2. INSPECTION AND MAINTENANCE OF MEDICAL DEVICES

Medical devices are fundamental components of modern health services used for diagnosis, treatment, and monitoring of patients. They are progressively being deployed to increase the capabilities of health diagnostic and treatment services. On the other hand, the potential to manage and maintain medical equipment in most developing countries remain rather weak (World Health Organization, 1998). It is required to have practical methods and powerful management strategies to meet the challenges of ever increasing number and use of medical devices.

2.1. Essential Medical Equipment

Basic medical equipment is widely used in the healthcare facilities. This essential equipment is supportive to provide primary healthcare to the public (Cheng, 2004a). *World Health Organization* (WHO) classifies essential medical equipment in four main categories. The list given in each category includes the devices required for a specified health service delivery. The type of equipment is significantly dependent on the local health practice, physical characteristics and culture of the population (World Health Organization, 1998).

1. Diagnostic imaging equipment

Diagnostic imaging equipment is used to take pictures, which help physicians to diagnose a patient's medical condition (McKay, 1986).

- Diagnostic X-ray equipment
- Ultra-sound equipment

  Ultra-sound equipment may be less frequently used, and is usually added if the budget is available in a hospital.

2. Laboratory equipment

A variety of laboratory equipment is used for analysis or measurement purposes.

- Microscope
- Blood counter
- Analytical balance
- Colorimeter/spectrophotometer
- Centrifuge
- Water bath
- Incubator/oven
- Refrigerator
- Distillation and purification apparatus

3. General electro-medical equipment

- Portable electrocardiograph
- External defibrillator
- Portable anesthesia unit

- Respirator
- Dental chair unit
- Suction pump
- Operating theatre lamp
- Diathermy unit

4. Other support equipment

- Operating theatre table
- Delivery table
- Autoclave- for general sterilization.
- Small sterilizer-for specific services (e.g., dentistry)
- Cold chain and other preventive medical equipment
- Electrical generator
- Electrical power regulator
- Air conditioner, dehumidifier
- Refrigerator
- Ambulance-four-cylinder diesel, four-wheel drive vehicle equipped with medical equipment for emergencies; complete accessories, spare tires and tools
- Gynecological examination table
- Small, inexpensive equipment and instruments

Individual hospital authorities decide which type and what number of these devices are required for their own health service purposes.

2.2. Medical Equipment Management

Medical Equipment Management Program (MEMP) is established in hospitals to provide safe and reliable operation of medical equipment and promote its effective utilization (Stiefel, 2009). This program defines procedures and policies to manage activities related to medical equipment, from their selection and acquisition to decommission. MEMP ensures that devices can provide reliable and accurate information to clinicians, operate safely for patients, and are used to their fullest capacity (University of Michigan Hospitals, 2010).

The life cycle of medical devices should be thoroughly considered for effective management. Deficiencies in managing each stage of the life cycle, especially in the earlier phases can cause more problems in the succeeding stages. For example, if the maintenance capabilities are considered during acquisition stage, it can hinder the challenges that might be faced during the maintenance stage of the equipment.

2.2.1. Life Cycle of Medical Equipment

A typical life cycle of medical equipment has the stages shown in Figure 2.1 (Cheng and Dyro, 2004; also World Health Organization, 1998). Proper management of each phase can have a positive impact on the others.

- *Planning*

In the planning stage, distinct policies on acquisition, utilization and maintenance of medical equipment are clearly outlined. This can significantly minimize the problems arising from the contracts, spare parts and maintenance of the equipment (World Health Organization, 1998). For example, considering the skill level of operators, ensure that only appropriate technology is acquired. Most costs incurred during the life cycle of a device are hidden from

view (Figure 2.2). For proper planning of a large number of devices, a full consideration of all elements in the equipment's life cycle is required.

