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A User - Requirements Approach in Medical Devices Maintenance System Development: A Case Study from an Industry Perspective

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***Abstract*—**This paper is a part of research, in which the way the biomedical engineers follow in their work is analyzed. The goal of this paper is to present a method for specification of user requirements in the medical devices maintenance process. Data Gathering Methods, Research Model Phases and Descriptive Analysis is presented. These technology and verification rules can be implemented in Medical devices maintenance management process to the maintenance process.

***Keywords*—**Quality Function Deployment (QFD), User - requirements approach**.**

I. Introduction

TECHNOLOGICAL developments and increasing sub-specialization of medical care mean that providing high quality care for patients. The medical device must firstly be clinically effective and safeto be considered well-designed. The design of devices should take account of the needs of the people that will use it and be treated by it. This requires consideration of a number of factors including the capabilities and working patterns of clinical users, the needs and lifestyles of patient users, the environments in which the device will be used, and the system(s) of which it will be part [1].As the healthcare industry is extremely complex medical devices are a diverse group of products that ranges from simple items such as sticking plasters to complex devices such as heart by-pass machines.

A. Medical Devices and User-Centered Design

The last decade has seen an increased focus on the design of medical devices, specifically in relation to user issues in medical device design, with focusing on device design, poor usability, human error and patient safety. Numbers of initiatives have been set up with the aim of improving such aspects. In 2007, the United Kingdom's National Patient Safety Agency investigated the role of medical devices in patient safety incidents. Their review, which looked at all deaths and severe incidents reported to have occurred in the UK National Health Service (NHS), identified many incidents where the design of a medical device had potentially contributed to the incident [2]. These included incidents where developers had not correctly understood the context of use of their device and had not anticipated likely error situations, as well as instances where devices had not been designed with users' expectations in mind, with errors occurring when the device did not function as the user had expected [1].

Ergonomics/human factors have played a significant role in safety of medical devices, (Martin et al., 2008) highlighted the contribution that the discipline can make towards improved safety in health care, particularly with regard to the design of medical devices [1].

The medical error report from the Institute of Medicine has greatly increased people's awareness of the frequency, magnitude, complexity, and seriousness of medical errors. As the eighth leading cause of death in the US, ahead of motor vehicle accidents, breast cancer, or AIDS, medical errors occur in many medical situations [3].

Health information technology (HIT) has undoubtedly reduced the risk of serious injury for patients during hospital stays [4].

Liu conducted a study in the field of shoulder surgery" A brief fatigue inventory of shoulder health developed by QFD technique". They used a QFD technique to develop an instrument to assess the severity of symptoms of neck and shoulder painand to determine the origin of these symptoms [5].

Kianfar added the QFD methodology to Reliability-Centered Maintenance (RCM) to improve RCM capability in preserving the functions of the plants. Their objective was to preserve the plant functions with least resources. They found that more efficiency will be attained in RCM if the methodology of QFD was added to RCM [6].

Self-management initiatives increasingly rely on the use of technologies to facilitate the process of care in the home. These technologies range from medical devices such as glucose monitors to comprehensive computer-mediated telemedicine systems that provide interactive support as well as World Wide Web access. Although such devices are required to meet certain standards, very little is known about their usability [4]. Problematic user interfaces can induce errors and thereby compromise patient safety. The use of such systems can present some difficulties for health care professionals. Therefore, it is reasonable to assert that these same systems may present formidable challenges to chronic care patients who are typically older, less educated, and often have minimal experience with computers [7].

The aims of this paper are to present an analysis of the methods developed for assessing user needs in medical

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devices. It examines the factors that make capturing user requirements during medical device.

B. Requirements Specification

This study investigated existing medical devices, with the aim of developing an improved version of them based on the point view of maintenance. There has not yet been any published research on collecting user requirements during the development of a completely novel medical device based on the point view of maintenance. This paper describes a user-centered approach to develop of novel medical devices. The aim of the user research was to validate and refine the concept for the new device, as well as to collect user information, experiences and preferences of medical devices operators.

II. Methodology

Quality Function Deployment phases were applied to build the MDMS. The steps in brief were:

- Designing a questionnaire to investigate the performance aspects of Medical Devices Maintenance Systems (MDMS) and to understand Prince Hamzeh Hospital (PHH) and Specialty Hospital (SH) staff requirements.
- Data analysis.

A. Empirical Data Gathering Methods

The empirical data were collected by different sources of evidence. There were two important sources for gathering empirical data: questionnaire and interviews. In these two cases, hospitals were visited physically in order to get direct observation of the different kinds of medical device maintenance problems they were facing.

As a complement of this approach, interviews were made with the different personnel involucrate to get the data related to the technical requirements. All the support of the case company was presented to access the different kind of documentation and information such as agendas, files and administrative papers required for this thesis study.

B. Questionnaire Design

Knowing the evaluation model that is going to be applied was not enough to know the effectiveness of the MDMS, Therefore, the question at that point was how it should be gathered data to measure the effectiveness of the MDMS.

