hence, the valuable lessons can be learned from system problems and the fast intervention can be applied before system failure. Additionally, a preventive maintenance program can be created. It brings the qualified biomedical services and also health services.

For several years, the Food and Drug Administration (FDA) collects the information about the medical devices. It has a database about medical device failures and presents the database to share in all medical sectors [3]. In addition, there are some studies about medical device failures [4-9]. They are generally related to the software problems of medical devices. But, to our good knowledge, there is no study focusing on the medical device failures generated during the performance tests of medical devices.

The problems cited in this study were the problems that were determined from the performance test results. It is important to note that there were no serious injuries or death caused by these problems, that only the medical device does not meet the international standards and its usage can be dangerous to the patient because of its performance problems.

The initial purpose of this study is to analyze the performance test results of medical devices, and thereby to provide detection of failures in advance and to create a preventive maintenance program according to the analysis results.

The general purpose is to make sure from the performance of the medical devices, to recover the changes in the measurement sensitivity, to interfere to the problems immediately, and to provide the appropriateness of the medical devices to the international standards. Accordingly, it is to serve the high quality and the most safe health services to the patients.

II. METHOD

In this study, total 542 medical devices (six different types of medical devices) at the departments of operation room and intensive care, were tested in Cerrahpasa Faculty of Medicine in Istanbul University [10-11]. The devices were infant incubators, defibrillators, ventilators, anesthesia units, electrosurgical units and physiological monitoring systems. The

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distribution of the tested medical devices can be seen in Fig. 1.

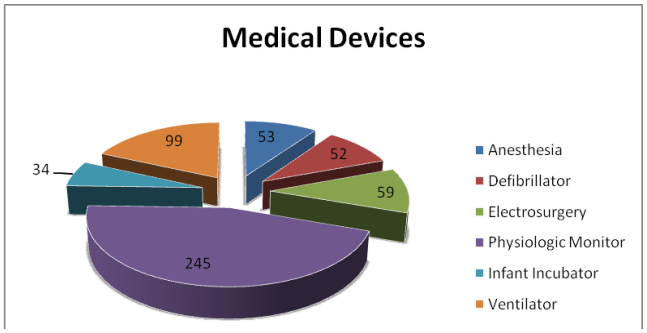

Fig. 1 Distribution of medical devices participating in the study

The performance tests of these medical devices were performed and interpreted according to the Inspection and Preventive Maintenance System (IPM) procedures which were developed by Emergency Care Research Institute (ECRI) [12-13]. The performance tests and the devices used for tests can be seen in Table 1. The results were obtained with less uncertainties that were calculated by using procedures declared in the Guide to the Expression of Uncertainty in Measurement (GUM).

TABLE 1 PERFORMANCE TESTS AND TEST DEVICES

Device Under Test	Performance Tests	Simulator/Analyzer/ Test and Measurement Device
Infant Incubators	Temperature test	Temperature/humidity datalogger (Extech) Desibelmeter (Extech) Thermocupl (Extech)
	Humidity test	
	Noise test	
	Baby probe test	
Defibrillators	ECG pulse test (BPM)	Patient Simulator (Rigel UNISIM)
	ECG amplitude test	
	ECG arythmia test	
	Energy test	Defibrillator Analyzer (Datrend PHASE-3)
	Charge time test	
	Synchronized discharge test	
Physiological Monitor	ECG pulse test (BPM)	Patient Simulator (Rigel UNISIM)
	ECG amplitude test	
	ECG frequency test	
	ECG ST test	
	ECG printer test	
	Pacemaker test	
	ECG alarm test	
	Breath performance test	
	Breath alarm test	
	NIBP performance test	
	NIBP cuff pressure test	
	NIBP cuff leakage test	
	NIBP alarm test	
	IBP static pressure test	
	IBP dynamic pressure	
	IBP alarm test	
	sPO2 performance test	
	sPO2 alarm test	
Ventilators	Tidal volume test	Flow Analyzer (imt PF300)
	Minute volume test	
	Frequency test	
	Inspiratory time test	
	Expiratory time test	
	I:E ratio test	
	Peak pressure test	
	O2 concentration test	
	Flow test	