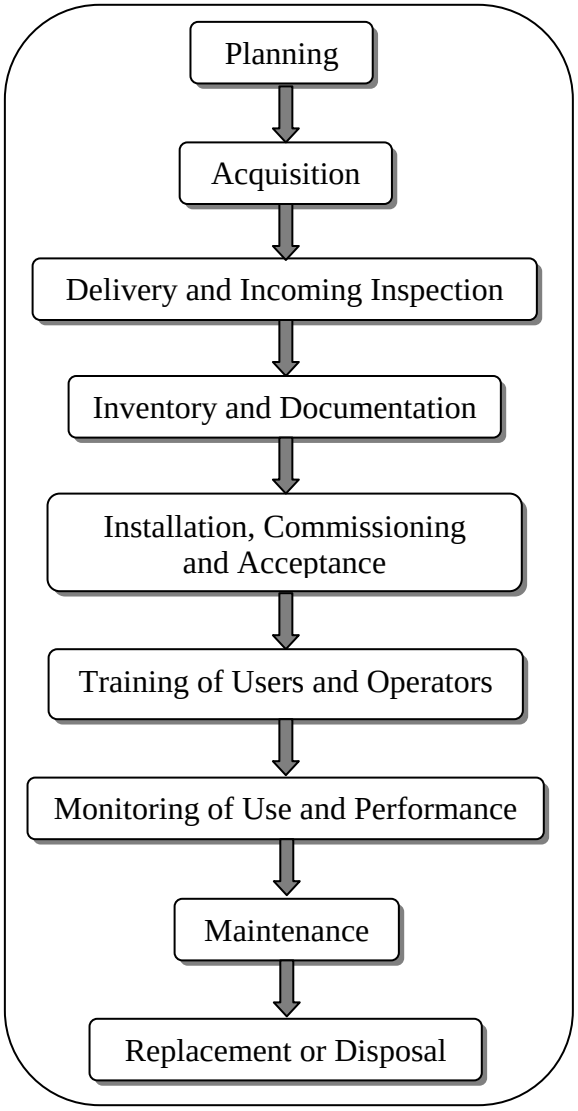


Figure 2.1. A typical life cycle of medical equipment

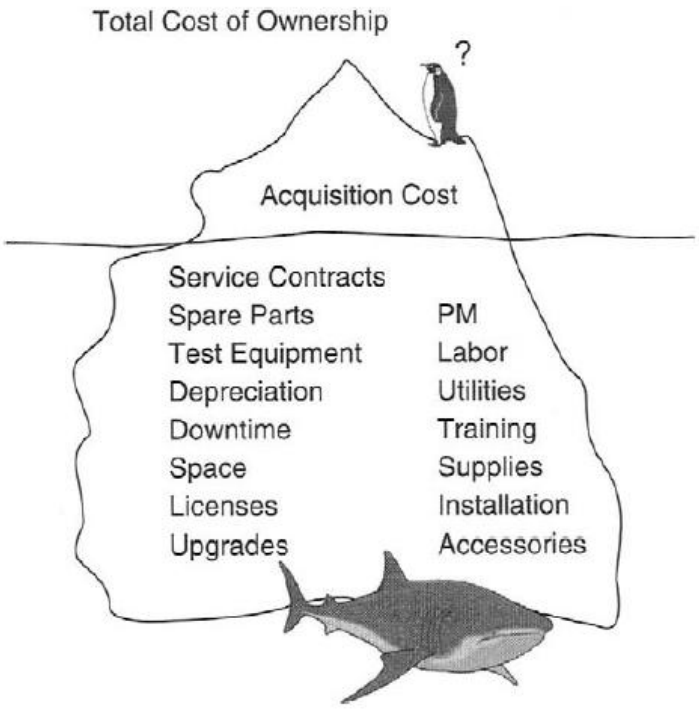


Figure 2.2. Acquisition iceberg (source: Cheng and Dyro, 2004)

- *Acquisition*

Evaluation and procurement (Harding and Epstein, 2004a; 2004b) are two main aspects of the acquisition phase. Evaluation process includes safety, performance and maintainability assessment of devices. Moreover, the models and manufacturers of equipment are standardized. In the procurement process, it is emphasized that the supplier must supply operating and service manuals, and must provide operation and service training and essential spare parts.