The individual interviews and on-site observations were effective and appropriate methods to collect data in this research. However, certain parts of information should be collected in a different way and survey questionnaires were one of the best approaches.

A questionnaire was designed and distributed in PHH and SH, providing information on four criteria related to the performance of medical devices maintenance staff. Each criterion included different sub criteria; each sub criterion had a descriptor associated constructed with levels that described plausible impacts of alternatives with respect to each sub criterion.

The questionnaire, written in English and Arabic, was built based on many sources. They included brainstorming with the expertise of the Medical Device Maintenance Field (MDMF); medical devices work orders and my experience in the MDMF. The questionnaire was sent after preparing for three referrers in the MDMF for validating it; it was checked up by Eng. Akram Al-Tawarah who is the chairman of quality department in the Royal Scientific Society (RSS), by Dr. Iyad malkawi from World Health Organization (WHO) and by Eng. Hamed Al- Dogaah from RSS.

The questionnaire contained around thirty questions some of them accompanied with two point scale ranging from disagree which scored zero to agree which scored one. This scale was used because of being more precise. The questionnaire was also divided into two sections: requirements and wishes.

The requirements covered some suggested required aspects of medical devices performance which were: - responsiveness, reliability, availability and reproducibility as shown in Table I. The wishes covered some optional aspects of medical devices performance as shown in Table I.

TABLE I
Requirements and Wishes of Medical Devices Operators

responsiveness category	Short maintenance period	Existence of more than one workshop	Organization structure (the location ofthe workshop)	Failure Response time	The nature of maintenance system (hospital maintenance staff or contracted local agents)
reliability category	Safe medical device	High Mean Time Between Failures (MTBF) i.e. hard duty	Training the operators on the device(during installation and periodic training)		
availability category	Existence of redundant device	Spare parts availability	Speed of obtaining the spare parts.	Performing PM	
reproducibility category	Calibration the maintained device	Doing checkup process for the device after the maintenance process and before delivering it to the operator			

Wishes	Existence of a contact person in the maintenance department in the hospital to follow up the different procedures	Assigning a person representing the maintenance department in the medical devices purchasing committee	Using the original agent spare parts in non-critical medical device maintenance	Existence of a senior engineer in all work shifts (specially the night shift)	Existence of an integral full computerized maintenance system with an electronic troubleshooting database showing the cause of failures presenting the suggested action to deal with that failure

TABLE II
CLASSIFIES THE QUESTIONNAIRE'S QUESTIONS ACCORDING TO THE CATEGORIES

The question	The category
Based on your experience, how long does the maintenance process for the critical devices take in average?	(Responsiveness), (short maintenance period)(critical)
Based on your experience, how long does the maintenance process for the non-critical devices take in average?	(Responsiveness), (Serviceability)(short maintenance period)(Noncritical)
In your opinion, in which case will the maintenance process for the critical devices take less time?	(Responsiveness, Structure of organization)(critical)
Based on your experience, how long in average does the maintenance staff take to respond to critical device failure alarm?	Responsiveness, Fast response of the maintenance staff for the failure alarm(Response time).(critical)
In your opinion, which maintenance strategy do you prefer to be adopted by the hospital to maintain the critical devices?	Responsiveness, The nature of maintenance system (hospital maintenance staff or contracted local agents).critical
In your opinion, which maintenance strategy do you prefer to be adopted by the hospital to maintain the non-critical devices?	Responsiveness, The nature of maintenance system (hospital maintenance staff or contracted local agents).Noncritical
In your opinion, does the maintenance staff perform any improvement programs for the critical devices like preventive maintenance?	Availability, Improvement programs like PM, critical
In your opinion, does the maintenance staff perform any improvement programs for the non-critical devices like preventive maintenance?	Availability, Improvement programs like PM, non-critical
In your opinion, in case of critical device failure, the availability of redundant devices is:-	Availability, Existence of redundant device, critical
From your experience, after the maintenance process of critical devices, the maintained medical device will show the same results for the same tests.	Reproducibility, calibration the maintained device to (critical)
From your experience, after the maintenance process of noncritical devices, the maintained medical device will show the same results for the repeated tests.	Reproducibility, calibration the maintained device (Noncritical)
From your experience, after the maintenance process of non-critical devices, the maintenance staffs check the device up before delivering it.	Reproducibility, Doing checkup for the device after the maintenance process and before delivering it to the operator. Non Critical
From your experience, after the maintenance process of critical devices, the maintenance staff checks the device up before delivering it.	Reproducibility, Doing checkup for the device after the maintenance process and before delivering it to the operator. Critical
Based on your experience, after the maintenance process of non-critical devices, how long in average does the medical device work properly before it fails again?	Reliability, High MTBF (hard duty),noncritical
From your experience, after the maintenance process of critical devices, how long does the medical device work properly before it fails again?	Reliability, High MTBF (hard duty),critical
In your opinion, does the maintenance department perform any training courses for the operators at the installation of the critical medical devices?	Reliability, Installation training the operators on the device, critical
In your opinion, does the maintenance department perform any periodic training courses for the operators of the critical medical devices?	Reliability, Periodic training the operators on the device, critical
Based on your experience, after the maintenance process of non-critical devices, the safety of maintained medical device is:-	Reliability, Safe medical device, non-critical
Based on your experience, after the maintenance process of critical devices, the safety of maintained medical device is:-	Reliability, Safe medical device, critical
Based on your experience, the availability of spare parts when we face a	Availability, Spare parts availability, critical

