MEDEMAS -Medical Device Management and Maintenance System Architecture

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Abstract. In the proposed study, a medical device maintenance management system (MEDEMAS) is designed and implemented which provides a data pool of medical devices, the maintenance protocols and other required information for these devices. The system also contains complete repair and maintenance history of a specific device. MEDEMAS creates optimal maintenance schedule for devices and enables the service technician to carry out and report maintenance/repair processes via remote access. Thus predicted future failures are possible to prevent or minimize. Maintenance and repair is essential for patient safety and proper functioning of the medical devices, as it prevents performance decrease of the devices, deterioration of the equipment, and detrimental effects on the health of a patient, the user or other interacting people. The study aims to make the maintenance process more accurate, more efficient, faster and easier to manage and organize; and much less confusing. The accumulated history of medical devices and maintenance personnel helps efficient facility planning.

Keywords: medical device, medical device maintenance, maintenance protocol, scheduling.

1 Introduction

World Health Organization defines a medical device as "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of; diagnosis, prevention, monitoring, treatment or alleviation of disease or injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life [1]".

It is mentioned in the same document that safety and performance of medical devices should be continually assessed when they are in use, since these characteristics can only be proven if one measures how a device stands up in these conditions. It is not possible to predict all possible failures or incidents caused by device misuse with pre-marketing review processes. It is through actual use

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that unforeseen problems related to safety and performance can occur[1]. Joint Commission International Accreditation sets the standard for medical equipment and utility systems as: "The organization plans and implements a program for inspecting and maintaining medical equipment and documenting results[2]".

The aim of this research is to design and develop medical device maintenance management software which will keep record of medical devices, their information, maintenance protocols and repair/maintenance histories; MEDEMAS assigns the foregoing maintenance dates and the technicians responsible for them; informs the relevant technicians and the users of the medical device. The required tools and devices to carry put the task are also scheduled. The architecture makes it possible to carry out the maintenance process remotely.

It has been reported in the literature that successful applications of various maintenance optimization models are rare. Computational difficulties; difficulties of collection of data and modeling of failure distribution; and the gap between theory and practice are the major problems in applying these models. To close the gap between theory and practice, an in-depth investigation is essential to develop an effective methodology for modeling equipment's failure distribution or degradation process. Some key points are what information is required for modeling, how such information is obtained, how the model parameters are estimated, and how the model is updated when new information becomes available [3].

2 Design Considerations

The most comprehensive and challenging side of the study is the optimization of maintenance scheduling. We intend to make the study a well constructed preventive maintenance. All actions carried out on a planned, periodic, and specific schedule to keep an item/equipment in stated working condition through the process of checking and reconditioning [4].

While planning maintenance scheduling, the number and the availability status of maintenance equipment should be taken into consideration. Similarly, the number, status, and expertise of technicians; availability of medical device to be maintained and its maintenance history are also required. In case of failure the action to be taken is to adjust a new maintenance schedule after approximating repair period; meanwhile the technician will be directed to a repair request form for the medical device. These operations should not be done manually; underlying software should make maintenance scheduling and the related jobs automatically.

The application has a powerful evaluating facility. Evaluation of the medical devices, the technicians and the maintenance processes can be calculated automatically using database scoring. These databases contain grading of processes/properties which will be added up to make evaluations. Keeping information of and evaluating the technical staff is especially important as a significantly large proportion of total human errors occur during the maintenance phase; however, human error in maintenance has not been given the attention it deserves [5].

3 System Architecture

In MEDEMAS, a main server is remotely accessed by technicians with PDAs through GPRS/WLAN. Main server can be accessed by hospital personnel for data entry, management and reporting facilities. Computers through either internet or intranet can be used. The management system topology can be seen in Fig. 1.

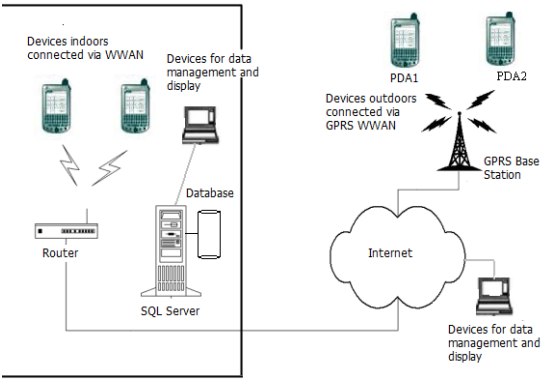

Fig. 1. Typical remote access management scenario

There are two main types of access to the application. First one is remote maintenance access which is used by the technician on process. The access is limited with technician's authorities, and his intervention (update/delete records etc.) is limited. Main process is filling out the maintenance form and sending it to the main server. Besides this, the technician is supplied with the maintenance protocol and the maintenance history of the device; he is informed about the jobs ahead he is responsible for and is alerted for incomplete jobs.

Direct application management is the second access type. Both internet and intranet can be used, and almost all data manipulation, reporting, display, evaluation and tracking are via this type. It can be further divided into three: The

Table 1. Anaesthetic ventilator Standard and Measurement Values, a section from maintenance form/database. Values and criteria are derived from the reference given.

Criteria[6]	Allowed/Recommended Values[6]	Measured Values
Maximum mains voltage	250 V	
Maximum case leakage current	100 μA	
Maximum patient leakage current	$< 320\mu$A	
Maximum earth leakage current	5 mA	
Operating Temperature	5°C to 45°C	

first process is forming databases of all devices, maintenance protocols, technicians, trainings, maintenance equipment, maintenance calendar, etc. Recording, update and deletion are main processes in terms of data management. The measurements and controls will be made for compliance with International/European Medical Device Standards. Some standard values and test values are given as sample in Table1 above.

The second process is displaying the database; it includes construction of many reports. Preparing proper reports, it will be possible to track the devices in the hospital, the status of devices, the most problematic devices, the problems experienced, the cost of individual devices in terms of maintenance, etc. The reporting process helps the directors in following the medical equipment, detecting the devices most problematic or most expensive to maintain, finding out the most experienced problems and the reasons of problems. Similarly, it is possible to track the technical staff. With proper reports, it is possible to track technicians, their performances, their success rates and timings; evaluation of technicians can be made.

The third process is designing and implementing an optimal maintenance schedule. An underlying program runs in cases of maintenance entry or update. A change in technician record or maintenance accessory record also causes the program to run. The program creates a new schedule, optimizing parameters like technician, maintenance device, medical device availability, recommended device maintenance period, approximate repair duration, historical data about maintenance activity of the medical device, etc.

4 Conclusion Remarks and Future Work

The application architecture of MEDAMAS is carefully built. Database creation and data management modules are completed. Databases are supplied with the flexibility to allow automatic processes. Underlying automation and remote-connection applications are still under construction.

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