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Anesthesia Units	Tidal volume test	Flow Analyzer (imt PF300) and Gas Concentration Analyzer (imt OR703)
	Minute volume test	
	Frequency test	
	Inspiratory time test	
	Expiratory time test	
	I:E ratio test	
	Peak pressure test	
	O2 concentration test	
	Flow test	
	Gas concentration test	
Electrosurgical Units	Cutting power test	Electrosurgical Unit Analyzer (Rigel UNITHERM)
	Coagulation power test	
	Bipolar power test	
	HF leak test	
	REM alarm test	

After the performance tests were completed and their results were interpreted, all data entered into the related columns on the operation page as Table 2.

TABLE 2 EXAMPLE ROWS FROM DATA LIST

Location	Device Name	Brand Code	Serial No	Status	Error
Operation room	Anesthesia Unit	Draeger	ARE 0003	Passed	No problem
Operation room	Physiological Monitoring Systems	Siemens	5087	Failed	Respira-tion errror
Operation room	Electrosurgical Unit	Valleylab	F7J5 7029A	Passed	No problem
Intensive Care Unit	Ventilator	Siemens	3097 66	Failed	Pressure check error
Infant Intensive Care Unit	Infant Incubator	Mennen	3555 4168	Failed	Display error
Catheter Laboratory	Electrosurgical Unit	Martin	BO 88 74	Failed	Power circuit error
Infant Intensive Care Unit	Ventilator	Siemens	18133	Passed	No problem
Totally, the data of 542 medical devices were listed.					

The interpretation of performance test result was expressed as the words “Passed” or “Failed”. The expression for the medical devices that meet international standards is “Passed”, and for the inappropriate medical devices, the expression is “Failed”.

The data entered to the operation page contain the information about the location of the device, the device name, the manufacturer of the device, the serial number, the interpretation of the performance test results (Passed or Failed) and the explanation of the problem.

The device manufacturers were coded to make the analysis easier. The codes of manufacturers can be seen in Table 3.

TABLE 3 THE CODES OF MANUFACTURERS OF MEDICAL DEVICES

Brand	Code	Brand	Code	Brand	Code
Abbott	A01	Draeger	D03	Mennen	M05
Aesculap	A02	Ellman	E01	Mesa	M06
Air Shields	A03	Erbe	E02	Mindray	M07
AMS	A04	GE	G01	Nellcor	N01
Artema	A05	Grishaber	G02	Nihon Kohden	N02
Atom	A06	Heal Force	H01	Olympus	O01
Baxter	B01	HME	H02	Petas	P01
Bear Cup	B02	HP	H03	Philips	P02
Bexen	B03	Infant Star	I01	Schiller	S01
Binas	B04	Infra Sonik	I02	Siemens	S02
Bionet	B05	Invivo	I03	Spacelabs	S03
Birtcher	B06	Kontron	K01	Taema	T01
BSI	B07	Life Point	L01	Takaoka	T02
CMS	C01	Maquet	M01	Utah Finesse	U01
Corpuls	C02	Martin	M02	Valleylab	V01
Datex Ohmeda	D01	Medprema	M03	Welch Allyn	V02
Dinamap	D02	Medtronik	M04	Zoll	Z01

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The database was filtered and sorted according to the search criteria for analysis. Firstly, the errors of each type of medical device were investigated. The percentage of errors was shown in pie charts. Thus, it is possible to see which error occurs in which ratio. The errors that generated in these medical devices were coded to use on pie chart easily. The error codes were given in Table 4.