critical device failure is:-	
Based on your experience, the availability of spare parts when we face a non-critical device failure is:-	Availability, Spare parts availability, noncritical
Based on your experience, how long in average does the spare parts take time to arrive in the case of critical devices failure?	Availability, Speed of getting the spare parts. critical
Based on your experience, how long in average does the spare parts take time to arrive in the case of non-critical devices failure?	Availability, Speed of getting the spare parts. Non critical
In case of critical devices failures, do you prefer that there is a contact person in the maintenance in the hospital to follow up the different procedures like harrying up the acceptance of the hospital administration to purchase needed spare parts.	Availability, Existence of administrative person
In case of non-critical medical device maintenance, do you prefer to use always the original agent spare parts?	Availability, Using original spare parts

C. Samples of the Research

This research focused on two hospitals in Amman, PHH and SH. Questionnaires were sent to the staff (doctors, staff nurses and technicians) of radiology department, laboratory, operational theatres, ophthalmology and hemodialysis. They were distributed to 1200 operator in PHH 903 useful questionnaires were received from the survey; yielding a 75% percent response rate.

The responses to the questionnaire were presented and analyzed using Statistical Package for the Social Science (SPSS) version 17 for windows. Using SPSS the values of mean, standard deviation (sigma) and frequencies for each performance aspect were found. The results to hypothesis tests have been exposed to justify them.

D. Research Model

This study used the HOQ in QFD as the analysis model. QFD appeared to be able to provide MDMS with a better understanding of customers' translation of these expectations into appropriate service specifications and perform existing process assessment (lim et al., 1999).

A generic QFD framework was applied as a reference model for MDMS. The six-phase implementation framework was presented, together with the findings of empirical research. A brief outline of the six phases and the research methodology adopted was shown below.

E. Research Model Phases

F. Customers' Requirements

The first phase of the process was to define all the external customers (medical device operators) and their requirements. There were multiple tiers of customers, such as:

- Radiology department staff
- Laboratory staff
- Operational theatres staff
- Ophthalmology department staff
- Hemodialysis department staff

Identifying customers' expectations was the most crucial step of the QFD process and it involved the identification of what customers expect from the service. The questionnaires method was utilized to establish customers' expectations.

Planning Matrix

The customers' requirements were ranked by applying interpolation method. The medical device operators' satisfaction was measured with available maintenance system by comparing it with a MDMS in other hospital.

A questionnaire survey comprising around 30 questions was conducted at two hospitals in Amman. This questionnaire was given to the staff of concerned departments.

Response ranking in this phase was done based on interpolation method. The performance aspect with the highest mean value was assigned 5, the one with the lowest mean value was assigned 1 and the interpolation method was applied to calculate the rank of each performance aspect based on its mean value.

The medical device operators' satisfaction with available maintenance system could be measured by calculating the following measures:

- Planned satisfaction rating
- Improvement factor

These measures were combined with the customer importance weighting to calculate the overall weighting for each customer's requirement.

G. Technical Requirements

In this phase the medical device maintenance staff was interviewed of the two hospitals and all the measurable characteristics of the Medical Device Maintenance Process (MDMP); which they perceived they related to meet the operators' requirements; were identified.

H. Interrelations

In this phase the requirements were translated as expressed by the customers into the technical characteristics of the MDMP. It has been identified in this phase where the interrelations between the customer and technical requirements were significant.

The level of interrelation discerned was weighted on a four point scale (high, medium, low, none). A symbol representing this level of interrelation was entered in the interrelation portion of HOQ. Each level of interrelation weighting was assigned a score. For instance; High=9, Medium=3, Low=1 and none=0.

I. Roof

In this phase it has been identified where the technical requirements characterizing the MDMP supported or impeded one another. It has been worked through the cells of roof matrix considering the pairings of technical requirements these represent.

The key question was to be answered: In the case of improving one requirement, will that deteriorate or improve in the other technical requirements? If the answer was that will deteriorate, an engineering trade-off existed and a symbol (-) was entered into the cell to represent this answer. On the other hand if the answer was that will improve; a symbol (+) was entered into the cell to represent this answer.

J. Targets

In this phase the following sections were established:

Technical priorities (relative importance of each technical requirement)

Competitive benchmarks (relative position of the existing product)

Targets (engineering target values to be met by the new product design)

The technical priorities were calculated by summing up the multiplication of overall weighting and interrelation weighting score for each requirement.