- *Delivery and Incoming Inspection*

Incoming devices should be checked carefully for possible damages in the shipment process, conformity with the purchase order, and all required accessories, spares, and documents.

- *Inventory and Documentation*

Inventory and documentation are important aspects of equipment management and standardization (Barerich, 2004; Cohen and Cram, 2004). Inventory entries should include all accessories, spares, and manuals of each device.

- *Installation, Commissioning and Acceptance*

In-house technical staff or the suppliers can perform installation and commissioning stage. In the latter, in-house staff should monitor the process and record it in the equipment service history.

- *Training of Users and Operators*

Proper training of users and operators assures effectiveness and safety of medical devices, and decreases maintenance errors.

- *Monitoring of Use and Performance*

In-house technical staff should act as a link between user and supplier and monitor the supplier's technical services.

- *Maintenance*

Medical equipment must always be maintained in working condition, and calibrated periodically for safety and accuracy (McCauley, 2004; Cheng, 2004a).

- *Replacement and Disposal*

When a medical device is old and its spares run out of supplies, it should be replaced and disposed according to the safety procedures (Cheng, 2004b).

The management of each stage mentioned above can be enriched if the resources are available. For example, in addition to corrective maintenance, preventive maintenance can be added to enrich the maintenance element of the management plan (Cheng and Dyro, 2004).

2.2.2. Joint Commission Standards for Medical Equipment

In accordance with the life cycle phases of medical equipment, biomedical/clinical engineers should comply continuously with two primary Joint Commission medical equipment standards EC.02.04.01 and EC.02.04.03. Standard EC.02.04.01 must be used by healthcare organizations to manage safety and security risks. Standard EC.02.04.03 presents guideline to inspects, tests, and maintains medical equipment. The elements of performance for these two standards are as follows (JCAHO, 2008):

- **Standard *EC.02.04.01*:** The organization manages safety and security risks.
  1. The organization has a systematic approach to selecting and acquiring medical equipment.
  2. The organization maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use and equipment incident history. The organization evaluates new types of equipment before initial use to determine whether they should be included in the inventory.
  3. The organization identifies the activities for maintaining, inspecting, and testing for all medical equipment on the inventory. Organizations may use different maintenance strategies based on the type of equipment. **Strategies must include defined intervals for inspecting, testing, and maintaining equipment on the inventory** [bolded by Sharareh Taghipour]. Defined intervals are based on criteria such as manufacturers'

recommendations, risk levels, and current organization experience. In addition, predictive maintenance, reliability centered maintenance, interval-based inspections, corrective maintenance, or metered maintenance [means maintaining according to the working age of a device] may be selected to ensure reliable performance.

4. The organization identifies frequencies for inspecting, testing, and maintaining medical equipment on the inventory based on criteria such as manufacturers' recommendations, risk levels, or current organization experience.
5. The organization monitors and reports all incidents in which medical equipment is suspected in or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990 (Samuel, 1991).
6. The organization has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.
7. For organizations that provide the technical component of advanced diagnostic imaging and elect to use The Joint Commission CMS imaging supplier accreditation option (Joint Commission Accreditation Ambulatory Care, 2010): The organization identifies activities and frequencies to maintain the reliability, clarity, and accuracy of the technical quality of diagnostic images produced.

- **Standard *EC.02.04.03*:** The organization inspects, tests, and maintains medical equipment.
  1. Before initial use of medical equipment on the medical equipment inventory, the organization performs safety, operational, and functional checks.
  2. The organization inspects, tests, and maintains all life-support equipment. These activities are documented.

3. The organization inspects, tests, and maintains non–life-support equipment identified on the medical equipment inventory. These activities are documented.
4. The organization conducts performance testing of and maintains all sterilizers. These activities are documented.
5. The organization performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented.