TABLE 4 THE ERRORS OF "FAILED" MEDICAL DEVICES IN HIGH RISK GROUP

Medical Device	Total #	Number	Errors	Error Code
Infant Incubator	34	28	No problem	100
		1	Not working	101
		1	Over Heat	102
		2	Display Error	103
		1	Baby Probe Error	104
		1	Broken Cover	105
Defibrillator	52	43	No problem	200
		1	Not working	201
		2	Low/High Energy	202
		2	Low Battery	203
		1	Lead Error	204
		1	Paddle Error	205
		1	BPM Error	206
		1	Synchronization Error	207
Ventilator	99	87	No problem	300
		1	Not working	301
		1	Power Circuit Error	302
		4	Volume Check Error	303
		2	Pressure Check Error	304
		1	O2 Sensor Error	305
		1	Flow Sensor Error	306
		1	Dirty Filter	307
		1	Connection Leakage	308
Anesthesia Unit	53	30	No problem	400
		1	Not working	401
		2	Power Circuit Error	402
		1	Volume Check Error	403
		1	Pressure Check Error	404
		2	O2 Sensor Error	405
		1	Flow Sensor Error	406
		2	Dirty Filter	407
		1	Connection Leakage	408
		12	Gas Concentration Error	409
Electrosurgical Unit	59	45	No problem	500
		1	Not working	501
		2	Power Circuit Error	502
		1	High/Low Cut Power	503
		2	High/Low Coag. Power	504
		2	High/Low Bipolar Power	505
		1	Broken Pencil Electrode	506
		1	Footswitching Error	507
		3	Patient Return Elect. Error	508
		1	Alarm Error	509
Physiological Monitor	245	194	No problem	600
		4	Not working	601
		7	Power Circuit Error	602
		2	ECG Pulse Meas. Error	603
		4	IBP Error	604
		10	Respiration Error	605
		17	NIBP Error	606
		4	Broken SPO2 Probe	607
		3	High/Low O2 Saturation	608

Secondly, the medical device failures were investigated separately for each type of device by considering their manufacturers. The analysis results were given in graphics after the analysis of performance test results was completed.

III. RESULTS

In our analysis, medical device failures were detected within 21% of the total 542 medical devices from different departments of Cerrahpasa Faculty of Medicine in Istanbul University. 115 medical devices were signed as "Failed" while 427

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medical devices were signed as “Passed”. When the “Failed” devices were analyzed according to the errors, several technical problems were observed. The problems were summarized in Table 4.

Thirty-four infant incubators were tested and approximately 18% of them were signed as “Failed” in this study. As seen from Fig. 2(a), it was observed that 6 incubators had problems; 17% of them have “broken cover”, 34% of them have “display error”, 17% of them have “baby probe error” and 17% of them have “over heating”.

When the incubators were studied by considering their manufacturers, it was seen that the incubators coded with D01 and G01 have more problems than the others. The preferable incubators might be M03 and A04 coded incubators (Table 5).

TABLE 5 THE # OF FAILURES FOR EACH BRAND OF MEDICAL DEVICES

Infant Incubator						
Brand	M03	G01	D01	A03	A04	
Failed #	1	1	1	1	2	
Total #	9	3	3	6	13	
Defibrillator						
Brand	Z01	V02	B03	L01	H03	N02
Failed #	1	1	1	1	2	3
Total #	4	2	3	3	6	34
Ventilator						
Brand	I02	I01	M01	D01	D03	S02
Failed #	1	1	1	1	2	6
Total #	3	2	20	10	23	41
Anesthesia Unit						
Brand	A04	S02	K01	G01	D01	D03
Failed #	1	1	2	2	4	13
Total #	2	2	3	2	13	31
Electrosurgical Unit						
Brand	P01	E02	B06	A02	M02	V01
Failed #	1	1	1	2	3	6
Total #	5	5	4	8	13	24
Physiological Monitor						
Brand	C01	H02	K01	P01	D03	M05
Failed #	2	1	1	2	4	27
Total #	7	4	4	15	70	58
Brand	D01	N02	S01	I03	H02	G01
Failed #	5	3	2	1	1	2
Total #	18	24	8	6	4	27

17% defibrillators have failed in this study. 23% of the failed defibrillators have low-high energy level, while 22% of them have low battery capacity (Fig. 2(b)). There are minimum deviations in the parameters related to ECG.