K. Descriptive Analysis

The performance aspect of critical and non-critical devices for each category as a whole unit was investigated and then the performance aspects of each category's components were also investigated as in table III. In both cases, the highest mean value for the performance aspect indicated most customers' satisfaction.

For the previous two cases, the performance aspect in both critical and non-critical devices that dissatisfied the operators of medical devices at most was indicated. The lowest mean value for the performance aspect indicated most customers' dissatisfaction.

In the case of responsiveness for critical devices as a whole category, the mean value was (3.39±0.0167) in terms of 95% confidence interval and the sigma value was (0.8026) as shown in Table III. It was noted that it had a relatively high mean; thus indicating the satisfaction of medical devices operators on the maintenance period and on the failure response time of the critical devices.

Concerning the availability for critical devices as a whole category, because of having the highest mean value, the operators were satisfied at most on the availability of spare parts, time of obtaining it, doing PM and availability of redundant of the critical devices.

TABLE III
DESCRIPTIVE STATISTICS OF THE ANALYSIS OF PERFORMANCE INDICATORS OF ALL CATEGORIES AS A WHOLE UNIT FOR CRITICAL AND NONCRITICAL DEVICES

	Critical devices			Noncritical devices		
	Mean	Standard deviation	Confidence interval	Mean	Standard deviation	Confidence interval
Responsiveness	3.3937	0.8026	3.3937±0.01677	3.2204	1.22481	3.2204±0.24
Availability	3.4909	0.74536	3.4909±0.015	3.6024	0.79529	3.6024±0.016
Reliability	3.0219	0.65934	3.0219±0.013	3.1246	0.49748	3.1246±0.001
Reproducibility	3.0205	0.60244	3.0205±0.012	2.4003	0.78866	2.4003±0.015

Regarding the reliability for critical devices as a whole category, it had relatively low value of mean reflected the little satisfaction of medical devices operators with the safety of maintenance, the efficiency of maintenance and Training of them on installation of the critical devices.

Regarding the reproducibility for critical devices as a whole category, it had the lowest value of mean value showing the dissatisfaction of operators with doing checkup after maintenance and the process of calibration the maintained critical device.

In the case of responsiveness for noncritical devices as a whole category, it was observed that it had a relatively high mean indicating the satisfaction of medical devices operators on the maintenance period and on the failure response time of the non-critical devices.

In the case of availability for noncritical devices as a whole category, Because of having the highest mean value, the operators were satisfied at most on the availability of spare parts, time of obtaining it, doing PM and availability of redundant of the non-critical devices.

Regarding the reliability for noncritical devices as a whole category, it had high value of mean reflected the satisfaction medical devices with the safety of maintenance, the efficiency of maintenance and Training of operators on installation of the non-critical devices.

When investigating the reproducibility for noncritical devices as a whole category, it had the lowest value of mean showing the most dissatisfaction of operators with doing checkup after maintenance and the process of calibration the maintained critical device.

It was noticed from the above analysis of critical and noncritical devices for all categories as a whole unit that the availability was the most satisfied category for the critical and non-critical medical devices operators. It was also noticed that the reproducibility category was the most dissatisfied one for the critical and non-critical medical devices operators.

The availability category for the non-critical medical devices was more satisfied for medical device operators than the availability category for the critical medical devices. The reproducibility for the critical medical devices category was more satisfied than the reproducibility for the noncritical medical devices category.

The performance indicators of each category including its critical devices in details were also investigated and the beginning was with the responsiveness category which included short maintenance period and failure response.

The analysis showed that the failure response for critical devices was the one satisfying the medical devices operators at most for the critical devices responsiveness because it had the highest mean value as shown in Table IV.

TABLE IV
DESCRIPTIVE STATISTICS OF THE ANALYSIS OF PERFORMANCE INDICATORS IN THE CRITICAL DEVICES OF ALL CATEGORIES

		Mean	Standard deviation	Confidence interval
Responsiveness Category	Short maintenance period	3.2	1.225	3.2±0.024
	Response time	3.57	0.982	3.57±0.019
Availability Category	Spare parts Availability	3.52	0.996	3.52±0.02
	Speed of obtaining the spare parts	4.04	0.901	4.04±0.018
	Performing PM	3.14	1.313	3.14±0.026
	Existence of redundant device	3.27	1.314	3.27±0.026
Reliability Category	Safe medical device	2.37	0.735	2.37±0.014
	High MTBF	3.70	0.991	3.70±0.019
	Training periodic.	3.11	1.312	3.11±0.026
	Training Installation.	2.91	1.294	2.91±0.025
Reproducibility Category	calibration maintained device	3.70	0.991	3.70±0.019
	check up after maintenance	2.34	0.939	2.34±0.018

When investigating the answers choices of failure response for critical devices question listed in Table V and Fig. 1, it was noted that the answer choice (fifteen minutes-thirty minutes) was the most satisfied failure response for the medical device operators. It had the highest frequency value with 351, so the failure response time for it should be kept within that range of period.