2.3. Preventive Maintenance of Medical Equipment

Medical devices are often complex repairable systems consisting of a large number of interacting components, which perform a system's required functions. A repairable system, upon failure, can be restored to satisfactory performance by any method except replacement of the entire system (Ascher and Feingold, 1984).

Medical devices usually undergo several types of tests/inspections during their life cycles as described here (Atles, 2008):

- *Acceptance Test*

A series of qualitative and quantitative tasks designed to verify the safety and performance of newly received equipment, as well as conformity to applicable codes, regulations and standards.

- *Operational Check*

Visual and operational check of the equipment's safety and functionality typically performed at the beginning of the day or work period, or just before using equipment on a patient.

- *Safety and Performance Inspection (SPI)*

A set of qualitative and quantitative tasks designed to verify the safety and performance of each piece of equipment by detecting potential and hidden failures and taking appropriate actions.

After accomplishing the acceptance test for a newly received device, SPIs are scheduled to be performed periodically. If any problem is found at inspection, corrective actions are taken to restore the device or its defective parts to an acceptable level. In addition, a set of failure preventive actions may be taken to prevent future failures and/or restore device function; these include part replacement, calibration, lubrication, etc. to address age or usage related deterioration.

When a device fails while it is in use, the operator reports the problem, and again appropriate actions (corrective maintenance) are taken. When the repair of a device is no longer technically feasible or cost effective, replacement becomes the best or the only option (Atles, 2008). Figure 2.3 describes major tests and actions performed during a device's life cycle.

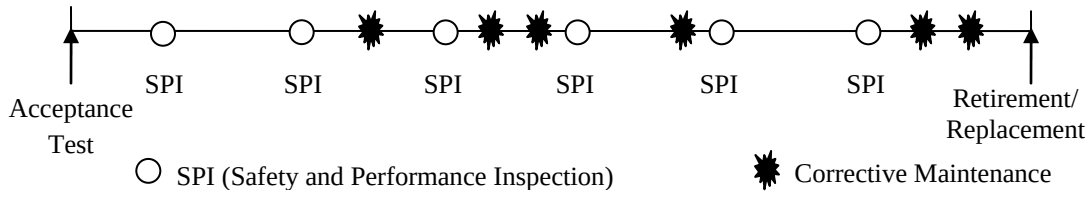


Figure 2.3. Major tests and actions performed during a device's life cycle

2.4. Computerized Maintenance Management Systems

Computerized Maintenance Management Systems (CMMS) are database applications in an organization that assist in planning and management functions required for effective maintenance (Gulati and Smith, 2009). A CMMS to a medical device is similar to an electronic medical record to a patient. It provides the information required for assets management, resource management, financial management, workload, workflow management and regulatory compliance (Cohen, 2008). A CMMS is essential in most healthcare organizations due to the Joint Commission for the Accreditation of Healthcare Organization requirements under the Environment of Care Standards (Cram, 1998).

One of the most important steps in implementing either a computerized or non-computerized equipment management system in a hospital, is to have a complete and accurate inventory of all equipment in the MEMP. The inventory should also include the devices that are serviced by other organizations, but they still must be tracked. Each device must have an equipment control number, which is labeled to the device. Equipment control number can be the hospital asset or property number, or can be an independent number assigned to the device. The inventory should be frequently updated as new devices are added. Without an accurate inventory system, tracking equipment maintenance and repair, alerts and recalls is almost impossible (Cohen and Cram, 2004).

The core functionalities of a CMMS consist of the modules shown in Figure 2.4 (Cohen, 2008; also see Bagadia, 2006). More details of the CMMS modules are explained in Section 2.4.1.