As shown in Table 5, the best manufacturer of defibrillator was N02 coded manufacturer. The second better result was obtained from Z01 coded defibrillators.

Ninety-nine intensive care ventilators were tested and approximately 12% of them did not meet international standards. Observing the problems of ventilators according to their manufacturers, it can be said that I01 and I02 coded ventilators have higher error percentages than the others. The ventilators showing higher efficiency were SO2, M01 and D03 coded ventilators (Table 5).

For ventilators, it can be said that there are deviations in the values of "volume check" and "pressure check" (Fig. 2(c)). Oxygen and flow sensors may measure with error and should be changed periodically.

Fig. 2(d) shows that the big problem of the anesthesia units was the gas concentration error caused by vaporizers. As shown in Fig. 2(d), 52% of 23 failed units include gas concentration errors. The other problems occurred in the ventilation part of anesthesia units are particularly errors of the volume check, pressure check, oxygen and flow sensors generated in ventilation.

D03 coded anesthesia units showed minimum error. D01 coded unit was the second better anesthesia unit. But, the error of both of them was generally gas concentration error. G01, S02, A04 coded units have power deviations and showed the low performance (Table 5).

Fifty-nine electrosurgical units were tested in this study and approximately 24% of them were signed as “Failed”. As seen from Fig. 2(e), 22% of failed electrosurgical units include patient plate errors. 14% of inappropriate ventilators include errors

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in “high/low coagulation power” and the other 14% include errors in “high/low bipolar power”.

When the electrosurgical units were studied by considering their manufacturers, as shown in Table 5, P01 and E02 coded units have fewer problems.

It was seen that 21% of 245 physiological monitors failed. The most important problem of physiological monitors was the errors of noninvasive blood pressure (NIBP) and respiration (Fig. 2(f)). The ECG parameters of monitors include minimum deviations.