TABLE V
ANSWERS' CHOICES OF FAILURE RESPONSE CATEGORY FOR CRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
more than 8 hours	11	1.2	1.2	1.2
1 hour - 8 hours	133	14.7	14.7	15.9
30 min.-1 hour	250	27.7	27.7	43.6
15 min.-30 min.	351	38.9	38.9	82.5
less than 15 min.	158	17.5	17.5	100.0

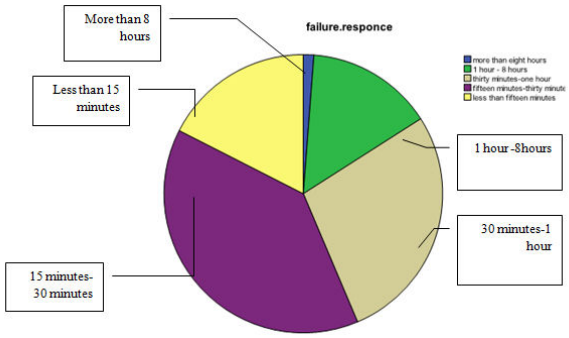

Fig. 1 Frequencies of answers' choices of failure response of critical devices question

It was noticed from Table IV that the maintenance period for critical devices was the one dissatisfying the medical devices operators at most in the critical devices responsiveness because it had the lowest mean value.

When investigating the answers choices of maintenance period for critical devices question listed in table VI, it was observed that the answer choice (3 days-1 week) was the most dissatisfied maintenance period for the medical device operators. It had relatively the highest frequency value with 243 so the period of maintenance should be decreased as much as it could be.

TABLE VI
ANSWERS' CHOICES OF MAINTENANCE PERIOD CATEGORY FOR CRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
more than one week	60	6.6	6.6	6.6
3 days-1 week	243	26.9	26.9	33.6
1-3 days	214	23.7	23.7	57.3
less than 1 day	210	23.3	23.3	80.5
less than one hour	176	19.5	19.5	100.0

The performance indicators of reproducibility category including its critical devices were investigated. It included: do checkup after maintenance for critical devices and the process of calibration the maintained critical device.

The analysis of performance indicators of the critical devices reproducibility category in Table IV showed that the do checkup after maintenance for critical devices was the one dissatisfying the medical devices operators because it had a relatively low mean value of (2.34±0.018).

When investigating the answers choices of doing checkup after maintenance for critical devices question listed in Table VII and Fig. 2, it was observed that the answer choice (seldom) was the most dissatisfied frequency of doing checkup for the medical device operators. It had the highest frequency value of 366 so the frequency of checking up the device before delivering it to the operators should be increased.

TABLE VII
ANSWERS' CHOICES OF DOING CHECKUP AFTER MAINTENANCE FOR CRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
not at all	171	18.9	18.9	18.9
seldom	366	40.5	40.5	59.5
often	272	30.1	30.1	89.6
usually	78	8.6	8.6	98.2
always	16	1.8	1.8	100.0

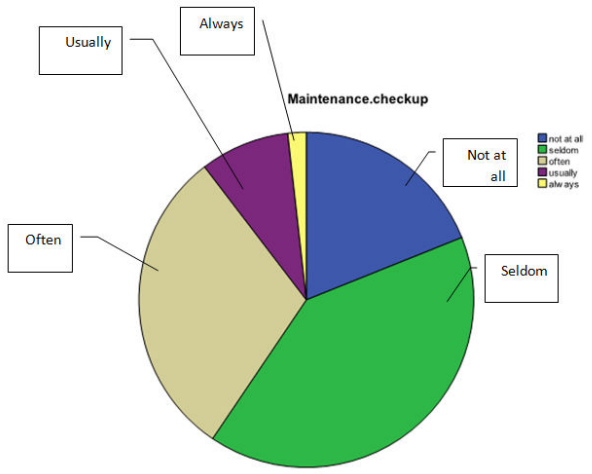

Fig. 2 Frequencies of answers' choices of do checkup after maintenance question

For critical devices performance indicators analysis of reproducibility category, it was remarked that the parameter calibration the maintained criticaldevice was the satisfied one because it had the highest mean value.

When investigating the answers choices of the calibration of the maintained critical device question listed in Table VIII, it was observed that the answer choice (usually) was the most satisfied occurrence of calibration for the medical device operators. It had the highest frequency value of 420, so the possibility of calibration the maintained device should be increased.

TABLE VIII
ANSWERS' CHOICES OF CALIBRATION THE MAINTAINED CRITICAL DEVICE QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
seldom	161	17.8	17.8	17.8
often	134	14.8	14.8	32.7
usually	420	46.5	46.5	79.2
always	188	20.8	20.8	100.0

The analysis of performance indicator in the critical devices availability category in Table IV showed that the speed of obtaining the spare parts was the one most frequently selected by the medical devices operators at most because it had the highest mean value of (4.04±0.018).