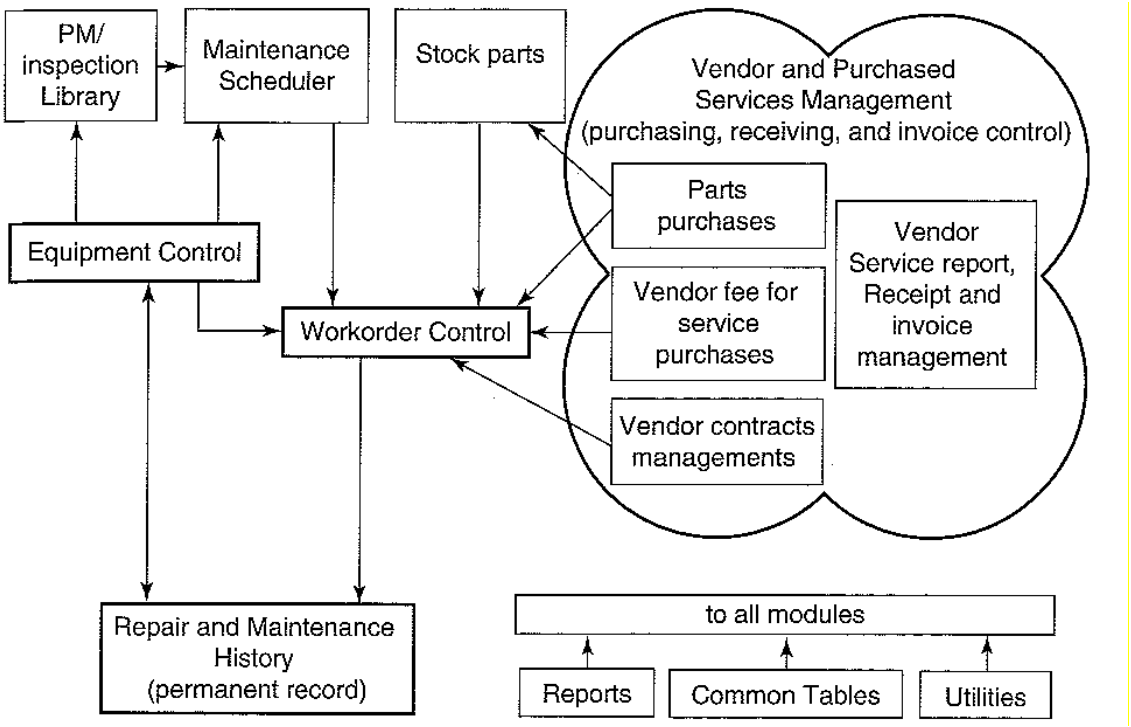


Figure 2.4. CMMS overview (source: Cohen, 2008)

2.4.1. CMMS Core Modules

- Inventory control

Inventory control is the core module of a CMMS. It allows an operator to track the inventory movement, i.e. moving in and out of an item from the inventory or from a location to another (Sapp, 2010). To proper planning of service and repair/replacement of each device, healthcare organizations should know the quantity, type, age and the other information related to the device.

- Work order management system

Work order or work request is an electronic document used to schedule routine inspection and maintenance. Work order management system is the heart of the CMMS. Using this module

a work order can be created, followed up and completed. It stores all corrective and preventive maintenance requests. It keeps track of the initial customer request, device information, requestor information, date and time of the request, nature of the problem, its urgency, and a summary of the assistance provided so far. All activities performed to a work order should be clearly documented and go into the device's repair and maintenance history.

If the CMMS is equipped with an invoice system, a bill is issued and documented for the work order. The work, which is performed, by vendors or external service providers should be also tracked to have a complete history of all devices.

- Scheduling/planning

This module determines the work required to be performed to satisfy a request. It specifies the most efficient way to perform the work, the schedules and the required resources. Several scheduling procedures are usually considered in the CMMS. It includes periodic or fixed scheduling, floating scheduling, and synchronized scheduling by feature such as device type, location, specialty, and others (Cohen, 2008). Periodic scheduling is scheduling of an activity, such as preventive maintenance periodically, regardless the time of the last action. Floating is scheduling of an activity based on the last time the action has been completed for the device, and the conditions of the device. Synchronized scheduling by feature allows to schedule actions according to a technician's expertise, type of the device, department, etc.

