

# RELIABILITY OF THE MAINTENANCE SERVICES DATA FOR MEDICAL DEVICES

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The aim of this paper is to develop a method for analyzing the data maintenance of medical equipment. It presents a classification of different types of fault and establishing guidelines for data analysis results at medical equipment seen as whole as well as structural components, taking into account different types of faults occurring during operation. The results of this analysis can be used as a basic theory in the development of a program to optimize the maintenance of a medical device.

Medical devices are 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 [1]. Medical devices usually undergo several types of tests/inspections during their life cycles: acceptance test, operational check, safety and performance inspection (SPI) [2]. After accomplishing the acceptance test for a newly received device, SPI's 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.

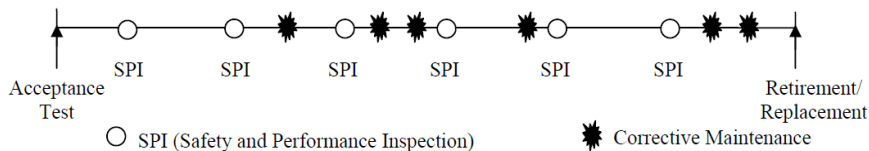


Figure 1. Major tests performed during a device's life cycle

We analyzed data collected in the category of defect have been detected in various reports corrective maintenance performed over time. Have been identified fourteen categories depending corrective action, which are of type: electrical, mechanical, electronic, programming, calibration, installation, transport, accessories, clean environment, user error, false alarm, training and other (unclassifiable).

Table I. Risk associated with potential problems of downtime for these medical devices.

Equipment Name	Severity (Rate 1-10 10=Most Severe)	Occurrence probability (Rate 1-10 10=Highest Probability)	Detection Probability (Rate 1-10 10 Lowest Probability)	Risk Priority S*O*D
Blood gas analyzer	9	9	10	810
Defibrillator with ECG Monitor	8	5	6	240
Hematology Analyzer	8	8	10	640
Ventilator/ adult	10	6	8	480

We have analyzed clinical challenges that engineers are currently facing, in particular, medical equipment maintenance management. We tried to developed some models and methods that can be used practically. Models were constructed include the actual procedures used to maintain medical devices in hospitals, and considering the record of equipment maintenance data.

[1] R. Miniati, F. Dori, E. Iadanza, F. Medici. A New Failure Analysis for Maintenance Management in Complex Hospitals, *Proceedings of World Academy Of Science Engineering And Technology*, **Volume** 34, (2008) pp. 42-48.  
 [2] B. Wang, R. Eliason, S. Vanderzee. A Promising Medical Equipment Management Outcome Benchmark, *Journal of Clinical Engineering*, **July/September** (2006) pp.145-151.