When investigating the answers choices of speed of obtaining the spare parts question listed in Table IX, it was observed that the answer choice (one week - one month) was the most preferred period needed to obtain the spare part for the medical device operators, it had the lowest frequency value of 56. The time less than one hour had a very high frequency with 329, so the spare parts time should be kept within that range of period.

TABLE IX
ANSWERS' CHOICES OF SPEED OF OBTAINING THE SPARE PARTS CATEGORY FOR CRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
1 week - 1 month	56	6.2	6.2	6.2
one day-one week	181	20.0	20.0	26.2
one hour-eight hours	337	37.3	37.3	63.6
less than one hour	329	36.4	36.4	100.0

The analysis of performance indicator in the critical devices availability category in Table IV showed that the PM performing was the one dissatisfied the medical devices operators at most because it had the lowest mean value (3.14±0.026).

When investigating the answers choices of PM performing question listed in Table X and Fig. 3, it was remarked that the answer choice (not at all) was the most dissatisfied maintenance period for the medical device operators. It had a relatively high frequency value with 146, so the culture of PM should be adopted.

TABLE X
ANSWERS' CHOICES OF PREVENTIVE MAINTENANCE FOR CRITICAL DEVICES

	Frequency	Percent	Valid Percent	Cumulative Percent
not at all	146	16.2	16.2	16.2
seldom	132	14.6	14.6	30.8
often	230	25.5	25.5	56.3
usually	241	26.7	26.7	82.9
always	154	17.1	17.1	100.0

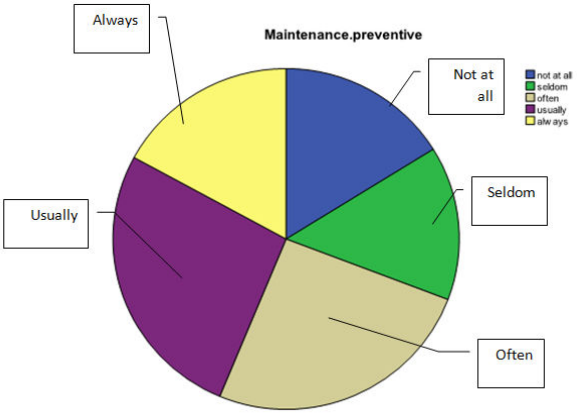

Fig. 3 Frequencies of answers' choices of preventive maintenance for critical devices question

The reliability category was then investigated. It included maintenance safety for critical devices, maintenance efficiency (MTBF) for critical devices, periodic and at installation training for critical devices.

The analysis of performance indicator in the critical devices reliability category in Table IV showed that the maintenance efficiency (MTBF) was the one satisfied the medical devices operators at most because it had the highest mean value of (3.7 ±0.019).

When investigating the answers choices of maintenance efficiency (MTBF) question listed in Table XI, it was observed that the answer choice (one month-six months) was the most frequently selected failure response for the medical device operators. It had the highest frequency value with 420, so the maintenance efficiency period should be kept as high as it could to attain that high MTBF.

TABLE XI
ANSWERS' CHOICES OF MAINTENANCE EFFICIENCY OF CRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
1 day-1 week	161	17.8	17.8	17.8
1 week-1 month	134	14.8	14.8	32.7
1 month-6 months	420	46.5	46.5	79.2
more than 6 months	188	20.8	20.8	100.0

The analysis of performance indicator in the critical devices reliability category in Table IX showed that the maintenance safety for critical devices was the one dissatisfied the medical devices operators at most because it had the lowest mean value of (2.37 ±0.014).

When investigating the answers choices of maintenance safety for critical devices question listed in Table XII, it was observed that the answer choice (very high) was the least selected maintenance safety for the medical device operators. It had the lowest frequency value of 65, so the safety of the maintained medical device before delivering it to the operators should be increased.

TABLE XII
ANSWERS' CHOICES OF MAINTENANCE SAFETY FOR CRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
very high	65	6.9	7.2	7.2
high	517	54.8	57.3	64.5
moderate	247	26.2	27.4	91.8
low	74	7.8	8.2	100.0

The performance aspects of non-critical devices in each category were investigated. The data were shown in Table XIII.

When investigating the answers choices of maintenance period of noncritical devices question listed in Fig. 4, it was noted that the answer choice (less than one hour) was the most selected maintenance period for the medical device operators. So the maintenance period time should be kept within that range of period. It was also remarked that the choice (more than one week) had a small frequency which enhanced the satisfaction of the medical devices operators.