- Vendor management

In some hospitals, the most sophisticated equipment such as MRI, scanner, analyzers, etc., are maintained and services by the original equipment manufacturer (OEM). A good CMMS should integrate the vendor and in-house work to have complete histories of all equipment.

Vendor management system should also include the contracts and purchase management subsystems to allow for recording the contracts with the external service providers and purchase transactions made from the vendor.

- Parts management

Most organization uses a just-in-time process for ordering repair parts. Parts usually are divided into three categories: stock parts, contract parts, and noncontracted parts (Cohen, 2008). Stock parts are those, which are purchased and kept in stock by an organization to be used when needed. They are not usually immediately assigned to a specific work order. Contract parts are those included in a prepaid contract. Prepaid contracts are made with external service providers for a certain period. Noncontracted parts are those, which are purchased usually just in time for a specific work order or maintenance action.

- Preventive maintenance

Preventive maintenance is a fundamental module of a CMMS. It generates PM work orders, prioritizes them based on some given criteria, and manipulates them until they are accomplished.

- Labor

Tracking labor resources can be performed using this module. It includes the information of all maintenance personnel and their expertise.

- Purchasing

Purchasing module is to initiate the requisition of parts and materials against a work order and track the delivery and cost data of the item when the part or material arrives (Sapp, 2010).

- Budgeting

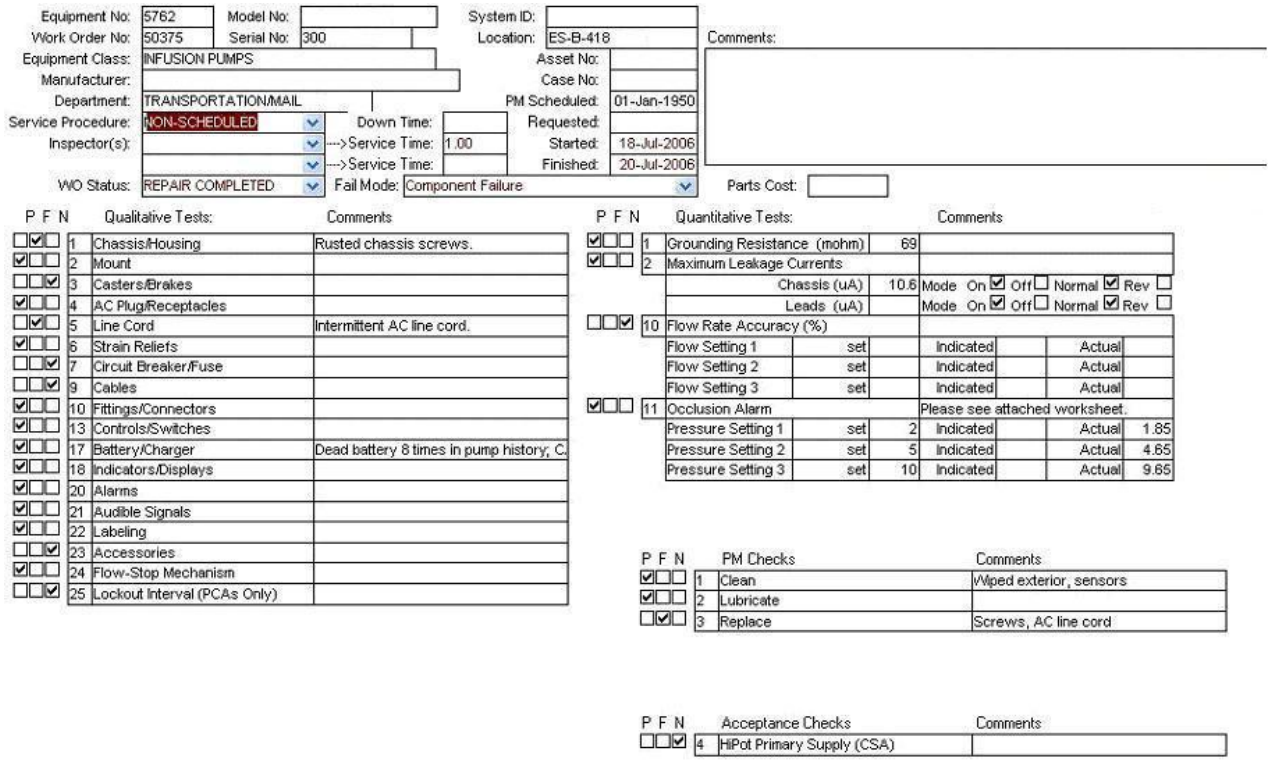
Budgeting module is integrated with the planned resources (labor hours, parts and materials) usage on the work orders. It includes the labor, parts and materials rates to calculate or estimate the costs associated with a work order.

