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Medical Device Integrated System Accelerated Life Testing

Khaled Atua (PhD) & Saeid Baniasad (PhD)[1]

[1]System Engineering Services, Baxter International Inc., Round Lake, IL, USA

khaled_atua@hotmail.com; saeid_baniasad@baxter.com

Abstract. This paper defines the accelerated life test design and technique to evaluate medical device system reliability. The proposed method includes developing system functional diagram to capture the overall ecosystem of the device and all control and noise factors that affect device performance. The test simulates real life therapy level stresses including temperature, patient use, disposable setting, power source alterations, medical prescription and duty cycle. These operation elements are used at different rates to balance the aging of different subsystems and rate of different failure mechanisms. The sample size of the test units is determined based on minimizing the overestimation error of the Mean Time Between Failure (MTBF) value. All observed events, and failures are categorized, and identified as failure per the expected complaint handling systems in real life. The test/tester setup errors and customer errors can also be tracked separately in the test and a mechanism of feeding back to human factors analysis, manufacturing, and service departments are identified to help optimize and inform product design and sustaining engineering activities. Test results and findings are to be compared to field data and benchmarked against a predicted number of failures based on the reliability requirements analysis established prior to product release. Test data and performance parameters are to be tracked and used to establish and optimize proactive and predictive maintenance interval and strategies for limited life and degrading components. Finally, a standardized testing method is to be revised based on lessons learned, and to be generalized for future product tests.

1. Introduction

It is well-established that demonstrating medical device reliability at the system therapy level is challenging in many dimensions. Accelerated life testing under laboratory conditions is one technique often used to simulate the complex real life usage of the medical device in the field. However, the traditional approach of component/subsystem/system-level reliability testing & analysis often allows some system and user interaction failures to escape to the field. The methodology described in this paper attempts to address this issue by establishing a dynamic profile of real-life therapy conditions to expose system interactions and failure modes by managing the signal and control factors, and by including many ecosystem noise factors under controlled laboratory conditions. The methodology also addresses the rationales for identifying the proper sample size for system testing that minimizes the error of overestimating the reliability (Mean Time Between Failure) from in-house lab testing before product is released to the field.

Therapy-System-level reliability testing is a complex task that involves evaluating and demonstrating the reliability of all the components of the system working together to perform the Therapy-System-Level mission task(s). A well-designed Therapy System Reliability Test should incorporate factors from design, human factors, manufacturing, service, and real-life therapy operations in the field. These factors

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include environmental conditions, human and end user interaction and programming, disposable and single use elements loading/removal, maintenance and cleaning, etc. A well-designed Therapy System Reliability Test should attempt to expose user interaction and system integration issues/failures not seen during standalone component or subsystem testing. Identified issues and failures provide valuable feedback to Human Factors, Manufacturing, and Service before the product is released to the field. Unlike what is often accepted or assumed in component reliability demonstration testing, Therapy system testing should not be designed or expected to be failure-free.

2. Therapy System Level Reliability Test Design

The Therapy System-level Reliability test design had multiple objectives listed as follows:

1. Demonstrate the targeted or required Reliability Metric can be achieved (e.g., Mean Time between Failure (MTBF), Mean-Cumulative Failures (MCF), etc.).
2. Discover system interactions, boundary issues and system sensitivities under laboratory conditions
3. Provide objective evidence that the system can maintain the reliability target over the expected service life (ESL) of the product.
4. Provide information on top failure modes and limited life components and inform or confirm the development of proactive maintenance or service strategies, if needed.
5. Identify Use/User errors and Human Factors related issues such as misuse, physical damage, etc.
6. Provide feedback to Service and Manufacturing functions based on observations/issues/failures.

3. System Description

The test item is a typical home-used medical device operated by the patient with prescription information fed into the system via either manual entry, or prescription stored on USB read device. The System is also intended for use by trained clinicians, trained patients, and non-clinician caregivers. The system is also designed to be transportable. The system user interacts with the system vi the user interface for programming, data entry, therapy information monitoring, and observation and clearing alarms and errors. System is configured to deliver medication through a disposable set that is stored at the patient's house. The operation of the device requires the patient to connect the set and bags, and either program the device to run the prescription or download a prescription from a USB thumb. The system configuration is shown in Figure 1.