TABLE XIII
PERFORMANCE ASPECTS OF NON CRITICAL DEVICES IN EACH CATEGORY

	Maintenance. period	Spare parts time	Spare parts availability	PM	Calibration of the maintained device	Maintenance checkup.	Maintenance safety	Maintenance. Efficiency
Mean	3.67	3.92	3.39	3.50	2.38	2.42	2.46	3.79
Sigma	1.155	.916	.982	1.21	0.814	1.088	0.763	1.004

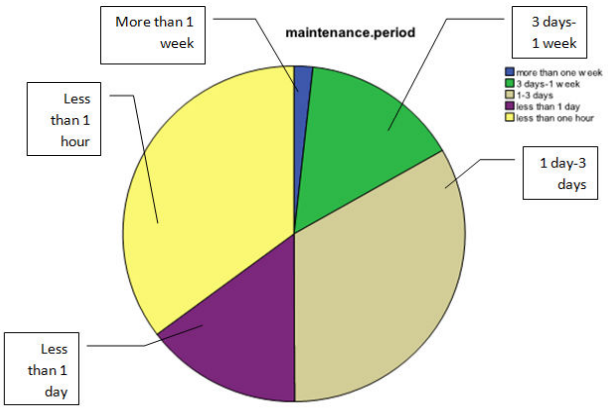

Fig. 4 Frequencies of answers' choices of maintenance period the noncritical devices question

Thenoncritical devices reproducibility category was investigated. The analysis showed that the calibration of the maintained non critical devices was the one least selected by the medical devices operators with a relatively low mean value of (2.38±0.016).

When investigating the answers choices of calibration of the maintained non critical devices question listed in Table XV, it was observed that the answer choice (seldom) was the mostmaintained device should be increased.

TABLE XIV
ANSWERS' CHOICES OF CALIBRATION OF THE MAINTAINED NONCRITICAL DEVICE QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
not at all	91	10.1	10.1	10.1
seldom	482	53.4	53.4	63.5
often	228	25.2	25.2	88.7
usually	102	11.3	11.3	100.0

The analysis of non-critical devices reproducibility category showed that the check up the device after maintenance for noncritical devices was the one satisfied the medical devices operators with a relatively higher mean value of (2.42±0.021).

When investigating the answers choices of checking up the device after maintenance for noncritical devices question listed in Table XVI, it was remarked that the answer choice (always) was the least selected by the medical device operators. It had the lowest frequency value of 45 so the possibility of doing checkup after maintenance should be increased.

TABLE XV
ANSWERS' CHOICES OF CHECK UP AFTER MAINTENANCE FOR NONCRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
not at all	186	20.6	20.6	20.6
seldom	342	37.9	37.9	58.5
often	227	25.1	25.1	83.6
usually	103	11.4	11.4	95.0
always	45	5.0	5.0	100.0

The analysis of performance indicator in the noncritical devices availability category in Table XIII showed that the speed of obtaining the spare parts was the one satisfied the medical devices operators at most because it had the highest mean value (3.92 ±0.018).

When investigating the answers choices of speed of obtaining the spare parts question listed in Table XVII, it was noticed that the answer choice (one week - one month) was the least selected spare parts time for the medical device operators. It had the lowest frequency value of 59 so the obtaining spare parts time should be kept within that range of period.

TABLE XVI
ANSWERS' CHOICES OF SPEED OF OBTAINING THE SPARE PARTS FOR NON-CRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
1week-1 month	59	6.5	6.5	6.5
one day-one week	238	26.4	26.4	32.9
one hour-eight hours	318	35.2	35.2	68.1
less than one hour	288	31.9	31.9	100.0

The analysis of performance indicator in the noncritical devices availability category in Table XIII showed that the availability of spare parts was the one dissatisfied the medical devices operators at most because it had the lowest mean value (3.39 ±0.019).

When investigating the answers choices of (the availability of spare parts question listed in Table XVIII and Fig. 5, it was remarked that the answer choice (very low) was the least selected maintenance period for the medical device operators. It had relatively the lowest frequency value of 29, so the availability of spare parts should be increased.

TABLE XVII
ANSWERS' CHOICES OF AVAILABILITY OF SPARE PARTS QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
very low	29	3.2	3.2	3.2
low	120	13.3	13.3	16.5
moderate	349	38.6	38.6	55.1
high	284	31.5	31.5	86.6

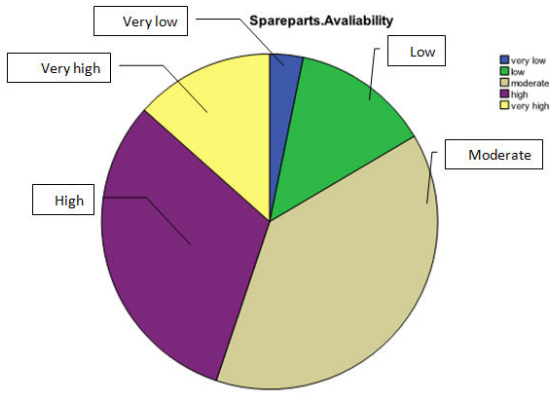

Fig. 5 Frequencies of answers' choices of availability of spare parts question

The analysis of performance indicator in the noncritical devices reliability category in Table XIII showed that the maintenance efficiency (MTBF) was the one satisfied the medical devices operators at most because it had the highest mean value (3.79±0.02).

When investigating the answers choices of maintenance efficiency (MTBF) question listed in Table XIX, it was observed that the answer choice (one month-six months) was the most selected maintenance efficiency (MTBF) value by the medical device operators. It had the highest frequency value with 390 so the maintained device should be kept within that high maintenance efficiency.