2.4.2. Scheduled and Non-Scheduled Work Orders

The maintenance and inspection data are usually available in the CMMS of a hospital, stored in either scheduled or non-scheduled work orders. Scheduled work orders are used for routine tests (SPIs); however, when a device fails or has a defective part, a non-scheduled work order is requested to fix the problem. Both scheduled and non-scheduled work orders include the basic information of a device and a test checklist designed for a particular class of device. The checklist contains qualitative and quantitative tests; technicians or clinical engineers should use this list to ensure that all necessary tests and checks are accomplished. Figure 2.5 shows a sample of a work order created for corrective maintenance (non-scheduled work order).

Qualitative tests mainly consist of visual inspection of the main parts/components of a device. For example, for a general infusion pump, these include testing its chassis/housing, line cord, battery/charger, etc. Quantitative tests include measuring parameters of a device to check whether the parameters are in control. Grounding resistance and maximum leakage currents are among the quantitative tests for a general infusion pump.

A work order presents all PM checks and actions, such as cleaning, lubricating or replacement of a device or its parts. A work order is also created for an acceptance test of a newly received device.



Equipment No:	5762	Model No:		System ID:	
Work Order No:	50375	Serial No:	300	Location:	ES-B-418
Equipment Class:	INFUSION PUMPS			Asset No:	
Manufacturer:				Case No:	
Department:	TRANSPORTATION/MAIL			PM Scheduled:	01-Jan-1950
Service Procedure:	NON-SCHEDULED	Down Time:		Requested:	
Inspector(s):		---> Service Time:	1.00	Started:	18-Jul-2006
		---> Service Time:		Finished:	20-Jul-2006
WO Status:	REPAIR COMPLETED	Fail Mode:	Component Failure	Parts Cost:	

Comments:

P	F	N		Qualitative Tests:	Comments
☐	☑	☐	1	Chassis/Housing	Rusted chassis screws.
☑	☐	☐	2	Mount	
☐	☐	☑	3	Casters/Brakes	
☑	☐	☐	4	AC Plug/Receptacles	
☐	☑	☐	5	Line Cord	Intermittent AC line cord.
☑	☐	☐	6	Strain Reliefs	
☐	☐	☑	7	Circuit Breaker/Fuse	
☐	☐	☑	9	Cables	
☑	☐	☐	10	Fittings/Connectors	
☑	☐	☐	13	Controls/Switches	
☑	☐	☐	17	Battery/Charger	Dead battery 8 times in pump history; C.
☑	☐	☐	18	Indicators/Displays	
☑	☐	☐	20	Alarms	
☑	☐	☐	21	Audible Signals	
☑	☐	☐	22	Labeling	
☐	☐	☑	23	Accessories	
☑	☐	☐	24	Flow-Stop Mechanism	
☐	☐	☑	25	Lockout Interval (PCAs Only)	