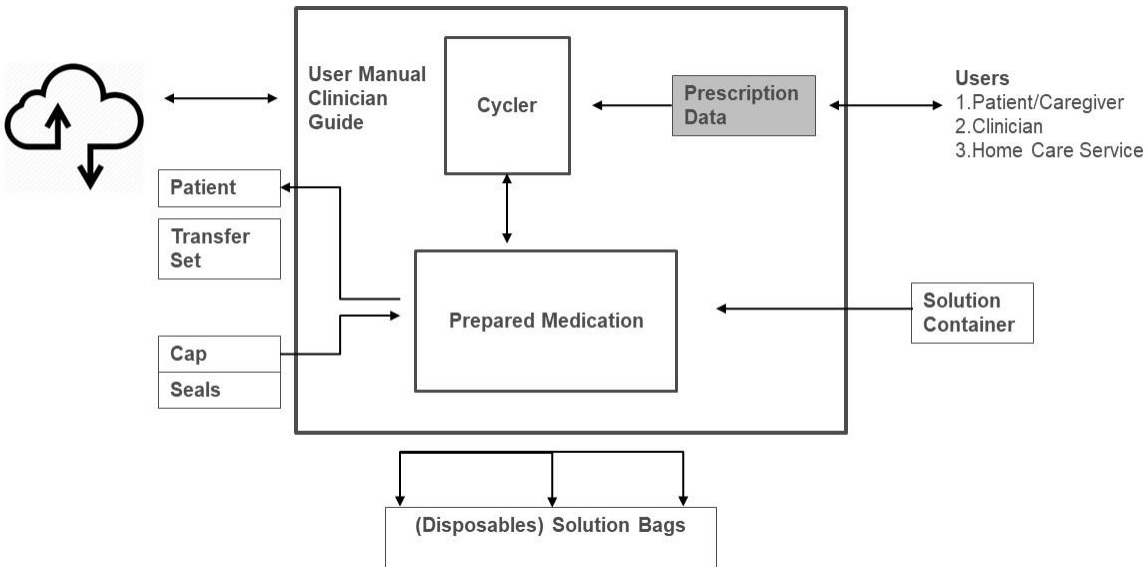

Figure 1. Medical Device System Configuration

4. Test Design Methodology Overview

The P-Diagram was constructed to define and list all types of signal, noise and control factors affecting the operation of the device. The design parameters were all allocated to control and noise factors in 5 main categories [1]:

- Piece to piece variation due to manufacturing defects and process control
- Change over time due to ageing of material or degradation due to usage and wear out
- Customer Usage in terms of misuse scenarios, handling, user error, cleaning, etc.
- External Environment such as during operation, shipping, and storage,
- System Interaction with disposable sets, patient loading and using and entering data into the device, disposable setting at patient's home, system competitivity to manufacturer database cloud, and service interface application.

Some of the critical design factors are used to design the test variables, activities, and measured outputs as illustrated in Figure 2. The test was conducted in an accelerated life context using multiple accelerants as follows:

1. Higher temperature
2. Manipulating system Software to change fluid flow rate & fill volume
3. 3x missions per day & reduced idle time (increased duty cycle)
4. Disposable bag height, therapy types
5. Other manual activation such as exercising AC/DC power, door actuation, loading and unloading of disposable elements, applying cleaning process, etc.

The repair and service was conducted per the standard service manual and following the standard troubleshooting procedures, calibration, etc.
Test results were analysed on a regular basis, and feedback provided to design, human factors, manufacturing, and service stakeholders for consideration of future design changes, service process enhancement, and manufacturing instructions updates and review.