TABLE XVIII
ANSWERS' CHOICES OF MAINTENANCE EFFICIENCY (MTBF) FOR NONCRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
less than one day	15	1.7	1.7	1.7
one day-one week	106	11.7	11.7	13.4
one week-one month	164	18.2	18.2	31.6
one month-six months	390	43.2	43.2	74.8

The analysis of performance indicator in the noncritical devices reliability category in Table XIII showed that the maintenance safety was the one dissatisfied the medical devices operators at most because it had the lowest mean value of (2.46 ±0.015).

When investigating the answers choices of maintenance safety question listed in Table XIX, it was remarked that the answer choice (very low) was the least selected maintenance efficiency value by the medical device operators. It had the lowest frequency value of 46, so the maintenance safety of the medical device is satisfied.

TABLE XIX
ANSWERS' CHOICES OF MAINTENANCE SAFETY FOR NONCRITICAL DEVICES QUESTION

	Frequency	Percent	Valid Percent	Cumulative Percent
very low	46	5.1	5.1	5.1
low	482	53.4	53.4	58.5
moderate	301	33.3	33.3	91.8
high	59	6.5	6.5	98.3

III. RESULTS AND DISCUSSIONS

This work used QFD to build MDMS in PHH. It investigated the responsiveness, reliability, availability and reproducibility of medical devices in PHH. The work included data collection, analysis of the data, obtaining the results and building a system of MDMS based on VOC and technical abilities.

Through this research, it could be seen that applying QFD in building MDMS clarified the targets and how to achieve them. Among ten targets three of them were achieved and the others could not be achieved by implementing the suggested procedures.

This model could be used to show the decision makers which variables were mostly affecting the performance of MDMS and then reasonable decision should be taken on such variables to improve the performance.

The majority of performance measures of medical devices operators were related to responsiveness, reliability, availability or reproducibility. It was deduced that the frequency of doing checkup for the critical devices after maintenance and the possibility of calibration of maintained device should be both enhanced.

It was understood that the availability of non-critical devices, the amount of their spare parts in the main store should be both improved and the frequency of performing PM for them should all be increased.

Another main conclusion was the maintenance period of critical devices which should be decreased to less than three days so performing PM should be made more frequently for critical devices. It was estimated that the safety and calibration of maintained non critical device should be improved.

For optimizing the planned satisfaction rating, the periodic training of operators should be only concentrated on. It was concluded that the highest improvement needed to be done was found in doing checkup after maintenance process and the existing of safe medical device.

It was deduced that the existing of safe medical device and do checkup after maintenance process requirements were the performance aspects that had the highest priority to begin with. It was concluded also that the enough budget performance aspect had the highest technical priority so it should be thought of it firstly and trying to solve its problems.

In general, it was drawn that the situation of PHH in some performance aspects such as; availability of work specialty was better than that in SH. There were some cases such as; the infrastructure and the transportation within the hospital, where the situation of PHH and SH were the same. The majority of

the cases indicated that the situation of PHH was not better than in SH.

Administrative procedures in PHH should be studied and improved in order to reduce the routine time required for requesting spare parts. Some requirements of the QFD in PHH have not been met, such as; enough staff performance, types of spare parts contracts, availability of work specialty, devices strength and continuous education and training.

REFERENCES

[1] J.L. Martin, B.J. Norris, E. Murphy, J.A Crowe, "Medical device development: the challenge for ergonomics". Applied Ergonomics. Vol. 39, 2008, 271-283.

[2] E. Boakes, B. Norris, S. Scobie, "The role of design and human factors in medical device patient safety incidents". Proceedings of Improving Patient Safety Conference 'From Safe Design to Safe Practice'. The Ergonomics Society, Loughborough, UK, 2008.

[3] J. Zhang, T.R. Johnson, V.L. Patel, D.L. Paige, T. Kubose, "Using usability heuristics to evaluate patient safety of medical devices". Journal of Biomedical Information. Vol. 36, 2003, 23–30.

[4] J. Horsky, J. Zhang,V.L., Patel,"To err is not entirely human: complex technology and user cognition". Journal of Biomedical Information. Vol. 38 2005, 264–266.

[5] S. Liu, Y. Lee, Y. Huang, "A brief fatigue inventory of shoulder health developed by quality function deployment technique". Journal of Shoulder Elbow Surgery, Vol. 18, 2009, 418-23.

[6] A. Kianfar, "Methodology and theory plant function deployment via RCM and QFD". Journal of Quality in Maintenance Engineering, Vol. 6, 2010, 354-366.

[7] D.R. Kaufman, V.L. Patel, C. Hilliman, P.C. Morin, J. Pevzner, R.S. Weinstock, R. Goland, S. Shea, J. Starren, "Usability in the real world: assessing medical information technologies in patients' homes. Journal of Biomedical Information. Vol. 36, 2003, 45–60.