P	F	N		Quantitative Tests:			Comments			
☑	☐	☐	1	Grounding Resistance (mohm)		69				
☑	☐	☐	2	Maximum Leakage Currents						
				Chassis (uA)		10.6	Mode On ☑ Off ☐ Normal ☑ Rev ☐			
				Leads (uA)			Mode On ☑ Off ☐ Normal ☑ Rev ☐			
☐	☐	☑	10	Flow Rate Accuracy (%)						
				Flow Setting 1	set		Indicated		Actual	
				Flow Setting 2	set		Indicated		Actual	
				Flow Setting 3	set		Indicated		Actual	
☑	☐	☐	11	Occlusion Alarm			Please see attached worksheet.			
				Pressure Setting 1	set	2	Indicated		Actual	1.85
				Pressure Setting 2	set	5	Indicated		Actual	4.65
				Pressure Setting 3	set	10	Indicated		Actual	9.65

P	F	N		PM Checks	Comments
☑	☐	☐	1	Clean	Wiped exterior, sensors
☑	☐	☐	2	Lubricate	
☐	☑	☐	3	Replace	Screws, AC line cord

P	F	N		Acceptance Checks	Comments
☐	☐	☑	4	HiPot Primary Supply (CSA)	

Figure 2.5. A typical work order (designed for a general infusion pump)

"P" (pass), "F" (failed), or "N" (not applicable) are the possible results of each qualitative or quantitative test on the work order. When a test is performed on a component, and it is found to be non-defective, the result is "P"; however, in the case of failure of a part, the result is shown as "F". Since a general test checklist is designed for a class of equipment, some qualitative or quantitative tests may not be applicable to particular devices in that class; for these devices, the test result is given as "N". Quantitative and qualitative tests are specifically performed for components/features of a device, but PM checks show the actions performed at the device level.

Currently, most hospitals merely follow manufacturers' recommended intervals for periodic SPI of devices. SPI intervals differ from 6 to 12 months depending on the device type and risk level (U.S. FDA/CDRH, 2005). Class III (high risk) devices such as defibrillators should

be inspected every 6 months, and class II (medium risk) devices like ECGs should be inspected annually. However, the optimality and even the necessity of these recommended intervals are questionable. It is essential to establish an evidence-based inspection or maintenance regimen derived from analysis of field data.

2.5. Concluding Remarks

According to standard EC.02.04.01 for Medical Equipment (see Section 2.2.2), healthcare organizations must identify maintenance activities to maintain, inspect, and test all medical equipment on the inventory. They must employ appropriate strategies, including the intervals for maintenance activities. However, not much research has been presented in the literature to address proper strategies and the methods for implementing them. In the research reported in this dissertation, we propose several strategies, which can be used to meet some requirements of standard EC.02.04.01. We propose a model to decide on inclusion of medical devices in the MEMP, methods for trend analysis of maintenance data, and finally several models to find the optimal periodic inspection interval for a repairable system such as a medical device. The proposed models and methods are discussed in the rest of the thesis.

3. PRIORITIZATION OF MEDICAL DEVICES

3.1. Literature Review

The ever-increasing number and complexity of medical devices demands that hospitals establish and regulate a *Medical Equipment Management Program* (MEMP) to ensure that critical devices are safe and reliable and that they operate at the required level of performance. As fundamental aspects of this program (Stiefel, 2009) inspection, preventive maintenance, and testing of medical equipment should be reviewed continuously to keep up with today's technological improvements and the increasing expectations of healthcare organizations.

No longer content to merely follow manufacturers' recommendations, hospital clinical engineering departments all around the world including Canada, Australia, and United States have begun to employ more efficient and cost-effective maintenance strategies. Gentles et al [http://CESOData.ca accessed 27 April 2010] have begun to develop a unique database to collect comparative data on inventory and maintenance of the most critical devices used in hospitals across Canada and the United States. This project will provide a large statistical failure data set which could be used to establish optimum intervals for routine maintenance scheduling. Ridgway et al (2009) provide concise guidelines for maintenance management of medical