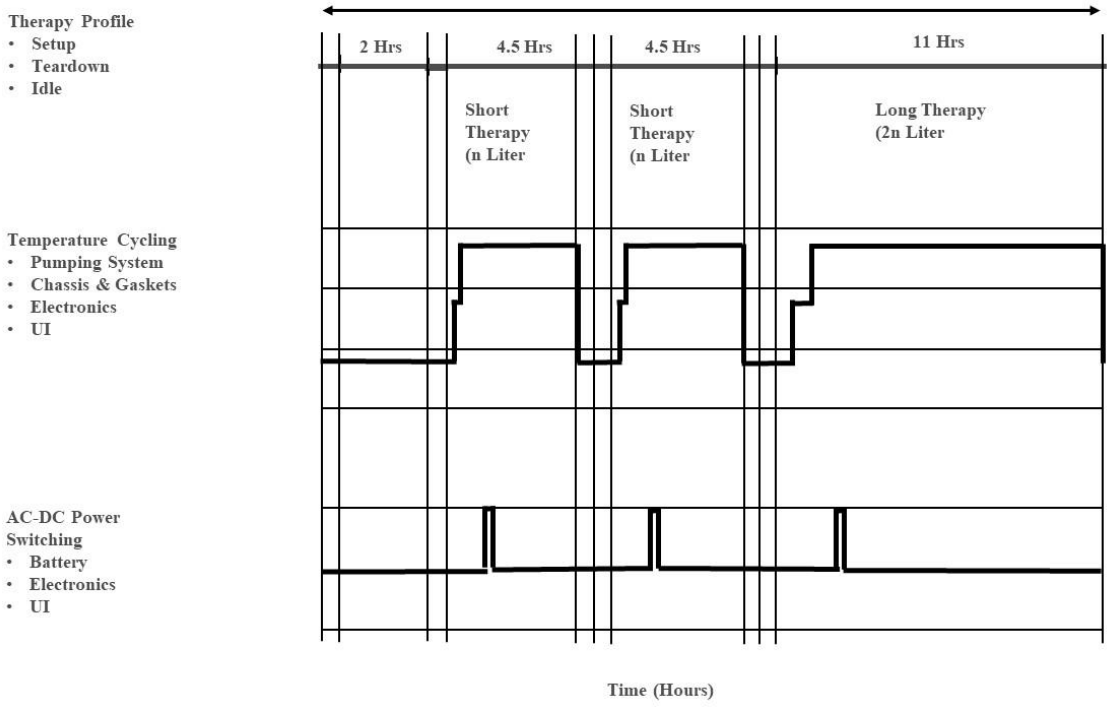

Figure 2. Combined Usage and Stress Cycling Profile

5. Preventive Maintenance (PM) Items

The Design and Service departments defined a list of limited life components and items that are prone to wear out and performance degradation over time. These items were listed for Proactive Service and maintenance (PM) based on time limits. In this test, PM components will not be replaced per the defined PM intervals, rather it will be tested until failure; and associated design parameters will be tracked and monitored for degradation over life. The objective of running these PM items to failure is to confirm and calculate the actual reliability of these items via actual time to failure of each. This is to understand if some expensive elements listed for PM remain within calibration limits; and may require just frequent recalibration instead of the scheduled replacement.

6. Test Sample Size

The sample size of the test was determined based on the reliability requirements, or target MTBF, which is interpreted into expected number of failure. Another factor considered was the fact that the MTBF will be monitored based on a N months rolling average value in the field after launch. System life testing should be designed to produce enough number of system failure to avoid overestimation of actual reliability. Use misuse, and wider usage profile spectrum allow for more issues and failures to be uncovered in the field, while never experienced during testing. We also know that electromechanical systems are complicated; and that they include many different modules and subsystems, along with a Software that is interacting with hardware and producing many errors due to triggers or thresholds violated. Published standards such as [2] indicates the testing time to achieve the target reliability metrics, such as MTBF. These standards indicate the testing time for specified number of f failures using Chi-Square distribution. They also indicate how the test time will change as the sample size is changing in the test, e.g., test time per sample decreases as the sample size increases. However, these standards don't recommend the proper sample size to produce enough number of failures to avoid the overestimation of the MTBF compared to real value realized in the field after launch. The sample size is determined to fulfill the minimum testing time with the maximum number of produced unique issues and errors, yet fulfilling the target MTBF.

7. System Acceleration Factor Calculation and Balance

The system acceleration factor achieved by the test setup and design will not be applied on all system modules. For each module, an individual acceleration Factor is calculated per the applicable failure mechanisms applicable to components in each module. Table 1 summarizes the applicable acceleration factors and rationale and algorithm used to calculate these individual acceleration factors:

Table 1. Modular Acceleration Factors for Different Accelerants & Application on Different Subsystems with Multiple Failure Mechanisms.

Subsystem / Component Category	Duty Cycle	Temp.	Power Cycle	Fill Volume - Flow Rate	Manual Actuation	No of Therapy - Missions	Cleaning
Electronic (PCB, Battery)	AF1	AF2	AF4			AF7	
Pumping System	AF1	AF2		AF5		AF7	
Moving Part (Door, etc.)	AF1				AF6	AF7	
Chassis / Enclosure:	AF1	AF3			AF6	AF7	AF8
User Interface (Keypad)	AF1	AF2			AF6	AF7	AF8
User Interface (Screen)	AF1	AF2	AF4			AF7	AF8
Heater-Heating System	AF1	AF2		AF5		AF7	

Where:

AF1. Ratio: test duty cycle / real life duty cycle for each subsystem

AF2. Most common model using acceleration factor calculated per temperature rise.

AF3. Aging of Polymer-based material; formulae and additional information are available in [3] and [4]

AF4, AF5, AF6, AF7, AF8: are linearly proportional to the rate of device usage, duty cycle & number of actuations, etc. Generic accelerants and other failure mechanisms can be found in other sources [5].

8. Conclusions & Recommendations

The following conclusions and recommendations are drawn from this study:

1. Defining the different control and noise factors is crucial in defining successful testing method that test for failure modes and simulate actual usage and operating environment.
2. Test sample size is crucial to accuracy and confidence in results to avoid error in actual MTBF.
3. Aging rate varies for different subsystems and components as acceleration factors in system life testing varies per the accelerant, failure mechanisms, and usage profile of each item.

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