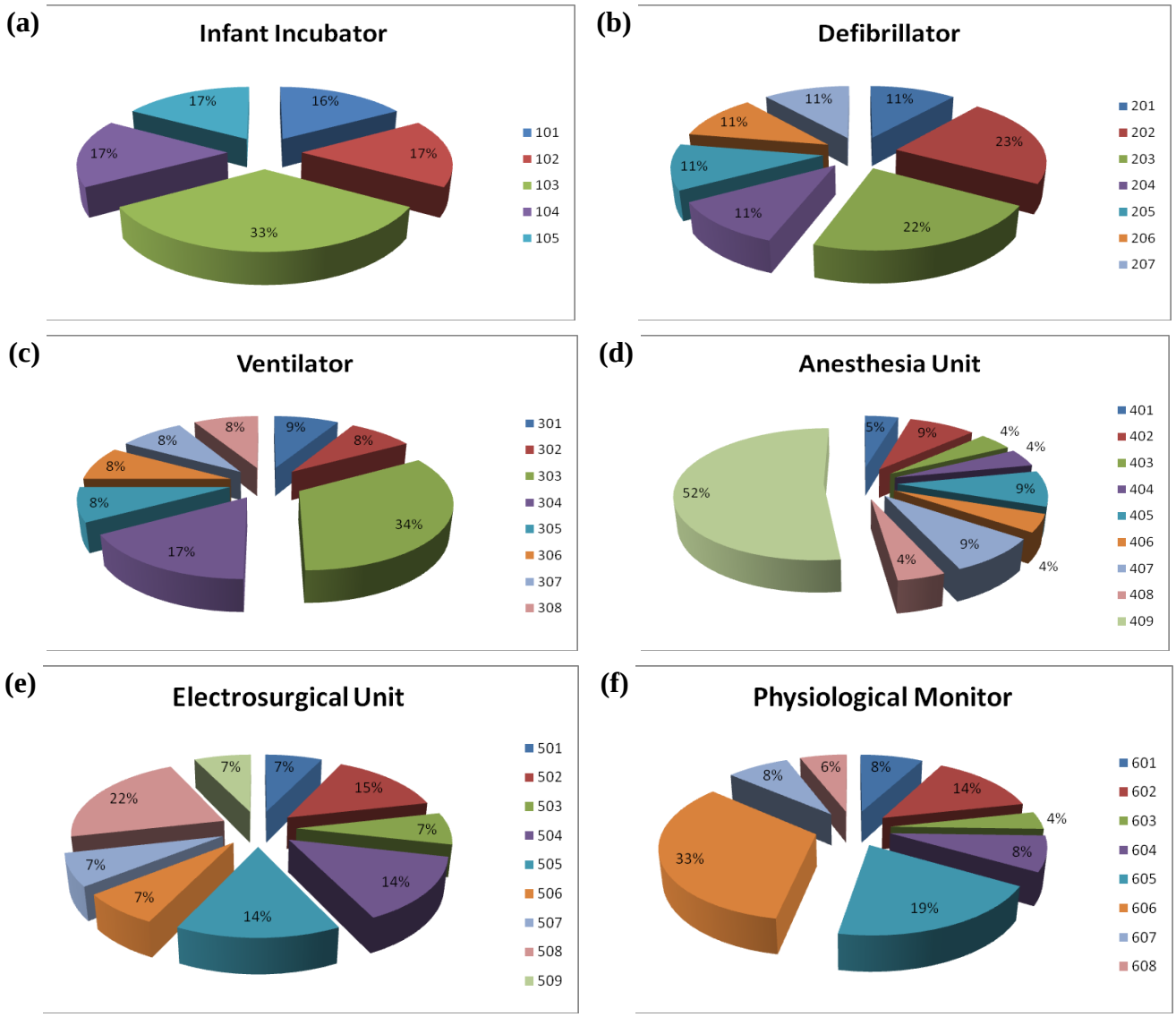

Fig. 2 The errors of tested medical devices.

According to the study on the brands of monitors (Table 5), it was seen that the best physiological monitor with less error was the D03 coded monitor. After this, G01 coded monitor came. M05 coded monitor had more problems compared to other physiological monitors.

IV. DISCUSSION

This study presents approaches for using the devices’ problems to improve the quality assurance practices. The most important conclusion is that the usage of many information about the problems of each medical device causes the significant reduction on device failures and causes the significant rise on the corrective maintenance.

The study includes the medical device errors that are resulted from the inappropriateness of the medical devices to the international standards while the other studies in the literature only include the hardware and software errors causing the medical device failure. For example, a defibrillator may give lower energy than the setting or the gas concentration of an anesthesia unit may be higher than the setting. If the problem is not solved in time, it is possible to be a medical device failure or medical device accident. Because of this, the results of performance tests were analyzed and a preventive maintenance

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program was created to prevent the medical device failures or medical device accidents.

Some spare parts, such as oxygen sensors, flow sensors, filters, pulse oximeter probes, electrosurgical unit pencil electrodes and patient electrodes were stocked for the preventive maintenance program. The performance measurements for problematic devices were planned as more frequent. It was planned to trace the performance of spare parts required to be replaced. And, their change intervals were determined.

Additionally, this study shows that which manufacturer-model medical devices form the medical device inventory and mostly, which manufacturer medical devices cause the problems. In this way, this study also gave the skill to select the right device during new device purchase.

V. CONCLUSION

This analysis demonstrates that some particular biomedical applications may help to avoid the medical device failures. The collection and analysis of performance test results can help to prevent the big problems. Because of this, gathering fault data and, related to this, stocking of the required spare parts are important.

In future, the expectation will be the expansion of the analysis including all medical devices. Extending of this study to include other medical devices is important. In this way, this study could be used for a wide medical device inventory.

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